

7. The Trust and the doctors then consider how best to proceed in accordance with the court's ruling.
8. The Trust may be required to pay a proportion of the legal costs of the Official Solicitor, as well as its own.

## APPENDIX 6

### PROCEDURES FOR CASES INVOLVING CHILDREN UNDER 12 (SEE SECTIONS 3.6, 7 AND APPENDIX 5)

If life threatening, take second opinion. Parents refuse consent for essential transfusion for immediate or anticipated need even after careful and complete counselling. If child capable of giving consent and administer does so, life-saving transfusion, document fully and inform legal dept/manager if non-emergency, approach Trust Legal Dept/Duty Manager to seek advice from Trust's Solicitors. Keep parents informed of intentions respect his wishes.

Trust's solicitors contact 'Official Solicitor' who will probably interview parents, child & medical staff Official Solicitor will act on child's behalf Trust applies to High Court (in Scotland the Court or Sheriff Court) for *Order* giving consent for proposed treatment Public Hearing (court will be asked to rule that names of family, hospital and doctors remain confidential). Doctors give evidence of need and lack of alternatives.

The Official Solicitor will represent the child. The parents may be heard and have legal representation. Court may grant order and may impose other conditions. Court's paramount consideration will be child's best interest. Trust's doctors proceed according to court ruling.

## The Jehovah's Witness Patient

T Moodley

Commentator: Ahmed M

Moderator: Brouckaert N



Department of Anaesthetics

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## **APPENDIX 5**

### **SIMPLIFIED PROCEDURE FOR APPLICATION TO COURTS FOR A 'SPECIFIC ISSUE ORDER'**

1. Child and parents refuse consent to treatment. Doctors believe Treatment must be given, in the best interests of the child. This would Not be an emergency situation - if it is, the doctor should act in the best interests of the child, having taken a second opinion, and record his Actions carefully in the medical records.
2. Doctors seek advice from their Trust Legal Department or Chief Executive who in turn seeks solicitors' advice. Parents should be kept Informed and invited to case conferences.
3. If solicitors advise proceeding, they will involve the Official Solicitor, a Government-appointed solicitor, whose function is to represent the Interests of minors or others who are 'incompetent'. The Official Solicitor or a member of his staff will probably wish to see the parents and the child, to discuss the situation. The Official Solicitor may then instruct solicitors to act on his and the child's behalf.
4. The Trust applies to the High Court (in Scotland the Court of Session or Sheriff Court) for an order giving consent to the proposed treatment. The terms of the proposed order should be discussed in advance with the Official Solicitor.
5. A hearing, which is generally heard in chambers but can be held in public with the names of the family, the hospital and the doctors directly involved kept confidential, permits the doctor(s) recommending treatment to give evidence, based on a previously prepared affidavit. The court will wish the doctor to state the reasons for the recommended treatment, together with other options considered and the reasons for discarding those options. Independent expert advice may also be required. The Official Solicitor will probably call his own experts to give evidence. The parents may wish to have separate legal representation.
6. The court may grant the order and may impose further conditions. The court's paramount consideration will be the welfare of the child.

- to be carried out straight away with out my first having the opportunity to consider them
- that this limitation of consent shall remain in force and bind all those treating me unless and until I expressly revoke it in writing.
- that I am one of Jehovah's Witnesses with firm religious convictions and I have decided to obey the Bible command "Keep abstaining from.....Blood" (Acts 15:28, 29), with full realisations of the implications of this position.

I understand

- that any procedure in addition to the investigation or treatment described on this form will only be carried out if it is necessary and in my best interests and can be justified for medical reasons
- that my express refusal of blood or blood components will be regarded as absolute and will not be overridden in ANY circumstances by a purported consent or a relative or other persons or body. Such refusal will be regarded as remaining in force even though I may be regarded as remaining in force even though I may be unconscious and/or affected by medication, stroke or other condition rendering me incapable of expressing my wishes and consent to treatment options, and the doctor(s) treating me consider that such REFUSAL MAY BE LIFE THREATENING

I accept

- full legal responsibility for this decision and release Community Hospitals Group and all those treating me from any liability for any adverse consequences arising out of the restrictions on my consent.
- Signature: .....Name:.....  
Address:.....

**PATIENT NOTES**

- The Doctor/Dentist is here to help you. He/She will explain the proposed treatment and what the alternatives are. You can ask any questions and seek further information.  
You can refuse the treatment.
- You may ask for a relative, friend, religious advisor or nurse to be present.
- You may ask to see the Doctor/Dentist alone.

**DOCTOR/DENTIST NOTES**

- A patient has the right to grant or withhold consent prior to examination or treatment.
- Patients should be given sufficient information in a way they can understand, about the proposed treatment and the possible alternatives. Patients must be allowed to decide whether they will agree to the treatment and they may refuse or withdraw consent to treatment at any time. The patient's consent to treatment should be recorded on this form (further guidance is given in HC (90) 22.

**SECTION 1 - INTRODUCTION**

- 1.1 In 2005, the Royal College of Surgeons of England published a booklet entitled 'Code of Practice for the Surgical Management of Jehovah's Witnesses' [1]. This document did not address any aspects of the role of the anaesthetist in the management of these patients. It did, however, raise the awareness of many members of the surgical team to some of the problems that might be encountered.
- 1.2 This booklet has been prepared to advise on the anaesthetic management of such patients. It will be of value, to give broad principles and direct an anaesthetist faced with the dilemma of a patient refusing blood or blood products to the appropriate resource.

**SECTION 2 - BELIEFS**

- 2.1 The Jehovah's Witness movement is some 120 years old, having been founded in North Eastern United States of America. It is an actively proselytising Christian organisation. In 1945, the spiritual administration of Jehovah's Witnesses promulgated the understanding that adherents to the faith should not receive transfused blood or blood products, based on Genesis 9:3,4, Leviticus 17:11,12 and Acts 15:28,29 (Appendix 1), all of which describe the prohibition of the consumption of blood. Jehovah's Witnesses' interpretation of this is that an individual's life is represented as being in the blood. The prohibition of blood transfusion is a deeply held core value and is a sign of respect for life.
- 2.2 Most Jehovah's Witnesses will, therefore, not accept a transfusion of whole blood or its major derivatives. This includes fresh frozen plasma (FFP), packed cells, white blood cells and platelets. *Absolute* rules regarding blood products, however, does not exist and some Witnesses may accept the use of plasma protein fraction (PPF) or components such as albumin, immunoglobulins and haemophilic preparations with each Witness deciding individually whether to accept these. Other clinical interventions may have to be dealt with on a personal basis: organ transplantation, for example, is not specifically forbidden for Jehovah's Witnesses and each individual is expected to reach his/her own decision.

- 2.3 Cardiac bypass may be accepted provided the pump is primed with nonblood fluids and blood is not stored in the process. Auto transfusion is acceptable to many Jehovah's Witnesses provided the equipment is arranged in a closed circuit that is constantly linked to the patient's circulation and there is no storage of the patient's blood. Jehovah's Witnesses will not accept pre-operative collection, storage and later reinfusion of blood. The use of an epidural blood patch may be acceptable to some Jehovah's Witnesses.
- 2.4 Administration of blood to a competent patient against their will and in conflict with their genuinely held beliefs has been likened by the Witnesses to rape. It will not result in expulsion from the community if it was carried out against the expressed wishes of the patient but may have as deep a psychological effect as forceful sexual interference.
- 2.5 It is calculated that there are 5.9 million active Jehovah's Witnesses in over 230 countries worldwide. Additionally, another 8 million attend prayer meetings and might be expected to share some beliefs. The current Great Britain and Ireland Jehovah's Witness population is 145,000, but this is likely to be an underestimate. Recent knowledge of the risk of transmission of disease and other complications of blood transfusion have in many cases been cited as further support for the Jehovah's Witnesses' refusal to accept blood transfusion. Increasing awareness of this risk generally by the medical profession has altered views on the need for transfusion and altered our perception of the problems occurring as a result of acute unexpected blood loss.
- 2.6 Because of the variability between individual beliefs and the extent of adherence to the basic tenets, it is common for a Witness patient to wish to consult with the Elders of the community for help in reaching a decision regarding accepting blood-product related medical treatment. Most active communities maintain a committee of Elders, known as the 'Hospital Liaison Committee for Jehovah Witnesses', which can be contacted and whose telephone numbers are listed in the local telephone directory. Appendix 2 gives the main contact numbers for the national central committees.
- 2.7 The local 'Hospital Liaison Committee for Jehovah Witnesses' can also act as a local resource for information regarding the beliefs and practices of Jehovah's Witnesses. They have access to a great deal of reference material and information.

## APPENDIX 4

### CONSENT TO TREATMENT FOR MEDICAL OR DENTAL INVESTIGATION TREATMENT OR OPERATION WHERE THE PATIENT IS A JEHOVAH'S WITNESS – ADULT

Patient's Surname:.....Hospital No.....  
 Other Names: Sex (*please circle*) Male/Female Date of Birth: .....

DOCTOR/DENTIST *This part to be completed by Doctor or Dentist (See notes below)*

Type of operation, investigation or treatment for which written evidence of consent is considered appropriate:

.....  
 I confirm that I have explained the above operation, investigation or treatment, and such appropriate options as are available and the type of anaesthetic, if any (general/local/sedation) proposed to the patient in terms which in my judgement are suited to the understanding of the patient. I acknowledge that this limited consent, as expressed below, will not be over-ridden unless revoked or modified in writing.

Signature:.....Date:.....  
 Name of Doctor/Dentist:.....

PATIENT *This part to be completed by the patient*

- 1 Please read this form and the notes at the bottom of the form very carefully.
- 2 If there is anything you do not understand about the explanation or if you want more information, you should ask the Doctor/Dentist.
- 3 Please check that all the information on the form is correct. If it is, and you understand the explanation, and then sign the form.

I am the patient, I agree

- subject to the exclusions below to what is proposed and which has been explained to me by the Doctor/Dentist named on this form.
- to the use of the type of anaesthetic that I have been told about.

I have told the Doctor/Dentist

- that my consent excludes transfusion of blood components but includes (delete and add as necessary) the administration of non-blood volume expanders such as saline dextran, Haemaccel, hetastarch and Ringer's solution (others). In addition the procedures listed below are those I would NOT wish

**SECTION 3 - THE LEGAL POSITION IN RESPECT OF ANAESTHESIA AND CONSENT**

- 3.1 Jehovah's Witnesses are generally well informed, both about their legal position and the options for treatment. Any competent adult is entitled to accept surgery but also to exclude specifically certain aspects of management such as the administration of a blood transfusion. The recent recommendations from the Department of Health in respect of consent forms provide for the inclusion of a box for the patient to complete and this may contain specific exclusions from the consent. Most practising Jehovah's Witnesses will carry with them clear Advance Directive prohibiting blood transfusions. Many have also executed a more detailed Healthcare Advance Directive (living will) with comprehensive personal instruction on a variety of matters and have lodged copies with their general practitioner as well as family and friends. Appendix 3 gives the full wording of a typical directive which specifically states that 'in the event of emergency treatment including general anaesthesia and surgery....' it forbids the administration of blood or blood components. The advance directive goes on to state that 'my express refusal of blood is absolute and is not to be overridden in any circumstances'. It is important to realise that individual Jehovah's Witnesses may have different views and the doctor's obligation is to respect the wishes of the individual patient.
- 3.2 It is the view that such an advance medical directive by a competent adult, if properly signed and witnessed, must be respected unless there is some reason to suppose that the patient has changed their view since the directive was executed.
- 3.3 It is strongly recommended that the views held by each Jehovah's Witness patient should be ascertained to find out which aspects of treatment are acceptable and which are not.
- 3.4 To administer blood to a patient who has steadfastly refused to accept it either by the provision of an advance directive or by its exclusion in a consent form is unlawful, ethically unacceptable and may lead to criminal and/or civil proceedings [2].
- 3.5 In the management of trauma or when dealing with an unconscious patient whose status as a Jehovah's Witness may be unknown, the doctor caring for the patient will be expected to perform to the best of

receive copies of my medical records, and to take legal action to ensure that my wishes are honored. If my first appointed agent is unavailable, unable, or unwilling to serve, I appoint an alternate agent below to serve with the same power and authority.

9. Signature \_\_\_\_\_ Date \_\_\_\_\_  
 Address \_\_\_\_\_

10. STATEMENT OF WITNESSES: The person who signed this document did so in my presence. He or she appears to be of sound mind and free from duress, fraud, or undue influence. I am 18 years of age or older. Also, I am not the person appointed as agent or alternate agent by this document.

Signature of witness \_\_\_\_\_ Signature of witness \_\_\_\_\_  
 Address \_\_\_\_\_ Address \_\_\_\_\_

---

**HEALTH-CARE AGENT\***

Name: \_\_\_\_\_  
 Address: \_\_\_\_\_  
 Telephonets): \_\_\_\_\_

**ALTERNATE HEALTH-CARE AGENT\***

Name: \_\_\_\_\_  
 Address: \_\_\_\_\_  
 Telephonets): \_\_\_\_\_

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\* Note: You may choose any adult to be your agent, but it is recommended that you not choose your physician, any of your physician's employees, or any employee of a hospital or nursing home where you might be a patient unless the individual is related to you by blood, marriage, or adoption.

Durable Power of Attorney for Health Care  
 (signed document inside)

**NO BLOOD**





## APPENDIX 1

### THE HOLY BIBLE AUTHORISED KING JAMES VERSION

#### Genesis Chapter 9, Verses 3-4

3. Every moving thing that liveth shall be meat for you; even as the green herb have I given you all things.
4. But flesh with the life thereof, *which is* the blood thereof, shall ye not eat. Leviticus Chapter 17, Verses 11-12
11. For the life of the flesh *is* in the blood: and I have given it to you upon the altar to make an atonement for your souls: for it *is* the blood *that* maketh an atonement for the soul.
12. Therefore I said unto the children of Israel, No soul of you shall eat blood, neither shall any stranger that sojourneth among you eat blood. Acts Chapter 15, Verses 28-29.
28. For it seemed good to the Holy Ghost, and to us, to lay upon you no greater burden than these necessary things;
29. That ye abstain from meats offered to idols, and from blood, and from things strangled, and from fornication: from which if ye keep yourselves, ye shall do well. Fare ye well.

## APPENDIX 2

### HOSPITAL LIAISON COMMITTEES CONTACT NUMBERS

Hospital Information Services  
24 Hour Service (110)7611000  
1 Robert Broom Drive East  
Rangeview, Krugersdorp, 1739  
Fax + 27117611305  
Email: [his@jw.org.za](mailto:his@jw.org.za)

### HOSPITAL INFORMATION SERVICES

Private Bag X2067, Krugersdorp, 1740  
South Africa  
Telephone 011 7611000  
Fax 011 7611305  
Cell 083 2265959

## SECTION 4 - CLINICAL MANAGEMENT

- 4.1 It is essential that surgeons who are aware that an elective patient is a Jehovah's Witness should alert the anaesthetic department as soon as possible in order to ensure that a consultant anaesthetist is prepared to manage the patient's care. Early warning of any potential intervention that could lead to the need for blood or blood products is also advisable.
- 4.2 Anaesthetists have the right to refuse to anaesthetise an individual in an elective situation but should attempt to refer the case to a suitable qualified colleague prepared to undertake it. The surgeon should be informed as soon as possible if any difficulty ensues. In an emergency, the anaesthetist is obliged to provide care and *must* respect the patient's competently expressed views.
- 4.3 The introduction of an early warning system for the delivery of a child to a Jehovah's Witness mother can also be beneficial so that appropriate staff is available. This arrangement should apply to booking of delivery dates by both obstetricians and midwives.
- 4.4 The Jehovah's Witnesses have established a number of Hospital Liaison Committees in South Africa (usually based in the major cities). The telephone numbers are listed in the directory and those of the major centres are included in. Representatives of these Committees are available at any time to advise or assist with the management of individual Jehovah's Witnesses. The Hospital Liaison Committees may have a schedule of physicians prepared to manage these patients. It is suggested that departments of anaesthesia carry out their own internal inquiries and have available a list of anaesthetists willing to manage such patients.
- 4.5 Full pre-operative investigations and consultations with the patient should take place as early as possible, in order to ascertain the degree of limitation on intra-operative management.
- 4.6 At the pre-operative visit it is very important to take the opportunity to see the patient without relatives or members of the local community who may influence and impede full and frank discussion of the acceptability of certain forms of treatment. At this stage, treatments which are regarded as acceptable should be established and the patient made fully aware of the risks of non-acceptance of blood or

blood products. Agreed procedures and non-acceptable treatments should be entered into the clinical notes and signed as a record.

At the patient's request, members of the Hospital Liaison Committee for Jehovah's Witnesses may be part of these discussions. Their prime role should be to avoid confrontation and assist understanding on both sides.

4.7 Major procedures can be carried out in stages in order to limit acute blood loss and the choice of operative technique may also influence outcome; examples are performing a unilateral procedure on two separate occasions rather than bilaterally in one session.

4.8 Pre-operative anaemia should be investigated and treated. The use of recombinant erythropoietin to improve haemoglobin levels has been documented. Erythropoietin is a glycoprotein hormone and is synthesized in the secreted by the renal cortex and interstitial cells in response to tissue hypoxia. It is the main regulator of erythropoiesis. Epoetin alpha is genetically engineered molecule. It is an extremely slow treatment that might not be clinically justified or cost effective. It is administered subcutaneously. Patients need to return to hospital on day 21, 14 and 7 for their doses. Iron should always be co-administered. It may be beneficial, however, to improve the iron stores by pre-administration of iron supplements. Discussion of an individual case with a haematologist could be beneficial. Erythropoietin has not shown to reduce mortality and may in fact be pro thrombotic.

Recombinant erythropoietin and other erythropoietin-receptor agonists are commonly used in patients who have chronic renal failure or cancer with bone marrow suppression, to increase haemoglobin levels and avoid the need for blood transfusions. Recombinant erythropoietin has also been used in critically ill patients for the same purpose. In the most recently published trial, Corwin and colleagues randomly assigned 1460 critically ill patients to receive either 40 000 units of recombinant erythropoietin or placebo weekly for up to 3 weeks. The increase in haemoglobin concentration at day 29 was greater in the erythropoietin group than in the placebo group (mean 16 [SD 20] g/L v. 13 [SD 18] g/L,  $p < 0.001$ ).

However, in contrast to findings from previous trials, there was no difference between the 2 groups in the number of patients receiving blood transfusions or in the number of units transfused. This failure to affect transfusion requirements was attributed to the use of a more

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<u>Acceptable</u>	<u>Not Acceptable</u>	<u>Questionable</u>
Crystalloids	Whole Blood	Albumin
Colloids	Red Cells	Immunoglobins
Gelatins	Platelets	Vaccines
G-CSF (most)	White Cells	Coagulation Factors
Epo. (most)	Plasma (FFP)	Hemodilution
		Cell Saver
		Organ transplant

## CONCLUSION

Involve hospital liaison committee. Clarify what is acceptable. Scrutinize the Advance Directive. Informed consent and contingency planning. Plan for principle of bloodless surgery.

restrictive transfusion strategy. Overall, there was no significant difference in mortality at day 29 between the 2 groups (hazard ratio 0.79, 95% CI 0.56–1.10). However, in a subgroup analysis, mortality was significantly lower among trauma patients in the erythropoietin group than among trauma patients receiving placebo. These findings from the subgroup analysis should be considered only as hypothesis generating, but because they are consistent with those from a previous large trial of erythropoietin in critically ill patients, further investigation is warranted. Importantly, there was a significant increase in the rate of deep vein thrombosis among patients receiving erythropoietin (hazard ratio 1.41, 95% CI 1.06–1.86).

In a systematic review of 9 studies, including the most recent study by Corwin and colleagues, Zarychanski and co-authors evaluated the use of erythropoietin in critically ill patients. They found a significant reduction in the odds of a patient receiving at least 1 red blood cell transfusion (odds ratio 0.73, 95% CI 0.64– 0.84). There were no differences observed in mortality or occurrence of deep vein thrombosis. On the basis of these findings, erythropoietin appears effective in increasing haemoglobin levels in critically ill patients and may result in a reduced frequency of blood transfusions, but this latter effect is likely abrogated by the use of a restrictive transfusion strategy. In addition, the use of erythropoietin does not reduce mortality, and concerns remain regarding the potential increased risk for thrombotic events.

- 4.9 Increasingly, obstetric or major lower limb procedures may be performed under local or regional anaesthesia alone and, in this situation, some patients may retract their prohibition when confronted with the need for a blood transfusion as a life saving measure. Any change in the patient's views at this point, made of their own volition and without duress, should be regarded as a modification in the scope of consent and should be witnessed and a contemporaneous entry be made in the patient's anaesthesia and clinical record. While patients who have received sedation may not strictly meet the legal standard of competence to give or modify a pre-existing valid consent, any such modification must be acted upon in the interests of saving the life of the patient.

## SECTION 5 - INTRA-OPERATIVE MANAGEMENT

5.1 A number of techniques are available to reduce intra-operative blood loss.

These may include: careful positioning to avoid venous congestion/compression/occlusion, elevation of surgical field above level of the heart reduces venous bleeding. Spontaneous ventilation will allow better venous return compared to IPPV, however this may be offset by hypercarbia. Regional anaesthesia decreases arterial and venous pressure and reduces intra-operative bleeding. Hypotensive anaesthesia or controlled hypotension does reduce bleeding, but is high risk in patients with atherosclerosis.

This technique is contra- indicated in the anaemic patient, and should not be part of Pre-operative autologous donations or haemodilution. Agents used to achieve these ends include volatiles, potent opioids, sodium nitroprusside, beta blockers and alpha 2 agonist. Maintenance of normothermia to avoid platelet dysfunction.

Surgical techniques include meticulous surgery, electrocautery, argon beam enhanced devices, laser, harmonic scapel. Tissue or fibrin sealants are now available. They consist of purified thrombin and fibrinogen from animal sources. Surgical approach is also an important factor e.g. OPCAB versus CABG, laparoscopic and endoscopic surgery, interventional radiography. The use of tourniquets where appropriate, meticulous haemostasis, use of vasoconstrictors and haemodilution.

There should be time for pre-operative consideration of the use of one or more of these techniques.

## SECTION 8 – RECOMMENDATIONS

1. Anaesthesia departments should review their procedure for being alerted at an early stage of the scheduling of Jehovah's Witness patients for elective surgery.
2. An internal survey should be carried out and regularly reviewed of those senior members of the anaesthetic department prepared to care for followers of the Jehovah's Witness faith.
3. In an emergency, an anaesthetist is obliged to care for a patient in accordance with the patient's wishes and irrespective of the anaesthetist's own views.
4. Properly executed Advance Directives must be respected and special Jehovah's Witness consent forms should be widely available for use as required.
5. Each Jehovah's Witness must be consulted, whenever possible, to ascertain what treatments they will accept.
6. Discussions with Jehovah's Witness patients should be fully recorded in the notes and their acceptance or rejection of treatments be likewise recorded and witnessed.
7. In the case of children, local procedures for application to the High Court for a 'Specific Issue Order' should be reviewed and available for reference.
8. A 'Specific Issue Order' should only be applied for when it is felt to be entirely necessary to save the child in an elective or semi-elective situation.
9. In a life-threatening emergency if a child unable to give competent consent, all life-saving treatment should be given, irrespective of the parents' wishes.
10. Wherever possible, consultant staff (both anaesthetic and surgical) should be directly involved with the care of Jehovah's Witness patients from the outset.

- 6.5 Avoid hypoxia, give supplemental oxygen if required. Maintain normovolemia.
- 6.6 Auto transfuse ongoing blood loss e.g. cell saver.
- 6.7 Continue antifibrinolytic therapy if deemed appropriate.

## SECTION 7 - OTHER PAEDIATRIC CONSIDERATIONS

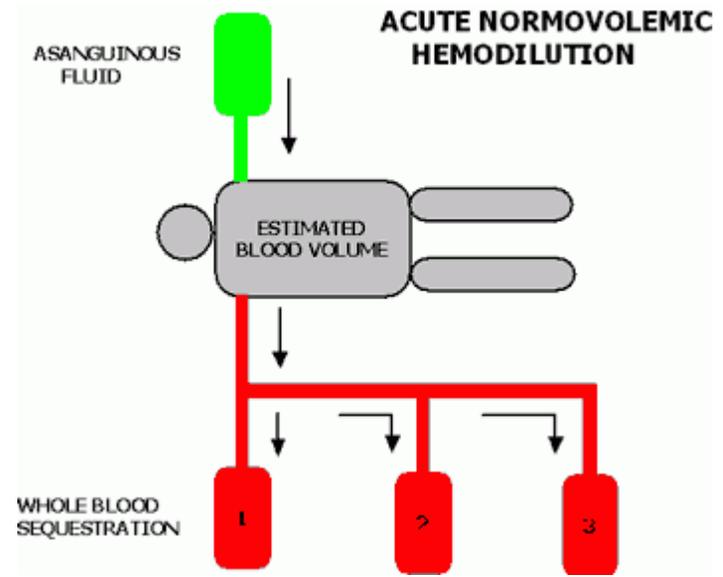
7.1 Children of sound mind aged 12 years and have a statutory right to consent to procedures on their own account and there is no legal requirement to obtain consent from a parent or guardian as well. The child's consent takes precedence over parental objections although parents also have a common-law right to proceedings on behalf of children under the age of 18 years.

Children younger than 16 years may be competent to give their own consent if they demonstrate a clear grasp of the proposed treatment and the risks, benefits or consequences of acceptance or rejection of a proposed treatment. This is referred to as 'Gillick-competence'. However, this is likely only to apply to children above the age of 12 years.

A situation could be envisaged where a child under the age of 16 years, of Jehovah's Witness parents, were to consent to an elective blood transfusion in the face of parental opposition. Consent in this situation would be sound provided that the child could show evidence of 'Gillick competence'.

7.2 In a recent case [7], a 14 year old and her parents, with strongly held beliefs, refused a transfusion required to manage her severe burn injuries. It was found by the Family Court, following the opinion of an expert in child psychiatry, that these beliefs were founded upon the context of her own family experience alone and that there was a distinction between a view of that kind and the constructive formulation of an opinion which occurred with adult experience. While it was accepted that the patient's opinions were firmly held, they were necessarily based upon a limited understanding of matters and that she was not in possession of all the details which it would be right and appropriate to have in mind when making such a decision. The Official Solicitor was appointed to act as 'guardian ad litem' and consent was granted to the use of blood products as necessary.

## 5.2 Acute Normovolemic Hemodilution



Acute Normovolemic haemodilution is the process of removing one or more units of blood at the beginning of surgery (prior to surgical incision) for transfusion to the patient either during or at the end of the operation.

ANH reduces or eliminates the need for allogeneic blood, and is one of the least costly methods of autologous blood procurement.

ANH can be implemented during cardiac, major general, hepatic, neurological, orthopedic, and urologic procedures

During ANH, whole blood is drawn from a patient prior to surgery, while restoring the circulating blood volume with acellular fluid.

The collected blood is anticoagulated with a citrate based anticoagulant and stored in the operating room at room temperature to preserve platelet, clotting factor, and white blood cell function

This procedure results in: - ↓ O2 carrying capacity - ↓ viscosity - ↑ SNS stimulation - ↑ VR, SV, CO - ↓ # of RBC's lost during surgery

How Much Volume of Blood Can Be Drawn?

ANH is usually limited to a volume of 2,000 mL or a target haematocrit (Hct) of 28%, whichever comes first.

$$V = EBV \times (HI - HF) / HAV$$

Must remember that with a JW patient the blood must stay in continuity with the body.

Indications for Acute Normovolemic Hemodilution (ANH) 1. The anticipated intraoperative blood loss is 1 liter or more. 2. Any type of surgery associated with significant blood loss. 3. The desire for the patient not to receive previously donated autologous/donor blood products.

Relative Contraindications for ANH 1. Anaemia 2. ↓ renal function & cannot excrete large amounts of fluid. 3. When an ↑ in cardiac output is undesirable. (Aortic stenosis and coronary artery disease) 4. Limitations of cardiac or pulmonary function

- 5.2 A 'cell saver' system may be acceptable to the Jehovah's Witness and can be used in certain operations where blood loss is unlikely to result in blood contamination. Nevertheless, discussions of the use of a cell saver should be carried out with the patient to ensure acceptability. Blood from the surgical site is suctioned and stored in a reservoir bag. As the blood is suctioned an anticoagulant is mixed with to prevent clot formation. Aspirated blood then sits in the reservoir bag. The reservoir has filters which are used to remove bacteria, cancer cells and amniotic fluid contaminants. The RBC's are then washed.

into a sterile syringe before taking the diagnostic samples and then reinfused into the patient. This strategy can reduce the mean amount of blood lost through blood sampling by 50%. Similar reductions in blood loss associated with diagnostic testing have been demonstrated with the use of automated closed arterial systems. In most of the studies, eliminating the loss of discarded blood before diagnostic testing was associated with higher haemoglobin levels than levels in control patients, but none of the studies reported a reduction in blood transfusions. Although this may have been due to the small number of patients included in these studies, the amount of blood saved with these techniques alone may not be large enough to avoid the need for blood transfusion in critically ill patients.

## SECTION 6 - POSTOPERATIVE CARE

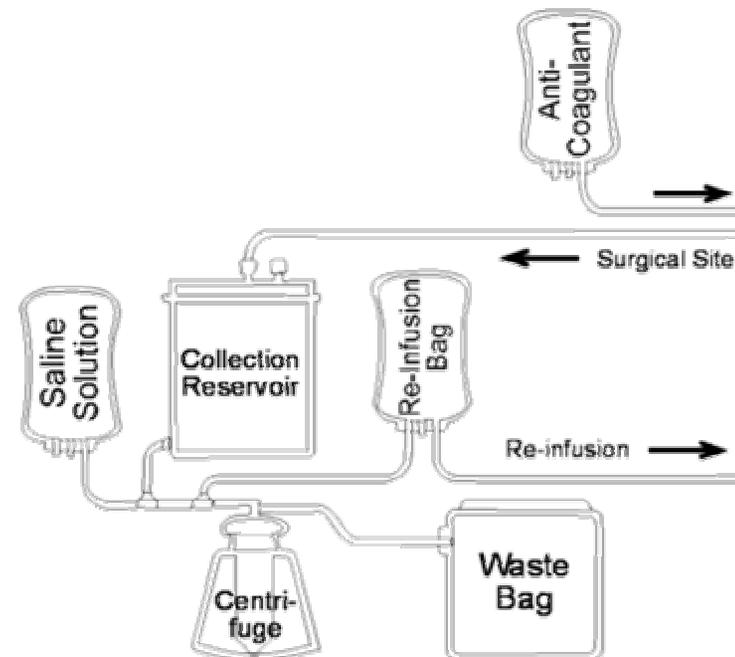
- 6.1 Postoperative care should ensure that any postoperative oozing is detected and the surgeon consulted early so that the correct surgical procedure to control it can be carried out. Careful recording of postoperative blood loss is essential and should be reviewed on a regular basis if any bleeding continues. Simple measures must be initiated such as direct compression, with early re-exploration if bleeding continues.
- 6.2 Following massive blood loss it may be necessary to consider elective ventilation to enhance oxygen delivery. A recent case of leaking abdominal aortic aneurysm had a haemoglobin level of 2.8 g dl-1 on admission to the ICU [6]. Elective ventilation continued for a total of 14 days. He was treated additionally with total parenteral nutrition, intravenous iron, folic acid and subcutaneous epoetin alfa.
- 6.3 Active cooling has also been described in the postoperative period to reduce oxygen consumption and increase dissolved oxygen carriage, but this technique is not widely accepted [6].
- 6.4 Hyperbaric oxygen therapy has been described also in the management of severe blood loss anaemia. Swift reversal of hypoxia is possible but the technique has limited application. Nevertheless, referral for hyperbaric therapy may be considered if an appropriate facility is available.

arterial catheters contribute to increased sampling and blood loss because of the ease of sampling and because of the added requirement to discard the first few millilitres of infusate-blood mixture obtained when collecting blood from a fluid-infusing catheter. Studies from the 1980s reported a mean blood loss per patient of 377 mL/d in cardiothoracic ICUs, 240 mL/d in general surgical ICUs and 41.5 mL/d in medical–surgical ICUs. A more recent study involving 1136 patients in 145 western European ICUs found considerable blood loss through blood sampling, averaging 41.1 mL/d per patient. In one study involving patients admitted to an ICU for more than 3 days, blood sampling accounted for 17% of the total blood loss. In 2 American studies, retrospective analysis identified that blood sampling accounted for 50% of the variation in the amount of red blood cells transfused. Not surprisingly, there appears to be a correlation between the severity of illness and both the number of blood draws and the total amount of blood sampled. This increased blood loss through diagnostic testing places the most acutely ill patients at increased risk of anaemia and exposes them to the attendant risks of blood transfusion.

Approaches to reduce iatrogenic blood loss in critically ill patients have included the use of small-volume (paediatric) blood collection tubes, the elimination or reduction of discarded blood when collecting blood from in-dwelling catheters and the altering of test-ordering behaviour.

In 2 studies, the use of paediatric blood collection tubes reduced the volume by 37% and 47% respectively. In the first study, this was associated with a significant reduction in the proportion of patients requiring blood transfusions. The introduction of point-of-care testing could further reduce the volume of samples drawn. In addition to improved turnaround time and decreased personnel time, these bedside diagnostic tests often require less than 0.5 mL. As the reliability and affordability of these technologies improve, they may become a valuable addition to blood conservation strategies.

Current technology already exists to eliminate the loss of discarded blood associated with blood sampling from in-dwelling catheters. Using a simple technique with a 3-way stopcock, the sample is drawn



### Complications

- Air embolism

### Advantages

- Clean RBC with high Hct
- Flexible – different type of surgery

### Disadvantages

- Requires expertise
- Expensive and sophisticated equipment
- Needs setup time

### Contra-indications

- Bowel contents spillage
- Sepsis/bacteraemia
- Oncology surgery

5.3 A number of drugs have been used in an effort to reduce fibrinolysis, increase coagulability and reduce blood loss; eg tranexamic acid and aprotinin, aminocaproic acid, desmopressin and recombinant activated factor VII.

Antifibrinolytic agents are general haemostatic agents that inhibit the breakdown of blood clots. They are used in a variety of medical conditions to reduce bleeding. A meta-analysis of the perioperative use of antifibrinolytic agents suggested that the use of tranexamic acid, epsilon aminocaproic acid or aprotinin in selected cases can reduce the need for blood transfusions and reoperation without increasing the risk of adverse events. The pooled estimates suggested that aprotinin may reduce the need for blood transfusions and reoperation as compared with tranexamic acid and epsilon aminocaproic acid, but further studies are required.

More recently, safety concerns associated with aprotinin have been raised. Preliminary results from a large phase III trial comparing the use of 3 antifibrinolytic agents in high-risk cardiac surgery patients suggest an increased risk of death associated with aprotinin. The relative effectiveness of these different agents and the potential adverse effects will be better understood when the complete results of this trial are available. The generalizability of the findings from the phase III trial for the treatment of bleeding in other critically ill patient populations is uncertain. Aprotinin is no longer available.

A systematic review of tranexamic acid for haemostasis in patients with undifferentiated upper gastrointestinal bleeding demonstrated a reduction in the recurrence of bleeding and in mortality. However, the incremental benefits when combined with newer endoscopic therapies and proton pump inhibitor therapy have not been evaluated. On the basis of these studies, the use of antifibrinolytic agents may be useful for controlling bleeding in selected critically ill patients. However, the effectiveness of these agents in reducing transfusion requirements and the risk of thrombotic complications and death in a broad spectrum of critically ill patients remains unclear.

#### **Desmopressin**

Desmopressin acetate (1-deamino-8-D-arginine vasopressin [DDAVP]) is a synthetic analogue of arginine vasopressin. It induces the release of stored factor VIII and von Willebrand factor from

in blood and the oxygen content on perfluorocarbons, patients have to be given 100% oxygen to provide effective oxygenation with this product. Such high inspired oxygen concentrations may induce acute lung injury. To date, perflubron (Oxygent) has been tested in combination with acute Normovolemic Haemodilution in a phase III trial involving patients undergoing elective noncardiac surgery. Overall, the patients who received perflubron received fewer allogeneic blood transfusions than the control patients. The full efficacy and safety profile of perfluorocarbon -based haemoglobin substitutes and their potential role in critically ill patients remains to be clarified through future studies.

Artificial oxygen carriers are a group of agents capable of carrying oxygen from the lungs to the tissues. So called oxygen transport bridge. Haemoglobin based oxygen carriers (HBOC). These take advantage of the physiological function of Hb to carrier oxygen. They can be recombinant products or bovine derived. The advantage of HBOC in the plasma is the increased diffusive transport of oxygen in the microcirculation owing to improved rheology. Hemopure is an HBOC approved for South Africa. It is polymerised bovine Hb. It consists of 13g/dl of polymerised bovine derived Hb.

#### **Advantages**

- No crossmatch
- Long shelf life
- Can be stored in room temperature
- Acceptable to Jehovah's Witness
- Decreased risks on disease transmission

#### **Disadvantages**

- Interferes with Hb lab measurements
- Renal toxic effects
- Adverse effects on vascular tone and BP.
- Preventing sub acute anaemia in critically ill patients

#### *Reducing blood loss associated with diagnostic testing*

Diagnostic testing is an important cause of blood loss in critically ill patients. Blood samples for diagnostic testing are commonly taken up to 24 times per day depending on patient illness acuity, ease of sampling and institutional practice. In-dwelling central venous or

Despite the initial promise of diaspirin cross-linked haemoglobin in reducing the need for blood transfusion in cardiac and noncardiac surgery patients, a phase III randomized controlled trial involving trauma patients was stopped after an interim analysis showed higher mortality in the treatment group than in the control group (38% v. 15% at 48 hours,  $p = 0.01$ ; 46% v. 17% at 28 days,  $p = 0.003$ ). Although the underlying reason for the increased mortality is unclear, diaspirin cross-linked haemoglobin has been removed from the market.

Other haemoglobin substitutes currently under investigation in phase III clinical trials involve the polymerization of blood cells, which is purported to attenuate vasoconstriction by reducing the risk of extravasations of the product and thereby limiting the scavenging of nitric oxide. These products include Polyheme, derived from outdated human blood, and Hem pure, derived from bovine haemoglobin. In phase II clinical trials, Polyheme was associated with a reduced need for blood transfusions in acute trauma and urgent surgery patients and was not associated with either systemic or pulmonary artery hypertension. A pivotal phase III multicentre randomized controlled trial comparing Polyheme and standard crystalloid in prehospital resuscitation has recently been completed.

Preliminary results reported by the manufacturer showed a decrease in the need for allogeneic blood transfusions in the Polyheme group, but the study failed to demonstrate non-inferiority in mortality as compared with standard treatment. In phase II trials, Hem pure was associated with a reduction in the need for blood transfusions in patients undergoing elective orthopaedic, cardiac and noncardiac surgery. These findings have resulted in the product's approval in South Africa as an alternative to blood transfusions, and Hemopure is currently under review by the US Food and Drug Administration. The use of modified haemoglobin substitutes for the treatment of critically ill patients holds promise, but further research on the efficacy and safety of these products is required.

Perfluorocarbons are another class of haemoglobin substitute that are attractive because they transport both oxygen and carbon dioxide and can release oxygen to the tissues at a rate of about twice that of haemoglobin. Perfluorocarbons have the advantage of a long shelf life and no risk of transmission of blood-borne infections. However, because of the linear relation between the partial pressure of oxygen

endothelial cells. A dose of 0.3  $\mu\text{g}/\text{kg}$  given subcutaneously usually results in a 3- to 5-fold increase in levels of factor VIII and von Willebrand factor. For this reason, desmopressin therapy is effective in controlling and preventing bleeding in patients with mild haemophilia A and von Willebrand's disease and in patients who are haemophilia carriers. It has also been shown to be effective in controlling and preventing bleeding in patients who have congenital platelet disorders and those who have platelet dysfunction associated with renal failure.

However, critically ill patients often have elevated levels of factor VIII and von Willebrand factor, both acute phase reactants, and the balance of benefits and potential harms of desmopressin for these patients is unclear. A meta-analysis of desmopressin in the treatment of perioperative bleeding showed only a small, no significant reduction in blood loss without evidence of a reduction in the need for blood transfusions. Desmopressin therefore may not be effective in improving haemostasis or in reducing acute blood loss in critically ill patients who do not have specific bleeding disorders such as mild haemophilia A, von Will brand's disease and uraemia.

#### ***Recombinant activated factor VII***

Recombinant activated factor VII (recombinant factor VIIa) is a coagulation factor concentrate that is approved for use world wide in patients with factor deficiencies (haemophilia) and in Europe for use in patients with congenital platelet disorders. Numerous case reports and series have reported reduced blood loss associated with the use of recombinant factor VIIa in surgical patients, trauma patients, patients receiving massive transfusions, those with liver disease and patients with gastrointestinal bleeding.

A few randomized controlled trials evaluating the clinical effectiveness of recombinant factor VIIa have involved critically ill patients, including patients with trauma, those with gastrointestinal bleeding, those undergoing cardiac surgery <sup>or</sup> liver transplantation and patients with intracranial haemorrhage. A recent systematic review examined the evidence for prophylactic and therapeutic use of recombinant factor VIIa in patients without haemophilia and concluded that its effectiveness as a haemostatic agent remains uncertain. In that review, the pooled estimates for adverse outcomes showed no significant trends for increased thromboembolic complications

(relative risk 1.28, 95% confidence interval [CI] 0.84–1.95,  $p = 0.3$ ), cardiovascular events (relative risk 2.18, 95% CI 0.82–5.79,  $p = 0.1$ ) and stroke (relative risk 2.02, 95% CI 0.57–7.17,  $p = 0.3$ ).

Boffard and colleagues recently published 2 parallel, multicentre randomized controlled trials that examined the use of recombinant factor VIIa versus placebo in patients with blunt ( $n = 143$ ) and penetrating ( $n = 134$ ) trauma. Patients who received 8 units of blood were randomly assigned to receive either recombinant factor VIIa (initial dose of 200  $\mu\text{g}/\text{kg}$  plus additional doses of 100  $\mu\text{g}/\text{kg}$  1 and 3 hours later) or placebo.

Overall, there was no significant difference between the treatment and placebo groups in the number of units of blood subsequently transfused (primary outcome measure). Among patients who survived more than 48 hours, recombinant factor VIIa was associated with a reduction in the number of transfusions by 2.6 units (90% CI 0.7–4.6,  $p = 0.02$ ) in the blunt trauma group and by 1.0 unit (90% CI 0.0–4.6,  $p = 0.10$ ) in the penetrating trauma group. No differences in mortality or thromboembolic events between the groups were noted, but the trial was not powered to evaluate these end points.

Bosch and colleagues evaluated the use of recombinant factor VIIa in a randomized controlled trial involving 245 patients with upper gastrointestinal bleeding and cirrhosis. In addition to endoscopy and standard care, patients were randomly assigned to receive either 8 doses of recombinant factor VIIa (100  $\mu\text{g}/\text{kg}$  each) or placebo over 30 hours. No differences between the 2 groups were observed in controlling bleeding within 24 hours after the first dose, the incidence of recurrent bleeding between 24 hours and day 5, the number of blood transfusions or the number of deaths within 5 days.

Among 399 patients with intracranial haemorrhage, a phase II multicentre randomized double-blind dose-finding study of recombinant factor VIIa showed a reduction in mortality (overall odds ratio 1.8, 95% CI 1.1–3.0,  $p = 0.02$ ) and in disability, using the modified Rankin score (odds ratio 2.2, 95% CI 1.3–3.8,  $p = 0.004$ ). Only patients who were seen within 4 hours after the onset of symptoms and who had a Glasgow coma score of more than 5 and no history of cardiac or thromboembolic disease were included. The

investigators found a no significant increase in thrombotic events among patients receiving recombinant factor VIIa. Preliminary results from another multicentre randomized controlled trial of recombinant factor VIIa involving patients with intracranial haemorrhage ( $n = 821$ ) did not show similar benefits in reducing morbidity and mortality. Pending the full publication of these results, the role of recombinant factor VIIa will need to be re-evaluated.

On the basis of the studies to date, the routine use of recombinant factor VIIa in critically ill patients cannot be recommended. However, use in specific patients who have massive uncontrolled bleeding and who do not respond to standard treatments and conventional blood components may still be a reasonable option, after potential benefits and risks of thrombotic complications are weighed.

- 5.4 Haemoglobin substitutes may delay or reduce the exposure to allogeneic blood transfusions in trauma patients with acute blood loss. These products can replace the use of blood products during acute blood loss and, when combined with acute Normovolemic Haemodilution in the perioperative setting, could reduce the need for blood transfusions. Their use in critically ill patients could reduce the need for blood in patients requiring massive transfusions. There are 2 classes of haemoglobin substitutes: modified haemoglobins and the perfluorocarbons. The artificial haemoglobin solutions are either recombinant products or are derived from outdated human red blood cells or bovine haemoglobin. The potential advantages of haemoglobin substitutes include their availability without need for cross-matching, a long shelf life, the ability to store the products at room temperature and a reduced risk of disease transmission. Disadvantages include their relatively short half-life after administration (24–48 hours), their interference with laboratory haemoglobin measurements, renal toxic effects, and adverse effects on vascular tone and blood pressure. The most recent generations of haemoglobin-based oxygen carriers have been modified to prevent rapid dissociation and short half-life, to avoid renal toxic effects and to reduce vasoconstriction by decreasing nitric oxide scavenging.