SCHEDULE

PART 3

ELIGIBILITY CRITERIA FOR DONORS OF WHOLE BLOOD AND BLOOD COMPONENTS

Acceptance criteria for donors of whole blood and blood components

1.

Under exceptional circumstances, individual donations from donors who do not comply with following criteria may be authorised by a qualified healthcare professional in the blood establishment. **[**[F1]All such cases must be clearly documented and subject to—

(a) in relation to Great Britain, the requirements in regulation 7;

(b) in relation to Northern Ireland, the quality management provisions in Articles 11, 12, and 13 of Directive 2002/98/EC.**]**

The criteria in this paragraph do not apply to autologous donations.

Textual Amendments

F1 Words in Sch. 1 Pt. 3 para. 1 substituted (31.12.2020) by The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/4), **reg. 14** (as substituted by S.I. 2020/1304, regs. 1, 14); 2020 c. 1, Sch. 5 para. 1(1)

1.1. Age and body weight of donors

Age	**18 to 65 years**	
	17 years	Where, in the opinion of a qualified health professional, the donor has sufficient knowledge and understanding of what is involved in the process of blood donation to give their informed consent, or otherwise with the written consent of a person with parental responsibility.
	First time donors over 60 years	— at the discretion of the doctor in the blood establishment
	Over 65 years	— with permission of the doctor in the blood establishment, given annually
Body weight	≥ 50 kg for donors either of whole blood or apheresis blood components	

1.2. Haemoglobin levels in donor's blood

Haemoglobin	For females ≥ 125 g/l	For males ≥ 135 g/l	*Applicable to allogeneic donors of whole blood and cellular components*

1.3. Protein levels in donor's blood

Protein	≥ 60 g/l	*The protein analysis for apheresis plasma donations must be performed at least annually*

1.4. Platelet levels in donor's blood

Platelets	Platelet number greater than or equal to 150 x 10^9 /l	*Level required for apheresis platelet donors*

DEFERRAL CRITERIA FOR DONORS OF WHOLE BLOOD AND BLOOD COMPONENTS

Deferral criteria for donors of whole blood and blood components

2.1. Permanent deferral criteria for donors of allogeneic donations

Cardiovascular disease	Prospective donors with active or past serious cardiovascular disease, except congenital abnormalities with complete cure
Central nervous system disease	A history of serious CNS disease
Abnormal bleeding tendency	Prospective donors who give a history of a coagulopathy
Repeated episodes of syncope, or a history of convulsions	Other than childhood convulsions or where at least three years have elapsed since the date the donor last took anticonvulsant medication without any recurrence of convulsions
Gastrointestinal. Genitourinary, haematological, immunological, metabolic, renal, or respiratory system diseases	Prospective donors with serious active, chronic, or relapsing disease
Diabetes	If being treated with insulin
Infectious diseases	Hepatitis B, except for HBsAg-negative persons who are demonstrated to be immune
	Hepatitis C
	HIV – 1 and 2
	HTLV I/II
	Babesiosis (*)
	Kala Azar (visceral leishmaniasis) (*)
	Trypanosomiasis cruzi (Chagas' disease) (*)

Malignant diseases	Except in situ cancer with complete recovery
Transmissible spongiform encephalopathies (TSEs) (e.g. Creutzfeldt Jakob Disease, variant Creutzfeldt Jakob Disease)	Persons who have a family history which places them at risk of developing a TSE, or persons who have received a corneal or dura mater graft, or who have been treated in the past with medicines made from human pituitary glands. For variant Creutzfeldt Jacob disease, further precautionary measures may be recommended.
Intravenous (IV) or intramuscular (IM) drug use	Any history of non-prescribed IV or IM drug use, including body-building steroids or hormones
Xenotransplant recipients	
Sexual behaviour	Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood

2.2. Temporary deferral criteria for donors of allogeneic donations

2.2.1. *Infections*

Duration of deferral period

After an infectious illness, prospective donors shall be deferred for at least two weeks following the date of full clinical recovery.

However, the following deferral periods shall apply for the infections listed in the table:

Brucellosis (*)	2 years following the date of full recovery
Osteomyelitis	2 years after confirmed cured
Q fever (*)	2 years following the date of confirmed cure
Syphilis (*)	1 year following the date of confirmed cure
Toxoplasmosis (*)	6 months following the date of clinical recovery
Tuberculosis	2 years following the date of confirmed cure
Rheumatic fever	2 years following the date of cessation of symptoms, unless evidence of chronic heart disease
Fever >38°C	2 weeks following the date of cessation of symptoms
Flu-like illness	2 weeks after cessation of symptoms
Malaria (*)	
— individuals who have lived in a malarial area within the first five years of life	3 years following return from last visit to any endemic area, provided person remains symptom free;

	may be reduced to 4 months if an immunologic or molecular genomic test is negative at each donation.
— individuals with a history of malaria	3 years following cessation of treatment and absence of symptoms. Donations may be accepted thereafter only if an immunologic or molecular genomic test is negative
— asymptomic visitors to endemic areas	6 months after leaving the endemic area unless an immunologic or molecular genomic test is negative
— individuals with a history of undiagnosed febrile illness during or within six months of a visit to an endemic area	3 years following resolution of symptoms; may be reduced to 4 months if an immunologic or molecular test is negative
[[F2]West Nile Virus (WNV) (*)	28 days after leaving a risk area of locally acquired West Nile Virus unless an individual Nucleic Acid Test (NAT) is negative**]**

Textual Amendments

F2 Words in Sch. Pt. 3 para. 2.2.1 Table substituted (18.7.2016) by The Blood Safety and Quality (Amendment) Regulations 2016 (S.I. 2016/604), regs. 1, **2(2)**

Textual Amendments

F2 Words in Sch. Pt. 3 para. 2.2.1 Table substituted (18.7.2016) by The Blood Safety and Quality (Amendment) Regulations 2016 (S.I. 2016/604), regs. 1, **2(2)**

2.2.2. *Exposure to risk of acquiring a transfusion-transmissible infection*

— Endoscopic examination using flexible instruments, — mocusal splash with blood or needlestick injury, — transfusion of blood components, — tissue or cell transplant of human origin, — major surgery, — tattoo or body piercing, — acupuncture unless performed by a qualified practitioner and with sterile single-use needles, — persons at risk due to close household contact with persons with hepatitis B.	Defer 6 months, or 4 months provided a NAT test for hepatitis C is negative
Persons whose behaviour or activity places them at risk of acquiring infectious diseases that may be transmitted by blood.	Defer after cessation of risk behaviour for a period determined by the disease in question, and by the availability of appropriate tests.

2.2.3. *Vaccination*

Attenuated viruses or bacteria	4 weeks
Inactivated/killed viruses, bacteria or rickettsiae	No deferral if well
Toxoids	No deferral if well
Hepatitis A or hepatitis B vaccines	No deferral if well and if no exposure
Rabies	No deferral if well and if no exposure If vaccination is given following exposure defer for one year
Tick-borne encephalitis vaccines	No deferral if well and if no exposure

2.2.4. *Other temporary deferrals*

Pregnancy	6 months after delivery or termination, except in exceptional circumstances and at the discretion of a physician
Minor surgery	1 week
Dental treatment	Minor treatment by dentist or dental hygienist – defer until next day (NB: Tooth extraction, root-filling and similar treatment is considered as minor surgery)
Medication	Based on the nature of the prescribed medicine, its mode of action an the disease being treated

2.3. Deferral for particular epidemiological situations

Particular epidemiological situations (e.g. disease outbreaks)	Deferral consistent with the epidemiological situation

2.4. Deferral criteria for donors of autologous donations

Serious cardiac disease	Depending on the clinical setting of the blood collection
Active bacterial infection	

Changes to legislation:
There are currently no known outstanding effects for the The Blood Safety and Quality Regulations 2005, PART 3.