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Donor deferral policies for men who have sex with men: past, present and future

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We review the history and evolution of blood donor criteria for men who have sex with men (MSM). Deferral policies in many jurisdictions, including Australia, New Zealand, Canada, the United States, Brazil and many western European countries are based on a period of abstinence from MSM, often of 12 months duration. Several countries (Italy, Spain and Portugal) defer donors based on sexual behaviours considered to be at high risk, regardless of whether the partner is same sex or opposite sex. Compliance is a key determinant in the efficacy of any deferral policy. We summarize research themes and strategies discussed at a January 2017 meeting held in Toronto, Canada, to provide an evidence basis for future policy changes.

Key words: donor deferrals, men who have sex with men.

Introduction

Few donor criteria are as contentious as those for men who have sex with men (MSM) [1–7]. MSM were noted to be a very high-risk group for AIDS when cases first started appearing in North America in the late 1970s and early 1980s. The US deferral for a man who has had sex with another man even once since 1977 was first mandated by the Food and Drug Administration (FDA) in the 1980s, as it was thought to be the date AIDS appeared in North America, although little was known about HIV as the causal agent for AIDS [8]. Soon after, other regulatory agencies followed suit [1–3]. Since then, knowledge about HIV has expanded dramatically, and numerous changes have occurred in both blood collection and testing and in public health and societal perspectives. Although there has been tremendous progress in HIV treatment, a diagnosis of HIV infection still has important lifetime consequences, including ongoing medication use, transmission to others, and possible employment and insurance repercussions. Therefore, prevention of HIV transmission remains paramount for blood centres. However, as issues of social justice have gained focus with respect to the inclusivity of people with nonheterosexual gender identity in modern societies, attention has been drawn to blood donor deferral for MSM as a practice requiring modernization [1–7]. This, in turn, has led to politicization of blood donor deferral policies including the use of organized protest and boycott of blood collection events in some jurisdictions. The last few years have seen eligibility criteria changes in several countries, mainly towards less lengthy time-based deferrals [3, 9]. However, most countries still do not allow donation from sexually active MSM, and there is no international consensus on deferral policies. Focusing on North America and Europe, we review current policies and knowledge gaps, and how these might be addressed by research. In particular, we highlight the deliberations at a recent meeting held in Toronto, Canada, in January 2017 that brought together invited experts, stakeholder groups and researchers to encourage focused research in Canada in this area that will inform future policy changes.

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Current deferral policies

The epidemiology and risk factors for HIV vary in different countries. For example, in South Africa, there is a very high HIV rate in the general population

(approximately 11%), the majority of HIV infections are in the heterosexual population and the risk of HIV in MSM is similar to the general population [3]. There is no deferral specifically for MSM; donors are deferred for what are considered high-risk sexual behaviour, such as multiple sexual partners [10]. In Eastern Europe, intravenous drug use and heterosexual transmission are the predominant risk factors for HIV infections [11]. In Western Europe and North America, the HIV rate in the general population is considerably lower than in South Africa (less than 0·5%); MSM account for between one-third and two-thirds of prevalent and incident HIV infections, and the rate of HIV in MSM is many times higher than in the male heterosexual population [11–13]. Two main approaches are in use for MSM eligibility assessment: time-based deferrals after the last occurrence of male to male sex and deferral after high-risk sexual behaviours, usually defined as new partners or multiple partners of either sex. Table 1 summarizes policies in selected countries that have published studies and/or performed detailed risk assessments related to their MSM policies.

Time-based deferrals

In many developed countries, blood centres are regulated as biologics manufacturers, and a uniform donor questionnaire, self-completed by the donor or administered by a nonmedical staff member, is used to assess eligibility. Questions separate donors into broad risk categories, with an affirmative answer placing a donor in the higher risk bucket and resulting in deferral from donation. As discussed above, as MSM account for a significant proportion of prevalent and incident HIV infections, they globally are considered a high-risk group using this simple categorization. In the mid-1980s, these countries implemented a permanent deferral for any MSM ever or MSM since 1977 [3, 8]. There was no change in this permanent deferral policy for over a decade. In 2000, Australia was the first country with a time-based deferral to adopt a national deferral policy of 12 months after last MSM. New Zealand introduced a 10-year deferral policy and changed to 5 years in 2009, while Canada changed from an indefinite deferral to a 5-year deferral in 2013 [3, 9, 14, 15].

Legal challenges to the indefinite deferral policy occurred in several of these countries, alleging discrimination. Blood operators in Australia and Canada successfully defended their policies on the basis of recipient safety [3]. However, in Canada, the judge presiding over the complaint expressed reservations about the ever-lengthening deferral period since 1977 [9]. Court challenges, concern over loss of younger donors and the desire to re-evaluate deferral policies based on current evidence led to detailed risk analysis by blood operators, expert advisory committees and/or regulatory authorities of the possible safety impact of criteria changes in several countries, including the UK, the United States, New Zealand and Canada [16–19]. Many of these countries had implemented nucleic acid testing (NAT) in addition to antibody testing for HIV, reducing the window period to less than 10 days and introduced automation and standardization of procedures such that error rates in testing and quarantining of positive units are extremely low. Data from Australia, where HIV rates remained stable and extremely low after adoption of the national 12-month deferral policy were reassuring [15, 20]. Additionally, modelling studies performed in the United States, Canada, the UK and France evaluating various scenarios predicted negligible risk increments (less than 1 in 1 million units) with a change to a 12-month deferral [21–24]. Compliance studies performed in the general donor population demonstrated that noncompliance rates with the MSM criterion were very low, of the order of 0·2 to 2·4%, and decreased when deferral times were decreased [14, 20, 25]. In Canada, in particular, structured, ongoing consultation with highly involved stakeholder groups, including representatives of patient groups requiring frequent treatment with blood or plasma protein products, LGBTQ (Lesbian, Gay, Bisexual, Trans, Queer) rights activists and community groups also was also very important in achieving consensus to move forward [9].

In part due to these risk assessments, many blood operators, with the agreement of their regulatory agency, have moved to a 12-month deferral period. For example, the United States, Canada, Mexico, Germany, the Netherlands, Norway, Sweden, the United Kingdom and France all had a permanent deferral when a Vox Sanguinis International Forum reviewed policies in 2010-2011; these countries have all implemented a 12-month deferral. A 12-month deferral policy is also in place or will be implemented in 2017-2018 in Finland, Belgium, Ireland, the Czech Republic, Brazil and Israel; Columbia is also considering a change from a permanent deferral to a time-limited deferral [3, 19, 26–29]. Policies in Brazil may change soon depending on the outcome of a current Supreme Court case. Japan moved from a 12-month to a 6-month deferral policy in 2011 [3]. However, some European countries, such as Denmark, Austria and Croatia, still have a permanent deferral in place [3, personal communication].

In 2016, France moved from a permanent deferral policy to a 12-month deferral policy for MSM for most donations but added an interesting approach for apheresis plasma donation that provides additional donor eligibility for MSM [personal communication]. Apheresis plasma has a longer shelf-life and higher permissible frequency of donation compared to other blood components. A

Table 1 Countries with a time-based deferral (Australia to the United States) and gender-neutral risk activities-based (Italy, Spain) deferral policy

Country [references]	Policy changes	Analysis	Comments
Australia [15, 20]	• 2005 – 12-month common national deferral policy	• stable, very low HIV rates after change, contrary to modelling studies -0·23% noncompliance rate	• request to move to 6-month deferral rejected by regulator
Canada [9, 14]	• 2013 – change from permanent deferral for MSM since 1977 to 5-year deferral • 2016 – 12-month deferral	• stable, very low HIV rates after changes, contrary to modelling studies -noncompliance rate decreased from 0·67% to 0·44% after change to a 5-year deferral	• support from patient and advocacy groups assisted in gaining regulatory approval for changes
France [22]	• 2016 – change from permanent to 12-month deferral	• modelling study emphasized importance of compliance rate in determining risk increment	• pilot project in quarantined plasma donors
New Zealand [7, 16]	• 2000 – 10-year common national deferral policy • 2009 - 5-year deferral • 2014 – 1-year deferral		• change to 1-year deferral made after risk assessment by external review group
UK [17, 21, 27]	• 2011 – change from permanent to 12-month deferral • 2017 – recommendation to move to a 3-month deferral (SaBTO)[a]	• noncompliance rate of 0·4% after implementation of 12-month deferral • stable, very low HIV rate after changes, contrary to modelling studies	• change to 1-year deferral made after risk assessment by SaBTO, plan to implement 3-month deferral in 2018
United States [19, 25, 32]	• 2015 – FDA Guidance Document permitted change from permanent deferral for MSM since 1977 to 12-month deferral • 2017 – 12-month deferral in place at majority of US blood centres	• noncompliance rate of 2·4% before change in policy	• enhanced monitoring of rates and risk factors for TTIs put in place prior to change in policy
Italy [33, 34]	• no MSM deferral since ministerial decree In 2001 • 4 months or permanent deferral for higher risk sexual behaviours, regardless of same or opposite sex partner	• no change in HIV rates pre- (1999) and post (2009-10) implementation • HIV rates higher than the United States, Canada, rest of Western Europe, Australia • noncompliance identified in one-third of HIV-positive donors	• no recent national data
Spain [35]	• no MSM deferral • Spanish Blood Donation Laws and Ministry of Health guide for blood donor selection (2004-5) specify 12-month deferral for more than 1 partner or occasional partner	• high HIV rates compared to the United States, Canada, rest of Western Europe, Australia, particularly in repeat donors	• recent regional data, no published national data

[a]SaBTO,Advisory Committee on the Safety of Blood, Tissues and Organs.

'quarantined plasma' program provides some of the transfusable plasma in France, where plasma is only released into inventory after the donor has returned to donate and been retested at least 2 months after the quarantined donation. Donors who were in the window period at initial donation would have positive infectious disease markers 2 months later. Given this additional safety layer, a novel program was introduced involving MSM donors. In France, all donors are asked about and deferred for more than one sexual partner in the last 4 months. This same question and criterion are used for MSM quarantined plasma donors. The impact of this change on infectious disease rates, risk factors in HIV-positive donors, and donor compliance will be assessed before considering expanding the program to other types of donation.

Although the observation period is variable in different jurisdictions, implementation of a shorter time-based deferral has not led to an increase in HIV-positive donations or donor noncompliance to date [14, 20]. The expected increase in HIV-positive donors predicted by modelling studies did not occur, suggesting that the assumptions used in these studies are extremely conservative and significantly overestimate risk increments associated with a decrease in deferral periods [30, 31].

Regulatory considerations

A major regulatory change occurred in the United States in December 2015, when the FDA issued a new guidance document permitting a 12-month deferral after MSM [19]. This change was implemented by the majority of US blood centres in 2016. However, individual blood centres may have not changed their policy due to local medical concerns or needed upgrades to procedures or software. The Council of Europe Guide to the preparation, use and quality assurance of blood components states that individuals with sexual behaviour that puts them at high risk of acquiring severe transfusion-transmissible infectious diseases should be permanently deferred [3]. This has been interpreted in various ways by national blood operators, in part related to the epidemiology of HIV in their particular country [3, 11]. Regulators from several countries expressed their shared perspective that changes to the donor deferral for history of MSM should be 'evidence-driven and based on sound science' and that studies should be carried out to assess potential impacts of policy changes and monitor postimplementation safety impacts [36].

Blood centres may collect plasma for fractionation (source plasma), in addition to transfusable blood components. This plasma may be part of a whole blood or plateletpheresis donation. Therefore, the position of international fractionators, who currently require permanent deferral for MSM, may influence blood centre practice or complicate implementation of changes in MSM deferral policies for transfusable components. In Sweden and several other European countries, male donors are first asked if they have ever had sex with another male, and if the answer is yes, then asked if this occurred in the last 12 months. MSM behaviour more than 12 months ago would result in the donation being processed into transfusable components but not into plasma destined for fractionation.

Gender-neutral or risk activities-based policies

Several countries, including Spain, Portugal and Italy, have implemented policies based on sexual behaviours considered to be at higher risk, regardless of whether the partner is same sex or opposite sex; these may be referred to as 'gender-neutral' or 'risk-based' deferral policies [3, 33–35]. Higher risk sexual activities may include sex with a new partner or with multiple partners, particularly if the partner's risk behaviour is unknown. There are several differences in blood centre functioning in these countries compared to those with time-based deferrals. Donors have an interview with a physician prior to donating, making an individual risk assessment more feasible. There is variability between blood centres, with no national blood operator and less standardization. Changes in donor policies were adopted by law, without a formal risk assessment or analysis of the impact of changes in policy.

An Italian ministerial decree in 2001 changed policy from a permanent deferral for MSM to sexual deferrals based on two levels of risk regardless of same sex or opposite sex partner. In 2015, a standardized national donor self-administered screening questionnaire was introduced, replacing questionnaires used in different centres. After donors answer the questionnaire, they have a face-to-face interview with a trained physician. Donors are deferred for 4 months as last sexual contact for sex with a new sexual partner whose risk behaviour is unknown, or for occasional sexual contact with a partner whose risk behaviour is unknown. Donors are indefinitely deferred for usual/recurrent sex with more than one partner whose risk behaviour is unknown or multiple new partners. An Italian study compared HIV rates before (1999) and after (2009-10) the change in policy. HIV rates did not change significantly but were fairly high in both first-time and repeat donors (12·3 per 100 000 and 3·8 per 100 000 in 2010, respectively) [33]. Approximately 90% of HIV cases occurred in male donors; MSM was considered the likely risk factor in 26% of these. In 2015, HIV prevalence was 14·2 per 100 000 in first-time donors. An analysis of national hemovigilance data

summarized risk factors identified in postdonation interviews conducted with the 349 HIV-positive donors found between 2009 and 2011, inclusively [34]. Close to one-third of the donors had sexual behaviours in the 4 months prior to donation that should have led to deferral, including 33 donors with MSM. Noncompliant donors stated that they did not realize that they had engaged in a risky behaviour, or thought that the behaviour was associated with minimal risk.

In Spain, donors are deferred for 12 months for sex with more than one concurrent partner, or sex with an occasional partner. A recent study from Catalonia, Spain, evaluating HIV infection rates in donors from 2005 to 2014, found an overall prevalence of HIV of 7·7 per 100 000 donations; rates in repeat donors were only slightly lower than in first-time donors [35]. Ten of the 214 infected donors (4·7%) had NAT only positive results, indicating recent infection. MSM was a frequent risk factor for both NAT only positive and other HIV-positive donors. The authors commented that rates in first-time donors were very similar to the overall Spanish population, indicating a lack of effectiveness of the donor screening process.

By comparison, overall rates of HIV reported in all Western European countries, the United States and Canada during similar time periods were 1·8, 2·8 and 0·5 per 100 000 donations, respectively [11, 14, 25]. At Canadian Blood Services, the HIV prevalence rates in first-time and repeat donors are approximately 2 per 100 000, and 0·2 per 100 000 donations, respectively, and one of 39 HIV-positive cases (2·6% of cases) had NAT only positive results in the last 10 years [37]. In the large NHLBI Retrovirus Epidemiology Donor Study (REDS-II) in the United States, HIV prevalence rates in first-time and repeat donors were nine per 100 000 and 1·5 per 100 000 donations, respectively; 14 of 403 cases (3·5% of cases) had NAT only positive results [25]. In modelling studies, higher HIV rates in repeat donors and high NAT only cases (NAT yield cases) result in higher residual risk rates, as these are new incident infections associated with more potential window period donations, while infections in first-time donors are likely related to remote risk [1, 21–24]. Although it is tempting to attribute the lower HIV rates in donors solely to differences in donor criteria, as shown by the Italian hemovigilance data, donor understanding and compliance is a key determinant of the efficacy of any deferral policy. Indeed, in many countries, including Canada, the United States and the UK, an exponential decrease in rates of HIV-positive donors occurred in the 1990s and onwards. This was not related to any change in criteria but likely due to enhanced public education about HIV risk factors, increased availability of HIV testing and reduced stigma around MSM and HIV. Many of these factors are part of a broader societal context unrelated to blood centre policies and procedures. The 2010 European MSM Internet Survey (EMIS) collected self-reported data on HIV testing from over 180 000 MSM in 38 European countries. The rate of participants who had their last HIV test in the setting of blood donation varied considerably by country of residence, from a low of 0·9% in the UK to 12·1% in Austria; both of these countries had a permanent deferral for MSM at the time of the study [38]. These large differences in compliance contribute to the difficulty of predicting the efficacy of a given policy in a different jurisdiction.

Future policy changes

Assessment of the safety of a 12-month deferral may lead to a further shortening of the period of abstinence from MSM before donating blood. The Australian Red Cross Blood Service, for example, is attempting to further shorten the deferral period to 6 months, and the Japanese Red Cross recently decreased to a six-month deferral policy. The UK Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) in a July 2017 Donor Selection Criteria Report recommended a reduction to a three-month deferral policy for MSM; the NHSBT in UK has stated that this change will be implemented in 2018 [27]. This was considered to be a safe deferral period based on an approach using twice the window period plus the initial noninfectious period (after infection but prior to sufficient viral particles being present in the bloodstream to cause infection). Using current NHSBT testing protocols, the window periods for HBV are 30 days, and the initial noninfectious phase is estimated at 15 days; window periods for HCV and HIV are considerably shorter. A shortening of the deferral period would allow increased participation by MSM in blood donation [39]. However, this approach still would not permit the majority of sexually active MSM to donate blood. Simple adoption of the approach taken in Spain and Italy is problematic, both from a risk perspective and an operational feasibility perspective. From a risk perspective, data show an increase in risk of HIV transmission is possible, as outlined above. From an operational feasibility perspective, in countries with nonclinical staff screening donors such as Canada and the United States, questions are asked in a flow chart format without clinical discretion of the screener. Broad criteria may be possible to administer in this context but could exclude many currently eligible safe donors [40] Blood centres face the challenge of how to move forward with future changes in criteria, while maintaining the safety and adequacy of the blood supply and the trust of high interest groups. Ideally, policy decisions should be based on epidemiologic and scientific data. Data must be

sufficiently robust to convince regulators that safety has not been compromised. Although the epidemiology of HIV has been extensively studied in the MSM population, public health research has understandably focused on identifying high-risk cohorts and behaviours to target risk reduction strategies. On the other hand, blood centres are most interested in how to identify a low-risk cohort of MSM with no other reasons for deferral (such as intravenous drug use) who would be interested in blood donation. From this perspective, as stated in the FDA 2015 Guidance document, data are currently lacking to support alternative screening approaches that are not based on a deferral period from MSM [19]. The SaBTO committee similarly concluded in their 2017 Donor Selection Criteria Report that there was insufficient evidence to support adoption of a gender-neutral or risk activities-based approach [27].

What is perhaps less clear is specifically what evidence would satisfactorily support such change. A study assessing the HIV incidence in a low-risk group of potential MSM donors is not feasible due to both the large sample size necessary to accurately quantify incidence in a low-risk group and the difficulty of obtaining a representative sample of MSM. Many MSM are not affiliated with any organized group, and there is no list of donors to draw a sample from. Other approaches such as advertising or approaching men at gay venues may lead to samples biased towards MSM with high-risk behaviour.

Setting the research agenda

In 2016, the Canadian federal Minister of Health pledged 3 million dollars (Canadian) to support a research program in this area. The objective of the program was to ensure the generation of adequate evidence-based research for alternative screening approaches for blood or plasma donors. These data could then be used to support changes to the current 12-month MSM deferral policy in Canada while maintaining the safety and adequacy of the blood supply. To kick-start this effort, in January 2017 Health Canada, Canadian Blood Services and Héma-Québec, in collaboration with Health Canada and various high interest groups hosted a two-day meeting in Toronto, bringing together Canadian and international experts in blood regulations and policies, high interest patient and community groups and researchers in a variety of disciplines. Sociologists, epidemiologists and others performing research in the gay community are not necessarily well versed in the regulatory framework of blood donation and the operational issues involved in blood donor screening. They are often strong advocates for the gay community, and some have publicly been critical of blood centre policies. Conversely, blood centre physicians, scientists and epidemiologists are extremely knowledgeable about blood donation but are not well placed and may lack context to perform research in the gay community. Bringing together individuals of diverse backgrounds enabled 'brainstorming' about research

Table 2 Research themes and questions, Toronto Research Meeting, January 2017

1. What research is needed to inform development of individual risk assessment donor policy?
   - Discussions on risk factors, the application of data currently available to identify low-risk donors, and strengths and limitations of current data.
   - Explore potential approaches to research that will inform the development of donor screening questions/donor policy with emphasis on both the quality of data and feasibility.
   - How do we find a low-risk population for studies?
   - What data would be required to ensure safety of individual risk assessment policy?

   Those most interested would be: Population research methodologists, epidemiologists interested in HIV risk factors
2. What research is needed to assess the operational feasibility of potential policies and their acceptability?
   - How can we assess the practicality and effectiveness of proposed donor policies prior to their implementation?
   - Discussion of methods for testing screening questions and their strengths and limitations.
   - How can we assess the acceptability of donor policy to donors and stakeholders and impact of a policy on sufficiency of the blood supply?
   - Discussion of the main end-points that are needed to assess the effectiveness of proposed screening questions, the acceptability of a policy and impact on sufficiency.

   Those most interested would be: Psychology and sociology researchers, methodologists interested in questionnaire design and testing, those interested in donor, patient and LGBTQ stakeholder liaison
3. How can risk of proposed policies be modelled and how should pre- and postimplementation surveillance be addressed?
   - Focus on methodology and end-points pre- and postimplementation of a policy that would assess the impact on safety, sufficiency and stakeholder satisfaction.
   - Discussion of mathematical models that could be applied to assess the risk of potential policies including strengths and limitations of models and the data requirements.

   Those most interested would be: Mathematical modellers, statisticians, epidemiologists interested in program evaluation and surveillance methodology

Table 3 Research strategies identified to address questions, Toronto Research Meeting, January 2017

1. Individual risk assessment
   - Perform a systematic review of published and reported cohort studies done in Canada and countries with similar epidemiology of HIV (Western Europe, the United States, Australia)
   - Attempt to re-analyse data sets to focus on lower risk cohorts
   - Add a blood donation module on to ongoing or imminent studies, questions would focus on determining what proportion of the MSM study population would be eligible to donate using certain criteria, what would acceptability of criteria be
   - As the window period is short, risk questions should focus on recent (2–3 months) behaviours
   - If performing a study similar to France, trial different questions and try to define a risk threshold
2. Operational feasibility and acceptability of potential policies
   - Use the risk-based decision-making framework (RBDM) to explore what level of risk is acceptable to stakeholders and the public
   - Develop education and training of staff around diversity, important for new policy implementation
   - Develop education about reasons for approach taken to enhance compliance
   - Evaluate the feasibility and acceptability of new approaches using plasma donation clinics, with additional safety steps (quarantine and/or fractionation)
3. Risk modelling and surveillance
   - Model developers should work together to develop a standardized approach internationally
   - Some factors are difficult to include in models as data may be difficult to obtain, for example, HIV rate in monogamous MSM
   - Use of large data sets to pool data may improve accuracy
   - Attempt to clarify definitions of factors, such as monogamous, compliance, to ensure validity
   - Use recent estimates and data to improve accuracy
   - May be useful to interpret risk at the patient level rather than solely at the donor level

priorities and ways to leverage existing studies in the MSM community to address issues related to blood donation.

The meeting first sets the stage for future projects by discussing national and international deferral practices, policy development and ongoing research projects. Secondly, researchers were asked to think about key research questions to be answered, and the type of studies that would contribute to providing answers in a timely way. Finally, they were supplied with details about the MSM research grant program, which was launched in February 2017. This first meeting of the minds was an important first step in paving the way for better understanding between researchers active in the gay community and blood centre epidemiologists and scientists, and will lead to collaborative efforts moving forward. Although the goal was to kick-start research projects to support policy changes in Canada, blood centre physicians and researchers from other countries, including the United States, Australia, France and the UK attended the meeting and are interested in similar research questions, and may collaborate on proposed studies.

The research themes were divided into three main categories, recognizing that there is overlap between areas: development of an individual risk assessment donor policy, operational feasibility and acceptability of potential policies, and risk assessment pre-implementation using modelling and postimplementation using surveillance tools (Table 2). Table 3 lists the types of research projects that participants thought might help address research questions. Under the theme of individual risk assessment, the proposed research strategies attempt to identify key characteristics, such as number of sexual partners or new partners in a given time period that would potentially identify a lower risk subgroup in the broader MSM population. Under the theme operational feasibility and acceptability, the impact of potential changes in criteria on the current donor base, and the acceptability and perception of proposed criteria to both current and MSM donors would be assessed. Possible donor policies must be acceptable to stakeholders and donors and implementable in the context of the Canadian blood system. Plasma donation clinics, where products may be subjected to additional safety safeguards such as quarantine, pathogen reduction or fractionation procedures, could be used to evaluate new approaches. Finally, as data collection from pilot projects may take many years, mathematical modelling can make use of data from smaller data sets taking into account a range of uncertainty and different key factors such as donor compliance. Data from all these types of studies can be incorporated by the blood supplier into the risk-based decision framework (RBDM) which takes into account many aspects of risk analysis.

The landscape around the MSM deferral continues to change with time. While many jurisdictions continue to move towards better approaches to 'right size' the risk

associated with bloodborne pathogens that are sexually transmitted, it is unlikely that uniformity of approach will ever be brought to this issue. Some countries are unwilling to accept donors from the MSM population owing to ongoing homophobic cultural mores while others will be financially constrained to implement alternatives that permit expanded donor inclusion. But for most nations, the times are changing and science is being used to create more balanced policy. The intention of this review was to provide a status update of the approaches that are being taken to increase access to donation by MSM as well as their female partners. There are clearly multiple ways to address the interface between blood safety and social justice and novel ideas continue to help refine our approach to this long-standing deferral.

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