



## **SaBTO Review of Donor Selection Criteria**

### **Questions and Answers**

#### **What does the term 'MSM' mean?**

MSM or 'men who have sex with men' refers to any man who has or has had anal or oral sex with another man. The term does not refer only to gay and bisexual men but also heterosexual men who have had sex with a man/men. Blood donor selection criteria are not applied to MSM on the basis of their sexuality, but due to specific sexual behaviours (anal and oral sex between men) which increase the risk of transmission and infection with blood-borne viruses and other sexually transmitted infections.

#### **What is the current blood donor selection criteria for MSM?**

Currently the policy is to ask those in groups shown to have a particularly high risk of carrying blood-borne viruses not to give blood. This includes men who have ever had anal or oral sex with men, with this exclusion resting on specific sexual behaviour rather than sexuality. There is, therefore, no exclusion of gay men who have never had anal or oral sex with a man, nor of women who have sex with women. Men who have ever had anal or oral sex with another man are currently asked not to donate blood permanently. The only sexual behaviours that would result in this exclusion are anal or oral sex between men. Other activities that could be considered 'sexual', for example kissing, would not be cause for exclusion from blood donation.

#### **What has changed?**

The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) has reviewed the most up-to-date scientific evidence and a study on compliance with permanent exclusion. As a result of this review the Committee recommended to the UK Health Ministers a change in the deferral policy from a permanent exclusion to a fixed period deferral of 12 months.

Ministers in England, Scotland and Wales have accepted SaBTO's advice and recommendations and announced that the blood donor selection criteria for men who have had sex with men in those countries will change on 7 November 2011 from a permanent exclusion to a fixed period deferral of 12 months from the latest relevant sexual contact.

Currently, men who have ever had oral or anal sex with another man, even if a condom was used, are permanently excluded from blood donation in the UK. The change means that in future only men who have had anal or oral sex with another

man in the past 12 months (with or without a condom) will be asked not to donate blood. Men whose last relevant sexual contact with another man was more than 12 months ago will be able to donate (subject to meeting the other donor selection criteria).

### **When will the change come into effect?**

The Scottish National Blood Transfusion Service (SNBTS) will implement the change at blood donation sessions across Scotland on 7 November 2011. Until this date the existing permanent exclusion will continue to apply.

The blood services in South Wales and England will also implement the change on the same date. For further information on blood donation in these countries:

- Welsh Blood Service (covering South, West and part of Mid Wales: <http://www.welsh-blood.org.uk/> or call 0800 25 22 66.
- English Blood Service (covering England and North Wales) <http://www.giveblood.co.uk> or call 0300 123 23 23

### **What will the change mean in practice at blood donation sessions?**

The Scottish National Blood Transfusion Service will implement the change at blood donation sessions across Scotland on 7 November 2011. Until this date the existing permanent exclusion will continue to apply.

At blood donation sessions, all donors are asked to complete a questionnaire to assess whether they meet the criteria. This is to ensure that the supply of blood to patients is as safe as possible. The questionnaire will be changed so that the question regarding sex between men determines whether a potential donor is a man who has had sex with a man in the past 12 months, rather than ever in their lifetime.

If a potential donor answers 'yes' to any question that could suggest they are at an increased risk of carrying blood-borne infections they will be asked to speak in confidence to a registered nurse. Further appropriate questions will be asked to understand the risk factors associated with the behaviour disclosed. The registered nurse will then make a decision based on the individual situation presented. For men who have had anal or oral sex with another man in the previous 12 months, they would be asked not to donate until 12 months have passed since this contact.

Health screening areas are set up to minimise the risk of being overheard, background music reduces the opportunity for this. Any record relating to identifiable individuals of a confidential or sensitive nature is always written on a separate record and sealed in an envelope to maintain confidentiality.

Blood donation works on the principles of kindness and mutual trust and we ask all potential and existing donors to adhere to the blood donor selection criteria by providing completely honest answers to all the questions asked, both for the protection of their own health and that of others. Compliance with all donor selection criteria is crucial in order to ensure the continued safety of the blood supply. Anyone may require a blood transfusion in the future and it is in the best interests of us all to ensure that we strive to maintain blood safety.

## **What has changed since this was last reviewed?**

The criteria across all of the UK Blood Services for accepting blood donors are recommended to the UK Government by the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO). These criteria are regularly reviewed to ensure they are appropriate and based on the most up to date scientific evidence. Donor selection policies that are proportionate and based purely on evidence are necessary to help ensure that donors comply with the health check process.

A previous review of the permanent exclusion of men who have sex with men in 2006 found that despite developments in testing and improved knowledge of the epidemiology of blood borne infections, there was insufficient data regarding compliance to determine the potential impact of any changes, therefore no changes to the policy were recommended at that time. A study was commissioned to increase the understanding of compliance with the permanent deferral. This study reported in December 2010.

The review that has prompted the change, carried out by SaBTO and completed in May 2011, found that:

- Improvements in blood donation testing, including universal Nucleic acid Amplification Technology (NAT) testing and smaller donation pool sizes which increases sensitivity, have been implemented since the last review and these have greatly reduced the various 'window periods' for detection of infections in donated blood.
- All tests are fully automated and are monitored by advanced IT systems, reducing the risk of any error in the testing process.
- The introduction of a 12 month deferral would maintain blood safety and bring the criteria for MSM in line with those for other groups that are at an increased risk of carrying blood-borne infections.
- A 12 month deferral would not affect the safety of the blood supply, however compliance with the rule (and all donor selection criteria) is crucial.
- If donors do not comply with donor selection criteria and donate blood shortly after any behaviour that places them at risk of acquiring a blood-borne infection, there is a possibility that they might donate blood during the 'window period' where infection will not be detected by available screening tests, but could be transmitted via a blood donation.

## **What new evidence has been reviewed?**

The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) and an expert Steering Group comprised of relevant experts and stakeholders reviewed detailed scientific research and other evidence including:

- The results of a mixed methods study which explored compliance with the current permanent exclusion of men who have sex with men, assessed the possible consequences of a revision to this criterion and examined how best any revision might be formulated and communicated
- Data from a qualitative study involving compliers and non-compliers with the current lifetime deferral
- Modelling studies on the impact on risk of the introduction of fixed-period deferrals for MSM
- Epidemiology of donors with markers of infection

- Data on risk factors and reasons for non-compliance (where appropriate) collected from donors with markers of infection.

For more information on SaBTO's review :

<https://www.gov.uk/government/publications/donor-selection-criteria-review>

### **Should patients receiving blood transfusions be concerned about the change?**

No. All of the policies in place to ensure the safest possible blood for patients are based on the most up to date scientific evidence and are reviewed on a regular basis. The review carried out by the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) concluded that changing from a permanent exclusion to a 12 month fixed period deferral would not impact on the safety of the blood supply.

Whilst there is an acceptance that no medical treatment can have zero risk for patients, we would like to reassure patients receiving transfusions that the blood supply is as safe as it reasonably can be and amongst the safest in the world. SNBTS and other Blood Services have a clear responsibility to minimise the risk of any blood transfusion transmitting an infection. Blood donor selection criteria and a wide range of other blood safety measures, including stringent testing, mean there has been no documented transmission of a blood-borne virus in the UK since 2005, with no HIV transmission since 2002.

Clearly any transmission would be one too many and the purpose of the blood donor selection criteria, alongside other safety measures, is to minimise any potential harm to recipients of blood donations (as well as to protect the health of donors). A 12 month fixed period deferral since the latest relevant sexual contact between men is considered sufficient to ensure the continued safety of the blood supply. The change brings the criteria for men who have sex with men in line with those for the majority of other groups that are deferred from blood donation for 12 months due to sexual behaviours.

Donor adherence with this and all donor selection criteria is key to the safety of the blood supply. For more information on blood safety click

[http://www.scotblood.co.uk/media/29549/uk\\_blood\\_services\\_joint\\_statement\\_blood\\_safety\\_august\\_2011\\_2.pdf](http://www.scotblood.co.uk/media/29549/uk_blood_services_joint_statement_blood_safety_august_2011_2.pdf)

### **Were blood recipients / patient groups / donors consulted as part of the review?**

Yes. As part of the review, new research was presented in July 2009 and a public meeting was held in October 2009 attended by a range of organisations representing the interests of donors, blood recipients and people affected by current blood donor selection criteria related to sexual behaviour.

SaBTO has also been supported by a Steering Group of relevant experts (<https://www.gov.uk/government/publications/donor-selection-criteria-review>) and stakeholders in carrying out its review, including representation from the various groups that are likely to be affected by, and interested in, the outcome. The Steering

Group reviewed the research and available evidence and made its own recommendations to inform SaBTO's review.

### **Has the policy been changed because of Equalities laws?**

The Equality Act 2010 was considered as part of the review. The Act states that blood services do not contravene anti-discrimination legislation by excluding people from donating blood as long as this exclusion or deferral is based on a reasonable and reliable assessment of risk to the public or the individual.

The criteria for blood donors across all of the UK Blood Services are recommended to the UK Government by the Advisory Committee on the Safety of Blood, Tissue and Organs (SaBTO). In order to ensure the continued safety of the blood supply, currently those in groups shown to be at an increased risk of carrying blood-borne viruses are asked not to give blood for either a fixed period or permanently. MSM are currently permanently excluded from blood donation. However, SaBTO has concluded on the basis of the most up to date scientific evidence that a permanent exclusion is not required and that a fixed period deferral of 12 months from latest relevant sexual contact is sufficient to maintain the safety of the blood supply.

### **How can it be fair to continue to treat all gay men as high risk?**

Men who have sex with men as a group have been shown to be at a statistically higher risk of acquiring HIV and other sexually acquired infections including HBV in the UK. See the Health Protection Agency (HPA) website for further information <http://www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/HIVAndSTIs/>

Currently in Scotland, for those who have been tested for HIV, the prevalence of HIV in the heterosexual non intravenous drug using population is 0.1% while the prevalence in MSM is between 3-4%.

Although some would prefer a system that assesses every individual's behaviour and level of risk rather than applying deferrals to groups, SaBTO's review concluded that there is insufficient evidence available to be able to determine the impact on blood safety of such a system. It is also not certain that all people could objectively assess their own level of risk.

We appreciate that it can be disappointing for anyone who wishes to donate blood but is not able to meet the donor selection criteria. The criteria are based on complex assessments of risk and must by their nature be based on evidence and statistics that are recorded at a population level. However, this results in assessments of certain groups as being at a higher risk than others of carrying blood borne infections, and can make those that are deferred from donation feel they are being placed into a 'category' even if they feel that their own sexual behaviour and risk-taking would not be a risk to the blood supply.

As there is a small possibility that the tests we use may not pick up infections, particularly those which have been recently acquired, we must follow deferral rules that estimate risk based on behaviour. We are sorry for any inadvertent offence this causes and would welcome anyone that does not currently meet the donor selection criteria to come forward if this changes in the future.

## **Why is it not possible to introduce a system through which every donor's individual level of risk is assessed as they have done in Italy, Latvia and Spain?**

SaBTO's review concluded that there is insufficient evidence available to be able to determine the impact on blood safety of such a system. Any changes made to blood donation policies must be evidence based. It is also not certain that all people could objectively assess their own level of risk.

The review also found that the introduction of extensive donor questions regarding sexual behaviour could lead to a loss of existing donors who would be likely to find the process intrusive, potentially impacting upon the sufficiency of the blood supply. The Blood Services are therefore required to follow deferral rules that estimate the statistical risk of certain groups based on behaviour (e.g. anal or oral sex between men).

## **What is a window period?**

All blood donations are tested on every occasion for evidence of infection with Human Immunodeficiency Virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), Human T-cell Lymphotropic Virus (HTLV), and syphilis. In addition, donors who have been exposed to a risk of certain infections found outside the UK, but which are transmissible by blood transfusion (e.g. malaria and Chagas' disease), undergo specific testing before their blood is released for use.

There have been great advances in testing which have significantly improved blood safety in the UK in recent years. However, if a person donates blood during the 'window period', the infection may not be detected as the immune response may not yet be evident in the blood. This means the infection could be transmitted via a blood donation during this period.

## **Why is the deferral period 12 months?**

All blood donations are tested on every occasion for evidence of infection with Human Immunodeficiency Virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), Human T-cell Lymphotropic Virus (HTLV), and syphilis. In addition, donors who have been exposed to a risk of certain infections found outside the UK, but which are transmissible by blood transfusion (e.g. malaria and Chagas' disease), undergo specific testing before their blood is released for use.

Although in recent years there have been great advances in testing which have significantly improved blood safety in the UK, if a person donates blood during the 'window period' the infection may not be detected but could be transmitted via a blood donation.

The evidence reviewed by SaBTO showed that men who have sex with men as a group continue to be at a statistically higher risk of contracting blood-borne viruses such as HIV and HBV in the UK. Due to the nature of HBV infection, and of the screening tests used, it is necessary to allow 12 months from any higher risk behaviour as this is long enough for the donor to have undergone and recovered from an infection. A deferral period of 12 months is considered sufficient to allow for the complete clearance of HBV in a recovered individual. Those individuals who do not recover from HBV infection will be detected by the screening tests.

The change brings the criteria for men who have sex with men in line with other groups that are deferred from blood donation for 12 months due to sexual behaviours. Donor adherence with this and all donor selection criteria is key to the safety of the blood supply.

**I've recently had a negative HIV test result and know that I am negative, so why can't I give blood?**

As there is a small possibility that the tests we use may not pick up infections, particularly those which have been recently acquired, we must follow deferral rules that estimate risk based on behaviours. We are sorry for any inadvertent offence this may cause and would welcome anyone that does not currently meet the donor selection criteria to come forward if this changes in the future.

**I always use condoms, why can't I give blood?**

While safer sex, through the use of condoms, does reduce the transmission of infections, it cannot eliminate the risk altogether. Condoms have one of the highest success rates at preventing many sexually transmitted infections and they are made to strict standards, with a very low failure rate when used correctly. However, people do not always use them correctly and so reliance upon this method to ensure the safety of the blood supply is not considered sufficient.

**Why hasn't SaBTO recommended a deferral/exclusion for promiscuous heterosexuals?**

Men who have sex with men as a group have been shown to be at a statistically increased risk of acquiring blood-borne viruses in the UK. It is specific sexual behaviours rather than sexuality that increase the risk of virus transmission (e.g. anal or oral sex between men).

Although some would prefer a system that assesses every individual's behaviour and level of risk rather than applying deferrals to groups, SaBTO's review concluded that there is insufficient evidence available to be able to determine the impact on blood safety of such a system. It is also not certain that all people could objectively assess their own level of risk.

Based on published data, the review also concluded that the introduction of extensive donor questions regarding sexual behaviour could lead to a loss of existing donors who would be likely to find the process intrusive. The Blood Services are therefore required to follow deferral rules that estimate the statistical risk of certain groups based on behaviour. We are sorry for any inadvertent offence this may cause.

**There is no shortage of blood in this country so why was the review carried out?**

It is important to ensure that all donor selection criteria are based on the most up to date scientific evidence to ensure the continued safety of the blood supply and of donors.

New blood donors are needed all the time and it is crucial to regularly review the donor selection criteria to ensure as many people as possible are able to donate to meet the demand for blood for patients.

## **Isn't there a risk of those gay men who don't agree with the policy donating anyway?**

There is always that possibility for any of the blood donor selection criteria. Blood donation works on the principles of kindness and mutual trust and we ask all potential and existing donors to adhere to the blood donor selection criteria by providing completely honest answers to all the questions asked, both for the protection of their own health and that of others. Compliance with all donor selection criteria is crucial in order to ensure the continued safety of the blood supply. Anyone may require a blood transfusion in the future and it is in the best interests of us all to ensure that we strive to maintain blood safety.

## **I don't feel comfortable answering questions related to my sexuality and sexual behaviour in the blood donation environment, why should I adhere to the donor selection criteria?**

You can check the donor selection criteria before you attend a blood donation session through information available on UK Blood Service websites and donor telephone lines.

- Scottish National Blood Transfusion Service: <http://www.scotblood.co.uk/> or call 0845 90 90 999
- NHS Blood and Transplant: English Blood Service (covering England and North Wales)  
<http://www.giveblood.co.uk> or call 0300 123 23 23
- Welsh Blood Service (covering South, West and part of Mid Wales: <http://www.welsh-blood.org.uk/> or call 0800 25 22 66.
- Northern Ireland Blood Transfusion Service: <http://www.nibts.org/> or call 028 9032 1414.

Blood donation sessions are designed to provide as confidential an environment as possible. We do not ask potential donors to answer any questions in front of anyone other than the health screener. If sensitive information is disclosed a check is made to ascertain that this was not answered in error. Once this is confirmed the donor is referred in confidence to a registered nurse. The nurse will ensure there is a secure environment to reassure the donor that their confidentiality will be maintained.

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## **Is it against the law to lie about my sexual history in order to give blood?**

Currently there is no law regarding sexual history and blood donation. However, a legal case was recently successfully brought against a blood donor in Canada who was found to have knowingly donated blood despite not meeting the selection criteria, resulting in an infection being identified through testing in his donation.

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providing completely honest answers to all the questions asked, both for the protection of their own health and that of others. Compliance with all donor selection criteria is crucial in order to ensure the continued safety of the blood supply. Anyone may require a blood transfusion in the future and it is in the best interests of us all to ensure that we strive to maintain blood safety.

**What are the donor selection criteria for men who have sex with men in other countries?**

A 2009 European Blood Alliance (EBA) survey of 23 blood services reported that 20 countries defer MSM permanently (or since 1977) and three countries (Latvia, Spain and Italy) reported that they have fixed period deferrals in place. For Latvia a deferral is used if indicated by individual assessment. For Spain a deferral of at least six months operates after a change of partner (heterosexual or MSM), with permanent exclusion for individuals with more than one sexual partner. In Italy a deferral of four months from the risk behaviour operates for multiple partners or change of regular partner.

In Australia, Argentina and Japan, a 12 month fixed period deferral operates, and in South Africa six months. In 2008, a review in New Zealand led to a reduction in the deferral period from 10 to five years after last relevant sexual contact. In the USA and Canada, men who have sex with men are permanently excluded.

It should be noted that the evidence on which donor selection criteria are established include detailed epidemiological information about the extent of infection with blood-borne viruses in the local population, and the methods of donation testing in use. This is why policies can vary from country to country.

**What are the other donor selection criteria related to sexual behaviour?**

A number of groups in addition to MSM are deferred or excluded from blood donation due to sexual behaviours which place them at an increased risk of acquiring a blood-borne virus. The table below sets out the current deferral period and exclusions related to sexual behaviour:

	<b>Behavioural risk</b>	<b>Duration</b>
1	Sex with a sex worker	At least 12 months after last relevant sexual contact
2	Accepting money or drugs for sex / commercial sex workers	Permanent
3	Sex with an intra-venous drug user	At least 12 months after last relevant sexual contact
4	Sex with anyone who has ever had sex in parts of the world where HIV/AIDS is common	At least 12 months after last relevant sexual contact
5	Sex with anyone infected by HIV, hepatitis B or C virus	At least 12 months after last relevant sexual contact
6	Females who have sex with a man who has had sex with another man	At least 12 months after last relevant sexual contact
7	Men who have ever had anal or oral sex	At least 12 months after

	with a man (MSM)	last relevant sexual contact
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**Why has the criteria for commercial sex workers not changed from a permanent exclusion to a fixed period deferral as part of this review?**

The review carried out by the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) found that there was insufficient evidence on virus prevalence in commercial sex workers to allow modelling of the impact on virus risk through donation of any changed donor selection criteria for this group.

There was also no evidence on how compliance might be affected by any change in criteria. SaBTO recommended that high quality evidence on these areas should be obtained to allow future consideration of changing the criteria for commercial sex workers. Whilst it is recognised that risks may vary amongst different groups of sex workers, it is not possible to question donors in detail to establish individual risk. In addition, permanent exclusion remains in place for any individual with a history of intravenous drug use. Changing the criteria for sex workers could potentially cause confusion and possibly lead to individuals who do not meet with selection criteria because of previous drug use donating in error.