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Knowledge and awareness of appropriate blood product use in perioperative patients among clinicians at an academic hospital

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in partial fulfilment of the requirements for the degree of
Master of Medicine
in the branch of Anaesthesiology.
Johannesburg, 2014.

Declaration

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

Signature

Signed at

On this date

Presentations arising from this project

1. Department of Anaesthesiology Academic meeting – 10 July 2013
2. Department of Obstetrics and Gynaecology research meeting – 4 November 2013
3. Department of General Surgery and Trauma Academic meeting – 3 December 2013
4. SASA Congress 2014 Gaisford Harrison Registrar Research Competition – 18 March 2014

Abstract

Modern medicine has a continued reliance on allogeneic blood products. This is an expensive, scarce resource with inherent risks to patients. There is no current literature evaluating the level of knowledge and awareness of rational blood product use in South Africa.

The purpose of this research was to describe the level of clinicians' knowledge and awareness related to the ordering and administration of blood products from the South African National Blood Service for perioperative patients at Chris Hani Baragwanath Academic Hospital.

A prospective, descriptive, contextual study design was used. A questionnaire and an information letter were distributed.

A total of 172 of 210 (81.9%) distributed questionnaires were returned. Departments included were Anaesthesiology, General Surgery and Trauma, Orthopaedic Surgery and Obstetrics and Gynaecology. Interns, medical officers, registrars and consultants were included.

Clinicians' knowledge of the risks associated with blood product administration appears to be poor. Awareness of consent, costs, ordering and administration protocols was also disappointing. In this study respondents from Anaesthesiology performed significantly better than their colleagues and consultants performed significantly better than their junior colleagues.

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Chapter 1 - Overview of the study

In this chapter the background of this research is introduced followed by the purpose and objectives. The research assumptions, demarcation of the study field, ethical considerations, research methodology, significance of the study, validity, reliability and study limitations follow.

1.1 Background

Modern medicine has a continued reliance on allogeneic blood products. This is an expensive and scarce resource, with inherent risks to patients. Escalating costs and declining supplies have deepened the need to rationalise transfusion practice.

The Transfusion Requirements In Critical Care (TRICC) study (1) in 1999 directed subsequent recommendations and guidelines for the use of red cell concentrate (RCC). A liberal approach to transfusion was compared to a restrictive approach in critically ill patients. It was found that the restrictive approach was as effective and possibly superior to a liberal approach (1). This recommendation has been extended to most patient groups in a 2012 Cochrane Collaboration Review on transfusion thresholds (2).

The rational use of transfused platelets and fresh frozen plasma (FFP) is less well defined. A Cochrane Collaboration Review (3) on prophylactic platelet transfusion found no evidence that a prophylactic platelet transfusion policy prevents bleeding and that a platelet count of 10×10^9/litre should remain the recommended level for triggering a transfusion to prevent spontaneous bleeding.

FFP appears to have the highest rate of inappropriate use compared with other blood products (4, 5). Significant variation in usage is also seen (6, 7). FFP has not been proven to be of benefit in the setting of abnormal laboratory coagulation tests (4, 5, 8), although prophylactic transfusion may account for up to 50% of use (6, 7, 9, 10). Generally, FFP administration is not rational and is not given in sufficient amounts (9). Visser et al (11) published an evaluation of FFP use in 2012 in a South African tertiary hospital. Transfusions were considered inappropriate in 39,5% of cases. The authors cited lack of knowledge regarding indications for FFP administration and stated that intervention is necessary to improve rational use.

Most authors and clinicians note a clinical assessment is fundamentally important in the decision to transfuse blood products (12-15). Many of the guidelines do encourage this practice but specific awareness of the guidelines seems to be lacking as demonstrated by specific questions asked in a number of surveys (10, 12-15).

Despite considerable interest in blood product alternatives, these products have limited application in very specific circumstances (16-18). A complete alternative to any blood product has not been convincingly proven.

In 2011, 43 657 procedures were performed in all operating theatres at Chris Hani Baragwanath Academic Hospital (CHBAH) (19). Between 5000 and 6000 blood products are ordered monthly from the South African National Blood Service (SANBS) at CHBAH (20). Up to 30% of these orders are cancelled or wasted (20). This includes returned units that must be discarded and units that are not collected from the SANBS after being ordered.

In the South African setting it is of paramount importance that medical professionals have the competencies, skills and knowledge to administer the limited and expensive blood products safely to the most appropriate patients. There is no current literature evaluating the level of knowledge and awareness of rational blood product use in this country.

1.2 Problem statement

CHBAH utilises the services of the SANBS to provide allogeneic blood products for use on patients in the form of blood components. Blood product supply is in high demand and is expensive. Medical doctors are responsible for the ordering and prescription to administer blood component therapy at CHBAH.

The perceived situation of current practice is that medical personnel lack the competencies, skills and knowledge related to risks, cost, appropriate ordering, administration, guidelines and physiology of blood product transfusion. The consequence of this is blood product use and costs are not optimal as revealed by an audit of these services at CHBAH (21).

1.3 Purpose

The purpose of this research was to describe the level of clinicians' knowledge and awareness related to all aspects of the ordering and administration of blood products from the SANBS for perioperative patients at CHBAH.

1.4 Objectives

The primary objectives of this study were to determine the knowledge and awareness of clinicians with regard to:

- Risks associated with the transfusion of blood products.
- Resources and costs associated with the transfusion of blood products.
- Donations, ordering and return of blood products.
- Safe administration of blood products to a patient.
- Transfusion thresholds and triggers for blood product administration.

The secondary objectives of this study were to compare knowledge levels among the different specialty departments and clinician ranks.

1.5 Research assumptions

The following definitions were used:

South African National Blood Service (SANBS): a non-profit organisation that provides patients with sufficient, safe quality blood products and medical services related to blood transfusion in an equitable and cost-effective manner (22, 23).

Blood product: a component of blood collected from a human donor (23). For purposes of this study this was confined to RCC, platelets and FFP.

Crossmatch: units of RCC are tested for compatibility with a specific specimen for transfusion (23-25). Standard crossmatch is done within two hours by the SANBS. An emergency crossmatch, completed in 30 minutes, only confirms partial compatibility (23-25). Crossmatched products will be held in reserve for 24 hours unless otherwise indicated by the attending doctor.

Type and screen: a patient's blood specimen that is tested to determine blood group and ensure that it does not contain problematic antibodies which could delay finding compatible blood (23, 24). The specimen is held for 96 hours at the SANBS.

Red cell concentrate (RCC): erythrocytes obtained from a unit of whole blood that have the plasma and buffy coat removed (23, 24).

Platelets: platelets for transfusion are prepared from the buffy layers of whole blood donations within 8 hours of collection and stored with continuous agitation for up to 5 days at 22 °C (23).

Fresh frozen plasma (FFP): plasma that is separated from anticoagulated whole blood and is frozen within 18 hours of donation (23). FFP contains all coagulation factors at physiological levels (25).

Major surgical blood ordering schedule (MSBOS): consists of a list of the recommended maximum number of units of blood which are routinely crossmatched for elective procedures (26).

Health Professions Council of South Africa (HPCSA): the statutory body which governs the professional accreditation of doctors and other health professionals in South Africa (27). Categories of doctors that are defined by the HPCSA and were used in this study are described below.

Intern: A doctor who has graduated from university and is completing further supervised training for a period of two years as recognised by the HPCSA (28). This category of doctors is not registered by the HPCSA for independent practice.

Community service doctor: a doctor who is completing his/her community service as prescribed by the HPCSA prior to being granted full registration for independent practice (28, 29). This doctor has usually completed two years internship that is acknowledged by the HPCSA as an extended period of training following graduation with a medical degree. For the purposes of this study these doctors are included in the medical officer group.

Medical officer: a doctor employed by the provincial government in a designated medical officer post (29). These doctors may have no formal postgraduate training in the discipline in which they may work. These doctors are registered by the HPCSA for independent practice.

Registrar: a doctor who is in the process of acquiring a specialist qualification endorsed by the HPCSA (30).

Consultant: a doctor who has a specialist qualification endorsed by the HPCSA (31).

Clinician: for the purposes of this research all the groups of doctors described above were referred to as clinicians.

Formal blood product education: for the purposes of this research this comprises of the annual SANBS seminar at CHBAH, annual intern cardiopulmonary resuscitation course at CHBAH and departmental academic meetings.

1.6 Demarcation of the study field

The study was conducted at CHBAH. This hospital is a large central hospital occupying 0.70 km^2 with 3 200 beds and 6 760 staff members (32). It is located in the Soweto area of Johannesburg and it is one of the teaching hospitals affiliated to the University of the Witwatersrand (32).

1.7 Ethical considerations

Verbal assent was obtained from the Heads of Departments of Anaesthesiology, General Surgery and Trauma, Orthopaedic Surgery, Obstetrics and Gynaecology and the Chairman of the CHBAH Local Blood Committee prior to the proposal being submitted for formal approval. Ethics approval was obtained from the Human Research Ethics Committee (Medical) (Appendix 1) and the Post-Graduate Committee of the University of the Witwatersrand (Appendix 2). Subsequently, consent to perform the study was obtained from the Medical Advisory Committee of CHBAH (Appendix 3).

Clinicians were invited to take part in the study and were given a self-administered questionnaire (Appendix 4). The questionnaire contained an information letter (Appendix 5)

detailing the purpose of the study, ethics and CHBAH Medical Advisory Committee approval. The agreement to complete the questionnaire implied consent. Anonymity of participants and questionnaires was ensured by not recording participants' names on the questionnaires, which were then placed in a sealed envelope in a container with other questionnaires. Furthermore, confidentiality was ensured as the researcher and supervisors were the only people to have access to the raw data.

The study was conducted in adherence to the principles of the Declaration of Helsinki 2008 (33) and South African Good Clinical Practice Guidelines (34).

1.8 Research methodology

1.8.1 Research design

A prospective, descriptive, contextual study design was used.

1.8.2 Study population

Clinicians working with perioperative patients in the Anaesthesiology, General Surgery and Trauma, Orthopaedic Surgery and Obstetrics and Gynaecology Departments belonging to the professional ranks of intern, medical officer, registrar and consultant formed the population group studied.

1.8.3 Study sample

Sample size

Approximately 600 doctors are employed at CHBAH (32), of which about 200 work with perioperative patients (32). The sample size was realised by the number of respondents who completed the questionnaire.

Sampling method

A convenience sampling method, which involves the selection of readily available subjects or objects for a study (35), was used.

Inclusion criteria

Clinicians from the Departments of Anaesthesiology, General Surgery and Trauma, Orthopaedic Surgery and Obstetrics and Gynaecology.

Exclusion criteria

- Clinicians who indicate that they had never been involved in the administration of blood products at CHBAH.
- Clinicians who declined to participate.
- Clinicians on annual, special or sick leave at the time of data collection.

1.8.4 Self-administered questionnaire

Questionnaire development

In order to develop a questionnaire that would accurately assess competencies, skills and knowledge related to blood products amongst clinicians the literature was reviewed.

Questions were formulated using previous surveys and textbooks (10, 12-15, 26, 36-38) and adapted using the SANBS Clinical Guidelines for the use of Blood Products in South Africa (23).

Three senior anaesthesiologists and a senior haematologist, all with blood product expertise, validated the questionnaire. This was done in order to ensure validity and reliability.

Questionnaire distribution

All clinicians fitting the inclusion criteria within the departments outlined were identified. The questionnaires and an information letter were distributed at academic meetings to those clinicians who agreed to participate in the study.

1.8.5 Data analysis

Data were analysed using descriptive and inferential statistics using Microsoft Excel for Mac 2011 and GraphPad InStat. For descriptive analysis of data that were normally distributed mean and standard deviation (SD) were used. Analysis of variance testing (ANOVA) testing

was used to compare means between groups. A p-value < 0.05 was taken as statistically significant.

1.9 Significance of the study

This study was designed to evaluate blood product competencies, skills and knowledge of clinicians at CHBAH and may provide a baseline understanding of practice surrounding administration. Furthermore, it may lay a foundation for further studies to be conducted on this topic.

This research may be of value to CHBAH management, the CHBAH Local Blood Committee and the SANBS as the results may be used to optimise utilisation of blood products. These resources are under constant pressure and rationalisation of ordering and administration may be of benefit.

1.10 Validity and reliability

In this study the questionnaire was assessed and validated by three senior anaesthesiologists and a senior haematologist, all with blood product expertise. It was developed following an extensive literature review. Instruments used in similar studies were used as a comparison for the development of the questionnaire. This ensured validity and reliability of the research tool.

1.11 Project outline

Chapter 1: Overview of the study
Chapter 2: Literature review and background
Chapter 3: Research design and methods
Chapter 4: Data analysis and discussion of results
Chapter 5: Summary, limitations, recommendations and conclusions

1.12 Conclusion

In this chapter the background of this research was introduced followed by the purpose and objectives. The research assumptions, demarcation of the study field, ethical considerations, research methodology, significance of the study, validity and reliability followed.

Chapter 2 - Literature review and background

2.1 Introduction

The WHO launched a patient safety programme in 2008 with the slogan of "better knowledge for safer care" (39). This programme urges the prioritisation of patient safety. A research priority list compiled by WHO Patient Safety (39) identifies inadequate competencies and skills as well as the lack of appropriate knowledge and transfer among the top six research priorities in developed and developing countries.

These research priorities (39) are specifically appropriate for the transfusion of blood products, which is a distinctive technology that blends science and altruism (40). Modern medicine has a continued reliance on blood products. This is an expensive, scarce resource with inherent risks to patients.

It is therefore of the utmost importance that the medical profession must have the competencies, skills and knowledge to administer blood products safely to the most appropriate patients.

In this chapter a brief history of blood transfusion is given followed by a discussion of various aspects of blood products that will influence clinicians' competencies, skills and knowledge of their administration. These aspects include blood product safety, resources, cost, ordering, administration, major transfusion studies, guidelines for administration, physiology, alternatives to blood products, surveys of practice, effective guideline implementation and clinician education.

2.2 History of blood and blood product transfusion

The history of blood and blood product transfusion is controversial among authors (41-43). A brief timeline is elucidated below but may be in dispute and incomplete. The evolving nature and safety concerns of blood products are demonstrated:

1628: William Harvey discovered the circulation of blood (42, 43).
1665: The first recorded successful blood transfusion occurs in England. Physician Richard Lower documents a dog to dog blood transfusion (42, 43).

1666: Edmund King and Richard Lower together claim transfusion of the first human. This is in dispute. Jean Baptiste Denis makes the same claim. (41-43)
1666 to 1800s: No transfusion work was done for political and religious reasons (41-43).
1818: British obstetrician, James Blundell, performs the first successful transfusion of human blood to a human patient for the treatment of postpartum haemorrhage (42, 43).
1907: Ludvig Hektoen suggests that the safety of transfusion might be improved by crossmatching blood between donors and patients to exclude incompatible mixtures. Reuben Ottenberg performs the first blood transfusion using blood typing and crossmatching (42).
1910: W.W. Duke publishes the first documented platelet transfusion (44).
1914 to 1915: Long-term anticoagulants, among them sodium citrate, are developed, allowing longer preservation of blood (42).
1936: John Elliot posits the use of plasma as a blood substitute (45).
1940: The government in the United States of America (USA) establishes a national blood collection programme (42).
1948: The Red Cross begins the first nationwide blood programme for civilians by opening its first collection centre in Rochester, New York (42).
1954: The first platelet transfusions are shown to decrease mortality from haemorrhage in patients with acute leukaemia (46).
1971: Hepatitis B Virus (HBV) testing of donated blood begins (42).
1985: Red Cross Blood Services regions begin testing for Human Immunodeficiency Virus (HIV) (42).
1990: Introduction of first specific test for Hepatitis C Virus (HCV) (47).
2002: West Nile virus identified as transfusion transmissible (47).
2003: First West Nile Virus positive unit of blood intercepted (47).
2008: Four probable cases of transmission of prion disease via blood products in the United Kingdom (48).

2.3 Blood product safety

Blood product administration carries a risk of adverse effects. These include infectious disease transmission and non-infectious complications relating to transfusion (23). Literature states that certain blood products carry higher specific risks than others but figures differ between regions (8, 23, 24, 48).

- RCC has an increased chance of incompatibility reactions compared with other blood products (23, 24, 48, 49).

- Platelets are more likely to become contaminated with bacteria due to storage at room temperature (8, 23, 24, 48).
- Plasma derived products like FFP have an increased chance of transmitting viral infections and causing immunologic reactions when compared with other products (4, 5, 8, 23, 24, 48, 50).

The total adverse reaction rate to blood product transfusion was approximately 0.24% in the USA in 2009, with 1 in 414 transfusions requiring a diagnostic or therapeutic intervention and 317 (0.002%) life-threatening reactions (51). Serious Hazards of Transfusion, the United Kingdom's haemovigilance group, received 1464 reports with the potential for mortality and morbidity in 2010 (52). Among these there were 13 deaths and 101 cases of major morbidity, resulting in a serious outcome for 7.8% of cases reported. Between regions, large discrepancies exist in reports on transfusion reactions and complications. This is likely due to differences in reporting. The reported overall rates from various sources are compared in Table 2.1. (48, 51-56)

Table 2.1 Comparison of transfusion risks by region (48, 51-56)

Type of Risk	**Developed world**	**Developing world (Sub-Saharan Africa)**
Infections		
HIV	1 in 1-4.5 million	1 in 1000
HBV	1 in 30 000-200 000	4.3 in 1000
HCV	1 in 1-3 million	2.5 in 1000
Immunologic Reactions		
Acute haemolytic reaction	1 in 13 000	No data
Delayed haemolytic reaction	1 in 9000	No data
Transfusion Associated Lung Injury	1 in 70 000	No data
Transfusion error	1 in 14000-18000	No data

Up to 3% of HIV infections worldwide are transmitted through the transfusion of contaminated blood and blood products (57). HBV and HCV, syphilis and other infectious agents, can also infect recipients of blood products (57). Emerging infectious agents, including prions, transmissible via transfusion, continue to be identified (54).
Median overall risks reported by Jayaraman et al (56) of becoming infected with HIV, HBV and HCV from a blood transfusion in Sub-Saharan Africa were 0,1%, 0,43%, and 0,25%

respectively according to a mathematical model although the completeness of data is questioned by the authors.

The SANBS and Western Province Blood Transfusion Service reported 467 non-infectious adverse events in 2009 representing 0,05% of transfusions for this period (53). One case of HBV transmission was confirmed by the SANBS for the same period.

Clinicians seem to be aware that there are risks associated with blood product administration but the ability to quantify the specific risks in their area and obtain informed consent may be questioned.

2.4 Blood product resources

Escalating costs and declining supply of blood products have amplified the pressure on clinicians to rationalise transfusion practice.

The WHO report on Universal Access to Safe Blood Transfusion (40) highlights that blood transfusion is a crucial component of health care. Someone requires blood every second. Artificial substitutes cannot routinely replace the need for donated human blood.
In developed countries, transfusion is most commonly used to support innovative medical and surgical procedures. In countries where diagnostic and treatment options are limited, a much greater proportion of blood is used to treat obstetric emergencies and severe anaemia, often resulting from malaria and malnutrition.

Whatever the degree of development of health care, transfusion is the only option for survival for many patients. Every country needs to meet its requirements for blood and blood products and ensure that blood supplies are safe. Blood safety is fundamental for the achievement of the health-related Millennium Development Goals on reducing child mortality, improving maternal health and combating HIV/AIDS. (40)

The report (40) concludes: “Blood transfusion is a distinctive technology that blends science and altruism. Though its collection, processing and use are technical, its availability depends entirely on the selflessness of the blood donor who donates this precious gift. “

2.4.1 Blood products in South Africa

An indication of blood product supply in South Africa can easily be discovered from visiting the SANBS website (58). Prominently displayed on the homepage are collections and target fulfilment for the month and the blood stock level, measured in days, inferring the system is under constant pressure.

The number of donations has increased between 7% and 10% since 2007. The SANBS collected 790 258 units of blood from donors in 2009 (53). A total of 841 361 blood products were issued during 2009 (53).

Clinician knowledge and efficient management of this precious resource is enormously important in providing health care delivery in South Africa.

2.4.2 Chris Hani Baragwanath Academic Hospital and blood products

The SANBS guideline (23) is supplemented by the United Kingdom Handbook of Transfusion Medicine (24) at CHBAH as it is the most comprehensive guideline (59). The hospital does not have a major surgical blood ordering schedule (MSBOS) (59). There is however, a CHBAH Local Blood Committee that meets on a monthly basis regarding transfusion practice, costs, reporting and other related issues (59).

In 2011, 43 657 procedures were performed in all operating theatres at CHBAH (19). Between 5000 and 6000 blood products are ordered monthly from the SANBS (20). Up to 30% of these orders are cancelled or wasted (20). This includes returned units that must be discarded and units that are not collected.

The SANBS offers the option of ordering blood on returnable basis. Blood is transported in a temperature-controlled hamper as seen in Figure 2.1. Provided the hamper remains sealed, the blood is returned before 10 hours after issue and remains below 10 °C, it will be accepted by the SANBS and the fee for blood will fall away. Administrative and service fees will however be levied. (23, 60)

Figure 2.1 SANBS hamper



2.5 Economics of blood products

Determining the actual costs of blood product transfusion is complex. The first Cost-of-Blood Consensus Conference and other models (61, 62) make the recommendation to utilise activity based costing methods so a robust and comprehensive evaluation can be made.

The actual cost of blood to individuals, health-care providers and society is difficult to determine. Unless all contributing cost elements are accounted for, beginning with blood donation, continuing through preparation and transfusion administration and lasting throughout long-term reporting and look-back programmes, the cost of blood is very likely to be miscalculated.

2.6 SANBS blood product fees

The 2012 SANBS public patient price list (60) quotes the prices seen in Table 2.2 for the specified services. Additional fees are charged for delivery, after hour service, emergency request and administration sets along with other administrative costs. Private patient charges are 20 to 25% higher than that of public patients (63). These costs are the charges levied by the SANBS, which clinicians should consider.

Table 2.2 SANBS processing and blood product fees. (60)

Type and screen	R 272.85
Crossmatch	R 609.33
RCC	R 1369.39
RCC (leucocyte depleted)	R 2237.52
Platelet concentrate (pooled)	R 5769.40
Platelet concentrate (pooled and leucocyte depleted)	R 7264.02
Platelet concentrate (single donor)	R 7936.60
FFP (donor retested)	R 1095.49
FFP (cryo-poor and donor retested)	R 883.79

2.7 Blood product ordering from the SANBS

A requisition form, for blood or blood components outlining specific patient information, is completed by a clinician (23). Details of previous medical, obstetric and transfusion history must be documented. The diagnosis, reason for transfusion, number and type of components required and the date and time when the blood or blood components are required are included on the form. This information assists the SANBS staff in identifying the recipient and in finding compatible units (23). Orders for platelets and FFP at CHBAH are made with the requisition form (23). A patient blood specimen is not crossmatched to platelets or FFP unless specifically requested by a clinician at CHBAH (23).

2.7.1 RCC ordering from the SANBS

A requested type and screen entails drawing a patient blood specimen that will be grouped and tested to determine blood group and ensure that it does not contain problematic antibodies, which could delay finding compatible blood. The specimen will

be held for 96 hours at the SANBS. A crossmatch confirms compatibility of RCC units with a specific patient specimen. A standard crossmatch is done within two hours by the SANBS. An emergency crossmatch can be done in 20 to 30 minutes. Crossmatched products will be held in reserve for 24 hours unless otherwise indicated by the attending clinician. (23)

Two small studies (64, 65) looking at ratios of crossmatch to transfusion highlighted inefficient use of resources showing poor targeted blood ordering for appropriate patients with nearly 60% of crossmatched units not transfused. Authors expressed the need for ordering guidelines in each facility. There is disparity in the literature with regard to procedures that require a type and screen or crossmatch before elective surgery. It appears to be a challenge to clinicians to make an evidence-based decision. Clinicians at CHBAH appear to follow similar ordering patterns (20, 21, 59, 66).

Guidelines suggest that all hospitals should have a MSBOS. Suggestions for type and screen have been recommended for elective surgery requiring a mean transfusion rate of 0.5 units of RCC per procedure. Another recommendation made is a type and screen being done for procedures with a greater than 5% chance of transfusion. This represents a 10-fold difference as conveyed by Dexter et al (67). They suggest a new approach to identify procedures with a minimal estimated blood loss (EBL) and negate the need for a type and screen. These authors claim to have validated a method to determine whether a type and screen should be done for specified procedures. This complex method involves the facility determining what an operation's expected EBL would be and then assessing a number of procedures and actually measuring the blood loss and transfusion rate. A large incidence of transfusion would need to be observed for a procedure to warrant type and screen. The authors stress that this method needs to be implemented independently and recommendations should differ at each facility. (67)

2.8 Administration of blood products

The procedure for administration of blood products may vary but safety is always the main concern (23). Informed consent is required (23). At CHBAH verbal consent is adequate (59). The unit must be checked for leaks, broken seals or discolouration. A bedside verification process must be completed according to the SANBS guidelines (23).

- All information is read aloud by two qualified and registered attendants checking the blood.

- The recipient's name and identification number on the unit must be identical to that on the hospital record.
- The identification number on the unit must correlate with the unit identification number on the requisition form or label.
- The donor's blood groups must be recorded on the blood unit.
- Verification that a compatibility test between the donor and the recipient has been performed should be documented.
- If possible the patient's blood groups should be confirmed from previous transfusion records in the patient's record.
- The date and time of expiry of the unit must be checked. Expired blood must not be transfused.

If any abnormalities are noted during verification the product should not be transfused and must be returned to the SANBS.

If a transfusion reaction is suspected the transfusion must be stopped immediately, the administration set changed and the vein kept open with a transfusion of normal saline. The initial administration set, remaining blood products, a patient blood and urine specimen must be returned to he SANBS. A complete reaction report, documenting the reason for transfusion and subsequent events, must be completed. (23)

2.8.1 SANBS recommendations for administration of RCC

RCC is usually transfused through a large needle or cannula, the size of which is selected according to the calibre of the patient's veins. Meticulous attention to aseptic technique when setting up the transfusion is important to avoid contamination. The transfusion site should be visible through a transparent dressing so that any inflammation or infiltration may be seen immediately. The transfusion should be repositioned if inflammation is observed. (23)

Baseline observations of vital signs should be recorded prior to commencing the transfusion. The patient is then observed closely for 30 minutes to detect any untoward reaction and to ensure that the desired rate of transfusion is maintained. In cases of major blood loss patients should be monitored every 15 minutes throughout the transfusion. In less severe cases the recipient's vital signs should be checked every half hour after the initial 30 minute observation. Patients at risk for circulatory overload should be observed for 12 to 24 hours after transfusion.

The rate of the transfusion depends on the clinical condition of the patient. A rate of 5 ml per minute is recommended for the first 30 minutes and if there is no sign of untoward reaction the rate can then be increased. RCC transfusions must be completed within 6 hours. (23)

Prevention of the transfusion of debris requires use of 70 – 240 μm mesh filters. The filter should be covered with blood to ensure that the full filtering area is used. (23)

Blood warming is not routinely indicated and refrigerated blood may be transfused without harm over several hours. If cold blood is administered at a slow rate it does not appear to affect the circulatory system. However, in cases where rapid transfusion is necessary, complications can be avoided by warming the blood to not more than 37 °C. Overheating of the blood can cause extensive haemolysis. Blood should be warmed with a blood warmer specifically designed for this purpose. (23)

The only fluids that can be given concurrently through the same intravenous device as a red cell transfusion are normal saline, 4% albumin, plasma protein fractions and compatible plasma (23).

2.8.2 SANBS recommendations for administration of platelets

Pooled platelets should be transfused in accordance with clinical guidelines (see Table 2.3) but also with reference to an individual patient's clinical status. A peripheral smear, confirming the platelet count, is recommended before administration (23). The platelet count should increase by 20 to 60 x 10^9/litre per standard adult dose containing a minimum of 2.4 x 10^{11} pooled platelets with a volume of 200 to 300mls (23, 25).

Platelets are never refrigerated and are available in 10 minutes (23). Platelets are stored with continuous agitation for up to 5 days at 22 °C (23). Platelets should be transfused immediately through a 170 – 260 μm filter administration set, specified for platelet use, over a period of 15 to 30 minutes at room temperature (23). Transfusion through a standard red cell administration set will reduce the number of platelets received (23). It is recommended that, as far as possible, group specific platelet concentrates be administered (23). However, clinical demands and stock availability dictates that patients frequently receive platelet transfusions that are not blood group matched (23).

Single donor platelets are derived from one donor with minimum yield of 2,4 x 10^{11} platelets and a volume of 200 to 300 ml. Leucocyte reduction occurs during an apheresis procedure; therefore single donor platelets are recommended for patients who experience febrile reactions as a result of sensitisation to leucocyte antigens. Single donor platelets are also recommended for patients who are on long-term platelet therapy e.g. leukaemia. (23)

2.8.3 SANBS recommendations for administration of FFP

FFP contains all coagulation factors at near normal physiological levels (4, 6, 23, 68). FFP is thawed from frozen, typically -30 °C, in approximately 40 minutes (23). It is recommended to thaw FFP at 37°C (69). It should be administered through a blood administration set after thawing at a dose of 15 to 20 ml/kg (23). The unit should be transfused as rapidly as possible, in 15 to 20 minutes per unit, with a recommended maximum delay after thawing of up to four hours, as labile coagulation factors deteriorate within a few hours of thawing (23). Ideally, FFP of the same blood group as the patient should be administered (23). If this is not available, a different group can be given (23).

Table 2.3 Summary of recent published guidelines for blood product transfusion

Guideline or Recommendation Body	Year, (Reference)	Recommended Haemoglobin level for transfusion (g/dl) in healthy adults	Recommended platelet level for transfusion ($x10^9$/litre)	Recommended Fresh frozen plasma (FFP) transfusion indication, dose	Additional comments
AABB	2012, (70)	7-8	-	-	Consider symptoms.
SIMTI Working Party	2011, (71)	<6: almost always require transfusion 6-8: in presence of risk factors or symptoms 8-10: in presence of symptoms indicating hypoxia >10: rarely necessary	50: surgical procedure	Coagulation disorder 10-15 ml/kg	Individual risk factors may necessitate use of different trigger levels. Assess intraoperative haemoglobin, blood loss and clinical parameters.
American Red Cross	2010, (72)	<6: transfuse 6-10: as per indications >10: transfusion not necessary	10-20 50-procedures	Coagulation disorder 10-20 ml/kg	Alter guideline in anticipated blood loss.
Napolitano et al.	2009, (73)	7	-	-	Recommend against "trigger" haemoglobin level. ACS: 8 g/dl.
AAGBI	2008, (74)	7	-	-	
SANBS	2008, (23)	7-8	10-20 50-procedures	Coagulation disorder 15-20 ml/kg	Higher in presence of cardiac disease. 6-10 g/dl in obstetric haemorrhage.
NBUGI	2007, (75)	7	-	-	
United Kingdom Blood services	2007, (24)	7	30 50-100 for procedures	Coagulation disorder 15 ml/kg	No data for patients with ACS. 9-10 g/dl in presence of ischaemic heart disease. Clinicians must assess for adequate oxygenation.
ASA Task Force	2006, (76)	Necessary below 6 Unnecessary above 10	50-100	Coagulation disorder 10-15 ml/kg	Important preoperative evaluation and optimisation.
BCTMAG	2003, (77)	7	-	-	9 g/dl in presence of cardiac disease.
ASBT	2001, (78)	7	10 -20 50-procedures	Coagulation disorder 10-20 ml/kg	Exercise clinical judgement.

AABB: American Association of Blood Banks; **SIMTI**: Italian Society of Transfusion Medicine and Immunohaematology; **AAGBI**: Association of Anaesthetists of Great Britain and Ireland; **SANBS**: South African National Blood Service; **NBUGI**: National Blood Users Group Ireland; **ASA**: American Society of Anesthesiologists; **BCTMAG**: British Columbia Transfusion Medicine Advisory Group; **ASBT**: Australasian Society of Blood Transfusion; **ACS**: acute coronary syndrome. **Coagulation disorder** includes specific factor deficiencies, Haemophilia A and B, warfarin overdose, Thrombotic Thrombocytopaenic Purpura (TTP), massive transfusion and others.

2.9 Landmark blood product studies

A landmark trial, Transfusion Requirements In Critical Care (TRICC) (1), published in 1999, directed subsequent recommendations that are still used today. These authors hoped to define optimal transfusion practice for critically ill patients with anaemia. A restrictive approach was compared to a liberal approach for transfusion. Findings indicated that a restrictive approach, consisting of a threshold at 7 g/dl for transfusion was at least as effective as, and possibly superior to, a liberal transfusion strategy, consisting of a 10 g/dl threshold. Haemoglobin concentration in the restrictive strategy was maintained in the 7 to 9 g/dl range and between 10 and 12 g/dl in the liberal strategy. These authors recommended the use of the restrictive transfusion strategy for all critically ill patients with the exception of those with coronary ischaemic syndromes.

Subsequently, the Anemia and Blood Transfusion in the Critically Ill (CRIT) study (79), published in 2004, observed that the number of RCC units transfused is an independent predictor of a worse clinical outcome in critically ill patients. Minimising transfusion exposure is an important principle. Berger et al (80) indicated recently that a single unit transfusion policy can be used safely although this study was conducted on patients with haematological disease.

The Anaemia and Blood Transfusion in Critical Care (ABC) investigators published a study (81) in 2002 that indicated an association between transfusions and diminished organ function as well as between transfusions and mortality. A sub-study of the Sepsis Occurrence in Acutely Ill Patients (SOAP) study in 2008 (82) did not confirm this finding despite using the same approach as the ABC study. The view that transfusions are associated with an increased mortality rate in acutely ill patients was not supported. This requires further research for clarification.

The Functional Outcomes in Cardiovascular Patients Undergoing Surgical Hip Fracture Repair (FOCUS) trial (83), published in 2011, confirmed the findings of their earlier pilot study (84). FOCUS was designed to determine whether patients with cardiovascular disease or risk factors undergoing surgical repair of hip fracture benefit from a higher or lower transfusion trigger specifically with regard to functional recovery and new cardiac events. Findings were in keeping with the TRICC study in that the restrictive group was at least as effective as a liberal transfusion strategy even in patients with cardiovascular disease or risk factors.

In 2012, the Cochrane Collaboration Review on transfusion thresholds and other strategies for guiding allogeneic red cell transfusion (2) looked at clinical outcomes of patients in 19 studies, including TRICC and FOCUS, comparing liberal versus restrictive transfusion thresholds in the context that the trends in current guidelines favour the restrictive approach (see Table 2.3). These authors found the restrictive threshold level did not increase complication rate and other outcome measures including mortality, cardiac morbidity, infections and length of hospital stay, when compared with liberal transfusion strategies. Thus, currently the restrictive strategy is favoured by this review despite statistically significant patient heterogeneity.

Another 2012 Cochrane Collaboration Review (3) of prophylactic platelet transfusion for prevention of bleeding in patients with haematological disorders concluded that there is no evidence that a policy of prophylactic platelet transfusion prevents bleeding. The current practice of using a platelet count of 10×10^9/litre to trigger a prophylactic transfusion is still recommended and prophylactic platelet transfusions were more effective than platelet-poor plasma at preventing bleeding (3).

Authors (4-6, 68, 85) comment on the lack of convincing, methodologically sound trials to outline appropriate FFP use. This does not mean that FFP administration is not effective. Clinical scenarios for administration may include:

- coagulopathy with bleeding
- coagulopathy without bleeding
- coagulopathy without bleeding, prior to an invasive procedure.

In a 2007 systematic review, Stanworth et al (5) suggests FFP administration has, over time, become accepted practice in all scenarios mentioned above. These practices may not have been subjected to the clinical research evaluation that they should have been. The need for appropriately powered studies to define rational use of FFP is a recurrent theme in papers (4-6, 68, 85, 86).

Most authors and published guidelines urge clinicians to make decisions to transfuse in a clinical context (2, 23, 24, 70-78). Therefore this process should demonstrate some subjectivity. However, these studies mentioned above, as well as recommendations, are conducted with patient safety in mind. The administration of allogeneic blood products

is not a benign or cheap endeavour. Striving for optimum patient care and cost-effectiveness should be the objective of all involved in health care.

Transfusion literature specific to cardiac surgery, acute coronary syndromes, massive transfusion and chronic anaemia was not reviewed due to the specialised and differing concerns in these patient groups and is not discussed in this report.

2.10 Blood product administration guidelines

In 1942 Adams and Lundy (87) advised preoperative transfusion if the measured haemoglobin was less than 8 to 10 g/dl. Confidence was placed in these numbers for years despite a lack of evidence supporting or refuting these numbers. The 10 g/dl level was favoured at the time based on physiological principles.

Citing the lack of clinical studies around the physiological adaptations to anaemia in a disease state in 1997, Hébert et al (88) stated that it is was not possible to offer guidelines on how to increase, maintain or measure optimum oxygen delivery and where the role for transfusion lay in high-risk patients.

A summary of various current guidelines is given in Table 2.3 for completeness. Several of these advise against a single threshold and recommend a range between 6 and 10 g/dl depending on the presence of comorbidity (2, 23, 24, 70-78). Most guidelines also emphasise the importance of a clinical evaluation.

Guidelines for platelet administration are also mostly in agreement (23, 24, 71, 72, 76, 78). A platelet count below 10 to 30 x 10^9/litre is quoted as requiring a platelet transfusion. A summary of prospective and retrospective studies confirms the appropriate level as 10 x 10^9/litre (8, 89-91). Levels of 50 x 10^9/litre for surgical and invasive procedures and 100 x 10^9/litre for ophthalmic and neurosurgical procedures are recommended (23, 24, 71, 72, 76, 78, 91). This recommendation is only supported by expert opinion and not by convincing evidence according to Gajic et al (8) and Arnold et al (92). A recent publication (35) comparing dosages of prophylactic platelet transfusions in preventing haemorrhage concluded the platelet dose has no significant effect on the incidence of bleeding in patients with hypoproliferative thrombocytopenia. Clinical haemostasis is the goal of treatment (91). The SANBS provide buffy coat derived

platelets, from five donors per pool, suspended in plasma (23). This is equivalent to one adult dose.

Prophylactic platelet transfusion, in the absence of bleeding, occurs in half to two thirds of all platelet administrations according to Arnold et al (92)and Greeno et al (90). A 2007 observational evaluation by Cameron et al (89) found that 78% of platelet transfusions given to non-surgical patients were administered with platelet counts above 10 x 10^9/litre and one third above 20 x 10^9/litre. Additionally 21% of transfused surgical patients had platelet counts above 100 x 10^9/litre.

Clinical use of FFP has grown in the last 20 years (4, 5, 86). Guidelines (23, 24, 71, 72, 76, 78) for FFP use are summarised in Table 2.3. All demonstrate reasonable consensus on recommendations for fresh frozen plasma transfusion, despite the lack of robust evidence as confirmed in systematic reviews (4, 5, 8, 68, 86). In an analysis of five international guidelines on plasma by Iorio et al (86) criticism is made that no guideline is complete or well structured. These authors recommend the production of local guidelines to ensure applicability.

A coagulation defect is the recommended indication for FFP administration (23, 24, 71, 72, 76, 78). Most guidelines state this is a clinical assessment of a coagulopathy i.e.: evidence of bleeding secondary to a coagulopathy. FFP is not recommended prophylactically for correction of abnormal laboratory coagulation tests or prior to invasive procedures, as it has not been proven in this setting (4, 5, 8, 93). Prophylactic transfusion may account for up to 50% of administration (6, 7, 9, 10).

These recommendations are not borne out in clinical practice. FFP appears to have the highest rate of inappropriate use of all blood products (4, 5). Great variation in practice was shown in 2011 in two assessments of current use in the United Kingdom (6, 7). Overall FFP administration is not rational and is not given in sufficient amounts (6, 7, 9).

Visser et al (11) published an evaluation of FFP use in 2012 in a South African tertiary hospital. Transfusions were considered inappropriate in 39,5% of cases. The authors cited a lack of knowledge regarding indications for FFP administration and stated that intervention is necessary to improve rational use.

Clinicians appear to not be following guidelines. Most clinicians and authors acknowledge that a clinical assessment is important in the decision to transfuse blood products (12-15). Many of the guidelines do encourage this practice but specific awareness of the guidelines seems to be lacking as demonstrated by specific questions asked in surveys (10, 12-15).

2.11 Physiology of RCC, platelets and FFP

The decision to administer blood products must be made with a basic understanding of haematological physiology, pathophysiology and the physiology of blood product administration.

2.11.1 Physiology of haemoglobin, anaemia, oxygen transport and transfusion

Red cells contain approximately 640 million haemoglobin molecules. Haemoglobin is the molecule responsible for the majority of oxygen transport. Heme, an iron-porphyrin compound is joined to the protein globin consisting of 4 polypeptide chains. Oxygen is bound according to its partial pressure. The relationship between haemoglobin and oxygen is demonstrated by the S-shaped oxyhaemoglobin dissociation curve. Efficient binding of oxygen occurs in the lungs at a high partial pressure and unloading occurs at a tissue level where there is a low partial pressure. This affinity can be altered by physiological adaptive mechanisms. Haemoglobin and cardiac output are the main determinants of tissue oxygenation. There is significant physiological reserve but there is a level of oxygen delivery below which demands of the body will not be met. This level is dependent on many individual factors such as age, weight, metabolic demands, disease states and other factors. Adaptations occur in response to acute anaemia including a shift of the oxyhaemoglobin curve, haemodynamic changes and microcirculatory alterations. (88, 94-96)

Acute haemorrhage can result in hypovolaemia and anaemia. Hypovolaemia can be managed with intravenous fluids but severe anaemia is usually managed with transfusion of allogeneic red cells. The critical level of haemoglobin has been alleged to be around 6 g/dl for most individuals (95). Red cell transfusion is the fastest way of raising haemoglobin and has saved many lives since the first documented transfusion. The goal of RCC transfusion is to restore adequate tissue oxygenation. Whether this transfused blood actually improves tissue oxygen delivery has recently been questioned

(88). Transfusions given above the critical level of haemoglobin have not conclusively shown any benefit (95). The clinical benefit seen after transfusion may not be consequent to improved oxygen delivery but rather an improvement in the microcirculatory milieu and flow mechanics (55, 96). It is still unclear whether storage time of allogeneic cells has adverse effects for the recipient (97). This is the subject of ongoing research.

2.11.2 Platelet physiology

Platelets or thrombocytes are formed in the bone marrow. Normal levels range between 150 and 450 $x10^9$/litre. Glycoproteins on the surface adhere to injured areas of a vessel wall where endothelial cells are damaged and collagen is exposed. The platelet membrane also contains large amounts of phospholipid that activates multiple stages of the clotting cascade. Platelets have a half-life of 8 to 12 days. (49)

Transfused platelets should function as normal. A single transfusion should increase the platelet count by 20 to 40 x 10^9/litre (23). One method to assess the success of a platelet transfusion is measuring the absolute platelet increment (91). This consists of subtracting pretransfusion platelet counts from a posttransfusion measurement 10 to 60 minutes after the transfusion. Prevention or termination of haemorrhage is the clinical goal.

2.11.3 Plasma and coagulation

Coagulation depends on the balance between procoagualants and anticoagulants normally present in plasma (49). These are produced mainly in the liver and vascular endothelium (49). In the normal state anticoagulants predominate so that circulating blood does not clot (49). When a vessel wall is damaged procoagulants in the area become activated and the process of coagulation is initiated (49). FFP is presumed to contain near normal levels of coagulation factors (4, 6, 23, 68).

2.12 Alternatives to blood products

Considerable interest has been shown in the range of products and interventions to reduce allogeneic RCC and other blood product requirements (16-18). These may include:

- Preoperative:
    - intravenous or oral iron supplementation
    - erythropoiesis stimulating agents
    - autologous blood donation
    - designated donation.
- Intraoperative:
    - blood salvage techniques
    - normovolaemic haemodilution
    - haemostatic agents
    - synthetic oxygen carriers.
- Postoperative:
    - haemostatic agents
    - intravenous or oral iron supplementation
    - avoidance of anticoagulants and antiplatelet agents.

Potential platelet substitutes include (18):

- infusible platelet membranes
- microspheres
- cryopreserved platelets
- lyophilised platelets.

Recombinant factor VIIa is a possible FFP substitute (5).

These products have different roles to play and are proven in very limited and specific circumstances. No complete alternative to blood products has been proven. Autologous blood donation is increasing in popularity in the private sector in South Africa (98).

2.13 Surveys of practice

Surveys have highlighted the variations in clinical practice of blood product transfusion despite the multitude of available guidelines. There is, however, paucity in the literature with regard to describing physicians' knowledge of risks, cost, appropriate ordering, administration, guidelines and physiology of blood product transfusion.

Surveys conducted with clinicians from 1987 to 2004 (12, 14, 15, 26) have shown a trend towards the accepted preoperative haemoglobin level moving from 10 to 8 g/dl. No absolute level of haemoglobin concentration, which improves patient safety at surgery, has been demonstrated and this remains controversial (88, 95, 99).

Interestingly, Matot et al (15) found a significant difference in lower haemoglobin limit for transfusion between anaesthesiologists and gynaecologists for healthy patients undergoing caesarean section (15) in their 2004 survey: 7.5 and 8 g/dl respectively. A similar difference was found between physicians and surgeons treating acute upper gastrointestinal bleeding by Jairath et al (100). Matot et al (15) also commented that anaesthesiologists and gynaecologists who spend the majority of their time in obstetrics chose lower transfusion thresholds.

Surveys of treating clinicians seemed to show a marked variation in transfusion threshold for similar patients (12-15, 26, 36, 100-103). This is most markedly demonstrated by Nahum et al (103) and Lavardière et al (102) with a span of up to 5 g/dl between responses in the paediatric critical care setting. Consequently, the same patient may be at risk of tissue hypoxia due to undertransfusion or fluid overload and exposure to the risks associated with overtransfusion. The authors note that it is very difficult to recommend a haemoglobin threshold for transfusion to the critically ill child. This variation in practice may be attributable to uncertainty.

Differences in practice related to year of graduation were found in some surveys (12, 13, 26, 36, 100). Authors suggest this difference may represent teaching, guidelines or consensus at the time of training. One study reported no differences in responses among clinicians with differing levels of experience (15).

According to some surveys, physicians seem to favour the administration of at least two units of red cell concentrate rather than adopting a 'single unit and re-evaluate' policy (13, 15, 101). Limited knowledge of the amount by which one unit of RCC would raise the haemoglobin level was also shown when directly asked in one survey (26).

When asked if the hospital at which they worked had a MSBOS, 40 to 50% of clinicians did not know or were unaware of the availability of a MSBOS (12, 14, 26).

The question of transfusion and related immunosuppression was asked in two surveys. Among American gynaecological oncologists surveyed in 1995 (101) more than half the respondents felt tumour status was not relevant in the decision to transfuse. In a South African survey published in 1992 (26) more than half of respondents were unaware or denied blood product transfusion can be immunosuppressive.

Clinicians' knowledge of costs and risks associated with blood product transfusion have only been assessed in one survey which reported a poor awareness of these (26). Questions designed to evaluate this knowledge were correctly answered by less that 50% of respondents.

In 1992 Irving (26) reported that 43% of surveyed clinicians indicated that they would use pooled platelets with a measured platelet level above 50 x 10^9/litre. This is not in keeping with the recommendations in guidelines (23, 24, 71, 72, 76, 78). The American Society of Anaesthesiologists guidelines (76) state that platelet transfusion is ineffective in patients with idiopathic thrombocytopaenic purpura. Despite this, 55% of respondents to Nutall et al's (14) survey would administer platelets in this setting. A platelet counts less than 100 x 10^9/litre, not 50 x 10^9/litre, was also indicated as the level at which 51% of anaesthesiologists would transfuse platelets in this study (14). Educational endeavours to encourage closer guideline implementation were recommended by these authors (14, 26).
With regard to prophylactic FFP transfusion, clinicians are split in their answers. There is demonstrated discord in observed practice (6, 7) and 90% of surveyed physicians administer FFP prophylactically prior to an invasive procedure (10). Moreover, 40 to 50% of physicians administer FFP prophylactically, citing a laboratory result showing a coagulopathy as the trigger (10).

All these surveys demonstrate variation in practice, which may be within acceptable guidelines but certain areas of knowledge and protocol certainly appear to be lacking or have not been adequately assessed. However, surveys assess attitudes and current knowledge but may not assess actual practice. A prospective observational audit may be a better assessment of actual practice.

2.14 Clinician education

Attempts have been made to improve transfusion practices, particularly those that aim at reducing unnecessary transfusions, by educating clinicians. Theoretically this would reduce exposure to risk as well as related costs. Systematic reviews, looking at the effectiveness of various interventions, have been published by Tinmouth (104) in 2007, Tinmouth et al (105) in 2005 and Wilson et al (106) in 2002. Verlicchi (107) published a review in 2010 on evaluating the clinical appropriateness of blood transfusion with regard to educational tools.

Verlicchi (107) expressed that experience internationally has shown that the passive dissemination of recommendations and guidelines is ineffective, regardless of the importance of the subject. The author describes the success, or lack thereof, of various educational processes used among clinicians.

- Distribution of printed educational material is widely used but appears to have limited beneficial effects on professional practice.
- Educational meetings, conferences or workshops designed for healthcare providers, showed small, if any, efficacy on improving guideline application.
- Local consensus processes was of uncertain efficacy.
- Educational outreach visits showed consistent but small effects.
- Local opinion leaders successfully reduce non-compliance with clinical guidelines with an effect comparable to other strategies. Identification of these leaders, as well as the most successful methods to obtain the desired results, remains uncertain.
- Audit and feedback is the most widely used strategy to improve the application of guidelines. Retrospective audits are summarised and presented to a group of individuals with the purpose that they modify their practice, if inconsistent with accepted guidelines. The effectiveness has been shown to be small to moderate.

Verlicchi (107) seems to criticise evidence-based medicine (EBM) in that only randomised trials or systematic reviews constitute 'evidence' and the definitive hierarchy of this evidence with a single best possibility. The author seems to favour the idea that each doctor's own experience and reasoning can be used to manage clinical practice in the day-to-day experience. This may explain the authors' finding of minimal effectiveness of most educational interventions.

Contrasting this, Tinmouth (104), Tinmouth et al (105) and Wilson et al (106) suggest that health care practitioners' transfusion practices can be altered by interventions designed to change transfusion behaviour in their systematic reviews. All studies reviewed showed an effective overall reduction in utilisation of blood products and a reduction in inappropriate transfusions administered.

The authors mentioned above (104-106) do however admit that these results should be interpreted with caution due to the heterogeneity of the studies examined. Statistical analyses were not possible and results were interpreted qualitatively. Most studies are also more than 10 years old. There may also be an element of publication bias in that studies that did not show a significant result may not have been published. No cost-benefit analysis was done in any studies. No studies had a direct measurement of undertransfusion.

Combined interventions have also not improved practice and a return to baseline has been observed following completed interventions and during ongoing interventions (104-106).
In Verlicchi's review (107) he describes that in transfusion medicine prospective auditing has been considered the most effective, although the most labour-intensive intervention, because it takes place before the transfusion occurs, preventing inappropriateness rather than merely registering it.
The surveys of practice conducted appear to demonstrate a vacuum of knowledge or uncertain practice. Educational interventions attempted appear sporadic at best and have not convincingly demonstrated a sustained improvement in transfusion practice or knowledge.

2.15 Effective guideline implementation and adherence among clinicians

The gap between clinical research findings, guidelines and clinical practice and the need for improvement has been well demonstrated (108-110).

Evidence for the use of multifaceted interventions, to effectively implement clinical guidelines, was published by Prior et al (111) in a systematic review. The data set precluded a formal statistical meta-analysis due to heterogeneity of studies. Interventions included educational outreach, educational meetings and interactive educational interventions, clinical reminder and decision support systems, patient-

specific interventions and the production of simple practical guidelines. Ineffective strategies included didactic education and passive dissemination strategies such as posting the guideline on a web site, or providing the guideline to clinicians in printed form. There was little research into costs of guideline implementation, or relative costs to benefits.

A recent Cochrane Collaboration Review (108) of the effects of printed education material on professional practice and health care outcomes echoes what Prior et al (111) express. These authors confirmed that the best method of information dissemination remains controversial and is dependent on many factors.

A 1999 publication (112) questioning why physicians do not follow clinical guidelines attempted to identify barriers to the successful implementation of guidelines including:

- lack of awareness of guidelines
- lack of familiarity with the guidelines
- lack of agreement with guidelines
- lack of self efficacy in implementation
- lack of outcome expectancy
- inertia of previous practice
- external and environmental barriers to guideline implementation.

Conversely, another recent Cochrane Collaboration Review (110) on tailored interventions to overcome identified barriers to change found that interventions tailored to prospectively identified barriers are more likely to improve professional practice than no intervention or simple distribution of new guidelines. The methods used to identify these barriers and tailor interventions to address them need to be further elucidated.

In summary, the best method of information dissemination and successful uptake still remains controversial and is dependent on many factors (108, 111).

2.16 Transfusion medicine education at CHBAH

The SANBS and Blood Committee of CHBAH host a blood product transfusion seminar annually. Attendance is voluntary and specific topics vary. Attendees complete an evaluation from which is analysed by the SANBS (66). In 2011 about half of respondents

felt that the purpose of the seminar was met and a contribution to capacity building was made at the seminar. Only 61% felt the seminar improved knowledge and understanding of blood product transfusion practice. No evaluation or changes in practice as a result of this seminar have been described or measured.

Additionally, the annual cardiopulmonary resuscitation course for interns at CHBAH provides blood product education and information. SANBS guideline booklets are distributed to all interns.

2.17 Summary

From the literature it is clear that a large number of clinicians are unaware of the risks, cost and appropriate ordering of blood products. Despite the availability of blood product administration guidelines, practice falls short of accepted recommendations. Studies looking at educational interventions state that the best methods of guideline dissemination and uptake remain controversial and are dependent on many factors.

2.18 Conclusion

This chapter discussed the history of blood transfusion followed by a discussion of various aspects of blood products that will influence clinicians' competencies, skills and knowledge of their administration. These aspects include blood product safety, resources, cost, ordering, administration, major transfusion studies, guidelines for administration, physiology, alternatives to blood products, surveys of practice, effective guideline implementation and clinician education. The next chapter, chapter 3, will discuss the research methodology of this study.

Chapter 3 - Research design and methods

In this chapter the perceived situation at CHBAH is introduced as a problem statement, followed by the purpose and objectives of this research. In-depth discussion of the ethical considerations, research methodology, validity and reliability follow.

3.1 Problem statement

CHBAH utilises the services of the SANBS to provide allogeneic blood products for use on patients in the form of blood components. Blood product supply is in high demand and is expensive. Medical doctors are responsible for the ordering and prescription to administer blood component therapy at CHBAH.

The perceived situation of this current practice was that medical personnel lack the competencies, skills and knowledge related to risks, cost, appropriate ordering, administration, guidelines and physiology of blood product transfusion. The consequence of this is blood product use and costs are not optimal as revealed by an audit of these services at CHBAH (21).

3.2 Purpose

The purpose of this research was to describe the level of clinicians' knowledge and awareness related to all aspects of the ordering and administration of blood products from the SANBS for perioperative patients at CHBAH.

3.3 Objectives

The primary objectives of this study were to determine the knowledge and awareness of clinicians with regard to:

- Risks associated with the transfusion of blood products.
- Resources and costs associated with the transfusion of blood products.
- Donations, ordering and return of blood products.
- Safe administration of blood products to a patient.
- Transfusion thresholds and triggers for blood product administration.

The secondary objectives of this study were to compare knowledge levels among the different specialty departments and clinician ranks.

3.4 Ethical considerations

Verbal assent was obtained from the Heads of Departments of Anaesthesiology, General Surgery and Trauma, Orthopaedic Surgery, Obstetrics and Gynaecology and the Chairman of the CHBAH Local Blood Committee prior to the proposal being submitted for formal approval.

Ethics approval was obtained from the Human Research Ethics Committee (Medical) (Appendix 1) and the Post-Graduate Committee of the University of the Witwatersrand (Appendix 2). Subsequently consent to perform the study was obtained from the Medical Advisory Committee of CHBAH (Appendix 3).

Clinicians were invited to take part in the study and were given a self-administered questionnaire (Appendix 4). The questionnaire contained an information letter (Appendix 5) detailing the purpose of the study, ethics and CHBAH approval. The agreement to complete the questionnaire implied consent. Anonymity of participants and questionnaires was ensured by not recording participants' names on the questionnaires. Completed questionnaires were sealed in an envelope and placed in a container with other questionnaires. Furthermore, confidentiality was ensured as the researcher and supervisors were the only people to have access to the raw data.

The study was conducted in adherence to the principles of the Declaration of Helsinki 2008 (33) and South African Good Clinical Practice Guidelines (34).

3.5 Research methodology

3.5.1 Research design

A prospective, descriptive, contextual study design was used.

A prospective study is defined as a study in which the variables will be measured at the time at which the study takes place (35). This study was prospective in that a group of

clinicians were identified for study and the data were collected from them during the course of the study.

A descriptive study aims to describe a situation or identify problems through observation, description or classification without manipulating variables (35, 113). No treatment or intervention is tested (113). This study was descriptive in design in that it planned to provide new information on the study variables defined in the objectives.

A contextual study is one that takes place in a specific location (35). This study was contextual as it was conducted at one hospital only – CHBAH.

3.5.2 Study population

Clinicians working with perioperative patients in the Anaesthesiology, General Surgery and Trauma, Orthopaedic Surgery and Obstetrics and Gynaecology Departments belonging to the professional levels intern, medical officer, registrar and consultant formed the population group studied.

3.5.3 Study sample

Sample size

Approximately 600 doctors are employed at CHBAH (32), of which about 200 work with perioperative patients (32). The sample size was realised by the number of respondents who completed the questionnaire.

Sampling method

All members within the departments outlined were identified with the assistance of the departmental secretary and the Human Resources Department. A convenience sampling method, which involves the selection of readily available subjects or objects for a study (35), was used. Clinicians working at CHBAH, with perioperative patients, were invited to participate. Registrars on the University of the Witwatersrand's academic circuit, rotating through CHBAH at the time of the study, were included.

Inclusion criteria

Clinicians from the Departments of Anaesthesiology, General surgery and Trauma, Orthopaedic surgery and Obstetrics and Gynaecology.

Exclusion criteria

- Clinicians who indicated that they had never been involved in the administration of blood products at CHBAH.
- Clinicians who declined to participate.
- Clinicians on annual, special or sick leave at the time of data collection were excluded.

3.5.4 Self-administered questionnaire

Questionnaire development

In order to develop a questionnaire that would accurately assess competencies, skills and knowledge related to blood products amongst clinicians the literature was reviewed. Terms such as "awareness", "knowledge", "survey", "audit" and "comfort" were included in the search. A few of the studies reviewed included their questionnaires and these served as a preliminary guide. Other studies did not include their questionnaires but the questions could be inferred from the results provided.

Questions were formulated using previous surveys (10, 12-15, 26, 36) and adapted using the SANBS Clinical Guidelines for the use of Blood Products in South Africa (23).

The questionnaire assessed the following:

- professional rank and department of clinicians
- knowledge of risks of blood product administration
- knowledge of resources and costs associated with the transfusion of blood products
- blood product donation, ordering and return
- administration of blood products according to the SANBS guideline (23)
- transfusion thresholds and triggers for blood product administration
- formal blood product education attendance.

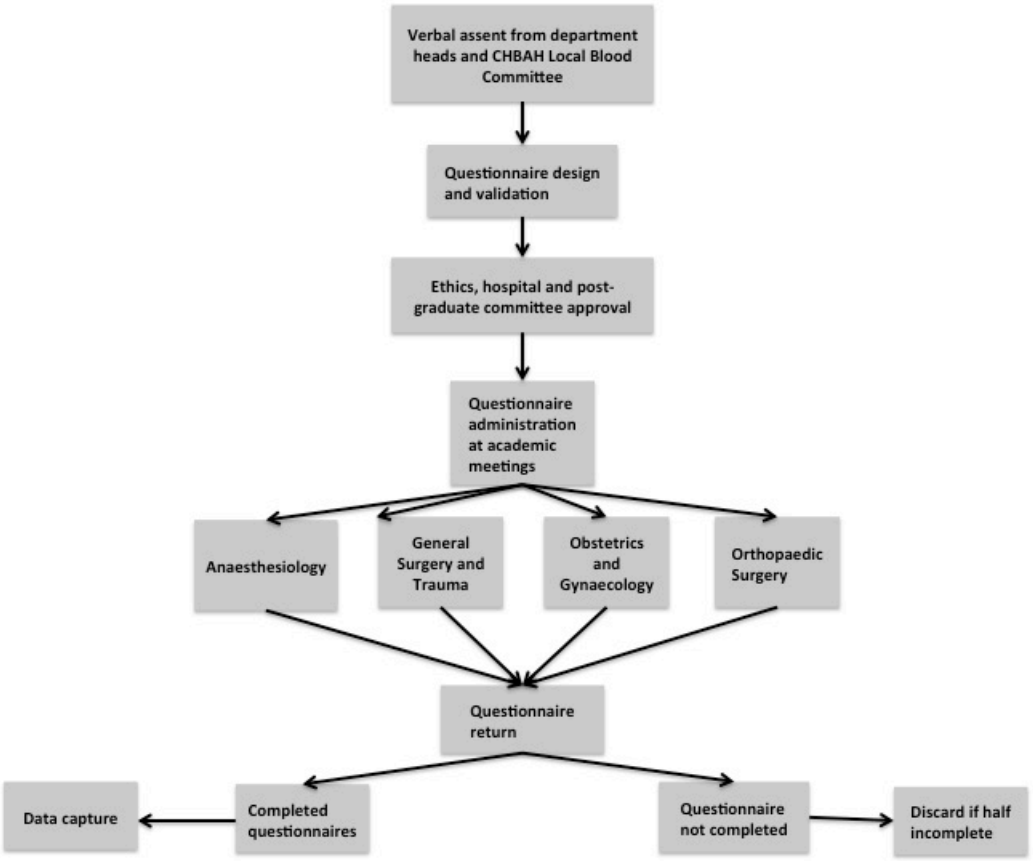
Three senior anaesthesiologists and a senior haematologist, all with blood product expertise, validated the questionnaire. This was done in order to ensure validity and reliability.

Questionnaire distribution

All clinicians fitting the inclusion criteria within the departments outlined were identified with the assistance of the departmental secretary and the Human Resources Department. An indication of appropriate times to approach these clinicians was sought, e.g. departmental academic meetings. The maximum number of attendees at these meetings was also estimated with this assistance.

The questionnaires were distributed on chairs or desks prior to the meetings. The researcher introduced the study verbally at the beginning of the meetings and invited clinicians to participate by completing the questionnaires found on their chairs or desks. The study was explained in an information letter (Appendix 5), introducing the researcher and topic, communicating the aims of the study and inviting the clinicians to participate in the study. The researcher attended the entire meeting to avoid data contamination. Completed questionnaires, sealed in an unmarked envelope, were collected at the end of these meetings and placed in a container. Blank questionnaires were recollected from the chairs or desks. It is unclear whether an individual chose not to complete the questionnaire or if no individual was seated there. Only the researcher and supervisors had access to the raw data, which was kept in a safe place. The researcher entered the data obtained from the questionnaire into a Microsoft Excel for Mac 2011 spread sheet.

Figure 3.1 Questionnaire design and administration flow chart



3.5.5 Data analysis

A bio-statistician was consulted. Data were analysed using descriptive and inferential statistics using Microsoft Excel for Mac 2011 and GraphPad InStat. For descriptive analysis of data that were normally distributed mean and standard deviation (SD) were used. ANOVA testing was used to compare means between groups. A p-value < 0.05 was taken as statistically significant. Unanswered questions were assumed to be the 'don't know' option at data capture. No returned questionnaires were discarded as all had more than half completed.

3.6 Validity

Face validity: this concept is an assessment of the degree to which a research tool appears to measure what it is intended to measure. Experts in the field, based on their intuitive judgement, assess face validity of an instrument (35). In this study the

questionnaire was assessed and validated by three senior anaesthesiologists and a senior haematologist, all with blood product expertise.

Content validity: this concept assesses how well the research tool covers all the components of the variable it proposes to measure, i.e. are the questions asked representative of the phenomenon being studied (35). This questionnaire was developed following an extensive literature review.

Criterion-related validity: this concept is whether an instrument measures what it is expected to measure by comparing it to another measurement tool that is known to be valid (35). Instruments used in similar studies were used as a comparison for the development of the questionnaire.

3.7 Reliability

Reliability refers to the ability of a study or a study instrument to produce consistent, reproducible results if used over time or by different investigators (35). It also refers to the extent to which independent utilisation of the same tool would replicate the same results under similar conditions. The questionnaire was developed following an extensive literature review. Having the questionnaire assessed by three senior anaesthesiologists and a senior haematologist, all with blood product expertise, ensured the reliability of the research tool.

3.8 Conclusion

In this chapter the perceived situation at CHBAH was introduced as a problem statement, followed by the purpose and objectives of this research. In depth discussion of the ethical considerations, research methodology, validity and reliability followed.

Chapter 4 - Data analysis and discussion of results

4.1 Introduction

In this chapter the results of this study are presented as per the research objectives. The data presented include demographic data of the study sample and the knowledge and awareness of clinicians with regard to blood products. The findings are described and analysed using descriptive and inferential statistics and percentages are rounded off to two decimal places.

The primary objectives of this study were to determine the knowledge and awareness of clinicians with regard to:

- risks associated with the transfusion of blood products
- resources and costs associated with the transfusion of blood products
- donations, ordering and return of blood products
- safe administration of blood products to a patient
- transfusion thresholds and triggers for blood product administration.

The secondary objectives of this study were to compare knowledge levels among the different specialty departments and clinician ranks.

The specific questions asked are presented before the results for each objective. The full questionnaire and answers are attached as Appendix 4.

4.2 Results

4.2.1 Demographic data

This study was conducted at CHBAH from January to March 2013. Questionnaires were distributed at departmental academic meetings. The number of attendees had been estimated and questionnaires were distributed on chairs or desks prior to meetings.

There were 210 questionnaires distributed with 172 (81.90%) returned. Anaesthesiology received 60 questionnaires and returned 56 (93.33%). General Surgery and Trauma received 50 questionnaires and returned 36 (72%). Orthopaedic Surgery

received 50 questionnaires and returned 40 (80%). Obstetrics and Gynaecology received 50 and returned 40 (80%). Blank questionnaires collected from desks or chairs after the meetings are included in these figures. It is unclear whether an individual chose not to complete the questionnaire or if no individual was seated there. These data are presented in Table 4.1

Table 4.1 Questionnaire distribution and return rate

Department	Questionnaires distributed per department (Total=210)	Questionnaires returned per department n (%)
Anaesthesiology	60	56 (93.33%)
General Surgery and Trauma	50	36 (72%)
Orthopaedic Surgery	50	40 (80%)
Obstetrics and Gynaecology	50	40 (80%)

Of the 172 returned completed questionnaires 56 (32.55%) were from Anaesthesiology, 36 (20.93%) from General Surgery and Trauma, 40 (23.26%) from Orthopaedic Surgery and 40 (23.26%) from Obstetrics and Gynaecology. No returned questionnaires had to be discarded. These data are presented in Table 4.2

Table 4.2 Completed questionnaire rate

Department	Completed questionnaires per department Total =172 n (%)
Anaesthesiology	56 (32.55%)
General Surgery and Trauma	36 (20.93%)
Orthopaedic Surgery	40 (23.26%)
Obstetrics and Gynaecology	40 (23.26%)

Of the 172 returned questionnaires 49 (28.49%) were from interns, 31 (18.02%) were from medical officers, 57 (33.14%) were from registrars and 35 (20.35%) were from consultants.

In the last two years, formal education on blood products was attended by 59 (34.30%) respondents. No formal education attendance was reported by 102 (59.30%) respondents and 9 (5.23%) did not know if they had attended formal education.

Results relating to the primary objectives are summarised in Table 4.7 for reference purposes.

4.2.2 Knowledge and awareness of clinicians with regard to risks associated with the transfusion of blood products

The first objective of this study was assessed using the following questions with multiple-choice answers.

Is it compulsory to obtain written consent for blood product transfusion at your hospital?

What is the risk, in percentage per transfusion, of blood product administration in South Africa?

- Infectious complication e.g. HIV ?
- Non-infectious complication e.g. acute haemolytic reaction?

The most common cause for an adverse transfusion reaction is?

Is blood product administration immunosuppressive?

Written consent is not required at CHBAH for blood product transfusion. Currently, oral consent is sufficient. Fifty-four (31.40%) respondents answered this correctly, 108 (62.79%) answered incorrectly and 10 (5.81%) respondents did not know the policy at CHBAH.

Infectious risk was correctly quantified by 108 (62.79%) respondents. This risk was overestimated by 31 (18.02%) respondents, underestimated by 5 (2.91%) and 28 (16.28%) did not know the infectious risk percentage. Non-infectious risk was correctly quantified by 83 (48.26%) respondents. This risk was overestimated by 52 (30.23%), underestimated by 2 (1.16%) and 35 (20.35%) respondents did not know the non-infectious risk percentage. These results are presented in Table 4.3

Table 4.3 Knowledge of risk

Risk	Correct Number (n) (%)	Overestimate n %	Underestimate n %	Don't know n %
Infectious Risk	108 (62.79%)	31 (18.02%)	5 (2.91%)	28 (16.28%)
Non-infectious risk	83 (48.26%)	52 (30.23%)	2 (1.16%)	35 (20.35%)

Total risk, for infectious and non-infectious complications, collectively, was correctly quantified by 66 (38.37%) respondents, 19 (22.09%) respondents got both incorrect and 24 (13.95%) did not know the total risk.

Clerical and laboratory error were identified correctly as the main reasons for complications arising from blood product transfusion by 95 (55.23%) respondents. A total of 52 (30.23%) respondents were incorrect. Of these, graft versus host disease was answered by 22 (12.79%) respondents, haemolysis by 28 (16.28%) and infection by 2 (1.16%) respondents. Twenty-five (14.53%) respondents indicated that they did not know the main reasons for complications. These results are presented in Table 4.4

Table 4.4 Clinicians' knowledge of reasons for complications

Correct (clerical or lab error)	**95 (55.23%)**
Incorrect	**52 (30.23%)**
Graft versus host disease	22 (12.79%)
Haemolysis	28 (16.28%)
Infection	2 (1.16%)
Don't know	**25 (14.53%)**

Ninety-three (54.07%) respondents correctly answered that blood product transfusion is immunosuppressive. Thirty-one (18.02%) respondents answered incorrectly. Forty-eight (27.91%) respondents did not know if blood product administration is immunosuppressive.

4.2.3 Knowledge and awareness of clinicians with regard to resources and costs associated with the transfusion of blood products

The second objective of this study was assessed using the following questions with multiple-choice answers.

What is the approximate cost of the following.

- One unit of RCC?
- One unit of platelet concentrate (pooled)?
- One unit of platelet concentrate (single donor apheresis)?
- One unit of FFP?
- A crossmatch?
- A type and screen?

Regarding the costs of blood products, 50 (29.07%) respondents estimated the cost of RCC correctly, 29 (16.86%) estimated the costs of pooled platelets correctly, 51 (29.65%) respondents estimated the costs of single donor platelets correctly and 46 (26.74%) estimated the cost of FFP correctly.

Overestimations were made by 30 (17.44%) respondents regarding the cost of RCC, 38 (22.09%) regarding the costs of pooled platelets and 89 (51.74%) respondents overestimated the cost of FFP. No respondents overestimated the costs of single donor platelets.

Underestimations were made by 80 (46.51%) respondents regarding the cost of RCC, 79 (45.93%) regarding the costs of pooled platelets, 87 (50.58%) regarding the costs of single donor platelets and 12 (6.98%) respondents underestimated the cost of FFP.

No awareness of costs was indicated by 12 (6.98%) respondents regarding the cost of RCC, 26 (15.11%) regarding the costs of pooled platelets, 34 (19.77%) regarding the costs of single donor platelets and 25 (14.53%) regarding the cost of FFP.

Correct estimations of the cost of a crossmatch were made by 14 (8.14%) respondents and of a type and screen by 52 (30.23%) respondents.

Overestimations were made by 11 (6.4%) respondents for the cost of a crossmatch and 41 (23.84%) for the cost of a type and screen.

Underestimations regarding the costs of a crossmatch were made by 127 (73.84%) respondents for a crossmatch and 39 (22.67%) for a type and screen.

Costs were unknown by 20 (11.63%) respondents for a crossmatch and 40 (23.25%) for a type and screen. These data are represented in Table 4.5

Table 4.5 Knowledge regarding costs of blood products and associated processing

Product	Correct number (%)	Overestimate n (%)	Underestimate n (%)	Don't know n (%)
RCC	50(29.07%)	30 (17.44%)	80 (46.51%)	12 (6.98%)
Pooled platelets	29 (16.86%)	38 (22.09%)	79 (45.93%)	26 (15.11%)
Single donor platelets	51 (29.65%)	0 (0%)	87 (50.58%)	34 (19.77%)
FFP	46(26.74%)	89 (51.74%)	12 (6.98%)	25 (14.53%)
Crossmatch	14 (8.14%)	11 (6.4%)	127 (73.84%)	20 (11.63%)
Type and screen	52 (30.23%)	41 (23.84%)	39 (22.67%)	40(23.25%)

4.2.4 Knowledge and awareness of clinicians with regard to donations, ordering and return of blood products

The third objective of this study was assessed using the following questions with multiple-choice answers.

Are blood donors in South Africa voluntary and non-remunerated?
Does your hospital utilise a major surgical blood ordering schedule (MSBOS)?
What is a crossmatch?
What is a type and screen?
Are you aware of the South African National Blood Service hamper system?

Respondents correctly identified blood donors as voluntary and non-remunerated 157 (91.28%) times, incorrectly 6 (3.49%) times and 9 (5.23%) respondents did not know.

CHBAH does not utilise a MSBOS. This was correctly answered by 6 (3.49%) respondents, 87 (50.58%) answered incorrectly and 79 (45.93%) did not know.

Regarding processes for ordering blood products, 83 (48.26%) respondents defined crossmatch correctly, 38 (22.09%) incorrectly and 51 (29.65%) did not know. A correct definition of a type and screen was given by 94 (54.65%) respondents, incorrect definitions by 50 (29.07%) respondents and 28 (16.28%) respondents did not know.

Sixty-six (38.37%) respondents were aware of the SANBS hamper system, 17 (9.89%) were unaware of the system and 89 (51.74%) were uncertain of the hamper system. These data are represented in Table 4.6

Table 4.6 Knowledge regarding donation, ordering and return of blood products

	Donors	**MSBOS utilisation**	**Crossmatch**	**Type and screen**	**Hamper system awareness**
	number (%)	n (%)	n (%)	n (%)	n (%)
Correct	157 (91.28%)	6 (3.49%)	83 (48.26%)	94 (54.65%)	66 (38.37%)
Incorrect	6 (3.49%)	87 (50.58%)	38 (22.09%)	50 (29.7%)	17 (9.89%)
Don't know	9 (5.23%)	79 (45.93%)	51 (29.65%)	28 (16.28%)	89 (51.74%)

4.2.5 Knowledge and awareness of clinicians with regard to safe administration of blood products, transfusion thresholds and triggers

The fourth and fifth objectives of this study were assessed using the following questions with multiple-choice answers.

At what temperature/s can the following blood products be administered:

- RCC?
- Platelets?
- FFP?

A 24 year old male is involved in a motor vehicle accident and suffers severe injuries. He is a non-smoker and has no known comorbid illness. He requires surgery. The operation is accompanied by profuse bleeding. He is resuscitated with crystalloids. He does not exhibit a volume deficit and the bleeding is now controlled. At what haemoglobin (in g/dl) would you transfuse him with red cell concentrate?

One unit of packed red cells should raise the haemoglobin by (in g/dl)? Assume no ongoing bleeding.

At which platelet count ($x10^9$/litre) would you administer platelet concentrate to prevent spontaneous bleeding?

One mega-unit of platelets should normally raise the platelet count by ($x10^9$/litre)?

What would you regard as a safe platelet count ($x10^9$/L) above which an invasive or surgical procedure may be carried out?

Under what circumstances do you administer FFP:

- Coagulopathy with bleeding due to clotting factor deficiency?

- Abnormal laboratory clotting studies with no clinical bleeding (no history of a bleeding diathesis)?
- Abnormal laboratory clotting studies with no bleeding prior to a procedure or surgery?
- Severe burns?
- Massive transfusion?
- Volume expansion?
- Heparin treatment reversal?
- Warfarin treatment reversal?

What is the correct dose of FFP in adults?

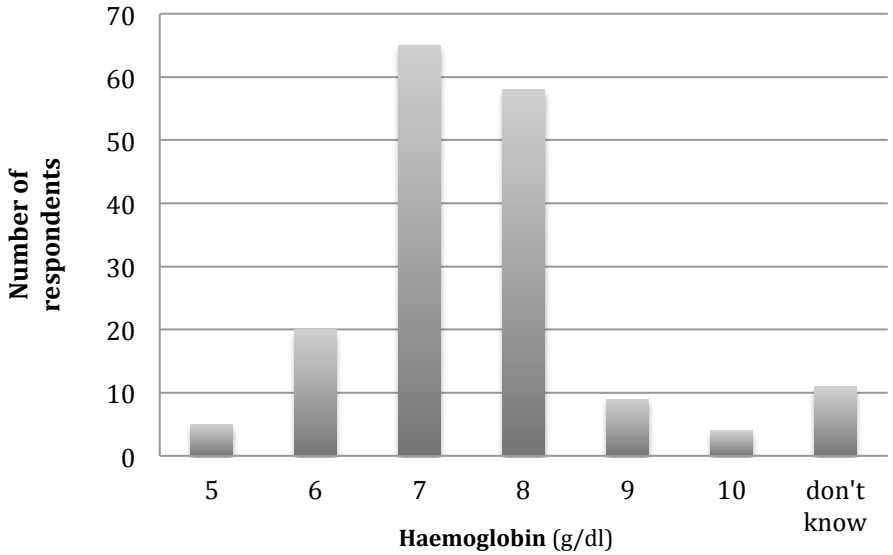
RCC

RCC can be administered cold, at body temperature or at room temperature according to the SANBS. One hundred and sixty eight (97.67%) answered at least one of these options while 4 (2.3%) respondents did not know the correct temperature for administration of RCC.

A total of 123 (71.51%) respondents correctly responded to the haemoglobin trigger question with 7 or 8 g/dl. Respondents answered 7 g/dl 65 (37.80%) times and 8 g/dl 58 (33.72%) times.

Five (2.9%) respondents answered 5 g/dl, 20 (11.63%) answered 6 g/dl, 9 (5.23%) answered 9 g/dl, 4 (2.3%) answered 10 g/dl and 11 (6.40%) were unsure. These data are represented in Figure 4.1

Figure 4.1 Haemoglobin level RCC transfusion trigger



Transfusion of one unit of RCC will increase haemoglobin by 1 to 2 g/dl. This was correctly indicated by 156 (90.69%) respondents, 11 (6.39%) incorrectly and 5 (2.91%) respondents did not know.

Platelets

Platelets should only be transfused at room temperature. This was correctly answered by 90 (52.32%) respondents, incorrectly by 74 (43.02%) and 8 (4.65%) respondents did not know.

A level of 10 x 10^9/litre was identified as correct for transfusion of platelets to prevent spontaneous bleeding by 41 (23.84%) respondents. One hundred and twenty two (70.93%) answered incorrectly and 9 (5.23%) did not know.

One mega-unit of platelets raising the platelet count by 20 to 60 x 10^9/litre was correctly answered by 78 (45.34%) respondents, incorrectly by 55 (31.98%) and 39 (22.67%) did not know.

A safe platelet count, above which an invasive or surgical procedure may be carried out, was correctly answered as 50 x 10^9/litre by 82 (47.67%) respondents, incorrectly by 83 (48.26%) and 7 (4.1%) respondents were unsure.

FFP

Transfusion of FFP at room temperature or body temperature was correctly answered by 143 (83.14%) respondents, incorrectly by 22 (12.79%) and 7 (4.07%) respondents did not know.

The appropriate indication to administer FFP, for a coagulopathy with bleeding due to a clotting factor deficiency, was correctly answered by 150 (87.21%) respondents, incorrectly by 17 (9.88%) respondents and 5 (2.90%) did not know.

The absence of an indication for FFP administration, in SANBS guidelines, for abnormal laboratory clotting studies with no clinical bleeding and no history of a bleeding

diathesis was correctly answered by 137 (79.65%) respondents, incorrectly by 19 (11.05%) and 16 (9.3%) did not know.

The lack of an indication, in SANBS guidelines, for FFP administration for abnormal laboratory clotting studies, with no bleeding prior to a procedure or surgery was correctly answered by 71 (41.28%) respondents, incorrectly by 84 (48.84%) and 17 (9.88%) did not know.

No guideline recommends FFP administration in severe burns. This was correctly indicated by 52 (30.23%) respondents, incorrectly by 80 (46.51%) respondents and 40 (23.26%) respondents did not know.

The indication for FFP administration in a massive transfusion was correctly answered by 152 (88.37%) respondents, incorrectly by 4 (2.32%) and 16 (9.30%) did not know.

The incorrect use of FFP, purely as a volume expander, was correctly identified by 117 (68.02%) respondents, incorrectly by 34 (19.77%) respondents and 21 (12.21%) did not know.

The incorrect use of FFP for heparin treatment reversal was correctly identified by 99 (57.56%) respondents, incorrectly by 46 (26.74%) and 28 (16.28%) did not know.

The correct use of FFP for reversal of warfarin treatment was correctly identified by 126 (73.26%) respondents, incorrectly by 19 (11.04%) and 27 (15.70%) did not know.

The correct dosage of FFP was cited by 66 (38.37%) respondents. An incorrect answer was given by 39 (22.67%) respondents. Of these, 9 (5.23%) respondents answered one unit of FFP, 6 (3.49%) with two units of FFP, 17 (9.88%) with 5 ml/kg and 7 (4.07%) with 50 ml/kg. Sixty-seven (38.95%) indicated that they did not know the correct dosage.

4.2.6 Summary of results

Results concerning the primary objectives are summarised in Table 4.7 for reference purposes.

Table 4.7 Summary of results

	Question	Correct number (%)	Incorrect n (%)	Don't know n (%)
Consent and risk	Consent	54 (31.4%)	108 (62.79%)	10 (5.81%)
	Infectious risk	108 (62.79%)	36 (20.93%)	28 (16.28%)
	Non-infectious risk	83 (48.26%)	54 (31.39%)	35 (20.35%)
	Reasons for complications	95 (55.23%)	52 (30.23%)	25 (14.53%)
	Immunosuppression	93 (54.07%)	31 (18.02%)	48 (27.91%)
Resources, cost, ordering and return	RCC	50 (29.07%)	110 (63.95%)	12 (6.98%)
	Platelets (pooled)	29 (16.86%)	117 (68.02%)	26 (15.12%)
	Platelets (single donor)	51 (29.65%)	87 (50.58%)	34 (19.77%)
	FFP	46 (26.74%)	101 (58.72%)	25 (14.53%)
	Crossmatch	14 (8.14%)	138 (80.23%)	20 (11.63%)
	Crossmatch description	83 (48.26%)	38 (22.09%)	51 (29.65%)
	Type and screen	52 (30.23%)	80 (46.51%)	40 (23.26%)
	Type and screen description	94 (54.65%)	50 (29.07%)	28 (16.28%)
	Donors	157 (91.28%)	6 (3.49%)	9 (5.23%)
	MSBOS	6 (3.49%)	87 (50.58%)	79 (45.93%)
	Hamper awareness	66 (38.37%)	Unaware 17 (9.89%)	89 (51.74%)
Temperature for administration	RCC	168 (97.67%)	0 (0%)	4 (2.33%)
	Platelets	90 (52.33%)	74 (43.02%)	8 (4.65%)
	FFP	143 (83.14%)	22 (12.79%)	7 (4.06%)
Haemoglobin	Trigger transfusion	123 (71.51%)	38 (22.09%)	11 (6.39%)
	One unit RCC raise	156 (90.7%)	11 (6.4%)	5 (2.9%)
Platelets	Prevent spontaneous bleed	41 (23.84%)	122 (70.93%)	9 (5.23%)
	Raise platelet count	78 (45.35%)	55 (31.98%)	39 (22.67%)
	Administration prior to procedure	82 (47.67%)	83 (48.25%)	7 (4.07%)
FFP	Coagulopathy with bleeding	150 (87.21%)	17 (9.88%)	5 (2.91%)
	Abnormal lab test	137 (79.65%)	19 (11.05%)	16 (9.3%)
	Abnormal lab test prior to procedure	71 (41.28%)	84 (48.84%)	17 (9.88%)
	Severe burns	52 (30.23%)	80 (46.51%)	40 (23.26%)
	Massive transfusion	152 (88.37%)	4 (2.32%)	16 (9.3%)
	Volume expansion	117 (68.02%)	34 (19.77%)	21 (12.21%)
	Heparin reversal	99 (57.56%)	46 (26.74%)	28 (16.28%)
	Warfarin reversal	126 (73.26%)	19 (11.05%)	27 (15.7%)
	Correct dose	66 (38.37%)	39 (22.67%)	67 (38.95%)

4.3 Comparison of knowledge levels of the different specialty departments and clinician ranks

The secondary objectives of this study were to compare knowledge levels among the different specialty departments and clinician ranks.

The mean and standard deviation (SD) for correctly answered questions was 16.76 (4.58) from 32 questions for all respondents. Specialty department means were: Anaesthesiology 19.98 (3.84), General Surgery and Trauma 16.28 (4.05), Orthopaedic Surgery 13.83 (4.17) and Obstetrics and Gynaecology 15.63 (3.51). Clinician rank means were: interns' 14.82 (4.49), medical officers' 15.65 (4.03), registrars' 17.0 (4.34) and consultants' 20.09 (3.67). These results are presented in Tables 4.8 and 4.9

Table 4.8 Questionnaire results for specialty departments

	Number of respondents	Mean	Standard deviation
Anaesthesiology	56	19.98	3.84
General Surgery and Trauma	36	16.28	4.05
Orthopaedic Surgery	40	13.83	4.17
Obstetrics and Gynaecology	40	15.63	3.51
Total	172	16.76	4.58

Table 4.9 Questionnaire results for clinician ranks

	Number of respondents	Mean	Standard deviation
Interns	49	14.82	4.49
Medical officers	31	15.65	4.03
Registrars	57	17.0	4.34
Consultants	35	20.09	3.67

4.3.1 Specialty departments

After consultation with a bio-statistician the assumptions for ANOVA (equal variance and normality) were tested and met. ANOVA testing was used to compare means between specialty department groups. The p value was <0.0001, therefore significant. The Bartlett test was not significant, hence the assumption of equal variances across specialties is not violated. Bonferroni testing and correction procedure was used for post-testing to identify where the significant differences lie. A p-value of less than 0.05 was considered to be statistically significant.

ANOVA testing did identify a significant difference between specialty departments and with Bonferroni testing Anaesthesiology performed significantly better (p=0.000) than the other departments. No significant differences in performance were demonstrated between General Surgery and Trauma, Orthopaedic Surgery and Obstetrics and Gynaecology (p>0.05). This is presented in Tables 4.10 and 4.11

Table 4.10 Analysis of variance table for specialty departments

Source of Variation	Degrees of freedom	Sum of squares	Mean square
Treatments (between columns)	3	985.87	328.62
Residuals (within columns)	168	2542.0	15.131
Total	171	3527.9	

F= 21.719

Bartlett statistic (corrected) = 1.192

p= 0.7311

Table 4.11 Bonferroni multiple comparisons test for specialty departments

Comparison	Mean difference	t value	p value
Anaesthesiology vs. Obstetrics and Gynaecology	4.357	5.411	<0.001
Anaesthesiology vs. Orthopaedic Surgery	6.157	7.646	<0.001
Anaesthesiology vs. General Surgery and Trauma	3.704	4.458	<0.001
Obstetrics and Gynaecology vs. Orthopaedic Surgery	1.800	2.069	>0.05
Obstetrics and Gynaecology vs. General Surgery and Trauma	-0.6528	0.7305	>0.05
Orthopaedic Surgery vs. General Surgery and Trauma	-2.453	2.745	>0.05

4.3.2 Clinician rank

After consultation with a bio-statistician the assumptions for ANOVA (equal variance and normality) were tested and met. ANOVA testing was used to compare means between ranks of clinicians. The p value was <0.0001, therefore significant. The Bartlett test was not significant, hence the assumption of equal variances across ranks was not violated. Bonferroni testing and correction procedure was used for post-testing to identify where the significant differences lie. A p-value of less than 0.05 was considered to be statistically significant.

ANOVA testing did identify a significant difference between clinician ranks. With Bonferroni testing consultants performed better than other ranks ($p<0.005$). Interns, medical officers and registrars performed similarly with no significant difference between them demonstrated ($p>0.005$). This is presented in Tables 4.12 and 4.13

Table 4.12 Analysis of variance table for rank

Source of Variation	Degrees of freedom	Sum of squares	Mean square
Treatments (between columns)	3	614.04	204.68
Residuals (within columns)	168	2969.2	17.674
Total	171	3583.2	

F=11.581

Bartlett statistic (corrected) = 1.78

p=0.6193

Table 4.13 Bonferroni multiple comparisons test for rank

Comparison	Mean difference	T value	P value
Consultants vs. registrars	3.086	3.418	<0.001
Consultants vs. medical officers	4.441	4.283	<0.001
Consultants vs. interns	5.269	5.664	<0.001
Registrars vs. medical officers	1.355	1.444	>0.05
Registrars vs. interns	2.184	2.666	>0.05
Medical officers vs. interns	0.8288	0.8591	>0.05

4.4 Discussion

The safety of blood products, obtained from the SANBS, appear to be on a par with international standards and are certainly the safest in Sub-Saharan Africa (48, 51-56). However, risks are not completely eliminated and clinicians' knowledge of the risks associated with blood product administration appears to be poor with only 38.37% of respondents able to accurately quantify both the infectious and non-infectious risk. Just over half of respondents identified the most common cause of an adverse reaction to blood product transfusion as clerical or laboratory error and a similar number appreciated that blood product administration is immunosuppressive. These findings are similar to Irving's South African survey published in 1992 (26) with 30 to 60% of respondents able to appropriately quantify risks of blood product transfusion. Knowledge and the ability to quantify the complications of blood product use are

required to obtain informed consent. The results of this study bring into question the ability of clinicians to obtain informed consent.

Poor awareness of costs was also demonstrated with approximately half of all respondents overestimating costs of FFP, underestimating costs of RCC and platelets and 73.84% underestimating the cost of a crossmatch. Previous surveys have not directly assessed knowledge of blood product costs.

With regard to donations, ordering and return of blood products to the SANBS 91.28% of respondents correctly stated that donors are voluntary and non-remunerated. A lack of understanding of the definitions and difference between a crossmatch and a type and screen was shown with only 48.26% defining a crossmatch correctly and 54.65% defining a type and screen correctly. Respondents indicating that they did not know these definitions numbered 29.65% and 16.28% respectively.

Between 40 and 60% of anaesthesiologists, working in the USA, surveyed in 1987 (12) required that blood be crossmatched for certain procedures indicating the variation in practice at the time. The alternative option of a type and screen was not assessed. Comments in a 2003 survey of members of the American Society of Anesthesiologists (14) seem to indicate that these respondents knew the difference between a crossmatch and a type and screen but cited delays in obtaining blood products when a type and screen was requested and therefore a crossmatch was preferentially requested. The rationality of crossmatching blood was assessed by two studies (64, 65) and a more protocol-based approach to optimise RCC ordering is suggested. These studies (12, 14, 64, 65) did not directly question respondents' knowledge of the difference between a crossmatch and a type and screen. CHBAH does not utilise a MSBOS but knowledge and appropriate application of the system in previous studies (12, 14, 26, 65, 114) was poor. Awareness of the SANBS hamper system was only demonstrated by 38.37% of respondents.

It would seem respondents' knowledge of RCC is better than that of platelets and FFP with 97.67% of respondents indicating an acceptable transfusion temperature, 71.51% indicating an appropriate haemoglobin level transfusion trigger of 7 to 8 g/dl and 90.69% stating that a single unit of RCC would raise the haemoglobin by 1 to 2 g/dl. The trend of accepting a lower haemoglobin, as in previous surveys (12-15, 26, 36, 100, 101, 114), appears to be sustained and is reflected in this study.

Platelet knowledge was not as robust with 23.84% of respondents correctly stating a level of 10 x 10^9/litre at which to transfuse platelets to prevent spontaneous bleeding, 45.34% stating correctly that one mega-unit would raise a platelet count by 20 to 60 x 10^9/litre, 47.67% correctly identifying a platelet count of 50 x 10^9/litre as a safe cut off for surgery and the correct platelet transfusion temperature cited by 52.32% of respondents.

Previous audits and surveys of platelet transfusion triggers (10, 14, 26, 90, 92) also demonstrated poor adherence to guidelines. In these studies anywhere between 20 and 75% of platelet transfusions were in accordance with guidelines at the time and most platelet transfusions are administered to prevent, rather than treat, bleeding.

Clinical use of FFP has grown in the last 20 years (4, 5, 86). Guidelines (23, 24, 71, 72, 76, 78) demonstrate consensus, although vague, on recommendations for fresh frozen plasma transfusion, despite the lack of strong evidence as confirmed in systematic reviews (4, 5, 8, 68, 86). Criticism can be made that no guidelines are complete and authors recommend the production of local guidelines to ensure applicability.

A coagulation defect is the recommended indication for FFP administration (23, 24, 71, 72, 76, 78). Most guidelines state this is a clinical assessment of a coagulopathy i.e.: evidence of bleeding secondary to a coagulopathy. FFP is not recommended prophylactically for correction of abnormal laboratory coagulation tests or prior to invasive procedures, as it has not been proven in this setting (4, 5, 8, 93).

In this study respondents answers to questions based on FFP use were compared to the SANBS guideline (23) and the United Kingdom Handbook of Transfusion Medicine (24). The appropriate use of FFP for coagulopathy with bleeding due to clotting factor deficiency, massive transfusion and reversal of warfarin treatment was correctly answered by 87.21%, 88.37% and 73.26% of respondents respectively. Temperature for administration and dosing of FFP are outlined in guidelines and 83.14% and 38.37% of respondents, respectively, were in line with recommendations. Inappropriate FFP administration for heparin treatment reversal was correctly identified by 57.56% of respondents.

The following indications for FFP are not recommended in guidelines and are not evidence-based. These were therefore assessed as incorrect, if identified as an indication for administration, although clinical scenarios may certainly warrant administration. Responses compared with guidelines were as follows.

- FFP is not indicated in abnormal laboratory clotting studies with no clinical bleeding and no history of a bleeding diathesis - 79.65% of respondents correct.
- FFP is not indicated in abnormal laboratory clotting studies with no bleeding prior to a procedure or surgery - 41.28% of respondents correct.
- FFP is not indicated in severe burns - 30.23% of respondents correct.
- The inappropriate use of FFP, purely, as a volume expander - 68.02% of respondents correct.

Respondents' answers with regard to FFP use were similar to previous reports where FFP appears to have the highest rate of inappropriate use of all blood products (4, 5). Large variations in practice were shown in three assessments of current use of plasma in the United Kingdom and South Africa (6, 7, 11). These authors cited lack of knowledge regarding indications for FFP administration and stated that intervention is necessary to improve rational use.

In this study respondents from Anaesthesiology performed better than their colleagues ($p=0.000$) with a mean 19.98 (3.84) correct answers, although overall results remain disappointing. There were no significant differences in performance of General Surgery and Trauma, Orthopaedic Surgery and Obstetrics and Gynaecology ($p>0.005$). Perhaps the better performance demonstrated by Anaesthesiology respondents can be attributed to observing a clinical response to administration of blood products acutely with patient monitoring.

Among the clinician ranks, consultants performed significantly better ($p\leq0.005$) than their junior colleagues with a mean 20.09 (3.67) correct answers. This is almost certainly due to experience.

When compared with previous surveys and audits (10, 12-15, 26, 36, 65, 100-103, 115, 116) the results of this study are certainly comparable and similarly discouraging. Comparing these results to those of the only previous South African survey (26), conducted in 1992, overall performance is similar although there are differences between questions asked. Areas in which respondents appear to have performed better,

or at least in accordance with current guidelines, are haemoglobin triggers for RCC transfusion, response to RCC administration and massive transfusion protocols. Knowledge of risks, costs, platelet and FFP use are similarly disheartening.

In the last two years formal education on blood products had been attended by 34.30% of respondents. The CHBAH annual seminar (66) is the most likely setting for this education. No evaluation or changes in practice as a result of the seminars have been described or measured. Previous studies (104-107) differ in reporting success with different educational interventions including lectures, meetings, printed materials and audits. Other authors (108-112) posit reasons why clinicians do not follow guidelines. This study did not explore reasons for the apparent poor knowledge or whether guidelines are actually implemented.

4.5 Conclusion

Clinicians' knowledge of risks, resources, costs, ordering and return of blood products is discouraging. Disturbing trends appear to be common and in dispute with some local and international guidelines. Of particular concern is the lack of appropriate knowledge to obtain informed consent and the lack of guidance with regard to FFP administration.

It could be argued that knowledge of costs is inconsequential if blood products are used appropriately and in accordance with guidelines but this does not appear to be the case, particularly with regard to platelets and FFP.

In this chapter the results of this study have been presented and discussed as per the research objectives. The data presented include demographic data of the study sample and responses to a questionnaire. The findings have been described and analysed using descriptive and inferential statistics.

In the final chapter a summary, the limitations, recommendations and conclusions of the study are presented.

Chapter 5 - Summary, limitations, recommendations and conclusions

In this chapter the purpose, objectives, study design and results of this study will be briefly reviewed. The limitations of the study will be addressed, recommendations for clinical practice and further research made and a conclusion presented.

5.1 Summary of the study

5.1.1 Purpose of the study

The purpose of this study was to describe the level of clinicians' knowledge and awareness related to all aspects of the ordering and administration of blood products from the SANBS for perioperative patients at CHBAH.

5.1.2 Objectives of the study

The primary objectives of this study were to determine the knowledge and awareness of clinicians with regard to:

- risks associated with the transfusion of blood products
- resources and costs associated with the transfusion of blood products
- donations, ordering and return of blood products
- safe administration of blood products to a patient
- transfusion thresholds and triggers for blood product administration.

The secondary objectives of this study were to compare knowledge levels among the different specialty departments and clinician ranks.

5.1.3 Summary of the research methodology used in the study

A prospective, descriptive, contextual study design was used. Clinicians working in the Anaesthesiology, General Surgery and Trauma, Orthopaedic Surgery and Obstetrics and Gynaecology Departments at CHBAH belonging to the professional levels intern, medical officer, registrar and consultant formed the sample group studied.

A convenience sampling method, which involves the selection of readily available subjects or objects for a study (35), was used. Approximately 600 doctors are employed at CHBAH (32), of which about 200 work with perioperative patients (32). The true sample size was realised from the number of respondents (38).

Clinicians were invited to take part in the study and were given a self-administered questionnaire (Appendix 4). The questionnaire contained an information letter (Appendix 5) detailing the purpose of the study, Human Research Ethics Committee and CHBAH approvals. The agreement to complete the questionnaire implied consent. The questionnaires were distributed to those clinicians who agreed to participate in the study. The researcher collected questionnaires sealed in an unmarked envelope at the end of these meetings and placed them in a container for subsequent analysis.

5.1.4 Summary of results

There were 210 questionnaires distributed with 172 (81.90%) returned. The departments of Anaesthesiology, General Surgery and Trauma, Orthopaedic Surgery, Obstetrics and Gynaecology were included. Interns, medical officers, registrars and consultants from these departments were included.

The mean total (SD) for correctly answered questions was 16.76 (4.58) from 32 questions for all respondents. Anaesthesiolgy respondents mean was 19.98 (3.84), General Surgery and Trauma 16.28 (4.05), Orthopaedic Surgery 13.83 (4.17) and Obstetrics and Gynaecology 15.63 (3.51).

Interns' mean was 14.82 (4.49), medical officers' 15.65 (4.03), registrars' 17.0 (4.34) and consultants' 20.09 (3.67).

Clinicians' knowledge of the risks associated with blood product administration appears to be poor. Awareness of consent, costs, ordering and administration protocols was also disappointing. In this study respondents from Anaesthesiology performed significantly better than their colleagues and consultants performed significantly better than their junior colleagues.

5.2 Limitations of the study

The main limitations of this study lie in its design and sampling method. The study design was contextual in that it is limited to certain disciplines only and is confined to CHBAH. Results may not be applicable to other academic hospitals in South Africa. The study only provides insight to the situation at CHBAH. Also, interns and medical officers may only work in a particular department temporarily. The use of convenience sampling may contribute to bias.

The questionnaires were distributed on chairs or desks prior to the meetings. The researcher attended the subsequent meeting to avoid data contamination. Blank questionnaires were recollected from the chairs or desks. It is not clear whether an individual chose not to complete the questionnaire or if no individual was seated there.

As the study was reliant on a self-administered questionnaire it depended on the honesty of respondents and the quality of their submitted data. The study also aimed to assess awareness of guidelines. However, awareness cannot be interpreted as use of, or adherence to these guidelines. Correct answers to the questionnaire may not have indicated awareness of the guidelines, but rather may reflect a consistency between the guidelines and the respondents' judgement and knowledge. The use of multiple choice questions in the questionnaire may have increased the measured levels of awareness by offering options that respondents may have been previously unaware.

Heads of Departments and The Local Blood Committee were approached timeously for permission to conduct the study in their departments and were thus aware of the upcoming audit. This may have resulted in an effort to improve the education and knowledge of blood product administration and guidelines in anticipation of the study and hence, may not reflect reality. The results may have been influenced with exposure to guidelines or education that would occur with time or due to the need for awareness of guidelines that the study highlights.

In practice, junior clinicians may be acting on the instruction of senior clinicians. This may have affected their responses. This study did not explore reasons for the apparent poor knowledge or whether guidelines are actually implemented.

5.3 Recommendations from the study

5.3.1 Recommendations for clinical practice

The study has addressed a relevant and particular knowledge deficit within the CHBAH and therefore is of value to the SANBS, management of the institution and clinical departments. Regular formal education on risk, resources, blood product ordering and administration with appropriate feedback may be of value. Regular audits and feedback are also recommended. Attaching information on costs, definitions and risks to the SANBS ordering form may be of benefit to clinicians and patients. The introduction of a MSBOS at CHBAH is also recommended. This will involve discussion with the SANBS, hospital management and medical colleagues.

5.3.2 Recommendations for further research

Research into reasons for the apparent poor knowledge and whether guidelines are actually implemented should be undertaken. Implementation and impact of any educational intervention must be followed up. The blood product transfusion seminar is a potential area for intervention. Should a MSBOS be introduced at CHBAH, the changes in ordering and administration patterns of blood products would need to be assessed.

5.4 Conclusion

Clinicians' knowledge of risks, resources, costs, ordering and return of blood products is discouraging. Disturbing trends appear to be common and in disagreement with some local and international guidelines. Of particular concern is the lack of appropriate knowledge to obtain informed consent and the lack of guidance with regard to FFP administration.

It could be argued that knowledge of costs is inconsequential if blood products are used appropriately and in accordance with guidelines but this does not appear to be the case, particularly with regard to platelets and FFP.

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Appendix 1: Human Research Ethics Committee (Medical) approval

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Dr Bradley J Yudelowitz

CLEARANCE CERTIFICATE	**M120748**
PROJECT	Knowledge and Awareness of Appropriate Blood Product Use in Perioperative Patients among Clinicians at an Academic Hospital
INVESTIGATORS	Dr Bradley J Yudelowitz.
DEPARTMENT	Department of Anaesthesiology
DATE CONSIDERED	27/07/2012
DECISION OF THE COMMITTEE*	Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 27/07/2012 **CHAIRPERSON** .....
(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable
cc: Supervisor : Ms Juan Scribante

DECLARATION OF INVESTIGATOR(S)
To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10004, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES...

Appendix 2: University of Witatersrand Post-Grauduate Committee approval

Faculty of Health Sciences
Medical School, 7 York Road, Parktown, 2193
Fax: (011) 717-2119
Tel: (011) 717-2076

Reference: Ms Salamina Segole
E-mail: salamina.segole@wits.ac.za
19 October 2012
Person No: 0103232F
PAG

Dr BJ Yudelowitz
P O Box 821
Wendywood
Johannesburg
2131
South Africa

Dear Dr Yudelowitz

Master of Medicine (in the specialty Anaesthesia): Approval of Title

We have pleasure in advising that your proposal entitled "*Knowledge and awareness of appropriate blood product use in perioperative patients among clinicians at an academic hospital*" has been approved. Please note that any amendments to this title have to be endorsed by the Faculty's higher degrees committee and formally approved.

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

Appendix 3: CHBAH Medical Advisory Committee Approval

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

MEDICAL ADVISORY COMMITTEE
CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

PERMISSION TO CONDUCT RESEARCH

Date: 29 August 2012

TITLE OF PROJECT: Knowledge and awareness of appropriate blood product use in perioperative patients among clinicians at an academic hospital

UNIVERSITY: Witwatersrand

Principal Investigator: Dr B Yudelowitz

Department: Anaesthesiology

Supervisor (If relevant): Ms J Scribante and Prof E Oosthuizen

Permission Head Department (where research conducted): Will be obtained

Date of start of proposed study: January 2013
Date of completion of data collection: February 2013

The Medical Advisory Committee recommends that the said research be conducted at Chris Hani Baragwanath Hospital. The CEO /management of Chris Hani Baragwanath Hospital is accordingly informed and the study is subject to:-

- Permission having been granted by the Committee for Research on Human Subjects of the University of the Witwatersrand.
- the Hospital will not incur extra costs as a result of the research being conducted on its patients within the hospital
- the MAC will be informed of any serious adverse events as soon as they occur
- permission is granted for the duration of the Ethics Committee approval.

.....
Recommended
(On behalf of the MAC)
Date: 29 August 2012

.....
Approved/Not Approved
Hospital Management
Date: 03/09/12

Appendix 4: Questionnaire

Blood Product Questionnaire

kindly complete ALL questions by *circling* the correct answer

1 Which department do you work in?

Anaesthetics	Orthopaedics	O&G	Trauma	Gen. Surg	other:_____

2 What is your current employment status/ position?

Intern	Comm. Serv.	MO	Registrar	Consultant

3 Does your hospital utilise a **Major Surgical Blood Ordering Schedule (MSBOS)**?

Yes	No	don't know

4 Is it compulsory to obtain **written** consent for blood product transfusion at your hospital?

Yes	No	don't know

5 What is the risk, in **percentage per transfusio**n, of blood product adminstration in South Africa?

5.1	**Infectious** complication e.g. HIV	0%	0.001-1%	1-5%	5-10%	>10%	don't know
5.2	**Non-infectious** complication e.g. acute haemolytic reaction		0%	0.001-5%	5-10%	>10%	don't know

6 The most common cause for an adverse transfusion reaction is?

clerical/lab error	infection	haemolysis	graft versus host disease	don't know

7 Is blood product administration **immunosuppressive**?

Yes	No	don't know

8 What is the approximate **cost** of one unit of the following products?

8.1	**Red cell concentrate?**	<R500	R500-1000	R1000-2000	R2000-3000	R3000-4000	>R4000	don't know
8.2	**Fresh frozen plasma (FFP)?**	<R500	R500-1500	R1500-2500	R2500-3500	R3500-4500	>R4500	don't know
8.3	**Platelet concentrate (pooled)?**	<R1500	R1500-3000	R3000-4500	R4500-6000	R6000-7500	>R7500	don't know
8.4	**Platelet concentrate (single donor apheresis)?**		<R1000	R1000-2500	R2500-4000	R4000-6000	R6000-8000	don't know

9 What are the costs of a **crossmatch** and a **type & screen** and what is the **difference** between them?

9.1	**crossmatch**	<R100	R100-300	R300-500	R500-700	R700-900	>R900

9.2 **What** is a crossmatch? _____

9.3	**type & screen**	<R100	R100-300	R300-500	R500-700	R700-900	>R900

9.4 **What** is a type & screen? _____

10 At what **temperature/s (T°)** can the following blood products be administered? (YOU MAY CHOOSE MORE THAN ONE OPTION)

10.1	Red cell concentrate	cold	room T°	body T°	don't know
10.2	Platelets	cold	room T°	body T°	don't know
10.3	Fresh frozen plasma (FFP) after thawing	cold	room T°	body T°	don't know

Please turn over

11 Are you aware of the South African National Blood Service **hamper** system?

Yes	No	don't know

12 At which platelet count (x10^9/L) would you administer platelet concentrate to **prevent spontaneous** bleeding?

5	10	20	50	100	150	don't know

13 One **mega-unit of platelets** should normally raise the platelet count by (x10^9/L)?

<10	10-20	20-60	>60	don't know

14 What would you regard as a safe platelet count (x10^9/L) above which an **invasive or surgical procedure** may be carried out? (**not** ophthalmic or neurosurgical)

5	10	20	50	100	150	don't know

15 Under what circumstances do you administer FFP?

15.1	coagulopathy with bleeding due to clotting factor deficiency	Yes	No	don't know
15.2	abnormal laboratory clotting studies with no clinical bleeding (no history of a bleeding diathesis)	Yes	No	don't know
15.3	abnormal laboratory clotting studies with no bleeding prior to a procedure or surgery	Yes	No	don't know
15.4	severe burns	Yes	No	don't know
15.5	massive transfusion	Yes	No	don't know
15.6	intravascular volume expansion	Yes	No	don't know
15.7	urgent heparin reversal	Yes	No	don't know
15.8	urgent warfarin reversal	Yes	No	don't know

16 What is the correct dose of FFP in adults?

1 unit	2 units	5ml/kg	10-20ml/kg	50ml/kg	don't know

17 A 24 year old male is involved an motor vehicle accident and suffers severe injuries. He is a non-smoker and has no known comorbid illness. He requires surgery. The operation is accompanied by profuse bleeding. He is resuscitated with crystalloids. He does not exhibit a volume deficit and the bleeding is now controlled. At what haemoglobin (in g/dL) would you transfuse him with red cell concentrate?
red cell concentrate?

5	6	7	8	9	10	don't know

18 One unit of packed red cells should **raise** the haemoglobin by (in g/dL)? Assume no ongoing bleeding.

<0.5	1-2	2-3	>3	don't know

19 Have you received any formal education with regard to transfusion practice in the last 2 years?

Yes	No	don't know

20 Are blood donors in South Africa?

voluntary & remunerated	voluntary & non-remunerated	involuntary & remunerated	involuntary & non-remunerated	don't know

Thank you for your participation

Appendix 5: Information letter

Dear colleague,

Hello, my name is Bradley Yudelowitz and I am an anaesthesiology registrar on the University of the Witwatersrand's anaesthesiology registrar circuit. I would like to invite you to participate in a research study entitled: Knowledge and awareness of appropriate blood product use in perioperative patients among clinicians at an academic hospital**.** This will be handed in to the University of the Witwatersrand, Department of Health Sciences as part of my MMed degree. The study involves the assessment of blood product transfusion practices at Chris Hani Baragwanath Academic Hospital.

The study has been approved by the Human Research Ethics Committee (HREC) (Medical) (Number M120748) and the Post-graduate Committee of the University of the Witwatersrand. Furthermore, permission to conduct the study has been obtained from the CHBAH Medical Advisory Committee, Chairman of the Local Blood Committee and the heads of departments involved.

Consent will be implied by agreeing to complete the questionnaire and is entirely voluntary. Please know that you are free to withdraw from the study at any time without having to provide a reason. Not taking part in or withdrawing from the study carries no penalty or repercussion of any sort.

Questionnaires are not marked in any way for identification and no identifying data will be collected. The questionnaire should only take approximately 10 minutes to complete. Once completed questionnaires will be placed into a sealed envelope. The contents of the completed questionnaires will only be viewed by my research supervisors and myself.

Results published will have no identifying data and will be made available to participants.
The study offers no benefit to participants, but may result in positive changes for the future.

If you have any questions or concerns with regard to the study, you may contact the following people with your queries:

- Professor Cleaton-Jones (chairperson of the HREC): 011 717 1234
- Bradley Yudelowitz (researcher): 0827749114

Thank you for taking the time to read this letter.

Yours sincerely

Bradley Yudelowitz