Change Notification UK National Blood Services No. 15 - 2021

These changes apply to the Whole Blood and Components Donor Selection Guidelines

The Department of Health and Social Care has asked the UK Blood Services to start collecting plasma for the manufacture of medicines. The Standing Advisory Committee on the Care and Selection of Donors, has made the following changes to the WBDSG to provide updated guidance on the collection of Plasma by apheresis.

15.1. Donor Weight

Please amend the following sections in this entry:

Definitions: EBV – Estimated Blood Volume. This is calculated using the Nadler formula (Ref: Chapter 3.7 Guidelines for the Blood Transfusion Services in the UK).

EBV – Extra Corporeal Volume. This is the total volume outside the donor’s circulation at any time during a donation procedure. It includes all blood, plasma and components in the collection packs, the machine harness and testing samples.

Discretionary: a) If male and over 50kg of weight (7 stone 12 pounds), accept.

b) If female, 20 years of age or older and over 50kg of weight (7 stone 12 pounds), accept.

c) If female, less than 20 years of age with an EBV estimated blood volume of 3500ml or greater (as per chart AAppendix 1), accept.

d) Treatment with anti-obesity drugs, accept.

Component Donation: During any planned component donation procedure, the donor’s ECV must not exceed 16% of their EBV at any point in the procedure.

Careful consideration should be taken when calculating the EBV for transgender donors to ensure the most appropriate chart is selected.

See if relevant: Appendix 1 - Estimated Blood Volume for Female donors (after Nadler) by height and weight

Appendix 3 – Maximum permitted ECV for component donation

Sleep Apnoea

\Continued
Additional Information

No donor should lose more than 15% of their estimated blood volume (EBV) during any donation procedure. During apheresis procedures the extra corporal volume should not exceed 15% EBV (excluding anticoagulant).

This is Limits on donation volume are in place to protect the donor from adverse effects such as fainting, and becoming anaemic. The ECV is the total volume of blood and plasma removed from the donor at any time. It includes all blood and plasma in collection packs and contained within the machine harness. This is to protect the donor from adverse effects such as fainting and becoming anaemic.

There is a minimum legal donor weight of 50kg at which a donation can be accepted. In young women there is a significant risk of fainting if their donation exceeds 15% of their EBV thus a minimum EBV of 3500ml is needed.

For individuals with a body mass index greater than 40, there is a risk that the formula used to calculate blood volume may result in an overestimation of EBV.

The 50kg lower weight limit is not appropriate for double red cell donations because of the increased volume, and iron that is being taken from the donor.

Reason for change: The addition of restrictions to reduce the faint rate in younger female donors in line with recent research and Council of Europe guidance.

Increase in the permitted ECV to 16% for component donors. Additional information on donors with a BMI greater than 40. A new table of maximum permitted ECV has been added as an appendix.

15.2. Frequency of Donation

Please amend the following sections in this entry:

Includes: Apheresis, blood, component, lymphocyte, platelet, stem cell donation and mobilised granulocytes.

Discretionary: 1. Whole Blood:

A minimum interval of 12 weeks between donations should normally be observed. Donors who regularly attend at intervals of less than 16 weeks should be informed that they are at increased risk of iron deficiency. They should be advised to reduce their frequency of donation to an average of 16 weeks or more.

Donors with genetic haemochromatosis may donate at intervals of less than 12 weeks.

Whole blood donors changing to platelet donation should wait a minimum of four weeks.
2. **Components:**
   
   a) **Double Red Cells:**
   A minimum interval of 26 weeks between donations should normally be observed. Donors who attend at intervals of less than 32 weeks should be informed that they are at increased risk of iron deficiency. They should be advised to reduce their frequency of donation to an average of 32 weeks or more.

   Donors with genetic haemochromatosis may donate at intervals of less than 26 weeks.

   b) **Apheresis Platelets and/or Plasma:**
   A minimum interval of two weeks between donations should normally be observed, with a maximum of 24 donations per year. The combined total of platelet and plasma donations in any 12-month period should not be more than 26.

   Donors of convalescent plasma can donate at weekly intervals, provided they meet all other requirements for plasma donation. They should not donate more than 26 donations in any 12-month period.

   Donors who attend at intervals of less than four weeks may be at increased risk of iron deficiency.

   Donors who attend at intervals of less than four weeks should be informed that they are at increased risk of iron deficiency. They should be advised to reduce their frequency of donation to an average of four weeks or more.

   Apheresis Platelet donors returning to whole blood donation from platelet donation should wait a minimum of four weeks.

   c) **Apheresis Leucocytes including Mobilised Granulocytes:**
   These are usually directed donations.
   There should be a minimum of 48 hours between procedures and a donor should not undergo more than two procedures within a seven day period.

   An apheresis granulocyte donor returning to whole blood donation should wait a minimum of eight weeks.

   d) **Stem Cell Donors:**
   A donor should not give any routine donations for 12 months following bone marrow harvest, for six months following peripheral blood stem cell harvest and for three months following lymphocyte donation.

   d) **Donors who change donation type**
   Care must be taken to ensure that limits on the frequency of donation are maintained for donors who move between donation types. The following deferral periods should be applied:
   - Donors moving from whole blood to component donation (except double red cells): 4 weeks
   - Donors moving from platelet or plasma component donation to whole blood: 4 weeks since last component donation (and at least 12 weeks since the most recent whole blood donation)
   - Donors moving from whole blood to double red cell donation: 12 weeks
   - Donors moving from double red cell donation to other component donation: 8 weeks.

\Continued
This guidance is consistent with the Council of Europe publication 'Guide to the preparation, use and quality assurance of blood components - 14th edition'.

Reason for change: A minimum period of time has been added for donors returning to whole blood donation following Apheresis Granulocyte donation.
The permissible donation frequency for platelet and plasma donors, including convalescent plasma, has been increased. Further guidance on donation intervals for donors changing donation type has been added.
Guidance regarding apheresis granulocyte collection has been removed.

15.3. Haemoglobin estimation

Please amend the following sections in this entry:

Discretionary:

a) Potential donors whose haemoglobin concentration is estimated to be below the acceptable level may be asked to give a further sample of blood for testing by alternative means. If the haemoglobin concentration is not less than the levels shown above, accept.

b) If the haemoglobin concentration for males is greater than 180 g/l and for females is greater than 165 g/l and Polycythaemia Rubra Vera has been excluded accept refer to the Polycythaemia and Raised Haemoglobin entry.

See if relevant: Polycythaemia and Raised Haemoglobin

Reason for change: A discretion to accept a non clonal disorder has been added.
The guidance for donors with a high haemoglobin has been moved to the revised Polycythaemia and Raised Haemoglobin entry.

15.4. Polycythaemia and Raised Haemoglobin

Please amend the following sections in this entry:

Discretionary: If following specialist investigation has excluded a polycythaemia is not diagnosed as Polycythaemia Rubra Vera, or another myeloproliferative neoplasm, and no treatment or further investigation is planned, accept the donor can be accepted for whole blood donation or for double red cell donation. Donors with a haemoglobin above the normal range should not usually be accepted for plasma or platelet donation.

Reason for change: A discretion to accept a non clonal disorder has been added.
Clarification of the suitable donation types for donors with a haemoglobin above the normal range has been added.

\Continued
A-Z index changes
1. Retitle the ‘Polycythaemia’ entry in the index as ‘Polycythaemia and Raised Haemoglobin’.

2. Add the following entries to the A-Z entry as links to this entry:
   Haemoglobin, high
   High haemoglobin

15.5. Haematological Disease

Please amend the following sections in this entry:

Discretionary:
   a) If following specialist investigation a polycythaemia is not diagnosed as Polycythaemia Rubra Vera, or another myeloproliferative neoplasm, and no treatment or further investigation is planned, accept
   b) If following specialist investigation a thrombocythaemia is not diagnosed as Essential Thrombocythaemia, or another myeloproliferative neoplasm, and no treatment or further investigation is planned, accept

See if relevant:
   Anaemia
   Haemochromatosis
   Haemoglobin Disorders
   Haemolytic Anaemia
   Immune Thrombocytopenia
   Malignancy
   Polycythaemia and Raised Haemoglobin

Reason for change: Discretions to accept non-clonal disorders have been added.
The discretionary and see if relevant sections have been updated to include the revised Polycythaemia and Raised Haemoglobin entry.

15.6. Haemoglobin Disorders

Please amend the following sections in this entry:

See if relevant:
   Anaemia
   Polycythaemia and Raised Haemoglobin
   Sickle Cell Trait
   Transfusion

Reason for change: High oxygen affinity haemoglobins have been added to the ‘Obligatory’ entry.
A link has been added to ‘Polycythaemia’, ‘Transfusion’ and ‘Sickle Cell Trait’.
‘Additional Information’ has been added
The see if relevant section has been updated.

\Continued
15.7 Appendices to the Whole Blood and Components Donor Selection Guidelines

Please add a new Appendix:

**Appendix 3 Maximum permitted Extra Corporeal Volume for component donors**

**Female donors**

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