Evidence-Based Policy and Practice Leads to Changes in the Criteria for MSM to Donate Blood

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Summary

On November 7, 2011, the permanent deferral from blood donation of men who have sex with men (MSM) changed in England, Scotland and Wales, to a 12-month deferral since last relevant sexual contact. This change was made following an evidence-based policy review by the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO). The review concluded that the available evidence supported the introduction of a 12-month fixed period deferral and that the risks associated with a 12-month deferral of MSM were equivalent to a permanent deferral. The permanent deferral for MSM was introduced in 1985 in response to the spread of acquired immunodeficiency syndrome (AIDS) caused by HIV. The change was supported by new data on the level of compliance with the permanent deferral, advances in the testing and processing of donated blood, changes in the epidemiology of sexually transmitted infections (STIs) and improved scientific knowledge. This review discusses how the decision to change the deferral period was reached and highlights some of the remaining issues relating to this contentious matter.

changes in the USA. Titmuss recognised that a system based on voluntary blood donation was superior to alternative, commercial systems and that quality of life and community are increased when people are encouraged to give, often literally, the gift of life to strangers. Voluntary blood donation systems are now commonly used throughout the world but not all members of society are permitted to participate equally in the altruistic process of blood donation.

In setting policies for deferral from blood donation, it is imperative that robust, evidence-based deferrals are used. These are essential to public health policies which are designed to minimise the risk of harm and protect the health of donors and patients. Deferral criteria are, by-and-large, uncontroversial and do not stimulate excessive debate. The exceptions to this are those deferral criteria based on behaviours, specifically those relating to sexual behaviours which are potentially linked to increased prevalence of infection with transfusion-transmitted infections (TTIs). This category of deferral criteria includes policies relating to blood donation by men who had ever had oral or anal sex with men (MSM), policies which remain controversial and become indefensible if not evidence-based.

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 such as minimising harm, respect for persons, and equity.

The Evidence Supports Change to Policies Relating to Blood Donation by MSM

In the European Union, minimum requirements for the medical selection and health assessment of blood donors are set out in EU Directives on Blood Safety (2002/98/EC [2] and 2004/33/EC [3]). Directive 2004/33/EU states a requirement for a permanent deferral of 'persons whose sexual behaviour

Introduction

Blood donation remains one of the most precious gifts that an individual can bestow upon a fellow human being. In 1970, Richard Titmuss's book, 'The Gift Relationship: From Human Blood to Social Policy' [1] resulted in almost immediate policy

puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood'. This carefully worded sentence focuses on sexual behaviour rather than sexual orientation and is open to interpretation at the member state level.

In the UK, between 1983 and 2011, MSM were permanently deferred from donating blood. 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 a TTI. An evidence-based review conducted in 2011 [4] concluded that a change in policy was now warranted, and in November 2011 a 12-month deferral was introduced in England, Scotland and Wales [5]. Other countries, including Australia, New Zealand and South Africa, have fixed-period deferrals for MSM.

Data on the epidemiology of HIV in the UK is available from a number of sources. The Unlinked Anonymous Prevalence Monitoring Programme (UAPMP) survey includes 16 GUM clinics; 8 in London, 1 in Scotland and 7 elsewhere in the UK. The samples are unlinked from any patient identifiers, to maintain anonymity, but it is recorded whether the patient is already known to be HIV-positive (previously diagnosed infection) or if they test positive on that occasion. UAPMP data from 2008 of previously undiagnosed HIV infections, which includes both those tested and diagnosed on the day and those who remain unaware of their status, shows that the prevalence was higher in MSM (3.1%; 291/9,473) compared with heterosexual attendees (0.35%; 322/92,694). Prevalence was higher in heterosexual females (0.4%) than in heterosexual males (0.32%). Among heterosexuals HIV was more common in people born in sub-Saharan Africa (2.1%; 118/5,721) compared with those born in the UK (0.18%; 126/67,751) or elsewhere (0.42%; 80/19,222). The proportion of infections in those unaware of their status has been falling and was 23% in 2008, although this is likely to be an overestimate because it is known that some patients who are aware of their status choose not to disclose it when attending a GUM clinic.

No transfusion can ever be risk-free, so changes in donor deferral policies need to be introduced on the basis of a comparative risk assessment of different policies with the current policy. The Donor Selection Criteria Review conducted in the UK by SaBTO [4] considered evidence from modelling studies on the change in risk in HIV infectious donations for different deferral periods for MSM based on the assumption of full compliance. 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. These findings were informed by a study which evaluated the level of compliance with the permanent deferral and attitudes towards alternative policies that indicated that a reduction in the deferral period would lead to improved compliance [6]. This study used a mixed methods approach using a random location 'Omnibus' survey of 1,028 men who have ever had any sexual experience with a man (MSM), and 3,914 men and women in the general

population, to determine the level of compliance with existing deferral criteria and attitudes towards alternatives. In the study, 3.2% of all men reported as MSM. Nearly half had ever had oral or anal sex with a man and a quarter had done so in the past 12 months. In addition, 11% of MSM had given blood since becoming ineligible and 2.5% had donated in the past year. 'Non-compliers' were more likely to identify as straight and less likely to have had oral or anal sex with a man in the past 12 months. Predominant reasons for ineligible donation were categorising oneself as low risk or discounting sexual experience that barred donation. Others included conviction that screening safeguarded blood; misunderstanding of the rule; the need for secrecy around sexual history; and rarely, resentment over inequity of the deferral. Just a quarter of MSM were aware that experience of oral or anal sex with a man barred blood donation. One third considered that only unprotected sex prohibited donation. In the general population sample, 8 in 10 recognised the Blood Service's key concern as being the safety of blood and 4 in 10 considered the lifetime MSM deferral excessive.

In this study, MSM participants rarely considered blood donation to be an individual right but there was a strong belief in the right to fair treatment for all potential donors.

The study also examined views on revisions to the MSM deferral, with the preference being an individual risk assessment but this was recognised as complex, expensive and difficult to administer in a donation session. A 12-month deferral (since last sex with a man) was preferred to a 5-year equivalent and would newly confer eligibility to 46% of MSM survey respondents. Almost all qualitative interview participants (all currently compliant with the lifetime MSM exclusion) maintained that they would comply with a 5-year and a 12-month MSM deferral, particularly if provided with sufficient information on the rationale for the exclusion.

In the UK between 2003 and 2008, the probability of an infectious HIV blood donation not being detected by current testing methods was estimated as 1 in 4 million donations, however the true value could be as low as 1 in 8.3 million or up to 1 in 2.2 million donations [4]. A recent study by Davison et al. [7] looked at the residual risk of a HIV infectious donation being released into the blood supply between 2005 and 2007 for both a 5-year and a 12-month deferral period. For fixed-period deferrals of either 12 months or 5 years, any incident infections would be due to non-compliance as both are much greater than the current HIV window period. A 5-year deferral was estimated to result in a 0.4–7.4% increase in HIV infectious donations being released for transfusion. For a 12-month deferral the increase was 0.5–9.9 depending upon the scenario. The modelling suggests that the length of the deferral period is less important than compliance with the rule, with 100% compliance with either a 12-month or a 5-year deferral reducing the risk by 30%. The difference in the increase in risk between a 12-month and 5-year deferral was very small unless incidence increased as a result of non-compliance of MSM to the

criterion. In terms of the additional risk expected due to the newly eligible MSM, the minimum and maximum increases observed under the different scenarios (0.001 and 0.022 expected extra HIV infectious donations per million) would equate to one additional HIV infectious donation every 455 and 21 years, respectively.

Taken together with new data on the residual risk of an infectious donation being released for transfusion, the evidence no longer supported 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. Evidence is supported by the improvements in testing, reduction in window periods for specific infections, increased automation and international surveillance that have occurred over the past 10 years.

Engagement and Ownership

The recommendations for a change in deferral policy in the UK came from a Steering Group comprised of leading experts in the field who were joined by patient groups and key stakeholders, including blood services and LGBT (lesbian, gay, bisexual and transgender) groups. Their 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.' Early ownership of such a significant remit was key to the review's success and the subsequent implementation of the recommendations. Data was scrutinised in detail and donor deferral was changed to donor selection, a small but significant change that quickly established a remit focused on ensuring that donors are selected, or permitted to donate, on the basis of the most up-to-date evidence.

The Steering Group operated within a framework that prioritised the need to maintain the safety of the blood supply under the precautionary principle. The inclusion of a broad range of stakeholders on the Steering Group ensured that the impact of any changes on the blood supply chain affecting donors, patients, the UK blood services and the wider NHS could be identified and resolved. Using this approach of early engagement, plans could be developed by the UK Blood Services and extensive guidance prepared to enable a timely policy change.

Risk and Surveillance

Donation by MSM remains an emotive subject, and a 12-month deferral is seen by some as conservative and by others as too liberal. 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. When considering decisions regarding donor deferral criteria, it is crucial that we have an adequate understanding of the nature and acceptability of the risks of transfusion.

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.

Perhaps the most important finding to come out of the UK review and the message that should be consistently given to all donors is the need for compliance with any deferral policy. Complete compliance with a 12-month deferral period would lead to a 29% reduction in the risk of HIV infection by transfusion compared to baseline. 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. A number of additional surveillance studies have been introduced in the UK to monitor compliance with the new policy.

Future Changes

Alternative approaches to donor selection could be considered, including individual risk assessments for each donor. Currently, there is 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 [8] 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. It is possible that, as technology develops and there is increased evidence on the effectiveness of individual risk assessment based deferrals, that further changes may be warranted.

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 has introduced a policy change that is supported by the latest available scientific evidence.

Disclaimer

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.

Disclosure Statement

None of the authors have any conflicts of interest.

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