

**SHARE YOUR HEALTH  
AND VITALITY WITH  
SOMEONE IN NEED**



# **Canadian MSM Criteria: The court case and beyond**

**Mindy Goldman, MD  
ORBCON Symposium  
March 24, 2012**



**Canadian Blood Services**  
*it's in you to give*

# Outline

- Background and nature of proceedings
  - claim for negligent misrepresentation by Canadian Blood Services (CBS)
  - counterclaim for discrimination based on sexual orientation by KF
  - Canadian Charter of Rights and Freedoms
- Issues and answers identified by Justice Aitken

# Outline

- CBS Board Resolution, 2007
- What is new since 2007
  - international developments
  - alternative questions
  - emerging pathogens
- CBS Board Resolution, 2011

# Background

- Permanent deferral for MSM, even once, since 1977 in Canada
- KF donated blood several times from 1990 to 2002, denied MSM and did not use CUE
- KF sent an anonymous e-mail to CBS, stating that both he and his partner were gay men and active blood donors
- CBS sought to identify KF through his e-mail account to be able to defer him and recall components

# Claim

- KF refused to identify himself
- The internet provider refused to identify him
- CBS commenced action for negligent misrepresentation to force disclosure of KF's identity
- Once identified, CBS learned his last donation had been discarded (Syphilis pos.)

# Counterclaim

- KF countersued
  - CBS
  - The Attorney General of Canada (Health Canada)
- Claimed that the donor deferral policy is discriminatory under section 15 of the Canadian Charter of Rights and Freedoms
- EGALE, Canadian AIDS Society, and Canadian Hemophilia Society intervened and presented expert witnesses

# What is the Canadian Charter of Rights and Freedoms?

- Entrenched as part of Canada's constitution
- Guarantees certain political and human rights
- Applies to all government laws and actions



# Relevant sections of the Charter

➤ Section 15:

*“Every individual is equal before and under the law and has the right to the equal protection and equal benefit of the law without discrimination and, in particular, **without discrimination** based on race, national or ethnic origin, colour, religion, sex, age or mental or physical disability.”*

➤ Sexual orientation is considered an “analogous ground” and is therefore protected under the Charter

# Relevant sections of the Charter

- Section 1:
  - The Canadian Charter of Rights and Freedoms guarantees the rights and freedoms set out in it, **subject only to such reasonable limits** prescribed by law as can be **demonstrably justified** in a free and democratic society.
- Limitations may be placed on equality rights to meet an important objective, such as public safety
- Limitation of rights should be no more than is reasonably necessary to meet the safety objectives

# In other words

➤ To be successful, KF had to prove:

**Issue A-** That CBS is a government body, and therefore the Charter applies and

**Issue B-** The MSM policy is **discriminatory** and violates his **equality rights** under section 15 and

**Issue C-** The limit on his equality rights is not demonstrably justified as reasonable under section 1

# So.....what happened?

- Case heard over 9 weeks by Justice C Aitken, Ontario Superior Court between September and December 2009
- Several experts provided testimony on the nature of the risks associated with MSM activities and impacts on the safety of the blood supply
- A 187 page judgment rendered September 8, 2010 finding in favour of CBS
- Judgment available at [www.blood.ca](http://www.blood.ca)

# Issues & Answers

- What did Justice Aitken decide on main claim by CBS for negligent misrepresentation?
- Did KF commit negligent misrepresentation when he lied to CBS about his donor health history, knowing CBS would rely on his answers?

*Yes, he “...consciously lied when completing donor health assessment.”*

# Issues & Answers

- Is the Charter a shield to KF's negligent misrepresentation? (in other words: Was KF justified in lying to CBS because he disagreed with the MSM policy?)

*No, “We expect those with the most knowledge in a particular area impacting on our safety and security to be the ones setting the standards in this area. We do not expect individuals to be able to set their own standards when our collective well-being is at stake.”*

# Issues & Answers

- What did Justice Aitken decide on KF's counterclaim for discrimination?

**Issue A** - Does the Charter apply to CBS?

*No, CBS is not a government entity.*

**Issue A** - Is there a Charter claim against the Attorney General of Canada (Health Canada)?

*No independent claim demonstrated.*

# Issues & *Answers*

- Although Justice Aitken determined that the Charter does not apply to CBS (Issue A), she nevertheless completed a full Charter analysis of what she would have decided if the Charter *did* apply (Issue B).

# Issues & Answers

- **Issue B** - Were KF's section 15 rights violated?
  - Is donating blood a **right**?

*No, “Put simply, blood donation is a **gift**. A gift is freely offered, but also must be freely received or freely declined. Canadian law has never recognized a duty or requirement to accept a gift. There is no requirement under the law for CBS, or any other blood provider, to accept the gift of blood from anyone.”*

# Issues & Answers

➤ **Issue B** - Were KF's section 15 rights violated?

- Does the MSM deferral policy make a **discriminatory distinction** based on sexual orientation?

*No, "...The distinction is not based on sexual orientation."*

*"The MSM population, when considered as one group, has a high relative prevalence of HIV and some other blood-borne, sexually transmitted pathogens when compared with the non-MSM population. This provides a factual basis for the MSM policy. Treating MSM differently from non-MSM is based on the actual characteristics of MSM relevant to blood safety."*



**Canadian Blood Services**  
it's in you to give

# Issues & Answers

- Justice Aitken continued her analysis assuming KF's section 15 rights *had* been violated (i.e. the MSM policy does discriminate based on sexual orientation)
- The next step was to decide if the MSM policy could be justified under section 1 (i.e. whether the policy is “justified under a free and democratic society”) (Issue C)

# Issues & Answers

- **Issue C** - Does the MSM deferral policy have a pressing and substantial objective?

*Yes, “The specific objective of the MSM deferral policy is to minimize the risk of transmission by blood transfusion of HIV and other known, new or emerging sexually transmitted, blood-borne pathogens.”*



**Canadian Blood Services**  
*it's in you to give*

# Issues & Answers

- **Issue C** - Does the MSM donor deferral policy impair equality rights no more than is reasonably necessary to satisfy the safety objective?

*No, “...evidence was lacking of the existence of real concerns that would make a deferral period of 33 years necessary in order to maintain the current level of safety.”*

# Issues & Answers

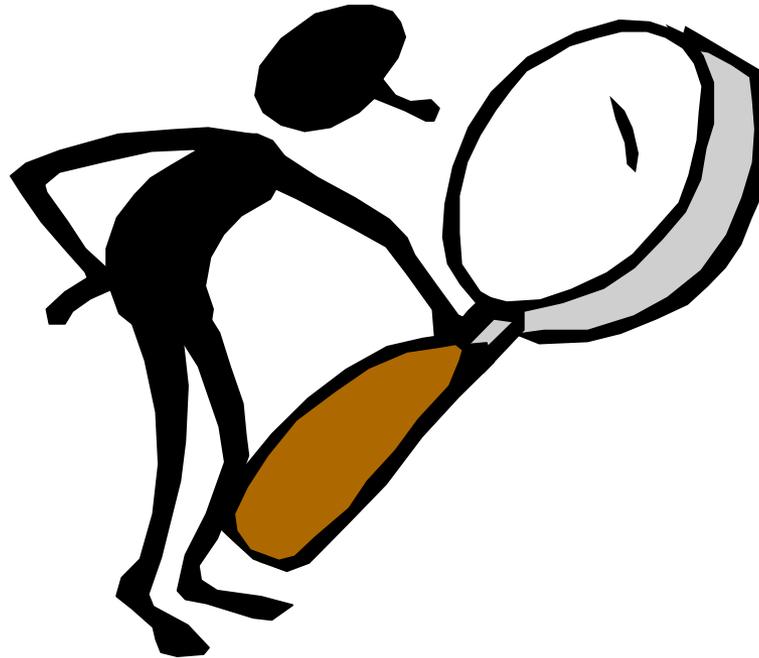
- **Issue C** - In determining what deferral period would be acceptable, Justice Aitken noted

*“A high level of deference would have to be shown to CBS and [Health] Canada in deciding the length of the deferral period.”*

# Summary

- There is an obligation to be truthful when answering donor assessment questions
- CBS is not bound by the Charter
- There is no right to give blood in Canada
- The MSM policy is not based on sexual orientation but on epidemiology and safety considerations
- The length of the current deferral period was questioned, but ultimately needs to be determined by Health Canada and CBS

# Beyond the court case



# CBS Board Resolution, 2007

- In 2007, Board passed a resolution to:
  - maintain current deferral policy
  - close knowledge gaps, including
    - experience of other blood agencies
    - risks and benefits of behaviour-based screening
    - emerging pathogens in specific populations
  
- Review policy in 3-5 years

# What is new since 2007?



## ➤ United States

- reduced risk estimates in modelling study

*Anderson et al. Transfusion 2009; 49:1102*

- AMA resolution supporting 5 year deferral
- meeting of ACBSA in June 2010, voted against change
- support for further research

## ➤ Australia

- no evidence of increased HIV risk with 12 month deferral

*Seed et al. Transfusion 2010; 50:2722*

# What is new since 2007?



## ➤ New Zealand

- decreased from a 10 year to a 5 year deferral period

## ➤ Sweden

- is considering a 12 month deferral, criteria for plasma fractionation is problematic

## ➤ UK

- decreased to a 12 month deferral

## ➤ Héma-Québec

- will submit a 5 year deferral proposal to Health Canada

# What is new since 2007?



- CBS study on donor perception and impact of alternate gender-neutral behaviour questions
- 2008, anonymous mail survey of 40,000 CBS donors, 45% response rate
- Donor eligibility should be based on
  - Scientific evidence **39.7%**
  - Recipient concerns **1.5%**
  - Both **58.8%**

*Goldman et al. Transfusion 2011; 51:1829*

# Alternate questions based on gender-neutral behaviours

<b>Topic</b>	<b>First-time donors</b>	<b>Repeat donors</b>
<b>Lifetime number of sexual partners</b>	<b>n=3,660</b>	<b>n=13,659</b>
0-1	45	34
2-9	41	50
10 or more	14	16
<b>Number of sexual partners, last 12 months</b>		
0-1	89.8	94.6
2-9	9.9	5.3
10 or more	0.3	0.1
<b>Most people know about the experiences of their sexual partner(s) well enough to say whether their partner(s) could be carrying HIV/AIDS virus</b>		
Yes	37	42

# Emerging pathogens

- HIV infection first noted in MSM, hemophilia, transfused population groups
- MSM may be “sentinel population” for other new agents that may be transmitted by both sexual contact and transfusion
- There was an 8 year gap between introduction of HIV in population and test development and implementation
- New agents are recognized and characterized much more quickly



# TRANSFUSION



*Litsea massoygenens*



*Trypanosoma cruzi*



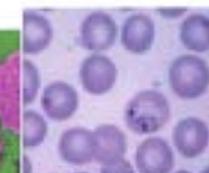
*Anolis sagrei*



*Carollia brownii*



HIV



*Plasmodium vivax*



*Bacillus anthracis*



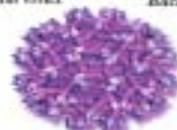
CJD Prion



Chikungunya Virus



*Ixodes scapularis*



Dengue Virus



*Rickettsia sibirica*



Hepatitis B Virus

A Supplement to Transfusion  
Emerging Infectious Disease Agents and their Potential Threat to Transfusion Safety

# AABB Transfusion Transmitted Diseases Committee (TTDC)

- AABB TTDC reviewed information about agents with actual or potential risk of transfusion transmission in US or Canada
- 68 agents identified and assigned a risk priority level under 3 categories
  - scientific/epidemiologic evidence regarding blood safety: transfusion transmission, prevalence in asymptomatic people
  - public perception and/or regulatory concern for blood safety: discussed at BPAC
  - public concern about agent discussed in press, queries to AABB and operators

➤ **Red Orange Yellow White** highest to lowest priority



**Canadian Blood Services**  
*it's in you to give*

# TTDC Report, Red Category – highest priority

<b>Agent</b>	<b>Risk factors/exposure routes</b>
vCJD	geographic, BSE
Dengue virus	geographic outbreaks, mosquitoes
<i>Babesia</i> species	geographic, ticks



# TTDC Report, Orange Category

<b>Agent</b>	<b>Risk factors/exposure routes</b>
Chikungunya virus	geographic outbreaks, mosquitoes
St. Louis encephalitis virus	geographic outbreaks, mosquitoes
Leishmania	geographic, sandflies
<i>Plasmodium</i> (malaria)	geographic, mosquitoes
<i>T. cruzi</i> (Chagas)	geographic, reduviid bugs



# TTDC Report, Yellow Category

<b>Agent</b>	<b>Risk factors/exposure routes</b>
Chronic wasting disease	? deer and elk consumption
HHV – 8*	MSM, geographic (Africa)
HIV variants*	geographic (Africa), sexual transmission
Parvovirus B19	outbreaks - school, respiratory
Influenza A, H5N1	outbreaks - pandemic, respiratory
Simian foamy virus	exposure to nonhuman primates, bite
<i>Borrelia burgdorferi</i> (Lyme)	geographic, ticks
Hepatitis A	geographic, contaminated water, food

# CBS measures, emerging risks

Agent	Risk factors/exposure routes	Measures
vCJD	geographic, BSE in diet	identification and deferral of at risk donors
SARS	geographic, respiratory	identification and deferral of at risk donors
Simian Foamy Virus	exposure to nonhuman primates, bite	identification and deferral of at risk donors
Influenza A, H5N1	possible pandemic, respiratory	comprehensive planning, including deferral of symptomatic donors
<i>Plasmodium</i> (malaria)	geographic, mosquitoes	frequent updating of donor deferral criteria due to shifting risk areas
XMRV*	possibly associated with chronic fatigue syndrome (CFS)	information sheet and deferral of CFS donors

\* Possible agent, now shown to be laboratory artefact

# CBS measures, emerging risks

<b>Agent</b>	<b>Risk factors/exposure routes</b>	<b>Measures</b>
WNV	geographic outbreaks, mosquitoes	donor testing
Parvovirus B19	outbreaks, respiratory	donor testing by manufacturer of pooled plasma protein products
<i>T. cruzi</i> (Chagas)	geographic, reduviid bugs	identification of at risk donors, change in component production followed by testing

# Emerging pathogens



**vCJD**



**Chagas Disease**

# What is new since 2007?

- Many other blood agencies have performed risk assessments and several have changed their deferral policies
- Data from Australia (12 month deferral) show no increase in HIV risk
- Behaviour-based screening using simple questions would result in unacceptable loss of safe donors
- There have been varied risk factors for emerging pathogens

# CBS Board Resolution, 2011

- In September 2011, Board passed a resolution to:
  - change to a defined time period deferral
  - initially, would be between 5 and 10 years
  - stakeholder support necessary before moving forward
  - incremental change subject to ongoing review
  
- Proceed rapidly to a Health Canada submission

# Consultation process

- Summary of relevant background information prepared, reviewed by an expert advisory panel
- Meetings with representatives of patient groups, LGBTTTQ groups, National Liaison Committee taking place in March, 2012
- National public opinion poll, including:
  - Community Based Research Centre
  - Canadian Federation of Students
  - blood donors
  - general public

# Summary

- CBS Board reassessed available information and passed a resolution to change to a defined deferral period
- Ongoing consultation will determine the time frame, between 5 and 10 years since last MSM contact
- After consultation, a submission will be made to Health Canada in spring 2012
- Any implemented change will be subject to ongoing review

# Acknowledgements

- Jodi Murray, legal counsel
- Lorna Tessier, National Director,  
Stakeholder Relations & Translation

