

Issued by JPAC: 26 May 2021

Implementation: To be determined by each Service

Change Notification UK National Blood Services No. 16 - 2021

Changes required for implementation of the FAIR study

These changes apply to the Whole Blood and Components Donor Selection Guidelines

The FAIR study was commissioned by the UK Forum in order to find a safe way to apply donor selection criteria which would allow low risk men who have sex with men (MSM) to donate blood. Following SaBTO approval, its recommendations were approved by the Department of Health and announced in December 2021. The UK Transfusion Services have agreed to implement these changes on June 14, 2021.

16.1. Addiction and Drug Abuse

Please amend the following sections in this entry:

Obligatory: **Must not donate if:**

- a) Has ever injected, or has been injected with, drugs; even a long time ago or only once. This includes bodybuilding drugs, [injected tanning agents](#) and [injected chemsex drugs](#).
- b) Adversely affected by any drug, including alcohol, which may affect the process of obtaining valid consent. This may be until the next session, or permanently, if the donor's behaviour is likely to constitute a hazard to other donors or to staff.
- c) Less than seven days from taking disulfiram (Antabuse®).

Reason for change: ~~An 'Obligatory' entry has been added for donors who have taken disulfiram (Antabuse®) in the last seven days.~~

~~A link has been added to 'Cirrhosis'.~~

[Updated as part of the implementation of recommendations from the FAIR study; specific references to injected tanning agents and injected chemsex drugs have been added to the obligatory section.](#)

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16.2. Blood Safety Entry

Please amend the following sections in this entry:

Definitions: **Individual risk** is based on the donor's sexual behaviour, including new partners and number of partners.

Partner risk is based on sexual contact with a partner who may, at a population level, be at higher risk of acquiring infection, as described in this entry.

Sexual contact is defined as oral, vaginal or anal sex.

Anal sex is defined as penile-anal intercourse only. It does not apply to oro-anal sex or the use of sex toys.

Chemsex is sex while using stimulant drugs taken for the specific purpose of enhancing sexual experience and reducing inhibitions. Chemsex does **not** refer to sex after using alcohol or recreational drugs for other purposes, nor the use of drugs such as Viagra or Cialis to treat erectile dysfunction.

Obligatory: **2. You must never donate if:**

- a) You are HIV positive or receiving treatment for HIV.
- b) You are HTLV positive.
- c) You are a hepatitis B carrier.
- d) You are a hepatitis C carrier.
- e) You have ever been diagnosed with syphilis, even if treated
- f) You have ever injected or been injected with drugs; even a long time ago or only once. This includes bodybuilding drugs, ~~and~~ injected tanning agents and injected chemsex drugs. You may be able to give if a doctor prescribed the drugs. Please ask.

3. You must not donate for at least three months if:

You are working as a sex worker. You may be accepted for donation if it is longer than three months since you last received money or drugs for anal, vaginal or oral sex.

4. Individual risk criteria

- a) You must not donate for at least three months if you have taken part in chemsex activity, including the use of stimulant drugs. This risk applies for all sexual contact
- b) You must not donate if you have been diagnosed with gonorrhoea, until at least three months after completion of treatment and discharge from further follow up.
- c) You must not donate if in the last three months,
 - you have had more than one sexual partner, AND
 - you have had anal sex with any of your partners.
- d) You must not donate if in the last three months, you have had anal sex with a new sexual partner. For the purpose of donor selection, a new partner is someone that you have not had sex with before or a previous partner with whom you have restarted a sexual relationship.

If you are in a sexual relationship with one partner only, you can donate once it is three months from the date of first sexual contact, even if you are having anal sex.

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5. Partner risk criteria

You must not donate for at least three months after sexual contact with a partner who is, or you think may be:

- a) HIV or HTLV positive.
- b) A hepatitis B carrier.
- c) A hepatitis C carrier.
- d) A partner who has ever received money or drugs for sex.
- e) A partner who has ever injected, or been injected with, drugs: even a long time ago or only once. This includes bodybuilding drugs, **injectable injected** tanning agents **and injected chemsex drugs**. You may be able to give if a doctor prescribed the drugs. Please ask.
- f) A partner who has, or you think may have been sexually active in parts of the world where HIV/AIDS is very common. This includes most countries in Africa. **(This does not apply for donors in Scotland and Wales.)** There are exceptions, so please ask.

See if Relevant: Addiction and Drug Abuse
Hepatitis B
Hepatitis C
HIV
Homosexual and Bisexual Individuals
HTLV
Infection – General
Non-consented Exposure to Human Bodily Fluids
Pre- or Post-Exposure Prophylaxis for HIV
Sexually Transmitted Disease
Syphilis

Additional Information: ~~Following the publication of the SaBTO Donor Selection Criteria Report 2017 the deferral period for most risks in this category has been reduced from 12 to three months. In addition the permanent deferral of sex workers has been changed to three months.~~

~~This review considered advances in the sensitivity of testing procedures currently in use in the UK, the prevalence of transfusion transmissible infections and the current level of compliance with the 12 month exclusion for donors at higher risk of blood borne infections that has been in effect until now.~~

~~There may be exceptions for female partners of men who have ever had sex with men. They may be allowed to donate on the basis of an individual risk assessment.~~

The FAIR (For the Assessment of Individualised Risk) study considered changes to the donor selection policy to allow a more individualised risk-based approach to donor selection policy. In their 2020 report, the FAIR group specifically looked at the guidelines which applied to men who have sex with men (MSM) and recommended an approach based on assessment of a donor's recent sexual behaviour and experience. This approach has been agreed by SaBTO and has now been implemented by the UK Transfusion Services.

Changes to donor selection criteria mean that donors who were previously excluded because of their sexuality and/or gender can now be accepted, if they meet the individual risk criteria outlined in FAIR (see section 5, above). These rules must be applied equally to **all** donors.

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FAIR identified several factors associated with a higher risk of blood borne infections. These include the recent diagnosis of a bacterial sexually transmitted disease and the following sexual behaviours:

- new or multiple sexual partners
- anal sex
- participation in chemsex activity

Drugs used for chemsex include methamphetamine, mephedrone and GHB/GBL, but other drugs may be used (e.g. ketamine, poppers, cocaine). Chemsex is a high risk activity because it usually involves multiple sexual partners, sometimes for extended periods of time. The drugs involved also reduce inhibition leading to riskier sexual activity.

Infection with some sexually transmitted diseases, particularly gonorrhoea or syphilis, is associated with a higher risk of acquiring blood borne infections. Donors who have had gonorrhoea can give three months after completing treatment. Donors who have had syphilis are permanently deferred as their blood will still react in screening tests, even if they have been successfully treated

Some partner risk criteria still apply to donors who have a partner in a population group at higher risk of infection. For affected donors, these risk criteria should be applied even if the donor is eligible under individual risk criteria. These risks are being reviewed and will be updated as further evidence is available.

The drugs used in both **Pre- and Post-Exposure Prophylaxis for HIV (PrEP and PEP)** may interfere with the routine HIV screening tests carried out on all blood donations. For this reason, donors who have taken PrEP or PEP should not donate for three months, even if they ~~have not had a sexual partner in a risk group~~ are otherwise eligible under individual risk criteria.

'Blood Safety Leaflet Information' is available in the 'Document Library' of 'www.transfusionguidelines.org'.

Reason for change: The entry was revised to include individual risk assessment of recent sexual behaviour for all donors. The deferral for donors whose sexual partners has been sexually active in Sub-Saharan Africa has been removed for donors in Scotland and Wales. This supports implementation of recommendations from the FAIR study.

16.3. Health Care Worker

Please amend the following sections in this entry:

Definitions **Non-Consented Exposure to Human Body Fluids:**
A non-consented injury or assault in which an individual is exposed to potentially infective material that could be transferred through donation. The causes may range from a sharps injury to bites, punches and abrasions or **heterosexual** sexual assault where mucous membranes have been contaminated with human blood or other body fluids. It also applies to any inoculation injury with abnormal prions from any species.

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1. History of Non-Consented Exposure to Human Body Fluids

Update information This entry was last updated in:
DSG-WB Edition 203, Release 03 Issue ~~01~~ 32

Reason for change ~~Definition has been updated to change from inoculation injury to non-consented exposure to human body fluids.~~
The 'Definitions' section was updated as part of the implementation of recommendations from the FAIR study.

2. No History of Non-Consented Exposure to Human Body Fluids

Update information This entry was last updated in:
DSG-WB Edition 203, Release 03 Issue ~~01~~ 32

Reason for change ~~This entry has been revised to improve clarity.~~
The 'Definitions' section was updated as part of the implementation of recommendations from the FAIR study.

16.4. Herpes Simplex

Please amend the following sections in this entry:

Additional Information: The herpes simplex viruses (HSV 1 and 2) can cause both cold sores and genital herpes. When the virus is actively multiplying it can cause tingling in the affected area and sores. There is a theoretical risk that the virus, or any secondary infection, could be passed on through transfusion. This is why donors with an active infection are not allowed to donate.

There is no need to defer donors who have a sexual partner with Herpes.

Reason for change: ~~This entry has been extensively rewritten to improve clarity.~~ This entry was revised to support the implementation of recommendations from the FAIR study; a clarification regarding sexual partners has been added.

16.5. Homosexual and Bisexual Individuals

Please remove this entry.

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A-Z index changes: Please remove the following entries:

Bisexual – Female
Bisexual – Male
Gay
Homosexual and Bisexual Individuals
Lesbian
Male Homosexual

Please update the following entries in the A-Z index so they lead to 'Non-Consented Exposure to Human Body Fluids'

Male Homosexual Rape
Male Homosexual sexual assault
Rape – Male Homosexual
Sexual Assault – male homosexual

16.6. Non-Consented Exposure to Human Body Fluids

Please amend the following sections in this entry:

Definitions: Non-Consented Exposure to Human Body Fluids:

A non-consented injury or assault in which an individual is exposed to potentially infective material that could be transferred through donation. The causes may range from a sharps injury to bites, punches and abrasions or ~~heterosexual~~ sexual assault where mucous membranes have been contaminated with human blood or other body fluids. It also applies to any inoculation injury with abnormal prions from any species.

1. Affected Individual

Obligatory: Must not donate if:

- ~~With~~ The incident involved any material containing abnormal prions.
- Less than four months after the date of an inoculation injury or contamination of mucosa or non-intact skin with human blood or body fluids.
- Under ongoing investigations following exposure.

Reason for change: See below

2. Current or Former Sexual Partner of Affected Individual

Obligatory: Must not donate if:

The donor's sexual partner is being monitored for evidence of transmitted infection following exposure to a known infected individual.

~~The affected partner has been exposed to known infective material and is being monitored for evidence of transmitted infection, until the affected partner has been told that there is no evidence of infection.~~

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Reason for change: ~~This entry was updated to remove the reference to a separate entry for Northern Ireland. This is to reflect changes in donor selection criteria for donors in Northern Ireland (1st June 2020) which are in line with the other UK Blood Services and the SaBTO Donor Selection Criteria Review Report (2017).~~
The wording of this entry has been revised to improve clarity.

16.7. Pre- and Post-Exposure Prophylaxis for HIV prevention

Please amend the following sections in this entry:

See if Relevant: Blood Safety Entry
HIV
~~Homosexual and Bisexual Individuals~~
Non-consented Exposure to Human Body Fluids

Additional Information: The use of Pre-Exposure Prophylaxis (PrEP), e.g. Truvada®, to prevent HIV is increasing. ~~Patients~~ Individuals taking PrEP are unlikely to be eligible to donate due to ~~criteria within the~~ blood safety entry ~~guidelines~~. However, PrEP is also available via private prescription and/or online pharmacies and may be used by individuals who would not otherwise be deferred.

Use of PrEP may interfere with testing for HIV by delaying seroconversion or giving unclear results in a positive donor. For this reason, it is important that donors who have taken PrEP in the previous three months are not accepted to donate, even if they do not have another blood safety risk.

Post-Exposure Prophylaxis (PEP) has a similar mechanism of action to PrEP and may also interfere with testing results. In the UK PEP is prescribed to people who have been exposed to someone who may have HIV. This includes sexual activity or a needle stick injury. Donors who have received PEP will usually be ineligible to donate for the same reason they were given PEP. If the underlying reason for taking PrEP or PEP warrants a longer deferral period, this should be applied.

This guidance will be updated as more information about the use and effects of PrEP/PEP becomes available.

Reason for change: ~~New entry~~ This entry was revised to support the implementation of recommendations from the FAIR study.

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16.8. Proctitis

Please amend the following sections in this entry:

See if Relevant: ~~Homosexual and Bisexual Individuals~~
Inflammatory Bowel Disease
Malignancy
Sexually Transmitted Disease

Reason for change: ~~New entry~~ The 'see if relevant' section was updated as part of the implementation of recommendations from the FAIR study.

16.9. Sexually Transmitted Disease

Please amend the following sections in this entry:

1. Affected Individual

Obligatory: Refer to WBDSG entry for the condition.
~~See:~~
~~Is there is a specific A-Z index entry for the condition?~~

If there is no specific entry, must not donate if:
Less than ~~42~~ **three** months from completing treatment.

~~Discretionary: If other causes do not exclude and not on treatment, accept.~~

See if Relevant: Blood Safety Entry

For chlamydia (excluding Lymphogranuloma Venereum) see:
Infection – Acute

For genital warts see:
Warts

For genital herpes see:
Herpes Simplex

For syphilis see:
Syphilis

~~Additional Information: Certain sexually transmitted infections, such as syphilis and gonorrhoea, are more likely to be associated with other sexually transmitted infections that can be passed on through donation. For these, a 12 month deferral is required so that there is less risk of other infections being missed by the Blood Services and then being passed on to a recipient of donated material.~~

~~Reason for change: The links have been revised and 'Additional Information' has been added.~~

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2. Current or Former Sexual Partner of Affected Individual

Obligatory: ~~See: Is there is a specific A-Z index entry for the disease with which there has been contact?~~

Refer to WBDSG entry for the condition.

If there is no specific entry or the entry has no guidance on assessing sexual partners, must not donate if:

- a) The potential donor is undergoing, or waiting for, investigations.
- b) ~~a)~~ The potential donor required treatment and it is less than ~~12~~ **three** months since completing that treatment.
- c) ~~b)~~ The potential donor did not require treatment and it is less than ~~12~~ **three** months from the last sexual contact with the infected partner.

Discretionary:

- a) If the donor's sexual partner has been diagnosed with chlamydia, genital warts or genital herpes and the donor is not undergoing treatment or investigation, accept.
- b) If there is no WBDSG entry for the condition, or the entry has no guidance on assessing sexual partners, and it is more than three months since the donor's sexual partner completed treatment, accept.

See if Relevant: Blood Safety Entry

For chlamydia (excluding Lymphogranuloma Venereum) see:
Infection - Acute

For genital warts see:
Warts

For genital herpes see:
Herpes Simplex

For syphilis see:
Syphilis

Additional Information: ~~Certain sexually transmitted infections, such as syphilis and gonorrhoea, are more likely to be associated with other sexually transmitted infections that can be passed on through donation. For these, a 12 month deferral is required so that there is less risk of other infections being missed by the Blood Services and then being passed on to a recipient of donated material.~~

Information: ~~This entry is compliant with the Blood Safety and Quality Regulations 2005.~~

Reason for Change ~~There has been a modification to 'Obligatory' to improve clarity, the links have been revised and 'Additional Information' has been added.~~

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Additional Information: Certain sexually transmitted infections, such as gonorrhoea, are more likely to be associated with other sexually transmitted infections and/or blood borne viruses that can be passed on through blood and component donation. A three-month deferral is required so that there is less risk of other infections being missed by the Blood Services and then being passed on to a recipient of donated material.

Reason for change: This entry was updated to support the implementation of recommendations from the FAIR study; the deferral period after a sexually transmitted disease, or treatment after sexual contact with an infected person, has been reduced to three months.

A-Z index changes Please update the following entry in the A-Z index with a link to 'Sexually Transmitted Disease':

Lymphogranuloma Venereum

Please add the following entries in the A-Z index as links to 'Sexually Transmitted Disease'

LGV (infection)
MGEM (infection)
Mycoplasma genitalium

16.10. Syphilis

Please amend the following sections in this entry:

1. Affected Individual

Reason for change: See below

2. Current or Former Sexual Partner of Affected Individual

Obligatory: **Must not donate if:**
a) The potential donor ~~required treatment~~ was diagnosed with syphilis (See 1. Affected Individuals).
b) It is less than ~~12~~ **three** months since ~~last sexual contact with an~~ **the** infected partner. ~~has completed treatment.~~

Discretionary: a) If ~~the potential donor did not require treatment and~~ it is more than three months from the last sexual contact with ~~the~~ **an** infected partner, accept.
b) If ~~the potential donor did not require treatment and~~ it is more than ~~12~~ **three** months since the infected partner has completed treatment, accept.

Information: ~~This entry is compliant with the Blood Safety and Quality Regulations 2005.~~

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Reason for See below

Change:

Reason for This entry was updated to support the implementation of the recommendations from the FAIR study; the deferral period after sexual contact with an infected person, has been reduced to three months.
Change:

16.11. Transgender Individuals

Please amend the following sections in this entry:

Definitions **Cisgender (cis).** Someone whose gender identity is the same as the sex they were assigned at birth.

Transgender (trans) describes someone whose gender is not the same as, or does not sit comfortably with, the sex they were assigned at birth.

Obligatory: Assessment of the haemoglobin concentration should be according to the gender assigned on the day of donation.

Additional ~~A careful and sympathetic consideration of sexual risk factors needs to be undertaken. A man who has had his gender reassigned as a woman who, as a man, had not had high risk sexual activity, can be accepted if, as a woman, they have a sexual relationship with a man.~~
Information:

The higher haemoglobin concentration of men, compared to women, is related to testosterone levels. ~~As part of the gender reassignment process the sex hormone levels are changed so that a woman who becomes a man will receive testosterone.~~ Testosterone levels will rise if a person who was assigned female at birth receives hormone therapy as part of transitioning. This will result in the haemoglobin concentration rising to the higher range seen in cis men. The opposite will be true ~~if a man becomes a female~~ if a person who was assigned male at birth transitions.

For blood services that use leucocyte antibody screening as a TRALI risk reduction measure, donors who were assigned female at birth and have changed gender should be included.

Reason for change: ~~The title of this entry has been changed from 'sex change'.~~ This entry was revised to support the implementation of recommendations from the FAIR study; the additional information section has been revised.

16.12. Warts

Please amend the following sections in this entry:

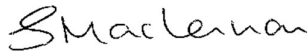
Additional Warts (including verruca) are caused by infection with the human papilloma virus (HPV) of which there are over 100 different types. They may occur on the skin and mucous membranes. The virus is spread by skin to skin contact and it can be very infectious. Genital warts are possibly the commonest sexually transmitted disease but they do not necessarily indicate high risk sexually activity, so no specific deferral is required. ~~It may however be sensible to discuss the possibility of high risk sexual activity if they have been recently acquired.~~
Information:

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Molluscum contagiosum is also caused by a virus and can be managed in the same way as warts.

Treatment may lead to unhealed wounds or sores and these pose a risk for bacteria entering the blood. Bacteria can be a serious threat to anybody receiving blood or blood components. This is because bacteria can multiply to dangerous levels after collection.

Reason for change: ~~This entry has been extensively rewritten to improve clarity.~~ This entry was revised to support the implementation of recommendations from the FAIR study; the instruction to discuss the possibility of high risk sexual activity has been removed.



Dr Sheila MacLennan
Professional Director - Joint UKBTS Professional Advisory Committee
☎ Direct Dial : (0113) 820 8638 ✉ sheila.maclennan@nhsbt.nhs.uk