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EDITORIAL

SaBTO review of blood donor selection criteria related to sexual behaviour

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On 7 November 2011, the permanent deferral from blood donation of men who have sex with men (MSM) will change in England, Scotland and Wales, to a 12-month deferral since last relevant sexual contact. This follows an evidence-based policy review by the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) which concluded that the available evidence supported the introduction of a 12-month fixed period deferral (Donor Selection Criteria Review, 2011). The review found that the risks associated with a 12-month deferral of MSM were equivalent to a permanent deferral and the existing policy was inappropriate.

In many countries, MSM are permanently deferred from donating blood. These policies were introduced as a response to the spread of acquired immunodeficiency syndrome (AIDS) in the early 1980s. Since that time our understanding of the causative agent, human immunodeficiency virus (HIV), and our ability to detect it have improved significantly. It is accepted that policies relating to blood donation should be equitable and based on the latest available scientific evidence. In order to achieve this, regular reviews of blood donor selection policies are required. The UK policy on blood donation by MSM was last reviewed in 2006, but at that time data on compliance with the permanent deferral were not available. Recently, the findings of a study on the level of compliance with the permanent deferral and attitudes towards alternative policies have become available (Grenfell *et al*., 2011). This, together with new data for the residual risk of an infectious donation being released for transfusion under a number of deferral periods, prompted a further policy review. The findings of this review conducted by a Steering Group of SaBTO, have recently been published (SaBTO, 2011).

The Steering Group was comprised of leading experts in the field, joined by patient groups and key stakeholders. Its remit was to 'Review the evidence base for donor deferral and exclusion in the UK in relation to sexual behaviours and make recommendations to SaBTO on the most appropriate ways to ensure the safety of the blood supply'. This remit included:

1. evaluating the evidence base for deferral and exclusion policies;
2. defining the infections of interest, both known and unknown;
3. reviewing the epidemiology of transfusion transmitted infections (TTIs);
4. assessing the performance of current testing procedures;
5. determining the residual risks for specific TTIs;
6. reviewing relevant policies in other countries;
7. evaluating the operational impact of any recommendations;
8. recommendations for disseminating the outcome of the review.

Under this remit, the Steering Group took full account of the scientific evidence available, including the nature of uncertainties and assumptions used to reach conclusions. They also identified specific areas of research where further work is required to reduce uncertainty and also took account of the requirements of the Equality Act 2010. Finally, the Steering Group considered the impact of its advice on all stakeholders in the blood supply chain, including donors, patients, the UK blood services and the wider NHS, taking full account of the need to maintain the safety of the blood supply under the Precautionary Principle.

The assessments of risk are complex and are based on evidence and statistics that are recorded at a population level. This results in assessments of certain groups as being at a higher statistical risk than others of carrying blood-borne infections. The Steering Group carried out a rigorous review of the latest available evidence, as detailed above but with particular reference to: (i) the risk of infection being transmitted in blood; (ii) attitudes to compliance with the donor selection criteria and (iii) improvements in testing of donated blood. The Steering Group found the evidence no longer supported

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the permanent exclusion of MSM and recommended that only men who have had anal or oral sex with another man in the past 12 months, with or without a condom, should be deferred from blood donation. This recommendation was made on the basis that the available evidence indicated that the safety of the blood supply would not be affected by the change.

The UK has a robust surveillance system for monitoring the number of infections in both new and repeat blood donors. Data is also collected on possible risk exposures of blood donors found to be infected with blood-borne viruses and whether these donors complied with the donor selection criteria. Residual risk estimates are produced and published on an annual basis by the NHSBT/HPA Epidemiology Unit using modelling which incorporates data on the number of infected donors detected per year. Such information is reviewed regularly by specialist advisory committees to the UK blood services. Mechanisms are therefore in place which will allow monitoring of the effect of the change, both in terms of numbers of infected donors, their identified risks for infection and the calculated residual risk of transmission of infection through blood transfusion (NHSBT & HPA, 2010).

An alternative approach, which was considered but rejected by the Steering Group, was the introduction of a deferral based on an individual risk assessment for each donor. The review concluded that there was insufficient evidence available from countries where such policies have been introduced to determine its impact on blood safety. It is also well known that individuals cannot objectively assess their own level of risk, and published data from North America suggest that extensive questioning of all donors on their sexual behaviour could lead to a loss of existing donors who may find the process intrusive (Goldman *et al*., 2011). These findings highlight the need for policies that balance matters of blood safety with sufficiency of supply.

The review also considered the permanent deferral from donation of individuals who have ever accepted money or drugs in exchange for sex. There were insufficient data on the compliance of commercial sex workers with the permanent deferral for the review to determine the impact of any change in policy and consequently no recommendations for change could be made. SaBTO did, however, recognise the need for studies to be conducted in order to collect this information.

Perhaps the most important finding to come out of the review and the message that should be consistently given to all donors is the need for compliance with any deferral policy. It is interesting to note that under the permanent deferral, it was shown that 11% of MSM had donated blood since becoming ineligible, although the majority of non-compliers had not had a risk exposure within the 12 months prior to donation (Grenfell *et al*., 2011). Complete compliance with the new deferral period would lead to a 29% reduction in the risk of HIV infection by transfusion. Blood donation works on the principles of kindness and mutual trust, and compliance with the blood donor selection criteria allows for protection of donor and recipient health. This, along with a wide range of other blood safety measures, including stringent testing, means there has been no documented transmission of a blood-borne virus in the UK since 2005, with no HIV transmission since 2002.

The deferral from blood donation of MSM, whether for a fixed period or permanently, will continue to be a keenly debated issue with competing views being expressed on both sides of the argument, however, mainland UK will be introducing a policy change that is supported by the latest available scientific evidence.

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