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CLINICAL DECISION MAKING OF NEONATAL INTENSIVE CARE PROFESSIONAL NURSES REGARDING THE EMPLOYMENT OF BEDSIDE BLOOD PRODUCT FILTERS DURING NEONATAL BLOOD TRANSFUSION

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MASTERS CURATIONIS

in

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DEDICATION

This research study is dedicated to all neonatal intensive care professional nurses who unselfishly work hard to safeguard the lives of the helpless - the neonates.

May you continue to give without expecting to receive!

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DECLARATION

I, LETENNWE JOSEPHINE MORUDU**,** declare that the research study *'Clinical decision making of neonatal intensive care professional nurses regarding the employment of bedside blood product filters during neonatal blood transfusion*' is my own work and that all the sources used and quoted in this research study have been indicated and reflected by means of a complete reference.

_____ _____

Researcher's signature Date

Ms. L.J. Morudu

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SUMMARY

A lack of information is identified on the ability of professional nurses working in a neonatal intensive care unit to make competent clinical decisions pertaining to the employment of bedside blood product filters during neonatal transfusion. In addition, a lack of complete guidelines existed to aid professional nurses in instances where they are faced with such a decision.

A descriptive survey was conducted to determine and describe the knowledge professional nurses working in neonatal intensive care unit have regarding the employment of bedside blood product filters during the transfusion of a neonate with blood or blood products, as well as their ability to make competent clinical decisions in the regard. A questionnaire was designed, which was validated by experts in neonatal intensive care nursing and blood transfusion. The questionnaires were distributed to 10 nominated public and private hospitals with neonatal intensive care units in Gauteng, South Africa, for completion. Participants were self-nominated; they participated in the study of their own free will. Neither the participants' nor the hospitals' names were revealed at any stage. Numbers were used to identify the questionnaires. 120 questionnaires were completed and were analysed using descriptive statistics.

In the following step, the results obtained from the questionnaires together with literature were used to recommend guidelines for neonatal transfusion utilisation by professional nurses working in neonatal intensive care units. The recommended guidelines were divided into two categories: General guidelines and Specific blood products guidelines.

Validity and reliability was enhanced by using staff from ten neonatal intensive care units from the private and public health care sector in Gauteng, South Africa; obtaining a sufficient sample size (n=120); involvement of experts in the field of neonatal nursing science and blood transfusion, as well as a statistician

from the University of Pretoria; and verification of results with literature.

Ethical principles were adhered to: confidentiality was maintained as no names of any of the hospitals or the participants were disclosed. All information regarding the study was provided to the relevant parties and the participants voluntarily signed an informed consent form. Permission to conduct the study was obtained from the selected hospitals' management. Approval to conduct the study was obtained from the Ethics Committee of the Faculty of Health Science, University of Pretoria. There were no known risks involved in the study.

Recommendations were made for more research on the same topic to be conducted and their outcomes be compared to the results yielded by this study and research to be conducted to related topics. The findings of this study were meant to improve the clinical practice of nursing in neonatal intensive care units. It was therefore recommended that these guidelines be implemented by neonatal intensive care units, training institutions and the South African Blood Transfusion Services**.**

OPSOMMING

Die navorser het ’n intensiewe oorsig van die bestaande literatuur rakende die kliniese besluitneming van professionele verpleegkundiges in neonatale intensiewe sorgeenhede gedoen.

Dit het duidelik uit dié navorsingsoorsig geblyk dat daar baie min gedoen is om die vermoëns vas te stel van professionele verpleegkundiges wat in die neonatale intensiewe sorgeenheid werk met betrekking tot kliniese besluitneming wat die aanwending van bloedprodukfilters tydens neonatale transfusie betref. Aanvullend het die oorsig onthul dat daar geen volledige riglyne bestaan, of voorsien word, vir professionele verpleegkundiges in gevalle waar hul met so ’n besluit gekonfronteer word.

Die studie is in twee fases gedoen. In Fase een is ’n vraelys ontwerp gebaseer op konsepte en temas uit die literatuur geïdentifiseer, waarna dit gevalideer is deur kundiges. Die vraelyste is uitgegee aan 10 genomineerde privaat- en publieke hospitale met neonatale inesiewe sorgeenhede in Gauteng vir voltooiing. Die voltooide vraelyste is gesorteer en geanaliseer. Deelnemers is self-genomineerd; die navorser het hulle toegelaat om self te besluit of hulle wou deelneem aan die studie of nie. Deelnemers en hospitale se name is op geen stadium bekend gemaak nie. Nommers is gebruik om die vraelyste te identifiseer.

In Fase twee is die uitslae van die vraelyste gebruik om riglyne te ontwerp om gebruik te word in neonatale intensiewe sorgeenhede deur professionele verpleegkundiges vir neonatale transfusie. Riglyne vir neonatale transfusie is geformuleer volgens die uitkoms van die vraelyste in kombinasie sowel as die oorsig van die reeds bestaande literatuur deur middel van induktiewe en deduktiewe beredenering. Aangesien professionele verpleegkundiges kennis moet dra van algemene riglyne om spesifieke riglyne te kan toepas, is die

riglyne in twee kategorieë verdeel: Algemene riglyne en Spesifieke bloedprodukte riglyne.

Deur hierdie studie in twee verskillende omgewings, naamlik privaat- en publieke instansies te doen, en 10 eenhede van een area (Gauteng) in Suid-Afrika daarby te betrek, sowel as om ’n relatief groot steekproef te gebruik, is die oordraagbaarheid van die uitkoms van die studie na ander streke verhoog. Die navorser het aanbeveel dat verdere studies oor dieselfde onderwerp gedoen word, en die uitkomste daarvan vergelyk word met die resultaat van hierdie studie. Die uitkoms die studie sal dan meer oordraagbaar wees na ander streke in Suid- Afrika. Die uitgebreide literatuuroorsig, die betrokkenheid van kundiges en die navorser se eie ondervinding en kennis in die neonatale intensiewe sorgverpleegkunde, het bygedra tot die vertrouenswaardigheid van die studie. Kundiges op die gebied van neonatale verpleegkunde en bloedtransfusie was betrokke, sowel as ’n biostatistikus verbonde aan die Universiteit van Pretoria.

Etiese beginsels is gevolg. Die navorser was nie bewus van, en is ook nie gekonfronteer met enige etiese dilemmas of probleme tydens die studie nie. Konfidensialiteit is deurgaans gehandhaaf in die studie deurdat geen name van die deelnemers of hospitale genoem is nie. Alle inligting met betrekking tot die studie is aan die relevante partye verstrek en die deelnemers het almal uit eie vrye wil ’n ingeligte toestemmingsvorm onderteken. Toestemming om die studie te doen is ook verkry van die genomineerde hospitale se bestuur. Toestemming om die studie te doen is verkry van die Etiese Komittee van die Fakulteit van Gesondheidswetenskappe, Universiteit van Pretoria. Daar was geen risiko’s betrokke aan die studie nie, slegs voordele, aangesien die doel van die studie was om die professionele verpleegkundiges in die neonatale intensiewe sorgeenhede behulpsaam te wees met besluitneming rakende die gebruik van bloedprodukfilters tydens transfusie van bloed of bloedprodukte aan ’n neonaat.

Die bevindings van die studie is bedoel om die kliniese praktyk van verpleging in neonatale intensiewe sorgeenhede te verbeter. Gevolglik word ’n aanbeveling gemaak dat hierdie riglyne geïmplimenteer word in neonatale intensiewe sorgeenhede, opleidingsinstansies sowel as die Suid-Afrikaanse Bloedoortappingsdiens.

KEYWORDS

- Microaggregate filter
- Leukodepleting filter
- Whole blood
- Packed red blood cells
- Neonatal intensive care nurses
- Inline-filters
- Neonate
- Clinical decision making
- Leukodepletion
- Employment

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LIST OF ABBREVIATIONS

µm	**micrometer**
AIDS	**Acquired Immune Deficiency Syndrome**
CMV	**Cytomegalovirus**
HIV	**Human Immunodeficiency Virus**
SABTS	**South African Blood Transfusion Services**
BCSH-BTTF	**British Committee for Standards in Haematology – Blood Transfusion Task Force**
NYSCHBT	**New York State Council on Human Blood and Transfusion Services**
NYSCHB&TS-TPC	**New York State Council on Human Blood and Transfusion Services – Transfusion Practices Committee**
HLA	**human leukocyte antigen**
TT-CMV	**transfusion transmitted cytomegalovirus**
nvCJD	**new variant Creutzfeldt-Jakob disease**
BRM	**biological response modifiers**
SABTS	**South African Blood Transfusion Services**
IV	**intravenous**
ICU	**intensive care unit**

CHAPTER ONE

OVERVIEW AND LAYOUT OF THE STUDY

1.1 INTRODUCTION

Transfusion of blood and blood products (including whole blood, packed cells, fresh frozen plasma and platelets) to neonates is a common procedure performed in neonatal intensive care units. This procedure comprises the introduction of blood components into the vein of the neonate, to supply the actual volume of blood in cases such as severe blood loss, shock or septicemia; or to introduce constituents like clotting factors or antibodies that are deficient in the neonate (Weller, 2004:396).

The blood and blood products need to be transfused using specific equipment, which include blood product filters. The two most common types of blood product filters are microaggregate and leukodepleting blood product filters. Though other bedside blood product filters such as platelet filters and fresh frozen filters are also available, in this study the term ‘bedside blood product filters’ referred to microaggregate and leukodepleting filters.

A microaggregate filter is a mesh filter with a pore size of between 170µm and 240µm. Its purpose is to prevent harmful clots or coagulation debris from being transfused to neonates during the transfusion process (BCSH-BTTF, 2004:435; Bick, 1998:249; New York State Council on Human blood and Transfusion services [NYSCHBT] 2004:7; South African Blood Transfusion Services [SABTS], 2003:9; Roe, 1992:146).

A leukodepleting filter consists of a non-woven fabric which assists in the removal of leukocytes, clots, coagulation debris and any small particles, including air that might have gained entry into the blood or blood product used for neonatal transfusion. It can be employed at both the blood bank laboratories and at the bedside, and has a pore size of 40µm (µm = unimicron) and less (Asahi Medical, 1996:9; Bick, 1998:249; Bird, 2001:419

PALL Medical, 2002: clinical update & PALL Medical, 1999**:** Blood Transfusion Filter).

Presently in the clinical area transfusion guidelines to neonates are often doctor-, unit- or hospital specific. In neonatal nursing practice there are inconsistencies pertaining to the employment and availability of bedside blood products filters, and also regarding the necessity of employing such a filter if the blood or blood product is leukodepleted. It was therefore deemed necessary to establish whether neonatal intensive care professional nurses are able to make clinical decisions regarding the employment of bedside blood product filters during neonatal transfusion and to draft guidelines that will assist them in this regard.

For the purpose of this study, the term 'professional nurses' are used to refer to neonatal intensive care professional nurses that imply professional nurses registered with the South African Nursing Council (SANC) and working in a neonatal intensive care unit (Nursing Act, 2005).

The aim of the study was to determine and describe the ability of professional nurses in making clinical decisions regarding the employment of bedside blood products filters during neonatal blood transfusion.

1.2 BACKGROUND

The transfusion requirements of neonates are considered as unique. A lack of evidence remains regarding the advantages or disadvantages for transfusion practices in neonates, and this makes recommendations challenging (British Committee for Standards in Haematology – Blood Transfusion Task Force [BCSH-BTTF], 2004:433).

As a professional nurse working in a neonatal intensive care unit, the researcher has been involved in neonatal blood transfusions over a period of years. Following the prescription of a transfusion, it was expected of her to make clinical decisions on how the procedure should be performed and whether a microaggregate or a leukodepleting filter was to be used in the

specific situation.

Further, there is a contradiction when transfusing whole blood or blood products to neonatal patients. The South African Blood Transfusion Services (SABTS) recommends that blood products containing red blood cells should be transfused through a sterile pyrogen-free transfusion set, which has a standard in-line microaggregate filter with a micro pore size of 170µm-240µm to prevent potentially harmful clots and coagulation debris that might have formed during collection or storage of blood or blood products (SABTS, 2003:8-10).

The SABTS states that the second generation blood filters with a pore size of 40µm made their appearance in the 1970s. These filters were used to remove the very small aggregates of degenerating platelets, particles and fibrins that might have formed during storage, and which could pass through standard filters. These filters were initially intended only for red cell component filtration (SABTS, 2003:8-10). Early studies, however, indicated that they were clinically beneficial in respect of pulmonary function, that is, in the prevention of pulmonary microemboli (Bird, Nel & James, 2003:419).

However, the SABTS reports that during the last decade, sophisticated bedside leukodepleting filters have been developed, and these filters are able to remove 99.9% (log3) or more of leukocytes in blood or blood products used for transfusion. The SABTS further notes that the routine use of second-generation bedside blood product filters is not recommended since they are too costly (SABTS, 2003:8-10). The conflict of deciding between expense and sophisticated filters is also mentioned in the article by Bird, et al. (2003:419) who state: “The costs are considerable ($400 million in the USA per annum) and therefore its universal introduction in South Africa needs to be considered carefully.”

Pharmaceutical representatives contradict these statements and stress the importance of employing the leukodepleting filters as these filters have a pore size of 40µm or less. This is especially important where neonates are concerned. The smaller pore size of the leukodepleting filter is beneficial

when the size of bacteria, viruses or fibrins is taken into consideration (PALL Medical, 2000a: Clinical update, PALL Medical, 2000b: Clinical update & PALL Medical, 1998: Clinical update).

The debate impacts on the clinical setting. The availability is often related to the person responsible for ordering hospital stock. If the person do not recognise the benefit of these filters, but only take into consideration the costs involved for the hospital and the patient, the items are not ordered.

In addition, a decision should be made by the professional nurse as to where the filter should be positioned, for example, should the filter be in-line or non in-line, and, if in-line, should it be proximal or distal?

The professional nurse responsible for transfusion should aspire to respond in the best interest of the neonate when deciding on which blood product filter to use amidst these conflicting recommendations (Roe, 1992:146; SABTS, 2003:vi; Seghatchian, 2003:105-106; Wilson, 2004:28-32).

The researcher decided to determine and describe the clinical decision making regarding the use of bedside blood product filters faced by the professional nurse each time he or she has to transfuse the neonate with blood or blood products.

1.2.1 Current practice regarding neonatal transfusion

Once prescribed by a doctor, blood or blood products are commonly transfused by a professional nurse to the neonate. The professional nurse first verifies whether the parents have given their consent for the transfusion. A blood specimen is then obtained from the neonate and sent to the SABTS to verify the neonate's blood group. In addition a compatibility test is conducted to ensure that the blood or blood products are suitable for the neonate. The professional nurse then ensures that the neonate has a patent intravenous line and, if not, one is inserted. As an advocate for the neonatal patients, the professional nurse serves as the liaison officer between the parents, the doctor, the medical aid, the pharmaceutical companies and the SABTS

(Kozier & Erb, 1987:1390; SABTS, 2003:6-7).

Once the blood or blood products arrives in the neonatal intensive care unit, the professional nurse checks and records that the correct products for the right neonate have been provided. The expiry date and blood group, the donor, type of blood or blood product and if it is leukodepleted are noted (Kozier & Erb, 1987:1390-1392; SABTS, 2003:7).

Once the professional nurse has ensured that the neonate will receive the correct blood or blood component, the professional nurse should decide what blood product filter (a microaggregate filter or a leukodepleting filter) should be employed. The professional nurse must decide what administration set to employ and whether to utilise an infusion pump or a syringe drive. The professional nurse must further ensure that the blood or blood products are warmed to the required temperature, and transfused at the prescribed rate (Bick, 1998:249; BCSH, 2003:437; Kozier & Erb, 1987:1390).

Professional nurses are also responsible for conducting the clinical observations of the neonate before, during and after transfusion. It is therefore imperative that the professional nurse has the appropriate knowledge of what transfusion related reactions neonates can present with, and to monitor for and manage these reactions (Brunner & Suddarth, 2007:1108-1111; Horne, 1997:1243). The professional nurse has to keep a record of all the events, including the transfusion reactions the neonate presented with and report all abnormalities to the doctor, the hospital management, the SABTS and the Haemovigilance Committee of South Africa (Avery, Fletcher, & MacDonald, 1994:986; Wilson, 2004:30).

1.2.2 Indications and advantages of blood transfusion

Blood transfusion is a cornerstone therapy for many serious and common conditions in the neonatal intensive care unit, contributing to total quality care and the saving of lives. Without blood or blood products it would be impossible to implement many of the modern regimens used for malignant diseases, or to perform surgery that has once been regarded as complex but

is now considered routine (Cloherty, Eichenwald & Stark, 2003:464; Wilson, 2004:28; SABTS, 2003:vi).

Blood or blood products are used as replacements for severe blood loss to prevent neonatal hypotension and shock or as a replacement during exchange transfusion for treating severe hyperbilirubinaemia or acute renal failure (Avery, et al. 1994:985; SABTS, 2003:11-12 & 16-17).

The concentration of red cells in the system is also increased by blood transfusion. This, in turn, increases the oxygen carrying capacity and volume, leading to increased tissue perfusion and improved aerobic metabolism, as well as an increased uptake of nutrients by the cells. It further enhances glucose storage and increases energy levels (SABTS, 2003:12; BCSH, 2003:43). Furthermore, blood transfusion reduces lethargy and the over-usage of stored adipose tissue (fat), promoting weight gain and improving the neonates' health, thus also improving recovery rates (Avery, et al. 1994:985-986; Wilson, 2004:28-9).

1.2.3 Blood products commonly used

Commonly used blood or blood products are: whole blood, leukodepleted packed red blood cells (LPRBC), platelets, fresh frozen plasma (FFP), albumin (20% or 40%) and autologous irradiated red blood products (Avery, et al. 1994:985-988; Brunner & Suddarth, 2007:1103; SABTS, 2003: vi).

Alternatives usually used while awaiting blood products for short-term treatment include normal saline (0.9%) and Ringer's lactate or dextrin, while for long-term treatment multivitamins and iron are used (Asahi Medical, 1996:2; Dreyer, 1996:183-184 & 212-213).

1.2.4 Transfusion associated reactions and the role of leukodepletion

The doctor responsible for prescribing and/or transfusing blood or blood products to the neonate and the professional nurse who plays a role in the transfusion, are involved in the evaluation of the risk/benefit ratio of the blood

or blood product to the neonate. According to the SABTS (2003:40) all blood or blood products carry a risk of adverse effects, and can range from being sensitive to donor cells or proteins to the transmission of diseases, including HIV. Risks are commonly referred to as ‘reactions’.

The list of potential reactions is lengthy, and there are many different ways of classification. Reactions can include incompatibility, transmissible diseases, bacterial contamination and storage lesions due to the age of the transfused blood or blood products, anaphylactic reactions and acute lung injury (SABTS, 2003:43). According to the SABTS (2003:40-41), they attempt to minimise these reactions by performing several procedures, for example the intense health screening of all donors, thorough testing of all donated blood units and leukodepleting most of the blood and/or blood products.

The confusion that professional nurses seemed to experience whenever they had to employ a bedside blood product filter when the blood or blood product was leukodepleted, gave rise to the question: can professional nurses make clinical decisions regarding the employment of bedside blood product filters during neonatal transfusion? For the purpose of this study, the focus was on leukodepletion as the main procedure utilised to minimise transfusion reactions in neonates.

Leukodepletion is the process whereby donor leukocytes are reduced within blood or blood products in an attempt to minimise transfusion associated reactions or complications (SABTS, 2003:20). Reactions or complications can include febrile non-haemolytic transfusion reactions or immune-mediated platelet destruction (Nel & Heyns, 2003:22; SABTS, 2003:46).

Most neonatal units employ leukodepleted blood or blood products from exonerative blood donors in an attempt to prevent alloimmunisation. The most effective prophylaxis has been reported from studies using the lowest amount of white cells (leukocytes) contamination per blood unit (Asahi Medical, 1996:8-10; Wang-Rodriguez, Fry, Fiebig, Lee, Busch, Mannino & Lane, 2000:25).

Even if leukodepletion reduces the risks of transmitting primary cytomegalovirus, HIV and the hepatitis A-B-C viruses to neonates, the level of residual leucocytes required to protect the recipient of blood from transfusion related complications and infections, is still unknown (PALL Medical, 1998; Flesland, Solheim & Seghatchian, 2001:211). Seghatchian (2003:105-106) notes that leukodepletion may not provide protection to neonates from septicemia, embolism and some viral infections.

Microscopic air is believed to be one of the main complications associated with causes of sudden death among neonates admitted to intensive care units. The microscopic air is believed to cause an embolus that gets trapped either in the brain, lung or heart, resulting in the sudden death of the neonate. This is evident from studies conducted on the causes of sudden death among neonates in intensive care units during post infusion with any form of a maintenance solution (Bick, 1998:249; Brunner & Suddarth, 2007:1109-1110; PALL Medical, 1999b: clinical update; Romaine, Hazlehurst & Jewell, 2004:51).

According to the SABTS (2003:21), when compared to non-leukodepleted blood products, the use of leukodepleted blood products overall provide greater benefits with reduced risks and complications.

1.2.5 Bedside blood products filters

Transfusion medicine is changing in line with new developments for the production of purer and safer blood or blood products. Some standards and some goals are reached, whilst new goals and challenges are appearing for the continual improvement of clinical outcomes. The diversity in risk reduction strategies makes it crucial for each country to carefully assess the benefits attributable to proposed interventional programmes (Beckman & Seghatchian, 2000:113).

The international and national transfusion services' standards of transfusion require that blood products be transfused at least via an administration set that has an inbuilt filter with a pore size of between 70µm and 240µm,

meaning a microaggregate filter (BCSH–BTTF, 2004:435; Bick, 1998:249; Bird, et al. 2003:419; NYSCHBTS, 2004:7; SABTS, 2003:9).

Pharmaceutical companies' stress that the pore size must be reduced to between 20µm and 40µm, thus indicating a leukodepleting filter since there are no microaggregate filters available in the market for neonates. This filter does not only trap pathogens and debris at that size, it traps microscopic air (van Lingen, Baerts, Marquering & Ruijs, 2004:658; Kunac, Ball & Broadbent, 1999:321-322 & Puntis, 1992:16-19).

For the purpose of this study the researcher concentrated on microaggregate filters and leukodepleting filters, since these are the blood product filters employed mostly by neonatal intensive care units during transfusion of neonates at bedside.

1.3 PROBLEM STATEMENT

A professional nurse has the responsibility of making a clinical decision when administering blood or blood products to the neonate who has to receive a blood transfusion amidst conflicting recommendations. The decision includes whether or not to employ a bedside blood product filter, and if the decision is to employ one, it is expected of the professional nurse to know whether to use a microaggregate or a leukodepleting filter.

Thus, the professional nurse's decision relates directly to the knowledge she or he has regarding the blood or blood products commonly used to transfuse neonates, and of to the relevant bedside blood product filters to employ. She or he has to understand implications of the differences between the bedside blood product filters as indicated in the concept clarification.

If the clinical decision made by the professional nurse is incorrect, it can have detrimental effects on the health of the neonate and can result in morbidity or mortality.

1.4 RESEARCH QUESTION

The research question was: “What is professional nurses’ ability in clinical decision making regarding the employment of bedside blood product filters during neonatal transfusion?”

1.5 AIM AND OBJECTIVES

The aim of the study was to determine and describe the clinical decision making of professional nurses regarding employment of bedside blood products filters during neonatal blood transfusion.

The study had two objectives as set out below.

1.5.1 Objective One

To determine and describe the professional nurses’ ability to make clinical decisions regarding the employment of bedside blood product filters during neonatal blood transfusion.

1.5.2 Objective Two

To recommend transfusion guidelines that will assist professional nurses to make clinical decisions regarding the employment of specific bedside blood product filters during neonatal transfusion based on the finding of the first objective and a literature review.

1.6 CLARIFICATION OF KEY CONCEPTS

1.6.1 Neonates

Neonates are infants from birth to 28 days post birth, irrespective of gestational age (Urdang & Swallow, 1983:729; Weller, 2004:272). In this study the term ‘neonates’ refer to infants admitted in the neonatal intensive care unit.

1.6.2 Blood and blood products

Blood is a complex component of tissue (commonly known as whole blood) that circulates through the heart and blood vessels, supplying nutritive materials to all parts of the body and carrying away waste products. It is a red viscid fluid and consists of plasma in which are suspended erythrocytes (red blood cells), leukocytes (white blood cells), lymphocytes, platelets (thrombocytes) and albumin (BCSH–BTTF, 2004:437-440; Brunner & Suddarth, 2007:1103; NYSCHBTS, 2004:3-9; Weller, 2004:54). A blood product is a component derived from blood. In this study 'blood or blood products' referred to whole blood, packed red blood cells, fresh frozen plasma and platelets.

1.6.3 Blood transfusion

Blood transfusion is the introduction of blood from the vein of one person (donor), or from the blood bank, into the vein of another (recipient) in cases such as, for example, severe blood loss, trauma and septicemia. It is used to supplement the volume of blood and introduce constituents such as clotting factors and antibodies that are deficient in the patient or recipient (Kozier & Erb, 1987:1387; Urdang & Swallow, 1983:136; Weller, 2004:56).

For the purpose of this study, the term 'blood transfusion' refer to the introduction of blood or blood products (from a donor at the blood bank) into the neonate's (recipient's) vein through an intravenous access by either a doctor or professional nurse to, for example, replace lost blood or treat septicemia.

1.6.4 Bedside blood product filters

Bedside blood product filters refer to specifically designed filtration sets that are used as part of the intravenous set during transfusion of blood or blood product to a recipient. It includes especially microaggregate and leukodepleting filters, but can include other bedside filters such as those used

for plasma and platelets (Roe, 1992:146; Weller, 2004:158). For the purpose of this study 'bedside blood product filters' refers to microaggregate filters with a pore size of between 170µm and 240µm, or a leukodepleting filter with a pore size of 20µm - 40µm.

1.6.5 Neonatal intensive care professional nurses

This refers to professional nurses registered at the South African Nursing Council according to the Nursing Act, Act no. 33 of 2005. They obtained their tertiary qualification at a university or nursing college and were employed in a public or private hospital. They were responsible for nursing of neonates in the neonatal intensive care units. In this study the term 'professional nurses' is used to refer to neonatal intensive care professional nurses.

1.6.6 Clinical decision making

'Clinical decision making' refers to the application of knowledge and skills, and the ability to think critically and scientifically in a practical situation. In this study it is concerned with the employment of bedside blood product filters (microaggregate and leukodepleting filters) during neonatal blood transfusion in the neonatal intensive care unit.

1.7 SETTING

Polit, Beck and Hungler (2001:44) describe a setting as a site where data collection will occur such as in homes, clinics or a social situation, under which the study is conducted, or the environment in which it is conducted. For the purpose of this study the setting was both government and private hospitals with neonatal intensive care units in Gauteng in South Africa. Ten hospitals were utilised. These different settings were included so that the outcomes of the study could accommodate both government and private hospitals. The names of the hospitals are not reported to maintain confidentiality. Therefore, if the results were exposed to other settings afterwards, generalisation could be increased.

1.8 RESEARCH DESIGN

The research design is the overall plan for collecting and analysing data, including specifications for enhancing the internal and external validity of the study (Polit, Beck & Hungler, 2001:40 & 167). In this study a descriptive survey research design was utilized.

According to Brink (2000a:103 & 247; 2001:109) descriptive studies are designed to gain more information about characteristics within a particular field of study and then to describe the phenomenon. Survey studies are concerned with gathering information from a sample of the population and the emphasis in the collection of data being on the structured indirect observation, questionnaires or interviews. No manipulation of variables is involved and there is no intention of establishing a cause and effect relationship (Polit, Beck & Hungler, 2001:180; Brink 2000a:102-103).

This type of design was chosen as more information was required regarding the ability of professional nurses to decide whether or not to employ a bedside blood product filter during neonatal transfusion, and, if it was decided that one had to be employed, which bedside blood product filter to employ with which blood products. Based on this information guidelines was recommended to assist professional nurses in clinical decision making during neonatal transfusion.

1.9 RESEARCH METHODS AND TECHNIQUES

Research methods and techniques are strategies utilised for conducting the study from identification of the problem to the final plans for collecting data (Uys & Basson, 1994:37-38). It is the methods used by the researcher to gather and analyse information relevant to the research question. They also optimise control over factors that could influence the outcome of the study (Bless; Higson-Smith & Kagee, 2006:71; Polit, Beck & Hungler. 2001:13).

The study had two objectives:

1. To determine and describe the professional nurses' ability to make clinical decisions regarding the employment of bedside blood product filters during neonatal blood transfusion.

2. To recommend transfusion guidelines to assist professional nurses to make clinical decisions regarding the employment of specific bedside blood product filters during neonatal transfusion.

The research design, methods and techniques are presented in a summarized manner in Table 1.1, and are discussed in detail in Chapter 3 regarding the population, sampling technique and sampling size, data collection and data analysis, as well as the validity, reliability and trustworthiness of the respective objectives.

Table 1.1: Research methods and techniques

Objective	Population / Unit of analysis	Sampling & sample size	Data collection	Data analysis	Validity & reliability / trustworthiness
Objective one: To determine and describe the professional nurses' ability to make clinical decisions regarding the employment of bedside blood product filters during neonatal blood transfusion.	Professional nurses working in neonatal intensive care units.	Sampling technique: Convenience or accidental sampling. Sample size: 120 professional nurses working in ten selected neonatal intensive care units in public and private hospitals in Gauteng.	Self-administered questionnaires	Descriptive statistics – mean and percentage	Strategies: • In-depth literature review, consulting experts in neonatal intensive care nursing science and neonatal transfusion, and a statistician in development and analysis of the questionnaire. • Sample size of 120 • Maintaining anonymity of hospitals and participants to reduce Hawthorne effect and reduce biasness.

Table 1.1: Research methods and techniques (cont.)

Objective	Population / Unit of analysis	Sampling & sample size	Data collection	Data analysis	Validity & reliability / trustworthiness
Objective two: To recommend transfusion guidelines to assist professional nurses to make clinical decisions regarding the employment of specific bedside blood product filters during neonatal transfusion.	Findings of first objective and documents on neonatal transfusion and in particular employment of bedside blood product.	Sampling technique: Literature search - Pubmed, Cochrane, journals (hard copies and electronic journals), health legislation, textbooks, hospital policies and other relevant transfusion literature or information. Sample: National and international literature and information relevant to neonatal transfusion and employment of bedside blood product filters.	The findings of the questionnaires, review of relevant literature and information and expert opinion on recommended guidelines.	Organisation and synthesis of information, and validation by experts.	Strategies: • Prolonged engagement • Triangulation of sources • Assistance of librarian • Expert opinion • Thick description of research process.

1.10 ETHICAL CONSIDERATIONS

Ethical approval to conduct the study was obtained from the Research Ethics Committee of the University of Pretoria (Annexure A) as a measure to protect the subjects under study as well as the researcher.

Ethical considerations require that all stakeholders be informed prior to the commencement of the study (de Vos, et.al. 2002:64). The researcher obtained institutional consent from all the hospitals of which the neonatal intensive care units were included in the study. Consent from the professional nurses in the neonatal intensive care units was received and they were also given a choice as to whether or not to participate in the study. By doing so any feelings of guilt regarding non-participation was eliminated.

The professional nurses who participated in the study were not required to identify themselves. In this way individual privacy and confidentiality were maintained as suggested by de Vos et al. (2002:67). Maintaining anonymity was further enhanced through the assigning of numbers to all questionnaires. The participants chose the questionnaires randomly. The hospital names

where the professional nurses worked were not included (de Vos, et al. 2002:67).

All relevant information about the researcher was made available to participants. The information included the researcher's qualifications, work place, experience in neonatal intensive care nursing, the name of the university where she studied, the name of her supervisor and her contact numbers. This was done to increase the transparency of the study.

1.11 LIMITATIONS

The study was limited in terms of its scope because it focused only on the employment of blood product filters during neonatal transfusion. The researcher acknowledges that there are several other factors of equal importance, such as the type of blood product transfused and blood grouping. It would, therefore, be recommended to repeat the study with the focus on different factors of importance during neonatal transfusion.

It was also limited as it only included professional nurses working in public or private neonatal intensive care units in Gauteng. It would therefore be recommended that the study be repeated in the other provinces throughout South Africa.

The outcomes of the study included guidelines for clinical decision making during neonatal transfusion, but these guidelines have not yet been implemented or tested in practice. A follow-up study is recommended to evaluate guidelines for validity, user-friendliness and utilisation in clinical practice.

1.12 CONCLUSION

Chapter 1 gave an overview of the study. This chapter provided the background where professional nurses working in neonatal intensive care units are expected to make clinical decisions regarding the employment of bedside blood product filters during neonatal transfusion.

The key concepts were clarified, the problem statement and research question were outlined and the objectives of the study were presented. A description of the background and setting was given. The research design, research methods and techniques were introduced. The ethical considerations were discussed, as well as validity, reliability and trustworthiness.

The literature review is presented in the following chapter.

CHAPTER TWO

LITERATURE REVIEW

2.1 INTRODUCTION

The previous chapter gave an overview of the study. This chapter addresses the literature review related to neonatal blood transfusion and bedside blood filters.

Blood transfusion is the introduction of whole blood or a blood component into a vein of the recipient (Weller, 2004:396; Mosby's, 1983:1089). Blood transfusion is one of the therapeutic interventions used daily in the medical field to save millions of lives across the world, yet at the same time it is viewed as one of the costly medical interventions with severe adverse effects, especially if not well utilised (Nel & Heyns, 2003:1-2; United States Department of Health & Human Services - National Institute of Health, 2007:145; Weller, 2004:396).

Before the 1980s blood transfusion was considered to be relatively risk free, especially with the introduction of leukodepleted blood or blood products, but a dramatic change occurred in this period due to concerns of transfusion related complications such as the cytomegalovirus (CMV) and Hepatitis A-B-C infections, and later, the human immunodeficiency virus (HIV) (Bowden, Slichter, Sayers, Weisdorf, Cays, Schoch, Banaji, Haake, Welk, Fisher, McCullough & Miller, 1995:3598; Wilson, 2004:28).

During the late 20th century blood transfusion became the mainstay of clinical practice - especially in intensive care units – but, despite its significant advances, risks also became prevalent. Subsequently, transfusion triggers were introduced where the benefit of transfusion outweighed the risks associated with the transfusion of blood or blood products to patients (BCSH-BTTF, 2004:433; SABTS, 2003:vi; Seghatchian, 2003:105; Wilson, 2004:28).

Neonates in intensive care units are among the most intensively transfused of all hospital patients. The neonate may require specific blood or blood products for specific conditions, for example, packed red blood cells for anaemia, fresh frozen plasma for hypovolaemia or platelets for bleeding disorders. The neonates' safety is of paramount importance when the intensity of their transfusion, their age and potential life expectancy are taken into consideration (Murray & Roberts, 2003:101; New York State Council on Human Blood and Transfusion Services - Transfusion Practices Committee [NYSCHB&TS-TPC], 2004:2).

During their hospitalisation in intensive care units, neonates tend to present with health problems such as anaemia, infections, an increased respiratory and heart rate coupled with high oxygen demands, failure to thrive, and lethargy, in other words, their metabolic demands are increased (Cloherty; Eichenwald & Stark, 2003:490-1). This compromises their immune system and they tend to become vulnerable to infections, increasing their demands for antibiotics and prolonging their stay in hospital, which makes their medical treatment extremely expensive (Wilson, 2004:28-30).

As a means to protect them from developing complications and shortening their stay in intensive care units, neonates are often transfused with blood or blood products; but blood transfusion has its own complications or reactions which neonates may be exposed to. These reactions or complications may be in the form of fever, severe chills, hypotension, vomiting, an increased heart and respiratory rate coupled with general body cyanosis, lethargy, decreased urine output and blood in their urine. Disseminated intravascular coagulation (DIC) may also occur. Neonates can easily be diagnosed as having respiratory distress or neonatal septicemia instead of a transfusion reaction, especially if a change in the neonates' clinical condition presents itself 7 to 10 days after a blood transfusion (Brunner & Suddarth, 2007:1109; Cloherty, et al. 2003:464-7; Nel & Heyns, 2003:22-23; Wilson, 2004:30-1).

What complicates the whole situation is that some neonates may display these adverse reactions immediately during transfusion (immediate reaction that is within 15 to 30 minutes or within 24 hours of commencing the therapy);

while others may react at a later stage (late transfusion reaction that is within 7 to 10 days after transfusion therapy). Based on this, neonatal intensive care professional nurses and doctors find it difficult to associate the change in the neonate's condition with transfusion therapy, especially if it occurs at a later stage, such as 7 to 10 days after transfusion (American Association of Blood Banks, 2002:5-9; Cloherty, et al. 2003:255-259; Galel & Fontaine, 2006:147; Nel & Heyns, 2003:22-24; Wilson, 2004:31).

2.2 INDICATIONS FOR BLOOD TRANSFUSION

According to Deacon and O'Neill (1999:406) and Cloherty, et al. (2003:466-467 & 487-490), packed red blood cells, whole blood, fresh frozen plasma or platelets are blood products commonly used to treat several neonatal conditions.

Neonatal blood transfusion is indicated to correct neonatal anaemia caused by haemolytic disease of the neonate, to replace phlebotomy losses caused by day to day blood sampling performed on neonates while they are being treated in intensive care units, or to manage neonatal hypotension and/or thrombocytopenia (BCSH-BTTF, 2004:435-439; Cloherty, et al. 2003:462-464; Murray & Roberts, 2003:101).

Blood transfusion is used to treat acute neonatal blood loss due to vasa previa (rupture of anomalous vessel or communicating vessel in a multilobed placenta), abruption placenta, cord accidents and feto-maternal transfusion. These conditions may expose the neonate to hypovolemic shock and anaemia, and necessitate the transfusion of blood products to neonates. On the other hand, neonatal blood transfusion is commonly indicated to maintain perfusion pressure and re-expand the circulating blood volume (Cloherty, et al. 2003:462-464; Deacon & O'Neill, 1999:390-393).

Sick neonates, for example, with sepsis, pneumonia or broncho-pulmonary displasia, may require increased oxygen-carrying capacities and therefore may need blood transfusion, specifically red blood cells, to achieve this. Growing premature neonates may indicate a need for transfusion by

exhibiting poor weight gain, apnoea, tachypnea or poor feeding. The neonate's general condition and his or her physiological needs play a major role to decide whether or not to transfuse the neonate**.** An example is that a neonate with significant respiratory disease or congenital heart disease may need a haematocrit maintained above 40% (Avery, et al. 1994:985-986; BCSH-BTTF**,** 2004:437; Cloherty, et al. 2003:464-467 & 485; Wilson, 2004:28-30).

In preterm infants it is believed that transfusion with a small volume of packed red blood cells can increase the neonates' circulating blood volume and maintain the haematocrit level above 40%. This ensures that the neonate's oxygen carrying capacity is enhanced, leading to increased tissue oxygenation and perfusion, and reducing the workload on their metabolic status. In turn, their respiratory and heart rate will be reduced to normal ranges, while their ability to absorb food and gain weight is increased (Foetus & Newborn Committee - Canadian Paediatric Society, 2002:4; Wilson, 2004:30).

Furthermore, transfusing the neonate with blood or blood products may improve the neonates' immune system, enhance their defense mechanisms and lead to a reduction in their antibiotic requirements. Blood transfusion can increase their ability to fight infections, while shortening their stay in hospital and leading to a reduction of their medical costs (BCSH-BTTF, 2004:433-434; Cloherty, et al. 2003:465-466 & 489-490; Deacon & O'Neill, 1999:406).

Blood transfusion with red blood cells prevent system overloading in neonates who require fluid replacement but are susceptible to being overloaded, for example in neonates with cardiomyopathies or renal conditions. It prevents anaemia of prematurity associated with normal neonatal growth and/or the development of the preterm neonate (Cloherty, et al. 2003:464-466; Deacon & O'Neill, 1999:406-407; Foetus and Newborn Committee - Canadian Paediatric Society, 2002:4; SABTS, 2003:17; Wilson, 2004:29).

Neonates with ABO incompatibilities, in other words a neonate whose blood group is different from that of his or her mother, may require immediate

exchange transfusion for the management of neonatal hyperbilirubinaemia. In this instance, a large volume of blood or blood products may be required (Wilson, 2004:29-30; Cloherty, et al. 2003:464-466; Deacon & O'Neill, 1999:405-408). A neonate who requires cardiac bypass surgery requires large volumes of blood or blood products to survive (BCSH, 2003:44; Foetus & New Born Committee - Canadian Paediatric Society, 2002:1–7; SABTS, 2003:17).

The transfusion of neonates and the relevant blood or blood products are prescribed by those responsible for the care of the neonates. However, because indications for transfusion continue to be inconsistent among health care workers, clinically appropriate reasons should be given for a transfusion (Agarwal, 2006:145; Brunner & Suddarth, 2007:1107 & 505-506; Nel & Heyns, 2003:1; SABTS, 2003:vi; Wilson, 2004:28).

2.3 COMPLICATIONS

Blood products are, however, living human tissue used in the treatments of neonates, and just like any other biological products, are not without disadvantages, side effects or adverse reactions.

A wide range of complications and side effects are associated with blood transfusion. The complications range from relatively minor problems such as febrile transfusion reactions, to serious complications, such as CMV (cytomegalovirus) transmission, HIV transmission and anaphylactic reactions. Blood transfusion can even result in the death of the neonate (Deik, Blajchinan, Blumberg, Kirkley & Wood, 1996:187-94; United States Department of Health - National Institute of Health, 2007:150-152; Wilson, 2004:30-31).

2.3.1 Complications due to transfusion service

On the other hand, transfusion reaction may be attributed not to in-hospital mistakes, but to errors that occur at the transfusion service since it can happen during the preparatory phase of blood or blood products. The phlebotomist may, for example, neglect to inspect the blood bag in the

manner recommended by the manufacturer, or may label it wrong, or fail to regularly mix the contents within the collection bag during the donation period. He or she may fail to spot some of the defects during the final inspection session prior to releasing the blood or blood product from the blood collection session (BCSH, 2004:43; Royal Prince Hospital, 2000:Transfusion Protocol; Standards of Practice for Blood Transfusion in South Africa, 2004:14-15 & 20-26).

2.3.2 In-hospital errors

Serious complications as a result of blood or blood products transfusion can be related to in-hospital errors. In-hospital errors could happen from the moment the neonate is identified, pre-warming the blood or blood product, spiking the bag, priming up the administration line, or during connecting the administration line to a filter and to the venous line on the neonate. Further complications may occur while observing the neonate during the transfusion procedure (Urdang & Swallow, 1983:1098; SABTS, 2003:7-10, SABTS, 2005:34-35; NYSCHB&TS-TPC, 2004:7).

Additional in-hospital risks and complications may include: (i) the use of incorrect equipment, (ii) transfusion of the incorrect neonate, (iii) missing the transfusion reaction on time or failing to report it; (iv) failure to follow the correct procedure when warming up the products, and (v) failing to properly check the products prior to transfusion and missing the expiry date. The aforementioned may be referred to as prescriptive and/or administrative errors (BCSH, 2004:44; Kozier & Erb, 1987:1390-1392; Regulations Regarding Blood & Blood Products, 1990; Human Tissue Act, 1989; SABTS, 2003:7-10; SABTS, 2005:34).

In-hospital errors may be caused by an instrumental mistake such as: (1) the pharmaceutical company may supply a wrong filter batch, and (2) since most blood product filters are similar, medical staff may utilise this without realising his or her mistake. An example of this is that platelet filters may be packed in red cell packs and only a well-skilled or knowledgeable nursing practitioner or doctor will be able to recognise it (Beckman & Seghatchian, 2000:114;

Sowemimo-Coker, Kim, Brandwein & Wenz, 1998:1; SABTS, 2003:9; BCSH-BTTF, 2004: 47-48).

2.3.3 Infection

A substantial amount of research published since the early 1980s suggests that the exposure to donor leukocytes may trigger an immune response in the recipient, leading to an increased risk of infections, morbidity and mortality (Saarinen, Koskimies & Myllyla, 1993:290; Seghatchian, 2000:47-48). It has been demonstrated by Hume, Popovsky and Anderson (1998:414-415) that there is an association between blood transfusion and increased nosocomial infections and mortality in the critically ill. This data has in turn led to the hypothesis that leukocytes in stored blood products suppress immunity. However, it is unclear whether infectivity is confined to leukocytes or whether platelets and plasma may also carry pathogens (Barrowcliffe, 1998:332; Blumberg, 1997:34-40; Vignali, Braga, Gianotti, Radaelli, Gentilini, Russo & Di Carlo, 1996:170-175; Wang-Rodriguez, et al. 2000:25-26).

In addition, blood or blood products are currently considered a dangerous drug due to their potential to transmit irreversible infections such as HIV, CMV (cytomegalovirus) and Hepatitis A-B-C. The virus that causes these infections can be transmitted to neonates via blood or blood products that have been obtained from donors who have not been properly screened during the donation period (Nel & Heyns, 2003:24).

2.3.4 Transfusion reactions

According to Urdang and Swallow (1983:1089), some neonates may display unintentional reactions or systemic adverse effects to being transfused with blood products. Examples of this include significant hypotension due to the activation of the bradykinin/kininogen system, pseudo haemologic reactions, transfusion related acute lung injury and immune-mediated platelet destruction, post-transfusion purpura, delayed haemolytic transfusion reaction, alloimmunisation or bacterial contamination (Brunner & Suddarth, 2007:1110; Wilson, 2004:31; Nel & Heyns, 2003:22-25).

Common risks that the neonate may be exposed to inludes febrile nonhemolytic reaction, acute hemolytic reaction, allergic reaction and circulatory overload (Brunner & Suddarth, 2007:1109-1110; Nel & Heyns, 2003:22-24).

Febrile nonhemolytic reactions is caused by antibodies of donor leukocytes that remain in the unit of blood or blood component (Brunner & Suddarth, 2007:1109). Nel and Heyns (2003:22) note that this is the most common type of transfusion reaction and accounts for 90% of reactions.

An acute hemolytic reaction occurs when the antibodies already present in the recipient's plasma rapidly combine with antigens on donor erythrocytes, and the erythrocytes are hemolysed (destroyed) in the circulation (intravascular hemolysis). The most rapid hemolysis occurs in ABO incompatibility, rendering it the most dangerous and potentially life–threatening reaction. This reaction can occur after the transfusion of as little as 10mls of packed red blood cells to the patient (Brunner & Suddarth, 2007:1109; Nel & Heyns, 2003:22).

Allergic reactions are thought to be caused by a sensitivity reaction to a plasma protein within the blood component being transfused, and its symptoms includes uticaria, itching and flushing. Occasionally this reaction is severe and presents with bronchospasm, laryngeal edema and shock (Brunner & Suddarth, 2007:1109; Nel & Heyns, 2003:22). Circulatory overload is when too much blood is infused too quickly to the neonate and hypervolaemia occurs (Brunner & Suddarth, 2007:1110).

2.4 ROLE PLAYERS INVOLVED IN NEONATAL BLOOD TRANSFUSION

The transfusion of blood or blood products can save a neonate's life if the role players involved in transfusion are able to make clinical decisions regarding the types of blood or blood products commonly used to transfuse neonates, but also its indications, possible reactions it can cause, as well as which equipment to employ during transfusion (Brunner & Suddarth, 2007:1107).

The following section describes the role players involved in neonatal tranfusion.

Several individuals are involved in the transfusion of a neonate. They include the blood transfusion services, the pharmaceutical as well as medical aid companies, the doctor, the professional nurse and the parent(s). All these role players are interested in safeguarding the well-being of a neonate (Foetus & Newborn Committee - Canadian Paediatric Society, 2002:1-3 & Nel & Heyns, 2003:3-4).

2.4.1 Role of the South African Blood Transfusion Services (SABTS)

Blood transfusion is universally recognised as a medical intervention that saves millions of lives each year. Blood safety remains the cornerstone responsibility of the SABTS as it is concerned with the overall process of acquiring blood or blood products, testing both the donor and the recipient, and the processing, packing and storing of processed products (Nel & Heyns, 2003:1; SABTS, 2003:vi & 40; SABTS, 2005:13). Designing and supplying simple, understandable request forms in a language acceptable to all is also the responsibility off the SABTS. It further has to ensure that proper request forms are utilised for specific blood or blood products, and that the request forms are properly completed by those who request blood or blood products. This includes proper client identification and diagnosis to protect the client from unnecessary exposure to transfusion complications (SABTS, 2003:1; SABTS, 2005:5-6).

Apart from supplying the nation with blood or blood products, the SABTS plays an important role in the education and training of those in charge of transfusing the patients. This pertains to all the health care workers who utilise the blood products. These individuals have to be competent and knowledgeable as they play a key role in achieving the overall goal of the SABTS, namely o save lives (BCSH-BTTF, 2004:435-436; Nel & Heyns, 2003:2).

Quality control is a major responsibility of the SABTS. Accuracy is essential to

competent and successful transfusion and errors can be prevented only by daily adherence to systems that ensure correct results from beginning to end. This can be achieved through quality control of the products produced. The purpose of quality control in this instance is to help identify deviations from the expected results and to prevent errors in the final results (Hoppe & Tourault, 2000:249; SABTS, 2005:4-5).

Most blood banks across the world have performance criteria in place for their equipment, reagents and components to help achieve positive ends, and South Africa is no exception in this regard (BSCH-BTTF, 2004:437-438; Hoppe & Tourault, 2000:248-249; SABTS, 2003:12; SABTS, 2005:13-15).

2.4.2 Role of pharmaceutical companies

Lee and Barnett (1992:1) state the responsibility of pharmaceutical companies is to supply both the government and private hospitals with administration sets and filters for blood or blood products. Hence they collaborate with all stakeholders in transfusion medicine such as the blood bank, and private as well as government hospitals. Pharmaceutical companies are also concerned with the training of doctors, professional nurses and blood transfusion services employees in South Africa with regard to the products, including aspects such as their indications, advantages and disadvantages. In addition, the companies must ensure that correct bedside blood products filters are utilised for indicated or specific blood or blood products, for example, platelets filter-to-filter platelets and red cells filter for red cells according to the stated pore size (Lee & Barnett, 1992:1; Morris, Maynard, Granger & Ellson, 1998:10-29). They suggest pharmaceutical companies could run in-service training, workshops, seminars or symposiums together with the blood banks and hospitals. Lee and Barnett (1992:1) advocate these should be directed at professional nurses and doctors in order to improve and increase their knowledge regarding the leukodepleting process; which bedside blood product filter is the most suitable for which blood or blood product; when such a filter should be employed and for how long and how often it can be utilised.

It is further advised that pharmaceutical companies should supply the

hospitals with literature on research studies conducted regarding the administration sets and bedside blood product filters they supply. This literature should clarify the importance and indications of employing bedside blood product filters during neonatal transfusion with blood or blood products (SABTS, 2003:1-2; Wang-Rodriguez, et al. 2000:26-27).

2.4.3 Role of medical aid companies

A significant role of the medical aid companies is to safeguard the patients' medical funds. In other words, they must ensure that the care, treatment and equipment utilised are relevant to the patient's condition. The transfusion of blood or blood products is one of the treatments scrutinised by medical aid companies in order to verify that a blood transfusion has not been prescribed unnecessarily, and that suitable equipment will be utilised; they demand sufficient motivation when a bedside blood product filter is to be employed during neonatal transfusion (Murray & Roberts, 2003:102-103).

2.4.4 Role of the doctor

The major role of the doctor is to assess the appropriateness of neonatal transfusion and prescribe it. This should be in line with the guidelines of transfusion as laid down by the experts in transfusion medicine and regulations from the Department of Health (Human Tissue Act as amended, 1989; Medicine & Related Substances, 2002; National Health Act as amended 2004; Potter, 2001:1243; Regulations Regarding Blood & Blood Products, 1990). In paediatrics, however, this seems to be a problematic issue as no consensus regarding the appropriate concentrations at which to transfuse red blood cells to a neonate exists. Consequently, there seems to be a trend for allowing lower haemoglobin concentrations in stable asymptomatic neonates. Therefore, the doctor should thoroughly assess the neonate's clinical status as this will enable her or him to decide whether or not to transfuse the neonate. She or he should weigh up both the advantages and disadvantages of transfusion to neonates (BCSH, 2004:43; Foetus & Newborn Committee - Canadian Paediatric Society, 2002:1; NYSCHB&TS-TPC, 2004:1; Potter, 2001:1242-1243).

Once the doctor decides to transfuse the neonates, the neonates' parent(s) have to be contacted and an explanation must be given as to why their neonate requires transfusion. The parent(s) should be informed concerning the indications for transfusion and made to understand the reasons why their neonate is to be transfused. They should also be informed of the effects, side-effects and/or complications associated with blood or blood product transfusion. The latter is a shared responsibility between the doctor and the professional nurse (Brunner & Suddarth, 2007:1109; SABTS, 2003:4; SABTS, 2005:32). This must be done in order for the parent(s) to make an informed decision before granting permission for a transfusion. Though Potter (2001:1242) and Deacon and O'Neill (1999:405) assess that the parent(s) must sign an informed consent form, it is important to note that not all hospitals have informed consent forms for blood transfusion. However, specifications for informed consent are the responsibility of each transfusion facility and its risk management advisors (Deacon & O'Neill, 1999:405; NYSCHB&TS-TPC, 2004:1). Where there is no informed consent for parents to sign, it is of utmost important that at least a note be placed on the patient's chart, signed by the transfusing doctor, attesting that the indications, the risks (including possibly fatal adverse effects), benefits, estimated number of, and alternatives to transfusion have been explained to the parents (Deacon & O'Neill, 1999:405; Nel & Heyns, 2003:3; NYSCHB&TS-TPC, 2004:1; Weller, 2004:97-98).

Once parental informed consent is granted, a blood or blood product requisition form supplied by the SABTS has to be filled in by either the doctor or the professional nurse. This form contains information about the recipient of blood (the neonate) and his or her parents. Information such as the patient's full names, date of birth, hospital number, date of sample, ward name and number, type of blood product, and number of units ordered must be indicated on it. The forms are filled out at the patient's bedside by questioning the neonate's parent(s) on his or her behalf (Potter, 2001:1242; SABTS, 2003:6-7). On the same form the doctor should outline details of previous medical, obstetrics, and transfusion history, the current diagnosis, the reason for transfusion, and the date and time when the blood products should be

available (Avery, et al. 1994:985; Human Tissue Act, 1989; Medicine & Related Substances Act, 2002; National Health Act, 2003; SABTS, 2003:6). Documentation of the indications for transfusion must include pertinent signs and symptoms of the patient's condition, as well as his or her haematological data (SABTS, 2003:6-7; SABTS, 2005:31).

Also to be clearly indicated by the doctor on the neonate's clinical records is: the amount of blood or blood products to be transfused to the neonate, over how many hours or for how long (NYSCHB&TS-TPC, 2004:1; SABTS, 2003:6). The doctor should also have knowledge regarding the different types of administration sets and related equipment, such as bedside blood product filters, to be employed during transfusion so that he or she can make a clinical decision when accepting or rejecting its employment during neonatal transfusion (SABTS, 2005:32).

The doctor can be a transfusionist him- or herself; that is, he or she can administer blood or blood products to the neonate and do all the necessary observations required on a neonate during transfusion, including inserting an intravenous line into the neonate (Afrox Health Care, 1999: Protocol SABTS, 2003:6; SABTS, 2005:32;).

2.4.5 Role of the professional nurse

The professional nurse acts as a cornerstone for the whole procedure of neonatal transfusion; she or he 'co-ordinates' the whole transfusion procedure (Brunner & Suddarth, 2007:506; Potter, 2001:1242; SABTS, 2003:6). The professional nurse must thus ensure that whatever decisions are made on behalf of the neonate by whoever is involved in his or her care, is in the best interest of the neonate (Aiken & Catalano, 1994:236; Deacon & O'Neill, 1999:745-747; Potter, 2001:1242).

The professional nurse has a shared responsibility with the doctor to ensure that the parent(s) of the neonate is/are aware of the transfusion procedure and understand/s its indications, advantages and disadvantages. She or he must act as an advocate for both the neonate and the parent(s) when the

informed consent is to be signed by the parents. It is crucial that the professional nurse must be supportive and understanding, whether the parent(s) accept or refuse the transfusion. She or he must also verify that the parent(s) understand the whole procedure (Deacon & O'Neill, 1999:405; Kozier & Erb, 1987:1390; NYSCHB&TS-TPC, 2004:1; Potter, 2001:1242; SABTS, 2003:7-8; SABTS, 2005:32; Urdang & Swallow, 1983:1089; Weller, 2004:98).

Once the parent(s) understand and have accepted that the neonate is going to be transfused, the professional nurse has to accurately identify the neonate. This involves a co-check with either the doctor, another professional or enrolled nurse to ensure that the right neonate is transfused using the right product and utilising the right equipment to reduce transfusion related reactions that may occur (Horne, 1997:1242-1243; Potter, 2001:1243; SABTS, 2003:8).

The professional nurse is also expected to obtain a blood specimen from the neonate for cross matching by the SABTS. She or he must also fill in the blood request forms as stipulated by the SABTS – this includes obtaining the previous transfusion history of the neonate (Brunner & Suddarth, 2007:506; Human Tissue Act, 1989; Kozier & Erb, 1987:1390; Regulations Regarding Blood & Blood Products, 1990; SABTS, 2003:6-7).

As the professional nurse serves as a liaison officer between the blood transfusion services, the doctor, the hospital, the pharmaceutical companies, the medical aid companies and the parents, he or she must verify with the blood bank that the freshest blood products - as per the doctor's prescription and/or the unit's transfusion policy - for the neonate are available (SABTS, 2003:17; NYSCHB&TS-TPC, 2004:6; Afrox Health Care, 1999: Protocol; BCSH-BTTF, 2004:436).

Once the professional nurse is sure that the blood or blood products will be available, she must prepare the neonate for transfusion by inserting an intravenous line (if the neonate doesn't have one), put the neonate on a cardio-pulmonary monitor as well as taking precautionary measures to handle

an emergency should the need arise. She or he must record the neonate's vital baseline data: blood pressure, pulse rate, respiration rate, temperature and peripheral oxygen saturations as this will serve as guidelines for assessing the neonate's condition during the transfusion procedure. The neonate may display clinical changes that may indicate improvement or deterioration, and without this vital baseline data it is difficult to monitor the neonate's progress (Brunner & Suddarth, 2007:1107-1109; Potter, 2001:1242-1243; SABTS, 2003:8). Baseline vital data should be conducted prior to transfusion (pre-transfusion), during the process of transfusion (intra-transfusion) and after transfusion (post-transfusion) (Brunner & Suddarth, 2007:1108; SABTS, 2003:8 & 41-42; Potter, 2001:1242).

On receiving the blood or blood products, it is the professional nurse's responsibility to execute the whole transfusion procedure. He or she must ensure that the right patient is transfused, that the details on the blood or blood product unit are checked, that the blood group, including its titer, is correct and that the bag is intact. The professional nurse must be able to make a clinical decision as to whether or not to employ a bedside blood product filter on the equipment to be utilised for neonatal transfusion (SABTS, 2003:7; Brunner & Suddarth, 2007:1107; NYSCHB&TS-TPC, 2004:1; Potter, 2001:1242-1243).

Prior to transfusion, it is the duty of the professional nurse to ensure that the blood or blood product is at the right temperature as cold or overheated blood must not be administered to the neonate (SABTS, 2003:9-10; BCSH-BTTF, 2004:437; NYSCHB&TS-TPC, 2004:8).

It is preferred to have the neonate on a vital data monitor for continuous monitoring during transfusion. The monitor should have the facility for heart rate, respiratory rate and saturations, with alarm limits set at all times (SABTS, 2003:8; Afrox Health Care, 1999: Protocol; NYSCHB&TS-TPC, 2004:8).

The professional nurse has to make sure that the blood or blood products are transfused to a neonate at the rate prescribed by the doctor. The transfusion

period should be kept between 4 and 6 hours. If the neonate is transfused quickly, in less than 4 hours, she or he could present with circulatory overload. Also, if transfused for more than 6 hours, the blood or blood products are exposed to the warm temperature of the ward and this promotes bacterial growth; as a result, the neonate could be exposed to bacterial infections (Brunner & Suddarth, 2007:1110).

Observations are to be done within the first 15 minutes of transfusion. If no transfusion reaction occurs during this time, observations must be repeated every 30 minutes thereafter, and then every hour until the transfusion procedure is completed. All relevant information must be documented, that is, all observations made should be recorded on the neonate's clinical records (Brunner & Suddarth, 2007: 1107; NYSCHB&TS-TPC, 2004:1; SABTS, 2003:8-9; Potter, 2001:1242-1243).

If the neonate displays no immediate transfusion reactions, the professional nurse must, at the end of the procedure, keep the remaining blood or blood products, the blood bag and all the equipment employed during the transfusion procedure safe. These are to be stored in the refrigerator for a minimum of 2 days to a maximum of 5 days before they can be thrown away. In the event that the neonate presents with transfusion reaction, the following procedure applies: the transfusion procedure must be stopped immediately, the treating doctor must be notified immediately, and the blood products - with equipment attached to it - together with the neonate's blood and urine specimens must be sent to the SABTS for investigation. The Haemovigilance Committee must be notified of the reaction as well (Brunner & Suddarth, 2007:1112 & 1111; Nel & Heyns, 2003:1; Potter, 2001:1243; SABTS, 2003:4 & 8).

After transfusion, the neonate must be observed for a period of 7 to 10 days as latent transfusion reactions could then occur. Should the neonate present with latent transfusion reaction, and the blood unit (bag) and transfusion equipments have been thrown away, the treating doctor should be notified forthwith. The blood bank must be contacted and supplied with the neonate's details as they appear on his or her document. This includes the blood unit

number, donor number/name, name and surname of the neonate, his or her hospital number and the date of transfusion, as well as a blood and a urine specimen of the neonate (Afrox Health Care, 1999: Protocol; Brunner & Suddarth, 2007:1111; Cloherty, et al. 2003:490; SABTS, 2003:8).

All procedures performed on the neonate should be recorded, namely the neonate's response(s), as well as all the communication with the stakeholders such as parents, doctor and the Haemovigilance Committee (Brunner & Suddarth, 2007:1107-1108; Kozier & Erb, 1987:1392; Scope of Practice for Registered Nurses, 1991).

2.4.6 Role of the parents

Having to make a decision on whether to allow a blood transfusion on their neonate, is a profoundly difficult situation for the parent(s). It is here that the support of a team of health professionals who understand their concerns in such daunting circumstances, and who can communicate information in a compassionate yet sensible way, greatly influence their decision making capabilities. According to Deacon and O'Neill (1999:748) and Cloherty et al. (2003:249), due to the high prevalence of HIV and AIDS, parents in present times find themselves in a dilemma. Therefore, they often rely on the information supplied by the health professionals to make a rational and educated decision, especially in critical situations. For them to be able to accept their role as parents, they depend on how and to what extent they are being involved, and the amount of information given to them regarding their neonate's condition by those treating him or her. However, in the end they should make the final decision as to whether or not their neonate is to be transfused (Cloherty, et al. 2003:249; Deacon & O'Neill, 1999:748).

The parents' consent or refusal of blood transfusion to their neonate should be acknowledged and documented in the chart or on an appropriate form which is consistent with the policies of the hospital (Deacon & O'Neill, 1999:405; NYSCHB&TS-TPC, 2004:1).

Deacon and O'Neill (1999:405 & 749) note that religion and extended family

members play a major role in most families' decision making concerning their lives, including what health practices to follow. Thus, it would be logical for them to look for guidance and support from their religion and/or family members regarding the acceptance of blood transfusion as a means of treating their neonate's condition or disease. Hence, if health care professionals understand and respect the guidelines laid out by the parents' respective religions concerning blood transfusion, the parents may be able to make a better moral, ethical and informed decision regarding the transfusing of their neonate (Aiken & Catalano, 1994:21; Deacon & O'Neill, 1999:744-749).

2.5 BLOOD AND BLOOD PRODUCTS

Several types of blood or blood products are used to transfuse critically ill neonates in intensive care units. In South Africa blood or blood products that have been donated by voluntary donors and subjected to stringent testing may be transfused. Blood products commonly used include the following: whole blood, packed red blood cells, platelets, fresh frozen plasma and albumin (Brunner & Suddarth, 2007:1103; BCSH, 2003:44-45; BCSH-BTTF, 1999:436-440; Deacon & O'Neill, 1999:406-408; Foetus & Newborn Committee - Canadian Paediatric Society, 2002:3; NYSCHB&TS-TPC, 2004:3; SABTS, 2003:4, 11-18 & 40).

2.5.1 Whole blood

Blood is commonly referred to as whole blood. It is a red viscid fluid which consists of plasma in which are suspended red blood cells (erythrocytes), white blood cells (leukocytes), platelets (thrombocytes) and lymphocytes; hence the term whole blood. The function thereof is to nutritive material to all parts of the body carrying away waste products (Weller, 2004:54).

2.5.2 Packed red blood cells

Red blood cells are also known as corpuscles and contain haemoglobin. The function of Haemoglobin is to carry oxygen to tissues and cells (Weller,

2004:54). Packed red blood cells refers to a preparation of red blood cells separated from liquid plasma, and is often administered to neonates with severe anaemia in order to restore adequate levels of haemoglobin and red cells without overloading the vascular system of the neonate with excess fluid (Urdang & Swallow, 1983: 791-2).

2.5.3 Platelets

Platelets are also known as thrombocytes and they are concerned with clotting of blood (Weller, 2004: 54).

2.5.4 Fresh frozen Plasma

Fresh frozen plasma is the watery, colorless, fluid portion of the lymph and the blood in which the leukocytes, erythrocytes and platelets suspended. It contains no cells and is made up of water, electrolytes, protein, glucose, fats, bilirubin and gases. Its function is to carry the cellular elements of the blood through the circulation, transportation of nutrients and helps with maintance of acid base balance of the body and removal of wastes from the tissues (Urdang & Swallow, 1983:852).

2.5.5 Albumin

It is a water - soluble, heat - coagulable protein containing carbon, hydrogen, oxygen, nitrogen and sulfur; commonly known as human albumin - plasma volume expander. It is commonly used in the management of hypoproteinaemia, hyperbilirubinaemia and hypovolaemic shock (Urdang & Swallow, 1983:35).

For neonates to be transfused with this blood or blood products, adults have to donate them at a legally recognised institution known as the blood bank via several methods (Urdang & Swallow, 1983: 109 & 133).

2.6 DONATION

Urdang and Swallow (1983:345) and Weller (2004:126) concur the donation of blood or blood products refers to the known ways in which humans or other organisms give living tissue to be used in another body, such as in the case of blood for transfusion. The three methods utilised to donate this blood or blood products are allogeneic, designated and autologous blood donations**.**

2.6.1 Allogeneic blood donation

Allogeneic or voluntary transfusion refers to the introduction of blood or blood products that have been obtained from regular voluntary blood donors as opposed to those withdrawn from the patients themselves or their close family or relatives (the neonates' close family or relatives in this case). These blood or blood products contain antigens that are compatible to those of the neonate. Voluntary blood donors donate their blood regularly and the SABTS have enough time to test and prepare it for utilisation when required. This ensures that the safety of the blood products compares favourably with that of the rest of the developed world. Normally allogeneic blood products are utilised to transfuse neonates (Osborn, 2000:5; Potter, 2001:1242; SABTS, 2003:vi & 2; SABTS, 2005:32-33).

In South Africa voluntary non-remunerated donors donate blood or blood products, commonly known as allogeneic blood or blood products, which are used to transfuse patients. The recipient's blood group is compatible with the donor's blood group, meaning that both the recipient's and donors' ABO grouping and RhD type have been established (BCSH-BTTF, 2004:435; Brunner & Suddarth, 2007:1104-1106; NYSCHB&TS-TPC, 2004:1-3; Potter, 2001:1242; SABTS, 2003:vi; SABTS, 2005:9-13).

Blood or blood products used for transfusing children under the age of one must be prepared from blood donated by donors who had donated their blood regularly for a period of one year. Their blood products must have tested negative during that period for all mandatory microbiological markers. This means their donated blood had been free of all microbes and/or pathogens

that might have introduced infection to the neonate during the previous year (BCSH, 2003:43; SABTS, 2003:16; SABTS, 2005:9-13). If blood or blood products are unobtainable or the family is against its use, alternative methods can be considered such as blood or blood products that have been donated by family members (designated blood donation), or by the patient him- or herself (autologous blood donation) (SABTS, 2003:2). Allogeneic blood products are an alternative to autologous blood or blood products.

2.6.2 Designated blood donation

Designated blood donation is the donation of blood or blood products by either a close family member or a friend whose blood group is compatible to that of the neonate who requires a transfusion. The problem with this type of blood donation in an emergency situation is that it is not fully tested or gamma irradiated before transfusion. A further disadvantage is that it also carries the risk of “graft versus host” disease (Foetus and Newborn Committee-Canadian Paediatric Society, 2002:3; NYSCHB&TS-TPC, 2004:9; Osborn, 2000:7; SABTS, 2003:2; SABTS, 2005:9-13 & 40).

Also problematic is the fact that selected donors must conform to the accepted voluntary donor criteria**,** for example, the donation procedure is only done during weekdays and office hours. Due to the stringency of the testing procedures and requirements of irradiation, at least two working days are required prior to availability of the products for transfusion**.** This type of donation does not necessarily protect the neonate from transfusion reactions, it may actually put the neonate’s life at risk due to the duration it takes for it to be prepared. If not tested, it may even expose Rhesus factor incompatibilities (Deacon & O’Neill, 1999:406; NYSCHB&TS-TPC, 2004:9; SABTS, 2003:3).

2.6.3 Autologous blood donation

Autologous blood donation or autotransfusion is when the patient’s own blood is drawn from him or her prior to the operation, and stored in case the patient requires blood post-operatively. Suitable candidates must be able to tolerate the rapid withdrawal of a large volume of blood (450ml-500ml), must tolerate

long-term reduction of haemoglobin levels, and have a body weight of above 50kg with a haematocrit of above 33%. Most importantly, he or she should be between the age of 16 and 70 years. The procedure must be initiated approximately six weeks prior to the operation depending on the amount of blood needed. It is clear that this makes neonates and paediatrics unsuitable candidates (Brunner & Suddarth, 2007:110; Potter, 2001:1242; SABTS, 2003:2-3; SABTS, 2005:38-40).

Designated and autologous blood donation methods require careful planning and cannot be carried out for emergency operations because they are not available on short notice, and, as noted before, their implementation can only be carried out on weekdays and during office hours (SABTS, 2003:2-3). Due to the complicated preparatory procedures and risks associated with designated or autologous blood donation methods, alternative methods of blood donation may be utilised to obtain blood or blood products from the patient.

2.6.4 Alternative donation methods

Alternative donation methods are methods used to obtain blood or blood products when the normal ways of obtaining blood or blood products (as mentioned above) are not acceptable or suitable to the patient or patients' family, when they are difficult to obtain, or the blood bank has ran out of blood or blood products. These procedures require careful planning and may expose the patient to more risks associated with transfusion since they are mostly prepared within the hospitals, for example, in operating theatres. According to the SABTS (2003:2-3), this may not be suitable for obtaining blood or blood products that are to be used for transfusion.

Acute normovolaemic haemodilution is the withdrawal of blood from the patient before or shortly after induction of anaesthesia, the simultaneous replacement with appropriate volumes of acellular fluid, and the return of blood to the patient's circulatory system, as indicated during intra-operative blood loss. The anaesthetist is the one responsible for the drawing of blood and for deciding whether or not the drawn blood should be transfused back to

the patient (BCSH-BTTF, 2004:445; SABTS, 2003:3; SABTS, 2005:39-40). If the anaesthetist decides not to transfuse the patient post-operatively, the patient's blood may be wasted because it is not allowed to be stored in the hospital's refrigerator for more than 6 hours. Another critical problem is that the hospital staff may fail to keep the blood clot free by adding either too much or too little of an anticoagulant such as heparin. Too much heparin will make the patient bleed and too little will not help to prevent the products from clotting, thus exposing the patient to pulmonary emboli. Neonates and paediatrics are not suitable candidates for this type of transfusion therapy (BCSH-BTTF, 2004:445).

If, because of religious beliefs or for other reasons, the neonate's family is against the employment of donated blood products as a mode of treatment, alternative transfusion therapy products or agents can be used to manage the neonate, temporarily relieve his or her condition, or temporarily prevent complications from arising. These include the following drugs or agents: haemostatic drugs or agents, growth factors, vitamins & minerals and isotonic solutions such as dried plasma, Voluvan™, Haemacell™, ringer's lactate and saline (0.9%) (Deacon & O'Neill, 1999:406-407; Wilson, 2004:31-32).

2.7 ALTERNATIVE TRANSFUSION THERAPY AGENTS

Alternative transfusion agents are temporary products employed in the absence of donated blood products. They may benefit the neonate whose parents are against transfusion due to either personal or religious reasons. However, these drugs or agents provide only a temporary solution and do not replace blood or blood products. They do not serve as a long-term solution where the neonate's condition requires blood or blood products to improve. Alternative transfusion therapy agents include the following: haemostatic drugs and agents, hormonal treatment, isotonic solutions and/or vitamins and minerals supplementation (Foetus & Newborn Committee - Canadian Paediatric Society, 2002:2-3).

2.7.1 Haemostatic drugs and agents

Haemostatic drugs and agents are medications which can be employed to slow down the bleeding process**,** completely stop it or inhibit bleeding from occurring in specific conditions, for example in children undergoing cardiac surgery or repeat surgical procedures. They may be either local or systemic agents and include fibrin glue, antifibrinolytic agents, desmospressin™ and aprotinin™ (BCSH-BTTF, 2004:445; SABTS, 2003:3).

2.7.2 Hormonal treatment

Erythropoietin is an example of a hormone that may be effective in some conditions such as anaemia in renal failure. It is a recombinant human erythropoietin (EPO) that stimulates red blood cell production and may reduce red cell transfusion requirements in neonates over a period of time. However, its effects appear to be relatively modest and do not reduce transfusion requirements within the first two weeks of life, which is the period when sick neonates mostly need to be transfused. The optimal dose, timing and nutritional support required during EPO in these patients have yet to be defined (BCSH-BTTF, 2004:438; Foetus & Newborn Committee - Canadian Paediatric Society, 2002:2; Osborn, 2000:6; SABTS 2003:3).

2.7.3 Vitamin and mineral supplementation

Vitamins and minerals are often given to neonates with low haemoglobin levels with the intention of protecting them from transfusion related reactions or minimising their exposure to blood products. This method of treatment takes considerable time to correct the neonate’s condition and may even require the boost of blood or blood products. Vitamins and minerals commonly used include iron, multivitamins, folate and vitamins K, E and B12. Nutritional support must also be provided (BCSH-BTTF, 2004:444-445; Foetus & Newborn Committee - Canadian Paediatric Society, 2002:3).

2.7.4 Isotonic solutions

Isotonic solutions have the same osmotic pressure (same concentration of solutes) as the fluid with which they are compared to**.** They include normal saline 0.9%, Voluvan™, Haemacell™ and Ringers lactate. They have the same osmotic pressure as the blood plasma. These fluids only help to improve or correct the condition of the neonate who suffers from hypovolaemia. They cannot replace blood or blood products in neonates who require blood or blood product replacement such as, for example, a neonate with anaemia or who is hypovolaemic due to severe blood loss from placenta previa or multiple blood sampling (Urdang & Swallow, 1983:586; Weller, 2004:223).

Blood transfusion is a medical intervention used worldwide to save lives. Blood safety is concerned with the overall process of delivering blood or blood products to the patient. Collaborative global efforts to improve the safety of the blood supply in the developing and industrialised countries have resulted in blood products being safer than it has probably ever been (Nel & Heyns, 2003:1). It must, however, be recognised that blood products are living human tissue and, as in the case of other biological products, employing them is not without risks (Nel & Heyns, 2003:1; Wilson, 2004:28).

2.8 PREVENTION OF COMPLICATIONS

During their stay in neonatal intensive care units, neonates (especially those who are critically ill like micro-premature neonates or those who are small for their gestational age), are given central venous lines (CVLs) or umbilical venous lines (UVLs). These are used for the administration of fluids and medications, including blood products, and help to reduce the number of painful intravenous procedures without additional morbidity. Van Lingen, et al. 2004:658) point out it has been found in the treatment of newborn infants that the contamination of intravenous fluids by particles, microorganisms, toxins and air may be the cause of significant complications. They note that debris or particle containment was implicated in the pathogenesis of pulmonary artery granulomata, especially among neonates receiving intravenous fluids and/or

medications. Plastic material from a syringe, storage bags and/or administration sets**,** was found to be the cause of fatal bowel necrosis amongst neonates. Microbial contamination was described in a number of instances, and was the result of the contamination of infusion solutions or mediums like blood products.

Particles or debris are an inevitable by-product of blood products as well as manufacturing devices as they occur in most infusion solutions, blood products and infusion equipment. They are also generated by manipulations such as piercing or spiking the blood bag, aspirating blood from the receiving bag, connecting the anaesthetic set to the syringe, and attaching the giving set to the neonate. The levels of particles or debris in infusion therapy are alarmingly high. It has been estimated that a patient on invasive therapy with blood products forming part of it, can receive millions of particles per day (Granger & Ellson, 1997:24-27; Morris, et al. 1998:3 & 11; van Lingen, et al. 2004:658).

The clinical effects debris or particles have, have been studied for almost 50 years. A 1988 report of a post-mortem microscopic examination of children's lungs documented the presence of granulomata containing cotton fibres (Granger & Ellson, 1997:26).

Nosocomial infection is a major problem in neonatal intensive care. It is responsible for significant morbidity and mortality. Preterm and term neonates who require intensive care are immuno-compromised and susceptible to opportunistic infections. Van Lingen et al. (2004:660) state that, for any intravascular line infection, the potential sources of bacteraemia are related to the cannula, to contamination of the infusate and to prolonged catheter placement.

On the other hand, an increased incidence of infections in patients who have received blood transfusions suggests that such transfusions may be associated with clinically significant immuno-modulatory effects. Blood transfusion increases humoral immunity and decreases cell mediated immunity. The mechanism of blood transfusion induced immuno-modulation

may involve altered cytokine regulation with a shift toward a type-2 (Th2) immune response. The occurrence of infections can be largely abrogated through the use of leukodepleted blood products (Blumberg, 1997:34; Wang-Rodriguez, et al. 2000:25-26).

2.8.1 Leukodepletion

Blood products are contaminated with a large number of leukocytes or white blood cells (WBC). Leukodepletion is the process whereby donor leukocytes are reduced to the level of >5x10 to the power of 8 (7 to 8 million) red cell per unit of packed red cells, and >5x10 to the power of 6 (5 million) red cell per unit of platelets. The lowest level of leukodepletion is less than 1x10 to the power of 9 of WBC per unit of blood (Gilbert, Rider, Turton & Pamphilon, 2002:17; BCSH-BTTF, 2004:433-434; SABTS, 2003:20-21; Soli, Blanco, Riggert, Martinez-Clavel, Lucas, Lunghi, Belloni, Wolf, von Waeg & Antoon 2001:108-109).

2.8.1.1 Leukocyte counting

There are various methods of leukocyte counting available, and the counting sensitivity differs from method to method. A Coulter counter method or Log one reduction and Flow cytometre, which is a Log 4 reduction, has great difference in sensitivity. But the most accurate measure of leukocyte removal is by looking at the absolute number of leukocytes remaining after filtration (Asahi Medical, 1996:3-4; Gilbert, et al. 2002:17-19).

The term ‘Log’ is used to define the rate at which leukocytes are being reduced and the rate at which reactions can be reduced, that is the relationship between reduction and removal efficiency, for example, 2 Log reduction = 99.0% removal of donor white cells (leukocytes), 3 Log reduction = 99.9% removal of leukocytes, and 4 Log reduction = 99.99% removal of leukocytes (Accorsi & Iacone, 2000:65-67; Asahi Medical, 1996:3-4; BCSH-BTTF, 2004:433-434; Rowe, 2000:61-62).

If the pre-count of leukocytes is 2x10 to the power of nine, then a 3 Log reduction is required to make the post count of 10 to the power of six. In other words, 99.9% of donor leukocytes will be removed (Asahi Medical, 1996:2-4; Gilbert, et al. 2002:1-2; Masse, 2000:57-59; Rowe, 2000:61-62; Soli, et al. 2001:108; Sowemimo-Coker, et al. 1998:1-4).

Whole blood has 2.6 ± 0.7x10 to the power of nine per 400ml bag, which is seven thousand million leukocytes per 400ml bag. Packed red cell concentrates has 2.4 ± 0.8x10 to the power of nine per 400ml bag, which is eight thousand million leukocytes per 400ml bag (Asahi Medical, 1996:2).

According to the policy of universal luekodepletion, the highest level of luekodepletion should be less than 1x10 to the power of 6, which is ten million of white blood cells per unit of blood. In other words, more than a 1000 000 white cells should be removed per unit of blood product for it to be considered safe and not capable of producing transfusion reactions in its recipient (Seghatchian, 2003:105; Soli, et al. 2001:108).

In South Africa, donor leukocytes are reduced to the level of 5x10 to the power of five, thus five million leukocytes per red cell bag. This is the specification for leukodepletion as defined by the SABTS guidelines (SABTS 2003:20). This allows for 99% of donor leukocytes to be removed and tested by the statistical process monitoring methodology to ensure that the blood units contains less than 5x10 to the power of 6 leukocyte per unit of blood prior to being dispensed. In other words, it must be within 95% of confidence limit, leaving it with a 5% chance of exposing the recipient to transfusion related reactions (SABTS, 2003:20).

Another method used for counting and measuring blood cells within a given amount of fluid is called flow cytometry. Cytometry pertains to obtaining a unit of blood from each donor using a cytometre (Masse, 2000:57-59; Urdang & Swallow, 1983:299).

For testing the blood samples a fluorescent micromplate assay is used. With this method the absolute leukocyte concentration is calculated by dividing the

number of white cell events by the number of bead events. This is possible because a known number of beads are added to the sample. Leukocytes are used since they are the only nucleated cells present in standard blood components (Asahi Medcal, 1996:2-4; Gilbert, et al. 2001:19 & 24).

2.8.1.2 Leukodepletion methods

Five methods are commonly used to facilitate leukodepletion, namely centrifugation and buffy coat removal, freezing, washing, screen filtration and selective filtration. Each of these methods will be briefly discussed.

- **Centrifugation and buffy coat removal**

Centrifugation is the removal of the layer found between the granulocytes and the plasma. Components of different densities contained in a liquid are separated by spinning them at a high speed. Centrifugation is an inexpensive method of leukodepleting blood products, especially red cells. The unit of blood is spun in a centrifuge for 20 minutes to pack the red cells, following which the white cells can be removed (Asahi Medical, 1996:5-6; Urdang & Swallow, 1983:196; Weller, 2004:79).

The buffy coat, or granulocytes characterised by the presence of cytoplasmic granules, is composed of white cells, platelets and debris. The blood is centrifuged first, that is, spun and packed for 20 minutes, and then the layer between the granulocytes and plasma is removed. Its efficiency is only a maximum of 80%. It is recommended that buffy coat removal be utilised with the filtration technique and not alone (Asahi Medical, 1996:5-6; Urdang & Swallow, 1983:476). However, the problem with this method is that there is a high rate of red cell loss while its efficiency is low, only between 40% and 80%. The red blood cells that are contained within the plasma (the liquid medium) are spun in an attempt to separate them - but by spinning, them most red cells are destroyed because they are fragile and unable to handle pressure (Asahi Medical, 1996:5-6; Brunner & Suddarth, 2007:1106; Willis, Lown, Simpson & Erber, 1998:645-646).

- **Freezing**

With this method, glycerol is firstly added to each unit of packed red cells. The unit is then unit centrifuged to remove excess glycerol before being frozen below 0°C. Glycerol is added to keep the cells viable and to keep them moist during storage as this helps to prevent them from sheering and tearing. This is the method used to store blood components for prolonged periods of time, especially red blood cells before they can be used (Asahi Medical, 1996:5).

The thawing procedure is expensive, very complicated and requires a high degree of skill to execute correctly. On the other hand, red cells can be haemolysed during the thawing procedure, but very few centres have adequate facilities to perform this procedure. Frozen red cells are used under unusual circumstances, for example, for patients with very rare blood types (Asahi Medical, 1996:5; Brunner & Suddarth, 2007:1106)

- **Washing**

In this method cells are washed either manually or by a cell washer with normal saline. This method is extremely time-consuming, expensive and complex, while a great deal of original red cells can be lost as well. Asahi Medical (1996:5) rates its efficiency between 60% and 95%.

- **Screen filtration**

During screen filtration a mesh allows cells of a certain size to pass through and others to be trapped. The mesh usually comes in a pore size of 20µm and is similar to a microaggregate filter. The efficiency of this method depends on the age of the blood products - the older the blood products, the more efficient the filter. It is not recommended for blood products less than seven days old (Asahi Medical, 1996:6).

- **Selective filtration**

This is the most common method currently used for the prevention of non-

haemolytic febrile transfusion reactions and human leukocyte antigen sensitisation (HLA). Its efficiency is far higher than that of the other methods mentioned. A combination of depth and adsorption filters may be employed during this method. Depth filters usually consist of densely packed fibres where particles are excluded either by adherence or by adsorption onto the fibres, or by entrapment between the fibres as they pass through the fibres. Adsorption filters work in a slightly different manner in that they rely on the properties of white cells to selectively adhere to the fibres of the filter (Asahi Medical, 1996:7). Soli et al. (2001:109) add these filters normally rely on gravity to flow the blood products from one bag to another with a permitted standardised height difference. It is also normal for air to enter the filter during the filtration process.

During the past few years, concerns regarding the lack of the efficiency of blood transfusion for treating critically ill neonates have been compounded by high profile occurrences of undesirable transfusion-induced effects (Wilson, 2004:28; PALL Medical, 2000a: clinical update & PALL Medical, 2000b: clinical update).

2.8.1.3 Indications for leukodepletion

Seghatchian (2003:106) maintains pre-storage leukodepletion is the one criterion preferred and advocated by most of the developed and developing world when leukodepletion is performed. Leukocytes are removed while still intact as opposed to post-storage leukodepletion in which blood products are stored for a few days.

Pre-storage leukodepletion is the removal of donor leukocytes from the blood products immediately after the donor has been bled – either on the day of collection, by day one but always by the end of day two. Pre-storage leukodepletion is currently the trend in transfusion medicine (Bird, 2001:822; Seghatchian, 2003:105-106; Soli, et al. 2001:108).

Post-storage leukodepletion is performed a few days after obtaining the blood products from the donor. Blood products are stored in a refrigerator for a few

days. This is especially applicable where leukodepletion is performed at a central institution which is far away from where the blood has been collected. Blood products undergo fragmentation and tend to release their intracellular contents within minutes of being removed from the body. Refrigerating them immediately does not stop them from fragmenting (SABTS, 2003:20; Seghatchian, 2003:106; Llewelyn, Taylor, Todd, Stevens, Murphy, & Williamson, 2004:490).

The principle of post storage leukodepletion is often practiced in South Africa because there is only one central station where leukodepletion can be performed, and substations where phlebotomy is done are often far from it. As a result, locally it may take two to three days for donated blood to reach the central station for leukodepletion (Bird, 2001:822; SABTS, 2005:19-20).

It was discovered in the 1950s that leukocytes present in the blood sensitise transfusion recipients, resulting in non-haemolytic febrile transfusion reaction. Since then, allogeneic leukocytes in blood and blood products have been shown to be involved in a number of adverse responses in recipients (Asahi Kasei Medical, 2004:145-147).

There are a few methods used to leukodeplete blood products, namely: centrifugation and buffy coat removal, freezing, washing, screen filtration and selective filtration. In South Africa three methods are utilised, namely: buffy coat removal, selective filtration and screen filtration (Asahi Medical, 1996:5-7).

Preterm infants are currently being resuscitated at lower and lower gestational ages when no protective levels of maternal antibodies prior to birth have been acquired. This puts them at an even higher risk of transfusion transmitted cytomegalovirus (TT-CMV). At the same time, the exact mechanisms of why the recipients of blood products have increased rates of bacterial infections, remain elusive; the type of transfusion-associated immuno-suppression remains unknown (Foetus & Newborn Committee - Canadian Paediatric Society, 2002:1).

Due to their functionally immature B lymphocytes, neonates have limited abilities to produce significant antibody concentrations. Hence, multiple transfusions for neonates may produce antibodies and the more donors the neonate is exposed to, the more likely it is to be positive for human leukocyte antigens (HLA) antibodies. This poses a problem for finding them a compatible cross match negative blood donor, meaning the neonate develops HLA alloimmunisation (Cloherty, et al. 2003:49; Seghatchian, 2003:105 & 114-115 & PALL Medical, 1998: clinical update).

It was discovered that B-lymphocytes are vector prions (hosts) of the new variant of Creutzfeldt-Jakob disease (nvCJD), and that the transmission of transmissible bovine spongiform encephalopathy (TBSE) is five to seven times higher in buffy coat than in plasma. TBSE is a cattle disease that was observed in Britain during the 1980s. In 1996 it was reported that a cluster of young people in the United Kingdom (UK) presented atypical clinical features and longer durations of vCJD. It was subsequently termed 'new variant Creutzfeldt-Jakob disease' (nvCJD). Due to its epidemiological and neuropathological grounds, it was linked to dietary exposure and to TBSE (Seghatchian, 2003:105 & 114-115; Cloherty, et al. 2003:491).

Chu (1999:1-3) mentions that the transfusion of blood products may cause immune deviation towards the secretion of cytokines, which may down regulate cellular immunity. Neonates and paediatrics are often immune-compromised and the unintentional immune-suppressive effects of blood transfusion will only compound this predicament.

Transfusion practices have advanced since 1994, particularly with respect to safety issues regarding the risk of transfusion transmitted diseases. As yet there are no current alternatives to transfusion therapy and blood products are the only solution to managing conditions that require blood products replacements. Risks associated with transfusion cannot be completely eliminated, but procedures that can assist in reducing risks may be indicated. An example is the leukodepletion of blood products; thus the reduction of donor white cells from the blood products which are to be used for neonatal

transfusion (BCSH-BTTF, 2004:433-434; Nel & Heyns, 2003:22-26; NYSCHB&TS-TPC, 2004:2; SABTS, 2003:20-22; Seghatchian, 2003:105).

Research conducted in the past decade has denoted an increased appreciation of white cell depletion from red cells and platelets to prevent the potential adverse effects - and to reduce transmission or reactivation - of the CMV, HIV, Hepatitis A-B-C and other viruses. During the past few years, concerns regarding the lack of effiency of blood transfusion for treating critically ill neonates have been compounded by high profile occurrences of undesirable transfusion-induced effects (Accorsi & Iacone, 2000:65; PALL Medical, 2000b: clinical update; PALL Medical, 1998: clinical update & Seghatchian, 2003:105).

The CMV is one of the viruses that are known to be transmitted by blood transfusion, as CMV may be found within the white cell or donated blood products. The removal of donor white cells from blood products may significantly reduce the chances of transmitting CMV to recipients of blood products during transfusion; consequently reducing the transfusion transmitted CMV (TT-CMV) to blood products recipients considerably (PALL, Medical, 1998: clinical update & PALL Medical, 2000b: clinical update). Therefore, it is perceivable that the removal of buffy coat by either a blood bank or bedside filtration, in other words removing both leukocytes and platelets, may prove beneficial in reducing the potential risk of transfusion related complications.

In 1999 universal leukodepletion was introduced in the UK as a means to minimise the theoretical risk of nvCJD transmission by blood transfusion. Although the relative risk of nvCJD transmission remains unknown, the removal of donor leukocytes from the blood components has an additional advantage, namely a reduction in the incidence of alloimmunisation (Foetus & Newborn Committee - Canadian Paediatric Society, 2002:3; Gilbert, et al. 2002:17).

Leukodepletion by filtration at bedside is as effective as using seronegative blood products in the prevention of transfusion associated CMV infections

among neonates when allogeneic blood transfusions are required (Asahi Medical, 1996:7; Foetus & Newborn Committee - Canadian Paediatric Society, 2002:4; Seghatchian, 2003:105-117; Saarinen, et al. 1993:209).

The employment of leukodepleted blood products to all neonates regardless of their body weight has tended to protect the recipients of blood products from the abovementioned complications and infections (PALL Medical, 1998: Clinical Update; Sowemimo-Coker, et al. 1998:1). In addition, the employment of leukodepleted blood products may reduce incidences of infections in neonates, resulting in minimal antibiotic requirements and a shorter stay in hospital. This, in turn, will lead to a reduction in medical costs (Blumberg, 1997:34; Gilbert, et al. 2001:17 & Saarinen, et al. 1993:287).

Aside from these benefits, some additional advantages of leukodepletion have been highlighted in research over the past ten years. They include the improvement in the functional quality of erythrocytes during storage, and a slower decline of important parameters of metabolism, namely intra-erythrocytes and extra-cellular potassium levels, in blood bank filtered blood products. This is thought to be linked to the lower levels of contaminating enzymes, frolysed leukocytes or platelets in similar products (Llewelyn, et al. 2004:497-498; Soli, et al. 2001:108).

According to Barrowcliffe (1998:361) and Seghatchian (2003:105), some new requirements regarding the implementation of universal leukodepletion were also formulated. They are:

- the validation/standardisation of various leukodepletion processes to ensure compliance with set specifications;
- the standardisation/harmonisation of sampling and low leukocyte counting technologies to ensure the interchangeability of results; and
- the assessment of filtration-induced generation/retention of major biological response modifiers (BRM) having potential for the development of transfusion reactions.

However, leukodepletion alone may not provide complete protection from some viral transmissions such as non-haemolytic transfusion related

reactions, CMV, HIV, and so forth. The key issue is not the 3-4log10 reduction of residual leukocytes, but the design of new generation filters or leukodepletion processes with better performance characteristics to further reduce some specific leukocytes subsets and their fragments, as well as the activation of coagulation and inflammatory systems (Seghatchian, 2003:105)

2.8.1.4 Cautions

Transfusion medicine is changing in line with new developments for production of purer and safer blood products. Though some standards and some goals are reached, new goals and challenges are appearing for continual improvement of the clinical outcome. The diversity in risk reduction strategy makes it crucial that each country carefully assesses the benefits attributable to the proposed interventional programme/s. Compliance with national and international standards requires that all blood products must be transfused through an administration set containing an integral filter (Flesland, et al. 2001:211; Seitz, 1998:359).

Initially, leukodepletion (with a bedside filter) after storage tended to be the predominant method, but filtration efficacy turned out to be highly variable, even after only brief periods of storage at 4˚C. Hence, pre-storage leukodepletion has rapidly become the preferred method. But, the majority of pre-storage filtrations still take place after a certain holding period, for example, overnight and especially where leukodepletion is done centrally. It has been observed that better leukodepletion results are obtained when red blood cells (RBCs) are filtered immediately post venesection (post donation) at lower temperatures. These limitations make pre-storage filtration time-consuming, with intense labour requirements. Pre-storage filtration means processing of the blood products immediately after their withdrawal from the donor. This is one of the major pre-requisites for an adequate and effective leukodepletion process (Bird, 2001:822; SABTS, 2003:20; Soli, et al. 2001:108-109; Seghatchian, 2000:47). The introduction of universal leukodepletion has led to the same manufacturing process being carried out at more than one centre, which makes leukodepletion very costly (SABTS, 2003:20; Seitz, 1998:359; Heiden & Keller-Stanislawski, 2000:69-70).

Regional units may be established for adequate delivery of blood transfusion services, and this must function under the control of the license holder. According to the Human Tissue Act (1989), the Minister of Health requires that a blood transfusion service must be licensed to a non-profit organisation that is able to provide a blood transfusion service throughout the entire country. In South Africa this refers to the South African National Blood Transfusion Services (SANBS). This means that the Department of Health has prescribed norms and standards through which prescribed blood transfusion and related services should be provided, and that the holder of the license should comply with them (Human Tissue Act, 1989; National Health Act, 2003; Seghatchian, 2000:47).

The Human Tissue Act (1989) and National Health Act (2003) further protect the blood donor from exploitation. It only permits blood to be drawn from him or her for medical or dental purposes and only after the donor has given his or her written consent.

There is still no clear evidence as to the minimum level of residual leucocytes or lymphocytes subsets needed to prevent certain immunomodulatory effects and transmission of infections including CMV and non-haemolytic febrile transfusion reactions (Romaine, et al. 2000:52; Seitz, 1998:360; Wilson, 2004:28). According to Wilson (2004:31), the following problems, which can be related to leukodepletion, remain largely unknown: (i) the level of infectivity required to prevent transmission of pathogens to recipient of blood during transfusion, (ii) is infectivity confined to leukocytes, or (iii) will reduction of leukocytes on blood products used for transfusion to less than 5x10 to power of 6 per unit of blood be sufficient to prevent transmission of pathogens to the recipient.

The removal of viruses - particularly the HIV virus - through the leukodepletion process still has to be proven. Patients have tested HIV positive post-transfusion; the mode of transmission being blood products. The size of the virus appears to be the cause of the problem since the virus seems to be smaller than the pore size of the blood product filters available in the market

(Romaine, et al. 2004:52-53; SABTS, 2003:20).

Furthermore, there is some evidence that certain donations or filter combinations frequently lead to membrane blockage or filtration failure. This is possibly due to high levels of micro-vesicles or large cells, or cellular aggregate or pinched and/or structurally abnormal WBC. This is of particular relevance to sickle-cell trait. In order to establish a national evidence-based policy throughout transfusion therapy, a comprehensive evaluation of donor-related issues, filtration failure and recurrent blockage are urgently needed (Barrowcliffe, 1998:361; Llewelyn, et al. 2004:497-498).

Barrowcliffe (1998:361) and Wilson (2004:31) highlight that contact activation and changes in haemostatic parameters and functional integrity, or the aggregation state of cellular components, may also occur. In addition, they state that true distribution of abnormal prion (hosts) in various blood components is still unknown, and the possible roles played by cell-derived fragments and micro-vesicles in leukofiltered products also need in-depth analysis, as some filters may retain and others may generate cellular fragments and micro-vesicles due to shear induced injury.

2.8.2 Bedside filtration

Particulate associated disease is most likely to be seen among patients who are given frequent intravenous therapy. Neonates receiving intensive care nursing are an example of such patients with blood transfusion being one of the intravenous therapies that neonates are exposed to. These patients often end up with a high particulate load (Kunac, et al. 1999:321; van Lingen, et al. 2004:658).

Bedside filtration means the application of bedside blood products filters to administration sets used for administering blood products to neonates, with an attempt to remove precipitates (in this study it referred to contaminating leukocytes and any pathogens; viruses, microbes, debris or microaggregates) that might have been formed or collected during donation, storage or in the

event of preparation for neonatal transfusion (Cardo, Salata, Harman, Mendez & Weina; 2006:1-2; Weller, 2004:158).

The application of filtration technology to the transfusion of blood products to neonates has advanced considerably over the years. According to Domanski (2006:1-2), Time (2007:Clinical Updates) and SABTS (2003:9), compliance with national and international standards requires that all blood components must be transfused through an administration set containing an integral filter. Accorsi & Iacone (2000:65-66), Cardo, et.al. (2006:2-3) and Seghatchian (2003:107-109) reiterate that, within a few hours of collection, platelets aggregation occurs. After a day or more the leukocytes start losing their viability and combine with the aggregating platelets. Finally, fibrin precipitation occurs consolidating the loosely bound structures and forming stable microaggregates. The size of the microaggregates varies between 10µm and 200µm and this can be of similar size as the pre-capillary arterioles of the lungs. Inadvertent infusion of the microaggregates within blood products can result in the occlusion of these vessels.

When glass bottles with rubber bungs were the standard infusion systems, the most frequently identifiable debris included whole rubber particles, cellulose fibres, glass, chemical particles and fungi. Starch granules, diatoms and fragments of crustacean were also seen. Cellulose fibres were found in all particles contaminated intravenous (IV) fluids and consisted of bast and cotton fibres derived from the substance of rubber bungs. With the advancement of technology, plastic infusion systems have largely replaced glass bottles and rubber bungs, but the problem of particulate contaminants has not disappeared (PALL Medical, 1999: clinical update; van Lingen, et al. 2004:658).

Reports of particles in the lungs of children from post-mortem examinations have been published since the 1980s. Some reports documented granulomata containing cotton wool fibres in 5% to 10% of neonates and children who had received intravenous therapy. Glass particles have been discovered in the lungs of neonates, and some reported cases described fatal bowel necrosis in a neonate due to plastic material from a syringe or

administration set (PALL Medical, 1999: clinical update; van Lingen, et al. 2004:658). Further histological examination of the bowel showed infarction and thrombus in the mesenteric arteries containing irregular fragments of polypropylene. The infusion of microaggregates has been implicated in various transfusion associated complications. It is believed that microaggregates are able to release biochemically active components which can contribute to the development of respiratory dysfunction (van Lingen, et al. 2004:658).

Leukocytes are regarded as the core component of a microaggregate. The transfusion of the chronically ill and immune-comprised patients (of whom neonates form a major part) often requires a greater level of leukocyte depletion. Recent developments in this field have enabled leukocyte depletion by filtration to be performed either at the patient bedside or in the blood bank. The introduction of high flow leukocyte depleting filters for use in areas such as theatres and intensive care units (ICUs), has allowed the added clinical benefits associated with these devices to be extended to those patients who require rapid and multiple transfusion of blood products (Accorsi & Iacone, 2000:65; Wilson, 2004:30).

The clinical complications associated with transfusion therapy can, to a large extent, be prevented by the use of appropriate bedside blood product filters. The concept of a multi-component system is pursued with enthusiasm and it is important to define the practical sensitivity of leukocyte counting techniques for leukodepleted blood products at the levels relevant to the “decision making point” as currently applied by the UK guidelines and the Council of Europe (Seghatchian, 2000:47; Soli, et al. 2001:1080).

2.8.2.1 Bedside blood product filters

The pore size of the bedside blood product filters plays a crucial role in preventing even smaller pathogens and debris, such as microscopic air and viruses, from entering the neonate’s circulatory system. The pore size for a leukodepleting bedside blood product filter is normally between 20µm and 40µm, while micro-aggregate filters are between 170µm and 240µm (SABTS,

2003:9; Kapadia, Smith & Valentine, 1992:3-6 & PALL Medical, 1999b: clinical update). Presently, two types of blood product filters meant for bedside employment during neonatal transfusion are available, namely leukodepleting and microaggregate blood filters.

- **Leukodepleting bedside filters**

Leukodepleting bedside blood product filters can be employed to: (i) remove small blood clots formed during storage and/or debris found within the collection bag, and (ii) remove residual donor white cells (leukocytes) from blood products and/or trap microscopic air and viruses prior to intra-transfusion. Two types of leukodepleting filters will be discussed in this study namely, screen and depth leukodepleting bedside blood filters.

Screen filters are made of non-woven polyester fibre. It is mesh-like and allows cells or microorganisms of a certain size to pass through and others to be trapped. Cells or microorganisms bigger than 20µm will be trapped and those smaller will pass through. The weave prevents the movement of cells or microorganisms between fibres, thus maintaining a fixed pore size. The polyester material causes the least damage to the red cells. During use, the pore size becomes smaller due to plasma protein deposition on the screen, hence the possibility exists that particles smaller than the pore size can be retained. They are capable of removing high levels of leukocytes from red cells and platelets at the time of transfusion. Screen filters have been designed to deplete blood products of leukocytes by adsorbing the leukocytes in addition to filtering out microaggregates (Asahi Medical, 1996:6; Cardo, et al., 2006:6; de Vries, Gu & van Oeveren, 2005:118-120).

Depth filters work on the principle of adsorptive separation and, to a lesser degree, on mechanical separation. These filters consist of packed adsorptive material. For filtration to be effective, the adsorption force of the blood debris to the filter must be greater than the force acting in the direction of the flow. They compose of densely packed fibres, where particles are excluded either by adherence or by entrapment between the fibres as they pass through the filter. Adsorption filters work in a slightly different way in that they rely on the

properties of white cells to selectively adhere to the fibres in the filter (Asahi Medical, 1996:7; Asahi Kasei Medical, 2004:1).

- **Microaggregate bedside filters**

Microaggregate bedside filters are capable of removing only microaggregates, blood clots and debris that may have collected within the blood bag during storage. They only trap bigger pathogens that would otherwise pass through a standard 170µm intravenous (IV) giving set filter. They contain a sift-like filter and operate on one of two principles: screen filtration or depth filtration (Kapadia, et al. 1992:3-4). This filters are only meant to be used on adults and not neonates since the require large volume of blood or blood products to prime them up which will be a waste of blood products in a neonatal intensive care nursing.

The filter attachment point may play a role in preventing particles found in the administration set, or those that might have entered the set during the priming up period (PALL Medical, 1999a: Clinical update; PALL Medical, 1999b: clinical update & SABTS, 2003:9).

Neonates are particularly at risk developing transfusion related reactions because they receive a greater load of contaminants per kilogram of body weight than adult patients, and this has the potential for inducing life-long sequelae. Kunac, et al. (1999:321-322) note it has been claimed that the placement of an in-line filter proximal to the cannula but distal to the administration set, may protect the patient from being transfused with particulates, because it allows filtration of the fluid as it is delivered to the patient.

Opinions on the role and employment of bedside blood products filters in routine clinical practice, such as during neonatal transfusion, vary from hospital to hospital and/or form one neonatal unit to another.

2.8.2.2 Indications for bedside blood product filters

De Palma, Criss, Roseff and Luban (2003:16) maintain it is of the utmost importance that the safest methods be employed during transfusion therapy to protect neonates from transfusion-induced complications. They add that neonates are immunologically immature, and it is a potentially life-threatening risk for them to be exposed to inadvertent particles and allogeneic WBC-induced immune-suppression during blood transfusion. Wang-Rodriguez et al. (2000:25) explain that premature infants require frequent small-volume transfusions of packed red blood cells due to anaemia of prematurity in combination with multiple phlebotomies.

Introducing inadvertent particles such as microscopic air or micro-emboli, fibrin threats or microaggregates to neonates, is profoundly dangerous during blood transfusion. This can lead to the development of potentially life-threatening complications like pulmonary embolism, and even death. The risk is even higher if central or umbilical catheters are used, although there have been cases involving peripheral venous access (van Lingen, et al. 2004:658; Granger & Ellson, 1997:24-25).

Air arises in a transfusion system in various ways. These include degassing as the blood products are warmed, accidental disconnections, incomplete priming or when a vented transfusion container runs dry. Several precautions can be taken to reduce the risk of air embolism: by, for example, using a luer lock connection to all IV equipment, and by incorporating in-line air detectors on infusion pumps. The most important precaution, however, would be to use an appropriate bedside blood product filter (Granger & Ellson, 1997:26-27; Morris, et al. 1998:3-8; PALL Medical, 1999: clinical update; van Lingen, et al. 2004:659).

Microbial contamination has been reported to be positively correlated to the frequency with which stopcocks and hubs are manipulated (Morris, et al. 1998:3-8; Chu, 1999:3). There is also a high risk of contaminating the intravenous tubing injection site, or connecting sites, which leads to migration of the pathogens up the inside of the catheter into the bloodstream, leading to

catheter related sepsis. It is possible to protect the neonate against effects of contamination. The particles or debris can be removed from the blood products used to transfuse neonates, especially if the appropriate bedside blood product filter is utilised (PALL Medical, 1999a: clinical update; PALL Medical, 1999b: clinical update & van Lingen, et al. 2004:659).

Microbes, including bacteria, can gain access to, and contaminate the intravenous (IV) line. It has the ability to release toxins while trapped within the bedside blood product filter. However, appropriate bedside blood filters can effectively retain both microbes and bacteria, while restricting their toxins from entering the neonatal circulation (PALL Medical, 2002: clinical update; PALL Medical, 2000b: clinical update & PALL Medical, 1998: clinical update).

The use of bedside blood product filters with a smaller µm (unimicron) size does not only reduce or prevent incidences or complications associated with transfusion therapy, but they will also trap and prevent microscopic air from entering the neonate's circulatory system during transfusion. Therefore, they protect the neonate from dying from an air embolus, which might have developed due to inadequate priming up of the administration set prior to transfusion (PALL Medical, 1999b: clinical update; Granger & Ellson, 1997:26-27; van Lingen, et al. 2004:660-661).

According to Granger and Ellson (1997:26-27) and Kunac et al. (1999:321), effective air eliminating bedside blood product filters enable venting of entrapped air into the atmosphere, thereby preventing the system from becoming air-locked.

The filter should have both an appropriate µm (pore) size, coupled with an appropriate membrane. Some studies conducted in animals have shown a significant reduction in septic and thrombotic complications due to the use of a toxin retentive bedside blood product filter (Bird, et al. 2003:419; Granger & Ellson, 1997:24-27). Bedside blood product filters are blood product specific, thus, for example, red cell blood product filters cannot be employed on plasma or platelets (Bird, et al. 2003:419; Granger & Ellson, 1997:24-27; Saarinen, et al.1993:290).

Bedside filters have often been associated with reducing microbial contamination due to contaminated infusion fluids. Blood or blood products are an example of transfusion fluids commonly used in intensive care units. Several outbreaks and isolated cases of sepsis have been reported in neonates. The contamination of the intravenous tubing at the connecting sites may lead to the migration of pathogens up the inside of the catheter into the blood stream and cause catheter-related sepsis. Septicemia will result in the prolonged stay of the neonate in the intensive care unit as the management of septicemia requires antibiotics. The prolonged stay in intensive care unit together with the utilisation of antibiotics, will incur additional costs for the neonate's parents ((PALL Medical, 1999b: clinical update; van Lingen, et.al. 2004:658).

The employment of appropriate bedside blood product filters and sets will result in reduced costs when neonates are nursed in neonatal intensive care units. Bedside filters have been shown to remove impurities, microorganisms, air and particles that may cause undesirable side effects in the neonate and reduce complications associated with transfusion therapy (Breillatt Jr. & Pokropinski, 1998: Clinical Guidelines; PALL Medical, 2002: clinical update; PALL Medical, 1999b: clinical update & van Lingen, et al. 2004:658).

2.8.2.3 Contra-indications for bedside blood product filters

The SABTS (2003:9 & 2005:34) recommends that the filter should be a micro-aggregate filter with a pore size of between 170µm and 240µm which is attached proximal to the administration set**.** According to them, the reasons for this are twofold. Firstly, the filter will trap any clots formed during storage, and, secondly, these filters are less costly than leukodepleting filters. However, they are not capable of trapping any microscopic air, micro-emboli or viruses.

Pharmaceutical companies stress the importance of the employment of a bedside blood product filter with a pore size of 40µm and less. Furthermore, the bedside blood product filter must not be attached to the administration set

but rather to a receiving bag. It can also be manually attached to the administration set. Those that are not attached to the administration set but are, for example, attached to a collection bag, may promote contamination since there are multiple manipulations involved before the blood can be administered to the neonate. The blood bag has to be spiked to be connected to the bedside blood product filter, and then the blood or blood product must be filtered into a collection bag. Once the filtration process has been completed, the full collection bag is connected to a syringe for aspiration. After aspiration the syringe is connected to an administration or anaesthetic extension set. The administration set is then connected to the baby for transfusion. But, the whole procedure is time-consuming and requires high standards of aseptic techniques (Bird, et al. 2003:419; Kunac, et al. 1999:322 & Towns, 2007:114).

The bedside blood product filter that is attached proximal to the administration set cannot trap any plastics or small plastic particles that may be found within the administration sets (Bird, et al. 2003:419; Kunac, et al. 1999:321; Time, 2007: Clinical Update). Van Lingen et al. (2004:658) point out a further disadvantage associated with bedside blood product filters attached proximally. They mention that personnel tend to re-use them repeatedly; sometimes the same bedside blood product filter is used to administer clear intravenous solutions leading to the unloading and detaching of filtered particles or debris from the filter. These particles are then channeled through the administration set into the neonate's circulatory system.

The inability of most personnel working in neonatal intensive care units to differentiate between different bedside blood product filters for different blood product filters, often leads to the destruction of some of the blood cells. If, for example, platelets are filtered via a red cell blood product filter, they are destroyed and the neonate receives a platelets free fluid at a high cost, since platelets are very expensive (Sowemimo-Coker, et al. 1998: 5).

Health care institutions are concerned with providing quality care to patients, especially in the intensive care units. To ensure that quality care is rendered and patients are protected, international and national health care institutions

have policies or protocols to be followed when performing a procedure on a patient (SABTS, 2005:4-6; Nel & Heyns, 2003:3). For the purpose of this study, these protocols and/or policies referred specifically to those that pertain to the provision of health care regarding the employment of a bedside filter to blood products during neonatal transfusion to minimise the exposure of the neonate to transfusion-related reactions.

2.9 LEGISLATION

Urdang & Swallow (1983:898 & 1017) explain that written documents include policies, protocols, procedures, guidelines and/or orders for the conduct of patient care in various stipulated clinical situations. These are usually formulated by professional members of a department in a hospital or other health care facility. Rules and regulations form boundaries within which one needs to function, and also serve as guidelines which professionals follow when performing common procedures in different institutions. In other words, they help standardise common procedures for different institutions.

The researcher is of the opinion that transfusion therapy is one of the common procedures performed on patients at different hospitals that requires standardisation throughout the country. All health institutions and professionals transfusing patients should adhere to strict and rigid protocols and/or guidelines, as this will help to safeguard the life of the recipient of the blood products, for example, the neonate. Urdang and Swallow, (1983:898) add that protocols and/or guidelines can aid professionals transfusing neonates to recognise signs and symptoms of transfusion reactions, guide them regarding what steps to follow during such reactions, help them to decide what equipment to employ and where blood products can be obtained, and also what procedure and forms to use to obtain such products.

In South Africa, it is expected of the admitting hospital, the treating doctor or professional nurse to liaise with the blood bank in order to obtain blood products for patients that are about to undergo a blood transfusion. They also have a shared responsibility of obtaining informed consent from patients prior to transfusing them with blood products (SABTS, 2003:6-7).

However, blood products are associated with side effects and adverse reactions. Hence, as stipulated by the regulations relating to the Scope of Practice for Registered Professional Nurses (1991), the Human Tissue Act (1989), the Regulations Regarding Blood and Blood Products (1990) and the new National Health Act (2003), it is the duty of the admitting doctor or attending professional nurse to inform the patients not only of the effects or advantages of transfusion therapy, but also of the side effects, adverse reactions and disadvantages (SABTS, 2003:7-9).

Only health professionals are allowed to remove blood products (venesection) and transfuse patients. There are control measures in place that regulate the obtaining of a blood specimen from a patient and transfusing them after the specimen has been cross-matched at the blood bank for compatibility. A medical practitioner or a dentist, or a person acting under the supervision of both, may withdraw blood from the body of a living person or administer blood products to another living person. Therefore, a neonatal intensive care professional nurse can only obtain a blood specimen from the neonate for cross-matching at the blood bank, and can only transfuse the neonate once provided with a relevant prescription sheet for blood products (Human Tissue Act, 1989; Regulations Regarding Blood and Blood Products, 1990; SABTS 2003:6-9).

The professional nurse is allowed to transfuse the neonate when he or she can observe the neonate for indications, effects and side effects associated with transfusion therapy. This means the professional nurses are governed by their scope of practice which regulates their general acts while caring for the patients, namely to co-ordinate, diagnose and regulate all nursing regimens, such as prescribing, treating and advocating for the neonate (Scope of Practice for Registered Professional Nurses, 1991).

The professional nurse or the administering doctor is obligated to report any adverse blood transfusion reactions to the blood bank. It is the duty of the blood bank to report such reactions to the Director General of the Department of Health (DOH). The hospital and the blood bank should keep the records of

the reactions brought to their attention (Nel & Heyns, 2003:3; SABTS, 2003:7-8).

The Director General of the DOH may, upon receiving such a report, appoint an Inspector of Anatomy. The latter will then conduct an investigation of such reports, consolidate them into a structured official report, and design a programme where such incidents can be addressed, corrected and utilised in a continuous improvement programme. Alternatively, after the full investigation has been completed, it can be recommended to amend the present guidelines for transfusion therapy employed at various institutions (Human Tissue Act, 1989; Nel & Heyns, 2003:3 & Regulations Regarding Blood & Blood Products, 1990).

Pertaining to South Africa, the SABTS recommends that all blood products must be transfused through a sterile pyrogen-free transfusion set with an inline filter (BCSH-BTTF, 2004:435; NYSCHBTS&TPC, 2004:7; SABTS, 2003:9). This transfusion set may be a clot screen filter in the independent administration set to remove gross debris, such as a microaggregate filter, or a specific leukodepleting filter (SABTS, 2003:9).

However, this recommendation can be perceived as ill-defined when one considers the conflicting theories regarding which bedside blood filter pore size will produce the desired result. This is a problematic issue since it has not been established which pore size is most effective. In addition, the recommendations of the SABTS and pharmaceutical companies differ, thus adding to the confusion. The former recommends the bedside blood product filter should be in line with administration proximally, be easily identifiable and have a pore size of between 170µm and 240µm. On the other hand, the latter recommends the employment of a bedside filter which is blood product specific and has a pore size of 40µm.

2.10 CONCLUSION

In this chapter the literature search conducted was discussed. It was pointed out that, though the literature research included the blood transfusion

procedure as a whole, more attention was given to neonatal transfusion.

The following aspects were included in this chapter: advantages and indications for blood transfusion; contra-indications, disadvantages, side effects and adverse reactions; common transfusion reactions and role players involved in neonatal blood transfusion and the types of blood products commonly used. The methods of blood donation, alternatives to transfusion therapy and complications associated with transfusion therapy were presented**.** Leukodepletion, the recommended criteria for leukodepletion, methods used for leukodepletion, indications and advantages thereof and problems related to leukodepletion were also highlighted. Bedside filtration, the indications and advantages of bedside blood product filters as well as the disadvantages or contradictions of these blood product filters were included. Regulations, protocols and guidelines were presented and discussed.

CHAPTER THREE

RESEARCH DESIGN AND METHODOLOGY

3.1 INTRODUCTION

Chapter 2 provided an in-depth literature review on topics related to blood and blood product transfusion, role players involved, alternative donation agents and relevant legislation.

The focus of this chapter is to describe the research design and methodology relating to the research question, aim and objectives.

3.2 PROBLEM STATEMENT

The problem statement of the study is discussed in depth in Chapter 1. In short it is described as follows: When a neonate needs a blood transfusion, the decision making responsibility regarding employment of a leukodepleting or microaggregate bedside filter is attributed to the professional nurse. The prime requisites as a basis for decision making are extensive knowledge and understanding of the blood filters and/or blood products used for transfusing neonates, as well as their employment in relevant cases.

The researcher experienced that professional nurses involved with the transfusion of neonates had problems differentiating between different filters. Conflicting circulating policies and opinions regarding the availability and employment of these products, as well as the lack of registered clinical indication codes or competence indicators, contributed to the indecision experienced by professional nurses.

3.3 RESEARCH QUESTION

The research question was: “What is professional nurses’ ability to make clinical decisions regarding the employment of bedside blood product filters

during neonatal transfusion?"

3.4 AIM OF THE STUDY

The aim of the study was to determine and describe the ability of professional nurses in making clinical decisions regarding the employment of bedside blood products filters during neonatal blood transfusions. Additionally, it was to recommend transfusion guidelines to assist them in this regard.

3.5 OBJECTIVES

The objectives of the study to achieve the stated aim were as follows:

3.5.1 Objective One

The first objective was to determine and describe the professional nurses' ability to make clinical decisions regarding the employment of bedside blood product filters during neonatal blood transfusion.

3.5.2 Objective Two

The second objective was to recommend transfusion guidelines to assist professional nurses to make clinical decisions regarding the employment of specific bedside blood product filters during neonatal transfusion.

3.6 RESEARCH DESIGN

A research design is the researcher's overall plan for answering the research question. It spells out the strategies the researcher plans for collecting and analysing data, including specifications for enhancing the internal and external validity of the study (Polit, Beck & Hungler, 2001:167 - 8 & 470).

In this study descriptive survey was utilised. Survey studies are concerned with gathering information from a sample of the population and the emphasis in the collection of data being on the structured indirect observation,

questionnaires or interviews. No manipulation of variables is involved and there is no intention of establishing a cause and effect relationship (Polit, Beck & Hungler. 2001:180 and Brink 2000a:102-103).

The method used for data collection was a self-administered questionnaire. This type of design was chosen to determine and describe the clinical decision making of neonatal intensive care professional nurses regarding the employment of bedside blood product filters during neonatal transfusion. Resulting from this decision and, if one was to be employed, which bedside blood product filter was to be employed with which blood products. Based on the description of the professional nurses' ability to make clinical decisions regarding the employment of bedside blood product filters during neonatal transfusion, transfusion guidelines were recommended.

3.7 RESEARCH METHODS AND TECHNIQUES

Research methods and techniques are strategies utilised for conducting the study - from identification of the problem to the final plans for collecting and analysing data (Polit, Beck & Hungler, 2001:13). It forms a structural framework within which the study is implemented; it is thus a blueprint that guides the researcher in planning and implementing the study. At the same time, it optimises control over factors that could influence the outcome of the study (Polit, Beck & Hungler, 2001:13 – 14; Bless, et al. 2006:71).

The research methods and techniques will be discussed as it relates to the set research objectives.

3.8 OBJECTIVE ONE

The first objective was to determine and describe the professional nurses' ability to make clinical decisions regarding the employment of bedside blood product filters during neonatal blood transfusion.

3.8.1 Setting

The setting indicates the environment where the study is conducted; it can be either an experimental or social situation (Polit, Beck & Hungler, 2001:44 & 471). For the purpose of this study, the setting was both public and private hospitals with neonatal intensive care units in Gauteng, South Africa. Public and private hospitals were included in this study to increase generalisation. Ten hospitals were utilised. The names of the hospitals are not included in the report to maintain confidentiality.

3.8.2 Population

The population of a study is the entire aggregation of cases or individuals who meet a designated set of criteria (Polit, Beck & Hungler, 2001:40). De Vos et al. (2002:198) state it includes “all members of some clearly defined group of people with distinguishing criteria”.

In this study the population comprised of professional nurses working in neonatal intensive care units; in Gauteng Region, South Africa.

3.8.3 Sampling

Sampling is the process whereby the sample is drawing a portion of a population as a representative of that population (De Vos et al., 2002:198), or the process of selecting a portion of the population to represent the entire population under study (Polit, Beck & Hungler, 2001:470 & 234). It is important to understand the concept representativeness and its relationship to generalisability for one can only generalise the findings of the study when one can assume that what one observed in the sample of respondents would also be observed in any other group of respondents from the population (De Vos et al., 2002:198).

Convenience or accidental sampling was used in this study. Professional nurses included in this study happened to be in the right place at the right time. Hence, all professional nurses working in the neonatal intensive care

units of the ten nominated private as well as public hospitals in Gauteng Region, South Africa at the time of the study, were afforded the opportunity to participate in the study. The criteria for inclusion in this study required the professional nurses to be working in one of the neonatal intensive care units where the study was conducted at the time of the study, irrespective of their years of experience or type of post basic qualification. They could held a permanent or a part-time post at the time. All professional nurses not working in neonatal intensive care, irrespective of their years of experience in nursing or the type of post basic qualifications they held, and other categories of staff working in the neonatal intensive care unit, were excluded from the study.

The total number of professional nurses, including regular part-time professional nurses, was obtained and a corresponding number of questionnaires were handed to the respective unit managers for distribution. This method of sampling was utilised so that a larger sample size could be acquired in a shorter space of time, while reducing the Hawthorne effect on the professional nurses under study. In addition, the level of biasness on the researcher's side was also decreased (Polit, Beck & Hungler, 2001:175 and de Vos, et al. 2002:207).

3.8.4 Sample size

Sample size refers to the number of participants in a sample (Polit, Beck & Hungler, 2001:244). No simple equation could be utilised to determine the sample size suitable for this specific study as convenience sampling was used and the size would be determined by the number of participants available at that time. Polit, Beck and Hungler (2001:245) further state that the larger the sample size, the more representative of the population it is likely to be.

In this study, it was the statistician's recommendation to include 200 participants for fair statistical inferences at the end of the study. The total number of unspoiled questionnaires handed in the end was 120.

3.8.5 Data collection

The data collection technique chosen in this study was a self-administered questionnaire. Existing suitable questionnaires could not be found. An in-depth literature review was used to design a questionnaire as suggested by de Vos et al. (2002:127-128) and Polit, Beck and Hungler (2001:267 - 8).

An extensive literature search was conducted for information that could assist the researcher in the development of a questionnaire to determine and describe the knowledge professional nurses have regarding blood or blood products as well as bedside blood product filters. Additionally, to ascertain the professional nurses' ability to decide which bedside blood product filters to employ with which blood or blood product. Based on the literature, important concepts were identified regarding the knowledge of the professional nurses and their ability to make clinical decisions regarding the employment of bedside blood product filters during neonatal transfusion. The identified concepts were used in the construction of the questionnaire (de Vos, et al. 2002:127-128), which was done in collaboration with the statistician of the University of Pretoria.

A self-administered questionnaire was designed for the purpose of collecting data in this study. De Vos et al. (2002:172-4) and Polit, Beck and Hungler (2001:269 - 270) concede that self-administered questionnaires are often used for sensitive issues, which in this case concerned the knowledge professional nurses had regarding a topic that everyone assumed they were well informed about, namely, the employment of bedside blood product filters during neonatal transfusion. Realising the professional nurses could be unwilling to participate because their possible lack of knowledge and ability could be exposed, the researcher chose to use an anonymous self-administered questionnaire and thus the threat of being exposed was eliminated.

A criterion for using a self-administered questionnaire is that the population under study has to be adequately literate (de Vos, et al. 2002:172-174; Polit, Beck & Hungler, 2001:270). All the professional nurses who participated in

this study had received tertiary education and were therefore expected to be literate and able to complete the questionnaire.

The questionnaire consisted of multiple choice questions, open and closed ended questions as well as statements requiring responses from the participants. Where the researcher was uncertain whether or not all possible alternatives had been included, a fixed alternative with either an open ended or closed ended question was utilised (see Annexure D) as suggested by de Vos et al. (2002:179-180). The purpose of using this format was to have a high degree of structure in order to facilitate analysis.

De Vos et al. (2002:175) advise that a questionnaire be brief, yet long enough to incorporate all questions necessary for collecting relevant information, thus obviating a situation where the lack of pertinent information is detected at a later stage. These authors note further that it is important to work according to an economic principle, so that participants can communicate as much information as possible in the briefest possible time.

The questionnaire used in this study had four sections with forty-three questions relevant to the topic. The questionnaire was sub-divided into four sections, namely demographic data, knowledge: blood filters, knowledge: blood products and legal aspects. Thus, adequate information regarding the topic could be obtained as the questions were structured in a way that all necessary information should be obtained. It was economical to the effect that participants were afforded a chance of giving as much information as possible in the briefest possible time, as it took a participant approximately 20 to 30 minutes to complete the questionnaire.

The researcher consulted three experts in the field of neonatal intensive care nursing - two unit managers in neonatal intensive care units and a neonatal nurse educator - for clarification and verification of the content of the questionnaire. A statistician from the University of Pretoria was consulted for the construction of the questionnaire.

Once ethical approval had been obtained from the Ethics committee of the

University of Pretoria (Annexure A) and hospitals (Annexure B), the researcher liaised with the unit managers for the distribution of the letters of consent and questionnaires to the participants. The self-administered questionnaires were delivered by hand to all the involved neonatal intensive care units**.** The professional nurses were encouraged to complete the questionnaires voluntary and in their own time. The professional nurses were encouraged to completed the questionnaires and then to drop it into a designated closed and marked container in the unit manager's office.

The researcher distributed 200 questionnaires for completion. The questionnaires were numbered from 1 to 200 to ensure an easy follow-up process, but also for privacy reasons. By using only numbers and no names limited the threat of exposure that might be experienced by the subjects under study, thereby encouraging them to participate. The researcher had no personal contact with the participants and numbers were used to identify the questionnaires. It was not possible to trace the identity of the participants.

The self-administered questionnaires were collected from the respective neonatal intensive care unit managers at an agreed time by the researcher. Of the 200 questionnaires distributed, 180 were taken by participants and, of these, only 150 were returned. Of those, 30 questionnaires were considered spoiled due to factors such as being incomplete, missing pages or not complying with the instructions for completion. The total number of completed questionnaires included in the study were therefore 120. By counting and keeping record of the returned questionnaires, the researcher can establish whether the response was good or bad, as suggested by de Vos et. al. (2002:172), which in this case was considered to be good.

3.8.6 Data analysis

Data analysis means interpreting the data obtained during data collection (Polit, Beck & Hungler, 2001:460). The purpose of data analysis is to impose some order on a large body of information so that general conclusions can be reached and communicated in a research report. The overall aim is to organise, synthesise and provide structure to research data (Polit, Beck &

Hungler, 2001:381).

The completed self-administered questionnaires were analysed via quantitative data analyses using descriptive statistics. Quantitative data analysis, according to Polit, Beck and Hungler (2001:331 & 469), is the "manipulation of numeric data through statistical procedures for the purpose of describing a phenomena or assessing the magnitude and reliability of relationships among them". A statistician assigned by the University of Pretoria guided the data analysis process and assisted with data analysis.

By analysing the demographic data and the professional nurses' level of training, the researcher was able to establish the experience and the educational level of those who participated. The information could contribute to understanding the background of the participants who contributed to the study.

Descriptive statistics were used to present the data obtained from the analysed questionnaires. The content of the questionnaires were sorted, arranged and presented in a scientific manner. All questionnaires were analysed per sub-sections according to three named codes, namely correct, incorrect or data missing. A memorandum with correct answers was designed so that, should the need arise, anyone (especially those who are familiar with the topic), will be able to analyse the study findings. The completed questionnaires were analysed and compared with the memorandum to identify aspects of importance and limitations concerning the knowledge of professional nurses regarding the employment of bedside blood product filters during neonatal transfusion (see Annexure E).

In the end all similar responses from all the participants were added up; thus a univariate (one variable) analysis of data was used in this study. The sum of the added responses was converted into a percentage. Frequency counts and percentages were used to report the analysed data obtained from the sub-sections for easy understanding of the analysed questionnaires. These were used to determine the professional nurses' ability to make clinical decisions regarding the employment or non-employment of bedside blood product filters

during neonatal transfusion.

The assistance of the statistician in this study ensured that the quantitative data analysis of the research did not evolve into a chaotic mass of numbers, but enabled the researcher to reduce, summarise, organise, evaluate, interpret, and communicate numeric information into written information. Statistical Packages for the Social Sciences (SPSS) were utilised. The greater the percentage of correct answers, the greater the knowledge the professional nurses had and, conversely, the lesser the percentage of correctly answered questions, the greater the lack of knowledge the professional nurses had.

These percentages are displayed in tables, pie or bar graphs for easy interpretation and understanding (refer to Chapter 4 and Annexure F). The graphs were employed for displaying the frequency counts and percentages obtained from the study findings and the pie and bar graphs were used concurrently. This means that all the data gathered on that specific variable were summarised for easy comprehension and utilisation as suggested by de Vos et al. (2002:255-256). No comparisons were made between any participants.

3.8.7 Validity and reliability

Validity refers to the ability of the data collecting instrument to measure and obtain information relevant to what is being measured. It is concerned with the accuracy and truthfulness of the scientific findings and the reliability, stability and repeatability of the data collection instrument. It is also concerned with the ability of the researcher to collect and record information accurately (Brink, 2000a:124; Polit, Beck & Hungler, 2011:308 & 473). In this study the researcher performed an extensive literature study to identify concepts that should be included in developing the questionnaire as well as investigating whether there were any other questionnaires available that could be utilised.

Content validity is concerned with establishing if the questionnaire will measure what it is supposed to measure (Brink, 2000a:168 & de Vos, et al. 2002:167). Three experts in neonatal intensive care concentrated on the

content and criterion-related issues while the statistician dealt with construct validity. This helped to enhance the validity of the results obtained from the study.

The sample size is another method of establishing the validity and reliability of the study, because the larger the sample the more reliable the results. However, where convenient sampling has been employed, it is difficult to establish which sample size will be adequate to establish reliability of the study (de Vos, et al. 2002:199-200). For the purpose of this study 200 questionnaires were distributed: 180 were taken by participants and only 150 were returned. Of the 150 returned 30 were regarded as spoilt and only 120 could be used for analysis. The sample size (60% of the distributed self-administered questionnaires) obtained in this study was regarded as acceptable, but its outcome can only be generalised if the study can be repeated in other setting(s) and with bigger samples.

The original copies of the returned questionnaires and the analysed data will be stored as stipulated by Ethics Committee of the University of Pretoria should any interested person require them to assess the validity and reliability of the results. Electronic copies of the statistical analysis of the questionnaire are available on both the statistician's and researcher's computers should they be required for future references or comparisons.

3.9 OBJECTIVE TWO

The second objective of the study was concerned with recommendation of transfusion guidelines to assist the professional nurses to make clinical decisions regarding the employment of micro-aggregate and leukodepleting filters during neonatal transfusion.

3.9.1 Unit of analysis

"A unit of analysis is the entire aggregation of cases that meets a designated set of criteria and it is not restricted to human subjects." (de Vos, et al. 2002:107). The unit of analysis refers to the sources of information to meet

the objective.

For the purpose of the second objective it included national and international transfusion guidelines, existing policies of different hospitals, a scientific literature search and the results of the previous objective. All documents conforming to the eligibility criteria which were accessible to the researcher were used as a pool of data for the study. The aim of using the accessible documents was to gather as many documents as possible for the purpose of identifying and grouping themes and concepts for proper structuring of guidelines for easy understanding and utilisation by professional nurses during neonatal transfusion.

3.9.2 Data collection

Based on the findings of the first objective, namely the description of professional nurses' ability to make clinical decisions regarding bedside blood product filters during neonatal transfusion, inconsistencies related to decision making as well as knowledge gaps were identified.

With this in mind, the researcher collected as much relevant information as possible to develop guidelines for neonatal transfusion, and especially for decision making regarding employment of bedside blood product filters. An in-depth literature search (both national and international) was conducted. The assistance of a librarian was obtained to search for relevant documents. Information was obtained from Pubmed, Cochrane, journals (hard copies and electronic journals), health legislation, textbooks, hospital policies and other relevant transfusion literature. Common practices and a clearer understanding could be described of what was being practiced in different hospitals, and what was supposed to be practiced. These were utilised to recommend guidelines.

3.9.3 Data analysis

The focus during data analysis was to organise, synthesise and provide structure of the crucial aspects of neonatal transfusion in general, as well as

with specific reference to the use of bedside blood product blood filters during neonatal transfusion. When the researcher was satisfied with the organisation of the information, recommended guidelines were drafted. These guidelines are described in Chapter 5.

Three experts in neonatal intensive care nursing, a neonatal intensive care nursing science educator, two consultants from SABTS and four pharmaceutical representatives were consulted for validation of, and recommendations on the drafted guidelines. They were allowed two to three weeks to assess and analyse the guidelines and to give input where necessary. Their input included having an open discussion with the researcher, making written recommendations on the guidelines sample, as well as communicating via email until consensus was reached. The results are discussed in more detail in Chapter 5.

3.10 TRUSTWORTHINESS

According to Polit, Beck and Hungler (2001:312 & 472), trustworthiness is the "degree to which a study meets the criteria of credibility, transferability, dependability and confirmation". De Vos et al. (2002:351) refer to it as an attempt to establish the "truth value" of the study, namely its applicability, consistency and neutrality.

Credibility is the confidence in the truth of data or an alternative to internal validity. Its goal is to demonstrate that the inquiry was conducted in such a manner as to ensure that the subject was accurately identified and described (Polit, Beck & Hungler, 2001:460; de Vos, et al. 2002:351-352). In this study, a wide variety of sources were employed to establish the credibility of the guidelines. Validation of the recommended guidelines was done by three experts in neonatal intensive care nursing and the neonatal intensive care nursing science educator, four pharmaceutical representatives and two consultants from SABTS. In addition, the researcher undertook an in-depth literature study. Furthermore, prolonged engagement was achieved in that the researcher ensured that adequate time was spent in the field.

Transferability is the ability to generalise the findings of the study or an alternative to external validity. In other words, it demonstrates that the burden of the applicability of one set of findings to another context rests more with the person who makes the transfer (De Vos, et al. 2002:252; Polit, Beck & Hungler, 2001:316 & 472).

For the purpose of this study transferability referred to the ability of the developed transfusion guidelines to be utilised by other professional nurses across the country, thus enabling them to make clinical decisions regarding the employment of bedside blood product filters during neonatal transfusion. It included facilitating the training of professional nurses at various institutions. Transferability was further enhanced by a thick descripition of the results to make generalisation possible.

Dependability is the stability of data over time and under different conditions. Dependability can be viewed as an alternative to reliability. According to Polit , Beck and Hungler (2001:315 & 460) and de Vos et al. (2002:252), the researcher attempts to account for changing conditions in the phenomenon chosen for study as well as changes in the design created by an increasingly refined understanding of the settings. In this study, methods used to increase credibility included prolonged engagement of the researcher in the field of neonatal intensive care nursing. Validation of the questionnaire by three experts, representatives from the pharmaceutical companies and the nurse educator in neonatal nursing science, also helped to enhance dependability.

Confirmation refers to the objectivity or neutrality of the data. This means two or more independent people should be able to agree on the relevance or meaning of the data (Polit, Beck & Hungler, 2001:459 & 315; de Vos, et al. 2002:252). For the purpose of this study experts in neonatal intensive care nursing, the neonatal intensive care nursing science educator and pharmaceutical representatives, were utilised in designing and approving of the questionnaires as wells as for reviewing the transfusion guidelines.

3.11 ETHICAL CONSIDERATIONS

Ethical considerations are concerned with the protection of human subjects from biomedical and behavioural research that might be harmful to them. Committees such as the National Commission for the protection of Human Subjects of Biomedical and Behavioral Research (US) ensure that the rights of participants in research are protected (de Vos, et al. 2002:73-74; Deacon & O'Neill, 1999:746). Ethical considerations are commonly formulated as declarations that outline correct from incorrect practices and what ought to be. This pertains to the fundamental standards of right and wrong that an individual learns and internalises, usually in the early stages of childhood development (Aiken & Catalano, 1994:22).

Deacon and O'Neill (1999:744) explain that codes of ethics are written lists of professional values and standards of conduct. Because they are presented in general statements, they do not provide specific answers to all ethical problems that might possibly arise; they rely mostly on the individual's moral reasoning.

As this study concerned the knowledge of human beings, an issue that could have been perceived as sensitive, it was vital that the rights of both the participants and the researcher had to be protected (Polit , Beck & Hungler, 2001:74 - 85).

Ethical principles require that all stakeholders (in this case the hospitals and professional nurses) be informed regarding the proposed topic before any research study is commenced. This allows them to decide whether or not they will participate. If the decision is made to participate, permission is obtained from them (de Vos, et al. 2002:64). In this study the principles of utilitarianism and beneficence were applied. These ethical considerations strive to achieve the greatest benefit for the most people involved through balancing the interest and priorities of all as suggested by Deacon and O'Neill (1999:745).

A letter of permission requesting consent from the public and private hospitals to undertake the study was drafted (see Annexure B). Approval to conduct the

study was obtained from the Research Ethics Committee of the University of Pretoria prior to the distribution of these letters to the respective hospitals (see Annexure A).

The researcher then approached public and private hospitals in Gauteng, South Africa, to obtain permission to conduct the study in their institutions. Ten hospitals that were accessible to the researcher were chosen. Once permission to conduct the study in their hospital was granted by the hospital managers or chief executive officers of the private hospitals and the superintendents of the public hospitals, the same letter was taken to the neonatal intensive care unit managers for approval to conduct the study in their units. The reason for this was to involve them and for the researcher to obtain cooperation and access to the sample (see Annexure B).

Once permission had been obtained from the unit managers, an information leaflet and consent form for the participants was drafted (see Annexure C). The professional nurses were informed that participation is voluntary. Individuals who participated in the study were not identified, thus their privacy and confidentiality were maintained. The researcher also availed herself to answer all questions the participants might have had regarding the study.

Nonmaleficence is an ethical principle that requires that more good than harm be done by researchers to subjects (Deacon & O'Neill, 1999:746). To maintain this principle in this study, numbers were assigned to questionnaires. Instead of the participants' names, these numbers were utilised to identify the responses, thus ensuring anonymity. To protect the participants from exposure, for example, not to divulge whether a participant was able to understand and interpret the questions and complete the questionnaire correctly or incorrectly, they were allowed to choose questionnaires at random. Confidentiality was maintained so that any feelings of inadequacy the participants might have experienced were considerably reduced.

Veracity or truthfulness requires that researchers tell the truth about themselves and the study (Deacon & O'Neill, 1999:746). In this study, the relevant information concerning the researcher was made available to the

participants. This included her qualifications, workplace, experience in neonatal intensive care nursing as well as her contact details, the name and contact details of her supervisor and the university where the researcher was studying at the time of the study (De Vos, et al. 2002:207).

3.12 CONCLUSION

In this chapter the research design and methodology are described in terms of population, sampling, data collection and data analysis. The measures of validity and reliability (objective 1) and trustworthiness (chapter 2) and the relevant ethical issues were described. The findings of objective 1 will be described in Chapter 4 and the findings of objective 2 will be discussed in Chapter 5.

CHAPTER FOUR

FINDINGS OF OBJECTIVE ONE

4.1 INTRODUCTION

Findings of the study refer to the outcomes or the results of the study. The aim of this study was to determine and describe the ability of professional nurses to make clinical decisions regarding the employment of bedside blood product filters during neonatal transfusion (objective 1), and to recommend transfusion guidelines that will assist them in this regard (objective 2).

To achieve the first objective a questionnaire was used to determine and describe the ability of neonatal intensive care professional nurses to make clinical decisions regarding bedside blood product filters and blood or blood products.

This chapter describes the outcome of the analysis of the questionnaires.

4.2 OUTLINING OF THE SUB-SECTIONS OF THE QUESTIONNAIRE

The questionnaire (attached as Annexure D) was divided into four main sections: demographic data, bedside blood product filter knowledge, blood or blood product knowledge and knowledge of legal aspects surrounding neonatal transfusion.

The demographic data in this study were used to give background information on the participants involved and it aided the researcher to understand the outcome of the questionnaire.

The remaining three sections - the participants' knowledge of bedside blood product filters, blood or blood products and the legal aspects pertaining to neonatal transfusion, related to the purpose of the study.

A univariate (one variable) analysis of data was used to describe the response to each question in the three categories, namely correct, incorrect or missing data. Frequency counts programmes were used to analyse the sub-sections (Uys & Basson, 1994:115-6). Similar responses were added and a total number was allocated to each response per category. This number was then converted into a percentage, for example: Section A: Question 1: n=42 (32%) = correct; n=57 (44%) = incorrect and n=31 (24%) = missing data. Tables and graphs were utilised in this regard to display the outcomes of the questionnaires for easy interpretation and analysis. (See Annexure F for graphs).

By analysing the correct, incorrect and missing data responses of the participants, the researcher was able to determine the ability of professional nurses to make clinical decisions regarding the employment of bedside blood products filters during neonatal transfusion with blood or blood products.

4.3 FINDINGS OF THE QUESTIONNAIRES

One hundred and twenty questionnaires were analysed (n=120) in this study. However, the participants indicated more than one answer in some of the tables and, therefore, the percentages were worked out according to the number of responses given in individual tables**.** Accordingly, ***n*** indicates the total number of participants and **%** denotes the participants' responses in percentages.

4.3.1 Section A: Demographic data

The purpose of the demographic data was to simplify the diverse groups of the participants under study. The term 'diverse group of participants' in this study referred to professional nurses who had various qualifications in neonatal intensive care nursing. The type of education they received in neonatal intensive care nursing was considered to be indicative of: (i) the level of education they had received on blood or blood products, and (ii) their training regarding the employment of bedside blood product filters during neonatal transfusion. For the purpose of this study, type of education they

received in neonatal intensive care nursing referrers to who, where, how, when and how long ago have participants received their education and or training on blood and blood products as well as the various types of bedside blood product filters available in the market.

4.3.1.1 Sector of employment

The type of sector where the professional nurses were employed was included in this study so that the outcome thereof can be generalised to both sectors and to provide background information as it is assumed that there are differences in the level of exposure to the use of bedside blood product filters, and that these filters are more often used in private sectors than in government sectors. The data is not used in this study to draw conclusions, but is available for further studies.

Table 4.1: Sector of employment

Sector	n	%
1. Private	48	40%
2. Government	72	60%

As indicated in Table 4.1, more professional nurses (60%) who worked in the government sector responded to the questionnaire than those who worked in the private sector (40%). In a follow-up study, the relationship between the two sectors and the knowledge the professional nurses in each sector have regarding the employment of bedside blood product filters during neonatal transfusion could be determined.

4.3.1.2 Highest qualifications

In neonatal intensive care nursing it is expected that the qualifications of the professional nurses and years of experience would influence their competency in clinical decision making regarding the employment of bedside blood product filters during neonatal transfusion. For the purpose of this study it is expected that the professional nurse should at least have a diploma in

neonatal intensive care nursing or have more than three years experience in neonatal nursing care.

Table 4.2: Highest qualifications

Highest qualifications	n	%
1. Neonatal ICU experience	46	38%
2. Diploma in neonatal intensive care	36	30%
3. Degree in neonatal intensive care	1	1%
4. Other (Specify)	37	31%
5. Missing data	0	0%

Professional nurses working in neonatal intensive care units are expected to have received specialised education in neonatal intensive care nursing as this enables them to make independent clinical decisions when caring for neonates on a day to day basis. According to Table 4.2, 38% of the professional nurses had experience in neonatal intensive care nursing. Thirty-one per cent had other qualifications in professional nursing. These included a diploma in midwifery, a certificate in paediatric nursing, a diploma in general intensive care nursing or a certificate in neonatal intensive care nursing. Some of the professional nurses indicated that they had more than one diploma/certificate in more than one of these areas of professional nursing, for example, they held a diploma in general intensive care nursing as well as a certificate in neonatal intensive care nursing/paediatric nursing. Thirty per cent had a diploma in neonatal intensive care nursing and 1% had a degree in neonatal intensive care nursing. This indicates most of the professional nurses working in neonatal intensive care nursing had some form of post basic nursing education.

4.3.1.3 Years of experience in a neonatal intensive care unit

Experience endows people with confidence - especially if an individual is faced with a situation where he or she has to make an independent, competent decision on behalf of those who cannot. Confidence gained through experience will aid the decision-maker in a significant and positive

way.

Table 4.3: Years of experience in a neonatal intensive care unit

Years of experience	n	%
1. <2 years	30	25%
2. 3–5 years	44	36%
3. 6–10 years	25	21%
4. >10 years	19	16%
Missing data	2	2%

Table 4.3 indicates that 73% of the professional nurses working in neonatal intensive care units had more than 2 years' experience in neonatal intensive care nursing, with 25% stating they had limited working experience in this field. Bearing in mind that the lack of experience could have a direct impact on the professional nurse's ability to make clinical decisions regarding the employment of bedside blood products filter during neonatal transfusion with blood or blood products, this finding raises concern. It may lead to the professional nurse feeling less confident in making such critical decisions. The fact that a quarter of the professional nurses had limited working experience in neonatal intensive care nursing is troublesome. In the researcher's opinion, a quarter involves a too large number of inadequately trained professional nurses and, as a result, they probably have limited ability to make clinical decisions regarding the employment of blood product filters during neonatal transfusion.

4.3.1.4 Conclusive remarks on demographic data

The demographic analysis indicated that professional nurses working in neonatal intensive care units had various levels of education and experience in the field of neonatal intensive care nursing. Of the professional nurses in this study, 1% held a degree – the highest qualification – in neonatal intensive care nursing, 30% had a diploma in neonatal intensive care nursing, and 31% had a certificate in midwifery, paediatric nursing or neonatal nursing. Some indicated they had more than one qualification in these areas, for example a

diploma in general intensive care nursing and a certificate in neonatal intensive care nursing or paediatric nursing.

As indicated by table 4.2: 69% of participants have no post basic qualification in neonatal intensive care nursing while 27% from table 4.2 have less than 3 years of experience in neonatal nursing care. This means that there may be more professional nurses with limited knowledge in neonatal intensive care nursing. This is indicating that though it is expected of them, they probably lack knowledge to make clinical decisions when faced with a situation that requires them to do so. Based on the above data there is a need for transfusion guidelines that will assist professional nurses working in neonatal intensive care units to make clinical decisions when faced with the procedure of transfusing neonates with blood or blood products.

4.3.2 Section B1: Knowledge of blood and blood products

Transfusion of blood or blood products to patients is commonly regarded as one of the responsibilities of the professional nurse (Potter, 2001:1242). The professional nurses are therefore expected to have sufficient knowledge on blood or blood products commonly used to transfuse neonates and the type of transfusion reactions the latter may present with. They should be able to assess whether the blood or blood products are leukodepleted and to what level it has been leukodepleted. They should also be able to determine whether the blood or blood products are safe to transfuse the neonate with, and be able to choose the appropriate bedside blood product filter to employ with the prescribed blood or blood products.

4.3.2.1 Education received on blood and blood products

Based on the results in Table 4.4, 55% of the professional nurses in neonatal intensive care units did receive education on blood and blood products, while 45% did not. This shows that a high percentage of professional nurses received no education on blood or blood products, indicating that an unacceptably high number of professional nurses had insufficient knowledge regarding blood or blood products used to transfuse neonates. Further studies

regarding the knowledge professional nurses have in this regard may be beneficial in this field of nursing.

Table 4.4: Education received regarding blood or blood products

Education received regarding blood or blood products used to transfuse neonates	**N**	**%**
1. Yes	66	55%
2. No	54	45%
3. Missing data	0	0%

Professional nurses can either acquire education regarding blood or blood products commonly used to transfuse neonates formally, meaning at a college or university, or informally, meaning in a hospital at bedside or by studying reading material on the subject such as the hospital policy or protocol. Continuous education in this regard keeps the professional nurse abreast with the latest developments in transfusion of blood and blood products. The format of education has to enhance their level of knowledge.

As illustrated in Table 4.5, of the professional nurses 24% indicated they had received education 24 months or longer before the time of the study and 35% did not indicate how long ago they had received education. This signifies that most of the professional nurses had no knowledge about the latest information regarding transfusion of neonates with blood or blood products. It further implies they would have been unable to make clinical decisions regarding the employment of bedside blood product filters when expected to transfuse the neonate with blood or blood products.

Table 4.5: Period when last education was received

How long ago did you receive education on blood and blood products?	n	%
1. <6 months ago	13	11%
2. 7–12 months ago	25	21%
3. 13-24 months ago	11	9%
4. >24 months ago	29	24%
5. Missing data	42	35%

Professional nurses are expected to stay updated at all times. Attending training sessions such as workshops, seminars or short courses – especially those which are in line with their practice – keep them abreast with the latest technological developments and disease management.

Table 4.6 shows that 63% of the professional nurses received their education in a hospital setting from a colleague, doctor or medical representative. Twenty-six per cent did not indicate their sources, while 11% received it from other sources such as reading the leaflets which accompany the units of blood supplied to hospitals by the blood bank, or medical journals and research articles. This implies that approximately two thirds of the professional nurses received education regarding types of blood products or blood products commonly used to transfuse neonate in a practical setting, and not at an educational institution. It can thus be assumed that the education they received was limited, depriving them of confidence when expected to make clinical decisions regarding the employment of bedside blood or blood products filters during neonatal transfusion.

Table 4.6: Person responsible for giving education

Who gave you the education?	n	%
1. A colleague, for example, a unit manager	48	39%
2. A doctor	10	9%
3. A medical representative	18	15%
4. Other (Specify)	13	11%
5. Missing data	31	26%

It is assumed that the source, for example a college (tutor), university (lecturer) or hospital (medical representative), from which the educational information originates determines the quality and level of such education.

Table 4.7 shows that most of the professional nurses (51%) received education in a hospital setting in the form of in-service training; 16% reported they it was in the form of informal discussions with a colleague or colleagues at the patient's bedside. When considering these two percentages (51% and 16%), it is clear that the hospital was the main area where the professional nurses received education regarding blood or blood products.

Table 4.7: Format used to give the education

The education was given in the form of …?	n	%
1. In-service training	61	51%
2. Seminar	0	0%
3. Symposium	0	0%
4. Other (Specify)	19	16%
5. Missing data	40	33%

The deduction can be made that the depth of education was inadequate. Of the participants, 33% failed to indicate where they had received their education. Accordingly, a disconcerting number of professional nurses may have received no education with regard to blood or blood products. It is assumed that this might render them incapable of making clinical decisions

concerning the employment of bedside blood product filters during neonatal transfusion.

4.3.2.2 Knowledge of commonly used blood and blood products

The blood product most commonly used to transfuse neonates is packed red blood cells. Secondly it is fresh frozen plasma, and then platelets, while whole blood is used less frequently, as indicated in Table 4.8. The 2% of participants, who indicated other products, pointed out that they were familiar with albumin and immunoglobulin. This suggests that professional nurses were exposed to various types of blood or blood products used to transfuse neonates, with packed red blood cells being the most commonly used, followed by fresh frozen plasma and platelets. Because more than one product was indicated by some participants, the number of responses was more than 120. It is clear that they were most knowledgeable about packed red blood cells, fresh frozen plasma and platelets since they stipulated them as the blood or blood products they commonly used to transfuse neonates.

Table 4.8: Blood and blood products commonly used to transfuse neonates

Blood and blood products commonly used are …?	**n**	**%**
1. Platelets	52	21%
2. Fresh frozen plasma	56	22%
3. Packed red blood cells	115	46%
4. Whole blood	23	9%
5. Other (specify)	5	2%
6. Missing data	0	0%

4.3.2.3 Knowledge of leukodepletion of blood and blood products

Leukodepletion is the process whereby white cells are reduced from blood or blood products used to transfuse neonates (Cloherty, et al. 2003:490; SABTS,

2003:20). It is believed that this process has resulted in the reduction of transfusion-related reactions to the recipients of blood or blood products, who, in this study, pertained to neonates. Tables 4.9 to 4.12 focus on the knowledge professional nurses had regarding the leukodepletion of blood or blood products. Blood or blood products utilised for transfusing neonates are to be leukodepleted at all times (SABTS, 2003:21).

Table 4.9 shows that 39% of the professional nurses indicated that the blood products are not always leukodepleted, 38% were not sure about this, 22% indicated that the products are always leukodepleted and 1% did not provide any information. This signifies that either the blood or blood products are not always leukodepleted, in which case neonates has to be protected from donor white cells by employing a bedside blood product filter with the transfusion procedure, or the professional nurses did not know how to establish whether the blood products were leukodepleted or not. If the latter rings true, it is evident that that the professional nurses did not have adequate knowledge regarding the leukodepletion of blood or blood products commonly used to transfuse neonates.

Table 4.9: Leukodepletion of blood and blood products

Is the product always leukodepleted?	n	%
1. Yes	26	22%
2. No	48	39%
3. Unsure	45	38%
4. Missing data	1	1%

As discussed in Chapter 2, professional nurses are expected to have knowledge regarding the level to which blood or blood products are leukodepleted.

As shown in Table 4.10, 44% of the professional nurses had no knowledge of the level to which the blood or blood products commonly used to transfuse neonates are leukodepleted, while only 1% indicated that they were familiar with this level. It is clear from this table that the professional nurses were not

familiar with the level to which the blood or blood products they used to transfuse neonates had been leukodepleted: 37% did not provide information in this regard and 18% were unsure. This indicates they were unaware of the level of safety to which the product should be leukodepleted, and were therefore unable to make decisions regarding the choice of a bedside blood product filter when transfusing the neonate.

Table 4.10: Level to which blood or blood products are leukodepleted

Are you familiar with the level to which these products are leukodepleted	**N**	**%**
1. Yes	1	1%
2. No	53	44%
3. Unsure	21	18%
4. Missing data	44	37%

From the results shown in Table 4.11 it is evident that there was a lack of education regarding the process and procedure of leukodepletion. Of the professional nurses, 5% obtained information regarding leukodepletion in-service, in other words from a colleague or colleagues at the patient's bedside, while 1% received information at a symposium. Nine per cent read about it in journals, medical chronicles and clinical updates provided by medical representatives or during informal discussions with a colleague**.** It can be assumed that the 85% missing data either represents professional nurses who did not have any knowledge or information on what leukodepletion is all about, or were just reluctant to answer the question.

Table 4.11: Method of acquiring information on leukodepletion

How did you acquire the above information?	N	%
1. In-service	6	5%
2. Seminar	0	0%
3. Symposium	1	1%
4. Other (Specify)	11	9%
5. Missing data	102	85%

The fact that professional nurses seem to have little knowledge and understanding of leukodepletion, and were furthermore not educated about it, is of great concern to the researcher. It is therefore suggested that a further study is conducted to ascertain what knowledge, understanding and education professional nurses in ICU paediatric units have regarding this issue.

Further, blood or blood products should regularly be checked to verify if they are leukodepleted and to what level (British Committee for Standards in Haematology - Blood Transfusion Task Force [BCSH-BTTF], 2004:434 & PALL Medical, 2000b: clinical update).

Based on the information displayed in Table 4.12, 57% of the professional nurses did not know whether regular checks were done in the neonatal intensive care unit to verify if the blood or blood products were leukodepleted, while 30% was not sure if the blood or blood products were checked. Only 9% indicated that checks were done to verify whether the blood or blood products were leukodepleted.

Table 4.12: Monitoring and establishing the levels to which the blood or blood products are leukodepleted

Is it a regular practice to check the level to which these products are leukodepleted?	n	%
1. Yes	11	9%
2. No	68	57%
3. Unsure	36	30%
4. Missing data	5	4%

4.3.2.4 Transfusion reactions

The neonate's vital data is to be monitored ¼ hourly, or at least ¼ -½ hourly if transfused with blood or blood products from different donors (Brunner & Suddarth, 2007:1107).

According to Table 4.13, a sufficient number (81%) of professional nurses was familiar with the frequency with which neonates should be observed when being transfused with two units of blood or blood products from different donors. However, the remaining 19% raises concerns, given the fact that transfusion reactions may cause instant death to the neonate. Fourteen per cent monitored the neonate ½ hourly, 3% failed to provide information and 2% indicated that they observed the neonate only when they deemed it necessary.

Table 4.13: Frequency of monitoring the neonate's vital signs

How often should the neonate's vitals signs be monitored when transfused with more than one donor?	n	%
1. ¼ hourly	46	38%
2. ¼-½ hourly	52	43%
3. ½ hourly	17	14%
4. When necessary	2	2%
5. Missing data	3	3%

The above suggests there were a fair number of professional nurses with limited knowledge regarding how often the neonate's vital signs had to be monitored when products from different donors were being transfused.

Neonates commonly present with transfusion related reactions during the transfusion procedure. Based on the information given in Table 4.14, it is clear that the majority (74%) of professional nurses working in neonatal intensive care units were aware that the neonates could present with transfusion-related reaction(s) during transfusion, while 16% knew that neonates could show a reaction within 24 hours. Four per cent anticipated any reaction to occur within 3-6 days or 8-10 days post transfusion respectively. Those who did not answer the question constituted 1%.

Table 4.14: Time after transfusion to present with acute transfusion reaction(s)

How soon can a neonate present with acute signs of transfusion reaction(s)?	n	%
1. During transfusion	89	74%
2. Within 24hrs post transfusion	19	16%
3. 3-6 days post transfusion	5	4%
4. 7-10 days post transfusion	5	4%
5. Unsure	1	1%
6. Missing data	1	1%

As indicated in Table 4.14 the majority professional nurses had adequate knowledge with regard to how soon a neonate can present with acute transfusion related reactions.

The neonate is considered to have latent transfusion related reactions if signs of reaction present themselves within 7-10 days post transfusion with blood or blood products. Table 4.15 illustrates that 61% of the participants indicated that the neonate will present with latent transfusion reaction within 24 hours; 24% thought it would occur within 3-6 days post transfusion. Ten per cent anticipated it to be within 7-10 days post transfusion and 4% did not provide information.

Table 4.15: Time after transfusion to present with latent transfusion reaction(s)

How long post transfusion with blood or blood products, will a neonate present with latent transfusion reaction?	**n**	**%**
1. During transfusion	1	1%
2. Within 24hrs post transfusion	73	61%
3. 3-6 days post transfusion	29	24%
4. 7-10 days post transfusion	12	10%
5. Missing data	5	4%

Based on Table 4.15 it is evident that the majority of professional nurses have limited knowledge regarding the time post transfusion that neonates can present with latent transfusion reactions.

Respiratory distress is the most common transfusion related reaction neonates present with (de Vries, et al. 2005:121). According to Table 4.16, 46% of the professional nurses expected the neonate to present with biological response reactions, 12% indicated pneumonia, 26% indicated respiratory distress and 9% indicated metabolic acidosis. Five per cent

indicated other responses such as oedema, jaundice, pyrexia and tachypnea. Two per cent did not answer the question. It is therefore obvious that the majority of professional nurses had no knowledge of what transfusion reactions neonates commonly present with.

Table 4.16: Common transfusion reactions

Which transfusion reaction is common among neonates?	**n**	**%**
1. Pneumonia	16	12%
2. Biological response reactions	59	46%
3. Respiratory distress	35	26%
4. Metabolic acidosis	11	9%
5. Other (Specify)	6	5%
6. Missing data	2	2%

The above data is unsettling because not identifying the neonate's adverse reaction to transfusion, may result in misdiagnosis, incorrect treatment or even death.

4.3.2.5 Conclusive remarks on blood and blood products knowledge

An analysis of the information shown in Tables 4.4 to 4.16 indicates that the professional nurses working in neonatal intensive care units did have some knowledge of blood or blood products commonly used to transfuse neonates. However, they had limited knowledge regarding the process of leukodepletion and the level to which these products should be leukodepleted to render them safe to transfuse neonates - in other words, to protect the neonate from developing transfusion related reactions. It is also evident that the majority of professional nurses were not aware of how long after transfusion the neonate could present with latent transfusion related reactions or what the common transfusion related reactions could be.

The findings indicated a lack of ability of professional nurses working in neonatal intensive care units to make clinical decisions regarding neonatal

blood transfusion. They therefore need to have guidelines regarding when and how often the neonate should be observed during and post transfusion, to what level the blood or blood products should be leukodepleted to render them safe to transfuse neonates, and what the transfusion related reactions are that the neonates commonly present with. The availability of transfusion guidelines within neonatal intensive care units can be of great benefit to professional nurses to address these needs.

4.3.3 Section B2: Knowledge of bedside blood product filters

Bedside blood product filter knowledge enables professional nurses to decide which filter is suitable for which blood product, when to employ such a filter, how often it can be re-used, how many units of blood or blood products can be filtered through it, and where on the administration set it should be placed.

Tables 4.17 to 4.36 outline the knowledge professional nurses had regarding bedside blood product filters and their employment during neonatal transfusion with blood or blood products.

4.3.3.1 Education on bedside blood product filters

Table 4.17 reports that 70% of the professional nurses had been exposed to these blood product filters for over a period of two years, 24% for less than two years and 6% did not provide information in this regard. This demonstrates that a sufficient number of professional nurses had good exposure to bedside blood product filters. This is significant as it can imply that more professional nurses in the field may have sufficient knowledge in this regard and should therefore be able to make clinical decisions regarding its employment during neonatal transfusion. The troublesome issue in this instance is that a high number, more than a quarter (30%), had limited exposure, and this could become problematic if they should have the responsibility of transfusing neonates.

Table 4.17 Years of exposure to bedside blood product filters

For how long have you been using bedside blood product filters?	n	%
1. <2 years	29	24%
2. 2-5 years	19	16%
3. 6-10 years	37	31%
4. >10 years	28	23%
5. Missing data	7	6%

The longer the professional nurse is exposed to the use of bedside blood product filters, the more confident she or he is expected to be in employing such a filter when transfusing the neonate with blood or blood products. This means she or he will be able to choose the correct filter for the correct blood or blood products and utilise it as recommended by the production company. It is considered that the professional nurse would have sufficient knowledge if he or she has been exposed to bedside blood product filters for a minimum period of two years.

Education regarding any equipment to be employed during the care of a neonate not only enhances the professional nurse's competency, but also increases their confidence, making them cost-effective by initially selecting the right blood, blood products and filters.

As indicated in Table 4.18, 57% of the professional nurses received education regarding the employment of bedside blood product filters during neonatal transfusion, while 43% did not. This means that more than one quarter of the professional nurses received no training in this regard, and was therefore considered not competent to make these clinical decisions. At issue here is the fact that it does not suffice for only 57% of professional nurse to have had received education on bedside blood product filters.

Table 4.18: Education received regarding bedside blood product filters

Did you receive any education regarding bedside blood product filters?	n	%
1. Yes	68	57%
2. No	52	43%
3. Missing data	0	0%

Due to changes in disease patterns as well as in technology and new ways of managing diseases, the more professional nurses stay informed of such changes, the easier it will be for them to make clinical decisions on behalf of patients who are under their care. However, this does not imply that professional nurses, who had received their education a long time ago, for example over 24 months ago, are wholly incapable of making such decisions, but only that they may feel uncertain and less confident when faced with having to make them independently. It is also possible that they may apply outdated principles. The more recent their education, the more competent they are expected to be in this regard**.**

Table 4.19 shows that more than a third of the professional nurses failed to indicate how long ago they had received education regarding the employment of bedside blood product filters during neonatal transfusion. Even though it cannot be established exactly how long before the study was conducted had 37% had received education, it is relevant that a third indicated they had received education more than 24 months ago, and another third indicated less than 24 months ago.

Table 4.19: Period since last education received

How long ago was the education received?	n	%
1. <6 months ago	10	8%
2. 7-12 months ago	18	15%
3. 13-24 months ago	14	12%
4. >24 months ago	34	28%
5. Missing data	44	37%

This confirms that only a small number of professional nurses were familiar with the changes regarding transfusion therapy and were therefore deemed competent enough for making clinical decisions in this regard.

4.3.3.2 Positioning of bedside blood product filters

According to de Vries et al. (2005:118-119), both national and international standards recommend that a bedside blood product filter should be in-line with the blood administration set proximally.

As illustrated in Table 4.20, 30% of the professional nurses did not provide an answer to the question. This possibly means that they did not know where the filter should be positioned. Twenty-seven per cent reported that it should be in-line distally, while 24% indicated in-line proximally. Twenty per cent indicated not in-line but attached to a bag. This table reflects that the majority of professional nurses working in neonatal intensive care units were either not familiar with, or had limited knowledge of the national and international standards of neonatal transfusion regarding the positioning of the bedside blood product filter on the administration set.

Table 4.20: Positioning criteria for bedside blood product filters

The preferred position of the bedside blood product filter on the administration set as set out by national and international standards	n	%
1. In-line proximally	29	24%
2. In-line distally	32	27%
3. Not in-line but attached to a bag	24	20%
4. Missing data	36	30%

Because blood or blood products are prepared and handled by human beings and placed in plastic bags for storage, they are continually exposed to contamination. During storage, residual white cells progressively die while micro clots may also be formed. Not using a filter at all may put the neonate at a greater risk of developing complications related to blood transfusion (PALL Medical; 2000b: clinical update).

According to Table 4.21, 78% of the professional nurses responded that not employing a filter at all during neonatal transfusion was the practice. Also, 22% did not know or realise that, by not employing a bedside blood product filter during neonatal transfusion, the neonate could be placed at risk of developing transfusion related complications or reactions.

Table 4.21: Positioning of bedside blood product filters putting neonate at risk

What filter position in-line will expose the neonate to transfusion reaction?	n	%
1. In-line proximally	7	6%
2. In-line distally	8	7%
3. Not in-line but attached to a bag	6	5%
4. Not using a filter at all	94	78%
5. Missing data	5	4%

This is an alarming finding considering that the limitation of knowledge could be critical when uninformed professional nurses work in neonatal intensive care units.

Leukocyte depletion is costly. In South Africa the universal leukodepletion of red blood cell concentrates may add more than two hundred million rand to the overall transfusion therapy costs (SABTS, 2003:20). Therefore, the practice that is the most cost-effective and least time consuming, is applying a filter that is in-line with the administration as it involves less manipulation and limited contamination of the intravenous site and/or administration set. It is also an attempt to lessen the exposure of the neonate to infections that could eventually prolong his or her stay in hospital. Table 4.24 above reports 45% of the professional nurses indicated that the most cost-effective and least time consuming practice, is to employ a bedside blood product filter that is in-line with the administration set. Thirty-seven per cent indicated that employing a filter that is not in-line but attached to a bag fits these requirements, 4% highlighted a practice of not employing a filter while 14% did not respond to the question. This means a high percentage (55%) had insufficient knowledge regarding the practices that are most cost-effective and less time consuming while nursing neonates in intensive care units.

Table 4.22: Cost-effective and least time consuming positioning of bedside blood product filters

What is the most cost-effective and least time consuming positioning of a bedside blood product filter?	n	%
1. In-line proximally	34	28%
2. In-line distally	20	17%
3. Not in-line but attached to a bag	44	37%
4. Without a filter	5	4%
5. Missing data	17	14%

When considering that parents are not only responsible for paying the bill, but are also anxious about the condition of their neonate, the above is

unacceptably high. Studies pertaining to the ability of professional nurses caring for neonates in intensive care units regarding their understanding and adherence to practices that are cost-effective and less time consuming should be encouraged.

A bedside blood product filter that is in-line and attached proximally to the administration set may lead to unloading and channeling of previously filtered particles into the neonate's circulation if used over and over again (PALL Medical, 2000b: clinical update & PALL Medical, 1999a: clinical update).

Table 4.23 shows that less than 50% of the professional nurses indicated that an in-line filter attached proximally and used over and over again may lead to the unloading and channeling of previously filtered particles into the neonate's system, thereby putting the latter at a greater risk of developing transfusion related complications. Thirteen per cent responded that an in-line filter attached distally and re-used many times could cause this problem, while 15% indicated the cause was a filter that was not in-line, but attached to a bag. It is disconcerting that 27% (nearly a third) of the professional nurses did not even answer the question – this may mean they had no knowledge regarding bedside blood product filters.

Table 4.23: Filter positioning leading to unloading and channeling of particles if re-used

Which filter will lead to unloading and channeling of previously filtered particles if used over and over again?	**n**	**%**
1. In-line proximally	54	45%
2. In-line distally	16	13%
3. Not in-line but attached to a bag	18	15%
4. Missing data	32	27%

4.3.3.3 Indications for bedside blood product filters

When transfusing a neonate with leukodepleted blood or blood products, a microaggregate blood filter should be employed. This filter helps to minimise

transfusion related reactions by trapping particles that might be found within the blood or blood products, but it will not trap air or small pathogens like viruses (PALL Medical, 2000b: clinical update & PALL Medical, 1999a: clinical update).

Table 4.24 shows that more than a third of the professional nurses were not aware of which bedside blood product filter should be employed when transfusing the neonate with leukodepleted blood or blood products. Fifty-seven per cent indicated they would employ a leukodepleting filter. It is stressed that employing a leukodepleting filter is not to the detriment of the neonate, as it may further leukodeplete the blood product and this can only benefit the neonate. However, it is a matter of concern that only 11% knew that the appropriate filter to be used in this case was a microaggregate filter.

Table 4.24: Bedside blood product filters for transfusion of leukodepleted blood or blood products

Which filter should be employed with the above procedure?	**N**	**%**
1. A leukodepleting blood filter	68	57%
2. A microaggregate blood filter	13	11%
3. An adult blood filter	12	10%
4. None at all	12	10%
5. Missing data	15	13%

These results clearly attest to the fact that professional nurses had limited knowledge regarding the employment of the correct bedside blood product filter during neonatal transfusion with blood or blood products.

The SABTS recommend the employment of a bedside blood product filter to all blood or blood products irrespective of who donated the products. The purpose of the filter is to prevent debris and pathogens from entering the system of the neonate (PALL Medical, 2000b: clinical update).

Table 4.25 illustrates 67% of the professional nurses would use a bedside

blood product filter when transfusing a neonate with autologous blood or blood products, 25% indicated uncertainty while 8% indicated they would not use a filter. It means more than a third of the professional nurses working in neonatal intensive units knew it was vital to employ a bedside blood product filter when transfusing neonates with autologous blood or blood products. The 33% who indicated uncertainty or did not consider it as important obviously did not realise how dangerous the non-employment of these products could be to the neonate during transfusion therapy. Their lack of knowledge (33% is an unacceptably high percentage) regarding this issue is disturbing and having transfusion guidelines in neonatal units to assist them is therefore crucial.

Table 4.25: Bedside blood product filters for transfusion of autologous blood or blood products

Is it important to employ a bedside blood product filter when transfusing a neonate with blood or autologous blood products?	**N**	**%**
1. Yes	80	67%
2. No	10	8%
3. Unsure	30	25%
4. Missing data	0	0%

It is unsafe practice to re-use a bedside blood product filter 6 to 12 hours after its initial use since it may lead to channeling and unloading of particles previously filtered into the neonate's circulatory system. Unless otherwise indicated on the filter packet, most filters are to be used once on a single unit of blood or blood product and, if it must be re-used, it should be within 6 hours (PALL Medical, 2005: Filter selection guide). The manufacturer normally provides guidelines regarding the risks and safety aspects of the filter.

Sixty per cent of the professional nurses as indicated in Table 4.26 responded they would not re-use a filter, 15% responded that they would re-use one and 25% indicated they were unsure as to whether they would or would not re-use a filter. Since it is apparent that 40% of the professional nurses lacked

knowledge regarding the re-use of bedside blood product filters, an urgent need exists for guidelines to assist them in this regard.

Table 4.26: Safety of re-using bedside blood product filters

Is it safe to re-use a filter 6 to 12 hours after its initial use?	**n**	**%**
1. Yes	18	15%
2. No	72	60%
3. Unsure	30	25%
4. Missing data	0	0%

Although it is noted in the findings of Table 4.26 that, only if crucially necessary (meaning, there is no other bedside filter available within the hospital, the blood products are not leukodepleted and the neonates life depends on the transfusion procedure) a bedside blood product filter can be re-used only within 6 hours of its initial use, it is still unsafe to re-use a bedside blood product filter at random. It remains important, however, that professional nurses follow the instructions on the packages of the filter as stipulated by the manufacturer (PALL Medical, 2000a: clinical update).

In Table 4.27 it is illustrated that 76% of the professional nurses agreed that they would not re-use the filter - even if it is not blocked. This reveals that a satisfactory number of professional nurses had sufficient knowledge in this regard. The 17% who indicated uncertainty poses a problem in that it indicates too many professional nurses lack knowledge in this regard. When the 2% who failed to respond and the 5% who responded in the affirmative are added together, it increases the concern regarding the awareness and education of professional concerning the re-use of bedside blood product filters whether it is blocked or not.

Table 4.27: Re-use of a bedside blood product filter

Can one re-use a bedside blood product filter as often as one likes as long as the filter is not blocked?	n	%
1. Yes	6	5%
2. No	91	76%
3. Unsure	20	17%
4. Missing data	2	2%

As set out by the SABTS (SABTS, 2003:9), the required bedside blood product filter pore size is 170µm-240µm.

It is obvious from Table 4.28 that professional nurses working in neonatal intensive care units did not know the appropriate bedside blood product filter pore size: 85% indicated they were unsure of what the recommended filter pore size was, 4% indicated <40µm and 3% indicated it was between 50µm and 160µm. As only 8% provided the correct answer, it is apparent that most professional nurses had no knowledge regarding the filter pore size and what role it plays in preventing pathogens and debris from entering the circulatory system of the neonate.

Table 4.28: Required bedside blood product filter pore size

The required bedside blood product filter pore size as set out by the SABTS is:	N	%
1. <40µm	5	4%
2. 50-160µm	4	3%
3. 170-240µm	9	8%
4. Unsure	102	85%
5. Missing data	0	0%

As highlighted by the aforementioned information, the majority of professional nurses were not aware of the set transfusion requirement by SABTS. It is thus

vital for all neonatal intensive care units to have transfusion guidelines to aid professional nurses in these units.

Though it is assumed that there are various reasons why most neonatal intensive care units are reluctant to employ bedside blood product filters during neonatal transfusion, no clear ones are apparent. In most units or hospitals either the unit manager or the treating doctor is the one who decides whether a bedside filter is to be employed, and which one it should be.

As shown in Table 4.29, 58% of the professional nurses gave reasons other than costs or availability as to why most neonatal intensive care units are reluctant to employ bedside blood product filters during neonatal transfusion. The reasons included reducing the risks of exposing the neonate to infections due to manipulations of the line, or a lack of knowledge when ordering them. Some were unsure about the reasons: 39% indicated that it was due to costs, 1% reported it was due to the unavailability of filters and 2% did not answer the question.

Table 4.29: Common reasons for reluctance to employ bedside blood product filters

Most neonatal intensive care units are reluctant to employ bedside blood product filters during neonatal transfusion due to …	**N**	**%**
1. Costs	47	39%
2. Unavailability	1	1%
3. Other (Specify)	70	58%
4. Missing data	2	2%

It is clear that the professional nurses were not aware of the actual reason(s) why there seemed to be reluctance on the part of the neonatal intensive care units to employ bedside blood product filter during neonatal transfusion.

A bedside blood product filter has to be employed when transfusing the neonate with all types of blood or blood products, including if the blood or

blood products are leukodepleted. The purpose of employing a bedside blood product filter is to remove all debris and pathogens that may have formed during the preparation, storage or administration periods (PALL Medical, 2002: clinical update).

Table 4.30 indicates that 48% of the professional nurses reported they would employ a bedside blood product filter when transfusing a neonate with leukodepleted blood or blood products. Twenty-four per cent would not and 28% were unsure of whether a bedside blood product filter should or should not be employed. It is evident that a large number of professional nurses were not aware of when and why bedside blood product filters should be employed during neonatal transfusion.

Table 4.30: Bedside blood product filter with leukodepleted blood or blood products

Can one use a bedside blood product filter when transfusing a neonate with leukodepleted blood or blood products?	**n**	**%**
1. Yes	57	48%
2. No	29	24%
3. Unsure	34	28
4. Missing data	0	0%

Leukodepletion does not result in a hundred per cent removal of leukocytes found within blood or blood products used for neonatal transfusion. A leukocyte reducing filter is the appropriate filter for filtering red blood cells, the purpose being to remove residual leukocytes within the unit of blood to be used for transfusing the neonate (Cloherty, et al. 2003:286).

Some professional nurses responded to the question more than once, hence the total number of responses to this question was more than 120. Table 4.31 illustrates that 29% indicated red blood cells can be filtered through a depleting filter. Those who were unsure represented 28% and 43% responded that they red blood cells cannot be filtered through a depleting filter. It is

unacceptable that more than a quarter (29%) of the professional nurses were not aware whether or not red blood cells could be filtered through a leukocyte reducing bedside blood product filter.

Table 4.31: Red blood cells and leukocyte reducing bedside blood product filters

Can red blood cells be filtered through a leukocyte reducing bedside blood product filter?	**n**	**%**
1. Yes	41	29%
2. No	60	43%
3. Unsure	38	28%
4. Missing data	0	0%

A red cell filter cannot be used to filter platelets as it will lead to the platelets' destruction (PALL Medical, 1999a: clinical update).

As illustrated in Table 4.32, 27% of the professional nurses indicated they would filter platelets through a red cell filter, and 30% indicated that they would not. Those who were unsure constituted 43%. Considering this information, it is apparent that the majority of the professional nurses working in a neonatal intensive care unit had limited knowledge regarding bedside blood product filters and their employment to specific blood or blood products. By ensuring that transfusion guidelines are available in their units, their knowledge will not only be enhanced and increased, but risks posed to neonates will be reduced.

Table 4.32: Platelets and red cell filters

Can one filter platelets through a red cell filter?	n	%
1. Yes	22	27%
2. No	36	30%
3. Unsure	52	43%
4. Missing data	0	0%

Bedside blood filters are commonly packed in packs that seem similar from a distance; they also share a common shape which makes differentiation between them difficult. Prior to opening the pack, the professional nurse must verify that the one containing the correct filter for the blood or blood product is opened. This involves double checking the packages.

From Table 4.33 it is clear that 73% of the professional nurses found it difficult to differentiate between red blood cell filters and other bedside blood product filters. For 27% it was easy to make the distinction, 30% found it not easy and 43% indicated that they were not sure. Their ignorance should be addressed in further studies in which their limited knowledge regarding this issue should be investigated.

Table 4.33: Differentiating red blood cell filters from other bedside blood product filters

Is it easy to differentiate red blood cell filters from other bedside blood product filters?	n	%
1. Yes	32	27%
2. No	36	30%
3. Unsure	52	43%
4. Missing data	0	0%

There are no neonatal microaggregate filters available in the market, only adult ones' are and they require large volumes of blood to be primed up

therefore; most neonatal intensive care units employ leukodepleting filters at bedside to filter blood or blood products used for neonatal transfusion.

Table 4.34 shows that 1% did not provide an answer to the question, 10% thought some were available and 6% of the professional nurses indicated that there were none available. Eighty-three per cent were not sure if neonatal microaggregate filters were available in the market, making it apparent that the professional nurses did not have adequate knowledge regarding the availability of neonatal microaggregate filters. The findings in this table support those in Table 4.33 where it is indicated that 73% of the professional nurses were incapable of differentiating between red blood cell filters and other blood product filters.

Table 4.34: Availability of microaggregate filters

Are microaggregate filters available in the market for neonates?	**n**	**%**
1. Yes	12	10%
2. No	7	6%
3. Unsure	100	83%
4. Missing data	1	1%

Irradiation of blood or blood products donated by direct family members (the mother or father) will significantly reduce the risk of exposing the neonate to human leukocyte antigen incompatibility - which is a common transfusion reaction among first degree relatives. Irradiated blood or blood products may be used if there are concerns about the immunocompetence of the neonate - the use of a bedside blood product filter will substantially reduce the risk of exposing the neonate to lymphocytes and CMV (cytomegalovirus). (Cloherty, et al. 2000:466 - 467 & PALL Medical, 1998: clinical update).

Of the professional nurses, 43% acknowledged that a bedside blood product filter had to be employed when transfusing a neonate with irradiated blood or blood products (Table 4.35). According to 11% it was not necessary, 44% were not sure and 2% did not answer the question. A high percentage (57%)

had limited knowledge regarding indications of employing or not employing bedside blood product filters during neonatal transfusion with blood or blood products.

Table 4.35: Irradiated blood or blood products and bedside filtration

Is it necessary to filter irradiated blood or blood products?	**n**	**%**
1. Yes	51	43%
2. No	13	11%
3. Unsure	54	44%
4. Missing data	2	2%

The doctor or professional nurse responsible for transfusing the neonate is the one responsible for ensuring that the procedure is conducted safely. Therefore, it is this person's responsibility to decide if a bedside blood product filter should be employed during neonatal transfusion with blood or blood products.

Some of the professional nurses indicated two categories of health professionals, for example both professional nurses and unit managers, hence the total number of responses was more than 120. The results, illustrated in Table 4.36, shows 34% of the responses believed it should be the professional nurse performing the transfusion procedure, 31% thought it was the unit manager's responsibility and 19% indicated it must be the doctor. Sixteen per cent specified others: some regarded it as the responsibility of the blood bank, while others thought that, whoever makes the decision, he or she should follow the unit policy or protocol. However, due to the differences in the transfusion practices found in the various hospitals and units where this study was conducted, it is difficult to decide if the professional nurses had sufficient or insufficient knowledge as to who the responsible person should be.

Table 4.36: Person responsible for deciding on employment of a bedside blood product filter

Who should decide if a bedside blood product filter should be employed during neonatal transfusion?	n	%
1. Prescribing doctor	25	19%
2. Unit manager	41	31%
3. Nurse performing transfusion	45	34%
4. Other (Specify)	21	16%
5. Missing data	0	0%

4.3.3.4 Conclusive remarks on knowledge of bedside blood product filters

The analyses of Tables 4.17 to 4.36 indicate that most professional nurses had limited knowledge regarding the employment of bedside blood product filters during neonatal transfusion. The majority did not know the safest positioning for the filter. They were also not aware of the required pore size recommended by the SABTS to protect the neonate from pathogens that could collect or form in the blood or blood products during the preparation, storage or administration stages and which could enter the neonate's circulatory system. If the professional nurse is acquainted with the product(s) and the correct and safe employment thereof, she or he can contribute significantly toward protecting the neonate from exposure to transfusion related reactions or complications.

The professional nurses had insufficient knowledge regarding which bedside blood product filters are specific for which blood or blood products, especially where transfusing the neonate with leukodepleted, irradiated or autologous blood or blood products are concerned. Considering that many of them could have had limited exposure to blood or blood product filters, or that it was unavailable in their units, it is not surprising that most of them indicated that it was difficult to differentiate between bedside blood product filters, including microaggregate and leukodepleting filters.

Based on this analysis the researcher deduced that the lack of knowledge professional nurses had regarding the employment of bedside blood product filters during neonatal transfusion with blood or blood products, was instrumental in their inability to make clinical decisions in this regard. It is therefore crucial that transfusion guidelines be drafted to assist them.

4.3.4 Section C: Knowledge regarding legal aspects of neonatal transfusion

Knowledge of legal aspects regarding the transfusion procedure will assist the professional nurses to act within their scope of practice. At the same time, it will allow them to know what is legally expected of them with regard to transfusion of neonates with blood and blood products.

Tables 4.37 to 4.41 report on the knowledge professional nurses had regarding the legal aspects surrounding the employment of bedside blood product filters during neonatal transfusion with blood or blood products, and whether they were able to make clinical decisions in this regard.

4.3.4.1 Policies regarding neonatal transfusion

Urdang and Swallow (1983:1017) stipulate the importance for neonatal intensive care units to have protocols, policies or standing orders to serve as guidelines for professional nurses regarding all procedures that are to be performed on neonates while they are under their care.

According to Table 4.37, however, only 30% of the professional nurses indicated that there was such a protocol or policy available in their units. A further 30% indicated it was not available, and 39% were not sure whether any was available in their particular units. One per cent did not answer the question. Thirty per cent comprises a small percentage acknowledging the availability of either a protocol or policy regarding neonatal transfusion in their unit, while 30% is a high number to indicate the unavailability of it in the same units. Adding together the 30% who indicated there was no protocol or policy

available, the 39% who were unsure and the 1% who failed to respond, it is clear that 70% of the professional nurses had no access to protocols or policies to refer to.

Table 4.37: Availability of protocols or policies regarding neonatal transfusion

Is there any protocol or policy regarding neonatal transfusion procedure in your unit?	n	%
1. Yes	36	30%
2. No	36	30%
3. Unsure	47	39%
4. Missing data	1	1%

This is disturbing for three reasons: (i) it can indicate there was limited (or no) support available in the neonatal intensive care unit regarding neonatal transfusion, (ii) the professional nurses were just not aware of the availability of such support protocols or policies in their unit, or (iii) both the aforementioned reasons were applicable. The ramifications of this are worrying. When professional nurses have to transfuse a neonate with blood or blood products, it is the accepted norm that they are competent and knowledgeable to do it, and that guidelines are available in the unit to assist them if needed. However, the results of Table 4.37 suggest that the situation regarding the availability of protocols and policies in neonatal intensive care units regarding neonatal transfusion be reviewed.

All employees working in hospital units are expected to be aware of all protocols or policies that exist within their units. However, Table 4.38 shows 38% of the participants were not sure if all personnel in a unit had knowledge of the existence of a transfusion protocol or policy in their units. Thirty-two per cent did not answer the question and 23% indicated that the personnel in their units were not aware of the existence of such protocols or policies. Only 7% indicated they were aware of its existence. Because it is mostly unit managers who are expected to know of such protocols or policies in the units, it is not possible to establish with certainty whether employees are aware of the

available protocols or policies in their units. This may be the reason why the professional nurses found it problematic to answer this question.

Table 4.38: Personnel's awareness regarding neonatal transfusion protocols or policies

Are all personnel in your unit aware of the neonatal transfusion protocol or policy?	n	%
1. Yes	8	7%
2. No	27	23%
3. Unsure	45	38%
4. Missing data	40	32%

4.3.4.2 Informing parents regarding transfusion

Parents have to be informed of all procedures that are to be performed on their neonates; this includes neonatal transfusion procedure (Deacon & O'Neill, 1999:405). They must be instructed on the indications and complications thereof in order for them to make educated and informed decisions on behalf of their neonate. The parents are the ones ultimately responsible for the health of their neonate, provided that it is not to the detriment of the neonate (Deacon & O'Neill, 1999:748).

Table 4.39 shows 77% of the professional nurses indicated that parents should be informed, 19% thought they should not, 3% was not sure while 1% did not answer the question. This indicates that more professional nurses were informed regarding the rights of both the neonate and the parents, and that they realised these rights had to be respected at all times. The accumulative 23% who answered no, or who were unsure or did not respond to the question engender serious concerns; they may transfuse without informing the parents, and by doing so, violate the parents' rights.

Table 4.39: Informing parents regarding neonatal transfusion

Should parents be informed prior to transfusion of their neonate with blood or blood products?	n	%
1. Yes	92	77%
2. No	23	19%
3. Unsure	4	3%
4. Missing data	1	1%

The doctor responsible for treating the patient should inform the parents but, due to the nature of their practice, they are often unavailable. The professional nurse, who has a shared responsibility in this regard; is the one who is then left with the responsibility of informing the parents (SABTS, 2003: 4).

Professional nurses chose more than one person; hence the number of responses exceeded 120. According to Table 4.40, the majority (71%) highlighted that the treating doctor was the one responsible for informing the parents, 28% indicated the professional nurse and 1% the transfusionist from the transfusion services. Considering that 71% indicated the doctor and 28% the nurse, it suggests that the professional nurses had a clear indication concerning who should inform the parents.

Table 4.40: The person responsible for informing the neonate's parents

Who should inform the parents?	n	%
1. A doctor	108	71%
2. A transfusionist from the transfusion services	1	1%
3. A professional nurse	40	28%
4. Missing data	0	0%

4.3.4.3 Observing of neonates during transfusion

A doctor, and if not available the professional nurse who has a shared responsibility in this regard, is the one to transfuse and observe the neonate

during the transfusion procedure (SABTS, 2003:6). Table 4.41 indicates that the professional nurses responded to more than one question and therefore the number of participants was more than 120. According to 71%, the professional nurse should be the one who transfuses and observes the neonate during the transfusion procedure, 13% indicated that it should be the doctor and 16% indicated others such as an experienced enrolled nurse, a newly qualified enrolled nurse or a professional nurse trained in intensive care nursing. This confirms that the majority believed the correct person responsible for transfusing and observing the neonate, was the professional nurse.

Table 4.41: Person responsible for observing the neonate during transfusion

Who should transfuse and observe the neonate during the transfusion procedure?	**n**	**%**
1. A doctor	19	13%
2. A transfusionist from the transfusion services	0	0%
3. A professional nurse	103	71%
4. Other (Specify)	23	16%
5. Missing data	0	0%

4.3.4.4 Conclusive remarks on legal aspects

An analysis of Tables 4.37 to 4.41 showed that most professional nurses were, in the first instance, not aware of the existence of any transfusion protocol or policy in their units and, secondly, were unable to tell if all personnel working in their units were aware of such protocols or policies in the units. It is obvious that they could have been making clinical decisions based on their experience in neonatal nursing, instead of basing it on the protocol or policy of the unit. Some were aware that it is initially the responsibility of the doctor to inform the parents of pre-transfusion procedures, but the majority was of the opinion that it is the responsibility of the professional nurse. They seemed not to know that, only if the doctor is not available, it then becomes the responsibility of the professional nurse. It can thus be deduced that,

though the majority of professional nurses were in agreement that the parents had to be informed when a transfusion on their neonate was considered, very few were familiar with whose responsibility this was ultimately. The majority were also in doubt as to whether protocols or policies regarding this issue were available in their units. Their lack of knowledge in this regard influenced their competent decision making skills. Transfusion guidelines are vital to extend their knowledge and assist them in making clinical decisions in this regard.

Tables 4.1 to 4.41 are displayed on either pie graphs or bar graphs for easy understanding and interpretation. (See Annexure F for graphs).

4.4 CONCLUSION

By making use of tables, the researcher was able to determine and describe the knowledge professional nurses had regarding the employment of bedside blood product filters, especially microaggregate and leukodepleting filters, blood or blood products and the legal aspects concerning neonatal transfusion. Their ability to make clinical decisions in this regard was also illustrated. It became clear that most professional nurses had limited knowledge, rendering them incapable of making such decisions. Consequently, recommendation of transfusion guidelines to assist them in making informed, competent decisions with regard to the employment of bedside blood product filters during neonatal transfusion is considered to be of paramount importance.

Recommended guidelines for neonatal transfusion are described in the following chapter.

CHAPTER FIVE

RECOMMENDED GUIDELINES FOR NEONATAL TRANSFUSION

5.1 INTRODUCTION

The focus of Chapter 4 was to discuss the findings obtained through analysis of the questionnaires in order to determine and describe the ability of professional nurses to make clinical decisions regarding bedside blood product filters.

In this chapter the researcher recommends general transfusion guidelines as well as guidelines specifically pertaining to the employment of bedside blood products filters.

5.2 CLINICAL DECISION MAKING

Clinical decision making is a process which health care professionals (professional nurses in the case of this study) use to gather information, evaluate it and make a judgment that results in the provision of safe nursing care. It involves choosing an action after weighing the risks and benefits of the alternatives. Most clinical decisions are made under conditions of uncertainty. The degree of uncertainty decreases when available medical literature is relevant and evidence-based, but when the published medical literature is insufficient and/or not evidence-based the degree of uncertainty increases (White, Nativio, Kobert & Engberg, 2007:1).

Deacon and O'Neill (1999:744) note clinical decision making can also be viewed as a decision of science, in other words, considering problems and issues to reach a reasonable conclusion. Professional nurses in general, as health care professionals, rely on the science of planning, implementing and evaluating care for patients. The professional nurses are comfortable when they are able to assemble facts based on proven scientific data before

intervening in a patient issue. The principles apply when clinical decisions are made relating to the employment of bedside blood product filters.

Taking into consideration the insufficient information available concerning transfusion of blood or blood products to neonates via employing bedside blood product filters, as well as the analysis of the questionnaires, an essential need for transfusion guidelines emerged. In this regard, transfusion guidelines can significantly aid professional nurses in making clinical decisions regarding the employment of bedside blood product filters when faced with the responsibility of transfusing the neonate with blood or blood products.

5.3 PURPOSE OF THE RECOMMENDED GUIDELINES

The purpose of the recommended guidelines was to aid professional nurses to:

- identify and be knowledgeable regarding the blood or blood product prescribed,
- employ the bedside blood product filter specific to the type of blood or blood product prescribed,
- minimise the chances of neonates developing transfusion related reactions, and
- observe the neonate for any transfusion reactions and be able to respond promptly and accurately if a reaction occur.

Based on the above purpose, the general aspects pertaining to neonatal transfusion will be discussed in section 5.4.

5.4 GENERAL ASPECTS PERTAINING TO NEONATAL TRANSFUSION

The general aspects pertaining to neonatal transfusion include legal and ethical aspects of neonatal transfusion.

5.4.1 Legal aspects of neonatal transfusion

In South Africa, the transfusion of blood or blood products to all patients is regulated by various acts and regulations. It is vital for health care professionals not only to be knowledgeable regarding all legal aspects surrounding blood or blood products transfusion, but to consider and apply it accordingly. Failure to adhere to stipulated rules and regulations renders the procedure illegal and unethical. Professional nurses concerned with the transfusion of blood or blood products to neonates must therefore also be knowledgeable in this regard.

The acts and regulations that should be considered entails:

- National Health Act, no. 61 of 2003 (as amended by no. 869 of July 2004).
- Medical, Dental and supplementary Health Service Professions Amendment Act, no. 18 of 1995.
- Medicine and Related Substance Amendment Act, no. 59 of 2002 (as amended by no. 115 of 17 January 2003).
- Nursing Act, no.33 of 2005 (as amended by no. 492 of 26 May 2006).
- Acts and Omissions of Registered nurses, no. R 387 (of 1985) (as amended by no. R. 2490 of 26 October 1990.
- Scope of Practice for Registered Professional nurses no. R.2598 of 1978 (as amended no. R.260 of 15 February 1991).
- Human Tissue Act, No.65 of 1983 (as amended no.51 of 26 May 1989).
- Regulations Regarding Blood and Blood Products, no R.1935 of 1990**.**
- Principles of Batho Pele, Public Service Regulation of 1999 and 2001.
- The Bill of Rights, no. 23696 of 8 August 2002.
- Children's Act, no 38 of 2006 (as amended by no. 28944 of 19 June 2006).
- Policy and Procedure regarding intravenous infusion - hospital/unit specific.

- Policy and procedure regarding blood or blood products transfusion - hospital/specific.
- Doctor's prescription – hospital/unit specific.
- Parents or Legal Guardians' informed consent document - hospital/unit specific.

5.4.2 Ethical aspects of neonatal transfusion

The status of ethical issues in practice has become more prevalent in recent years due to various factors, including a heightened awareness of the patient's rights and financial constraints. Deacon and O'Neill (1999:744) maintain: "Ethical concerns about patient care and treatment have escalated with the years due to issues of quality care versus costs while at the same time science and technology forge ahead in the discovery of new avenues of treatment." In this study, ethical aspects involved the emotional commitment the professional nurses demonstrated towards the sick individual – the neonate – as well as the parents. This emotional care resulted in their willingness to act in the best interest of the individuals involved: the neonate who was oblivious to all his or her surroundings, and the parents who were emotionally as well as psychologically affected by the blood transfusion procedure.

Currently, concerns regarding transfusion related infections and reactions, particularly the HIV, CMV and Hepatitis A-B-C, compels medical health practitioners more than ever to involve and inform patients of the transfusion procedure and its related complications. In this study it meant providing the parents of the neonates with all the relevant information concerning the transfusion, thus endowing them with knowledge that allowed them to make an informed decision as to whether they would agree to a transfusion or not (Principles of Batho Pele of 2001; Bill of Rights 2002). This decision was ultimately the responsibility of the parents, but they had to be informed and educated about all aspects of the transfusion. They firstly had to be made aware that the need for a transfusion existed. Subsequently, the indications, advantages and disadvantages of transfusing blood or blood products as well

as those of employing a microaggregate or a leukodepleting filter during the procedure, had to be explained to them.

However, parents can experience this decision-making as a problematic issue because one has to realise the larger context within which it is embedded. To make a sound decision on behalf of their neonate's blood transfusion, parents can be influenced by several factors: cultural norms, religious beliefs and emotional distress**.** Even the routine of the unit/or hospital where the child is admitted, or the ability of the professional nurse responsible for their child at that time to convey relevant and accurate information can influence parents' decision making abilities (Deacon & O'Neill, 1999:744-745). Therefore, in a stressful situation such as having to decide for or against a blood transfusion for their neonate, parents are in dire need of guidance, support and understanding of knowledgeable and caring health care professionals. Though it is usually the goal of all involved to act in the best interest of the neonate, sensitive issues such as the religious or cultural beliefs of the parents can cause a dilemma when the well-being of the neonate is at stake. Based on their interpretation of scriptures in the Bible, the Jehovah's Witnesses, for example, refuse blood transfusion as they consider it a violation of God's laws (*http://en.wikipedia.org/wiki/Jehovah's_Witnesses#Ethics_and_morality*).
Thus, providing the best possible care for the neonate requires considerable commitment, mutual respect and understanding from the medical professionals as well as the parents.

Parents are required to sign a consent form after they have been informed by the relevant health care professional about the procedures involved in the transfusion of their neonate. Though it is usually required that a medical doctor informs parents regarding the procedure, a professional nurse often assumes the role since he or she spends more time with the parents and neonate, and is therefore in a more likely position to assist the parents to make a moral and informed decision regarding the transfusion procedure (Deacon & O'Neill, 1999:744-745 & 767-767; Cloherty, et al. 2003:247-248).

5.5 GENERAL GUIDELINES FOR THE TRANSFUSION OF BLOOD AND BLOOD PRODUCTS

The researcher recommends transfusion guidelines for neonatal blood or blood product transfusion based on the information obtained from the literature search conducted for this study, as well as from the findings after the data obtained from the questionnaires in this study had been analysed. Common concepts, themes and headings were identified for structuring the guidelines as well as the general contents that needed to be included.

For the purpose of easy understanding of the transfusion procedure as well as the employment of a bedside blood product filter, the general guidelines developed in this study for the transfusion of blood or blood products are discussed next. It will be followed by a discussion of specific blood products guidelines.

The general guidelines (precautions that need to be considered with each transfusion therapy that is whether whole blood or blood components are being transfused to the neonate) are regarded as a crucial foundation for guidelines to pre-transfusion consideration in terms of required equipment, administrative aspects, transfusion procedure, transfusion reactions and actions that need to be taken during transfusion reaction.

5.5.1 Pre-transfusion considerations

The professional nurse must take the following into consideration before commencing transfusion therapy on a neonate:

- Check the prescription chart of the neonate's medical documents to verify the doctor's prescription.
- Identify the neonate by using his or her identification bands on the arm or leg as well as the admission forms to ensure that it is the correct neonate for the prescription. Verify this with a witness: a medical doctor, another professional nurse or an enrolled nurse.
- Ensure that the parents have signed an informed consent form for the transfusion procedure.

- Check with the blood bank on the availability of the blood products, taking into account that they should not be older than five days because the serum potassium becomes substantially elevated after this time period.
- Supply the SABTS with the condition and age of the neonate so that suitable blood products can be prepared.
- Ensure that the blood ordering forms are correctly filled out and, where possible, verify with a witness and let them co-sign the form.
- Prepare the neonate for the extraction of a blood sample for cross-matching at the SABTS.
- Collect between 0.5ml - 1ml of blood as per unit protocol using a clotting micro-tube for the collected blood sample.
- Arrange for the collection of a blood specimen and order form to be taken to the blood bank.
- Assess the intravenous line insertion point. Establish whether it is inflamed or not and what intravenous fluid runs through it. If necessary, insert a new line pending the unit's protocol.
- Assess the neonate's' baseline vital data and record the findings on the neonate's' clinical records. Report abnormalities to the treating doctor.
- On delivery of the blood products, ensure that the cooler box used to transport the blood is sealed, and that the temperature inside is less than 4ºC. This will ensure that the cold chain mechanism is maintained throughout the delivery period: from the blood bank, during the transportation thereof till its arrival in the ward.
- If they are not going to be administered immediately, place the blood products in the designated refrigerator at a temperature of less than 4ºC or keep them in the cooler box.
- Once they have to be administered, remove the blood products from the cooler box or refrigerator and leave them exposed to warm up to room temperature.

5.5.2 Required equipment for transfusion

Specific blood or blood products require specific equipment to ensure that the transfusion procedure is safe and cost effective. The following must be kept at hand before commencing the procedure:

- Blood or blood product specific administration set.
- Bedside blood product specific filter.
- Administration pump or syringe drive.
- Pump or syringe drive holder such as a drip stand.
- Blood prescription, intake and output and vital data recording charts.
- Cardio-pulmonary monitor or pulse oximeter.
- Thermometer.
- Blood warmer.
- Emergency equipment for resuscitation of the neonate.
- Intravenous line.
- 0.9% normal saline (isotonic solution).
- Administration set for clear intravenous fluid.
- Sterile pack with two to three hand towels, a gown, cap, mask and two lotion cloths.

5.5.3 Administrative aspects

5.5.3.1 Neonate

Check whether the blood unit is correct for the recipient and confirm the following with a witness such as a medical doctor, professional nurse or an enrolled nurse.

- The neonate’s full name and surname, the name of the hospital, the number and name of the ward, the neonate’s hospital number, and the treating doctor. This must correspond with the information on the neonate’s hospital records, his or her stickers and the identification band on his or her arm or leg.

5.5.3.2 Blood or blood products

- The ABO group of the donor and the Rhesus factor (RH) and titer.
- Check if compatibility testing has been done.
- The ABO group of the donor and the Rhesus factor (RH) and titer.
- The blood transfusion serial number should correspond with the one on the label attached to the blood unit.
- Check the expiry date.
- Check if the blood product is irradiated, in other words, whether it has been donated by a family member or close relative. If it has not been irradiated, send it for irradiation to prevent the neonate from developing graft versus host disease.
- Carefully inspect and assess the container to ensure the following:
    - The hermetic seal is intact.
    - There is no evidence of the bag being pierced or damaged, in other words make sure the bag is not leaking anywhere.
    - Assess the contents of the bag for foreign particles such as clots or debris.
- Verify the following:
    - That the certificate of safety is attached to the unit of blood and has been tested for the prevention of blood related infections, for example HIV and hepatitis, as prescribed by the standards of practice recommended by the SABTS.
    - That the blood product has been leukodepleted. Assess to what level the product has been leukodepleted.
- Check the expiry date:
    - The expiry date of packed red blood cells is determined by the composition of the anticoagulant solution into which it has been collected and is as follows: for citrate phosphate dextrose plus adenine (CPD-A1) the expiry date is 35 days post collection.
    - The label on each container of blood products gives the date of venesection and the type and volume of anticoagulant solution into which it was added. This makes it easy for the transfusionist to

verify the blood product expiry date given on the label prior to transfusing the neonate.

- Record keeping:
  - Record the above information on the document provided by the neonate's hospital records.
- Together with the witness check and sign the following:
  - The blood bag.
  - The card label that is attached to the blood bag.
  - The neonate's file and blood transfusion recording chart.

Once all the necessary equipment has been collected and the blood or blood product have been fully checked according to the administration procedures as set out above, choose a suitable bedside blood product filter as discussed in the specific product transfusion guidelines in section 5.6 of this chapter.

5.5.4 Transfusion procedure

- Reconfirm the neonate's identification to ensure that the correct neonate is transfused with the correct blood or blood product.
- Ensure that the neonate is attached to a cardio-pulmonary or saturation monitor to be able to pick up any slight change in the neonate's condition
- Reassess the neonate's vital signs. Obtain the blood pressure, pulse rate, respiratory rate, peripheral saturation and temperature as this will form the baseline vital data to compare to should any transfusion related reactions be suspected.
- Record the findings on the neonate's hospital record.
- Wash your hands, put on a plastic apron, create a sterile working area and open all packs onto it to minimise the chances of contamination of the blood or blood product pre-transfusion.
- Re-wash your hands (aseptically), wear sterile gloves and arrange your equipment on the sterile area, that is, the administration set and the filter.
- Connect the blood unit to the administration set and filter.
- If using a blood product filter that is attached to the bag, attach the syringe to the administration set as per the unit's protocol. Spike the blood unit

with the filter and allow running according to the directions stipulated by the producing company.

- Reassess the intravenous line insertion point. Establish that it is not inflamed and also what intravenous fluid runs through it to avoid using an infused line or using a line that was used for a fluid that is incompatible with blood or blood products, for example, dextrose water.
- Ensure that the blood product filter is suitable for the prescribed blood products by checking with a witness present. (Refer to the specific blood or blood product transfusion guideline – section 5.6).
- Run the blood products through the filter to expel air and adhere to the aseptic technique throughout the whole procedure.
- Avoid squeezing the blood products through the bedside blood product filter if it appears blocked and re-check the filter with a witness present. Where necessary, change the filter and keep the blocked filter for the producing company. The producing company will replace the filter plus collect the blocked filter for investigation.
- Re-inspect the insertion site and potency of the intravenous line.
- Attach the administration set to the fluid pump or syringe driver.
- Ensure that the blood or blood product is at room temperature, namely between 21ºC and 24ºC. Cold blood will expose the neonate to hypothermia while warm blood will lead to the activation of bacteria which will release its toxins into the blood products causing the neonate to develop infection.
- Connect the blood administration set with the filter and to the neonate when certain they are well primed up, in other words, when there is no air in the administration set and the site is not inflamed. Air within the administration set will expose the neonate to pulmonary embolus and sudden death. An infused line will lead to blood products collecting into the tissue, which can cause tissue necrosis of the surrounding area to the point where the neonate can loose a limb.
- Reassess the doctor’s prescription to ensure the correct rate is dialed on the infusion pump or syringe driver.
- Commence the transfusion and observe the neonate’s vital signs after 15 minutes post commencement of transfusion.

- Remain with the neonate for the next 10-15 minutes in order to observe him or her closely and to ensure that he or she does not react. Discontinue the procedure immediately should he or she present with any signs of transfusion reaction.
- Continue monitoring the neonate's vital data, namely the heart rate, respiratory rate, saturation, respiratory efforts, body temperature and skin colour at least every half an hour.
- If the neonate shows no signs of reaction, record the vital data every 30 minutes.
- Assess the intravenous line insertion point and surrounding area for every hour until the procedure is complete.
- Unless prescribed otherwise by the treating medical doctor, the transfusion procedure should be within the prescribed duration, which is not more than 4 hours or less than 2 hours.
- Avoid adding or administering medications or drugs with blood or blood products simultaneously, otherwise a reaction may be triggered. Similar precautions must be exercised with dextrose solutions since they may result in haemolysis or aggregation of red cells within the transfusion set.
- Once the transfusion procedure is over, discontinue the administration set used for transfusing blood or blood products and connect the separate administration set used for clear solution. Avoid flushing the blood or blood product administration set with a filter attached to it, as this will lead to unloading and channeling of previously filtered particles into the neonate's circulatory system.
- Ensure that the solution used post transfusion is compatible with blood or blood products, in other words, it is isotonic. If not, clear the mini extension set near the intravenous cannula on the neonate's' insertion point with normal saline (isotonic solution). This will help to prevent agglutination of cells left in the extension set.
- Adequate and relevant record keeping is vital as is reporting of all abnormalities.
- Record the time of commencing the transfusion procedure as well as the time it was completed.

- Continue to observe the neonate for transfusion reaction up to 10 days post transfusion as neonates have the tendency of presenting with latent transfusion reaction.
- Ensure that the donor blood or blood products, the bag that contained the blood or blood products, the bedside blood product filter and the administration set are kept safe in the fridge for a minimum of 7-10 days post transfusion. These will have to be sent to the SABTS for investigation should the neonate present with acute, delayed or latent transfusion reactions or die unexpectedly.

5.5.5 Types of transfusion reactions

Transfusion reactions can either be acute or delayed. Clinical signs and symptoms with which the neonate can present are indicated in the text boxes below. The possible acute reactions are outlined first and are followed by the possible delayed or latent reactions.

Acute reactions

These are the reactions that the neonate may display within 24 hours of transfusion and may include the following clinical signs and symptoms:

- An increase in body temperature of more than 1ºC during or shortly after transfusion. In the absence of any other pyretic situation, it is commonly known as ‘febrile non-haemolytic reaction’.
- Urticaria – the sudden development of pruritic skin eruptions (heat bumps) of varying shapes and sizes with well defined erythematous margins and pale centres; or an unexplained rash of any kind.
- Signs of respiratory distress namely, wheezing, tachypnea accompanied by increased difficulty in breathing as evidenced by the use of accessory muscles and accompanied by dessaturations, apnea and cyanosis
- Severe dypsnea, pulmonary and/or laryngeal edema, bronchospasm and/or laryngospasm. The neonate may also display signs of restlessness.
- Sudden developments of tachycardia, bradycardia or arrhythmias, hypotension and distended neck veins.
- Diaphoresis or cold and clammy skin and profound shock.
- Haematuria, oliguria and/or anuria.
- Hypoglycemia

Figure 5.1: Acute reactions

Delayed or latent reactions

These are reactions that the neonate can display 2-10 days after transfusion, and may include the following signs and symptoms:

- Bleeding disorders characterised by bleeding into tissues, especially underneath the skin or mucus membranes**,** producing ecchymoses or petechiae and low platelets counts. This may be due to graft versus host disease whereby the neonate's antigens do not recognise the donor's antigens, especially if the blood products are not irradiated.
- Prolonged clotting times as evidenced by bleeding at the intravenous insertion point or at the heal site when pricked to obtain a blood sample to perform a dextrose stick test.
- A very sick neonate with signs of septicaemia, acidosis, hypoxia or hypothermia with thrombocytopenia.
- Unexplained lethargy, irritability and persistent PALLor.
- Respiratory distress that lasts over 2-3 weeks and abdominal distension accompanied by hepatomegaly on abdominal palpitation**.**

Figure 5.2: Delayed or latent reactions

5.5.6 Action to be taken during transfusion reactions

The transfusionist, that is the professional nurse or medical doctor, should closely monitor the neonate for any signs and symptoms indicating transfusion reaction(s). If any suspected signs or symptoms occur, the following steps must be taken:

- Stop the transfusion procedure immediately.
- Change the blood administration set to an ordinary clear solution administration set. Do not simply turn the blood products off and replace it with an isotonic solution on the same line, because the products left in the blood product administration set may cause a major transfusion reaction.
- Keep the vein open with normal saline or isotonic solution. Initiate cardiopulmonary resuscitation as indicated and notify the treating medical doctor.
- Closely monitor the neonate's vital data and general condition continuously.

- Obtain a urine specimen when possible and continue monitoring his or her urine output.
- All the remaining donor blood, together with the used blood administration set, should be sent back to the SABTS for investigation. Collect the neonate's blood specimen in a clotting tube and send it to the SABTS as they are the licensees who supplied the blood or blood products.

5.5.7 Record keeping

- Record keeping remains vital and has to include the following:
    - The type of reaction the neonate presented with, for example, urticaria or signs of respiratory problems.
    - The time of reaction, in other words how soon post commencing transfusion did the neonate show signs of reaction, for example, within 15 minutes of commencing transfusion.
    - The vital signs of the neonate, namely heart and respiratory rates, blood pressure, body temperature, saturations, breathing patterns, skin colour and general condition of the skin.
    - The neurological response which includes the pitch of the sound made by the neonate when crying.
    - The neonate's general condition.
    - The action taken including the treating doctor's response.

5.6 SPECIFIC BLOOD OR BLOOD PRODUCT TRANSFUSION GUIDELINES

With the abovementioned general transfusion guidelines as a background, the following paragraphs describe the guidelines for the specific blood products commonly used in neonatal intensive care units, namely packed red blood cells, whole blood, platelets and fresh frozen plasma.

Neonates have small volumes of fluid (blood) circulating throughout their bodies and are therefore sensitive to large volumes of fluid replacement therapy whenever such therapy is required. The aforementioned specific

blood products are commonly used to treat neonatal fluid related requirement conditions.

Packed red blood cells are most commonly used to treat anaemia in neonates. Though this condition can have other causes, it is most often caused by multiple phlebotomies due to treatment the neonate receives while in intensive care. The next option used is whole blood which is commonly used for exchange transfusion due to hyperbilirubinaemia. Platelets, for septicaemia, and fresh frozen plasma, for hypovolaemia, are less frequently used.

Professional nurses have to familiarise themselves with these blood products and their clinical indications. Most importantly, however, they must be able to make a clinical decision regarding what equipment to employ when it is expected of them to transfuse the neonate with one of the mentioned blood products. Accordingly, it was important to develop the following specific blood products transfusion guidelines.

5.6.1 Packed red blood cells and whole blood

5.6.1.1 Indications for using packed red blood cells

- Neonatal anaemia where minimal fluid administration is required without increasing the blood volume.
- For improving oxygen carrying capacity and tissue oxygenation.
- For treating active bleeding and haemolytic diseases.

5.6.1.2 Indications for using whole blood

- For exchange transfusion – usually with neonates that present with hyperbilirubinaemia that exceeds 400mg/dl to prevent them from developing kernicterus – disseminated intravascular coagulation, hypovolaemia and autoimmune thrombocytopaenia.

5.6.1.3 Required equipment for packed red blood cells and whole blood

- Red cells or whole blood filter. The color for both product filters is often red and is a smaller size than the platelets and fresh frozen plasma filters.
- A standard blood administration set or Y-type blood administration set with an inbuilt filter**.** If one of these two types of bedside blood product filters are available, follow unit protocol or manufacturers guidelines for the appropriate employment thereof.
- If the administration set does not have an inbuilt filter, have a micro-aggreegate or leukodepleting filter at hand.
- For equipment, refer to the general guidelines for required equipment for transfusion (see 5.4.2).

5.6.1.4 Administrative aspects of packed red blood cells and whole blood

- The volume to be transfused is usually given in increments of 10-20mls per kilogram to prevent over hydrating the neonate.
- Check the expiry date to ensure that the blood is as fresh as possible: not older than six days because potassium levels within the red blood cells rise as the blood ages which might put the neonate at risk of developing hyperkalaemia.
- Ensure that the blood products were kept in a refrigerator or a transporting cooler box at a temperature of below 4ºC. Only remove the blood products from the fridge or cooler box when they are to be used to maintain the cold chain.
- The blood products should not be pre-warmed (as warm blood will lead to the activation of bacteria which will release its toxins into the blood products causing the neonate to develop infection) and should be kept at room temperature between 21ºC and 24ºC. Cold blood may cause hypothermia or even the sudden death of the neonate.
- Only warm up the blood products if large volumes are to be transfused to the neonate within a short space of time, for example, for exchange transfusion. The use of a blood warmer with automatic temperature control

or an in-built thermometer that will constantly measure the blood product temperature during exchange transfusion may be suitable. This is the safest and most preferred way of warming up the blood or blood products.

- Immersing the blood or blood products in hot water may result in uneven warming of the products, which may damage cells and cause denaturation of the blood products. Do not pre-warm the blood product by using a microwave, hot water or even a human body. Pre-warming via hot water or a microwave may lead to overheating of the blood or blood products which, in turn, may lead to extensive heamolysis resulting in severe transfusion reaction and possible death of the neonate.
- Establish whether or not the blood products are leukodepleted and, if they are leukodepleted, determine what the level of leukodepletion is.
- If the blood products are leukodepleted, a microaggregate filter must be employed. If they are not, employing a bedside leukodepleting filter will be appropriate. The former is capable of trapping pathogens and debris that may be found within the blood products such as plastic from the bag or administration set, while the latter will assist in removing the donor leukocytes, pathogens and microscopic air from the administration set.
- Co-check with a witness whether the chosen bedside filter is suitable for the prescribed blood products at hand. This is done by reading the cover of the bedside blood product filter to establish if it is a microaggregate or a leukodepleting filter.
- It is vitally important to thoroughly check the suitability of the filters. They are often colour coded, therefore the colour must be checked to ensure that the right filter is employed: red = red cells, blue = fresh frozen plasma and green = platelets. They can also be differentiated by size: small = red cells, medium = platelets, while large = fresh frozen plasma.
- The pore size of the filter will also help to verify if the filter at hand is a microaggregate or a leukodepleting filter.
- Both filters will be more effective if they are distally attached to the transfusion administration set rather than proximally, while not employing a bedside blood product filter places the neonate at great risk of developing transfusion related complications.

- If using the Y-typed administration set with an in-built filter, ensure that the chamber is half filled with blood products. This will prevent red cell destruction as they drop from the bag into the chamber.
- Evaluate and assess the competency indicator of the filter. This means establishing how many units of blood or blood products are meant to be filtered through the bedside blood product filter. Is the filter meant to filter only one unit of blood or blood product at a time or more? For example single red cell unit filter.
- Connect the administration set to the bedside blood filter if it is not built-in on the administration set.
- Avoid re-using a filter after 12 hours of filtering blood products through it. Re-using will lead to blood cells destruction and a waste of blood products since the filter will be blocked.
- The re-use of a blood product filter, even if it is not blocked, over and over again is not allowed. The filter must only be re-used as directed by the manufacturer, for example, filter for one or two units of red cells only.

See general guidelines (section 5.5) for additional information regarding the transfusion of blood or blood products.

5.6.2 Platelets

5.6.2.1 Indications for platelets

Platelets are often indicated for the treatment of bleeding disorders or to control bleeding episodes, for example, bleeding from the venepuncture site.

5.6.2.2 Required equipment

- Platelets.
- Platelets specific administration set.
- Platelets filter - often packed in a green pack or is of medium in size.
- If the filter is attached to the administration set, its chamber is single and is usually smaller than the red cell filter.

- Assess whether the filter is for a mega bag or a standard bag.
- Administration pump or syringe drive.
- Pump or syringe drive holder such as a drip stand.
- Blood prescription, intake and output and vital data recording charts.
- Cardio-pulmonary monitor or pulse oximeter.
- Emergency equipment for resuscitation.
- Intravenous line.
- 0.9% normal saline (isotonic solution).
- Administration set for clear intravenous fluid.
- Sterile pack with two to three hand towels, a gown, cap, mask and two lotion cloths.

5.6.2.3 Administrative aspects for platelets

5.6.2.3.1 Neonate

Check whether the platelets are correct for the recipient and confirm the following with a witness such as a medical doctor, professional nurse or an enrolled nurse.

- The neonate's full name and surname, the name of the hospital, the number and name of the ward, the neonate's hospital number, and the treating doctor. This must correspond with the information on the neonate's hospital records, his or her stickers and the identification band on his or her arm or leg.
- Ensure that they are kept at room temperature - between 21ºC and 24ºC.
- Check the expiry date.
- Avoid shaking them; this will lead to their destruction.
- Ensure that they are transfused within 6 hours of reaching the unit.
- The required volume is normally prescribed by the treating doctor, but in case of emergency the recommended volume is 0.2mls of platelets per kilogram and that should increase the neonates' platelets count by 75,000 to 100,000/mm^3.

5.6.2.3.2 Platelets products

- Check the ABO group, Rhesus factor (RH) and titer of the donor.
- Check the expiry date.
- Check if the platelets are irradiated, in other words, whether it has been donated by a family member or close relative. If it has not been irradiated, send it for irradiation to prevent the neonate from developing graft versus host disease.
- Carefully inspect and assess the container to ensure the following:
    - The hermetic seal is intact.
    - There is no evidence of the bag being pierced or damaged, in other words make sure the bag is not leaking anywhere.
    - Assess the contents of the bag for foreign particles such as clots or debris.
- Verify the following:
    - That the certificate of safety is attached to the unit of platelets and has been tested for the prevention of blood related infections, for example HIV and Hepatitis A-B-C as prescribed by the standards of practice recommended by the SABTS.
- Record keeping:
    - Record the above information on the document provided by the neonate's hospital records.
- Together with the witness check and sign the following:
    - The blood bag.
    - The card label that is attached to the blood bag.
    - The neonate's file and blood transfusion recording chart.

Once all the necessary equipment has been collected and the platelets have been fully checked according to the administration procedures as set out above, choose a suitable bedside blood product filter as discussed in paragraph 5.5.

5.6.2.3 Transfusion procedure of platelets

- Check with a witness to ensure that the platelets filter is employed since employing the wrong filter, for example, a red blood cell filter, may result in the destruction of the platelets.
- Avoid using a 170µm filter as it will reduce the amount of platelets to be transfused; it will destroy the majority of platelets.
- Administer the platelets over a period of between 15-30 minutes. Longer transfusion times may negate the effects, particularly in an actively bleeding neonate.
- Closely monitor the neonate for signs of fluid overload.
- Avoid warming up the platelets as this will destroy them.
- Once exposed to room temperature they cannot be cooled. Therefore, put them back in the freezer for later use.
- Refer to general transfusion guidelines for additional information (refer to 5.5).

5.6.3 Fresh frozen plasma

5.6.3.1 Indications for fresh frozen plasma

Fresh frozen plasma is often used to correct hypotension or hypovolemia.

5.6.3.2 Required equipment

- Normal clear fluid administration set.
- Fresh frozen plasma specific filter (often blue in colour or the biggest in size).
- Fresh frozen plasma.
- If the filter is attached to the administration set, its chamber is single and is usually bigger than the red cell and platelets filter.
- Assess if the filter is for filtering one or two units of fresh frozen plasma.
- Administration pump or syringe drive.
- Pump or syringe drive holder such as a drip stand.

- Blood prescription, intake and output and vital data recording charts.
- Cardio-pulmonary monitor or pulse oximeter.
- Emergency equipment for resuscitation.
- Intravenous line.
- 0.9% normal saline (isotonic solution).
- Administration set for clear intravenous fluid.
- Sterile pack with two to three hand towels, a gown, cap, mask and two lotion cloths.

5.6.3.3 Administrative aspects of fresh frozen plasma

5.6.3.3.1 Neonate

Check whether the fresh frozen plasma is correct for the recipient, in other words whether it can be used for the neonate, and confirm the following with a witness such as a medical doctor, professional nurse or an enrolled nurse.

- The neonate's full name and surname, the name of the hospital, the number and name of the ward, the neonate's hospital number, and the treating doctor. This must correspond with the information on the neonate's hospital records, his or her stickers and the identification band on his or her arm or leg.
- Ensure that they are at room temperature (between 21ºC and 24ºC) pre-transfusing them to neonate.
- Check the expiry date.

5.6.3.3.2 Fresh frozen plasma products

- Ensure that the fresh frozen plasma is frozen**;** do not use if found defrosted in the freezer.
- Ensure that the freezer's temperature was constantly below 4ºC.
- Check expiry date.
- Use warm water to defrost if it is required urgently, otherwise leave it to defrost at room temperature (21ºC-24ºC).

- Check and co-check with a witness to ensure that the filter to be employed is definitely fresh frozen plasma (FFP) as the FFP filter tends to look similar to a red cells or whole blood filter.
- Indicated volume is normally 10-20mls per kilogram.
- Assess the volume (in ml) or the number of fresh frozen plasma units to be filtered through the filter as indicated by the manufacturer – that is, its clinical indication.
- The ABO group of the donor and the Rhesus factor (RH) and titer.
- Check the expiry date.
- Carefully inspect and assess the container to ensure the following:
    - The hermetic seal is intact.
    - There is no evidence of the bag being pierced or damaged, in other words make sure the bag is not leaking anywhere.
    - Assess the contents of the bag for foreign particles such as clots or debris.
- Verify the following:
    - That the certificate of safety is attached to the unit of fresh frozen plasma and has been tested for the prevention of blood related infections, for example HIV and Hepatitis A-B-C, as prescribed by the standards of practice recommended by the SABTS.
- Record keeping:
    - Record the above information on the document provided by the neonate's hospital records.
- Together with the witness check and sign the following:
    - The blood bag.
    - The card label that is attached to the blood bag.
    - The neonate's file and blood transfusion recording chart.

Once all the necessary equipment has been collected and the fresh frozen plasma has been fully checked according to the administration procedures as set out above, choose a suitable bedside filter as discussed previously.

5.6.3.4 Transfusion procedure for fresh frozen plasma

- Once defrosted, assess the contents for the presence of any deposits.
- Ensure that the neonate is attached to a cardio-pulmonary monitor since fresh frozen plasma has the potential of precipitating pulmonary edema amongst neonates, especially those whose cardio-pulmonary functioning is compromised or those with tissue edema.
- Transfuse as prescribed, usually within 15-30 minutes.
- Check vital signs within 15 minutes of transfusion to exclude any reactions.
- The defrosted fresh frozen plasma can be re-used within 6 hours, thereafter it must be kept in the freezer for 24 hours in case the neonate presents with signs of reaction.
- Ensure that a fresh frozen filter is employed during transfusion of the fresh frozen plasma to neonates. Failure to do so may expose neonates to cytomegalovirus (CMV), HIV and Hepatitis A-B-C - these viruses are not only confined to white cells, but can also be found in fresh plasma.

5.7 CONCLUSION

The guidelines for neonatal transfusion were designed as a tool to assist the neonatal intensive care professional nurse in making a clinical decision regarding the employment of a bedside blood product filter for neonatal transfusion.

In order for the neonatal intensive care professional nurse to be able to choose a suitable bedside blood product filter for a specific blood product, the following were discussed in this chapter: general guidelines to the transfusion of blood products, the required equipment for transfusion, the administrative aspects, transfusion procedure and actions to be taken during transfusion reaction(s). Guidelines for transfusing the neonate with specific blood products were also drafted as an addition to the general guidelines.

The researcher attempted to assist the neonatal intensive care professional nurse in making competent and safe clinical decision regarding which bedside blood product filter is suitable for which blood product.

The next chapter outlines the conclusions drawn by the researcher, as well as the recommendations made based on the findings of this study.

CHAPTER SIX

CONCLUSIONS AND RECOMMENDATIONS

6.1 INTRODUCTION

The previous chapters provided an overview of the study, a literature review, discussion of the research methodology and the findings of the two respective objectives. In this chapter conclusions are drawn and further recommendations are made.

Transfusion of blood or blood products to neonates is a common procedure in neonatal intensive care units, but it is a procedure associated with detrimental risks if the decision making of the professional nurses is incorrect. These decisions are also related to the employment of bedside blood product filters, and in particular microaggregate and leukodepleting blood filters. The need was therefore identified to determine and describe the ability of professional nurses to make clinical decisions regarding the employment of bedside blood product filters during neonatal transfusion.

6.2 OBJECTIVE 1

During the first objective of the study the researcher aspired to determine and describe the ability of professional nurses to make clinical decisions regarding the employment of bedside blood product filters during neonatal transfusion.

A self-administered questionnaire was developed and validated by experts in neonatal intensive care nursing. It was distributed to 10 hospitals in both the government and private sectors to be completed by 200 professional, of which 120 responses could be included of nurses who worked in neonatal intensive care units in Gauteng, South Africa. Permission to include the neonatal intensive care facilities in the designated institutions in the study was obtained from their respective managements.

It was discovered that most professional nurses had limited knowledge and were therefore not capable of making clinical decision as regards the employment of bedside blood product filters.

6.3 OBJECTIVE 2

Based on the outcome of the questionnaire and literature review, general guidelines were recommended for blood transfusion as well as specific guidelines for the use of bedside blood product filters for designated blood or blood products.

These guidelines were then distributed to the same experts in neonatal intensive care nursing who analysed the questionnaire as well as pharmaceutical companies' representatives who are experts on indications of employing bedside blood product filters on neonates during their transfusion with blood or blood product for review and recommendations.

In this chapter conclusions are drawn from the findings while further recommendations and suggestions are made that could follow as a result of this study.

6.4 CONCLUSIONS

The findings of the research (refer to Chapters 4 and 5) can be concluded in the following sections.

6.4.1 Knowledge of blood and blood products

It was clear from the analysis of the questionnaire that professional nurses working in neonatal intensive care units had some knowledge regarding blood or blood products commonly used to transfuse neonates, but they did not know at what stage the neonate will present with latent transfusion reactions, nor what the common transfusion related reactions could be.

The study also highlighted that professional nurses were not familiar with the process of leukodepletion and were therefore not conversant with the levels to which blood products should be reduced in order for them to prevent neonates from developing transfusion related reactions.

6.4.2 Knowledge of bedside blood product filters

A large number of professional nurses who participated in this study lacked knowledge regarding the different available types of bedside blood product filters on the market. They also reported that it was difficult to differentiate between these filters at a glance. They were unfamiliar with the recommended filter pore size as laid down by the SABTS. As a result of their lack of knowledge regarding bedside blood product filters (see Annexure E) some professional nurses incorrectly stated that they would filter platelets via a red blood cell filter. This procedure will result in the platelets being destroyed and the neonate transfused with plasma only, indicating poor nursing care.

6.4.3 Knowledge of legal aspects

The majority of the professional nurses were familiar with the legal aspects of neonatal transfusion with blood or blood products. A large number indicated that the professional nurse should be the one to inform the parents of the transfusion procedure. According to the SABTS (2003:4), however, the doctor is the one to inform the parents and have them sign consent to transfuse their neonate; only if the doctor is not available, the professional nurse must take over the role of informing the parents of all procedures involved with their neonate's transfusion. The professional nurse will only be capable and competent in this regard if he or she has enough knowledge.

Based on the collected and analysed data recommendations for neonatal transfusion guidelines, with the inclusion of the employment of blood product specific bedside filters, was vital.

6.4.4 Recommended guidelines for neonatal transfusion

Neonatal transfusion guidelines were drafted in order to assist professional nurses in making clinical decisions when faced with the responsibility of transfusing of blood or blood products to neonates. The guidelines are divided into three sections, namely general transfusion guidelines, specific blood or blood products guidelines and equipment to be employed with each type of blood or blood product.

6.4.4.1 General neonatal transfusion guidelines

The general neonatal transfusion guidelines addressed the general precautions to be considered before transfusing the neonate with blood or blood products. This included pre-transfusion considerations, administrative aspects, types of transfusion reactions, actions to be taken during transfusion reaction and record keeping.

General guidelines were addressed first so as to make the specific guidelines simpler and clearer for the professional nurses to understand. It is recommended that they familiarise themselves with the general guidelines first before they become acquainted with the specific guidelines.

6.4.4.2 Specific blood or blood product transfusion guidelines

Specific guidelines addressed the diverse handling and pre-transfusion management of the various blood or blood products, for example packed red blood cells, platelets and fresh frozen plasma, as well as the different reactions specific to each blood product the neonate may present with. Professional nurses who understand and are conversant with the differences in the handling and pre-transfusion management of specific blood or blood products, as well as the different reactions to each specific blood and blood product the neonate may present with over and above the reactions named under general guidelines, will be able to render quality service.

The abovementioned blood products are not the only blood products available in the market used to transfuse neonates, but they are the ones commonly used and professional nurses require more guidelines in this regard.

The other aspect of vital importance is the equipment to be employed with each blood product, especially microaggregate and leukodepleting filters, as no one single bedside blood product filter can be used for all of them. Packed red blood cell filters, for example, cannot be used to filter platelets since it will destroy the platelets - and vice versa - exposing the neonate to severe transfusion reactions. It was therefore of vital importance that general guidelines as well as specific ones were drafted.

Based on the above guidelines, the researcher made recommendations to ensure that professional nurses and others involved with neonatal transfusion procedure benefit and find support in this regard.

6.5 RECOMMENDATIONS

Based on the research findings recommendations are made relating to the clinical practice (section 6.5.1), training institutions (section 6.5.2), SABTS (section 6.5.3), pharmaceutical companies (section 6.5.4) and future research (section 6.5.5).

Neonatal transfusion guidelines should be available in all neonatal units as a protocol or policy to assist neonatal intensive care professional nurses in making clinical decisions regarding the employment of bedside blood product filters during neonatal transfusion with blood or blood products. The guidelines should be made available in both the government and private sector.

All stakeholders, that is the SABTS, pharmaceutical companies, hospitals and all nursing training institutions (universities and colleges) should carry the responsibility for educating professional nurses regarding the importance and indications of employing bedside blood product filters during the transfusion of the neonate with blood or blood products.

The aim of the guidelines is to assist professional nurses to make clinical decisions regarding the employment of bedside blood product filters when faced with transfusing the neonate with blood or blood products.

6.5.1 Recommendations for clinical practice

It is recommended that more formal as well as informal in-service education and training be provided to professional nurses regarding the processing of blood products - especially the leukodepletion process by the SABTS - and the employment of bedside blood product filters during neonatal transfusion. Pharmaceutical companies that manufacture these bedside blood products need to be part of this education and training because their input is considered to be valuable and necessary.

Newly qualified professional nurses should be provided with informative brochures or personal pocket booklets to assist them when having to make clinical decisions regarding the employment of bedside blood product filters during neonatal transfusion. Since theses nurses often lack information or knowledge regarding blood or blood products and bedside blood product filters during neonatal transfusion, they rely on experienced professional nurses or better qualified persons for assistance – *better qualified* referring here to persons or professional nurses who have had longer and more experience in this domain.

Frequent awareness campaigns regarding transfusion of blood or blood products and including how blood or blood products are processed by the SABTS for transfusion to neonates, should be held by the various stakeholders in both government and private hospitals. This will enhance the professional nurses' knowledge in this regard and simplify their choices in selecting the relevant bedside blood product filters to employ with specific blood or blood products

Through frequent awareness campaigns from pharmaceutical companies professional nurses will become familiar with bedside blood product filters; subsequently they will be able to make clinical decisions regarding the

employment of the correct bedside blood product filter during neonatal transfusion.

The importance of employing bedside blood product filters during neonatal transfusion should be included in hospital quality improvement programmes, since bedside blood product filters are indicated essential for reducing risks associated with transfusion related reactions and complications in neonates. Such programmes will improve the quality of care rendered by professional nurses and possibly shorten the neonates' stay in the intensive care unit. Following the correct procedure from the outset, forms the core of the total quality care patients expect from all involved in their care.

By including the importance of employing bedside blood product filters during neonatal transfusion in the hospital quality improvement programmes, the hospitals will also be increasing more awareness regarding the importance of employing specific filters during transfusion of neonates with blood or blood products. It will also increase the professional nurse's knowledge regarding various blood or blood products and the processing thereof.

6.5.2 Recommendations for training institutions

The researcher recommends that the training institutions include the transfusion guidelines in their basic curriculum so as to educate professional nurses regarding the importance of - and indications for - the employment of bedside blood product filters during neonatal transfusion with blood or blood products.

By giving the student nurses' adequate education regarding this issue at university or college levels, the training institutions will be laying a foundation for them to understand the indications and to know where they should be positioned on the administration set. In this way they could learn the pore sizes and be able to differentiate between them. Equipped with the necessary confidence and knowledge, the professional will be able to make clinical decisions when required and necessary.

Regular workshops and/or seminars should be held by all stakeholders, especially pharmaceutical companies and the SABTS at training institution level – that is college or university level. The object of these workshops/seminars should be to concentrate on discussing issues surrounding blood product transfusion to the neonate, with special attention paid to bedside blood products filtration and the importance of the correct application thereof.

6.5.3 Recommendations for the SABTS

The SABTS should utilise the transfusion guidelines to conduct in-service training within the hospitals they serve, and their teaching institutions should also employ the guidelines as a tool to educate their students on the neonatal transfusion procedure, and the indications of employing bedside blood products filters during neonatal transfusion.

The SABTS should further collaborate with hospitals, training institutions and pharmaceutical companies in order to stay aware of what is being practiced in these institutions, and to establish whether it is in line with what is recommended as far as transfusion therapy is concerned.

6.5.4 Recommendations for pharmaceutical companies

Pharmaceutical companies should provide government and private hospitals, the SABTS and training institutions with researched articles or journals regarding the implications and indications of employing bedside blood product filters during neonatal transfusion. In this way, all stakeholders involved will have up-to-date knowledge and information available at all times.

The pharmaceutical companies should also periodically hold consultations with the SABTS to ensure that they both impart the same information to the hospitals and training sectors.

6.5.5 Recommendations for research

More research regarding the employment of bedside blood filters, especially microaggregate and leukodepleting filters during neonatal blood transfusion is recommended as supportive studies to this one, to establish the extent of knowledge deficit professional nurses have regarding the employment of bedside blood product filters during neonatal transfusion.

It is recommended that further studies be conducted as to why most institutions are reluctant to employ bedside blood product filters during neonatal transfusion, and to also establish the reasons why these filters are unavailable at most hospitals.

Pertaining to the occurrence of transfusion related reactions in neonates, it is essential that more studies be conducted in this domain. In further studies the following could be investigated: how many neonates present with transfusion reactions? Which are the most common transfusion reactions presenting in neonates? Reports of the outcomes of such studies must be given to the Haemovigilance Society for the exposure of neonatal transfusion reactions to all relevant stakeholders.

The researcher recommends that more studies be conducted regarding additional methods to be implemented to enhance professional nurses' knowledge regarding the employment of bedside blood product filters during neonatal transfusion with blood or blood products.

Studies regarding steps to be taken to implement common neonatal transfusion guidelines at the various health sectors (government or private sectors).

Further studies could be conducted to establish the effect of transfusion guidelines on the professional nurses' ability to make clinical decisions during neonatal transfusion with blood or blood products.

Other studies to ascertain the professional nurse's ability to differentiate between bedside blood product filters could also be conducted.

6.6 LIMITATIONS OF THE STUDY

The following limitations were identified:

- The study was conducted in Gauteng only which in itself is a limitation since the results obtained from the study cannot be generalised to other South African regions or even regions outside of South Africa.

- Some participants might have misunderstood or misinterpreted the questions while completing the questionnaires.

6.7 SUMMARY

The aim of the study was to determine and describe the ability of professional nurses working in neonatal intensive care units to make clinical decisions regarding the employment of bedside blood product filters during neonatal transfusion with blood or blood products, using a descriptive survey.

The findings of the study revealed that professional nurses had a limited ability in this regard. It was therefore imperative that transfusion guidelines be recommended in order to assist professional nurses in making clinical decisions when faced with the responsibility of transfusing neonates with blood or blood products. Through the availability of transfusion guidelines professional nurses will be assisted to make clinical decisions regarding the employment of bedside blood product filters during neonatal transfusion. Neonates will be less exposed to developing transfusion related reactions or complications, and their parents will save on expenses.

The researcher firmly believes that it is the right of the neonate to receive quality care from all those responsible for its well-being. It is the researcher's dream to see all those entrusted with the neonate's care being capable,

confident and determined to make clinical decisions on behalf of the neonate – irrespective of where they practice.

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UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

ANNEXURE A

AUTHORISATION TO PARTICIPATE IN THE STUDY

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

AUTHORISATION TO PARTAKE IN A RESEARCH PROJECT

TITLE: CLINICAL-DECISION MAKING OF NEONATAL INTENSIVE CARE PROFESSIONAL NURSES REGARDING THE EMPLOYMENT OF BEDSIDE BLOOD PRODUCT FILTERS DURING NEONATAL BLOOD TRANSFUSION

TH E HEAD OF DEPARTMENT AND/ OR HOSPITAL:

……..

……...

DATE: ……

1. INTRODUCTION

We\ I understand that our/my unit personnel has been selected and asked to partake in a research study.

The aim of this study is to evaluate the knowledge of neonatal nurse practitioners regarding the use of blood filters during transfusion of blood products to neonates.

By so doing more will be learned about importance of using such filters during neonatal transfusion, the risks involved if not utilising them, and which filters are to be used when which blood product is to be transfused.

Some deficits around the knowledge of neonatal nurse practitioners regarding available types of blood filters within the market, their indications, advantages or disadvantages may be identified and strategies and plans can be formulated to uplift such knowledge deficits.

2. EXPLANATION OF THE PROCEDURE

The study involves answering some questions with regard to the experience of neonatal nurses regarding the utilisation of blood product filters, different types that exists in the market, who should be responsible in deciding if blood\ blood products filters should be used and if they are to be used what are their impact on patient care if not what is the impact on patient care as well.

i. The researcher will leave the questionnaires in the unit, as well as an empty envelope to put in the answered questionnaires, for easy access.

ii. The researcher will then after a week come and pick up the answered questionnaires from the unit.

iii. If you wish to take the questionnaire with and answer it from home, you are more than welcome to do so as long as you will bring it back filled to the unit and put it in the envelop of answered questionnaires.

3. RISKS AND DISCOMFORT INVOVED

There will be no risks involved, as it is only knowledge that is being evaluated patients are not touched and no treatment is being given to either the nurses or patients.

4. POSSIBLE BENEFITS OF THIS STUDY

More of these studies should be instituted on the neonatal intensive care units as this will help broaden their knowledge and uplift the image and field of nursing.

5. We/ I understand that even if our/ my unit personnel is not willing to take part, they will still receive questionnaires and be we/I will be informed of the outcomes of the study.

6. We/ I may withdraw from the Study at any time.

7. INFORMATION

If there may arise any questions concerning the study, you may contact:

The researcher's study leader:

MS. C. Maree.

Mobile number: 083 286 6696.

8. CONFIDENTIALITY

❒ All information and records obtained whilst on this study will be regarded as confidential.

❒ Results will be published in such a manner that the participants and the participating hospital units remain unidentifiable.

9. CONSENT TO PARTICIPATE IN THIS STUDY

i. We/I have read the above information in a language that we or I understand before signing this consent form.

ii. The content and meaning of this information have been explained to us.

iii. We/I have been given the opportunity to ask Questions and we/I are satisfied that they have been answered satisfactorily.

iv. We/ I understand that if We / I do not participate it will not alter my/ our management in any way.

v. We/ I hereby Volunteer that my personnel take part in this study

vi. We/ I have received a copy of this informed consent document.

Person obtaining the Informed Consent:

……

(Please print your name on provided line above)

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

ANNEXURE B

ETHICAL COMMITTEE LETTER

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

University of Pretoria

31 Bophelo Road
HW Snyman South Building
Level 2, Room 2.33

P O Box 667
Pretoria
0001

Faculty of Health Sciences Research Ethics Committee
University of Pretoria
Tel: 012 354 1677 **Fax to E-Mail:** 086 6516047
E-Mail: deepeka.behari@up.ac.za
Date: 3/10/2007

Number : **S215/2005**

Title : Knowledge of neonatal intensive care nurses about the use of micro-aggregate filters during transfusion of blood/blood products to neonates

Investigator : T Morudu, Dept of Nursing Science, University of Pretoria (SUPERVISOR: C MAREE)

Sponsor : None

Study Degree : **M.Cur (Advanced Neonatal Nursing Science)**

This Student Protocol has been considered by the Faculty of Health Sciences Research Ethics Committee, University of Pretoria on 2/10/2007 and found to be acceptable.

Advocate AG Nienaber	(female)BA(Hons) (Wits); LLB; LLM (UP); Dipl.Datametrics (UNISA)
Prof V.O.L. Karusseit	MBChB; MFGP (SA); M.Med (Chir); FCS (SA): Surgeon
Prof M Kruger	(female) MB.ChB.(Pret); Mmed.Paed.(Pret); PhDd. (Leuven)
Dr N K Likibi	MB.BCh.; Med.Adviser (Gauteng Dept.of Health)
Snr Sr J. Phatoli	(female) BCur (Et.Al) Senior Nursing-Sister
Dr L Schoeman	(female) Bpharm, BA Hons (Psy), PhD
Prof J.R. Snyman	MBChB, M.Pharm.Med: MD: Pharmacologist
Dr R Sommers	(female) MBChB; M.Med (Int); MPhar.Med;
Prof C W van Staden	MBChB; Mmed (Psych); MD; FTCL; UPLM; Dept of Psychiatry
Prof TJP Swart	BChD, MSc (Odont), MChD (Oral Path) Senior Specialist; Oral Pathology
Dr AP van der Walt	BChD, DGA (Pret) Director: Clinical Services, Pretoria Academic Hospital

Student Ethics Sub-Committee

Prof R S K Apatu	MBChB(Legon); PhD(Cambridge)
Dr A M Bergh	(female) BA (*cum laude*), Rand Afrikaans University BA (Hons) (Linguistics), University of Stellenbosch Secondary Education Diploma (*cum laude*), University of Stellenbosch BA (Hons) (German) (*cum laude*), University of South Africa (Unisa) BEd (Curriculum Research and Non-formal Education) (*cum laude*), University of Pretoria PhD (Curriculum Studies), University of Pretoria
Dr S I Cronje	DD (UP) – Old Testament Theology
Dr M M Geyser	(female) BSc; MBChB; BSc HONS (Pharm); Dip PEC; MpraxMed; FCEM(SA) and MSc (Clinical Epidemiology)
Advocate T Landman	(female) LLB (UP); (Member of the Pretoria Society of Advocates); BA Hons Psychology (UNISA); BCur (RAU)
Mrs N Briers	(female) BSc(Stell), BSc (Hons) (Pret),MSc (Pret) DHETP (Pret)
Dr S A S Olorunju	B.Sc Hons; M.Sc; Ph.D
Dr L Schoeman	(female) BPharm, BA Hons (Psy), PhD
Dr R Sommers	SECRETARIAT (female) MBChB; M.Med (Int); MPharMed

DR R SOMMERS; MBChB; M.Med (Int); MPhar.Med.
SECRETARIAT of the Faculty of Health Sciences
Research Ethics Committee
University of Pretoria

DR L SCHOEMAN; Bpharm, BA Hons (Psy), PhD
CHAIRPERSON of the Faculty of Health Sciences Research
Students Ethics Committee – University of Pretoria

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ANNEXURE C

INFORMATION LEAFLET

INFORMATION LEAFLET /DOCUMENT

TITLE: CLINICAL DECISION MAKING OF NEONATAL INTENSIVE CARE PROFESSIONAL NURSES REGARDING THE EMPLOYMENT OF MICROAGGREGRATE AND LEUKODEPLETING FILTERS DURING NEONATAL BLOOD TRANSFUSION.

1. INTRODUCTION

You are invited to volunteer for a research study, this information leaflet / document is to assist you decide if you want participate or not. Before you agree to take part in this study, you should fully understand what is involved. If you have any questions, which are not well explained in this leaflet, do not hesitate to ask the researcher. You should not agree to take part unless you are completely satisfied about the questions asked on the questionnaires.

2. THE PURPOSE OF THE STUDY

There is several blood and blood products filters that exist in the market, each with its own advantages and disadvantages and the unit you are working in may be using one of those, e.g. Microaggregate filters with a pure size of 50-170 µm (uni-microns) and the leukodepleting filters with a pore size of 40µm. This can be inline with the administration set or be attached to a receiving bag.

The South African Blood Transfusion Services (SABTS) and International Blood Transfusion Services stipulates that a blood filter has to be in-situ during neonatal transfusion, while the nurse practitioner, who operates in a neonatal ICU is at a dilemma of deciding whether to employ or not employ a bedside blood filter when transfusing neonates. If so, which filter is the most suitable and on which blood products should they employ it?

The purpose of this study is to establish if neonatal intensive care professional nurses are capable making sound clinical decisions regarding the employment of bedside blood product filter during neonatal transfusion with blood products.

Through your participation, their capabilities can be measured / established and guidelines will be drafted to assist them in making such a decision based on scientific information and well defined insight.

Relevant education and training regarding the employment of bedside blood product filters will be organized so that appropriate and suitable filters will be employed during neonatal transfusion.

3. ETHICAL APPROVAL

The proposal of the study was submitted to the faculty of health science research ethics committee, at the University of Pretoria and was approved by same. The study has been structured in accordance with the declaration of Helsinki (last update: October 2000), which deals with recommendations guiding nurses in clinical research involving human subjects. A copy of which may be obtained from the researcher should you wish to review it.

4. PARTICIPANT RIGHTS

Your participation in the study is entirely voluntary and you can refuse to participate, without stating a reason. Your refusal will not deny you the opportunity to scrutinize the questionnaire. The Researcher retains the right not to consider your input / questionnaire if it is considered to be in the best interest of the outcome of the study, yours or the unit / employer as well as the company that manufactured the blood products and / or blood product filter.

5. RISKS INVOLVED

There are no risks involved since only knowledge is tested and participants are not known, i.e. no names, will be used to identify respondents but numbers will be assigned to questionnaires and respondents will randomly select this questionnaires. Medical trial with risks of reactions is not the issue neither humans nor human tissue will be involved.

6. ANONYMITY AND CONFIDENTIALITY

All information obtained during the study is confidential. Data that may be reported in scientific journals will not include any information which identifies you, your unit / employer or the company that manufactures the blood products bedside filter in this study. You / your unit / employer and the company that produces the blood products bedside filters will be informed of any findings that are of importance to the improvement of your knowledge, regarding the use of bedside blood product filters.

Disclosing the result of the outcome of the questionnaires from your unit to the third party, including the ones mentioned above will be through your permission and it will be in written form. The only exception to this rule will be cases in which a law exists that compel us to report units' \ individuals that are a danger to the care of neonates. In this, you will be informed of our intent to disclose such information to the authorized state agency.

7. INFORMED CONSENT

I hereby confirm that I have been informed by the researcher, professional nurse L.J Morudu (Tinie) about the nature, conduct and benefits of her study, i.e. establishing the knowledge of neonatal intensive care nurses about the employment of bedside blood product filters during transfusion of blood products to neonates.

I have also received, read the above information (information leaflet and informed consent) regarding the study. I may, at any stage, without prejudice withdraw my questionnaire and consent from the study. I have had sufficient opportunity to ask questions and (of my own freewill) declared myself prepared to participate in the study. I am aware that the results of the study will be anonymously processed into a trial report.

PLEASE PRINT WHEN WRITING THE FOLLOWING INFORMATION:

Participant's name: _____ Date:_____

Participant's signature: _____

Witness's name: _____ Date:_____

Witness's signature: _____

ANNEXURE D

FINDINGS OF THE STUDY

QUESTIONNAIRE: KNOWLEDGE OF NEONATAL INTENSIVE CARE NURSES ABOUT THE USE OF FILTERS DURING TRANSFUSION OF BLOOD/BLOOD PRODUCTS TO NEONATES

INDICATE YOUR ANSWERS BY TICKING THE APPROPRIATE BLOCK/S
NB: It is important to answer ALL the questions.

For office use only

RESPONDENT QUESTIONNAIRE NUMBER: v1 [ ][ ][ ] 1-3

SECTION A: DEMOGRAPHIC DATA

1. Please indicate the sector/s you are working in.

1. Private		v2	4
2. Government		v3	5

2. Please indicate your highest qualification.

1. Neonatal ICU experience		v4	6
2. Diploma in neonatal intensive care		v5	7
3. Degree in neonatal intensive care		v6	8
4. Other (Specify) ……..		v7	9

3. How many years of experience do you have working in a neonatal intensive care unit (neonatal ICU)?

1. < 2 years		v8	10
2. 2 to 5 years		v9	11
3. 6 to 10 years		v10	12
4. > 10 years		v11	13

SECTION B: KNOWLEDGE SECTION

B1: BLOOD FILTERS:

4. For how many years have you been using blood filters during transfusions in a neonatal ICU?

1. < 2 years		v12	14
2. 2 to 5 years		v13	15
3. 6 to 10 years		v14	16
4. > 10 years		v15	17

5. Did you receive any form of training or education regarding the use of blood filters in a neonatal ICU?

1. Yes		v16		18
2. No		v17		19

If your answer to question 5 is "Yes", please fill in question 6-8 and if "No", Skip them and continue with the rest of the questions.

6. If 'Yes', when did you last receive training or education regarding the use of blood filters in a neonatal ICU?

1. < 6 months ago		v18		20
2. 6 to 12 months ago		v19		21
3. 13 to 24 months ago		v20		22
4. > 24 months ago		v21		23

7. From whom did you receive training or education regarding the use of blood filters in a neonatal ICU?

1. A colleague, *e.g.* a unit manager		v22		24
2. A doctor		v23		25
3. A medical representative		v24		26
4. Other (Specify) ……..		v25		27

8. In which format was the training or education given?

1. In the form of:				
2. In-service training		v26		28
3. Seminar		v27		29
4. Symposium		v28		30
5. Other (Specify) ……..		v29		31

9. Different types of blood filter are marketed, and each type has advantages and disadvantages. Which of the following types of filter meet the criteria set by national and international blood transfusion services?

A filter (part of a transfusion set) that is:				
1. In-line, proximally				
2. In-line, distally		v30		32
3. Not in-line, but attached to a bag				

10. To your knowledge, which practice puts the neonate at the greatest risk of developing complications associated with blood transfusion?

Using a filter that is:				
1. In-line, proximally				
2. In-line, distally		v31		33

3. Not in-line, but attached to a bag	
4. Not using a filter at all	

11. Which one of the following practices is the most cost effective and the least time consuming?

Using a device:	
1. With a filter: In-line, proximally	
2. With a filter: In-line, distally	
3. With a filter: Not in-line, but attached to a bag	
4. Without a filter	

v32 [ ] 34

12. Which filter may lead to unloading and channelling of previously filtered particles if used over and over again or if left in contact with blood/blood products for prolonged periods of time?

A filter that is:	
1. In-line, proximally	
2. In-line, distally	
3. Not in-line, but attached to a bag	

v33 [ ] 35

13. Which filter should you use when transfusing leukodepleted blood/ blood products to a neonate?

1. A leukodepleting blood filter	
2. A micro-aggregate blood filter	
3. An adult blood filter	
4. None at all	

v34 [ ] 36

14. Would you say it is important to use a filter when transfusing autologous blood/blood products to a neonate?

1. Yes	
2. No	
3. Unsure	

v35 [ ] 37

15. Would you agree that it is safe to re-use a blood filter six to twelve hours after its initial use?

1. Yes	
2. No	
3. Unsure	

v36 [ ] 38

16. Is it true that one can re-use a blood filter as often as one likes as long as it is not blocked?

1. Yes	

2. No		v37		39
3. Unsure				

17. The pore size of a blood filter is vital for effective filtering of pathogens and debris. The required pore size, as set out by the South African Blood Bank Services, is……. µm (micrometre)?

1. < 40um				
2. 50- 170um		v38		40
3. 180- 240um				
4. unsure				

SECTION B2: BLOOD PRODUCTS:

18. Did you receive any form of education and training regarding neonatal blood or blood products transfusion?

1. Yes		v39		41
2. No		v40		42

If your answer is Yes, please continue to answer question 19-21 and if no skip them, answer the rest.

19. If, `Yes`: when last did you receive education and training regarding neonatal blood/ blood products transfusion?

1. < 6months ago		v41		43
2. 6 to 12 months ago		v42		44
3. 13 to 24 months ago		v43		45
4. > 24 months ago		v44		46

20. From whom did you receive education and training regarding neonatal blood /blood products transfusion?

1. A colleague			v45		47
2. A Doctor			v46		48
3. A medical representative			v47		49
4. Other, specify……..		v48			50

21. In which format was the education and training given?

In the form of: .

1. In-service training& education			v49		51
2. Serminar			v50		52
3. Symposium			v51		53
4. Other, specify……..		v52			54

22. Which blo od or blood products do you commonly use?

1. Platelets			v53	55
2. Fresh frozen plasma			v54	56
3. Packed red blood cells			v55	57
4. Whole blood			v56	58
5. Other, specify……		v57		59

23. Based on your experience, is this blood product always leukodepleted?

1. Yes			
2. No		v58	60
3. unsure			

24. If, `Yes`, are you familiar with the level to which it is normally reduced?

1. Yes			
2. No		v59	61
3. unsure			

25. If, `Yes`, how did you acquire this information?

1. Inservice education and training			v60	62
2. Serminar			v61	63
3 Symposium			v62	64
4. Other, specify		v63		65

26. Based on your experience, is it a regular practice to check and verify to which level is this product leucodepleted ?

1. Yes			
2. No		v64	66
3. unsure			

27. If you were to transfuse a neonate with two units of bloob/ blood products which are from different donors, how often will you monitor the recipient`s vital data

1. 1/4 hourly			
2. 1/4-1/2 hourly		v65	67
3. 1/2- hourly			
4. When necessary			

28. Based on your knowledge and experience, how soon can a neonate present with signs of reaction to transfusion?

1. During transfusion			
2. Within 24 hours post transfusion			
3. 3 to 7 days post transfusion		v66	68
4. 7 to 10 days post transfusion			
5. unsure			

29 When do Neonates present with Late Transfusion reactions?

1. During transfusion			
2. Within 24 hours post transfusion		v67	69
3. 3 to 7 days post transfusion			
4. 7 to 10 days post transfusion			

SECTION C: LEGAL ASPECTS

30. According to your knowledge is there any protocol or policy regarding donor/ recipient testing in your unit?

1. Yes			
2. No		v68	70
3. unsure			

31. If, `Yes`, is all personnel in your unit aware of it?

1. Yes			
2. No		v69	71
3. unsure			

32. Based on your knowledge or experience, should parents be informed prior to transfusing their neonate?

1. Yes			
2. No		v70	72
3. unsure			

33. If, `Yes`, who should inform them?

1. A Doctor		v71	73
2. A Transfusionist from blood transfusion services		v72	74
3. A Professional Nurse		v73	75

34. According to you who should transfuse and observe the neonate during transfusion?

1. A doctor			v74	76
2. A Transfusionist from blood transfusion services?		v61	v75	77
3. A professional nurse			v76	78
4. Other, specify……..		v77		79

35. Based on your knowledge or experience, why is most of neonatal intensive care units, reluctant to employ blood or blood products filters during neonatal transfusion?

1. Specify……	v78		80

36. To your knowledge, is it appropriate to use a filter when transfusing a neonate with a leucodepleted blood or blood product?

1. Yes			
2. No			
3. Unsure			
		v79	81

37. Can one filter red blood cells through a leukocyte reducing blood filter?

1. Yes			
2. No			
3. Unsure			
		v80	82

38. Can one filter platelets through a red blood cell filter?

1. Yes			
2. No			
3. unsure			
		v81	83

39. Based on your experience, is it easy to differentiate between a red blood cell filter and other blood filters?

1. Yes			
2. No			
3. Unsure			
		82	84

40. Are there any neonatal micro-aggregate filters available in the market?

1. * Yes			
2. * No			
3. * Unsure			
		83	85

41. Which transfusion reaction do neonates commonly present with?

1. Pneumonia			
2. Biologic response reactions			
3. Respiratory distress syndrome		v84	86
4. Metabolic acidosis			
5. Other (Specify) ……			

42. Is it necessary to use a blood filter when irradiated blood/blood products is/are transfused to a neonate?

1. Yes		v85		87
2. No				
3. Unsure				

43. In your experience, who should be responsible for deciding whether a filter should be used during transfusion of blood/blood products to a neonate?

1. Prescribing doctor		v86		88
2. Unit manager		v87		89
3. Nurse performing transfusion		v88		90
4. Other (Specify) ……		v89		91

:OR YOUR PARTICIPATION!

ANNEXURE E

QUESTIONNAIRE

QUESTIONNAIRE: KNOWLEDGE OF NEONATAL INTENSIVE CARE NURSE
USE OF FILTERS DURING TRANSFUSION OF BLOOD/BLOOD PRODUCTS

INDICATE YOUR ANSWERS BY TICKING THE APPROPRIATE BLOCK/S
NB: It is important to answer ALL the questions.

For offi

RESPONDENT QUESTIONNAIRE NUMBER: v1 2

SECTION A: DEMOGRAPHIC DATA

1. Please indicate **the sector/s** you are working in.

1. Private	
2. Government	

2. Please indicate your **highest** qualification.

1. Neonatal ICU experience	
2. Diploma in neonatal intensive care	
3. Degree in neonatal intensive care	
4. Other (Specify) ……..	

v7

3. How many years of experience do you have working in a neonatal intensive care unit (neonatal ICU)?

1. < 2 years	
2. 2 to 5 years	
3. 6 to 10 years	
4. > 10 years	

SECTION B: KNOWLEDGE SECTION

B1: BLOOD FILTERS:

4. For how many years have you been using blood filters during transfusions in a neonatal ICU?

1. < 2 years	
2. 2 to 5 years	
3. 6 to 10 years	
4. > 10 years	

5. Did you receive any form of training or education regarding the use of blood filters in a neonatal ICU?

1. Yes	
2. No	

If your answer to Question **5** is "**Yes**", please answer questions **6-8** and if "**No**" skip them and continue with the rest of the questions.

6. If "**Yes**" when did you last receive training or education regarding the use of blood filters in a neonatal ICU?

1. < 6 months ago	
2. 6 to 12 months ago	
3. 13 to 24 months ago	
4. > 24 months ago	

7. If "**Yes**" from whom did you receive training or education regarding the use of blood filters in a neonatal ICU?

1. A colleague, *e.g.* a unit manager	
2. A doctor	
3. A medical representative	
4. Other (Specify) ……	

v25

8. If "**Yes**" in which format/s was the training or education given?

1. In the form of:	
2. In-service training	
3. Seminar	
4. Symposium	
5. Other (Specify) ……	

v29

9. Different types of blood filter are marketed, and each type has advantages and disadvantages. Which of the following types of filter meet the criteria set by national and international blood transfusion services?

A filter (part of a transfusion set) that is:	
1. In-line, proximally	
2. In-line, distally	
3. Not in-line, but attached to a bag	

10. To your knowledge, which practice puts the neonate at the **greatest** risk of developing complications associated with blood transfusion?

Using a filter that is:	
1. In-line, proximally	
2. In-line, distally	

3. Not in-line, but attached to a bag	
4. Not using a filter at all	

11. Which one of the following practices is the **most** cost effective and the least time consuming?

Using a device:	
1. With a filter: In-line, proximally	
2. With a filter: In-line, distally	
3. With a filter: Not in-line, but attached to a bag	
4. Without a filter	

12. Which filter may lead to unloading and channelling of previously filtered particles if used over and over again or if left in contact with blood/blood products for prolonged periods of time?

A filter that is:	
1. In-line, proximally	
2. In-line, distally	
3. Not in-line, but attached to a bag	

13. Which filter should you use when transfusing leukodepleted blood/ blood products to a neonate?

1. A leukodepleting blood filter	
2. A micro-aggregate blood filter	
3. An adult blood filter	
4. None at all	

14. Would you say it is important to use a filter when transfusing autologous blood/blood products to a neonate?

1. Yes	
2. No	
3. Unsure	

15. Would you agree that it is safe to re-use a blood filter six to twelve hours after its initial use?

1. Yes	
2. No	
3. Unsure	

16. Is it true that one can re-use a blood filter as often as one likes as long as it is not blocked?

1. Yes	

2. No	
3. Unsure	

17. The pore size of a blood filter is vital for effective filtering of pathogens and debris. The required pore size, as set out by the South African Blood Bank Services, is……. µm (micrometre)?

1. < 40um	
2. 50- 170um	
3. 180- 240um	
4. Unsure	

SECTION B2: BLOOD PRODUCTS:

18. Did you receive any form of education and training regarding neonatal blood or blood products transfusion?

1. Yes	
2. No	

If your answer to Question **18** is "**Yes**", please answer questions **19-21** and if "**No**" skip them and continue with the rest of the questions.

19. If "**Yes**" when last did you receive education and training regarding neonatal blood/ blood products transfusion?

1. < 6months ago	
2. 6 to 12 months ago	
3. 13 to 24 months ago	
4. > 24 months ago	

20. If "**Yes**" from whom did you receive education and training regarding neonatal blood /blood products transfusion?

1. A colleague	
2. A Doctor	
3. A medical representative	
4. Other, specify……..	v48

21. If "**Yes**" in which format/s was the education and training given?

In the form of: .

1. In-service training& education	
2. Serminar	
3. Symposium	
4. Other, specify……..	v52

22. Which blood or blood products do you commonly use?

1. Platelets	
2. Fresh frozen plasma	
3. Packed red blood cells	
4. Whole blood	
5. Other, specify……	v57

23. Based on your experience, is this blood product always leukodepleted?

1. Yes	
2. No	
3. Unsure	

24. If "**Yes**" are you familiar with the level to which it is normally reduced?

1. Yes	
2. No	
3. Unsure	

25. If "**Yes**" how did you acquire this information?

1. Inservice education and training	
2. Serminar	
3 Symposium	
4. Other, specify	v63

26. Based on your experience, is it a regular practice to check and verify to which level is this product leucodepleted ?

1. Yes	
2. No	
3. Unsure	

27. If you were to transfuse a neonate with two units of bloob/ blood products which are from different donors, how often will you monitor the recipient`s vital data

1. 1/4 hourly	
2. 1/4-1/2 hourly	
3. 1/2- hourly	
4. When necessary	

28. Based on your knowledge and experience, how soon can a neonate present with signs of reaction to transfusion?

1. During transfusion	
2. Within 24 hours post transfusion	
3. 3 to 7 days post transfusion	
4. 7 to 10 days post transfusion	
5. Unsure	

29 When do Neonates present with Late Transfusion reactions?

1. During transfusion	
2. Within 24 hours post transfusion	
3. 3 to 7 days post transfusion	
4. 7 to 10 days post transfusion	

SECTION C: LEGAL ASPECTS

30. According to your knowledge is there any protocol or policy regarding donor/ recipient testing in your unit?

1. Yes	
2. No	
3. Unsure	

31. If, `Yes`, are all personnel in your unit aware of it?

1. Yes	
2. No	
3. Unsure	

32. Based on your knowledge or experience, should parents be informed prior to transfusing their neonate?

1. Yes	
2. No	
3. Unsure	

33. If "**Yes**" who should inform them?

1. A Doctor	
2. A Transfusionist from blood transfusion services	
3. A Professional Nurse	

34. According to you who should transfuse and observe the neonate during transfusion?

1. A doctor		
2. A Transfusionist from blood transfusion services?		v61
3. A professional nurse		
4. Other, specify……..		v77

35. Based on your knowledge or experience, why are most neonatal intensive care units, reluctant to employ blood or blood products filters during neonatal transfusion?

1. Specify……
2. Not sure

v78

36. To your knowledge, is it appropriate to use a filter when transfusing a neonate with a leucodepleted blood or blood product?

1. Yes		
2. No		
3. Unsure		

37. Can one filter red blood cells through a leukocyte reducing blood filter?

1. Yes	
2. No	
3. Unsure	

38. Can one filter platelets through a red blood cell filter?

1. Yes	
2. No	
3. Unsure	

39. Based on your experience, is it easy to differentiate between a red blood cell filter and other blood filters?

1. Yes	
2. No	
3. Unsure	

40. Are there any neonatal micro-aggregate blood filters available on the market

1. Yes	
2. No	
3. Unsure	

41. Which transfusion reaction do neonates commonly present with?

1. Pneumonia	
2. Biologic response reactions	
3. Respiratory distress syndrome	
4. Metabolic acidosis	
5. Other (Specify) ……	

v84

42. Is it necessary to use a blood filter when irradiated blood/blood products is/are transfused to a neonate?

1. Yes	
2. No	
3. Unsure	

43. In your experience, who should be responsible for deciding whether a filter should be used during transfusion of blood/blood products to a neonate?

1. Prescribing doctor	
2. Unit manager	
3. Nurse performing transfusion	

4. Other (Specify) ……	

v89

THANK YOU FOR YOUR PARTICIPATION!

ES ABOUT THE
TO NEONATES

fice use only

0	0	1-3

v2	70	4
v3	80	5

v4	40	6
v5	35	7
v6	10	8
30	35	9

v8	25	10
v9	38	11
v10	22	12
v11	12	13

v12	20	14
v13	24	15
v14	40	16
v15	20	17

v16	60	18
v17	32	19

v18	8	20
v19	18	21
v20	14	22
v21	35	23

v22	33	24
v23	5	25
v24	27	26
49	8	27

v26	52	28
v27	2	29
v28	4	30
8	30	31

	25	
v30	28	32
	20	

	5	
v31	9	33

6
80

33
16
v32 39 34

6

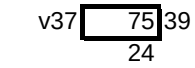
40
v33 18 35
20

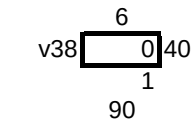
64
10
v34 12 36
10

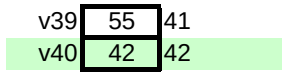
64
v35 15 37
28

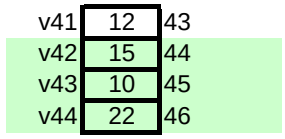
17
v36 60 38
25

4


v37
75
39
24


6
v38
0
40
1
90


v39
55
41
v40
42
42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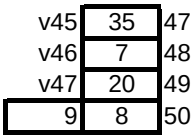
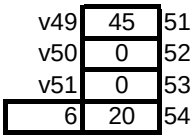
12
43
v42
15
44
v43
10
45
v44
22
46


v45
35
47
v46
7
48
v47
20
49
9
8
50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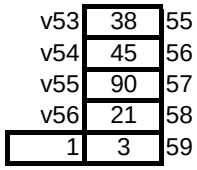
45
51
v50
0
52
v51
0
53
6
20
54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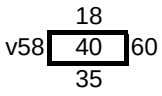
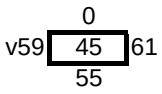
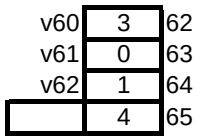
v54 45 56
v55 90 57
v56 21 58
1 3 59


18
v58 40 60
35


0
v59 45 61
55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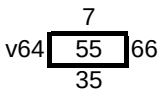
v61 0 63
v62 1 64
4 65


7
v64 55 66
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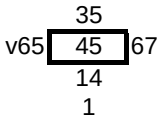
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v65 45 67
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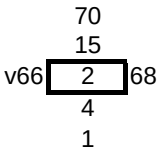
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15
v66
2
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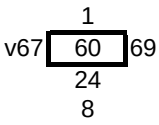
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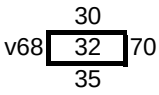
69
24
8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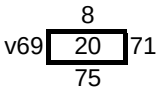
v68
32
70
35


8
v69
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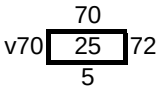
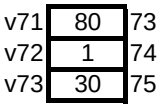
71
75


70
v70
25
72
5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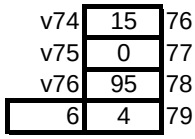
80
73
v72
1
74
v73
30
75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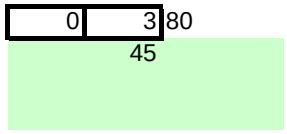
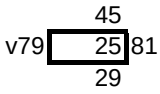
76
v75
0
77
v76
95
78
6
4
79


0
3
80
45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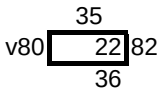
v79
25
81
29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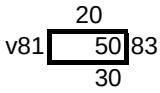
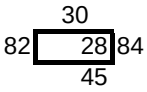
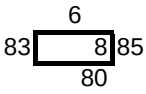
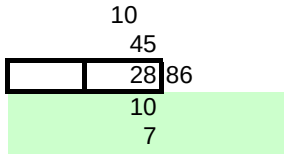
22
82
36

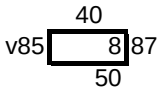

20
v81
50
83
30

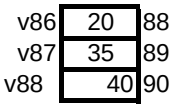

30
82
28
84
45

?


6
83
8
85
80


10
45
28
86
10
7


40
v85
8
87
50


v86
20
88
v87
35
89
v88
40
90

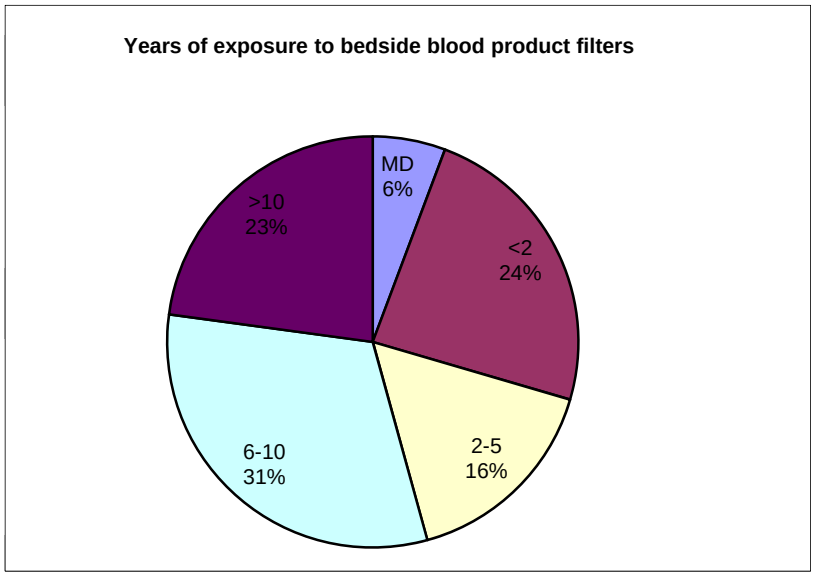
8	17

91

ANNEXURE F

GRAPHS AND TABLES

Graph 4.17: Years of exposure to bedside blood product filters



Graph 4.29: Reasons for reluctance to employ bedside blood product filters