Issued by JPAC: 07 October 2020	**Implementation:** To be determined by each Service

Change Notification UK National Blood Services No. 45 - 2020

Transfusion

These changes apply to the Bone Marrow and Peripheral Blood Stem Cell, Cord Blood and Living Tissue Donor Selection Guidelines

Please make the following changes:

Bone Marrow and Peripheral Blood Stem Cell Donor Selection Guidelines

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. ~~Refer to a Designated Medical Officer if:~~ 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 ~~with red cells, platelets, fresh frozen plasma (FFP), cryoprecipitate,~~ intravenous or subcutaneous human normal immunoglobulin. This includes mothers whose babies have required intra-uterine transfusion. b) Had a plasma exchange performed. **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 ~~4~~ 3 below if transfused abroad.

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	c) If treatment with human immunoglobulin has been limited to small quantities of specific immunoglobulin as prophylaxis (e.g. rhesus, tetanus, hepatitis, immunoglobulin etc.), accept. ~~d) If the only transfusion has been within the last week of life, accept~~ ~~e~~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. Heart valve, ocular tissue, skin and pancreatic islet donors only:**~~ ~~Provided the donor's total transfusion exposure is limited to less than 80 units of blood or blood components, accept. – See 4 below if transfused abroad~~ ~~4~~ **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. ~~b) If tissue will be sterilized by irradiation post-donation: Accept (testing not required)~~ ~~c) For Eyes only, if the risk was for Malaria or South American trypanosomiasis, accept for corneas only (testing not required).~~ **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 ~~(with the exception of Malaria and South American trypanosomiasis for cornea donors only, or for tissues that are terminally sterilised)~~ before accepting the donor.

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	Coagulation concentrates: People who have received blood derived coagulation concentrates (these are made from the blood of many donors) regularly may have been put at risk of infections that can be passed through blood. **Donors transfused since 1980:** In the autumn of 2003 a UK recipient of blood, taken from a healthy donor who later developed vCJD, died from vCJD. Since then there has been a very small number of cases of infection with the vCJD prion in recipients of blood from donors who have later developed vCJD. In view of this, people transfused or possibly transfused since 1980 ~~(except in the last week of life)~~ should not normally be accepted. ~~Because of shortages in supply, this does not currently apply to the donation of heart valves, ocular tissue, pancreatic islets and skin.~~ Any history of transfusion after 1980 must be recorded and remain part of the documentation associated with the donation. Plasma exchange results in the patient having been exposed to multiple donors. In view of the increased vCJD risk, donations may not be taken from individuals who have had a plasma exchange performed since 1980. Commonly used PCCs, such as Beriplex or Octaplex, currently used in the UK, are prepared from non-UK donors. They are administered as one-off doses to reverse anticoagulation or 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	~~To permit donation from donors who have received a one-off dose of PCC since 1999 for prophylaxis or reverse anticoagulation. To improve clarity with regard to donors transfused in other parts of the world.~~ 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.

Cord Blood Donor Selection Guidelines

Transfusion

Includes	Treatment with Blood Components, Products and Derivatives.
Obligatory	**1. Must not donate if:** **At any time the mother has:** a) Received, or thinks they may have received, a transfusion of blood or blood components in a country endemic for malaria or South American trypanosomiasis. See 'Discretionary' section below for exceptions. b) Has received regular treatment with blood derived coagulation factor concentrates.

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	c) Intra-uterine transfusion has been required in this pregnancy. **2. Since January 1st 1980:** a) Anywhere in the world, the ~~donor~~ mother has received, or thinks they may have received, a transfusion of blood or blood components, or ~~with red cells, platelets, fresh frozen plasma (FFP), cryoprecipitate,~~ intravenous or subcutaneous human normal immunoglobulin. This includes mothers whose babies have required intra-uterine transfusion. b) Had a plasma exchange performed. **3. Before January 1st 1999:** Treated with prothrombin complex to reverse over-anticoagulation.
Discretionary	**1.** a) If on medical inquiry it is unlikely that the mother has been transfused, accept. b) Received, or thinks they may have received, a transfusion of blood or blood components before 1st Jan 1980, accept – See ~~4~~ 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) If the only transfusion has been within the last week of life, accept~~ ~~e~~d) Treated with prothrombin complex (PCC) to reverse over-anticoagulation after 1st January 1999, accept. **2. Autologous Transfusion:** If **only** the mother's own blood has been used, accept. ~~**3. Heart valve, ocular tissue, skin and pancreatic islet donors only**: Provided the donor's total transfusion exposure is limited to less than 80 units of blood or blood components, accept. – See 4 below if transfused abroad~~ 4 **3. ~~Donor~~ Mother transfused in a country endemic for malaria or South American trypanosomiasis:** a) Check the Geographical Disease Risk Index. If transfused in an at risk endemic country and a validated malarial antibody test and/or (as appropriate) a validated test for T.cruzi antibody is negative, at least 4 months after exposure accept. If transfusion happened after January 1st 1980, see point 4 below. ~~b) If tissue will be sterilized by irradiation post-donation: Accept (testing not required)~~ ~~c) For **Eyes** only, if the risk was for Malaria or South American trypanosomiasis, accept for corneas only (testing not required).~~

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	4. Mother transfused since January 1st 1980: Discuss with the **Designated Medical Officer** who will decide if the donation may be accepted. The full transfusion history must be recorded and remain part of the documentation.
See if Relevant	Bleeding Disorder Immunoglobulin Therapy Immunosuppression Malaria Prion Associated Diseases South American Trypanosomiasis Risk Geographical Disease Risk Index
Additional Information	**Transfused donors** have previously contributed to the spread of some diseases. This happened with hepatitis C. **All transfused ~~donors~~ mothers:** Transfusions in some countries may have put the donor at risk of malaria or South American trypanosomiasis. It is necessary to exclude these infections ~~(with the exception of Malaria and South American trypanosomiasis for cornea donors only, or for tissues that are terminally sterilised)~~ before accepting the donation. ~~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~~ Mothers transfused since 1980:** In the autumn of 2003 a UK recipient of blood, taken from a healthy donor who later developed vCJD, died from vCJD. Since then there has been a very small number of cases of infection with the vCJD prion in recipients of blood from donors who have later developed vCJD. The risk of transplacental infection of a foetus with abnormal prion is not known but, even though it is thought to be small, cannot be ignored. In view of this, ~~people~~ mothers transfused or possibly transfused since 1980 ~~(except in the last week of life)~~ should not normally be accepted~~.~~ ~~Because of shortages in supply, this does not currently apply to the donation of heart valves, ocular tissue, pancreatic islets and skin.~~ Any history of transfusion after 1980 must be recorded and remain part of the documentation associated with the donation. Plasma exchange results in the patient having been exposed to multiple donors. In view of the increased vCJD risk, donations may not be taken from individuals who have had a plasma exchange performed since 1980. Commonly used PCCs, such as Beriplex or Octaplex, currently used in the UK, are prepared from non-UK donors. They are administered as one-off doses to reverse anticoagulation or peri-operative prophylaxis. Since 1999, coagulation factors prepared from UK donors have no longer been used as a risk reduction measure for vCJD transmission.

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Reason for Change	~~To permit donation from donors who have received a one-off dose of PCC since 1999 for prophylaxis or reverse anticoagulation. To improve clarity with regard to donors transfused in other parts of the world~~. I) To remove information only relevant to deceased tissue donors. II) To update guidance relating to South American Trypanosomiasis risk. III) To add guidance relating to mothers transfused since January 1st 1980. IV) To harmonise the definition of what constitutes a transfusion. V) Ensure consistent use of the term 'mother' rather than 'donor'.

Living Tissue Donor Selection Guidelines

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. Must not donate if:** **Since January 1st 1980:** a) Anywhere in the world, the donor has received, or thinks they may have received, a transfusion of blood or blood components, or ~~with red cells, platelets, fresh frozen plasma (FFP), cryoprecipitate,~~ intravenous or subcutaneous human normal immunoglobulin. This includes mothers whose babies have required intra-uterine transfusion. b) Had a plasma exchange performed. **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 4 below if transfused abroad c) If treatment with human immunoglobulin has been limited to small quantities of specific immunoglobulin as prophylaxis (e.g. rhesus, tetanus, hepatitis, immunoglobulin etc.), accept.

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	~~d) If the only transfusion has been within the last week of life, accept~~ d~~e~~) 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. Heart valve~~, ocular tissue, skin and pancreatic islet~~ donors only:** Provided the donor's total transfusion exposure is limited to less than 80 units of blood or blood components, accept. – See 4 below if transfused abroad. **4. Donor transfused before 1st January 1980 in a country endemic for malaria or South American trypanosomiasis :** a) Check the Geographical Disease Risk Index. If transfused in an at risk endemic country and a validated malarial antibody test and/or (as appropriate) a validated test for T.cruzi antibody is negative on the donation sample accept. b) If tissue will be sterilized by irradiation post-donation: Accept (testing not required) ~~c) For Eyes only, if the risk was for Malaria or South American trypanosomiasis, accept for corneas only (testing not required).~~
See if Relevant	Bleeding Disorder Immunoglobulin Therapy Immunosuppression Malaria Prion Associated Diseases South American Trypanosomiasis Risk Geographical Disease Risk Index
Additional Information	**Transfused donors** have previously contributed to the spread of some diseases. This happened with hepatitis C. **All transfused donors**: Transfusions in some countries may have put the donor at risk of malaria or South American trypanosomiasis. It is necessary to exclude these infections (with the exception of donations of tissues that are terminally sterilised) before accepting the donor. **Coagulation concentrates:** People who have received blood derived coagulation concentrates (these are made from the blood of many donors) regularly may have been put at risk of infections that can be passed through blood. **Donors transfused since 1980**: In the autumn of 2003 a UK recipient of blood, taken from a healthy donor who later developed vCJD, died from vCJD. Since then there has been a very small number of cases of infection with the vCJD prion in recipients of blood from donors who have later developed vCJD.

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	In view of this, people transfused or possibly transfused since 1980 ~~(except in the last week of life)~~ should not normally be accepted. Because of shortages in supply, this does not currently apply to the donation of heart valves~~, ocular tissue, pancreatic islets and skin~~. Any history of transfusion after 1980 must be recorded and remain part of the documentation associated with the donation. Plasma exchange results in the patient having been exposed to multiple donors. In view of the increased vCJD risk, donations may not be taken from individuals who have had a plasma exchange performed since 1980. Commonly used PCCs, such as Beriplex or Octaplex, currently used in the UK, are prepared from non-UK donors. They are administered as one-off doses to reverse anticoagulation or 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	~~To permit donation from donors who have received a one-off dose of PCC since 1999 for prophylaxis or reverse anticoagulation. To improve clarity with regard to donors transfused in other parts of the world~~. I) To remove information only relevant to deceased tissue donors. II) To update guidance relating to South American Trypanosomiasis risk. III) To harmonise the definition of what constitutes a transfusion.

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