United Kingdom Blood Transfusion Services (UKBTS)

Tissue Donor Selection Guidelines Deceased Donors (TDSG-DD)

Edition 203 - 01 June 2007

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Introduction

These guidelines form a constituent part of Chapter 20 (Tissue banking: selection of donors) of the Guidelines for the Blood Transfusion Services in the United Kingdom, 8th Edition, 2013.

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.

The Joint Professional Advisory committee (JPAC) of the UKBTS is responsible for this document. JPAC 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.

Latest Updates lists alterations to the guidelines made since publication of this edition.

Advice on these guidelines can be obtained from:

Dr G Miflin, Medical and Research Director National Health Service Blood & Transplant (NHSBT) E-mail gail.miflin@nhsbt.nhs.uk

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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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Preferably by e-mail to akila.chandrasekar@nhsbt.nhs.uk with 'TDSG-DD' in the subject line.

This section was last updated in TDSG-DD Edition 203, Release 44 Issue 01

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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 (SAC-TCTP) and for Transfusion Transmitted Infection (SAC-TTI). 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).

Ocular Guidelines. The TDSG-DD contains information on the selection of donors of ocular tissue. There is continuing consultation with the Ocular Tissue Transplant Standards Group (OTTSG). This may lead to further changes in these guidelines, which will be notified through the website www.transfusionguidelines.org.uk

Questions and comments about the ocular guidelines should be addressed in the first instance to Professor John Armitage, e-mail w.j.armitage@bristol.ac.uk (who will ensure that they are referred to the Chair of the OTTSG).

Change Notification.

A Change Notification Letter is used to communicate 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 the publisher, **Caroline Smith**, preferably by e-mail to <u>caroline.smith@nhsbt.nhs.uk</u>

This section was last updated in TDSG-DD Edition 203, Release 03.

General Principles

This document provides guidance for the selection of deceased 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-DD 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-DD 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-DD Edition 203, Release 02, Issue 01.

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Acanthamoeba (ocular infection)

Obligatory Eyes:

Must not donate if: Past or active infection.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Accident

Includes Trauma

Obligatory If there is significant trauma, in particular penetrating trauma:

Refer to a Designated Medical Officer.

If the donor is accepted the rationale must be documented.

Discretionary Eyes.

If eyes uninvolved, accept.

See if Relevant Neurosurgery

Tetanus Immunization

Transfusion

Additional Information Blunt chest trauma can result in damage to cardiovascular tissue.

An open wound or other source of infection is a risk for tissues becoming contaminated.

Reason for Change Additional links have been added.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 35

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-DD Edition 203, Release 02

Acupuncture

See Complementary Therapy

Reason for Change To replace the entry for acupuncture with a link to complementary therapy. The acupuncture

entry was virtually a duplicate of the entry for complementary therapy. By using a link it will

make future changes to the guidelines simpler.

Update Information

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

Addiction and Drug Abuse

Obligatory Must not donate if:

Has injected, or has been injected with drugs in the past 12 months.

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. 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

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-DD Edition 203, Release 29

African Trypanosomiasis

(Sleeping Sickness)

Obligatory Must not donate.

Discretionary Eyes:

Accept for corneas only.

Additional Information As corneas are avascular there is not considered to be a risk of transmitting protozoal infections.

Reason for Change A 'Discretion' has been added for 'Eyes'.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Age

Obligatory

1. Bone, structural.

- Must not donate if:
- a) Over 50 years of age.b) Under 17 years of age.
- 2. Whole heart for tissue allografts.

Must not donate if:

- a) Over 70 years of age.
- b) A child of less than 32 weeks gestation (see Children below).

3. Costal cartilage.

Must not donate if:

- a) Over 40 years of age.
- b) Under 10 years of age.

4. Eyes.

If the donor is under three years old **Refer to Eye Bank** and, if applicable, observe the testing for **Children** below.

5. Skin.

May be collected from a donor of any age but, if applicable, observe the testing for **Children** below.

6. Tendons.

Must not donate if:

- a) Over 60 years of age.
- b) Under 17 years of age.

Children:

a) Under 18 months old.

If the mother would not be excluded by the Tissues Safety Entry and agrees to testing, and all her results are negative (for the infectious markers used for living tissue donors) and the markers of infection in the child are negative (as used for deceased donors), accept.

b) Breastfed in the preceding 12 months.

As in a) above, but only accept if the breast milk has been provided exclusively by the mother.

See if Relevant Tissues Safety Entry

Additional Information The biomechanical properties and cellularity of tissues vary with age.

Children, particularly those who are breastfed, may acquire infection risks from their mother or from the provider of breast milk if this has not been exclusively their mother.

Reason for Change To state an upper age limit of 70 for whole heart donation for preparation of allografts.

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

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

AIDS

See HIV

Tissues Safety Entry

Update Information This entry was last updated in

Alcoholism

Obligatory Bone, structural.

Must not donate if:

General nutrition is affected.

See if Relevant Cirrhosis

Additional Information
If nutrition is poor the quality of bone is likely to be poor.

See Addiction and Drug Abuse

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Allergy

Discretionary Accept.

See if Relevant Steroid Therapy

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Alternative Therapies

See Complementary Therapy

Update Information This entry was last updated in

TDSG-DD 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

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.

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

Update Information This entry was last updated in

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-DD Edition 203, Release 41

Ankylosing Spondylitis

Obligatory 1. Eyes.

Must not donate if: Active uveitis.

2. Cardiovascular Tissue. Must not donate if:

The cardiovascular system is involved.

Additional Information Ankylosing spondylitis can affect the eyes, heart valves and the major artery of the body (aorta).

See Autoimmune Disease

Reason for Change Minor changes have been made and a link to 'Autoimmune Disease' added.

Update Information This entry was last updated in

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-DD 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-DD Edition 203, Release 02

Antidepressant Therapy

See Mental Health Problems

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Antifungals

See Infection - General

Update Information This entry was last updated in

Antivirals

See Infection - General

Update Information This entry was last updated in

TDSG-DD 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-DD Edition 203, Release 02

Arthropod Borne Encephalitis

See Infection - Acute

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Asthma

See if Relevant Infection - General

Steroid Therapy

Reason for Change The 'Obligatory' entry has been removed. This prevented many donors dying with asthma from

being accepted as they would have been treated with steroids.

Update Information This entry was last updated in

TDSG-DD 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.

Discretionary Eyes

If no ocular involvement, accept.

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

Immunosuppression

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 A link to Immunosuppression has been added.

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

This entry was last updated in TDSG-DD Edition 203, Release 11

Avascular Necrosis of the Femoral Head (Hip)

Obligatory Must not donate:

Affected femoral heads.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Babesiosis

Obligatory Must not donate.

Discretionary Eyes:

Accept for corneas only.

Additional Information As corneas are avascular there is not considered to be a risk of transmitting protozoal infections.

Reason for Change A 'Discretion' has been added for 'Eyes'.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Basal Cell Carcinoma

Obligatory 1. Must not donate if:

a) Still receiving treatment.

b) Any wound has not healed.

2. Eyes.

Must not donate if:

From an eye with active Basal Cell Carcinoma (BCC) of the eyelid, unhealed wounds or corneal involvement e.g., exposure keratitis.

3. Skin.

Must not donate:

From the area affected by the lesion.

Discretionary Eyes.

Unhealed wounds not affecting the eye, if cornea is to be stored by organ culture, accept. See

additional information.

See if Relevant Malignancy

Eye Disease

Additional Information

Although basal cell carcinoma is a form of cancer it only spreads locally. As it does not 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 during storage.

Exclusion of donors with unhealed wounds not affecting the eyes does not apply to corneas stored by organ culture as this gives an opportunity to detect infection, but does apply to corneas stored at 4°C.

Donors with healed BCC of the eyelids can be accepted for eye donation, unless ocular tissue might be affected by the effects of treatment. Treatment records should be reviewed, esp. in relation to the effects of treatment e.g., radiotherapy, and eyes must undergo slit lamp examination in the eye bank.

Reason for Change

To add guidance regarding donors with basal cell carcinoma of the eyelid.

Update Information

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

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-DD Edition 203, Release 09

BCG Immunization

See

Update Information

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

Bilharzia

See Infection - Acute

BCG

Update Information This entry was last updated in

Bipolar Disorder

See Mental Health Problems

Reason for Change This is a new entry.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Bleeding Disorder

Includes Carriers

Affected Individual

Obligatory Must not donate if:

Treated with blood derived coagulation factor concentrates.

See if Relevant Transfusion

> Additional People who have received blood derived coagulation concentrates (these are made Information

from the blood of many hundreds of individual donors) may have been put at risk of

infections that can be passed through donations.

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

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 This entry was last updated in

Blind Donor

Obligatory Eyes:

Determine the cause of blindness and discuss with a Designated Medical Officer

Discretionary Other Tissues:

If no other contraindication, accept.

Additional Information Donors with corneal blindness must be deferred. Most donors with retinal and optic nerve

blindness can be accepted.

Reason for Change To provide additional information regarding which types of blindness affect eye donation.

Update Information Publication: TDSG - LD Edition 203, Release 33

Blood Pressure - High

Discretionary Accept.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Blood Transfusion

See Transfusion

Update Information This entry was last updated in

TDSG-DD 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-DD Edition 203, Release 48.

Bone Graft

See Tissue and Organ Recipients

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 35

Borrelioses

See Infection - Acute

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Botulism Immunization

See Immunization - Non-Live

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Brain Surgery

See Neurosurgery

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Brain Tumour

See if Relevant Malignancy

Neurosurgery

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Breast Lump

Obligatory Must not donate if:

a) Malignant.

b) Not fully investigated and cleared of malignancy.

Discretionary Eyes.

If related to malignancy, see Malignancy.

See if Relevant Malignancy

Reason for Change The 'Discretionary' entry for 'Eyes' (malignancy) has changed.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 35

Breastfeeding

Obligatory For infants that have been breastfed in the last 12 months:

See Age

Reason for Change This is a new entry.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Bronchitis

Acute

See Infection - Acute

Chronic

See if Relevant Infection - General

Steroid Therapy

Update Information This entry was last updated in

Brucellosis

Undulant Fever

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Cancer

See Malignancy

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Candida

See Thrush - Oral

Thrush - Vaginal

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Cannabis

See Addiction and Drug Abuse

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Cardiac Surgery

Obligatory Cardiovascular Tissue Donor:

Donors with a history of previous cardiac valve surgery:

Refer to a Designated Medical Officer.

See if Relevant Endocarditis

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 35

Cardiomyopathy

Obligatory 1. Eyes:

Must not donate if:

a) Associated with extraocular muscle paresis, e.g. Kearns-Sayre Syndrome.

b) Not recovered from infective causes.

2. Other Tissues:

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-DD Edition 203, Release 26

Cardiovascular Disease

Obligatory Cardiovascular Tissue Donor:

Donors with a history of cardiac valve abnormalities:

Refer to a Designated Medical Officer.

See if Relevant Cardiac Surgery

Cardiomyopathy Endocarditis Myocarditis

Reason for Change Additional links have been added.

An entry has been added for donors with a history of valve abnormalities.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Catarrh

Acute

See Infection - Acute

Chronic

See if Relevant Infection - General

Update Information This entry was last updated in

TDSG-DD 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-DD Edition 203, Release 31

Cervical Dysplasia

Obligatory

Must not donate if:

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.
- c) If undergoing investigation or treatment, refer to designated clinical support oficer

Eyes - 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-DD Edition 203, Release 48.

Chagas' Disease

South American Trypanosomiasis

Obligatory Must not donate.

Discretionary Eyes:

Accept for corneas only.

See if Relevant South American Trypanosomiasis Risk

Additional Information As corneas are avascular there is not considered to be a risk of transmitting protozoal infections.

Reason for Change A 'Discretion' has been added for 'Eyes'.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Chicken Pox

Contact

See Infectious Diseases - Contact with

Herpes Zoster (Varicella Zoster)

See Infection - Acute

Eyes:

Herpes - Ocular

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Chlamydia

See if Relevant Lymphogranuloma Venereum

See Infection - Acute

Reason for Change A link to 'Lymphogranuloma Venereum' has been added.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02, Issue 02

Cholecystitis

See Gall Bladder Disease

Update Information This entry was last updated in

Cholera Immunization

See Immunization - Non-Live

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Chondromalacia

Discretionary Accept.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Christmas Disease

See Bleeding Disorder

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Chronic Fatigue Syndrome

See Post Viral Fatigue Syndrome

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Cirrhosis

Obligatory Must not donate if:

a) Complicated by hepatoma.

b) Infectious or autoimmune cause.

Discretionary 1. If secondary to alcohol or genetic cause, accept.

2. Bone Donation

check that the quality of bone is unaffected.

3. Eyes:

If related to malignancy, see Malignancy.

See if Relevant Alcoholism

Autoimmune Disease

Malignancy

Reason for Change Additional links have been added.

Update Information This entry was last updated in

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

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

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Coagulation Factor Concentrates

See Bleeding Disorder

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Coeliac Disease

Discretionary Accept.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Colitis

See Inflammatory Bowel Disease

Infection – General

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 46

Colostomy

Obligatory Must not donate if:

For malignancy or inflammatory bowel disease.

Discretionary 1. If the reason for the colostomy is not of itself a reason to exclude and the stoma is healthy,

accept.

2. Eyes:

a) If related to inflammatory bowel disease and there is no evidence of ocular involvement,

accept.

b) If related to malignancy, see Malignancy.

Reason for Change The 'Discretionary' entry for 'Eyes' (malignancy) has changed.

Update Information This entry was last updated in TDSG-DD Edition 203, Release 35

Communication Difficulties

Obligatory

1. All persons giving consent must:

- a) Fully understand the donation process.
- b) Give their informed consent to the process and to the testing of the donor's 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 where there is an exchange of confidential information between the persons giving consent and the qualified health professional, they must:

- 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 or to the persons giving consent.
- c) Fully understand their duty of confidentiality and the confidential nature of any information obtained from the 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.

Any persons giving consent must:

- a) 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 person giving consent by telephone.

A qualified health professional may assist 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 information leaflets, the health and medical history questionnaire and consent statements. The persons giving consent 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 persons giving consent and to assist in establishing effective communication between them 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 persons giving consent or 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 persons giving consent and the qualified health professional may compromise the confidentiality of the process and the safety of any tissue donated. Interpreters are often part of a close community, or a family member, and this may inhibit or embarrass the persons giving consent in any confidential exchange of information. This may result in the non-disclosure of

sensitive information that could affect the eligibility of the deceased person 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 any tissue donated at risk. There is also a requirement to communicate the results of any testing performed by the Blood Services that may be of relevance to the donor's partner/family's health in a way that protects their confidentiality. The continuing availability of an independent interpreter, to maintain 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 person giving consent, it can be taken by telephone

Update Information

This entry was last updated in TDSG-DD Edition 203, Release 02, Issue 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 reuse 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 47.

Cone Biopsy

See Cervical Carcinoma in Situ

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

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-DD Edition 203, Release 02

Contact Lenses

Obligatory Eyes:

Must not donate if:

Underlying disease, e.g. keratoconus or infection.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Contact with Infectious Disease

See Infectious Diseases - Contact with

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Contagious Pustular Dermatitis

Orf

See Infection - Acute

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Contraceptive Implant

Discretionary Accept.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 35

Contraceptive Injection

Discretionary Accept.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Contraceptive Pill

Discretionary Accept.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Corneal Transplant

Obligatory Must not donate.

See if Relevant Prion Associated Diseases

Update Information This entry was last updated in

Coronary Thrombosis

Includes Heart Attack

Myocardial Infarct

Discretionary Accept but may not be suitable for heart valves.

Update Information This entry was last updated in

TDSG-DD 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).

Definition

Symptoms of Covid-19 include:

- · Recent onset of a new, continuous cough
- · High temperature
- Loss of, or a change in, normal sense of taste or smell

Testing: PCR (polymerase chain reaction) and rapid lateral flow tests (LFTs), usually by throat and/or nose swab, to detect the presence of SARS-CoV-2. This does not include testing for antibodies to SARS-CoV-2

Confirmed Infection: The donor has had a positive test for the presence of SARS-CoV-2 (Coronavirus).

Suspected Infection: Compatible symptoms as per UK GOV definition given above and who has not been tested or is awaiting test result.

Recovery from Coronavirus symptoms:

In line with Public Health England advice, donors can be considered to have recovered if they are well and free of fever and respiratory symptoms. Some individuals may have a cough or reduced sense of smell or taste for some weeks after resolution of their infection, but can be considered as recovered for the purposes of tissue and cell donation.

1. Person with confirmed or suspected COVID-19

Obligatory Must not donate if:

- a. Less than 7 days since resolution of symptoms due to confirmed COVID-19.
- b. Awaiting test results for suspected COVID-19.

Discretionary

- a. Confirmed symptomatic infection (COVID-19) if **more** than **7 days** have passed since resolution of symptoms, accept.
- b. Confirmed SARS-CoV-2 infection following diagnostic test without clinical symptoms if **more** than **7 days** have passed since most recent confirmed diagnostic test, accept.
- c. Suspected infection:
 - If testing was not performed, and if more than 7 days after resolution of symptoms, see Infection – Acute entry.
 - If testing was performed, and COVID-19 has been ruled out as a clinical diagnosis, see Infection – Acute entry.

d. For respiratory symptoms/failure not related to infection, or where COVID-19 was ruled out as a clinical diagnosis following testing, and if the underlying cause does not otherwise contradict donation, accept.

See 'Additional Information' section below.

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).

Deceased tissue donors may have been subject to respiratory swab testing either on admission to hospital, or as organ donors. All organ donors are tested for SARS-CoV-2 on respiratory samples prior to donation. It is important to ascertain that, if the donor has been tested, the test was negative before proceeding with retrieval of tissues.

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.

This entry has been revised several times during the Covid-19 pandemic in response to evolving evidence and changes in public health and government advice. The guidance within this entry is focussed on Covid-19.

Reason for Change

Addition of links to the 'Infection – Acute' and 'Contact with Infectious Disease' entries in the 'See if Relevant' section.

Update Information

This entry was last updated in TDSG-DD Edition 203, Release 53

Coronavirus Vaccination

Obligatory Recipients of a COVID-19 vaccine outside the UK vaccination program, including participants in clinical trials or donors vaccinated outside the UK

Refer to Designated Clinical Support Officer for individual risk assessment. See additional information.

Discretionary Recipients of a COVID-19 vaccine in the UK vaccination programme: Accept

See if Relevant Coronavirus Infection

Immune thrombocytopenia
Immunoglobulin therapy

Additional Information
All COVID-19 vaccines currently authorised in the UK are non-live.

Immune thrombocytopenia (ITP) can occur after all types of COVID-19 vaccines. The incidence is unclear but may be similar to other vaccine induced ITP. There have been a small number of reports of vaccine induced thrombosis and thrombocytopenia syndrome (VITTS), in people receiving virus vector based (non-replicating) coronavirus vaccine. VITTS patients have severe clinical symptoms whilst ITP may be sub-clinical and go unnoticed on symptoms alone.

VITT in the donor or treatment of the donor with IVIg following diagnosis of VITT is not a contraindication to tissue donation (pulmonary & aortic grafts, arteries, bone, tendons meniscus, skin and cornea /sclera). These tissues are not considered to be at risk for passenger lymphocyte syndrome. Islet transplantation is deemed to be low risk of passenger lymphocyte syndrome and could proceed after careful discussion and documentation of risk versus benefits with the patient.

For donors vaccinated as part of a clinical trial or outside of the UK, the type of vaccine used should be established to determine the appropriate deferral period.

There may be new types of vaccine that become available, and it may not be known which type of vaccine was used for immunisation. In situations where information about vaccine type is missing or the vaccination is experimental, a four-week deferral period should be applied.

The British Society for Immunology has published an infographic to explain to the general public the different types of COVID-19 vaccines, including brand names, available in the UK, in other countries, and in clinical trials. See the following link: https://www.immunology.org /coronavirus/connect-coronavirus-public-engagement-resources/types-vaccines-for-covid-19

Reason for Change

Remove 7-day deferral post vaccination, and new 'see if relevant' links, update of 'Additional Information' section.

Update Information

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

Cortisone (Periarticular)

See Steroid Therapy

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Cortisone Tablets

See Steroid Therapy

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Creutzfeldt-Jakob Disease

See Prion Associated Diseases

Update Information This entry was last updated in

Crimean Fever

See Viral Haemorrhagic Fever

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 19

Crohn's Disease

See Inflammatory Bowel Disease

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Cystitis

See Infection - General

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Cytomegalovirus

See Infection - General

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Death from Unknown Causes

Obligatory Must not donate.

Discretionary If there is nothing to suggest that the retrieval of the tissues would be hazardous to staff and a

post-mortem examination establishes that the cause/s of death would not exclude donation,

accept.

Reason for Change There has been a change to the wording of 'Discretionary' to better reflect the EU Tissue

Directive.

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

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

Deep Vein Thrombosis

Discretionary If the underlying cause does not exclude, accept.

See if Relevant Malignancy

Update Information This entry was last updated in

Dementia

Obligatory Must not donate.

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

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

Depression

See Mental Health Problems

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Dermatitis

Obligatory Skin Donation

Must not donate: Areas of affected skin.

Discretionary Other Tissues:

If no other contraindication, accept.

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-DD 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-DD Edition 203, Release 02

Diabetes Mellitus

Obligatory Pancreatic Tissue:

Must not donate.

Discretionary Other Tissues:

Accept.

See if Relevant Infection - General

Reason for Change An entry has been added to indicate that pancreatic tissue should not be donated.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Diarrhoea

Includes D & V

Entero-colitis Food Poisoning Gastric Flu Gastro-enteritis

Obligatory Must not donate if:

Associated with inflammatory bowel disease.

Discretionary Eyes:

a) If related to inflammatory bowel disease and there is no evidence of ocular involvement and

the corneas are to be stored by organ culture, accept.

b) If related to infection and the corneas are stored by organ culture, accept.

See if Relevant Infection - General

Reason for Change The 'Discretionary' entry for 'Eyes' has been amended.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Diphtheria

See Infection - Acute

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Diphtheria Immunization

See Immunization - Non-Live

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Diphtheria Tetanus Immunization

See Immunization - Non-Live

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Diphtheria Tetanus Pertussis Immunization

See Immunization - Non-Live

Update Information This entry was last updated in

Disabled Donor

Obligatory Must not donate if:

Contractures will prevent retrieval.

Discretionary If the underlying cause of the disability does not contra-indicate donation, accept.

See if Relevant Spina Bifida

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Disease of Unknown Actiology

Obligatory See:

Is there is a specific entry for the disease?

Must not donate.

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, tissues could be accepted for clinical use, based on current available evidence. For example, the most frequent form of pulmonary fibrosis is idiopathic pulmonary fibrosis (IPF) where there is no identifiable underlying cause. Diagnostic criteria for IPF have evolved over the years, and IPF is currently defined as a disease characterized by the histopathologic pattern of interstitial pneumonia occurring in the absence of an identifiable cause of lung injury. IPF is believed to be a heterogeneous disorder caused by various interactions between genetic components and environmental exposures. Although an understanding of the pathogenesis of IPF is incomplete, recent advances delineating specific clinical and pathologic features of IPF have led to better definition of the molecular pathways that are pathologically activated in the disease. On this

basis, IPF is not an absolute contraindication for tissue donation.

Reason for Change To clarify that if the safety and quality of the tissues 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-DD Edition 203, Release 48.

Diverticulosis

Discretionary Accept.

See if Relevant Infection - General

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Down's Syndrome

Includes Mosaic Down's Syndrome

Obligatory Eyes.

Must not donate.

Discretionary Other Tissues:

If no other contraindication, accept.

Additional Information These syndromes are associated with corneal disease.

Reason for Change A 'Discretionary' entry has been added for other tissues.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Drowning

Obligatory 1. Cardiovascular Tissue:

Must not donate:

If immersed for more than 12 hours.

2. Eyes

Refer to the Designated Medical Officer.

3. Skin.

Must not donate.

Reason for Change The entry for 'Eyes' has changed from 'Must not donate'.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Drug Abuse

See Addiction and Drug Abuse

Update Information This entry was last updated in

TDSG-DD 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-DD Edition 203, Release 02

DTP Immunization

See Immunization - Non-Live

Update Information This entry was last updated in

Duodenal Ulcer

See Peptic Ulcer

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Dysplasia of the Hip

Discretionary Accept.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Ear Piercing

See Body Piercing

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Ebola Fever

See Viral Haemorrhagic Fever

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 19

Eczema

See Dermatitis

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Ehlers-Danlos Syndrome (Disease)

Obligatory Must not donate.

All tissues with the exception of pancreatic islets

Discretionary Pancreatic Islets:

Accept

Reason for Change Pancreatic islets have been added to the list of tissues that may be donated.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 26

Electrolysis

Discretionary Accept.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Elliptocytosis

See Hereditary Elliptocytosis

Reason for Change This entry has been changed to 'Hereditary Elliptocytosis'.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Emphysema

Discretionary Accept.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Encephalitis

Discretionary Eyes.

If caused by bacterial infection and the corneas are to be stored by organ culture, accept.

See Infection - General

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Endocarditis

Obligatory 1. Must not donate if:

Active infection.

2. Cardiovascular tissue: History of infection:

Must not donate.

Discretionary 1. If infection resolved, for non-cardiovascular tissue, accept.

2. Eyes

If the cause is bacterial and the corneas are to be stored by organ culture, accept.

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-DD Edition 203, Release 02

Endometriosis

Discretionary Accept.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 35

Epilepsy

Obligatory Must not donate if:

a) Recent onset and not fully investigated.

b) Secondary to malignancy or degenerative neurological disease.

Discretionary Eyes:

If related to malignancy, see Malignancy.

See if Relevant Malignancy

Neurosurgery

Reason for Change The 'Discretionary' entry for 'Eyes' (malignancy) has changed.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Episcleritis

See Inflammatory Eye Disease

Reason for Change To include an entry for 'Episcleritis'.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Eye Disease

Obligatory 1. Must not donate if:

- a) Ocular tissue transplanted
- b) Malignancy
- 2. Eyes
- a) Active ocular inflammation or infection
- b) Congenital or acquired ocular disorders or previous ocular surgery that may preclude a successful graft outcome. This includes iridocorneal syndrome and keratoconus

- c) History of malignant tumours of the anterior segment, or retinoblastoma, ocular metastasis or ocular melanoma
- d) Past history of ocular Herpes or interstitial keratitis in either eye

Discretionary

1. Eyes

- a) Past ocular trauma discuss with medical eye bank advisor
- b) If a donor has fully recovered from an isolated past episode of inflammatory eye disease (e. g. uveitis or episcleritis), and the condition is not associated in the donor with other general contraindications to donation, accept
- c) If a donor has fully recovered from an isolated past episode of scleritis, accept for cornea donation only

2. Other Tissues:

If no other contraindication, accept.

See if Relevant

Autoimmune Disease Basal Cell Carcinoma

Central Nervous System Disease

Glaucoma

Immunosuppression
Infection - General
Laser Treatment
Malignancy
Ocular Surreny

Ocular Surgery
Ocular Tissue Recipient

Steroid Therapy

Tissue and Organ Recipients

Herpes – ocular

Additional Information

For donors with a past history of inflammatory, infectious or traumatic ocular conditions, relevant clinical records, especially ophthalmology records, should be reviewed.

Reason for Change

To add link to 'Basal Cell Carcinoma' entry.

Update Information

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

Eye Drops

See:

Is there any relevant entry.

See if Relevant Autoimmune Disease

Glaucoma

Infection - General Steroid Therapy

Update Information

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

Factor V Leiden

Discretionary Accept.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Febrile Episodes

See Pyrexia

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Fever

See Pyrexia

Update Information This entry was last updated in

TDSG-DD 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-DD Edition 203, Release 25

Filariasis

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Fits

See Epilepsy

Update Information This entry was last updated in

Food Allergy

See Allergy

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Food Poisoning

See Diarrhoea

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Foreign Travel

See Travel

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Fungal Infection

See Infection - General

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Fungal Infection of Nails

See Infection - Chronic

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

G6PD Deficiency

Discretionary Accept.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Gall Bladder Disease

Discretionary If recovered or had 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-DD Edition 203, Release 35

Gastrectomy

See if Relevant Malignancy

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 35

Gastrointestinal Disease

See Inflammatory Bowel Disease

Infection – General Malignancy

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 46

Genital Herpes Infection

See Herpes - Genital

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Genital Warts

Discretionary Accept.

See if Relevant Sexually Transmitted Disease

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

German Measles

See Rubella

Reason for Change The entry now links to 'Rubella'.

Update Information This entry was last updated in

TDSG-DD 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-DD Edition 203, Release 02

Gilbert's Disease

See Gilbert's Syndrome

Update Information This entry was last updated in

TDSG-DD 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-DD Edition 203, Release 02

Glandular Fever

See Infection - Acute

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Glasses

Discretionary Eyes:

Accept.

Update Information This entry was last updated in

TDSG-DD 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 Organ 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.

Reason for Change A link has been added to 'Ocular Tissue Recipient'.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 35

Goitre

See Thyroid Disease

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Gonorrhoea

See Sexually Transmitted Disease

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Gout

Discretionary Even if on treatment, accept.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Grand Mal

See Epilepsy

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Granuloma Inguinale

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Grave's Disease

See Thyroid Disease

Update Information This entry was last updated in

TDSG-DD 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-DD 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

Reason for Change There is now a requirement to 'Refer to a Designated Medical Officer'.

A link has been added to 'Transfusion'.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Haematological Disease

Obligatory Must not donate if:

a) Malignant.

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

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

b) Monoclonal gammopathy of unknown significance (MGUS) - see 'Malignancy' entry.

See if Relevant Anaemia

Haemoglobin Disorders
Immune Thrombocytopenia

Malignancy

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) moved to the 'Discretionary'

section, and a reference to the 'Malignancy' entry added.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 46

Haematuria

Obligatory Must not donate if:

a) Uncontrolled infection.

b) Due to malignancy.

Discretionary Eyes.

a) If caused by bacterial infection and the corneas are to be stored by organ culture, accept.

b) If related to malignancy, see Malignancy.

See if Relevant Kidney Disease

Reason for Change The 'Discretionary' entry for 'Eyes' (malignancy) has changed.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Haemochromatosis

Obligatory 1. Cardiovascular Tissue:

Must not donate if: Cardiac involvement.

2. Pancreas: Must not donate if:

Diabetic.

Discretionary Other tissues, accept.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Haemoglobin Disorders

Obligatory Must not donate if:

Has a sickle-cell or thalassaemia syndrome.

Discretionary 1. Eyes:

Even if has a sickle-cell or thalassaemia syndrome, accept.

2. All tissues:

Donors with traits for abnormal haemoglobin, accept.

See if Relevant Anaemia

Sickle-Cell Trait Thalassaemia Trait Transfusion

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

Update Information This entry was last updated in

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 A note to 'Refer to a Designated Medical Officer' if there is no entry for the cause of the

condition has been added.

Additional links have been added.

To include an entry for 'Haemolytic Anaemia'.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Haemophilia

See Bleeding Disorder

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Haemophilus Influenzae Type B Immunization

See Immunization - Non-Live

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Haemorrhoids

Includes Piles

Discretionary Accept.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 35

Hand, Foot and Mouth Disease

See Infection - Acute

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Hashimoto's Disease

See Thyroid Disease

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Hay Fever

See Allergy

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Head Injury

See Accident

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 35

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-DD Edition 203, Release 02

Heaf Test

Obligatory Must not donate until:

Healing.

Update Information This entry was last updated in

Health Care Worker

History of Inoculation Injury

See Inoculation Injury

No Inoculation History

Discretionary Accept.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Heart Operation

See Cardiac Surgery

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Henna Painting

Discretionary Accept.

See if Relevant Body Piercing

Update Information This entry was last updated in

TDSG-DD 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-DD Edition 203, Release 02

Hepatitis A

1. Affected Individual

Obligatory Must not donate if:

Less than 6 months from recovery

Discretionary If less than 6 months from infection, but fully recovered, documented HAV RNA

negative and anti HAV IgG positive after recovery, accept.

See if Relevant Travel

Additional Hepatitis A is 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

and water. It can also be spread sexually. There is no long term infection with the virus but there are many reports of transmission by transfusion. Infection may be symptom free but can be serious and occasionally fatal. The Blood Services do not

test for this infection.

Reason for Change To clarify the wording of the discretionary entry

2. Current or Former Sexual Partner of Affected Individual

Obligatory Must not donate if:

Less than 6 months from recovery of current sexual partner, or from last sexual

contact if a former sexual partner.

Discretionary If shown to be immune, 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.

Reason for Change To permit acceptance of donors who are shown to be immune.

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

Obligatory Must not donate if:

Less than 6 months from recovery of the last affected person in the home, or from

the last contact if no longer sharing.

Discretionary If shown to be immune, 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.

Reason for Change To permit acceptance of donors who are shown to be immune.

4. Immunization

Obligatory Known Exposure:

Must not donate if:

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

Discretionary No known Exposure:

Accept.

See if Relevant Hepatitis B - Post Immunization

Travel

Additional Information Hepatitis A immunization 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 immunization may be combined with Hepatitis B immunization.

If less than 6 months from immunisation following known exposure, the donor may be accepted following individual risk assessment if the risk of delaying transplant outweighs the risk of transmission of hepatitis A.

Reason for Change

The deferral period for immunization post known exposure has been reviewed

following guidance from Public Health England.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 34

Hepatitis A Immunization

See Hepatitis A - Post Immunization

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

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

or

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 HBsAq 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

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 required.

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 Information Hepatitis C is neither contagious nor spread by the faecal-oral route. It is usually 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 34

Hepatitis E

Infection

Obligatory Must not donate if:

Less than 6 months from recovery.

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

positive, accept.

See if Relevant Travel

Additional Information Hepatitis E is an infectious hepatitis that is usually spread through contaminated 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 Change The obligatory deferral has been reduced from 12 to 6 months and a discretion to

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-DD Edition 203, Release 31

Hepatitis of Unknown Origin

Affected Individuals

Must not donate if: Obligatory

Less than 24 months from recovery.

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

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 Change Clarification regarding hepatitis B markers has been added to the additional

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-DD Edition 203, Release 17

Hepatitis of Viral Origin

See Hepatitis A

> Hepatitis B Hepatitis C Hepatitis E

Hepatitis of Unknown Origin

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Hereditary Elliptocytosis

Discretionary Accept.

Reason for Change This entry replaces the previous entry for 'Elliptocytosis'. Update Information This entry was last updated in TDSG-DD Edition 203, Release 02

Hereditary Spherocytosis

Discretionary Accept.

Update Information This entry was last updated in

TDSG-DD 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

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Herpes - Ocular

Includes Simplex & Zoster Infection

Obligatory Eyes:

Must not donate if:

Past or active infection in either eye.

Discretionary Other Tissues:

If no active infection or other contraindication, accept.

Additional Information Ocular herpes can lead to serious complications in the tissue recipient, e.g. primary graft

failure, and this risk must be minimized as far as possible.

Reason for Change To clarify that even if only one eye is affected, donation of both eyes is contraindicated.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 33

Herpes - Oral

Obligatory Must not donate if:

Fresh lesions.

Discretionary If lesions are healing, accept.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Herpes Simplex

Herpes - Genital See if Relevant

Herpes - Oral

Eyes:

Herpes - Ocular

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Herpes Zoster

See if Relevant Infection - Acute

Infectious Diseases - Contact with

Eyes:

Herpes - Ocular

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Hip Dysplasia

Discretionary Accept.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

HIV

AIDS Includes

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 Information HIV infection can be spread through sexual activity, including oral and anal sex. 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

Must not donate. Obligatory 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 HIV is neither contagious nor spread by the faecal-oral route. It is usually only spread Information

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-DD Edition 203, Release 29

Homeopathy

See Complementary Therapy

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Homosexual and Bisexual Individuals

Female

Discretionary Accept

Additional There is no evidence that there is an increased risk of sexually transmitted infections

Information in homosexual or bisexual females compared to heterosexual females.

Reason for Change This is a new entry, combining the previous entries for 'Homosexual' and 'Bisexual'

individuals. 'Additional Information' has been added.

Female sexual partners of men who have sex with men

Obligatory Must not donate if:

Male partner has had oral or anal sex with another man, even if a condom or other

protective was used.

Discretionary

1. Pancreatic islets and hepatocytes:

Current practice for donor selection is similar to that for solid organs and their acceptance is patient specific. There is no specific restriction regarding MSM behaviour but individual risk/benefit assessment is required.

2. Other tissues/cells:

If 3 months or more from last sexual contact with a man who has ever had sex with another man, accept.

See if Relevant

Tissue Safety Entry

Additional Information

Men who have sex with other men have a higher chance of having an undiagnosed infection which could be passed to their female partner. Waiting 3 months from the last sexual contact helps to ensure that the infections tested for by the Blood 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.

Male

Obligatory

Must not donate if:

Has had oral or anal sex with another man in the last 3 months, even if a condom or other protective was used.

Discretionary

1. Pancreatic islets and hepatocytes:

Current practice for donor selection is similar to that for solid organs and their acceptance is patient specific. There is no specific restriction regarding male-sexwith-male (MSM) behaviour but individual risk/benefit assessment is required.

2. Other tissues:

One of four possible scenarios may apply:

- a) Family / next of kin / GP / hospital not aware of any MSM activity. No evidence of MSM activity, **accept**
- b). Male known by family / next of kin / GP / hospital to have engaged in MSM activity in the past, but known to have had no MSM sexual activity in previous 3 months, **accept**.
- c) Male known by family / next of kin / GP / hospital to be engaged in MSM activity and is presumed/known to be sexually active in the 3 months before death, **not eligible to donate.**
- d) Male known by family / next of kin / GP / hospital to have engaged in MSM activity in the past. Family unaware of date of last MSM activity, **not eligible to donate.**

See if Relevant

Tissue Safety Entry

Additional Information

The guidance has been changed in line with recommendations from the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO), 2017. This review considered advances in the sensitivity of testing procedures currently in use in the UK, the prevalence of transfusion transmissible infections in men who have had sex with men, the level of compliance with the 12 month exclusion for those donors at higher risk of blood borne infections and, where applicable, the additional processes used to reduce the risk of transmission of viral infection. This review recommended that the deferral period for men who have had sex with men should be reduced to 3 months after last sexual contact. 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

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-DD Edition 203, Release 29

Hormone Replacement Therapy

Discretionary

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.

1. All tissues 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.

2. Eyes:

If related to malignancy, see Malignancy.

See if Relevant **Prion Associated Diseases**

Thyroid Disease

Reason for Change The 'Discretionary' entry has been re-worded for clarity and the 'Discretionary' entry for 'Eyes'

(malignancy) has changed.

Update Information This entry was last updated in

TDSG-DD 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 Change This entry was updated in line with the recommendations of the SaBTO Donor

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

Additional Information HTLV 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-DD Edition 203, Release 29

Human Bite

See Inoculation Injury

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Human Pituitary Extract

See Pituitary Extract - Human

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Huntington's Chorea

See Huntington's Disease

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

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-DD Edition 203, Release 02

Hydatid Disease

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Hydatidiform Mole

See Pregnancy

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Hydrocephalus

Obligatory Must not donate if:

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

Discretionary Eyes:

Shunt infection - if the corneas are to be stored by organ culture, accept.

See if Relevant Neurosurgery

Spina Bifida

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

not be collected from bacteraemic subjects.

Reason for Change A 'Discretion' has been added for 'Eyes'.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Hyperthyroidism

See Thyroid Disease

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Hypnotics

Discretionary Accept.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Hypothyroidism

See Thyroid Disease

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Idiopathic Pulmonary Fibrosis

See Diseases of Unknown Aetiology

Update Information

This entry was last updated in TDSG-DD Edition 203, Release 48.

Idiopathic Thrombocytopenic Purpura (ITP)

See Immune Thrombocytopenia

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

lleostomy

Obligatory Must not donate if:

a) For malignancy

b) Inflammatory bowel disease.

Discretionary 1. All tissues:

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

accept.

2. Eyes:

a) If related to malignancy, see Malignancy.

b) If related to inflammatory bowel disease and there is no evidence of ocular involvement,

accept.

Reason for Change The 'Discretionary' entry for 'Eyes' (malignancy) has changed.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 35

Immune Thrombocytopenia

Obligatory Must not donate if:

Associated with malignancy

Discretionary If underlying cause of thrombocytopenia is not a contraindication, accept. Refer to relevant

DSG entry. Refer to designated clinical support officer if further advice required.

See if Relevant If treated with immunoglobulin:

Immunoglobulin Therapy

Transfusion Malignancy

If treated with plasma exchange:

Transfusion

If treated with immunosuppresive therapy:

Immunosuppression

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-DD Edition 203, Release 45

Immunization

Non-exposed

See Immunization - Live

Immunization - Non-Live

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

of immunization 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 Immunization

6. Tetanus:

See

Tetanus Immunization

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-DD Edition 203, Release 41

Immunization - Live

No Exposure

Obligatory Must not donate if:

Less than eight weeks from administration.

Discretionary If more than four weeks from administration of a live immunization other than smallpox

immunization and the inoculation site has healed, accept.

See if Relevant BCG

Smallpox Immunization

Additional Information Live immunizations 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 immunization should have been controlled and so should not be passed on through donated material. There are special rules for BCG and smallpox immunizations.

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

This entry was last updated in TDSG-DD Edition 203, Release 09

Immunization - Non-Live

No Exposure

Obligatory 1. Hepatitis B

Must not donate if:

Less than seven days after administration

2. Coronavirus: See 'Coronavirus Vaccination' entry

Discretionary Other non-live immunizations, accept.

See if Relevant Immunization, Post Exposure

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

Hepatitis B may be required.

"Non-Live" immunizations do not use material that can cause infection. This means there is no

risk to people receiving blood or tissues from a recently immunized donor.

Reason for Change To add Coronavirus Vaccination to obligatory section.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 43

Immunodeficiency

See Immunosuppression

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

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, accept.

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 This entry was last updated in

TDSG-DD Edition 203, Release 45

Immunosuppression

Obligatory Must not donate if:

a) Immunosuppressed.

Discretionary

a) Donors who are on immunosuppressive therapy (if the underlying condition is not a contra-

indication):

If ALL the following criteria are met:

The quality of the tissue being donated is not affected

 NAT testing is performed for HIV, HCV and HBV in addition to mandatory antibody tests and shown to be negative

 The tissue being donated is not affected by severe local infection and there is no evidence of systemic infection.

(OR) For corneas only: In cases of bacterial infection (where there is no active ocular infection) and the corneas are to be stored by organ culture.

Donor may be accepted subject to a documented risk assessment (refer to the Additional Information section).

b) Donors with recovered immunodeficiency:

Refer to a Designated Medical Officer.

See if Relevant

Autoimmune Disease
Immunoglobulin Therapy
Steroid Therapy
Infection – acute
Infection - chronic

Additional Information

The Human Tissue (Quality and Safety for Human Application) Regulations, 2007, as amended, specifies a range of allogeneic donor deferral criteria. These are set out in Annex A of the HTA 'Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment'. Regulatory requirements for donor testing are set out in Annex B of the Guide and specify the requirement for serological testing irrespective of NAT testing.

Annex A, part 1.1.8 states: 'Indications that test results of donor blood samples will be invalid due to...treatment with immunosuppressive agents.'

Whilst antibody detection relies on the host response, antigen and molecular assays directly detect components of the infectious agent. Assays which directly detect the virus are not affected adversely by immunosuppression and are appropriate to use to support decision making in this situation. This is permitted under the SaBTO Guidance on the microbiological safety of human organs, tissues and cells used in transplantation (2020).

The regulatory requirement, as set out in the HTA Guide is as follows: Para 85: 'Donors must be excluded from donation if any of the criteria in Annex A apply unless donation is justified on the basis of a documented risk assessment approved by the Designated Individual (DI)'. To comply with the regulatory requirement Tissue Establishments (TEs) must ensure that they have a current documented risk assessment that covers all the tissues in question before authorising a donation for clinical use on the basis of the discretionary criteria set out above.

Donors on immunosuppression may be prone to an increased risk of infection and symptoms may be masked by immunosuppressive medication. All available information must be carefully assessed as part of donor evaluation and expert opinion sought where required.

Reason for Change

To allow acceptance of tissues where the safety and quality is not compromised by immunosuppression. Additional Information section updated to include information particularly regarding regulation.

Update Information

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

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

Infection - Acute

Obligatory See

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

Must not donate if:

Less than two weeks from recovery from a systemic infection.

Discretionary

1. All tissues:

If the clinician caring for the potential donor thinks that therapy given for a localised infection has successfully cleared it, accept.

Common acute local viral respiratory tract infections including colds, sore throats, and seasonal influenza, accept. See additional information.

Cold sores and genital herpes, accept.

2. Eyes.

If caused by bacterial infection and the corneas are to be stored by organ culture, accept.

See if Relevant

Congo Fever

Coronavirus Infection

Crimean Fever

Ebola Fever

Herpes - Genital

Herpes - Oral

Lassa Fever

Marburg Fever

MRSA (Methicillin Resistant Staphylococcus Aureus)

Myocarditis

Steroid Therapy

West Nile Virus

Additional Information

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.

Potential donors who have been cared for on an ITU may have a local chest infection as a result of ventilation - these patients are acceptable as donors.

Donors who have bacterial pneumonia are acceptable as eye donors. Other tissues may be accepted if the infection has been successfully treated, or with individual risk assessment to exclude severe or systemic sepsis. The same applies to a donor with seasonal influenza who had developed secondary bacterial infection.

Donors who have had a positive screening test for MRSA (carriers) are acceptable, whereas donors with active MRSA infection at the time of death are not acceptable.

There is no evidence that cold sores, genital herpes and common viral respiratory infections such as seasonal influenza, colds and sore throats can be passed on by processed tissue grafts.

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.

A risk assessment should be performed to ensure that retrieval staff are not put at risk from the infection.

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-DD Edition 203, Release 41

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.
- d) If undiagnosed or untreated local infection, refer to designated clinical support officer.

3. Typhoid and Paratyphoid

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

4. Eyes.

If caused by bacterial infection and the corneas are to be stored by organ culture, 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-DD Edition 203, Release 42.

Infection - General

Obligatory Se

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-DD Edition 203, Release 02

Infection - Tropical

Obligatory Must not donate if:

Filariasis or Leishmaniasis

Discretionary Eyes:

If Leishmaniasis, accept for corneas only.

See if Relevant Congo Fever

Crimean Fever
Ebola Fever
Lassa Fever
Marburg Fever
Malaria

South American Trypanosomiasis Risk

Other infections, see: Infection - General

Additional Information As corneas are avascular there is not considered to be a risk of transmitting protozoal infections.

Reason for Change A 'Discretion' has been added for 'Eyes'.

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

Infectious Diseases - Contact with

Obligatory See

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

Must not donate if:

- a) Within the incubation period for the condition or, if this is not known, less than four weeks from last contact.
- b) Skin only Contact with skin conditions that may be transmissible by the donated material, (such as scabies, ringworm, tinea)

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) **All tissues except skin** Contact with skin conditions which are not transmissible by donated material (e.g. scabies, ringworm, tinea) if no signs of infection, accept.
- e) **Skin only** Contact with skin conditions which may be transmissible by donated material (e. g. scabies, ringworm, tinea). If the donated tissue is to be sterilised prior to transplant, accept.

f) 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 'obligatory' and 'see if relevant' sections.

Update Information

This entry was last updated in TDSG-DD Edition 203, Release 53

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 ${\sf HP}^{\sf R}$.

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-DD Edition 203, Release 48.

Inflammatory Bowel Disease

Includes Crohn's Disease

Ulcerative Colitis

Obligatory Must not donate.

Discretionary Eyes:

If no ocular involvement and if the corneas are to be stored by organ culture, accept.

Other Tissues:

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-DD Edition 203, Release 46

Inflammatory Eye Disease

See Eye Disease

Influenza Immunization

See Immunization - Non-Live Update Information This entry was last updated in TDSG-DD Edition 203, Release 02

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-DD Edition 203, Release 02

Injected Drugs of Misuse

See Addiction and Drug Abuse

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Inoculation Injury

Includes Human Bite

Definition A non-consented injury or assault in which an individual is exposed to potentially infective

material that could be transferred through donation. The causes may range from a sharps injury to bites, punches and abrasions or heterosexual sexual assault where mucous membranes have been contaminated with human blood or other body fluids. It also applies to any

inoculation injury with abnormal prions from any species.

Obligatory Must not donate if:

a) With material containing abnormal prions.

b) Less than 3 months after the date of an inoculation injury, or contamination of mucosa or non-

intact skin with blood or body fluids.

See if Relevant Animal Bite

Additional Information 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 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-DD Edition 203, Release 29

Inoculations

See Immunization

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Irritable Bowel Syndrome

Discretionary Accept.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

ITP

See Immune Thrombocytopenia

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Japanese Encephalitis Immunization

See Immunization - Non-Live

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Jaundice

Obligatory Must not donate if:

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.

Discretionary a) If the cause of jaundice was non-viral (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-DD Edition 203, Release 02

Kala-Azar

Obligatory Must not donate.

Discretionary Eyes:

Accept for corneas only.

Additional Information

As corneas are avascular there is not considered to be a risk of transmitting protozoal infections.

Update Information Th

This entry was last updated in TDSG-DD 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**.

2. Eyes:

If not immunosuppressed, accept.

Additional Information If the donor 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.

Discretionary Eyes:

If not immunosuppressed, accept.

Update Information

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

Kidney Recipient

See Tissue and Organ Recipients

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Kidney Stones

See if Relevant Infection - General

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Klinefelter's Syndrome

Discretionary

Accept.

Update Information

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

Laser Treatment

Obligatory

1. All tissues:

Must not donate if: For malignancy.

Discretionary

1. Tissues other than Eyes:

a) If for Basal Cell Carcinoma, treatment is completed and fully recovered, accept.

b) If for Cervical Carcinoma in Situ, see <u>Cervical Dysplasia</u> entry.

c) If for cosmetic purposes, accept when healed.

d) If laser refractive surgery to the cornea, accept when healed.

2. Eves:

a) if donor has had laser-refractive surgery to the cornea – accept when healed (see 'Additional Information' section)

b) If laser surgery to other structures of the eye (retina, iris, trabecular meshwork or ciliary body), accept.

c) If related to malignancy, see Malignancy.

See if Relevant

Basal Cell Carcinoma
Cervical Dysplasia
Ocular Surgery

Additional Information

Laser refractive surgery affects the anterior part of the cornea. Corneal tissue from donors with healed laser refractive surgery can be used for Descemet Membrane Endothelial Keratoplasty (DMEK). The tissue establishment might apply additional criteria for donors with a history of laser-refractive surgery, especially a minimum age for use of corneal tissue for DMEK.

Update Information

This entry was last updated in TDSG-DD Edition 203, Release 48.

Lassa Fever

See Viral Haemorrhagic Fever

Update Information

This entry was last updated in TDSG-DD Edition 203, Release 19

Legionnaire's Disease

See Infection - Acute

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Leishmaniasis

Includes Kala-azar

Obligatory Must not donate.

Discretionary Eyes:

Accept for corneas only.

Additional Information As corneas are avascular there is not considered to be a risk of transmitting protozoal infections.

Reason for Change A 'Discretion' has been added for 'Eyes'.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Leptospirosis

See Infection - Acute

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Lesbian

Discretionary Accept.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Leukaemia

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Listeriosis

See Infection - Acute

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Lyme Disease

See Infection - Acute

Update Information

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

Lymphogranuloma Venereum

Obligatory

Must not donate.

Update Information

This entry was last updated in TDSG-DD 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

Must not donate (if no testing is available):

Applies to all groups as defined above

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 **less** 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. See information below in this section.

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 **less** than **4 months** since date last present in a malaria risk area: Obtain a blood sample for MAT and NAT. See information below in this section.

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 **less** than **4 months** since return: Obtain a blood sample for MAT and NAT. See information below in this section.

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 event is more than four months prior to donation, and MAT is negative, NAT is not required. If the exposure event is less than four months prior to donation, NAT must be done and shown to be negative, irrespective of MAT results. For donors with a history of malaria where treatment was completed and symptoms have resolved at least four months prior to donation, if MAT is negative, NAT is not required. In case of positive MAT results with a confirmed negative NAT test, 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.

3. Eyes

Accept for corneas only - 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 malaria antibody testing.

As corneas are avascular there is not considered to be a risk of transmitting protozoal infections.

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-DD Edition 203, Release 54

Malaria - Contact in UK

Discretionary Accept.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Malignancy

Obligatory 1. Eyes:

Must not donate if:

a) Haematological malignancy.

b) Malignant tumour of anterior segment.

- c) Ocular melanoma.
- d) Ocular metastasis.
- e) Retinoblastoma.
- f) Malignant melanoma with known metastatic disease.

2. Other tissues:

Must not donate.

Discretionary

1. Eyes:

If not excluded under 'Obligatory', accept for corneas only.

2. Other tissues:

- 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 followup, accept.
- c) Monoclonal gammopathy of uncertain significance (MGUS) with IgG paraproteins at <15 g/l and normal serum free light chain ratio: if diagnosed more than 12 months ago, accept For other MGUS: refer to designated clinical support officer for individual risk assessment. See additional information section for other MGUS and smouldering myeloma.
- **d)** If the potential donor has been cured of a carcinoma in situ (CIS) and discharged from followup, 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.

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.
- f) Primary turmours of the central nervous system with a low risk of distant metastasis are acceptable for all tissues except for sclera: See additional information section for information.

See if Relevant

Basal Cell Carcinoma
Cervical Carcinoma in Situ
Immunosuppression
Transfusion
Haematological Disease

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 e.g. smouldering myeloma should not be accepted for tissue donation. Monoclonal gammopathy of uncertain significance (MGUS) with IgG paraproteins (rather than IgA or IgM) at <15 g/l and normal serum free light chain ratio has a 1% risk of progression to multiple myeloma over 25 years.

MGUS must be distinguished from smouldering myeloma, which is diagnosed when paraprotein levels are above 30 g/l and bone marrow plasma cells are >10% total nucleated cells. Donors with smouldering myeloma must 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 (i.e. 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.

Primary CNS Tumours:

- (a) Refer to the Appendix 5 for WHO classification of tumours of the CNS (shown in the Guide to the Quality and Safety of Tissues and Cells for Human Application). Grade I and II tumours have low potential for metastasis and Grade III & IV are aggressive tumours. High grade CNS tumours need careful evaluation and those that are not spread outside CNS can be accepted except for sclera donation.
- (b) Refer to SaBTO document "Transplantation of organs from deceased donors with cancer or a history of cancer" for generic advice: https://www.gov.uk/government/publications /transplantation-of-organs-from-donors-with-a-history-of-cancer,

Eyes - only corneas are accepted under discretionary (1) above as these are avascular and therefore are not likely to be involved in distant metastasis. The vascular parts of the eye are excluded. The predominant mode of progression of primary tumours of the CNS is by invasion and infiltration. Due to the anatomical proximity of the CNS and orbit, these donors should be deferred from sclera donation.

Reason for Change Advice has been added for basal cell carcinoma treated systemically.

Update Information This entry was last updated in TDSG-DD Edition 203, Release 35

Malignant Hypertension

Discretionary Accept.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Malignant Melanoma

See Malignancy

Update Information This entry was last updated in

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-DD Edition 203, Release 02

Marburg Fever

See Viral Haemorrhagic Fever

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 19

Marfan's Syndrome

Obligatory Must not donate.

a) Bone structural

b) Eyes

c) Cardiovascular Tissue

d) Tendons

Discretionary Bone non-structural, Skin and Pancreatic Islets:

Accept

Reason for Change Pancreatic islets have been added to the list of tissues that may be donated.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 26

Mastectomy

See if Relevant Malignancy

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 35

Measles

Affected Individual

See Infection - Acute

Contact

See Infectious Diseases - Contact with

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Measles Immunization

See Immunization - Live

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Measles Mumps Rubella (MMR) Immunization

See Immunization - Live

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Measles Rubella Immunization

See Immunization - Live

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Medication (Drugs)

See Drug Treatment

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Meningitis

Affected Individual

Discretionary Eyes:

If caused by bacterial infection and the corneas are to be stored by organ culture,

accept.

See Infection - Acute

Contact

Discretionary Even if on prophylactic antibiotics, accept.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Meningococcal Meningitis Immunization

See Immunization - Non-Live

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Menopause

Discretionary Accept.

See if Relevant Hormone Replacement Therapy

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Mental Health Problems

Obligatory If the donor has had a new mental health problem within the last 12 months, or their condition

has deteriorated in the last 12 months: Refer to a Designated Medical Officer.

Discretionary If the donor has known mental health problems and has been stable in the last 12 months,

whether on medication or not, accept.

See if Relevant Central Nervous System Disease

Rabies

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

medication. There is no reason why they cannot donate whether on medication or not provided

a firm diagnosis has been made and their condition has not deteriorated in the last 12

months. It is important to exclude other central nervous system disease including prion disease

and rabies, which could present as new or deteriorating mental health problems.

Reason for Change The entry has been changed to allow donors with known mental health conditions at the time of

death to be accepted.

'Additional information' has been added

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 17

Migraine

See if Relevant Headache

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Mitral Valve Prolapse

Discretionary Accept.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Molar Pregnancy

Hydatidiform Mole

See Pregnancy

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Mpox (Monkeypox)

1. Affected Individuals

Obligatory Must not donate

Discretionary If the donor had 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
- It is at least 14 days since all skin lesions had healed, and
- It is more than seven days since completing any antiviral or antibiotic therapy, and
- The donor was had been discharged from all follow up (including public health surveillance)

accept.

2. Contact with an individual with Mpox

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

individual with Mpox.

Obligatory Must not donate

Discretionary If it is more than 21 days since last contact, and

- · the donor had 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 if applicable,

accept.

See additional information below for donors who received vaccination.

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 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 had received routine vaccination with Imvanex or another thirdgeneration smallpox vaccination in an occupational setting, can be accepted

provided that they were 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 had received vaccination either because they could have been a close contact, had risk of exposure, or had received vaccination because they were

health care workers.

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

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 54

MRSA

Methicillin Resistant Staphylococcus Aureus

See if Relevant Infection - General

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

exposure of the donor is not relevant to donation.

Update Information This entry was last updated in

TDSG-DD 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-DD 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-DD Edition 203, Release 02

Mumps Immunization

See Immunization - Live

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Muscular Dystrophy

Obligatory 1. All tissues other than eyes:

Must not donate if:

1. Has severe contractures.

2. Cardiovascular Tissue:

Must not donate.

3. Structural Bone: Must not donate if:

Osteoporotic.

Discretionary Eyes.

Accept.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Myalgic Encephalomyelitis

See Post Viral Fatigue Syndrome

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Myasthenia Gravis

Obligatory Must not donate.

Discretionary Eyes:

Accept.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Myelodysplastic Syndrome

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-DD 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

Myocarditis

Obligatory 1. Cardiovascular Tissue:

Must not donate.

2. Other Tissues: Must not donate if: not recovered.

Discretionary Eyes.

If caused by bacterial infection and the corneas are to be stored by organ culture, accept.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Myxoedema

See Thyroid Disease

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Ménière's Disease

Discretionary Accept.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Necrotising Fasciitis

Obligatory Must not donate

Reason for Change This is a new entry

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 25

Needle-Stick Injury

See Inoculation Injury

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Nephritis

See Kidney Disease

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Neurofibromatosis

Obligatory Must not donate if:

History of malignant change.

Discretionary

If related to malignancy, see Malignancy.

Reason for Change The 'Discretionary' entry for 'Eyes' (malignancy) has changed.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Neurological Conditions

See Central Nervous System Disease

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Neurosurgery

Must not donate. Obligatory

Discretionary 1. All Tissues:

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 (donors with non-metastizing primary tumours of the central nervous system may

be accepted), the donor may be accepted by a Designated Medical Officer.

2. Eyes:

If related to malignancy, see Malignancy.

See if Relevant Malignancy

Prion Associated Diseases

Reason for Change The 'Discretionary' entry for 'Eyes' (malignancy) has changed.

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

> This entry was last updated Edition 203, Release 35

Night Sweats

Obligatory Must not donate if:

Unexplained.

Discretionary If due to the menopause, accept.

Update Information This entry was last updated in

TDSG-DD 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-DD 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-DD Edition 203, Release 02

NSAID

See Nonsteroidal Anti-Inflammatory Drugs (NSAID)

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

NSU

See Non-Specific Urethritis

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Ocular Surgery

Obligatory Eyes:

Must not donate.

Other Tissues:

Must not donate if ever received ocular tissue allograft transplant.

Discretionary

1. Eyes:

a. If the procedure is unlikely to prejudice quality and outcome of graft, accept.

b. If cataract surgery only, accept

c. If laser-refractive surgery to the cornea, accept when healed

d. If laser-refractive surgery to any other ocular structure (retina, iris trabecular meshwork or ciliary body) accept.

e. If both cataract surgery and any type of laser-refractive surgery, discuss with designated clinical support officer.

See additional information section

2. Other Tissues

If no other contraindication, accept.

See if Relevant

Eye Disease
Glaucoma
Laser Treatment
Malignancy

Ocular Tissue Recipient
Tissue and Organ Recipients

Additional Information

Laser-refractive surgery to the cornea renders corneal tissue unsuitable for standard corneal transplant procedures. Corneal tissue from donors with healed laser refractive surgery can be used for Descemet Membrane Endothelial Keratoplasty (DMEK).

A Tissue Establishment might apply additional donor selection criteria for donors with a history of ocular surgery, such as a minimum age for donors with a history of laser-refractive surgery and a maximum age for donors with a history of cataract surgery.

The combination of cataract and laser-refractive surgery in a donor eye renders corneal tissue unsuitable for standard corneal transplant procedures.

Recipients of ocular tissue allografts must not donate; e.g. donors who have received cornea transplant or a sclera graft during glaucoma surgery must not donate

Reason for Change

Additional detail on discretionary criteria for ocular tissue donors with a history of ocular surgery has been added, together with additional information.

Update Information

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

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-DD Edition 203, Release 02

Operations

See if Relevant Ocular Surgery

Update Information

This entry was last updated in TDSG-DD Edition 203, Release 35

Orf

Contagious Pustular Dermatitis

See Infection - Acute

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Organ Donor

Discretionary Accept.

See if Relevant Transfusion

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 35

Organ Recipient

See Tissue and Organ Recipients

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Oseltamivir

See Tamiflu®

Osteoarthritis

Discretionary Accept.

Update Information This entry was last updated in

TDSG-DD 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-DD Edition 203, Release 25

Osteomalacia

Obligatory Bone donation:

Must not donate.

Update Information This entry was last updated in

TDSG-DD 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 1. If two years from completing treatment and cure, unaffected bone may be accepted.

2. Eyes:

If the corneas are to be stored by organ culture, accept.

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.

Reason for Change The 'Discretionary' entry for 'Eyes' has been amended.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Osteoporosis

Obligatory Structural bone:

Must not donate if:

Donor has, or is at risk of, osteoporosis.

Discretionary May be acceptable for donation of non-weight bearing bone.

See if Relevant Steroid Therapy

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Ovarian Cyst

Obligatory

Must not donate if:

Malignant.

Discretionary Eyes:

If related to malignancy, see Malignancy.

See if Relevant Malignancy

Reason for Change The 'Discretionary' entry for 'Eyes' (malignancy) has changed.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 35

Paget's Disease of Bone

Includes Osteitis Deformans

Obligatory Bone:

Must not donate.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Pain Killers

Obligatory Assess the reason for treatment, see any relevant entry and, if necessary:

Refer to a Designated Medical Officer.

See if Relevant Arthritis

Malignancy

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Paratyphoid

See Chronic Infection

Reason for Change To replace the entry for paratyphoid with a link to chronic infection. By using a link it will make

future changes to the guidelines simpler.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 17

Peptic Ulcer

Includes Gastric and Duodenal Ulcer and Erosions

Obligatory Must not donate if:

Associated with malignant change.

Discretionary

Eyes.

If related to malignancy, see Malignancy.

See if Relevant Transfusion

Reason for Change The 'Discretionary' entry for 'Eyes' (malignancy) has changed.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02, Issue 35

Pericarditis - Viral

See Infection - Acute

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Peritonitis

See Infection - General

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 35

Peritonsillar Abscess

See Infection - Acute

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Permanent Make-Up

See Body Piercing

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Perthes' Disease

Discretionary Accept.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Petit Mal

See Epilepsy

Update Information This entry was last updated in

TDSG-DD 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-DD Edition 203, Release 02

Plasma Dilution

Obligatory Must not donate if:

A pre-transfusion sample is not available and plasma dilution from intra-venous infusions is estimated to be more than 50% following significant blood loss. This can be calculated from the

algorithm in Appendix 4.

See Appendix 4 - Calculation of Plasma Dilution.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02, Issue 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-DD Edition 203, Release 02, Issue 02

Pleurisy

See if Relevant Infection - General

Malignancy

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Pneumococcal Immunization

See Immunization - Non-Live

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Pneumonia

See Infection - Acute

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Pneumothorax

Spontaneous

Discretionary Accept.

Traumatic

See Accident

Update Information This entry was last updated in

TDSG-DD 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-DD Edition 203, Release 30

Polio Contact

See Infectious Diseases - Contact with

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Polio Injected Immunization

See Immunization - Non-Live

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Polio Oral Immunization

See Immunization - Live

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Polycythaemia

Obligatory Must not donate.

Discretionary If confirmed as secondary polycythaemia, accept.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Polymyalgia Rheumatica

See Autoimmune Disease

Reason for Change To include 'Polymyalgia Rheumatica' under 'Autoimmune Disease'.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Porphyria

Obligatory Must not donate if:

Suffers from porphyria.

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

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

Erythropoietic Porphyria (CEP), accept for all tissues except skin.

See if Relevant Hepatitis

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

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

Porphyrias may be associated with skin lesions.

Reason for Change This is a new guideline.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 11

Post Viral Fatigue Syndrome

Obligatory Must not donate if:

Not resolved.

Update Information This entry was last updated in

TDSG-DD 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

See if Relevant Tissues Safety Entry

HIV

Homosexual and Bisexual Individuals

Human Bite

Additional Information

The use of Pre-Exposure Prophylaxis (PrEP), e.g. Truvada[®], to prevent HIV is increasing. Patients taking PrEP are unlikely to be eligible to donate due to tissue safety guidelines. However, PrEP is also available via private prescription and/or online pharmacies and may be used by individuals who would not otherwise be deferred.

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

Update Information Update Information

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

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.

Discretionary Eyes:

If resulted in malignancy, see Malignancy.

See if Relevant Malignancy

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-DD Edition 203, Release 35

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).

are at noity.

b) Individuals who have potentially 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

Additional Information See the Position Statement on Creutzfeldt-Jakob Disease available in the JPAC Document

_ibrary.

Reason for Change The entry has been modified to comply with advice from the MSBTO committee of the DH.

Appropriate links have been added.

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

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

Prisons

Obligatory Must not donate if:

Has been held in prison during the preceding twelve months.

Discretionary a. If just held in a police cell for a period not exceeding 96 hours, accept.

b. If held in prison for more than 96 hours but released more than three months ago, refer to

designated medical officer

See if Relevant Addiction drug abuse

Homosexual and bisexual individuals

Additional Information A deceased person cannot be questioned about 'at risk behaviour' that has occurred in prison.

Risk behaviour is unlikely to have occurred while held in police custody under police powers of

arrest.

The 12 month deferral period specified above may be reduced to 3 months by doing individual

risk assessment. This guidance presumes that a validated NAT test for HIV, HBV and HCV is

negative, if this test is stopped for any reason the guidance will change

Reason for Change An additional discretion has been added. Relevant other entries have been added. Additional

information has been updated

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 31

Proctitis

See Inflammatory Bowel Disease

Infection – General

Update Information

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

Progressive Multifocal Leukoencephalopathy

Obligatory

Must not donate.

Update Information

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

Psoriasis

Obligatory Must not donate if:

a) Generalized or severe.

b) There is secondary infection.

c) 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-DD Edition 203, Release 48.

Psychiatric Problems

See Mental Health Problems

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Pulmonary Embolism

Discretionary Accept.

See if Relevant Malignancy

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Pyelonephritis

Discretionary Eyes:

If the corneas are to be stored by organ culture, accept.

See Infection - General

Reason for Change The 'Discretionary' entry for 'Eyes' has changed to include a reference to organ culture.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Pyrexia

Not Related to Travel in Malarious Areas

Obligatory If less than two weeks from an undiagnosed episode of pyrexia:

Refer to a Designated Medical Officer.

See if Relevant Infection - General

Related to Travel in Malarious Areas

See Malaria

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Pyruvate Kinase Deficiency

Discretionary Accept.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Q Fever

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Quinsy

Discretionary Eyes:

If the corneas are to be stored by organ culture, accept.

See Infection - Acute

The 'Discretionary' entry for 'Eyes' has changed to include a reference to organ culture. Reason for Change

Update Information This entry was last updated in

TDSG-DD 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-DD Edition 203, Release 41

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) Tissue to be collected has been irradiated.

Discretionary

If related to malignancy and the eyes were not included in the field of irradiation, see Malignancy

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

c) 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-DD 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.

Discretionary Eyes:

If related to malignancy, see Malignancy.

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.

Reason for Change A 'Discretion' has been added for 'Eyes'.

Update Information This entry was last updated in

TDSG-DD 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-DD 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-DD Edition 203, Release 02, Issue 02

Relapsing Fever

See Infection - Acute

Update Information This entry was last updated in

Relenza®

Approved Name Zanamivir

See Infection - Acute

Reason for Change This entry now redirects to the 'Infection – Acute' entry.

Update Information This entry was last updated in:

TDSG-DD Edition 203, Release 41

Renal Colic

See if Relevant Infection - General

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Renal Disease

See Kidney Disease

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Respiratory Disease

See if Relevant Infection - General

Steroid Therapy

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Resurfacing of Hip

See Tissue and Organ Recipients

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 35

Retinitis Pigmentosa

Discretionary Accept.

Update Information This entry was last updated in

Reyes Syndrome

Obligatory **Eyes**:

Must not donate.

Discretionary Eyes:

If more than three months after recovery, accept

Other Tissues:

If no other contraindication, accept.

See if Relevant Infection - Acute

Reason for Change To add a discretionary acceptance for eyes

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 33

Rheumatic Fever

Obligatory 1. Cardiovascular Tissue:

Must not donate.

2. Other Tissues: Must not donate if:

Active infection.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Rheumatoid Arthritis

Discretionary 1. If mild and the only treatment is NSAIDs, accept.

2. Eyes:

Accept if no ocular involvement.

See Autoimmune Disease

Reason for Change The entry has been changed for consistency from 'Must not donate' to 'See Autoimmune

Disease'.

Update Information This entry was last updated in

TDSG-DD 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-DD Edition 203, Release 02

Risk Factors

See Tissues Safety Entry

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Rodent Ulcer

See Basal Cell Carcinoma

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Rubella

Acute Infection.

See Infection - Acute

Congenital

Obligatory Eyes:

Must not donate.

Discretionary Other Tissues:

If no other contraindication, accept.

See Infection - Acute

Reason for Change A 'Discretionary' entry has been added for other tissues.

Contact

See Infectious Diseases - Contact with

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Rubella Immunization

See Immunization - Live

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Salpingitis

See if Relevant Sexually Transmitted Disease

> See Infection - General

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Sandfly Fever

See Infection - Acute

Update Information This entry was last updated in

TDSG-DD 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 1. If more than five years since finishing all treatment and full recovery, accept

If no ocular involvement, 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.

Discretionary Eyes:

If no ocular involvement, accept.

Additional

Information

Chronic sarcoidosis can cause a range of problems, particularly with the lungs but also with the heart. 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-DD Edition 203, Release 17

Schistosomiasis

See Infection - Acute

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Sclera Recipient

See Ocular Tissue Recipient

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Scleritis

See Inflammatory Eye Disease

Reason for Change To include an entry for 'Scleritis'.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Semi-Permanent Make-Up

See Body Piercing

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02, Issue 02

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

Homosexual and Bisexual Individuals

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-DD Edition 203, Release 29

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, there must be evidence of a test of cure available after

treatment.

See if Relevant Tissues Safety Entry

Chlamydia Genital Warts Herpes - Genital Syphilis

Sexual Partner

Obligatory See:

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 Donor did not require treatment and it is more than three months since the infected

partner has completed treatment, accept.

Donor required treatment: if fully treated, and if it is at least three months from completion of treatment, accept. Additionally, for gonorrhoea, there must be

evidence of a test of cure available after treatment.

See if Relevant Tissues Safety Entry

Chlamydia
Genital Warts
Herpes - Genital
Syphilis

Reason for Change The obligatory deferral period for infected individuals and sexual partners has been reduced to

3 months. For gonorrhoea, there is an additional proviso that a test of cure has been performed.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 42.

Shingles

Affected Individual

See if Relevant Herpes - Ocular

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-DD Edition 203, Release 02

Sickle-Cell Disease

See Haemoglobin Disorders

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Sickle-Cell Trait

Discretionary Accept.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Sideroblastic Anaemia

Obligatory Must not donate

See if Relevant Myelodysplastic Syndrome

Reason for Change Must not donate' has been extended to all tissues.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Skin Cancer

See Malignancy

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Skin Disease

Obligatory

1. Must not donate if:

- a) The condition is infected or infectious.
- b) Malignant.

2. Skin Donor:

Must not donate:

- a) If the skin disease is part of a generalized condition.
- b) Affected skin.

Discretionary

1. Eyes:

- a) If related to malignancy, see Malignancy.
- b) If any infection is bacterial and the corneas are to be stored by organ culture, accept.

2. Skin:

If malignancy was a Basal Cell Carcinoma and treatment is completed, accept unaffected skin

3. Other Tissues:

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

See if Relevant

Dermatitis

Infection - General Malignancy Psoriasis

Reason for Change

Discretions have been added for 'Eyes' and 'Skin'.

'Malignancy' has been added to 'Obligatory' and additional links have been included.

Update Information

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

Sleeping Sickness

(African Trypanosomiasis)

Obligatory Must not donate.

Discretionary Eyes:

Accept for corneas only.

Additional Information As corneas are avascular there is not considered to be a risk of transmitting protozoal infections.

Reason for Change A 'Discretion' has been added for 'Eyes'.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Smallpox Immunization

Contacts

Obligatory

Must not donate if:

1. All Tissues:

a) Any secondarily infected site has not yet healed.

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

2. Skin Only:

Less than two weeks after the last lesion healed on the infected contact.

Discretionary

All Tissues Except Skin:

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

Must not donate if:

1. All Tissues:

- 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.

2. Skin Only:

Less than two weeks after the last lesion healed.

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-DD Edition 203, Release 02

South American Trypanosomiasis

Obligatory Must not donate.

Discretionary Eyes:

Accept for corneas only.

See if Relevant South American Trypanosomiasis Risk

Additional Information As corneas are avascular there is not considered to be a risk of transmitting protozoal infections.

Reason for Change The 'Discretionary' entry for 'Eyes' has been amended.

Update Information This entry was last updated in

TDSG-DD 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) If at least four months from the date of last exposure, including transfusion abroad, and a validated *T. cruzi* antibody test is negative, accept.

2) **Eyes**:

Accept for corneas only (testing not required). For other ocular tissues, as (1) above.

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.

As corneas are avascular there is not considered to be a risk of transmitting protozoal infections.

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-DD Edition 203, Release 42.

Spherocytosis

See Hereditary Spherocytosis

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Spina Bifida

Obligatory Must not donate if:

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

b) Has an infected pressure sore.

Discretionary Eyes

Shunt infection or infected pressure sore - if the corneas are to be stored by organ culture,

accept.

Additional Information Donated bone is cultured to exclude occult bacterial and fungal infection. However it should not

be collected from bacteraemic subjects.

Reason for Change A 'Discretion' has been added for 'Eyes'.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Spinal Surgery

See if Relevant

Neurosurgery Transfusion

Update Information

This entry was last updated in

TDSG-DD Edition 203, Release 02, Issue 35

Splenectomy

Obligatory Must not donate if:

a) For malignancy.

b) For a myeloproliferative disorder.

c) For immune thrombocytopenia (ITP).

Discretionary 1. All Tissues:

a) If for trauma, accept.

b) If taking prophylactic antibiotics, accept.

2. Eyes:

If related to malignancy, see Malignancy.

See if Relevant Immune Thrombocytopenia

Malignancy Transfusion

Reason for Change The 'Discretionary' entry for 'Eyes' (malignancy) has changed.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02, Issue 35

Squamous Cell Carcinoma

See Malignancy

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Steroid Therapy

Obligatory Discuss with a Designated Medical Officer if:

Has been regularly taking steroid tablets, injections or enemas, or applying creams over large

areas.

For information on other situations where steroid therapy may be acceptable, refer to entry for

immunosuppression.

Discretionary 1. a) If occasional use of creams over small areas of skin for minor skin complaints, accept.

b) If using steroid inhalers for prophylaxis, accept.

c) Cornea only: If corneas are stored in organ culture and in the absence of other contraindications, accept. See additional information section

See if Relevant Autoimmune Disease

Immunosuppression

Skin Disease

Tissue and Organ Recipients

Infection – acute Infection – chronic Eye Disease

Additional Information

Steroid therapy in high doses causes immunosuppression. This may mask infective and inflammatory conditions that would otherwise prevent donation. For further information refer to 'Immunosuppression' entry.

The underlying condition requiring steroid treatment should always be taken into consideration.

Eye donors receiving steroid treatment e.g. steroid eye drops, should be evaluated on a case by case basis, taking into consideration the indication for treatment as well as any possible side effects. Relevant clinical records, especially ophthalmology records, should be reviewed.

Reason for Change

Links to the Infection – acute, Infection – chronic and Eye Disease entries have been added.

Discretionary section amended regarding cornea donation.

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

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

Stroke

Discretionary Accept.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Subacute Bacterial Endocarditis

SBE

See Endocarditis

Reason for Change This entry is replaced by the entry for '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-DD Edition 203, Release 02

Syphilis

1. Affected Individual

Obligatory Must not donate.

Discretionary

If fully treated in the past and confirmatory tests exclude recent infection, discuss

with a Designated Medical Officer.

Additional Information The interpretation of syphilis testing is often difficult. The advice of an experienced microbiologist may be required before a decision on safety can be made.

Reason for Change

Discretionary' entry has been modified.

Additional Information' has been added

2. Current or Former Sexual Partner of Affected Individual

Obligatory Must not donate if:

a) The potential donor required treatment.

b) The potential donor did not require treatment and it is less than 12 months since the infected partner has completed treatment.

Discretionary

a) If the potential donor did not require treatment and it is more than 3 months from

the last sexual contact with the infected partner, accept.

b) If the potential donor did not require treatment and it is more than 12 months since

the infected partner has completed treatment, accept.

c) If the potential donor did require treatment, refer to the 'Affected Individual' section

above'

See if Relevant Tissue Safety Entry

A section covering 'Current or Former Sexual Partner of Affected Individual' has Reason for Change

been added.

This entry has been modified in line with the recommendations of the SaBTO Donor

Selection Criteria Review Report published on 23rd July 2017.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 29

Syphilis Sexual Contact

See Syphilis

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 29

Systemic Lupus Erythematosus

Obligatory Must not donate.

Discretionary If the tissues to be donated are not affected by the condition, subject to individual risk

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-DD Edition 203, Release 42.

Tamiflu®

Approved Name Oseltamivir

See Infection - Acute

Reason for Change This entry now redirects to the 'Infection – Acute' entry.

Update Information This entry was last updated in:

TDSG-DD 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-DD Edition 203, Release 42.

Tattoo

See Body Piercing

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Temporal Arteritis

See Autoimmune Disease

Reason for Change The entry has been changed for consistency from 'Must not donate' to 'See Autoimmune

Disease'.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

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-DD Edition 203, Release 02

Thalassaemia Major

Obligatory Must not donate.

Discretionary Eyes:

Accept.

See if Relevant Transfusion

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Thalassaemia Trait

Discretionary Accept.

Update Information This entry was last updated in

TDSG-DD 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-DD Edition 203, Release 02

Threadworms

Discretionary Even if on treatment, accept.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Thrombocytosis

Obligatory Must not donate if:

Due to a myeloproliferative disorder.

Additional Information People with unexplained persistently raised platelet counts should not be accepted.

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-DD 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

TDSG-DD Edition 203, Release 02

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-DD Edition 203, Release 46

Thrush - Vaginal

Obligatory Must not donate if:

a) Related to immunodeficiency.

Discretionary 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-DD Edition 203, Release 46

Thyroid Disease

Obligatory Must not donate if:

a) Under investigation.

b) Malignant.

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

Discretionary Eyes

a) If related to malignancy, see Malignancy.

b) If associated with Thyroid Eye Disease (Grave's Disease): accept if no history of corneal

involvement.

See if Relevant Autoimmune disease

Reason for Change To add an additional discretion for 'Eyes'.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 35

Thyroxine

See Thyroid Disease

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Tick-Borne Encephalitides

See Infection - Acute

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Tick-Borne Encephalitis Immunization

See Immunization - Non-Live

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Tissue and Organ Recipients

Obligatory All donors:

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 tissue, or cells, has been transplanted, accept.
- c) For donations of heart valves, skin, ocular tissue and pancreatic islets: If at anytime a allogeneic 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 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 who have received a tissue or organ transplant since 1980, will be excluded from donation except for donation of heart valves, ocular tissue, pancreatic islets and skin. These tissues provide considerable benefits to patients.

See Transfusion

Reason for Change To update discretionary entry to accept skin, heart valve, ocular tissue and pancreatic islets

from those who might have received allogeneic tissue transplant.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 35

Tissue Recipient

See Tissue and Organ Recipients

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Tissues Safety Entry

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.
- 6a. For donors of tissues/cells other than haematopoietic progenitor cells, pancreatic

islet cells or hepatocytes:

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

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

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

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

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

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

A partner who is, or you think may be:

a) HIV or HTLV positive

b) A hepatitis B carrier

c) A hepatitis C carrier

d) A partner who has received money or drugs for sex

e) A partner who has injected, or been injected with non-prescription drugs. This includes, for example, bodybuilding drugs or injectable tanning agents. You may be able to give if a doctor prescribed the drugs, please ask.

f) A partner who has been, or you think may have been, sexually active in parts of the world where HIV/AIDS is very common. This includes most countries in Africa. There are exceptions, so please ask.

See if Relevant

Addiction and Drug Abuse

Homosexual and Bisexual Individuals

Hepatitis of Viral Origin

HIV

HTLV

Infection - General

Pre- or Post-Exposure Prophylaxis for HIV

Additional Information

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

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

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

The drugs used in both 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 should not donate for three months, even if they have not had a sexual partner in a risk group.

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

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

Update Information

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

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. Toxoplasma IgG results from organ donors, if

available, do not require further investigation.

Reason for Change To clarify that toxoplasma IgG results from organ donors, if available do not require further

investigation

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 30

Transfusion

Includes 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.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) or 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) If the only transfusion has been within the last week of life, accept.
- e) Treated with prothrombin complex (PCC) to reverse over-anticoagulation after 1st January 1999, accept.

f) 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, ocular tissue, skin and pancreatic islet 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 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, accept.
- b) If tissue will be sterilized by irradiation post-donation: Accept (testing not required)
- c) For Eyes only, if the risk was for Malaria or South American trypanosomiasis, accept for corneas only (testing not required).

See if Relevant

Bleeding Disorder

Immunoglobulin Therapy

Immunosuppression

Malaria

Prion Associated Diseases

South American Trypanosomiasis Risk

Geographical Disease Risk Index

Appendix 3 - Calculation of Plasma Dilution.

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 Malaria and South American trypanosomiasis for cornea donors only, or for 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 (except in the last week of life) should not normally be accepted. Because of shortages in supply, this does not currently apply to the donation of heart valves, ocular tissue, pancreatic islets and skin. 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 perioperative prophylaxis. Since 1999, coagulation factors 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-DD Edition 203, Release 45

Transgender Individuals

Obligatory Assessment of the donor suitability should be according to the gender assigned.

Discretionary Obtain history and refer to designated medical officer if necessary.

See if Relevant Tissue Safety Entry

Homosexual and bisexual individuals

Additional Information A careful and sympathetic consideration of sexual risk factors needs to be undertaken. Men

who have sex with other men have a higher chance of having an undiagnosed infection which could be passed to anyone receiving their blood, tissues or cells. Consideration should be given

to the medications used during gender re-assignment

Reason for Change To change the title of the entry from 'Sex Change' to 'Transgender Individuals' and simplify the

contents.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 35

Trauma

See Accident

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Travel

See if Relevant Geographical Disease Risk Index

Malaria

South American Trypanosomiasis Risk

Infection - Tropical

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Trisomy 21 (Down's Syndrome)

Includes Mosaic Down's Syndrome

Obligatory Eyes:

Must not donate.

Discretionary Other Tissues:

If no other contraindication, accept.

Reason for Change A 'Discretionary' entry has been added for other tissues.

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

Trisomy E (Trisomy 18)

Obligatory Eyes:

Must not donate.

Discretionary Other Tissues:

If no other contraindication, accept.

Reason for Change A 'Discretionary' entry has been added for other tissues.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Tropical Areas

See Infection - Tropical

Geographical Disease Risk Index

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Tropical Diseases

See Infection - Tropical

Update Information This entry was last updated in

TDSG-DD 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.

endemic area.

d) The donor has had sex in the last 28 days with someone who has had a confirmed Zika

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

Virus infection in the three months preceding the sexual contact.

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 neither symptoms nor evidence of infection.

See if Relevant

Infection - General

Malaria

South American Trypanosomiasis
The 'Geographical Disease Risk Index'

Additional Information

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.

It is geographically widespread but since 2005 it has reached epidemic proportions in parts of India and islands in the Indian Ocean. It is known to be spread by blood in symptomatic cases and on theoretical grounds could be spread by transfusion and transplantation of tissues and organs from people with pre-symptomatic or asymptomatic disease. A number of visitors returning from endemic areas to the UK have been diagnosed with this infection.

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 arthropod borne disease worldwide. Dengue is currently considered endemic in approximately 128 countries.

Overall, 15-90% of cases may have an asymptomatic course of infection, but clinical presentation varies with age group. However there is a risk of change in disease presentation and potential for increased incidence of more severe disease in older age groups due to co-circulation of different dengue types and emergence of new types in endemic areas patterns.

Yellow Fever Virus is a Flavivirus. 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 that is transmitted to humans through the bite of a carrier mosquito. Zika Virus can also be transmitted human to human through sexual contact. Zika infection is a rapid acute infection that in the majority of cases is asymptomatic or has very mild general symptoms. A small number of cases may have more apparent symptoms but hospitalisation is rare. Zika infection may be mistaken for Chikungunya or Dengue infections as the virus often co-circulate.

The main vector for these viruses is Aedes aegypti (Aedes albopictus is another emerging vector), which is found worldwide between latitudes 35°N and 35°S. There is no epidemiologically important animal reservoir for these viruses. The main geographical areas affected by these viruses include the Caribbean, South and Central America, Mexico, Africa, the Pacific Islands, SE Asia, Indian sub-continent, Hawaii. Additionally Dengue fever has been reported in Australia and there have been outbreaks of Dengue and Chikungunya in Europe.

Position statements are available in the JPAC Document Library.

Information

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

Reason for Change

The scope of this entry has been extended to include Yellow Fever.

Update Information

This entry was last updated in: TDSG-DD Edition 203, Release 50

Trypanosoma Cruzi Infection

Obligatory Must not donate.

Discretionary Eyes:

Accept for corneas only.

See if Relevant South American Trypanosomiasis Risk

Additional Information As corneas are avascular there is not considered to be a risk of transmitting protozoal infections.

Reason for Change The 'Discretionary' entry for 'Eyes' has been amended.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Tuberculosis

Affected Individual

Obligatory 1. Must not donate if:

a) Infected.

b) Less than 24 months from confirmation of cure.

c) Under follow-up.

2. Bone:

Must not donate previously infected bone.

See if Relevant BCG

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 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.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Tumour Chemotherapy

See Malignancy

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Turner's Syndrome

Discretionary Accept.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Typhoid

See Chronic Infection

Reason for Change To replace the entry for typhoid with a link to chronic infection. By using a link it will make

future changes to the guidelines simpler.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 17

Typhoid Injected Immunization

See Immunization - Non-Live

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Typhoid Oral Immunization

See Immunization - Live

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Ulcerative Colitis

See Inflammatory Bowel Disease

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Urethritis (Non-Specific)

See Non-Specific Urethritis

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Urinary Tract Infection

See Infection - General

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Vaccination

See Immunization

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Vasculitis

Obligatory Must not donate.

Discretionary Eyes: If no known ocular involvement, accept.

See if Relevant Autoimmune disease

Immunosuppression
Steroid Therapy
Immunoglobulin Therapy

Reason for Change To allow discretionary acceptance of cornea donors

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 33

Viral Disease

See Infection - General

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Viral Haemorrhagic Fever

Includes Crimean-Congo Fever

Ebola Virus Disease Lassa Fever

<u>Lassa Fever</u> 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-DD Edition 203, Release 41

Vitamin Treatment

Discretionary Accept.

Update Information This entry was last updated in

Vitiligo

See Autoimmune Disease

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Von Recklinghausen's Disease

See Neurofibromatosis

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Von Willebrand's Disease

See Bleeding Disorder

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Warts

Discretionary Even if o

Even if on local treatment, accept.

Update Information

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

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 d

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-DD 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-DD Edition 203, Release 02

Wilson's Disease

Discretionary Accept.

Update Information This entry was last updated in

TDSG-DD 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-DD Edition 203. Release 25

XMRV

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

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

to donation.

This is a new entry. Reason for Change

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 12 Issue 01

Yaws

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Yellow Fever

See Infection - Acute

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Yellow Fever Immunization

See Immunization - Live

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Zanamivir

See Relenza®

Latest Updates

This page lists all changes to TDSG-DD 203 after Release 02. This page constitutes **Section 2 of Appendix 1 - Changes to donor selection guidelines**.

The changes are listed with the most recent change at the bottom.

Changes introduced with Release 03

A change was made to the version control definitions and all Issue numbering information removed. No other changes where introduced.

Changes introduced with Release 04

Age See Change Notification No. 8 – 2009

Changes introduced with Release 05

Tamiflu[®] (oseltamivir) See Change Notification No. 28 - 2009 Relenza[®] (zanamivir) See Change Notification No. 29 - 2009

Changes introduced with Release 06

Acupuncture See Change Notification No. 33 - 2009 Complementary Therapy See Change Notification No. 35 - 2009

Changes introduced with Release 07

Body Piercing See Change Notification No. 02 - 2010 Inoculation Injury See Change Notification No. 04 - 2010

Changes introduced with Release 08

West Nile Virus (WNV) See Change Notification No. 09 - 2010

Changes introduced with Release 09

Immunization - Live See Change Notification No. 06 - 2011
BCG See Change Notification No. 07 - 2011
Infertility See Change Notification No. 08 - 2011
Sexually Transmitted Disease See Change Notification No. 09 - 2011

Changes introduced with Release 10

West Nile Virus See Change Notification No. 11 - 2011

Changes introduced with Release 11

Porphyria See <u>Change Notification No. 20 - 2011</u> Immunosuppression See <u>Change Notification No. 21 - 2011</u>

Changes introduced with Release 12

XMRV See Change Notification No. 25 - 2011 Hepatitis C See Change Notification No. 27 - 2011

Changes introduced with Release 13

West Nile Virus (WNV) See Change Notification No. 05 - 2012

Changes introduced with Release 14

Acne See Change Notification No. 15 - 2012
Pregnancy See Change Notification No. 16 - 2012
Psoriasis See Change Notification No. 17 - 2012
Toxoplasmosis See Change Notification No. 18 - 2012

Changes introduced with Release 15

West Nile Virus (WNV) See Change Notification No. 01 - 2013

Changes introduced with Release 16

Hepatitis B See Change Notification No. 08 - 2013 Hepatitis B Post Immunization See Change Notification No. 09 - 2013 Infection - Chronic See Change Notification No. 10 - 2013

Changes introduced with Release 17

Acupuncture See Change Notification No. 02 - 2014

Alitretinoin, Toctino, Acne and Dermatitis See Change Notification No. 03 - 2014

Central Nervous System Disease See Change Notification No. 05 - 2014

Hepatitis of Unknown Origin See Change Notification No. 08 - 2014

Kidney Disease See Change Notification No. 10 - 2014

Malignancy See Change Notification No. 11 - 2014

Mental Health Problems See Change Notification No. 12 - 2014

Sarcoidosis See Change Notification No. 13 - 2014

South American Trypanosomiasis Risk See Change Notification No. 14 - 2014

Paratyphoid and Typhoid See Change Notification No. 15 - 2014

Changes introduced with Release 18

Haematological Disease See Change Notification No. 30 - 2014

SARS See Change Notification No. 31 - 2014

Tissues Safety See Change Notification No. 32 - 2014

Homosexual & Bisexual Individuals See Change Notification No. 36 - 2014

Sex Change See Change Notification No. 39 - 2014

Changes introducted with Release 19

Viral Haemorrhagic Fever Risk See Change Notification No. 43 – 2014

Changes Introduced with Release 20

Communication Difficulties See Change Notification No.7 - 2015 Complementary Therapy See Change Noficiation No.8 - 2015

Infertility See Change Notification No.9 - 2015

Changes Introduced with Release 21

Complementary Therapy See Change Notification No. 12 - 2015 Injectable Tanning Agents See Change Notification No.15 - 2015

Changes Introduced with Release 22

Age pulmonary patch allografts See Change Notification No.16 -2015

Changes Introduced with Release 23

Appendix 2 Table of Immunizations
Tropical Viruses

West Nile Virus
Viral Haemorrhagic Fever

See Change Notification No. 04 - 2016
See Change Notification No. 09 - 2016
See Change Notification No. 09 - 2016
See Change Notification No. 11 - 2016

Changes Introduced with Release 24

Tropical Viruses See Change Notification No. 014 - 2016
Viral Haemorrhagic Fever See Change Notification No. 015 - 2016

Changes Introduced with Release 25

Endoscopy
Fibromyalgia
Necrotising Fasciitis
Osteogenesis Imperfecta
Severe Excercise Intolerance Disease (SEID)
Xenotransplantation

See Change Notification No. 24 - 2016
See Change Notification No. 26 - 2016
See Change Notification No. 27 - 2016
See Change Notification No. 28 - 2016
See Change Notification No. 29 - 2016

Changes Introduced with Release 26

Cardiomyopathy
Ehlers Danlos Syndrome
Hepatitis A
Marfans Syndrome
Transfusion

See Change Notification No. 44 - 2016
See Change Notification No. 45 - 2016
See Change Notification No. 47 - 2016
See Change Notification No. 47 - 2016
See Change Notification No. 48 - 2016

Changes Introduced with Release 27

Malignancy See Change Notification No. 05 - 2017

Changes Introduced with Release 28

Malaria See Change Notification No. 17 - 2017

Changes Introduced with Release 29

Age See Change Notification No. 21 - 2017

Radiation Therapy See Change Notification No. 22 - 2017

Tissue and Organ Recipients See Change Notification No.23 - 2017

Tissue Safety Entry - See Change Notification No. 27 - 2017

Addiction and Drug Abuse - See Change Notification No. 28 - 2017

Body Piercing - See Change Notification No. 30 - 2017

Complementary Therapy - See Change Notification No. 32 - 2017

Hepatitis B - See Change Notification No. 34 - 2017

Hepatitis C - See Change Notification No. 36 - 2017

HIV - See Change Notification No. 38 - 2017

Homosexual and Bisexual Individuals - See Change Notification No. 40 - 2017

HTLV - See Change Notification No. 42 - 2017

Inoculation Injury - See Change Notification No. 43 - 2017

Sex Worker - See Change Notification No. 46 - 2017

Syphilis - See Change Notification No. 48 - 2017

Bleeding Disorder - See Change Notification No. 50 - 2017

Changes Introduced with Release 30

Poisoning - See <u>Change Notification No. 01 - 2018</u> Toxoplasmosis - <u>See Change Notification No.02 - 2018</u>

Changes Introduced with Release 31

Central Nervous System Disease - Change Notification No. 04 - 2018

Hepatitis A - Change Notification No. 09 - 2018

Hepatitis E - Change Notification No. 10 - 2018

Prisons - Change Notification No. 12 - 2018

Tissue and Organ Recipient - Change Notification No. 13 - 2018

Transfusion - Change Notification No. 14 - 2018

Viral Haemorrhagic Fever - Change Notification No. 15 - 2018

Changes Introduced with Release 32

Haemodilution algorithm - Change Notification No. 07 - 2018

Changes Introduced with Release 33

Blind Donor - Change Notification No. 23 - 2018

Eye Disease - Change Notification 24 - 2018

Herpes - Ocular Change Notification No. 25 - 2018

Infection - Acute - Change Notification No. 27 - 2018

Infection - Chronic - Change Notification No. 28 - 2018

Laser Treatment - Change Notification No. 29 - 2018

Reyes Syndrome - Change Notification No. 30 - 2018

Thyroid Disease - Change Notification No. 31 - 2018

Transgender Individuals - Change Notification No. 32 - 2018

Vasculitis - Change Notification No. 33 - 2018

Changes Introduced with Release 34

Hepatitis A - Change Notification No. 12 - 2019

Pre- and Post Exposure Prophylaxis for HIV - Change Notification No. 13 - 2019

Tissue Safety Entry - Change Notification No. 14 - 2019

Viral Haemorrhagic Fever - Change Notification No. 15 - 2019

Complementary Therapy - Change Notification No. 17 - 2019

Eye Disease - Change Notification No. 18 - 2019

Hepatitis C - Change Notification No. 19 - 2019

Infammatory Bowel - Change Notification No. 20 - 2019

Malignancy - Change Notification No. 21 - 2019

Sexually Transmitted Diseases - Change Notification No. 23 - 2019

Laser Treatment - Change Notification No. 31 - 2019

Ocular Surgery - Change Notification No. 32 - 2019

Changes Introduced with Release 35

Surgery - Change Notification No. 16 - 2019

Changes Introduced with Release 36

Coronavirus Infection - Change Notification No. 05 - 2020

Changes Introduced with Release 37

Coronavirus Infection - Change Notification No. 08 - 2020

Changes Introduced with Release 38

Coronavirus Infection - Change Notification No. 10 - 2020

Changes Introduced with Release 39

Coronavirus Infection - Change Notification No. 16 - 2020

Changes Introduced with Release 40

Coronavirus Infection - Change Notification No. 33 - 2020

Changes Introduced with Release 41

Animal Bite - Change Notification No. 36 - 2020
Rabies - Change Notification No. 37 - 2020
Viral Haemorragic Fever - Change Notification No. 38 - 2020
Infection - Acute - Change Notification No. 39 - 2020
Tamiflu & Relenza - Change Notification No. 40 - 2020

Changes Introduced with Release 42

Tamoxifen - Change Notification No. 42 - 2020 Infection - Chronic - Change Notification No. 43 - 2020 South American Trypanosomiasis Risk - Change Notification No. 44 - 2020 Systemic Lupus Erythematosus - Change Notification No. 46 - 2020 Sexually Transmitted Disease - Change Notification No. 61 - 2020

Changes Introduced with Release 43

COVID-19 Vaccine - Change Notification No.74 - 2020

Changes Introduced with Release 44

COVID-19 Vaccination - Change Notification No.05 - 2021

Changes Introduced with Release 45

Immune Thrombocytopenia - Change Notification No.12 - 2021 Immunoglobulin Therapy - Change Notification No.13 - 2021 Transfusion - Change Notification No.14 - 2021

Changes Introduced with Release 46

Acne & Teratogenetic Medications - Change Notification No.19 - 2021
Colitis, Proctitis & Gastrointestinal Disease - Change Notification No. 20 - 2021
Coronavirus Infection - Change Notification No. 22 - 2021
Coronavirus Vaccination - Change Notification No. 23 - 2021
Haematological Disease - Change Notification No. 24 - 2021
Immunization - Change Notification No. 26 - 2021
Infertility - Change Notification No. 27 - 2021
Inflamatory Eye Disease - Change Notification No. 28 - 2021
Thrush - Oral & Vaginal - Change Notification No. 30 - 2021

Changes Introduced with Release 47

Complementary Therapy - Change Notification No. 04 - 2022

Changes Introduced with Release 48

Infertility- Change Notification No. 13 - 2022
Psoriasis - Change Notification No. 14 - 2022
Body Piercing - Change Notification No. 15 - 2022
Cervical Dysplasia - Change Notification No. 16 - 2022
Diseases of unknown aetiology - Change Notification No. 17 - 2022

Changes Introduced with Release 49

Coronavirus Infection- Change Notification No. 30 - 2022

Changes Introduced with Release 50

Yellow Fever - Change Notification No. 21 - 2022

Changes Introduced with Release 51

Immunosuppression - Change Notification No. 38 - 2022 Monkeypox - Change Notification No. 41 - 2022

Changes Introduced with Release 52

Basal Cell Carcinoma - Change Notification No. 53 - 2022 Steriod Therapy - Change Notification No. 54 - 2022 Table of Immunisations - Change Notification No. 55 - 2022

Changes Introduced with Release 53

Coronavirus Infection (COVID-19) - Change Notification No. 51 - 2022 Infectious Diseases, Contact with - Change Notification No. 52 - 2022

Changes Introduced with Release 54

Mpox (Monkeypox) - Change Notification No. 13 - 2023 Malaria - Change Notification No. 21 - 2023

Appendix 1 - Changes to donor selection guidelines

Section 1

Changes introduced with TDSG-DD 203 Release 02 from TDSG-DD 202 Release 04

There have been changes made to the following entries:

Accident

Acne

Acne Rosacea

Acupuncture

African Trypanosomiasis

Age

Anaemia

Animal Bite

Ankylosing Spondylitis

Anti-Androgens

Antibiotic Therapy

Arthritis

Asthma

Autoimmune Disease

Babesiosis

Bipolar Disorder

Bleeding Disorder

Blind Donor

Body Piercing

Breast Lump

Breastfeeding

Cardiomyopathy

Cardiovascular Disease

Central Nervous System Disease

Chagas' Disease

Chikungunya Virus

Chlamydia

Cirrhosis

Clinical Trials

Colitis

Colostomy

Communication Difficulties

Death from Unknown Causes

Diabetes Mellitus

Diarrhoea

Disease of Unknown Aetiology

Down's Syndrome

Drowning

Dutasteride (Avodart)

Ehlers-Danlos Syndrome (Disease)

Elliptocytosis

Endocarditis

Endoscopy

Epilepsy

Episcleritis

Etretinate

Eye Disease

Finasteride (Proscar)

Gall Bladder Disease

Gastrointestinal Disease

German Measles

Glaucoma

Guillain-Barré Syndrome

Haematuria

Haemoglobin Disorders

Haemolytic Anaemia

Hepatitis B

Hepatitis B - Post Immunization

Hepatitis C

Hepatitis of Unknown Origin

Hereditary Elliptocytosis

Herpes – Ocular

Hormone Replacement Therapy

Hydrocephalus

lleostomy

Immune Thrombocytopenia

Immunoglobulin Therapy

Immunosuppression

Infection - Chronic

Infection - Tropical

Inflammatory Bowel Disease

Inflammatory Eye Disease

Inoculation Injury

Jaundice

Kala-Azar

Laser Treatment

Leishmaniasis

Malaria

Malignancy

Marfan's Syndrome

Mental Health Problems

Myeloproliferative Syndrome

Neurofibromatosis

Neurosurgery

Ocular Surgery

Osteomyelitis

Ovarian Cyst

Peptic Ulcer

Pituitary Extract - Human

Platelet Disorder

Polymyalgia Rheumatica

Pregnancy

Prion Associated Diseases

Prisons

Proctitis

Psoriasis

Pyelonephritis

Quinsy

Radiation Therapy

Radionuclides

Reyes Syndrome

Rheumatoid Arthritis

Rubella

Scleritis

Sexually Transmitted Disease

Shingles

Sideroblastic Anaemia

Skin Disease

Sleeping Sickness

South American Trypanosomiasis

South American Trypanosomiasis Risk

Spina Bifida

Splenectomy

Steroid Therapy

Subacute Bacterial Endocarditis

Surgery

Syphilis

Tamoxifen

Temporal Arteritis

Thyroid Disease

Tigason

Tissue and Organ Recipients

TransfusionThrombocytosis

Trisomy 21 (Down's Syndrome)

Trisomy E (Trisomy 18)

Trypanosoma Cruzi Infection

West Nile Virus

Section 2 Changes to TDSG-DD 203 after Release 02

See: Latest Updates

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

Appendix 3 - Calculation of Blood and Plasma Dilution

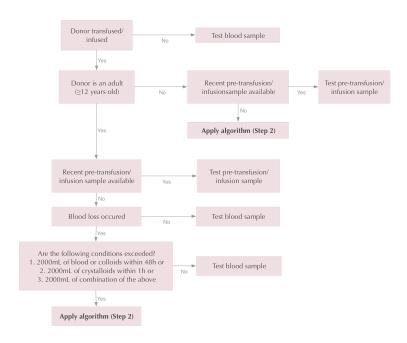
Haemodilution algorithm

Appendix 3 – Calculation of Blood & Plasma Dilution

Please find attached an algorithm for determining the suitability of post-transfusion/infusion samples for mandatory screening for transmissible infections.

Determining the Suitability of Post-transfusion/Infusion Samples for Mandatory Screening for Transmissible Infections

Determing sample suitability - Step 1



Determining sample suitability - Step 2

Donor ID:	Date & Time blood sample taken:		
STEP 2A			
Calculate plasma volume	Donor weight (kg)		_mL
Calculate blood volume	Donor weight (kg)		_mL
A) Record total volume of blood transfused in the 48 h prior to death or sample collection (whichever comes first)	mL of RBC transfused/48 hmL of whole blood transfused/48 hmL of reconstituted blood/48 h	Sum A:	mL
B) Record total volume of colloid infused in the 48 h prior to death or sample collection (whichever comes first)	mL plasma/48 hmL platelets/48 hmL albumin/48 hmL HES or other colloids/48 h	Sum B:	mL
C) Record total volume of crystalloid infused in the 1 h prior to death or	mL	Sum C:	mL

sample collection (whichever comes first)

Step 2B

Calculated Plasma Volume	mL	Sum B + Sum C		mL
Calculated Blood Volume	mL	Sum A + Sum B + Sum C		mL
Calculate plasma dilution	Is Sum B + Su	m C > plasma volume?	No	Yes
Calculate blood dilution	Is Sum A + Su	m B + Sum C > blood volume?	No	Yes

If the answers to both questions are 'No', the post-transfusion/infusion sample is acceptable

If the answer to **either** of the questions is 'Yes' use a pre-transfusion/infusion sample. If a suitable sample is not available, seek expert advice and inform transplant centre, testing laboratory, tissue bank as necessary.

RBC = red blood cells; HES = hydroxyethyl starch

Based on the algorithm developed by the Food and Drug Administration, USA

 $\underline{www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/ucm091345.}\\ \underline{pdf}~(Appendices~2\&3)$

This appendix was last updated in TDSG-DD Edition 203, Release 32, Issue 01

Appendix 4 - 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: Pfizer/BioNTech COVID-19 vaccine, AstraZeneca COVID-19 vaccine, Moderna COVID-19 vaccine; Janssen Ad26.COV2-S; Novavax (Nuvaxovid [®]); COVID-19 Vaccine Valneva: see 'Coronavirus vaccination' entry	Non-Live
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®	Live
Influenza, injected	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 activity has an exposure risk, or for some travellers to endemic areas: Rabipur [®] , Verorab [®]	Non-Live

	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	Live
	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)	Live
Tetanus	Would usually be given Diphtheria, Tetanus and Polio. Revaxis [®]	Non-Live
Tick-borne encephalitis	Tico-vac [®]	Non-Live
Tuberculosis	BCG vaccine	Live
Typhoid - injected	Typhim Vi [®] Combined with hepatitis A: Viatim [®]	Non-Live
Typhoid - Oral	Given in capsule form Vivotif [®]	Live
Varicella (chickenpox)	Usually given to healthcare workers. Varilrix [®] , Varivax [®]	Live
Yellow Fever	Stamaril [®]	Live

Appendix 5 - Grading of selected central nervous system tumours (WHO 2016 classification)

į	II	III	IV
	•		
		•	
			•
			•
			•
	•		
		•	
		•	

Other astrocytic tumours	I	II	Ш	IV
Pilocytic astrocytoma	•			
Subependymal giant cell astrocytoma	•			
Pleomorphic xanthoastrocytoma		•		
Anaplastic pleomorphic xanthoastrocytoma			•	

Ependymal tumours	I	II	Ш	IV
Subependymoma	•			
Myxopapillary ependymoma	•			
Ependymoma		•		
Ependymoma, RELA fusion-positive		•	•	
Anaplastic ependymoma			•	T

Other gliomas	I	II	Ш	IV
Angiocentric glioma	•			
Chordoid glioma of third ventricle		•		

Choroid plexus tumours	I	II	Ш	IV
Choroid plexus papilloma	•			
Atypical choroid plexus papilloma		•		

	1		
Choroid plexus carcinoma		•	

Tumours of the pineal region	I	II	Ш	IV
Pineocytoma	•			
Pineal parenchymal tumour of intermediate differentiation		•	•	
Pineoblastoma				•
Papillary tumour of the pineal region		•	•	

Meningiomas	I	II	Ш	IV
Meningioma	•			
Atypical meningioma		•		
Anaplastic (malignant) meningioma			•	

Embryonal tumours	ı	II	Ш	IV
Medulloblastoma (all subtypes)				•
Embryonal tumour with multi-layered rosettes, C19MC-altered				•
Medulloepithelioma				•
CNS embryonal tumour, NOS				•
Atypical teratoid/rhabdoid tumour				•
CNS embryonal tumour with rhabdoid features				•

Neuronal and mixed neuronal-glial tumours	I	II	Ш	IV
Dysembryoplastic neuroepithelial tumour	•			
Gangliocytoma	•			
Ganglioglioma	•			
Anaplastic ganglioglioma			•	
Dysplastic gangliocytoma of cerebellum (Lhermitte–Duclos)	•			
Desmoplastic infantile astrocytoma and ganglioglioma	•			
Papillary glioneuronal tumour	•			
Rosette-forming glioneuronal tumour	•			
Central neurocytoma		•		

Extraventricular neurocytoma	•	
Cerebellar liponeurocytoma	•	

Tumours of the cranial and paraspinal nerves	I	II	Ш	IV
Schwannoma	•			
Neurofibroma	•			
Perineurioma	•			
Malignant peripheral nerve sheath tumour (MPNST)		•	•	•

Mesenchymal, non-meningothelial tumours	I	II	Ш	IV
Solitary fibrous tumour/haemangiopericytoma	•	•	•	
Haemangioblastoma	•			

Tumours of the sellar region	I	II	III	IV
Craniopharyngioma	•			
Granular cell tumour	•			
Pituicytoma	•			
Spindle cell oncocytoma	•			

Source: adapted from: Louis DN, Ohgaki H, Wiestler OD et al. (2016) World Health Organization histological classification of tumours of the central nervous system. Geneva: WHO Press/Lyon: International Agency for Research on Cancer.