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Review

Re-examining blood donor deferral criteria relating to injecting drug use

Brendan Quinn[a,b,*], Clive Seed[c], Anthony Keller[c], Lisa Maher[d], David Wilson[a,d], Michael Farrell[e], Sharon Caris[f], Jennifer Williams[c], Annie Madden[g], Alexander Thompson[h], Joanne Pink[c], Margaret E. Hellard[a]

[a] Burnet Institute, Melbourne, Australia
[b] Department of Epidemiology and Preventive Medicine, Monash University, Melbourne,Australia
[c] Australian Red Cross Blood Service, Australia
[d] Kirby Institute, University of New South Wales, Australia
[e] National Drug & Alcohol Research Centre, University of New South Wales, Australia
[f] Haemophilia Foundation Australia, Australia
[g] Australian Injecting & Illicit Drug Users League, Australia
[h] St. Vincent's Hospital, Melbourne, Australia

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ABSTRACT

Background and aims: Potential Australian blood donors are deferred indefinitely if they report a history of injecting drug use (IDU), or for 12 months if they report having engaged in sexual activity with someone who might have ever injected. Given incremental improvements in blood safety, this study sought to examine whether Australia's IDU-related eligibility criteria reflected current scientific evidence, were consistent with international best practice and, if current IDU-related policies were to be changed, how this should happen.
Methods: An expert committee was formed to review relevant literature with a focus on issues including: the epidemiology of IDU in Australia and key transfusion-transmissible infections (TTIs) among Australian people who inject drugs (PWID); and, 'non-compliance' among PWID regarding IDU-related blood donation guidelines. International policies relating to blood donation and IDU were also reviewed. Modelling with available data estimated the risk of TTIs remaining undetected if the Blood Service's IDU-related guidelines were changed.
Results: Very few (<1%) Australians engage in IDU, and IDU risk practices are reported by only a minority of PWID. However, the prevalence of HCV remains high among PWID, and IDU remains a key transmission route for various TTIs. Insufficient data were available to inform appropriate estimates of cessation and relapse among Australian PWID. Modelling findings indicated that the risk of not detecting HIV becomes greater than the reference group at a threshold of non-admission of being an active PWID of around 1.8% (0.5–5.1%). Excluding Japan, all Organisation for the Economic Co-operation and Development member countries permanently exclude individuals with a history of IDU from donating.
Conclusion: Numerous research gaps meant that the study's expert Review Committee was unable to recommend altering Australia's current IDU-related blood donation guidelines. However, having identified critical knowledge gaps and future areas of research, the review made important steps toward changing the criteria.

Introduction

To maintain the safest possible blood supply, 'deferral' of potential blood donors due to group risk (e.g., according to involvement in certain behaviours) remains standard practice worldwide. In Australia, this has been effective in mitigating the risk from known transfusion-transmissible infections (TTIs). For example, the prevalence of human immunodeficiency virus (HIV),

* Corresponding author at: Burnet Institute, GPO Box 2284, Melbourne, Victoria 3001, Australia. Fax: +61 3 9282 2138.
E-mail address: brendan.quinn@burnet.edu.au (B. Quinn).

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hepatitis C virus (HCV), hepatitis B virus (HBV), human T-lymphotropic virus (HTLV) and syphilis among accepted blood donors remains substantially lower compared to Australia's general population and, overall, has been stable or falling over the past decade (Kirby Institute, University of New South Wales, & Australian Red Cross Blood Service, 2014). Further, there has been an absence of reported cases of transfusion-transmitted HIV or HCV since nucleic acid testing (NAT) commenced in Australia in 2000 (Seed, Kiely, Law, & Keller, 2010) [previously, there were 13 cases of transfusion-transmitted HCV after HCV-antibody testing commenced in 1990, and one of HIV in 1998 after anti-HIV screening commenced in 1985 (Pitt, 2012)].

Reflecting international guidelines and predominant practice, the Australian Red Cross Blood Service's (the '*Blood Service*') current deferral criteria relating to injecting drug use (IDU) reflect the proven transmission and infectivity of established TTIs via IDU (Baggaley, Boily, White, & Alary, 2006; Mast, Alter, & Margolis, 1999; Rezza et al., 1990). Although substantial coverage of sterile injecting equipment exists for people who inject drugs (PWID) in Australia (Wodak & Lurie, 1997), and safe injecting practices are common among PWID (Iversen & Maher, 2014), the risk of TTI transmission is reduced but not eliminated in this group (Dore, Law, MacDonald, & Kaldor, 2003). The high prevalence and incidence of HCV infection among PWID (Pouget, Hagan, & Des Jarlais, 2012) is especially a primary rationale for the exclusion of this group from donating blood/blood products. Specifically, potential Australian donors are deferred indefinitely if they report: *(a) Ever using drugs by injection, or having been injected, even once, with drugs not prescribed by a doctor or dentist*. Further, because TTIs can be sexually transmitted [with varying degrees of infectivity (Sasadeusz, Locarnini, Kidd, Bradford, & Danta, 2008)], sexual partners of PWID are at increased risk of infection. Consequently, potential donors are deferred for 12 months if they report, *(b) Having engaged in sexual activity in the past 12 months with someone who might respond 'yes' to (a)*.

The Blood Service's multi-tiered approach to mitigating transmission risk (Mison, Seed, Margaritis, Hyland, & Australian Red Cross Blood Service Nucleic Acid Technology Study Group, 2003) underpins Australia's exemplary track record of blood supply protection (Seed, Kiely, & Keller, 2005). Specifically, these complementary tiers include: (1) *Community and donor education* about blood donation eligibility criteria and reasons for donation deferral via numerous means [e.g., the media, brochures/handouts and the Blood Service website (Australian Red Cross Blood Service, 2016)]; (2) *Donor selection*, whereby potential volunteer donors aged 16–80 years self-complete a pre-donation screening questionnaire designed to elicit specific information regarding factors indicating increased risk for TTI exposure (e.g., travel history, lifestyle). Donors who disclose relevant risk behaviour/s are temporarily or indefinitely deferred from donation. There are penalties including fines and imprisonment for anyone providing false or misleading information; (3) *Testing* of every donated blood product via antibody screening and the highly-sensitive NAT for HBV, HCV, HIV, HTLV and syphilis. The NAT supplements tests for viral antibody or antigen markers by targeting viral RNA or DNA (Mison et al., 2003), therefore improving blood safety (Busch & Dodd, 2000); and, (4) *Pathogen reduction* via the application of physical and/or chemical methods to inactivate infectious agents (only applicable to plasma products).

However, indefinitely deferring people with any history of IDU (despite number or 'remoteness' of injecting occasions) is conservative compared to the Australian Therapeutic Goods Administration's (TGA's) current infectious disease standard for blood, cellular therapies and tissues, which recommends a minimum deferral of five years since last injection occasion (TGA, 2013). Importantly, the TGA requirements reflect minimum donor deferral requirements for these products (Personal Communication, February 2016).

Potential amendments to the blood donation guidelines need to assess possible risks and benefits and be evidence-based, proportionate and, in the case of minority groups such as PWID, equitable (Brailsford et al., 2015). Between 1996 and 2000, this approach led to all Australian jurisdictions changing the deferral period for men who have sex with men from a permanent or five-year deferral to 12 months (Seed et al., 2010). No evidence has indicated a subsequent, significant increase in transfusion-transmitted HIV infection in Australia.

The Blood Service's IDU-related donor policies have not been revised since the 1980s. Given incremental improvements in blood safety, it is timely to consider whether the eligibility criteria reflect current scientific evidence, are consistent with international best practice and appropriate to Australia. To this end, the Blood Service convened an expert committee to: (a) Review the available evidence; and, (b) Model the estimated risk associated with changing the current IDU-related deferral period, to determine whether people with IDU should be excluded from donating blood/blood products in Australia and, if relevant policies were to be changed, how this should happen.

Methods

The current review succeeds a 2012 evaluation of the Blood Service's sexual activity-based donation criteria (Pitt, 2012). Reflecting previous investigation's format, the current review entailed: examining relevant literature and current international policies related to blood donation and IDU and risk modelling with available data. Key stakeholders (e.g., organisations working on issues related to blood-borne viruses) were also contacted with requests for comments, relevant empirical data and research findings in an attempt to address identified knowledge and data gaps.

Review Committee

In late 2013 the Blood Service convened a committee to guide the review's conduct. It comprised representatives from diverse research backgrounds and disciplines (e.g., clinical, public health, statistical), in addition to community organisations relevant to PWID and peer representatives.

Literature review

A literature review was undertaken to identify: (1) Evidence that supported or challenged the appropriateness of the Blood Service's current IDU-related criteria; and, (2) Data to inform modelling of the estimated risk associated with changing the IDU-related deferral periods (see below). The literature review focussed on several key areas, including: (a) the epidemiology of IDU and injecting risk practices, including cessation and relapse, in Australia; (b) the incidence of IDU cessation and relapse among PWID; (c) the epidemiology of key TTIs (HBV, HCV, HIV, HTLV and syphilis) among Australian PWID; (d) the potential threat of emerging [new or as-yet undiscovered infectious disease agents, e.g., human parvovirus 4 (Stramer, Dodd, & AABB Transfusion-Transmitted Diseases Emerging Infectious Diseases Subgroup, 2013)] or re-emerging agents (known agents with increasing prevalence, e.g., dengue virus) transmissible via IDU; and, (e) 'non-compliance' among PWID regarding IDU-related blood donation guidelines (PWID are generally at greater risk of exposure to TTIs than the general population).

A search of electronic literature databases (e.g., *The Cochrane Library*, OVID MEDLINE) used a combination of medical subject