

Tissue Donors (Live) Donor Selection Guidelines (TL-DSG)

Edition 203 - 01 June 2007 Release 59 - 26 November 2024 Issue 01

Introduction

These guidelines form a constituent part of Chapter 20 (Tissue banking: selection of donors) of the <u>Guidelines for the Blood Transfusion Services in the United Kingdom</u>.

These criteria are reviewed regularly to ensure that the tissues obtained are of the highest quality and of sufficient quantity to meet the needs of recipients.

JPAC is responsible for this document and receives professional advice from the Standing Advisory Committees (SACs) that form part of its structure and from other relevant expert groups.

Users of these guidelines must ensure that they have the latest version and that recent changes have been implemented (usually within three months) by their national service.

<u>Latest Updates</u> lists alterations to the guidelines made since publication of this edition.

Comments about the content of these guidelines, including notification of errors, omissions and suggestions for improvements, should be sent to the Chair of SAC-Tissues and Cellular Therapy Products:

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Document and Change Control

These guidelines are under the continuing review of the Standing Advisory Committee for Tissues and Cellular Therapy Products (SACTCTP) and for Transfusion Transmitted Infection (SACTTI). This is to ensure that they are accurate and up to date. All changes have the approval of the Joint UKBTS Professional Advisory Committee (JPAC).

Change Notification.

A Change Notification Letter notifies changes to the **Medical Director** and the **Quality Manager** of each of the four national services. The **Professional Director of JPAC** is responsible for this notification. All changes will have the approval of the JPAC.

Implementation of changes is the responsibility of the individual Services.

Document version terminology.

A version shall be any of the following:

Extensive revisions of this document are known as 'Editions'.

Changes following the issue of 'Change Notification Letters' are known as 'Releases'.

Changes to the website, which do not involve a change to the medical or scientific content, are given an 'Issue' number.

Edition Date, Release Date and Issue Date is the date on which an Edition, Release or Issue is first published on the UKBTS website.

Changes to printed versions.

The **Quality Manager** of each Blood Service will effect changes to the document. They will be informed when a new electronic version is released. The **Quality Manager** is responsible for ensuring that there is an effective Document Control and Document Change procedure in operation within their Blood Service to ensure that only up to date versions are in use and that all authorized copies, both electronic and paper, are traceable.

Individual users of these guidelines are responsible for ensuring that they are using an up-to-date version.

Changes to the website versions.

The website will always display the up to date version. Any errors should be notified to JPACOffice@nhsbt.nhs.uk

General Principles

This document provides guidance for the selection of live donors of tissues. It must be read in conjunction with Chapter 20 of the Guidelines for the Blood Transfusion Services in the United Kingdom - 8th Edition, 2013, which lists the general, and some specific aspects of donor selection.

Donors are selected to ensure that their tissue is unlikely to harm any recipient. The ultimate responsibility for the selection of donors rests with the respective **National Medical Director**.

The immediate responsibility is with the **Qualified Healthcare Professional** who must ensure that the donor fulfills the respective selection guidelines. When it is not clear from these guidelines if an individual donation is acceptable, no tissue should be used without discussion with a **Designated Medical Officer**.

The prospective donor must be evaluated for their suitability to donate by a **Qualified Healthcare Professional** who has undergone appropriate training to use this document. They must verify their assessment by signing and dating the donation record.

Special note must be taken of the content of the Tissue Safety Entry in the A-Z.

It is the responsibility of the **Qualified Healthcare Professional** to ensure that relatives/partners clearly understand the nature of the donation process. Relatives/partners must also understand the health questions and other information presented to them. Relatives/partners are asked about confidential aspects of their relative's/partner's medical history, hence great care must be taken over privacy and confidentiality. This means that third party interpreters can only be used, as described in the **A-Z** entry on **Communication Difficulties**.

Where there is separate guidance for different tissues this is made clear.

When there is a recognized risk to the recipient, the guidelines must be followed.

The following terms may be used:

Including

Lists any other terms which may be covered by the Guideline.

Definition

Where additional clarity is required, a definition is provided.

Obligatory

This will indicate how the donor **must** be dealt with by the use of several terms:

Must not donate

The donor **must** not donate if any of the statements apply to them, **unless** a 'discretion' clearly applies. Often the exclusion will depend on time related factors. If a donation cannot be taken, relatives/partners **must** be clearly advised why.

Refer to Designated Medical Officer

Is used when there is a need to seek further advice. The **Designated Medical Officer** is a suitably trained person authorized to undertake this task by the **National Medical Director**.

Discretionary

Gives reasons why a donor may be permitted to donate. The statements are conditional. All statements that **must** be fulfilled come before the final statement that they may be accepted. If the donor fulfils these requirements, as well as all others that apply, then they can be accepted.

See if relevant

Is used when an **A-Z** entry may or may not need to be consulted. This will depend upon the information provided by the donor's relatives/partner.

Additional Information

This provides background information as to why a particular action or actions is required.

See

Means that the specified A-Z entry must be consulted.

Reason for Change

This indicates the background to any changes made to the entry since the last Edition or Release

Some or all of these terms may be used under each subject heading or sub-heading.

This section was last updated in TDSG-LD Edition 203, Release 02, Issue 01.

Medication

The underlying illness suffered by a donor, rather than the properties of any drug they have taken, is the usual reason for them not being eligible to donate.

In general, traces of drugs in tissues are harmless to their recipients. However, donors treated with certain drugs are deferred for periods associated with the pharmacokinetic properties of the drug. Examples are some drugs used to treat acne, psoriasis and some prostate problems. All such drugs have their own entry in the **A-Z** section.

This section was last updated in TDSG-LD Edition 203, Release 02, Issue 01.

Use of Alphabetical Listing (A-Z)

Any medical condition, or possible contraindication to donation, elicited at any point during donation processing or storage, must be managed according to the **A-Z** section of these guidelines. Any donated tissue, which, as a result, is unsuitable for clinical use, **must** be clearly labelled as unfit for use.

Any new health risks identified by this process should be notified to the Standing Advisory Committee on Tissues and Cellular Therapy Products, so they can be considered for incorporation into future revisions of these guidelines.

If late information is provided by the relatives/partner, or through any other source, that the donor was medically unfit, this must be recorded and reported to the **Designated Medical Officer**.

Donations must not be accepted from donors who exhibit health risks that are not listed in this guidance, without referral to, and acceptance by, the Designated Medical Officer.

This section was last updated in TDSG-LD Edition 203, Release 02, Issue 01.

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Achondroplasia

Obligatory Bone, structural:

Must not donate.

Discretionary Bone, non-structural:

Accept.

Additional Information People with achondroplasia have abnormal structural bone. This may not be suitable for

grafting.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

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 Tissues Safety Entry.

Discretionary

a) Accept if has not injected or been injected with other non-prescription drugs (other than drugs of addiction), such as bodybuilding drugs or injectable tanning agent within the past 3 months.

- b) Accept if has not injected or been injected with drugs of addiction within the last 12 months
- c) If has not injected or been injected with drugs of addiction within the last 3 months **refer to designated medical officer.** The donor may be accepted with individual risk assessment. See additional information section
- d) May be acceptable if injected drugs were prescribed by the donor's physician for a condition that would not lead to exclusion.
- e) Previous use of non-parenteral drugs does not necessarily require exclusion.

See if Relevant Tissues Safety Entry

Additional Information

Injecting drugs has been linked with the passing on of many infections, including hepatitis and HIV. It can be many years before any infection shows itself. Former drug users often do not realize that they can still pass infection on to others many years after they last used drugs themselves. 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. 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

Anyone obviously affected by alcohol or other drugs that can affect the mind, cannot give valid consent or fully understand why they are being asked certain questions.

Reason for Change

Obligatory section updated as a part of the implementation of recommendations from the FAIR III report, including addition of chemsex drugs.

Update Information

This entry was last updated in TDSG-LD Edition 203, Release 55

African Trypanosomiasis

(Sleeping Sickness)

Obligatory Must not donate.

Update Information This entry was last updated in TDSG-LD Edition 203, Release 02

Age

Obligatory Must not donate if:

Under seventeen years of age.

Discretionary Bone, non-structural:

Accept at any age over seventeen.

Additional Information Surgical bone is not processed for structural (weight bearing) use so an upper age limit is

not required.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Alcoholism

Discretionary Accept.

See if Relevant Cirrhosis

See Addiction and Drug Abuse

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Allergy

Discretionary Accept.

See if Relevant Steroid Therapy

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Anaemia

Discretionary 1. History of anaemia:

This must be assessed regarding its cause, current status and what treatment has been

received.

2. Iron deficiency:

If not under investigation or on treatment and the underlying cause is not a reason to

exclude, accept.

3. Other types:

Accept or exclude according to the guidelines.

4. In other cases:

Refer to a Designated Medical Officer.

See if Relevant Haemoglobin Disorders

Haemolytic Anaemia

Malignancy

If treated with blood components or products or by plasma exchange or filtration:

Transfusion

Additional Information People with severe long-standing anaemia may have abnormal structural bone. This may

not be suitable for grafting.

There are special rules for people who have received blood components or blood products.

Update Information

This entry was last updated in TDSG-LD Edition 203, Release 02

Animal Bite

(Non-Human)

Obligatory Must not donate if:

a) Ever bitten by a non-human primate.

b) Any wound is infected or not healed.

c) Less than 24 months since bitten anywhere in the world by a bat or by any other mammal outside of the British Isles.

See if Relevant

Human Bite Infection - General Rabies Immunization

Additional Information

Being bitten by a non-human primate should result in permanent deferral. Risks include simian T-lymphotropic virus, Herpes B, simian foamy virus and other as yet unknown viruses. Non-human primates include chimpanzees, gorillas, orangutans, gibbons, monkeys (old and new world), tarsiers, lemurs and lorises.

Animal bites may result in many different infections. Allowing all wounds to heal and for any obvious infection to have resolved should avoid problems. Rabies, and similar diseases, have long incubation periods and do not show as a wound infection. There is no evidence that these infections have ever been transmitted through a blood transfusion. These diseases appear to be confined to the nervous system during their incubation periods. There is evidence that they have been transmitted through organ, tissue and ocular transplants. For this reason there are different rules for material that may contain nervous system tissue.

Anyone who has been in unusual contact with a bat, such as handling a sick or injured bat, or woken to find that a bat has been with them while asleep, should be considered at risk of rabies. Bat bites are usually insignificant and easily overlooked. Merely being in a place where bats roost is not considered a risk.

Reason for Change

To extend the deferral period following being bitten by a bat or other mammal outside of the UK from 12 to 24 months, and to provide more information on the potential risks resulting from non-human primate bites. To provide a detailed definition of a non-human primate.

Update Information

This entry was last updated in TDSG-LD Edition 203, Release 40

Ankylosing Spondylitis

Discretionary Accept.

See Autoimmune Disease

Reason for Change A link to 'Autoimmune Disease' has been added.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Anthrax

Exposure

Discretionary Even if on prophylactic antibiotics, accept.

Additional Information

Anthrax infection most commonly affects the skin through direct contact with infected material such as animal hides. If spores have been inhaled there is no evidence that there is any spread to the bloodstream until the person has developed signs of infection. For this reason it is considered safe to accept exposed donors provided they have not shown signs of infection, even if they have been given prophylactic antibiotics.

Immunization

See Immunization - Non-Live

Infection

See Infection - Acute

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Antibiotic Therapy

Additional Information Treatment with antibiotics is not of itself a reason for deferral but the reason for the

treatment may be. When treatment is being given to prevent infection, rather than to treat it,

see if there is a relevant entry. If not, discuss with a **Designated Medical Officer**.

See Infection - General

Reason for Change Additional Information' has been added for clarity.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Arthritis

See if Relevant Ankylosing Spondylitis

Autoimmune Disease

Osteoarthritis Psoriasis

Rheumatoid Arthritis

Reason for Change A link has been added for 'Autoimmune Disease'.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Asthma

Obligatory Must not donate if:

Taking, or has completed, oral or parenteral steroids within the last seven days.

See if Relevant Infection - General

Steroid Therapy

Additional Information Steroid therapy can hide the signs and symptoms of infection. Tissue from an infected donor

could be dangerous to the person receiving them.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Autoimmune Disease

Obligatory See:

Is there an entry for the condition?

Must not donate if:

The donor has needed treatment to suppress the condition in the last 12 months.

See if Relevant If treated with immunoglobulin or plasma exchange or filtration:

Transfusion

Additional Information Treatment to suppress the condition may be with steroids, immunosuppressive drugs,

antimetabolites, antibodies directed against parts of the immune system as well as other therapies. These will affect the donor's immune system. This may make the donor more susceptible to certain types of infection and also will make some infections more difficult to

diagnose.

Autoimmune disease is caused by the body attacking itself. This is with antibodies that are in the fluid part of the blood (plasma), and with immune cells directly attacking target cells in

the part/s of the body affected.

Reason for Change Additional Information has been added to clarify treatment that may have been used to

suppress the condition.

Update Information Part of this advice is a requirement of the EU Tissue & Cells Directive.

This entry was last updated in TDSG-LD Edition 203, Release 02

Avascular Necrosis of the Femoral Head (Hip)

Obligatory Must not donate:

Affected femoral heads.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Babesiosis

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Basal Cell Carcinoma

Obligatory Must not donate if:

a) Still receiving treatment.

b) Any wound has not healed.

spread by the blood stream it is not a risk to people receiving donated material.

An unhealed wound is a risk for bacteria entering the blood. Bacteria can be a serious threat

to anybody receiving donated material. This is because the bacteria can multiply to

dangerous levels.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

BCG

Obligatory Must not donate if:

a) The inoculation site has not yet healed.

b) Less than four weeks after inoculation.

Additional Information BCG is an immunization with live bacteria. By four weeks, the infection caused by the

inoculation should have been controlled. If the wound has not healed it is possible that there may still be infection present. We do not want to pass BCG, or other infections, on to people

receiving donated material.

Reason for Change Advice has been given from SACTTI that a period of four weeks is sufficient to ensure that

there would be no circulating virus or bacteria at time of donation for live immunizations

other than smallpox.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 08

Bleeding Disorder

Includes Carriers

Affected Individual

Obligatory Must not donate if:

Treated with blood derived coagulation factor concentrates.

See if Relevant Transfusion

Additional Information People who have received blood derived coagulation concentrates (these are made from the blood of many hundreds of individual donors) may have been put

at risk of infections that can be passed through donations.

Reason for Change A link to 'Transfusion' has been added.

Family Members, Carers and Sexual Partners of Individuals Treated with Blood Derived Coagulation Factor Concentrates

Obligatory Must not donate if:

a) Treated with blood derived coagulation factor concentrates.

b) A sexual partner, or former sexual partner, of a person treated with blood derived coagulation factor concentrates.

c) Less than 3 months after the date of an inoculation injury with either blood derived coagulation factor concentrates, or from blood contamination from an affected individual.

Discretionary If 3 months or more from last sexual contact or inoculation injury, accept.

See if Relevant Inoculation Injury

Transfusion

Additional Information Blood derived coagulation concentrates:

These are made from the blood of many donors. They may put recipients at risk of infections that can be passed through blood. This risk may be shared by their

sexual partners.

Waiting 3 months from the last sexual contact or inoculation injury helps to ensure that the infections tested for by the Blood & Tissues Services will be picked up.

Reason for Change This entry was updated in line with the recommendations of the SaBTO Donor

Selection Criteria Review Report published on 23rd July 2017.

Update Information

Blood Pressure - High

Discretionary Ace

Accept.

Update Information

This entry was last updated in TDSG-LD Edition 203, Release 02

Body Piercing

Includes

Derma-rolling, ear and body piercing, permanent and semi-permanent makeup, tattooing (including memorial tattoos), platelet rich plasma (PRP) facials and ritual self-flagellation.

Obligatory

Must not donate if:

Less than 3 months after last piercing.

Discretionary

Piercings performed within the UK in a commercial setting: Accept

Piercings performed outside the UK or within the UK in an unlicensed non-commercial premises more than 3 months ago: Accept

Painting, stencilling or transfers applied to the skin without piercing: Accept

Additional Information

Under all current legislation it is a criminal offence to trade without registration (licensing) or to be in breach of the relevant byelaws. Similar provisions are in place in Scotland in the Civic Government (Scotland) Act 1982 (Licensing of Skin Piercing and Tattooing) Order 2006. Some London boroughs also require a 'special treatment' license. It is expected that all premises will follow infection control processes including using single needles for treatments.

In the UK local authorities are responsible for regulating and monitoring businesses providing semi-permanent skin colouring procedures (micropigmentation, semi-permanent make-up and temporary tattooing). The focus of legislation covering local authorities in England, Wales and Northern Ireland (Local Government (Miscellaneous Provisions) Act 1982) is on minimising infection risks using compulsory registration of practitioners and premises and optional powers to make byelaws.

For piercings performed outside the UK or within the UK in an unlicensed, non-commercial establishment less than 3 months ago, the donor may only be accepted following documented individual risk assessment and discussion with the transplant centre if the risk of delaying transplant outweighs the risk of transmission of infections.

Piercing has passed infection from person to person. Waiting 3 months helps to ensure that the infections tested for by the Blood & Tissues Services will be picked up.

Platelet rich plasma (PRP) facials (also known as 'Vampire Facials') have been associated with HIV transmission.

Ritual self-flagellation is carried out by some religious groups. The practice includes beating or flogging oneself with sharp objects. It may be associated with exposure to blood from other participants, either directly or through contamination of shared equipment.

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

To add Derma-rolling, ear and body piercing, tattooing (including memorial tattoos), platelet rich plasma (PRP) facials and ritual self-flagellation to the entry and to add information regarding PRP facials and ritual self-flagellation.

Update Information

This entry was last updated in TDSG-LD Edition 203, Release 46.

Breast Lump

Obligatory Must not donate if:

a) Malignant.

b) Not fully investigated and cleared of malignancy.

See if Relevant Malignancy

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 34

Bronchitis

Acute

See Infection - Acute

Chronic

See if Relevant Infection - General

Steroid Therapy

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Brucellosis

Undulant Fever

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Cardiac Surgery

See if Relevant Cardiovascular Disease

Endocarditis Transfusion

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 34

Cardiomyopathy

Obligatory Must not donate if:

a) Not recovered from infective causes.

b) cardiomyopathy secondary to an infiltrative process e.g. amyloidosis, sarcoidosis.

Reason for Change The entry has been changed to make it clear that cardiomyopathy is not an absolute

contraindication to donation of cardiovascular tissues.

Update Information This entry was last updated in TDSG-LD Edition 203, Release 27

Cardiovascular Disease

See if Relevant Cardiomyopathy

Endocarditis Myocarditis

Reason for Change Additional links have been added.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Catarrh

Acute

See Infection - Acute

Chronic

See if Relevant Infection - General

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Central Nervous System Disease

Obligatory Must not donate if:

a) Dementia.

b) History of CNS disease of unknown or suspected infective origin (e.g. multiple sclerosis (MS), optic neuritis, clinically isolated syndrome, transverse myelitis, Creutzfeldt-Jakob disease (CJD)).

c) Neurodegenerative conditions of unknown aetiology (e.g. Parkinson's disease).

Discretionary a) Individuals who have had Bell's palsy more than four weeks ago and have discontinued

any treatment for the condition for at least seven days, even if they have residual paralysis,

accept.

b) If a definite diagnosis of transient global amnesia has been made, accept.

c) If the cause of the disease is not established, refer to designated medical officer

See if Relevant Neurosurgery

Prion Associated Diseases

Rabies

Additional Information Often the exact cause of a degenerative brain condition only becomes known after death.

For this reason, when there is any doubt as to the underlying cause of a brain condition, it is considered safest not to accept a donation. It is thought that degenerative brain disease in

the form of vCJD has been transmitted by blood transfusion.

Transient global amnesia is a temporary and isolated disorder of memory. Affected individuals are usually over 50 years of age and there is an association with migraine. There

is no association with cerebrovascular disease.

Reason for Change To clarify that CNS disease of unknown origin, and clinically isolated syndrome, are reasons

for obligatory deferral and to permit individual risk assessment where appropriate.

Update Information This is a requirement of the EU Tissue & Cells Directive.

This entry was last updated in TDSG-LD Edition 203, Release 31

Cervical Dysplasia

Obligatory

Must not donate if:

- a) Undergoing investigation or treatment.
- b) Diagnosed with invasive cervical carcinoma.

Discretionary

a) If the donor had colposcopy treatment for abnormal cervical cells and has been discharged to routine screening, accept. It is not necessary to wait for a normal smear result before donating.

b) If only having regular review of smears, accept.

Additional Information

Cervical screening includes testing for high risk Human Papilloma Virus (HR-HPV). Women who are positive for HR-HPV may be called for routine smear tests at more frequent intervals. They can donate provided they are not undergoing other tests or awaiting colposcopy investigation.

Women with abnormal cells on a smear test are triaged according to their risk of developing cervical carcinoma. Women at higher risk will be referred for investigation and treatment via colposcopy.

Abnormalities identified at colposcopy include cervical intra epithelial neoplasia (CIN, Grades 1-3) and cervical glandular intra epithelial neoplasia (CGIN). CIN-3 is also known as cervical carcinoma in situ. By definition, patients with CIN or CGIN do not have invasive cervical carcinoma, so can be accepted once treated, fully healed and discharged. There is no need to wait for the results of their next routine smear, usually at 6 months post treatment, unless the donor has been advised that follow up will be necessary at the colposcopy clinic.

Reason for Change

Updated to clarify the scope of entry, when a donor can be accepted after treatment for cervical dysplasia and the significance of HR-HPV testing.

Update Information

This entry was last updated in TDSG-LD Edition 203, Release 46.

Chagas' Disease

South American Trypanosomiasis

Obligatory Must not donate.

See if Relevant South American Trypanosomiasis Risk

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Chicken Pox

Contact

See Infectious Diseases - Contact with

Herpes Zoster (Varicella Zoster)

See Infection - Acute

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Chondromalacia

Discretionary Accept.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Cirrhosis

Obligatory Must not donate if:

a) Complicated by hepatoma.

b) Infectious or autoimmune cause.

Discretionary If secondary to alcohol or genetic cause, accept.

See if Relevant Alcoholism

Autoimmune Disease

Malignancy

Reason for Change Additional links have been added.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Clinical Trials

Obligatory Must not donate if:

Participating in a clinical trial. This includes the use of drugs of any kind (oral, parenteral, transcutaneous, etc.) and applies to healthy individuals participating as volunteers - for

example in 'phase 1' clinical trials.

Discretionary If a **Designated Medical Officer** has examined and agreed the trial protocol, accept.

See if Relevant Complementary Therapy

Transfusion

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Coeliac Disease

Discretionary Accept.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Colostomy

Obligatory Must not donate if:

For malignancy or inflammatory bowel disease.

Discretionary If the reason for the colostomy is not of itself a reason to exclude and the stoma is healthy,

accept.

Update Information

This entry was last updated in TDSG-LD Edition 203, Release 34

Communication Difficulties

Obligatory

1. All donors must:

- a) Fully understand the donation process.
- b) Give their informed consent to the process and to the testing of their blood for diseases that may affect its suitability for use.

2. Third party interpreters:

If they are to be present at any part of the selection procedure where there is an exchange of confidential information between the donor and the qualified health professional, they

- a) Understand the importance of providing an accurate and truthful translation of the information provided, to enable the tissue/cell establishment to comply with regulatory requirements
- b) Not be personally known to the donor.
- c) Fully understand their duty of confidentiality and the confidential nature of any information obtained from the donor

See if Relevant

Disabled Donor

Additional Information

The Services are aware of their duties under Race Relations and Disability Discrimination Legislation and will, whenever and wherever reasonable, try to provide facilities for individuals whose first language is not English, or who have other difficulties in communicating. **Every donor must:**

- a) Complete a health and medical history questionnaire and undergo a personal interview performed by a health professional.
- b) Provide informed consent to proceed with the donation process. This consent must be given in the presence of the qualified health professional responsible for obtaining the health history. The qualified health professional may be physically present or in communication with the donor by telephone

A qualified health professional may assist a donor in the completion of the health and medical history questionnaire and in understanding the consent statement and any other information provided by the Blood/Tissue Service. To facilitate comprehension it is permissible to use alternative formats (e.g. a language other than English, audio, computer, Braille) for the donor information leaflets, the health and medical history questionnaire and consent statements. The donor must be able to clearly demonstrate they have understood this material. At present there is no standardized way of assessing comprehension so this will be a personal judgement made by the qualified health professional.

Use of third party interpreters.

It is permissible for any third party to act as an enabler by helping to reassure the donor and to assist in establishing effective communication between the donor and the qualified health professional. The third party **must not** however be present during any exchange of confidential information, unless they are **not** personally known to the donor and understand the need to accurately and truthfully communicate all the information, including personal and confidential information, provided by the person giving consent. Confidential parts of the process include the evaluation of the health and medical history questionnaire, the medical interview and the obtaining of valid consent.

Rationale.

There is concern that the use of third parties during any exchange of confidential information between the donor and the qualified health professional may compromise the confidentiality of the donor and the safety of the blood supply. Interpreters are often part of a close community, or a family member, and this may inhibit or embarrass the potential donor in any confidential exchange of information. This may result in the non-disclosure of sensitive information that could affect the individual's eligibility to donate. If a third party is not fully aware of the need to accurately and truthfully communicate all the information, including personal and confidential information, provided by the person giving consent, this may make the interpretation of information incomplete and potentially put both the donor and any donated tissue at risk. There is also a requirement to communicate the results of any testing

performed by the Blood/Tissue Services that may be of relevance to the donor's health in a way that protects their confidentiality. The continuing availability of an independent interpreter, to maintain donor confidentiality, should be taken into account when deciding if an individual donor may be accepted.

Reason for Change

- 1. To clarify that interpreters and translators do not need to understand all the regulatory requirements of the Human Tissue Act, but are aware of the importance of providing a truthful and accurate translation to enable the tissue/cell establishment to comply with regulatory requirements
- 2. To clarify that interpreters and translators have a duty of confidentiality
- 3. To clarify that consent for donation need not be signed by the donor, it can be taken by telephone

Update Information

This entry was last updated in TDSG-LD Edition 203, Release 20

Complementary Therapy

Obligatory

1. Must not donate if:

The condition for which treatment was given is not acceptable.

2. Therapies involving penetration by needles or other invasive procedures:

Must not donate if:

Less than 3 months from completing treatment

Discretionary

- a) If oral or topical complementary medicines only and reason for which treatment was given is acceptable, accept
- b) For all other therapies involving penetration by needles or other invasive procedures:

1. Performed within the NHS

If performed by a suitably qualified NHS healthcare professional on NHS premises, accept.

2. Performed outside of the NHS

2a) If performed by a Qualified Health Care Professional registered with the General Medical Council (GMC), Nursing and Midwifery Council (NMC), General Dental Council (GDC), The General Chiropractic Council (GCC), The General Optical Council (GOC), The General Osteopathic Council (GOsC), General Pharmaceutical Council (GPhC), Pharmaceutical Society of Northern Ireland (PSNI), or The Health and Care Professions Council (HCPC) (which regulates: Arts therapists, Biomedical Scientists, Chiropodists/Podiatrists, Clinical Scientists, Dieticians, Hearing Aid Dispensers, Occupational Therapists, Operating Department Practitioners, Orthoptists, Paramedics, Practitioner Psychologists, Physiotherapists, Prosthetists and Orthotists, Radiographers, Speech and Language Therapists), accept.

- 2b) Treatments performed within commercial premises in the UK: Accept.
- 2c) If performed within unlicensed, non-commercial premises in the UK, or for any treatment performed outside the UK more than 3 months ago: Accept.

Additional Information

Equipment that has been reused has passed infection from person to person. Therapists who are subject to discipline from statutorily constituted professional authorities are unlikely to re-use needles.

Commercial premises may be based in shops and clinics and also include operators running an acupuncture business from a residential premise such as their own homes. Under all current legislation it is a criminal offence to trade as an acupuncturist without registration (licensing) or to be in breach of the relevant byelaws. Similar provisions are in place in Scotland in the Civic Government (Scotland) Act 1982 (Licensing of Skin Piercing and Tattooing) Order 2006. Some London boroughs also require a 'special treatment' license. It is expected that all premises will follow infection control processes including using single needles for treatments.

In the UK local authorities are responsible for regulating and monitoring businesses providing tattooing, cosmetic piercings, semi-permanent skin colouring (micropigmentation, semi-permanent make-up and temporary tattooing), electrolysis and acupuncture. The focus of legislation covering local authorities in England, Wales and Northern Ireland (Local Government (Miscellaneous Provisions) Act 1982) is on minimising infection risks using compulsory registration of practitioners and premises and optional powers to make byelaws.

Healthcare professionals registered with statutory body may not need to register with the local authority as their statutory body is responsible for their regulation.

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.

When there is any doubt about infection being passed on, waiting 3 months means infections are more likely to be picked up by the tests used by Blood & Tissue Services.

Reason for Change The regulatory organisations for Pharmacists in the UK have been added.

The HCPC ceased to be the regulatory authority for Social Workers in England in 2019. The

list of health and care professionals regulated by the HCPC has been amended.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 61.

Congo Fever

Obligatory Must not donate if:

Less than twelve months following recovery or from return to the UK, if occurred abroad.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Contraceptive Implant

Discretionary Accept.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 34

Contraceptive Injection

Discretionary Accept.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Contraceptive Pill

Discretionary Accept.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Corneal Transplant

Obligatory Must not donate.

See if Relevant Prion Associated Diseases

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Coronary Thrombosis

Includes Heart Attack

Myocardial Infarct

Discretionary Accept.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Coronavirus Infection (COVID-19)

Includes COVID-19 disease (due to infection with SARS-CoV-2 virus, previously known as Novel

Coronavirus or 2019-nCoV).

1. Person with confirmed symptomatic COVID-19

Obligatory Must not donate if less than 7 days since resolution of symptoms

Discretionary If more than 7 days have passed since resolution of symptoms, and the donor

remains well, accept.

2. Person with confirmed SARS-CoV-2 without symptoms

Obligatory Must not donate if less than 7 days since confirmation of infection by positive

results in a diagnostic test.

Discretionary If more than 7 days have passed since confirmation of infection by positive

results in a diagnostic test, accept.

See additional information.

3. Person with suspected COVID-19

Obligatory Must not donate if less than 14 days since resolution of symptoms.

Discretionary a) If testing was not performed:

- If more than 14 days have passed since resolution of symptoms, and the donor remains well, accept.
- If more than 7 days but less than 14 days, See Infection Acute entry.

OR

b) If testing was performed, and COVID-19 has been ruled out as a clinical diagnosis, see Infection - Acute entry.

See if Relevant

Coronavirus Vaccination
Infection - Acute
Contact with Infectious Diseases

Additional Information

Common coronaviruses cause colds and respiratory tract infections but are not considered a risk for tissue transplant recipients. Since 2002 there have been outbreaks in humans of new strains of coronavirus, associated with severe pulmonary infections and mortality rates of 10-35% e.g. SARS and MERS.

COVID-19 is an illness characterised by respiratory symptoms, including coughing and breathlessness, and fever. It is caused by infection with a newly identified Coronavirus, SARS-CoV-2. Its full pathogenesis remains unknown but individuals with certain underlying chronic conditions, the elderly and immunocompromised individuals are at risk of more severe disease.

Some persons with SARS-CoV-2 infection may be asymptomatic. It is possible that they may have undergone testing for occupational health reasons (for example). Routine screening of living asymptomatic tissue/cell donors is not necessary. They are likely to have been screened before hospital admission for a planned procedure as per hospital policy.

There is no evidence at present that SARS-CoV-2 can be transmitted by tissue/ cell transplantation and therefore these measures are considered to be precautionary.

Post Donation Illness Donors must be provided with information about contacting the tissue establishment if they

develop any illness within 14 days after donation.

Reason for Change Delete outdated information in the definition section, and 'additional information' section.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 56

Deep Vein Thrombosis

Discretionary If the underlying cause does not exclude, accept.

See if Relevant Malignancy

Update Information This entry was last updated in TDSG-LD Edition 203, Release 02

Dementia

Obligatory Must not donate.

Update Information This is a requirement of the EU Tissue & Cells Directive.

This entry was last updated in TDSG-LD Edition 203, Release 02

Dermatitis

See if Relevant Infection - General

Steroid Therapy

Reason for Change To add a link to Alitretinoin.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 17

Diabetes Insipidus

Discretionary If the underlying cause does not exclude, accept.

See if Relevant Neurosurgery

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Diabetes Mellitus

Discretionary Accept.

See if Relevant Infection - General

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Diarrhoea

Includes D & V

Entero-colitis Food Poisoning Gastric Flu Gastro-enteritis

Obligatory Must not donate if:

a) Chronic or associated with inflammatory bowel disease.

b) Less than two weeks since full recovery.

See if Relevant Infection - General

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Disabled Donor

Obligatory 1. All donors must:

a) Fully understand the donation process

b) Give their informed consent to the process and to the testing of their blood for diseases that may affect the suitability of their tissues for use

2. Third party interpreters:

If they are to be present at any part of the selection procedure were there is an exchange of confidential information between the donor and the qualified health professional, they must:
a) Understand the requirements of the Human Tissue Act (HTA) relevant to the donation process

b) Not be personally known to the donor.

Discretionary Donors with difficulty in reading:

Ensure by questioning the donor that they:

a) Understand and fully complete the tick-box questionnaire

b) Give valid consent to donation and to the testing of their blood for diseases that may

affect its suitability for use.

See if Relevant Spina Bifida

Additional Information The Services are aware of their duties under Disability Discrimination Legislation and will,

whenever and wherever reasonable, try to provide facilities for disabled individuals. Every

donor must:

be provided with accurate educational materials, which are written in terms which can be

understood by members of the general public

complete a health and medical history questionnaire and undergo a personal interview performed by a health professional

provide written informed consent to proceed with the donation process which must be countersigned by the qualified health professional responsible for obtaining the health history.

A qualified health professional may assist a donor in the completion of the health and medical history questionnaire and in understanding the consent statement and any other information provided by the Service. To facilitate comprehension it is permissible to use alternative formats (e.g. audio, Braille, computer or alternative language) for the donor information leaflets, the health and medical history questionnaire and consent statements. The donor must be able to clearly demonstrate they have understood this material. At present there is no standardized way of assessing comprehension so this will be a personal judgement made by the qualified health professional.

Use of third party interpreters.

It is permissible for any third party to act as an enabler by helping to reassure the donor and to assist in establishing effective communication between the donor and the qualified health professional. The third party **must not** however be present during any exchange of confidential information, unless they are **not** personally known to the donor and understand the requirements of that part of the HTA relevant to the donation process. Confidential parts of the process include the evaluation of the health and medical history questionnaire, the medical interview and the obtaining of valid consent.

Rationale.

There is concern that the use of third parties during any exchange of confidential information between the donor and the qualified health professional may compromise the confidentiality of the donor and the safety of the donation. Interpreters are often part of a close community, or a family member, and this may inhibit or embarrass the potential donor in any confidential exchange of information. This may result in the non-disclosure of sensitive information that could affect the individual's eligibility to donate. If a third party is not fully aware of the relevant aspects of the HTA this may make the interpretation of information incomplete and potentially put both the donor and any donated tissue at risk. There is also a requirement to communicate the results of any testing performed by the Blood/Tissue Services that may be of relevance to the donor's health in a way that protects their confidentiality. The continuing availability of an independent interpreter, to maintain donor confidentiality, should be taken into account when deciding if an individual donor may be accepted.

Reason for Change

This is a revised entry to clarify the use of interpreters by the Blood & Tissue Services.

Update Information

This entry was last updated in TDSG-LD Edition 203, Release 02

Disease of Unknown Aetiology

Obligatory

See:

Is there is a specific entry for the disease?

Must not donate.

Discretionary

If safety and quality of the donation is unlikely to be affected, discuss with Designated Clinical Support Officer. See 'additional information' section.

Additional Information

When the cause of an illness is not clear, there is an unknown risk to any recipient of donated material.

In certain circumstances, the aetiology could be multi-factorial, although it is not clearly established, there are no concerns relating to person to person transmission. In these cases, cells could be accepted for clinical use, based on current available evidence, after taking into consideration the impact of the donation on the donor's health.

Reason for Change

To clarify that if the safety and quality of the tissues and cells is not impacted, donation can be permitted.

Update Information

This is a requirement of the EU Tissue & Cells Directive.

This entry was last updated in TDSG-LD Edition 203, Release 46.

Diverticulosis

Discretionary Accept.

See if Relevant Infection - General

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Drug Treatment

Obligatory The taking of some drugs may make a donor ineligible.

This could be due to the underlying disease or to the medication.

See:

Any specific entry for the disease or the drug.

Discretionary Self-medication with some drugs e.g. vitamins, aspirin, sleeping tablets, need not prevent a

donation being accepted, providing the donor meets all other criteria.

See if Relevant Addiction and Drug Abuse

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Dysplasia of the Hip

Discretionary Accept.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Ehlers-Danlos Syndrome (Disease)

Obligatory Must not donate.

Reason for Change This is a new entry.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Electrolysis

Discretionary Accept.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Emphysema

Discretionary Accept.

Update Information This entry was last updated in

Endocarditis

Obligatory Must not donate if:

Active infection.

See if Relevant Infection - General

Reason for Change This new entry replaces the previous entry for 'Subacute Bacterial Endocarditis'. It

recognizes that the cause of endocarditis is not always bacterial and the course is not

always subacute.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Endometriosis

Discretionary Accept.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 34

Epilepsy

Obligatory Must not donate if:

a) Recent onset and not fully investigated.

b) Secondary to malignancy or degenerative neurological disease.

See if Relevant Malignancy

Neurosurgery

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Eye Disease

Obligatory Must not donate if:

a) Active ocular inflammation.

b) History of malignancy.

c) Ocular tissue transplanted.

See if Relevant Autoimmune Disease

Central Nervous System Disease

Glaucoma

Infection - General
Malignancy
Ocular Surgery
Ocular Tissue Recipient

Ctoroid Thorony

Steroid Therapy

Tissue and Cell Allograft Recipients

Reason for Change A link has been added for 'Malignancy'.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Eye Drops

See:

Is there a relevant entry.

See if Relevant Autoimmune Disease

Glaucoma Infection - General

Steroid Therapy

person from donating. It is important to know exactly why the drops are being used.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Factor V Leiden

Discretionary Accept.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Fibromyalgia

Also Known As Fibromyositis or fibrositis

Obligatory Must not donate tendons

Discretionary All other tissues, accept

See if Relevant Disabled Donor

Nonsteroidal Anti-Inflammatory Drugs

Steroid Therapy

Additional Information Fibromyalgia is a common problem affecting soft tissues (muscles, tendons and ligaments)

rather than bones or joints. It is often linked to sleep disorders.

Reason for Change This is a new entry

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 25

Filariasis

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

G6PD Deficiency

Discretionary Accept.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Gall Bladder Disease

Obligatory Must not donate if:

Symptomatic.

Discretionary If recovered or has asymptomatic gallstones, accept.

See if Relevant Infection - General

Malignancy

Reason for Change A link has been added for 'Malignancy'.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 34

Genital Warts

Discretionary Accept.

See if Relevant Sexually Transmitted Disease
Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Giardiasis

Discretionary Accept.

Additional Information This is a local intestinal infection that does not affect donation.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Gilbert's Syndrome

Discretionary Accept.

Additional Information Gilbert's syndrome is an inherited defect in bilirubin metabolism. It is harmless but can

cause jaundice in the donor.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Glaucoma

Obligatory Must not donate if:

Received transplant of sclera during glaucoma surgery.

See if Relevant Ocular Tissue Recipient

Tissue and Cell Allograft Recipients

Additional Information If surgery was performed after 1997 and the sclera was supplied through UK Transplant,

this information will be stored on the National Transplant Database.

Update Information This entry was last updated in TDSG-LD Edition 203, Release 34

Gout

Discretionary Even if on treatment, accept.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Granuloma Inguinale

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Growth Hormone

Obligatory Must not donate if:

Has ever received human pituitary derived growth hormone.

Discretionary If treated exclusively with recombinant-derived growth hormone, accept. In the UK this has

been since 1987.

See if Relevant Prion Associated Diseases

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Guillain-Barré Syndrome

Obligatory Refer to a Designated Medical Officer:

Must not donate if:

a) Less than 24 months from resolution.

b) There has been any recurrence of symptoms.

c) The doctor who managed the donor cannot confirm a typical monophasic Guillain-Barré

syndrome that recovered completely within 12 months.

See if Relevant If treated with immunoglobulin or plasma exchange:

Transfusion

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Haematological Disease

Obligatory Must not donate if:

a) Malignant.

b) Clonal disorder such as primary polycythaemia (rubra vera), essential thrombocythaemia

or monoclonal gammopathy of unknown significance (MGUS).

Discretionary If polycythaemia or thrombocytosis is secondary to a non-malignant/clonal condition, accept.

See if Relevant

Anaemia

Haemoglobin Disorders
Immune Thrombocytopenia
Therapeutic Venesection

Additional Information Clonal disorders result from the proliferation of a single cell. Because they have the potential

to become malignant they are treated in the same way as malignancy.

Reason for Change Monoclonal gammopathy of unknown significance (MGUS) has been added as an example

of a clonal disorder.

'Additional Information' has been added.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Haematuria

Obligatory Must not donate if:

a) Due to infection.

b) Due to malignancy.

See if Relevant Kidney Disease

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Haemochromatosis

Discretionary Accept.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Haemoglobin Disorders

Obligatory Must not donate if:

Has a sickle-cell or thalassaemia syndrome.

Discretionary Donors with traits for abnormal haemoglobin, accept.

See if Relevant Anaemia

Sickle-Cell Trait Thalassaemia Trait Transfusion

Reason for Change A link has been added to Transfusion.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Haemolytic Anaemia

Obligatory See

a) Is there an entry for the condition?

b) If not: Refer to a Designated Medical Officer.

See if Relevant Autoimmune Disorder

G6PD Deficiency
Haemoglobin Disorders
Hereditary Elliptocytosis
Hereditary Spherocytosis
Pyruvate Kinase Deficiency

Transfusion

Reason for Change To include an entry for haemolytic anaemia.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Haemorrhoids

Includes Piles

Discretionary Accept.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 34

Headache

Occasional

Discretionary Accept.

Regular

Obligatory Must not donate if:

Not investigated.

Discretionary If investigated and diagnosis does not contra-indicate donation, accept.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Heaf Test

Obligatory Must not donate until:

Healing.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Health Care Worker

History of Inoculation Injury

See Inoculation Injury

No Inoculation History

Discretionary Accept.

This entry was last updated in Update Information

TDSG-LD Edition 203, Release 02

Henna Painting

Discretionary

Accept.

See if Relevant

Body Piercing

Update Information

This entry was last updated in

TDSG-LD Edition 203, Release 02

Hepatitis

Obligatory Note:

Hepatitis has a number of causes including infection and hypersensitivity to drugs.

Our concern is with viral hepatitis.

Discretionary

If fully recovered from non-viral hepatitis, accept.

See if Relevant Hepatitis A

Hepatitis B Hepatitis C Hepatitis E

Hepatitis of Unknown Origin

Update Information

This entry was last updated in TDSG-LD Edition 203, Release 02

Hepatitis A

1. Affected Individual

Obligatory

Must not donate if:

1. Less than 6 months from recovery of symptoms, or

2. Less than 6 months since the donor was diagnosed with hepatitis A infection following laboratory testing, or

3. 3. If the donor tested positive for Hepatitis A Virus (HAV) RNA at the time of donation.

Discretionary

1. If less than 6 months from infection, but fully recovered, documented HAV RNA negative and anti-HAV IgG positive after recovery, accept.

2. For tissues that will undergo processing that has been determined to inactivate HAV prior to transplantation, accept.

See if Relevant

Travel

Additional Information

Hepatitis A is a viral infection of the liver, spread by the faecal-oral route and by sewage-contaminated food and water. It can also be spread sexually. There is no long-term infection with the virus but there are reports of transmission by transfusion and organ transplantation. However there have been no documented cases of transmission via tissue allografts. Infection may be symptom free but can

be serious and occasionally fatal. The Blood Services do not routinely test tissue donors for this infection, however testing at the time of donation may have been

done.

The processing and decontamination protocols applied to certain types of tissue

allograft may be sufficient to inactivate the Hepatitis A Virus. Tissue establishments should perform a documented risk assessment to determine which tissues and processes this applies to.

Reason for Change

To add guidance for donors who test positive for HAV RNA at the date of donation, and to allow donation of tissues where the processing and decontamination protocols applied have been determined to inactivate hepatitis A virus.

2. Current or Former Sexual Partner of Affected Individual

Obligatory

Must not donate if less than 6 months:

- 1. Since a current sexual partner has recovered from symptoms of hepatitis A, or
- 2. Since a current sexual partner tested positive for Hepatitis A Virus (HAV) RNA, or
- 3. Since last sexual contact with a former sexual partner who had hepatitis A.

Discretionary

- 1. If less than 6 months from recovery of current sexual partner, since the current sexual partner tested negative for HAV RNA, or from last sexual contact with a former sexual partner, AND if shown to be immune, accept.
- 2. For tissues that will undergo processing that has been determined to inactivate HAV prior to transplantation, accept.

Additional Information

There is a risk of transmitting the infection through sexual activity. Infection may be symptom free but can be serious and occasionally fatal. The 6 month exclusion allows any infection to run its natural course and for any risk of passing the infection on through donation to have passed.

The processing and decontamination protocols applied to certain types of tissue allograft may be sufficient to inactivate the Hepatitis A Virus. Tissue establishments should perform a documented risk assessment to determine which tissues and processes this applies to.

Reason for Change

To expand the 'Obligatory' and 'Discretionary' sections to add guidance for donors whose sexual partner tested positive for HAV RNA within 6 months of the date of donation, and to allow donation of tissues where the processing and decontamination protocols applied have been determined to inactivate Hepatitis A Virus.

3. Person Currently or Formerly Sharing a Home with an Affected Individual

Obligatory

Must not donate if less than 6 months:

- 1. From recovery of the last affected person in the home, or
- 2. From the last contact with an affected person if no longer sharing, or
- 3. Since a person sharing a home tested positive for Hepatitis A Virus (HAV) RNA.

Discretionary

- 1. If less than 6 months from recovery of the last affected person in the home, from the last contact if no longer sharing, or since a person sharing a home tested positive for HAV RNA, AND shown to be immune, accept.
- 2. For tissues that will undergo processing that has been determined to inactivate HAV prior to transplantation, accept.

Additional Information

Because hepatitis A is spread by the faecal - oral route household contacts may easily become infected. Infection may be symptom free but can be serious and occasionally fatal. The 6 month exclusion allows any infection to run its natural course and for any risk of passing the infection on through donation to have passed.

The processing and decontamination protocols applied to certain types of tissue allograft may be sufficient to inactivate the Hepatitis A Virus. Tissue establishments should perform a documented risk assessment to determine which tissues and processes this applies to.

Reason for Change To expand the 'Obligatory' and 'Discretionary' sections to add guidance for donors currently or formerly sharing a house with an individual who had tested positive for HAV RNA within 6 months of the date of donation, and to allow donation of tissues where the processing and decontamination protocols applied have been determined to inactivate Hepatitis A Virus.

4. Immunisation

Obligatory Known exposure.

Must not donate if:

Less than six months after vaccine or intramuscular immunoglobulin was given.

Discretionary 1. No known exposure to Hepatitis A Virus, accept.

2. For tissues that will undergo processing that has been determined to inactivate

Hepatitis A Virus prior to transplantation, accept.

See if Relevant Hepatitis B - 6. Hepatitis B Immunisation

Travel

Additional Information Hepatitis A immunisation is advised before travel to parts of the world where other infections relevant to donating such as malaria are common. The donor should be

asked about any relevant travel history.

Hepatitis A immunisation may be combined with Hepatitis B immunisation.

If less than 6 months from immunisation following known exposure, the donor

may be accepted following individual risk assessment.

Reason for Change To allow donation of tissues where the processing and decontamination protocols

applied have been determined to inactivate Hepatitis A Virus.

Update Information This entry was last updated in

TL-DSG Edition 203 Release 59

Hepatitis B

1. Person with current hepatitis B infection

Obligatory Must not donate.

Additional Information Hepatitis B is a serious viral infection that can lead to chronic liver disease and liver cancer (hepatoma).

Individuals who are chronically infected are sometimes referred to as 'carriers'. They often have no, or minimal, symptoms associated with their infection.

Cases are often linked to place of birth, or mother's place of birth. The condition is very common in many parts of the world and vertical spread from mother to baby is often a major route of transmission. Hepatitis B may also be acquired by injecting drug use, sexual transmission and more rarely tattoos and piercings

2. Person with previous diagnosed (recovered) hepatitis B infection

Obligatory Must not donate:

if less than 12 months since diagnosis

Discretionary If more than 12 months since diagnosis of HBV infection, and if they have

successfully cleared the infection, accept.

Refer to the designated medical officer if advice on interpretation of test results is required.

See if Relevant Tissue Safety Entry

Additional Information

Leaving 12 months from diagnosis before testing allows sufficient time for a donor to clear any acute infection or develop markers of a chronic infection which will be detected on screening.

If less than 12 months from diagnosis the donor may be accepted if the risk of delaying transplant outweighs the risk of transmission of hepatitis B subject to documented individual risk assessment.

Anti-HBc is required as a mandatory test under the EU Cell and Tissue Directive for cell and tissue donations, and is therefore a regulatory requirement. If the donor is HBsAg negative and HBV DNA negative anti-HBs testing is not required. Anti-HBc must be carried out to comply with regulation and there is no requirement for anti-HBs levels. However some international stem cell registries require anti-HBs status to determine donor suitability.

3. Current or Former Sexual Partner of an infected individual

Obligatory Obtain history (including time since last sexual contact, and the dates that HBV immunisation given).

Must not donate if:

Less than 3 months from last sexual contact

Discretionary If more than 3 months since last sexual contact, accept.

If less than 3 months since last sexual contact, and the donor is shown to be naturally immune, accept.

Additional Information A donor with a period of less than 3 months since the last sexual contact with an infected individual may be accepted following individual risk assessment if risk of delaying transplant outweighs the risk of transmission of hepatitis B. A shortened time between last sexual contact and testing increases the risk of not detecting a recently acquired infection on screening.

The current partner of an individual with hepatitis B infection should have been offered immunisation. If the relationship started after the diagnosis of hepatitis B, immunisation may not have been carried out.

Reason for Change This entry has been modified in line with the recommendations of the SaBTO Donor Selection Criteria Review Report published on 23rd July (2017).

4. Current or former sexual partner of person who had recovered from hepatitis B infection at the time of last sexual contact

Obligatory

Obtain history (including time since last contact, date that the partner was diagnosed with HBV infection and the date that HBV immunisation of the donor commenced).

Must not donate if:

Less than 3 months from last sexual contact with the a partner who has been diagnosed with HBV infection **less than** 12 months ago.

Discretionary

a) If **more than** 3 months since last sexual contact, regardless of when the partner was diagnosed with the HBV infection, accept

b) If partner was diagnosed with HBV infection **more than** 12 months ago and has cleared the infection at the time of last sexual contact, accept.

Additional Information

A donor who had sexual contact less than 3 months ago with a partner who had been diagnosed with the HBV infection less than 12 months ago at the time of sexual contact, may be accepted following individual risk assessment if risk of delaying transplant outweighs the risk of transmission of hepatitis B.

The current partner of an individual with hepatitis B infection should have been offered immunisation. If the relationship started after the diagnosis of hepatitis B, immunisation may not have been carried out.

Reason for Change This entry has been modified in line with the recommendations of the SaBTO Donor Selection Criteria Review Report published on 23rd July 2017.

5. Person Sharing a Home with a person with hepatitis B infection

Obtain history to determine if they are still sharing a home, and if not, the time

since sharing ceased

Must not donate:

If less than 3 months since sharing ceased.

Discretionary If more than 3 months since sharing ceased, accept.

If less than 3 months since sharing ceased, and the donor is shown to be

naturally immune, accept

See if Relevant 6. Hepatitis B Immunization, below.

Additional Information A person sharing a home with a person infected with hepatitis B within the past 3 months may be accepted following individual risk assessment if the risk of

delaying transplant outweighs the risk of transmission of hepatitis B

Reason for Change This entry has been modified in line with the recommendations of the SaBTO Donor Selection Criteria Review Report published on 23rd July 2017.

6. Hepatitis B Immunization

Obligatory a) If Immunised Following Known Exposure:

Must not donate

b) If Immunised With No Known Exposure:

Must not donate if:

Less than 7 days after the last immunization was given.

Discretionary a) If Immunised Following Known Exposure:

If more than 3 months from immunization, accept

b) If Immunised With No Known Exposure:

If more than 7 days after the last immunization was given, accept.

See if Relevant Hepatitis A - 4. Immunization

Additional Information Immunization post exposure may be with specific anti-HB immunoglobulin as well as with HBsAg. Generally immunoglobulin would only be given after a known

exposure to hepatitis B. There is no requirement to monitor the anti-HBs level.

May be combined with hepatitis A immunization. Sensitive assays for HBsAg may be positive following recent immunization. This is why a 7 day deferral is required.

Reason for Change The immunisation section has been incorporated into the main Hepatitis B entry.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 29

Hepatitis C

1. Affected Individual

Obligatory Must not donate.

should be taken to determine eligibility.

See if Relevant Tissues Safety Entry

Additional Information Hepatitis C is a serious viral infection that can lead to chronic liver disease, liver cancer (hepatoma) and chronic fatigue syndrome. It has also been linked with malignant lymphomas and autoimmune disease. The infection is very easily spread by transfusion.

Individuals who are chronically infected are sometimes referred to as 'carriers'. They often have no, or minimal, symptoms associated with their infection.

Many cases are linked to previous drug use and, before the introduction of HCV screening of blood donations, to transfusion.

Individuals who have had Hepatitis C infection in the past, and have been told that they have been successfully treated, will usually remain HCV antibody positive for many years. As a negative HCV antibody screening test is required before their donation can be issued, their tissue/cells cannot be used.

Reason for Change 'Additional Information' has been added.

2. Current or Former Sexual Partners of HCV Positive Individuals

Obligatory Must not donate if

Less than 3 months from the last sexual contact

Discretionary

a) If less than 3 months from the last sexual contact and the donor/donor family reports that their current or former HCV positive partner has been successfully treated for hepatitis C infection and has been free of therapy for at least 6 months prior to the last sexual contact and continues in sustained remission, accept.

b) If more than 3 months since last sexual contact, accept.

See if Relevant Tissues Safety Entry

Additional Information Confirmation of the success of treatment of the HCV positive partner is not

Individuals who remain HCV RNA negative six months after completing treatment are likely to have been 'cured', with a risk of relapse of less than 1%

In the United Kingdom sexual transmission of HCV from an infected individual to a sexual partner is low, but not zero.

As the treated individual would have a very low (<1%) risk of relapse of infection and sexual transmission of the hepatitis C virus is rare, the transmission of hepatitis C from a successfully treated individual to a sexual partner is most unlikely. This guidance presumes that a validated NAT test for HCV is negative, if this test is stopped for any reason the guidance will change.

Reason for Change To include guidance for persons with treated and successfully cleared past Hepatitis C infection.

3. Person currently or formerly Sharing Home with an affected individual

Discretionary Accept.

See if Relevant Sexual Partners of HCV Positive Individuals above.

Additional Hepatitis C is neither contagious nor spread by the faecal-oral route. It is usually Information only spread through a direct blood to blood route. For these reasons household

contacts do not need to be deferred.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 33

Hepatitis E

Infection

Obligatory Must not donate if:

Less than 6 months from recovery.

If less than 6 months from recovery and HEV RNA negative and anti HEV IgG Discretionary

positive, accept.

See if Relevant Travel

> Additional Hepatitis E is an infectious hepatitis that is usually spread through contaminated Information food or water. Infection may be associated with travel to countries with poor

hygiene/sewage conditions but increasingly, cases of hepatitis E are being identified in the UK usually due to consumption of undercooked contaminated meat. Hepatitis E can affect non-human animals and has been found in pigs in the UK. There have been reports of transmission by transfusion and transplant. Infection in healthy individuals is often symptom free but in people with underlying problems in their immune systems it can be serious and occasionally fatal. The

Blood Services currently test for this infection.

Reason for The obligatory deferral has been reduced from 12 to 6 months and a discretion to Change

accept on full recovery added. Additional Information has been updated. The

deferral for household and sexual contacts has been removed.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 31

Hepatitis of Unknown Origin

Affected Individuals

Obligatory Must not donate if:

Less than 24 months from recovery.

a) If more than 12 months, but less than 24 months from recovery, obtain history Discretionary

and blood samples and refer to a **Designated Medical Officer**.

b) If more than 24 months from recovery, accept.

Additional If more than 12 months and less than 24 months from recovery: Information

c) If negative for all markers of hepatitis B, accept.

d) If HB core antibody is positive and HBsAg is negative, HBV-DNA is negative and anti-HBs has been documented at more than 100 iu/l at some time, accept.

Person Sharing Home

Obligatory Must not donate if:

Less than 12 months from recovery of the last affected person in the home.

See if Relevant Sexual Partner of Affected Individuals above.

Additional Most hepatitis of unknown origin will have been due to hepatitis A or hepatitis E Information (or non-viral causes). Additional testing for those who give a history of hepatitis

(or non-viral causes). Additional testing for those who give a history of hepatitis between 12 and 24 months before donation will exclude the rare case of HBV which may have delayed clearance of infection and therefore will still present a

risk through donation.

Reason for Clarification regarding hepatitis B markers has been added to the additional

Change information.

Sexual Partner of Affected Individuals

Obligatory Must not donate if:

Less than 12 months from recovery of partner.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 17

Hereditary Elliptocytosis

Discretionary Accept.

Reason for Change This entry replaces the previous entry for Elliptocytosis

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Hereditary Spherocytosis

Discretionary Accept.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Herpes - Genital

Obligatory Must not donate if:

Fresh lesions.

Discretionary If lesions are healing, provided there is no history of other Sexually Transmitted Diseases,

accept.

See if Relevant Sexually Transmitted Disease

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.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 55

Herpes - Oral

Obligatory Must not donate if:

Fresh lesions.

Discretionary If lesions are healing, accept.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Herpes Simplex

See if Relevant Herpes - Genital

Herpes - Oral

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Herpes Zoster

See if Relevant Infection - Acute

Infectious Diseases - Contact with

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Hip Dysplasia

Discretionary Accept.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

HIV

Includes AIDS

Current or Former Sexual Partners of Confirmed Case

Obligatory Must not donate if:

Less than 3 months from last sexual contact.

See if Relevant Tissues Safety Entry

Additional HIV infection can be spread through sexual activity, including oral and anal sex. Information Despite regular sexual contact transmission of infection may not happen. It may

Despite regular sexual contact transmission of infection may not happen. It may however not be transmitted for a long time into a relationship. This could be because the infection becomes more active in the infected partner, the uninfected partner acquires another infection or injury to a mucous membrane, or there is a

change in the use of, or failure of, barrier contraceptives (condoms etc.). In the early stages of infection the testing used by the Blood Services may not detect the virus allowing it to be passed on by transfusion or transplantation.

Waiting 3 months from the last sexual contact will ensure that any infection is picked up by the tests used by the Blood Services. This guidance presumes that a validated NAT test for HIV is negative, if this test is stopped for any reason the guidance will change.

Reason for Change This entry was updated in line with the recommendations of the SaBTO Donor Selection Criteria Review Report published on 23rd July 2017. The current and former sexual partner entries have been combined. Additional information section added

Infection

Obligatory Must not donate.

See if Relevant Tissues Safety Entry

Person Currently or Formerly Sharing a Home with an Affected Individual

Discretionary Accept.

See if Relevant Current or Former Sexual Partner of Affected Individual above.

Additional Information HIV is neither contagious nor spread by the faecal-oral route. It is usually only spread through a direct blood to blood or sexual route. For these reasons

household contacts do not need to be deferred.

Reason for Change This is an additional entry.

Update Information This advice is a requirement of the EU Tissue & Cells Directive.

This entry was last updated in TDSG-LD Edition 203, Release 29

Hormone Replacement Therapy

Obligatory Must not donate if:

a) Used for malignancy.

b) A recipient of human gonadotrophin of pituitary origin.

c) A recipient of human pituitary growth hormone.

Discretionary a) If treated with gonadotrophins that were exclusively non-pituitary derived, accept.

b) If treated with growth hormone that was exclusively recombinant, accept.

c) If treatment for menopausal symptoms or osteoporosis prevention, accept.

See if Relevant Prion Associated Diseases

Thyroid Disease

Reason for Change The discretionary entry has been re-worded for clarity.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

HTLV

Current and Former Sexual Partners of Confirmed Case

Obligatory Must not donate if:

Less than 3 months from last sexual contact

See if Relevant Tissues Safety Entry

Additional There is no defined infectious window period for HTLV. The risk of missing recent

Information infection with individual sample testing is low after 3 months.

Reason for This entry was updated in line with the recommendations of the SaBTO Donor

Change Selection Criteria Review Report published on 23rd July 2017.

Infection

Obligatory Must not donate.

See if Relevant Tissues Safety Entry

Person Currently or Formerly Sharing a Home with an Affected Individual

Discretionary Accept.

See if Relevant Current or Former Sexual Partner of Affected Individual above.

Additional HTLV is neither contagious nor spread by the faecal-oral route. It is usually only

Information spread through a direct blood to blood or sexual route. For these reasons

household contacts do not need to be deferred.

Reason for This is an additional entry.

Change

Update Information This advice is a requirement of the EU Tissue & Cells Directive.

This entry was last updated in TDSG-LD Edition 203, Release 29

Huntington's Disease

Obligatory If the diagnosis is uncertain:

Refer to a Designated Medical Officer.

Discretionary If diagnosis can be confirmed, accept.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Hydatid Disease

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Hydrocephalus

Obligatory Must not donate if:

Has an indwelling shunt and there is evidence of shunt infection.

See if Relevant Neurosurgery

Spina Bifida

Additional Information Donated bone is cultured to exclude active bacterial and fungal infection. However it should

not be collected from bacteraemic subjects.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Hypnotics

Discretionary Accept.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

lleostomy

Obligatory Must not donate if:

a) For malignancy

b) Inflammatory bowel disease.

Discretionary If the reason for the ileostomy is not of itself a reason to exclude and the stoma is healthy,

accept.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 34

Immune Thrombocytopenia

Obligatory Must not donate if:

Associated with malignancy

Discretionary If underlying cause of thrombocytopenia or treatment given is not a contraindication,

accept. Refer to relevant DSG entry. Refer to designated clinical support officer if further

advice required.

See if Relevant Malignancy

If treated with immunoglobulin:

Immunoglobulin Therapy

Transfusion

If treated with plasma exchange:

Transfusion

If treated with immunosuppressive therapy:

<u>Immunosuppression</u>

Additional Information Immune thrombocytopenia can be associated with malignancies, especially haematological

malignancies such as chronic lymphocytic leukaemia.

Reason for Change Amend the 'Obligatory' section, add 'Discretionary' and 'Additional Information' sections, add

link to 'immunoglobulin therapy' and 'malignancy' entries.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 44

Immunisation

Non-exposed

See Immunisation - Live

Immunisation - Non-Live

If you do not know if an immunisation is live or not, see the specific entry for the

type of immunisation or:

Refer to a Designated Medical Officer.

Post Exposure

Obligatory 1. BCG:

See BCG

2. Hepatitis A:

See

Hepatitis A

3. Hepatitis B:

See

Hepatitis B

4. Rabies:

See

Rabies

5. Smallpox:

See

Smallpox Immunisation

6. Tetanus:

See

Tetanus Immunisation

Reason for Change Update the 'Hepatitis A' part of the 'Post-exposure' section to refer directly to the 'Hepatitis

A' entry.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 44

Immunisation - Live

No Exposure

Obligatory Must not donate if:

Less than eight weeks from administration.

immunisation and the inoculation site has healed, accept.

See if Relevant BCG

Smallpox Immunisation

Additional Information Live immunisations use living viruses or living bacteria that will stimulate the immune system

but do not normally cause a severe illness. They may however cause severe illness in people who are already unwell and have a weakened immune system. By four weeks, any infection caused by the immunisation should have been controlled and so should not be

passed on through donated material. There are special rules for BCG and smallpox

immunisations.

Reason for Change Advice has been given from SACTTI that a period of four weeks is sufficient to ensure that

there would be no circulating virus or bacteria at time of donation for live immunisations

other than smallpox.

Update Information This advice is a requirement of the EU Tissue & Cells Directive.

> This entry was last updated in TDSG-LD Edition 203, Release 08

Immunisation - Non-Live

No Exposure

Excludes Post-exposure. See: Immunisation - Post Exposure

Obligatory 1. Hepatitis B

Must not donate if:

Less than seven days after administration.

Discretionary Other non-live immunisations, accept.

Additional Information Sensitive assays for HBsAg may be positive following recent immunisation. Full screening

for Hepatitis B may be required.

Note, hepatitis A immunisation may be combined with hepatitis B immunisation.

'Non-Live' immunisations do not use material that can cause infection. This means there is no risk to people receiving donated material from a recently immunised non-exposed donor.

Reason for Change To remove Coronavirus Vaccination from obligatory section, and additional information

section updated.

Update Information This entry was last updated in

TL-DSG Edition 203 Release 57

Immunoglobulin Therapy

Obligatory Must not donate if:

a) Immunosuppressed.

b) Donors with recovered immunodeficiency:

Refer to a Designated Clinical Support Officer.

Discretionary a) If the intravenous or subcutaneous human immunoglobulin was given before 1980,

b) Routine ante- and post- natal use of anti-D immunoglobulin, accept.

c) If single dose prophylactic immunoglobulin has been given, accept.

d) If treated with intravenous immunoglobulins after 1st January 1999: if underlying condition

is not a contraindication, accept. Refer to designated clinical support officer if further advice

required.

See if Relevant Hepatitis A

Hepatitis B Rabies

Tetanus Immunization

Additional Information Immunoglobulin used before 1980 is unlikely to be affected by vCJD.

Single dose immunoglobulin is unlikely to pose a significant risk for transmitting vCJD.

Since 1999, intravenous immunoglobulins prepared from UK donors have no longer been

used, as a risk reduction measure for vCJD transmission.

See If treated with intravenous or subcutaneous human immunoglobulin:

Transfusion

Reason for Change To permit donation from donors who have received intravenous immunoglobulin after 1st

January 1999, if the reason for treatment is not a contraindication.

Update Information The advice reflects advice from the MSBTO committee of the DH.

This entry was last updated in TDSG-LD Edition 203, Release 44

Immunosuppression

Obligatory Must not donate if:

a) Immunosuppressed.

b) Donors with recovered immunodeficiency: Refer to a Designated Medical Officer.

See if Relevant Autoimmune Disease

Immunoglobulin Therapy

Steroid Therapy

Reason for Change Additional links have been added.

Update Information This advice is a requirement of the EU Tissue & Cells Directive.

This entry was last updated in TDSG-LD Edition 203, Release 02

Infection - Acute

Obligatory See

Is there is a specific entry for the disease you are concerned about?

Must not donate if:

a) Infected.

b) Less than two weeks from recovery from a systemic infection.

c) Less than seven days from completing systemic antibiotic, anti-fungal or antiviral

treatment.

Discretionary Common viral respiratory tract infections such as colds, sore throats and seasonal influenza,

if recovering, accept. See additional information.

Cold sores, genital herpes, accept.

See if Relevant Congo Fever

Coronavirus Infection

Crimean Fever
Ebola Fever
Herpes - Genital
Herpes - Oral
Lassa Fever

Lassa Fever Marburg Fever

MRSA (Methicillin Resistant Staphylococcus Aureus)

Myocarditis

Steroid Therapy West Nile Virus

Additional Information

Many infections can be spread by donated material. It is important that the donor does not pose a risk of giving an infection to a recipient. Waiting two weeks from when the infection is better and seven days from completing systemic antibiotic, anti-fungal or antiviral treatment makes it much less likely that there will still be a risk of the infection being passed on.

There is no evidence that cold sores, genital herpes and common upper respiratory infections such as colds and sore throats can be passed on by donated material but it is still necessary to wait until any such infection is obviously getting better before allowing anyone to donate.

Three distinct types of influenza infection need to be considered separately: seasonal influenza, pandemic influenza and avian influenza. This guidance applies only to seasonal influenza; avian and pandemic influenza are out with the scope of this guidance. Donors with these diagnoses should not be accepted. Any outbreaks of avian or pandemic influenza will be communicated via public health alert guidance for professionals.

Seasonal influenza in the UK normally extends over a period of approximately 16 weeks during the winter months. Due to the spectrum of disease presentation, only the minority of infected individuals are tested for respiratory viruses and during the annual epidemics, most cases are diagnosed clinically. Systemic infection with viraemia is not a feature of seasonal influenza.

Unusual bacterial/fungal/protozoal infections

Specialist microbiological advice should be sought when considering using cells and tissues from donors who have had unusual infections in the past, including those acquired outside of Western Europe. This should include infections common in immuno-compromised patients, or infections which lie dormant or may be difficult to eradicate.

Reason for Change

Updated guidance regarding donors who are recovering from seasonal influenza.

Update Information

Part of this advice is a requirement of the EU Tissue & Cells Directive.

This entry was last updated in TDSG-LD Edition 203, Release 40

Infection - Chronic

Obligatory

Must not donate.

Discretionary

1. Acne:

Most donors with acne can be accepted.

2. Chronic fungal infections:

- a) If on local therapy for superficial infections only, accept.
- b) If on systemic anti-fungal treatment only for treatment of a localised, non-systemic fungal infection, and there are no complications, accept.
- c) If otherwise more than seven days from completing systemic antifungal therapy, accept.

3. Typhoid and Paratyphoid

If more than seven days from completion of antibiotic course and last symptoms, accept.

See if Relevant

Acne

Steroid Therapy

Additional Information

Typhoid and paratyphoid are gastrointestinal infections which rarely have a chronic carrier state. It is usually caught while travelling. It is passed by the faecal-oral route and is not transmitted by tissue or cell transplantation.

Unusual bacterial/fungal/protozoal infections

Specialist microbiological advice should be sought when considering using cells and tissues from donors who have had unusual infections in the past, including those acquired outside of Western Europe. This should include infections common in immuno-compromised patients, or infections which lie dormant or may be difficult to eradicate.

Local fungal infections, e.g. nail infection or athlete's foot

Systemic oral antifungal treatment may be prescribed to treat localised fungal nail infections or athlete's foot which are difficult to eradicate. Despite the systemic treatment, due to the fact that the infection is localised to the nails/digits the risk to donated tissue/cells is considered to be remote.

Reason for Change

To add guidance for acceptance of donors on oral antifungal treatment for localised nail infections or athlete's foot.

Update Information

Part of this advice is a requirement of the EU Tissue & Cells Directive.

This entry was last updated in TDSG-LD Edition 203, Release 41.

Infection - General

Obligatory See:

Is there a specific entry for the disease?

See if Relevant

Decide if the infection is of short duration with no long lasting carrier stage, e.g. flu:

Infection - Acute

Or if lasting a long time (more than a few weeks) and possibly with long lasting carriage of

the infecting organism, e.g. malaria or typhoid

Infection - Chronic

Update Information

This entry was last updated in TDSG-LD Edition 203, Release 02

Infection - Tropical

Obligatory Must not donate if:

Filariasis or Leishmaniasis

See if Relevant Congo Fever

Crimean Fever Ebola Fever Lassa Fever Marburg Fever Malaria

South American Trypanosomiasis Risk

Other infections, see: Infection - General

Update Information

This entry was last updated in TDSG-LD Edition 203, Release 02

Infectious Diseases - Contact with

Obligatory

Is there a specific entry for the disease with which there has been contact?

Must not donate if:

Within the incubation period for the condition or, if this is not known, less than four weeks from last contact.

Discretionary

- a) If the infection is known to lead to permanent immunity (e.g. chickenpox, measles, mumps, rubella, whooping cough) and there is a definite history of past infection with the disease with which contact has occurred, accept.
- b) Contact with common upper respiratory tract infections (e.g. colds, sore throats, influenza, SARS CoV-2), accept.
- c) Contact with norovirus and other causes of diarrhoea and vomiting, provided the donor is symptom free, accept.
- d) Contact with skin conditions which are not transmissible by donated material (such as scabies, ringworm, tinea) if no signs of infection, accept.
- e) Individuals who have been prescribed prophylactic antibiotics after contact with meningitis, anthrax or chlamydia, provided they are symptom free, accept.

See if Relevant

Coronavirus Infection

Hepatitis

Hepatitis A

Hepatitis B

Hepatitis C

Hepatitis E

HIV

HTLV

Meningitis

Monkeypox

Sexually Transmitted Disease

Smallpox Immunization

Syphilis

Tuberculosis

Additional Information

Many infectious diseases can be passed on through donated material, even before a potential donor develops any symptoms of the infection. This may lead to serious infection in the person receiving a donation.

Many diseases are not infectious and so are not normally a risk.

Contacts with meningitis or anthrax are often prescribed prophylactic antibiotics. These should prevent the disease from developing, so provided the potential donor is well, they may be accepted.

If in doubt, contact a 'Designated Clinical Support Officer'.

Reason for Change

To add 'discretionary' and 'additional information' sections and to update the 'see if relevant' section with additional links.

Update Information

This entry was last updated in TDSG-LD Edition 203, Release 51

Infertility

Obligatory

Must not donate if:

- a) Has ever been given human gonadotrophin of pituitary origin.
- b) If donor knows that they have ever been treated with Metrodin HP®.

Discretionary If treated exclusively with non-pituitary derived gonadotrophins, accept.

See if Relevant Prion Associated Diseases

Additional Information The use of human gonadotrophin of pituitary origin (follicle-stimulating hormone (FSH) and luteinizing hormone (LH)) had stopped in the UK by 1986. The situation in other countries

varied so specific dates cannot be given.

The 12 week period is an additional safeguard to avoid taking a donation early in a

pregnancy.

There is no evidence that transfer of tissues (eggs or embryos) between individuals might

lead to the spread of vCJD.

Metrodin HP[®] was withdrawn by the Committee on Safety of Medicines in 2003 and following advice from the Medicines and Healthcare products Regulatory Agency the precautionary principle has been applied to withdraw donors who have been treated with this product. Donors treated for infertility after 2003 in the UK will not have been treated with

this product.

Reason for Change To update the 'additional information' section with a statement that there is no evidence that

transplantation of eggs or embryos might lead to spread of vCJD.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 46.

Inflammatory Bowel Disease

Includes Crohn's Disease

Ulcerative Colitis

Obligatory Must not donate.

Discretionary If mild, with no evidence of infection, tissues can be accepted subject to individual

assessment. Refer to Designated Clinical Support Officer for advice if necessary.

See if Relevant Infection – General

Malignancy Radiation Therapy

Additional Information The cause of these conditions is not fully understood and may include infection. Lesions

caused by the disease can increase the risk of bacteria entering the blood stream.

Reason for Change 'See if Relevant' section has been added.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 44

Inherited Diseases

Obligatory See:

Is there a specific entry for the condition? If not:

Refer to a Designated Medical Officer.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Inoculation Injury

Includes Human Bite

Definition A

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 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.

injury with abhormal phons from

Obligatory Must not donate if:

a) The incident involved any 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 DSCO.

See if Relevant Animal Bite

Hepatitis HIV HTLV

Prion Associated Diseases Tissues Safety Entry Xenotransplantation

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.

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.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 55

Irritable Bowel Syndrome

Discretionary

Discretionary Accept.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Jaundice

Obligatory Must not donate if:

a) Jaundiced or has a history of jaundice.

b) If the cause of the jaundice was viral see the specific entry for that condition.

c) If the cause of the jaundice was not known, treat as Hepatitis of Unknown Origin.

a) If fully recovered from a non-viral cause of jaundice (this includes, but is not limited to,

physiological jaundice of the newborn, gall stones and drug reactions), accept.

b) If due to Gilbert's Syndrome, accept.

See if Relevant Gall Bladder Disease

Gilbert's Syndrome

Hepatitis A Hepatitis B Hepatitis C Hepatitis E

Hepatitis of Unknown Origin

Additional Information Many things can cause jaundice. The concern is with infectious causes that might be

passed on by donation.

Reason for Change In 'Obligatory' the link to Hepatitis B' has been changed to 'Hepatitis of Unknown Origin'.

There have been other minor changes to improve clarity and to avoid the unnecessary

exclusion of donors.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Kala-Azar

Obligatory Mus

Must not donate.

Update Information

This entry was last updated in TDSG-LD Edition 203, Release 02

Kidney Disease

Acute Nephritis

Obligatory Must not donate if:

Less than 12 months since recovery.

Discretionary 1. All tissues:

a) Self-limiting renal disease e.g. single attacks of glomerulonephritis, pyelitis, from which recovery has been complete, do not necessarily disqualify the donor.

b) If there is doubt about the diagnosis refer to a Designated Medical Officer.

Additional Information If the donor is well and has not received treatment to suppress the condition in the last 12 months it is unlikely that their donation will pose a risk to the recipient.

Reason for Change

To align the guidance with that for blood donors, the deferral period following an attack of 'Acute Nephritis' has been reduced from five years to 12 months

Chronic Nephritis

Obligatory

Must not donate.

Update Information

This entry was last updated in TDSG-LD Edition 203, Release 17

Klinefelter's Syndrome

Discretionary

Accept.

Update Information

This entry was last updated in TDSG-LD Edition 203, Release 02

Laser Treatment

Obligatory

Must not donate if:

For malignancy.

Discretionary

- a) If for Basal Cell Carcinoma, treatment is completed and fully recovered, accept.
- b) If for Cervical Carcinoma in Situ, see Cervical Dysplasia entry
- c) If for cosmetic purposes, accept when healed.
- d) If laser refractive surgery to the cornea, accept when healed.

See if Relevant

Basal Cell Carcinoma Cervical Dysplasia

Update Information

This entry was last updated in TDSG-LD Edition 203, Release 46.

Leishmaniasis

Includes

Kala-Azar

Obligatory

Must not donate.

Update Information

This entry was last updated in TDSG-LD Edition 203, Release 02

Leukaemia

Obligatory

Must not donate.

Update Information

This entry was last updated in TDSG-LD Edition 203, Release 02

Malaria

Definition

Resident – A donor who has ever been present in a malaria risk area (or areas), for a continuous period of 6 months or more (at any point in their lifetime)

Visitor – A donor who has visited or travelled through a malaria risk area (or areas) within the past 12 months

Unexplained febrile illness – A donor who had undiagnosed fever (that could have been malaria) while present in, or within four months of leaving, a malaria risk area.

Previous diagnosis of malaria – A donor who previously had a confirmed diagnosis of malaria, at any point in their lifetime.

Malaria risk area - Risk area for country as defined by the GDRI

MAT: Malarial Antibody Test

NAT: Nucleic Acid Test (for malaria)

Obligatory

1. Must not donate (if no testing is available)

Applies to all groups as defined above

2. Must not donate if testing is performed less than 4 months since:

Anti-malaria therapy has been completed and symptoms caused by malaria have resolved **OR**

Recovery of symptoms of unexplained febrile illness that could have been malaria OR

Last present in a malaria risk area (or areas) OR

Since return from a malaria risk area (or areas).

Discretionary

1a) Previous Malaria:

If **more** than **4 months** have passed since anti-malaria therapy has been completed and symptoms caused by malaria have resolved, obtain a blood sample for MAT and NAT test. See information below in this section.

1b) Unexplained Febrile illness:

If **more** than **4 months** from the date of recovery of symptoms of unexplained febrile illness that could have been malaria: Obtain a blood sample for MAT and NAT. If MAT negative, NAT is not required to release tissues. See information below in this section.

1c) Resident:

If **more** than **4 months** since date last present in a malaria risk area: Obtain a blood sample for MAT and NAT. If MAT negative, NAT is not required to release tissues. See information below in this section.

1d) Visitor:

If **more** than **4** and **less** than **12 months** since return: Obtain a blood sample for MAT and NAT. If MAT negative, NAT is not required to release tissues. See information below in this section.

If more than 12 months since return: testing not required, accept

NB. Please consider T. cruzi or a tropical virus risk if the area is also identified as a risk area for these infections

The results of MAT and NAT tests must be reviewed as a part of donor medical clearance to determine the suitability of tissues for clinical use. If the exposure, or, for donors with a history of malaria where treatment was completed and symptoms have resolved, was more than four months prior to donation and MAT is negative, NAT is not required. However, if MAT is positive and NAT is negative, in these donors, a risk assessment can be performed for accepting tissues for clinical release after seeking expert opinion.

2. If tissue will be sterilized by irradiation post-donation:

Accept - MAT and NAT testing not required.

See if Relevant

Geographical Disease Risk Index for countries with a current endemic malaria risk.

Additional Information

Symptoms and signs of possible malaria include: fever, flu-like illness, (including shaking chills, headache, muscle aches, and tiredness), anaemia, jaundice, nausea, vomiting, diarrhoea and cough.

SaBTO Guidance confirms that irradiation of the tissue can be allowed as an alternative to malarial antibody testing.

Some countries have malaria as well as tropical viral risk. Both risks have to be considered if the donor had symptoms after travel or stay.

Reason for Change

This guidance was updated based on advice from the SACTTI parasitology sub-group.

Update Information

This entry was last updated in TDSG-LD Edition 203, Release 52

Malaria - Contact in UK

Discretionary

Accept.

Update Information

This entry was last updated in TDSG-LD Edition 203, Release 02

Malignancy

Obligatory

Must not donate.

Discretionary

- a) If this was a basal cell carcinoma (rodent ulcer) and treatment is completed and all wounds are healed, accept. If any systemic medical treatment was required, refer to designated clinical support officer.
- b) If the potential donor has a non haematological (non-clonal) premalignant condition (e.g. polyposis coli, prostatic intraepithelial neoplasia PIN or Barrett's oesophagus) that is being regularly monitored, or has had a similar condition cured and has been discharged from follow-up, accept.
- c) If the potential donor has been cured of a carcinoma in situ (CIS) and discharged from follow-up, accept. Donors who have been returned to routine screening following treatment for cervical CIS can be accepted.

Examples of CIS include cervical or vulval CIS, ductal CIS of the breast (DCIS) and Bowen's disease.

- d) If the potential donor has had a diagnosis of melanoma in situ (including Lentigo Maligna), refer to Designated Clinical Support Officer to confirm they have not had an invasive melanoma (eg Lentigo Maligna Melanoma).
- e) Potential donors with a high risk of cancer due to family history or following genetic tests, even if had or having prophylactic surgery or on prophylactic medication (e.g. Tamoxifen), or on routine follow up, accept.

See if Relevant

Basal Cell Carcinoma
Cervical Carcinoma in Situ
Transfusion

Additional Information

Many malignancies spread through the blood stream and by invading surrounding tissues. Viruses that can be spread by blood and tissue donation can also cause some malignancies. For these reasons it is considered safer not to accept blood from people who have had a malignancy.

Basal cell carcinoma (rodent ulcer) does not spread through the blood, therefore people who have had successful treatment may donate.

The term carcinoma in situ (CIS) refers to a group of abnormal cells which have not invaded deeper tissue or spread to another part of the body. Donors who have been cured and discharged from follow up may donate. For cervical CIS, donors can be accepted if treatment is complete and any follow up smear, if performed, did not show abnormal cells. Regular screening smears are not defined as follow up.

Premalignant conditions are very common, particularly in older donors. Regular monitoring should prevent donors with invasive malignancy from being accepted. However donors with a haematological clonal pre-malignant condition should not be accepted for tissue donation.

Melanoma in situ which has been cured by excision is not associated with a risk of metastasis. Patients with a confirmed diagnosis of melanoma in situ (ie Breslow thickness of 0 and no regression) do not require ongoing follow up beyond the initial post-operative appointment.

Lentigo Maligna is a form of melanoma in situ found on the head and neck. It should be distinguished from Lentigo Maligna Melanoma which is a true malignant melanoma.

Reason for Change

Advice has been added for basal cell carcinoma treated systemically.

Update Information

This entry was last updated in TDSG-LD Edition 203, Release 34

Malignant Hypertension

Discretionary Accept.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Mantoux Test

Obligatory Must not donate unless:

Negative and no further investigations planned.

See if Relevant Tuberculosis

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Marfan's Syndrome

Obligatory Must not donate.

Bone structural

Discretionary Bone non-structural:

Accept

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Measles

Affected Individual

See Infection - Acute

Contact

See Infectious Diseases - Contact with

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Meningitis

Affected Individual

See Infection - Acute

Contact

Discretionary Even if on prophylactic antibiotics, accept.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Menopause

Discretionary Accept.

Hormone Replacement Therapy See if Relevant Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Mental Health Problems

Obligatory Must not donate if:

Not able to fully understand and consent to the donation process and to the testing of their

blood for diseases that may affect its suitability for use.

See if Relevant Communication Difficulties

Additional Information Many people have mental health problems that can be controlled with regular medication.

Providing individuals are well on the day of donation and have the mental capacity to give full informed consent, there is no reason why they cannot donate whether on medication or not. Individuals who are over anxious, depressed, manic or psychotic cannot always give

valid consent, or fully understand why they are being asked certain questions

To ensure that all donors with mental health conditions can donate if they are well enough to Reason for Change

do so and have the mental capacity to give full informed consent

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 17

Mitral Valve Prolapse

Accept. Discretionary

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Mpox (Monkeypox)

1. Affected Individuals

Obligatory Must not donate

Discretionary If the donor has recovered from confirmed or suspected Mpox infection and

- It is at least 28 days since the diagnosis of Mpox was made, and
- It is at least 14 days since recovery, and the donor remains well, and
- It is at least 14 days since all skin lesions have healed, and
- It is more than seven days since completing any antiviral or antibiotic therapy, and
- The donor has been discharged from all follow up (including public health surveillance),

accept.

Post Donation Illness

Donors must be provided with information about contacting the tissue establishment if they develop any illness within 21 days after donation. Donation

should be discarded.

2. Contact with an individual with Mpox

Includes Individuals who have been identified by public health teams as a close contact of

an individual with Mpox.

Obligatory Must not donate

the donor has no symptoms of Mpox, and

- the donor had completed any isolation period, and
- the donor had been discharged from all follow-up (including surveillance by public health), and
- the donor fulfils the criteria in section 3 below regarding vaccination of applicable,

accept.

Post Donation Illness If the donor has retrospectively reported contact with Mpox within incubation period, donation could be discarded or seek public health advice to determine the risk.

3. Immunisation for contact or risk

Excludes Individuals who have received vaccination because they work in a health care

setting - see section 4 below.

Obligatory Must not donate

Discretionary If the donor fulfils the criteria in section 2 above, and:

- it is more than four weeks since the most recent dose of a non-live or attenuated smallpox vaccination e.g. Imvanex, and:
- the course of vaccination (if more than one dose) is complete,

accept.

4. Immunisation - No known contact

Includes Individuals who have received vaccination because they work in a health care

setting.

Discretionary An individual who has received routine vaccination with Imvanex or another third-

generation smallpox vaccination in an occupational setting, can be accepted provided that they are not deemed to be at risk due to an exposure episode.

See if Relevant Immunisation

Additional Information

Mpox was previously known as Monkeypox. In November 2022, WHO recommended Mpox as the new name for Monkeypox disease. Mpox is endemic in some African countries. During 2022 a multi-country outbreak was identified with cases in the UK, Europe, North America and other regions.

The incubation period of Mpox is up to 21 days. The initial symptom are fever, myalgia, fatigue and headache. These symptoms are followed by a rash starting from the site of the primary infection, this rash develops into vesicles and pustules followed by scabs. Infectivity may start during initial symptoms and lasts until the rash clears and all scabs have dropped off.

Staff should be alert for donors who report rashes and illnesses consistent with Mpox, regardless of sexual behaviour, travel history or other risk factors.

Mpox does not spread easily between people. Human-to-human transmission occurs through contact with:

- · infectious material from skin lesions
- respiratory droplets in prolonged face-to-face contact
- virus-contaminated objects such as bedding or clothing

During the 2022 multi-country outbreak, the predominance of cases among men who have sex with men and the distribution of the Mpox skin rash at presentation, suggests Mpox transmission is associated with direct contact during sex.

Contacts may have received vaccination, to reduce the risk of serious illness. Usually vaccination will be with Imvanex or other third generation vaccine against smallpox. Contacts are eligible to donate once they satisfy the requirements of Sections 2 and 3 above.

Health care workers may also have received vaccination to protect against Mpox in the event of possible exposure to monkeypox during their work. They will be working in accordance with Infection Prevention and Control policies and with suitable Personal Protective Equipment, which if not breached means they are eligible to donate. Other recipients of vaccination for Mpox must be assessed according to section 3 above.

Imvanex is a live attenuated non-replicating third generation Smallpox vaccination. For donor selection purposes this can be assessed as a non-live vaccine but primarily donors must be assessed according to their individual risk of exposure to Mpox. The deferral of some donors for four weeks from the date of a non-live vaccination allows symptoms of Mpox from prior exposure to become evident (incubation period up to 21 days) and encompasses the time for maximum efficacy of the immunisation (up to four weeks). Donors should be deferred until completion of a course of vaccination.

Reason for Change

The title and contents have been updated with the new name as recommended by WHO. Inclusion of sections for donors who have received vaccination either because they could be a close contact, have risk of exposure, or have received vaccination because they are health care workers.

Additional Information applicable for the whole entry contained within one section.

Update Information

This entry was last updated in TDSG-LD Edition 203, Release 52

MRSA

Methicillin Resistant Staphylococcus Aureus

See if Relevant Infection - General

Additional Information Staphylococcus aureus is a widely occurring skin commensal. The carrier status or

exposure of the donor is not relevant to donation.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Multiple Sclerosis

Obligatory Must not donate.

Additional Information As the cause of multiple sclerosis is not certain and there is a possibility that there is an

underlying infectious agent, donation is not permitted.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Mumps

Affected Individual

See Infection - Acute

Contact

See Infectious Diseases - Contact with

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Muscular Dystrophy

Obligatory Structural Bone:

Must not donate if: Osteoporotic.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Myasthenia Gravis

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Myelodysplastic Syndrome

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Myeloproliferative Syndrome

Obligatory Must not donate.

Reason for Change This entry has been added to clarify the eligibility of donors with this condition.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Myocarditis

Obligatory Must not donate if:

Not recovered.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Ménière's Disease

Discretionary Accept.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Neurofibromatosis

Obligatory Must not donate if:

History of malignant change.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Neurosurgery

Obligatory Must not donate.

Discretionary a) If carried out in the UK after 1992, providing the reason for the surgery is not itself a

reason for exclusion, accept.

b) If burr hole surgery only, accept.

c) If it can be shown that Dura Mater was not used during surgery and there is no evidence

of malignancy, the donor may be accepted by a **Designated Medical Officer**.

See if Relevant Malignancy

Prion Associated Diseases

Update Information This is a requirement of the EU Tissue & Cells Directive.

This entry was last updated in TDSG-LD Edition 203, Release 34

Night Sweats

Obligatory Must not donate if:

Unexplained.

Discretionary If due to the menopause, accept.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Non-Specific Urethritis

Acute

See Infection - Acute

Chronic

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Nonsteroidal Anti-Inflammatory Drugs (NSAID)

Obligatory Assess reason for treatment and see relevant entry.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Ocular Surgery

See if Relevant Eye Disease

Laser Treatment Malignancy

Ocular Tissue Recipient

Tissue and Cell Allograft Recipients

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Ocular Tissue Recipient

Obligatory Must not donate if:

Has received a corneal, scleral or limbal tissue graft or limbal or corneal epithelial cells.

Additional Information If the surgery was performed after 1997 and the tissue was supplied through UK Transplant,

this information will be stored on the National Transplant Database.

See Prion Associated Diseases

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Organ Donor

Discretionary Accept.

See if Relevant Transfusion

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 34

Organ Recipient

Obligatory Must not donate

Reason for Change This is a new entry.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 54

Osteoarthritis

Discretionary Accept.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Osteogenesis Imperfecta

Obligatory Must not donate

Discretionary Skin

Accept for split skin allografts only; not suitable for the preparation of acellular dermal

allografts

Additional Information Osteogenesis Imperfecta is a congenital disorder that results in defective connective tissue

due to defects in the genes relating to production of Collagen I or other connective tissue proteins. Pathology includes bones that fracture easily, loose joints, poor muscle tone and

thin, discoloured sclera.

Reason for Change This is a new entry

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 25

Osteomalacia

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Osteomyelitis

Obligatory 1. Must not donate if:

a) Less than two years from completing treatment and cure.

b) Has chronic sinus.

2. Exclude:

Previously affected bone.

Discretionary If two years from completing treatment and cure, unaffected bone may be accepted.

Additional Information Sometimes it is difficult to be certain that all infection has been eliminated. Waiting two years

minimizes the risk of any infection being passed on by a donation.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Osteoporosis

Discretionary Accept.

See if Relevant Steroid Therapy

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Ovarian Cyst

Obligatory Must not donate if:

Malignant.

See if Relevant Malignancy

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 34

Paget's Disease of Bone

Includes Osteitis Deformans

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Pain Killers

Obligatory Assess reason for treatment and see relevant entry.

Must not donate if:

Taken for a serious long-term illness.

See if Relevant Nonsteroidal Anti-Inflammatory Drugs (NSAID)

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Peptic Ulcer

Includes Gastric and Duodenal Ulcer and Erosions

Obligatory Must not donate if:

Associated with malignant change.

See if Relevant Transfusion

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 34

Perthes' Disease

Discretionary Accept.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Pituitary Extract - Human

Includes Adrenocorticotrophic Hormone, Follicle Stimulating Hormone, Gonadotrophin, Growth

Hormone, Luteinising Hormone, Thyroid Stimulating Hormone.

Obligatory Must not donate if:

Has ever received injection(s) of Human Pituitary Extract.

See if Relevant Growth Hormone

Prion Associated Diseases

Additional Information Human Pituitary Extracts have been contaminated with abnormal prions and have led to the

spread of Creutzfeldt-Jakob Disease (CJD). They have been used to treat growth hormone deficiency and infertility. They have also been used in diagnostic tests to see if other endocrine glands such as the thyroid and adrenal work normally. They have not been used in the UK since 1985 and it is thought that all those exposed to these extracts have been notified of their increased risk of CJD. It is uncertain as to when their use stopped in other

countries.

Donors that have been given only synthetic pituitary hormones or gonadotrophin made from

urine may be accepted.

Reason for Change Additional information has been added for clarity.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Platelet Disorder

Obligatory See:

Is there an entry for the condition?

Discretionary If not covered by a specific entry, accept.

See if Relevant Haematological Disease

Immune Thrombocytopenia

Thrombocytosis

Reason for Change Some minor alterations have been made to improve clarity.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Pleurisy

See if Relevant Infection - General

Malignancy

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Poisoning

Obligatory Must not donate if:

There is evidence that the individual (donor/or mother of cord blood donor) has ingested, or been otherwise exposed to toxic substances that could be transmitted in donated material in

dosages that could endanger the health of recipients.

Discretionary If the individual is being monitored following exposure and the levels of the agent in question

are within safe limits, accept.

See if Relevant Addiction and Drug Abuse

Additional Information Advice may be sought from the National Poisons Information Service if required.

Reason for Change This is a new entry. This is a requirement of the Human Tissue Authority Guide to Quality

and Safety Assurance for Human Tissues and Cells for Patient Treatment

Update Information

This entry was last updated in TDSG-LD Edition 203. Release 30

Polycythaemia

Obligatory Must not donate.

If confirmed as secondary polycythaemia, accept. Discretionary

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Porphyria

Obligatory Must not donate if:

Suffers from porphyria.

If the potential donor suffers from Acute Intermittent Porphyria (AIP), Varigate Porphyria Discretionary

(VP), Hereditary Coproporphyria (HCP), Erythropoietic Protoporphyria (EPP) or Congenital

Erythropoietic Porphyria (CEP), accept.

See if Relevant Hepatitis

Porphyria Cutanea Tarda (PCT) is almost always an acquired condition associated with Additional Information

underlying liver disease, usually hepatitis of viral or unknown origin.

Reason for Change This is a new guideline.

This entry was last updated in Update Information

TDSG-LD Edition 203, Release 11

Post Viral Fatigue Syndrome

Myalgic Encephalopathy (ME) and Chronic Fatigue Syndrome (CFS) Includes

Must not donate if: Obligatory

Not resolved.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Pre- and Post Exposure Prophylaxis for HIV

Obligatory Must not donate if:

Donor has taken Pre-Exposure Prophylaxis (PrEP) or Post-Exposure Prophylaxis (PEP) in

the previous three months.

Assess any donor using PrEP or PEP for tissue safety risks relating to sexual activity.

Discretionary If it is over three months since use of PrEP or PEP and there is no other tissue safety risk,

accept

Tissues Safety Entry See if Relevant

Human Bite **Inoculation** Injury

Additional Information The use of Pre-Exposure Prophylaxis (PrEP), e.g. Truvada[®], to prevent HIV is increasing.

> Individuals taking PrEP are unlikely to be eligible to donate due to criteria within the tissue safety entry. 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.

Update Information

This entry was last updated in TDSG-LD Edition 203, Release 55

Pregnancy

Obligatory Must not donate if:

a) Resulted in a malignant (invasive) Hydatidiform mole.

b) Resulted in a non-malignant (non-invasive) Hydatidiform mole and treatment and follow up is ongoing.

c) It is less than 7 days from the last dose of methotrexate.

See if Relevant Transfusion

Additional Information Methotrexate is now increasingly used to medically treat ectopic pregnancy, to avoid surgery

and protect the fallopian tube. A week is needed for any residual methotrexate to clear the

system.

Reason for Change The addition of information about methotrexate.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 34

Prion Associated Diseases

Includes Sporadic, Familial and Variant Creutzfeldt-Jakob Disease (CJD), Gerstmann-Strãussler-

Scheinker Disease and Fatal Familial Insomnia

Obligatory Must not donate if:

1. Diagnosed with any form of CJD, or other human prion disease.

2. Identified at increased risk of developing a prion associated disorder. This includes:

a) Individuals at familial risk of prion-associated diseases (have had two or more blood relatives develop a prion-associated disease or have been informed following genetic counselling they are at risk).

b) Individuals who have been told that they have been put at increased risk from surgery, transfusion or transplant of tissues or organs.

- c) Individuals who have been told that they may be at increased risk because a recipient of blood or tissues that they have donated has developed a prion related disorder.
- d) Recipients of dura mater grafts.
- e) Recipients of corneal, scleral or other ocular tissue grafts.
- f) Recipients of human pituitary derived extracts.
- g) Since January 1st 1980 Recipients of any allogeneic human tissue.

Discretionary

If the donor has had two or more blood relatives develop a prion-associated disease and, following genetic counselling, they have been informed that they are not at risk, accept. This requires confirmation by a **Designated Medical Officer**.

See if Relevant

Pituitary Extract - Human Tissue and Organ Recipients Transfusion

Tissue and Cell Allograft Recipients

Additional Information

See the <u>Position Statement on Creutzfeldt-Jakob Disease</u> available in the JPAC Document Library.

Reason for Change

To reflect guidance from the Committee on the Microbiological Safety of Blood Tissues and Organs. There is the same concern over a possible second wave of cases of vCJD from accepting donors who have received tissue or organ transplants, as there is over donors who have been previously transfused.

Update Information

This is a requirement of the EU Tissue & Cells Directive.

This entry was last updated in TDSG-LD Edition 203, Release 23

Psoriasis

Obligatory Must not donate if:

- a) Generalized or severe.
- b) Associated with arthropathy.
- c) There is secondary infection.
- d) Immunosuppressed

Discretionary a) If the quality of the tissue being donated is not affected, accept

- b) If mild and only using topical treatment, accept.
- c) If the donor is on immunosuppressive medication, see Immunosuppression entry.

Additional Information

Psoriasis is primarily a skin condition caused by an autoimmune process. About one in ten people with psoriasis may develop joint problems (psoriatic arthropathy). Sometimes the disease is treated with powerful drugs to suppress the underlying autoimmune process. This may alter the body's defence mechanisms to infection.

Donations may be accepted if the safety and quality of the tissues is not affected.

See Autoimmune Disease

Immunosuppression

Reason for Change Treatment with Etretinate/Neotigason is no longer a reason for deferral. To clarify that if

there is no involvement of the tissue to be donated, donation may proceed. Link to

'immunosuppression' entry added.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 46.

Pulmonary Embolism

Discretionary Accept.

See if Relevant Malignancy

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Pyrexia

Not Related to Travel in Malarious Areas

Obligatory Must not donate if:

Less than two weeks from an episode of pyrexia.

Discretionary If related to a common cold or other upper respiratory tract infection from which

the donor is now recovered or recovering, accept.

See if Relevant Infection - General

Additional A raised temperature may be a sign of an infection, which could be passed on Information through a donation. Waiting two weeks from when the temperature returns to

normal reduces the risk of infection being transmitted by the donation.

There is no evidence that common colds and upper respiratory tract infections can be passed on by donation but it is still necessary to wait until any such

infection is obviously getting better before allowing donation.

Related to Travel in Malarious Areas

See Malaria

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Pyruvate Kinase Deficiency

Discretionary Accept.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Q Fever

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Rabies

Immunization - Non-exposed

Discretionary If non-exposed, accept.

Immunization - Post Exposure

Obligatory Must not donate until:

At least 24 months post exposure and fully cleared by treating physician.

Reason for Change To extend the deferral period post exposure to 24 months.

Infection

Obligatory Must not donate.

See if Relevant Animal Bite

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 40

Radiation Therapy

Obligatory Must not donate if:

a) For malignancy other than basal cell carcinoma.

b) For other treatments:

Refer to a Designated Medical Officer.

c) Bone to be collected has been exposed.

Discretionary a) If fully recovered and is acceptable according to immunosuppression advice, accept.

b) If for basal cell carcinoma or ductal carcinoma in situ of the breast, all treatment has been completed, the donor has been discharged from follow up and is eligible under the

Malignancy Guideline, accept.

See if Relevant Basal Cell Carcinoma

Immunosuppression

Malignancy

Additional Information Radiation therapy is sometimes used for non-malignant conditions, particularly for some skin

conditions. It is often used as a substitute for other treatments that work by suppressing the immune system such as high dose steroids and cytotoxic drugs. More information is likely to be required before a decision can be made as to if an individual can donate. This why a

referral to a 'Designated Medical Officer' is required.

Reason for Change Additional discretionary acceptance for basal cell carcinomas and ductal carcinoma in situ of

the breast. A link had been added to autoimmune disease, and additional information has

been added.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 29

Radionuclides

Obligatory 1. Radioactive iodine therapy:

Must not donate if:

- a) For malignancy.
- b) Administered in the preceding six months.

2. Other treatment or investigation: Refer to a Designated Medical Officer.

See if Relevant Malignancy

Thyroid Disease

Additional Information In general those used for diagnostic purposes are cleared within 24 hours. Some, e.g.

radioactive iodine, have long half-lives and affected donors must not be accepted unless at

least six months have passed.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Raynaud's Syndrome

Obligatory Must not donate if:

Part of a multisystem disorder.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Recipients of Normal Human Immunoglobulin

See if Relevant Hepatitis A

Immunosuppression Immunoglobulin Therapy

See Transfusion

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Reiter's Syndrome

Discretionary If fully recovered, accept.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Renal Colic

Obligatory Must not donate if:

a) Symptomatic.

b) Under investigation.

See if Relevant Infection - General

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Respiratory Disease

See if Relevant Infection - General

Steroid Therapy

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Retinitis Pigmentosa

Discretionary Accept.

See if Relevant Disabled Donor

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Rheumatic Fever

Discretionary Accept.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Rheumatoid Arthritis

Discretionary If mild and the only treatment is NSAIDs, accept.

See Autoimmune Disease

Reason for Change This entry is now linked to 'Autoimmune Disease'.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Ringworm

Obligatory Must not donate if:

On systemic treatment.

Discretionary If on local treatment only, accept.

See if Relevant Infection - General

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Rubella

Acute Infection

See Infection - Acute

Contact

See Infectious Diseases - Contact with

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Sarcoidosis

Acute

Obligatory Must not donate if:

a) Not recovered.

b) Less than five years from both finishing all treatment and full recovery.

Discretionary If more than five years since finishing all treatment and full recovery, accept.

Additional Information Acute sarcoidosis is normally a self limiting disease and does not require treatment in about 90% of cases. The cause is not known but there appears to be an immune defect that can run in families. Because of the uncertainty with this condition, only potential donors who have fully recovered and been off all

treatment for at least five years may donate.

Reason for Change To align the guidance with that for blood donors, new guidance to accept donors who required treatment but who have made a full recovery and have been off all

treatment for at least five years has been added.

'Additional Information" has been added.

Chronic

Obligatory Must not donate.

Additional Information Chronic sarcoidosis can cause a range of problems, particularly with the lungs but also with the heart, that may pose risks for a potential donor. The treatments used may also cause immunosuppression. For these reasons people with this condition

should not donate.

Reason for Change 'Additional Information' has been added.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 17

Sex Worker

Obligatory Must not donate.

Discretionary If 3 months or more has elapsed since the donor last received money or drugs for sex,

accept

See if Relevant Addiction and Drug Abuse

Hepatitis of Viral Origin

HIV

HTLV

Infection - General

Additional Information In this context sex is defined as vaginal, oral or anal sex with or without a condom

/protective. 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.

If received injectable drugs of addiction for sex, see 'Addiction and Drug Abuse' entry as a

12 month deferral may apply.

Reason for Change This entry was updated in line with the recommendations of the SaBTO Donor Selection

Criteria Review Report published on 23rd July 2017.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 55

Sexually Transmitted Disease

Infected Individual

Obligatory See

Is there is a specific entry for the disease?

Must not donate

Discretionary If fully treated, at least three months from completion of treatment, accept.

Additionally, for gonorrhoea, evidence of a test of cure after treatment is required.

This may be a verbal confirmation, provided by the donor.

See if Relevant Tissues Safety Entry

Chlamydia Genital Warts Herpes - Genital Syphilis

Sexual Partner

Obligatory \$

Is there is a specific entry for the disease with which there has been contact?

Must not donate if:

a) Donor required treatment and it is less than three months since completing that treatment.

b) Donor did not require treatment and it is less than three months from the last sexual contact with the infected partner.

Discretionary

- 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, evidence of a test of cure after treatment is required. This may be a 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.

See if Relevant Tissues Safety Entry

Chlamydia Genital Warts Herpes - Genital Syphilis

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.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 55

Shingles

Affected Individual

See Herpes Zoster

Reason for Change The links have been changed for clarity.

Contact

See Infectious Diseases - Contact with

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Sickle-Cell Trait

Discretionary Accept.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Skin Disease

Obligatory Must not donate if:

a) The condition is infected or infectious.

b) Malignant.

Discretionary If malignancy was a Basal Cell Carcinoma and treatment is completed, accept.

See if Relevant Dermatitis

Infection - General Malignancy Psoriasis

Reason for Change Malignancy has been added to Obligatory and additional links have been included.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Sleeping Sickness

(African Trypanosomiasis)

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Smallpox Immunization

Contacts

Obligatory Must not donate if:

a) Any secondarily infected site has not yet healed.

b) Less than eight weeks after secondarily infected site appeared.

Discretionary

If no new skin lesions, accept.

Additional Information

Close contacts of vaccinees (household or direct bodily contact) may become secondarily infected from direct skin contact with an infected inoculation site or from virus on clothing, bedding, dressings etc. If infection occurs, a new skin rash, blister or sore appears at the site of contact, which could be anywhere on the body. The rash represents a secondary vaccination site and presents exactly the same potential risk to patients and staff as that of a person who has been intentionally immunized.

Immunized Individual

Obligatory Mus

Must not donate if:

- a) The inoculation site has not fully healed.
- b) Any secondarily infected site has not fully healed.
- c) Less than eight weeks from inoculation or from the appearance of any secondarily infected site.

Additional Information Smallpox immunization is with live virus. By eight weeks, the infection caused by the inoculation should have been controlled. If the wound has not healed it is possible that there may still be infection present. We do not want to pass the virus, or other infection, on to staff, or to people receiving tissues.

Update Information

This advice is a requirement of the EU Tissue & Cells Directive.

This entry was last updated in TDSG-LD Edition 203, Release 02

Snake Bite

Obligatory

Must not donate until:

Recovered.

Update Information

This entry was last updated in TDSG-LD Edition 203, Release 02

South American Trypanosomiasis

Obligatory

Must not donate.

See if Relevant

South American Trypanosomiasis Risk

Update Information

This entry was last updated in TDSG-LD Edition 203, Release 02

South American Trypanosomiasis Risk

Obligatory

Must not donate if:

- 1) Born in South America or Central America (including Mexico).
- 2) Mother was born in South America or Central America (including Mexico).
- 3) Has had a transfusion in South America or Central America (including Mexico).
- 4) Has lived and/or worked in rural subsistence farming communities in these countries for a continuous period of four weeks or more.

Discretionary

- 1) For situations other than transfusion, if at least four months from the date of the last exposure, a validated test for *T. cruzi* antibody is negative, accept.
- 2) If transfused before 1st January 1980 and a validated test for T. cruzi antibody is negative on the donation blood sample, accept.

See if Relevant Geographical Disease Risk Index for countries with *T. cruzi* risk

Transfusion

Additional Information Infection with *T. cruzi* is very common in many parts of South or Central America and is

often symptomless. It can be passed from an infected mother to her unborn baby and by transfusion. The insect that passes the infection on is only common in rural areas and the greater time that an individual has spent living in housing conditions with thatched roofs or mud lined walls which harbour the insect vector, the greater their risk of becoming infected. Testing is available and should be performed if there is a possibility of infection. Waiting four months from the last time of exposure allows time for the antibodies that are tested for

to develop.

Camping or trekking in the jungle in South or Central America (including Mexico) is not

considered of high enough risk to merit exclusion.

Reason for Change To reduce deferral period following last date of exposure from six to four months and align

this entry with the 'Transfusion' entry.

To also align this entry with the Geographical Disease Risk Index and change the reference

to "Southern Mexico" to "Mexico".

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 41.

Spina Bifida

Obligatory Must not donate if:

a) Has an indwelling shunt and there is evidence of shunt infection.

b) Uses a catheter.

c) Has a pressure sore.

Additional Information Donated bone is cultured to exclude occult bacterial and fungal infection. However it should

not be collected from bacteraemic subjects.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Spinal Surgery

See if Relevant Neurosurgery

Transfusion

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 34

Splenectomy

Obligatory Must not donate if:

a) For malignancy.

b) For a myeloproliferative disorder.

c) For immune thrombocytopenia (ITP).

Discretionary a) If for trauma, when recovered accept.

b) If taking prophylactic antibiotics, accept.

See if Relevant

Immune Thrombocytopenia

Malignancy Transfusion

Update Information

This entry was last updated in TDSG-LD Edition 203, Release 34

Steroid Therapy

Obligatory Must not donate if:

a) Regularly taking steroid tablets, injections or enemas, or applying creams over large

areas.

b) The donor has needed treatment to suppress an autoimmune condition in the last 12

months.

c) Less than seven days after completing a course of oral or injected steroids for disorders

associated with allergy.

Discretionary a) If occasional use of creams over small areas of skin for minor skin complaints, accept.

b) If using steroid inhalers for prophylaxis, accept.

See if Relevant Autoimmune Disease

Skin Disease

Tissue and Cell Allograft Recipients

Additional Information Steroid therapy in high doses causes immunosuppression. This may mask infective and

inflammatory conditions that would otherwise prevent donation.

Reason for Change To clarify when donors who have used steroid therapy may donate.

Update Information Part of this advice is a requirement of the EU Tissue & Cells Directive.

This entry was last updated in TDSG-LD Edition 203, Release 02

Stroke

Discretionary Accept.

See if Relevant Disabled Donor

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Syphilis

1. Affected Individual

Obligatory Must not donate.

with a **Designated Medical Officer**.

Additional The interpretation of syphilis testing is often difficult. The advice of an experienced

Information microbiologist may be required before a decision on safety can be made.

2. Current or Former Sexual Partner of Affected Individual

Obligatory Must not donate if:

a) The potential donor was diagnosed with syphilis (see 'Affected Individual'

section above).

b) It is less than three months since last sexual contact with an infected partner.

Discretionary a) If it is more than three months from the last sexual contact with an infected

partner, accept.

b) If it is more than three months since an infected partner has completed

treatment, accept.

See if Relevant Tissues Safety Entry

Reason for Change The deferral period after sexual contact with an infected person has been reduced to three

months.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 55

Systemic Lupus Erythematosus

Obligatory Must not donate.

assessment, accept.

Discuss with Designated Clinical Support Officer for advice if required.

See if Relevant Immunosuppression

Reason for Change To permit discretionary acceptance of unaffected tissues subject to individual risk

assessment.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 41.

Tamoxifen

Obligatory See Malignancy entry.

Discretionary If taken for non-malignant conditions, accept.

Reason for Change To clarify that use of Tamoxifen for non-malignant conditions is not a contraindication to

donation.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 41.

Tetanus Immunization

Obligatory Must not donate if:

Less than four weeks from exposure.

Discretionary If non-exposed, accept.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Thalassaemia Major

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Thalassaemia Trait

Discretionary Accept.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Therapeutic Venesection

Obligatory Must not donate.

Discretionary If for haemochromatosis or confirmed secondary polycythaemia, accept.

See if Relevant Haemochromatosis

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Threadworms

Discretionary Even if on treatment, accept.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Thrombocytosis

Obligatory Must not donate if:

Due to a myeloproliferative disorder.

Additional Information Platelet counts in excess of 500 x 10e9/l should be repeated. If found to be persistently

raised the donor should not be accepted and referred for investigation.

Reason for Change This entry has been added to clarify the eligibility of donors with this condition.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Thrombosis

Discretionary If the underlying cause does not exclude, accept.

See if Relevant Malignancy

Update Information This entry was last updated in

Thrush - Oral

Obligatory Must not donate if:

a) Unexplained.

b) Related to immunodeficiency.

See if Relevant Infection: Chronic

Reason for Change This entry has been revised to link discretionary acceptance to the current 'Infection:

Chronic' entry.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 44

Thrush - Vaginal

Obligatory Must not donate if:

a) Related to immunodeficiency.

See if Relevant Infection: Chronic

Reason for Change This entry has been revised to link discretionary acceptance to the current 'Infection:

Chronic' entry.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 44

Thyroid Disease

Obligatory Must not donate if:

a) Under investigation.

b) Malignant.

c) Less than six months from treatment with radioactive iodine therapy.

See if Relevant Autoimmune disease

Reason for Change The 'Obligatory' statement for anti-thyroid tablets has been removed.

The reference in 'Discretionary' to treatment with thyroxine has been removed.

A link to 'Autoimmune Disease' has been added.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 34

Tissue and Cell Allograft Recipients

Excludes Xenograft recipients, recipients of biological grafts of non-human origin and bio-prosthetic

grafts and organ recipients.

Obligatory

All donors:

Must not donate if:

- a) Dura mater transplanted at any time.
- b) Ocular tissue transplanted at any time.
- c) Any other allogeneic human tissue or cell transplanted since 1st January 1980.

Discretionary

- a) If an autologous tissue, or cells, has been transplanted at any time, and there is no other reason to exclude the donor, accept.
- b) If an allogeneic tissue (except dura mater or ocular tissue) or cell transplant was performed before 1st January 1980, and there is no other reason to exclude the donor, accept.

See if Relevant

Immunosuppression
Ocular Tissue Recipient
Organ recipient
Prion Associated Diseases
Transfusion
Xenotransplantation

Additional Information

The transfer of tissues or cells between individuals and species has led to the spread of infection. The above guidelines are intended to minimise these risks.

People who have received a tissue or cell transplant since 1980 are excluded from donation of any tissues except for heart valves, ocular tissue, pancreatic islets and skin as a precautionary measure against the risk of transmission of vCJD in the same way as recipients of transfusion are.

Dura mater and ocular tissue allografts have been implicated in iatrogenic CJD. latrogenic CJD refers to the transmission of prions via inadvertent medical exposure. Recipients of dura mater and ocular tissue recipients are excluded.

Dura mater use stopped in the UK by 1993. The situation in other countries varied so specific dates cannot be given.

Tissue allograft recipients do not require immunosuppression. If the recipient was on immunosuppression for any other reason, see Immunosuppression entry.

Reason for Change T

This is a new entry.

Update Information

This entry was last updated in TDSG-LD Edition 203, Release 54

Tissue and Organ Recipients

Obligatory

Must not donate if:

- 1. At any time:
- a) Has needed immunosuppression.
- b) Dura mater transplanted.
- c) Ocular tissue transplanted.
- d) Xenotransplant performed.

2. Since January 1st 1980:

Any allogeneic human tissue or organ transplanted.

Discretionary

a) If an allogeneic tissue or cell transplant was performed before January 1st 1980 and there is no other reason to exclude the donor, accept.

b) If at anytime an autologous tissue, or cells, has been transplanted, accept.

See if Relevant

Immunosuppression
Ocular Tissue Recipient
Prion Associated Diseases
Xenotransplantation

Additional Information

The transfer of tissues or organs between individuals and species has lead to the spread of infection. The above guidelines are intended to minimize these risks.

There is now a concern that this could also happen with vCJD. This is because in the autumn of 2003 a UK recipient of blood, taken from a healthy donor who later developed vCJD, died from vCJD. Since then there have been several cases of infection with the vCJD prion in recipients of blood from donors who have later developed vCJD. In view of this, people who have received a tissue or organ transplant since 1980, will be excluded from donation in the same way as recipients of transfusion are. This date is before BSE, which is believed to have caused vCJD, was prevalent.

See Transfusion

Reason for Change

To clarify that transplantation of an autologous tissue, or cells, is not a contra-indication to donation, whether or not the tissue, or cells, were stored prior to transplantation.

Update Information

This entry was last updated in TDSG-LD Edition 203, Release 34

Tissues Safety Entry

Definition

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
- 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.

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

See if Relevant

Addiction and Drug Abuse

Hepatitis B

Hepatitis C

Hepatitis of Viral Origin

HIV

HTLV

Infection - General

Pre- or Post-Exposure Prophylaxis for HIV

Sexually Transmitted Disease

Syphilis

Additional Information

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.

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.

Update Information

This entry was last updated in TDSG-LD Edition 203, Release 55

Toxoplasmosis

Obligatory Must not donate if:

Confirmed current active infection at the time of donation.

See if Relevant Infection - Acute

Additional Information This is a common parasitic infection, often spread by cat faeces or eating undercooked

meat. It can be spread through transfusion. It may have serious consequences or even prove fatal for the recipient. Usually it does not cause symptoms, as the body's immune

system easily overcomes the parasite. Testing of tissue donors is not required.

Reason for Change To remove the requirement for six month deferral following resolution of infection.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 30

Transfusion

Includes Treatme

Treatment with Blood Components, Products and Derivatives.

Obligatory

1. Must not donate if:

At any time the donor has:

- a) Received, or thinks they may have received, a transfusion of blood or blood components in a country endemic for malaria or South American trypanosomiasis. See 'Discretionary' section below for exceptions.
- b) Has received regular treatment with blood derived coagulation factor concentrates.

2. Must not donate if:

Since January 1st 1980:

- a) Anywhere in the world, the donor has received, or thinks they may have received, a transfusion with red cells, platelets, fresh frozen plasma (FFP), cryoprecipitate. This includes mothers whose babies have required intra-uterine transfusion.
- b) Had a plasma exchange performed.

3. Before January 1st 1999:

- a) Treated with prothrombin complex to reverse over-anticoagulation.
- b) Received intravenous or subcutaneous human normal immunoglobulin.

Discretionary 1. a) If on medical inquiry it is unlikely that the donor has been transfused, accept.

- b) Received, or thinks they may have received, a transfusion of blood or blood components before 1st Jan 1980, accept See 4 below if transfused abroad
- c) If treatment with human immunoglobulin has been limited to small quantities of specific immunoglobulin as prophylaxis (e.g. rhesus, tetanus, hepatitis, immunoglobulin etc.), accept.
- d) Treated with prothrombin complex (PCC) to reverse over-anticoagulation after 1st January 1999, accept.
- e) If treated with intravenous immunoglobulins after 1st January 1999: if underlying condition is not a contraindication, accept. Refer to designated clinical support officer if further advice required.

2. Autologous Transfusion:

If only the donor's own blood has been used, accept.

- **3. Heart valve donors only:** Provided the donor's total transfusion exposure is limited to less than 80 units of blood or blood components, accept. See 4 below if transfused abroad.
- 4. Donor transfused before 1st January 1980 in a country endemic for malaria or South American trypanosomiasis :
- a) Check the Geographical Disease Risk Index. If transfused in an at risk endemic country and a validated malarial antibody test and/or (as appropriate) a validated test for T.cruzi antibody is negative on the donation sample accept.
- b) If tissue will be sterilized by irradiation post-donation: Accept (testing not required)

See if Relevant

Bleeding Disorder

Immunoglobulin Therapy

Immunosuppression

Malaria

Prion Associated Diseases

South American Trypanosomiasis Risk

Geographical Disease Risk Index

Additional Information

Transfused donors have previously contributed to the spread of some diseases. This happened with hepatitis C.

All transfused donors:

Transfusions in some countries may have put the donor at risk of malaria or South American trypanosomiasis. It is necessary to exclude these infections (with the exception of donations of tissues that are terminally sterilised) before accepting the donor.

Coagulation concentrates:

People who have received blood derived coagulation concentrates (these are made from the blood of many donors) regularly may have been put at risk of infections that can be passed through blood.

Donors transfused since 1980:

In the autumn of 2003 a UK recipient of blood, taken from a healthy donor who later developed vCJD, died from vCJD. Since then there has been a very small number of cases of infection with the vCJD prion in recipients of blood from donors who have later developed vCJD.

In view of this, people transfused or possibly transfused since 1980 should not normally be accepted. Because of shortages in supply, this does not currently apply to the donation of heart valves. Any history of transfusion after 1980 must be recorded and remain part of the documentation associated with the donation.

Plasma exchange results in the patient having been exposed to multiple donors. In view of the increased vCJD risk, donations may not be taken from individuals who have had a plasma exchange performed since 1980.

Commonly used PCCs, such as Beriplex or Octaplex, currently used in the UK, are prepared from non-UK donors. They are administered as one-off doses to reverse anticoagulation or peri-operative prophylaxis. Since 1999, coagulation factors and intravenous immunoglobulin prepared from UK donors have no longer been used as a risk reduction measure for vCJD transmission.

Reason for Change To permit donation from donors who have received intravenous immunoglobulin after 1st

January 1999, if the reason for treatment is not a contraindication.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 44.

Transgender Individuals

Definition 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.

Discretionary Obtain history and refer to designated medical officer if necessary

See if Relevant <u>Tissues Safety Entry</u>

Additional Information 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.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 55

Travel

See if Relevant Geographical Disease Risk Index

Malaria

South American Trypanosomiasis Risk

Infection - Tropical

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Tropical Viruses

Includes Chikungunya Virus, also known as CHIKV

Dengue Virus, also known as Dengue Fever

Yellow Fever, also known as YF

Zika Virus, also known as ZIKV, and Zika Virus Fever

Definition Tropical Virus Endemic Areas: are shown in the 'Geographical Disease Risk Index'

(GDRI) as a Tropical Virus Risk.

Obligatory

Must not donate if:

a) It is less than six months from a donor's return from a Tropical Virus Risk endemic area and the donor has been diagnosed with Chikungunya, Dengue, Yellow Fever or Zika virus infection whilst there or following their return to the UK.

b) It is less than six months from a donor's return from a Tropical Virus Risk endemic area and the donor has either had a history of symptoms suggestive of Chikungunya, Dengue, Yellow Fever or Zika virus infection whilst there or following their return to the UK.

c) In other cases it is less than four weeks from a donor's return from a Tropical Virus Risk endemic area.

Discretionary

All donors may be accepted six months after their return from an affected area or resolution of symptoms. This may be reduced to four weeks, if they have had no clinical evidence of infection.

See if Relevant

Infection - General

Malaria

South American Trypanosomiasis
The 'Geographical Disease Risk Index'

Additional Information

Chikungunya, Dengue, Yellow Fever and Zika virus are spread by the day-flying mosquito species Aedes aegypti and Aedes albopictus. As these mosquitos are typically found in tropical and subtropical regions, the main geographical areas affected by tropical virus infection are the Caribbean, South and Central America, Mexico, Africa, the Pacific Islands, Southeast Asia, Indian sub-continent, Hawaii and northern parts of Australia. The range of Aedes albopictus is also increasing into more temperate zones leading to outbreaks of tropical virus disease in new areas. There have been outbreaks of Dengue and Chikungunya in parts of Europe.

Chikungunya is an alpha virus that can cause a wide spectrum of disease. This may range from no or minimal symptoms to death. Most commonly it causes arthritis (typically in the knee, ankle and small joints of the extremities), high fever and a maculopapular rash.

Chikungunya virus is found in countries in Asia, Africa, Central and South America, and in the islands of the Caribbean. There is no evidence of person-to-person transmission except through blood transfer. Transfusion-transmission from an asymptomatic individual has not been documented. Nevertheless, restrictions after travel to a Chikungunya virus risk area were introduced to reduce any risk of transmission through blood or tissue donation.

Dengue Virus is a flavivirus that typically gives rise to abrupt high fever with a range of accompanying symptoms. Dengue fever (DF) is the most common insect-borne disease worldwide. Dengue is currently considered endemic in approximately 140 countries. Transfusion-transmission has been reported.

Overall, up to 75% of cases are asymptomatic or mild. If symptoms occur, they can range from non-specific acute febrile illness to severe disease including dengue haemorrhagic fever and dengue shock syndrome. Mild cases may be misdiagnosed as other febrile illnesses.

Yellow Fever Virus is a flavivirus which is found in Africa, South America, Central America and parts of the Caribbean. Symptoms of Yellow Fever include high temperature, headache, nausea and vomiting, muscle pains and backache. One in four individuals may suffer from jaundice and bleeding from the gastrointestinal tract and other sites.

Zika Virus is a flavivirus which was known to occur in Africa and parts of Southeast Asia. More recently, Zika Virus has been associated with epidemic outbreaks in the Pacific region and in the Americas. As well as mosquito-borne infection, Zika Virus can be spread through sexual transmission. Infection is usually asymptomatic or presents as a mild self-limiting febrile illness. More severe disease and hospitalisation are rare but infection during pregnancy carries a high risk of congenital abnormalities in the baby. Zika Virus infection may be mistaken for Chikungunya or Dengue infections as these viruses often co-circulate.

<u>Position statements</u> are available in the JPAC Document Library.

Reason for Change

Discretionary guidance has been revised.

Update Information

This entry was last updated in TL-DSG Edition 203 Release 57

Trypanosoma Cruzi Infection

Obligatory Must not donate.

See if Relevant South American Trypanosomiasis Risk

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Tuberculosis

Affected Individual

Obligatory Must not donate if:

b) Under follow-up.

a) Infected.

c) Ever had clinically active tuberculosis.

d) Diagnosed with latent tuberculosis within past two years.

Discretionary a) If don

a) If donor with a history of tuberculosis that has been successfully treated, with treatment being completed at least 24 months previously, been discharged from follow up, and has remained well and asymptomatic – refer to DCSO for individual risk assessment.

b) Donors with a diagnosis of latent tuberculosis currently not undergoing investigation, or more than seven days after completion of treatment: refer to DCSO for individual risk assessment.

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c) See Additional Information.

See if Relevant Bo

Heaf Test Mantoux Test

Contact

Obligatory Must not donate until:

Screened and cleared.

Discretionary If the donor has been informed that they do not need to be screened, accept.

See if Relevant BC

BCG Heaf Test Mantoux Test

Additional Information

Tuberculosis can be present in many tissues and be spread through the blood stream. It is sensible to exclude people who may have active disease from donating to prevent any possibility of transmitting the infection.

Individuals with latent tuberculosis do not have symptoms of active infection. Treatment is usually recommended for individuals aged under 65. Antibiotics used to treat tuberculosis can cause liver damage in older adults, and hence treatment may not be offered. If latent tuberculosis is thought to be drug resistant, or if the individual is taking immunosuppressive medication for any reason, they may be regularly monitored to check the infection does not become active.

DCSOs should consider all the TB risk factors in combination, and along with any clinical signs, symptoms, or radiological evidence of TB, treatment during review of donor eligibility, along with the processing methodology applied.

Donors with past treated tuberculosis can be accepted if tissues are to be terminally sterilised or processed in a manner validated to remove viable donor cells. However, this does not apply to any bone that has been the site of previous infection.

Reason for Change

Obligatory section updated to include past active TB and latent TB. Discretionary section updated to require that donors with a past history of treated TB be referred to DCSO for individual risk assessment. Additional points added to Discretionary section and Additional Information section updated.

Update Information

This entry was last updated in TL-DSG Edition 203 Release 58

Turner's Syndrome

Discretionary

Accept.

Update Information

This entry was last updated in TDSG-LD Edition 203, Release 02

Vasculitis

Obligatory

Must not donate.

Update Information

This entry was last updated in TDSG-LD Edition 203, Release 02

Viral Haemorrhagic Fever

Includes

Crimean-Congo Fever
Ebola Virus Disease
Lassa Fever
Marburg Fever

1. Affected Individual

Obligatory

Must not donate if:

a) Has ever been infected

2. Contact or traveller to endemic country

Obligatory

Must not donate if:

- a) Was present in an area during an active outbreak
- b) Under investigation for viral haemorrhagic fever
- c) Has been in contact with an individual who was present in an area during an active outbreak
- d) Was in contact with an individual infected with, or was under investigation for viral haemorrhagic fever
- e) less than six months after return to UK from an endemic area when there was no active outbreak

Under exceptional circumstances, the donor may be accepted subject to individual risk assessment. **Refer to designated medical officer**. See additional information section.

Discretionary

Accept if:

a) If more than 6 months after return to UK from an endemic area when there was no active outbreak at the time of visit

b) If the individual, or the contact person, under investigation had viral haemorrhagic fever infection excluded as diagnosis.

3. Sexual Partner of Affected Individual

Obligatory

Must not donate:

If the donor has had sex with an individual who had been diagnosed with a Viral Haemorrhagic Fever at any time before their last sexual contact.

See if Relevant

The Geographical Disease Risk Index for countries with a current endemic Viral Haemorrhagic Fever risk.

Additional Information

These infections have very high death rates and there is evidence that the virus may persist for some time after recovery. The 2014-16 outbreak of Ebola in West Africa had increased understanding about the persistence of the virus in affected individuals and the number of asymptomatic individuals who may be able to transmit the virus to others.

There is no routine screening test for EBOV currently available. There is an option to test donors serologically for the presence of anti-EBOV (antibodies) two months after the exposure event if a test becomes available. A reactive test would result in permanent deferral, a negative test would allow donation to proceed. Designated medical officers may seek expert advice where necessary, under exceptional circumstances.

There is evidence of persistent virus in individuals who recover from several forms of Viral Haemorrhagic Fever. For this reason, it is necessary to defer the sexual partners of these individuals.

Reason for Change

A permanent deferral has been introduced for donors who have had sex with an individual who has been diagnosed with a Viral Haemorrhagic Fever, and definition of Viral Haemorrhagic Fever provided.

Update Information

This entry was last updated in TDSG-LD Edition 203. Release 40

Vitamin Treatment

Discretionary

Accept.

Update Information

This entry was last updated in TDSG-LD Edition 203, Release 02

Warts

Discretionary

Even if on local treatment, accept.

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.

Update Information

This entry was last updated in TDSG-LD Edition 203, Release 55

West Nile Virus

Definition

West Nile Virus (WNV) Endemic Areas:

These are shown in the 'Geographical Disease Risk Index' (GDRI).

Obligatory

Must not donate if:

a) It is less than six months from a donor's return from a WNV endemic area and the donor has been diagnosed with WNV whilst there or following their return.

b) It is less than six months from a donor's return from a WNV endemic area and the donor has either had a history of symptoms suggestive of WNV whilst there or within 28 days of their return.

c) In other cases it is less than four weeks from a donor's return from a WNV endemic area.

Discretionary

- 1) All donors may be accepted six months after their return from an affected area. This may be reduced to four weeks if they have had neither symptoms nor evidence of infection. For donors who have been back in the UK for less than four weeks, who have not been diagnosed with WNV infection and who have not had symptoms suggestive of WNV infection, if a validated NAT for WNV is to be undertaken on the donated component(s), accept.
- 2) Donors who have been back in the UK for less than six months, who have had symptoms suggestive of WNV infection while abroad or within 28 days of return, (but no firm diagnosis of WVN infection) if a validated NAT for WNV is to be undertaken on the donated component (s), accept.

See if Relevant

The 'Geographical Disease Risk Index'

Additional Information

West Nile Virus is a flavivirus, similar to Dengue, which causes a wide spectrum of infection. This may range from no or minimal symptoms to death. It is geographically widespread, including areas in Europe and other parts of the world not affected by Malaria, and it has reached epidemic proportions in North America in recent years. There it has caused illness and death post transfusion and post transplantation of tissues and organs. It is spread by mosquitoes and so is more prevalent at times of the year when mosquitoes are active.

As the problem can vary both in relation to geography and time of the year it is not possible to state areas from which donors need to be deferred and dates of disease activity. These are provided in the 'Geographical Disease Risk Index'.

A 'Position Statement on West Nile Virus (WNV)' is available in the 'Document Library' of 'www.transfusionguidelines.org'.

Reason for Change

To increase the deferral of donors following infection with West Nile Virus or symptoms suggestive of West Nile Virus Infection to six months and to remove the requirement for a negative NAT test for these donors prior to donation.

Update Information

This entry was last updated in: TDSG-LD Edition 203, Release 23.

Whooping Cough

Contact

See Infectious Diseases - Contact with

Infection

See Infection - Acute

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Wilson's Disease

Discretionary Accept.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Xenotransplantation

Includes Xenografts

Heterografts

Non-Human Organ Perfusion

Recipient

Definition Any procedure that involves the transplantation, implantation, or infusion into a

human recipient of either (a) live cells, tissues, or organs from a non-human animal source, or (b) human body fluids, cells, tissues, or organs that have had ex vivo contact with live, non-human animal cells, tissues, or organs.

Xenotransplantation products include live cells, tissues and organs.

Biological products, drugs, or medical devices sourced from **nonliving cells**, tissues or organs from non-human animals, including but not limited to porcine insulin, porcine heart valves, and collagen matrices derived from acellular porcine, bovine or any other xenogeneic source (e.g. PelviSoft®, Bio-Oss®, Bio-Gide® and

Surgibone®) are not considered xenotransplantation products.

Obligatory Must not donate if:

Material from a living non-human animal source has been directly or indirectly in

contact with the donor's blood supply. This does not include animal bites.

Sexual Partners of Xenotransplant Recipients, Current and Former

Obligatory Must not donate.

Additional Exposure to non-human animal material, particularly when the person exposed is Information

immunosuppressed, may result in infections that would not normally affect

humans being passed on.

Reason for Change Further guidance re Recipient definition

Update Information This advice is a requirement of the EU Tissue & Cells Directive.

> This entry was last updated in TDSG-LD Edition 203, Release 25

XMRV

Discretionary Donors who have been tested positive for XMRV, accept.

As there is no evidence that XMRV is implicated in human disease, a positive test is not a Additional Information

bar to donation.

Reason for Change This is a new entry.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 12 Issue 01

Yaws

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-LD Edition 203, Release 02

Updates

Specification of Current Version			
Publication	TL-DSG	TL-DSG	
Edition	203		
Release	59		
Issue	01 26 November 2024		

All changes to TL-DSG Edition 203 after Release 01

Dalaa	Data	Change Notifications		
Release	Date	Title	CN No.	
59	26 November 2024	Hepatitis A	45 - 2024	
58	13 August 2024	Tuberculosis	33 - 2024	
57	18 April 2024	Tropical Viruses	13 - 2024	
		Coronavirus Vaccination	10 - 2024	
56	15 November 2023	Coronavirus Infection (COVID-19)	33 - 2023	
55	15 November 2023	Changes arising from the FAIR III report	17 - 2023	
54	04 July 2023	Tuberculosis	25 - 2023	
		Tissue and Cell Allograft Recipients	14 - 2023	
53	09 May 2023	Tropical Viruses	12 - 2023	
52	12 April 2023	Malaria	21 - 2023	
		Mpox (Monkeypox)	13 - 2023	
51 13 D	13 December 2022	Infectious Disease - Contact With	52 - 2022	
		Coronavirus Infection (COVID-19)	51 - 2022	
50	12 September 2022	Table of Immunisations	<u>55 -</u> 2022	
49	31 May 2022	Monkeypox	41 - 2022	
48	26 April 2022	Yellow Fever	21 - 2022	
47	07 April 2022	Coronavirus Infection	30 - 2022	
46	16 March 2022	Diseases of Unknown Aetiology	17 - 2022	
		Cervical Dysplasia	16 - 2022	
		Body Piercing	15 - 2022	
		Psoriasis	14 - 2022	
		Infertility	13 - 2022	
	-		2022	

45	22 February 2022	Complementary Therapy	<u>04 -</u> 2022
44	04 August 2021	Thrush - Oral & Vaginal	30 - 2021
		Infertility	27 - 2021
		Immunisation	<u>26 -</u> <u>2021</u>
		Immune Thrombocytopenia, Immunoglobulin Therapy and Transfusion	<u>25 -</u> 2021
		Coronavirus Vaccination	<u>23 -</u> 2021
		Coronavirus Infection	<u>22 -</u> 2021
		Colitis, Proctitis and Gastrointestinal Disease	20 - 2021
		Acne and Teratogenic Medications	19 - 2021
43	21 January 2021	COVID-19 Vaccination	05 - 2021
42	16 December 2020	COVID-19 Vaccination	74 - 2020
41	07 October 2020	Sexually Transmitted Disease	61 - 2020
		Systemic Lupus Erythematosus	46 - 2020
		Transfusion	<u>45 -</u> 2020
		South American Trypanosomiasis Risk	<u>44 -</u> 2020
		Infection - Chronic	<u>43 -</u> 2020
		Tamoxifen	42 - 2020
40	15 July 2020	Infection - Acute	41 - 2020
		Tamiflu [®] and Relenza [®]	<u>40 -</u> 2020
		Viral Haemorrhagic Fever	38 - 2020
		Rabies	<u>37 -</u> 2020
		Animal Bite	36 - 2020
39	08 June 2020	Coronavirus Infection	31 - 2020
38	23 March 2020	Coronavirus Infection	16 - 2020
37	24 February 2020	Coronavirus Infection	10 - 2020
36	17 February 2020	Coronavirus Infection	08 - 2020
35	24 January 2020	Coronavirus Infection	05 - 2020
34	12 November 2019	Surgery	16 - 2019
33	30 September 2019	Sexually Transmitted Disease	23 - 2019
		Malignancy	22 -

	I	1	2019
		Inflammatory Bowel Disease	20 - 2019
		Hepatitis C	19 - 2019
		Complementary Therapy	17 - 2019
		Viral Haemorrhagic Fever	15 - 2019
		Tissue Safety Entry	14 - 2019
		Pre- and Post-Exposure Prophylaxis for HIV	13 - 2019
		Hepatitis A	12 - 2019
32	26 September 2018	Transgender Individual	<u>32 -</u> 2018
		Infection - Chronic	28 - 2018
		Infection - Acute	27 - 2018
31	24 April 2018	Viral Haemorrhagic Fever	<u>15 -</u> 2018
		Transfusion	<u>14 -</u> 2018
		Hepatitis E	10 - 2018
		Hepatitis A	09 - 2018
		Central Nervous System Disease	04 - 2018
30	17 January 2018	Toxoplasmosis	02 - 2018
		Poisoning	01 - 2018
29	27 November 2017	Bleeding Disorder	50 - 2017
		Syphilis	48 - 2017
		Sex Worker	46 - 2017
		Inoculation Injury	<u>43 -</u> <u>2017</u>
		HTLV	42 - 2017
		Homosexual and Bisexual Individuals	<u>40 -</u> <u>2017</u>
		HIV	38 - 2017
		Hepatitis C	36 - 2017
		Hepatitis B	34 - 2017
		Complementary Therapy	32 - 2017
		Body Piercing	30 - 2017
		Addiction and Drug Abuse	28 - 2017
I	1		

		Tissue Safety Entry	<u>27 -</u> 2017
		Surgery	24 - 2017
		Tissue and Organ Recipients	23 - 2017
		Radiation Therapy	22 - 2017
28	01 August 2017	Malaria	<u>17 -</u> <u>2017</u>
27	10 October 2016	Hepatitis A	46 - 2016
		Cardiomyopathy	<u>44 -</u> 2016
26	01 September 2016	Tissue Safety Entry, Sex Change & Homosexual and Bisexual Individuals	36 - 2016
25	13 July 2016	Xenotransplantation	29 - 2016
		Severe Exercise Intolerance Syndrome (SEID)	28 - 2016
		Osteogenesis Imperfecta	27 - 2016
		Fibromyalgia	25 - 2016
		Endoscopy	24 - 2016
24	02 February 2016	Viral Haemorrhagic Fever	<u>15 -</u> 2016
		Tropical Viruses	<u>14 -</u> 2016
23	18 January 2016	Viral Haemorrhagic Fever	11 - 2016
		West Nile Virus	09 - 2016
		Tropical Viruses	08 - 2016
		Table of Immunisations	04 - 2016
22	04 August 2015	Homosexual and Bisexual Individuals (Northern Ireland)	17 - 2015
21	23 June 2015	Injectable Tanning Agents	15 - 2015
		Complementary Therapy	12 - 2015
20	17 March 2015	Infertility	09 - 2015
		Complementary Therapy	08 - 2015
		Communication Difficulties	07 - 2015
19	20 October 2014	Viral Haemorrhagic Fever Risk	43 - 2014
18	11 August 2014	Sex Change	40 - 2014
		Homosexual and Bisexual Individuals	37 - 2014
		Tissues Safety Entry	32 - 2014
		SARS	31 -

		2014
	Haematological Disease	30 - 2014
31 March 2013	Paratyphoid and Typhoid	15 - 2013
	South American Trypanosomiasis Risk	14 - 2013
	Sarcoidosis	13 - 2013
	Mental Health Problems	12 - 2013
	Malignancy	11 - 2013
	Kidney Disease	10 - 2013
	Hepatitis of Unknown Origin	08 - 2013
	Central Nervous System Disease	05 - 2013
	Aliretinoin, Toctino, Acne and Dermatitis	03 - 2013
	Acupuncture	02 - 2013
09 July 2013	Infection - Chronic	10 - 2013
	Hepatitis B - Post Immunisation	09 - 2013
	Hepatitis B	08 - 2013
04 June 2013	West Nile Virus	01 - 2013
29 June 2012	Toxoplasmosis	18 - 2012
	Psoriasis	17 - 2012
	Pregnancy	16 - 2012
	Acne	15 - 2012
28 March 2012	West Nile Virus	05 - 2012
24 January 2012	Hepatitis C	27 - 2011
	XMRV	25 - 2011
06 December 2011	Porphyria	20 - 2011
01 September 2011	Malaria	14 - 2011
08 August 2011	West Nile Virus	11 - 2011
21 June 2011	Sexually Transmitted Disease	09 - 2011
	Infertility	08 - 2011
	BCG	07 - 2011
	Immunisation - Live	06 - 2011
	09 July 2013 04 June 2013 29 June 2012 28 March 2012 24 January 2012 06 December 2011 01 September 2011 08 August 2011	31 March 2013 Paratyphoid and Typhoid South American Trypanosomiasis Risk Sarcoidosis Mental Health Problems Malignancy Kidney Disease Hepatitis of Unknown Origin Central Nervous System Disease Aliretinoin, Toctino, Acne and Dermatitis Acupuncture 109 July 2013 Infection - Chronic Hepatitis B - Post Immunisation Hepatitis B 104 June 2013 West Nile Virus 29 June 2012 Toxoplasmosis Prognancy Acne 28 March 2012 West Nile Virus 24 January 2012 Hepatitis C XMRV 10 December 2011 Malaria 10 Raugust 2011 West Nile Virus 21 June 2011 Sexually Transmitted Disease Infertility BCG

07	01 September 2010	West Nile Virus	09 -
06	03 March 2010	Inoculation Injury	<u>2010</u> 04 -
		, ,	2010
		Endoscopy	03 - 2010
		Body Piercing	02 - 2010
05	24 December 2009	Complementary Therapy	35 - 2009
		Acupuncture	33 - 2009
04	04 December 2009	Relenza [®] (Zanamivir)	29 - 2009
		Tamiflu [®] (Oseltamivir)	28 - 2009
03	03 January 2008	Bleeding Disorder	18 - 2007
		A change was made to the version control definitions and all Issue numbering information removed.	9
02	03 December 2007	Public release – for changes see Appendix 1 - Changes to the Guidelines	
01	01 June 2007	Consultation release – not for implementation	

Appendix 1 - Changes to Donor Selection Guidelines

Section 1

Changes introduced with TDSG-LD 203 Release 02 from TDSG-LD 202 Release 03

There have been changes made to the following entries:

Acupuncture

Animal Bite

Ankylosing Spondylitis

Anti-Androgens

Antibiotic Therapy

Antidepressant Therapy

Arthritis

Autoimmune Disease

Bipolar Disorder

Bleeding Disorder

Cardiomyopathy

Cardiovascular Disease

Chikungunya Virus

Chlamydia

Cirrhosis

Colitis

Communication Difficulties

Depression

Disabled Donor

Disease of Unknown Aetiology

Ehlers-Danlos Syndrome (Disease)

Elliptocytosis

Endocarditis

Endoscopy

Episcleritis

Eye Disease

Gall Bladder Disease

German Measles

Haemoglobin Disorders

Haemolytic Anaemia

Hepatitis B

Hepatitis B - Post Immunization

Hepatitis C

Hepatitis of Unknown Origin

Hereditary Elliptocytosis

Hormone Replacement Therapy

Immune Thrombocytopenia

Immunoglobulin Therapy

Immunosuppression Infection - Acute

Infection - Chronic

Inflammatory Eye Disease

Inoculation Injury

Jaundice

Mental Health Problems

Myeloproliferative Syndrome

Pituitary Extract - Human

Platelet Disorder

Polymyalgia Rheumatica

Prion Associated Diseases

Psoriasis

Rheumatoid Arthritis

Scleritis

Sexually Transmitted Disease

Shingles

Skin Disease

Steroid Therapy

Subacute Bacterial Endocarditis

Surgery

Syphilis

Temporal Arteritis

Thrombocytosis

Thyroid Disease

Tigason

Tissue and Organ Recipients Transfusion West Nile Virus

Section 2 Changes to TDSG-LD 203 after Release 02

See: Latest Updates

This appendix was last updated in TDSG-LD Edition 203, Release 02

Appendix 2 - Medical criteria for the withdrawal of donations following information received after donation

General considerations.

Circumstances that should have excluded donation may only become known after tissue has been taken. For the purposes of these guidelines, these circumstances are categorised below, along with appropriate actions. The action to be taken will be determined by any **A-Z** entry relevant to the safety of the recipient. If there is no relevant entry, a consideration of recipient safety will underlie the action taken.

Procedures must be maintained by all Services to ensure prompt reporting of late donation information and, if necessary, withdrawal of donated tissue. Concerns arising from hearsay reports should be addressed by procedures established to ascertain the credibility of any such concerns.

If donations have been used before a withdrawal could be initiated, the **Designated Medical Officer** must decide upon appropriate action. This will include, if there are likely to be severe consequences from having received the tissue transplant, contacting the clinician caring for the recipient and discussing notification of the recipient. In certain circumstances, a look-back procedure may need to be initiated.

1. Late notification of donation test results.

This may occur because:

- a) The results of microbiological screening tests are brought into question.
- b) Additional information becomes available, e.g. the results of further testing.
- c) It is discovered that testing was not performed within the agreed procedures (e.g. as a result of audit or notification of defective reagents by the manufacturer).
- d) A report is received from the recipient's medical attendants of a post-transplant infection thought to have been transmitted by the donation.

Action: Inform the Designated Medical Officer.

- 2. Notification of circumstances that should have triggered deferral at the time of donor selection.
- a) Circumstances which place a donor at risk of infection with blood borne organisms (Tissues Safety Entry).
- b) Donors in the 'at risk' categories relating to possible transmission of **Prion Associated Diseases** e.g. CJD and vCJD.
- c) Donors with Malignancy (other than those for which there is a discretion in the A-Z)
- d) Autoimmune Disease.
- e) Allergy.
- f) Donors with certain **Infectious Diseases** at the time of donation or who were in contact with and still within the incubation period of an **Infectious Disease** at the time of donation.
- g) Donors with diseases of unknown aetiology.

Action: Inform the Designated Medical Officer.

This appendix was last updated in TDSG-LD Edition 203, Release 02, Issue 01

Appendix 3 - Table of Immunisations

Diseases protected against	Comments and example trade names of adult preparations	
Anthrax	Rarely given available only through Public Health England.	Non-Live
Cholera	Oral vaccine. Dukoral®	Non-Live
COVID-19 (SARS-CoV-2)	All COVID-19 vaccines licenced in the UK are Non-Live. These include:	Non-Live
	 Pfizer BioNTech (tozinameran/Comirnaty[®]) AstraZeneca (Vaxzevira[®]) Moderna (Spikevax[®]) Janssen Ad26.COV2-S Novavax (Nuvaxovid[®]) COVID-19 Vaccine Valneva 	
HiB	Haemophilus influenza, Menitorex®	Non-Live
Hepatitis A	May be combined with typhoid or hepatitis B. Hepatis A only: Vaqta [®] , Avaxim [®] , Havrix [®] Combined with typhoid: Viatim [®] Combined with Hepatits B, Ambirix [®] , Twinrix [®] ,	Non-Live
Hepatitis B	May be combined with hepatitis A If unexposed and more than 7 days from last immunization, accept. See: Hepatitis B – Immunisation Engerix [®] , Fendrix [®] , HBvaxPRO [®] , Ambirix [®] , Twinrix [®]	Non-Live
HPV	Cervarix [®] , Gardasil [®]	Non-Live
Influenza-intra-nasal	Live vaccine given by intra-nasal spray, age 2- 18 Fluenz Tetra [®]	<u>Live</u>
Influenza, injection	annual flu jab, given by injection Several preparations, updated annually.	Non-Live
Japanese Encephalitis	Travel. Ixiaro [®]	Non-Live
Measles, Mumps, Rubella	MMR vaccines. M-M-RvaxPro®, Priorix®	Live
Meningitis	Meningococcal group C:, NeisVac-C [®] , Menjugate Kit [®] Meningococcal group B: Bexsero [®] , Trumenba [®] MenACWY Quadrivalent vaccine: Menveo [®] , Nimenrix [®] , MenQuadfi [®] Combined with H. influenzae type b (Hib): Menitorix [®]	Non-Live
Monkeypox	During the 2022 Monkeypox outbreaks, contacts of Monkeypox cases may receive Imvanex, a live attenuated non-replicating Smallpox vaccine. For donor selection purposes this should be assessed as a non-live vaccine. See DSG entry for Monkeypox	
Pertussis	Usually pregnant women, Boostrix-IPV [®] , Repavax [®]	Non-Live
Pneumococcal disease	Given to people with specific risks for example, people who have had a splenectomy or over 65s Pneumovax23 [®]	Non-Live
Polio, injected	Would usually be given Diphtheria, Tetanus and Polio (injection). Boostrix-IPV [®] , Revaxis [®] , Repevax [®]	Non-Live
Polio, oral	Not in routine use in UK. May be used abroad	Live

Rabies	Given to non-exposed individuals if occupation or	Non-Live
	activity has an exposure risk, or for some	
	travellers to endemic areas: Rabipur [®] , Verorab [®]	
Shingles	There are two vaccines available to prevent	<u>Live</u>
	shingles: Zostavax [®] and Shingrix [®] .(See below). Ensure the correct guidance is applied depending on the vaccine given. If vaccine name not certain, treat as a Live vaccine	
	Zostavax [®] for shingles prevention	<u>Live</u>
	Shingrix [®] for shingles prevention	Non-Live
Smallpox	Note this live vaccine requires an 8 week deferral If given, see DSG entry for Smallpox Immunization. See Monkeypox (above)	<u>Live</u>
Tetanus	Would usually be given Diphtheria, Tetanus and Polio. Revaxis [®] Boostrix-IPV [®] , Repevax [®]	Non-Live
Tick-borne encephalitis	Tico-vac [®]	Non-Live
Tuberculosis	BCG vaccine	<u>Live</u>
Typhoid - injected	Typherix [®] , Typhim Vi [®] Combined with hepatitis A: Viatim [®]	Non-Live
Typhoid - Oral	Given in capsule form Vivotif [®]	<u>Live</u>
Varicella (chickenpox)	Usually given to healthcare workers. Varilrix [®] , Varivax [®] ,	Live
Yellow Fever	Stamaril [®]	Live