

Developing more inclusive deferral policies for blood and plasma donors

In brief...

Identification of research priorities to generate evidence to support future changes to the MSM blood and plasma donor deferral policy.

What is this research about?

Deferral policies for blood and plasma donors are a key element in ensuring the safety of the blood system. In the 1980s, when it was established that patients contracted HIV from blood transfusions, blood operators began to defer populations at high-risk of exposure to HIV from donating blood. In Canada and elsewhere, men who have sex with men (MSM) were specifically deferred from donating when, early on during the HIV epidemic, this population was identified as high risk.

Since then, knowledge about HIV transmission and AIDS has improved, and laboratory tests that detect HIV in blood have been developed. However, while the MSM eligibility criteria have changed in the past few years, many countries including Canada still do not allow sexually active MSM to donate blood and plasma. The MSM deferral is one of the most controversial deferral policies, and while blood safety remains paramount, issues of social justice and inclusivity highlight the need for its modernization.

Deferral policies are based on evidence and must take into consideration scientific and technology advances as well as ethical and moral concerns. In 2017, an international meeting was held by Canadian Blood Services, Héma-Québec and Health Canada to review MSM deferral policies worldwide and the current state of science. The meeting led to a report that included research priorities intended to guide the research community.

What did the researchers do?

At the meeting, MSM deferral policies from various countries were reviewed with a particular focus on population HIV rates, donor HIV rates, donor noncompliance (failing to disclose high-risk behaviours in the screening questionnaire), and risk modelling. Discussions identified possible changes to existing MSM deferral policies, as well as the research needed to inform these changes.

What did the researchers find?

MSM deferral policies around the world vary due in part to the differences in HIV epidemiology. In countries, where the rate of HIV is similar in the MSM population compared with the rest of the population, there is no MSM-specific deferral policy. In countries where the rate of HIV in the MSM population is considerably higher than in the rest of the male population, blood operators defer MSM based on the time since last sexual activity. Other blood operators use gender-neutral criteria based on sexual behaviours that are considered to be higher risk, such as having new or multiple partners.

Donor deferral criteria for MSM are changing in many jurisdictions. Canada moved from an indefinite deferral for any MSM to a five-year deferral in 2013, and to a 12-month deferral in 2016. This is in line with many other countries. These changes were made possible because of the implementation by blood operators of automation and standardization of procedures and new technologies that allow for the detection of HIV (nucleic acid testing), thus reducing the window period (timeframe when a donor may be infectious, but tests are not yet able to detect the virus) to less than 10 days. The availability of data also allows for risk assessments and risk-modelling studies, and provides evidence to move from a precautionary to a risk management deferral policy.

Blood system regulators share the perspective that changes to the MSM policy should be evidence-based. Furthermore, potential impact of policy changes and post-implementation safety should be assessed and monitored.

Reviewing the impact of MSM deferral policies worldwide revealed the following findings.

- ◆ Several blood operators who used time-based deferrals of ten or five years have recently moved to a 12-month deferral. Decreasing the deferral time has not increased HIV rates in donated blood.
- ◆ In Canada, the rate of HIV in donated blood remained very low from 2012 to 2014, at 1 in 21.4 million donations. This was similar to the risk seen in 2006–2009, despite the MSM deferral criteria changing from an indefinite deferral to a five-year deferral in 2013.
- ◆ In Italy and Spain, where behaviour-based deferrals are used, donated blood had higher HIV rates than seen by other blood operators. Many of the HIV-positive donors were noncompliant donors who should have been screened out during the donor questionnaire. MSM was a frequent risk factor.
- ◆ In Spain, HIV rates in first-time donors were similar to those in the general population, suggesting that the specific behaviour-based donor screening process used was not effective at reducing HIV rates in donated blood.
- ◆ Donor noncompliance varies across jurisdictions and is impacted by the details of the deferral policy. In Canada, the donor noncompliance rate decreased from 0.67 per cent with a permanent deferral to 0.44 per cent with a five-year deferral.

The meeting established three key research strategies to inform changes to MSM deferral policies: (1) identify lower risk groups and/or behaviours within the MSM population; (2) determine the operational feasibility of any policy changes, including exploring the level of acceptable risk; and (3) measure the risk associated with any potential policy changes. Collaboration and sharing of large datasets could improve the accuracy of risk assessments and may lead to the development of a standardized international approach.

How can you use this research?

While understanding the experiences from blood systems across the globe is valuable, the development and implementation of MSM deferral policies are often context dependent. Policies must consider many elements including: the jurisdiction's epidemiology for transfusion-transmissible diseases such as HIV and hepatitis B; the technologies and processes that blood operators put in place to prevent the distribution of contaminated blood products; the ability for the system to monitor post-implementation safety; and the regulatory environment which may have been impacted by a tragic public health crisis.

Blood donor education is essential with any deferral policy but challenges are policy dependent. Behaviour-based policies compared with time-based policies, when not well understood by donors, may lead to increased donor noncompliance. For example, one-third of HIV-positive donors in Italy had engaged in high-risk behaviour that should have led to their deferral, but these donors stated that they did not realize their behaviour was risky.

The research priorities presented in this publication identify multiple ways to address the interface between blood safety and social justice. These will help researchers develop projects to appropriately address questions related to the long-standing deferral of MSM, and generate novel ideas and evidence to balance blood safety with donor equality.

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1. Goldman M, Shih AW-Y, O'Brien SF, Devine D. Donor Deferral Policies for Men Who Have Sex with Men: Past, Present and Future. *Vox Sang* 2018; 113: 95-103.

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