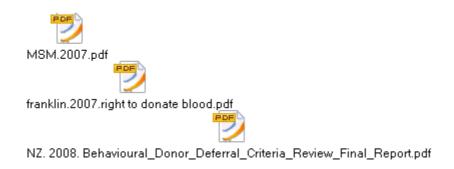
## Minnispunktar dags. 18. mars 2011. Listi fylgiskjala með minnispunktum yfirlæknis Blóðbankans.

\_\_\_\_\_

# Fylgiskjal 1.

# Þrjár mikilvægar greinar/skýrslur hvað þetta málefni varðar



# Fylgiskjal 2. Úrskurður í Evrópu



EN vertaling Opinion Equal Treatment Commission 2007-85 16 aug 2007.docx

# Fylgiskjal 3.

Samantekt um praxís annarra landa hvað þetta varðar.

- 1. Tafla úr grein kanadískra aðila í Transfusion Medicine Reviews
- 2. Tafla úr skýrslu frá Nýja Sjálandi 2008
- 3. Samantekt úr könnun EBA, European Blood Allliance um praxís ýmissa landa hvað varðar blóðgjafir MSM. (2009/2010)

# Men Having Sex With Men Donor Deferral Risk Assessment: An Analysis Using Risk Management Principles

William Leiss, Michael Tyshenko, and Daniel Krewski

Transfusion Medicine Reviews, Vol 22, No 1 (January), 2008: pp 35-57

Table 1. International Deferral Criteria, MSM, 2005

Criteria	Countries
Deferral based on specific activities	Italy ("risky activities")
1-y deferral since last exposure	Argentina
	Australia
	Japan
	Hungary
5-y deferral since last exposure	South Africa
10-y deferral since last exposure	New Zealand
Indefinite deferral, exposure since	
1977 or lifetime exposure	Canada
	United States
	UK
	France
	Switzerland
	Holland
	Norway
	Denmark
	Sweden
	Germany
	Finland
	Iceland
	Hong Kong

# Behavioural Donor Deferral Criteria Review Final Report to the New Zealand Blood Service April 2008

Table 1 Current deferral periods for men who have sex with men

Country	Current Deferral	Comment
ASIA PACIFIC		
Australia Hong Kong Japan Singapore NORTH AMERICA	Deferred for 12 months Deferred for an indefinite period Deferred for 12 months Permanently deferred	Complaint being considered by the Human Rights Commission
NORTH AMERICA		The USFDA has recently reaffirmed its position. In doing so it
United States	MSM since 1977 permanently deferred  MSM since 1977 permanently	indicated 'a willingness to consider new approaches to donor screening and testing, provided those approaches assure that blood recipients are not placed at increased risk of HIV of other transfusion transmitted disease.'  Canadian Blood Services recently reviewed their exclusion and
	deferred	remained with the permanent deferral of MSM from 1977.
EUROPE Austria Belgium Denmark Finland	Permanently deferred Permanently deferred Permanently deferred Permanently deferred	
France	Permanently deferred	The ABC newsletter published 8 September 2006 indicated that the French Minister of Health announced that 'the blanket prohibition on blood donation by gay men will end soon.' However, there is no evidence on either the EFS or AFSSAPS websites of any change in policy.
Germany	Permanently deferred	1
Ireland	MSM ever having oral or anal sex (even with a condom) permanently deferred	
Italy	National policy is to exclude on basis of 'risky behaviour'	All donors are interviewed by a doctor. The interpretation of 'risky behaviour' is unclear and inconsistently applied. At least some centres continue to exclude MSM.
Netherlands Norway Portugal	Permanently deferred Permanently deferred Permanently deferred	
Spain	No specific exclusion of MSM	In the late 1990's a move was made from excluding homosexual men to excluding people with promiscuous sexual behaviour from donating blood. A 12 month exclusion exists for anyone who has had more than a sexual partner in the last 12 months.
Sweden	Permanently deferred	During 2006 the Swedish National Board of Health and Welfare considered a proposal to reduce the deferral period to 6 months. Following consultation they decided to leave the permanent deferral in place.
Switzerland	MSM since 1977 deferred	
United Kingdom	MSM ever having oral or anal sex (even with a condom) permanently deferred	The United Kingdom Blood Transfusion Services have recently reviewed their behavioural exclusion criteria and have remained with permanent deferral following analysis of infections detected in blood donors over the period 1995-2006.
AFRICA		
South Africa	MSM deferral for 6 months (oral or anal sex with or without a condom)	

## Samantekt úr könnun EBA (European Blood Alliance) um reglur á alþjóðagrunni, version 2009/2010

2. Does MSM behaviour lead to

permanent or temporary deferral? And

3. Is there a question on heterosexual

contact with a person from (sub-

4. Does heterosexual contact with a

person from (sub-Saharan) Africa lead

1. Is there a question on MSM

behaviour on your donor

	EBA member	questionnaire?	if temporary how long?	Saharan) Africa on your donor questionnaire?	to permanent or temporary deferral? And if temporary how long?
1	Austria Red Cross	Yes	Permanent	No	If we get this information during the examination, the donor will be deferred permanently.
	Belgium Red Cross - Flanders	In the current version we have one general question on risk behavior ("Did you have risk behavior for AIDS?") and we refer to our statement of risk behavior on the verso site of our questionnaire where we indicate to not donate if"you, as man ever had sex with another man (or other men)". In the new version (from 2010) we explicit ask for MSM ("Sir, did you ever had sex with another man?")	Permanent	In the current version we don't ask for it. In the new version we ask for new sexual partners and for their origin.	An immigrant from sub-Saharian Africa has a temporary deferral of 5 years; his (European, or not -immigrant) partner has still to wait one year after the immigrant has no longer the "risk status".
3	Belgium Red Cross - French speaking	No. The information is present on the risk behaviour sheet; the donor has to fill in that he has read the information sheet. The question is orally re-asked during the medical selection.	Permanent	No	No (only when there is a change of sexual partner, the deferral delay is 4 months, independently from the partner's origin)
4	Denmark	Yes, "Have you ever had a sexual relationship to another man?"	Permanent	Before donation the donor has to read a brochure from the Danish National Board of Health (attached). In this brochure risk behaviors are defined - one of which is sexual contact with a person from sub-Saharan Africa. The question on the questionnaire is then: "Have you been exposed to risk for HIV infection as described in the brochure from the National Board of Health?"	Temporary, 6 months
5	Estonia	Yes	Permanent	No	No
6	Finland	Yes, "Have you ever had sex with another man?"	Permanent	No, only a general question on a new partner during the last 4 months.	No
7	France	Yes (formulated as following: "the MD will explore with you the following points If you have had man with man sexual contacts")	Permanent	No	No (question not raised), except if sexual contact(s) with more than one person in the last 4 months
8	Germany	Yes	Permanent	Yes	Temporary, 4 months
9	Greece	Yes	Permanent	No	No

10	Hungary
11	Iceland
12	Ireland
13	Italy
14	Latvia
15	Lithuania
16	Luxembourg
17	Malta
18	The Netherlands
19	Norway
20	Portugal
21	Slovenia

Yes	Permanent
No response	
Yes	Permanent
No	Not specifically as MSM. The case of multiple partners or recent change of partner, homo or heterosexual, is intended as "at risk behaviour" and a deferral period of 4 months from the last at risk exposure is mandatory.
Yes	Temporary deferral (individual)
No response	
Yes	Permanent

Yes	Permanent
Yes	Temporary, one year from last contact
No	No
No. Travel or trip to Africa is a reason for	No. Travel or trip to Africa is a reason for
temporary deferral at least for one year.	temporary deferral at least for one year.
Yes	Temporary until we know the result of the
	serological tests.
Not directly, we refer to travels abroad	Temporary deferral for 6 months unless other
and risky sexual contacts	compounding factors as below or other
	reasons to defer (eg malaria). We defer a donor for 6 months after a 'new' sexual contact.
Yes	Temporary deferral for 12 months. In case the
	person from (sub-Saharan) Africa has lived in
	the Netherlands for 12 months at least (at the
	moment of sexual contact) and, in addition, absence of HIV-infection in the African person
	is documented, deferral is not mandatory.
	l s decamented, deserrar is not managery.
Yes	Permanent if sexual contact has lived there for
	more than five years. Temporal (5 years) if
	sexual contact has lived there for more than 6
	monthts and less than 5 years.
Not specifically. There is a question	Only if it is a new partner during the last six
about the sexual contact with a new partner on the last 6 months and after	months.
that the medical doctor perform the	
question during the medical interview.	
-	
No. Travelling in sub-Saharan Africa is	Temporary deferral. Screening and NAT tests
interviewed individually by medical	are performed. Duration of deferral not
doctor.	specified.

22	Spain
23	Sweden
24	Switzerland
25	United Kingdom

Not separated from heterosexual sex.	Temporary deferral of at least 6 months if MSM or heterosexual contact (even just one contact) with a person different to their regular partner. Temporary deferral of at least 6 months if a change of regular sex partner has been produced. Permanent deferral if multiple sex partners (more than one, the regular one, both parts of the couple).
Yes	Permanent
Yes	Permanent
Yes	Permanent

Yes	Permanent deferral if sex with persons from African countries where VIH type O is prevalent. Temporary deferral of at least 6 months when lab testing guarantees the detection of HIV type O.
No (not directly)	Temporary, 6 months
Yes	The deferral for heterosexual contact with a person from (sub-Saharan) Africa is temporary. The duration of deferral is 5 years.
Yes	One year after last contact unless the partner also undergoes the mandatory screening test or is a donor in their own right.

Summary
Response Rate: 23/25

Yes: 19	Permanent: 20
No: 4	Temporary: 2
Other: -	No deferral: -
No response: 2	Other: 1
	No response: 2

Yes: 9	Permanent: 2
No: 13	Temporary: 11
Other: 1	No deferral: 8
No response: 2	Other: 2
	No response: 2

# Fylgiskjal 4. Upplýsingarit Blóðbankans og dæmi um sambærilegt frá öðrum löndum (Kanada og Bretland)

# Smitvarnir og blóðgjöf upplýsingar til blóðgjafa

Vinsamlegast
láttu vita ef
eitthvað kemur í ljós
varðandi heilsufar þitt
sem gæti gert fyrri
blóðgjafir þínar ónothæfar
fyrir sjúkling.



FBB-41141-001

#### Hafa ber í huga

Hver blóðeining er rannsökuð með tilliti til lifrarbólguveiru B og C ásamt alnæmisveiru.

Ekki er öruggt að merki um smit finnist þó að blóðgjafi sé sýktur. Þess vegna þurfa heilsufarsspurningar að vera mjög ítarlegar.

Ef merki um smit kemur í ljós er haft samband við blóðgjafann, hann tekinn af skrá og blóðinu fargað.

Gefðu ekki blóð í þeim tilgangi að fá rannsókn á hugsanlegu lifrarbólgueða HIV-smiti.

Þeir teljast til áhættuhóps sem vegna hegðunar sinnar, athafna eða kynlífs er hætt við að fá alvarlega smitsjúkdóma sem geta borist með blóði.

Þú getur bætt við blóðgjöf bvenær sem er án þess að gefa skýringu

#### Ekki gefa blóð ef:

- Þú hefur fengið vefjaígræðslu úr dýri eða heilavef úr mönnum.
- Þú hefur heyrt um Creutzfeldt- Jakob eða aðra smitandi heilahrörnunarsjúkdóma í ætt þinni.
- Þú hefur smitast eða gætir hafa smitast af lifrarbólgu- eða alnæmisveiru.
- Þú hefur einhvern tímann sprautað þig í æð eða vöðva með fíkniefnum, vefaukandi sterum, hormónum eða öðrum lyfjum án fyrirmæla læknis, jafnvel aðeins einu sinni.
- Þú ert karlmaður og hefur haft samfarir við sama kyn.
- 6. Þú hefur stundað vændi.

Ekki gefa blóð ef rekkjunautur þinn fellur undir lið 3 - 6

## Fresta þarf blóðgjöf í minnst 6 mánuði ef þú hefur:

- Fengið skartgripagötun.
- Verið í speglun með sveigjanlegum tækjum.
- Verið í nálastungumeðferð hjá öðrum en lækni, hjúkrunarfræðingi, ljósmóður eða sjúkraþjálfara.
- Fengið húðflúr eða aðra stungu í húð (t.d. rafháreyðing, förðun).
- Fengið blóð eða vefjaígræðslu frá mönnum.
- Stungið þig á notaðri nál (stunguslys) eða fengið á þig líkamsvessa frá einstaklingi sem telst til áhættuhóps.
- Deilt heimili með einstaklingi sem er smitaður af lifrarbólguveiru.
- Orðið fyrir nauðgun.
- Tekið fíkniefni í nös.
- Haft mök við einstakling sem stundar vændi eða á annan hátt telst til áhættuhópa.



## HEILSUFAR BLÓÐGJAFA VIÐ ENDURTEKNA BLÓÐGJÖF INNAN TVEGGJA ÁRA

					AFGREIÐSLA	BLOÐTAKA					
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(7)											
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e n		ef breyting frá síðustu blóðgjöf				ef breyting frá síðustu blóðgjöf					
<u>ā</u> 1	Netfang	ef breyting frá síðustu blóðgjöf			Atvinna	ef breyting frá síðustu blóðgjóf					
Ę											
	Einhver fylgikvilli við/eftir síðustu blóðgjöf?										
(	Gefið blóð anr	nars staðar en í Blóð	bankanum, o	lags og staður:							
Ég	sem <b>trú</b> hef lesið bæl	<b>naðarmál</b> . Þú getu kling Blóðbankans, í	r <b>hætt við</b> bl 'Smitvarnir o	óðgjöfina fyrirvarala g blóðgjöf - upplýsir	ust án þess að ngar til blóðgja	fa", í dag					
Ég hef le	esið bækling	Blóðbankans, "Sm	itvarnir og b	olóðgjöf - upplýsing	gar til blóðgja	fa", í dag					
					já	nei					
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	2.	Hefur þú síða			_						
				Íbúfen?kdóm?							
				KUUIII:							
	3.	Hefur þú frá sí	ðustu blóð	gjöf/sýnatöku:							
				eftirliti læknis eða slasa	st?						
		b. notað lyfin: Neot		utan/Proscar/Finol/		1 🗇					
		c. fengið blóð/feng	ið vefjaígræðs	lu (t.d. heila- eða hori	nhimnu)? 🗆						
		d. verið bólusett(ur	)?		[						
				dis?							
				urgang/hósta/hita? útbrot/lyfjaofnæmi)? .							
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		götun fyrir skartg	ripi?		[						
		<ol> <li>heyrt um Creutzf</li> </ol>	eldt-Jakob sjú	kdóm í ætt þinni?							
	4.			ınguð frá síðustu		1 🗇					
	5										
Ég er samþykk Ég ábyrgist að	ð og skilið uppl (ur) blóðgjöf í hafa svarað he	lýsingaefni Blóðbank dag og að Blóðbanki eilsufarsspurningum s	ans, fengið tæ nn geymi þes samkvæmt be	skifæri til að bera fram sa heilsufarsskýrslu ás stu vitund og að ég ti	n spurningar og samt tölvuskráð lheyri ekki nein	fengið fullnægjandi svör. um niðurstöðum rannsókna um tilgreindum áhættuhópi.					
_ags	Un	ameann bloogjala:									
Húðskoðun:	Нјі	úkr.fr				Strikamerki 569093912380					



HEILSUFAR BLÓÐGJAFA
VIÐ FYRSTU KOMU EÐA EF TVÖ ÁR ERU LIÐIN
FRÁ SÍÐUSTU BLÓÐGJÖF

			PERSÓNU-	AFGREIÐSLA	BLOĐTAKA	8						
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			S- A-			-011						
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prentstafi	Lögheimili			Aðsetur								
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Notiõ	Einhver fylgikvilli við/eftir síðustu bl	nver fylgikvilli við/eftir síðustu blóðgjöf?										
Z	Gefið blóð annars staðar en í Blóðbar					••••						
	Vinsamlega láttu okkur vita ef þú <b>veil</b> sem <b>trúnaðarmál</b> . Þú getur <b>h</b> a											
	Ég hef lesið bækling Blóðbankans, "Sn	nitvarnir og blóðg	jöf - upplýsii	ngar til blóðgjafa", í	dag							
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	•	já nei		ır þú haft:	, , , , , ,	já	ne					
1. Ert þ	ú við góða heilsu?		a. hjar	rta- eða æðasjúkdóm/	gigtsótt?							
	r þú s.l. mánuð:											
	að einhver lyf, þ.m.t. Magnýl/Íbúfen?											
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	r þú farið til útlanda eða búið											
erlen	dis?				ngar?							
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sýnat	öku?		Avo	dart/Propecia?								
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	lesið og skilið upplýsingaefni Blóðbanl		færi til að b	era fram spurningar	r og fengið fullnægir	andi svör.						
_	ykk(ur) blóðgjöf í dag og að Blóðbanl	_										
-	að hafa svarað heilsufarsspurningum			•								
					-							
Dags:	Undirskr	ift blóðgjafa:										



Home > Media Room >

- **▼Why Should I Donate?**
- ▼Can I donate?
- **▼What Can I Donate?**
- ▼How Can I Get Involved?
- **▼What Should I Know?**
- **▼**Forms
- ▼ Hospitals

## Public Statement Update on Review of MSM Deferral Policy

#### March 16, 2007

Currently, Canadian Blood Services indefinitely defers any male from donating blood if he has had sex with another male, even once, since 1977 (MSM). The MSM deferral is part of our screening procedures that are designed to identify a variety of behaviours and circumstances known to increase risk to the safety of the blood supply. As another example, we also indefinitely defer individuals from giving blood that have spent more than three months in the United Kingdom or France between 1980 and 1996, due to the increased risk of potential exposure to vCJD.

In keeping with Canadian Blood Services' commitment to ensuring the safety of the blood system, we continually review our policies and procedures to ensure they are still in the best interest of Canadian patients. As part of the review of the MSM deferral policy, the Board of Directors commissioned an independent risk assessment, which was undertaken by the McLaughlin Centre for Population Health Risk Assessment and finalized in February 2007.

In April 2007, Canadian Blood Services will undertake consultations with stakeholders and high interest groups to gather their views and input on the policy. This feedback will then be provided to the Canadian Blood Services' Board of Directors for consideration as they continue to review the MSM deferral policy and determine next steps.

Any change to our donor criteria would have to be considered safe from a scientific perspective, be in accordance with our mission to operate Canada's blood supply in a manner that gains the trust, commitment and confidence of Canadians, particularly patients, and be approved by the regulator, Health Canada.





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#### BEFORE YOU GIVE

Before giving blood please read this brochure.

- Drinking fluids before donation will help to maintain your blood volume.
- We will ask you to show proof of identity and complete a form that asks you about your health.
- You will be asked if you have engaged in actions that may transmit HIV and hepatitis.
- We will check your blood pressure, pulse and temperature.
   We will check your blood to make sure you are not anemic.
- You will then be asked to sign a statement that confirms that you have read and understood the information in the brochure and that you have answered all questions truthfully.

Your presence here is voluntary. You may leave at any time but please inform a member of the clinic staff.

#### DONOR PRIVACY

Whether you donate or not your answers are kept on file. We take appropriate measures to protect the confidentiality of your personal information. If you would like to obtain more information on our privacy program, please ask for our privacy brochure.

#### INFORMATION ON AIDS

AIDS is caused by a virus known as HIV. HIV can be spread when body fluids such as semen, blood or vaginal fluids from a person with the virus enter the bloodstream of someone else. Because HIV can be transmitted by blood, your blood will be tested for HIV. The tests for HIV cannot detect 100% of HIV infections.

#### HIV AND HEPATITIS VIRUS RISKS

The HIV and hepatitis viruses can be transmitted if:

- · You have used a needle to inject illegal drugs into yourself
- You have taken money or drugs for sex, since 1977
- You are a male who has had sex with another male, since 1977
- · You regularly receive blood products
- You have had sex with someone who has done any of the things listed above
- You have been in jail for longer than 48 hours in the past 12 months.

#### DEFINITION OF SEX

Sex refers to any of the following activities even if a condom or barrier device was used:

- Vaginal intercourse (contact between penis and vagina)
- Oral sex (mouth or tongue on someone's vagina, penis or anus)
- · Anal intercourse (contact between penis and anus).

#### DO NOT GIVE BLOOD IF:

Do not give blood if:

- You have engaged in activities that put you at risk for getting HIV or hepatitis
- You have had a test that shows you have AIDS or the HIV virus
- You want a test for HIV.

#### PREVENTING USE OF YOUR BLOOD

You may not want to say that you are at risk for getting HIV. For this reason, we provide a way you can make this known without telling any one. You will be asked to select a sticker in private from a choice of two. Choosing the "NO" sticker means your blood will not be used. The "YES" sticker means your blood will be used, if test results are okay. The stickers are bar-coded and read by a machine so your choice remains private.

# INFORMATION OF IMPORTANCE TO YOUR HEALTH

#### ALLERGIES

Latex products and medical gloves are used at the donor clinic. Please tell the clinic staff if you are allergic to latex or to the powder used in medical gloves.

#### WHILE YOU GIVE

Giving blood takes about 15 minutes. The needle used to take the blood is new and sterile.

#### POSSIBLE SIDE EFFECTS

There is usually no discomfort while giving. A small number of donors may:

- Feel faint, dizzy or nauseated
- · Feel tired for a day or two
- · Very rarely, faint and have muscle spasms
- · Have bruising, redness or a rash at the needle site
- · Suffer nerve damage, pain or numbness in the arm.

A decrease in iron stores (ferritin) may occur in frequent donors.

A diet rich in iron is advised for all donors.

#### **AFTER YOU GIVE**

- Put pressure on the needle site for about five minutes to stop the bleeding. We will then place a bandage on your arm.
- · Rest for five to ten minutes or so.
- If you feel faint sit down and rest for a few minutes with your head between your knees or lie down.
- To avoid a skin rash, when you return home, remove the bandage and wash the needle site with soap and water.
- Avoid doing anything strenuous for about 6 to 8 hours.
- . Drink plenty of fluids to replace the fluid that has been lost.

#### **HAZARDOUS JOBS**

People who work in jobs that expose them to risk (such as flight crews, scuba divers, bus drivers and heavy equipment operators) may require some time off before going back to work. For those who engage in risky sports, time off from the sport may be advised after giving blood.

#### HOW OFTEN YOU CAN GIVE

A blood donor may give every 56 days.

#### WHAT HAPPENS TO YOUR DONATION

Your donation is used to treat patients. A small part of your donation may be used for quality testing, teaching or stored for future testing but this is rare. As well, part of your donation may be donated or sold on a cost recovery basis instead of being discarded. It could then be used for research or further processed into drugs to treat patients inside or outside Canada. For further information please ask for our What Happens to YOUR Donation brochure.

Your blood will be tested for:

- Hepatitis B and C
- Syphilis
- AIDS virus (HIV)
- HTLV virus
- West Nile virus
- Blood group
- A Chagas disease test will be done if you have answered "yes" to any of the questions that identify a possible risk for acquiring Chagas disease. A Chagas disease test may also be done on a certain number of donors who answer "no" to these questions.
- Other tests, such as parvovirus B19, cytomegalovirus (also known as CMV) and bacteria may be done. This depends on the use of your blood.

There are unusual circumstances in which these tests cannot be done.

#### POSITIVE TEST RESULTS

If any of these tests show results that could affect your health this is what happens:

- · Your blood will not be used
- CBS staff will ask you for the name of your doctor and the results will be given to him or her
- Except for a positive West Nile virus test, your name will be added to a private list of those who cannot give blood
- If required by provincial law, the local or provincial health office will be informed of positive test results.

#### CONTACT CBS IF:

- After leaving the blood donor clinic you faint, or get a large bruise
- · After giving blood you decide your blood should not be used
- · You suffer from any illness or diarrhea within the next week
- . Within the next 14 days you have West Nile Virus
- You have a test within the next twelve months that shows you have hepatitis or HIV.

#### QUESTIONS?

If you have any questions or concerns please ask the clinic staff.

Or call 1 888 2 DONATE (1 888 236-6283). More information
may also be found at our website, www.blood.ca.

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## **UK Blood Transfusion & Tissue Transplantation Services**



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#### 禺

#### Why we ask men who have sex with men not to give blood

#### A guide for donors

Securing the safety of the national blood supply is our number one priority. We follow strict rules and regulations when collecting and processing blood to make sure we supply the safest possible blood.

We use two main strategies to keep blood donation as safe as possible.

- 1. Selecting 'safe' donors
- 2. Testing every donation

Selecting 'safe' donors means that we have to ask some people not to donate their blood. This includes all men who have had sex with other men.

#### Principles of selecting donors

There are over 450 rules guiding donor selection and there are many groups of people who we ask not to donate either for a short period or forever.

Some people in these groups may have a very low risk of blood-borne infections and their blood would probably be safe to give to patients, but it is safest to ask everyone within the groups that have been identified, not to give blood.

This request can be disappointing and frustrating to some people who wish to donate blood. Our decisions are based on information and research about the effects our policies will have on ensuring the safest blood supply possible, not out of a desire to discriminate against any particular group.

The aims of selecting donors are to:

- 1. select donors whose blood, as far as we can tell, is most unlikely to transmit any infection
- 2. collect enough blood to meet patients' needs.
- 3. make sure that donors themselves come to no harm through giving blood.

We have to balance these three aims while also keeping the selection process clear and simple.

#### Why do we ask men who have sex with men not to give blood?

We ask men who have sex with men not to give blood because men who have sex with men, as a group, are known to be at an increased risk of acquiring HIV and a number of other sexually transmitted infections (STIs), many of which are carried in the blood.

It is specific behaviours, rather than being a man who has sex with men, which places men who have sex with men at increased risk of HIV infection. Safer sex will keep most men who have sex with men free from infection, however research shows that allowing men who have sex with men as a group to donate blood would increase the risk of HIV infected blood entering the blood supply.

#### Testing does not detect all infections

We test all blood donations for HIV, hepatitis B and C, syphilis and HTLV. However, no testing process can be 'perfect'. We may miss infected donations because of the 'window period' between getting an infection and the test showing a positive result. There is also always a small risk of mistakes being made in the laboratory.

Selecting donors that are already in a low-risk group for these infections means that we will reduce the number of infected donations that could be missed by testing.

#### How the rule improves the safety of blood transfusions

Many men who have sex with men have not given blood since the AIDS epidemic began, and this has prevented many HIV infections being transmitted through transfusion. Also, the number of hepatitis B infections transmitted by blood transfusion fell considerably after this rule was introduced.

Abolishing the rule for men who have sex with men would increase the risk of HIV infected donations entering the blood supply in England by about five times, and changing the rule to allow men who have sex with men to donate one year after they last had sex with another man would increase the risk by 60%. (Reference: Soldan, K.; Sinka, K. Vox Sanguinis, Volume 84, Number 4, May 2003, pp. 265-273 (9)).

#### Keeping our rules simple

The rule about men who have sex with men is clear and simple. You can decide whether it applies to you without the need to discuss your personal life with our staff. The rule is based on an impartial assessment of available evidence. We ask that you observe it for the sake of blood safety.

#### **Further information**

People who are asked not to donate blood are entitled to a clear explanation as to why. If you would like more information than is contained in this leaflet, please see our contacts list.



# Fylgiskjal 5.

Sérstök kynning á vegum íslenskra heilbrigðisyfirvalda frá árinu 1986.



# Fylgiskjal 6.

Reglur sænskra heilbrigðisyfirvalda um hverjir mega gefa blóð, og hverjir ekki, og tilkynning þeirra um fyrirhugaðar breytingar.



Frågor och svar om blodgivning – grundläggande information information

http://www.socialstyrelsen.se/fragorochsvar/blodgivninggrundlaggandeinform

## 1. Vem fattar beslut om vilka regler som gäller för blodgivning?

Alla länder inom EU har enats om regler för blodgivare som ska gälla inom hela unionen. Medlemsländerna är skyldiga att införa dessa regler nationellt och har dessutom möjlighet att ställa högre krav inom respektive land, så länge de uppfyller grundkraven från EU. I Sverige har en blodsäkerhetslag införts för att sätta EU-direktiven i kraft. Det är Socialstyrelsen som fastställer vilka regler som gäller för blod och blodkomponenter avsedda för transfusion och det är Läkemedelsverket som fastställer de regler som gäller för den blodplasma som används till framställning av läkemedel. Blodcentralerna ska tillämpa dessa regler, men kan ställa högre krav på blodgivarna, om det finns särskild grund för detta.

#### 3. Vem får ge blod och vad är urvalskriterier?

Alla som vill ge blod måste uppfylla en rad kriterier där alla måste vara uppfyllda för att personen ska godkännas som blodgivare. Det är inte ovanligt att någon som vill bli blodgivare inte godkänns på grund av att personen inte uppfyller samtliga kriterier. En avstängning kan vara antingen tidsbegränsad eller permanent. Vissa kriterier är till för att skydda blodgivarna, medan andra ska skydda mottagarna av blodet.

Exempel på kriterier som avser skydda blodgivaren är:

- låg kroppsvikt
- hög ålder
- lågt hemoglobinvärde
- · vissa sjukdomstillstånd

Exempel på kriterier som avser skydda mottagaren är:

- infektioner och andra sjukdomar
- riskhändelser t.ex. kirurgiskt ingrepp, tatuering eller antibiotikabehandling
- riskbeteenden t.ex. injektionsmissbruk, sexuellt umgänge i utbyte mot pengar eller sexuellt umgänge mellan män
- utlandsvistelse t.ex. besök i länder där vissa infektionssjukdomar är vanliga

# 4. Varför utgör sexuellt umgänge mellan män ett riskbeteende?

Riskbeteende definieras av hur stor risken är att exponeras för smitta som kan överföras via blod vid ett visst sexuellt beteende. Beräkning av denna risk görs utifrån den kunskap vi har om hur många personer som smittas varje år och hur många som idag lever med sjukdomar som kan överföras via blod och blodprodukter. Sådana sjukdomar är t.ex. hiv, hepatit B, hepatit C samt syfilis. I Sverige är risken att exponeras för hiv uppskattningsvis minst 50 gånger högre för män som har sexuellt umgänge med kvinnor, förutsatt att det inte finns några fler riskfaktorer för hiv.

## Tilkynning sænskra heilbrigðisyfirvalda um fyrirhugaðar breytingar á reglum.

http://www.socialstyrelsen.se/fragorochsvar/blodgivningforandradereglerfra

# 1. Vad är nytt i Socialstyrelsens föreskrift, som gäller från och med 1 april 2010?

De viktigaste förändringarna från tidigare föreskrift är:

- Personer som har haft ett sexuellt riskbeteende tillåts lämna blod om minst 12 månader har gått sedan senaste risktillfället.
  - Personer med sexuellt riskbeteende avser:
  - alla som har haft sexuellt umgänge i utbyte mot pengar, droger eller annan ersättning
  - män som har haft sexuellt umgänge med män
  - kvinnor som har haft sexuellt umgänge med en man som i sin tur har haft sexuellt umgänge med en man.
  - Tidigare var dessa personer avstängda från att ge blod resten av livet.
- Krav på s.k. kombotest för hiv (som kan upptäcka både antikroppar och antigener) vid varje blodgivning har införts. Det är ett test som kan upptäcka smitta i blodprov tidigare än de hivtest som använts förut.
- Krav på testning för syfilis vid varje blodgivning finns nu. Tidigare har detta test enbart krävts första gången en person lämnar blod. Orsaken är att syfilis ökar.
- Krav på personlig intervju vid varje blodgivningstillfälle har införts.
   Redan tidigare finns ett krav på en sådan intervju första gången en person ger blod.
- Beslut om blodtappning ska fattas av legitimerad hälso- och sjukvårdspersonal.

Sænsk heilbrigðisyfirvöld hafa seinkað gildistöku þessara breytinga, vegna margvíslegra vandkvæða við innleiðingu.

# Fylgiskjal 7.

# Evróputilskipun um blóðbankaþjónustu (2002/98 og 2004/33)



# Fylgiskjal 8.

Reglugerð 441/2006 um blóðbankaþjónustu.



Reglugerð\_nr\_441\_2006.doc