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Men Who Have Sex with Men (MSM) Donor Eligibility Criteria Reassessment/Change Submission

Stakeholder Dialogue

Summary Report

Introduction

This summary report captures the key highlights from a stakeholder dialogue on the reassessment/change submission for men who have sex with men (MSM) donor eligibility criteria. The dialogue was held on September 19, 2018 at 2:00 – 3:30 p.m. EDT, using both a teleconference line and the WebEx platform.

The objectives of the consultation were to:

- Inform stakeholders of key scientific findings, emerging international practices, other pertinent factors concerning the notion of reducing the blood donation waiting period for the MSM population from 12 months to three months
- Inform stakeholders of current national criteria for trans donors
- Update the status of the MSM Research Grant Program
- Understand and consider stakeholder perspectives on the proposed deferral change
- Check assumptions and gain a deeper understanding of the complexity and impacts of the proposed change

Participants

Overall, 21 stakeholders from the following organizations/groups participated in this consultation:

Patient groups

- Aplastic Anemia & Myelodysplasia Association of Canada (AAMAC)
- Canadian Hemophilia Society
- Canadian Immunodeficiencies Patient Organization (CIPO)
- GBS/CIDP Foundation of Canada
- Sickle Cell Disease Association of Canada
- Thalassemia Foundation of Canada

Advocacy groups

- B.C. Federation of Students
- BloodWatch
- Canadian Centre for Diversity and Inclusion (CCDI)
- Canadian Centre for Gender + Sexual Diversity
- Community-Based Research Centre for Gay Men's Health (CBRC)
- Egale Canada Human Rights Trust

Other groups

- Canadian Federation of Nurses Unions (CFNU)
- Héma-Québec
- netCAD volunteer
- training contractor (trans sensitivity training development for staff)

Several representatives from other organizations were also invited but could not attend. These organizations have been contacted and offered an opportunity to engage.

Process

To open the dialogue, Mr. Ron Vezina (Vice-President, Public Affairs) discussed the importance of stakeholder relations and public participation in Canadian Blood Services' business, and emphasized the organization's commitment to moving this topic forward. Additionally, Mr. Dave Sumner (Director, Communications) highlighted how stakeholders could be involved in supporting next steps on changes to eligibility criteria.

Mr. Don Lapierre (Manager, Board and Stakeholder Relations) then discussed Canadian Blood Services' proposed next steps:

- Another incremental step in a time-based, eligibility criteria from 12 months to three months for the MSM population
- A similar request to Health Canada to decrease the waiting period for trans donors from 12 months to three months for high risk sexual partners
- A shift in approach to identify a low-risk subgroup of MSM donors will require results of ongoing studies in the MSM research grant program

Mr. Lapierre also explained Canadian Blood Services' position and rationale, the timeline of changes to MSM eligibility over time, and the timelines for pre- and post-submission.

To provide context and background for discussion, Dr. Mindy Goldman (Medical Director, Donor and Clinical Services) summarized scientific data for consideration and the current MSM research being conducted to help inform changes to eligibility criteria in the future.

Key highlights

The key highlights of the discussion among participants were:

- **Moving to a behaviour-based model:** Several stakeholders expressed the desire to move to a behaviour-based deferral and wanted more information, including what is needed in terms of research and data, potential barriers, anticipated timelines, the rationale to move to a three-month deferral and external considerations, such as political direction and policies in other countries.

- **Importance of communications around eligibility criteria/research:** Stakeholders also asked about the way in which various aspects of the MSM eligibility criteria and research will be communicated. They discussed the need to align the move to a three-month deferral with the publishing of research results (to avoid confusion), whether the research results will be published, and the terminology (e.g., "incremental movement") used in communicating this eligibility criteria change to the MSM community.

- **Clarity on high-risk sexual behaviour:** Some stakeholders sought clarification on what Canadian Blood Services considers high-risk sexual behaviour besides MSM. For example, one participant wondered whether sex with a fresh blood component recipient is considered high-risk. (See answer in summary table below)

Other questions/comments raised during the discussion were related to:

- The outcomes of trans sensitivity training for Canadian Blood Services' employees
- Detail on the current screening process for trans individuals, particularly in managing transfusion-related acute lung injury (TRALI) risk. A code directs our production department on how the blood should be processed to ensure low TRALI risk (components from trans donors are treated as components from female donors, with plasma sent for fractionation rather than transfusion)
- The need to ensure both safety for patient groups and non-discrimination in deferral policies

A more detailed account of the key highlights is provided below, with the questions/comments posed by stakeholders and responses provided by Dr. Goldman and other Canadian Blood Services employees.

Moving to a behaviour-based model	
What is needed to move to a behaviour-based model? What is the "big thing you can't	• We can't simply do what other countries have done for a variety of reasons. The epidemiology for HIV is different from country to country. Other blood operators also organize donor screening differently – for example, in Italy and Spain screening is done by physicians who take a donor's entire medical history into

Moving to a behaviour-based model	
get past" (as other countries have made this change)?	account. We do not have the resources for one-on-one physician screening, and our model is as a manufacturer of biologics. Also, their results for donor compliance with criteria is "nowhere near as good" as Canadian Blood Services, resulting in much higher residual risk for HIV than we currently have in Canada. • A direct comparison between our screening policies and that of other countries is not helpful in terms of maintaining safety. Our regulator, Health Canada, requires Canadian-specific data, and the epidemiology, screening methods, and donor motivations differ between countries. Many of the current research projects are looking at developing criteria/questions to identify a low-risk population of MSM who are interested in donating and meet the other eligibility criteria. • Once we have data from the research, we can then look at the risk increment of future changes. One option we wish to further explore is the possibility for source plasma donation by MSM, which would help us gather additional data to move forward to make changes for whole blood donation.
What about the social sciences in moving to this model?	• We agree that there is merit in applying a social science lens. Several of the current research projects are looking at social science/ethics aspects. • There is a program for plasma donors in France that shows what questions might look like to identify a low-risk subset. For example, they ask if a donor has had new sex partners in the past four months, more than one partner in the past four months, and if they have a mutually exclusive relationship with a partner. These may not necessarily be the complete set of questions for us to consider but we will share research outcomes in an aggregated format when data is available.
What is the expected timeline for moving to this model?	• It will depend on the research results. We only started in fall 2017 and it will take time before the results are in hand. • It will be a couple of years. We need to see the research results, implement changes operationally (e.g., adjust the IT system) and then seek approval from the regulator, which has 120 days for their assessment.
Is Canadian Blood Services receiving	• No, we don't receive direction from the Prime Minister's Office or Health Canada. We are independent, arm's length and work

Moving to a behaviour-based model	
any political direction?	through the regulatory branch. Health Canada is aware of where we want to go next in changing the eligibility criteria.
What is the "rush for an incremental step," especially with current research being conducted?	• We want to move now because we feel that the data we now hold are supportive of another incremental step. • We also want to influence the time period for behaviour-based deferral. For example, we could ask about behaviours in the last three months, as opposed to 12, which will help elicit more correct answers. • We can be less restrictive while maintaining safety.
Is Canadian Blood Services considering the Israeli model of plasma donation (moving deferred donors to the plasma donor pool)?	• Our understanding is that in Israel, MSM donors are being accepted: their plasma is being used for fractionation, but the other part of donation is discarded. We don't feel that is an appropriate model – we don't want to discard any part of a donation of whole blood. It's not a good use of the donor's gift.

Importance of communications around research/eligibility criteria change	
The change to a three-month deferral may happen while research findings are published. How will Canadian Blood Services ensure that people understand the change?	• We understand and acknowledge that there exists potential for public confusion if an incremental step is introduced while research findings are being explored and prior to results being released. • We will work on aligning the timing of our messaging with the researchers who are funded. Our submission will be a topic of discussion at an upcoming meeting with the funded researchers in December 2018.

Importance of communications around research/eligibility criteria change	
Will the research results be made public?	• We don't know. Some data will likely be published, but it is up to each researcher to make it public. They will be presenting their results to their own networks of stakeholders, at conferences, etc. • For us, making a change will not be the result of a single study, but rather an aggregation of all relevant studies. • Our regulator isn't limited to looking at only peer-reviewed, published data. To support our submission, we can submit data from researchers presented (in abstract or summary) without it going through peer review / journal publication. We do this quite often with other projects.
Messaging will be important. I caution against saying "headed in the right direction", "incremental movement", and "olive branch" to the MSM community.	• This change is based on scientific data, and evidence-based decisions making; our messaging will represent our intent to keep patients safe. We will look at adjusting the terminology we use in messaging to all communities. • We will continue to have one-on-one meetings with stakeholder organizations, so we can better understand their concerns and recommendations.

Clarity on high-risk sexual behaviour	
What is considered a high-risk sexual behaviour besides MSM?	• Currently, a woman having sex with MSM in the past 12 months is considered high risk. There are also criteria around having sex with someone who has used intravenous (IV) drugs or has paid money or drugs for sex.
Is sex with a fresh blood component	• We defer people who have been recently transfused. We used to defer people who had sex with a partner who got regular treatment with blood components (e.g., receiving IVIG monthly

recipient considered high-risk?	for immunodeficiency). Criteria were changed after a Health Canada submission at the end of April 2018.

Outcomes of trans sensitivity training	
Has the mandatory training module been rolled out? What has the response been?	• It will be mandatory for Canadian Blood Services' staff by the end of November. Many have done it already and have provided valuable feedback. The level of interest has been high and people want more information. • We've also received some positive feedback from trans donors who are repeat donors and report improved experiences.

Clarity on current screening process for trans individuals	
In the electronic screening tool, does it capture whether trans donors are transitioning from male to female or female to male, or can they simply select male or female without having to report their trans history? I'm asking in terms of managing TRALI risk.	• A code is added to a donor's file to instruct our production lab to treat components and to minimize TRALI risk – all components are used, but they are used as if a donor was female. All red blood cells are used, but the plasma is sent for further manufacturing rather than transfusion. That's what we do for all our female donors. • How a donor responds on the questionnaire, needs further work from the supplier of the software. Currently, in the first donation a donor can respond however they want. Subsequent donations depend on an algorithm, contingent on how the person is defined in the system. • Also Dr. Greta Bauer from the University of Western Ontario recently received a research grant to take the Trans PULSE project national. We're very happy that she's asked us to include some questions in a national study with the trans community about blood donation. We will start working with her this fall.

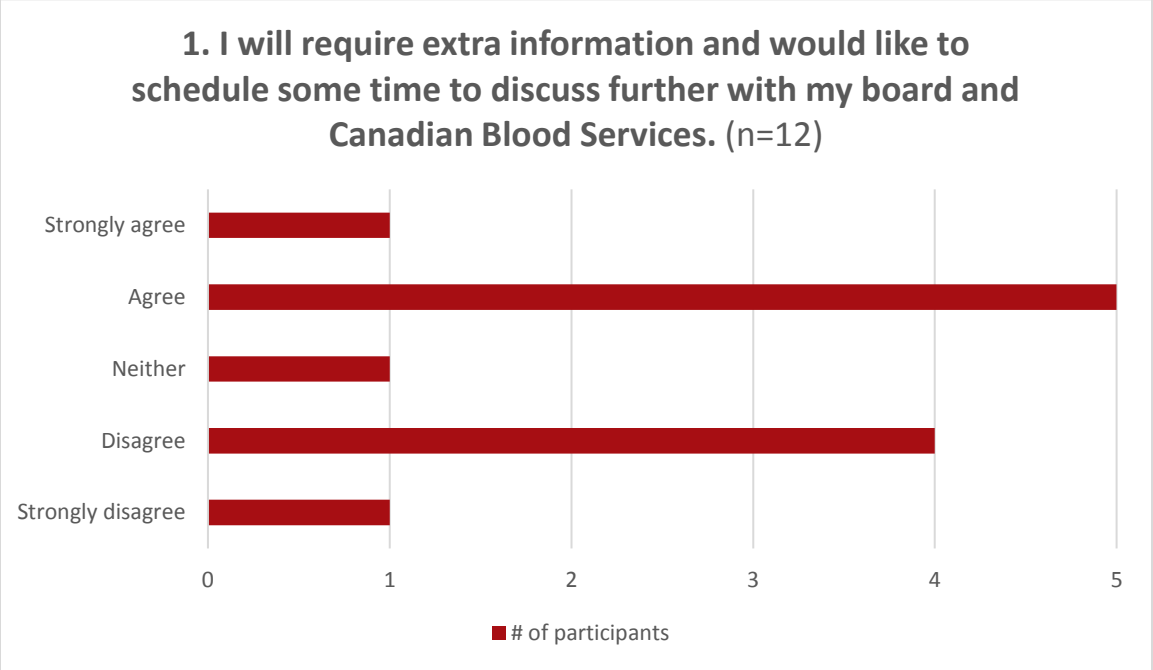
Ensuring both safety and non-discrimination	
As a patient that relies on monthly blood transfusions, this is not a question of discrimination. Our concern is that we want to have a safe blood supply and that we thoroughly look at things before making changes.	Participant in response: • But the history of MSM deferral is based on discrimination, which we need to fix. A blood drive in high school was an experience of discrimination – it forced me to come out of the closet, as I had to explain why I couldn't donate. Moving to behaviour-based deferral can increase donations while still ensuring safety. Canadian Blood Services: • Our #1 priority is to maintain a safe and adequate blood supply. That's our mandate. But at the same time, we want to have the broadest possible donor base without impacting safety. It may be slow, but we are making incremental changes.

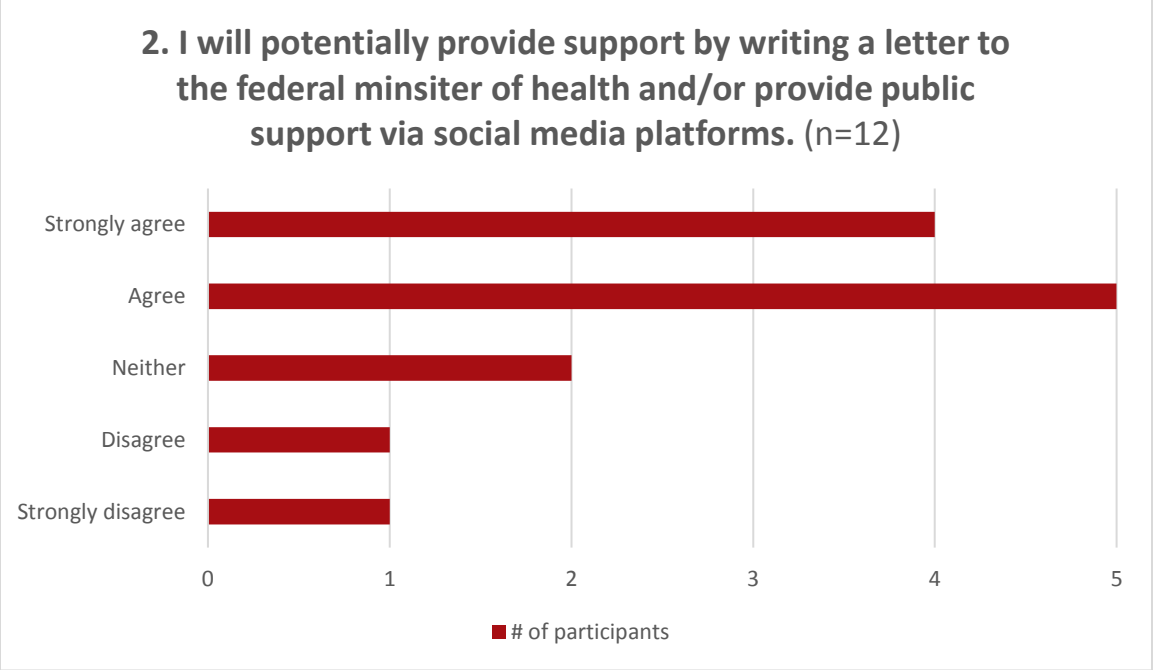
Next steps

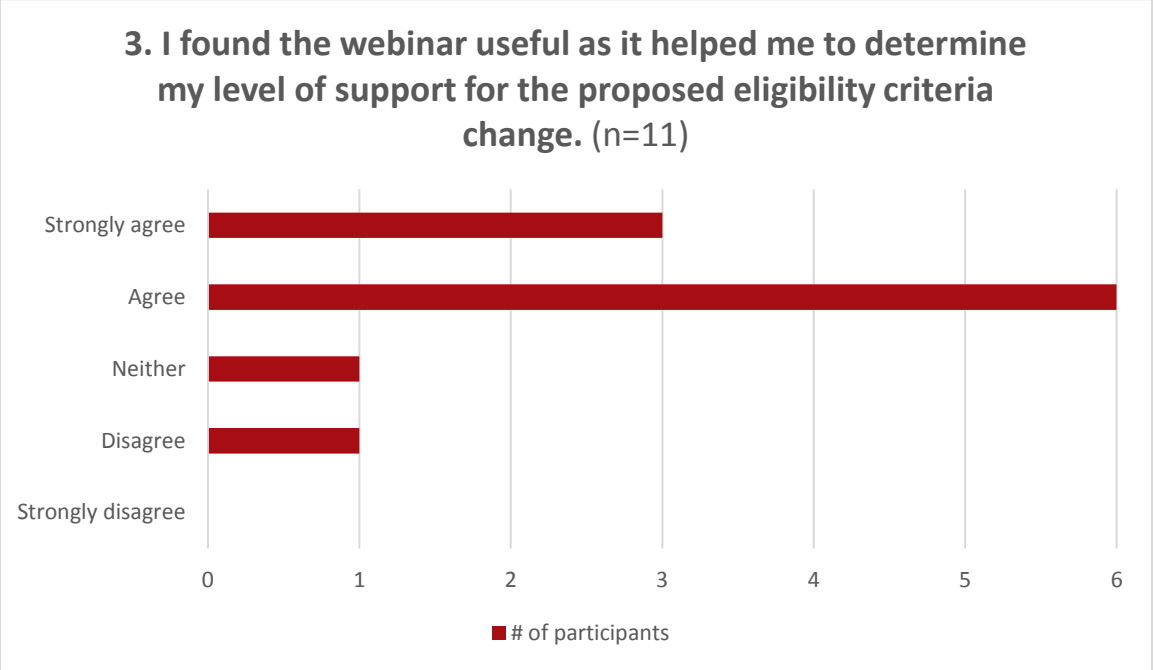
Mr. Lapierre invited stakeholders to reach out, as Canadian Blood Services will be scheduling interviews/meetings with interested groups over the next few weeks.

Stakeholders who are interested in supporting the eligibility criteria change are asked to send a letter to the federal Minister of Health. Canadian Blood Services will send a kit to these stakeholders, which will provide ideas on what might be included in their letter. Additionally, stakeholders will be provided with a social media support kit to help them publicly share their support on the eligibility criteria change.

Before closing, Mr. Lapierre posed a series of polling questions to help guide next steps. It should be noted that some participants were unable to respond to polling because of incompatible platforms being used. Follow up with all participants will occur throughout October. For those who participated in the polling, these were the results:


1. I will require extra information and would like to schedule some time to discuss further with my board and Canadian Blood Services. (n=12)
Strongly agree
Agree
Neither
Disagree
Strongly disagree
0
1
2
3
4
5
# of participants


2. I will potentially provide support by writing a letter to the federal minsiter of health and/or provide public support via social media platforms. (n=12)
Strongly agree
Agree
Neither
Disagree
Strongly disagree
0
1
2
3
4
5
# of participants


3. I found the webinar useful as it helped me to determine my level of support for the proposed eligibility criteria change. (n=11)
Strongly agree
Agree
Neither
Disagree
Strongly disagree
0
1
2
3
4
5
6
# of participants