United Kingdom Blood Transfusion Services (UKBTS) Tissue Donor Selection Guidelines Deceased Donors (TDSG-DD) Edition 203 - 01 June 2007 Release 28 - 01 August 2017

Introduction

These guidelines form a constituent part of Chapter 20 (Tissue banking: selection of donors) of the <u>Guidelines for the Blood</u> 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 L Williamson, Medical and Research Director National Health Service Blood & Transplant (NHSBT) E-mail lorna.williamson@nhsbt.nhs.uk

Prof M Turner, Medical & Scientific Director Scottish National Blood Transfusion Service (SNBTS) E-mail marcturner@nhs.net

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Dr K Morris, Medical Chief Executive Officer Northern Ireland Blood Transfusion Service (NIBTS) E-mail kieran.morris@nibts.hscni.net

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:

Dr Akila Chandrasekar NHSBT Tissue Services 14 Estuary Bank Speke Liverpool L24 8RB

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 17 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 caroline.smith@nhsbt.nhs.uk

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

Including 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

Surgery

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 02

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

Acitretin

Neotigason

See Acne

Psoriasis

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Acne

Obligatory Must not donate if:

- a) Has ever taken Etretinate (Tigason).
- b) Less than 24 months from the last dose of Acitretin (Neotigason).
- c) Less than four weeks from the last dose of Isotretinoin (Roaccutane) or Alitretinoin (Toctino).
- d) There is secondary infection

Discretionary

1. All tissues

Therapy with topical treatments, oral tetracycline, erythromycin and Dianette (cyproterone acetate and ethinyloestradiol), accept.

2. Eyes

If no ocular surface disease and corneas are to be stored by organ culture, accept even if treated with Etretinate (Tigason), Acitretin (Neotigason), Isotretinoin (Roaccutane) or Alitretinoin (Toctino).

Additional Information

Etretinate (Tigason), Acitretin (Neotigason), Isotretinoin (Roaccutane) and Alitretinoin (Toctino) can cause birth defects in babies exposed to them while inside the womb. It is important to allow time for the drug to be cleared from the donor. It takes longer to clear some drugs than others.

Secondary infection of acne is usually obvious with swelling and redness of affected spots. There is a risk of bacteria entering the blood. This could be a serious threat to anybody receiving tissues. This is because the bacteria can multiply to dangerous levels.

Eyes.

For corneas stored by organ culture (but not for corneas stored at 4°C) there is an opportunity to detect contaminating bacteria in the tissue and it should be safe to donate. Secondary infection of the lid margin (blepharitis) on its own should not preclude eye donation, but donations must not be taken if there is also ocular surface disease.

Reason for Change

To include information on Alitretinoin (Toctino).

Update Information

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

Acne Rosacea

Obligatory Eyes

Must not donate if:

Ocular involvement or ocular surface disease.

Discretionary

Other Tissues:

If no other contraindication, accept.

Reason for Change

The 'Obligatory' entry has been changed. Blepharitis has been removed. A 'Discretionary' entry has been added for other tissues.

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 ever injected, or has been injected with, drugs; even a long time ago or only once. This

includes bodybuilding drugs.

Discretionary a) May be acceptable if injected drugs were prescribed by the donor's physician for a condition

that would not lead to exclusion.

b) Previous use of non-parenteral drugs does not necessarily require exclusion.

See if Relevant Tissues Safety Entry

Additional Information Injecting drugs has been linked with the passing on of many infections, including hepatitis and

HIV. It can be many years before any infection shows itself.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

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. Cardiovascular tissue.

Must not donate if:

a) Over 60 years of age - for aortic valves

b) Over 65 years of age - for pulmonary valves

c) Over 70 years of age - for pulmonary patches

d) 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 add age limits for pulmonary patch 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 22

AIDS

See HIV

Tissues Safety Entry

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

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

Alitretinoin

Obligatory Must not donate if less than four weeks from the last dose of Alitretinoin (Toctino).

See if Relevant Acne

Dermatitis

Additional Information Alitretinoin is a drug analogous to Tretinoin and Isotretinoin used to treat acne and refractory

eczema.

Treatment with retinoids such as Alitretinoin can cause birth defects for babiesexposed to them before birth. It is important to allow time for the drug to be cleared from the donor. A one month

deferral for donation is recommended in the drug information sheet.

Reason for Change New entry.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 17

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

A link to 'Transfusion' has been added.

Update Information

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

Animal Bite

(Non-human)

Obligatory Must not donate if:

a) Ever bitten by a non-human primate.

b) Any wound is infected or not healed.

c) Less than 12 months since bitten anywhere in the world by a bat or by any mammal outside

of the British Isles.

See if Relevant Human Bite

Infection - General Rabies Immunization

Additional Information

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

There have been minor changes to make it clear that the reference is to non-human animals and to introduce guidance concerning bites from non-human primates.

Update Information

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

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

Infection

See Infection - Acute

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

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Anti-Androgens

Including Androgen Antagonists

See Dutasteride (Avodart)

Finasteride (Proscar)

Reason for Change To include a link for 'Anti-Androgens'.

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

Antifungals

See Infection - General

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Antivirals

See Infection - General

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Arthritis

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.

This entry was last updated in Update Information

TDSG-DD Edition 203, Release 02

Avodart

Dutasteride

See **Dutasteride** (Avodart)

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Babesiosis

Obligatory Must not donate.

Discretionary

Accept for corneas only.

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

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

Update Information This entry was last updated in

Basal Cell Carcinoma

Obligatory 1

1. Must not donate if:

a) Still receiving treatment.

b) Any wound has not healed.

Eyes.

Must not donate if:

From an eye where the eyelid is involved.

3. Skin.

Must not donate:

From the area involved by the lesion.

Discretionary Eyes

Exclusion of donors with unhealed wounds 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.

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.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

BCG

Obligatory Must not donate if:

a) The inoculation site has not yet healed.

b) Less than four weeks after inoculation.

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

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

receiving donated material.

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

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

than smallpox.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 09

BCG Immunization

See BCG

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Bilharzia

See Infection - Acute

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

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

infections that can be passed through donations.

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

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

Obligatory Must not donate if:

a) Treated with blood derived coagulation factor concentrates.

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

c) Has had an inoculation injury with blood derived coagulation factor concentrates.

Discretionary If six 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 six 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 has been extensively rewritten to improve clarity.

The deferral period has been reduced from twelve to six months. This is considered

safe as all tissue donors must now be tested for hepatitis B core antibody.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Blind Donor

Obligatory Eyes:

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

Discretionary Other Tissues:

If no other contraindication, accept.

Reason for Change To include an entry for 'Blind Donor'.

Update Information Publication: TDSG - LD Edition 203, Release 02, Issue 01

Date of issue: 1st May 2007.

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

Including Permanent and Semi-permanent Makeup

Obligatory Must not donate if:

Less than four months after last piercing.

Additional Information Piercing has passed infection from person to person. Waiting four months helps to ensure that

the infections tested for by the Blood & Tissues Services will be picked up.

This guidance presumes that a validated NAT test for hepatitis C is negative, if this test is

stopped for any reason the guidance will change.

Reason for Change The deferral period has been reduced from 6 to 4 months to reflect updated JPAC Standing

Advisory Committee on Transfusion Transmitted Infections guidance on infection risk. (JPAC

paper 09-34).

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 07

Bone Graft

See Surgery

Tissue and Organ Recipients

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

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 Biopsy

See Surgery

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

See Surgery

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

Update Information This entry was last updated in

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

TDSG-DD Edition 203, Release 02

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

Surgery

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

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

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 suspected infective origin (e.g. multiple sclerosis (MS), optic neuritis, 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.

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 Additional advice for donors with a history of optic neuritis, transverse myelitis, Bell's Palsy or

transient global amnesia has been added.

A new section Additional Information has been added.

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

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

Cervical Carcinoma in Situ

Obligatory Must not donate if:

Undergoing investigation or treatment.

Discretionary a) If investigation and treatment is concluded, accept.

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

Eyes:

Accept - see Malignancy

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Cervical Cone Biopsy

See Cervical Carcinoma in Situ

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Cervical Dysplasia

See Cervical Carcinoma in Situ

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

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

Herpes Zoster (Varicella Zoster)

See Infection - Acute

Eyes:

Herpes - Ocular

Contact

See Infectious Diseases - Contact with

Update Information This entry was last updated in

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

TDSG-DD Edition 203, Release 02

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

TDSG-DD Edition 203, Release 02

Clinical Trials

Obligatory Must not donate if:

Participating in a clinical trial. This includes the use of drugs of any kind (oral, parenteral,

transcutaneous, etc.) and applies to healthy individuals participating as volunteers - for example

in 'phase 1' clinical trials.

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

See if Relevant Complementary Therapy

Transfusion

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

Obligatory Must not donate if history of:

a) Crohn's disease.

b) Ulcerative colitis.

Discretionary 1. If more than two weeks since full recovery from an episode of infective colitis, accept.

2. Eyes:

If no ocular involvement, accept.

See if Relevant Infection - General

Inflammatory Bowel Disease

Malignancy.

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

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

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.

See if Relevant Surgery

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

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
- 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:

- a) The condition for which treatment was given is not acceptable.
- b) Less than four months from colonic irrigation or colonic hydrotherapy

2. Therapies involving penetration by needles: Must not donate if:

Less than four 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 (to include faecal microbiota therapy):

1. Performed within the NHS

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

2. Performed outside of the NHS

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),

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, Pharmacists, Practitioner Psychologists, Physiotherapists, Prosthetists and Orthotists, Radiographers, Social Workers in England and Speech and Language Therapists), accept.

Additional Information

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

This guidance presumes that a validated NAT test for hepatitis C 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 four months means infections are more likely to be picked up by the tests used by Blood & Tissue Services.

JPAC considers statutory registration of practitioners to afford the best overall guarantee that tissues and cells donated by individuals who have undertaken complementary therapy is safe. In the absence of statutory regulation of complementary therapy, there is currently no single body to which all therapists are accredited, and so to continue with the approval of one or more organisations would necessarily mean that others of possibly equal merit were excluded from approval.

Voluntary registration with a non-statutory body cannot provide assurance as to how high the standards of an organisation's members are or how diligent the non-statutory regulator is in enforcing them or the practitioner in applying them. Practitioners who choose not to join a voluntary register are still able to practise legally and to use the relevant title, as will a practitioner who has been removed from the register by the registering body.

There is no way of policing the enforcement by voluntary associations of the standards they require of their members as the organisations are not subject to supervision by the Council for Regulatory Healthcare Excellence (CHRE). Nor is there currently any external, independent consideration of "fitness to practise" cases referred to voluntary regulators. While statutory regulation cannot guarantee the absence of risk, its primary aim is to deliver enhanced patient safety and public protection. Statutory "protection of title" means that donor centres can safely assume that a person who practises in the name of the registered profession is actually registered.

Reason for Change

Pharmacists have been added to the list of professions regulated by the Health and Care Professions Council.

Update Information

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

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.

See if Relevant Surgery

Update Information This entry was last updated in

Contraceptive Injection

Discretionary Ad

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 e

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

Coronary Thrombosis

Including

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

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

TDSG-DD Edition 203, Release 02

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

TDSG-DD Edition 203, Release 02

Dementia

Obligatory Must not donate.

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

This entry was last updated in TDSG-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 Alitretinoin

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

Including 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

Dilatation and Curettage

See Surgery

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

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

TDSG-DD Edition 203, Release 02

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 Aetiology

Obligatory Must not donate.

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

material.

Reason for Change This entry has been added to clarify the eligibility of donors with diseases for which the cause is

not known.

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

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

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

Including 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

Dutasteride (Avodart)

Obligatory Must not donate if:

Less than six months since completion of treatment.

Discretionary Eyes:

Accept for corneas only.

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

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

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

1. Must not donate if: Obligatory

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.

Infection - General See if Relevant

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

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.

See if Relevant Surgery

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Epilepsy

Obligatory Must not donate if:

a) Recent onset and not fully investigated.

b) Secondary to malignancy or degenerative neurological disease.

Discretionary

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

Etretinate

Tigason

See Acne

Psoriasis

Reason for Change The 'Obligatory' entry has been deleted.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Eye Disease

Obligatory 1. Must not donate if:

a) Active ocular inflammation or infection.

b) Ocular tissue transplanted.

2. Eyes.

a) Congenital or acquired ocular disorders or previous ocular surgery that may preclude a successful graft outcome. This includes laser refractive surgery to the cornea.

b) History of malignant tumours of the anterior segment or retinoblastoma.

Discretionary 1. Eyes:

a) If laser surgery was to the retina, accept.

b) If cataract surgery, accept.

2. Other Tissues

If no other contraindication, accept.

See if Relevant Autoimmune Disease

Glaucoma

Immunosuppression Infection - General Malignancy Ocular Surgery

Ocular Tissue Recipient
Steroid Therapy

Tissue and Organ Recipients

Reason for Change A link to Immunosuppression has been added.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 11

Eye Drops

Obligatory Determine what they are being used to treat.

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

Fibroids - Removal

See Surgery

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

Finasteride (Proscar)

Obligatory Must not donate if:

Less than four weeks from completion of therapy.

Discretionary Eyes:

Accept for corneas only.

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

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

TDSG-DD Edition 203, Release 02

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

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 Surgery

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

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Gastrectomy

See if Relevant Malignancy

Surgery

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Gastrointestinal Disease

Obligatory Must not donate if:

a) Ulcerative colitis or Crohn's disease.

b) Malignant.

Discretionary Eyes:

a) If this is inflammatory bowel disease, there is no evidence of ocular involvement and corneas

are to be stored by organ culture, accept.

b) If related to malignancy, see Malignancy.

Reason for Change The 'Discretionary' entry for 'Eyes' (inflammatory bowel disease and malignancy) has changed.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

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

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

Surgery

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 02

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

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

Haematological Disease

Obligatory Must not donate if:

a) Malignant.

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

monoclonal gammopathy of unknown significance (MGUS).

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

See if Relevant Anaemia

Haemoglobin Disorders
Immune Thrombocytopenia
Therapeutic Venesection

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

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

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

clonal disorder.

'Additional Information' has been added.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

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

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

TDSG-DD Edition 203, Release 02

Haemolytic Anaemia

Obligatory See:

a) Is there an entry for the condition?

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

See if Relevant Autoimmune Disorder

G6PD Deficiency Haemoglobin Disorders Hereditary Elliptocytosis Hereditary Spherocytosis Pyruvate Kinase Deficiency

Transfusion

Reason for Change 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

Including Piles

Discretionary Accept.

See if Relevant Surgery

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

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 02

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

TDSG-DD Edition 203, Release 02

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

If fully recovered, and documented HAV RNA negative, anti HAV IgG positive after Discretionary

recovery, accept.

See if Relevant Travel

> Additional Hepatitis A is spread by the faecal - oral route and by sewage-contaminated food Information

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 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.

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

There is a risk of transmitting the infection through sexual activity. Infection may be Information 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 The obligatory deferral has been reduced from 12 to 6 months.

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 The obligatory deferral has been reduced from 12 to 6 months.

4. Immunization

Obligatory Known Exposure:

Must not donate if:

Less than six weeks 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.

Reason for Change The 'Additional Information' has been extended.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 26

Hepatitis A Immunization

See Hepatitis A - Post Immunization

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Hepatitis B

Infected Individual

Obligatory Must not donate.

See if Relevant Tissues Safety Entry

History of Infection

Obligatory Must not donate.

Discretionary If more than 12 months from recovery, obtain history and blood samples and: Refer

to Designated Medical Officer.

Additional Only accept if all markers (i.e. HBsAg, HBV-DNA and HB core antibody) are negative

Information or, HB core antibody positive, HBsAg negative, HBV-DNA negative and anti-HBs has

been documented at more than 100 iu/l at some time, i.e. natural immunity.

Current Sexual Partners of Infected Individuals

Obligatory Must not donate.

Discretionary Obtain history and blood samples and: Refer to Designated Medical Officer.

See if Relevant Hepatitis B - Post Immunization - 1. Known Exposure

Additional Only accept if HB core antibody positive, HBsAg negative, HBV-DNA negative and anti-HBs has been documented at more than 100 iu/l at some time, i.e. donor has

natural immunity to hepatitis B

or

if more than 12 months from the date the donor was immunised and all markers (i.e.

HBsAg, HBV-DNA and HB core antibody) are negative.

Former Sexual Partners of Infected Individuals

Obligatory Must not donate.

Discretionary Obtain history (including time from last sexual contact) and blood samples and:

Refer to a Designated Medical Officer.

See if Relevant Hepatitis B - Post Immunization - 1. Known Exposure

Additional Information a) If less than six months from last sexual contact:

Only accept if HB core antibody positive, HBsAg negative, HBV-DNA negative and anti-HBs has been documented at more than 100 iu/l at some time, i.e. donor has

natural immunity to hepatitis B.

or

if more than 12 months from the date the donor was immunised and all markers (i.e.

HBsAg, HBV-DNA and HB core antibody) are negative.

b) If more than six months from last sexual contact:

Accept if all markers (i.e. HBsAg, HBV-DNA and HB core antibody) are negative or, HB core antibody positive, HBsAg negative, HBV-DNA negative and anti-HBs has been documented at more than 100 iu/l at some time. No evidence of current

infection, with or without natural immunity.

Current or Former Sexual Partners of Person who has recovered from hepatitis B infection

Obligatory Must not donate if less than 12 months from last sexual contact.

Discretionary Obtain history (including date the partner cleared the HBV infection and the date

HBV immunisation of the donor commenced) and blood samples and Refer to

Designated Medical Officer.

See if Relevant Hepatitis B - Post Immunization, Known Exposure

Additional Information If more than 12 months from the date the partner was stated to have recovered from

/ cleared HBV

or

more than 12 months from the date that the donor received the first dose of a course

of HBV vaccine AND either

all markers (i.e. HBsAg, HBV-DNA and HB core antibody) are negative

or

HB core antibody positive, HBsAg negative, HBV-DNA negative and anti-HBs has been documented at more than 100 iu/l at some time, i.e. donor has natural immunity

to hepatitis B, accept.

Person Sharing Home

Obligatory Must not donate.

Discretionary Obtain history (if no longer sharing, include the time since sharing ceased) and blood

samples and: Refer to a Designated Medical Officer.

See if Relevant Hepatitis B - Post Immunization - 1. Known Exposure

Additional Information C

If still sharing or less than six months since last sharing:

Only accept if HB core antibody positive, HBsAg negative, HBV-DNA negative and anti-HBs has been documented at more than 100 iu/l at some time, i.e. donor has natural immunity to bonatitic P.

natural immunity to hepatitis B.

If has not shared for more than six months:

Accept if all markers (i.e. HBsAg, HBV-DNA and HB core antibody) are negative or, HB core antibody positive, HBsAg negative, HBV-DNA negative and anti-HBs has been documented at more than 100 iu/l at some time. No evidence of current

infection, with or without natural immunity.

Reason for Change Clarification regarding hepatitis B markers and natural immunity has been added to

the additional information.

Partners of an individual with hepatitis B infection may have been vaccinated against hepatitis B infection. If negative for anti-HBc there is no requirement for an anti-HBs

result.

New additional guidance has been added to cover donors who are/were the partners

of people who had recovered from hepatitis B infection.

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

This entry was last updated in TDSG-BM Edition 203, Release 16

Hepatitis B - Post Immunization

Known Exposure

Obligatory Must not donate.

Discretionary If more than 12 months from immunization obtain history and blood samples and:

Refer to Designated Medical Officer.

Additional Information

Only accept if negative for all markers (i.e. HBsAg, HBV-DNA and HB core antibody) or, HB core antibody positive, HBsAg negative, HBV-DNA negative and anti-HBs has

been documented at more than 100 iu/l at some time.

Immunization post exposure may be with specific anti-HB immunoglobulin as well as

with HBsAg.

May be combined with hepatitis A immunization.

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

information.

No Known Exposure

Obligatory If less than seven days from when the last immunization was given:

Refer to a Designated Medical Officer.

See if Relevant Hepatitis A - Post Immunization

Additional Sensitive assays for HBsAg may be positive following recent immunization. Full screening for Hepatitis B may be required.

May be combined with hepatitis A immunization.

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

This entry was last updated in

Hepatitis C

Affected Individual

Obligatory Must not donate.

Discretionary If the individual has been told that he/she is HCV antibody negative, then samples

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.

donation can be issued, their tissue/cells cannot be used.

Reason for Change 'Additional Information' has been added.

Current Sexual Partners of HCV Positive Individuals

Obligatory Must not donate.

Discretionary If the donor's HCV positive partner has been successfully treated for hepatitis C

infection and has been free of therapy for twelve months and continues in sustained

remission, accept.

See if Relevant Tissues Safety Entry

Additional Information

Confirmation of the success of treatment of the HCV positive partner is not required.

Reason for Change There is now sufficient evidence to establish that individuals who have a sustained virological response to treatment for hepatitis C infection (defined as remaining

virological response to treatment for hepatitis C infection (defined as remaining hepatitis C RNA negative six months after cessation of treatment) are likely to have been cured" and that the chance of relapse is less than 1%. (Data from the Pegasys Study presented at the 38th annual Digestive Diseases Week conference,

Washington, USA, 21 May 2007 by Shiffman et al [abstract ID #444]).

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."

Former Sexual Partners of HCV Positive Individuals

Obligatory Must not donate if:

Less than 12 months from last sexual contact.

Discretionary If less than 12 months from last sexual contact and it is reported that the donor's

former HCV positive partner has been successfully treated for hepatitis C infection

and has been free of therapy for twelve months and continues in sustained

remission, accept.

See if Relevant Tissues Safety Entry

Reason for Change The 'Discretionary' entry has been amended to be consistent with '2. Current sexual

partners of HCV positive individuals' above.

Person Sharing Home

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 12 Issue 01

Hepatitis E

Infection

Obligatory Must not donate if:

Less than 12 months from recovery.

See if Relevant Travel

Additional Information Hepatitis E is similar to Hepatitis A in the way that it is spread (faecal - oral route and sewage-contaminated food and water). It can affect non-human animals and has been found in pigs in the UK. There have been reports of transmission by transfusion.

Person Sharing Home

Obligatory Must not donate if:

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

Sexual Partner of Confirmed Cases

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 02

Hepatitis of Unknown Origin

Affected Individuals

Obligatory Must not donate if:

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

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.

Sexual Partner of Affected Individuals

Obligatory Must not donate if:

Less than 12 months from recovery of partner.

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.

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

Including Simplex & Zoster Infection

Obligatory Eyes:

Must not donate if: Past or active infection.

Discretionary Other Tissues:

If no active infection or 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

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

See if Relevant Herpes - Genital

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

Including

AIDS

Infection

Obligatory

Must not donate.

See if Relevant

Tissues Safety Entry

Current Sexual Partners of Confirmed Case

Obligatory

Must not donate.

See if Relevant

Tissues Safety Entry

Former Sexual Partners of Confirmed Case

Obligatory

Must not donate if:

Less than 12 months from last sexual contact.

See if Relevant

Tissues Safety 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 02

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

Male

Obligatory

Must not donate if:

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 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 12 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 12 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). The recommendations have been noted by the English Department of Health and the devolved authorities in Scotland, Wales and Northern Ireland.

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. During 2012 and 2013, SaBTO commissioned a subgroup to review the donor selection criteria and risks associated with the donation of tissues and cells by men who have had sex with men.

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 current level of compliance with the donor selection guidelines 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 12 months after last sexual contact.

Reason for Change

To allow the collection of pancreatic islets and hepatocytes without a deferral period from donors with a history of male-sex-with-male behaviour.

For other tissues to allow donation 12 months after last male-sex-with- male sexual contact.

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 12 months or more from last sexual contact, accept.

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). The recommendations have been noted by the English Department of Health and the devolved authorities in Scotland, Wales and Northern Ireland.

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 twelve 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 To allow the collection of pancreatic islets and hepatocytes without a deferral period

from donors who's partner has a history of male-sex-with-male behaviour

To allow donation 12 months after partner's last male-sex-with-male sexual contact

Hormone Replacement Therapy

Obligatory Must not donate if:

a) Used for malignancy.

b) A recipient of human gonadotrophin of pituitary origin.

c) A recipient of human pituitary growth hormone.

Discretionary

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

Infection

Obligatory Must not donate.

See if Relevant Tissues Safety Entry

Current Sexual Partners of Confirmed Case

Obligatory Must not donate.

See if Relevant Tissues Safety Entry

Former Sexual Partners of Confirmed Case

Obligatory Must not donate if:

Less than 12 months from last sexual contact.

See if Relevant Tissues Safety 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 02

Human Bite

See <u>Inoculation Injury</u>

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

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

Hysterectomy

See Surgery

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

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.

See if Relevant Surgery

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

Immune Thrombocytopenia

Obligatory Must not donate if:

a) Symptomatic.

b) Chronic.

c) Recovered, but less than five 5 years from recovery.

This applies to both adult and childhood disease.

See if Relevant If treated with immunoglobulin or plasma exchange:

Transfusion

If treated with immunosuppresive therapy:

Immunosuppression

Reason for Change The links have been revised.

The phrase, 'Recovered, but has ever had a recurrence' has been removed as this was

considered too restrictive.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

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:

Must not donate if:

Less than six weeks from exposure.

3. Hepatitis B:

See

Hepatitis B - Post Immunization

4. Rabies:

See

Rabies

5. Smallpox:

See

Smallpox Immunization

6. Tetanus:

See

Tetanus Immunization

Update Information

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

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 Hepatitis B:

If less than seven days from when the last immunization was given:

Refer to a Designated Medical Officer.

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.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

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 Medical 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.

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.

See If treated with intravenous or subcutaneous human immunoglobulin:

Transfusion

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

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

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

Immunosuppression

Obligatory Must not donate if:

a) Immunosuppressed.

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

Discretionary Eyes: For potential eye donors with a history of malignancy who are on chemotherapy, or

autoimmune disease who are on immunosuppressive therapy, and provided that NAT testing is

performed for HIV, HCV and HBV and shown to be negative, accept for corneas only.

See if Relevant Autoimmune Disease

Immunoglobulin Therapy

Steroid Therapy

Additional Information Assays which directly detect the virus are not affected adversely by immunosuppression and

are appropriate in this situation. This change is permitted under the SaBTO Guidance on the microbiological safety of human organs, tissues and cells used in transplantation (2011).

Reason for Change A discretionary criteria has been added to allow the donation of cornea only.

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

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

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.

2. Eves

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

See if Relevant Congo Fever Crimean Fever

Ebola Fever
Herpes - Genital
Herpes - Oral
Lassa Fever
Marburg Fever
MRSA
Steroid Therapy
West Nile Virus

Additional Information

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 but would not be acceptable for other tissues.

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.

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

Reason for Change

A two-week period of recovery from a systemic infection has been added on advice from the

SAC-TTI.

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 02

Infection - Chronic

Obligatory Mu

Must not donate.

Discretionary

1. Acne:

Most donors with acne can be accepted.

2. Chronic superficial fungal infections:

a) If on local therapy only, accept.

b) If more than seven days from completing systemic antifungal therapy, accept.

3. Typhoid and Paratyphoid

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

4. Eyes.

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

See if Relevant Acn

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

transfusion transmitted.

Reason for Change

To add an entry for typhoid and paratyphoid

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 16

Infection - General

Obligatory

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:

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

last contact.

Discretionary If there is a definite history of past infection with the disease with which contact has occurred,

accept.

See if Relevant Hepatitis

Meningitis

Sexually Transmitted Disease

Tuberculosis

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Infertility

Obligatory Must not donate if:

a) Has ever been given human gonadotrophin of pituitary origin.

b) Has received donated eggs or embryos since 1980.

c) If donor knows that they have ever been treated with Metrodin HP[®].

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

See if Relevant Prion Associated Diseases

Additional Information The use of human gonadotrophin of pituitary origin (follicle-stimulating hormone (FSH) and

luteinizing hormone (LH)) had stopped in the UK by 1986. The situation in other countries

varied so specific dates cannot be given.

There is a concern 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 add additional information to clarify when the use of human gonadotrophin of pituitary origin

(follicle-stimulating hormone (FSH) and luteinizing hormone (LH)) ceased in the UK.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 20

Inflammatory Bowel Disease

Including 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.

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 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

Inflammatory Eye Disease

Obligatory Eyes:

Must not donate.

Discretionary Other Tissues:

If no other contraindication, accept.

See if Relevant Autoimmune 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

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

Including Human Bite

Obligatory Must not donate if:

a) With material containing abnormal prions.

b) Less than four 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 hepatitis C is negative, if this test is

stopped for any reason the guidance will change.

Reason for Change The deferral period has been reduced from 6 to 4 months to reflect updated JPAC Standing

Advisory Committee on Transfusion Transmitted Infections guidance on infection risk. (JPAC

paper 09-34).

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 07

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

Isotretinoin

Roaccutane

See Acne

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

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 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 Thi

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

Kidney Donor

See Surgery

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

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

Laminectomy

See Surgery

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.

2. Eyes:

Must not donate if:

Has had laser refractive surgery to the cornea.

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, treatment is completed and a follow up smear did not show abnormal cells, accept.

c) If for cosmetic purposes, accept when healed.

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

2. Eyes:

a) If for retinal surgery, accept.

b) If related to malignancy, see Malignancy.

See if Relevant Basal Cell Carcinoma

Cervical Carcinoma in Situ

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

Update Information This entry was last updated in

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

Including 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

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

Obligatory

Must not donate if:

- a) The donor has ever had malaria.
- b) The donor has had an undiagnosed fever (that could have been malaria) while abroad or within four months of leaving a malaria endemic area.
- c) The donor has lived in any malarial endemic area for a continuous period of six months or more at any time of life.
- d) Less than 12 months after last leaving a malaria endemic area.

Discretionary

1a) Donors who have had malaria diagnosed in the past:

If more than three years have passed since anti-malaria therapy has been completed and symptoms caused by malaria have resolved and a validated test for malaria antibody is negative, accept.

If the donor (with a history of malaria) has revisited a malaria endemic area and at least four months have passed since return and a validated test for malaria antibody is negative, accept.

1b) Donors who have EVER had an undiagnosed fever that could have been malaria while in a malaria area or within four months of leaving a malaria endemic area: If at least four months have passed since the donor returned from the malaria endemic area, or from the date of recovery from symptoms (undiagnosed fever) that may have been caused by malaria, whichever is later, and a validated test for malaria antibody is negative, accept.

NB. this may have to be increased to six months if the area is also identified as a risk area for T. cruzi or a tropical virus; the longest stipulated deferral period must be applied

1c) Donors who have EVER been resident in a malaria endemic area for six months or more:

If at least four months have passed since the date of the last potential exposure to malaria, and a validated test for malaria antibody is negative, accept.

1d) For all other donors:

If at least four months and less than 12 months have passed since return from a malaria endemic area, and a validated test for malaria antibody is negative, accept.

If travel to a malaria endemic area is more than 12 months prior to donation and the donor has never been diagnosed with malaria, has never had an undiagnosed fever while abroad or within four months of leaving a malaria endemic area and has not lived in a malaria endemic area for a continuous period of six months or more at any time of life, the donor can be accepted without the need for malaria antibody testing.

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

Accept.

3. Eyes

Accept for corneas only.

If the donor does not comply with any of the above, discuss with the **Designated Medical Officer** who will decide if the donor may be accepted following a documented risk assessment.

See if Relevant

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

Additional Information

The SaBTO Guidance on the Microbiological Safety of Human Organs, Tissues and Cells used in Transplantation (2011) confirms that irradiation of the tissue can be allowed as an alternative to malaria antibody testing for donors with a travel history.

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.

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

Reason for Change

The 'Discretionary' entry has been expanded for clarity.

The interval since last leaving a malaria endemic area for malaria antibody testing has been reduced from 6 to 4 months. The 'additional information' section has also been amended.

The potential for discretionary acceptance after risk assessment has been explained

Update Information

This entry was last updated in TDSG-DD Edition 203, Release 28

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.
- b) If the potential donor has a non haematological (non-clonal) premalignant condition (e.g. polyposis coli, prostatic intraepithelial neoplasia PIN or Barrett's oesophagus) that is being regularly monitored, or has had a similar condition cured and has been discharged from follow-up, accept.
- c) If the potential donor has a carcinoma in situ (e.g. cervical or vulval carcinoma in situ, ductal carcinoma in situ of the breast DCIS, or Bowen s disease) that has been cured and has been discharged from follow-up, accept.
- d) If the potential donor has had lentigo maligna refer to clinical support to ensure that they have not had 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), accept.
- f) If this was a primary non-metastasizing tumour of the central nervous system, accept.

See if Relevant

Basal Cell Carcinoma
Cervical Carcinoma in Situ
Immunosuppression
Surgery

Surgery Transfusion

Additional Information

Many malignancies spread through the blood stream and by invading surrounding tissues. Viruses that can be spread by blood and tissue donation can also cause some malignancies. For these reasons it is considered safer not to accept blood from people who have had a malignancy. However, because basal cell carcinoma (rodent ulcer) and other Carcinomas in situ do not spread through the blood, people who have had successful treatment may donate. Cervical carcinoma in situ would be defined as cured if treatment is complete and a follow up smear 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.

Lentigo Maligna is a common skin condition of the elderly and should be considered a carcinoma in situ and the donor may be accepted once it has been cured. However Lentigo Maligna melanoma is a true malignant melanoma and the donor must be permanently deferred if they have had this condition.

Eyes - only corneas are accepted as these are avascular and therefore are not likely to be involved in distant metastasis. The vascular parts of the eye are excluded.

Reason for Change

Malignant melanoma with known metastatic disease has been added to the list of contraindications for cornea donation

Update Information

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

This entry was last updated in TDSG-DD Edition 203, Release 27

Malignant Hypertension

Discretionary Accept.

Update Information This entry was last updated in

Malignant Melanoma

See Malignancy

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Mantoux Test

Obligatory Must not donate unless:

Negative and no further investigations planned.

See if Relevant Tuberculosis

Update Information This entry was last updated in

TDSG-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

See Surgery

Update Information This entry was last updated in

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

Ménière's Disease

Discretionary Accept.

Update Information This entry was last updated in

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

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

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

TDSG-DD Edition 203, Release 02

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

Myomectomy

See Surgery

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

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

Neotigason

Acitretin

See Acne

Psoriasis

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Nephrectomy

See Surgery

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 Eyes:

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

Obligatory Must not donate.

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

Surgery

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 in TDSG-DD Edition 203, Release 02

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

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.

Discretionary 1. Eyes:

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

2. Other Tissues

If no other contraindication, accept.

See if Relevant Eye Disease

Laser Treatment Malignancy

Ocular Tissue Recipient

Reason for Change A 'Discretionary' entry has been added for other tissues together with a link for 'Malignancy'.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Ocular Tissue Recipient

Obligatory Must not donate if:

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

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

this information will be stored on the National Transplant Database.

See Prion Associated Diseases

Update Information This entry was last updated in

Operations

See if Relevant Ocular Surgery

See Surgery

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

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

See Surgery

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

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

Ovarian Cyst

Obligatory Must not donate if:

Malignant.

Discretionary Eyes:

If related to malignancy, see Malignancy.

See if Relevant Malignancy

Surgery

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

Paget's Disease of Bone

Including 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

Including 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 Surgery

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 02

Pericarditis - Viral

See Infection - Acute

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Peritonitis

See Infection - General

Surgery

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

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

Pituitary Extract - Human

Including 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 Th

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

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

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

Surgery

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 14

Prion Associated Diseases

Including Sporadic, Familial and Variant Creutzfeldt-Jakob Disease (CJD), Gerstmann-Sträussler-

Scheinker Disease and Fatal Familial Insomnia

Obligatory Must not donate if:

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

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

This includes:

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

- b) Individuals who have 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.

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

Library

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

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

Reason for Change A discretion has been added.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Proctitis

Obligatory Must not donate if:

a) Due to ulcerative colitis.

b) Crohn's disease.

c) Requiring treatment.

Discretionary 1. All Tissues:

If due to other causes and not on treatment, accept.

2. Eyes:

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.

See if Relevant Inflammatory Bowel Disease

Radiation Therapy

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

Progressive Multifocal Leukoencephalopathy

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Proscar

See Finasteride (Proscar)

Update Information This entry was last updated in

Prostatectomy

See Surgery

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Prostitutes

Obligatory Must not donate.

See if Relevant Tissues Safety Entry

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Psoriasis

Obligatory Must not donate if:

a) Has ever taken Etretinate (Tigason).

b) Less than 24 months from the last dose of Acitretin (Neotigason).

c) Generalized or severe.

d) Associated with arthropathy.

e) There is secondary infection.

Discretionary 1. All tissues:

If mild and only using topical treatment, accept.

2. Eyes:

If no ocular involvement, accept even if treated with Etretinate (Tigason) or Acitretin

(Neotigason).

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. In such cases donations should not be

taken.

See Autoimmune Disease

Reason for Change There has been an increase in the deferral period after using acitretin (Neotigason®) from 12 to

24 months.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 14

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.

Infection - Acute See

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

Rabies

Infection

Obligatory Must not donate.

See if Relevant **Animal Bite**

Immunization - Post Exposure

Obligatory Must not donate until:

At least 12 months post exposure and fully cleared by treating physician.

Immunization - Non-exposed

Discretionary If non-exposed, accept.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

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 Eyes:

See if Relevant

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

Basal Cell Carcinoma

Malignancy

Reason for Change In 'Obligatory' the term 'exposed' has been replaced by 'irradiated'.

A discretion has been added for 'Eyes'.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

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

TDSG-DD Edition 203, Release 02

Relenza®

Approved Name Zanamivir

Obligatory Must not donate if:

a) Was taking Relenza® as treatment for influenza.

b) At any time in the seven days prior to, or while taking Relenza®, the donor had symptoms of

influenza, (a temperature of greater than 38°C, or a history of fever and two or more of the

following symptoms: cough, headache, runny nose, diarrhoea/vomiting).

Discretionary If the potential donor was taking Relenza® as prophylaxis, they had not been advised to be

confined to home and did not have any symptoms of influenza, accept.

See if Relevant Infection - Acute

Additional Information Relenza® is a viral neuraminidase inhibitor (neuraminidase is an enzyme that helps the virus

spread from cell to cell). It is used to treat influenza and for post-exposure prophylaxis of influenza. It appears to be a very safe drug with little evidence for teratogenic (potential to

cause birth defects) or mutagenic (potential to cause malignancy) effect.

Reason for Change This is a new entry.

Update Information This entry was last updated in:

TDSG-DD Edition 203, Release 05.

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 Surgery

Tissue and Organ Recipients

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Retinitis Pigmentosa

Discretionary Accept.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Reyes Syndrome

Obligatory Eyes:

Must not donate.

Discretionary Other Tissues:

If no other contraindication, accept.

See if Relevant Infection - Acute

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

A link to 'Acute Infection' has been added.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

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 <u>Tissues Safety Entry</u>

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Roaccutane

Isotretinoin

See Acne

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

Contact

See Infectious Diseases - Contact with

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.

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

2. Eyes:

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

SARS (Severe Acute Respiratory Syndrome)

Obligatory Must not donate if:

a) Less than 21 days from leaving a country to which the Department of Health (DH) has advised deferring travel, because there is, or is thought to be, ongoing transmission of SARS.

b) Less than 21 days from last contact with a person with SARS.

c) Less than three months since recovery from SARS or possible SARS.

Discretionary If more than 21 days has passed since return from a SARS endemic area, or from the last

contact with a person affected by SARS and the donor has remained well, accept

Additional Information Since 2004 there have not been any known cases of SARS reported anywhere in the

world. Although the threat of SARS to public health seems to have passed, international health officials continue to remain vigilant. The World Health Organization (WHO) monitors countries

throughout the world for any unusual disease activity.

Reason for Change Under 'Additional Information' the extant entry states "DH advice can be found at: www.dh.gov.

uk/PolicyAndGuidance/HealthAdviceForTravellers/fs/en under 'Latest health updates'." The

site that this link used to go to no longer exists.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

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

1DSG-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 Change

Discretionary

- a) A woman who has had her gender reassigned as a man, accept.
- b) A man who has had his gender reassigned as a woman:

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:

A man who, as a man, had not had high risk sexual activity in the last 12 months, can be accepted if, as a woman, they have a sexual relationship with a man.

See if Relevant

Homosexual and bisexual individuals

Surgery

Additional Information

The guidance has been changed in line with recommendations from the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO). The recommendations have been noted by the English Department of Health and the devolved authorities in Scotland, Wales and Northern Ireland.

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.

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

Reason for Change

To allow the collection of pancreatic islets and hepatocytes without a deferral period from donors with a history of male-sex-with-male behaviour.

For other tissues/cells, to allow donation 12 months after last male-sex-with-male sexual contact.

For new links to be added.

Update Information

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

Sexually Transmitted Disease

Infection

Obligatory See:

Is there is a specific entry for the disease?

Must not donate if:

Less than twelve months from completing 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 twelve months since completing that

treatment.

b) Donor did not require treatment and it is less than twelve months from the last

sexual contact with the infected partner.

Discretionary Donor did not require treatment and it is more than 12 months since the infected

partner has completed treatment, accept.

See if Relevant Tissues Safety Entry

Chlamydia
Genital Warts
Herpes - Genital
Syphilis

Reason for Change Further discretionary advice has been added to allow acceptance of donors whose

partners have completed treatment over 12 months ago for syphilis.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 09

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 only.

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

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.

Contacts

Obligatory Mus

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.

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:

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

Discretionary

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

Accept for corneas only.

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 six 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 Southern 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 'Additional Information' has been amended

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 17

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

Surgery Transfusion

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02, Issue 02

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. Eves:

If related to malignancy, see Malignancy.

See if Relevant Immune Thrombocytopenia

Malignancy Surgery 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 02

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.

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.

2. Eyes:

See if there is an entry for the underlying condition. If acceptable and not on an

immunosuppressive dose, accept.

See if Relevant Autoimmune Disease

Immunosuppression

Skin Disease

Tissue and Organ Recipients

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

inflammatory conditions that would otherwise prevent donation.

Reason for Change 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

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

Surgery

Obligatory Must not donate if:

For malignancy.

Discretionary 1. Eyes:

If related to malignancy, see Malignancy.

2. Other Tissues:

If for Cervical Carcinoma in Situ (CIN) or Basal Cell Carcinoma and all other criteria are fulfilled,

accept.

See if Relevant Basal Cell Carcinoma

Cervical Carcinoma in Situ

Neurosurgery Ocular Surgery

Tissue and Organ Recipients

Transfusion Xenotransplantation

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 02

Syphilis

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 The 'Discretionary' entry has been modified.

'Additional Information' has been added.

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

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

Syphilis Sexual Contact

See Sexually Transmitted Disease

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Systemic Lupus Erythematosus

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Tamiflu®

Approved Name Oseltamivir

Obligatory Must not donate if:

a) Was taking Tamiflu® as treatment for influenza.

b) At any time in the seven days prior to, or while taking Tamiflu[®], the donor had symptoms of influenza, (a temperature of greater than 38°C, or a history of fever and two or more of the

following symptoms: cough, headache, runny nose, diarrhoea/vomiting).

confined to home and did not have any symptoms of influenza, accept.

See if Relevant Infection - Acute

Additional Information Tamiflu® is a viral neuraminidase inhibitor (neuraminidase is an enzyme that helps the virus

spread from cell to cell). It is used to treat influenza and for post-exposure prophylaxis of influenza. It appears to be a very safe drug with little evidence for teratogenic (potential to

cause birth defects) or mutagenic (potential to cause malignancy) effect.

Reason for Change This is a new entry.

Update Information This entry was last updated in:

TDSG-DD Edition 203, Release 05.

Tamoxifen

Obligatory Must not donate:

a) If used for malignancy.

b) While taking tamoxifen for non-malignant conditions.

Discretionary Eyes:

If related to malignancy, see Malignancy.

See if Relevant Infertility

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

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.

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

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Thrombosis

If the underlying cause does not exclude, accept. Discretionary

See if Relevant Malignancy

This entry was last updated in Update Information

TDSG-DD Edition 203, Release 02

Thrush - Oral

Obligatory Must not donate if:

a) Unexplained.

b) Related to immunodeficiency.

c) Less than seven days after completion of systemic treatment.

Discretionary If not related to immunodeficiency, even if using local therapy, accept.

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

Thrush - Vaginal

Obligatory Must not donate if:

a) Related to immunodeficiency.

b) Less than seven days after receiving systemic therapy.

If not related to immunodeficiency, even if using local therapy, accept. Discretionary

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

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:

If related to malignancy, see Malignancy.

See if Relevant Autoimmune disease

Surgery

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

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

A discretion has been added for 'Eyes'.

A link to 'Autoimmune Disease' has been added.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

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

Tigason

Etretinate

See if Relevant Acne

Psoriasis

Reason for Change The links have been changed.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02, Issue 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

1. All Tissues:

- a) If an allogeneic tissue or organ transplant was performed before January 1st 1980 and there is no other reason to exclude the donor, accept.
- b) If a non-stored autologous organ or a non-stored autologous tissue has been transplanted, accept.

2. Heart valves and skin:

Accept. The full transplant/transfusion history must be recorded and remain part of the documentation associated with the donation. The donation may only be issued after a documented risk assessment has been performed by the **Designated Medical Officer**. This must take into account the availability of alternative donors, the risks of vCJD transmission and the expected benefits of using a particular donation.

See if Relevant

Immunosuppression
Ocular Tissue Recipient
Prion Associated Diseases
Xenotransplantation

Additional Information

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

There is now a concern that this could also happen with vCJD. This is because in the autumn of 2003 a UK recipient of blood, taken from a healthy donor who later developed vCJD, died from vCJD. Since then there have been several cases of infection with the vCJD prion in recipients of blood from donors who have later developed vCJD.

In view of this, people who have received a tissue or organ transplant since 1980, will be excluded from donation except for donation of heart valves and skin. These donations are currently accepted because of shortages in supply. Accepted donors who have received a tissue or organ transplant/transfusion since 1980 are now required to have a risk assessment performed. This date is before BSE, which is believed to have caused vCJD, was prevalent. The **Designated Medical Officer** should consider the availability of alternative donors and discuss the risks and benefits with the physician of the intended recipient. This risk assessment should be shared with the recipient, or their next of kin as appropriate. For cornea donations, whenever possible donor and recipients should be age matched.

See

Surgery Transfusion

Reason for Change

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

The term 'Xenotransplant' has replaced 'Animal tissue' under Must not donate if:.

Update Information

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

Tissue Recipient

See

Tissue and Organ Recipients

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
- e) You have ever received money or drugs for sex
- f) You have ever injected, or been injected with, drugs; even a long time ago or only once. This includes bodybuilding drugs and injectable tanning agents. You may be able to give if a doctor prescribed the drugs. Please ask.

3. You must not donate for at least 12 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 ever received money or drugs for sex
- e) A partner who has ever injected, or been injected with, drugs: even a long time ago or only once. This includes bodybuilding drugs. 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.

4a. 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.

4b. For donors of tissues/cells other than haematopoietic progenitor cells, pancreatic islet cells or hepatocytes:

You must not donate for at least 12 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.

See if Relevant

Addiction and Drug Abuse

Homosexual and Bisexual Individuals

Hepatitis of Viral Origin

HIV

HTLV

Infection - General

Additional Information

The guidance has been changed in line with recommendations from the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO). The recommendations have been noted by the English Department of Health and the devolved authorities in Scotland, Wales and Northern Ireland.

Reason for Change

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

For other banked tissues/cells (eg amnion, bone, cornea ,heart valves, skin and tendon) to remove the current lifetime deferral and allow donation 12 months after last male-sex-with-male sexual contact.

Update Information

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

Toctino

See Alitretinoin

Reason for Change New entry.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 17

Toxoplasmosis

Obligatory Must not donate if:

Less than six months from recovery.

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. If the infection has caused symptoms that has lead to it being diagnosed, waiting six months from recovery will make it unlikely that it will be passed on by

donation.

Reason for Change 1

Entry has been simplified following a risk assessment by SACTTI.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 14

Transfusion

Including 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.
- b) Treated with blood derived coagulation factor concentrates. This includes prothrombin complex to reverse over-anticoagulation.

2. Must not donate if:

Since January 1st 1980:

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

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

b) If treatment with human immunoglobulin has been limited to small quantities of specific

immunoglobulin as prophylaxis (e.g. rhesus, tetanus, hepatitis, immunoglobulin etc.), accept.

c) If the only transfusion has been within the last week of life, accept.

2. Autologous Transfusion in the United Kingdom:

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

3. Donor transfused before 1st January 1980 in a country endemic for malaria or South American trypanosomiasis:

- a) If the donor received, or thinks they may have received, before 1st January 1980 a transfusion in a country endemic for malaria or South American trypanosomiasis check the Geographical Disease Risk Index. If transfused in an at risk country and a validated malarial antibody test and/or (as appropriate) a validated test for T.cruzi antibody is negative, accept.
- b) If the transfusion was not within a risk area for either malaria or South American trypanosomiasis, accept.
- For Eyes only, if the risk was for Malaria or South American trypanosomiasis, accept for corneas only.

4. 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 if Relevant

Bleeding Disorder

Immunoglobulin Therapy

Immunosuppression

Malaria

Prion Associated Diseases

South American Trypanosomiasis Risk

Geographical Disease Risk Index

Appendix 4 - 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) before accepting the donor.

Coagulation concentrates:

People who have received blood derived coagulation concentrates (these are made from the blood of many donors) 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 have been several cases of infection with the vCJD prion in recipients of blood from donors who have later developed vCJD.

In view of this, people 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 and skin. Any history of transfusion after 1980 must be recorded and remain part of the documentation associated with the donation. For cornea donations, whenever possible donor and recipients should be age matched.

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.

Reason for Change

To add pancreatic islets to the list of tissues that can be donated provided that less than 80 units of blood or blood components have been transfused.

Update Information

This entry was last updated in

TDSG-DD Edition 203, Release 26, Issue 01

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)

Including 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 In

Infection - Tropical

Update Information

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

Tropical Viruses

Definition

To include Dengue Virus, Dengue Fever and Chikungunya Virus, also known as CHIKV, Zika Virus and Zika Virus Fever.

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 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 or zika virus infection whilst there or following their return to the UK.

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

Discretionary

All donors may be accepted six months after their return from an affected area or resolution of symptoms. This may be reduced to four weeks, if they have had 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.

Zika virus is a flavivirus that is transmitted to humans through the bite of a carrier mosquito. 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 chikungunya virus, dengue virus and zika virus 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 Chikungunya, Dengue or Zika viruses. The main areas affected by all 3 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 Japan and Australia.

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 or dates of disease activity. These are provided in the Geographical Disease Risk Index.

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 Information about Zika virus has been added.

Update Information This entry was last updated in:

TDSG-DD Edition 203, Release 24

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.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Viral Disease

See Infection - General

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

Viral Haemorrhagic Fever

1. Affected Individual

Obligatory Must not donate

2. Contact or traveller to endemic country

Obligatory Must not donate if:

Less than 6 months from last contact with an affected individual or travel to an

endemic country

Discretionary If more than 6 months from last contact, completion of investigations or return to the

UK from endemic country, accept.

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.

Reason for Change Guidance for travellers to endemic countries and contacts with these infections has been

updated.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 24

Vitamin Treatment

Discretionary Accept.

Update Information This entry was last updated in

TDSG-DD Edition 203, Release 02

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 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 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

Infection

See Infection - Acute

Contact

See Infectious Diseases - Contact with

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

Including 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 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.

Reason for Change This is a new entry.

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 <u>Change Notification No. 28 - 2009</u> Relenza[®] (zanamivir) See <u>Change Notification No. 29 - 2009</u>

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

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 Plasma Dilution

CRYSTALLOID INFUSED:

INTERVAL PRIOR TO SAMPLING	VOLUME INFUSED (ml)	% RETAINED	VOLUME RETAINED (ml)
>24 HOURS		0	NONE
2 - 24 HOURS		25	
1 - 2 HOURS		50	
<1 HOUR		75	
TOTAL CRYSTALLOID RETAINED (ml):			

BLOOD/COLLOID INFUSED:

INTERVAL PRIOR TO SAMPLING	VOLUME INFUSED (ml)	% RETAINED	VOLUME RETAINED (ml)
24 - 48 HOURS		100 (Blood) 50 (Colloid)	
0 - 24 HOURS		100	
TOTAL BLOOD/COLLOID RETAINED (ml):			

ESTIMATED TOTAL BLOOD VOLUME:	% HAEMODILUTION
70 ml per kilogram of body weight*	(Crystalloid + Blood + colloid retained (ml)) x 100 estimated blood volume (ml)

ACCEPT (<50%) / REJECT (>50%)	
SIGNED:	
DATE:	
COMMENTS:	

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

^{*}To be used in cases of significant blood loss

^{*} In **critical care patients**, the circulating blood volume is typically 45-60 ml per kg body weight compared to the normal 70 ml. 50 ml should be used in the calculations for such patients.