

Change Notification for the UK Blood Transfusion Services

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Implementation: to be determined by each Service

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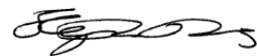
Transgender and Non-Binary Donors

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. Haemoglobin Estimation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
2. Transgender Individuals	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
3. Hormone Therapy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
4. Changes to the A-Z index	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
5. Revision to Chapter 3.15	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>



Dr Angus Wells
Chair of Standing Advisory Committee on Care & Selection of Donors (SACCSD)



Dr Stephen Thomas
Professional Director of JPAC

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

original text	«inserted text»	deleted text
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1. Changes apply to the **Whole Blood & Components DSG**

Haemoglobin Estimation

(revised entry)

<i>Obligatory</i>	<p>The haemoglobin concentration should be estimated each time a potential donor presents.</p> <p><u>Lower limits</u></p> <p>1. Whole Blood Donors Must not donate if the haemoglobin concentration is less than: a) Female donors: 125 g/l b) Male donors: 135 g/l «c) Not disclosed*: 125 g/l»</p> <p>2. Double Red Cell Donors Must not donate if the haemoglobin concentration is less than: «All» Male and Female donors: 140 g/l</p> <p>3. Component Donors who will only donate plasma Must not donate if the haemoglobin concentration is less than: a) Female donors: 120 g/l b) Male donors: 130 g/l «c) Not disclosed*: 125 g/l»</p> <p>4. All other Component Donors Must not donate if the haemoglobin concentration is less than: a) Female donors: 125 g/l b) Male donors: 135 g/l «c) Not disclosed*: 125 g/l»</p> <p><u>Upper limits</u></p> <p>All Donors Must not donate if the haemoglobin concentration is greater than: a) Female donors: 165 g/l b) Male donors: 180 g/l «c) Not disclosed*: 180 g/l»</p> <p>If a donor is not accepted, the reason why must be explained to them and, if appropriate, advice given to see their own GP.</p>
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<p><i>Discretionary</i></p>	<p>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.</p> <p>b) If the haemoglobin concentration for males is greater than 180 g/l and for females is greater than 165 g/l «is above the upper limits listed above,» refer to the Polycythaemia and Raised Haemoglobin entry.</p>
<p><i>See if Relevant</i></p>	<p>«Hormone Replacement and Sex Hormone Therapy» Polycythaemia and Raised Haemoglobin Transgender and non-binary individuals»</p>
<p><i>Additional Information</i></p>	<p>«* Blood Services should have donor selection processes that are inclusive of transgender and non-binary individuals. These may be based on asking donors their Sex Assigned at Birth or asking donors about their gender identity and transgender history. For the purposes of this entry, 'not disclosed' criteria apply to donors who are not comfortable to answer these details. It is important to ensure donors understand the rationale for asking these questions.</p> <p>Transgender and Non-binary donors may take gender affirming hormone therapy to support their transition. This may change the haemoglobin level in their blood and consideration can be given to changing the Haemoglobin criteria used to assess the donor, based on the therapy the donor is taking. See Transgender and Non-binary Individuals.»</p> <p>A 500 ml donation of whole blood contains about 250 mg of iron. It can take months for the average donor to replace this loss of iron from the diet. Taking a donation from a person with a haemoglobin concentration below the recommended value may make them anaemic.</p> <p>The lower haemoglobin acceptance limits apply only to plasmapheresis donors who will only donate plasma by apheresis. If it is anticipated that red cells or platelets will be collected during the procedure the donor must be assessed against «the limits for "all other component donors" above.» a haemoglobin limits of 125 g/L for female donors and 135 g/L for male donors.</p> <p>Component donors giving double units of red cells lose twice as much iron and so it is even more important that they start with a good haemoglobin concentration.</p>
<p><i>Reason for Change</i></p>	<p>«The entry has been revised to include guidance on assessing transgender and non-binary donors. The See if Relevant section has been revised.»</p> <p>The guidance for donors with a high haemoglobin has been moved to the revised Polycythaemia and Raised Haemoglobin entry.</p>

2. Changes apply to the **Whole Blood & Components DSG**

Transgender **«and Non-Binary»** Individuals

(revised entry)

<i>Definitions</i>	<p>«Transgender and non-binary individuals</p> <p>Trans is an umbrella term to describe people whose gender is not the same as, or does not sit comfortably with, the sex they were assigned at birth. Trans people may describe themselves using one or more of a wide variety of terms including (but not limited to) transgender, non-binary or gender queer. Gender affirming hormone therapy may be used as part of transition by transgender and non-binary individuals.»</p> <p><i>Cisgender (cis).</i> Someone whose gender identity is the same as the sex they were assigned at birth.</p> <p><i>Transgender (trans)</i> describes someone whose gender is not the same as, or does not sit comfortably with, the sex they were assigned at birth.</p>
<i>Obligatory</i>	<p><i>Assessment of the haemoglobin concentration should be according to the gender assigned on the day of donation.</i></p>
<i>«Discretionary</i>	<p>a) If the donor is taking masculinising hormone therapy (e.g. testosterone) to support their transition, the donor is well and the donor has been on treatment for more than 12 months, accept.</p> <p>b) If the donor is taking feminising hormone therapy, and the donor is well, accept.»</p>
<i>See if Relevant</i>	<p><u>«Anti-Androgens»</u></p> <p><u>Blood Safety Entry</u></p> <p><u>«Haemoglobin Estimation»</u></p> <p><u>«Hormone replacement and sex hormone therapy»</u></p> <p><u>Surgery</u></p>
<i>Additional Information</i>	<p>The higher haemoglobin concentration of men, compared to women, is related to testosterone levels. <i>Testosterone levels will rise if a person who was assigned female at birth receives hormone therapy as part of transitioning. This «Testosterone therapy» will result in the haemoglobin concentration rising to the higher range seen in cis men.</i> The opposite will be true if a person <i>«is taking feminising therapy.» who was assigned male at birth transitions.</i></p> <p>«Waiting 12 months after starting masculinising hormone therapy, ensures that donation does not interfere with the assessment and laboratory monitoring of their treatment. A high haemoglobin (polycythaemia) can be a complication of this therapy and blood donation may mean this complication is not recognised. Once treatment is stabilised, it may be appropriate to offer the donor an individualised haemoglobin screening range consistent with their therapy (e.g. Haemoglobin 135 to 180 g/l for donors taking testosterone). Donors must be counselled to inform the Blood Service if their treatment changes or discontinues.</p> <p>As well as hormones, donors may take other medication to modify the effect of sex hormones as part of gender-affirming treatment. This may include hormone blockers, such as anti-androgens, which could affect the donor’s eligibility.»</p>

	For blood services that use leucocyte antibody screening as a TRALI risk reduction measure, donors who were assigned female at birth and have changed gender should be included.
<i>Reason for Change</i>	«Entry title changed. Instruction to base haemoglobin screening on gender removed. Addition of guidance re gender-affirming hormone therapy.» This entry was revised to support the implementation of recommendations from the FAIR study; the additional information section has been revised.

3. Changes apply to the **Whole Blood & Components DSG**

Hormone Replacement «and Sex Hormone» Therapy (revised entry)

<p>«Includes» <i>Definitions</i></p>	<p>Hormone Replacement Therapy (HRT): Includes any form of HRT, including HRT for menopausal symptoms. «Includes any form of sex hormones, such as:</p> <ul style="list-style-type: none"> • Tablets, patches or topical gels) as treatment for menopausal symptoms • Testosterone replacement therapy <p>Gender Affirming Hormone Therapy: Masculinising or feminising hormones taken to support transition»</p>
<p><i>Obligatory</i></p>	<p>See: Is there an entry for the condition for which «the hormones are» HRT is being given?</p> <p>Must not donate if:</p> <p>a) Used for malignancy.</p> <p>b) A recipient of human gonadotrophin of pituitary origin.</p> <p>c) A recipient of human pituitary growth hormone.</p> <p>d) A recipient of replacement adrenal steroid hormones.</p>
<p><i>Discretionary</i></p>	<p>a) If treatment is for the menopause, its symptoms, or for osteoporosis prevention, accept.</p> <p>b) If treatment is for a shortage of sex hormones, e.g. in some cases of erectile dysfunction and is not related to the treatment of malignancy, accept.</p> <p>c) If treated with growth hormone that was exclusively recombinant, accept.</p> <p>d) If treated with gonadotrophins that were exclusively non-pituitary derived, accept.</p>
<p><i>See if Relevant</i></p>	<p><u>Adrenal Failure</u> «<u>Anti-Androgens</u>» <u>Haemochromatosis</u> <u>Malignancy</u> <u>Prion Associated Diseases</u> <u>Steroid Therapy</u> <u>Thyroid Disease</u> «<u>Transgender and Non-Binary Individuals</u>»</p>

<i>Additional Information</i>	<p>There are many reasons why an individual may be deficient in a specific hormone. If this is related directly to malignancy, or to the treatment of malignancy, or to the use of pituitary derived hormones (these have been linked with prion associated diseases), the donor cannot donate in order to protect any person who may receive a donation from that individual.</p> <p>«As well as hormones, donors may take other medication to modify the effect of sex hormones as part of gender-affirming treatment. This may include hormone blockers, such as anti-androgens, which could affect the donor’s eligibility.»</p> <p>If there is a risk to the safety of the donor, as may be the case with a deficiency of adrenal steroid hormones, then a donation should not be taken.</p>
<i>Information</i>	<p>Part of this entry is a requirement of the Blood Safety and Quality Regulations 2005.</p>
<i>Reason for Change</i>	<p>«The title and scope have been changed to include cross sex hormone therapy.»</p> <p>This entry has been extensively rewritten to improve clarity.</p>
<i>Donor Information</i>	<p>If you wish to obtain more information regarding a personal medical issue please contact your <u>National Help Line</u>.</p> <p>Please do not contact this web site for personal medical queries, as we are not in a position to provide individual answers.</p>

4. Changes apply to the **Whole Blood & Components DSG**

Changes to the A-Z index

The following entries will be **created**:

Intersex » Transgender and Non-Binary Individuals

Non-Binary Individuals » Transgender and Non-Binary Individuals

Sex Assigned at Birth » Transgender and Non-Binary Individuals

Transition » Transgender and Non-Binary Individuals

Cross-sex Hormone Therapy » Hormone Replacement and Sex Hormone Therapy

Gender-affirming Hormone Therapy » Hormone Replacement and Sex Hormone Therapy

Testosterone replacement therapy » Hormone Replacement and Sex Hormone Therapy

5. Changes apply to the **Red Book**

Chapter 3: Care and selection of whole blood and component donors

3.15: Blood tests

3.15.1: Estimation of the concentration of haemoglobin in donor blood

The haemoglobin (Hb) concentration should be determined each time a potential donor presents.

«The acceptable lower limits for haemoglobin screening by donation type (e.g. whole blood, plasmapheresis etc.) are detailed in the JPAC Donor Selection Guidelines¹ (see the entry for [Haemoglobin Estimation](#)).»

~~For each component type, the acceptable lower limits for venous blood are listed below.~~

- ~~• Whole blood and component donation (except plasma only):
125 g/L for female donors and 135 g/L for male donors~~
- ~~• Plasma only donation (by apheresis):
120 g/L for female donors and 130 g/L for male donors~~
- ~~• Double red cell donation (by apheresis):
140 g/L for all donors~~

Several methods of screening donors for their blood Hb concentration are available...

(No further changes in this section)