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CORE TRAINING FOR DOCTORS

Edited by Dr Daniel JB Marks, Academic Clinical Fellow in Translational Medicine, and **Dr Philip J Smith,** Academic Clinical Fellow and Specialist Registrar in Gastroenterology, University College London

Legal and ethical issues in blood transfusion

There are many legal and ethical challenges in blood transfusion medicine. These include ethical and legal duties to report transfusion reactions, the need to ensure beneficence and non-maleficence by using evidence-based practice, informed consent and the right to refuse treatment. The specific case of transfusion practice for Jehovah's Witnesses will be discussed in detail.

Regulation of blood transfusion

Blood transfusion laboratories are regulated by a number of bodies. The UK Blood Safety and Quality Regulations cover quality management, training, adverse event and reaction reporting and the traceability of blood in hospitals, and are overseen by the Medicines and Healthcare products Regulatory Agency. The Medicines and Healthcare products Regulatory Agency has the power to close down transfusion laboratories that do not meet the expected standards.

Adverse events and reactions to transfusion must be reported to the Medicines and Healthcare products Regulatory Agency via the Serious Adverse Blood Reactions and Events reporting mechanism and are also analysed by the Serious Hazards of Transfusion scheme which produces an annual report with recommendations on blood safety (Bolton-Maggs et al, 2012). Doctors have a legal and ethical obligation to report adverse events from blood transfusion. While haematologists complete the final haemovigilance report, all clinicians have a responsibility to report adverse events.

Dr Michael J Desborough *is Academic Clinical Fellow in Haematology and Transfusion Medicine and*
Professor Michael F Murphy *is Professor of Blood Transfusion Medicine and Consultant Haematologist, NHS Blood and Transplant, John Radcliffe Hospital, Oxford OX3 9DU*

Correspondence to: Dr MJ Desborough (michael.desborough@ouh.nhs.uk)

What is the evidence for the effective use of blood?

Although blood transfusion is a common procedure, there is little evidence to indicate which patients should receive a transfusion. Two large randomized controlled trials have sought to answer this question. The Transfusion Requirements in Critical Care (TRICC) trial (Hébert et al, 1999) randomized 838 critical care patients to either receive a liberal transfusion regimen where haemoglobin was maintained over 10 g/dl, or a restrictive group where haemoglobin was maintained over 7 g/dl. After 30 days, the mortality for the liberal transfusion group was 23.3% whereas it was 18.7% for the restrictive group. This suggested that it is not always beneficial to transfuse blood and in some cases can be harmful. It is possible that transfusion-associated circulatory overload (the leading reported cause of morbidity from blood transfusion) or the immunosuppressive effects of blood transfusion may be responsible but this is still unclear. Transfusion reactions alone are not sufficient to account for this difference.

The transfusion trigger trial for Functional Outcomes in Cardiovascular patients Undergoing Surgical hip fracture repair (FOCUS) (Carson et al, 2011) randomized 2016 patients with a fractured neck of femur to either receive a liberal transfusion regimen where haemoglobin was maintained above 10 g/dl or a restrictive regimen where haemoglobin was maintained above 8 g/dl. Patients were also transfused in the restrictive arm if they had symptomatic anaemia even if their haemoglobin level was above the threshold. In the liberal transfusion arm, 35.2% of patients died or were unable to walk across a room after 60 days of follow up, compared to 34.7% in the restrictive group. While this difference was not significant for these patients, it did demonstrate that there is no additional benefit to transfusing blood liberally to these patients.

In the non-bleeding patient with no other clear complications, there is no evidence for maintenance transfusion or so-

called 'top-up' transfusion before discharge. However, it should be noted that when reviewing reported adverse events from transfusion practice in the UK, there was considerably more mortality and morbidity from failure to transfuse when it was necessary than from inappropriate transfusion (Bolton-Maggs et al, 2012).

Prophylactic use of anti-D

Routine antenatal anti-D prophylaxis is offered to all RhD-negative pregnant women in order to prevent haemolytic disease of the newborn in future pregnancies. It does not benefit the fetus from the ongoing pregnancy and there is a very small risk of harm. A utilitarian decision is made, as significant benefits of routine antenatal anti-D prophylaxis to future pregnancies are considered to outweigh the small risk to the present pregnancy (Chilcott et al, 2003).

How should blood be allocated?

In some disaster situations in which there are many casualties, blood can rapidly become a scarce resource. When this is the case, judgements must be made on the best use of limited stocks of blood products. Once again, utilitarian principles are used to ensure the greatest benefit for the greatest number of patients. However, good blood stock management and emergency plans help to avoid these situations (Galloway et al, 2008).

Jehovah's Witnesses

Jehovah's Witnesses are a Christian group who will not accept transfusions of whole blood or any of its major components (red blood cells, platelets, plasma or white blood cells) (Rogers and Crookston, 2006). Important things to consider when managing these patients include informed consent and a discussion of the alternatives to transfusion, making an alternative management plan, and preparations for emergencies and unexpected blood loss.

It is important to assess what is and is not acceptable for individual Jehovah's Witnesses when discussing the use of blood products, as there is some variation in practice and the transfusion of some blood components is left up to individual conscience (Rogers and Crookston, 2006) (*Table 1*).

Informed consent

It is essential that informed consent includes a discussion about the alternatives to transfusion. Informed consent can be verbal or written, depending on individual hospital policies, but in either case should be documented in the patient's medical records. According to the Mental Capacity Act 2005, in the event that the patient is able to understand the information relevant to the decision, retain that information, weigh it up as part of the decision-making process, and communicate this decision he/she is deemed to have capacity. It is important that this decision is free from coercion. If the patient has capacity, his/her wishes not to be treated with blood products should be respected, even if this results in severe morbidity or mortality. Jehovah's Witnesses may sign advance decisions specifying their wishes in the event that they lose capacity.

The situation with children is more complicated. If a child is deemed to be at risk from not receiving a blood transfusion then an application can be made to the courts to administer the transfusion against the wishes of the family if necessary. Older children who are deemed to be Gillick competent (those that are able to demonstrate sufficient understanding and intelligence to understand fully the treatment proposed) are able to consent to treatment against their parents' wishes. However, they do not have the same rights to refuse treatment. In the event that the treating doctors feel that the child is at risk without a blood transfusion, and both the child and parents refuse, then a legal application can be made to the courts. It is best to negotiate before reaching this stage and to explore all the possible strategies that do not involve blood transfusion (Woolley, 2005).

Operations and other situations where blood loss is expected

When possible, it is best to make plans in advance in order to optimize blood conservation. Methods to reduce the need for transfusion include preoperative use of iron to correct iron deficiency anaemia (Munoz et al, 2012) and intraoperative cell salvage (Carless et al, 2010) where a patient's own blood is collected during a procedure (such as surgery) and transfused back into the patient (this is accepted by some Jehovah's Witnesses when there is no interruption in the circuit of blood). Tranexamic acid, which is an antifibrinolytic agent, significantly reduces perioperative blood transfusion requirements and may also improve operative mortality (Ker et al, 2012). Erythropoietin, folic acid and iron should be considered when deficiencies in these factors have been identified. These measures are often effective and can remove the need for blood product transfusion.

Table 1. The position of Jehovah's Witnesses on medical treatment

Position of Jehovah's Witnesses	Treatment type	Examples
Treatment that is acceptable	General	Most medical procedures and treatments that control bleeding or stimulate the production of blood
	Volume expanders	Non-blood products such as normal saline and Gelofusine
	Blood tests	No objections
Treatment that is not acceptable	Blood transfusion	Transfusion of any blood component
	Preoperative autologous blood deposit	Blood collected preoperatively for re-infusion later
Matters of patient choice	Intraoperative cell salvage	Collection of the patient's own blood from surgical sites which can be transfused back during the operation when required
	Haemodialysis or heart bypass	Most Jehovah's Witnesses will avoid blood priming in these procedures
	Some blood products	For example albumin, immunoglobulins and vaccines

Urgent or unexpected need for transfusion

Unexpected blood loss will often require urgent transfusion of blood components. Mortality rises rapidly when patients are not transfused and haemoglobin falls to 5–6 g/dl (Carson et al, 2002) and there have been many reported cases of Jehovah's Witnesses refusing blood transfusion in life-threatening circumstances (Dyer, 2012). If the patient has capacity or has specified in advance that he/she does not wish to have blood transfusion, he/she should not receive a transfusion, even if this results in death. Attempts should be made to optimize the remainder of the patient's management but blood products should not be administered.

Should we treat all patients like a Jehovah's Witness when blood loss or anaemia is expected?

As with Jehovah's Witnesses a process of informed consent should take place before each blood transfusion. The Safety of Blood, Tissues and Organs advisory committee has published guidance for consent for transfusion of blood components (Department of Health, 2012). Consent should be taken for all patients undergoing transfusion, and written informed consent should be taken for patients on a regular transfusion programme. Informed consent should include a discussion of what would happen if blood was not transfused at all and alternatives to blood transfusion such as the use of tranexamic acid, cell salvage or treatment with iron. It should include the common and severe risks of blood transfusion (*Table 2*).

Conclusions

It is essential to remember that the source of blood in the UK is from donors who have volunteered to donate. Ethically, donors should not be put through this procedure to obtain blood that is used inappropriately. As well as needing a better evidence base to guide practice for the use of blood, doctors can learn lessons from Jehovah's Witnesses by using methods for conserving blood and ensuring that each patient who receives a transfusion gives informed consent. **BJHM**

Table 2. Frequency of blood transfusion complications

Complication		Frequency per unit of red cells transfused
Febrile non-haemolytic transfusion reaction		1:100
Transfusion-associated circulatory overload		1:100
Allergic reaction		1:100–300
Transfusion-related acute lung injury		1:1250–5000
Anaphylaxis		1:20 000–50 000
Fatal haemolytic reaction		1:600 000
Infection	Hepatitis B	1:500 000
	Bacteria	1:1 million
	HIV	1:5.25 million
	Hepatitis C	1:30 million

From Heddle and Webert (2009)

KEY POINTS

- The transfusion of blood products is tightly regulated.
- Blood transfusion can be life saving, especially for patients who are acutely bleeding.
- Blood transfusion carries risks (some of which are unknown).
- Informed consent is essential before transfusion of blood to a patient.
- Treatments such as cell salvage, tranexamic acid and oral and parenteral iron can be used to reduce blood transfusion.
- Trial evidence suggests having a more restrictive threshold for transfusion leads to equally good if not better outcomes in some patient groups.

Conflict of interest: none.

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