Men who have Sex with Men (MSM): An evolving pathway to blood donation

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Chief Medical Officer
Cerus Corporation
Concord, C.A.
GLOBAL RATINGS

Fitch
Moody’s
S&P
Sevens

#SARainbowWinnersOnceMore
Diseases of Africa

MALARIA  ...STABLE.

AIDS  ...IMPROVING.

HOMOPHOBIA  ...RAMPANT!

ANTI-GAY LAWS (NOW 39 OF 54 NATIONS)
Gay men may now also donate blood in SA

The South African National Blood Service (SANBS) has implemented a new policy on blood donations which no longer discriminates against sexually-active gay men. May 22, 2014

Lessons after Orlando? Why South Africa ended ban on gay blood donors

PATH TO PROGRESS Calls are rising after the Pulse gay nightclub shootings to end the US ban on blood donations by gay men. South Africa, as a high HIV-positive population, offers another model.

By Ryan Lenora Brown, Correspondent | JUNE 18, 2016

QUIGLEY STATEMENT ON FDA POLICY CHANGE TO BLOOD DONOR DEFERRAL POLICY FOR MSM

Dec 23, 2014 | Press Release
CHICAGO – Today, U.S. Representative Mike Quigley (IL-05) released the following statement on the Food and Drug Administration’s (FDA) policy change of the blood donor deferral policy for men who have sex with men (MSM) from lifetime ban to one-year deferral:
History of the MSM Deferral

United States

1981  “Gay-related immunodeficiency” (GRID) first recognized, especially in promiscuous homosexual men
1982  CDC describes the 4-H club
   – Homosexuals
   – Hemophilia
   – Heroin use (shared needles)
   – Haitians
1982  Plasma pharmaceutical companies began excluding homosexuals, sex workers and IV drug abusers
1983  FDA ban instituted. Deferrals for Haitians and immigrants from sub-Saharan Africa who entered the US after 1977 were added
1985  HIV virus discovered, first HIV antibody testing began
1990  FDA introduced a lifetime ban for all Haitians and blacks from sub-Saharan Africa – massive protests ensue - FDA reverses its position
1992  FDA introduces guideline preventing blood donation “by men who have had sex with men, even once since 1977”
Percentages of Stage 3 (AIDS) among Adults and Adolescents with Diagnosed HIV Infection—United States

**MSM incidence 40-60 fold higher than general US population**

Note. Data have been statistically adjusted to account for missing transmission category.

- **Heterosexual contact** includes contact with a person known to have, or to be at high risk for, HIV infection.
- **Injection drug use (IDU)** includes hemophilia, blood transfusion, perinatal exposure, and risk factor not reported or not identified.
The Impact of Male-to-Male Sexual Experience on Risk Profiles of Blood Donors

A single lifetime MSM exposure does not define HIV risk

- National Health and Social Life Survey 1992
  - 9% of men report ever having sexual-experience with another man
  - 42% report not continuing after age 18

- Kinsey Institute report 1970
  - 20% men reported MSM at some time
  - 7% engaged in MSM after age 19
MSM Ban

- MSM donors were deferred for life, now equated with prostitutes and IV drug abusers

- Gay community feels
  - Policy is discriminatory
  - Policy is stigmatizing

- Gay organizations point to improved HIV testing as rendering the ban unnecessary

- Gay donors assert a right to give blood
Donor Selection

“The Human Rights Commission there has ruled that under the country’s constitution, men who have had sex with other men cannot be disqualified from donating blood solely for that reason. This decision was made against the backdrop of South Africa’s unusual HIV epidemiology and unique constitution that expressly protects the civil rights of gays and lesbians.

We should rebut the assertion that there is a right to donate blood. If the right to donate blood spreads from South Africa to the rest of the world, the rights of transfusion recipients will ultimately be subjugated.”
The Ontario Superior Court ruled that the deferral criteria for men who have sex with men is not discriminatory because it is based on health and safety considerations.

Blood donation is a gift, not a right.

There is no requirement under law to accept the gift of blood.

Donors have a duty to answer questions honestly.

The need for lifetime deferral period was not demonstrated.
The Court of Justice ruled that a homosexual man's blood donation cannot be refused unless a country has clearly determined that the person is at high risk of acquiring severe infectious diseases, such as HIV, and that there are no effective detection techniques or less onerous methods than a ban available to ensure a high level of health protection for recipients.

The Court of Justice said that "any limitations on the exercise of the rights and freedoms recognized by the Charter of Fundamental Rights of the EU may be imposed only if they are necessary and genuinely meet objectives of general interest recognized by the EU or the need to protect the rights and freedoms of others."

In this respect, all available tests to check the blood of a donor and protect the health of recipients must have first been carried out before imposing a permanent ban.
### What are Your Current National Deferral Policies for Men who Disclose Having Sex with Other Men? 2011 Survey

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<tr>
<th></th>
<th>United States</th>
<th>Canada</th>
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<td><strong>Received money or drugs in exchange for sex</strong></td>
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13 of 24 respondent countries with indefinite or permanent deferral for MSM. Brazil, Czech Republic, South Africa, New Zealand, Australia and Japan - 6 month to 5 year deferral. Italy, Spain, Poland, Russia and India reported no time-based deferral.
What are Your Current National Deferral Policies for Men who Disclose Having Sex with Other Men?
2011 Survey Updated

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<td>12 Month</td>
<td>12 Month</td>
<td>3 Month</td>
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Brazil, Czech Republic, New Zealand, Australia and Japan - 6 month to 5 year deferral. South Africa, Italy, Spain, Poland, Russia and India reported no time-based deferral.

HIV is Prevalent in the MSM Community

HIV in Australia: Annual Surveillance Report 2014

- Population 23.1 million (June 30, 2013)
- ~0.15% prevalence among adults aged ≥ 15 years
- HIV occurs at high levels among men who have sex with men
  - Prevalence of 8 – 12% among gay community-attached men

**Figure 1** Newly diagnosed HIV infection in Australia, by year

**Figure 3** Newly diagnosed HIV infection and diagnoses of newly acquired HIV infection in Australia, 2009 – 2013, by exposure category

Source: State/Territory health authorities
“The current duration for sexual activity-related deferral is 12 months as it covers the incubation period, the window period for testing, and allows an additional safety margin for detecting HIV, HBV, HCV, and HTLV.

The current standard of practice for safety margins applied by the Blood Service is to double the most conservative scenario for detecting an infection.”

**Based on third generation HIV Ab testing**

**ARCBS review May 2012**
No Evidence of Increased Risk of TT HIV in Australia Subsequent to 12–month MSM Deferral

<table>
<thead>
<tr>
<th>Period</th>
<th>Collections</th>
<th>HIV + Male</th>
<th>HIV + Female</th>
<th>Total</th>
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<tbody>
<tr>
<td>(5 years)</td>
<td>FTD</td>
<td>RPT</td>
<td>FTD</td>
<td>RPT</td>
</tr>
<tr>
<td>Before</td>
<td>4,03 M</td>
<td>12</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>After</td>
<td>4,96 M</td>
<td>4</td>
<td>9*</td>
<td>6</td>
</tr>
</tbody>
</table>

16 male donors identified in Period 1, 13 in Period 2 (p=0.07)
*6 in NSW, including one NAT yield

Seed et al Transfusion 2010: 50; 2722
No Evidence of Increased Risk of TT HIV in Australia Subsequent to 12-month MSM Deferral

Compliance is a Major Issue in HIV Risk

**TABLE 3. Potential infective risk factors* identified in HIV-positive donors before and after implementation of a 12-month deferral for MSM in Australia**

<table>
<thead>
<tr>
<th>Risk factor</th>
<th>5-year period</th>
<th>5-year period</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>IV drug use</td>
<td>3 (20.0)</td>
<td>1 (6.25)</td>
<td></td>
</tr>
<tr>
<td>Partner or contact with infective risk</td>
<td>4 (26.7)</td>
<td>4 (25.0)</td>
<td></td>
</tr>
<tr>
<td>Sex with individual from overseas</td>
<td>2 (13.3)</td>
<td>3 (18.8)</td>
<td></td>
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<tr>
<td>Sex with sex worker</td>
<td>1 (6.7)</td>
<td>1 (6.25)</td>
<td></td>
</tr>
<tr>
<td>Receipt of blood product</td>
<td>2‡ (13.3)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Other blood contact</td>
<td>1 (6.7)</td>
<td>3 (18.8)</td>
<td></td>
</tr>
<tr>
<td>Tattooing or piercing</td>
<td>1 (6.7)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Surgery or endoscopy</td>
<td>1 (6.7)</td>
<td>1 (6.25)</td>
<td></td>
</tr>
<tr>
<td>Male-to-male sexual contact (MSM)</td>
<td>2§ (13.3)</td>
<td>5¶ (31.3)</td>
<td>0.22**</td>
</tr>
<tr>
<td>Residence in high-risk country</td>
<td>1 (6.7)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Total donors with risk factors</td>
<td>15†</td>
<td>16†</td>
<td></td>
</tr>
</tbody>
</table>

Before: 20 of 24 donors interviewed, 15 with risk factors
After: 20 of 24 donors interviewed, 16 with risk factors

Seed et al. Transfusion 2010: 50; 2722
No Evidence of Increased Risk of TT HIV in Australia Subsequent to 12-month MSM Deferral

Conclusions

- Found no evidence that the implementation of the 12-month deferral for male-to-male sex resulted in an increased risk for HIV in Australia.

- The risk of noncompliance to the revised deferral rather than its duration appears to be the most important modifier of overall risk.
Male respondents = 14,706
Number ‘yes’ (i.e., ‘non-compliant’) responses = 34
Non-compliance rate 0 -12/12 34/14,476 0.23% (95% CI; 0.16-0.33)
Non-compliant within 0 - 6/12 24/14,476 0.17%

No statistical difference in non-compliance rate between first-time (0.16%) and repeat donors (0.24%)
Anonymous post donation survey
25,168 male respondents
- 596 (2.4%) reported MSM
- **280 (1.2%) reported MSM since 1977**

Prevalence of reactive screening tests versus no MSM history
- MSM >1-5 years  O.R. 7.1 (95% C.I. 1.2 - 41.7)
- MSM < 5 years  O.R. 5.3 (95% C.I. 2.6 - 10.4)
- MSM > 5 years, after 1977  
  O.R. 1.4 (95% C.I. 0.7 - 2.6)

Presence of unreported deferral risks was significantly higher for all donors who reported MSM
- O.R. 3.1-18.9 (p<0.01)

Sanchez, et al, REDS II Transfusion 2005; 45: 404-13
PRAISING ISIS, GUNMAN ATTACKS GAY NIGHTCLUB, LEAVING 50 DEAD IN WORST SHOOTING ON U.S. SOIL

‘We Will Not Give In to Fear,’ Obama Says as Florida Aches

BY LUCY SIMMONS AND RICHARD PERRÉKUTA

ORLANDO, Fla. — A mass shooting in the early hours of Sunday morning that left 50 people dead and 53 others injured at a gay nightclub shows how fear and hatred persists in the United States, President Barack Obama said Monday.

‘We will not give in to fear,’ Obama said at a news conference. ‘This is what we’ve always done in America.’

The attack, which occurred at the Pulse nightclub, was the deadliest in the United States since the 2012 shooting at a school in Newtown, Conn.

Obama said the attack was a reminder of the need for more gun control. He also called for an end to the debate over the Second Amendment and said that the country should focus on how to prevent such attacks in the future.

Meanwhile, the families of the victims are beginning to grieve and mourn.

‘I never thought this would happen to me,’ said Ryan Fowles, whose father was one of the victims.

Fowles said his father was a kind and considerate man.

‘He was a great person,’ Fowles said. ‘He was always there for me.’

Fowles said he plans to continue his father’s legacy by working for gun control.

‘I want to do something in his memory,’ Fowles said. ‘He was a great person.’

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‘I want to do something in his memory,’ Fowles said. ‘He was a great person.’
Interested persons are invited to submit comments, supported by scientific evidence such as data from research, regarding potential blood donor deferral policy options to reduce the risk of HIV transmission, including the feasibility of moving from the existing time-based deferrals related to risk behaviors to alternate deferral options, such as the use of individual risk assessments. Additionally, comments are invited regarding the design of potential studies to evaluate the feasibility and effectiveness of such alternative deferral options.
Summary of Responses to FDA Docket
Opened July 26, 2016: Blood Donor
Deferral Policy for Reducing the Risk of
HIV Transmission by Blood and Blood
Products

Jennifer Scharpf, M.P.H.
Office of Blood Research and Review, CBER

Blood Products Advisory Committee Meeting
April 4, 2017
Summary of Comments Received - II

- The 670 responses can be categorized as follows
  - Against further change in the deferral policy 517
    (252 appear linked to a single write-in campaign)
  - In support of further change in the deferral policy 86
    (includes one petition with 300 signatures)
  - Not responsive to the request for comments 35
  - Responsive to the specific questions 32
Potential FDA Next Steps

• Assess the impact of FDA’s current donor deferral recommendations, including the change to a 12 month deferral period for MSM

• Consider design of alternative donor history questionnaires

• Study the feasibility, effectiveness and operational impact of individual risk assessment strategies for assessing eligibility of all donors
Principles Moving Forward

• Process will be based on gathering the necessary scientific evidence regarding policy change while ensuring the continued safety of the blood supply
  — Epidemiology (infectious disease and behavioral risks)
  — Laboratory science (NAT and pathogen reduction technology)
  — Social science (donor education and questionnaires)

• Will work to maximize transparency of the process through stakeholder engagement and use of public meetings including scientific workshops and advisory committee meetings
Can a high and low risk MSM population be differentiated?
Can donor questions be designed that distinguish the two groups?
How do you assess the risk of a change without endangering patients?
Will a change increase or decrease compliance?
Can we learn lessons from the South African, Spanish and Italian experience that are pertinent to the US?
“However, there is an emerging understanding that the evolution of HIV biomarkers over time is profoundly altered by early initiation of ART...HIV tests simply do not work the way they should after HIV treatment has been initiated very early in infection”.

PrEP disrupts the window period model of blood safety

Introduction of PrEP has seen a rise in incidence of syphilis, HBV, and STDs.

CDC Recommendations for PrEP

PrEP Should be Considered for HIV-Uninfected Patients with Any of the Following Indications:

- Anyone who is in an ongoing sexual relationship with an HIV-infected partner.

- A gay or bisexual man who has had sex without a condom or has been diagnosed with a sexually transmitted infection within the past six months, and is not in a mutually monogamous relationship with a partner who recently tested HIV-negative.

- A heterosexual man or woman who does not always use condoms when having sex with partners known to be at risk for HIV (for example, injecting drug users or bisexual male partners of unknown HIV status), and is not in a mutually-monogamous relationship with a partner who recently tested HIV-negative.

- Anyone who has, within the past six months, injected illicit drugs and shared equipment or been in a treatment program for injection drug use.
Do Donor Selection Policies based on Risk Profiling of MSM Discriminate?

Western Societies are Based on Liberal Philosophy

- The problem with the donor questions is not that they discriminate; it is that they do not discriminate well enough
- Public Health is based on a Utilitarian Philosophy—"The end justifies the need".
- In Western Society, Individual rights are paramount
- Problem arises when we meet the touch points of discrimination: race, religion, gender, age, disabilities.
- How do we reconcile the two approaches?
- Perhaps we can learn from South Africa?
**Risk profiling in South Africa**

An Analogy Between Racial and Sexual Preference Profiling

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### Table: Cohort Breakdown

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<th>Cohort</th>
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**Legend:**

- **W** = White; **A** = Asian; **M** = Mixed Race; **B** = African
- **M** = Male; **F** = Female
- **R** = Repeat; **L** = Lapsed; **N** = New Donor

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Heyns, Benjamin et al JAMA Feb 2006
HIV-1 Prevalence in South Africa
Profiling Reduced the Risk to Patients

~ 80% of recipients of Safer Blood were Black
“The ends justify the means”
Risk Profiling is Not Condoned

Following the News that the Thabo Mbeki’s Blood was Discarded:

- Removed racial profiling as unacceptable in the South African historical context
- Instituted Individual Donor NAT
- Technology was used to bridge the need for a socially acceptable solution
- Perhaps the same is true for MSM deferrals?
  - Introduction of IDNAT to the US, or
  - Pathogen Inactivation would allow an additional layer of safety to allow a switch to behavioral based deferrals
  - In combination with a refined donor questionnaire
Pathogen Inactivation

- Pathogen Reduction Technologies (PRT) are available for plasma and platelets in the US.
- RBC and Whole Blood Technologies in development.
- Approved technologies in the US include INTERCEPT™ (Amotosalen/UVA light) for platelets and plasma and Octaplas™ (solvent detergent) for plasma.
- Highly effective for HIV, HBV, HCV, especially in the window period with low viral loads.
- INTERCEPT is effective against a broad array of other pathogens, including bacteria, viruses and protozoa.
- Behavioral deferrals could be introduced immediately without additional patient risk for platelets when used with INTERCEPT.
Conclusions

- Most countries include MSM behavior in the criteria for donor eligibility.
- There is a rising tide of protest by gay advocates claiming discrimination and inequity.
- The courts have generally upheld the right of Blood Services to employ donor history questions about MSM behavior in order to ensure patient safety.
- A growing number of countries have moved to increasingly brief, fixed-period deferrals, and some are considering behavioral risk questioning.

In the future:

- Early HIV therapy and PrEP may derail progress to less discriminatory policies.
- Pathogen Inactivation offers an additional layer of safety under which to evaluate behavioral questions.