Donation Criteria for Men who have Sex with Men (MSM): Update from Canadian Blood Services
Outline 1

• Current criteria
• Proposed criteria
• Stakeholder outreach
Outline 2

• Safety Assessment
  – Results since implementation of a 5 year deferral policy
• International perspective
• Considerations for a one year deferral
  – HIV
  – Emerging pathogens
• Next steps
Current criteria

• From late 1980s until July, 2013, CRCS, and then CBS and Héma-Québec had an indefinite deferral for MSM, even once, since 1977

• In late 2012, submissions were made to Health Canada by both blood operators to change to a 5 year deferral for MSM

• In addition to scientific justification and risk assessment, the submissions were accompanied by a summary of extensive stakeholder consultations and support

• The submissions were approved, and changes implemented in July, 2013
**Current criteria**

- Current question, male donors: *In the last five years, have you had sex with a man, even once?*

- Current question, female donors: *In the last 12 months, have you had sex with a man who had sex with a man, even once in the last 5 years?*

**Proposed criteria**

- Male donors: *(In the last 12 months, have you had sex with another man?)*

- Female donors: *(In the last 12 months, have you had sex with a man who, in the last 12 months, had sex with another man?)*
What have we heard from stakeholders?
Consultation objectives

Engage in dialogue with external stakeholders to:

- **Inform** of key scientific findings, emerging international practices, 2014 Ipsos Reid polling results and other pertinent factors concerning the notion of moving deferral for blood donation for the MSM population from 5 years to 12 months

- **Understand and consider** stakeholder perspectives on the revised discussion paper and proposed deferral change

- **Check assumptions and gain a deeper understanding** of the complexity and impacts of the proposed change
Stakeholder consultations

• Are a vital part of policy reassessment

• Report on donor selection criteria related to MSM, summarizing the issue sent to stakeholders in June 2015

• Consultations for patient groups have included a webinar, face to face meetings, National Liaison Committee meetings and open board meetings

• Ipsos Reid polling of donors, general population, Community Based Research Centre also undertaken
Arc of Stakeholder Engagement

Several “interactive points” of stakeholder engagement undertaken this past year

May
Internal Webinar

June
Webinar
External Stakeholders

Spring - Summer
Pride + Ally Events + Patient KIIs

Fall
Stakeholder Consultations Including NLC

Dec.
Pre-submission Webinar

Early 2016
Health Canada Submission

Canadian Blood Services
it's in you to give

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Patient advocacy groups

- Overall support for reduction in time-based deferral for MSM to one year
- Cautiously optimistic that this policy change will still protect against unknown emerging pathogens
- Support for any further incremental change would require new evidence
- Patient groups not directly impacted by this policy hesitant to engage
- Most willing to write letter of support
LGBTQ advocacy groups

- Overall support for reduction in time-based deferral for MSM to one year but do not feel it goes far enough
- Continue to seek gender-neutral, behaviour-based screening
- Support for any further incremental change would require change that allows for safe subset to donate
- Willing to assist with required research
- Continue to see policy as discriminatory
- Most willing to write letter of support
General public (including donors)

- Overall neutral or unaware

- Those who see this as more of a social justice issue (loud minority) often take to social media to seek gender-neutral, behaviour-based screening

- Often wish to argue interpretation of epidemiological statistics for risk categories

- Unaware of limitations (or strengths) of regulatory environment

- Are frequently not willing to seek out information once they have predetermined that policy is purely based on homophobia
Stakeholder letters of support

• As with submission for 5 year deferral, stakeholder support for change to a 12 month deferral is critical

• To date, there are 11 letters of support that have been sent to Health Canada
What’s up with the federal government?
Campaign promises vs. government agenda

• The Liberal Party of Canada’s election campaign platform included a commitment to change or remove the MSM deferral policy altogether

• This was not listed in the ministerial mandate letter but we are aware of political pressure on the government to accelerate action on this file

• Our plan is to continue with incremental changes that we believe are safe and that are supported by stakeholder groups

• Health Canada remains the regulator of the blood supply and must approve any and all proposed changes to the MSM eligibility policy
Safety Assessment
Results since implementation of 5 year deferral, CBS

• HIV positive donation rate was monitored

• Physicians noted risk factors for HIV positive donors

• The number of re-instated donors was evaluated (donors previously deferred who returned to donate)

• An anonymous survey was carried out in male donors before and after implementation to assess compliance
Results, 2 years post-implementation

• No change in HIV rates or in rates of any other infectious disease markers (0.2 to 0.5 per 100,000 donations in last few years)

• No HIV positive donors with MSM between 1977 and last 5 years as known risk (~ 5 HIV positive donors/year)

• Donor modeling study predicted increase of ~ 10 HIV positive donors/year, which was not observed

• Small gain in previously deferred and newly eligible donors (~115 donors)

• Small improvement in compliance with change to 5 year deferral (decrease from 0.7% to 0.4% of male donors not compliant)
International perspective

• Factors influencing international policies include
  • epidemiology of HIV in country
  • regulatory requirements, including plasma fractionation
  • methods of donor screening (standardized questionnaire vs. health assessment by MD)
  • history of response to emerging threats

• Many jurisdictions have convened expert committees to perform risk analysis of possible changes
# MSM deferral criteria in selected countries

<table>
<thead>
<tr>
<th>Countries</th>
<th>MSM</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>1 year</td>
<td>ABC, ARC, AABB advocated for 1 year FDA Guidance for Industry, Dec 2015</td>
</tr>
<tr>
<td>Australia</td>
<td>1 year</td>
<td>Change to 1 year showed no increased HIV risk</td>
</tr>
<tr>
<td>England, Scotland, Wales</td>
<td>1 year</td>
<td>Changed in 2011, no increased HIV risk</td>
</tr>
<tr>
<td>New Zealand</td>
<td>1 year</td>
<td>Changed from 5 years to 1 year recently (2014)</td>
</tr>
<tr>
<td>Sweden</td>
<td>1 year</td>
<td>Changed from indefinite to 1 year recently (~ 2013)</td>
</tr>
<tr>
<td>Finland</td>
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<tr>
<td>France</td>
<td>Changing to 1 year</td>
<td>Change to 1 year deferral for whole blood donors in 2016</td>
</tr>
<tr>
<td>Holland</td>
<td>1 year</td>
<td>Changed to 1 year in Dec/2015</td>
</tr>
<tr>
<td>Japan</td>
<td>6 months</td>
<td>Deferral for sexual activity with new partner, not necessarily MSM</td>
</tr>
<tr>
<td>Italy</td>
<td>Specific behaviours</td>
<td>Physicians assess donor risk</td>
</tr>
<tr>
<td>Spain</td>
<td>Specific behaviours</td>
<td>Physicians assess donor risk</td>
</tr>
<tr>
<td>South Africa</td>
<td>No deferral</td>
<td>Different epidemiology</td>
</tr>
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</table>
Summary, international criteria

• No international consensus, in part due to different epidemiology and screening procedures

• Many countries have recently moved to a 1 year deferral, often after detailed risk analysis

• Several years experience in Australia, UK with a 1 year deferral show low, stable HIV positive rates in donors
Considerations for 1 year deferral - HIV

• Anti-HIV-1, 2 testing, including subtype O

• Nucleic acid testing for HIV-1

• Window period = 9.5 days (time between when individual may be infectious and virus is detected by testing)

• 1-8 HIV positive donors/year, with over 800,000 donations tested, residual risk 1 in 8 million units

• No change in rate after implementation of 5 year deferral

• A 12 month deferral period ample to cover window period risk
Emerging pathogens

Zika virus

West Nile virus (WNV)
Surveillance and identification of emerging pathogens

- Time frame between emergence of a threat and implementation of mitigating factors shorter due to:
  - Advances in molecular biology
  - Enhanced monitoring of infectious threats
  - Targeted monitoring of high risk groups, including sexually active gay men
  - Better communication of information
  - Lower threshold for preventative action
Surveillance at CBS

• Department of epidemiology and surveillance led by Dr. Sheila O’Brien

• Follow all transmissible marker rates, calculate residual risks

• Interview all donors with positive results and matched controls to identify risk factors

• Perform large anonymous donor surveys to assess risk factors, attitudes of successful donors, compliance
Surveillance at CBS

• Individuals in our division, Medical Services and Innovation, are members of many relevant groups:
  • ISBT hemovigilance working group
  • EBA Emerging Infectious Diseases Group
  • Canadian Public Health Lab Network
  • Ontario Provincial Infectious Diseases Advisory committee and Vector-Borne Diseases Groups

• CBS Board of Directors, Scientific and Research Advisory Committee include public health, infectious disease experts
A Supplement to Transfusion

Emerging Infectious Disease Agents and their Potential Threat to Transfusion Safety
AABB Transfusion Transmitted Diseases Committee (TTDC), Emerging Pathogens

- AABB TTDC reviewed information about agents with actual or potential risk of transfusion transmission in US or Canada in 2009, updated online

- 68 agents identified and assigned a risk priority level based on
  - Scientific/epidemiologic evidence regarding blood safety: transfusion transmission, prevalence in asymptomatic people
  - Public perception and/or regulatory concern for blood safety: discussion at BPAC
  - Public concern about agent discussed in press, queries to AABB and operators

- **Red** Orange **Yellow** White highest to lowest priority
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<thead>
<tr>
<th>Agent (year updated)</th>
<th>Risk factors/exposure routes</th>
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<tr>
<td>vCJD (2011)</td>
<td>Geographic, BSE</td>
</tr>
<tr>
<td>Dengue virus (2014)</td>
<td>Geographic outbreaks, mosquitoes</td>
</tr>
<tr>
<td><em>Babesia</em> species (2013)</td>
<td>Geographic, ticks</td>
</tr>
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</tr>
<tr>
<td>--------------------------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>Chikungunya virus (2015)</td>
<td>Geographic outbreaks, mosquitoes</td>
</tr>
<tr>
<td>St. Louis encephalitis virus</td>
<td>Geographic outbreaks, mosquitoes</td>
</tr>
<tr>
<td>Leishmania</td>
<td>Geographic, sandflies</td>
</tr>
<tr>
<td>Plasmodium (malaria)</td>
<td>Geographic, mosquitoes</td>
</tr>
<tr>
<td>T. Cruzi (Chagas)</td>
<td>Geographic, reduviid bugs</td>
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</tbody>
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# Measures taken by CBS, emerging risks

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<th>Agent</th>
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<th>Measures</th>
</tr>
</thead>
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<tr>
<td>vCJD</td>
<td>Geographic, BSE in diet</td>
<td>Identification and deferral of at risk donors</td>
</tr>
<tr>
<td>SARS</td>
<td>Geographic, respiratory</td>
<td>Identification and deferral of at risk donors</td>
</tr>
<tr>
<td>WNV</td>
<td>Geographic outbreaks, mosquitoes</td>
<td>Donor testing</td>
</tr>
<tr>
<td>Parvovirus B19</td>
<td>Outbreaks, respiratory</td>
<td>Donor testing by manufacturer of pooled plasma protein products</td>
</tr>
<tr>
<td>Simian Foamy Virus</td>
<td>Exposure to nonhuman primates, bite</td>
<td>Identification and deferral of at risk donors</td>
</tr>
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<td><em>T. Cruzi</em> (Chagas)</td>
<td>Geographic, reduviid bugs</td>
<td>Testing of at risk donors</td>
</tr>
<tr>
<td><em>Influenza A, H5N1</em></td>
<td>Possible pandemic, respiratory</td>
<td>Comprehensive planning</td>
</tr>
<tr>
<td><em>Plasmodium</em> (malaria)</td>
<td>Geographic, mosquitoes</td>
<td>Frequent updating of at risk areas</td>
</tr>
<tr>
<td><em>XMRV</em></td>
<td>Possible associated with chronic fatigue syndrome (CFS)</td>
<td>Information sheet and deferral of CFS donors</td>
</tr>
<tr>
<td><em>Babesia</em></td>
<td>Geographic, ticks</td>
<td>Large donor study</td>
</tr>
<tr>
<td><em>Hepatitis E</em></td>
<td>Contaminated food, water</td>
<td>Large donor study</td>
</tr>
<tr>
<td><em>Zika virus</em></td>
<td>Geographic, mosquitoes</td>
<td>Travel deferral</td>
</tr>
</tbody>
</table>

*Possible agent, now shown to be laboratory artifact*
Summary, emerging pathogens

• Surveillance of emerging threats occurs at an industry level (AABB) as well as at CBS

• Risks for emerging threats have been related to geographic exposure, usually by an insect bite

• MSM have not been at higher risk for any of these pathogens

• Appropriate measures have been taken to address emerging pathogens
Next steps

• Both CBS and Héma-Québec are waiting to hear from Health Canada

• If approved, timing of implementation would depend on when approval is received, operational feasibility

• Likely to occur in early fall 2016

• Extensive post-implementation monitoring with annual reports to Health Canada (HIV rates, risk factors, compliance) will occur, as was done after the change to a 5 year deferral period
Questions of Clarification
Canadian Blood Services

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