

ORIGINAL ARTICLE

Is there a right to donate blood? Patient rights; donor responsibilities

Ian M. Franklin,*† *Scottish National Blood Transfusion Service, Edinburgh, UK and †University of Glasgow, Glasgow, UK.

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SUMMARY. The objective of this study was to analyse and assess critically whether there is a right to donate blood in the UK.

The aim was to provide a basis for blood services, in particular within the UK and European Union (EU), to address claims from deferred donors that there is a right to donate.

Recent and ongoing campaigns to change the current life-long deferral from blood donation in the UK, Canada and USA of men who have/have had sex with men (MSM) have highlighted issues over whether individuals have a right to donate blood. The issue is complicated by allegations of discriminatory behaviour, and in some countries politicians have contributed to the argument. As anti-discrimination and equality legislation is strengthened in the UK, other groups in addition to MSM may wish to claim a right to donate blood.

The methods adopted included discussions with colleagues in UK and European blood services and a review of the medical literature and wider sources using Internet search engines.

No clear right to donate blood is apparent, although it is recommended that donor deferral criteria should have a sound basis of evidence. Potential donors have a right to expect a clear explanation of the reason(s) for refusing a donation. Legal safeguards for recipients to receive safe blood transfusions exist.

It is concluded that blood recipients in the EU have a right to receive safe blood, and that this should be viewed as the overriding responsibility of blood services.

Key words: blood donor, blood safety, donation, rights.

Over the past few years, there has been increasing calls from, in particular, the gay community to permit ‘gay men’ to donate blood (Editorial, 2006a). University student organizations have also picked on this issue as a fight against discrimination, and the Scottish edition of the Big Issue (Russell, 2005) has also featured a campaign to permit ‘gay men’ to donate. Arthur Caplan, a previous Chair of the Advisory Committee to the US Department of Health and Human Services on Blood Safety and Availability, entered the fray recently in favour of allowing gay men to give blood (Caplan, 2006), and the main US blood service organizations have also stated their preference for a change to the current permanent deferral of men who have sex with men (Editorial, 2006b). In the UK, the blood donor selection criteria do not exclude gay men, but the donor health check questionnaire does contain the following statement:

Your lifestyle. Have you ever had oral or anal sex with another man with or without a condom or other form of protection?

Other questions consider sexual relationships in individuals from Africa or in Africa and the use of injected drugs. These questions are included to identify people who might be of higher than average risk of being positive for one of the three main transfusion-associated viruses [human immunodeficiency virus (HIV) and hepatitis B virus (HBV) and hepatitis C virus (HCV)]. Therefore, each donor exclusion criterion focuses on behaviour and not on inclination. The emphasis on behaviour and not inclination or orientation is reflected in the lack of any donor deferral for women who have sex with women. This behaviour has not been found to add to the risk of a donation being positive for one of the main transfusion-associated viruses.

The term ‘men who have had sex with men’ (MSM) is now used to identify precisely the behaviour that leads to an increase in risk of HIV or HBV, rather than the sexual orientation of the person. The one difference

Correspondence: Ian M Franklin, FRCP, FRCPath, Scottish National Blood Transfusion Service, Ellen’s Glen Road, Edinburgh EH17 7QT, UK.
e-mail: imf1c@clinmed.gla.ac.uk

between most exclusion criteria for recipient safety reasons and MSM (and intravenous drug use) behaviour is that MSM acquire a permanent deferral from blood donation in the UK. Other risk behaviours, including sexual relationships in Africa and indeed in the case of women who have had sex with an MSM, are temporary deferrals in the main for about 1 year. The UK and USA policy of permanent exclusion of MSM behaviour is not adopted universally (the USA deferral is MSM behaviour since 1977). Australia has had a deferral of 1 year since 2000. In New Zealand, it is currently 10 years. In South Africa, the deferral is 1 year. The epidemic of new cases of HIV/acquired immunodeficiency syndrome (AIDS) in southern Africa may make the distinction between MSM and heterosexual behaviour irrelevant there. In Europe, the Netherlands and Denmark also have a permanent deferral.

There has also been political involvement in some countries. In Sweden, the Prime Minister, Goeran Persson, said in 2005 (Agence France-Presse, 2005) that 'gay men should be allowed to give blood or donate organs'. Of course, this latter statement may be a case of a politician confusing orientation with behaviour, and may not be sensitive to distinctions of current or past actions, or indeed the levels of risk. In Italy, a politician 'ordered' a blood bank chief in Rome to accept blood from a 'gay' donor, and made threats of prosecution (Hooper, 2005).

Blood services have a duty to provide safe blood, and also to deliver sufficient quantity to their health systems. A sequence of donor exclusion criteria over the past few years – variant Creutzfeldt-Jacob Disease (vCJD) precautions, haemoglobin level changes – has depleted the donor pool. At the same time, blood services in the UK, among other countries, have been focussing more efforts on effective use strategies, which have seen reductions in blood usage from above 48 per 1000 population per year to around 40 red cell units per 1000. So, although supply remains an issue, safety is the number one priority. Blood services are hypersensitive to the safety issue. The infection of patients, especially those with haemophilia, with HIV and HBV in the past has left a residual anxiety, and cases of virus transmissions continue to make headlines (BBC News, 2005). Blood safety measures regularly cost much more to implement than other health interventions, when measured in terms of the number of Quality Adjusted Life Years (QALY) gained (AuBuchon 2000). The public appears to expect absolute safety, and the Consumer Protection Act (CPA) agrees that the public can expect to receive safe blood (Burton, 2001). Not surprisingly, blood services are cautious when any suggestions are made that safety

margins might be reduced. There is even the possibility that the EU blood directive, enforced in the UK as the Blood Safety and Quality Regulations 2005, requires the MSM deferral to remain because it specifies that 'persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood' must be deferred, although at what level a behaviour becomes 'high risk' is not defined.

The lobby supporting the acceptance of gay men (sic) as blood donors considers that there is a human right violation being visited upon gay men. So is this true, and is there a right to donate blood? In this article, the legal, blood safety and ethical arguments regarding the existence or otherwise of a right to donate blood will be considered. Although the specific instance of the exclusion of MSM as donors will be used as the example, the general issue of donor rights will also be addressed.

THE LEGAL BASIS FOR DONOR SELECTION

Discrimination against gay men

Is the lifetime deferral following MSM behaviour discriminatory against gay men? In the Netherlands, where a permanent deferral for MSM is also in force, a recent court case found that the deferral of MSM as donors was indeed 'discriminatory' but was also 'justified' on the grounds of blood safety (CGB, 2005). In Quebec, Canada, the Human Rights Commission ruled that donating blood was not a right, when a gay man pressed for the right to donate (Leonard, 2002).

The concept of human rights as a set of principles has evolved over the past 50–60 years, although prior statutes such as the Magna Carta in England and the Constitution of the United States of America lay down foundations for the rights of individuals against the state. The UN Universal Declaration of Human Rights was issued in 1948, and was followed in 1950 by the Council of Europe's Convention for the Protection of Human Rights and Fundamental Freedoms, the latest version of which dates from 2003. In this article, the European Convention on Human Rights is used as the principal source, since this is the basis for legislation in the UK.

Most blood services no doubt accept that they need to respond to diversity within their communities and provide an open and welcoming environment to encourage a voluntary blood donation. However, there are also duties of blood services to the recipient. It might well be argued that these duties to the recipient far exceed duties of inclusion to the donor. Duties to

the recipient would seem to be well covered in the European Union/Council of Europe Declaration of Human Rights and also the United States Constitution. It is difficult to discern, on reading these two important documents, where a right to donate blood should be construed. The US Constitution, in Section 1 of Article XIV (14th Amendment), does state that 'No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States'. This phrase might provide some leverage with regard to arguing that MSM are discriminated against unfairly, and in this way have their privileges abridged, although it might equally be argued that the rights of the recipient must not be abridged either. The US Bill of Rights, which is constructed from the first 10 amendments to the Constitution, also makes no clear reference that helps here.

Article 14 of the Convention for the Protection of Human Rights and Fundamental Freedoms (Rome, 4.XI.1950) protects individuals from discrimination on specified and 'or other status' grounds. This was reaffirmed in 2000 in Protocol No. 12 to the Convention for the Protection of Human Rights and Fundamental Freedoms (Rome, 4.XI.2000).

Article 1. General prohibition of discrimination

- 1 The enjoyment of any right set forth by law shall be secured without discrimination on any ground such as sex, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status.
- 2 No one shall be discriminated against by any public authority on any ground such as those mentioned in paragraph 1.

This latter phrase, taken together with the 'or other status', might seem to be applicable to blood service donor selection policies, at least in those countries where blood transfusion services are public bodies.

The UK Equality Act (www.opsi.gov.uk/acts/acts/2006/ukpga_20060003_en.pdf) received Royal Assent on 16 February 2006. The Act becomes law in 2007 and will strengthen the rights of groups and communities not to be discriminated against on the grounds of sexual orientation. A Commission for Equality and Human Rights will be established under the Act. Within the terms of the Act 'human rights' means – (a) the Convention rights within the meaning given by Section 1 of the Human Rights Act 1998, and (b) other human rights.

What these other rights are is not clear, and it seems likely that a referral of the rights of gay men to donate blood might well be tested through the Equality and Human Rights Commission, once the new Act is in

force. The Act also specifies that discrimination in the provision of services is unlawful on grounds of sexual orientation. It has been argued that blood services provide services to donors, although the prime function surely is the provision of safe and effective transfusions for patients. Nevertheless, legal challenge might come from this direction.

There is, however, more than one side to this argument, and the other side brings in the rights of the patient/recipient. This balance of rights between two groups was discussed by Lord Hoffman on BBC radio recently (Hoffman, 2006). Somewhat to the surprise of the barrister presenting the programme, the Law Lord stated that human rights were not absolute, but were relative, and could change in different legal jurisdictions, for example. Hoffman's view is not merely his opinion, either. In *Stone-v-South East Coast Strategic Health Authority et al.*, a balance in the judgement was made between making public personal records and the complainant's right to confidentiality. Stone alleged that his human rights would be breached and wanted to prevent intimate personal information about him appearing in the media. The High Court ruled that the report could be published in full. This was on the basis that although Stone had a right to privacy, that right was outweighed because, among other things, there was a public interest to make public what had gone wrong in his case (Hempsons Solicitors, 2006).

On balance, there would appear to be sufficient lack of clarity over a right to donate that the current conservative approach by blood services could be retained pending a challenge in the courts. If the lobbying of activists threatens to or does significantly disrupt the blood supply, it might even be appropriate for blood services to seek an adjudication on the discrimination and 'right to donate' issue, rather than either caving in to lobbyists or suffering blood shortages due to protests. Might one also ask how many people offended by not being acceptable as blood donors is equivalent to the infection of one recipient with HIV or some currently unknown disease?

CPA in the European Union and the right to safe blood

Within the European Union (EU), the CPA requires that individuals should be protected from harm from products. Mr Justice Burton handed down a judgement, in 2001, which concluded that blood for transfusion was a product under the CPA (Burton, 2001). Burton went on to state that because blood services emphasize the safety of their products, then recipients were entitled to receive a safe product and that an unsafe product was defective under the CPA. He found

against the National Blood Authority for England and North Wales on all counts with regard to the transmission of HCV by blood transfusion in 1991. This judgement would seem to make quite clear that the duty of a blood service within the EU is to provide safe blood to patients, although having been heard at a High Court a similar case could be taken to the House of Lords and potentially be overturned. It, therefore, represents a persuasive argument rather than a definitive judgement.

So, there may be a legal right of recipients of blood transfusion not to be infected or damaged otherwise by that transfusion. That would appear to be the basis for the Netherlands Equal Treatment Commission decision (CGB, 2005). One group's rights do not negate the rights of others. Even non-negligent harm would be liable for damages under the CPA. There appears to be no evidence of any specific right to donate, although it is accepted that there is a duty on the part of blood services to treat individuals in a respectful way and to give full explanations as to why a donation cannot be accepted. These reasons should be evidence based and not arbitrary or gratuitously discriminatory. This will be particularly important when the new UK Equality Bill becomes law.

RISKS TO BLOOD SAFETY

It seems established that blood services in the EU must provide safe blood, but also try to avoid discriminating unnecessarily against groups of potential donors. Are there any risks of changing the donor selection criteria to permit individuals who have indulged in MSM behaviour to donate blood? Indeed, if there are not, why make the distinction?

HIV/AIDS

Recent analyses have been carried out by the Health Protection Agency and the UK Blood Services of the known risk of HIV infection in blood transfusion (Soldan & Sinka, 2003, 2005). This suggests that although there is a slightly increased risk of accepting individuals with a history of MSM behaviour as blood donors, after 12 months of abstinence this difference is really quite small. Therefore, the evidence in terms of the known risk of HIV would seem to support a relaxation of the criterion from permanent to 1-year deferral. It is difficult to see how this could make blood safer, however. More worrying is that this safety modelling is dependent in a high degree on compliance with the 12-month abstinence rule. That means waiting for the full 12 months after an episode of MSM activity

before donating. Including more recently sexually active MSM (current to 6 months, for example) as donors does increase the risk from HIV measurably. Vu *et al.* (2002) considered that 'HIV prevention in the United States should continue to focus on MSM and IDUs' (injection drug users). Also, repeat donors who become HIV positive during their donation history tend to give a history of MSM behaviour that they chose not to declare previously.

The precautionary principle is also important here. Although there is no single definition of the principle, a number of government papers, from the Commission of the European Communities (EU, 2000) and the UK Government (UK-ILGRA, 2002), address this issue. In 2000, the EU Commission paper stated that the principle might be invoked where 'preliminary objective scientific evaluation, indicates that there are reasonable grounds for concern that the potentially dangerous effects on the *environment, human, animal or plant health* may be inconsistent with the high level of protection chosen for the Community'. We know that the degree of protection from harm required for transfused blood is higher than that for any other medical intervention. Perhaps, the precautionary principle suggests that it would be a high-risk strategy to consider a measure that might reduce blood safety from HIV or other agents in any way?

Unknown or other emerging risks

The risks from transfusion are not only from HIV, and blood services need to consider unknown risks as well. In the past, two types of behaviour have been associated with very substantially increased risks of transfusion-transmitted disease. These two risk behaviours are injecting drug use and MSM. In particular, HBV and HIV have been very strongly associated with MSM behaviour in the past, and HIV retains this association. Injecting drug use is associated with HIV, HBV and HCV transmission by blood donation. There would, therefore, seem to be a realistic possibility that an emerging infection, currently unknown, that was capable of transmission by blood, would be transmitted more easily by individuals with a history of MSM behaviour than donors who do not. That is, people who inject drugs or indulge in MSM represent a 'sentinel' population with respect to emerging risks. Therefore, there would appear to be an unknown and currently non-measurable risk of accepting MSM individuals back into the blood donor population. Recently, an ex-American Red Cross worker has expressed concern about the impact of the wider safety issues of MSM and its impact on blood safety (Seidenberg, 2006). Despite this, and apparently

on the basis that more recent emerging infections relevant to blood safety have involved acute viral infections (West Nile Virus, for example), there seems to be a turning away from the idea of sentinel populations by some transfusion experts (FDA, 2006). And yet, until 25 years ago, within the professional lifetime of many of us, HIV and HCV were unknown, emerging infections spreading from sentinel populations through blood transfusion.

Recent evidence suggests that Human Herpesvirus-8 (HHV-8) may also be transmitted by transfusion, and there is also evidence that HHV-8 is more frequent in gay men attending sexually transmitted disease clinics.

ETHICAL ISSUES. WHOSE RIGHTS, WHOSE RESPONSIBILITIES?

Where should the balance lie in the provision of safe blood for patients, whereas on the other hand not needlessly discriminating against groups of people who may wish to donate? For known current risks that can be tested for, blood is very safe. It is far safer than most other types of medical intervention, but it will never be zero risk. A succession of safety problems going back to HIV/AIDS in the early 1980s and earlier has left the public sensitized to blood safety concerns. This in turn has driven blood services towards providing blood with very low residual risks of known infections – zero risk has even been mentioned in the past but it seems now to be acknowledged that this is unattainable. Would it help if agreement could be reached between blood services, patients/recipients and governments (including regulators) as to the level of residual risk that is acceptable? Is a residual risk of 1 : 1,000,000 low enough? Alternatively, do we need to keep trying to reduce the current 1 : 20,000,000 risk of HCV, now both antibody and NAT are used? It seems that such a numerical agreement of risk is unlikely to be achieved in the near future. Meanwhile, judgements have to be made. At this point it seems appropriate to review what the rights and responsibilities of the various parties in the provision of blood for transfusion are. These are summarized in Table 1.

The donor

It would seem that any individual should have the right to attend a blood donor session, provided that they behave in an appropriate sociable way and are non-threatening to staff and other potential donors. They should have the right to complete the donor questionnaire and/or undergo a personal donor interview. As part of this process, they have a responsibility or duty to tell the truth.

If they are not accepted as a donor on that occasion, they have the right to expect a clear explanation as to why, and to be told when, if ever, they will be accepted as a donor with respect to that reason for deferral. Ideally, they should be given written information to take away that explains clearly and simply the reason(s). Those reasons should have a clear basis in evidence of increased risk to themselves as the donor or to any recipient. At this point, the deferred donor has a responsibility to act in a mature and polite way even though they may be disappointed.

If a donation is taken, they have the right to be informed of any positive tests that might lead to the donation not being used. They also, it might be argued, have a right not to have their donation wasted. If they should test positive for any of the markers of infectious disease, they should have the right to be appropriately counselled and advised of the consequences and appropriate information given to their medical practitioner to enable future care to be given. Alternatively, they should be referred to a specialist dealing with the relevant condition if such is available. If their donation is being taken for the purposes of a properly conducted clinical trial, or to be used for reagent purposes, the donor should be advised of this and given the opportunity to refuse participation and for their donation to be used routinely.

Blood service

The blood service might reasonably expect that blood donors who make appointments will keep them and turn up to donate. The service has a duty to welcome all individuals who come offering a donation and to show them respect. Blood services have a right to expect that these donors will tell them the truth in answer to the relevant questions. Any such questions asked, however should be relevant either to the safety of the individual offering to donate or the potential recipient. Therefore, these questions need to have an evidence base underlying them with regard to blood recipient or donor safety. Blood services have a right to refuse a donor if there is any concern at all, but if they do refuse to accept a donation they must offer a clear explanation why that is the case. Ideally, they should provide a valid explanation that the donor can take away with them.

If the blood service does take a donation, they have a duty to do this properly and with trained staff and having taken a donation not to waste it. They also should take all reasonable steps to ensure that best transfusion practice is in place in the hospitals to whom they supply their blood, and that inappropriate use and wastage is minimized.

Table 1. Blood donation; rights, responsibilities and expectations

Activity	Donor		Blood service		Recipients/patient	
	'Right'	Responsibility	Expectation	Duty	'Right'	Duty
Attend session	Yes	To behave in a respectful way to blood session staff	That donors will keep appointments	To welcome all, not keep people waiting		
Complete the questionnaire/PDI	Yes	To tell the truth	That donors will tell the truth	To ask questions relevant to donor and recipient safety; evidence based		
To give/accept a donation	No	To accept deferral politely		To refuse if concern about the above – to explain why		
To have the donation used	Not to have a donation wasted			Not to waste useable donations		
Have blood available for medical care		To respond to reasonable requests to donate		To provide blood at all times for emergency/ life-saving care and to avoid shortages for routine care	To have blood available at all times for emergency care	
Receive information about blood safety	Yes	To act upon the information/ education to inform their donation decision		To provide appropriate intelligible information for donors and patients	To be given appropriate intelligible and timely information to permit decision making	
Receive safe blood or safe alternatives				To ensure that blood provided to the health system is safe, and to work with colleagues to develop a secure transfusion system	Yes	

The patient

The patient would seem to have a right to receive safe blood. This is enshrined in the CPA. They also have a right to have the issues surrounding transfusion explained to them and any reasonable alternatives discussed and offered, in good time prior to the likely need, if possible. Recent documents issued from the Scottish Executive would suggest that patients must give consent prior to medical or surgical treatment, and it seems unavoidable that this must include blood transfusion. They would seem to have a right to have blood available to support their surgery or other illness so that they do not come to harm from lack of blood, and that blood shortages should not lead to repeated postponement of surgery or other procedures.

CONCLUSION

In coming to a conclusion about the status of a right to donate blood, it might be appropriate to consider what blood services are for. Although the answer might be obvious, it may not be to all. 'Meeting the transfusion needs of patients in Scotland' is the core purpose of the Scottish National Blood Transfusion Service. For the English blood service, it is 'to save and improve patients' lives'. Although it is not possible to meet the transfusion needs of patients or to save lives without providing a good service to donors, if artificial alternatives to blood transfusion were discovered, we would not continue to bleed donors – there would be no right to donate then. The 'right' to donate plasma was denied in the UK due to vCJD concerns, and in most of the rest of the world it remains denied to those people who have spent time in the UK. So blood services exist solely to meet the needs of patients in terms of safety and supply – donors are a means to an end. The term 'discrimination' should be reclaimed for its original meaning – to discriminate objectively in favour of safer blood.

In the USA, Caplan and others have urged the change in MSM deferrals on the basis of concerns over supply. Yet, there are other ways to manage supply than relaxing donation standards. Over the past decade, huge strides have been made in the awareness of the potential hazards of transfusion [Serious Hazards of Transfusion (Stainsby *et al.*, 2005), Transfusion Requirements in Critical Care (Hebert *et al.*, 1999)], in training in the effective use of blood (Scottish National Blood Transfusion Service, 2007), and in driving down waste. Ensuring that blood or platelet transfusions are given only when indicated should be achieved before relaxing the high standards of safety enjoyed over the past 15 years.

As the 'right to donate' lobby gains momentum, one voice is not being heard. That is the voice of patients. In the UK, people with haemophilia are now treated with recombinant products overwhelmingly, so this once loud lobby for blood safety has other concerns. The lack of progress towards any meaningful debate with patients over blood safety – patients have no representation on the UK governmental Advisory Committee on the Microbiological Safety of Blood, Tissues and Organs or the professional JPAC (JPAC, 2006) Standing Advisory Committee on Transfusion Transmitted Infection, for example – is an omission that may return to haunt us all. Even if consent to transfusion remains up on the 'too difficult' shelf, some form of real engagement with patients is overdue, and until it is achieved, the debate over the right to donate blood, as one of only many important issues, will remain unbalanced. A clear framework for what is and is not a right to donate is needed now. This would inform the current debate over MSM behaviour, and also assist in meeting the arguments by other groups and individuals who claim discrimination. How far the rights of patients override those of potential donors is a crucial question to which all blood services need an urgent answer.

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