JPAC Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee

Bone Marrow and Peripheral Blood Stem Cell Donor Selection Guidelines (BM-DSG)

Edition 203 - 01 June 2007

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Issue 01

Introduction

The **Bone Marrow and Peripheral Blood Stem Cell Donor Selection Guidelines for Unrelated Donors** form a constituent part of Chapter 22 of the Guidelines for the Blood Transfusion and Tissue Transplantation Services in the UK.

JPAC is responsible for this document and receives professional advice from the Standing Advisory Committees that form part of its structure and from other relevant expert groups. 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. The guidelines on this website are always up-to-date, but implementation dates may vary between the four UK Services. Please consult your local Service (England, Scotland, Wales or Northern Ireland) for details of implementation dates.

Please note, these guidelines are for use by medical professionals who are trained in their use. It is not possible to answer questions or provide personal medical advice through this website. Help with such matters may be available through a local blood transfusion and tissue transplantation helpline.

To navigate the guidelines online use the A-Z Search. To download a portable document file (PDF) as resource for a printed version see the Source Files. Users of these guidelines must ensure that they have the latest version and that recent changes have been implemented by their Service.

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 the Standing Advisory Committee on Cellular Therapy Products (SACCTP):

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Contents

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 unrelated allogeneic bone marrow and peripheral blood stem cell donors. It must be read in conjunction with Chapter 22 (haemopoietic progenitor cells) of the Guidelines for the Blood Transfusion Services in the United Kingdom - 8th Edition, 2013, which lists the general, and some specific aspects of donor selection.

Donors are selected firstly to ensure that they do not come to harm from giving their donation and secondly to ensure that their donation is unlikely to harm any recipient. The ultimate responsibility for the selection of donors rests with the respective **National Medical Director**.

The immediate responsibility is with the **Qualified Healthcare Professional** who must ensure that the donor fulfils the respective selection guidelines. When it is not clear if an individual donor is acceptable, the donation should not be collected without discussion with a **Designated Medical Officer**. It is recognized that a particular donation of bone marrow or peripheral blood stem cells may be potentially uniquely life saving. It is important that when a **Designated Medical Officer** makes a concession outside of these guidelines, that this is discussed with the medical team of the recipient and the reasoning for the concession documented.

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

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

It is the responsibility of the **Qualified Healthcare Professional** to ensure that the donor clearly understands the nature of the donation process. They must also understand the health questions and other information presented to them. The donor 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**.

Where there is separate guidance for **Bone Marrow** and for **Peripheral Blood Stem Cell** donors, this is made clear.

When there is a recognized risk to either the donor or the recipient, the guidelines **must** be followed.

The following terms may be used:

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

Definition
Where additional clarity is required, a definition is provided.

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

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

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

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

See if relevant
Is used when an **A-Z** entry may or may not need to be consulted. This will depend upon the information provided by the donor.

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-BM Edition 203, Release 02.

Medication

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

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

This section was last updated in TDSG-BM 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 stem cells, which, as a result, are unsuitable for clinical use, **must** be clearly labelled as unfit for use.

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

If late information is provided by the donor, 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 donors who exhibit health risks that are not listed in this guidance, without referral to, and acceptance by, the Designated Medical Officer.

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

A-Z Index

Accident

Includes Trauma

Obligatory **Must not donate if:**
a) Not recovered.

b) Still under follow-up.

c) Has a plaster-cast.

See if Relevant Neurosurgery
Surgery
Tetanus Immunization
Transfusion

Additional Information 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.

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

Acetylcholinesterase Deficiency

Obligatory **Bone Marrow Donor:**
Must not donate.

Discretionary **PBSC Donor:**
Accept.

Additional Information Bone marrow donation requires a general anaesthetic and acetylcholinesterase deficiency is an anaesthetic risk.

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

Addiction and Drug Abuse

Obligatory **Must not donate if:**
a) Has injected, or has been injected with drugs in the past 12 months

b) Adversely affected by any drug, including alcohol, which may affect the process of obtaining valid consent.

c) Has injected, been injected with, or taken non-parenteral chemsex drugs in the past 3 months. Please see Tissues Safety Entry.

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

b) Accept if has not injected or been injected with drugs of addiction within the last 12 months

c) If has not injected or been injected with drugs of addiction within the last 3 months – **refer to designated medical officer.** The donor may be accepted with individual risk assessment. See additional information section

d) May be acceptable if injected drugs were prescribed by the donor's physician for a condition that would not lead to exclusion.

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

See if Relevant Tissues Safety Entry

Additional Information	Injecting drugs has been linked with the passing on of many infections, including hepatitis and HIV. It can be many years before any infection shows itself. Former drug users often do not realize that they can still pass infection on to others many years after they last used drugs themselves. The deferral periods specified above may be reduced by doing individual risk assessment if the risk of acquiring an infectious disease may be outweighed by the risk of delaying a lifesaving transplantation. This guidance presumes that a validated NAT test for HIV, HBV and HCV is negative, if this test is stopped for any reason the guidance will change Anyone obviously affected by alcohol or other drugs that can affect the mind, cannot give valid consent or fully understand why they are being asked certain questions.
Reason for Change	Obligatory section updated as a part of the implementation of recommendations from the FAIR III report, including addition of chemsex drugs.
Update Information	This entry was last updated in TDSG-BM Edition 203, Release 52

Adrenal Failure

Includes	Addison's Disease
Obligatory	**Must not donate.**
Additional Information	Adrenal failure is due to the adrenal glands producing insufficient steroid hormones to maintain health. There are many causes, including autoimmune disease, infection, and congenital adrenal hyperplasia. Affected individuals take replacement steroid hormones. The dose of these must be increased during times of stress. BM donors are deferred, because of the increased risk of a general anaesthetic. PBSC donation could pose a risk to a donor, as the stress of donation could cause an increase in their cortisol requirements and fluid shifts during apheresis may not be well tolerated. There is also a possibility of transmission of autoimmune adrenal failure to the recipient.
Reason for Change	Changed PBSC donation from discretionary to obligatory ‘must not donate,’ as with bone marrow donors. ‘Additional information’ added.
Update Information	This entry was last updated in TDSG-BM Edition 203, Release 54

African Trypanosomiasis

Also Known As	Sleeping Sickness
Obligatory	**Must not donate.**
Update Information	This entry was last updated in BM-DSG Edition 203 Release 59

Age

Obligatory	**Must not donate if:** a) Over sixty years of age.

b) Under seventeen years of age.

Additional Information
The lower age limit takes account of national laws on age of consent. The upper age limit for recruitment to the British Bone Marrow Registry is fifty years.

Reason for Change
The upper age limit for acceptance has been raised from fifty-seven to sixty years.

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

Allergy

Obligatory
Ensure:
a) Procedures will not expose the donor to something they are allergic to, e.g. iodine, latex, lidocaine (previously known as lignocaine).

b) Inform Transplant Centre if:
Cells are from an individual with a known allergy.

See if Relevant
Asthma
Steroid Therapy

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

Anaemia

Obligatory
Inform Transplant Centre if:
Cells are from a donor that has an inherited disorder.

Discretionary
1. History of anaemia:
This must be assessed regarding its cause, current status and what treatment has been received.

2. Iron deficiency:
a) If not under investigation or on treatment and the underlying cause is not a reason to exclude, accept.

b) Medication to prevent, as opposed to treat, may be acceptable.

3. Other types:
a) Accept or exclude according to the guidelines.

b) In other cases:
Refer to a Designated Medical Officer.

See if Relevant
Haemoglobin Disorders
Haemolytic Anaemia
Malignancy

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

Additional Information
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).

Donating bone marrow will lower the haemoglobin concentration. People with a history of anaemia may not be able to make up this loss as easily as others.
Giving PBSC by apheresis results in a smaller loss of haemoglobin.

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

Anaesthetic

Obligatory

Bone Marrow Donor:
Must not donate if:
Previous severe reaction to general anaesthetic.

See if Relevant

Accident
Dental Treatment
Surgery
Transfusion

Update Information

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

Angina Pectoris

Obligatory

Must not donate.

See if Relevant

Cardiovascular Disease

Additional Information

A history of angina means that the donor has coronary artery disease. Removing blood from the circulation may put the donor at risk of having a heart attack.

Update Information

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

Animal Bite

(Non-Human)

Obligatory

1. All donors:
Must not donate if:
a) Ever bitten by a non-human primate

b) Any wound is infected or not healed.

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

See if Relevant

Human Bite
Infection - General
Rabies Immunization

Additional Information

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

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

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

Reason for Change

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

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

Ankylosing Spondylitis

Obligatory **Must not donate if:**
The cardiovascular system is involved.

Discretionary If mild and affecting the locomotor system only, accept.

See if Relevant Disabled Donor
Nonsteroidal Anti-Inflammatory Drugs (NSAID)

Additional Information Ankylosing spondylitis can affect the heart valves and the major artery of the body (aorta). Removing blood from the circulation may put the donor at risk of having a heart problem.

See Autoimmune Disease

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

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

Anthrax

Exposure

Discretionary Even if on prophylactic antibiotics, accept.

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

Immunisation

See Immunisation - Non-Live

Infection

See Infection - Acute

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

Anti Smoking Treatments

Obligatory **Must not donate if:**
Experiencing symptoms related to treatment.

Discretionary If well, accept donors using nicotine replacement therapy (patches, sprays etc) or Bupropion (Zyban, Amfebutamone).

See if Relevant Acupuncture

Additional Information Anti-smoking treatments can cause dizziness and nausea. Taking a donation from people who are affected may make their problems worse.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

Antibiotic Therapy

Additional Information Treatment with antibiotics is not of itself a reason for deferral but the reason for the treatment may be. When treatment is being given to prevent infection, rather than to treat it, see if there is a relevant entry. If not, discuss with a **Designated Medical Officer**.

See Infection - General

Reason for Change Additional Information has been added for clarity.

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

Anticoagulant Therapy

Obligatory **Must not donate if:**
a) Taking anticoagulant treatment.

b) Treatment was for cardiovascular disease.

c) Treatment was for axillary vein thrombosis.

d) Treatment was for repeated thrombophlebitis or thrombosis.

Discretionary If treatment has been completed more than seven days ago and a specific cause, not of itself a reason for exclusion, has been identified for an isolated deep vein thrombosis or pulmonary embolism, accept.

See if Relevant Cardiovascular Disease
Thrombosis

Additional Information Treatment with anticoagulants will make it more likely that a donor will bleed or bruise after donation. The effect of treatment wears off over some days and after seven days, the blood clotting mechanisms should be back to normal.

If the donor has cardiovascular disease, removing blood from the circulation will put the donor at risk of having a heart problem.

Some causes of thrombosis make it more likely that blood clots will happen again. This could be made worse by donating.

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

Anticonvulsant Therapy

Obligatory **Must not donate if:**
Taken for epilepsy.

Discretionary If used for treating bipolar disorder or chronic pain syndromes and the underlying condition is not a reason to exclude, accept.

See if Relevant Epilepsy
Mental Health Problems

Additional Information Faints following donation can lead to epileptiform convulsions due to a lack of oxygen reaching the brain. This could lead to a true epileptic fit in a person with a recent history of epilepsy.
It may also cause difficulties with the DVLA and/or employment in a person who has been free from fits for some time.

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

Antihistamine Tablets

Discretionary Accept.

See if Relevant Allergy

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

Anti-Obesity Drugs

Discretionary Accept.

See if Relevant Weight

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

Arrhythmias

Obligatory

1. Must not donate if:

a) Symptomatic or requires treatment

b) The donor is undergoing investigation

c) The donor has a history of an arrhythmia (eg Atrial Fibrillation, Atrial Flutter, Supraventricular Tachycardia, Ventricular Tachycardia) even if their symptoms have now settled.

2. In other cases:
Refer to a **'Designated Clinical Support Officer'**.

Discretionary

1. Donors with a previous history of an arrhythmia triggered by a non-cardiac medical condition which has now been treated (eg thyrotoxicosis), refer to a Designated Clinical Support Officer.

2. Donors who have been treated by ablation therapy for Supraventricular Tachycardia (including Wolff-Parkinson White Syndrome), refer to a Designated Clinical Support Officer.

3. Donors with a history of palpitations where the donor has been assessed clinically and a cardiac cause has been excluded, **accept.**

See if Relevant Cardiovascular Disease

Additional Information Some heart irregularities may be made worse through blood loss or by a general anaesthetic. This includes a risk that donation could trigger a recurrence in someone with a history of a previous arrhythmia. In cases where the donor's eligibility is not clear, Designated Clinical Support Officer referral ensures further information can be sought regarding their condition.

Reason for Change This entry has been revised to clarify the obligatory and descretionary criteria.

Update Information This entry was last updated in TDSG-BM Edition 203, Release 47

Arthritis

See if Relevant Ankylosing Spondylitis

Autoimmune Disease
Osteoarthritis
Psoriasis
Rheumatoid Arthritis

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

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

Asthma

Obligatory

1. Bone Marrow Donor:
Must not donate if:
Dependent on medication other than inhalers.

2. Bone Marrow & PBSC Donor:
Must not donate if:
a) Asthma is symptomatic.

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

Discretionary If exercise induced, accept.

See if Relevant
Infection - General
Steroid Therapy

Additional Information

The risk associated with a general anaesthetic is increased in people with asthma.

Taking a donation from a person with symptomatic asthma will lower the amount of oxygen the blood can carry and could make them worse.

Steroid therapy can hide the signs and symptoms of infection. Stem cells from an infected donor could be dangerous to the person receiving them.

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

Autoimmune Disease

Obligatory

See:
Is there an entry for the condition?

1. Must not donate if:
The donor has needed treatment to suppress the condition in the last 12 months.

2. Inform Transplant Centre if:
Cells are from a donor that has an autoimmune disorder.

See if Relevant
G-CSF
Liver Disease

If treated with immunoglobulin or plasma exchange or filtration:
Transfusion

Additional Information

PBSC Donors.
G-CSF may cause a flare of some autoimmune diseases. The risk should be assessed by the **Designated Medical Officer** and discussed with the donor.

Treatment to suppress the condition may be with steroids, immunosuppressive drugs, antimetabolites, antibodies directed against parts of the immune system as well as other therapies. These will affect the donor's immune system. This may make the donor more susceptible to certain types of infection and also will make some infections more difficult to diagnose.

Autoimmune disease is caused by the body attacking itself. This is with antibodies that are

in the fluid part of the blood (plasma), and with immune cells directly attacking target cells in the part/s of the body affected.

Transfusion of antibodies, or transfer of immune cells, could lead to similar damage in the people receiving them.

Reason for Change A note and link have been added about G-CSF flare of autoimmune disease.

Additional Information has been added to clarify treatment that may have been used to suppress the condition.

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

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

Babesiosis

Obligatory **Must not donate.**

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

Back Problems

Obligatory

1. Bone Marrow Donor:
Must not donate if:
a) Surgery within last five years.

b) Disc problem/sciatica.

c) Chronic pain requiring ongoing medical treatment.

2. PBSC Donor:
See:
Is there an entry for the underlying condition?

Must not donate if:
Not able to use the bleed facilities provided without risking their own safety or the safety of others (donors must not be bled in a wheelchair).

Discretionary

1. Bone Marrow Donor:
If the pain is infrequent, related to exertion or strain, accept.

2. PBSC Donor:
If the donor can tolerate the procedure, accept.

See if Relevant

Disabled Donor
Neurosurgery
Surgery

Additional Information The operation to remove bone marrow could make any problem worse.

Reason for Change An entry has been added for PBSC Donors.
An additional link has been added for 'Disabled Donor'.

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

Basal Cell Carcinoma

Obligatory

Must not donate if:
a) Still receiving treatment.

b) Any wound has not healed.

Additional Information

Although basal cell carcinoma is a form of cancer it only spreads locally. As it does not spread by the blood stream it is not a risk to people receiving donated material.

An unhealed wound is a risk for bacteria entering the blood. Bacteria can be a serious threat to anybody receiving donated material. This is because the bacteria can multiply to dangerous levels.

Update Information

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

BCG

Obligatory

Must not donate if:
a) The inoculation site has not yet healed.

b) Less than four weeks after inoculation.

Additional Information

BCG is an immunization with live bacteria. By four weeks, the infection caused by the inoculation should have been controlled. If the wound has not healed it is possible that there may still be infection present. We do not want to pass BCG, or other infections, on to people receiving donated material.

Reason for Change

Advice has been given from SACTTI that a period of four weeks is sufficient to ensure that there would be no circulating virus or bacteria at time of donation for live immunizations other than smallpox.

Update Information

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

Beta Blockers

Obligatory

Must not donate if:
a) Used for the treatment of cardiovascular disease.

b) Used to control symptoms of thyroid disease.

Discretionary

If used for non-cardiovascular disease or the donor has controlled hypertension, accept.

See if Relevant

Anxiety Disorders
Blood Pressure - High
Migraine

Additional Information

Beta blockers are often used to treat serious heart disease such as coronary artery disease (angina and after a myocardial infarction) and arrhythmias (abnormal heart rhythm). They may also be used to control the symptoms associated with an overactive thyroid gland. Patients with these disorders **must not donate**.

They are often used as treatment for hypertension (high blood pressure). There is evidence that shows that donors taking beta blockers do not have an increased incidence of adverse events related to donation.

They are also used to treat many other conditions such as migraine, tremor, anxiety and glaucoma. In most situations this should not prevent donation.

Reason for Change

A link to 'Anxiety Disorders' has been added.

Update Information

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

Bleeding Disorder

Includes Carriers

Affected Individual

Obligatory

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

b) There is a history of excessive bleeding or bruising.

Discretionary

Carrier state:
This does not necessarily prevent donation:
Refer to a Designated Medical Officer who will liaise with the haematologist that investigated the donor.

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.

If someone has had problems with bleeding or bruising taking blood or bone marrow could be harmful.

Some people with the carrier state (trait) for some bleeding disorders may be at risk of bleeding themselves.

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.

d) Diagnosed as affected (even mildly) by the disorder.

Discretionary

If 3 months 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.

Many bleeding disorders are inherited. Family members that are blood relations may be affected by the bleeding disorder so would be at risk of excessive bleeding or bruising. Most close blood relations would have been screened by a haematologist from whom additional information may be available.

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 has been extensively rewritten to improve clarity.

Update Information

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

Blood Pressure - High

Obligatory **Must not donate if:**

a) The cause of hypertension is under investigation.

b) Anti-hypertensive medication has been altered in the last four weeks.

c) Is having problems with feeling faint, fainting or giddiness.

d) Has suffered from heart failure.

e) Has renal impairment requiring dialysis, the use of erythropoietin or similar drugs, or is either under active investigation or continued follow up for their renal impairment.

f) Has required surgery for a blocked or narrowed artery including any type of amputation.

g) Has or has had gangrene.

Discretionary

a) If the donor is being regularly assessed for high blood pressure but treatment has not been commenced, accept.

b) If the donor is taking medication for raised blood pressure and neither the type nor the dose has been changed in the last four weeks and they are otherwise well, accept.

c) If gangrene was not related to diabetes or peripheral vascular disease (e.g. it was due to hypothermia or meningococcal meningitis) and all wounds are fully healed, even if amputation was required, accept.

See if Relevant

Cardiovascular Disease
Central Nervous System Disease
Intermittent Claudication

Additional Information

In the UK about one in twenty individuals has hypertension. Most people with hypertension are in good health and are fit to donate blood.

It is however important that complications due to raised blood pressure are carefully assessed and, where necessary, donors are excluded from donating (e.g. those with heart failure or damage to their kidneys, or those experiencing hypotensive side effects from their medication.

Reason for Change

The rationale for **not** accepting donors on medication, other than beta blockers or diuretics, for the treatment of hypertension was reviewed by the Standing Advisory Committee for the Care and Selection of Donors in 2008. It was decided that available data did not support the deferral of all individuals with controlled hypertension taking other medications.

Update Information

This entry was last updated in
DSG-WB Edition 202 Release 11

Blood Pressure - Low

Discretionary

If the donor is in good health and does not have faints or dizzy spells, accept.

Additional Information

Low blood pressure is not normally a problem. It is common in women and seems to be linked with levels of the female sex hormone oestrogen.

Low blood pressure can be caused by serious heart disease. In such cases a donation would not be taken.

Fainting can put a donor at risk of injury. Any donor who has problems with faints or dizzy spells should not donate.

Update Information

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

Blood Volume Estimation

Obligatory

Must not donate:
If the estimated blood volume is less than 3.8 litres.

See if Relevant

Weight

Additional Information

It is recommended that no donor should lose more than 13% of their blood volume during any donation procedure. This is to protect them from adverse effects such as fainting and becoming anaemic. There is a minimum donor weight at which a donation can be accepted. This is not always appropriate. Obesity also makes it desirable to use factors in addition to the donor's weight to estimate their blood volume. Fat contains far less blood as a proportion of its weight than muscle. In obese individuals the blood volume can be seriously overestimated from weight alone. Overestimating a donor's blood volume makes it more likely that they will have an adverse incident.

Reason for Change

This is a new entry to take account of increasing levels of obesity.

Update Information

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

Body Piercing

Includes

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

Obligatory

Must not donate if:
Less than 3 months after last piercing.

Discretionary

Piercings performed within the UK in a commercial setting: Accept

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

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

Additional Information

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

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

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

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

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

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

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

Reason for Change

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

Update Information

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

Breast Lump

Obligatory **Must not donate if:**
a) Malignant.

b) Not fully investigated and cleared of malignancy.

See if Relevant Malignancy

See Surgery

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

Bronchitis

Acute

See Infection - Acute

Chronic

Obligatory **Must not donate if:**
a) Repeated regular attacks of cough with sputum.

b) Dyspnoea at rest or on minimal exertion.

See if Relevant Infection - General
Steroid Therapy

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

Brucellosis

Undulant Fever

Obligatory **Must not donate.**

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

Cardiac Surgery

Obligatory **Must not donate.**

Discretionary If for congenital heart disease and has no residual disability, does not require antibiotic cover, and is not excluded because of their transfusion history:
Refer to a Designated Medical Officer.

See if Relevant Cardiovascular Disease
Endocarditis
Surgery
Transfusion

Additional Information Individuals who have had cardiac surgery, other than for congenital abnormality, are unlikely to be fit enough to safely have a large volume of blood removed. An individual who has had congenital abnormalities corrected can often lead a normal lifestyle and may be able to give blood safely. If the criteria under 'Discretionary' are met, the Designated Medical Officer can make a documented decision based on the individual's medical history.

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

Cardiomyopathy

Obligatory **Must not donate.**

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

Cardiovascular Disease

Obligatory **1. Must not donate if:**
a) Has ischaemic heart disease.

b) Recurrent thrombophlebitis or thrombosis.

2. Bone Marrow Donor:
Discuss with the anaesthetist if the donor has any other form of cardiovascular disease.

Discretionary If asymptomatic mitral valve prolapse only, accept.

See if Relevant
Angina Pectoris
Blood Pressure - High
Cardiac Surgery
Cardiomyopathy
Endocarditis
Myocarditis
Thrombosis

Reason for Change Additional links have been added.

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

Catarrh

Acute

See Infection - Acute

Chronic

Obligatory If on prescribed medication:
Refer to a Designated Medical Officer.

Discretionary If using a nasal decongestant only, accept.

See if Relevant Infection - General

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

Central Nervous System Disease

Excludes Cerebrovascular disease, including stroke, cerebral haemorrhage, embolus or transient ischaemic attack. See specific entry for Cerebrovascular Disease.

Obligatory **Must not donate if:**
a) Has Dementia (e.g. Alzheimer's disease).

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).

d) CNS tumour.

e) Parkinson’s Disease.

f) Having symptoms related to hypotension while taking dopamine receptor agonist drugs such as rotigotine, ropinirole and pramipexole.

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, once investigated and discharged from specialist follow-up, 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 DCSO.

d) If taken for a condition other than Parkinson’s Disease, as long as not having symptoms of hypotension related to dopamine receptor agonist drugs such as rotigotine, bromocriptine, ropinirole and pramipexole, accept.

See if Relevant

Cerebrovascular Disease
Epilepsy
Malignancy
Neurosurgery
Prion Associated Diseases
Rabies

Additional Information

As donation can result in a drop in blood pressure, there is the possibility that this could lead to further problems. Although the level of risk will vary from person to person, it is not acceptable to put an individual at increased risk, for what could be a severe adverse event, to any unnecessary further risk.

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.

Information

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

Reason for Change

Obligatory section updated to move ‘stroke, transient ischaemic attack/s or cerebral embolus’ to the new entry created for ‘cerebrovascular disease’. Revisions to the text of the ’ Discretionary’ and ‘Additional information’ sections.

Update Information

This entry was last updated in
BM-DSG Edition 203 Release 55

Cerebrovascular Disease

Definition

Diseases of the vasculature of the brain. This includes stroke, cerebrovascular accident (haemorrhagic or embolic), transient ischaemic attack. Cerebral haemorrhage includes haemorrhages or haematomas that are intracerebral, subdural, subarachnoid, or epidural.

Obligatory

Must not donate.

Discretionary

If a berry aneurysm has been treated by interventional radiology, and the person has not had a stroke or suffered neurological deficit, refer to DCSO for individual risk assessment.

See if Relevant

Central Nervous System Disease

Additional Information

Both embolic stroke and cerebral haemorrhage,(includes haemorrhages or haematomas that are intracerebral, subdural, subarachnoid, or epidural) may pose a risk of causing adverse events in stem cell donors. In order to reduce this risk, donors with a history of cerebrovascular disease must be excluded.

As regards cerebral haemorrhage after trauma, there is a concern that donors with previous traumatic brain injury may be at risk of further brain haemorrhage after stem cell donation. A small number of cases of cerebral haemorrhage in stem cell donors have been reported. In the few that occurred within 36 hours of donation, some of the donors had had previous traumatic brain injury (concussion).

Reason for Change This is a new entry.

Update Information This entry was last updated in CB-DSG Edition 203 Release 55

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-BM Edition 203, Release 44.

Chagas' Disease

This entry has been removed. See South American Trypanosomiasis.

Chicken Pox

Contact

See Infectious Diseases - Contact with

Herpes Zoster (Varicella Zoster)

See Infection - Acute

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

Chiropody

Obligatory **Must not donate if:**
There are open wounds or infection.

See if Relevant Fungal infection:
Infection - Chronic

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

Chondromalacia

Discretionary Accept.

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

Clinical Trials

Obligatory **Must not donate if:**
Participating in a clinical trial. This includes the use of drugs of any kind (oral, parenteral, transcutaneous, etc.) and applies to healthy individuals participating as volunteers - for example in 'phase 1' clinical trials.

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

See if Relevant Complementary Therapy
Transfusion

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

Clopidogrel

Obligatory **Must not donate**

Discretionary If prescribed for primary prevention of cardiovascular disease, discuss with DCSO.

Additional Information Clopidogrel is an antiplatelet drug which is used in the treatment and secondary prevention of cardiovascular disease and stroke. In this case, the underlying condition would be a contraindication to donation, in the interests of donor safety.

Occasionally Clopidogrel is used for primary prevention in patients who are intolerant of or hypersensitive to aspirin. Donor needs to be assessed by DCSO for the suitability of withholding clopidogrel for the relevant procedure.

Reason for Change This is a new entry.

Update Information This entry was last updated in TDSG-BM Edition 203, Release 47.

Coeliac Disease

Discretionary Accept.

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

Colostomy

Obligatory **Must not donate if:**
For malignancy or inflammatory bowel disease.

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

See if Relevant Surgery

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

Communication Difficulties

Obligatory

1. All donors must:
a) Fully understand the donation process.

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

2. Third party interpreters:
If they are to be present at any part of the selection procedure where there is an exchange of confidential information between the donor and the qualified health professional, they must:

a) Understand the importance of providing an accurate and truthful translation of the information provided, to enable the tissue/cell establishment to comply with regulatory requirements

b) Not be personally known to the donor.

c) Fully understand their duty of confidentiality and the confidential nature of any information obtained from the donor.

See if Relevant Disabled Donor

Additional Information

The Services are aware of their duties under Race Relations and Disability Discrimination Legislation and will, whenever and wherever reasonable, try to provide facilities for individuals whose first language is not English, or who have other difficulties in communicating. Potential donors with such difficulties are advised to seek advice from their local Blood Service before offering to donate stem cells to see if their needs can be met.
Every donor 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 donor in the completion of the health and medical history questionnaire and in understanding the consent statement and any other information provided by the Blood Service. To facilitate comprehension it is permissible to use alternative formats (e.g. a language other than English, audio, computer, Braille) for the donor information leaflets, the health and medical history questionnaire and consent

statements. The donor must be able to clearly demonstrate they have understood this material. At present there is no standardized way of assessing comprehension so this will be a personal judgement made by the health professional.

Use of third party interpreters.
It is permissible for any third party to act as an enabler by helping to reassure the donor and to assist in establishing effective communication between the donor and the qualified health professional. The third party **must not** however be present during any exchange of confidential information, unless they are **not** personally known to the donor and understand the need to accurately and truthfully communicate all the information, including personal and confidential information, provided by the person giving consent. Confidential parts of the process include the evaluation of the health and medical history questionnaire, the medical interview and the obtaining of valid consent. Any third party, with the permission of the donor, may accompany the donor 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 donor and the qualified health professional may compromise the confidentiality of the donor 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 potential donor in any confidential exchange of information. This may result in the non-disclosure of sensitive information that could affect the individual's eligibility to donate. If a third party is not fully aware of the need to accurately and truthfully communicate all the information, including personal and confidential information, provided by the person giving consent, this may make the interpretation of information incomplete and potentially put both the donor and the blood supply at risk. There is also a requirement to communicate the results of any testing performed by the Blood Services that may be of relevance to the donor's health in a way that protects their confidentiality. The continuing availability of an independent interpreter, to maintain donor confidentiality, should be taken into account when deciding if an individual donor may be accepted.

To comply with both the HTA and Health and Safety Regulations no donor can be accepted if it unnecessarily puts their own safety or the safety of others at risk.

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-BM Edition 203, Release 20

Complementary Therapy

Obligatory

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

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

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

Discretionary

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

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

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

2. Performed outside of the NHS
2a) If performed by a Qualified Health Care Professional registered with the General Medical Council (GMC), Nursing and Midwifery Council (NMC), General Dental Council (GDC), The General Chiropractic Council (GCC), The General Optical Council (GOC), The

General Osteopathic Council (GOsC) or General Pharmaceutical Council (GPhC), Pharmaceutical Society of Northern Ireland (PSNI), 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

Reason for Change

The regulatory organisations for Pharmacists in the UK have been added.
The HCPC ceased to be the regulatory authority for Social Workers in England in 2019. The list of health and care professionals regulated by the HCPC has been amended.

Update Information

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

Congo Fever

Obligatory

Must not donate if:
Less than twelve months following recovery or from return to the UK, if occurred abroad.

Update Information

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

Contraceptive Implant

Discretionary

Accept.

See if Relevant

Surgery

Update Information

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

Contraceptive Injection

Discretionary Accept.

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

Contraceptive Pill

Discretionary Accept.

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

Corneal Transplant

Obligatory **Must not donate.**

See if Relevant Prion Associated Diseases

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

Coronary Thrombosis

Includes Heart Attack
Myocardial Infarct

Obligatory **Must not donate.**

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

Coronavirus Infection (COVID-19)

Includes COVID-19 disease (due to infection with SARS-CoV-2 virus, previously known as Novel Coronavirus or 2019-nCoV).

1. Person with confirmed symptomatic COVID-19

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

Discretionary a) If **more** than **14 days** have passed since resolution of symptoms, accept.

b) If **less** than **14 days** since resolution of symptoms: refer to designated clinical support officer for individual risk assessment, if donation is urgent and cannot be delayed.

See additional information.

2. Person with confirmed SARS-CoV-2

Obligatory **Must not donate if less** than **14 days** since confirmation of infection by positive results in a diagnostic test.

Discretionary

If **less** than **14 days** have passed since confirmation of infection by positive results in a diagnostic test, refer to designated clinical support officer for individual risk assessment, if donation is urgent and cannot be delayed.

See additional information.

3. Person with suspected COVID-19

Discretionary

a) If **more** than **14 days** have passed since resolution of symptoms, and donor has been tested and advised they **do not** have COVID-19, and the donor remains well, accept.

b) If **less** than **14 days** have passed since resolution of symptoms, and:

- Donor has been tested and advised they **do not** have COVID-19, and the donor remains well.
  OR
- If the donor has **not** been tested to exclude the diagnosis of COVID-19.

Refer to designated clinical support officer for advice.

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).

Some individuals will have symptoms for a protracted length of time after the systemic and respiratory symptoms of the acute infection have resolved. A wide range of symptoms, including cardiac and neurological, have been reported. It is important to identify any of the specific ongoing symptoms such as chest pain, palpitations, shortness of breath, fatigue, even if seemingly mild or infrequent, that suggest that a donor may not have fully recovered to their pre-COVID-19 state of health, and that may put a donor at risk of an adverse event.

There is no evidence at present that SARS-CoV-2 can be transmitted by tissue/cell transplantation.

For Bone Marrow (HPC-M) donations, donation should be scheduled in accordance with current guidance from the Royal College of Surgeons and Association of Anaesthetists and in discussion with the collection centre.

Post Donation Illness

Donors must be provided with information about contacting the registry co-ordinating their donation and the collection centre they donated at if they develop any illness within 14 days after donation.

Reason for Change

Additional Information' section updated following removal of NICE recommendation to test donors.

Update Information

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

Coronavirus Vaccination

Obligatory **Must not donate if:**

i) Less than 14 days after the last immunization if the vaccine given was nucleic acid (mRNA) vaccine.

ii) Less than 28 days after the last immunization if the vaccine given was virus-vector-based (non-replicating virus) vaccine.

See additional information for further information on different types of vaccine.

iii) If donor felt unwell due to unexpected complications (other than common side effects) after any vaccination, refer to Designated Clinical Support Officer for individual risk assessment.

Timings above refer to interval between vaccination and start of G-CSF or general anaesthetic for BM donation.

Discretionary If the transplant cannot be delayed, Donors may be accepted less than 14 days (nucleic acid vaccines) or 28 days (viral vector vaccines) after the date of the most recent vaccination, subject to individual risk assessment. See additional information.

See if Relevant Coronavirus Infection

Additional Information All COVID-19 vaccines currently licensed in the UK are non-live. Normally, no deferral period is applied after immunisation with non-live vaccines. However as the effects of the newly developed coronavirus vaccines on donor health and donation safety are not fully established yet, as a precautionary principle, a 14 to 28 day post vaccine deferral period, depending on the type of vaccine is recommended.

Immune thrombocytopenia (ITP) can occur after all types of Covid 19 vaccines. There have been a small number of reports of vaccine induced thrombosis and thrombocytopenia syndrome (VITTS), in people receiving virus vector based (non-replicating) coronavirus vaccine. VITTS patients have severe clinical symptoms whilst ITP may be sub-clinical and go unnoticed on symptoms alone. The incidence is unclear but may be similar to other vaccine induced ITP. Therefore a 14 day deferral period has been recommended after vaccination with mRNA vaccines.

GCSF administration carries a small risk of inflammation associated thrombosis and thrombocytopenia. There is a theoretical concern that GCSF could exacerbate the immune response related to VITTS. Headaches and abdominal pain are side effects of GCSF which are primary symptoms associated with cerebral venous thrombosis and splanchnic vein thrombosis respectively, due to VITTS. As a precautionary measure the post vaccination deferral period for bone marrow and PBSC donors receiving virus-vector-based (non-replicating virus) vaccines has been extended to 28 days, for donor protection. As the reported events are extremely rare, donors may be accepted less than 28 days after vaccination subject to a careful individualised risk assessment.

Consideration of checking a platelet count after vaccination to rule out thrombocytopenia is recommended. This could be included as a part of medical assessment if undertaken 14 days or more after vaccination. If less than 14 days between vaccination and medical assessment, or vaccination was given after medical assessment, additional Full Blood Count should be done before commencing GCSF/ general anaesthetic (frozen cells) and before commencing patient conditioning (for fresh cells).

For donors who have commenced GCSF, the vaccination (first or second dose) must be delayed at least until 72 hours after stem cell collection (both PBSC & Bone Marrow Donation). This is a precautionary advice to avoid vaccination when receiving GCSF and allow for post donation recovery period.

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

There may be new types of vaccine that become available, and it may not be known which

type of vaccine was used for immunisation. In situations where information about vaccine type is missing or the vaccination is experimental, a four-week deferral period should be applied.

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

Reason for Change To update the obligatory and discretionary sections.

Update Information This entry was last updated in
BM-DSG Edition 203 Release 55

Dementia

Obligatory **Must not donate.**

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

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

Dental Treatment

Obligatory **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.

Discretionary If inspection or dental impressions only, accept.

See if Relevant
Surgery
Infection - General

Additional Information 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.

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

Dermatitis

Obligatory **Must not donate if:**
a) Venepuncture or harvest site is affected.

b) Using systemic therapy.

Discretionary If the area affected is small, the venepuncture or harvest site is unaffected and using topical treatment only, accept.

See if Relevant
Allergy
Infection - General
Steroid Therapy

Reason for Change To add a link to Alitretinoin.

Update Information This entry was last updated in TDSG-BM Edition 203, Release 17

Diabetes Insipidus

Obligatory **Must not donate.**

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

Diabetes Mellitus

Obligatory **Must not donate if:**

a) Requires treatment with insulin.
b) Has had a transplant of pancreatic tissue
c) Has significant end-organ complication -see discretionary
d) Suffers from Hypoglycaemic attacks

Diabetes is poorly controlled -see additional information

Discretionary The donor needs to be reviewed by the DCSO if they suffer from complications of diabetes mellitus which may cause a health risk to the donor or recipient. Complications include peripheral vascular disease, renal impairment, autonomic neuropathy, and cardiovascular disease.

Hypoglycaemic attacks are less common in Type II Diabetes but can still be a complication of some medications.

Additional Information Diabetes Mellitus can result in acute illness, chronic morbidities, and death, and hence national guidelines recommend maintaining good glycaemic control to prevent or minimise macrovascular and microvascular complications.
It is estimated that 3.8 million of the UK population have diabetes (8.6%) (The state of the nation 2019-A review of diabetes services in Wales).

Type I Diabetes (T1DM) comprises the minority (<10%) and the patients are insulin dependent, more prone to have hypoglycaemic events. It is, at least in part, considered to be genetically inherited. A review of the medical literature suggests that T1DM may be transmitted to the recipient after a successful transplant.

Type II Diabetes (T2DM) is commoner and many people with this type are in good health and do not require insulin treatment.
It is however important that complications due to diabetes are carefully assessed and, where necessary, donors are excluded from donating (e.g., those at risk of postural hypotension due to autonomic neuropathy, or those at risk of bacteraemia due to unhealed ulcers).
Diabetic patients are advised to maintain good glycaemic control -HbA1c 7-8% (52 -64mmol /mol) to prevent macrovascular and microvascular complications.

UK blood services accept donors who are on oral medications for Diabetes following 2008 review and recommendation by SAC-CSD, and later this recommendation was reviewed to accept donors using some non-insulin derived injectable drugs. SHOT donor haemovigilance has not reported any donor adverse events related to diabetes. (SHOT 2009-2021)
Blood Safety and Quality Regulations require UK blood services not to accept donors who are being treated with insulin, or who have received a transplant of human tissue.

Reason for Change Updating the guideline.

Update Information This entry was last updated in TDSG-BM Edition 203, Release 47.

Diarrhoea

Includes
D & V
Entero-colitis
Food Poisoning
Gastric Flu
Gastro-enteritis

Obligatory
Must not donate if:
a) Chronic or associated with inflammatory bowel disease.

b) Less than two weeks since full recovery.

See if Relevant
Infection - General

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

Digoxin

Obligatory
Must not donate.

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

Dilatation and Curettage

See
Surgery

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

Disabled Donor

Obligatory
1. All donors must:
a) Fully understand the donation process

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

2. Third party interpreters:
If they are to be present at any part of the selection procedure were there is an exchange of confidential information between the donor and the qualified health professional, they must:
a) Understand the requirements of the Human Tissue Act (HTA) relevant to the donation process
b) Not be personally known to the donor.

3. PBSC Donor:
Must be able to use the bleed facilities provided without risking their own safety or the safety of others (donors must not be bled in a wheelchair).

4. Bone Marrow donor:
Discuss with anaesthetist.

Discretionary
Donors with difficulty in reading:
Ensure by questioning the donor that they:
a) Understand and fully complete the tick-box questionnaire

b) Give valid consent to donation and to the testing of their blood for diseases that may affect its suitability for use.

See if Relevant
Self-catheterization

Spina Bifida

Additional Information

The Services are aware of their duties under Disability Discrimination Legislation and will, whenever and wherever reasonable, try to provide facilities for disabled individuals. Potential donors with such difficulties are advised to seek advice from their local Service before offering to donate stem cells to see if their needs can be met. **Every donor must:**

be provided with accurate educational materials, which are written in terms which can be understood by members of the general public

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

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

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

Use of third party interpreters.
It is permissible for any third party to act as an enabler by helping to reassure the donor and to assist in establishing effective communication between the donor and the qualified health professional. The third party **must not** however be present during any exchange of confidential information, unless they are **not** personally known to the donor and understand the requirements of that part of the HTA relevant to the donation process. Confidential parts of the process include the evaluation of the health and medical history questionnaire, the medical interview and the obtaining of valid consent. Any third party, with the permission of the donor, may accompany the donor 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 donor and the qualified health professional may compromise the confidentiality of the donor 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 potential donor in any confidential exchange of information. This may result in the non-disclosure of sensitive information that could affect the individual's eligibility to donate. If a third party is not fully aware of the relevant aspects of the HTA this may make the interpretation of information incomplete and potentially put both the donor and the blood supply at risk. There is also a requirement to communicate the results of any testing performed by the Blood Services that may be of relevance to the donor's health in a way that protects their confidentiality. The continuing availability of an independent interpreter, to maintain donor confidentiality, should be taken into account when deciding if an individual donor may be accepted.

To comply with both the HTA and Health and Safety Regulations no donor can be accepted if it unnecessarily puts their own safety or the safety of others at risk.

Reason for Change

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

Update Information

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

Disease of Unknown Aetiology

Obligatory

See:
Is there is a specific entry for the disease?

Must not donate.

Discretionary

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

Additional Information

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

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

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

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

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

Diuretics

Discretionary If taken for pre-menstrual syndrome, or to treat hypertension as either the only drug or in conjunction with Beta Blockers, accept.

See if Relevant Blood Pressure - High

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

Diverticulosis

Discretionary Accept.

See if Relevant Infection - General

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

Drug Treatment

Obligatory The taking of some drugs may make a donor ineligible.
This could be due to the underlying disease or to the medication.

See:
Any specific entry for the disease or the drug.

Discretionary Self-medication with some drugs e.g. vitamins, aspirin, sleeping tablets, need not prevent a donation being accepted, providing the donor meets all other criteria.

See if Relevant Addiction and Drug Abuse
Nonsteroidal Anti-Inflammatory Drugs

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

Electrolysis

Discretionary Accept.

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

Emphysema

Obligatory **Must not donate.**

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

Endocarditis

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

b) Has a heart defect and has been told to take antibiotics when having treatment (e.g. dental) that may result in bacteraemia.

See if Relevant Infection - General

Reason for Change This new entry replaces the previous entry for 'Subacute Bacterial Endocarditis'. It recognizes that the cause of endocarditis is not always bacterial and the course is not always subacute.

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

Endometriosis

Discretionary Accept.

See if Relevant Surgery

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

Epilepsy

Obligatory **Must not donate if:**
a) Requiring treatment for epilepsy.

b) Has had an epileptic episode in the last three years.

Discretionary **Previous epilepsy:**
A person with a past history of epilepsy who for the past three years has neither required anticonvulsant therapy, nor been subject to fits, may be considered as a donor.

See if Relevant Malignancy
Neurosurgery

Additional Information Faints following donation can lead to epileptiform convulsions due to a lack of oxygen reaching the brain. This could lead to a true epileptic fit in a person with a recent history of epilepsy.
It may also cause difficulties with the DVLA and/or employment in a person who has been free from fits for some time.

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

Eye Disease

Obligatory **1. Must not donate for BM or PBSC if:**
a) Active ocular inflammation

b) History of malignancy

c) Ocular tissue transplanted

2. Must not donate for PBSC if:
a) History of inflammatory eye disease (e.g. uveitis, scleritis, iritis, episcleritis, conjunctivitis)

b) Associated with severe or multisystem autoimmune disease

c) History of detached retina or any eye condition/injury that affects blood vessels of eye

d) History of bleeding or clots in the eye or retina such as optic neuritis, optic neuropathy, or autoimmune retinopathy

Discretionary

a) History of inflammatory eye disease:

- If transient viral conjunctivitis, which is fully resolved, accept.
- For others, where a clear infectious aetiology has been identified, and the inflammation is resolved, seek advice from DCSO.

b) If it is an isolated autoimmune inflammatory process, or if it is a recurring inflammation or increased risk or recurrence (e.g. HLA-B27) or exacerbation (toxoplasma chorioretinitis), accept for BM only, subject to advice from DCSO.

See if Relevant

Autoimmune Disease
Central Nervous System Disease
Glaucoma
Infection - General
Malignancy
Ocular Surgery
Ocular Tissue Recipient
Steroid Therapy
Tissue and Cell Allograft Recipients

Additional Information

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.

Infectious eye diseases can aggravate years after initial treatment and the role of GCSF in response to infectious agents is not fully understood.

Uveitis has been reported as a side effect of GCSF. A history of eye inflammation in association with systemic disease usually requires deferral due to the underlying condition. If such an association cannot be excluded at medical examination, consider BM only. Acceptable for donation only by BM method if recurring inflammation or increased risk for recurrence (e.g., HLA-B27).

Reason for Change

'Obligatory' and 'Discretionary' sections expanded. 'Additional Information' section added.

Update Information

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

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-BM Edition 203, Release 02

Faints

Obligatory
PBSC Donor:
Must not donate if:
History of either a severe syncopal attack or two consecutive faints following whole blood donation.

Discretionary
If the donor is accepted, careful observation is required.

Additional Information
A previous history of being prone to faints increases the likelihood of an adverse reaction to donation.

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

Filariasis

Obligatory
Must not donate.

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

G6PD Deficiency

Obligatory
1. Must not donate if:
Severe.

2. If accepted, must inform:
Transplant Centre, Collection centre and, If BM donor, the anesthetist.

Additional Information
This is an X linked red cell enzyme deficiency that is variable in its severity. Suitability as a donor should be discussed with a **Designated Medical Officer**. The condition would be transmissible to recipient of stem cells so Transplant Centres need to undertake their own risk assessment.

Reason for Change
To improve clarity and provide additional information.

Update Information
This entry was last updated in
TDSG-BM Edition 203, Release 29

Gall Bladder Disease

Obligatory
Must not donate if:
a) Symptomatic.

b) Associated with an inherited haemolytic anaemia e.g. spherocytosis.

Discretionary
If recovered or has asymptomatic gallstones, accept.

See if Relevant
Haemolytic Anaemia

Infection - General
Malignancy
Surgery

Reason for Change A link has been added for Haemolytic Anaemia and for Malignancy.

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

G-CSF

Obligatory **PBSC Donors:**
The donor must be advised of the adverse events associated with this drug.

See if Relevant Autoimmune Disease
Sickle-cell Trait

Reason for Change To introduce an entry for G-CSF.

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

Genital Warts

Discretionary Accept.

See if Relevant Sexually Transmitted Disease

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

Giardiasis

Discretionary Accept.

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

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

Glaucoma

Obligatory **Must not donate if:**
Received transplant of sclera during glaucoma surgery.

Discretionary If treatment is complete, no scleral transplant was given, or if treated by eye drops only, accept.

See if Relevant Ocular Tissue Recipient
Surgery
Tissue and Cell Allograft Recipients

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

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

Glycogen Storage Disease

Obligatory	**Must not donate**
Additional Information	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. Donation may present a risk to the donor, even for milder forms of glycogen storage disease
Reason for Change	This is a new entry
Update Information	This entry was last updated in TDSG-BM Edition 203, Release 29

Gout

Obligatory	**Must not donate.**
Discretionary	Accept if: a) For BM donation b) For PBSC: Discuss with DCSO. See 'Additional Information'
Additional Information	Gout is an acute arthritis caused by build-up of uric acid crystals in the joint space. There have been reports of severe exacerbation of gout following administration of G-CSF. In the interests of donor protection, caution should be exercised before considering donors with gout for PBSC donation. In these circumstances, donors should be counselled about the possibility of exacerbation of their condition and consent to this before proceeding to receive G-CSF. Affected individuals should be excluded from PBSC donation unless permitted by DCSO based on individual risk assessment.
Reason for Change	Exclude affected individuals from donation of PBSC unless permitted by DCSO.
Update Information	This entry was last updated in TDSG-BM Edition 203, Release 54

Granuloma Inguinale

Obligatory	**Must not donate.**
Update Information	This entry was last updated in TDSG-BM Edition 203, Release 02

Growth Hormone

Obligatory	**Must not donate if:** Has ever received human pituitary derived growth hormone.
Discretionary	If treated exclusively with recombinant-derived growth hormone, accept. In the UK this has been since 1987.
See if Relevant	Prion Associated Diseases
Update Information	This entry was last updated in TDSG-BM Edition 203, Release 02

Guillain-Barré Syndrome

Obligatory

Refer to a Designated Medical Officer:
Must not donate if:
a) Less than 24 months from resolution.

b) There has been any recurrence of symptoms.

c) The doctor who managed the donor cannot confirm a typical monophasic Guillain-Barré syndrome that recovered completely within 12 months.

See if Relevant

If treated with immunoglobulin or plasma exchange:
Transfusion

Update Information

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

Haematological Disease

Obligatory

Must not donate if:
a) Malignant.

b) Clonal disorder such as primary polycythaemia (rubra vera), essential thrombocythaemia or monoclonal gammopathy of unknown significance (MGUS).

Discretionary

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

See if Relevant

Anaemia
Haemoglobin Disorders
Immune Thrombocytopenia
Therapeutic Venesection

Additional Information

Clonal disorders result from the proliferation of a single cell. Because they have the potential to become malignant they are treated in the same way as malignancy.

Reason for Change

Monoclonal gammopathy of unknown significance (MGUS) has been added as an example of a clonal disorder.

'Additional Information' has been added.

Update Information

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

Haematuria

Obligatory

Must not donate if:
a) Due to infection.

b) Due to malignancy.

See if Relevant

Kidney Disease

Update Information

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

Haemochromatosis

Discretionary Accept.

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

Haemoglobin Disorders

Obligatory **Must not donate if:**
a) Thalassaemia major or intermedia
b) Sickle cell disease (HbSS, HbSC, HbSBthal, HbSD)
c) High affinity haemoglobin
d) Other clinically significant structural or functional haemoglobinopathies

Discretionary a) Donors with traits for abnormal haemoglobin, accept. Inform transplant centre

b) Donors with sickle cell trait – accept for bone marrow only.

See if Relevant Anaemia
Sickle-Cell Trait
Thalassaemia Trait
Transfusion

Reason for Change 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. There is no evidence of clinically significant sickling during PBSC collection in those with sickle cell trait. However, subclinical sickling has been demonstrated with PBSC collection, so those with sickle cell trait must donate by BM only.

Update Information This entry was last updated in TDSG-BM Edition 203, Release 29

Haemolytic Anaemia

Obligatory **See:**
a) Is there an entry for the condition?

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

See if Relevant Autoimmune Disorder
G6PD Deficiency
Haemoglobin Disorders
Hereditary Elliptocytosis
Hereditary Spherocytosis
Pyruvate Kinase Deficiency
Transfusion

Reason for Change To include an entry for haemolytic anaemia.

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

Haemorrhoids

Includes Piles

Discretionary Accept.

See if Relevant Anaemia

Surgery

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

Hazardous Activity

Obligatory **1. PBSC Donor:**
Must not donate if:
a) Required to undertake a hazardous activity the same working day.

b) Donors must be advised of the risks of delayed faints and told not to perform a hazardous occupation or hobby on the same day.

Discretionary **Hazardous occupation:**
If going off duty, accept.

Additional Information If a donor has an adverse event after donating, some activities (occupations or hobbies) may lead to harm to the donor or others.

Examples of hazardous activities include:
diving (all types), flying, parachuting, motor sport, climbing, etc.

Examples of hazardous occupations include:
air traffic controller, ambulance driver, climbing ladders or scaffolding, crane or heavy machine operator, diver, fire crew, flying, Large Goods Vehicle (LGV, HGV over 7.5 tonnes), bus or train driver, miner working underground, etc.

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

Headache

Occasional

Discretionary Accept.

See if Relevant Migraine

Regular

Obligatory **Must not donate if:**
Not investigated.

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

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

Heaf Test

Obligatory **Must not donate until:**
Healing.

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

Health Care Worker

History of Inoculation Injury

See Inoculation Injury

No Inoculation History

Discretionary Accept.

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

Henna Painting

Discretionary Accept.

See if Relevant Body Piercing

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

Hepatitis

Obligatory **Note:**
Hepatitis has a number of causes including infection and hypersensitivity to drugs. Our concern is with viral hepatitis.

Discretionary If fully recovered from non-viral hepatitis, accept.

See if Relevant
Hepatitis A
Hepatitis B
Hepatitis C
Hepatitis E
Hepatitis of Unknown Origin

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

Hepatitis A

1. Affected Individual

Obligatory **Must not donate if:**

- Less than 6 months from recovery, or
- Less than 6 months since the donor was diagnosed with hepatitis A infection following laboratory testing, if the recipient has not yet started transplant conditioning therapy. If the recipient has already started transplant conditioning therapy then the Transplant Centre must be informed immediately to allow a clinical risk assessment on the best way forward for the donor (refer to additional information).

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

See if Relevant Travel

Additional Information 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.

Blood services may screen for hepatitis A infection using a test for hepatitis A virus RNA. Donors who are diagnosed with hepatitis A infection during pre-donation screening (i.e. before the recipient has started transplant conditioning therapy) or as part of an outbreak investigation must be deferred for 6 months, even if they do not have any symptoms of the disease. After six months, they may donate without further testing.

Rarely, a donor may test positive for hepatitis A infection on the day of donation, after the recipient has already started transplant conditioning therapy. The Transplant Centre must then carry out an immediate clinical risk assessment regarding the risk of using the donation. Sometimes, when no good alternative HPC donor is available in a timely manner, the risk to the recipient from using the donation may be less than a significant delay to transplant to attempt to source an alternative donor.

2. Current or Former Sexual Partner of Affected Individual

Obligatory

Must not donate if:
Less than 6 months from recovery of current sexual partner, or from last sexual contact if a former sexual partner.

Discretionary

If shown to be immune, accept.

Additional Information

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

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

Obligatory

Must not donate if:
Less than 6 months from recovery of the last affected person in the home, or from the last contact if no longer sharing.

Discretionary

If shown to be immune, accept.

Additional Information

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

4. Immunisation

Obligatory

Known exposure.
Must not donate if:
Less than six months after vaccine or intramuscular immunoglobulin was given.

Discretionary

No known exposure:
Accept.

See if Relevant

Hepatitis B - Immunisation
Travel

Additional Information

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

Hepatitis A immunisation may be combined with hepatitis B immunisation.

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

Reason for Change

Some UK blood services have introduced universal donor testing for hepatitis A, using a test for hepatitis A virus RNA. Asymptomatic bone marrow, PBSC or lymphocyte donors may therefore rarely test positive either at pre-donation screening, or on the day of donation when pre-donation screening has been negative.

Update Information This entry was last updated in BM-DSG Edition 203 Release 58

Hepatitis B

1. Person with current hepatitis B infection

Obligatory **Must not donate.**

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

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

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

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

Obligatory **Must not donate:**
if less than 12 months since diagnosis

Discretionary If more than 12 months since diagnosis of HBV infection, and if they have successfully cleared the infection, accept.

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

See if Relevant Tissue Safety Entry

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

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

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

3. Current or Former Sexual Partner of an infected individual

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

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

Discretionary

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

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

Additional Information

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

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

Reason for Change

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

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

Obligatory

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

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

Discretionary

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

Additional Information

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

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

Reason for Change

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

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

Obligatory

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

Must not donate:
If less than 3 months since sharing ceased.

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

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

See if Relevant 6. Hepatitis B Immunization, below.

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

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

6. Hepatitis B Immunization

Obligatory **a) If Immunised Following Known Exposure:**

Must not donate

b) If Immunised With No Known Exposure:
Must not donate if:

Less than 7 days after the last immunization was given.

Discretionary **a) If Immunised Following Known Exposure:**
If more than 3 months from immunization, accept

b) If Immunised With No Known Exposure:
If more than 7 days after the last immunization was given, accept.

See if Relevant Hepatitis A - 4. Immunization

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

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

May be combined with hepatitis A immunization.

Sensitive assays for HBsAg may be positive following recent immunization. This is why a 7 day deferral is required.

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

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

Hepatitis C

1. Affected Individual

Obligatory **Must not donate.**

Discretionary If the individual has been told that he/she is HCV antibody negative, then samples should be taken to determine eligibility.

See if Relevant Liver Disease

Tissues Safety Entry

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

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

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

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

Reason for Change 'Additional Information' has been added.

2. Current or Former Sexual Partners of HCV Positive Individuals

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

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

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

See if Relevant Tissues Safety Entry

Additional Information Confirmation of the success of treatment of the HCV positive partner is not required
Individuals who remain HCV RNA negative six months after completing treatment are likely to have been ‘cured’, with a risk of relapse of less than 1%

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

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

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

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

Discretionary Accept.

See if Relevant Sexual Partners of HCV Positive Individuals above.

Additional Information

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

Update Information This entry was last updated in TDSG-BM Edition 203, Release 31

Hepatitis E

Infection

Obligatory **Must not donate if:**
Less than 6 months from recovery.

Discretionary If less than 6 months from recovery and HEV RNA negative and anti HEV IgG positive, accept.

See if Relevant Travel

Additional Information Hepatitis E is an infectious hepatitis that is usually spread through contaminated food or water. Infection may be associated with travel to countries with poor hygiene/sewage conditions but increasingly, cases of hepatitis E are being identified in the UK usually due to consumption of undercooked contaminated meat. Hepatitis E can affect non-human animals and has been found in pigs in the UK. There have been reports of transmission by transfusion and transplant. Infection in healthy individuals is often symptom free but in people with underlying problems in their immune systems it can be serious and occasionally fatal. The Blood Services currently test for this infection.

Reason for Change The obligatory deferral has been reduced from 12 to 6 months and a discretion to accept on full recovery added. Additional Information has been updated. The deferral for household and sexual contacts has been removed.

Update Information This entry was last updated in TDSG-BM Edition 203, Release 29

Hepatitis of Unknown Origin

Affected Individuals

Obligatory **Must not donate if:**
Less than 24 months from recovery.

Discretionary a) If more than 12 months, but less than 24 months from recovery, obtain history and blood samples and refer to a **Designated Medical Officer**.

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

Additional Information If more than 12 months and less than 24 months from recovery:
c) If negative for all markers of hepatitis B, accept.

d) If HB core antibody is positive and HBsAg is negative and HBV-DNA is negative, accept.

Person Sharing Home

Obligatory
Must not donate if:
Less than 12 months from recovery of the last affected person in the home.

See if Relevant
Sexual Partner of Affected Individuals above.

Additional Information
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.

Reason for Change
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

Obligatory
Must not donate if:
Less than 12 months from recovery of partner.

Update Information
This entry was last updated in
TDSG-BM Edition 203, Release 17

Hereditary Elliptocytosis

Obligatory
1. Must not donate if:
Clinically significant haemolysis.

2. Inform Transplant Centre if:
Cells are from a donor with hereditary elliptocytosis.

Additional Information
Hereditary elliptocytosis is a variably inherited but usually dominant condition. Suitability as a donor should be discussed with a **Designated Medical Officer**.

Reason for Change
This entry replaces the previous entry for Elliptocytosis

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

Hereditary Spherocytosis

Obligatory
1. Must not donate if:
Clinically significant haemolysis.

2. Inform Transplant Centre if:
Cells are from a donor with hereditary spherocytosis.

Additional Information
Hereditary spherocytosis is a variably inherited but usually dominant condition. Suitability as a donor should be discussed with a **Designated Medical Officer**.

Reason for Change
The entry has been changed to be consistent with the guideline for 'Hereditary Elliptocytosis'.

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

Herpes - Genital

Obligatory **Must not donate if:**
Fresh lesions.

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

See if Relevant Sexually Transmitted Disease

Additional Information There is no need to defer donors who have a sexual partner with Herpes if the donor themselves is asymptomatic.

Reason for Change Addition of 'Additional Information' section, to include clarification regarding sexual partners.

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

Herpes - Oral

Obligatory **Must not donate if:**
Fresh lesions.

Discretionary If lesions are healing, accept.

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

Herpes Simplex

See if Relevant Herpes - Genital
Herpes - Oral

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

Herpes Zoster

See if Relevant Infection - Acute
Infectious Diseases - Contact with

Update Information This entry was last updated in
TDSG-BM 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-BM 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.

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

See if Relevant Prion Associated Diseases
Thyroid Disease

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

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

HTLV

Current and Former Sexual Partners of Confirmed Case

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

See if Relevant Tissues Safety Entry

Additional Information There is no defined infectious window period for HTLV. The risk of missing recent infection with individual sample testing is low after 3 months.

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

Infection

Obligatory **Must not donate.**

See if Relevant Tissues Safety Entry

Person Currently or Formerly Sharing a Home with an Affected Individual

Discretionary Accept.

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

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

Reason for Change This is an additional entry.

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

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

Huntington's Disease

Obligatory **Must not donate if:**
Symptomatic.

Discretionary Asymptomatic carriers, accept.

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

Hydatid Disease

Obligatory **Must not donate.**

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

Hydrocephalus

Obligatory **Must not donate if:**
Has an indwelling shunt.

See if Relevant Neurosurgery
Spina Bifida

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

Hypercholesterolaemia

Obligatory **Must not donate if:**
a) Has caused symptomatic disease.

b) Associated with cardiovascular disease.

Discretionary If has not led to symptomatic disease, even if on treatment, accept.

See if Relevant Cardiovascular Disease

Additional Information Hypercholesterolaemia occurs when the level of cholesterol in the blood is outside of the reference range for the donor's age and sex. Usually this is managed by modifying the diet and often by the use of drugs. High levels of cholesterol are of themselves not a reason to defer a donor. If the hypercholesterolaemia has led to symptomatic disease, such as cardiovascular problems or transient visual or neurological problems the donor should not be accepted, even if their cholesterol has returned to normal levels.

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

Hypnotics

Discretionary Accept.

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

IgA deficiency

Obligatory **Must not donate.**

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

Ileostomy

Obligatory **Must not donate if:**
a) For malignancy

b) Inflammatory bowel disease.

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

See if Relevant Surgery

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

Immune Thrombocytopenia

Obligatory

Must not donate if:
a) Symptomatic.

b) Chronic.

c) Recovered, but less than six months from recovery.

This applies to both adult and childhood disease.

See if Relevant

If treated with immunoglobulin or plasma exchange:
Transfusion

If treated with immunosuppressive therapy:
Immunosuppression

Reason for Change

The links have been revised.

The phrase, 'Recovered, but has ever had a recurrence' has been removed and 'five years from recovery' has been reduced to six months as both were considered unnecessarily restrictive.

Update Information

This entry was last updated in
TDSG-BM 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-BM Edition 203, Release 42

Immunisation - Live

No Exposure

Obligatory
Must not donate if:
Less than eight weeks from administration.

Discretionary
If more than four weeks from administration of a live immunisation other than smallpox immunisation and the inoculation site has healed, accept.

See if Relevant
BCG
Smallpox Immunisation

Additional Information
Live immunisations use living viruses or living bacteria that will stimulate the immune system but do not normally cause a severe illness. They may however cause severe illness in people who are already unwell and have a weakened immune system. By four weeks, any infection caused by the immunisation should have been controlled and so should not be passed on through donated material. There are special rules for BCG and smallpox immunisations.

Reason for Change
Advice has been given from SACTTI that a period of four weeks is sufficient to ensure that there would be no circulating virus or bacteria at time of donation for live immunisations other than smallpox.

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

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

Immunisation - Non-Live

No Exposure

Obligatory
1. Hepatitis B
If less than seven days from when the last immunisation was given:

2. Coronavirus: See ‘Coronavirus Vaccination’ entry

Discretionary
Other non-live immunisations, accept.

See if Relevant
Immunisation - 2. Post Exposure

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

"Non-Live" immunisations do not use material that can cause infection. This means there is no risk to people receiving stem cells.

Reason for Change
To add Coronavirus Vaccination to obligatory section.

Update Information
This entry was last updated in
TDSG-BM Edition 203, Release 39

Immunoglobulin Therapy

Obligatory
Must not donate if:
a) Immunosuppressed.

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

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

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

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

See if Relevant
Hepatitis A
Hepatitis B
Rabies
Tetanus Immunization

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

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

See
If treated with intravenous or subcutaneous human immunoglobulin:
Transfusion

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

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

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

Immunosuppression

Obligatory
Must not donate if:
a) Immunosuppressed.

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

See if Relevant
Autoimmune Disease
Immunoglobulin Therapy
Steroid Therapy

Reason for Change
Additional links have been added.

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

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

Infection - Acute

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

Must not donate if:
a) Infected.

b) Less than two weeks from recovery.

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

Discretionary
a) Common viral respiratory tract infections such as colds, sore throats and seasonal influenza, if not severe, accept.

b) Other types of infection: see Additional Information.

c) If the patient has started conditioning, refer to DCSO. See Additional Information.

d) Cold sores, genital herpes: accept.

See if Relevant
Coronavirus Infection (COVID-19)
Herpes - Genital
Herpes - Oral
MRSA
Myocarditis

Steroid Therapy
Viral Haemorrhagic Fever
West Nile Virus

Additional Information

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

There is no evidence that cold sores or genital herpes can be passed on by transfusion 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.

Donors with mild symptoms or recovering from seasonal influenza may be considered for donation following review by the Designated Medical Officer to confirm that the donor if fit enough to undergo the donation process.

If the patient has started conditioning
Common respiratory infections: There is no evidence that common respiratory infections such as colds and sore throats can be transmitted by transfusion. G-CSF may cause side effects that overlap with those of common viruses e.g. headache, myalgia, fatigue but there is no evidence that G-CSF alters the course of such infections. Therefore, the decision on whether a donor can proceed depends on the severity of their symptoms, whether they would tolerate a possible worsening of them and whether they are well enough to travel and undergo a collection procedure or general anaesthetic (for BM).

Other types of infection
Liaison with the transplant centre is key. Sometimes, conditioning can be stopped or paused. Discussion with a microbiologist and the transplant centre may be needed to risk assess whether the donation can proceed. If the donor has a potentially serious infection, the donation may need to be postponed regardless of the patient's status.

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 immunocompromised patients, or infections which lie dormant or may be difficult to eradicate.

Information

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

Reason for Change

Additional guidance including for situations where the patient has started conditioning and information relating to common respiratory infections and other types of infection added.

Update Information

This entry was last updated in
BM-DSG Edition 203 Release 56

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-BM Edition 203, Release 38.

Infection - General

Obligatory
See:
Is there a specific entry for the disease?

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

Or if lasting a long time (more than a few weeks) and possibly with long lasting carriage of the infecting organism, e.g. malaria or typhoid
Infection - Chronic

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

Infection - Tropical

Obligatory
Must not donate if:
Filariasis or Leishmaniasis

See if Relevant

Congo Fever
Crimean Fever
Ebola Fever
Lassa Fever
Marburg Fever
Malaria
South American Trypanosomiasis Risk
Other infections, see:
Infection - General

Update Information

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

Infectious Diseases - Contact with

Obligatory

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

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

Discretionary

a) If the infection is known to lead to permanent immunity (e.g. chickenpox, measles, mumps, rubella, whooping cough) and there is a definite history of past infection with the disease with which contact has occurred, accept.

b) Contact with common upper respiratory tract infections (e.g. colds, sore throats, influenza, SARS CoV-2), accept.

c) Contact with norovirus and other causes of diarrhoea and vomiting, provided the donor is symptom free, accept.

d) Contact with skin conditions which are not transmissible by donated material (such as scabies, ringworm, tinea) if no signs of infection, accept.

e) Individuals who have been prescribed prophylactic antibiotics after contact with meningitis, anthrax or chlamydia, provided they are symptom free, accept.

See if Relevant

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

Tuberculosis

Additional Information

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

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

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

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

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

Update Information This entry was last updated in TDSG-BM Edition 203, Release 49

Infertility

Obligatory **Must not donate if:**
a) Under investigation.

b) Less than 12 weeks after completion of treatment with clomiphene (Clomid).

c) Less than 12 weeks after completion of treatment with tamoxifen.

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

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

Discretionary Take care to exclude pregnancy.

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-BM Edition 203, Release 44.

Inflammatory Bowel Disease

Includes Crohn's Disease
Ulcerative Colitis

Obligatory **Must not donate.**

Discretionary

Refer to designated clinical support officer. Donor may be considered if in stable remission and off treatment, but should not receive GCSF, so could donate bone marrow only.

See if Relevant

Infection – General
Malignancy
Radiation Therapy

Additional Information

The cause of these conditions is not fully understood and may include infection. Lesions caused by the disease can increase the risk of bacteria entering the blood stream. There is a risk of adoptive transfer of disease-causing cells which should be discussed with the recipient.

Reason for Change

'See if Relevant' section has been added.

Update Information

This entry was last updated in
TDSG-BM Edition 203, Release 42

Inherited Diseases

Obligatory

See:
Is there a specific entry for the condition? If not:
Refer to a Designated Medical Officer.

Update Information

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

Inoculation Injury

Includes

Human Bite

Definition

A non-consented injury or assault in which an individual is exposed to potentially infective material that could be transferred through donation. The causes may range from a sharps injury to bites, punches and abrasions or sexual assault where mucous membranes have been contaminated with human blood or other body fluids. It also applies to any inoculation injury with abnormal prions from any species.

Obligatory

Must not donate if:
a) The incident involved any material containing abnormal prions.

b) Less than 3 months after the date of an inoculation injury, or contamination of mucosa or non-intact skin with blood or body fluids.

c) Under ongoing investigations following exposure - **refer to DSCO**.

See if Relevant

Animal Bite
Hepatitis
HIV
HTLV
Prion Associated Diseases
Tissues Safety Entry
Xenotransplantation

Additional Information

Human blood or body fluids may be contaminated with infective material such that the infection may then be passed on by donated material. Waiting three months (if validated tests for infectious markers that include HBV, HCV HIV NAT are negative) helps to ensure that any infection is not passed on.

Donors who are under investigation may be accepted subject to individual risk assessment.

Reason for Change

The 'Definitions' section was updated as part of the implementation of recommendations from the FAIR III report. Additional 'see if relevant' links added. 'Additional information' section updated.

Update Information

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

Intermittent Claudication

Obligatory **Must not donate.**

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

Irritable Bowel Syndrome

Discretionary Accept.

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

Jaundice

Obligatory **Must not donate if:**
a) Jaundiced or has a history of jaundice.

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

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

Discretionary a) If fully recovered from a non-viral cause of jaundice (this includes, but is not limited to, physiological jaundice of the newborn, gall stones and drug reactions), accept.

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

See if Relevant
Gall Bladder Disease
Gilbert's Syndrome
Hepatitis A
Hepatitis B
Hepatitis C
Hepatitis E
Hepatitis of Unknown Origin

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

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

There have been other minor changes to improve clarity and to avoid the unnecessary exclusion of donors.

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

Kala-Azar

This entry has been removed. See Leishmaniasis.

Kidney Disease

Acute Nephritis

Obligatory **Must not donate if:**
Less than 12 months since recovery.

Discretionary **1. All tissues:**
a) Self-limiting renal disease e.g. single attacks of glomerulonephritis, pyelitis, from which recovery has been complete, do not necessarily disqualify the donor.

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

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

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

Chronic Nephritis

Obligatory **Must not donate.**

Update Information This entry was last updated in TDSG-BM Edition 203, Release 17

Klinefelter's Syndrome

Discretionary Accept.

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

Laser Treatment

Obligatory **Must not donate if:**
For malignancy.

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

b) If for Cervical Carcinoma in Situ, see Cervical Dysplasia entry.

c) If for cosmetic purposes, accept when healed.

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

See if Relevant Basal Cell Carcinoma
Cervical Dysplasia

Update Information This entry was last updated in TDSG-BM Edition 203, Release 44.

Leishmaniasis

Includes Kala-Azar

Obligatory **Must not donate.**

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

Leukaemia

Obligatory **Must not donate.**

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

Liver Disease

1. Non-Alcoholic Fatty Liver Disease (NAFLD)

Excludes Alcoholic Fatty Liver Disease (AFLD)

Obligatory **Must not donate if diagnosed with:**
- Non-alcoholic steatohepatitis (NASH)
- Cirrhosis

Discretionary A diagnosis of non-alcoholic fatty liver disease does not necessarily prevent donation. If the donor is otherwise well and managed with diet and lifestyle changes such as exercise, accept.

Additional Information NAFLD is a commonmedical condition, causedmainly bylifestyle factors suchasweight, type 2 diabetes, high blood pressure and high cholesterol. There is no drug treatment for this condition. It is usually managed with diet and lifestyle changes along with treatment of any associated medical conditions. Regular monitoring of the condition, e.g. blood tests and liver scans, should not preclude donation.

NASH is an advanced form of NAFLD. It is caused by an excessive accumulation of fat in the liver. This can progress to chronic liver inflammation and can result in cirrhosis if untreated.

2. Alcohol Related Liver Disease

Obligatory **Must not donate**

Discretionary If the donor is well, and

- not under specialist follow up, and
- has not been diagnosed with alcohol related hepatitis or cirrhosis,

accept.

Refer to a **Designated Clinical Support Officer (DCSO)** if there is uncertainty about the diagnosis or the extent of liver damage.

See if Relevant Addiction and Drug Abuse

Additional Information Alcohol-related liver disease is common but preventable liver damage that is caused by drinking too much alcohol. It is reversible in the early stages when it is characterised mainly by fatty liver changes. In some individuals it may progress to alcoholic hepatitis and alcoholic cirrhosis.

3. Infective Liver Disease

Includes Liver abscess, Glandular fever, Viral hepatitis

Obligatory Refer to the specific entry for the condition. If there is no specific entry, **must not donate.**

Discretionary If the donor is fully recovered and there is no specific guidance for the condition, refer to Infection – General.

See if Relevant For Glandular Fever, see Infection – Acute
Infection – General
Hepatitis

4. Autoimmune Liver Disease

Includes Autoimmune Hepatitis (AIH), Primary Biliary Cholangitis (PBC) and Primary Sclerosing Cholangitis (PSC).

Obligatory **Must not donate**

See if Relevant Autoimmune Disease
Hepatitis
Steroid Therapy

Additional Information Autoimmune liver disease in its early stages may be asymptomatic or present with mild symptoms such as itchy skin (pruritis) and fatigue. The donor may require no treatment or treatment for symptom control only for an extended period.

5. Drug or Pregnancy Induced Liver Disease

Includes Acute Liver Failure

Obligatory **Must not donate if:**

- Under active investigation, treatment or follow up by a specialist
- Has received a liver transplant
- Has chronic liver failure

Discretionary If the donor has recovered, is not on treatment and has been discharged from follow up, accept. If there is doubt about the diagnosis, refer to a DCSO.

See if Relevant Addiction and Drug Abuse
Tissue and Organ Recipients

Additional Information Liver failure may be acute or chronic. Acute liver failure (also known as fulminant liver failure) can be caused by drugs, such as paracetamol overdose, prescription medications, herbal preparations and ingestion of toxins. Liver problems can also occur during pregnancy e.g acute fatty liver of pregnancy (AFLP) and intrahepatic cholestasis of pregnancy (ICP). Acute liver failure can occur in an individual with no pre-existing liver disease. It is often reversible with full recovery if adequately treated.

Chronic liver failure is caused by longstanding liver disease such as autoimmune liver disease, hepatitis, alcohol related liver disease, liver cirrhosis, haemochromatosis and Wilson's disease.

6. Liver Cirrhosis

Obligatory **Must not donate**

Additional Information Cirrhosis can be caused by many different conditions and by several different liver conditions in combination. Transmissible viruses, some of which are not detected in transfusion service testing, can cause some cases. Because cirrhosis is a sign of worsening or progressive liver disease, it is considered safest not to accept individuals with cirrhosis.

7. Liver Tumours

Includes Liver Cancer, Hepatocellular Carcinoma, Bile Duct Cancer.

Obligatory **Must not donate**

Discretionary Donors with benign liver cysts or adenomas who are fit and well, even if regularly monitored, refer to DCSO.

See if Relevant Malignancy

Additional Information If in doubt about the diagnosis, refer to a DCSO.

8. Inherited Diseases Affecting the Liver

Obligatory Refer to the entry for the condition. If there is no specific entry, refer to a DCSO.

Discretionary a) If the donor is well and stable on treatment for Wilson's Disease, refer to DCSO.
b) If the donor has Gilbert's Syndrome, accept.

See if Relevant Inherited Diseases

Additional Information Wilson's disease is caused by an excessive accumulation of copper in the liver and other organs. e.g. brain. If diagnosed and treated early with chelating agents, such as Penicillamine and Trientine, and avoidance of high copper foods, the prognosis is good and individuals can lead a normal life. If there is uncertainty about the donor's health or treatment, refer to a Designated Clinical Support Officer.

Alpha-1-antitrypsin deficiency can occasionally cause liver disease in adults. This may lead to liver failure and the need for liver transplantation.

Gilbert's syndrome is an inherited defect in bilirubin metabolism. It is harmless but can cause jaundice (yellowing of the whites of the eyes).

Reason for Change This is a new entry.

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

Malaria

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

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

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

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

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

MAT: Malarial Antibody Test

NAT: Nucleic Acid Test (for malaria)

Obligatory **Must not donate (if no testing is available):**
Applies to all groups as defined above

Discretionary **1a) Previous Malaria:**

If **less** than **4 months** have passed since anti-malaria therapy has been completed and symptoms caused by malaria have resolved, refer to DCSO. See 'Additional Information' section.

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

1b) Unexplained Febrile illness:

If **less** than **4 months** from the date of recovery of symptoms of unexplained febrile illness that could have been malaria: refer to DCSO. See 'Additional Information' section.

If **more** than **4 months** from the date of recovery of symptoms of unexplained febrile illness that could have been malaria: Obtain a blood sample for MAT and NAT. See information below in this section.

1c) Resident:

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

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

1d) Visitor:

If **less** than **4 months** since return: Obtain a blood sample for MAT and NAT. Donors may be accepted with individual risk assessment with expert advice. See information below in this section.

If **more** than **4** and **less than12 months** since return: Obtain a blood sample for MAT and NAT. If MAT negative, NAT is not required to release stem cells. See information below in this section.

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

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

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

See if Relevant

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

Additional Information

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

Cases of malaria transmission have occurred many years after the donor 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 donate, it is safer to test for malaria antibodies rather than to wait a specific length of time. Malaria may be fatal.

For bone marrow/stem cell donors, if it is an emergency and due to the live saving nature of the treatment, donors may be accepted with individual risk assessment and expert advice for interpretation of MAT and NAT results, at any time point following exposure/recovery. If the donor informs of active malaria infection at donor assessment, they could be treated before donation. If the stem cells are not required for life saving treatment immediately, a four-month deferral should apply. Between 4 months and 12 months following recovery, either a negative MAT or a positive MAT/negative malaria NAT and risk assessment should be applied.

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

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

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

Malaria - Contact in UK

Discretionary Accept.

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

Malignancy

Obligatory **Must not donate.**

Discretionary a) If this was a basal cell carcinoma (rodent ulcer) and treatment is completed and all wounds are healed, accept. If any systemic medical treatment was required, refer to designated clinical support officer.

b) If the potential donor has a non haematological (non-clonal) premalignant condition (e.g. polyposis coli, prostatic intraepithelial neoplasia PIN or Barrett's oesophagus) that is being regularly monitored, or has had a similar condition cured and has been discharged from follow-up, accept.

c) If the potential donor has been cured of a carcinoma in situ (CIS) and discharged from follow-up, accept. Donors who have been returned to routine screening following treatment for cervical CIS can be accepted.

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

d) If the potential donor has had a diagnosis of melanoma in situ (including Lentigo Maligna), refer to Designated Clinical Support Officer to confirm they have not had an invasive melanoma (eg Lentigo Maligna Melanoma).

e) Potential donors with a high risk of cancer due to family history or following genetic tests, even if had or having prophylactic surgery or on prophylactic medication (e.g. Tamoxifen), or on routine follow up, accept.

See if Relevant Basal Cell Carcinoma
Cervical Carcinoma in Situ

Liver Disease
Surgery
Transfusion

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

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-BM 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-BM Edition 203, Release 02

Marfan's Syndrome

Obligatory **Must not donate if:**
Cardiac involvement.

Discretionary Otherwise accept.

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

Menopause

Discretionary Accept.

See if Relevant Hormone Replacement Therapy

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

Mental Health Problems

Obligatory **Must not donate if:**
Not able to fully understand and consent to the donation process and to the testing of their blood for diseases that may affect its suitability for use.

See if Relevant Communication Difficulties

Additional Information Many people have mental health problems that can be controlled with regular medication. Providing individuals are well on the day of donation and have the mental capacity to give full informed consent, there is no reason why they cannot donate whether on medication or not. Individuals who are over anxious, depressed, manic or psychotic cannot always give valid consent, or fully understand why they are being asked certain questions.

Reason for Change 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.

Update Information This entry was last updated in TDSG-BM Edition 203, Release 17

Migraine

Obligatory **Must not donate if:**
a) Attacks are frequent, severe, and require regular treatment.

b) On prophylaxis with clonidine.

Discretionary If on prophylaxis with beta-blockers or pizotifen (Sanomigran), accept.

See if Relevant Headache

Additional Information Migraine is caused by a disturbance in the normal blood flow to parts of the brain. In its more severe forms it can be severely disabling. By not accepting people with the more severe forms of migraine we hope to prevent precipitating an attack through the process of donating blood. Any donor who has had severe migraine associated with giving blood on more than one occasion should be advised not to continue as a donor.

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

Mpox (Monkeypox)

1. Affected Individuals

Obligatory **Must not donate**

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

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

accept.

Post Donation Illness Donors must be provided with information about contacting the registry co-ordinating their donation and the collection centre they donated at if they develop any illness within 21 days after donation. Seek public health advice to determine the risk.

2. Contact with an individual with Mpox

Includes Individuals who have been identified by public health teams as a close contact of an individual with Mpox.

Obligatory **Must not donate**

Discretionary 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.

Post Donation Illness If the donor has retrospectively reported contact with Mpox in the incubation period, seek public health advice to determine the risk.

3. Immunisation for contact or risk

Excludes Individuals who have received vaccination because they work in a health care setting – see section 4 below.

Obligatory **Must not donate**

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

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

accept.

If less than 4 weeks since most recent dose, **refer to DCSO** for individual risk assessment. See Additional Information Section.

4. Immunisation – No known contact

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

Discretionary An individual who has received routine vaccination with Imvanex or another third-generation smallpox vaccination in an occupational setting, can be accepted provided that they are not deemed to be at risk due to an exposure episode.

See if Relevant Immunisation

Additional Information

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

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

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

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

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

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

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

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

Other recipients of vaccination for Mpox must be assessed according to section 3 above.

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

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

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

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

MRSA

Methicillin Resistant Staphylococcus Aureus

See if Relevant Infection - General

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

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

Mumps

Affected Individual

See Infection - Acute

Contact

See Infectious Diseases - Contact with

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

Muscular Dystrophy

Obligatory **Bone Marrow Donor:**
Must not donate.

Discretionary **PBSC Donor:**
Accept if able to tolerate the length of the procedure.

See if Relevant Disabled Donor

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

Myasthenia Gravis

Obligatory **Must not donate.**

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

Myelodysplastic Syndrome

Obligatory **Must not donate.**

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

Myeloproliferative Syndrome

Obligatory **Must not donate.**

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

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

Myocarditis

Obligatory **Must not donate if:**
Less than 12 months from recovery.

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

Ménière's Disease

Discretionary Accept.

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

Narcolepsy

Obligatory **Must not donate.**

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

Neurofibromatosis

Obligatory **1. Must not donate if:**
History of malignant change.

2. Bone Marrow Donor:
Inform anaesthetist.

Additional Information The anaesthetist should be informed because of the risk of pheochromocytoma.

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

Neurosurgery

Obligatory **Must not donate.**

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

b) If burr hole surgery only, accept.

c) If it can be shown that Dura Mater was not used during surgery and there is no evidence of malignancy, the donor may be accepted by a **Designated Medical Officer**.

See if Relevant Malignancy
Prion Associated Diseases
Surgery

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

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

Night Sweats

Obligatory **Must not donate if:**
Unexplained.

Discretionary If due to the menopause, accept.

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

Non-Specific Urethritis

Acute

See Infection - Acute

Chronic

Obligatory **Must not donate.**

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

Nonsteroidal Anti-Inflammatory Drugs (NSAID)

Obligatory Assess reason for treatment and see relevant entry.

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

Discretionary If medication is self prescribed and the donor meets other criteria, accept.

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

Operations

See if Relevant Transfusion

See Surgery

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

Organ Donor

Discretionary Accept.

See if Relevant Transfusion

See Surgery

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

Osteoarthritis

Discretionary Accept.

See if Relevant Disabled Donor
Nonsteroidal Anti-Inflammatory Drugs

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

Osteomalacia

See if Relevant	Disabled Donor
Update Information	This entry was last updated in TDSG-BM Edition 203, Release 02

Osteomyelitis

Obligatory	**Must not donate if:** Less than two years from completing treatment and cure.
Additional Information	Sometimes it is difficult to be certain that all infection has been eliminated. Waiting two years minimizes the risk of any infection being passed on by a donation.
Update Information	This entry was last updated in TDSG-BM Edition 203, Release 02

Osteoporosis

Obligatory	**Bone Marrow Donor:** **Must not donate.**
Discretionary	**PBSC Donor:** If on treatment to prevent or treat, accept.
See if Relevant	Disabled Donor Steroid Therapy
Update Information	This entry was last updated in TDSG-BM Edition 203, Release 02

Ovarian Cyst

Obligatory	**Must not donate if:** Malignant.
See if Relevant	Malignancy Surgery
Update Information	This entry was last updated in TDSG-BM Edition 203, Release 02

Paget's Disease of Bone

Includes	Osteitis Deformans
See if Relevant	Disabled Donor Nonsteroidal Anti-Inflammatory Drugs
Additional Information	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-BM 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-BM 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-BM Edition 203, Release 02

Periods

Obligatory **Must not donate if:**
Period has been missed.

Discretionary If pregnancy can be excluded and the donor is well, accept.

See if Relevant Pregnancy

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

Perthes' Disease

Discretionary Accept.

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

Phlebitis

Obligatory **Must not donate if:**
a) More than one episode in 12 months.

b) Less than seven days off treatment.

Discretionary If recovered , accept.

See if Relevant Anticoagulant Therapy
Nonsteroidal Anti-Inflammatory Drugs (NSAID)

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

Platelet Disorder

Obligatory **Must not donate if:**
a) Causes excessive bleeding or bruising.
b) Has thromboctocytosis.

See if Relevant Haematological Disease
Immune Thrombocytopenia
Thrombocytosis

Additional Information Platelet counts in excess of 500 x 10^9 should be repeated. If found to be persistently raised the donor should not be accepted and referred for investigation.

Reason for Change Thrombocytosis and relevant links have been added.

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

Pleurisy

See if Relevant Infection - General
Malignancy

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

Pneumothorax

Spontaneous

Obligatory **Must not donate if:**
a) Not recovered.

b) Associated with emphysema.

Traumatic

See Accident

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

Poisoning

Obligatory **Must not donate if:**
There is evidence that the individual (donor/or mother of cord blood donor) has ingested, or been otherwise exposed to toxic substances that could be transmitted in donated material in dosages that could endanger the health of recipients

Discretionary If the individual is being monitored following exposure and the levels of the agent in question are within safe limits, accept.

See if Relevant Addiction and Drug Abuse

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

Reason for Change This is a new entry. This is a requirement of the Human Tissue Authority Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment

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

Polycystic Kidney Disease

Obligatory **Bone Marrow Donor**:
Request an anaesthetic assessment.

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

Polycythaemia

Obligatory **Must not donate.**

Update Information This entry was last updated in TDSG-BM 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

Liver Disease

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-BM Edition 203, Release 11

Post Viral Fatigue Syndrome

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

Obligatory **Must not donate if:**
Not resolved.

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

Pre- and Post-Exposure Prophylaxis for HIV

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

b) The donor has received an injection for PrEP in the previous 24 months.

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

Discretionary **If:**

- it is over three months since the donor last used oral PrEP or PEP, and/or
- it is over 24 months since the donor last received an injection for PrEP, and
- there is no other tissue safety risk,

accept.

See if Relevant HIV
Inoculation Injury
Tissues Safety Entry

Additional Information The use of Pre-Exposure Prophylaxis (PrEP) 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.

PrEP is normally given in tablet form but longer-acting injectable PrEP e.g. cabotegravir (Apretude®) may also be used in individuals who are not suitable for oral medication. Cabotegravir injections are given on an 8-weekly basis to ensure adequate HIV protection. Low levels of cabotegravir can be detected for many months in treated individuals, even after injections have been stopped.

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 oral PrEP in the previous three months, or injected PrEP in the previous 24 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.

Reason for Change Addition of a 24-month deferral for recipients of injectable PrEP.

Update Information This entry was last updated in
BM-DSG Edition 203 Release 58

Pregnancy

Obligatory **Must not donate if:**
a) Pregnant.

b) Less than one week has passed for every completed week of a recent pregnancy, up to a maximum of 6 months.

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

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

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

Discretionary If more than 6 months post-partum, accept. Donors may need advice regarding the safety of continuing to breast feed, if relevant

See if Relevant Surgery
Transfusion

Additional Information Methotrexate is now increasingly used to medically treat ectopic pregnancy, to avoid surgery and protect the fallopian tube. A week is needed for any residual methotrexate to clear the system.

For donors donating by PBSC, it is recommended that mothers who wish to continue breast-feeding after donation should not feed their infant (but may express and discard milk) from the point of first G-CSF administration to one week following the last dose of G-CSF.

For donors donating by BM, it is recommended that mothers who wish to continue breast-feeding after donation should not feed their infant (but may express and discard milk) from the point of administration of any sedating agent to 24 hours following the last dose of sedating anaesthetic or opiate analgesia.

Reason for Change The deferral period for pregnancies lasting six months or more has been reduced as iron stores are known to recover 6 months post delivery. Registries should give donors advice about breast-feeding such as that given by the WMDA.

https://wiki.wmda.info/index.php?title=Pregnancy

Update Information This entry was last updated in
TDSG-BM Edition 203, Release 29

Prion Associated Diseases

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

Obligatory **Must not donate if:**
1. Diagnosed with any form of CJD, or other human prion disease.

2. Identified at increased risk of developing a prion associated disorder.
This includes:
a) Individuals at familial risk of prion-associated diseases (have had two or more blood relatives develop a prion-associated disease or have been informed following genetic counselling they are at risk).

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

c) Individuals who have been told that they may be at increased risk because a recipient of blood or tissues that they have donated has developed a prion related disorder.

d) Recipients of dura mater grafts.

e) Recipients of corneal, scleral or other ocular tissue grafts.

f) Recipients of human pituitary derived extracts.

g) **Since January 1st 1980**Recipients of any allogeneic human tissue.

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

See if Relevant
Pituitary Extract - Human
Tissue and Organ Recipients
Transfusion
Tissue and Cell Allograft Recipients

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

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

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

This entry was last updated in
TDSG-BM Edition 203, Release 22

Psoriasis

Obligatory **Must not donate if:**
a) Generalized or severe.

b) Associated with arthropathy.

c) There is secondary infection.

d) Immunosuppressed

Discretionary a) If mild, the venepuncture/harvest site is unaffected and only using topical treatment, accept.

b) If the donor is on immunosuppressive medication, see Immunosuppression entry.

Additional Information Psoriasis is primarily a skin condition caused by an autoimmune process. About one in ten people with psoriasis may develop joint problems (psoriatic arthropathy). Sometimes the disease is treated with powerful drugs to suppress the underlying autoimmune process. This may alter the body's defence mechanisms to infection. In such cases donations should not be taken.

See
Autoimmune Disease
Immunosuppression

Reason for Change Treatment with Etretinate/Neotigason is no longer a reason for deferral. Link to ‘immunosuppression’ entry added.

Update Information

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

Pyrexia

Not Related to Travel in Malarious Areas

Obligatory **Must not donate if:**
Less than two weeks from an episode of pyrexia.

Discretionary If related to a common cold or other upper respiratory tract infection from which the donor is now recovered or recovering, accept.

See if Relevant Infection - General

Additional Information 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

See Malaria

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

Pyruvate Kinase Deficiency

Obligatory **1. Must not donate if:**
Severe.

2. If accepted, must inform:
Anaesthetist.
Transplant Centre.

Additional Information This is an autosomal recessive red cell enzyme deficiency that is variable in its severity. Suitability as a donor should be discussed with a **Designated Medical Officer**.

Reason for Change The entry has been brought into line with the guideline for 'G6PD Deficiency'.

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

Q Fever

Obligatory **Must not donate.**

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

Rabies

Immunization - Non-exposed

Discretionary If non-exposed, accept.

Immunization - Post Exposure

Obligatory **Must not donate until:**
At least 24 months post exposure and fully cleared by treating physician.

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

Infection

Obligatory **Must not donate.**

See if Relevant Animal Bite

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

Radionuclides

Obligatory **1. Radioactive iodine therapy:**
Must not donate if:
a) For malignancy.

b) Administered in the preceding six months.

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

See if Relevant Malignancy

	Thyroid Disease
Additional Information	In general those used for diagnostic purposes are cleared within 24 hours. Some, e.g. radioactive iodine, have long half-lives and affected donors must not be accepted unless at least six months have passed.
Update Information	This entry was last updated in TDSG-BM Edition 203, Release 02

Raynaud's Syndrome

Obligatory	**Must not donate if:** a) Part of a multisystem disorder. b) On treatment with vasodilators.
Discretionary	If this is an isolated condition and the donor is not taking vasodilators, accept.
Update Information	This entry was last updated in TDSG-BM Edition 203, Release 02

Recipients of Normal Human Immunoglobulin

See if Relevant	Hepatitis A Immunosuppression Immunoglobulin Therapy
See	Transfusion
Update Information	This entry was last updated in TDSG-BM Edition 203, Release 02

Reiter's Syndrome

Discretionary	If fully recovered, accept.
Update Information	This entry was last updated in TDSG-BM Edition 203, Release 02

Renal Colic

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

Respiratory Disease

Obligatory	**Must not donate if:** Out of breath on minimal exertion.
See if Relevant	Infection - General Steroid Therapy
Update Information	This entry was last updated in

TDSG-BM Edition 203, Release 02

Retinitis Pigmentosa

Discretionary Accept.

See if Relevant Disabled Donor

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

Rheumatic Fever

Obligatory **Must not donate if:**
a) Has had more than one attack.

b) It is less than two years from any symptomatic disease.

c) Requires antibiotic cover for dental treatment.

Additional Information Rheumatic fever can cause damage to the heart valves and this could make it unsafe to donate.

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

Rheumatoid Arthritis

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

See if Relevant Disabled Donor
Nonsteroidal Anti-Inflammatory Drugs (NSAID)

See Autoimmune Disease

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

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

Ringworm

Obligatory **Must not donate if:**
a) Affecting site of venepuncture or harvest.

b) On systemic treatment.

Discretionary If on local treatment only, accept.

See if Relevant Infection - General

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

Rubella

Acute Infection

See Infection - Acute

Contact

See Infectious Diseases - Contact with

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

Sarcoidosis

Acute

Obligatory **Must not donate if:**
a) Not recovered.

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

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

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

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

'Additional Information" has been added.

Chronic

Obligatory **Must not donate.**

Additional Information Chronic sarcoidosis can cause a range of problems, particularly with the lungs but also with the heart, that may pose risks for a potential donor. The treatments used may also cause immunosuppression. For these reasons people with this condition should not donate.

Reason for Change 'Additional Information' has been added.

Update Information This entry was last updated in TDSG-BM Edition 203, Release 17

Self-Catheterization

Obligatory **Must not donate.**

Additional Information Donors 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.

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

Sex Worker

Obligatory **Must not donate.**

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

See if Relevant
Addiction and Drug Abuse
Hepatitis of Viral Origin
HIV
HTLV
Infection - General

Additional Information In this context sex is defined as vaginal, oral or anal sex with or without a condom /protective. This guidance presumes that a validated NAT test for HIV, HBV and HCV is negative, if this test is stopped for any reason the guidance will change.

If received injectable drugs of addiction for sex, see 'Addiction and Drug Abuse' entry as a 12 month deferral may apply.

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

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

Sexually Transmitted Disease

Infected Individual

Obligatory **See:**
Is there is a specific entry for the disease?

Must not donate

Discretionary If fully treated, at least three months from completion of treatment, accept. Additionally, for gonorrhoea, evidence of a test of cure after treatment is required. This may be a verbal confirmation, provided by the donor.

See if Relevant
Genital Warts
Herpes - Genital
Infection - Acute
Syphilis
Tissues Safety Entry

Sexual Partner

Obligatory **See:**
Is there is a specific entry for the disease with which there has been contact?

Must not donate if:
a) Donor required treatment and it is less than three months since completing that treatment.

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

Discretionary a) Donor did not require treatment and it is more than three months since the infected partner has completed treatment, accept.

b) Donor required treatment: if fully treated, and if it is at least three months from completion of treatment, accept. Additionally, for gonorrhoea, evidence of a test of cure after treatment is required. This may be a verbal confirmation, provided by the donor.

c) If the donor's sexual partner has been diagnosed with chlamydia (except lymphogranuloma venereum, see (b) above), genital warts or genital herpes and the donor is asymptomatic and not undergoing treatment or investigation, accept.

See if Relevant
Genital Warts
Herpes - Genital
Infection - Acute
Syphilis
Tissues Safety Entry

Additional Information
Guidelines (NICE, BASHH) recommend that current sexual partners of lymphogranuloma venereum (LGV) probable or confirmed individuals should receive testing and empiric treatment with a chlamydial regimen. They can be accepted 3 months after completion of treatment.

Reason for Change
'See if Relevant' links have been updated.

Update Information
This entry was last updated in
BM-DSG Edition 203 Release 58

Shingles

Affected Individual

See
Herpes Zoster

Reason for Change
The links have been changed for clarity.

Contact

See
Infectious Diseases - Contact with

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

Sickle-Cell Trait

Obligatory
1. Bone Marrow Donor:
Inform Transplant Centre if:
Cells are from a donor that has sickle-cell trait.

2. PBSC Donor:
Must not donate.

Additional Information
PBSC donors with sickle-cell trait may be at risk of their red cells sickling if the WBC becomes very raised following treatment with G-CSF.

Reason for Change
PBSC donors with sickle-cell trait must not donate.

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

Skin Disease

Obligatory
Must not donate if:
a) The condition is infected or infectious.

b) Malignant.

c) Affecting site of venepuncture or harvest.

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

See if Relevant
Dermatitis
Infection - General
Malignancy
Psoriasis

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

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

Sleeping Sickness

This entry has been removed. See African Trypanosomiasis.

Smallpox Immunization

Contacts

Obligatory **Must not donate if:**
a) Any secondarily infected site has not yet healed.

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

Discretionary If no new skin lesions, accept.

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

Immunized Individual

Obligatory **Must not donate if:**
a) The inoculation site has not fully healed.

b) Any secondarily infected site has not fully healed.

c) Less than eight weeks from inoculation or from the appearance of any secondarily infected site.

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

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

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

Snake Bite

Obligatory **Must not donate until:**
Recovered.

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

South American Trypanosomiasis

Also Known As Chagas disease

Obligatory **Must not donate.**

See if Relevant South American Trypanosomiasis Risk

Update Information This entry was last updated in
BM-DSG Edition 203 Release 59

South American Trypanosomiasis Risk

Obligatory **Must not donate if:**
1) Born in South America or Central America (including Mexico).

2) Mother was born in South America or Central America (including Mexico).

3) Has had a transfusion in South America or Central America (including Mexico).

4) Has lived and/or worked in rural subsistence farming communities in these countries for a continuous period of four weeks or more.

Discretionary 1) If at least four months from the date of last exposure, including transfusion abroad, and a validated *T. cruzi* antibody test is negative, accept.

2) If less than four months following the date of last exposure, discuss with a **Designated Medical Officer.**

3) If transfused after 1st January 1980, discuss with the **Designated Medical Officer** who will decide if the donor may be accepted following a documented risk assessment. This must take into account the availability of alternative donors, the risks of vCJD transmission and the expected benefits of using a particular donor.

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

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

Camping or trekking in the jungle in South or Central America (including Mexico) is not considered of high enough risk to merit exclusion.

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

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

Spina Bifida

Obligatory **Must not donate if:**
a) Has an indwelling shunt.

b) Uses a catheter.

c) Has a pressure sore.

See if Relevant Disabled Donor

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

Spinal Surgery

See if Relevant Neurosurgery
Surgery
Transfusion

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

Splenectomy

Obligatory **Must not donate if:**
a) For malignancy.

b) For a myeloproliferative disorder.

c) For immune thrombocytopenia (ITP).

d) For haemolytic anaemia.

Discretionary a) If for trauma, when recovered accept.

b) If taking prophylactic antibiotics, accept.

See if Relevant Immune Thrombocytopenia
Malignancy
Surgery
Transfusion

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

Steroid Therapy

Obligatory **1. Must not donate if:**

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

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

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

associated with allergy.

2. Bone Marrow Donor:
Inform anaesthetist if:
Course of steroids in last month.

Discretionary

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

b) If using steroid inhalers for prophylaxis, accept.

See if Relevant

Autoimmune Disease
Liver Disease
Skin Disease
Tissue and Cell Allograft Recipients

Additional Information

Steroid therapy in high doses causes immunosuppression. This may mask infective and inflammatory conditions that would otherwise prevent donation.

Reason for Change

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

Update Information

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

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

Stroke

Obligatory

Must not donate.

Update Information

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

Surgery

Definition

Major surgery for the purposes of donor selection: Any surgical procedure where recovery is not achieved within two months.
Recovery from surgery: Donors can be considered to be recovered if they:

- are well,
- are back to activities of daily living (e.g. housework, employment, driving),
- have regained mobility

Obligatory

Must not donate if:
a) For malignancy or other condition that would preclude donation.
b) All wounds are not healed.
c) There are signs or symptoms of any infection.
d) Not fully recovered.
e) Less than four months after major surgery.
f) Less than seven days after other surgery.
g) Requiring post-operative treatment or follow-up that might indicate further intervention is required, excluding routine follow-up or physiotherapy.
h) If waiting for surgery that is:

- expected to occur within three months, or
- required due to possible malignancy or other condition that would preclude donation.

i) Less than seven days after completing postoperative prophylactic anticoagulant treatment.

Discretionary

a) If less than four months from the major surgical procedure, discuss with the DCSO who will decide if the donor may be accepted on a balance of risks following discussion with the Transplant Centre.
b) If the donor is waiting for surgery that is not required for possible malignancy, and:

- the procedure is not expected to take place within three months, or

- the procedure is minimally invasive, and it is not expected to take place within one month,

accept.
c) If it is less than three months since any surgical procedure performed outside of the UK and ROI, and all other criteria for surgery performed within the UK and ROI are met, discuss with the DCSO. See additional information.

See if Relevant

Anaesthetic

Anticoagulant Therapy

Basal Cell Carcinoma

Cervical Carcinoma in Situ

Dental Treatment

Neurosurgery

Ocular Surgery

Tissue and Cell Allograft Recipients

Transfusion

Xenotransplantation

Additional Information

Surgery may cause significant blood loss. It is important that donors waiting for an operation should not be put at risk of anaemia or poor iron stores by donating prior to planned surgery. Unless the type of surgery planned is unlikely to result in significant blood loss the donor should be deferred until after their planned surgery. This will minimize their own chance of needing a transfusion, which would of course prevent them from continuing as a donor. It is also important not to hinder the recovery of the donor. This requires waiting until they are fully recovered before they donate again.

Surgery may place the donor 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 or until the tests performed by the Blood & Tissues Services can pick up any infection that they test for that may have been transmitted to the donor by surgery.

The entry has been revised to include a definition of recovery and amendment of the definition of major surgery. The deferral after major surgery has been shortened.

Specific guidance for, donors awaiting surgery and postoperative thromboprophylaxis has been added.

As there may be uncertainty about additional risks for surgery performed outside of the UK and ROI, which may vary between countries, referral to DCSO for individual risk assessment is advised.

Reason for Change

Definition of major surgery changed. ‘Obligatory’, ‘Discretionary’ and ‘Additional Information’ sections updated. ‘See if Relevant’ links added.

Update Information

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

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-BM Edition 203, Release 52

Systemic Lupus Erythematosus

Obligatory **Must not donate.**

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

Tamoxifen

Obligatory See Malignancy entry.

Discretionary Less than 12 weeks after completion of treatment with tamoxifen – refer to designated clinical support officer.

See if Relevant Infertility

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-BM 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-BM Edition 203, Release 02

Thalassaemia Major

Obligatory **Must not donate.**

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

Therapeutic Venesection

Obligatory **Must not donate.**

Discretionary **1.** If for haemochromatosis, accept.

2. Bone marrow donation:
If for confirmed secondary polycythaemia, ask for anaesthetic opinion.

See if Relevant Haemochromatosis

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

Threadworms

Discretionary Even if on treatment, accept.

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

Thrombosis and Thrombophilia

Obligatory

1. Must not donate if:
a) Due to atherosclerosis (e.g. coronary thrombosis).
b) Recurrent thrombosis.
c) Less than seven days after completing anticoagulant therapy.
d) Has a thrombophilic trait and has had one or more episodes of thrombosis.
e) History of Vaccine Induced Thrombotic Thrombocytopenia (VITT), Thrombotic Thrombocytopenic Purpura (TTP) or Heparin Induced Thrombocytopenia (HIT)

2. Bone Marrow Donor:
Inform anaesthetist of past history of thrombosis.

Discretionary

a) If a specific cause for an isolated deep vein thrombosis or pulmonary embolism has been identified, not of itself a reason for exclusion, and anticoagulant therapy has been stopped for at least seven days, accept.
b) If the potential donor has a thrombophilia, refer to DCSO for expert clinical advice
c) If the potential donor has a history of Axillary Vein Thrombosis, refer to a DCSO. (Please see additional information)
d) If the potential donor has a history of Superficial Thrombophlebitis, and

- The donor is not on antithrombotic therapy, and
- No underlying cause has been identified which precludes donation,

accept – if in doubt **refer to DCSO.**

See if Relevant

Anticoagulant Therapy
Autoimmune Disease
Cardiovascular Disease
Coronavirus vaccination
Drug Index – preparations which may affect platelet function
Malignancy
Nonsteroidal Anti-Inflammatory Drug

Additional Information

G-CSF may induce a transient prothrombotic or hypercoagulable state in donors. Surgery (in bone marrow donation) is a well-known risk factor for thrombosis. The literature suggests several severe thrombotic events including a death in (related) donors donating bone marrow as well as PBSC. (Halter et al -2009)
This has led to a generally accepted policy to defer donors with (risk factors or a predisposition to) thrombotic events.

Thrombophilia is a broad medical term which describes a multifactorial condition where the blood has an increased tendency to clot. Individuals with thrombophilia can present with arterial or venous thrombosis. The causes of thrombophilia include inherited and acquired disorders, and a combination of causes may be present.
Inherited causes of thrombophilia may be discovered through family testing. These include:

- Antithrombin, Protein C and Protein S deficiency
- Factor V Leiden and prothrombin gene mutations

Acquired causes of thrombophilia may present later in life and can be associated with:

- Malignancy including myeloproliferative neoplasms
- Antiphospholipid syndrome and other autoimmune connective tissue disorders. These may be associated with a lupus anticoagulant and/or anticardiolipin antibodies on laboratory testing.

VITT, TTP and HIT are rare disorders characterised by arterial or venous thrombosis in combination with a low platelet count (due to platelet consumption). Donors who recover from these disorders are unlikely to be eligible to donate due to the therapy they received (e. g the primary treatment for TTP is plasma exchange with FFP) or an underlying condition (e. g. the indication for Heparin therapy that triggered HIT). VITT was recognised as a complication of some SARS-CoV-2 (COVID-19) vaccinations.

Axillary Vein Thrombosis can be precipitated by excessive use of the arm (e.g. sports or working above head level) but other precipitants include venous compression in thoracic outlet syndrome, diabetes, smoking, malignancy and venous canulation. The donor may be eligible to donate if the underlying cause has been identified and corrected, but this should be balanced with the remote risk of local complications from a subsequent donation.

Superficial thrombophlebitis is inflammation of a vein just under the skin, usually in the leg, which can be accompanied by a small blood clot. This is different to, and less serious than, a deep vein thrombosis (DVT). If the superficial clot extends to where the superficial and deep veins join, a DVT can develop. Superficial thrombophlebitis normally settles within two to six weeks. Some individuals may be treated with anticoagulants to reduce the risk of extension.

Reason for Change

Align with the recently updated WB-DSG This entry has been renamed and revised to include more detail about a range of thrombotic and thrombophilic disorders.

Update Information

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

Thrush - Oral

Obligatory

Must not donate if:
a) Unexplained.

b) Related to immunodeficiency.

See if Relevant

Infection: Chronic

Reason for Change

This entry has been revised to link discretionary acceptance to the current ‘Infection: Chronic’ entry.

Update Information

This entry was last updated in
TDSG-BM Edition 203, Release 42

Thrush - Vaginal

Obligatory

Must not donate if:
a) Related to immunodeficiency.

See if Relevant

Infection: Chronic

Reason for Change

This entry has been revised to link discretionary acceptance to the current 'Infection: Chronic' entry.

Update Information

This entry was last updated in
TDSG-BM Edition 203, Release 42

Thyroid Disease

Obligatory

Must not donate if:
a) Under investigation.

b) Malignant.

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

d) Less than 24 months from stopping treatment with anti-thyroid tablets.

Discretionary

If on stable maintenance treatment with thyroxine, accept.

See if Relevant

Autoimmune disease
Beta Blockers
Surgery

Reason for Change

Links to 'Autoimmune Disease' and 'Beta Blockers' have been added.

Update Information

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

Tissue and Cell Allograft Recipients

Excludes

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

Obligatory

All donors:
Must not donate if:
a) Dura mater transplanted at any time.

b) Ocular tissue transplanted at any time.

c) Any other allogeneic human tissue or cell transplanted since 1st January 1980, refer to DCSO.

Discretionary

a) If an autologous tissue, or cells, has been transplanted at any time, and there is no other reason to exclude the donor, accept.

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

See if Relevant

Immunosuppression
Ocular Tissue Recipient

Organ Recipient
Prion Associated Diseases

Surgery

Transfusion
Xenotransplantation

Additional Information

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.

Reason for Change

This is a new entry.

Update Information

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

Tissues Safety Entry

Definition

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

Partner risk is based on sexual contact with a partner who may, at a population level, be at higher risk of acquiring infection, as described in this entry.

Sexual contact is defined as oral, vaginal or anal sex.

Anal sex is defined as penile-anal intercourse only. It does not apply to oro-anal sex or the use of sex toys.

Chemsex is sex while using stimulant drugs taken for the specific purpose of enhancing sexual experience and reducing inhibitions. Chemsex does not refer to sex after using alcohol or recreational drugs for other purposes, nor the use of drugs such as Viagra or Cialis to treat erectile dysfunction.

Obligatory

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

1. You must not donate if:
You think you need a test for HIV/AIDS, HTLV or hepatitis.

2. You must never donate if:
a) You are HIV positive.

b) You are HTLV positive.

c) You are a hepatitis B carrier.

d) You are a hepatitis C carrier.

3. You must not donate for at least 12 months:
After stopping habitual use of injected drugs of addiction.

4. You must not donate for at least 3 months if:
a) You have taken Pre-Exposure Prophlyaxis (PrEP) / Truvada by mouth to prevent HIV.

b) You have taken or been prescribed Post-Exposure Prophylaxis (PEP) by mouth to prevent 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 24 months if:

You have received PrEP as an injection to prevent HIV e.g. cabotegravir (Apretude®).

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

6. 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.

7. 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.

8. 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 Unknown 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 oral PrEP or PEP in the previous three months, or received injectable PrEP in the previous 24 months, should not donate. This applies even if they are otherwise eligible under individual risk criteria.

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

Reason for Change Addition of a 24-month deferral for recipients of injectable PrEP.

Update Information This entry was last updated in
BM-DSG Edition 203 Release 58

Topical Medication

Obligatory **Must not donate if:**
There is broken or infected skin at the site of venepuncture or harvest.

Discretionary If the condition being treated does not exclude, accept.

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

Toxoplasmosis

Obligatory **Must not donate if:**
Less than six months from recovery.

Additional Information This is a common parasitic infection, often spread by cat faeces or eating undercooked meat. It can be spread through transfusion. It may have serious consequences or even prove fatal for the recipient. Usually it does not cause symptoms, as the body's immune system easily overcomes the parasite. If the infection has caused symptoms that has lead to it being diagnosed, waiting six months from recovery will make it unlikely that it will be passed on by donation.

Reason for Change Entry has been simplified following a risk assessment by SACTTI.

Update Information This entry was last updated in
TDSG-BM Edition 203, Release 14

Transfusion

Includes Treatment with Blood Components, Products and Derivatives.

Obligatory

1. Must not donate if:
At any time the donor has:
a) Received, or thinks they may have received, a transfusion of blood or blood components in a country endemic for malaria or South American trypanosomiasis. See 'Discretionary' section below for exceptions.

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

2. Since January 1st 1980:
a) Anywhere in the world, the donor has received, or thinks they may have received, a transfusion 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 donor has been transfused, accept.

b) Received, or thinks they may have received, a transfusion of blood or blood components before 1st Jan 1980, accept – See 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 donor's own blood has been used, accept.

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

4. Donor transfused since January 1st 1980:
Discuss with the Designated Medical Officer who will decide if the donor may be accepted following a documented risk assessment. This must take into account the availability of alternative donors, the risks of vCJD transmission and the expected benefits of using a particular donor.

See if Relevant

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

Additional Information

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

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

Coagulation concentrates:

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

Donors transfused since 1980:
In the autumn of 2003 a UK recipient of blood, taken from a healthy donor who later developed vCJD, died from vCJD. Since then there has been a very small number of cases of infection with the vCJD prion in recipients of blood from donors who have later developed vCJD.

In view of this, people transfused or possibly transfused since 1980 should not normally be accepted. 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.

Reason for Change

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 donors transfused since January 1st 1980.
IV) To harmonise the definition of what constitutes a transfusion.

Update Information

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

Transgender Individuals

Definition

Cisgender (cis) describes someone whose gender identity is the same as the sex they were assigned at birth.

Transgender (trans) describes someone whose gender is not the same as, or does not sit comfortably with, the sex they were assigned at birth.

Obligatory

Assessment of the donor suitability should be according to the gender assigned at the time of donation. See ‘Additional Information’ section.

Discretionary

Accept

See if Relevant

Tissues Safety Entry
Surgery

Additional Information

Consideration should be given to the medications used during gender re-assignment. An individual risk assessment is required with regard to potential effects on the donor, donated material and any potential risk to the recipient.

Assessment of haemoglobin concentration should be according to the gender assigned. The higher haemoglobin concentration of men, compared to women, is related to testosterone levels. Testosterone levels will rise if a person who was assigned female at birth receives hormone therapy as part of transitioning. This will result in the haemoglobin concentration rising to the higher range seen in cis men. The opposite will be true if a person who was assigned male at birth transitions.

Reason for Change

This entry was revised to support the implementation of the FAIR III report; the additional information section has been revised to reflect the circumstances of tissue and cell donations.

Update Information

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

Transient Ischaemic Attacks

Obligatory **Must not donate.**

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

Travel

See if Relevant
Geographical Disease Risk Index
Malaria
South American Trypanosomiasis Risk
Infection - Tropical

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

Tropical Viruses

Includes
Chikungunya Virus, also known as CHIKV
Dengue Virus, also known as Dengue Fever
Yellow Fever, also known as YF
Zika Virus, also known as ZIKV, and Zika Virus Fever

Definition **Tropical Virus Endemic Areas:** are shown in the 'Geographical Disease Risk Index' (GDRI) as a Tropical Virus Risk.

Obligatory **Must not donate if:**
a) It is less than six months from a donor's return from a Tropical Virus Risk endemic area and the donor has been diagnosed with Chikungunya, Dengue, Yellow Fever, or Zika virus infection whilst there or following their return to the UK.

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

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

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

If donor clearance is being carried out at less than four weeks since the donor has returned to the UK, a risk assessment will be required as to whether to proceed or delay the donation so that there is a clear four weeks since return to the UK and the donor has remained well.

See if Relevant
Geographical Disease Risk Index
Infection - General
Infection - Tropical
Malaria
South American Trypanosomiasis

Additional Information When an allogeneic stem cell donor who has been asymptomatic has returned from a tropical virus endemic area, the preferred option is to wait for 28 days from return before clearing the donor if the stem cell collection can be delayed. In exceptional circumstances and if there is a pressing clinical need to proceed to clearing the donor or collection within 28 days of return, a risk assessment should be undertaken in conjunction with the transplant centre clinicians as to how they will manage their patient. This should include awareness of the timing of the return of the donor from the tropical virus endemic area, the likelihood of receiving a tropical virus positive donation (with its associated risks) from an asymptomatic

donor, and the option of delaying the clearance of the donor and stem cell collection plus conditioning of the patient as far as possible towards the day 28 of the return of the donor.

In a situation where a risk assessment is being undertaken to clear a donation for clinical use before the preferred 28-day return from an endemic area due to urgent clinical need, consideration should be given to referring samples for any relevant available laboratory testing (e.g. to the Porton Down reference laboratory). Please note, if testing for these viruses (if available) is negative, it does not necessarily mean there is no risk of transmission at less than 28 days post travel.

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 35ºN and 35ºS. There is no epidemiologically important animal reservoir for these viruses. The main geographical areas affected by these viruses include the Caribbean, South and Central America, Mexico, Africa, the Pacific Islands, SE Asia, Indian sub-continent, Hawaii. Additionally, Dengue fever has been reported in Australia and there have been outbreaks of Dengue and Chikungunya in Europe.

Position statements are available in the JPAC Document Library.

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

Reason for Change Discretionary and Additional Information sections have been revised. An Information statement regarding compliance with BSQR has been deleted.

Update Information This entry was last updated in
BM-DSG Edition 203 Release 58

Trypanosoma Cruzi Infection

Obligatory **Must not donate.**

See if Relevant South American Trypanosomiasis Risk

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

Tuberculosis

Affected Individual

Obligatory

Must not donate if:

a) Infected.

b) Less than 24 months from completing treatment.

c) Under follow-up.

Discretionary

a) If donor 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) Donors 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 donor has been informed that they do not need to be screened, accept.

See if Relevant

BCG
Heaf Test
Mantoux Test

Additional Information

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

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-BM Edition 203, Release 51

Turner's Syndrome

Discretionary

Accept.

Update Information

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

Varicose Veins

Discretionary Accept.

See if Relevant Phlebitis
Surgery
Thrombosis

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

Vasculitis

Obligatory **Must not donate.**

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

Vitamin Treatment

Obligatory

Must not donate if:
a) There is an underlying cause for vitamin deficiency that is a reason for exclusion.

b) If the donor has neurological damage due to B12 deficiency.

Discretionary

a) If the donor is being treated for a deficiency, discuss with DCSO.

b) If on oral self-medication or prescribed treatment to prevent deficiency, accept.

Additional Information

Vitamins commonly given to treat a deficiency include vitamin D, vitamin B12 and folic acid. Vitamin D is usually caused by dietary lack and lack of exposure to sunlight which do not contraindicate donation.

Vitamin B12 deficiency may be dietary or due to failure of absorption. One such failure of absorption, pernicious anaemia, is an autoimmune disorder usually caused by the body attacking the lining of the stomach. Other causes of malabsorption include coeliac disease, small bowel bacterial overgrowth and surgical removal of the stomach. Acceptable if due to stomach operation or dietary deficiency (e.g. vegan), and donor meets haemoglobin requirements.

Stem cell donors will have blood tests done before donation. These would pick up any effects of vitamin deficiency that could impact on the safety of donation such as low calcium and anaemia and allow individualised management.

Reason for Change

To provide more detailed guidance regarding when affected donors can be accepted.

Update Information This entry was last updated in BM-DSG Edition 203 Release 56

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-BM Edition 203, Release 52

Weight

Obligatory

1. Bone Marrow Donor:
Must not donate if:
a) Body Mass Index over 35.

b) Under 50 kg (7 stone 12 lb).

2. PBSC Donor:
Must not donate if:
a) Body Mass Index over 40.

b) Under 50 kg (7 stone 12 lb).

c) The donor is so overweight that they have difficulty in getting onto or off the bleed bed.

d) Venous access is very difficult.

Discretionary

1. Bone Marrow Donor:
a) If the Body Mass Index >35 to <40: Refer to DCSO. Obtain anaesthetic option, considering other anaesthetic risk factors and technical feasability.

2. PBSC Donor:
a) If Body Mass Index 40 – <43: Refer to DCSO, considering venous access.

b) Treatment with anti-obesity drugs, accept.

Additional Information Blood service staff should not put their own health at risk by helping donors on and off the donation couch except in an emergency.

It is recommended that no donor should lose more than 13% of their blood volume during any donation procedure. This is to protect them from adverse effects such as fainting and becoming anaemic.

Obesity also makes it desirable to use more than a donor's weight to estimate their blood volume. Fat contains far less blood as a proportion of its weight than muscle. In obese individuals the blood volume can be seriously overestimated from weight alone. Overestimating a donor's blood volume makes it more likely that they will have an adverse incident.

Donors who are overweight or obese tend to have more moderate-severe pain with PBSC donation. BM harvest is technically a considerably more difficult procedure in overweight donors. There is much evidence to support the concept that the morbidly obese in general (i.

e. with a BMI >35) have a higher risk of premature death, anesthetic complications and occult cardiovascular disease.

However, it is recognised that a high BMI does not always reflect obesity and body habitus and many high BMI donors may be fit and suitable to donate.

Reason for Change The levels of BMI/weight at which a BM or PBSC donor can be accepted have been changed to align with WMDA guidance.

Update Information This entry was last updated in
BM-DSG Edition 203 Release 56

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 a) 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.

b) For donors who have been back in the UK for less than four weeks before clearance or donation, 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 see additional information.

c) Donors who have been back in the UK for less than six months, and more than 28 days, 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, 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.

At least one case was reported in the literature that WNV has caused illness and death after transplantation of stem cells from inadequately screened donors, but the spectrum of this illness in recipients is unknown as patients who develop a pyrexia post-transplant and pre-engraftment will not routinely undergo screening for WNV infection.

Testing a donor early in the incubation period and then collecting haematopoietic stem cells some days later may not assure component safety. Therefore, the time of testing of donors within 28 days of return from an affected area becomes important to ensure testing is not carried out too early in the incubation period. This must be balanced against the patient’s clinical need, and the likelihood of detecting infection in an asymptomatic donor.

When an allogeneic stem cell donor who has been asymptomatic, has returned from a WNV endemic area, the preferred option is to wait for 28 days from return before clearing the donor if the stem cell collection can be delayed. In exceptional circumstances and if there is a pressing clinical need to proceed to clearing the donor or collection within 28 days of

return, a risk assessment should be undertaken in conjunction with the transplant centre clinicians as to how they will manage their patient. This should include awareness of the timing of the return of the donor from the WNV endemic area, the likelihood of receiving a WNV positive donation (with its associated risks) from an asymptomatic donor, and the options of:

1. Delay the clearance of the donor and stem cell collection plus conditioning of the patient as far as possible towards the day 28 of the return of the donor (with possible individual WNV NAT testing)

2. Product cryopreservation with delayed conditioning until the WNV individual NAT result from the day of donation sample is known.

Data on the risk of a WNV positive donation entering the UK blood supply is available and is considered to be very low. The UK Blood Services have carried out 288,533 WNV NAT tests on asymptomatic whole blood donors within 28 days of returning from WNV affected areas from June 2013- 2020, and there have been no positives identified (Available Data-Standing Advisory Committee on Transfusion Transmitted Infections). Further data available in the literature suggests RNA detection is possible within 2 days and up to 13 days of exposure using individual donor NAT testing. If this is the case, individual NAT testing in asymptomatic donors within 13 days of return from a WNV endemic area would permit donation to proceed if there is a pressing clinical need.

All these considerations support a screening stratification approach to allow the transplant centre to make a judgement based on the perceived clinical need versus risk of transplanting a positive donation to the recipient if the donor is within 28 days of return from a WNV endemic area and there is a pressing clinical need to proceed with transplantation, and so therefore donation.

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

Reason for Change To include donor clearance as a timepoint for consideration in risk assessment.

Update Information This entry was last updated in:
BM-DSG Edition 203 Release 56

Whooping Cough

Contact

See Infectious Diseases - Contact with

Infection

See Infection - Acute

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

Xenotransplantation

Includes Xenografts
Heterografts
Non-Human Organ Perfusion

Recipient

Definition Any procedure that involves the transplantation, implantation, or infusion into a human recipient of either (a) live cells, tissues, or organs from a non-human

animal source, or (b) human body fluids, cells, tissues, or organs that have had ex vivo contact with live, non-human animal cells, tissues, or organs. Xenotransplantation products include live cells, tissues and organs.

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

Obligatory **Must not donate if:**
Material from a **living** non-human animal source has been directly or indirectly in contact with the donor's blood supply. This does not include animal bites.

Sexual Partners of Xenotransplant Recipients, Current and Former

Obligatory **Must not donate.**

Additional Information Exposure to non-human animal material, particularly when the person exposed is immunosuppressed, may result in infections that would not normally affect humans being passed on.

Reason for Change Further guidance re Recipient definition

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

This entry was last updated in
TDSG-BM Edition 203, Release 24

XMRV

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

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

Reason for Change This is a new entry.

Update Information This entry was last updated in
TDSG-BM Edition 203, Release 12 Issue 01

Yaws

Obligatory **Must not donate.**

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

Updates to the BM-DSG

Specification of Current Version		
Publication	BM-DSG	
Edition	203	
Release	58	
Issue	01	13 October 2025

All changes to BM-DSG Edition 203 after Release 01

Release	Date	Change Notifications	
		Title	**CN No.**
58	13 October 2025	Sexually Transmitted Disease	32 - 2025
		Tropical Viruses	31 - 2025
		Hepatitis A	30 - 2025
		Injectable PrEP for HIV prevention	22 - 2025
57	30 April 2025	Appendix 3 - Table of Immunisations	09 - 2025
56	13 August 2024	West Nile Virus	40 - 2024
		Weight	39 - 2024
		Vitamin Treatment	34 - 2024
		Infection - Acute	31 - 2024
55	18 April 2024	Tropical Viruses	13 - 2024
		Cerebrovascular Disease and CNS Disease	11 - 2024
		Coronavirus Vaccination	10 - 2024
54	29 January 2024	Coronavirus Infection (COVID-19)	01 - 2024
		Gout	37 - 2023
		Adrenal Failure	36 - 2023
		Eye Disease	35 - 2023
53	15 November 2023	Coronavirus Infection (COVID-19)	33 - 2023
52	15 November 2023	Changes arising from the FAIR III report	17 - 2023
51	04 July 2023	Tuberculosis	25 - 2023
		Surgery	24 - 2023
		Liver Disease	23 - 2023
		Tissue and Cell Allograft Recipients	14 - 2023
50	12 April 2023	Malaria	21 - 2023
		Thrombosis and Thrombophilia	15 - 2023
		Mpox (Monkeypox)	13 - 2023
49	13 December 2023	Infectious Diseases - Contact With	52 - 2022
		Coronavirus Infection (COVID-19)	51 - 2022
48	12 September 2022	Table of Immunisations	55 - 2022
		West Nile Virus	50 - 2022
47	31 May 2022	Monkeypox	41 - 2022
		Clopidogrel	36 - 2022
		Diabetes Mellitus	34 - 2022
		Arrhythmias	31 - 2022
46	26 April 2022	Tropical Viruses	21 - 2022
45	07 April 2022	Coronavirus Infection	30 - 2022
44	16 March 2022	Diseases of Unknown Aetiology	17 - 2022
		Cervical Dysplasia	16 - 2022

		Body Piercing	15 - 2022
		Psoriasis	14 - 2022
		Infertility	13 - 2022
43	22 February 2022	Complementary Therapy	04 - 2022
42	04 August 2021	Thrush - Oral & Vaginal	30 - 2021
		Infertility	27 - 2021
		Immunisation	26 - 2021
		Coronavirus Infection	21 - 2021
		Colitis, Proctitis and Gastrointestinal Disease	20 - 2021
		Acne and Teratogenic Medications	19 - 2021
41	04 May 2021	COVID-19 Vaccination	11 - 2021
40	21 January 2021	COVID-19 Vaccination	05 - 2021
39	16 December 2020	COVID-19 Vaccination	74 - 2020
38	07 October 2020	Sexually Transmitted Disease	61 - 2020
		Transfusion	45 - 2020
		South American Trypanosomiasis	44 - 2020
		Infection - Chronic	43 - 2020
		Tamoxifen	42 - 2020
37	15 July 2020	Infection - Acute	41 - 2020
		Tamiflu® and Relenza®	40 - 2020
		Viral Haemorrhagic Fever	38 - 2020
		Rabies	37 - 2020
		Animal Bite	36 - 2020
36	08 June 2020	Coronavirus Infection	30 - 2020
35	23 March 2020	Coronavirus Infection	15 - 2020
34	24 February 2020	Coronavirus Infection	10 - 2020
33	17 February 2020	Coronavirus Infection	08 - 2020
32	24 February 2020	Coronavirus Infection	05 - 2020
31	30 September 2019	Sexually Transmitted Disease	23 - 2019
		Malignancy	22 - 2019
		Inflammatory Bowel Disease	20 - 2019
		Hepatitis C	19 - 2019
		Complementary Therapy	17 - 2019
		Viral Haemorrhagic Fever	15 - 2019
		Tissue Safety Entry	14 - 2019
		Pre- and Post-Exposure Prophylaxis for HIV	13 - 2019
		Hepatitis A	12 - 2019
30	26 September 2018	Transgender Individuals	32 - 2018
		Infection - Chronic	28 - 2018
		Infection - Acute	26 - 2018
29	24 April 2018	Viral Haemorrhagic Fever	15 - 2018
		Transfusion	14 - 2018
		Pregnancy	11 - 2018
		Hepatitis E	10 - 2018
		Hepatitis A	09 - 2018
		Haemoglobin Disorders	08 - 2018
		Glycogen Storage Disease	06 - 2018
		G6PD Deficiency	05 - 2018
		Central Nervous System Disease	04 - 2018

28	17 January 2018	Poisoning	01 - 2018
27	27 November 2017	Bleeding Disorder	50 - 2017
		Syphilis	48 - 2017
		Sex Worker	46 - 2017
		Inoculation Injury	43 - 2017
		HTLV	42 - 2017
		HIV	38 - 2017
		Hepatitis C	36 - 2017
		Hepatitis B	34 - 2017
		Complementary Therapy	32 - 2017
		Body Piercing	30 - 2017
		Addiction and Drug Abuse	28 - 2017
		Tissue Safety Entry	27 - 2017
		Surgery	24 - 2017
		Tissue and Organ Recipients	23 - 2017
		Radiation Therapy	22 - 2017
26	01 August 2017	Malaria	17 - 2017
25	10 October 2016	Hepatitis A	46 - 2017
24	13 July 2016	Xenotransplantation	29 - 2016
		Severe Exercise Intolerance Disease (SEID)	28 - 2016
		Endoscopy	24 - 2016
23	02 February 2016	Viral Haemorrhagic Fever	15 - 2016
		Tropical Viruses	04 - 2016
22	18 January 2016	Viral Haemorrhagic Fever	11 - 2016
		West Nile Virus	09 - 2016
		Tropical Viruses	08 - 2016
		Appendix 2 - Table of Immunisations	04 - 2016
21	23 June 2015	Injectable Tanning Agents	15 - 2015
		Complementary Therapy	12 - 2015
20	17 March 2015	Infertility	09 - 2015
		Complementary Therapy	08 - 2015
		Communication Difficulties	07 - 2015
19	20 October 2014	Viral Haemorrhagic Fever Risk	43 - 2014
18	11 August 2014	Sex Change	38 - 2014
		Homosexual and Bisexual Individuals	34 - 2014
		Tissues Safety Entry	32 - 2014
		SARS	31 - 2014
		Haematological Disease	30 - 2014
		Change of Title	29 - 2014
17	31 March 2014	Weight	16 - 2014
		Paratyphoid and Typhoid	15 - 2014
		South American Trypanosomiasis Risk	14 - 2014
		Sarcoidosis	13 - 2014
		Mental Health Problems	12 - 2014
		Malignancy	11 - 2014
		Kidney Disease	10 - 2014
		Hepatitis of Unknown Origin	08 - 2014
		Hepatitis B	07 - 2014
		Hepatitis B - Post Immunisation	06 - 2014

		Central Nervous System Disease	05 - 2014
		Body Piercing	04 - 2014
		Aliretinoin, Toctino, Acne and Dermatitis	03 - 2014
		Acupuncture	02 - 2014
16	09 July 2013	Infection - Chronic	10 - 2013
		Hepatitis B - Post Immunisation	09 - 2013
		Hepatitis B	08 - 2013
15	04 June 2013	West Nile Virus	01 - 2013
14	29 June 2012	Toxoplasmosis	18 - 2012
		Psoriasis	17 - 2012
		Pregnancy	16 - 2012
		Acne	15 - 2012
13	28 March 2012	West Nile Virus	05 - 2012
12	24 January 2012	Hepatitis C	27 - 2011
		XMRV	25 - 2011
11	06 December 2011	Porphyria	20 - 2011
10	08 August 2011	West Nile Virus	11 - 2011
09	21 June 2011	Sexually Transmitted Disease	09 - 2011
		Infertility	08 - 2011
		BCG	07 - 2011
		Immunisation - Live	06 - 2011
08	01 September 2010	West Nile Virus	09 - 2010
07	03 March 2010	Endoscopy	05 - 2010
		Inoculation Injury	04 - 2010
		Body Piercing	02 - 2010
06	24 December 2009	Complementary Therapy	35 - 2009
		Acupuncture	33 - 2009
05	01 December 2009	Relenza® (Zanamivir)	31 - 2009
		Tamiflu® (Oseltamivir)	30 - 2009
04	31 July 2008	Appendix 4	05 - 2008
		Blood Pressure - High	01 - 2008
03	14 January 2008	Bleeding Disorder	18 - 2007
02	11 December 2007	Public release – for changes see Appendix 1 - Changes to the Guidelines	
01	01 June 2007	Consultation release − not for implementation	

Appendix 1 - Changes to Donor Selection Guidelines

Section 1

Changes introduced with BM-DSG 203 Release 02 from BM-DSG 202 Release 03

There have been changes made to the following entries:

Acupuncture
Age
Animal Bite
Ankylosing Spondylitis
Anti-Androgens
Antibiotic Therapy
Antidepressant Therapy
Arthritis
Autoimmune Disease
Back Problems
Beta Blockers
Bipolar Disorder
Bleeding Disorder
Blood Pressure - High
Blood Volume Estimation
Cardiovascular Disease
Chikungunya Virus
Chlamydia
Cirrhosis
Colitis
Communication Difficulties
Depression
Dermatitis
Disabled Donor
Disease of Unknown Aetiology
Elliptocytosis
Endocarditis
Endoscopy
Episcleritis
Eye Disease
Gall Bladder Disease
G-CSF
German Measles
Haemoglobin Disorders
Haemolytic Anaemia
Hepatitis B
Hepatitis B - Post Immunization
Hepatitis C
Hepatitis of Unknown Origin
Hereditary Elliptocytosis
Hereditary Spherocytosis
Hormone Replacement Therapy
Immune Thrombocytopenia
Immunoglobulin Therapy
Immunosuppression
Infection - Chronic
Inflammatory Eye Disease
Inoculation Injury
Jaundice
Laminectomy
Latex Allergy
Malaria
Mental Health Problems
Myeloproliferative Syndrome
Pituitary Extract - Human
Platelet Disorder
Polymyalgia Rheumatica
Prion Associated Diseases
Psoriasis
Pyruvate Kinase Deficiency
Rheumatoid Arthritis
Scleritis
Sexually Transmitted Disease

Shingles
Sickle-Cell Trait
Skin Disease
Steroid Therapy
Subacute Bacterial Endocarditis
Surgery
Syphilis
Temporal Arteritis
Thrombocytosis
Thyroid Disease
Tigason
Tissue and Organ Recipients
Transfusion
Weight
West Nile Virus

Section 2

Changes to BM-DSG 203 after Release 02

See: Updates

This appendix was last updated in BM-DSG 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 stem cells have 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 stem cells. 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 donor at risk of infection with blood borne organisms (**Tissues Safety Entry**).

b) Donors in the 'at risk' categories relating to possible transmission of **Prion Associated Diseases** e.g. CJD and vCJD.

c) Donors with **Malignancy** (other than those for which there is a discretion in the **A-Z**)

d) **Autoimmune Disease**.

e) **Allergy**.

f) Donors with certain **Infectious Diseases** at the time of donation or who were in contact with and still within the incubation period of an Infectious Disease at the time of donation.

g) Donors with diseases of unknown aetiology.

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

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

Appendix 3 - Table of Immunisations

Diseases Protected against	Comments and example trade names of adult preparations	
Anthrax	Rarely given	Non-Live
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®	**Live**
	Dukoral®	Non-live
COVID-19 (SARS-CoV-2)	All COVID-19 vaccines licensed in the UK are Non-Live.	Non-Live
Dengue	**Qdenga®, Dengvaxia®**	**Live**
Haemophilus influenza type b (Hib)	Menitorex®	Non-Live
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®	Non-Live
Hepatitis B	May be combined with hepatitis A. If unexposed and more than 7 days from last immunisation, accept. See: Hepatitis B – Immunisation Engerix®, Fendrix®, HBvaxPRO®, PreHevBri®, Ambirix®, Twinrix®	Non-Live
Human papillomavirus (HPV)	Cervarix®, Gardasil®	Non-Live
Influenza, intra-nasal	**Live vaccine given by intra-nasal spray, age 2-18.** **Fluenz Tetra®**	**Live**
Influenza, injection	Annual 'flu jab', given by injection. Several preparations, updated annually.	Non-Live
Japanese Encephalitis	Travel. Ixiaro®	Non-Live
Measles, Mumps, Rubella	**MMR vaccines. M-M-RvaxPro®, Priorix®**	**Live**
Meningitis	Meningococcal group C: NeisVac-C®, Menjugate Kit® Meningococcal group B: Bexsero®, Trumenba® MenACWY Quadrivalent vaccine: Menveo®, Nimenrix®, MenQuadfi® Combined with *H. influenzae* type b (Hib): Menitorix®	Non-Live
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 Mpox	Non-Live
Pertussis	Usually pregnant women, given in combination with Diphtheria, Tetanus and Polio vaccine or in combination with Diphtheria and Tetanus vaccine.	Non-Live
Pneumococcal disease	Given to people with specific risks: for example, people who have had a splenectomy or people over 65. Pneumovax®23	Non-Live
Polio, injected	Given in combination with other vaccines including, depending on the preparation,	Non-Live

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