Change Notification for the UK Blood Transfusion Services

Date of Issue: 15 November 2023 **Implementation:** to be determined by each Service

No. 17 - 2023

Changes arising from the FAIR III report

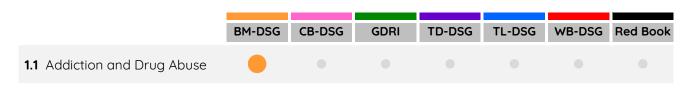
This notification includes the following changes:

	BM-DSG Bone Marrow & Peripheral Blood Stem Cell	CB-DSG	GDRI Geographical Disease Risk Index	TD-DSG Tissue - Deceased Donors	TL-DSG Tissue - Live Donors	WB-DSG Whole Blood & Components	Red Book Guidelines for the BTS in the UK
1 Addiction and Drug Abuse							
2 Chlamydia							
3 Herpes - Genital							
4 Homosexual and Bisexual Individuals				•			
5 Inoculation Injury							
6 Lesbian							
7 Lymphogranuloma Venereum							
8 Pre- and Post-Exposure Prophylaxis for HIV				•			
9 Prisons							
10 Sexually Transmitted Diseases							
11 Sex Worker							
12 Syphilis							
13 Tissues Safety Entry							
14 Transgender Individuals							
15 Warts							



Dr Stephen Thomas Professional Director of JPAC Changes are indicated using the following key

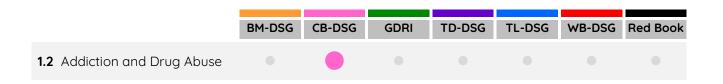
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Addiction and Drug Abuse

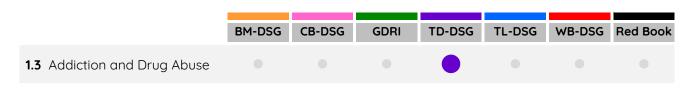
(revised entry)

Obligatory	Must not donate if:
	a) Has injected, or has been injected with drugs in the past 12 months
	b) Adversely affected by any drug, including alcohol, which may affect the process of obtaining valid consent.
	«c) Has injected, been injected with, or taken non-parenteral chemsex drugs in the past 3 months. Please see <u>Tissues Safety Entry</u> .»
Reason for Change	«Obligatory section updated as a part of the implementation of recommendations from the FAIR III report, including addition of chemsex drugs.»
	This entry was updated in line with the recommendations of the SaBTO Donor Selection Criteria Review Report published on 23rd July 2017.



Addiction and Drug Abuse

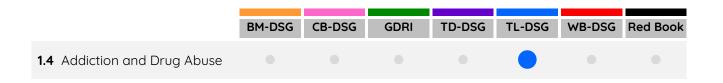
Obligatory	Must not donate if:
	a) The mother has injected, or been injected with drugs in the past 12 months.
	b) The mother is adversely affected by any drug, including alcohol, which may affect the process of obtaining valid consent.
	«c) The mother has injected, been injected with, or taken non-parenteral chemsex drugs in the past 3 months. Please see <u>Tissues Safety Entry</u> .»
Reason for Change	«Obligatory section updated as a part of the implementation of recommendations from the FAIR III report, including addition of chemsex drugs.»
	This entry was updated in line with the recommendations of the SaBTO Donor Selection Criteria Review Report published on 23rd July 2017.



Addiction and Drug Abuse

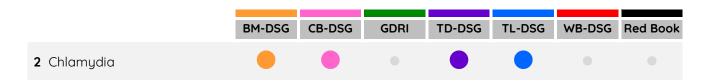
(revised entry)

Obligatory	Must not donate if:
	«a)» Has injected, or has been injected with drugs in the past 12 months. «b) Has injected, been injected with, or taken non-parenteral chemsex drugs in the past 3 months. Please see <u>Tissues Safety Entry</u> .»
Reason for Change	«Obligatory section updated as a part of the implementation of recommendations from the FAIR III report, including addition of chemsex drugs.»
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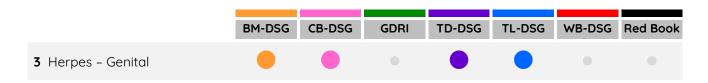
Addiction and Drug Abuse

Obligatory	Must not donate if:
	a) Has injected, or has been injected with drugs in the past 12 months
	b) Adversely affected by any drug, including alcohol, which may affect the process of obtaining valid consent.
	«c) Has injected, been injected with, or taken non-parenteral chemsex drugs in the past 3 months. Please see <u>Tissues Safety Entry</u> .»
Reason for Change	«Obligatory section updated as a part of the implementation of recommendations from the FAIR III report, including addition of chemsex drugs.»
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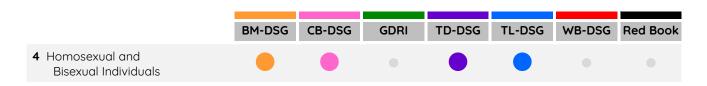
Chlamydia (revised entry)

See if Relevant	Lymphogranuloma Venereum «Sexually Transmitted Disease»
Reason for Change	«A link to 'Sexually Transmitted Disease' has been added and the link to 'Lymphogranuloma Venereum' has been removed.» A link to 'Lymphogranuloma Venereum' has been added.



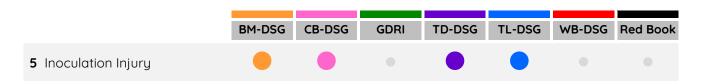
Herpes – Genital (revised entry)

«Additional information	There is no need to defer donors who have a sexual partner with Herpes if the donor themselves is asymptomatic.
Reason for change	Addition of 'Additional Information' section, to include clarification regarding sexual partners.»



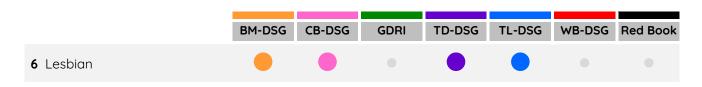
Homosexual and Bisexual Individuals

(this entry will be removed)



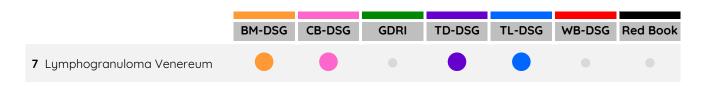
Inoculation injury

Definition	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.
Obligatory	Must not donate if:
	a) «The incident involved any» With material containing abnormal prions.
	b) Less than 3 months after the date of an inoculation injury, or contamination of mucosa or non-intact skin with blood or body fluids.
	«c) Under ongoing investigations following exposure – refer to DCSO»
See if Relevant	Animal bite
	« <u>Hepatitis</u>
	HIV
	<u>HTLV</u>
	Prion Associated Diseases
	<u>Tissues Safety Entry</u>
	<u>Xenotransplantation</u> »
Additional Information	«Human blood or body fluids may be contaminated with infective material such that the infection may then be passed on by donated material. Waiting three months (if validated tests for infectious markers that include HBV, HCV HIV NAT are negative) helps to ensure that any infection is not passed on.
	Donors who are under investigation may be accepted subject to individual risk assessment.»
	This guidance presumes that a validated NAT test for HIV, HBV and HCV is negative, if this test is stopped for any reason the guidance will change.
Reason for Change	«The 'Definitions' section was updated as part of the implementation of recommendations from the FAIR III report. Additional 'see if relevant' links added. 'Additional information' section updated.»
	This entry was updated in line with the recommendations of the SaBTO Donor Selection Criteria Review Report published on 23rd July 2017.



Lesbian

(this entry will be removed)



Lymphogranuloma Venereum

(this entry will be removed)

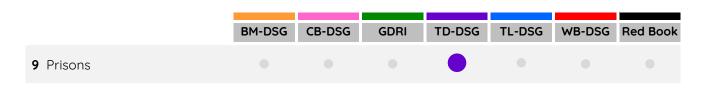
The following redirection will be added to the A-Z index:

Lymphogranuloma Venereum » Sexually Transmitted Disease



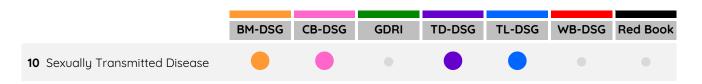
Pre- and Post-Exposure Prophylaxis for HIV

See if Relevant	Tissues Safety Entry HIV Homosexual and Bisexual Individuals Human Bite «Inoculation Injury»
Additional Information	The use of Pre-Exposure Prophylaxis (PrEP), e.g. Truvada®, to prevent HIV is increasing. «Individuals» <i>Patients</i> taking PrEP are unlikely to be eligible to donate due to «criteria within the» tissue safety «entry» <i>guidelines</i> . 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 tissue 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 through sexual activity or exposure through 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	«This entry was revised to support the implementation of recommendations from the FAIR III report.» This is a new entry.



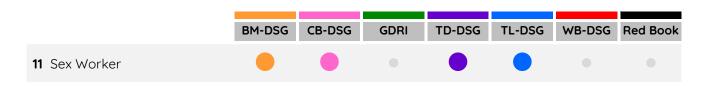
Prisons (revised entry)

See if Relevant	Addiction drug abuse Homosexual and bisexual individuals
Reason for Change	«Relevant entries have been updated.» An additional discretion has been added. Relevant other entries have been added. Additional information has been updated



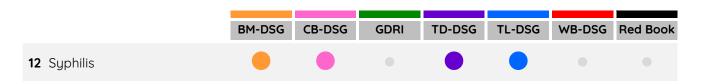
Sexually Transmitted Disease

Discretiona	If fully treated, at least three months from completion of treatment, accept. Additionally, for gonorrhoea, there must be evidence of a test of cure available after treatment «is required. This may be verbal confirmation, provided by the donor».	
Sexual Partner		
Discretiona	(a)» Donor did not require treatment and it is more than three months since the infected partner has completed treatment, accept.	
	«b)» Donor required treatment: if fully treated, and if it is at least three months from completion of treatment, accept.	
	Additionally, for gonorrhoea, there must be evidence of a test of cure available after treatment «is required. This may be verbal confirmation, provided by the donor.	
	c) If the donor's sexual partner has been diagnosed with chlamydia (except lymphogranuloma venereum, see (b) above), genital warts or genital herpes and the donor is asymptomatic and not undergoing treatment or investigation, accept.»	
«Additional Information	Guidelines (NICE, BASHH) recommend that current sexual partners of lymphogranuloma venereum (LGV) probable or confirmed individuals should receive testing and empiric treatment with a chlamydial regimen. They can be accepted 3 months after completion of treatment.»	
Reason for Change	«'Discretionary' section for 'sexual partner' updated following FAIR III report. Clarification added regarding test of cure for gonorrhoea. 'Additional Information' section added.»	
	The obligatory deferral period for infected individuals and sexual partners has been reduced to 3 months. For gonorrhoea, there is an additional proviso that a test of cure has been performed.	



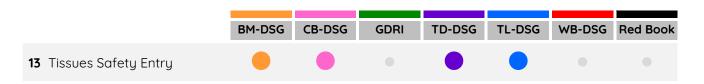
Sex Worker (revised entry)

See if Relevant	Addiction and Drug Abuse
	Homosexual and Bisexual Individuals
	Hepatitis of Viral Origin
	<u>HIV</u>
	<u>HTLV</u>
	Infection - General



Syphilis (revised entry)

Reason for Change	The 'Discretionary' entry has been modified.
	'Additional Information' has been added.
Current or Former Se	exual Partner of Affected Individual
Obligatory	Must not donate if:
	a) The potential donor «was diagnosed with syphilis (see 'Affected Individual' section above)» required treatment.
	b) The potential donor did not require treatment and It is less than «three» 12 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 3 months from the last sexual contact with «an» the infected partner accept.
	b) If the potential donor did not require treatment and it is more than «three» 12 months since «an» the infected partner has completed treatment, accept.
	c) If the potential donor did require treatment, refer to the 'Affected Individual' section above'
«See if Relevant	<u>Tissues Safety Entry</u> »
Reason for Change	A section covering 'Current or Former Sexual Partner of Affected Individual' has been added.
	This entry has been modified in line with the recommendations of the SaBTO Donor Selection Criteria Review Report published on 23rd July 2017.



Tissues Safety Entry

(revised entry)

«Definitions

Individual risk is based on the donor's sexual behaviour, including new partners and the number of partners in the 3 months prior to donation.

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

Information must be provided so that those at risk do not donate.

1. You must not donate if:

You think you need a test for HIV/AIDS, HTLV or hepatitis.

2. You must never donate if:

- a) You are HIV positive
- b) You are HTLV positive
- c) You are a hepatitis B carrier
- d) You are a hepatitis C carrier

3. You must not donate for at least 12 months:

After stopping habitual use of injected drugs of addiction.

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

- a) You have taken Pre-Exposure Prophlyaxis (PrEP) / Truvada for prevention of HIV
- b) You have taken or been prescribed Post-Exposure Prophylaxis (PEP) for prevention of HIV.

If the underlying reason for taking PrEP or PEP warrants a longer deferral period, this should be applied.

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

a) You have received money or drugs for sex

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- b) You have injected, or been injected with, non-prescription drugs, even only once. This includes, for example, bodybuilding drugs or injectable tanning agents. You may be able to donate if a doctor prescribed the drugs. Please ask.
- «c) You have injected, been injected with, or used non-parenteral Chemsex drugs.

6. Individual risk criteria (FAIR)

You must not donate for at least 3 months if:

- a) You have taken part in chemsex activity, including the use of stimulant drugs. This risk applies for all sexual contact.
- b) You have been diagnosed with gonorrhoea. You must wait for at least three months after you have successfully completed treatment and been discharged from further follow up.
- c) You have had more than one sexual partner in the last 3 months AND you have had anal sex with any of these partners.
- d) 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 in the last 3 months.

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.»

6a. For donors of tissues/cells other than haematopoietic progenitor cells, pancreatic islet cells or hepatocytes:

You must not donate for at least 3 months after sex (even if you used a condom or other protective) with:

a) (If you are a man): another man.

b) (If you are a woman): A man who has ever had oral or anal sex with another man, even if they used a condom or other protective.

6b. For donors of haematopoietic progenitor cells, pancreatic islet cells or hepatocytes:

There are no specific restrictions regarding donation after male-sex-withmale sexual contact, instead a documented individual risk/benefit donor assessment is required.

7. You must not donate for at least 3 months after sex (even if you used a condom or other protective) 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 received money or drugs for sex
- e) A partner who has injected, or been injected with non-prescription drugs. This includes, for example, bodybuilding drugs or «injected»

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injectable tanning agents. You may be able to give if a doctor prescribed
the drugs, please ask.

f) A partner who has been, 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. There are exceptions, so please ask.

See if Relevant

Addiction and Drug Abuse

«Hepatitis B»

«Hepatitis C»

Homosexual and Bisexual Individuals

Hepatitis of Viral Origin

HIV

HTLV

Infection - General

Pre- or Post-Exposure Prophylaxis for HIV

«Sexually Transmitted Disease»

«Syphilis»

Additional Information

The guidance has been changed in line with recommendations from the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO), 2017. The deferral period for men who have sex with men, sex with a person who has received money or drugs for sex, someone who has received money or drugs for sex, sex with a partner resident and sexually active in a high risk area, sex with a partner who was previously resident and sexually active in a high risk area for HIV/AIDS and who has not been screened, sex with a high risk partner (i.e. with HIV, HBC, HCV, syphilis, HTLV, person who has injected or been injected with non-medically prescribed drugs) has been reduced to 3 months. The deferral period for habitual drug users of injected drugs has been reduced to at least 12 months after stopping, and for users of non-addictive injected drugs (e.g body building drugs and injectable tanning agents) to at least 3 months after stopping.

This review considered advances in the sensitivity of testing procedures currently in use in the UK, the prevalence of transfusion transmissible infections and the level of compliance with the 12 month exclusion for those donors at higher risk of blood borne infections.

« The FAIR (For the Assessment of Individualised Risk) report (2020) recommended changes to blood donor selection policy to allow a more individualised risk-based approach. This approach was approved by ministers in devolved administrations and has now been implemented by the UK Transfusion Services.

The FAIR III working group recommended that a similar approach could be applied to tissue and cell donors in principle, acknowledging that the current donor selection policies already permit an individual risk assessment approach for life saving tissues and cells.

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.»

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 tissue and cell donors. For this reason, donors who have taken PrEP «or PEP» should not donate for three months, even if they «are otherwise eligible under individual risk criteria» have not had a sexual partner in a risk group.

For haematopoietic progenitor cells, pancreatic islet cells or hepatocytes there are no specific restrictions regarding donation after male-sex-withmale sexual contact. Instead, a documented individual risk/benefit donor assessment is required to allow donation.

The deferral periods specified above may be reduced by doing individual risk assessment if the risk of acquiring an infectious disease may be outweighed by the risk of delaying a lifesaving transplantation.

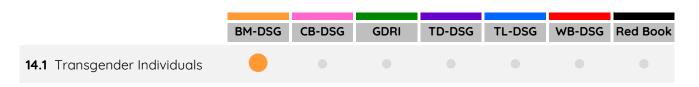
Reason for Change

«The entry was revised to include individual risk assessment of recent sexual behaviour for all donors. The deferral for donors whose sexual partners have been sexually active in Sub-Saharan Africa has been removed. This supports implementation of recommendations from the FAIR III Report.»

Addition of deferral period and additional information for donors who have used HIV PrEP or PEP.

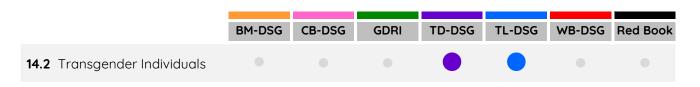
The following A-Z index entry will be created:

Chemsex » Tissues Safety Entry



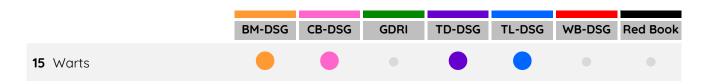
Transgender Individuals

«Definitions	Cisgender (cis) describes 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 donor suitability should be according to the gender assigned at the time of donation. See 'Additional Information' section.»
See if Relevant	Tissues Safety Entry
	Homosexual and bisexual individuals
	Surgery
Additional Information	«Consideration should be given to the medications used during gender reassignment. An individual risk assessment is required with regard to potential effects on the donor, donated material and any potential risk to the recipient.»
	A careful and sympathetic consideration of sexual risk factors needs to be undertaken. There is no specific restriction regarding donation for male-sex-with-male behaviour, but it should be documented to facilitate an in depth discussion should the donor be a potential match for a patient. This ensures that the current practice of individual risk/benefit assessment prior to donation is continued. The guidance has been changed in line with recommendations from the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO). The recommendations have been noted by the English Department of Health and the devolved authorities in Scotland, Wales and Northern Ireland.
	Assessment of haemoglobin concentration should be according to the gender assigned. The higher haemoglobin concentration of men, compared to women, is related to testosterone levels. «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 person who was assigned male at birth transitions.» As part of the gender reassignment process the sex hormone levels are changed so that a woman who becomes a man will receive testosterone. This will result in the haemoglobin concentration rising to the higher range seen in men. The opposite will be true if a man becomes a woman.
Reason for Change	«This entry was revised to support the implementation of the FAIR III report; the additional information section has been revised to reflect the circumstances of tissue and cell donations.»
	To change the title of the entry from 'Sex Change' to 'Transgender Individuals'. The discretionary section has been simplified.



Transgender Individuals

«Definitions	Cisgender (cis) describes 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 donor suitability should be according to the gender assigned «at the time of donation».
See if Relevant	Tissues Safety Entry
	Homosexual and bisexual individuals
Additional Information	A careful and sympathetic consideration of sexual risk factors needs to be undertaken. Men who have sex with other men have a higher chance of having an undiagnosed infection which could be passed to anyone receiving their blood, tissues or cells. Consideration should be given to the medications used during gender re-assignment. «An individual risk assessment is required with regard to potential effects on the donor, donated material and any potential risk to the recipient.»
Reason for Change	«This entry was revised to support the implementation of the FAIR III report; the additional information section has been revised to reflect the circumstances of tissue and cell donations.» To change the title of the entry from 'Sex Change' to 'Transgender Individuals' and simplify the contents.



Warts (revised entry)

«Additional Information	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. Molluscum contagiosum is also caused by a virus and can be managed in the same way as warts.
Reason for Change	'Additional Information' section added following FAIR III report.»