Change Notification for the UK Blood Transfusion Services

Date of Issue: 31 July 2024 **Implementation:** to be determined by each Service

No. 20 – 2024

Bleeding Disorders

This notification includes the following changes:

	BM-DSG Bone Marrow & Peripheral Blood Stem Cell	CB-DSG Cord Blood	GDRI Geographical Disease Risk Index	TD-DSG Tissue – Deceased Donors	TL-DSG Tissue – Live Donors	WB-DSG Whole Blood & Components	Red Book Guidelines for the BTS in the UK
1. Bleeding Disorder	○	○	○	○	○	●	○

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Changes are indicated using the key below. This formatting will not appear in the final entry.

original text	«inserted text»	~~deleted text~~

1. Changes apply to the **Whole Blood and Components DSG**

Bleeding Disorder (revised entry)

Includes	«Coagulation factor deficiencies: • Factor I (one) fibrinogen deficiency (afibrinogenaemia, hypofibrinogenaemia) • Factor II (two) prothrombin deficiency • Factor V (five) deficiency • Factor VII (seven) deficiency • Factor VIII (eight) deficiency (Haemophilia A) • Factor IX (nine) deficiency (Haemophilia B, Christmas Disease) • Factor X (ten) deficiency • Factor XI (eleven) deficiency • Factor XIII (thirteen) deficiency • Von Willebrand disease (types 1, 2 and 3)» ~~*Christmas disease, clotting factor treatment, factor deficiency (including carriers), haemophilia and Von Willebrand's disease.*~~
«Excludes	Platelet disorders – see Platelet Disorders Individuals who received Coagulation Factor Concentrates (including Prothrombin Complex Concentrates): • To treat and prevent the coagulopathy associated with trauma and/or massive transfusion • To reverse the effect of anticoagulants such as warfarin (see Transfusion)»

1. Affected «Individuals and Carriers» ~~*Individual*~~	
Obligatory	**Must not donate if:** «a) Diagnosed with Haemophilia A (Factor VIII deficiency), Haemophilia B (Factor IX deficiency), Type 2 Von Willebrand Disease, Type 3 Von Willebrand Disease. b) The donor has received a transfusion since 1st January 1980. c) The donor has ever: • received coagulation factor concentrates, including blood derived and recombinant products, and/or • received or is currently on treatment to reduce or prevent excessive bleeding e.g. desmopressin, tranexamic acid, oral contraceptive pill and similar hormone therapies.»

	~~*a) Treated with blood derived coagulation factor concentrates.*~~ «d) The donor has required or been advised they will require prophylactic treatment for surgery, dental treatment, or for any other procedure.» «e)» ~~*b)*~~ There is a history of excessive bleeding or bruising. «f) The donor is requiring monitoring and/or follow-up. g) There is associated organ involvement e.g. liver damage. h) For acquired disorders, the underlying cause or treatment precludes donation e.g. malignancy, monoclonal antibody therapy.»
Discretionary	**«If the donor has Type 1 Von Willebrand Disease and:** a) has not received a transfusion since 1st January 1980, and b) has never received any type of coagulation factor treatment, and c) has never received any other treatment to reduce or prevent excessive bleeding, and d) has not received or been advised that they will require prophylactic treatment, and e) has never had any excessive bleeding or bruising, and f) is not requiring monitoring or follow-up, and g) the underlying cause and/or treatment does not preclude donation, accept. **If the donor is a carrier of a coagulation factor deficiency, and:** a) has not received a transfusion since 1st January 1980, and b) has never received any type of coagulation factor treatment, and c) has never received any other treatment to reduce or prevent excessive bleeding, and d) has not received or been advised that they will require prophylactic treatment, and e) has never had any excessive bleeding or bruising, and f) is not requiring monitoring or follow-up, accept.» ~~***Carrier state:***~~ ~~*This does not necessarily prevent donation. Refer to a '**Designated Clinical Support Officer**' who will liaise with the haematologist that investigated the donor.*~~
See if Relevant	«Autoimmune Disease Ehlers Danlos Syndrome Malignancy Monoclonal antibody therapy and other biological modalities» Platelet Disorders Transfusion

Additional Information	«Coagulation factor deficiencies can be inherited or can be acquired, associated with haematological, neoplastic, cardiovascular, liver or autoimmune disease. Some deficiencies cause significant bleeding, either spontaneously or in response to even minimal trauma or minor procedures. Individuals will have been assessed and advised about their condition and bleeding risk. They may have received treatment or been informed regarding the need for treatment in the future. The donor may have also been provided with a Bleeding Disorders Information Card. Some people with the carrier state (trait) may be at risk of bleeding (symptomatic carriers). The diagnosis of the milder forms or carrier status of coagulation factor deficiencies may arise from family screening, or through testing during investigation for menorrhagia (heavy periods), or bleeding during pregnancy or childbirth. If someone has had problems with bleeding or bruising, they may be at increased risk of complications from donation. The guidance contained in this entry is not intended for use for donors without a coagulation factor deficiency, for example for someone who may have taken tranexamic acid for heavy periods due to an underlying gynaecological cause. The current International Society on Thrombosis and Haemostasis (ISTH) classification recognises three types of Von Willebrand Disease: Type 1 is a partial quantitative deficiency of Von Willebrand Factor and is typically a milder form; the levels of von Willebrand Factor may overlap with the levels found in unaffected individuals. More severe effects are usually seen with Von Willebrand Disease types 2 and 3. Care should be taken to determine the type of Von Willebrand Disease, as only donors with type 1 are potentially eligible.» ~~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.~~ ~~They represent one of the groups of individuals within whom emerging infections have spread before they have been recognized. This was the case with HIV and HCV infection. Because of this, the law requires that they are permanently excluded from becoming donors. It can be many years before any infection shows itself.~~ ~~If someone has had problems with bleeding or bruising, taking blood from them could be harmful.~~ ~~Some people with the carrier state (trait) for some bleeding disorders may themselves be at risk of bleeding. Also, if their blood is used to make fresh~~

	~~frozen plasma, this may not have enough of the clotting factor in it to be useful to the person receiving it.~~
«Information	Part of this entry is a requirement of the Blood Safety and Quality Regulations 2005.
~~*Reason for Change*~~	~~*See below.*~~

2. 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 four 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 three months or more from the last sexual contact, accept.
See if Relevant	Non-Consented Exposure to Human Body Fluids Transfusion
Additional Information	Blood derived coagulation concentrates are made from the blood of many hundreds of individual donors. They may put recipients at risk of infections that can be passed through blood. This risk may be shared by their sexual partners and anyone suffering an inoculation injury. Many bleeding disorders are inherited. Family members that are blood relations may be affected by the bleeding disorder. They could 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 three or four months from the last sexual contact or inoculation injury helps to ensure that the infections tested for by the Blood and Tissues Services will be picked up. This guidance presumes that a validated NAT test for hepatitis C is negative. If this test is stopped, the guidance will change.
Information	Part of this entry is a requirement of the Blood Safety and Quality Regulations 2005.
~~*Reason for Change*~~	~~*See below.*~~

~~*Additional Information*~~	~~The Northern Ireland Health Minister has announced a relaxation of the deferrals for MSM and other high-risk activities which will reduce from 12 months to three months. This is due to be implemented on 1st June 2020. The changes are in line with the other UK transfusion services and the recommendations of the SaBTO Donor Selection Criteria Review Report (2017).~~
«Reason for Change	Expansion of the Includes section and addition of an Excludes section to clarify the scope of the guidance contained in this entry. Expansion of obligatory and discretionary criteria applicable to affected individuals and carriers.»
Donor Information	If you wish to obtain more information regarding a personal medical issue, please contact your National Help Line. Please do not contact this web site for personal medical queries, as we are not in a position to provide individual answers.

The following redirections will be added to the **A-Z index**

Factor I (one) deficiency » Bleeding Disorder

Fibrinogen deficiency » Bleeding Disorder

Afibrinogenaemia » Bleeding Disorder

Hypofibrinogenaemia » Bleeding Disorder

Factor II (two) deficiency » Bleeding Disorder

Prothrombin deficiency » Bleeding Disorder

Factor V (five) deficiency » Bleeding Disorder

Factor XI (eleven) deficiency » Bleeding Disorder

Factor XIII (thirteen) deficiency » Bleeding Disorder

Von Willebrand disease » Bleeding Disorder

Types 1, 2 or 3 Von Willebrand disease » Bleeding Disorder