MSM DONOR POLICY: STUDIES FROM THE USA AND OTHER COUNTRIES

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• Nothing to disclose
# International Context for Blood Donation by MSM

<table>
<thead>
<tr>
<th>Country</th>
<th>Current Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>1-year deferral</td>
</tr>
<tr>
<td>Canada</td>
<td>5-year deferral (implemented July 2013)</td>
</tr>
<tr>
<td>Italy</td>
<td>Number of sexual partners in previous year regardless of sexual orientation</td>
</tr>
<tr>
<td>New Zealand</td>
<td>5-year deferral</td>
</tr>
<tr>
<td>Spain</td>
<td>Number of sexual partners in previous year regardless of sexual orientation</td>
</tr>
<tr>
<td></td>
<td>(under review)</td>
</tr>
<tr>
<td>South Africa</td>
<td>No specific MSM question on health history form; New sex partner in last 6 months? &amp; More than 1 sex partner in last 6 months? (implemented May 2014)</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>1-year deferral (implemented November 2011)</td>
</tr>
<tr>
<td>USA</td>
<td>Indefinite deferral</td>
</tr>
</tbody>
</table>
Risk Factor and Residual Risk Studies

- Published donor studies in settings which have predominantly HIV-1 clade B infections identify MSM as one of the primary risk factors for HIV in male blood donors
  - A recent US study will show similar results
- The implications are two-fold:
  - Donors in settings with MSM deferrals in place have donors who are not disclosing deferrable behaviors
  - Nondisclosure has the potential to place recipients at risk
- Settings with other clades may have different primary risk factors
  - Local epidemiology will drive donor suitability policies
- The last reported HIV residual risk in the US is 1 per 1,470,000 donations based on 2008 data Zou et al. Transfus Med Rev. 2012
  - 1 per 740,000 donations in first time donors
  - 1 per 1,860,000 donations in repeat donors
If the permanent deferral were lifted would men who have sex with men want to donate blood, and if so, who would be eligible?

Belanger et al. Transfusion 2013
Research on MSM and Blood Donation

UK Study by Grenfell, et al. *(BMJ 2011; 343)* found that 10.6% of MSM recruited in a large, population-based survey reported donating blood.

An unpublished 2007 Swedish Survey found that 19% of a sample of 334 male members of the Swedish LGBT Rights Federation reported donating blood.

These data enrich for persons interested in the topic and may be not reliable measures of compliance/noncompliance in donors.
Compliance with Deferral Policy

In mathematical modeling analyses compliance is one of the most important factors influencing risk

- **Australia Seed Vox Sang 2014**
  “The efficacy of this strategy is directly dependent on the donor’s full and frank disclosure (termed ‘compliance’) when answering the relevant screening question on the predonation questionnaire.”

- **France Pillonel Vox Sang 2012**
  “Qualitative study is needed to assess possible changes in compliance linked to a new policy.”

- **UK Davison Vox Sang 2011**
  “The impact of a change depends on compliance; if this stays the same or worsens, the risk is expected to increase because of more incident infections in MSM who donate blood.”
Compliance with the current 12-month deferral for male-to-male sex in Australia

C. R. Seed,¹ T. T. Lucky,² D. Waller,³ H. Wand,² J. F. Lee,¹ S. Wroth,¹ A. McDonald,² J. Pink,⁴ D. P. Wilson² & A. J. Keller¹

Vox Sanguinis (2014) 106, 14–22

• Anonymous online survey of volunteer Australian donors with a recent TTI-negative donation
• Primary objective to determine rate of and timing of noncompliance with the 12-month deferral policy
  • Other secondary objectives on survey

• 14 476 responses from male donors; 34 noncompliers
• Noncompliance 0.23%, 95% CI 0.16 – 0.33%
  • FT donors 0.16%
  • Repeat donors 0.24%
## Timing of Noncompliance

| Number of sexual partners in the 12 months prior to the last donation | Non-compliant male donors |  | Within 12 months, but not within 6 months |  |
|---|---|---|---|---|---|
| | Within 6 months | Number | % (95% CI) | Number | % (95% CI) |
| One | 8 | 33.33 | (15.63–55.32) | 5 | 50 (18.71–81.29) |
| 2–4 | 11 | 45.83 | (25.55–67.18) | 4 | 40 (12.16–73.76) |
| 5 or more | 5 | 20.83 | (7.13–42.15) | 1 | 10 (0.25–44.5) |
| Total (% by row) | 24 | 70.6 (52.5–84.9) | 10 | 29.4 (15.1–47.5) |

*a* Male donors who answered Yes to the following question: In the last 12 months, have you had male-to-male sex (that is, oral or anal sex) with or without a condom?
## Compliance Assessed in Male Blood Donors

<table>
<thead>
<tr>
<th>Country or Setting</th>
<th>Percent Noncompliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>0.23%</td>
</tr>
<tr>
<td>Canada</td>
<td>0.8 – 1.4%</td>
</tr>
<tr>
<td>Hong Kong</td>
<td>2.3%</td>
</tr>
<tr>
<td>USA (1993)</td>
<td>0.7%</td>
</tr>
<tr>
<td>USA (1998)</td>
<td>1.2%</td>
</tr>
</tbody>
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Seed, Vox Sang, 2014  
Goldman, Transfusion, 2011  
Lee, Transfusion, 2013  
Williams, JAMA, 1997  
Sanchez, Transfusion, 2005
HHS Response to MSM Blood Donor Deferral Policy
July 22, 2011

Blood, Organ, and Tissue Safety Working Group (BOTS WG) action plan:

- REDS-II
  - April 2013
  - TTD risk in current donors

- Root Cause Analysis of Quarantine Release Errors
  - September 2011

- REDS-III
  - January 2014
  - Donor Evaluation
    - Interpretation and understanding of questions
    - Motivation of donors

- Screen Strategy
  - Pilot study with interim policy of shortened MSM deferral activity

- 18-24 months
- 24-36 months * Pending available funding

- Review of MSM Deferral Policy
Brian Custer, Nicolas Sheon, Bob Siedle-Khan, Lance Pollack, Marian Sullivan, Vanessa Thornburg, Alan Mast, Bryan Spencer, Ram Kakaiya, Mike Busch, Alan Williams, Simone Glynn

for the NHLBI Recipient Epidemiology and Donor Evaluation Study (REDS-III)

funded by US FDA and REDS-III
REDs-III Domestic Blood Center Catchment Areas by County

Key
- Blood Centers of the Pacific
- BloodCenter of Wisconsin
- The Institute for Transfusion Medicine
- American Red Cross

[Map of the United States showing different blood center catchment areas marked with different colors]
Blood DROPS

Aim 1 – Focus groups of MSM to generate discussion on the current policy and reasons for compliance/non-compliance

Aim 2 – Assessment of compliance in a) male blood donors and b) males in the LGBT community

Aim 3 – Qualitative telephone interviews of MSM who are also blood donors

Analysis of data is currently ongoing
Aim 2.2 Male Blood Donor Recruitment

• Emails targeted to male donors with a successful donation in the year period before the campaign initiated (July 2012 – July 2013)

• Randomly selected list of male donors with email addresses

• Emails uploaded by each Blood Center either through Survey Gizmo or internally through other platforms and then recruitment emails sent out with links to survey

• Email waves conducted to allow for calibration to achieve targeted enrollment by site

• Respondents and responses not known to each Blood Center
### Self-Reported Compliance with MSM Policy

<table>
<thead>
<tr>
<th>Blood Center</th>
<th>Complete responses</th>
<th>Participants reporting noncompliance n (%)</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>583</td>
<td>23 (3.9, 2.6 – 5.9)</td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>887</td>
<td>17 (1.9, 1.2 – 3.1)</td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>876</td>
<td>24 (2.7, 1.8 – 4.1)</td>
<td></td>
</tr>
<tr>
<td>D</td>
<td>837</td>
<td>19 (2.3, 1.5 – 3.5)</td>
<td></td>
</tr>
<tr>
<td><strong>Overall</strong></td>
<td><strong>3183</strong></td>
<td><strong>83 (2.6, 2.1 - 3.2)</strong></td>
<td></td>
</tr>
</tbody>
</table>

No statistical difference in compliance among blood centers, Chi-Square p=0.1
## Donor Age and Donation History

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Comply with policy</th>
<th>Do not comply with policy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age group 18 – 34</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 donation</td>
<td>26 (3.4)</td>
<td>3 (7.3)</td>
</tr>
<tr>
<td>2-5 donations</td>
<td>181 (23.4)</td>
<td>8 (19.5)</td>
</tr>
<tr>
<td>6-10 donations</td>
<td>210 (27.2)</td>
<td>12 (29.3)</td>
</tr>
<tr>
<td>&gt;10 donations</td>
<td>355 (46.0)</td>
<td>18 (43.9)</td>
</tr>
<tr>
<td><strong>Age group 35 - 49</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 donation</td>
<td>15 (2.1)</td>
<td>-</td>
</tr>
<tr>
<td>2-5 donations</td>
<td>48 (6.6)</td>
<td>4 (16.7)</td>
</tr>
<tr>
<td>6-10 donations</td>
<td>83 (11.4)</td>
<td>1 (4.2)</td>
</tr>
<tr>
<td>&gt;10 donations</td>
<td>584 (80.0)</td>
<td>19 (79.2)</td>
</tr>
<tr>
<td><strong>Age group 50+</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 donation</td>
<td>7 (0.4)</td>
<td>-</td>
</tr>
<tr>
<td>2-5 donations</td>
<td>33 (2.1)</td>
<td>1 (5.6)</td>
</tr>
<tr>
<td>6-10 donations</td>
<td>72 (4.6)</td>
<td>2 (11.1)</td>
</tr>
<tr>
<td>&gt;10 donations</td>
<td>1456 (92.9)</td>
<td>15 (83.3)</td>
</tr>
</tbody>
</table>
Implications

US recipients are receiving blood products from MSM

- At least half of donors in the US are male
- 15.7 million red cell containing donations in 2011
  - There may be over 200,000 red cell containing donations from MSM/year

Fractionated plasma products include MSM donations

- According to BCA, about 1.8 million litres of recovered US plasma are used for fractionation
- Roughly 0.2L of plasma is recovered per whole blood donation and so recovered plasma is comprised of up to 9.0 million whole blood donations
  - If 50% are from males, there may be at least 117,000 donations from MSM/year included in plasma recovered for fractionation
Summary

• MSM is a primary risk factor for HIV in male blood donors in many but not all countries
• A small but measurable rate of non-compliance of 0.23% in Australia following the implementation of a 12-month deferral
• Noncompliance in the US appears to be higher, estimates range from 0.7% - 2.6%
  • Self-assessment of risk and/or nondisclosure are occurring
  • Some MSM in the US are not complying with the current policy
  • The rate of compliance by MSM with the current policy is not known
• Residual risk and noncompliance taken together indicate MSM without HIV are donating in the US
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