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Patients should consent to blood transfusion

Millions of people receive blood transfusions each year, but many will not be fully aware of the risks. **Anne-Maree Farrell** and **Margaret Brazier** argue for a formalised consent procedure

Within transfusion medicine, the question of whether separate informed consent should be obtained from patients for blood transfusion has provoked considerable debate. There has long been support for such an approach in the United States.¹ A *BMJ* editorial in 1997 made it clear that reform was on the professional agenda in the United Kingdom, despite the established position that obtaining general consent for medical treatment included consent for blood transfusion.² At the time, however, professional consensus proved elusive because of concerns over a range of practical problems, including who should be responsible for obtaining such consent and in what circumstances it should be obtained.³ The issue has now been brought to the fore again, highlighted by the recent stakeholder consultation launched by the UK government's independent Advisory Committee on the Safety of Blood, Tissue and Organs.

In its consultation document, the committee acknowledged that practice on obtaining consent for transfusion of blood components is inconsistent across the UK. In addition, it highlighted several concerns including whether patients are being given information on risks, benefits, and alternatives to transfusion, as well as being informed of their right to refuse transfusion.⁴ We echo the committee's concerns. Although current advice states that there is no legal requirement to obtain formal consent from the patient for transfusing blood components,⁵ we question the basis of such advice and its continuing legal probity.

Informing patients about blood transfusion

In the past, many patients, and their general practitioners, were unaware that they had received blood transfusions during medical treatment.⁶ Few published data exist on patient concerns

about blood transfusion in the UK, but several small studies conducted in the 1990s showed that patients would have welcomed more information about the risks, benefits, and alternatives to blood transfusion.³

Although improvements might have been expected over the past decade, the lack of published audits makes it difficult to ascertain whether the deficit in the provision of information and documentation about blood transfusions has been redressed within the National Health Service (NHS). The UK blood services publish information leaflets about blood transfusion for hospitals and healthcare professionals to give to patients, but the provision of such leaflets to patients is not mandatory and the take-up by hospitals has been variable. A recent audit showed that although such information leaflets were readily available in NHS trusts, many patients who had received blood transfusions had not received the leaflets. Perhaps this reflects the fact that NHS trusts do not see issues relating to blood transfusion in general as a high priority.⁷

Recent legal developments and consent

National health policy and practice has put greater emphasis on patient involvement and choice about medical treatment in recent years. Against this background, there have been important legal developments regarding the information that should be disclosed to patients concerning risks associated with their medical treatment. In a majority judgment handed down in *Chester v Afshar* by the House of Lords in 2004,

Cumulative data on mortality and morbidity from blood transfusion, 1996-2008¹⁰

Description	Death*	Major morbidity†	Minor or no morbidity	Outcome unknown	Total
Incorrect blood component transfused	24	109	3167	11	3311
Inappropriate or unnecessary blood transfusion	2	1	73	0	76
Handling and storage errors	0	0	139	0	139
Anti-D immunoglobulin	0	24	176	0	200
Acute transfusion reaction	18	31	782	3	834
Haemolytic transfusion reaction	11	40	344	1	396
Acute lung injury	40	147	49	0	236
Post-transfusion purpura	2	13	34	0	49
Graft versus host disease	13	0	0	0	13
Transmitted infections	14	46	6	0	66
Circulatory overload	1	6	11	0	18
Dyspnoea	0	1	0	0	1
Autologous transfusion	0	0	28	0	28
Total	125	417	4810	15	5367

* Transfusion reaction causal or contributory.

† Probably or definitely due to transfusion reaction.

it was held that patients should be told of any possible serious risks associated with their proposed medical treatment.⁸ Lord Steyn observed that in “modern law medical paternalism no longer rules and a patient has a *prima facie* right to be informed [of] a small, but well-established, risk, of serious injury.”⁸ He went on to say that the disclosure of information about the risks associated with medical treatment was considered to be of the utmost importance in terms of upholding the patient’s right to autonomy and dignity. Crucially, the Law Lords ruled that to succeed in a claim for negligence the patient did not have to prove that he or she would have rejected the treatment that had been inadequately explained to them, only that they might have sought further advice or time to reflect further before making a decision.

The procedure has serious infectious, as well as non-infectious, risks, ranging in frequency and severity

In the wake of this judgment, the General Medical Council issued revised guidance. It emphasises the duty of doctors to act in partnership with their patients with respect to obtaining their consent to medical treatment.⁹ Doctors are advised to disclose risks arising from treatment that may result in common but minor side effects, as well as rare but serious adverse outcomes that may result in permanent disability or death. The GMC cautions against making assumptions about the patient’s understanding of risk or the importance they might attach to dif-

ferent outcomes. The guidance specifically states that where risks are beyond the minor or routine, the patient’s written consent should be obtained.

These developments underline the need for a different approach to patients receiving blood transfusions in the UK. The procedure has serious infectious, as well as non-infectious, risks, ranging in frequency and severity (table).¹⁰ Some risks may be considered small or remote, such as the transmission of infectious diseases, but they are risks that patients are likely to attach importance to because they may result in serious morbidity or death. As the Court of Appeal in *Pearce v United Bristol Healthcare NHS Trust* made clear, doctors must inform patients of any “significant risk that would affect the judgment of a reasonable patient.”¹¹

COMMENTARY

How to seek consent and gain understanding

Farrell and Brazier set out the arguments for obtaining specific informed consent for allogeneic blood transfusion.¹ They do not deal with allogeneic blood products, but I think their article can be assumed to cover this too. This subject is controversial, and the question of how to seek and record consent has been the subject of a recent consultation by the Department of Health’s Advisory Committee on the Safety of Blood, Tissues and Organs. A question Farrell and Brazier avoid is who should be responsible for gaining informed consent? Should it be those who provide the blood (the transfusion service, probably most informed about the risks) or those who prescribe it (probably least informed)? This is of crucial importance in the debate and has considerable resource implications.

The table of adverse events in Farrell and Brazier’s paper, taken in isolation from the Serious Hazards Of Transfusion 2008 report, might make worrying reading. But what is the denominator? There were 5367 reported serious adverse events in 12 years from 28 887 455 issues of blood and blood products from the National Blood Service—an

Less than 0.02% of transfusions involve serious adverse events

incidence of 0.019%.² This calculation does not accurately describe risk but shows that the blood supply and its management is generally safe.

Are the risks of transfusion high enough to warrant specific informed consent? Let us look at an example from the area in which I work—elective coronary artery bypass grafting (CABG). The accepted national mortality for this procedure is 0.5–2%. In simple understandable language you could tell a patient that, at worst, two in every 100 elective patients might die.

Secondly, the chance of receiving a blood transfusion

during elective CABG is about 30%; there are no good national data at present, and transfusion practice varies widely from centre to centre. Given that 0.019% of all blood issues from the UK National Blood Service from 1996–2008 were associated with a reported adverse event, the risk to elective CABG patients is vanishingly small.

In my opinion patients should be informed of the risks of a procedure, the chances of receiving blood during that procedure, and what measures might be used to avoid unnecessary transfusion, but is this such a large risk that specific separate consent is required for the blood transfusion? A patient signing a standard NHS consent form will be giving their consent to a blood transfusion if required. I would hope that this was an informed choice and that the clinician as well as mentioning the possibility of a blood transfusion also mentions that transfusion itself has some risks, albeit small.

What is missing in the debate surrounding informed consent is the true nature of patient understanding, what information patients want to

know, and how to deal with patients who wish to know only the minimum. There is little work in the area of assessing the understanding of the information given to patients. Clinicians often find it difficult to be certain how much patients or their relatives have correctly understood the information given to them. Understanding is affected by who is giving them the information, how it is explained, and the time or environment required to assimilate information. A paternalistic approach is unacceptable in medical practice; a common sense approach—explaining things clearly, tailoring what is said to what the patient seems to want, and checking understanding—is required for good medical practice.

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- 2 Serious Hazards of Transfusion. Annual report 2008 summary. www.shotuk.org/wp-content/uploads/2010/03/Summary-2008.pdf.

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Time for change

We argue that it is now a legal requirement for patients to be informed of the specific risks posed by blood transfusion, in addition to those risks posed by their medical treatment or surgery. This should be done through a formal consent process initiated by treating healthcare professionals and including a discussion of the risks and benefits of, as well as the alternatives to, blood transfusion. Failure to do so may result in a claim of negligence or even battery. If patients are not made aware that a discrete and additional invasive and potentially risky procedure such as a blood transfusion may be carried out during their treatment, are they sufficiently informed, even in broad terms, of the “nature of the procedure which is intended”?¹² If they are not, then there is no consent to that procedure and the administration of the transfusion may be unlawful. It is established law that adult patients with capacity can refuse a blood transfusion, notwithstanding the views of their doctors that it may be in their best interests to have one.¹³

In the context of surgery, when a transfusion is likely to be needed, patients should be informed and consent obtained before the operation. When it is likely that multiple transfusions may be required at various times during the course of medical treatment, this should be explained and consent obtained at the start of such treatment. In an emergency or an unexpected situation when it is not possible to obtain consent in advance, the transfusion will be lawful in the absence of any evidence that the patient would have refused consent,¹⁴ but patients should be subsequently informed that it has taken place and have the reasons for transfusion explained. The fact that patients were informed about the likelihood of receiving a blood transfusion, as well as whether they consented to or refused such transfusion, should be noted in their medical records and the discharge summary. All patients receiving blood transfusions should be provided with an information sheet on discharge detailing possible signs and symptoms relating to adverse outcomes from blood transfusion and what to do if they experience them.

Data should be collected systematically within the NHS to determine the extent to which these requirements are being met, and remedial action should be taken where it is not. National blood policy has emphasised the need for greater patient awareness about the risks and choices associated with the safe and appropriate use of blood.¹⁵ Requiring that specific consent be obtained for blood transfusion in the UK is an important step towards not only enhancing such awareness but also recognising the importance of patient autonomy in the context of decision making about medical treatment.

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FROM BMJ.COM

HIV and TB in Uganda

Anjum B Khan is a specialty trainee year 4 doctor. He spent six months working in Uganda in a tuberculosis and HIV project run collaboratively by the Ugandan Ministry of Health and a non-governmental organisation. He writes about his time in Uganda:

“Life and death are very much seen as two sides of the same coin. So many times, bumping into someone I haven’t seen for a while, the phrase “I lost someone” comes up. As an outsider, the unusual thing is the lack of expressed emotion. It’s there alright: my ward is right next to the mortuary, you hear the wails of grief most mornings. Family is very important here, family networks are all. Brothers and sisters are everywhere, few of them siblings. But death happens here so often, the reaction is more muted.

Early death is nothing new in Africa of course. Malaria kills huge numbers of pregnant women and infants every year. Women die needlessly in childbirth. What is different about AIDS is the scale: more than 6% of people here in Uganda are affected and a mind-blowing 25% in southern Africa.

What makes HIV so important is whom it affects. Over the past few months I’ve got used to skeletal twenty somethings arriving on my tuberculosis ward. People whose alter egos I see walking around the town, healthy and full of life, appear on the floor of the clinic, or propped against the wall, lying very still. Coming from the West, we’re accustomed only to seeing elderly cancer sufferers look like this, or the terminally ill. The average age in the ward is 28. These people should be out there working in the fields, raising families, playing with kids.”

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FROM DOC2DOC

Whither the white coat?

In *BMJ Careers* last week Oliver Ellis reported on the return of the white coat (*BMJ Careers* 2010;341:76-7, <http://bit.ly/dBOfd5>). Poll results from doc2doc, BMJ Group’s global clinical online community, show that 52% of members think doctors should wear white coats. But members are still uncertain about the value of the practice.

bungeechump: “Surely patients’ perceptions are based on doctors’ manner, conduct, and skill, not whether they wear big white jackets?”

yoram chaiter: “What about protecting yourself from various things like blood, sputum, and so on?”

Odysseus: “White coats are a vestige of medical imperialism. It is to hide incompetence and puts a barrier between you and your fellow beings we call patients.”

shrink: “As a trainee I witnessed psychiatrists doing ward rounds in ankle long white coats. A lot of medicine, and even more of psychiatry, is about creating trust and make believe.”

MRH: “But where else would you stash your notebook, hanky, lippy, pen, and bleep/mobile?”

helen: “Forget white coats. Hats are a good infection control measure, and can be easily coloured to denote hierarchy position.”

What is the purpose of white coats? Are they necessary?

➤ Have your say at <http://bit.ly/bOgzJU>