International perspectives on blood donor eligibility, men who have sex with men (MSM)

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Disclosure

• I have been involved in formulating, implementing, and evaluating policy in this area for many years as a medical director for Canadian Blood Services

• I have no other conflict of interest
International policies

• No general consensus

• Factors influencing policy include
  – epidemiology of HIV
  – donor screening methods
  – regulatory requirements
  – government decrees
  – risk analysis, modeling
  – history of response to threats
Main approaches

Time-based deferral
- any MSM in time period → deferral for given time after last MSM

Risk activities based, “gender neutral” policies
- sexual behaviours considered to be high-risk, regardless of whether partner is same or opposite sex, in a given time frame → deferral for given time after risk factor

Alternative criteria + other safety measures
- plasma quarantine and retest
How to analyze results?

• Disease transmission is extremely rare
• Safety assessed by HIV rates, incidence rates in repeat donors, compliance, risk modeling studies
• Results will depend on many factors, in addition to actual criteria

Outside world
• HIV incidence, prevalence
• public health messaging
• ease of alternative testing

Donor centre
• method of administration of questionnaire
• donor understanding and compliance
Time based deferrals

• From 1980s until 2000, many countries had a permanent deferral for MSM “ever, or even once since 1977”

• In 2000, Australia moved to a 12 month deferral

• Since 2011, many countries have moved to shorter deferral periods of 3-12 months

• Risk modeling suggested absence of a significant risk increment

• In the UK, the Advisory Committee on the Safety of Blood, Tissues, and Organs (SaBTO) recommended a change to a 3 month deferral based on window period (WP) for HBV (pre-infectious period + 2 x WP)
# Time based deferrals, 2019

<table>
<thead>
<tr>
<th>Deferral time</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 months</td>
<td>England, Scotland, Wales (late 2017)</td>
</tr>
<tr>
<td>4 months</td>
<td>Denmark (announced by Health Ministry)</td>
</tr>
<tr>
<td>12 months</td>
<td>Canada, France, Sweden, Belgium</td>
</tr>
<tr>
<td></td>
<td>Australia, Netherlands, Finland, Germany</td>
</tr>
</tbody>
</table>
Results

• Change to a 12 month deferral was not accompanied by increase in HIV rates in donors, or increase in NAT only positive donors
• Risk increments likely over-estimated by modeling studies
• Post-implementation compliance studies show no change in non-compliance or slight improvement
• Awaiting publication of UK results with 3 month deferral
Strengths and weaknesses

👍 • Simple and similar to other risk questions
    • Standardized
    • Changes have enlarged overall donor pool

👎 • At some time interval, limited by window periods (? 3 months)
    • Defers all sexually active MSM, including those in a stable, monogamous relationship from donating
Risk activities based criteria (Italy, Spain)

- Donors asked about sexual partner (same sex or opposite sex), deferred for what is considered high-risk sexual behaviour, such as:
  - a new partner
  - multiple partners
  - casual partner(s) (not in mutually exclusive relationship)

- Time period of interest may be 4 months (Italy) or 12 months (Spain)

- In some countries, such as France, some of these criteria exist, in addition to specific MSM criteria
Risk activities based criteria (Italy, Spain)

- Other differences include use of MDs to screen donors, with ability to ask additional questions and refine individual risk assessments
- No national uniform questionnaire
- Less standardization and more variability between blood centres
Results

- Harder to evaluate on a national level
- Study from Catalonia, Spain, demonstrated high HIV rate (7.7/100,000), 61% of positive results in repeat donors
- 10 of 214 positive donors (4.7%) were NAT only positives
- 89% of all positive donors, 90% of NAT only positives were males
- MSM was a frequent risk factor in HIV positive donors
- HIV rates in donors in Spain and Italy are higher than other European countries (2006)
# HIV rates in donors

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>HIV rate/100,000</th>
<th>NAT only rate/100,000</th>
<th>Ratio 1&lt;sup&gt;st&lt;/sup&gt; time/repeat donors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catalonia ¹</td>
<td>7.7</td>
<td>0.36</td>
<td>1.2</td>
</tr>
<tr>
<td>Italy ²</td>
<td>3.8</td>
<td>NA</td>
<td>15.0</td>
</tr>
<tr>
<td>US (REDS II) ³</td>
<td>2.8</td>
<td>0.09</td>
<td>5.9</td>
</tr>
<tr>
<td>Canadian Blood Services ⁴</td>
<td>0.5</td>
<td>0</td>
<td>6.9</td>
</tr>
<tr>
<td>England ⁵</td>
<td>0.6</td>
<td>0</td>
<td>7.3</td>
</tr>
</tbody>
</table>

1. Bes, Transfusion 2017;57:2164
2. Suligoi, Blood Transfus 2010;8:178
3. Dodd, Transfusion 2016;56:2781
4. O’Brien, Transfusion 2019 ePubed
5. Annual review, 2014, NHSBT epidemiology unit, available online
Strengths and weaknesses

👍 • For MSM, greater characterization of high or low risk donors (increase in specificity)
  • Removes question and deferral specifically for MSM, reducing perceived stigma and prejudice against gay men

👎 • More complex approach, more interpretation possible
  • Higher residual risk using data from Spain and Italy
  • As applied in a “gender neutral” way, will substantially increase deferral of currently donating, TD marker negative donors (decrease specificity)
Additional measures that reduce infectious risk, such as quarantine and retest, may permit adoption of alternative criteria.

Israel: no deferral for MSM, plasma is quarantined and released into inventory after donor returns, donates and is retested > 4 months later; other components are discarded.

In France: all donors asked about > 1 sexual partner in last 4 months; MSM who meet this criterion can donate plasma, which is quarantined until donor returns, donates, and is retested ≥ 2 months later.

Could also be used with pathogen reduction technology or source plasma.
Strengths and weaknesses

👍 Additional steps may compensate for possible risk increase

- Provides useful data about eligibility, TD markers, and compliance for further policy changes
- Increased eligibility for MSM, although additional processing requirements, such as quarantine, may still require an MSM question

👎 Increased operational complexity and cost
- May lead to increased errors
- Quarantine and retest limited to plasma donation
- Sub-optimal performance of pathogen reduction may increase risk
Current situation in Canada

- Both Canadian Blood Services and Héma-Québec changed from an indefinite to a 5 year deferral (2013) and 12 month deferral (2016) after risk modeling and extensive stakeholder consultations.
- No change in very low TD marker rates, or in compliance (anonymous donor surveys).
- Submission under review at Health Canada to change to a 3 month deferral.
- Many research projects are underway as part of a federally funded research program.

More information is available at: Blood.ca → blood → men who have sex with men
Summary

- No international consensus on MSM policy
- Trend towards shorter time-based deferrals, with no adverse safety impact to date
- Risk behaviour-based strategies have shown high HIV rates in donors, although this may be influenced by factors other than the criteria themselves
- Quarantine and retest or pathogen reduction steps may mitigate for possible risk increments associated with alternative screening approaches