

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

Goldman et al.
Transfusion 2014;54:1887

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

Deferral time	Country
3 months	England, Scotland, Wales (late 2017)
4 months	Denmark (announced by Health Ministry)
12 months	Canada Australia New Zealand
	France Netherlands Finland
	Sweden Belgium Germany

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



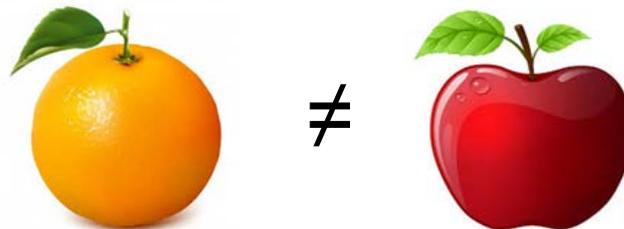
- At some time interval, limited by window periods (? 3 months)
- Defers all sexually active MSM, including those in a stable, monogamous relationship from donating

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

Jurisdiction	HIV rate/100,000	NAT only rate/100,000	Ratio 1 st time/repeat donors
Catalonia ¹	7.7	0.36	1.2
Italy ²	3.8	NA	15.0
US (REDS II) ³	2.8	0.09	5.9
Canadian Blood Services ⁴	0.5	0	6.9
England ⁵	0.6	0	7.3

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)

Alternative criteria + other safety measures

- 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 \geq 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
<https://blood.ca/en/blood/am-i-eligible/men-who-have-sex-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