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A survey of the intraoperative cell salvage in operating rooms at an academic hospital

Yemweni Leonard Yamba

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, 2021

Declaration

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



21 April 2021

Abstract

Background

Intraoperative cell salvage is a process of collecting shed blood from the surgical field, processing and re-infusing it to the patient. The aim of this study was to retrospectively survey the intraoperative cell salvage practice in the operating rooms at CHBAH over eight months.

Methods

A contextual, descriptive, retrospective design with consecutive convenience sampling of intraoperative cell salvage records, anaesthetic charts, patients' files and ICU charts was used.

Results

Intraoperative cell salvage was used in 50 patients, of which three were excluded as no blood was collected, seven other patients did not progress past the standby mode. Of the 47 patients included in the study, 25 (53.2%) were male, with a median (IQR) age of 33 (27.0 – 44.5) years. Of these patients, the majority, 20 (42.6%) were trauma and 30 (63.8%) were emergency patients. The mean (SD) pre- and postoperative haemoglobin levels of elective and emergency patients was 9.1 (3.3) and 12.0 (2.2) g/dl (p=0.0007) and 10.5 (1.50) g/dl and 10.4 (2.7) g/dl (p=0.8903), respectively. Autologous blood was re-infused in 40 (85.1%) patients. The median blood volume re-infused was similar during emergency (459 ml) and elective (466 ml) surgery. The estimated blood loss of 45 (95.7%) patients was more than 500 ml, with a median of 1 700 ml for emergency and 1 000 ml for elective patients (p=0.0120). Homologous blood was transfused in 30 (63.8%) patients. Two makes of cell saver machines were used and 7 (14.9%) non-catastrophic machine related problems were experienced.

Conclusion

This study showed that intraoperative cell salvage, although infrequently used at CHBAH, was used predominantly in emergency trauma-related surgeries with few machine-related complications. Intraoperative cell salvage was initiated approximately when the estimated blood loss volume was greater than 500 ml in most surgeries.

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Abbreviations

CHBAH	Chris Hani Baragwanath Academic Hospital
ICU	Intensive Care Unit
IQR	Interquartile range
FFP	Fresh frozen plasma
RBC	Red blood cell
SD	Standard deviation

Statement

The Research Report consists of a literature review, draft article, study proposal and appendices. The study proposal is included for background reference and is not for examination.

The formatting of this Research Report complies with the University of the Witwatersrand's Style Guide for Theses, Dissertations and Research Reports. The formatting of the draft article may differ from the author guidelines of the Southern African Journal of Anaesthesia and Analgesia, the journal to which it is intended to be submitted, in order to comply with the university's style guide.

Section 1: Review of the literature

1.1 Introduction

Four techniques can be used to transfuse autologous blood, namely preoperative blood donation, acute normovolaemic haemodilution, intraoperative cell salvage and postoperative blood salvage (1). Intraoperative cell salvage, the focus of this study, is also known as intraoperative red blood cell salvage, intraoperative autologous blood transfusion or intraoperative autotransfusion (2).

Intraoperative cell salvage has gained popularity and is used widely in operating rooms. Some of the reasons for this are the improvement in intraoperative cell salvage equipment (3, 4), less risk of transmission of infectious diseases (3), decrease in transfusion related complications (5), blood shortages (4) and cost (6) associated with homologous blood transfusion. Moreover, transfusion of older and stored homologous blood products, specifically in trauma patients, has been independently correlated with increased morbidity and mortality (5, 7).

In this literature review, the history, indications for, contra-indications to, principles of intraoperative cell salvage, re-infused cell salvaged blood volume, homologous blood transfusion, complications of, cost-effectiveness and quality control of intraoperative cell salvage will be discussed.

1.2 Brief history of intraoperative cell salvage

James Blundell (8), in 1818, investigated intraoperative cell salvage use after observing a woman dying of uterine haemorrhage following an unsuccessful resuscitation by the attendants. He used dogs to carry out intraoperative cell salvage.

Although the English surgeon William Highmore (9) was the first person to fully document the use of intraoperative cell salvage in the medical literature as published by the Lancet in 1874, intraoperative cell salvage use is, however, credited to John Duncan of Edinburgh (10). Duncan, in 1885, was the first to practically re-infuse shed collected blood from the surgical field to the patient through a cannulated vein in a stump by using a syringe. The patient was referred

for amputation of his crushed left leg following a railway injury. The re-infusion of autologous blood in the United States of America was used for the first time by Lockwood (11), in 1917.

The modernisation of intraoperative cell salvage equipment is attributed to Klebanoff (12), who, in 1968, invented and utilised the Bentley cardiotomy tube, commercialised by Bentley Laboratories in the 1970s, in open-heart surgery through the process of aspiration, filtration and re-infusion of shed blood from the patient's thoracic cavity back to the patient. In 1966, Richard Dyer's work (13) on collecting blood from mongrel dogs into glasses during surgical procedures was the advent of the collecting reservoir. Wilson and Taswell are credited with being the first to wash blood in a continuous-flow centrifuge, using a reusable stainless steel Latham bowl. They were also the first to describe the processing of autologous blood during intraoperative cell salvage (14).

Finally, the refinement of intraoperative cell salvage apparatus has subsequently dominated the history of intraoperative cell salvage through the introduction of centrifuge-based cell salvage and collecting reservoir systems (14). In 1976, intraoperative cell salvage devices were merchandised by Haemonetics of Braintree, Massachusetts, under the trademark Cell Saver® (11, 14). The term "cell saver" is commonly used to describe intraoperative cell salvage apparatus. Noon et al. (15), in collaboration with Sorenson Research Corporation, manufactured a cheap and practical collecting reservoir system made of a suction tube containing two channels and a collecting canister.

1.3 Indications for intraoperative cell salvage

A better understanding of the functioning and development of equipment for intraoperative cell salvage has led to its use in a wide range of situations (16). General indications or recommendations for intraoperative cell salvage are as follows:

- anticipated blood loss of 20% or more of estimated blood volume for both paediatric and adult patients during elective or emergency surgery (17),

- patients with risk factors for bleeding or with low preoperative haemoglobin (17),
- patients with rare blood groups or multiple antibodies leading to unobtainable cross-match with compatible homologous blood (16, 17),
- patients with objections to homologous blood transfusion but consenting to receive an autologous blood transfusion, for moral, religious (Jehovah's Witness) or other reasons (16, 17),
- more than one unit of homologous blood is required as an estimated transfusion for a particular surgery (16, 18), and
- more than 10% of patients require transfusion for that particular surgical procedure (16, 19).

Intraoperative cell salvage practice is well documented in cardiac surgery and widely used for both on- (20) and off-pump cardiac surgery (21). Other types of surgery where intraoperative cell salvage is used include trauma (22), orthopaedic (23, 24), vascular (25-27), neurosurgery (28, 29), obstetric (30), gynaecological (31), hepatic and biliary surgeries (32). In a survey of equipment and practice of intraoperative cell salvage use in the United Kingdom (33), the highest use was in obstetrics and gynaecology (25%), followed by orthopaedics and vascular surgery (19%). This was followed by trauma and general surgery. It has been, however, used in most of the surgical disciplines with surgical procedures associated with large blood loss.

Intraoperative cell salvage can be indicated in both elective and emergency surgery when blood loss of more than 500 ml in an adult is expected (18), provided that there are no contra-indications and at the discretion of the surgeon and anaesthetist caring for the patient (17). Surgeries with anticipated blood loss of such volume include but are not limited to trauma to the chest (34, 35) and/or abdomen (36), acetabular fracture (37), abnormal placentation (38, 39), ruptured ectopic pregnancy (40, 41), myomectomy (42, 43), craniotomy for arteriovenous malformation (44), open radical prostatectomy (45, 46), radical cystectomy (47,

48), coronary artery bypass graft surgery (49), open abdominal aortic aneurysm surgery (50) and liver transplantation (51) or liver resection surgery (52).

With regard to the urgency of surgery, severely injured patients are prone to excessive blood loss and can present for emergency surgical control of their bleeding following unsuccessful control of the bleeding source through appropriate resuscitation or due to haemorrhagic shock (53). Some obstetrical and gynaecological cases such as abnormal placentation (54) and ruptured ectopic pregnancy (55) can also present for emergency surgery with excessive blood loss pre- and intraoperatively. This highlights the probability of increased blood loss in patients presenting for some major and some emergency surgeries and offer the opportunity of using intraoperative cell salvage. Solomon et al. (56) reported that intraoperative cell salvage was more often used during emergency than elective surgery, and involved mostly trauma-, obstetric- and gynaecological-related procedures. Gonsoulin et al. (57), similarly, reported a significant blood loss in the group of patients coming for emergency hysterectomy compared to those coming for elective hysterectomy.

Some elective surgeries, however, can also be associated with anticipated or unexpected massive blood loss such as cardiopulmonary bypass surgery, aortic aneurysm repair, liver transplantation and certain neurosurgical procedures (58). Forrest et al. (59) reported that intraoperative cell salvage was mainly used during elective surgery and involved predominantly orthopaedic, urological and cardiovascular surgeries.

1.4 Contra-indications to intraoperative cell salvage

Contra-indications to autologous blood are grouped as absolute or relative (16, 17).

1.4.1 Absolute contra-indications

There are few absolute contra-indications and they are mainly related to substances used during intraoperative cell salvage that can result in red blood cell destruction (16). These include the use of alcohol, sterile water, hydrogen peroxide and any other hypotonic solutions. These substances in contact with red

blood cells lead to cell lysis, subsequently causing end-organ damage such as acute kidney injury (60, 61). Hence, for quality control purposes, autologous blood should contain a low or almost undetectable concentration of plasma free haemoglobin before re-infusion.

1.4.2 Relative contra-indications

There are limited data to support the relative contra-indications to intraoperative cell salvage. It is advisable that the medical team, especially the surgeon and anaesthetist, discuss the risks and benefits of intraoperative cell salvage in these circumstances and obtain informed consent from the patient where possible (16).

The relative contra-indications include the presence of certain contaminants, pharmacological agents, haematological disorders, the presence of malignancy (16, 17), miscellaneous substances such as catecholamines (pheochromocytoma) and carbon monoxide (16).

The contaminants regarded as relative contra-indications include amniotic fluid, urine, bone chips, bowel content, fat and infectious substance (16). Clotting agents such as Avitene™, Surgicel™ and Gelfoam™and irrigation solutions such as betadine and topical antibiotics are some of the pharmacological agents regarded as relative contra-indications (16). The presence of disorders such as sickle cell anaemia and thalassemia are haematological disorders that are relatively contra-indicated to the use of intraoperative cell salvaged blood (16).

1.5 Principles of intraoperative cell salvage

Circulating blood in the cardiovascular system is composed of cellular and acellular constituents. Both components are approximately equal in blood volume. The acellular component is made up of plasma, which contains water, coagulation factors, immunoglobulins, electrolytes and proteins such as albumin, α-1 acid glycoprotein, whereas the cellular constituent has erythrocytes, platelets and leucocytes (62).

If blood is centrifuged or allowed to settle in a tube, it will separate based on the density of its components. The heaviest component, the red blood cells, settle at the bottom, in the middle, there is a buffy coat consisting of leucocytes, platelets

and other substances and finally, at the top is the supernatant or the plasma (62). During intraoperative cell salvage, shed anticoagulated blood is aspirated by a double-lumen suction device and it then passes through a filter and into a collecting reservoir, where it is separated by a centrifuge, thereafter it is washed with normal saline and finally suspended in normal saline (63).

Four steps or stages occur during intraoperative cell salvage: collection, separation, washing and re-infusion.

During the first step, collection, a large double-lumen suction catheter connected to a 1 000 ml bag of heparinised saline is used. Heparinised saline runs from one lumen to the tip of the other lumen that aspirates shed blood at low pressure (between 100 – 150 mmHg, up to maximum aspiration pressure of 200 mmHg during increased blood loss) to prevent coagulation (64). Suctioned shed anticoagulated blood passes through a 25 – 40 µm filter into the collecting reservoir (65). The filter removes clots and other large substances or particulate matter (66).

Depending on the surgical procedure and the potential for significant blood loss, only two components, the collecting reservoir and the double-lumen tube, of intraoperative cell salvage can be set up initially before processing the blood in a “standby” mode. The “standby” mode may minimise the cost of the consumables should the shed anticoagulated blood in the collecting reservoir be insufficient for processing (64).

During separation, depending on the centrifuge system, anticoagulated mixed blood is pumped or aspirated into a spinning separation system, which centrifuges the blood to separate the red blood cell concentrate from the supernatant and the buffy coat. Supernatant followed by the buffy coat are discarded through the outer port into the waste bag, while the red blood cells are concentrated to a pre-set haematocrit of 50 – 70% (66).

If the cell saver machine is working in the automatic mode, washing will self-activate and normal saline will flow through the batches or layers of red blood cells to displace the remaining waste products such as cell debris, leucocytes, anticoagulants, free haemoglobin, amniotic fluid components and plasma into the waste line (66).

Finally, at the end of washing, the red blood cells will be suspended in normal saline and emptied into the re-infusate bag ready for re-infusion within six hours from the start of intraoperative cell salvage (67). Hishon et al. (68), in a prospective study of 101 paediatric patients undergoing cardiac surgery where intraoperative cell salvage was used, showed that there were minimal bacterial contamination and chemical changes in salvaged blood kept at room temperature for 18 hours.

1.6 Re-infused cell salvaged blood volume

It is difficult to determine the exact ratios of collected and re-infused blood volume during intraoperative cell salvage. No research has been identified that has determined the ideal percentage of re-infused blood volume from the volume of the collected blood.

Forrest et al. (59) stated anecdotally that the ratio of the collected and re-infused blood during intraoperative cell salvage should be 4:1 based on the assumption that 800 – 1 000 ml of blood in the collection reservoir is required before starting processing a bowl of 225 ml volume. In a case report of two patients who had intraoperative cell salvage, Kamiyoshihara et al. (69) reported that 60% of the 5 000 ml collected blood from the first patient and 32% of the 1 600 ml collected blood from the second patient were re-infused. In a study of intraoperative cell salvage in patients undergoing right hepatectomy, Lutz et al. (70) reported that an average blood volume of 2 435 (± 998) ml was collected and only 421 (±333) was re-infused, representing about 17% of the collected blood volume. These volumes of blood re-infused may depend on the particular surgery or patient risk factors such as risk for bleeding and haemodynamic status.

1.7 Homologous blood transfusion

It is difficult to predict if the re-infusion of autologous blood will be associated with more homologous blood transfusion during emergency than elective surgery or vice versa. No literature was identified at this time that compared the percentage of transfusion of homologous blood during elective versus emergency surgery while intraoperative cell salvage is also being used.

Ashworth et al. (29) demonstrated a reduction in homologous blood transfusion during adult elective procedures when intraoperative cell salvage is used. Brown et al. (71), however, found a reduction of homologous blood use in a group of patients transfused autologous and homologous blood during emergency trauma-related surgical procedures compared to those transfused homologous blood only.

1.8 Complications of intraoperative cell salvage

Complications of intraoperative cell salvage are grouped as machine and patient related.

1.8.1 Machine-related complications

Technical problems may be encountered with the equipment and machines used for intraoperative cell salvage. According to the survey of equipment and practice of intraoperative cell salvage across the United Kingdom by the UK Cell Salvage Group (33), non-catastrophic problems (35%) were experienced and these included software problems, suction problems, human error, broken doors and latches. Sensor failure, incorrect sensor reading, broken bowel sensor, valve failure, screen failure, loose arm holding, blown fuse, centrifuge problem, pumps failure and calibration errors are other associated problems. Maintenance of the equipment is required to minimise these technical problems (33)

1.8.2 Patient-related complications

Potential complications associated with re-infusion of salvaged blood include fat (72) or air (73) embolism, salvaged blood syndrome (74), coagulopathy (75), renal dysfunction (75-77), electrolyte and acid-base imbalance (78).

Fat embolism is associated with lipid molecules generated during the surgical procedure and subsequent embolisation when intraoperative cell salvage is used and autologous blood re-infused (72). During emptying of autologous blood into the re-infusate bag, air moves from the wastage back into the re-infusate bag and can result in air embolism (73). Other complications include salvaged blood syndrome, which is characterised by activation of intravascular coagulation and increased capillary permeability resulting in acute respiratory distress syndrome and renal injury (74). Coagulopathy might occur during re-infusion of large

volumes of autologous blood (more than 2 000 ml) because autologous blood does not contain platelets or clotting factors (75). Renal dysfunction is a potential complication associated with re-infusion of autologous blood and is related to the load of plasma free haemoglobin present in autologous blood (75-77). Electrolyte and acid-base abnormalities are the result of the high content of sodium (154 meq/L) and chloride (154 meq/L) in the normal saline used for washing during intraoperative cell salvage when large volumes of autologous blood are re-infused (78).

1.9 Cost-effectiveness

Studies have been done to compare the cost-effectiveness between the re-infusion of autologous blood and the transfusion of homologous blood. Cost-neutrality between using autologous blood and homologous blood transfusion has been found in some studies (36, 56, 79). However, Blumberg et al. (80) showed incremental hospital costs of about $1,000 – $1,500 per unit of homologous blood transfused when compared with similar patients who were re-infused no blood or 1 – 5 units of autologous blood. Odak et al. (81) also found intraoperative cell salvage in pelvic trauma surgery to be cost-effective. In contrast, Gause et al. (82) found a substantial increase in the use of homologous blood and blood loss when a cell saver was used for autologous blood transfusion during an instrumented lumbar laminectomy and fusion.

1.10 Quality control of a cell saving program

The quality of retrieved blood during intraoperative cell salvage is important to ensure patient safety. Quality concerns include low haematocrit (76) and fibrinogen (83) concentrations, high heparin residual and plasma free haemoglobin concentration, bacterial contamination (76), and the presence of leucocytes and platelets (84, 85).

During intraoperative cell salvage, an initial low haematocrit of the collected blood, 10% during orthopaedic surgery or 15% during cardiac surgery, should be bowl-centrifuged to a predetermined and acceptable value of above 50% (76, 86). A haematocrit of less than 50% shows ineffectiveness of the intraoperative cell

salvage process (76). Regularly measuring haematocrit from autologous blood is advised for quality purposes (76).

A concentration of 25 000 – 30 000 units of heparin mixed with 1 000 ml of normal saline is used for anticoagulation of aspirated blood from the surgical field (76, 83). Monitoring of heparin residual in washed autologous blood should be done periodically to ensure the quality of the autologous blood (76, 83). Normally, 95% of the heparin from collected blood should be eliminated during washing and a concentration target of less than 0.5 unit/ml achieved (76), to prevent coagulopathy associated with a high heparin residual in autologous blood (83, 87).

During intraoperative cell salvage, coagulopathy is also attributed to the removal of proteins (including fibrinogen, anti-thrombin III) and platelets. A low concentration of fibrinogen may also be due to hyperfibrinolysis secondary to the significant generation of thrombin initiated during intraoperative cell salvage (88). It is advisable to monitor the concentration of fibrinogen for quality purposes and a concentration of 20 – 30% of the normal value in the autologous blood is acceptable (40).

A quality assessment should also be performed for the plasma free haemoglobin concentration in shed collected blood, which varies considerably between surgical procedures from as low as 19 mg/dl to as high as 309 mg/dl or more (77). A large concentration of plasma free haemoglobin is a sign of haemolysis and may have complications such as renal dysfunction (77, 89). Adequate centrifugation and washing remove 90 – 98% of plasma free haemoglobin from autologous blood. A low concentration of plasma free haemoglobin in the processed washed autologous blood is innocuous (90).

It is important to periodically assess the quality of autologous blood to determine the presence of leucocytes and platelets. The presence of activated leucocytes and platelets in the ready-to-transfuse autologous blood may induce salvaged blood syndrome or reperfusion syndrome, characterised by disseminated intravascular coagulopathy and/or acute respiratory distress syndrome (74). Innerhofer et al. (91), however, reported contamination of processed washed autologous blood with activated polymorphonuclear cells without any significant clinical outcome. The use of leucocyte depletion filters during re-infusion of

autologous blood minimises the possible occurrence of salvaged blood syndrome and ensures patient safety (65).

Not using an aseptic technique during the intraoperative cell salvage process may lead to bacterial contamination (92, 93). Adequate washing (94) and the use of leucocyte depletion filters (95) can minimise these concerns. In addition, using an aseptic technique (92) and administering prophylactic antibiotics can minimise bacterial contamination (96). It has been suggested that autologous blood samples should be analysed at regular intervals for quality control purposes (90, 97).

Hospitals should regularly audit the practice of intraoperative cell salvage (75, 98). A dedicated collection form should be used to document all the intraoperative cell salvage procedures and volumes of autologous blood re-infused to the patients (75).

The availability of the trained staff members or technicians operating the intraoperative cell salvage and equipment 24 hours a day is highly recommended in hospitals where surgery with a large blood volume loss is expected (98). Szpisjak et al. (99) demonstrated that, in four models for reducing the cost of intraoperative cell salvage, cross-training an existing employee to play the role of a technician was efficient in reducing the cost when the caseload of patients per year was more than 55. The Association of Surgical Technologists (100) recommends the use of intraoperative cell salvage to be undertaken by a Certified Registered Technologist® (technician) for best practices.

1.11 Summary

In this section, a brief history of intraoperative cell salvage is presented followed by a discussion of the indications, contra-indications, the principles, of intraoperative cell salvage. The re-infused cell salvage volume, homologous blood transfusion, complications, cost-effectiveness and quality control of intraoperative cell salvage is also discussed.

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The following are sample references:

1. Jun BC, Song SW, Park CS, Lee DH, Cho KJ, Cho JH. The analysis of maxillary sinus aeration according to aging process: volume assessment by 3-

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Section 3: Draft article

A survey of the intraoperative cell salvage in operating rooms at an academic hospital

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Key words: intraoperative cell salvage, autologous blood, homologous blood

Abstract

Background

Intraoperative cell salvage is a process of collecting shed blood from the surgical field, processing and re-infusing it to the patient. The aim of this study was to retrospectively survey the intraoperative cell salvage practice in the operating rooms at CHBAH over eight months.

Methods

A contextual, descriptive, retrospective design with consecutive convenience sampling of intraoperative cell salvage records, anaesthetic charts, patients' files and ICU charts was used.

Results

Intraoperative cell salvage was used in 50 patients, of which three were excluded as no blood was collected, seven other patients did not progress past the standby mode. Of the 47 patients included in the study, 25 (53.2%) were male, with a median (IQR) age of 33 (27.0 – 44.5) years. Of these patients, the majority, 20 (42.6%) were trauma and 30 (63.8%) were emergency patients. The mean (SD) pre- and postoperative haemoglobin levels of elective and emergency patients was 9.1 (3.3) and 12.0 (2.2) g/dl (p=0.0007) and 10.5 (1.50) g/dl and 10.4 (2.7) g/dl (p=0.8903), respectively. Autologous blood was re-infused in 40 (85.1%) patients. The median blood volume re-infused was similar during emergency (459 ml) and elective (466 ml) surgery. The estimated blood loss of 45 (95.7%) patients was more than 500 ml, with a median of 1 700 ml for emergency and 1 000 ml for elective patients (p=0.0120). Homologous blood was transfused in 30 (63.8%) patients. Two makes of cell saver machines were used and 7 (14.9%) non-catastrophic machine related problems were experienced.

Conclusion

This study showed that intraoperative cell salvage, although infrequently used at CHBAH, was used predominantly in emergency trauma-related surgeries with few machine-related complications. Intraoperative cell salvage was initiated approximately when the estimated blood loss volume was greater than 500 ml in most surgeries.

Introduction

Intraoperative cell salvage has gained popularity and is used widely in operating rooms. Some of the reasons for this are the improvement in intraoperative cell salvage equipment (1, 2), less risk of transmission of infectious diseases (1), decrease in transfusion-related complications (3), blood shortages (2) and cost (4) associated with homologous blood transfusion. Moreover, transfusion of older and stored homologous blood products, specifically in trauma patients, has been independently correlated with increased morbidity and mortality (3, 5). However, intraoperative cell salvage is not without potential consequences such as coagulopathy, especially when large volumes of autologous blood are re-infused (6), fat (7) and air (8) embolism, salvaged blood syndrome (9), renal dysfunction (10), acid-base and electrolyte abnormalities (11).

Studies compared the cost-effectiveness between the re-infusion of autologous blood and the transfusion of homologous blood. Cost-neutrality between using autologous blood and homologous blood transfusion has been found in some studies (12-14). However, Blumberg et al. (15) showed incremental hospital costs of about $1 000 – $1 500 per unit of homologous blood transfused when compared with similar patients who were re-infused no blood or 1 – 5 units of autologous blood. Odak et al. (16) also found intraoperative cell salvage in pelvic trauma surgery to be cost-effective. In contrast, Gause et al. (17), in a retrospective audit of 188 patients following instrumented lumbar laminectomy and fusion, found an increase in cost with the use of intraoperative cell salvage due to significant bleeding and the need for concurrent use of homologous blood.

Hospitals should regularly audit the practice of intraoperative cell salvage (18, 19). A dedicated collection form should be used to document all the intraoperative cell salvage procedures and volumes of autologous blood re-infused to the patients and kept in the patients' files for regular audit (18). The operating rooms at Chris Hani Baragwanath Academic Hospital (CHBAH) are resource-restricted and patients presenting for certain surgeries have high blood transfusion requirements. Intraoperative cell salvage is used in surgical procedures where substantial blood loss is expected at the discretion of the surgeon and anaesthetist. However, the practice of intraoperative cell salvage at CHBAH has not been described

previously. The aim of this study is to retrospectively survey the intraoperative cell salvage practice in the operating rooms at CHBAH over an eight-month period.

Methods

A contextual, descriptive, retrospective study design was followed. Approval to conduct the study was obtained from the Human Research Ethics Committee (Medical) and other relevant authorities.

The study population consisted of all the records of the patients who had intraoperative cell salvage performed during surgical procedures, between 1 January and 31 August 2019, in the operating rooms at CHBAH. A consecutive, convenience sampling method was used.

The data collection sheet, a Microsoft Excel® spreadsheet, consisted of data already collected for clinical management purposes from the intraoperative cell salvage records, anaesthetic charts, patients' files and ICU charts. The collected data included:

- participant characteristics
- the patient's pre and postoperative haemoglobin
- the autologous blood volume collected, processed and re-infused intraoperatively and postoperatively
- estimated blood volume loss intraoperatively
- units of homologous blood and blood products transfused intraoperatively or postoperatively
- make of cell saver machine used and complications related to the use of cell saver machines
- postoperative destination of the patients.

The surgical disciplines included in the study were trauma, general surgery, orthopaedics, neurosurgery, vascular surgery, obstetrics and gynaecology. The Haemonetics Cell Saver 5® and Haemonetics Cell Saver ELITE® machines were used during the study. The data were collected by one author (YLY).

Categorical data are presented using percentages and frequencies. Continuous variables were described using means and standard deviations, interquartile

ranges and minimum and maximum ranges depending on the distribution of the data. For normally distributed groups comparisons were made using independent t-tests with a Welsh correction for unequal variances and Mann Whitney U tests were used if groups were not normally distributed. A p-value of < 0.05 was considered statistically significant. Where data were incomplete and excluded from the analyses, this is indicated.

Results

Intraoperative cell salvage was initiated in 50 patients during the study period. Three patients had no blood collected at all and did not progress past the standby stage and were not included in the analysis. The trajectory of intraoperative cell salvage use is shown in Figure 1.

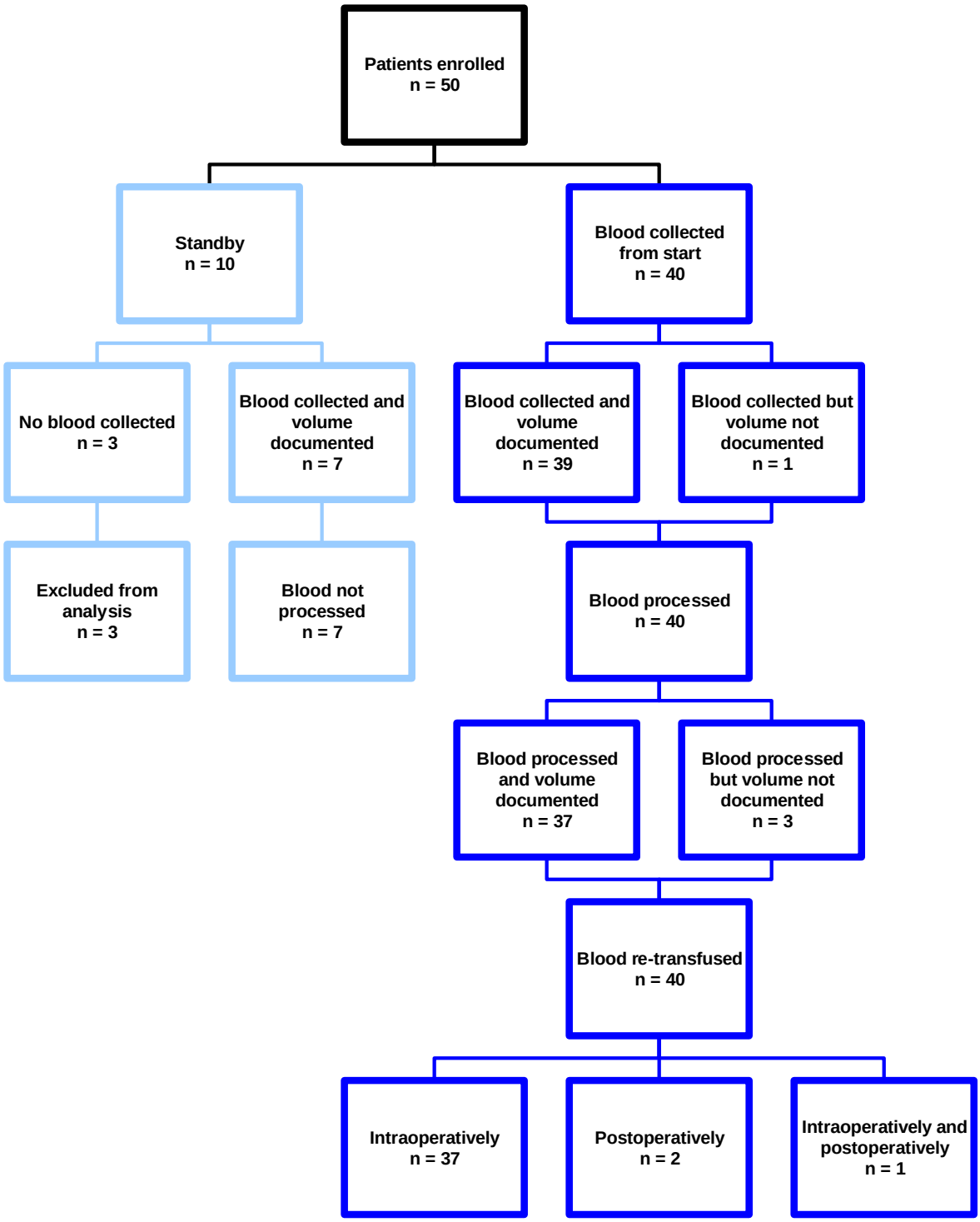


Figure 1 Trajectory of intraoperative cell salvage use

Of the 47 patients included in the study, 25 (53.2%) were male and 22 (46.8%) were female. The patients' median (IQR) age was 33 (27.0 – 44.5) years with a minimum of 20 years and a maximum of 75 years. The surgical discipline, type of surgery, indication for surgery and urgency of surgery are shown in Table 1.

Table 1 Surgical discipline, type of, indication for and urgency of surgery

Variable	Number	Percentage
Surgical discipline		
General surgery	2	4.3
Trauma	20	42.6
Orthopaedics	10	21.3
Neurosurgery	2	4.3
Obstetrics	9	19.2
Gynaecology	2	4.3
Vascular	2	4.3
Type of surgery		
Laparotomy	12	25.5
Open reduction and internal fixation	10	21.3
Caesarean section	6	12.8
Thoracotomy	6	12.8
Total abdominal hysterectomy	3	6.4
Other	10	21.3
Indication for surgery		
Gunshot wound of chest and/or abdomen	14	29.8
Acetabular fracture	10	21.3
Stab chest	5	10.6
Caesarean section related procedures	6	12.8
Postpartum haemorrhage	3	6.4
Other	9	19.1
Urgency of surgery		
Elective	17	36.2
Emergency	30	63.8

Other types of surgery consisted of 2 craniotomies, 2 open vascular surgeries, 2 sternotomies, 2 relook laparotomies, 1 hepatic resection, and 1 Whipple procedure. Other indications for surgery consisted of 2 abdominal aortic aneurysms, 2 ruptured ectopic pregnancies and 2 hepatobiliary diseases, 1 blunt abdominal trauma, 1 arteriovenous malformation in the brain and 1 brain tumour.

The mean (SD) preoperative haemoglobin levels of the elective and emergency patients were 9.1 (3.3) and 12.0 (2.1) g/dl, respectively. There was a statistically significant difference between these haemoglobin levels (p=0.0007). The mean (SD) postoperative haemoglobin levels of the elective and emergency patients were 10.5 (1.5) g/dl and 10.4 (2.7) g/dl respectively with no statistically significant difference between the two (p=0.8903).

The urgency of surgery, indication for surgery, blood volume collected and the reason for not processing the blood for the 7 patients who were initially on standby mode are shown in Table 2. Three of these patients received homologous blood.

Table 2 Urgency of surgery, indication of surgery, blood volume collected and the reason for not processing the blood for the 7 patients who were initially on the standby mode

	Urgency of surgery	Indication	Volume (ml)	Reason for not processing blood
1	Emergency	Gunshot wound abdomen	400	Insufficient volume
2	Emergency	Gunshot wound abdomen	200	Insufficient volume
3	Emergency	Imminent uterine rupture	800	Demised
4	Elective	Placenta praevia	200	Insufficient volume
5	Elective	Extra uterine pregnancy	250	Insufficient volume
6	Elective	Hepatobiliary disease	700	Decided not to process
7	Elective	Acetabular fracture	750	Decided not to process

The volumes of autologous blood collected, processed and re-infused, as well as the estimated volume of intraoperative blood loss, are shown in Table 3. As per Figure 1, please note that volumes were not documented for all patients and only those with recorded volumes are included. The volumes of blood re-infused were documented for all 40 patients who were re-infused, although the volume of blood processed was only documented for 37 of these patients. Estimated blood loss volumes were documented for 29 emergency and 17 elective surgery patients. Only 2 (4.3%) of these patients had an estimated blood loss of less than 500 ml. The median (IQR) estimated blood loss for the emergency surgery patients was 1 700 (1 100 – 3 000) ml and for the elective surgery patients, it was 1 000 (800 – 1 500) ml. There was a statistically significant difference between these two volumes (p=0.0120).

Table 3 Autologous blood volumes and estimated blood loss

Autologous blood	Median	IQR	Total
Collected*:			
• Total (n=46)	1 000	800 – 1 785	64 248
• Emergency (n=29)	1 045	850 – 2 000	46 102
• Elective (n=17)	1 000	735 – 1 441	18 146
Processed:**			
• **Total** (n=37)	2 630	1 880 – 3 924	124 014
• **Emergency** (n=27)	2 630	1 801.5 – 3 712	92 574
• **Elective** (n=10)	2 500	2 033.5 – 4 190.3	31 440
Re-transfused intraoperatively:			
• **Total** (n=37)	459	324 – 690	21 074
• **Emergency** (n=25)	459	324 – 689	14 459
• **Elective** (n=12)	466	369.3 – 692.5	6 565
Re-transfused postoperatively:			
• **Total** (n=2)	288.5	257.8 – 319.3	577
• **Emergency** (n=1)	NA	NA	227
• **Elective** (n=1)	NA	NA	350
Re-transfused both intraoperatively and postoperatively:			
• **Total** (n=1)	NA	NA	700
• **Emergency** (n=1)	NA	NA	700
• **Elective** (n=0)	NA	NA	0
Estimated blood loss intraoperatively:			
• **Total** (n=46)	1 500	1 000 – 2 325	84 600
• **Emergency** (n=29)	1 700	1 100 – 3 000	63 450
• **Elective** (n=17)	1 000	800 – 1 500	21 150

*Collected: Blood from surgical field into the reservoir. **Processed: Blood drawn from reservoir + fluids from surgical field + wash fluid

Of the 47 patients included in the study, 30 (63.8%) patients received homologous blood with 25 (83.3%) being emergency surgery patients. Of these 3 (6.4%) patients received homologous blood only and 27 (57.4%) received both homologous and autologous blood. Thirteen (27.7%) patients received autologous blood only and 4 (8.5%) received no blood products at all. Table 4 shows the units of different types of homologous blood products transfused intraoperatively to emergency and elective patients.

Table 4 Units of different types of homologous blood products transfused intraoperatively to emergency and elective patients

Blood product	Patients n (%)			Units transfused n (%)	
	Total	Emergency	Elective	Emergency	Elective
RBC*	29 (61.7)	24 (51.1)	5 (10.6)	76 (90.5)	8 (9.5)
FFP**	19 (40.4)	16 (34.0)	3 (6.4)	67 (91.8)	6 (8.2)
Platelets	10 (21.3)	10 (100)	0 (0)	12 (100)	0 (0)
Cryoprecipitate	6 (12.8)	6 (100)	0 (0)	59 (100)	0 (0)

∗ RBC: Red blood cells. ∗∗FFP: Fresh frozen plasma

Table 5 shows the combination of different blood products and autologous blood and the number of patients to whom they were transfused.

Table 5 Combination of different blood products and autologous blood and the number of patients to whom they were transfused

Different blood products transfused	Homologous blood	Autologous blood
	Patients n (%)	
RBC*	11 (36.7)	10 (90.9)
FFP**	1 (3.3)	1 (100)
RBC+ FFP	7 (23.3)	5 (71.4)
RBC + FFP + platelets	5 (16.7)	5 (100)
RBC + FFP + cryoprecipitate	1 (3.3)	1 (100)
RBC + FFP + platelets + cryoprecipitate	5 (16.7)	5 (100)
Total	30 (100)	27 ((90.0)

∗ RBC: Red blood cells ∗∗FFP: Fresh frozen plasma

Seven (14.9%) non-catastrophic problems were encountered with the cell saver machines. The cell saver machine make and problems encountered during use are shown in Table 6.

Table 6 Cell saver make and problems encountered

Cell saver machine make	How often used n (%)	Problems	Number (%)
Haemonetics Cell Saver Elite®	38 (80.9%)	Sensor malfunction	2 (11.1)
		Run on manually only	1 (11.1)
		Did not work	0 (0)
Haemonetics Cell Saver 5®	9 (19.1%)	Sensor malfunction	2 (11.1)
		Run on manually only	1 (11.1)
		Did not work	1 (11.1)

Postoperatively 22 (46.8%) patients were transferred to the intensive care unit, 6 (12.8%) to the high care unit, 16 (34.0%) to the wards and there were 3 (6.4%) deaths on the table.

Discussion

Intraoperative cell salvage practice has been previously indicated in a variety of different surgical disciplines such as trauma (20), orthopaedic (21, 22), cardiac (22-24), vascular (25-27), neurosurgery (28, 29), obstetric (30), gynaecological, specifically ruptured ectopic pregnancy (31), hepatic and biliary procedures (32). Intraoperative cell salvage is used at CHBAH for all these disciplines, except for cardiac surgery, as this is not done at the hospital. In this study, intraoperative cell salvage was used most commonly in trauma surgery (42.6%), which is not surprising as the incidence of trauma in South Africa is known to be high (33). This was followed by obstetrics and gynaecology (23.5%). Intraoperative cell salvage was used more often during emergency (63.8%) surgeries possibly due to the high number of trauma-related surgical procedures. In a survey of equipment and practice of intraoperative cell salvage use in the United Kingdom (34) the highest use was in obstetrics and gynaecology (25%) and only 10% of use was in trauma, which ranked in fourth place. CHBAH is a central hospital with a large number of obstetrical patients, approximately 32 000 annually, presenting both for normal vaginal or caesarean section delivery. It is, however, impractical to initiate the intraoperative cell salvage in all the patients with a potential risk of significant blood loss, due to time constraint and lack of personnel to set it up. Additionally, cell salvage machines were not always available in the obstetric theatres at all times during this study which may account for the low usage in obstetrics over the study period.

It is recommended that intraoperative cell salvage is used in surgeries with an anticipated blood volume loss of 500 ml or more (35). In this study, 95.7% of patients had an estimated blood loss of more than 500 ml, indicating that the choice of surgeries for intraoperative cell savage use was appropriate. The surgeries for which intraoperative cell salvage was used most in this study were gunshot wounds to the chest and/or abdomen (29.8%), acetabular fractures (21.3%) and stabbed chests (10.6%). These surgeries are known to have a large

blood loss (13, 36, 37). CHBAH has a specialised unit for pelvic trauma surgery which may account for the 10 patients with acetabular fractures receiving intraoperative cell salvage.

Intraoperative cell salvage is frequently used for religious or moral reasons such as in Jehovah's Witnesses (38, 39). Jehovah's Witnesses do present for surgeries at CHBAH, however, during this study period, none presented for surgery where intraoperative cell salvage was indicated.

Approximately 65 000 surgeries are performed annually at CHBAH, although not all require anaesthetist involvement. Of these cases, approximately 12 000 are major emergency surgeries. It is acknowledged that not all major emergency surgeries result in major bleeding requiring blood transfusion. However, as only 30 emergency surgeries had intraoperative cell salvage documented over the eight-month study period, this may indicate that opportunities for intraoperative cell salvage are lost. No assistance is available from technicians during intraoperative cell salvage at CHBAH and salvageable blood may be lost prior to the anaesthetist setting up the cell saver machine, especially in emergencies where anaesthetists may be busy anaesthetising a potentially unstable patient. Other reasons for lost salvageable blood might be contaminated blood and clotted blood that cannot be retrieved. Annually there are approximately 20 000 major elective surgeries conducted at CHBAH. The nature of many of these surgeries may lend themselves to the use of intraoperative cell salvage, however, only 17 cases of intraoperative cell salvage were documented for elective surgery during the study period. A possible explanation for this could be that when large volumes of blood loss are anticipated in patients going for elective surgery, blood is ordered from the blood bank prior to the surgery. Once blood bank blood is available, it is less labour intensive to use than to commence intraoperative cell salvage. Intraoperative cell salvage may also be infrequently used in both emergency and elective surgeries due to a lack of intraoperative cell salvage consumables and having no technician to assist with the procedure. Infrequent use of intraoperative cell salvage is not attributed to a lack of operator confidence as training is frequent and ongoing in the department.

In this study, the median volume of blood re-infused was similar between the emergency and elective surgery patients (459 ml and 466 ml respectively). As the estimated blood loss was greater in the emergency surgery patients, it could have been expected that the re-infused volumes would also have been greater. As mentioned, no assistance is available from technicians and salvageable blood may be lost prior to the anaesthetist setting up the cell saver machine, especially in emergencies where anaesthetists may be busy anaesthetising a potentially unstable patient.

This study shows that 57.4% of patients were transfused homologous blood products, with more units being transfused to the emergency than elective surgery patients. As intraoperative cell salvage returns only packed red cells to patients and not other blood products such as platelets and clotting factors this finding could be expected.

In this study, 20% of patients did not progress past the standby mode, which is similar to a study by Waters et al. (40) where 16.8% of patients did not progress further than the standby mode. This is much lower than in the study by Milne et al. (41), where 79% of patients did not progress past this mode. When using intraoperative cell salvage, one must be cognisant of cost. The cost of having a patient on standby is equivalent to cross-matching, two units of red blood cells (39). However, anticipating in advance if a patient is going to progress beyond the standby mode is not always easy due to difficulty in accurately predicting the intraoperative blood loss (42).

There was a significant difference between the preoperative haemoglobins of patients going for elective and emergency surgery with the latter having lower haemoglobins. This could be due to the nature of the injury such as gunshot wounds and stabs to the chest and abdomen where it is known that large volumes of blood can be lost (13, 43, 44). Haemodilution, as a result of aggressive fluid resuscitation, could also result in these lower haemoglobins. These patients are ideal candidates for intraoperative cell salvage as ordering blood from blood bank inevitably results in a delay in commencing blood replacement.

In this study, two makes of cell saver machine were used and non-catastrophic problems (14.9%) were encountered during surgeries. This is lower than the 35%

in the United Kingdom Cell Salvage Action Group survey (34). None of their problems were catastrophic either. When using equipment, technical problems could be kept to a minimum by having an adequate maintenance program and trained staff, especially qualified technicians (19). At CHBAH, there is formal training for anaesthetists, but no qualified technicians are available.

The results of this study must be read against the limitations of it being a retrospective study with a small sample size. It is suggested that further research be conducted into the cost-effectiveness of intraoperative cell salvage and the reasons why it is so seldom used in the department. The quality of the cell salvaged blood should be regularly audited, as suggested by Klein et al. (19).

Conclusion

Blood is a scarce and expensive resource in South Africa and intraoperative cell salvage could contribute to better utilisation of available blood resources. This study showed that intraoperative cell salvage, although infrequently used at CHBAH, was used predominantly in emergency trauma-related surgeries with few machine-related complications. Intraoperative cell salvage was initiated appropriately when the estimated blood loss volume was greater than 500 ml in most surgeries.

Conflict of interest

The authors declare that we have no financial or personal relationships which may have inappropriately influenced us in writing this paper.

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Section 4: Proposal

A survey of the intraoperative cell salvage in operating rooms at an academic hospital

Yemweni L Yamba

1596049

Supervisor	Helen Perrie Department of Anaesthesiology
Co-supervisor	Juan Scribante Department of Anaesthesiology
Co-supervisor	Melissa Kim Stubbs Department of Anaesthesiology

4.1 Introduction and problem statement

Four techniques can be used to transfuse autologous blood namely, preoperative blood donation, acute normovolemic haemodilution, intraoperative cell salvage and postoperative blood salvage (1). Intraoperative cell salvage, the focus of this study, is also known as intraoperative red blood cell salvage, intraoperative autologous blood transfusion or intraoperative autotransfusion (2).

Intraoperative cell salvage has gained popularity and is used widely in operating rooms. Some of the reasons for this are the improvement in intraoperative cell salvage equipment (3, 4), less risk of transmission of infectious diseases (3), decrease in transfusion related complications (5), blood shortages (4) and cost (6) associated with homologous blood transfusion. Moreover, transfusion of older and stored homologous blood products, specifically in trauma patients, has been independently correlated with increased morbidity and mortality (5, 7).

Studies have been done to compare the cost-effectiveness between the re-infusion of autologous blood and transfusion of homologous blood. Cost-neutrality between using autologous blood and homologous blood transfusion has been found in some studies (8-10). However, Blumberg et al. (11) showed incremental hospital costs of about $1,000 – $1,500 per unit of homologous blood transfused when compared with similar patients who were re-infused no blood or 1 – 5 units of autologous blood. Odak et al. (12) also found cost-effectiveness of intraoperative cell salvage in pelvic trauma surgery. In contrast, Gause et al. (13) found a substantial increase in the use of homologous blood and blood loss when a cell saver was used for autologous blood transfusion during an instrumented lumbar laminectomy and fusion.

The use of intraoperative cell salvage should be individualised by taking into consideration the patient’s starting haemoglobin or haematocrit, age and gender (14). Intraoperative cell salvage is indicated in both elective and emergency surgery when blood loss of more than 500 ml in adult patients is expected (15), provided that there are no contra-indications (16), as well in the case of low preoperative haemoglobin (16). Where uncertainty exists regarding the need for blood transfusion intraoperatively, the cell saver can be set-up in “standby” mode.

The “standby” mode cost is equivalent to that of the reagents used to cross-match two units of homologous blood (14).

Autologous blood collected following intraoperative cell salvage should be labelled with patient demographics and re-infused within four to six hours of completion of processing (17) .The re-infusion of autologous blood is not without risks or complications. Potential complications associated with re-infusion of salvaged blood include fat (18) or air (19) embolism, salvaged blood syndrome (20), coagulopathy (21), renal dysfunction (21-23), electrolyte and acid-base imbalance (24).

Hospitals should regularly audit the practice of intraoperative cell salvage (21, 25). A dedicated collection form should be used to document all the intraoperative cell salvage procedures and volumes of autologous blood re-infused to the patients (21). The operating rooms at Chris Hani Baragwanath Academic Hospital (CHBAH) are resource restricted and patients presenting for certain surgeries have high blood transfusion requirements. Intraoperative cell salvage is used in surgical procedures where substantial blood loss is expected at the discretion of the surgeon and anaesthetist. However, the practice of intraoperative cell salvage at CHBAH has not been described previously.

4.2 Aim and objectives

4.2.1 Aim

The aim of this study is to retrospectively survey the intraoperative cell salvage practice in the operating rooms at CHBAH over an eight-month period.

4.2.2 Objectives

The objectives of the study are to:

- determine the surgical disciplines and types of surgery for which intraoperative cell salvage was used
- determine the indications of the surgery

- determine if the surgery was an emergency or elective procedure
- determine the pre and postoperative haemoglobin
- determine the volume of the blood collected, processed and re-transfused following intraoperative cell salvage
- determine the additional use of homologous blood and blood products
- determine if autologous blood not used intraoperatively was re-transfused postoperatively
- determine the estimated blood volume loss during surgical procedures
- determine the problems experienced with the cell saver machines
- determine the post-surgical destination of the patients.

4.3 Research assumptions

The following definitions will be used in this study.

Cell Saver: in this study, the Haemonetics Cell Saver 5® and Haemonetics Cell Saver ELITE® machines will be used.

4.4 Demarcation of study field

The study will be conducted in the Department of Anaesthesiology, Intensive Care Unit (ICU) and all the surgical disciplines at CHBAH. CHBAH is a 2 888-bed central hospital located in Gauteng. The hospital has 25 theatres and on average 65 000 surgeries are performed annually. It is affiliated to the Faculty of Health Sciences of the University of the Witwatersrand.

4.5 Ethical considerations

Approval to conduct the study will be obtained from the Human Research Ethics Committee (Medical) and the Graduate Studies Committee of the University of the Witwatersrand. Once this is obtained, permission to conduct the study will be requested from the Medical Advisory Committee of CHBAH (Appendix A).

Approval to access stored records will be obtained from the Heads of Department of Anaesthesiology (Appendix B), all the surgical disciplines: Traumatology/General Surgery (Appendix C), Obstetrics and Gynaecology (Appendix D), Orthopaedics (Appendix E) and ICU (Appendix F).

In this retrospective study no identifying information will be recorded on the data collection sheet. Each patient record will be allocated a study number. Patient's names, hospital numbers and study numbers will be recorded and filed separately to ensure anonymity.

Confidentiality will be ensured as only the researcher and supervisors will have access to the raw data. The raw data will be stored securely for six years after completion of this study on a password protected electronic database.

The Head of Department of Anaesthesiology at CHBAH will be notified as well of the other disciplines at their request of the practice of intraoperative cell salvage and any pitfall in the practice will be addressed in the future for optimal care of the patients.

The study will be conducted according to the principles of the Declaration of Helsinki (26) and the South African Guidelines for Good Clinical Practice (27).

4.6 Research methodology

4.6.1 Research design

This is a contextual, descriptive, retrospective study.

A retrospective study measures variables that have occurred in the past (28). In this retrospective study, data will be obtained from previously completed records.

A contextual study focuses on a particular context or environment (29). This study will be conducted at CHBAH.

A descriptive study describes variables without manipulating them (28). This study will describe a survey of the intraoperative cell salvage practice in the operating rooms at CHBAH.

4.6.2 Study population

The study population consists of all the records of the patients who had intraoperative cell salvage performed during surgical procedures, between 1 January and 31 August 2019, in the operating rooms at CHBAH.

4.6.3 Study sample

Sample size

The sample size will be determined by the number of patients who had intraoperative cell salvage performed during surgical procedures in the operating rooms at CHBAH for the period 1 January to 31 August 2019.

Sampling method

In this study, a consecutive, convenience sampling method will be used. Convenience sampling includes all conveniently available subjects in a non-probable manner. Consecutive sampling will attempt to include all the subjects meeting the inclusion criteria into the study (30).

Inclusion and exclusion criteria

The inclusion criterion of this study is the postoperative records of patients who had intraoperative cell salvage at CHBAH from the 1 January to 31 August 2019.

Illegible records will be excluded.

4.6.4 Data collection

Data will be collected from CHBAH once the study is approved.

The data collection sheet, a Microsoft Excel® spreadsheet, will consist of data already collected for management purpose, anaesthetic charts, patient's files from all the surgical disciplines (traumatology/general surgery, obstetrics and gynaecology, orthopaedics) and ICU charts during the study period. The data collection sheet (Appendix G), consists of:

- participant characteristics (age, sex, surgical discipline, type of surgery, indications for surgery and either elective or emergency surgery)
- pre and postoperative haemoglobin
- autologous blood volume collected, processed and re-infused intraoperatively or postoperatively
- estimated blood volume loss intraoperatively
- units of homologous blood and blood products transfused intraoperatively or postoperatively
- make of cell saver machine used
- complications related to the use of cell saver machines
- postoperative destination of the patients.

All the data obtained from the data collected for management purpose, anaesthetic charts, ICU charts and patient's ward files from all the surgical disciplines will be recorded with patients name and hospital number and allocated a study number on a separate Microsoft Excel® spreadsheet, allowing for the identification of specific records if required. Only the study number will be used during data capturing.

Data capturing will be done in the Department of Anaesthesiology, ICU and all the surgical disciplines at CHBAH by a single researcher. Records will not be removed from the hospital premises.

4.6.5 Data analysis

A Microsoft Excel® spreadsheet will be used to capture data obtained. Data will be analysed in consultation with a biostatistician using the statistical program STATA version 15 (StataCorp, USA). Categorical data will be presented using percentages and frequencies. Normally distributed continuous variables will be presented using means and standard deviations. Continuous data not normally distributed will be presented using medians and interquartile ranges. Incomplete data variables will be excluded from certain analyses.

4.7 Significance of the study

Information on the current practice of the intraoperative cell salvage and autologous blood re-transfusion for patients presenting for some surgical procedures would provide useful information on our current practice, problems experienced during the intraoperative cell salvage procedure, help to monitor the standard of care and improve the quality of health care provided to the patients.

4.8 Validity and reliability of the study

The validity of a study measures the accuracy of the concepts being investigated. Reliability relates to the consistency of the technique used for measurements (31).

Validity and reliability of the study will be ensured by the following:

- use of appropriate research design
- analysing the data in consultation with a biostatistician
- one data collector
- checking accuracy for every tenth entry into Microsoft Excel® spreadsheet.

4.9 Potential limitations

Study limitations are methodological constraints on the generalisability of the findings (31).

Due to the contextual nature of the study, the findings of the investigations may not be representative of what may be occurring in other hospitals, both locally or internationally.

Data of the study will be collected retrospectively and the results may be influenced by the quality of the data.

4.10 Project outline

4.10.1 Time frame

Activity	Apr 2019	May 2019	Jun 2019	Oct 2019	Jan 2020	Apr 2020	May 2020	Jun 2020	Aug 2020	Sep 2020
Proposal preparation										
Literature review										
Proposal submission										
Ethics approval										
Postgraduate approval										
Data collection										
Data analysis										
Draft article										
Submission										

4.10.2 Budget

Item	Price per page	Number of pages	Copies	Total
Proposal	1	15	10	R 150
Ethics	1	10	25	R 250
Post graduate form	1	2	6	R 12
Complete report	1	100	4	R 400
Grand total				**R 812**

The Wits Department of Anaesthesiology will incur the costs of paper and printing.

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4.12 Appendices

Appendix A: Letter to Medical Advisory Committee CHBAH

Dr Yemweni Leonard Yamba

Department of Anaesthesiology

University of the Witwatersrand

Attention: The Medical Advisory Committee of Chris Hani Baragwanath Academic Hospital

Re: A survey of intraoperative cell salvage practice in the operating rooms at an academic hospital

Dear Yasmin Jeenah

I am a registrar in the Department of Anaesthesiology. For the research component of my M Med I would like to conduct a survey of the intraoperative cell salvage practice in the operating rooms at Chris Hani Baragwanath Academic Hospital. The study has been approved by the Human Research Ethics Committee (Medical) (protocol number: **M190521**) and Graduate Studies Committee.

The survey will involve reviewing anaesthetic records, intensive care unit charts and ward's files/records of all the surgical disciplines of the patients on whom the cell saver was used during the time period 1 January to 31 August 2019. Records will be reviewed on the hospital premises and not be removed.

I would like to request permission to conduct this study at Chris Hani Baragwanath Academic Hospital. There will be no financial implications for the hospital.

Attached please find a copy of the proposal for this study.

A copy of the final report will be made available to you if requested.

Yours sincerely

Dr Yemweni Leonard Yamba

076689 3114

happinessyamba@gmail.com

Appendix B: Approval Head of Department of Anaesthesiology Chris Hani Baragwanath Academic Hospital

Appendix B: Request to HOD of Anaesthesiology Chris Hani Baragwanath Academic Hospital

Dr Yemweni Leonard Yamba

Department of Anaesthesiology

University of the Witwatersrand

Attention: The HOD of Anaesthesiology Chris Hani Baragwanath Academic Hospital

Re: **A survey of the intraoperative cell salvage practice in the operating rooms at an academic hospital**

Dear Dr Lines

I am a registrar in the Department of Anaesthesiology. For the research component of my M Med I would like to conduct a survey of the intraoperative cell salvage practice at Chris Hani Baragwanath Academic Hospital. Approval to conduct this study will be requested from the Human Research Ethics Committee [Medical] and Graduate Studies Committee.

The survey will involve reviewing anaesthetic records, intensive care unit charts and ward's files/records of all the surgical disciplines of the patients on whom the cell saver was used during the time period 1 January to 31 August 2019. Records will be reviewed on the hospital premises and not removed.

I would like to request permission to review patient anaesthetic charts and data collection sheets of patients who underwent intraoperative cell salvage in the Department of Anaesthesiology. There will be no financial implications for Chris Hani Baragwanath Academic Hospital.

Yours sincerely

Dr Yamba

0766893114

happinessyamba@gmail.com

Permission granted

06/08/2019

Dr D. Lines

Page 1 / 1

Appendix C: Approval Head of Department of General surgery and Traumatology Chris Hani Baragwanath Academic Hospital

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA
CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

Directorate: Department of Surgery

☎011 933 8804 / 9267 / 8386

011 938 2002

30th July 2019

The Chairperson
CHBAH Ethics Committee
CHBAH

Re: Permission for Research Activity (MMed Anaethetics)

I have read the Research Protocol submitted by Dr Yamba (registrar –Anaesthetic dept) entitled: **" a survey of the intraoperative cell salvage practice in the operating rooms at an Academic Hospital".**

I agree and support this project and hence ask for permission for the use of our hospital records to conduct this study/research project.

Dr. Yamba 's supervisors are H Price, J Scribante and M Stubbs from Department of Anaesthesiology, Faculty of Health Sciences, School of Clinical Medicine, Wits University.

The study will be at no additional cost to the hospital.

Yours faithfully.

Kindest regards.

Prof MD Smith
Head and Chief Specialist,
Department of Surgery,
Chris Hani Baragwanath Academic Hospital and the
University of the Witwatersrand.

cc: Dr MM Lesia: CEO, CHBAH
Prof Velaphi: HOD Paeds Dept
Prof Pettifor: Chief Specialist – Paeds Dept

Appendix D: Approval Head of Department of Obstetrics and Gynaecology Chris Hani Baragwanath Academic Hospital

UNIVERSITY OF THE WITWATERSRAND JOHANNESBURG

OBSTETRICS AND GYNAECOLOGY
School of Clinical Medicine

Department of Obstetrics and Gynaecology
Chris Hani Baragwanath Academic Hospital, PO Bertsham 2013, South Africa. Telephone: t 27 11 933 8156

Date: - 29 July 2019

RE: A survey of the intraoperative cell savage practice in the operating rooms at an academic hospital

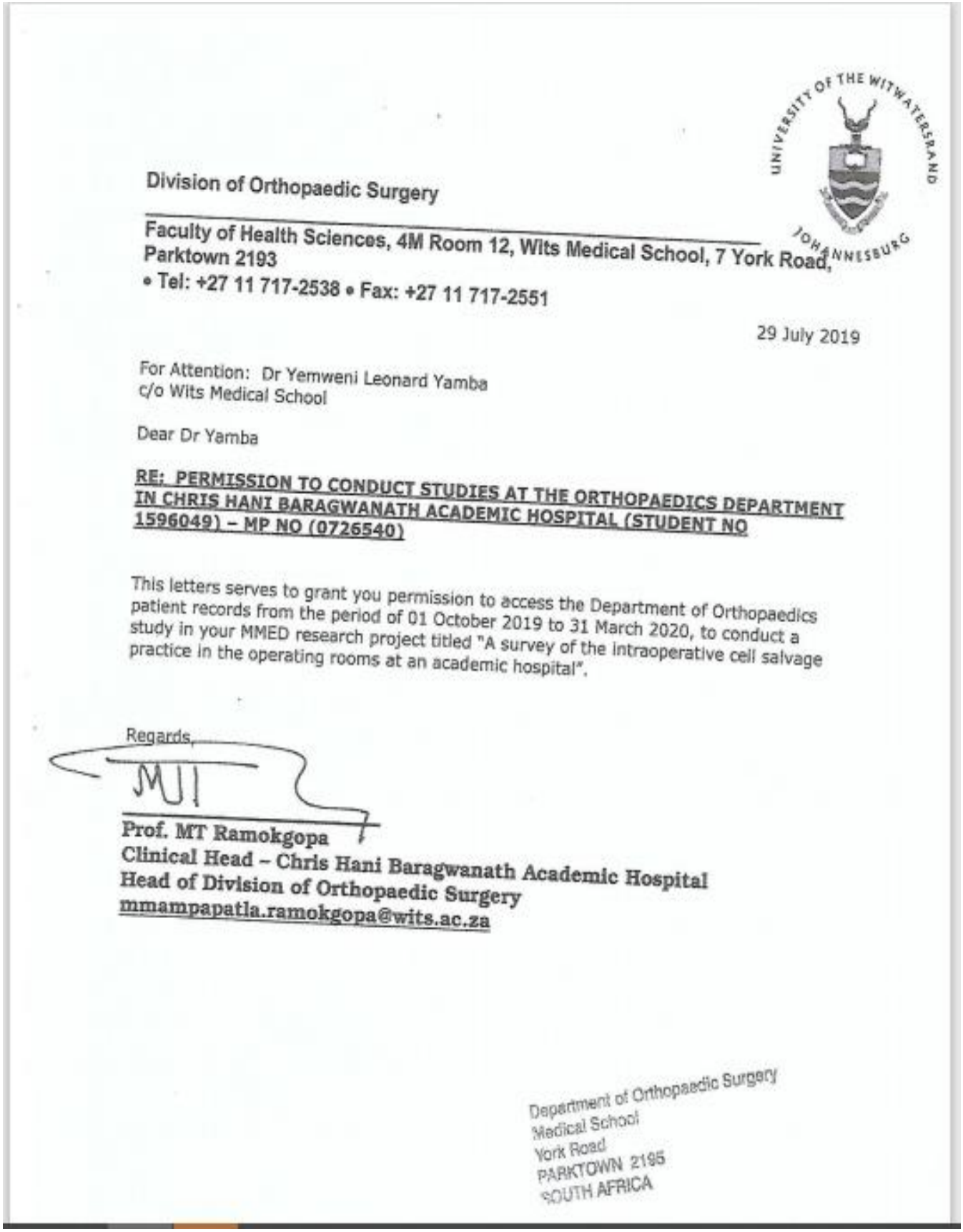
To whom it may concern,

I have discussed this study with Dr Yamba and permission is hereby granted to Dr Yamba to perform his study in the department of Obstetrics and Gynaecology.
Study design: Retrospective cross-sectional study
Dates of records: - 1st January 2019 to 31 August 2019
Date of data collection will be 1st October

Thank you

Professor Y. Adam
Clinical Head and Adjunct Professor
Obstetrics & Gynaecology Department
Chris Hani Baragwanath Academic Hospital
The University of the Witwatersrand
Date: 29 July 2019

Appendix E: Approval Head of Department of Orthopaedic Chris Hani Baragwanath Academic Hospital



Division of Orthopaedic Surgery

Faculty of Health Sciences, 4M Room 12, Wits Medical School, 7 York Road, Parktown 2193
• Tel: +27 11 717-2538 • Fax: +27 11 717-2551

29 July 2019

For Attention: Dr Yemweni Leonard Yamba
c/o Wits Medical School

Dear Dr Yamba

RE: PERMISSION TO CONDUCT STUDIES AT THE ORTHOPAEDICS DEPARTMENT IN CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL (STUDENT NO 1596049) – MP NO (0726540)

This letters serves to grant you permission to access the Department of Orthopaedics patient records from the period of 01 October 2019 to 31 March 2020, to conduct a study in your MMED research project titled "A survey of the intraoperative cell salvage practice in the operating rooms at an academic hospital".

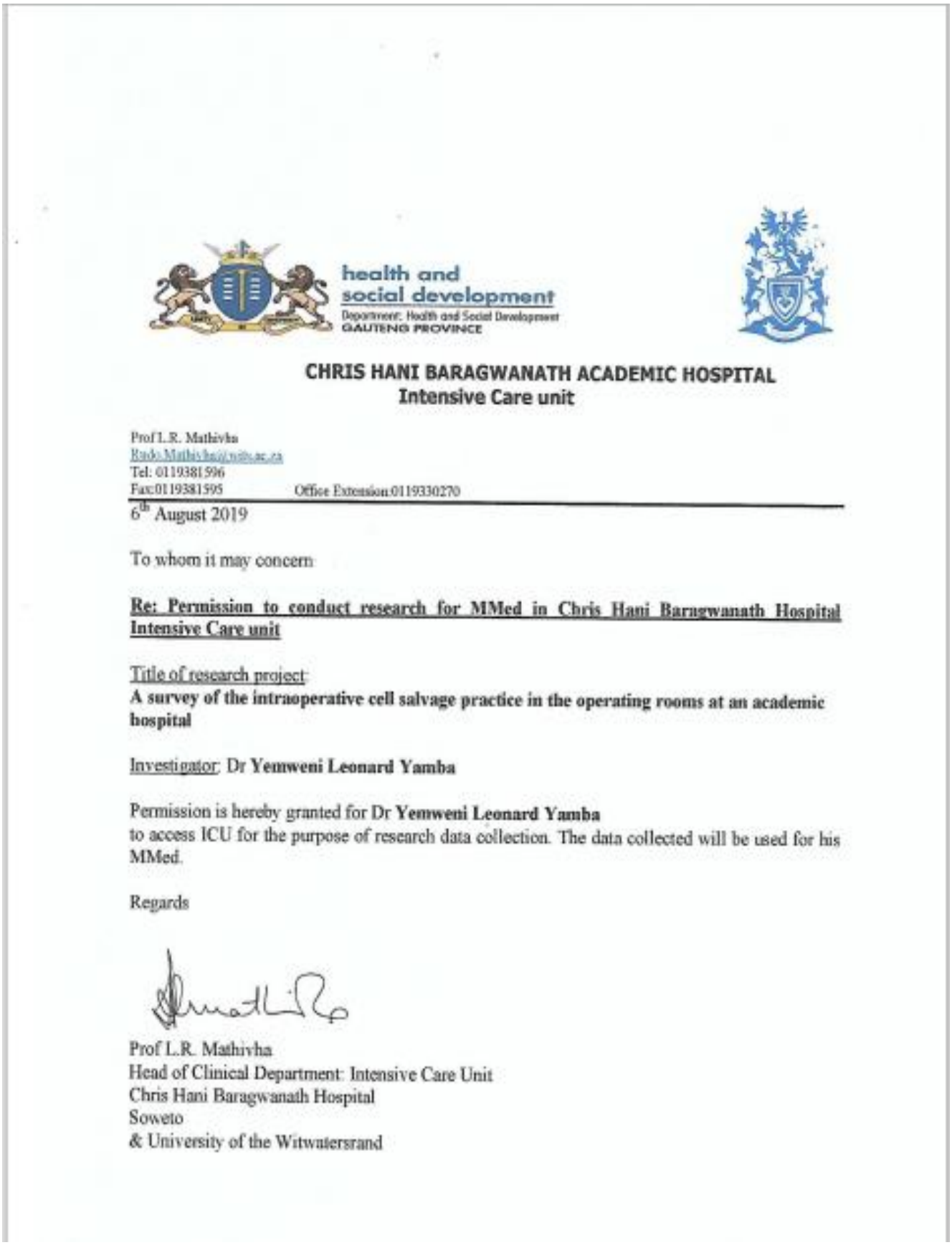
Regards,

MJ

Prof. MT Ramokgopa
Clinical Head – Chris Hani Baragwanath Academic Hospital
Head of Division of Orthopaedic Surgery
mmampapatla.ramokgopa@wits.ac.za

Department of Orthopaedic Surgery
Medical School
York Road
PARKTOWN 2195
SOUTH AFRICA

Appendix F: Approval Head of Department of Intensive Care unit/High Care Unit Chris Hani Baragwanath Academic Hospital



health and social development
Department: Health and Social Development
GAUTENG PROVINCE

CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL
Intensive Care unit

Prof L.R. Mathivha
Rudo.Mathivha@wits.ac.za
Tel: 0119381596
Fax:0119381595 Office Extension 0119330270

6th August 2019

To whom it may concern

Re: Permission to conduct research for MMed in Chris Hani Baragwanath Hospital Intensive Care unit

Title of research project:
A survey of the intraoperative cell salvage practice in the operating rooms at an academic hospital

Investigator: Dr **Yemweni Leonard Yamba**

Permission is hereby granted for Dr **Yemweni Leonard Yamba**
to access ICU for the purpose of research data collection. The data collected will be used for his MMed.

Regards

Prof L.R. Mathivha
Head of Clinical Department: Intensive Care Unit
Chris Hani Baragwanath Hospital
Soweto
& University of the Witwatersrand

Appendix G: Data collection sheet

Study number	
Date	

PARTICIPANT CHARACTERISTICS:

Age in years	
Sex	
Surgical discipline	
Type of surgery	
Indications for surgery	
Elective/emergency surgery	

HAEMOGLOBIN

Preoperative (gm/dl)	
Postoperative (gm/dl)	

AUTOLOGOUS BLOOD VOLUMES:

Collected (ml)	
Processed (ml)	
Re-transfused intraoperatively (ml)	
Re-transfused postoperatively (ml)	

Estimated blood loss intraoperatively (ml)	

HOMOLOGOUS BLOOD:

Homologous blood given	Yes	No

IF YES, BLOOD PRODUCTS GIVEN? Within a specific time period e.g. intraoperatively

Blood product	Volume (ml)	Time period	
		Intraoperative	Postoperative

CELL SAVER MACHINE

Make	

POSTOPERATIVE DESTINATION

DESTINATION	Yes	No
Intensive care unit		
High care		
Ward		

Section 5: Annexures

5.1 Ethics approval

UNIVERSITY OF THE WITWATERSRAND JOHANNESBURG

R14/49 «Tit Init name»

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M190521

NAME: (Principal Investigator)	Dr Y Yamba
DEPARTMENT:	Anaesthesiology Chris Hani Baragwanath Academic Hospital
PROJECT TITLE:	A survey of the intraoperative cell salvage practice in the operating rooms at an academic hospital
DATE CONSIDERED:	31/05/2019
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Helen Perrie
APPROVED BY:	CB Penny Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	08/10/2019

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

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on the Third Floor, Faculty of Health Sciences, Phillip Tobias Building, 29 Princess of Wales Terrace, Parktown, 2193, University of the Witwatersrand. I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in **May** and will therefore be due in the month of **May** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Yamba Yamba

Principal Investigator Signature

09/10/2020

Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

5.2 Graduate studies approval

UNIVERSITY OF THE WITWATERSRAND JOHANNESBURG

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

Reference: Mrs Sandra Benn
E-mail: sandra.benn@wits.ac.za

05 September 2019
Person No: 1596049
PAG

Dr YLJ Yamba
961 Florin Road
Strubens Valley
Ext 3
1724
South Africa

Dear Dr Yemweni Yamba

Master of Medicine in Anaesthesia: Approval of Title

We have pleasure in advising that your proposal entitled *A survey of the intraoperative cell salvage practice in the operating rooms 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

5.3 Turnitin report



19th August, 2020

The Chairperson
Graduate Studies Committee
Faculty of Health Sciences
University of the Witwatersrand

Dear Madam,

Re: M Med: **An audit of intraoperative cell salvage in operating rooms at an academic hospital**

Dr Yemweni Leonard Yamba, student number: 1596049, has submitted his research report to Turnitin which revealed a similarity index of 13%. These similarities appear not to be plagiarism but mainly the use of common terminology and phrases specific to the topic of the research.

Yours sincerely,

H Perrie

Helen Perrie
Supervisor

1598049:FOR_TURNITIN_REPORT.docx

ORIGINALITY REPORT

13%	8%	10%	1%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	hdl.handle.net Internet Source	1%
2	es.scribd.com Internet Source	1%
3	Submitted to University of Witwatersrand Student Paper	1%
4	academic.oup.com Internet Source	1%
5	L Davies, T Brown, S Haynes, K Payne, R Elliott, C McCollum. "Cost-effectiveness of cell salvage and alternative methods of minimising perioperative allogeneic blood transfusion: a systematic review and economic model", Health Technology Assessment, 2006 Publication	<1%
6	bjcvs.org Internet Source	<1%
7	jamanetwork.com Internet Source	<1%