

Who should donate blood? Policy decisions on donor deferral criteria should protect recipients and be fair to donors

S. R. Brailsford,¹ D. Kelly,² H. Kohli,³ A. Slowther,⁴ N. A. Watkins⁵ & on behalf of the Blood Donor Selection Steering Group of the Advisory Committee for the Safety of Blood, Tissues, Organs

¹Clinical Directorate National Health Service Blood and Transplant, Colindale, UK, ²Liver Unit, Birmingham Children's Hospital, Birmingham, UK, ³Department of Public Health, NHS Lanarkshire, Bothwell, UK, ⁴Division of Health Sciences, Warwick Medical School, University of Warwick, Warwick, UK, and ⁵Clinical Directorate National Health Service Blood and Transplant, Cambridge, UK

Received 31 July 2014; accepted for publication 20 June 2015

SUMMARY

An important element in the development of voluntary blood donation schemes throughout the world has been the attention given to minimising the risk to recipients of donated blood, primarily the risk of transfusion transmitted infections. In response to the appearance of human immunodeficiency virus (HIV) in the 1980s a range of national policies emerged that excluded populations at high risk of contracting HIV from donating blood, with a particular focus on men who have sex with men (MSM), the primary reason being the protection of recipients of donated blood. Recently some countries, including the UK, have revised their policies, informed by advances in screening tests, epidemiological evidence of transmission rates and an increasing concern about unfair discrimination of specific groups in society. Policy makers face a difficult task of balancing safety of recipients; an adequate blood supply for those who require transfusion; and societal/legal obligations to treat everyone fairly. Given that no transfusion is risk free, the question is what degree of risk is acceptable in order to meet the needs of recipients and society. Decisions about acceptance of risk are complex and policy makers who set acceptable risk levels must provide ethically justifiable reasons for their decisions. We suggest it is possible to provide a set of reasons that stakeholders could agree are relevant based on careful evaluation of the evidence of all relevant risks and explicit acknowledgement of other morally relevant values. We describe using such a process in the Safety of Blood Tissue and Organs (SaBTO) review of donor deferral criteria related to sexual behaviour.

Key words: deferral, donor, ethics.

INTRODUCTION

In 2011 national policy on donor deferral criteria for blood donation changed in England, Scotland and Wales from a life-time ban on donation for men who had ever had oral or anal sex with men (MSM) to a requirement that only men who had relevant sexual relations in the previous 12 months should be asked not to donate blood. While similar policy changes have occurred or are being considered in other countries there is no international consensus on donor deferral criteria. Other groups such as those who have ever received money for sex or used intravenous drugs continue to be excluded from donating blood in many countries including the UK. In this paper we consider the factors that inform debate on this contentious policy issue.

BACKGROUND

Titmuss's book, *The Gift Relationship: From Human Blood to Social Policy* (Titmuss, 1970) resulted in almost immediate policy changes in the United States. The book recognised that a system based on voluntary blood donation was superior to alternative, commercial systems. The factors that motivate people to donate blood within a voluntary system are complex. A meta-analysis of antecedents of blood donation behaviour and intentions found that the strongest correlations were with donor-related factors such as experience of donation, self-identity and anticipated regret at not donating (Bednall *et al.*, 2013). The authors suggested a strategy for increasing donation should include emphasising the emotional benefit to the donor. This shift in understanding of the motivation for blood donation can inform strategies to improve donation but also provides insight into the effect of policies that exclude potential donors from the act of donation. A policy that excludes some people from an activity that is an acknowledged benefit must be justified. In the case of blood donation this justification is grounded in the requirement to protect the health of donors and recipients.

Correspondence: Dr Anne Slowther, Warwick Medical School, University of Warwick, Coventry CV4 7AL, UK.
Tel.: +44 24 7657 4513; fax: +44 24 7647 3079; e-mail a-m.slowther@warwick.ac.uk

In many countries donors with specific health problems are excluded from donation for their own benefit. For example, patients with chronic fatigue syndrome (CFS), a relapsing condition associated with easily induced and prolonged episodes of fatigue, are permanently deferred from blood donation to avoid exacerbating their symptoms. Similarly, many donors are temporarily deferred because of low levels of haemoglobin. Donor exclusion also occurs if there is a direct risk of harm to recipients from donated blood. These deferral criteria are generally uncontroversial. In contrast deferral criteria based on specific behaviours with potentially increased prevalence of donor infection such as sexual behaviour or intravenous drug use have been challenged in recent years leading to changes in policy in some countries. The debate and variation in national policies derive from two key factors: the perception and tolerance of risk, and the relative importance given to particular moral values (Fanklin, 2007; Leiss *et al.*, 2008; Galarneau, 2010). We consider these in the context of donor deferral based on specific sexual behaviours and identify general principles that could be used to develop ethically justifiable and socially acceptable donor deferral criteria for blood and tissue.

MAINTAINING A SAFE BLOOD SUPPLY

For nearly a century, hepatitis B transmission in blood and serum has been recognised. More recent emergence of blood borne infections such as hepatitis C virus (HCV), human immunodeficiency virus (HIV) and variant Creutzfeld-Jacob disease (vCJD) has had a profound effect on blood services policies internationally. Minimum requirements for the medical selection and health assessment of blood donors are set out in EU Directives on Blood Safety (2002/98/EC and 2004/33/EC). Directive 2004/33/EU states a requirement for a permanent deferral of 'persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood' but this is not further defined and is interpreted at the member state level.

In the UK, between 1983 and 2011, men who had ever had oral or anal sex with another man (MSM) were permanently deferred from donating blood. In November 2011, a 12 month deferral was introduced in England, Scotland and Wales following recommendations from the UK Advisory Committee on the Safety of Blood Tissue and Organs, 2011 (SaBTO). Other countries, including Australia, New Zealand and South Africa have fixed-period deferrals for MSM. In 2008, a review in New Zealand led to a reduction in the deferral period from 10 to 5 years after last MSM activity. Others countries are currently reviewing their deferral criteria for MSM. Details of the current deferral periods for MSM are shown in Table 1. Currently individuals who have ever accepted money or drugs in exchange for sex remain permanently deferred in the UK. The review conducted in New Zealand also led to a reduction of the deferral period for sex workers to 12 months and for sex workers from countries outside New Zealand to 5 years, and others are

currently reviewing their deferral criteria for MSM. Details of the current deferral periods for MSM are shown in Table 1.

PERCEPTION AND TOLERANCE OF RISK

The exclusion of MSM from blood donation in 1983 was directly related to the emerging evidence of increased prevalence of a specific blood borne virus, HIV, in this population and hence the increased risk of transfusion transmitted infection (TTI). Risk of TTI was the main focus of recent international reviews of donor selection criteria, including the UK review (Hughes & Saxton, 2008), acknowledging that any change in policy must maintain minimal risk for recipients.

Risk assessment takes account of likelihood of, and consequences/impact of, an adverse event (Royal Society Study Group, 1992). However an acceptable risk does not directly correlate with a low risk. In some situations a very low risk of harm may be unacceptable while in others a greater risk may be accepted when balanced against other considerations. No transfusion can ever be risk free, therefore in considering whether a change in donor deferral policy will result in an unacceptable risk it is first necessary to know what the comparative risks of different policies will be compared with the current policy. The SaBTO Donor Selection Criteria Review considered the evidence from modelling studies on the change in risk in HIV infectious donations for different deferral periods for MSM. Judgements about acceptable risk at an individual level are based on both empirical facts and personal values. Interpretation of risk at a population level must take account of the fact that individuals and groups will have different perceptions of, and tolerance for, risk. Risks are perceived as less acceptable if they are involuntary inequitably distributed and damage identifiable victims (Sjoberg, 2000). Risks of TTIs can be seen as fulfilling these criteria. Risk tolerance will depend on how individuals perceive a specific risk and how they weigh competing risks. For example it is possible that people requiring multiple transfusions might accept a higher risk in order to ensure that sufficient compatible blood is available.

MORAL VALUES AND DONOR SELECTION

Those responsible for the collection and provision of blood and blood products have a moral obligation to ensure that recipients are not put at unnecessary risk. They also have a moral obligation to protect donors from harm and not to unfairly discriminate against them. Any difference in treatment of donors should be based on morally relevant reasons, for example minimising recipient harm from transfusion and ensuring an adequate supply of compatible blood to respond to current need. Thus evidence of increased risk of infection in donated blood is a morally relevant difference that allows what would otherwise be seen as discriminatory practice in not accepting the offer to donate blood.

Given the obligation to minimise harm, evidence that certain behaviours are associated with a higher risk of TTI, and the presence of a window period when such infections may not

Table 1. Current deferral periods for MSM.

Country	Current deferral	Comment
Asia Pacific		
Australia	Deferred for 12 months	Changed in 2006/2007
Hong Kong	Deferred for an indefinite period	
Japan	Deferred for 12 months	Date of change unknown
New Zealand	Deferred for 12 months	Changed December 2014
Singapore	Permanently deferred	
North America		
United States	MSM since 1977 permanently deferred	The US FDA announced in December 2014 that they would be issuing draft guidance on the change to the MSM deferral (intention to change to a 12 M deferral)
Canada	Deferred for 5 years	Change from permanent to 5 year deferral in 2013
Europe		
Austria	Permanently deferred	
Belgium	Permanently deferred	
Denmark	Permanently deferred	
Finland	Deferred for 12 months	Change from permanent deferral 1 January 2014
France	Permanently deferred	The ABC newsletter published 8 September 2006 indicated that the French Minister of Health announced that 'the blanket prohibition on blood donation by gay men will end soon'. However, there is no evidence on either the EFS or AFSSAPS websites of any change in policy
Germany	Permanently deferred	Currently under review
Ireland	MSM ever having oral or anal sex (even with a condom) permanently deferred	Review of possible options submitted to department of health January 2015
Italy	National policy is to exclude on basis of 'risky behaviour'	In place since at least 2001. All donors are interviewed by a doctor. The interpretation of 'risky behaviour' is unclear and inconsistently applied. At least some centres continue to exclude MSM
Netherlands	Permanently deferred	
Norway	Permanently deferred	
Portugal	Permanently deferred	
Spain	No specific exclusion of MSM	In the late 1990s a move was made from excluding homosexual men to excluding people with promiscuous sexual behaviour from donating blood. A 12 month exclusion exists for anyone who has had more than one sexual partner in the last 12 months
Sweden	12 months deferral for blood donors donating for patient use and permanent deferral for donating plasma for fractionation	The 12 month deferral came into effect in January 2012, (regulated by the National Board of Health and Welfare (Socialstyrelsen). The regulation includes a requirement for personal interview prior to each blood donation, and the need for combined tests (antigen + antibody) The permanent deferral is regulated by the Medical Product Agency (Läkemedelsverket)
Switzerland	MSM since 1977 deferred	
United Kingdom	MSM ever having oral or anal sex (even with a condom) deferred for 12 months (England, Scotland and Wales) Northern Ireland permanent deferral	Change from a permanent deferral in England, Scotland and Wales in November 2011
Africa		
South Africa	MSM deferral for 6 months (oral or anal sex with or without a condom)	2014 change to no MSM deferral. Changed to 6 M deferral for donor with new sexual partner and permanent deferral for donors with multiple sexual partners (individual sample HIV NAT screening in place)

be detected in donated blood, it may be morally permissible to exclude specific groups of people from donating based on behavioural risk. This is the justification for current national donor deferral criteria. In making this judgement a range of morally relevant considerations need to be taken into account. Policy makers must determine what level of risk is acceptable

in order to ensure that there is an adequate blood supply for those who need it. If the level of acceptable risk is set so low that blood supplies are insufficient, potential recipients will suffer serious, possibly fatal, harm. Policy makers must also consider other societal values as well as practical and economic considerations which may impact on the healthcare system overall. An

important, and increasingly explicit, societal value is that of treating people fairly and without discrimination. The UK Equality Act 2010 makes it illegal to unfairly discriminate on the grounds of sexual orientation (National Archives, 2010). The Act does however permit blood donor deferral if a reasonable judgement is made on the basis of available data. The moral question for policy makers in this situation is what level of risk of TTI justifies specific exclusion/deferral criteria for a potential donor based on their lifestyle rather than their known infectivity.

BALANCING RISK AND VALUES

Decisions about acceptance of risk are complex and policy makers who set acceptable risk levels must provide ethically justifiable reasons for their decisions. Transparency of process is an important ethical criterion for such decisions (Daniels & Sabin, 1997). In the context of blood donation (and we would argue other forms of organ and tissue donation) we suggest it is possible to provide a set of reasons that stakeholders could agree are relevant based on careful evaluation of the evidence of all relevant risks and explicit acknowledgement of other morally relevant values. Thus in considering donor deferral criteria it will be necessary to take into account:

- Evidence of the risk of transmission of a blood-borne infection from donated blood.
- The need to maintain adequate supplies of blood for all recipient groups.
- Whether the risk is sufficient to justify treating donors differently.
- Whether the parameters for defining the high risk donor group are fairly set (avoiding unnecessarily wide and therefore discriminatory parameters).
- The feasibility, and resource implications, of setting narrower parameters which require more intensive screening processes.
- Whether there is any other reason to treat different donor groups differently.

In decisions regarding donor deferral criteria it is thus crucial that we have an adequate understanding of the nature and acceptability of the risks of transfusion. It is also important, given the societal value placed on equality and non-discrimination, that we use the same framework for setting deferral criteria for different groups. Different countries may come to different conclusions but the requirement for consistency and transparency is universal.

In the UK, the 2011 SaBTO review of donor deferral criteria related to MSM and commercial sex workers established the minimum data required to make changes to these categories of deferrals in the UK. These included effectiveness of current testing strategies, differences in prevalence and incidence of TTIs between different risk groups, and the level of compliance with current donor deferral criteria (SaBTO, 2011). In considering the evidence against these criteria the review concluded that a

life-time deferral for MSM was no longer evidence-based. This ultimately led to a change in policy that saw the introduction of a 12-month deferral period. The deferral criterion, while no longer relating solely to sexual orientation, still specifies a target group (all men who have had oral or anal sex with a man in the previous 12 months) rather than focussing on the sexual behaviour history of an individual donor. This is in contrast to some other European countries such as Italy and Spain whose deferral criteria are based on a history of a change in sexual partner (temporary deferral) or multiple sexual partners (permanent deferral). In making its recommendation the review group considered this approach to deferral criteria but concluded that there was insufficient evidence at that time to support the proposition that individual risk assessments would increase or maintain safety. There was also a concern that the introduction of extensive donor health check questionnaires regarding sexual history would lead to a loss of existing donors. Evidence published because the review suggests that the change of deferral criteria in Italy to individual risk assessment has not led to an increase in the percentage of MSM among HIV positive blood donations (Suligoi et al., 2013).

The review did not make a similar recommendation for commercial sex workers because of lack of evidence relating to the criterion of compliance. Other countries may set different criteria or appraise the evidence differently. It has recently been recommended that the deferral period for commercial sex workers in Australia be reduced to 6 months (Australian Red Cross Blood Service, 2012). The publication of national criteria including justification for recommendations will facilitate open debate on the evidence and values underpinning policy.

CONCLUSION

Blood and tissue donation raise complex ethical issues which create difficult decisions for both individuals and society. The perception and tolerability of risk is an important factor in many of these decisions and the evaluation of risk is itself a complex process which occurs in the context of personal and societal values. Policy makers should provide explicit and transparent reasons to justify decisions that have life altering implications for patients.

ACKNOWLEDGMENTS

The views expressed in this manuscript are entirely those of the authors and do not represent the views of UK Blood Services or the Department of Health. A. S. was a member of the SaBTO donor selection criteria working group, contributed to all drafts of the paper and led on the final version. N. W. was a member of the SaBTO donor selection criteria working group, wrote the initial draft of the paper and contributed to all drafts. S. R. was a member of the SaBTO donor selection criteria working group, wrote the initial draft of the paper and contributed to all drafts. H. K. was a member of the SaBTO donor selection criteria working group, contributed to all drafts of the paper.

D. K. chaired the SaBTO donor selection criteria working group which evaluated the literature, analysed the data, and made the recommendations. D. K. had the original idea for the paper and contributed to all drafts of the paper.

CONFLICTS OF INTEREST

The authors have no competing interests.

REFERENCES

- Advisory Committee on the Safety of Blood Tissue and Organs (2011) *Donor Selection Criteria Review*. Department of Health, UK.
- Australian Red Cross Blood Service (2012) *Blood Donor Deferrals Relating to Sexual Activity*. URL http://www.bloodrulesreview.com.au/files/upload/blood_review_report_may_2012_electronic_version.pdf (Accessed 30/07/12).
- Bednall, T.C., Bove, L.L., Cheetham, A. & Murray, A.L. (2013) A systematic review and meta-analysis of antecedents of blood donation behaviour and intentions. *Social Science & Medicine*, **96**, 86–94.
- Daniels, N. & Sabin, J. (1997) Limits to health care: fair procedures, democratic deliberation, and the legitimacy problem for insurers. *Philosophy and Public Affairs*, **26**, 303–350.
- Fanklin, I.M. (2007) Is there a right to donate blood? Patient rights; donor responsibilities. *Transfusion Medicine*, **17**, 161–168.
- Galarneau, C. (2010) Blood donation, deferral, and discrimination: FDA Donor Deferral Policy for men who have sex with men. *Am Journal of Bioethics*, **10**, 29–39.
- Hughes, A. & Saxton, P. (2008) *Blood donation by MSM in New Zealand: Understanding the Roles of Populational HIV Prevalence, Individual Risk Behaviours, and Risk Reduction Versus Risk Elimination*. Research, Analysis and Information Unit Analysis Paper. Auckland, New Zealand AIDS Foundation.
- Leiss, W., Tyshenko, M. & Krewski, D. (2008) Men having sex with men donor deferral risk assessment: an analysis using risk management principles. *Transfusion Medicine Reviews*, **22**, 35–57.
- National Archives (2010) *Equality Act*. URL <http://www.legislation.gov.uk/ukpga/2010/15/contents> (Accessed 30/07/12)
- Royal Society Study Group (1992) *Risk: Analysis, Perception and Management*. Royal Society, London.
- Sjoberg, L. (2000) Factors in risk perception. *Risk Analysis*, **20**, 1–11.
- Suligoi, B., Pupella, S., Vincenza, R., Raimondo, M., Velati, C. & Grazzini, G. (2013) Changing blood donor screening criteria from permanent deferral for men who have sex with men to individual sexual risk assessment: no evidence of a significant impact on the human immunodeficiency virus epidemic in Italy. *Transfusion*, **11**, 441–448.
- Titmuss, R.M. (1970) *The Gift Relationship: From Human Blood to Social Policy*. Allen and Unwin, London.

Copyright of Transfusion Medicine is the property of Wiley-Blackwell and its content may not be copied or emailed to multiple sites or posted to a listserv without the copyright holder's express written permission. However, users may print, download, or email articles for individual use.