

Cord Blood Donor Selection Guidelines (CB-DSG)

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Introduction

These guidelines form a constituent part of Chapter 22 (haemopoietic progenitor cells) of the Guidelines for the Blood Transfusion Services in the United Kingdom.

The criteria are reviewed regularly to ensure that the stem cells obtained are of the highest quality and of sufficient quantity to meet the needs of recipients.

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

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

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

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

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Document and Change Control

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

Change Notification.

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

Implementation of changes is the responsibility of the individual Services.

Document version terminology.

A version shall be any of the following:

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

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

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

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

Changes to printed versions.

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

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

Changes to the website versions.

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

General Principles

This document provides guidance for the selection of cord blood donations. It must be read in conjunction with Chapter 22 (haemopoietic progenitor cells) of the Guidelines for the Blood Transfusion Services of the United Kingdom - 8th Edition, 2013, which lists the general, and some specific aspects of donor selection.

Cord Blood is taken from the placenta of newborn infants. As placentae are normally treated as a waste product there is no risk to the infant or the mother. To ensure the donated material is safe to use it is important to exclude risk factors in the mother. On occasions tests may need to be performed on the cord blood but no additional testing of the infant should be required. Unless stated specifically, all guidelines apply to the mother of the infant whose cord blood is collected.

Mothers are selected firstly to ensure that their baby's cord blood stem cells are unlikely to harm any recipient. The ultimate responsibility for the selection of mothers rests with the respective **National Medical Director**.

The immediate responsibility is with the **Qualified Healthcare Professional** who must ensure that the mother fulfils the respective selection guidelines. When it is not clear from these guidelines if an individual is acceptable, cord blood should not be released for issue without discussion with a **Designated Medical Officer**.

The mother must be evaluated by a **Qualified Healthcare Professional** who has undergone appropriate training to use this document, to assess the suitability of their infant's cord blood for donation. 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 the mother clearly understands the nature of the donation process. They must also understand the health questions and other information presented to them. The mother is asked about confidential aspects of their 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**.

When there is a recognized risk to a 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 mother **must** be dealt with by the use of several terms:

Must not donate

The mother **must** not be accepted 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, the mother **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 mother 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 mother 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 mother.

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-CB Edition 203, Release 02

Medication

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

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

This section was last updated in TDSG-CB Edition 203, Release 02.

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 cord blood, 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 Stem Cells, so they can be considered for incorporation into future revisions of these guidelines.

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

Donations must not be accepted from mothers 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-CB Edition 203, Release 02.

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Accident

<i>Includes</i>	Trauma
<i>Obligatory</i>	Must not donate if: a) Not recovered. b) Still under follow-up. c) Has a plaster-cast.
<i>See if Relevant</i>	<u>Neurosurgery</u> <u>Surgery</u> <u>Tetanus Immunization</u> <u>Transfusion</u>
<i>Additional Information</i>	An unhealed wound or sore is a risk for bacteria entering the blood. Bacteria in blood can be a serious threat to anybody receiving stem cells. This is because the bacteria can multiply to dangerous levels. A plaster-cast can hide a wound or sore.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Addiction and Drug Abuse

<i>Obligatory</i>	Must not donate if: a) The mother has injected, or been injected with drugs in the past 12 months. b) The mother is adversely affected by any drug, including alcohol, which may affect the process of obtaining valid consent. c) The mother has injected, been injected with, or taken non-parenteral chemsex drugs in the past 3 months. Please see <u>Tissues Safety Entry</u>.
<i>Discretionary</i>	a) Accept if mother has not injected or been injected with other non-prescription drugs (other than drugs of addiction), such as bodybuilding drugs or injectable tanning agent within the past 3 months. b) Accept if mother has not injected or been injected with drugs of addiction within the last 12 months c) If mother has not injected or been injected with drugs of addiction within the last 3 months – refer to designated medical officer. The donation may be accepted with individual risk assessment. See additional information section d) May be acceptable if injected drugs were prescribed by the mother's physician for a condition that would not lead to exclusion. e) Previous use of non-parenteral drugs does not necessarily require exclusion.
<i>See if Relevant</i>	<u>Tissues Safety Entry</u>
<i>Additional Information</i>	Injecting drugs has been linked with the passing on of many infections, including hepatitis and HIV. It can be many years before any infection shows itself. Former drug users often do not realize that they can still pass infection on to others many years after they last used drugs themselves. The deferral periods specified above may be reduced by doing individual risk assessment if the risk of acquiring an infectious disease may be outweighed by the risk of delaying a lifesaving transplantation. This guidance presumes that a validated NAT test for HIV, HBV and HCV is negative, if this test is stopped for any reason the guidance will change Anyone obviously affected by alcohol or other drugs that can affect the mind, cannot give valid consent or fully understand why they are being asked certain questions.
<i>Reason for Change</i>	Obligatory section updated as a part of the implementation of recommendations from the FAIR III report, including addition of chemsex drugs.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 51

African Trypanosomiasis

(Sleeping Sickness)

Obligatory

Must not donate.

Update Information

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

Age

Obligatory

Must not donate if:

Mother is under seventeen years of age.

Additional Information

This takes account of national laws on age of consent.

Update Information

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

Allergy

Discretionary

Accept.

See if Relevant

Steroid Therapy

Update Information

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

Anaemia

Obligatory

Must not donate if:

a) Mother or Father homozygous or heterozygous for inherited haemoglobin disorder or enzymopathy.

Inform Transplant Centre if:

b) Cells are from a baby that has an inherited disorder.

Discretionary

1. a) If the cord blood is tested for the relevant condition and is shown to be unaffected, accept.

b) For X linked disorders, if father affected and male baby, accept. If mother affected and female baby, accept.

c) For non-X linked disorders, if baby heterozygous (trait), accept.

2. History of anaemia:

This should be assessed regarding its cause, current status and what treatment has been received.

3. Iron deficiency:

If not under investigation and the underlying cause is not a reason to exclude, accept.

4. Other types:

Accept or exclude according to the guidelines.

5. In other cases:

Refer to a Designated Medical Officer.

See if Relevant

Haemoglobin Disorders

Haemolytic Anaemia

Malignancy

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

<i>Additional Information</i>	A successful transplant will mean the recipient will produce the same blood as the donor. This would be unacceptable for a homozygous (major) form of blood disorder but would probably be acceptable for a heterozygous (minor form, or trait). By informing the transplant centre, details can be passed on to the person receiving the transplant. This can avoid unnecessary problems in the future. For example searching for the cause of small red cells or anaemia in a person who has had a transplant from a donor with thalassaemia minor (trait).
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Animal Bite

(Non-Human)

<i>Obligatory</i>	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 other mammal outside of the British Isles.
<i>See if Relevant</i>	<u>Human Bite</u> <u>Infection - General</u> <u>Rabies Immunization</u>
<i>Additional Information</i>	Being bitten by a non-human primate should result in permanent deferral. Risks include simian T-lymphotropic virus, Herpes B, simian foamy virus and other as yet unknown viruses. Non-human primates include chimpanzees, gorillas, orangutans, gibbons, monkeys (old and new world), tarsiers, lemurs and lorises. Animal bites may result in many different infections. Allowing all wounds to heal and for any obvious infection to have resolved should avoid problems. Rabies, and similar diseases, have long incubation periods and do not show as a wound infection. There is no evidence that these infections have ever been transmitted through a cord blood donation. 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.
<i>Reason for Change</i>	To reduce the deferral period following being bitten by a bat or other mammal outside of the UK from 24 to 12 months.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 46.

Ankylosing Spondylitis

<i>Discretionary</i>	Accept.
<i>See</i>	<u>Autoimmune Disease</u>
<i>Reason for Change</i>	A link to 'Autoimmune Disease' added.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Anthrax

Exposure

<i>Discretionary</i>	Even if on prophylactic antibiotics, accept.
<i>Additional Information</i>	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 mothers provided they have not shown signs of infection, even if they have been given prophylactic antibiotics.

Immunization

<i>See</i>	<u>Immunization - Non-Live</u>
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Infection

<i>See</i>	<u>Infection - Acute</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Antibiotic Therapy

<i>Additional Information</i>	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 .
<i>See</i>	<u>Infection - General</u>
<i>Reason for Change</i>	Additional Information has been added for clarity.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Arthritis

<i>See if Relevant</i>	<u>Ankylosing Spondylitis</u> <u>Autoimmune Disease</u> <u>Osteoarthritis</u> <u>Psoriasis</u> <u>Rheumatoid Arthritis</u>
<i>Reason for Change</i>	A link has been added for Autoimmune Disease.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Asthma

<i>Obligatory</i>	Must not donate if: Taking, or has completed, oral or parenteral steroids within the last seven days.
<i>See if Relevant</i>	<u>Infection - General</u> <u>Steroid Therapy</u>

<i>Additional Information</i>	Steroid therapy can hide the signs and symptoms of infection. Stem cells from an infected donor could be dangerous to the person receiving them.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Autoimmune Disease

<i>Obligatory</i>	Must not donate if: The mother has needed treatment to suppress the condition in the last 12 months.
<i>See if Relevant</i>	If treated with immunoglobulin or plasma exchange or filtration: <u>Transfusion</u>
<i>Additional Information</i>	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 mother's immune system. This may make her more susceptible to certain types of infection and also will make some infections more difficult to diagnose.
<i>Reason for Change</i>	Additional Information has been added to clarify treatment that may have been used to suppress the condition. Autoimmune disease will not be transmitted through cord blood or amniotic membrane.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Babesiosis

<i>Obligatory</i>	Must not donate.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Basal Cell Carcinoma

<i>Obligatory</i>	Must not donate if: a) Still receiving treatment. b) Any wound has not healed.
<i>Additional Information</i>	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.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

BCG

<i>Obligatory</i>	Must not donate if: Immunized in this pregnancy.
<i>Additional Information</i>	BCG is an immunization with live bacteria. We do not want to pass BCG, or other infections, on to people receiving donated material.
<i>See</i>	<u>Immunization - Live</u>

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

Bleeding Disorder

Includes Carriers

Affected Individual

Obligatory **Must not donate if:**
Treated with blood derived coagulation factor concentrates.

See if Relevant Transfusion

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

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

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

Obligatory **Must not donate if:**
a) Treated with blood derived coagulation factor concentrates.

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

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

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

See if Relevant Inoculation Injury
Transfusion

Additional Information **Blood derived coagulation concentrates:**
These are made from the blood of many donors. They may put recipients at risk of infections that can be passed through blood. This risk may be shared by their sexual partners.

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

Reason for Change This entry was updated in line with the recommendations of the SaBTO Donor Selection Criteria Review Report published on 23rd July 2017

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

Blood Pressure - High

Obligatory If the mother has had severe hypertension in pregnancy:
Refer to a Designated Medical Officer.

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

Body Piercing

<i>Includes</i>	Derma-rolling, ear and body piercing, permanent and semi-permanent makeup, tattooing (including memorial tattoos), platelet rich plasma (PRP) facials and ritual self-flagellation.
<i>Obligatory</i>	Must not donate if: Less than 3 months after last piercing.
<i>Discretionary</i>	Piercings performed within the UK in a commercial setting: Accept Piercings performed outside the UK or within the UK in an unlicensed non-commercial premises more than 3 months ago: Accept Painting, stencilling or transfers applied to the skin without piercing: Accept
<i>Additional Information</i>	Under all current legislation it is a criminal offence to trade without registration (licensing) or to be in breach of the relevant byelaws. Similar provisions are in place in Scotland in the Civic Government (Scotland) Act 1982 (Licensing of Skin Piercing and Tattooing) Order 2006. Some London boroughs also require a 'special treatment' license. It is expected that all premises will follow infection control processes including using single needles for treatments. In the UK local authorities are responsible for regulating and monitoring businesses providing semi-permanent skin colouring procedures (micropigmentation, semi-permanent make-up and temporary tattooing). The focus of legislation covering local authorities in England, Wales and Northern Ireland (Local Government (Miscellaneous Provisions) Act 1982) is on minimising infection risks using compulsory registration of practitioners and premises and optional powers to make byelaws. For piercings performed outside the UK or within the UK in an unlicensed, non-commercial establishment less than 3 months ago, the donor may only be accepted following documented individual risk assessment and discussion with the transplant centre if the risk of delaying transplant outweighs the risk of transmission of infections. Piercing has passed infection from person to person. Waiting 3 months helps to ensure that the infections tested for by the Blood & Tissues Services will be picked up. Platelet rich plasma (PRP) facials (also known as 'Vampire Facials') have been associated with HIV transmission. Ritual self-flagellation is carried out by some religious groups. The practice includes beating or flogging oneself with sharp objects. It may be associated with exposure to blood from other participants, either directly or through contamination of shared equipment. This guidance presumes that a validated NAT test for HIV, HBV and HCV is negative, if this test is stopped for any reason the guidance will change.
<i>Reason for Change</i>	To add Derma-rolling, ear and body piercing, tattooing (including memorial tattoos), platelet rich plasma (PRP) facials and ritual self-flagellation to the entry and to add information regarding PRP facials and ritual self-flagellation.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 43.

Breast Lump

<i>Obligatory</i>	Must not donate if: a) Malignant. b) Not fully investigated and cleared of malignancy.
<i>See if Relevant</i>	<u>Malignancy</u>
<i>See</i>	<u>Surgery</u>

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

Brucellosis

Undulant Fever

Obligatory **Must not donate.**

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

Cardiac Surgery

See if Relevant Cardiovascular Disease
Endocarditis
Surgery
Transfusion

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

Cardiomyopathy

Obligatory **Must not donate if:**
Not recovered from infective causes.

Reason for Change This is a new entry

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

Cardiovascular Disease

See if Relevant Cardiomyopathy
Endocarditis
Myocarditis

Reason for Change Additional links have been added.

Update Information

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

Catarrh

Acute

See Infection - Acute

Chronic

See if Relevant Infection - General

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

Central Nervous System Disease

Obligatory **Must not donate if:**

- a) Dementia.
- b) History of CNS disease of unknown or suspected infective origin (e.g. multiple sclerosis (MS), optic neuritis, clinically isolated syndrome, transverse myelitis, Creutzfeldt-Jakob disease (CJD)).
- c) Neurodegenerative conditions of unknown aetiology (e.g. Parkinson's disease).

Discretionary

- a) Individuals who have had Bell's palsy more than four weeks ago and have discontinued any treatment for the condition for at least seven days, even if they have residual paralysis, accept.
- b) If a definite diagnosis of transient global amnesia has been made, accept.
- c) If the cause of the disease is not established, refer to designated medical officer

See if Relevant Neurosurgery
Prion Associated Diseases
Rabies

Additional Information Often the exact cause of a degenerative brain condition only becomes known after death. For this reason, when there is any doubt as to the underlying cause of a brain condition, it is considered safest not to accept a donation. It is thought that degenerative brain disease in the form of vCJD has been transmitted by blood transfusion.

Transient global amnesia is a temporary and isolated disorder of memory. Affected individuals are usually over 50 years of age and there is an association with migraine. There is no association with cerebrovascular disease.

Reason for Change To clarify that CNS disease of unknown origin, and clinically isolated syndrome, are reasons for obligatory deferral and to permit individual risk assessment where appropriate.

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

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

Cervical Dysplasia

Obligatory **Must not donate if:**

- a) Undergoing investigation or treatment.

b) Diagnosed with invasive cervical carcinoma.

Discretionary

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

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

Additional Information

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

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

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

Reason for Change

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

Update Information

This entry was last updated in
TDSG-CB Edition 203, Release 43.

Chagas' Disease

South American Trypanosomiasis

Obligatory

Must not donate.

See if Relevant

South American Trypanosomiasis Risk

Update Information

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

Chicken Pox

Contact

See

Infectious Diseases - Contact with

Herpes Zoster (Varicella Zoster)

Obligatory

Must not donate if:

Has had chicken pox or shingles during this pregnancy.

See

Infection - Acute

Update Information

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

Chiropody

<i>Obligatory</i>	Must not donate if: There are open wounds or infection.
<i>See if Relevant</i>	Fungal infection: <u>Infection - Chronic</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Chondromalacia

<i>Discretionary</i>	Accept.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Cirrhosis

<i>Obligatory</i>	Must not donate if: a) Complicated by hepatoma. b) Infectious or autoimmune cause.
<i>Discretionary</i>	If the cause is genetic, accept.
<i>See if Relevant</i>	<u>Alcoholism</u> <u>Autoimmune Disease</u> <u>Malignancy</u>
<i>Reason for Change</i>	Additional links have been added.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Clinical Trials

<i>Obligatory</i>	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.
<i>Discretionary</i>	If a Designated Medical Officer has examined and agreed the trial protocol, accept.
<i>See if Relevant</i>	<u>Complementary Therapy</u> <u>Transfusion</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Coeliac Disease

<i>Discretionary</i>	Accept.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Colostomy

<i>Obligatory</i>	Must not donate if: For malignancy or inflammatory bowel disease.
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<i>Discretionary</i>	If the reason for the colostomy is not of itself a reason to exclude and the stoma is healthy, accept.
<i>See if Relevant</i>	<u>Surgery</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Communication Difficulties

<i>Obligatory</i>	1. All mothers must: a) Fully understand the donation process. b) Give their informed consent to the process and to the testing of their blood for diseases that may affect the suitability of their baby's stem cells/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 mother 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 mother. c) Fully understand their duty of confidentiality and the confidential nature of any information obtained from the donor.
<i>See if Relevant</i>	<u>Disabled Donor</u>
<i>Additional Information</i>	The Services are aware of their duties under Race Relations and Disability Discrimination Legislation and will, whenever and wherever reasonable, try to provide facilities for individuals whose first language is not English, or who have other difficulties in communicating. Every mother must: a) Be provided with accurate educational materials, which are written in terms which can be understood by members of the general public. b) Complete a health and medical history questionnaire and undergo a personal interview performed by a health professional. c) Provide written informed consent to proceed with the donation process which must be countersigned by the qualified health professional responsible for obtaining the health history. A qualified health professional may assist a mother 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 mother 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 health professional. Use of third party interpreters. It is permissible for any third party to act as an enabler by helping to reassure the mother and to assist in establishing effective communication between the mother and the health professional. The third party must not however be present during any exchange of confidential information, unless they are not personally known to the mother 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. Any third party, with the permission of the mother, may accompany the mother through other parts of the donation process that do not include the exchange of confidential information. Rationale. There is concern that the use of third parties during any exchange of confidential information between the mother and the health professional may compromise the confidentiality of the mother and the safety of any donated material. Interpreters are often part of a close

community, or a family member, and this may inhibit or embarrass the mother in any confidential exchange of information. This may result in the non-disclosure of sensitive information that could affect the individual's eligibility to donate. If a third party is not fully aware of the need to accurately and truthfully communicate all the information, including personal and confidential information, provided by the person giving consent, this may make the interpretation of information incomplete and potentially put both the mother and the donated material at risk. There is also a requirement to communicate the results of any testing performed by the Blood/Tissue Services that may be of relevance to the mother or her baby'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 mother 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.

Update Information This entry was last updated in
TDSG-CB Edition 203, Release 19.

Complementary Therapy

Obligatory **1. Must not donate if:**
The condition for which treatment was given is not acceptable.

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

Must not donate if:
Less than 3 months from completing treatment

Discretionary a) If oral or topical complementary medicines only and reason for which treatment was given is acceptable, accept

b) For all other therapies involving penetration by needles or other invasive procedures:

1. Performed within the NHS
If performed by a suitably qualified NHS healthcare professional on NHS premises, accept.

2. Performed outside of the NHS

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

2b) Treatments performed within commercial premises in the UK: Accept.

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

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

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

is expected that all premises will follow infection control processes including using single needles for treatments.

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

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

This guidance presumes that a validated NAT test for HIV, HBV and HCV is negative, if this test is stopped for any reason the guidance will change.

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

<i>Reason for Change</i>	The regulatory organisations for Pharmacists in the UK have been added. The HCPC ceased to be the regulatory authority for Social Workers in England in 2019. The list of health and care professionals regulated by the HCPC has been amended.
<i>Update Information</i>	This entry was last updated in TDSG-LD Edition 203, Release 42.

Congo Fever

<i>Obligatory</i>	Must not donate if: Less than twelve months following recovery or from return to the UK, if occurred abroad.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Corneal Transplant

<i>Obligatory</i>	Must not donate.
<i>See if Relevant</i>	<u>Prion Associated Diseases</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Coronary Thrombosis

<i>Includes</i>	Heart Attack Myocardial Infarct
<i>Discretionary</i>	Accept.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Coronavirus Infection (COVID-19)

<i>Includes</i>	COVID-19 disease (due to infection with SARS-CoV-2 virus, previously known as Novel Coronavirus or 2019-nCoV).
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1. Person with confirmed symptomatic COVID-19

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

Discretionary If **more than 7 days** have passed since resolution of symptoms, and the donor remains well, accept.

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

Obligatory **Must not donate if less than 7 days** since confirmation of infection by positive results in a diagnostic test.

Discretionary If **more than 7 days** have passed since confirmation of infection by positive results in a diagnostic test, accept.

See additional information.

3. Person with suspected COVID-19

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

Discretionary a) If testing was not performed:

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

OR

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

See if Relevant Coronavirus Vaccination
Infection - Acute
Contact with Infectious Diseases

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

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

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

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

Post Donation Illness Donors must be provided with information about contacting the tissue establishment if they develop any illness within 14 days after donation

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

Update Information This entry was last updated in
TDSG-CB Edition 203, Release 52

Deep Vein Thrombosis

<i>Discretionary</i>	If the underlying cause does not exclude, accept.
<i>See if Relevant</i>	<u>Malignancy</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Dementia

<i>Obligatory</i>	Must not donate.
<i>Update Information</i>	This is a requirement of the EU Tissue & Cells Directive. This entry was last updated in TDSG-CB Edition 203, Release 02

Dental Treatment

<i>Obligatory</i>	Must not donate if: a) Less than seven days since root canal treatment, dental capping or having a tooth removed. b) Less than 24 hours since a filling, scale and polish or other superficial treatments. c) All wounds are not healed. d) There is any infection.
<i>Discretionary</i>	If inspection or dental impressions only, accept.
<i>See if Relevant</i>	<u>Surgery</u> <u>Infection - General</u>
<i>Additional Information</i>	Dental extractions and other treatments can result in bacteria getting into the blood stream. The waiting times after treatment are to allow healing and for any bacteria that have entered the blood stream to be cleared.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Dermatitis

<i>Obligatory</i>	Must not donate if: Mother has infected perineal dermatitis.
<i>See if Relevant</i>	<u>Allergy</u> <u>Infection - General</u> <u>Steroid Therapy</u>
<i>Reason for Change</i>	To add a link to Alitretinoin.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 16

Diabetes Insipidus

<i>Discretionary</i>	If the underlying cause does not exclude, accept.
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<i>See if Relevant</i>	<u>Neurosurgery</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Diabetes Mellitus

<i>Obligatory</i>	Must not donate if: Uncontrolled infection.
<i>Discretionary</i>	Accept.
<i>See if Relevant</i>	<u>Infection - General</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Diarrhoea

<i>Includes</i>	D & V Entero-colitis Food Poisoning Gastric Flu Gastro-enteritis
<i>Obligatory</i>	Must not donate if: a) Chronic or associated with inflammatory bowel disease. b) Less than two weeks since full recovery.
<i>See if Relevant</i>	<u>Infection - General</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Dilatation and Curettage

<i>See</i>	<u>Surgery</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Disabled Mother

<i>Obligatory</i>	1. All mothers must: a) Fully understand the donation process b) Give their informed consent to the process and to the testing of their blood for diseases that may affect the suitability of their baby's stem cells/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 mother and the qualified health professional, they must: a) Understand the requirements of the Human Tissue Act (HTA) relevant to the donation process b) Not be personally known to the mother.
<i>Discretionary</i>	Mothers with difficulty in reading: Ensure by questioning the mother that they: a) Understand and fully complete the tick-box questionnaire b) Give valid consent to donation and to the testing of their blood for diseases that may affect its suitability for use.

<i>See if Relevant</i>	<u>Self-Catheterization</u> <u>Spina Bifida</u>
<i>Additional Information</i>	The Services are aware of their duties under Disability Discrimination Legislation and will, whenever and wherever reasonable, try to provide facilities for individuals whose first language is not English, or who have other difficulties in communicating. Every mother must: be provided with accurate educational materials, which are written in terms which can be understood by members of the general public complete a health and medical history questionnaire and undergo a personal interview performed by a health professional provide written informed consent to proceed with the donation process which must be countersigned by the qualified health professional responsible for obtaining the health history. A health professional may assist a mother 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. audio, Braille, computer or alternative language) for the information leaflets, the health and medical history questionnaire and consent statements. The mother 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 health professional. Use of third party interpreters. It is permissible for any third party to act as an enabler by helping to reassure the mother and to assist in establishing effective communication between the mother and the health professional. The third party must not however be present during any exchange of confidential information, unless they are not personally known to the mother and understand the requirements of that part of the HTA relevant to the donation process. Confidential parts of the process include the evaluation of the health and medical history questionnaire, the medical interview and the obtaining of valid consent. Any third party, with the permission of the mother, may accompany the mother through other parts of the donation process that do not include the exchange of confidential information. Rationale. There is concern that the use of third parties during any exchange of confidential information between the mother and the health professional may compromise the confidentiality of the mother and the safety of any donated material. Interpreters are often part of a close community, or a family member, and this may inhibit or embarrass the mother in any confidential exchange of information. This may result in the non-disclosure of sensitive information that could affect the individual's eligibility to donate. If a third party is not fully aware of the relevant aspects of the HTA this may make the interpretation of information incomplete and potentially put both the mother and the donated material at risk. There is also a requirement to communicate the results of any testing performed by the Blood/Tissue Services that may be of relevance to the mother or her baby'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 mother may be accepted.
<i>Reason for Change</i>	This is a revised entry to clarify the use of interpreters by the Blood & Tissue Services.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Disease of Unknown Aetiology

<i>Obligatory</i>	See: Is there is a specific entry for the disease? Must not donate.
<i>Discretionary</i>	If safety and quality of the donation is unlikely to be affected, discuss with Designated Clinical Support Officer. See 'additional information' section.
<i>Additional Information</i>	When the cause of an illness is not clear, there is an unknown risk to any recipient of donated material.

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

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

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

This entry was last updated in
TDSG-CB Edition 203, Release 43.

Diverticulosis

Discretionary Accept.

See if Relevant Infection - General

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

Drug Treatment

Obligatory The taking of some drugs may make a mother 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 mother meets all other criteria.

See if Relevant Addiction and Drug Abuse

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

Electrolysis

Discretionary Accept.

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

Emphysema

Discretionary Accept.

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

Endocarditis

Obligatory **Must not donate if:**
Active infection.

<i>See if Relevant</i>	<u>Infection - General</u>
<i>Reason for Change</i>	This new entry replaces the previous entry for 'Subacute Bacterial Endocarditis'. It recognizes that the cause of endocarditis is not always bacterial and the course is not always subacute.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Endometriosis

<i>Discretionary</i>	Accept.
<i>See if Relevant</i>	<u>Surgery</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Epilepsy

<i>Obligatory</i>	Must not donate if: a) Mother has taken drugs with known haematological toxicity during this pregnancy. b) Recent onset and not fully investigated. c) Secondary to malignancy or degenerative neurological disease.
<i>See if Relevant</i>	<u>Malignancy</u> <u>Neurosurgery</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Eye Disease

<i>Obligatory</i>	Must not donate if: a) Active ocular inflammation b) History of malignancy c) Ocular tissue transplanted
<i>Discretionary</i>	History of inflammatory eye disease: • If transient viral conjunctivitis, which is fully resolved, accept. • For others, seek advice from DCSO.
<i>See if Relevant</i>	<u>Autoimmune Disease</u> <u>Central Nervous System Disease</u> <u>Glaucoma</u> <u>Infection - General</u> <u>Malignancy</u> <u>Ocular Surgery</u> <u>Ocular Tissue Recipient</u> <u>Steroid Therapy</u> <u>Tissue and Cell Allograft Recipients</u>
<i>Additional Information</i>	Inflammatory eye disease can be due to: a) Infectious causes, such as toxoplasmosis, CMV, leptospirosis, tuberculosis

b) Isolated auto immune or non-infectious such as HLA-B27 associated, traumatic /sympathetic ophthalmopathy, drug induced

c) Associated with systemic diseases such as Behcet's Disease, arthritis, connective tissue diseases.

Reason for Change To add 'Discretionary' and 'Additional Information' sections.

Update Information This entry was last updated in
TDSG-CB Edition 203, Release 53

Eye Drops

Obligatory **Determine what they are being used to treat.**

See:

Is there a relevant entry.

See if Relevant Autoimmune Disease
Glaucoma
Infection - General
Steroid Therapy

Additional Information Eye drops are used to treat a wide range of conditions, some of which would prevent the person from donating. It is important to know exactly why the drops are being used.

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

Factor V Leiden

Discretionary Accept.

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

Filariasis

Obligatory **Must not donate.**

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

Food Allergy

Discretionary Accept.

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

G6PD Deficiency

Obligatory **Must not donate if:**
Mother or Father affected by clinically significant disease, and infant is affected.

<i>Discretionary</i>	a) If infant shown to be unaffected, accept. b) If father affected and male infant, accept. c) If infant could be affected, obtain information about clinical severity of G6PD deficiency in the parent, follow-up information on child donor and discuss with Designated Medical Officer.
<i>Additional Information</i>	This is an X linked red cell enzyme deficiency that is variable in its severity. A transplant centre may accept a donor with G6PD deficiency if the phenotype is mild
<i>Reason for Change</i>	To improve clarity and provide additional information
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 29

Gall Bladder Disease

<i>Obligatory</i>	Must not donate if:
	a) Symptomatic.
	b) Associated with an inherited haemolytic anaemia e.g. spherocytosis.
<i>Discretionary</i>	a) If recovered or has asymptomatic gallstones, accept. b) If infant shown to be unaffected by any haemolytic process, accept.
<i>See if Relevant</i>	<u>Haemolytic Anaemia</u> <u>Infection - General</u> <u>Malignancy</u> <u>Surgery</u>
<i>Reason for Change</i>	A link has been added for 'Haemolytic Anaemia' and for 'Malignancy'.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Genital Warts

<i>Discretionary</i>	Accept.
<i>See if Relevant</i>	<u>Sexually Transmitted Disease</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Giardiasis

<i>Discretionary</i>	Accept.
<i>Additional Information</i>	This is a local intestinal infection that does not affect donation.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Gilbert's Syndrome

<i>Discretionary</i>	Accept.
<i>Additional Information</i>	Gilbert's syndrome is an inherited defect in bilirubin metabolism. It is harmless but can cause jaundice in the mother and her baby.
<i>Update Information</i>	This entry was last updated in

TDSG-CB Edition 203, Release 02

Glaucoma

<i>Obligatory</i>	Must not donate if: Received transplant of sclera during glaucoma surgery.
<i>See if Relevant</i>	<u>Ocular Tissue Recipient</u> <u>Surgery</u> <u>Tissue and Cell Allograft Recipients</u>
<i>Additional Information</i>	If surgery was performed after 1997 and the sclera was supplied through UK Transplant, this information will be stored on the National Transplant Database.
<i>Reason for Change</i>	A link has been added for 'Ocular Tissue Recipient'.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Glycogen Storage Disease

<i>Obligatory</i>	Must not donate
<i>Additional Information</i>	Glycogen storage disease (GSD) is the result of defects in the processing of glycogen synthesis or breakdown within muscles, liver, and other cell types. GSD in humans is genetic caused by an inborn error of metabolism (genetically defective enzymes) involved in these processes. There is insufficient evidence to determine whether donations from a baby with a glycogen storage disease could present a risk to recipients.
<i>Reason for Change</i>	This is a new entry
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 29

Gout

<i>Discretionary</i>	Even if on treatment, accept.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Granuloma Inguinale

<i>Obligatory</i>	Must not donate.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Growth Hormone

<i>Obligatory</i>	Must not donate if: Has ever received human pituitary derived growth hormone.
<i>Discretionary</i>	If treated exclusively with recombinant-derived growth hormone, accept. In the UK this has

been since 1987.

<i>See if Relevant</i>	<u>Prion Associated Diseases</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Guillain-Barré Syndrome

<i>Obligatory</i>	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 mother cannot confirm a typical monophasic Guillain-Barré syndrome that recovered completely within 12 months.
<i>See if Relevant</i>	If treated with immunoglobulin or plasma exchange: <u>Transfusion</u>
<i>Reason for Change</i>	A link has been added to 'Transfusion'.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Haematological Disease

<i>Obligatory</i>	Must not donate if: a) Malignant. b) Clonal disorder such as primary polycythaemia (rubra vera), essential thrombocythaemia or monoclonal gammopathy of unknown significance (MGUS).
<i>Discretionary</i>	If polycythaemia or thrombocytosis is secondary to a non-malignant/clonal condition, accept.
<i>See if Relevant</i>	<u>Anaemia</u> <u>Haemoglobin Disorders</u> <u>Immune Thrombocytopenia</u> <u>Therapeutic Venesection</u>
<i>Additional Information</i>	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.
<i>Reason for Change</i>	Monoclonal gammopathy of unknown significance (MGUS) has been added as an example of a clonal disorder. 'Additional Information' has been added.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Haematuria

<i>Obligatory</i>	Must not donate if: a) Due to infection. b) Due to malignancy.
<i>See if Relevant</i>	<u>Kidney Disease</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Haemochromatosis

<i>Discretionary</i>	Accept.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Haemoglobin Disorders

<i>Obligatory</i>	Must not donate if: Mother or Father homozygous or heterozygous for inherited haemoglobin disorders and infant affected.
<i>Discretionary</i>	If the cord blood or infant/child is tested for the condition and the infant is shown to be unaffected or heterozygous (trait), accept and inform the transplant centre.
<i>See if Relevant</i>	<u>Anaemia</u> <u>Sickle-Cell Trait</u> <u>Thalassaemia Trait</u> <u>Transfusion</u>
<i>Reason for Change</i>	Stem cells from a donor who is heterozygous for a haemoglobin disorder may be accepted for transplant after a risk assessment by the transplant centre.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 29

Haemolytic Anaemia

<i>Obligatory</i>	See: a) Is there an entry for the condition? b) If not: Refer to a Designated Medical Officer.
<i>See if Relevant</i>	<u>Autoimmune Disorder</u> <u>G6PD Deficiency</u> <u>Haemoglobin Disorders</u> <u>Hereditary Elliptocytosis</u> <u>Hereditary Spherocytosis</u> <u>Pyruvate Kinase Deficiency</u> <u>Transfusion</u>
<i>Reason for Change</i>	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.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Haemorrhoids

<i>Includes</i>	Piles
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<i>Discretionary</i>	Accept.
<i>See if Relevant</i>	<u>Surgery</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Headache

Occasional

<i>Discretionary</i>	Accept.
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Regular

<i>Obligatory</i>	Must not donate if: Not investigated.
<i>Discretionary</i>	If investigated and diagnosis does not contra-indicate donation, accept.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Heaf Test

<i>Obligatory</i>	Must not donate until: Healing.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Health Care Worker

History of Inoculation Injury

<i>See</i>	<u>Inoculation Injury</u>
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No Inoculation History

<i>Discretionary</i>	Accept.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Henna Painting

<i>Discretionary</i>	Accept.
<i>See if Relevant</i>	<u>Body Piercing</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Hepatitis

<i>Obligatory</i>	Note: Hepatitis has a number of causes including infection and hypersensitivity to drugs. Our concern is with viral hepatitis.
<i>Discretionary</i>	If fully recovered from non-viral hepatitis, accept.
<i>See if Relevant</i>	<u>Hepatitis A</u> <u>Hepatitis B</u> <u>Hepatitis C</u> <u>Hepatitis E</u> <u>Hepatitis of Unknown Origin</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Hepatitis A

1. Affected Individual

<i>Obligatory</i>	Must not donate if: Less than 6 months from recovery.
<i>Discretionary</i>	If less than 6 months from infection, but fully recovered, documented HAV RNA negative and anti HAV IgG positive after recovery, accept.
<i>See if Relevant</i>	<u>Travel</u>
<i>Additional Information</i>	Hepatitis A is spread by the faecal - oral route and by sewage-contaminated food and water. It can also be spread sexually. There is no long term infection with the 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
<i>Reason for Change</i>	To clarify the wording of the discretionary entry.

2. Current or Former Sexual Partner of Affected Individual

<i>Obligatory</i>	Must not donate if: Less than 6 months from recovery of current sexual partner, or from last sexual contact if a former sexual partner.
<i>Discretionary</i>	If shown to be immune, accept.
<i>Additional Information</i>	There is a risk of transmitting the infection through sexual activity. Infection may be symptom free but can be serious and occasionally fatal. The 6 month exclusion allows any infection to run its natural course and for any risk of passing the infection on through donation to have passed.
<i>Reason for Change</i>	To permit acceptance of donors who are shown to be immune.

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

<i>Obligatory</i>	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.
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<i>Discretionary</i>	If shown to be immune, accept.
<i>Additional Information</i>	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.
<i>Reason for Change</i>	To permit acceptance of donors who are shown to be immune.

4. Immunization

<i>Obligatory</i>	Known exposure. Must not donate if: Less than six months after vaccine or intramuscular immunoglobulin was given.
<i>Discretionary</i>	No known exposure: Accept.
<i>See if Relevant</i>	<u>Hepatitis B - Post Immunization Travel</u>
<i>Additional Information</i>	Hepatitis A immunization is advised before travel to parts of the world where other infections relevant to donating such as malaria are common. The donor should be asked about any relevant travel history. Hepatitis A immunization may be combined with Hepatitis B immunization. If less than 6 months from immunisation following known exposure, the donor may be accepted following individual risk assessment if the risk of delaying transplant outweighs the risk of transmission of hepatitis A.
<i>Reason for Change</i>	The deferral period for immunization post known exposure has been reviewed following guidance from Public Health England.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 31

Hepatitis B

1. Person with current hepatitis B infection

<i>Obligatory</i>	Must not donate.
<i>Additional Information</i>	Hepatitis B is a serious viral infection that can lead to chronic liver disease and liver cancer (hepatoma). Individuals who are chronically infected are sometimes referred to as 'carriers'. They often have no, or minimal, symptoms associated with their infection. Cases are often linked to place of birth, or mother's place of birth. The condition is very common in many parts of the world and vertical spread from mother to baby is often a major route of transmission. Hepatitis B may also be acquired by injecting drug use, sexual transmission and more rarely tattoos and piercings

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

<i>Obligatory</i>	Must not donate: if less than 12 months since diagnosis
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<i>Discretionary</i>	If more than 12 months since diagnosis of HBV infection, and if they have successfully cleared the infection, accept. Refer to the designated medical officer if advice on interpretation of test results is required.
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See if Relevant Tissue Safety Entry

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

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

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

3. Current or Former Sexual Partner of an infected individual

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

Must not donate if:
Less than 3 months from last sexual contact

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

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

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

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

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

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

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

Must not donate if:
Less than 3 months from last sexual contact with the a partner who has been diagnosed with HBV infection **less than** 12 months ago

Discretionary a) If **more than** 3 months since last sexual contact, regardless of when the partner was diagnosed with the HBV infection, accept
or
b) If partner was diagnosed with HBV infection **more than** 12 months ago and has cleared the infection at the time of last sexual contact, accept.

<i>Additional Information</i>	A donor who had sexual contact less than 3 months ago with a partner who had been diagnosed with the HBV infection less than 12 months ago at the time of sexual contact, may be accepted following individual risk assessment if risk of delaying transplant outweighs the risk of transmission of hepatitis B. The current partner of an individual with hepatitis B infection should have been offered immunisation. If the relationship started after the diagnosis of hepatitis B, immunisation may not have been carried out.
<i>Reason for Change</i>	This entry has been modified in line with the recommendations of the SaBTO Donor Selection Criteria Review Report published on 23rd July 2017.

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

<i>Obligatory</i>	Obtain history to determine if they are still sharing a home, and if not, the time since sharing ceased Must not donate: If less than 3 months since sharing ceased.
<i>Discretionary</i>	If more than 3 months since sharing ceased, accept. If less than 3 months since sharing ceased, and the donor is shown to be naturally immune, accept
<i>See if Relevant</i>	6. Hepatitis B Immunization, below.
<i>Additional Information</i>	A person sharing a home with a person infected with hepatitis B within the past 3 months may be accepted following individual risk assessment if the risk of delaying transplant outweighs the risk of transmission of hepatitis B.
<i>Reason for Change</i>	This entry has been modified in line with the recommendations of the SaBTO Donor Selection Criteria Review Report published on 23rd July 2017.

6. Hepatitis B Immunization

<i>Obligatory</i>	a) If Immunised Following Known Exposure: Must not donate b) If Immunised With No Known Exposure: Must not donate if: Less than 7 days after the last immunization was given.
<i>Discretionary</i>	a) If Immunised Following Known Exposure: If more than 3 months from immunization, accept b) If Immunised With No Known Exposure: If more than 7 days after the last immunization was given, accept.
<i>See if Relevant</i>	<u>Hepatitis A - 4. Immunization</u>
<i>Additional Information</i>	Immunization post exposure may be with specific anti-HB immunoglobulin as well as with HBsAg. Generally immunoglobulin would only be given after a known exposure to hepatitis B. There is no requirement to monitor the anti-HBs level. May be combined with hepatitis A immunization. Sensitive assays for HBsAg may be positive following recent immunization. This is why a 7 day deferral is required.
<i>Reason for Change</i>	The immunisation section has been incorporated into the main Hepatitis B entry.
<i>Update Information</i>	This entry was last updated in TDSG-CD Edition 203, Release 27

Hepatitis C

1. Affected Individual

<i>Obligatory</i>	Must not donate.
<i>Discretionary</i>	If the individual has been told that he/she is HCV antibody negative, then samples should be taken to determine eligibility.
<i>See if Relevant</i>	<u>Tissues Safety Entry</u>
<i>Additional Information</i>	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 tissues/cells cannot be used.
<i>Reason for Change</i>	'Additional Information' has been added.

2. Current or Former Sexual Partners of HCV Positive Individuals

<i>Obligatory</i>	Must not donate if Less than 3 months from the last sexual contact
<i>Discretionary</i>	a) If less than 3 months from the last sexual contact and the donor/donor family reports that their current or former HCV positive partner has been successfully treated for hepatitis C infection and has been free of therapy for at least 6 months prior to the last sexual contact and continues in sustained remission, accept. b) If more than 3 months since last sexual contact, accept.
<i>See if Relevant</i>	<u>Tissues Safety Entry</u>
<i>Additional Information</i>	Confirmation of the success of treatment of the HCV positive partner is not required Individuals who remain HCV RNA negative six months after completing treatment are likely to have been 'cured', with a risk of relapse of less than 1% In the United Kingdom sexual transmission of HCV from an infected individual to a sexual partner is low, but not zero. As the treated individual would have a very low (<1%) risk of relapse of infection and sexual transmission of the hepatitis C virus is rare, the transmission of hepatitis C from a successfully treated individual to a sexual partner is most unlikely. This guidance presumes that a validated NAT test for HCV is negative, if this test is stopped for any reason the guidance will change.
<i>Reason for Change</i>	To include guidance for persons with treated and successfully cleared past Hepatitis C infection.

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

<i>Discretionary</i>	Accept.
<i>See if Relevant</i>	Sexual Partners of HCV Positive Individuals above.
<i>Additional Information</i>	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.
<i>Update Information</i>	This entry was last updated in TDSG-BM Edition 203, Release 31

Hepatitis E

Infection

<i>Obligatory</i>	Must not donate if: Less than 6 months from recovery.
<i>Discretionary</i>	If less than 6 months from recovery and HEV RNA negative and anti HEV IgG positive, accept.
<i>See if Relevant</i>	<u>Travel</u>
<i>Additional Information</i>	Hepatitis E is an infectious hepatitis that is usually spread through contaminated food or water. Infection may be associated with travel to countries with poor hygiene/sewage conditions but increasingly, cases of hepatitis E are being identified in the UK usually due to consumption of undercooked contaminated meat. Hepatitis E can affect non-human animals and has been found in pigs in the UK. There have been reports of transmission by transfusion and transplant. Infection in healthy individuals is often symptom free but in people with underlying problems in their immune systems it can be serious and occasionally fatal. The Blood Services currently test for this infection.
<i>Reason for Change</i>	The obligatory deferral has been reduced from 12 to 6 months and a discretion to accept on full recovery added. Additional Information has been updated. The deferral for household and sexual contacts has been removed.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 29

Hepatitis of Unknown Origin

Affected Mothers

<i>Obligatory</i>	Must not donate if: Less than 24 months from recovery.
<i>Discretionary</i>	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.
<i>Additional</i>	

<i>Information</i>	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 and HBV-DNA is negative, accept.
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Person Sharing Home

<i>Obligatory</i>	Must not donate if: Less than 12 months from recovery of the last affected person in the home.
<i>See if Relevant</i>	Sexual Partner of Affected Individuals above.
<i>Additional Information</i>	Most hepatitis of unknown origin will have been due to hepatitis A or hepatitis E (or non-viral causes). Additional testing for those who give a history of hepatitis between 12 and 24 months before donation will exclude the rare case of HBV which may have delayed clearance of infection and therefore will still present a risk through donation.
<i>Reason for Change</i>	Clarification regarding hepatitis B markers has been added to the additional information. To remove the requirement for anti-HBs levels to be >100 iu/l for acceptance of stem cell donations from donors who are anti-HBc-positive provided the HBV DNA result is negative.

Sexual Partner of Affected Individuals

<i>Obligatory</i>	Must not donate if: Less than 12 months from recovery of partner.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 16

Hereditary Elliptocytosis

<i>Obligatory</i>	1. Must not donate if: Either parent has significant haemolysis. 2. Inform Transplant Centre if: Cells are from a infant with/or at risk of hereditary elliptocytosis.
<i>Discretionary</i>	Even if a parent has significant haemolysis, if the cord blood is tested for the condition and the infant is shown to be unaffected, accept.
<i>Additional Information</i>	Hereditary elliptocytosis is a variably inherited but usually dominant condition. Suitability as a donor should be discussed with a Designated Medical Officer .
<i>Reason for Change</i>	This entry replaces the previous entry for 'Elliptocytosis'.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Hereditary Spherocytosis

<i>Obligatory</i>	1. Must not donate if: Either parent has significant haemolysis. 2. Inform Transplant Centre if: Cells are from a infant with/or at risk of hereditary spherocytosis.
<i>Discretionary</i>	Even if a parent has significant haemolysis, if the cord blood is tested for the condition and the infant is shown to be unaffected, accept.

<i>Additional Information</i>	Hereditary spherocytosis is a variably inherited but usually dominant condition. Suitability as a donor should be discussed with a Designated Medical Officer .
<i>Reason for Change</i>	The entry has been brought into line with the guideline for 'Hereditary Elliptocytosis'.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Herpes - Genital

<i>Obligatory</i>	Must not donate if: a) Fresh lesions. b) Primary infection occurred during this pregnancy.
<i>Discretionary</i>	If lesions are healing, provided there is no history of other Sexually Transmitted Diseases, accept.
<i>See if Relevant</i>	<u>Sexually Transmitted Disease</u>
<i>Additional Information</i>	There is no need to defer donors who have a sexual partner with Herpes if the donor themselves is asymptomatic.
<i>Reason for Change</i>	Addition of 'Additional Information' section, to include clarification regarding sexual partners.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 51

Herpes - Oral

<i>Obligatory</i>	Must not donate if: a) Fresh lesions. b) Primary infection occurred during this pregnancy.
<i>Discretionary</i>	If lesions are healing, accept.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Herpes Simplex

<i>See if Relevant</i>	<u>Herpes - Genital</u> <u>Herpes - Oral</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Herpes Zoster

<i>See if Relevant</i>	<u>Infection - Acute</u> <u>Infectious Diseases - Contact with</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

HIV

Includes AIDS

Current or Former Sexual Partners of Confirmed Case

Obligatory **Must not donate if:**
Less than 3 months from last sexual contact

See if Relevant Tissues Safety Entry

Additional Information HIV infection can be spread through sexual activity, including oral and anal sex. Despite regular sexual contact transmission of infection may not happen. It may however not be transmitted for a long time into a relationship. This could be because the infection becomes more active in the infected partner, the uninfected partner acquires another infection or injury to a mucous membrane, or there is a change in the use of, or failure of, barrier contraceptives (condoms etc.). In the early stages of infection the testing used by the Blood Services may not detect the virus allowing it to be passed on by transfusion or transplantation.

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

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

Infection

Obligatory **Must not donate.**

See if Relevant Tissues Safety Entry

Person Currently or Formerly Sharing a Home with an Affected Individual

Discretionary Accept.

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

Additional Information HIV is neither contagious nor spread by the faecal-oral route. It is usually only spread through a direct blood to blood or sexual route. For these reasons household contacts do not need to be deferred.

Reason for Change This is an additional entry.

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

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

Hormone Replacement Therapy

Obligatory **Must not donate if:**
a) Used for malignancy.

b) A recipient of human gonadotrophin of pituitary origin.

c) A recipient of human pituitary growth hormone.

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

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

<i>See if Relevant</i>	<u>Prion Associated Diseases</u> <u>Thyroid Disease</u>
<i>Reason for Change</i>	The discretionary entry has been re-worded for clarity.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

HTLV

Current and Former Sexual Partners of Confirmed Case

<i>Obligatory</i>	Must not donate if: Less than 3 months from last sexual contact
<i>See if Relevant</i>	<u>Tissues Safety Entry</u>
<i>Additional Information</i>	There is no defined infectious window period for HTLV. The risk of missing recent infection with individual sample testing is low after 3 months.
<i>Reason for Change</i>	This entry was updated in line with the recommendations of the SaBTO Donor Selection Criteria Review Report published on 23rd July 2017

Infection

<i>Obligatory</i>	Must not donate.
<i>See if Relevant</i>	<u>Tissues Safety Entry</u>

Person Currently or Formerly Sharing a Home with an Affected Individual

<i>Discretionary</i>	Accept.
<i>See if Relevant</i>	Current or Former Sexual Partner of Affected Individual above.
<i>Additional Information</i>	HTLV is neither contagious nor spread by the faecal-oral route. It is usually only spread through a direct blood to blood or sexual route. For these reasons household contacts do not need to be deferred.
<i>Reason for Change</i>	This is an additional entry.
<i>Update Information</i>	This advice is a requirement of the EU Tissue & Cells Directive. This entry was last updated in TDSG-CB Edition 203, Release 27

Huntington's Disease

<i>Obligatory</i>	If the diagnosis is uncertain: Refer to a Designated Medical Officer.
<i>Discretionary</i>	If diagnosis can be confirmed, accept.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Hydatid Disease

<i>Obligatory</i>	Must not donate.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Hydrocephalus

<i>Obligatory</i>	Must not donate if: Has an indwelling shunt.
<i>See if Relevant</i>	<u>Neurosurgery</u> <u>Spina Bifida</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Hypnotics

<i>Discretionary</i>	Accept.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Ileostomy

<i>Obligatory</i>	Must not donate if: a) For malignancy b) Inflammatory bowel disease.
<i>Discretionary</i>	If the reason for the ileostomy is not of itself a reason to exclude and the stoma is healthy, accept.
<i>See if Relevant</i>	<u>Surgery</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Immune Thrombocytopenia

<i>Obligatory</i>	Must not donate if: Mother received treatment for the condition in the 12 months before this pregnancy.
<i>See if Relevant</i>	If treated with immunoglobulin or plasma exchange: <u>Transfusion</u> If treated with immunosuppressive therapy: <u>Immunosuppression</u>
<i>Reason for Change</i>	The links have been revised. There is no evidence that this condition can be transmitted through cord blood or amniotic membrane.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Immunisation

Non-exposed

See [Immunisation - Live](#)
[Immunisation - Non-Live](#)

If you do not know if an immunisation is live or not, see the specific entry for the type of immunisation or:
Refer to a Designated Medical Officer.

Post Exposure

Obligatory

- 1. BCG:**
See
[BCG](#)
- 2. Hepatitis A:**
See
[Hepatitis A](#)
- 3. Hepatitis B:**
See
[Hepatitis B](#)
- 4. Rabies:**
See
[Rabies](#)
- 5. Smallpox:**
See
[Smallpox Immunisation](#)
- 6. Tetanus:**
See
[Tetanus Immunisation](#)

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

Update Information This entry was last updated in
 TDSG-CB Edition 203, Release 41

Immunisation - Live

No Exposure

Obligatory **Must not donate if:**
 Immunised during this pregnancy.

See if Relevant [BCG](#)
[Smallpox Immunisation](#)

Additional Information Live immunisations use living viruses or living bacteria that will stimulate the immune system but do not normally cause a severe illness. They may however cause severe illness in people who are already unwell and have a weakened immune system.

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

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

Immunisation - Non-Live

No Exposure

<i>Excludes</i>	Post-exposure. See: <u>Immunisation</u> - Post Exposure
<i>Obligatory</i>	1. Hepatitis B Must not donate if: Less than seven days after administration
<i>Discretionary</i>	Other non-live immunisations, accept.
<i>Additional Information</i>	Sensitive assays for HBsAg may be positive following recent immunisation. Full screening for Hepatitis B may be required. Note, hepatitis A immunisation may be combined with hepatitis B immunisation. 'Non-Live' immunisations do not use material that can cause infection. This means there is no risk to people receiving donated material from a recently immunised non-exposed donor.
<i>Reason for Change</i>	To remove Coronavirus Vaccination from obligatory section, and additional information section updated.
<i>Update Information</i>	This entry was last updated in CB-DSG Edition 203 Release 54

Immunoglobulin Therapy

<i>Obligatory</i>	Must not donate if: a) Immunosuppressed. b) Mothers with recovered immunodeficiency: Refer to a Designated Medical Officer.
<i>Discretionary</i>	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.
<i>See if Relevant</i>	<u>Hepatitis A</u> <u>Hepatitis B</u> <u>Rabies</u> <u>Tetanus Immunization</u>
<i>Additional Information</i>	Immunoglobulin used before 1980 is unlikely to be affected by vCJD. Single dose immunoglobulin is unlikely to pose a significant risk for transmitting vCJD.
<i>See</i>	If treated with intravenous or subcutaneous human immunoglobulin: <u>Transfusion</u>
<i>Reason for Change</i>	A link to 'Transfusion' has been added.
<i>Update Information</i>	The advice reflects advice from the MSBTO committee of the DH. This entry was last updated in TDSG-CB Edition 203, Release 02

Immunosuppression

<i>Obligatory</i>	Must not donate if: a) Immunosuppressed.
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b) Mothers with recovered immunodeficiency:
Refer to a Designated Medical Officer.

See if Relevant Autoimmune Disease
Immunoglobulin Therapy
Steroid Therapy

Reason for Change Additional links have been added.

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

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

Infection - Acute

Obligatory **See:**
Is there is a specific entry for the disease you are concerned about?

Must not donate if:

- a) Evidence of active infection
- b) Less than two weeks from recovery.
- c) Less than 7 days from completing systemic antibiotic, antifungal or antiviral treatment.

Discretionary Common viral respiratory tract infections such as colds, sore throats and seasonal influenza, if recovering, accept. See additional information.

Cold sores, genital herpes, accept.

See if Relevant Congo Fever
Coronavirus Infection
Crimean Fever
Ebola Fever
Herpes - Genital
Herpes - Oral
Lassa Fever
Marburg Fever
MRSA (Methicillin Resistant Staphylococcus Aureus)
Myocarditis
Steroid Therapy
West Nile Virus

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

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

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

Seasonal influenza in the UK normally extends over a period of approximately 16 weeks during the winter months. Due to the spectrum of disease presentation, only the minority of infected individuals are tested for respiratory viruses and during the annual epidemics, most

cases are diagnosed clinically. Systemic infection with viraemia is not a feature of seasonal influenza.

Unusual bacterial/fungal/protozoal infections

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

Reason for Change Updated guidance regarding donors who are recovering from seasonal influenza.

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

This entry was last updated in
TDSG-CB Edition 203, Release 37

Infection - Chronic

Obligatory **Must not donate.**

Discretionary **1. Acne:**
Most donors with acne can be accepted.

2. Chronic fungal infections:

a) If on local therapy for superficial infections only, accept.

b) If on systemic anti-fungal treatment only for treatment of a localised, non-systemic fungal infection, and there are no complications, accept.

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

3. Typhoid and Paratyphoid

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

See if Relevant Acne
Steroid Therapy

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

Unusual bacterial/fungal/protozoal infections

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

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

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

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

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

This entry was last updated in
TDSG-CB Edition 203, Release 38.

Infection - General

<i>Obligatory</i>	See: Is there a specific entry for the disease?
<i>See if Relevant</i>	Decide if the infection is of short duration with no long lasting carrier stage, e.g. flu: <u>Infection - Acute</u> 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 <u>Infection - Chronic</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Infection - Tropical

<i>Obligatory</i>	Must not donate if: Filariasis or Leishmaniasis
<i>See if Relevant</i>	<u>Congo Fever</u> <u>Crimean Fever</u> <u>Ebola Fever</u> <u>Lassa Fever</u> <u>Marburg Fever</u> <u>Malaria</u> <u>South American Trypanosomiasis Risk</u> Other infections, see: <u>Infection - General</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Infectious Diseases - Contact with

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

Coronavirus Infection
Hepatitis
Hepatitis A
Hepatitis B
Hepatitis C
Hepatitis E
HIV
HTLV
Meningitis
Monkeypox
Sexually Transmitted Disease
Smallpox Immunization
Syphilis
Tuberculosis

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

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

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

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

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

Update Information This entry was last updated in
TDSG-CB Edition 203, Release 48

Infertility

Obligatory **Must not donate if:**
a) Has ever been given human gonadotrophin of pituitary origin.

b) If donor knows that they have ever been treated with Metrodin HP®.

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

See if Relevant Prion Associated Diseases

Additional Information The use of human gonadotrophin of pituitary origin (follicle-stimulating hormone (FSH) and luteinizing hormone (LH)) had stopped in the UK by 1986. The situation in other countries varied so specific dates cannot be given.
The 12 week period is an additional safeguard to avoid taking a donation early in a pregnancy.

There is **no evidence** that transfer of tissues (eggs or embryos) between individuals might lead to the spread of vCJD.

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

Reason for Change To update the 'additional information' section with a statement that there is no evidence that transplantation of eggs or embryos might lead to spread of vCJD.

Update Information This entry was last updated in
TDSG-CB Edition 203, Release 43.

Inflammatory Bowel Disease

<i>Includes</i>	Crohn's Disease Ulcerative Colitis
<i>Obligatory</i>	Must not donate.
<i>Discretionary</i>	Accept if mother well and in stable remission off treatment. Inform transplant centre there is a history of autoimmune disease in a first-degree relative.
<i>See if Relevant</i>	<u>Infection – General</u> <u>Malignancy</u> <u>Radiation Therapy</u>
<i>Additional Information</i>	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.
<i>Reason for Change</i>	'See if Relevant' section has been added.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 41

Inherited Diseases

<i>Obligatory</i>	See: Is there a specific entry for the condition? If not: Refer to a Designated Medical Officer.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Inoculation Injury

<i>Includes</i>	Human Bite
<i>Definition</i>	A non-consented injury or assault in which an individual is exposed to potentially infective material that could be transferred through donation. The causes may range from a sharps injury to bites, punches and abrasions or sexual assault where mucous membranes have been contaminated with human blood or other body fluids. It also applies to any inoculation injury with abnormal prions from any species.
<i>Obligatory</i>	Must not donate if: a) The incident involved any material containing abnormal prions. b) Less than 3 months after the date of an inoculation injury, or contamination of mucosa or non-intact skin with blood or body fluids. c) Under ongoing investigations following exposure - refer to DSCO.
<i>See if Relevant</i>	<u>Animal Bite</u> <u>Hepatitis</u> <u>HIV</u> <u>HTLV</u> <u>Prion Associated Diseases</u> <u>Tissues Safety Entry</u> <u>Xenotransplantation</u>

<i>Additional Information</i>	Human blood or body fluids may be contaminated with infective material such that the infection may then be passed on by donated material. Waiting three months (if validated tests for infectious markers that include HBV, HCV HIV NAT are negative) helps to ensure that any infection is not passed on. Donors who are under investigation may be accepted subject to individual risk assessment.
<i>Reason for Change</i>	The 'Definitions' section was updated as part of the implementation of recommendations from the FAIR III report. Additional 'see if relevant' links added. 'Additional information' section updated.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 51

Irritable Bowel Syndrome

<i>Discretionary</i>	Accept.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Jaundice

<i>Obligatory</i>	Must not donate if: a) Jaundiced or has a history of jaundice. b) If the cause of the jaundice was viral see the specific entry for that condition. c) If the cause of the jaundice was not known, treat as Hepatitis of Unknown Origin .
<i>Discretionary</i>	a) If fully recovered from a non-viral cause of jaundice (this includes, but is not limited to, physiological jaundice of the newborn, gall stones and drug reactions), accept. b) If due to Gilbert's Syndrome, accept.
<i>See if Relevant</i>	<u>Gall Bladder Disease</u> <u>Gilbert's Syndrome</u> <u>Hepatitis A</u> <u>Hepatitis B</u> <u>Hepatitis C</u> <u>Hepatitis E</u> <u>Hepatitis of Unknown Origin</u>
<i>Additional Information</i>	Many things can cause jaundice. The concern is with infectious causes that might be passed on by donation.
<i>Reason for Change</i>	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.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Kala-Azar

<i>Obligatory</i>	Must not donate.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Kidney Disease

Acute Nephritis

<i>Obligatory</i>	Must not donate if: Less than 12 months since recovery.
<i>Discretionary</i>	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 .
<i>Additional Information</i>	If the donor is well and has not received treatment to suppress the condition in the last 12 months it is unlikely that their donation will pose a risk to the recipient.
<i>Reason for Change</i>	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

<i>Obligatory</i>	Must not donate.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 16

Laser Treatment

<i>Obligatory</i>	Must not donate if: For malignancy.
<i>Discretionary</i>	a) If for Basal Cell Carcinoma, treatment is completed and fully recovered, accept. b) If for Cervical Carcinoma in Situ, see <u>Cervical Dysplasia</u> entry. c) If for cosmetic purposes, accept when healed. d) If laser refractive surgery to the cornea, accept when healed.
<i>See if Relevant</i>	<u>Basal Cell Carcinoma</u> <u>Cervical Dysplasia</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 43.

Leishmaniasis

<i>Includes</i>	Kala-Azar
<i>Obligatory</i>	Must not donate.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Leukaemia

<i>Obligatory</i>	Must not donate.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Malaria

<i>Obligatory</i>	Must not donate if: a) The mother has ever had malaria. b) The mother has had an undiagnosed fever (that could have been malaria) while abroad or within four months of leaving a malaria endemic area. c) The mother 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.
<i>Discretionary</i>	1a) Mothers 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) Mothers 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. 1c) Mothers 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 mothers: 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 mother 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 mother can be accepted without the need for malaria antibody testing. 1e) For all of the above (a-d): If malaria antibody testing is indicated as outlined above and the result is inconclusive or positive, obtain details of exposure and treatment and discuss with the Designated Medical Officer. If the malaria antibody test is positive or inconclusive, additional nucleic acid testing (NAT) for malaria on a maternal and a cord blood sample may be utilised to determine the safety of the cord blood donation. In case of confirmed negative NAT results, a risk assessment must be documented and, if accepted, the details must be discussed at selection with the transplant centre.
<i>See if Relevant</i>	<u>Geographical Disease Risk Index</u> for countries with a current endemic malaria risk.
<i>Additional Information</i>	Cases of malaria transmission have occurred many years after the mother was last at risk of becoming infected with malaria. This is mainly a problem in people who have had repeated episodes of infection with malaria. This is uncommon, but before allowing someone who has had, or may have had malaria to give a donation, it is safer to test for malaria antibodies rather than to wait a specific length of time. Malaria may be fatal. Some countries have malaria as well as tropical viral risk. Both risks have to be considered if the mother had symptoms after travel or stay.
<i>Reason for Change</i>	The 'Discretionary' entry has been expanded to include information on the option for NAT testing if required.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 46.

Malaria - Contact in UK

<i>Discretionary</i>	Accept.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Malignancy

<i>Obligatory</i>	Must not donate.
<i>Discretionary</i>	a) If this was a basal cell carcinoma (rodent ulcer) and treatment is completed and all wounds are healed, accept. If any systemic medical treatment was required, refer to designated clinical support officer. b) If the potential donor has a non haematological (non-clonal) premalignant condition (e.g. polyposis coli, prostatic intraepithelial neoplasia PIN or Barrett's oesophagus) that is being regularly monitored, or has had a similar condition cured and has been discharged from follow-up, accept. c) If the potential donor has been cured of a carcinoma in situ (CIS) and discharged from follow-up, accept. Donors who have been returned to routine screening following treatment for cervical CIS can be accepted. Examples of CIS include cervical or vulval CIS, ductal CIS of the breast (DCIS) and Bowen's disease. d) If the potential donor has had a diagnosis of melanoma in situ (including Lentigo Maligna), refer to Designated Clinical Support Officer to confirm they have not had an invasive melanoma (eg Lentigo Maligna Melanoma). e) Potential donors with a high risk of cancer due to family history or following genetic tests, even if had or having prophylactic surgery or on prophylactic medication (e.g. Tamoxifen), or on routine follow up, accept.
<i>See if Relevant</i>	<u>Basal Cell Carcinoma</u> <u>Cervical Carcinoma in Situ</u> <u>Surgery</u> <u>Transfusion</u>
<i>Additional Information</i>	Many malignancies spread through the blood stream and by invading surrounding tissues. Viruses that can be spread by blood and tissue donation can also cause some malignancies. For these reasons it is considered safer not to accept blood from people who have had a malignancy. Basal cell carcinoma (rodent ulcer) does not spread through the blood, therefore people who have had successful treatment may donate. The term carcinoma in situ (CIS) refers to a group of abnormal cells which have not invaded deeper tissue or spread to another part of the body. Donors who have been cured and discharged from follow up may donate. For cervical CIS, donors can be accepted if treatment is complete and any follow up smear, if performed, did not show abnormal cells. Regular screening smears are not defined as follow up. Premalignant conditions are very common, particularly in older donors. Regular monitoring should prevent donors with invasive malignancy from being accepted. However donors with a haematological clonal pre-malignant condition should not be accepted for tissue donation. Melanoma in situ which has been cured by excision is not associated with a risk of metastasis. Patients with a confirmed diagnosis of melanoma in situ (ie Breslow thickness of

0 and no regression) do not require ongoing follow up beyond the initial post-operative appointment.

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

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

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

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

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-CB Edition 203, Release 02

Marfan's Syndrome

Discretionary Accept.

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

Measles

Affected Individual

See Infection - Acute

Contact

See Infectious Diseases - Contact with

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

Meningitis

Affected Individual

See Infection - Acute

Contact

Discretionary Even if on prophylactic antibiotics, accept.

Update Information

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

Mental Health Problems

<i>Obligatory</i>	Must not donate if: Not able to fully understand and consent to the donation process and to the testing of their blood for diseases that may affect its suitability for use.
<i>See if Relevant</i>	<u>Communication Difficulties</u>
<i>Additional Information</i>	Many people have mental health problems that can be controlled with regular medication. Providing individuals are well on the day of donation and have the mental capacity to give full informed consent, there is no reason why they cannot donate whether on medication or not. Individuals who are over anxious, depressed, manic or psychotic cannot always give valid consent, or fully understand why they are being asked certain questions.
<i>Reason for Change</i>	To ensure that all donors with mental health conditions can donate if they are well enough to do so and have the mental capacity to give full informed consent.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 16

Mitral Valve Prolapse

<i>Discretionary</i>	Accept.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Mpox (Monkeypox)

1. Affected Individuals

<i>Obligatory</i>	Must not donate
<i>Discretionary</i>	If the donor has recovered from confirmed or suspected Mpox infection and • It is at least 28 days since the diagnosis of Mpox was made, and • It is at least 14 days since recovery, and the donor remains well, and • It is at least 14 days since all skin lesions have healed, and • It is more than seven days since completing any antiviral or antibiotic therapy, and • The donor has been discharged from all follow up (including public health surveillance), accept.
<i>Post Donation Illness</i>	Donors must be provided with information about contacting the tissue establishment if they develop any illness within 21 days after donation. Donation should be discarded.

2. Contact with an individual with Mpox

<i>Includes</i>	Individuals who have been identified by public health teams as a close contact of an individual with Mpox.
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<i>Obligatory</i>	Must not donate
<i>Discretionary</i>	If it is more than 21 days since last contact, and • the donor has no symptoms of Mpox, and • the donor had completed any isolation period, and • the donor had been discharged from all follow-up (including surveillance by public health), and • the donor fulfils the criteria in section 3 below regarding vaccination of applicable, accept.
<i>Post Donation Illness</i>	If the donor has retrospectively reported contact with Mpox within incubation period, donation could be discarded or seek public health advice to determine the risk.

3. Immunisation for contact or risk

<i>Excludes</i>	Individuals who have received vaccination because they work in a health care setting – see section 4 below.
<i>Obligatory</i>	Must not donate
<i>Discretionary</i>	If the donor fulfils the criteria in section 2 above, and: • it is more than four weeks since the most recent dose of a non- live or attenuated smallpox vaccination e.g. Imvanex, and: • the course of vaccination (if more than one dose) is complete, accept.

4. Immunisation – No known contact

<i>Includes</i>	Individuals who have received vaccination because they work in a health care setting.
<i>Discretionary</i>	An individual who has received routine vaccination with Imvanex or another third-generation smallpox vaccination in an occupational setting, can be accepted provided that they are not deemed to be at risk due to an exposure episode.
<i>See if Relevant</i>	<u>Immunisation</u>
<i>Additional Information</i>	Mpox was previously known as Monkeypox. In November 2022, WHO recommended Mpox as the new name for Monkeypox disease. Mpox is endemic in some African countries. During 2022 a multi-country outbreak was identified with cases in the UK, Europe, North America and other regions. The incubation period of Mpox is up to 21 days. The initial symptom are fever, myalgia, fatigue and headache. These symptoms are followed by a rash starting from the site of the primary infection, this rash develops into vesicles and pustules followed by scabs. Infectivity may start during initial symptoms and lasts until the rash clears and all scabs have dropped off. Staff should be alert for donors who report rashes and illnesses consistent with Mpox, regardless of sexual behaviour, travel history or other risk factors. Mpox does not spread easily between people. Human-to-human transmission occurs through contact with: • infectious material from skin lesions • respiratory droplets in prolonged face-to-face contact • virus-contaminated objects such as bedding or clothing

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

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

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

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

<i>Post Donation Illness</i>	If the donor has retrospectively reported contact with Mpox Monkeypox within incubation period, donation could be discarded or seek public health advice to determine the risk.
<i>Reason for Change</i>	The title and contents have been updated with the new name as recommended by WHO. Inclusion of sections for donors who have received vaccination either because they could be a close contact, have risk of exposure, or have received vaccination because they are health care workers. Additional Information applicable for the whole entry contained within one section.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 49

MRSA

Methicillin Resistant Staphylococcus Aureus

See if Relevant Infection - General

Additional Information Staphylococcus aureus is a widely occurring skin commensal. The carrier status or exposure of the mother is not relevant to donation.

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

Mumps

Affected Individual

See Infection - Acute

Contact

<i>See</i>	<u>Infectious Diseases - Contact with</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Muscular Dystrophy

<i>Discretionary</i>	Accept.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Myasthenia Gravis

<i>Obligatory</i>	Must not donate.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Myelodysplastic Syndrome

<i>Obligatory</i>	Must not donate.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Myeloproliferative Syndrome

<i>Obligatory</i>	Must not donate.
<i>Reason for Change</i>	This entry has been added to clarify the eligibility of donors with this condition.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Myocarditis

<i>Obligatory</i>	Must not donate if: a) Not recovered. b) Occurred during this pregnancy.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Ménière's Disease

<i>Discretionary</i>	Accept.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Neurofibromatosis

<i>Obligatory</i>	Must not donate if: History of malignant change.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Neurosurgery

<i>Obligatory</i>	Must not donate.
<i>Discretionary</i>	a) If carried out in the UK after 1992, providing the reason for the surgery is not itself a reason for exclusion, accept. b) If burr hole surgery only, accept. c) If it can be shown that Dura Mater was not used during surgery and there is no evidence of malignancy, the mother may be accepted by a Designated Medical Officer .
<i>See if Relevant</i>	<u>Malignancy</u> <u>Prion Associated Diseases</u> <u>Surgery</u>
<i>Update Information</i>	This is a requirement of the EU Tissue & Cells Directive. This entry was last updated in TDSG-CB Edition 203, Release 02

Night Sweats

<i>Obligatory</i>	Must not donate if: Unexplained.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Non-Specific Urethritis

Acute

See Infection - Acute

Chronic

<i>Obligatory</i>	Must not donate.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Nonsteroidal Anti-Inflammatory Drugs (NSAID)

<i>Obligatory</i>	Assess reason for treatment and see relevant entry.
<i>Discretionary</i>	If medication is self prescribed and the mother meets other criteria, accept.

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

Ocular Surgery

See if Relevant Eye Disease
Laser Treatment
Malignancy
Ocular Tissue Recipient
Tissue and Cell Allograft Recipients

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

Ocular Tissue Recipient

Obligatory **Must not donate if:**
Has received a corneal, scleral or limbal tissue graft or limbal or corneal epithelial cells.

Additional Information If the surgery was performed after 1997 and the tissue was supplied through UK Transplant, this information will be stored on the National Transplant Database.

See Prion Associated Diseases

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

Operations

See if Relevant Transfusion

See Surgery

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

Organ Donor

Discretionary Accept.

See if Relevant Transfusion

See Surgery

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

Organ Recipient

Obligatory **Must not donate.**

Discretionary **Refer to a DCSO** for individual risk assessment

Reason for Change This is a new entry.

Update Information This entry was last updated in
TDSG-CB Edition 203, Release 50

Osteoarthritis

<i>Discretionary</i>	Accept.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Osteomalacia

<i>Discretionary</i>	Accept.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Osteomyelitis

<i>Obligatory</i>	Must not donate if: Less than two years from completing treatment and cure.
<i>Additional Information</i>	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.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Osteoporosis

<i>See if Relevant</i>	<u>Steroid Therapy</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Ovarian Cyst

<i>Obligatory</i>	Must not donate if: Malignant.
<i>See if Relevant</i>	<u>Malignancy</u> <u>Surgery</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Paget's Disease of Bone

<i>Includes</i>	Osteitis Deformans
<i>Discretionary</i>	Accept.
<i>Additional Information</i>	Paget's disease of bone is very common in the UK affecting about 1 in 20 adults aged over 50 years. The cause is not known. Many people with the condition have no symptoms and so will be accepted by the blood and tissue services. There is no evidence that it is spread by donation. It is most commonly treated with painkillers and bisphosphonates. The use of these drugs is accepted for other conditions, so there seems no reason why individuals with Paget's disease of bone on treatment should not be accepted, provided that they are otherwise acceptable.

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

Pain Killers

Obligatory Assess reason for treatment and see relevant entry.

Must not donate if:
Taken for a serious long-term illness.

See if Relevant Nonsteroidal Anti-Inflammatory Drugs (NSAID)

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

Peptic Ulcer

Includes Gastric and Duodenal Ulcer and Erosions

Obligatory **Must not donate if:**
Associated with malignant change.

See if Relevant Surgery
Transfusion

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

Perthes' Disease

Discretionary Accept.

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

Pituitary Extract - Human

Includes Adrenocorticotrophic Hormone, Follicle Stimulating Hormone, Gonadotrophin, Growth Hormone, Luteinising Hormone, Thyroid Stimulating Hormone.

Obligatory **Must not donate if:**
Has ever received injection(s) of Human Pituitary Extract.

See if Relevant Growth Hormone
Prion Associated Diseases

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

Donors that have been given only synthetic pituitary hormones or gonadotrophin made from urine may be accepted.

Reason for Change Additional information has been added for clarity.

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

Platelet Disorder

<i>Obligatory</i>	Must not donate if: a) Causes excessive bleeding or bruising and could be transmitted by stem cells. b) Has thrombocytosis.
<i>See if Relevant</i>	<u>Haematological Disease</u> <u>Immune Thrombocytopenia</u> <u>Thrombocytosis</u>
<i>Additional Information</i>	Maternal platelet counts in excess of 500×10^9 should be repeated. If found to be persistently raised the mother should not be accepted and referred for investigation.
<i>Reason for Change</i>	Thrombocytosis' and relevant links have been added.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Pleurisy

<i>See if Relevant</i>	<u>Infection - General</u> <u>Malignancy</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Pneumothorax

Spontaneous

<i>Discretionary</i>	Accept.
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Traumatic

<i>See</i>	<u>Accident</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Poisoning

<i>Obligatory</i>	Must not donate if: There is evidence that the individual (donor/or mother of cord blood donor) has ingested, or been otherwise exposed to toxic substances that could be transmitted in donated material in dosages that could endanger the health of recipients.
<i>Discretionary</i>	If the individual is being monitored following exposure and the levels of the agent in question are within safe limits, accept.
<i>See if Relevant</i>	<u>Addiction and Drug Abuse</u>
<i>Additional Information</i>	Advice may be sought from the National Poisons Information Service if required.
<i>Reason for Change</i>	This is a new entry. This is a requirement of the Human Tissue Authority Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment

Update Information This entry was last updated in
TDSG-CB Edition 203, Release 28

Polycythaemia

Obligatory **Must not donate.**

Discretionary If confirmed as secondary polycythaemia, accept.

Update Information This entry was last updated in
TDSG-CB 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) or Hereditary Coproporphyria (HCP), accept.

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.

Erythropoietic Protoporphyria (EPP) and Congenital Erythropoietic Porphyria (CEP) have porphyrins in the red cells causing the red cell life span to be reduced.

Reason for Change This is a new guideline.

Update Information This entry was last updated in
TDSG-CB Edition 203, Release 10

Post Viral Fatigue Syndrome

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

Obligatory **Must not donate if:**
a) Not resolved.
b) Affected during this pregnancy.

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

Pre- and Post Exposure Prophylaxis for HIV

Obligatory **Must not donate if:**
Donor has taken Pre-Exposure Prophylaxis (PrEP) or Post-Exposure Prophylaxis (PEP) in the previous three months.

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

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

See if Relevant Tissues Safety Entry
HIV
Human Bite
Inoculation Injury

Additional Information

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

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

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

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

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

Reason for Change

This entry was revised to support the implementation of recommendations from the FAIR III report.

Update Information

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

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.

See if Relevant

Surgery
Transfusion

Update Information

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

Prion Associated Diseases

Includes

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 been told that they have been put at increased risk from surgery, transfusion or transplant of tissues or organs.
 - c) Individuals who have been told that they may be at increased risk because a recipient of blood or tissues that they have donated has developed a prion related disorder.
 - d) Recipients of dura mater grafts.

- e) Recipients of corneal, scleral or other ocular tissue grafts.
- f) Recipients of human pituitary derived extracts.
- g) **Since January 1st 1980** Recipients of any allogeneic human tissue.

<i>Discretionary</i>	If the mother has had two or more blood relatives develop a prion-associated disease and, following genetic counselling, they have been informed that they are not at risk, accept. This requires confirmation by a Designated Medical Officer .
<i>See if Relevant</i>	<u>Pituitary Extract - Human</u> <u>Tissue and Cell Allograft Recipients</u> <u>Transfusion</u>
<i>Additional Information</i>	See the <u>Position Statement on Creutzfeldt-Jakob Disease</u> available in the JPAC Document Library.
<i>Reason for Change</i>	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.
<i>Update Information</i>	This is a requirement of the EU Tissue & Cells Directive. This entry was last updated in TDSG-CB Edition 203, Release 21

Psoriasis

<i>Obligatory</i>	Must not donate if: a) Generalized or severe. b) There is a secondary Infection. c) Immunosuppressed.
<i>Discretionary</i>	a) If mild and only using topical treatment, accept. b) If the donor is on immunosuppressive medication, see <u>Immunosuppression</u> entry.
<i>Additional Information</i>	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.
<i>See</i>	<u>Autoimmune Disease</u> <u>Immunosuppression</u>
<i>Reason for Change</i>	Treatment with Etretnate/Neotigason is no longer a reason for deferral. To clarify that if there is no involvement of the tissue to be donated, donation may proceed.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 43.

Pulmonary Embolism

<i>Discretionary</i>	Accept.
<i>See if Relevant</i>	<u>Malignancy</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Pyrexia

Not Related to Travel in Malarious Areas

<i>Obligatory</i>	Must not donate if: Less than two weeks from an episode of pyrexia.
<i>Discretionary</i>	If related to a common cold or other upper respiratory tract infection from which the mother is now recovered or recovering, accept.
<i>See if Relevant</i>	<u>Infection - General</u>
<i>Additional Information</i>	A raised temperature may be a sign of an infection, which could be passed on through a donation. Waiting two weeks from when the temperature returns to normal reduces the risk of infection being transmitted by the donation. There is no evidence that common colds and upper respiratory tract infections can be passed on by donation but it is still necessary to wait until any such infection is obviously getting better before allowing donation.

Related to Travel in Malarious Areas

<i>See</i>	<u>Malaria</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Pyruvate Kinase Deficiency

<i>Obligatory</i>	Must not donate if: Mother and father have symptomatic disease.
<i>Discretionary</i>	Unless mother and father both have symptomatic disease, accept.
<i>Additional Information</i>	This is an autosomal recessive red cell enzyme deficiency that is variable in its severity. This means it only has relevance if both parents have symptomatic disease.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Q Fever

<i>Obligatory</i>	Must not donate.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Rabies

Immunization - Non-exposed

<i>Discretionary</i>	If non-exposed, accept.
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Immunization - Post Exposure

<i>Obligatory</i>

Must not donate until:

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

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

Infection

Obligatory **Must not donate.**

See if Relevant Animal Bite

Update Information This entry was last updated in
TDSG-CB Edition 203, Release 37

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.

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

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

See if Relevant Basal Cell Carcinoma
Immunosuppression
Malignancy

Additional Information Radiation therapy is sometimes used for non-malignant conditions, particularly for some skin conditions. It is often used as a substitute for other treatments that work by suppressing the immune system such as high dose steroids and cytotoxic drugs. More information is likely to be required before a decision can be made as to if an individual can donate. This why a referral to a 'Designated Medical Officer' is required.

Reason for Change Additional discretionary acceptance for basal cell carcinomas and ductal carcinoma in situ of the breast. A link had been added to autoimmune disease, and additional information has been added.

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

Radionuclides

Obligatory **1. Radioactive iodine therapy:**
Must not donate if:

a) For malignancy.

b) Administered in this pregnancy or the preceding six months.

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

See if Relevant Malignancy
Thyroid Disease

Additional Information In general those used for diagnostic purposes are cleared within 24 hours. Some, e.g. radioactive iodine, have long half-lives and affected mothers must not be accepted.

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

Raynaud's Syndrome

<i>Obligatory</i>	Must not donate if: Part of a multisystem disorder.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Recipients of Normal Human Immunoglobulin

<i>See if Relevant</i>	<u>Hepatitis A</u> <u>Immunosuppression</u> <u>Immunoglobulin Therapy</u>
<i>See</i>	<u>Transfusion</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Renal Colic

<i>Obligatory</i>	Must not donate if: a) Symptomatic. b) Under investigation.
<i>See if Relevant</i>	<u>Infection - General</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Respiratory Disease

<i>See if Relevant</i>	<u>Infection - General</u> <u>Steroid Therapy</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Retinitis Pigmentosa

<i>Discretionary</i>	Accept.
<i>See if Relevant</i>	<u>Disabled Mother</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Rheumatic Fever

<i>Discretionary</i>	Accept.
<i>See if Relevant</i>	<u>Infection - Acute</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Rheumatoid Arthritis

<i>Discretionary</i>	If mild and the only treatment is NSAIDs, accept.
<i>See</i>	<u>Autoimmune Disease</u>
<i>Reason for Change</i>	This entry is now linked to 'Autoimmune Disease'.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Ringworm

<i>Obligatory</i>	Must not donate if: On systemic treatment.
<i>Discretionary</i>	If on local treatment only, accept.
<i>See if Relevant</i>	<u>Infection - General</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Rubella

Acute Infection

<i>See</i>	<u>Infection - Acute</u>
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Congenital

<i>Obligatory</i>	Must not donate if: Baby has congenital rubella.
<i>Reason for Change</i>	This is a new entry.

Contact

<i>See</i>	<u>Infectious Diseases - Contact with</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Sarcoidosis

Acute

<i>Obligatory</i>	Must not donate if: a) Not recovered. b) Less than five years from both finishing all treatment and full recovery.
<i>Discretionary</i>	If more than five years since finishing all treatment and full recovery, accept.
<i>Additional</i>	

<i>Information</i>	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.
<i>Reason for Change</i>	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

<i>Obligatory</i>	Must not donate.
<i>Additional Information</i>	Chronic sarcoidosis can cause a range of problems, particularly with the lungs but also with the heart, that may pose risks for a potential donor. The treatments used may also cause immunosuppression. For these reasons people with this condition should not donate.
<i>Reason for Change</i>	'Additional Information' has been added.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 16

Self-Catheterization

<i>Obligatory</i>	Must not donate.
<i>Additional Information</i>	Mothers who need to self-catheterize are likely to have bacteraemia following the procedure. Bacteria in a donation can lead to severe and even fatal reactions.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Sex Worker

<i>Obligatory</i>	Must not donate.
<i>Discretionary</i>	If 3 months or more has elapsed since the donor last received money or drugs for sex, accept
<i>See if Relevant</i>	<u>Addiction and Drug Abuse</u> <u>Hepatitis of Viral Origin</u> <u>HIV</u> <u>HTLV</u> <u>Infection - General</u>
<i>Additional Information</i>	In this context sex is defined as vaginal, oral or anal sex with or without a condom /protective. This guidance presumes that a validated NAT test for HIV, HBV and HCV is negative, if this test is stopped for any reason the guidance will change. If received injectable drugs of addiction for sex, see 'Addiction and Drug Abuse' entry as a 12 month deferral may apply.
<i>Reason for Change</i>	This entry was updated in line with the recommendations of the SaBTO Donor Selection Criteria Review Report published on 23rd July 2017.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 51

Sexually Transmitted Disease

Infected Individual

<i>Obligatory</i>	See: Is there is a specific entry for the disease? Must not donate
<i>Discretionary</i>	If fully treated, at least three months from completion of treatment, accept. Additionally, for gonorrhoea, evidence of a test of cure after treatment is required. This may be a verbal confirmation, provided by the donor.
<i>See if Relevant</i>	<u>Tissues Safety Entry</u> <u>Chlamydia</u> <u>Genital Warts</u> <u>Herpes - Genital</u> <u>Syphilis</u>

Sexual Partner

<i>Obligatory</i>	See: Is there is a specific entry for the disease with which there has been contact? Must not donate if: a) Mother required treatment and it is less than three months since completing that treatment. b) Mother did not require treatment and it is less than three months from the last sexual contact with the infected partner.
<i>Discretionary</i>	a) Donor did not require treatment and it is more than three months since the infected partner has completed treatment, accept. b) Donor required treatment: if fully treated, and if it is at least three months from completion of treatment, accept. Additionally, for gonorrhoea, evidence of a test of cure after treatment is required. This may be a verbal confirmation, provided by the donor. c) If the donor's sexual partner has been diagnosed with chlamydia (except lymphogranuloma venereum, see (b) above), genital warts or genital herpes and the donor is asymptomatic and not undergoing treatment or investigation, accept.
<i>See if Relevant</i>	<u>Tissues Safety Entry</u> <u>Chlamydia</u> <u>Genital Warts</u> <u>Herpes - Genital</u> <u>Syphilis</u>
<i>Additional Information</i>	Guidelines (NICE, BASHH) recommend that current sexual partners of lymphogranuloma venereum (LGV) probable or confirmed individuals should receive testing and empiric treatment with a chlamydial regimen. They can be accepted 3 months after completion of treatment.
<i>Reason for Change</i>	Discretionary' section for 'sexual partner' updated following FAIR III report. Clarification added regarding test of cure for gonorrhoea. 'Additional Information' section added.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 51

Shingles

Affected Individual

<i>See</i>	<u>Herpes Zoster</u>
<i>Reason for Change</i>	The links have been changed for clarity.

Contact

<i>See</i>	<u>Infectious Diseases - Contact with</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Sickle-Cell Trait

<i>Obligatory</i>	Inform Transplant Centre if: Cells are from a baby that has sickle-cell trait.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Skin Disease

<i>Obligatory</i>	Must not donate if: a) The condition is infected or infectious. b) Malignant.
<i>Discretionary</i>	If malignancy was a Basal Cell Carcinoma and treatment is completed, accept.
<i>See if Relevant</i>	<u>Dermatitis</u> <u>Infection - General</u> <u>Malignancy</u> <u>Psoriasis</u>
<i>Reason for Change</i>	Malignancy' has been added to 'Obligatory' and additional links have been included.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Sleeping Sickness

(African Trypanosomiasis)

<i>Obligatory</i>	Must not donate.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Smallpox Immunization

Contacts

<i>Obligatory</i>	Must not donate if: Secondarily inoculated during this pregnancy.
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<i>Discretionary</i>	If no new skin lesions, accept.
<i>Additional Information</i>	Close contacts of vaccinees (household or direct bodily contact) may become secondarily infected from direct skin contact with an infected inoculation site or from virus on clothing, bedding, dressings etc. If infection occurs, a new skin rash, blister or sore appears at the site of contact, which could be anywhere on the body. The rash represents a secondary vaccination site and presents exactly the same potential risk to patients and staff as that of a person who has been intentionally immunized.

Immunized Individual

<i>Obligatory</i>	Must not donate if: Inoculated during pregnancy.
<i>Additional Information</i>	Smallpox immunization is with live virus. We do not want to pass the virus on to people receiving stem cells.
<i>Update Information</i>	This advice is a requirement of the EU Tissue & Cells Directive. This entry was last updated in TDSG-CB Edition 203, Release 02

Snake Bite

<i>Obligatory</i>	Must not donate until: Recovered.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

South American Trypanosomiasis

<i>Obligatory</i>	Must not donate.
<i>See if Relevant</i>	<u>South American Trypanosomiasis Risk</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

South American Trypanosomiasis Risk

<i>Obligatory</i>	Must not donate if: 1) Mother was born in South America or Central America (including Mexico). 2) Mother's mother was born in South America or Central America (including Mexico). 3) Has had a transfusion in South America or Central America (including Mexico). 4) Mother has lived and/or worked in rural subsistence farming communities in these countries for a continuous period of four weeks or more.
<i>Discretionary</i>	1) If at least four months from the date of last exposure, including transfusion abroad, and a validated <i>T. cruzi</i> antibody test is negative, accept. 2) Mother transfused since January 1st 1980: Discuss with the Designated Medical Officer who will decide if the donation may be accepted. The full transfusion history must be recorded and remain part of the documentation.
<i>See if Relevant</i>	<u>Geographical Disease Risk Index</u> for countries with <i>T. cruzi</i> risk <u>Transfusion</u>

<i>Additional Information</i>	Infection with <i>T. cruzi</i> is very common in many parts of South or Central America and is often symptomless. It can be passed from an infected mother to her unborn baby and by transfusion. The insect that passes the infection on is only common in rural areas and the greater time that an individual has spent living in housing conditions with thatched roofs or mud lined walls which harbour the insect vector, the greater their risk of becoming infected. Testing is available and should be performed if there is a possibility of infection. Waiting four months from the last time of exposure allows time for the antibodies that are tested for to develop. Camping or trekking in the jungle in South or Central America (including Mexico) is not considered of high enough risk to merit exclusion.
<i>Reason for Change</i>	To reduce deferral period following last date of exposure from six to four months. To permit individual risk assessment if transfused after 1st January 1980. To also align this entry with the Geographical Disease Risk Index and change the reference to "Southern Mexico" to "Mexico".
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 38.

Spina Bifida

<i>Obligatory</i>	Must not donate if: a) Has an indwelling shunt. b) Uses a catheter. c) Has a pressure sore.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Spinal Surgery

<i>See if Relevant</i>	<u>Neurosurgery</u> <u>Surgery</u> <u>Transfusion</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Splenectomy

<i>Obligatory</i>	Must not donate if: a) For malignancy. b) For a myeloproliferative disorder. c) For immune thrombocytopenia (ITP). d) For haemolytic anaemia.
<i>Discretionary</i>	a) If for trauma, when recovered accept. b) If taking prophylactic antibiotics, accept. c) Discretions are available to accept donors with Haemolytic Anaemia and Immune Thrombocytopenia.
<i>See if Relevant</i>	<u>Immune Thrombocytopenia</u> <u>Malignancy</u> <u>Surgery</u> <u>Transfusion</u>

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

Steroid Therapy

<i>Obligatory</i>	Must not donate if: a) Regularly taking steroid tablets, injections or enemas, or applying creams over large areas. b) The mother has needed treatment to suppress an autoimmune condition in the last 12 months. c) Less than seven days after completing a course of oral or injected steroids for disorders associated with allergy. d) The mother has infected perineal dermatitis
<i>Discretionary</i>	a) If occasional use of creams over small areas of skin for minor skin complaints, accept. b) If using steroid inhalers for prophylaxis, accept. c) The short term administration of steroids to the mother to induce fetal lung maturation is not an exclusion to donation, accept.
<i>See if Relevant</i>	<u>Autoimmune Disease</u> <u>Skin Disease</u> <u>Tissue and Cell Allograft Recipients</u>
<i>Additional Information</i>	Steroid therapy in high doses causes immunosuppression. This may mask infective and inflammatory conditions that would otherwise prevent donation. <i>There is no evidence that the short-term use of steroids to induce fetal lung maturation can mask or increase the risk of maternal infection.</i>
<i>Reason for Change</i>	To allow mothers who receive short term administration of steroids to induce fetal lung maturation to donate.
<i>Update Information</i>	Part of this advice is a requirement of the EU Tissue & Cells Directive. This entry was last updated in TDSG-CB Edition 203, Release 02

Stroke

<i>Discretionary</i>	Accept.
<i>See if Relevant</i>	<u>Disabled Mother</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Surgery

<i>Definition</i>	Major Surgery: Any surgical procedure resulting in an inability to return to normal activities of daily living (e. g. routine housework, previous employment and/or driving) for six months or more.
<i>Obligatory</i>	Must not donate if: a) For malignancy. b) All wounds are not healed. c) There is any infection. d) Normal mobility has not been regained.

- e) Less than six months from major surgery.
- f) Less than seven days from other surgery.
- g) Requiring post-operative treatment, or attending hospital regularly.

Discretionary 1. If for Cervical Carcinoma in Situ (CIN) or Basal Cell Carcinoma and all other criteria are fulfilled, accept.

If less than six months from major surgery or less than seven days from other surgery, discuss with the **Designated Medical Officer** who will decide if the mother may be accepted on a balance of risks.

See if Relevant Basal Cell Carcinoma
Cervical Carcinoma in Situ
Complementary therapy
Neurosurgery
Ocular Surgery
Tissue and Organ Recipients
Transfusion
Xenotransplantation

Additional Information Surgery may place the mother at risk of infection, either from unhealed wounds or due to infection risks from infected staff or equipment. Although these risks are very small it is important to wait long enough for the risks to have gone.

Reason for Change To align the 'Obligatory' and 'Discretionary' entries.

Update Information This entry was last updated in
TDSG-CB Edition 203, Release 41

Syphilis

1. Affected Individual

Obligatory **Must not donate.**

Discretionary If fully treated in the past and confirmatory tests exclude recent infection, discuss with a **Designated Medical Officer**.

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

2. Current or Former Sexual Partner of Affected Individual

Obligatory **Must not donate if:**
a) The potential donor was diagnosed with syphilis (see 'Affected Individual' section above).
b) It is less than three months since last sexual contact with an infected partner.

Discretionary a) If it is more than three months from the last sexual contact with an infected partner, accept.
b) If it is more than three months since an infected partner has completed treatment, accept.

See if Relevant Tissues Safety Entry

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

Update Information This entry was last updated in
TDSG-CB Edition 203, Release 51

Systemic Lupus Erythematosus

Obligatory **Must not donate.**

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

Tamoxifen

Obligatory See Malignancy entry.

Discretionary If taken for non-malignant conditions, accept.

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

Update Information This entry was last updated in
TDSG-CB Edition 203, Release 38.

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-CB 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-CB Edition 203, Release 02

Threadworms

Discretionary Even if on treatment, accept.

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

Thrombocytosis

Obligatory **Must not donate if:**

	Due to a myeloproliferative disorder.
<i>Additional Information</i>	Platelet counts in excess of 500 x 10e9/l should be repeated. If found to be persistently raised the donor should not be accepted and referred for investigation.
<i>Reason for Change</i>	This entry has been added to clarify the eligibility of donors with this condition.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Thrombosis

<i>Discretionary</i>	If the underlying cause does not exclude, accept.
<i>See if Relevant</i>	<u>Malignancy</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Thrush - Oral

<i>Obligatory</i>	Must not donate if: a) Unexplained. b) Related to immunodeficiency.
<i>See if Relevant</i>	<u>Infection: Chronic</u>
<i>Reason for Change</i>	This entry has been revised to link discretionary acceptance to the current 'Infection: Chronic' entry.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 41

Thrush - Vaginal

<i>Obligatory</i>	Must not donate if: a) Related to immunodeficiency.
<i>See if Relevant</i>	<u>Infection: Chronic</u>
<i>Reason for Change</i>	This entry has been revised to link discretionary acceptance to the current 'Infection: Chronic' entry.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 41

Thyroid Disease

<i>Obligatory</i>	Must not donate if: a) Under investigation. b) Malignant. c) Radioactive iodine administered in this pregnancy or the preceding six months. d) Less than 24 months from stopping treatment with anti-thyroid tablets.
<i>See if Relevant</i>	<u>Autoimmune disease</u>

	<u>Surgery</u>
<i>Reason for Change</i>	The reference in 'Discretionary' to treatment with thyroxine has been removed.
	A link to 'Autoimmune Disease' has been added.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Tissue and Cell Allograft Recipients

<i>Excludes</i>	Xenograft recipients, recipients of biological grafts of non-human origin and bio-prosthetic grafts and organ recipients.
<i>Obligatory</i>	All donors: Must not donate if: a) Dura mater transplanted at any time. b) Ocular tissue transplanted at any time. c) Any other allogeneic human tissue or cell transplanted since 1st January 1980, refer to DCSO.
<i>Discretionary</i>	a) If an autologous tissue, or cells, has been transplanted at any time, and there is no other reason to exclude the donor, accept. b) If an allogeneic tissue (except dura mater or ocular tissue) or cell transplant was performed before 1st January 1980, and there is no other reason to exclude the donor, accept.
<i>See if Relevant</i>	<u>Immunosuppression</u> <u>Ocular Tissue Recipient</u> <u>Organ recipient</u> <u>Prion Associated Diseases</u> <u>Surgery</u> <u>Transfusion</u> <u>Xenotransplantation</u>
<i>Additional Information</i>	The transfer of tissues or cells between individuals has led to the spread of infection. The above guidelines are intended to minimise these risks. People who have received a tissue or cell transplant since 1980 are normally excluded from donation as a precautionary measure against the risk of transmission of vCJD in the same way as recipients of transfusion are. The DCSO 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 Dura mater and ocular tissue allografts have been implicated in iatrogenic CJD. Iatrogenic CJD refers to the transmission of prions via inadvertent medical exposure. Recipients of dura mater and ocular tissue recipients are excluded. Dura mater use stopped in the UK by 1993. The situation in other countries varied so specific dates cannot be given.
<i>Reason for Change</i>	This is a new entry.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 50

Tissue and Organ Recipients

<i>Obligatory</i>	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: Refer to a Designated Medical Officer if the mother has received an allogeneic tissue transplant.
<i>Discretionary</i>	a) If an allogeneic tissue or cell transplant was performed before January 1st 1980 and there is no other reason to exclude the donor, accept. b) If at anytime an autologous tissue, or cells, has been transplanted, accept.
<i>See if Relevant</i>	<u>Immunosuppression</u> <u>Ocular Tissue Recipient</u> <u>Prion Associated Diseases</u> <u>Xenotransplantation</u>
<i>Additional Information</i>	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 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.
<i>See</i>	<u>Surgery</u> <u>Transfusion</u>
<i>Reason for Change</i>	To clarify that transplantation of an autologous tissue, or cells, is not a contra-indication to donation, whether or not the tissue, or cells, were stored prior to transplantation.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 27

Tissues Safety Entry

<i>Definition</i>	Individual risk is based on the donor's sexual behaviour, including new partners and the number of partners in the 3 months prior to donation. Partner risk is based on sexual contact with a partner who may, at a population level, be at higher risk of acquiring infection, as described in this entry. Sexual contact is defined as oral, vaginal or anal sex. Anal sex is defined as penile-anal intercourse only. It does not apply to oro-anal sex or the use of sex toys. Chemsex is sex while using stimulant drugs taken for the specific purpose of enhancing sexual experience and reducing inhibitions. Chemsex does not refer to sex after using alcohol or recreational drugs for other purposes, nor the use of drugs such as Viagra or Cialis to treat erectile dysfunction.
<i>Obligatory</i>	Information must be provided so that those at risk do not donate.

1. You must not donate if:

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

2. You must never donate if:

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

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

After stopping habitual use of injected drugs of addiction.

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

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

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

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

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

6. Individual risk criteria (FAIR):**You must not donate for at least 3 months if:**

- a) You have taken part in chemsex activity, including the use of stimulant drugs. This risk applies for all sexual contact.
- b) You have been diagnosed with gonorrhoea. You must wait for at least three months after you have successfully completed treatment and been discharged from further follow up.
- c) You have had more than one sexual partner in the last 3 months AND you have had anal sex with any of these partners.
- d) You have had anal sex with a new sexual partner. For the purpose of donor selection, a new partner is someone that you have not had sex with before or a previous partner with whom you have restarted a sexual relationship in the last 3 months.

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

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

A partner who is, or you think may be:

- a) HIV or HTLV positive
- b) A hepatitis B carrier
- c) A hepatitis C carrier
- d) A partner who has received money or drugs for sex
- e) A partner who has injected, or been injected with non-prescription drugs. This includes, for example, bodybuilding drugs or injected tanning agents. You may be able to give if a doctor prescribed the drugs, please ask.

See if Relevant

Addiction and Drug Abuse
Hepatitis B
Hepatitis C
Hepatitis of Viral Origin
HIV
HTLV
Infection - General
Pre- or Post-Exposure Prophylaxis for HIV
Sexually Transmitted Disease
Syphilis

Additional Information

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

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

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

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

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

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

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

<i>Reason for Change</i>	The entry was revised to include individual risk assessment of recent sexual behaviour for all donors. The deferral for donors whose sexual partners have been sexually active in Sub-Saharan Africa has been removed. This supports implementation of recommendations from the FAIR III Report.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 51

Toxoplasmosis

<i>Obligatory</i>	Must not donate if: a) Maternal recovery less than six months before this pregnancy.
<i>Additional Information</i>	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 led to it being diagnosed, waiting six months from recovery will make it unlikely that it will be passed on by donation. A cord blood bank might undertake testing for toxoplasma, usually in the form of serological testing of the maternal donor. This is not a mandatory test, however it is recommended by SaBTO. The donation should not be released for clinical use if IgM positive.
<i>Reason for Change</i>	To clarify that testing is not mandatory and that absence of a test is not a cause for deferral.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 41

Transfusion

<i>Includes</i>	Treatment with Blood Components, Products and Derivatives.
<i>Obligatory</i>	1. Must not donate if: At any time the mother has: a) Received, or thinks they may have received, a transfusion of blood or blood components in a country endemic for malaria or South American trypanosomiasis. See 'Discretionary' section below for exceptions.

b) Has received regular treatment with blood derived coagulation factor concentrates.

c) Intra-uterine transfusion has been required in this pregnancy.

2. Since January 1st 1980:

a) Anywhere in the world, the mother has received, or thinks they may have received, a transfusion of blood or blood components, or intravenous or subcutaneous human normal immunoglobulin. This includes mothers whose babies have required intra-uterine transfusion.

b) Had a plasma exchange performed.

3. Before January 1st 1999:

Treated with prothrombin complex to reverse over-anticoagulation.

Discretionary

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

b) Received, or thinks they may have received, a transfusion of blood or blood components before 1st Jan 1980, accept – See 3 below if transfused abroad

c) If treatment with human immunoglobulin has been limited to small quantities of specific immunoglobulin as prophylaxis (e.g. rhesus, tetanus, hepatitis, immunoglobulin etc.), accept.

d) Treated with prothrombin complex (PCC) to reverse over-anticoagulation after 1st January 1999, accept.

2. Autologous Transfusion:

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

3. Mother transfused in a country endemic for malaria or South American trypanosomiasis:

a) Check the Geographical Disease Risk Index. If transfused in an at risk endemic country and a validated malarial antibody test and/or (as appropriate) a validated test for T.cruzi antibody is negative, at least 4 months after exposure accept. If transfusion happened after January 1st 1980, see point 4 below.

4. Mother transfused since January 1st 1980:

Discuss with the Designated Medical Officer who will decide if the donation may be accepted. The full transfusion history must be recorded and remain part of the documentation.

See if Relevant

Bleeding Disorder
Immunoglobulin Therapy
Immunosuppression
Malaria
Prion Associated Diseases
South American Trypanosomiasis Risk
Geographical Disease Risk Index

Additional Information

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

All transfused mothers:

Transfusions in some countries may have put the donor at risk of malaria or South American trypanosomiasis. It is necessary to exclude these infections before accepting the donation.

Coagulation concentrates:

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

Mothers transfused since 1980:

In the autumn of 2003 a UK recipient of blood, taken from a healthy donor who later developed vCJD, died from vCJD. Since then there has been a very small number of cases of infection with the vCJD prion in recipients of blood from donors who have later developed vCJD. The risk of transplacental infection of a foetus with abnormal prion is not known but, even though it is thought to be small, cannot be ignored.

In view of this, mothers transfused or possibly transfused since 1980 should not normally be accepted. Any history of transfusion after 1980 must be recorded and remain part of the documentation associated with the donation.

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

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

<i>Reason for Change</i>	I) To remove information only relevant to deceased tissue donors. II) To update guidance relating to South American Trypanosomiasis risk. III) To add guidance relating to mothers transfused since January 1st 1980. IV) To harmonise the definition of what constitutes a transfusion. V) Ensure consistent use of the term 'mother' rather than 'donor'.
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<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 38.
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Travel

<i>See if Relevant</i>	<u>Geographical Disease Risk Index</u> <u>Malaria</u> <u>South American Trypanosomiasis Risk</u> <u>Infection - Tropical</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Tropical Viruses

<i>Definition</i>	Tropical Virus endemic areas are shown in the Geographical Disease Risk Index (GDRI) as a Tropical Virus Risk.
<i>Obligatory</i>	Must not donate if: a) A mother has been diagnosed with Chikungunya, Dengue, Yellow Fever or Zika virus infection whilst in an endemic area or following her return to the UK during this pregnancy. b) A mother has either had a history of symptoms suggestive of Chikungunya, Dengue, Yellow Fever or Zika virus infection whilst in an endemic area or following her return to the UK during this pregnancy. c) In other cases it is less than four weeks from a mother's return from a Tropical Virus Risk endemic area.
<i>See if Relevant</i>	<u>Geographical Disease Risk Index</u> <u>Malaria</u> <u>South American Trypanosomiasis Risk</u> <u>Infection - Tropical</u>
<i>Additional Information</i>	Chikungunya is an alpha virus that can cause a wide spectrum of disease. This may range from no or minimal symptoms to death. Most commonly it causes arthritis (typically in the

knee, ankle and small joints of the extremities), high fever and a maculopapular rash.

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

Dengue Virus is a flavivirus that typically gives rise to abrupt high fever with a range of accompanying symptoms. Dengue fever (DF) is the most common arthropod borne disease worldwide. Dengue is currently considered endemic in approximately 128 countries.

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

Yellow Fever Virus is a Flavivirus. Symptoms of Yellow Fever include high temperature, headache, nausea and vomiting, muscle pains and backache. One in four individuals may suffer from jaundice and bleeding from the gastrointestinal tract and other sites.

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

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

Position statements are available in the JPAC Document Library.

<i>Information</i>	This entry is compliant with the Blood Safety and Quality Regulations 2005.
<i>Reason for Change</i>	The scope of this entry has been extended to include Yellow Fever.
<i>Update Information</i>	This entry was last updated in: TDSG-CB Edition 203, Release 44.

Trypanosoma Cruzi Infection

<i>Obligatory</i>	Must not donate.
<i>See if Relevant</i>	<u>South American Trypanosomiasis Risk</u>
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Tuberculosis

Affected Individual

<i>Obligatory</i>	Must not donate if:
	a) Infected.
	b) Less than 24 months from completing treatment.
	c) Under follow-up.

- Discretionary* a) If mother with a history of tuberculosis or latent tuberculosis has been successfully treated, with treatment being completed at least 24 months previously, been discharged from follow up, and has remained well and asymptomatic – accept.
- b) Mothers with a diagnosis of latent tuberculosis currently not undergoing investigation, or more than 7 days after completion of treatment: refer to DCSO for individual risk assessment.

See if Relevant BCG
Heaf Test
Mantoux Test

Contact

Obligatory **Must not donate until:**
Screened and cleared.

Discretionary If the mother 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 mothers who may have active disease from donating to prevent any possibility of transmitting the infection.

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

Reason for Change To provide clarity that 24 month deferral is following completion of treatment, rather than confirmation of cure. To provide information and guidance regarding latent tuberculosis.

Update Information This entry was last updated in
TDSG-CB Edition 203, Release 50

Turner's Syndrome

Discretionary Accept.

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

Vasculitis

Obligatory **Must not donate.**

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

Viral Haemorrhagic Fever

Includes

Crimean-Congo Fever
Ebola Virus Disease
Lassa Fever
Marburg Fever

1. Affected Individual

Obligatory **Must not donate if:**
a) Has ever been infected

2. Contact or traveller to endemic country

Obligatory **Must not donate if:**
a) Was present in an area during an active outbreak

b) Under investigation for viral haemorrhagic fever

c) Has been in contact with an individual who was present in an area during an active outbreak

d) Was in contact with an individual infected with, or was under investigation for viral haemorrhagic fever

e) less than six months after return to UK from an endemic area when there was no active outbreak

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

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

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

3. Sexual Partner of Affected Individual

Obligatory **Must not donate:**
If the donor has had sex with an individual who had been diagnosed with a Viral Haemorrhagic Fever at any time before their last sexual contact.

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

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

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

There is evidence of persistent virus in individuals who recover from several forms of Viral

Haemorrhagic Fever. For this reason, it is necessary to defer the sexual partners of these individuals.

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

Update Information This entry was last updated in
TDSG-CB Edition 203, Release 37

Vitamin Treatment

Discretionary Accept.

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

Warts

Discretionary Even if on local treatment, accept.

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

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

Reason for Change 'Additional Information' section added following FAIR III report.

Update Information This entry was last updated in
TDSG-CB Edition 203, Release 51

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 WNV 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-CB Edition 203, Release 21.

Whooping Cough

Contact

See Infectious Diseases - Contact with

Infection

See Infection - Acute

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

Wilson's Disease

Discretionary Accept.

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

Xenotransplantation

Includes Xenografts
Heterografts
Non-Human Organ Perfusion

Recipient

Definition Any procedure that involves the transplantation, implantation, or infusion into a human recipient of either (a) live cells, tissues, or organs from a non-human animal source, or (b) human body fluids, cells, tissues, or organs that have had ex vivo contact with live, non-human animal cells, tissues, or organs.
Xenotransplantation products include live cells, tissues and organs.

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

<i>Obligatory</i>	Must not donate if: Material from a living non-human animal source has been directly or indirectly in contact with the mother's blood supply. This does not include animal bites.
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Sexual Partners of Xenotransplant Recipients, Current and Former

<i>Obligatory</i>	Must not donate.
<i>Additional Information</i>	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.
<i>Reason for Change</i>	Further guidance re Recipient definition
<i>Update Information</i>	This advice is a requirement of the EU Tissue & Cells Directive. This entry was last updated in TDSG-CB Edition 203, Release 23

XMRV

<i>Discretionary</i>	Donors who have been tested positive for XMRV, accept.
<i>Additional Information</i>	As there is no evidence that XMRV is implicated in human disease, a positive test is not a bar to donation.
<i>Reason for Change</i>	This is a new entry.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 11 Issue 01

Yaws

<i>Obligatory</i>	Must not donate.
<i>Update Information</i>	This entry was last updated in TDSG-CB Edition 203, Release 02

Updates

Specification of Current Version		
Publication	CB-DSG	
Edition	203	
Release	55	
Issue	01	30 April 2025

All changes to CB-DSG Edition 203 after Release 01

Release	Date	Change Notifications	
		Title	CN No.
55	30 April 2025	Appendix 3 - Table of Immunisations	<u>09 - 2025</u>
54	18 April 2024	Coronavirus Vaccination	<u>10 - 2024</u>
53	29 January 2024	Eye Disease	<u>35 - 2023</u>
52	15 November 2023	Coronavirus Infection (COVID-19)	<u>33 - 2023</u>
51	15 November 2023	Changes arising from the FAIR III report	<u>17 - 2023</u>
50	04 July 2023	Tuberculosis	<u>25 - 2023</u>
		Tissue and Cell Allograft Recipients	<u>14 - 2023</u>
49	12 April 2023	Mpox (Monkeypox)	<u>13 - 2023</u>
48	13 December 2022	Infectious Diseases - Contact With	<u>52 - 2022</u>
		Coronavirus Infection (COVID-19)	<u>51 - 2022</u>
47	12 September 2022	Table of Immunisations	<u>55 - 2022</u>
46	31 May 2022	Monkeypox	<u>41 - 2022</u>
		Malaria	<u>37 - 2022</u>
		Animal Bite	<u>35 - 2022</u>
45	26 April 2022	Tropical Viruses	<u>21 - 2022</u>
44	08 April 2022	Coronavirus Infection	<u>30 - 2022</u>
43	16 March 2022	Disease of Unknown Aetiology	<u>17 - 2022</u>
		Cervical Dysplasia	<u>16 - 2022</u>
		Body Piercing	<u>15 - 2022</u>
		Psoriasis	<u>14 - 2022</u>
		Infertility	<u>13 - 2022</u>
42	22 February 2022	Complementary Therapy	<u>04 - 2022</u>
41	04 August 2021	Toxoplasmosis	<u>31 - 2021</u>
		Thrush - Oral ® Vaginal	<u>30 - 2021</u>
		Surgery	<u>29 - 2021</u>
		Infertility	<u>27 - 2021</u>
		Immunisation	<u>26 - 2021</u>
		Coronavirus Infection	<u>22 - 2021</u>
		Colitis, Proctitis and Gastrointestinal Disease	<u>20 - 2021</u>
		Acne and Teratogenic Medication	<u>19 - 2021</u>
40	21 January 2021	COVID-19 Vaccination	<u>05 - 2021</u>
39	16 December 2020	COVID-19 Vaccination	<u>74 - 2020</u>
38	07 October 2020	Sexually Transmitted Disease	<u>61 - 2020</u>
		Transfusion	<u>45 - 2020</u>
		South American Trypanosomiasis	<u>44 - 2020</u>
		Infection - Chronic	<u>43 - 2020</u>
		Tamoxifen	<u>42 - 2020</u>

37	15 July 2020	Infection - Acute	<u>41 - 2020</u>
		Tamiflu® and Relenza®	<u>40 - 2020</u>
		Viral Haemorrhagic Fever	<u>38 - 2020</u>
		Rabies	<u>37 - 2020</u>
		Animal Bite	<u>36 - 2020</u>
36	08 June 2020	Coronavirus Infection	<u>31 - 2020</u>
35	23 March 2020	Coronavirus Infection	<u>17 - 2020</u>
34	24 February 2020	Coronavirus Infection	<u>10 - 2020</u>
33	17 February 2020	Coronavirus Infection	<u>08 - 2020</u>
32	24 January 2020	Coronavirus Infection	<u>05 - 2020</u>
31	30 September 2019	Sexually Transmitted Disease	<u>23 - 2019</u>
		Malignancy	<u>22 - 2019</u>
		Inflammatory Bowel Disease	<u>20 - 2019</u>
		Hepatitis C	<u>19 - 2019</u>
		Complementary Therapy	<u>17 - 2019</u>
		Viral Haemorrhagic Fever	<u>15 - 2019</u>
		Tissue Safety Entry	<u>14 - 2019</u>
		Pre- and Post-Exposure Prophylaxis for HIV	<u>13 - 2019</u>
		Hepatitis A	<u>12 - 2019</u>
30	26 September 2018	Infection - Chronic	<u>28 - 2018</u>
		Infection - Acute	<u>26 - 2018</u>
29	24 April 2018	Viral Haemorrhagic Fever	<u>15 - 2018</u>
		Transfusion	<u>14 - 2018</u>
		Pregnancy	<u>11 - 2018</u>
		Hepatitis E	<u>10 - 2018</u>
		Hepatitis A	<u>09 - 2018</u>
		Haemoglobin Disorders	<u>08 - 2018</u>
		Glycogen Storage Disease	<u>06 - 2018</u>
		G6PD Deficiency	<u>05 - 2018</u>
		Central Nervous System Disease	<u>04 - 2018</u>
28	17 February 2018	Poisoning	<u>01 - 2018</u>
27	27 November 2017	Bleeding Disorder	<u>50 - 2017</u>
		Syphilis	<u>48 - 2017</u>
		Sex Worker	<u>46 - 2017</u>
		Inoculation Injury	<u>43 - 2017</u>
		HTLV	<u>42 - 2017</u>
		HIV	<u>38 - 2017</u>
		Hepatitis C	<u>36 - 2017</u>
		Hepatitis B	<u>34 - 2017</u>
		Complementary Therapy	<u>32 - 2017</u>
		Body Piercing	<u>30 - 2017</u>
		Addiction and Drug Abuse	<u>28 - 2017</u>
		Tissue Safety Entry	<u>27 - 2017</u>
		Surgery	<u>24 - 2017</u>
		Tissue and Organ Recipients	<u>23 - 2017</u>
		Radiation Therapy	<u>22 - 2017</u>
26	01 August 2017	Malaria	<u>17 - 2017</u>
25	24 February 2017	Kidney Stones	<u>07 - 2017</u>
24	10 October 2016	Hepatitis A	<u>46 - 2016</u>

23	13 July 2016	Xenotransplantation	<u>29 - 2016</u>
		Severe Exercise Intolerance Disease (SEID)	<u>28 - 2016</u>
		Endoscopy	<u>24 - 2016</u>
22	02 February 2016	Viral Haemorrhagic Fever	<u>15 - 2016</u>
		Tropical Viruses	<u>13 - 2016</u>
21	18 January 2016	Viral Haemorrhagic Fever	<u>11 - 2016</u>
		West Nile Virus	<u>09 - 2016</u>
		Tropical Viruses	<u>07 - 2016</u>
		Table of Immunisations	<u>04 - 2016</u>
20	23 June 2015	Injectable Tanning Agents	<u>15 - 2015</u>
		Complementary Therapy	<u>12 - 2015</u>
19	17 March 2015	Infertility	<u>09 - 2015</u>
		Complementary Therapy	<u>08 - 2015</u>
		Communications Difficulties	<u>07 - 2015</u>
18	20 October 2014	Viral Haemorrhagic Fever	<u>43 - 2014</u>
17	11 August 2014	Homosexual and Bisexual Individuals	<u>35 - 2014</u>
		Steroid Therapy	<u>33 - 2014</u>
		Tissue Safety Entry	<u>32 - 2014</u>
		SARS	<u>31 - 2014</u>
		Haematological Disease	<u>30 - 2014</u>
16	31 March 2014	Paratyphoid and Typhoid	<u>15 - 2014</u>
		South American Typanosomiasis	<u>14 - 2014</u>
		Sarcoidosis	<u>13 - 2014</u>
		Mental Health Problems	<u>12 - 2014</u>
		Malignancy	<u>11 - 2014</u>
		Kidney Disease	<u>10 - 2014</u>
		Infection - Acute	<u>09 - 2014</u>
		Hepatitis of Unknown Origin	<u>08 - 2014</u>
		Hepatitis B	<u>07 - 2014</u>
		Hepatitis B - Post Immunisation	<u>06 - 2014</u>
		Central Nervous System Disease	<u>05 - 2014</u>
		Body Piercing	<u>04 - 2014</u>
		Aliretinoin, Toctino, Acne and Dermatitis	<u>03 - 2014</u>
		Acupuncture	<u>02 - 2014</u>
15	09 July 2013	Infection - Chronic	<u>10 - 2013</u>
		Hepatitis B - Post Immunisation	<u>09 - 2013</u>
		Hepatitis B	<u>08 - 2013</u>
14	04 June 2013	West Nile Virus	<u>10 - 2013</u>
13	Issue 02		
	29 June 2012	Fertility Treatment - entry replaced with link to Fertility	
	Issue 01		
	29 June 2012	Toxoplasmosis	<u>18 - 2012</u>
		Psoriasis	<u>17 - 2012</u>
		Acne	<u>15 - 2012</u>
12	28 March 2012	West Nile Virus	<u>05 - 2012</u>
11	24 January 2012	Hepatitis C	<u>27 - 2011</u>
		XMRV	<u>25 - 2011</u>
10	06 December 2011	Porphyria	<u>20 - 2011</u>
09	08 August 2011	West Nile Virus	<u>11 - 2011</u>

08	21 June 2011	Sexually Transmitted Disease	<u>09 - 2011</u>
		Infertility	<u>08 - 2011</u>
07	01 September 2010	West Nile Virus	<u>09 - 2010</u>
06	03 March 2010	Inoculation Injury	<u>04 - 2010</u>
		Endoscopy	<u>03 - 2010</u>
		Body Piercing	<u>02 - 2010</u>
05	24 December 2009	Complementary Therapy	<u>35 - 2009</u>
		Acupuncture	<u>33 - 2009</u>
04	01 December 2009	Relenza® (Oseltamivir)	<u>31 - 2009</u>
		Tamiflu® (Zanamivir)	<u>30 - 2009</u>
03	21 January 2008	Bleeding Disorder	<u>18 - 2007</u>
		<i>A change was made to the version control definitions and all Issue numbering information removed.</i>	
02	11 December 2007	Public release – for changes see <u>Appendix 1 - Changes to the Guidelines</u>	
01	01 June 2007	Consultation release – not for implementation	

Appendix 1 - Changes to Donor Selection Guidelines

Section 1

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

There have been changes made to the following entries:

Acupuncture
 Animal Bite
 Ankylosing Spondylitis
 Anti-Androgens
 Antibiotic Therapy
 Antidepressant Therapy
 Arthritis
 Autoimmune Disease
 Bipolar Disorder
 Bleeding Disorder
 Cardiomyopathy
 Cardiovascular Disease
 Chikungunya Virus
 Chlamydia
 Cirrhosis
 Colitis
 Communication Difficulties
 Depression
 Disabled Donor
 Disease of Unknown Aetiology
 Ehlers-Danlos Syndrome (Disease)
 Elliptocytosis
 Endocarditis
 Endoscopy
 Episcleritis
 Eye Disease
 Gall Bladder Disease
 German Measles
 Haemoglobin Disorders
 Haemolytic Anaemia
 Hepatitis B
 Hepatitis B - Post Immunization
 Hepatitis C
 Hepatitis of Unknown Origin
 Hereditary Elliptocytosis
 Hormone Replacement Therapy
 Immune Thrombocytopenia
 Immunoglobulin Therapy
 Immunosuppression
 Infection - Acute
 Infection - Chronic
 Inflammatory Eye Disease
 Inoculation Injury
 Jaundice
 Mental Health Problems
 Myeloproliferative Syndrome
 Pituitary Extract - Human
 Platelet Disorder
 Polymyalgia Rheumatica
 Prion Associated Diseases
 Psoriasis
 Rheumatoid Arthritis
 Scleritis
 Sexually Transmitted Disease
 Shingles
 Skin Disease
 Steroid Therapy
 Subacute Bacterial Endocarditis
 Surgery
 Syphilis
 Temporal Arteritis
 Thrombocytosis
 Thyroid Disease
 Tigason

Tissue and Organ Recipients
Transfusion
West Nile Virus

Section 2
Changes to TDSG-CB 203 after Release 02

See: [Latest Updates](#)

This appendix was last updated in TDSG-CB 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 cord blood has been taken. For the purposes of these guidelines, these circumstances are categorised below, along with appropriate actions. The action to be taken will be determined by any **A-Z** entry relevant to the safety of the recipient. If there is no relevant entry, a consideration of recipient safety will underlie the action taken.

Procedures must be maintained by all Services to ensure prompt reporting of late donation information and, if necessary, withdrawal of donated cord blood. 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 stem cell transplant, contacting the clinician caring for the recipient and discussing notification of the recipient.

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 mother at risk of infection with blood borne organisms (**Tissues Safety Entry**).
- b) Mothers in the 'at risk' categories relating to possible transmission of **Prion Associated Diseases** e.g. CJD and vCJD.
- c) Mothers with **Malignancy** (other than those for which there is a discretion in the **A-Z**)
- d) **Autoimmune Disease**.
- e) Mothers 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.
- f) Mothers with diseases of unknown aetiology.

Action: Inform the **Designated Medical Officer**.

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

Appendix 3 - Table of Immunisations

Diseases Protected against	Comments and example trade names of adult preparations	
Anthrax	Rarely given	<u>Non-Live</u>
Cholera	There are two vaccines available to prevent cholera: Dukoral® and Vaxchora®; see rows below. Ensure the correct guidance is applied depending on the vaccine given. If vaccine name not certain, treat as a Live vaccine.	
	Vaxchora®	<u>Live</u>
	Dukoral®	<u>Non-live</u>
COVID-19 (SARS-CoV-2)	All COVID-19 vaccines licensed in the UK are Non-Live.	<u>Non-Live</u>
Dengue	Qdenga®, Dengvaxia®	<u>Live</u>
Haemophilus influenza type b (Hib)	Menitorix®	<u>Non-Live</u>
Hepatitis A	May be combined with typhoid or hepatitis B. Hepatitis A only: Vaqta®, Avaxim®, Havrix® Combined with typhoid: ViATIM® Combined with hepatitis B: Ambirix®, Twinrix®	<u>Non-Live</u>
Hepatitis B	May be combined with hepatitis A. If unexposed and more than 7 days from last immunisation, accept. See: <u>Hepatitis B – Immunisation</u> Engerix®, Fendrix®, HBvaxPRO®, PreHevBri®, Ambirix®, Twinrix®	<u>Non-Live</u>
Human papillomavirus (HPV)	Cervarix®, Gardasil®	<u>Non-Live</u>
Influenza, intra-nasal	Live vaccine given by intra-nasal spray, age 2-18. Fluenz Tetra®	<u>Live</u>
Influenza, injection	Annual 'flu jab', given by injection. Several preparations, updated annually.	<u>Non-Live</u>
Japanese Encephalitis	Travel. Ixiaro®	<u>Non-Live</u>
Measles, Mumps, Rubella	MMR vaccines. M-M-RvaxPro®, Priorix®	<u>Live</u>
Meningitis	Meningococcal group C: NeisVac-C®, Menjugate Kit® Meningococcal group B: Bexsero®, Trumenba® MenACWY Quadrivalent vaccine: Menveo®, Nimenrix®, MenQuadfi® Combined with <i>H. influenzae</i> type b (Hib): Menitorix®	<u>Non-Live</u>
Mpox (formerly known as Monkeypox)	Imvanex® / MVA-BN is a live attenuated non-replicating Smallpox vaccine. It may be used for pre-exposure Mpox prophylaxis in healthcare workers or for post-exposure prophylaxis in contacts of Mpox cases. If given for Mpox vaccination, treat as a non-live vaccine. See DSG entry for <u>Mpox</u>	<u>Non-Live</u>
Pertussis	Usually pregnant women, given in combination with Diphtheria, Tetanus and Polio vaccine or in combination with Diphtheria and Tetanus vaccine.	<u>Non-Live</u>
Pneumococcal disease	Given to people with specific risks: for example, people who have had a splenectomy or people over 65. Pneumovax®23	<u>Non-Live</u>
Polio, injected	Given in combination with other vaccines including, depending on the preparation,	<u>Non-Live</u>

	Diphtheria, Tetanus, Pertussis and Haemophilus influenzae.	
Polio, oral	Not in routine use in UK. May be used abroad	<u>Live</u>
Rabies	Given to non-exposed individuals if occupation or activity has an exposure risk, or for some travellers to endemic areas. Rabipur [®] , Verorab [®]	<u>Non-Live</u>
Respiratory Syncytial Virus (RSV)	Abrysvo [®] , Arexvy [®]	<u>Non-Live</u>
Shingles	There are two vaccines available to prevent shingles: Zostavax[®] and Shingrix[®]; see rows below. Please note, Shingrix [®] has replaced Zostavax [®] in the UK vaccination programme for individuals aged 60-79 years.	
	Zostavax[®] for shingles prevention	<u>Live</u>
	Shingrix [®] for shingles prevention	<u>Non-Live</u>
Smallpox	Note this live vaccine requires an 8-week deferral. If given, see DSG entry for <u>Smallpox Immunisation</u>. See also Mpox (above).	<u>Live</u>
Tetanus	Given in preparation with other vaccines including, depending on the preparation, Diphtheria, Tetanus, Pertussis and Haemophilus influenzae.	<u>Non-Live</u>
Tick-borne encephalitis (TBE)	TicoVac [®]	<u>Non-Live</u>
Tuberculosis	BCG vaccine	<u>Live</u>
Typhoid, injected	Typhim Vi [®] Combined with hepatitis A: ViATIM [®]	<u>Non-Live</u>
Typhoid, oral	Given in capsule form. Vivotif[®]	<u>Live</u>
Varicella (chickenpox)	Usually given to healthcare workers. Varilrix[®], Varivax[®]	<u>Live</u>
Yellow Fever	Stamaril[®]	<u>Live</u>