v₁

Position Statement

April 2024

The contents of this document are believed to be current. Please continue to refer to the website for in-date versions.

Donor Selection and Donation Management for Transgender and Non-Binary Donors

- 1. Blood Services should welcome all donors regardless of sex or gender.
- 2. Donor Selection policies and procedures need to adapt to meet the needs of transgender and non-binary donors. A recent survey of Scottish donors found that at least 0.8% of participants do not identify as male or female.¹
- 3. Blood Services must ensure any changes to donor selection do not undermine donor and patient safety.
- 4. 'Donor sex' is relevant to recipient safety because past pregnancy may be associated with the development of HLA and HNA antibodies. Within the context of the Red Book, 'donor sex' is the sex assigned at birth (SAAB). The term 'male' refers to individuals who were assigned male at birth (AMAB) and 'female' refers to individuals who were assigned female at birth (AFAB).
 - a. The Red Book specifies that several components should be manufactured from donations collected from male donors only e.g. FFP, cryoprecipitate.² This is an important safety step to reduce the risk of Transfusion Related Acute Lung Injury (TRALI).
 - b. Blood Services may use this approach to the manufacture of other plasma rich components (e.g. red cells for neonatal exchange transfusion).
 - c. HLA and HNA antibody screening can be used to allow female donors to donate apheresis platelets. Changing or extending the use of white cell antibody screening will not be considered in this document.
 - d. Donor questions about previous pregnancy have not been used as a TRALI reduction measure by UK Blood Services. This is because of concerns that donors may not want to disclose details of a pregnancy, or donors may not be aware of an early pregnancy loss.
- 5. The key issues for donor safety are haemoglobin testing and blood volume.

\₁1

- 6. Haemoglobin testing aims to stop donors becoming anaemic because of donation and to identify anaemic donors who should not donate. It also helps to ensure the quality of red cell components.
 - a. The European Directive, on which BSQR is based, was written almost twenty years ago and provides haemoglobin limits for male and female donors. Men have a higher haemoglobin than women and this is recognised in the limits within BSQR. The higher haemoglobin level in men is related to testosterone levels. Individuals taking masculinising hormones have a higher haemoglobin level and the opposite is true for individuals taking feminising hormones.
 - b. Some transgender and non-binary individuals will use a range of gender affirming hormone therapies (e.g. testosterone, oestrogens or GNRH agonists). This may or may not continue long term. It may take a year or more to reach a stable dose of therapy which is assessed by clinical and laboratory testing. 3.4 During this time it is proposed that individuals on hormone therapy do not donate until they reach a stable treatment dose. This is to prevent any interference with monitoring of their response to therapy. Once established on a stable therapy donors can be accepted. At this point Blood Services could assess the donor against a haemoglobin range that takes account of their hormone therapy (e.g. 135 180 g/L for donors on masculinising hormone therapy).
- 7. Blood volume estimates inform faint reduction measures as well as the criteria for apheresis donation. These calculations are available for males and females.
 - a. Hormone therapy will have effects on plasma volume as well as Hb. Other factors (e.g. previous therapy with puberty blockers) may need to be considered too.
 - b. SACCSD will undertake a literature review and liaise with relevant clinicians to explore if we can develop a more individualised approach for assessing blood volume in transgender and non-binary donors. Before this work is completed, using blood volume estimates for female donors is the safest approach as this will predict a lower blood volume for any combination of height and weight.
- 8. Gender identity alone is not a robust way of managing donors or their donations. Blood Services need to develop procedures to allow the safe assessment of all donors and management of their donations.
 - a. Asking donors for their sex assigned at birth (SAAB) could act as a direct replacement for our current use of 'donor sex'. This is also known as 'sex registered at birth'.
 - b. SAAB is used by some NHS organisations to gather information and make treatment decisions. Obtaining this information will allow services to make full use of donations collected from AMAB donors, and to manage the safety of donors and the blood supply. SAAB should not be asked in isolation but gathered in addition to questions about the individual's gender identity.
 - c. As an alternative, services can ask donors their gender and whether they have a trans history. 'Trans' or 'transgender' 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 variety of terms including 'non-binary'. Some non-binary people don't see themselves as trans, so it is important to define the terminology used in donor questions and information, and to ensure clear explanation is available for donors.⁶
 - d. Blood Services must recognise that some donors may choose not to disclose their SAAB or trans history. Services should offer an option for donors who 'prefer not to answer'.

v1

- 9. Once an approach is chosen, Blood Services must implement processes to ensure the correct information is recorded for all active donors.
 - a. SAAB, or gender identity and trans history, must not be deduced or assumed from historical records. Any change must be supported by staff training and donor information.
 - b. If services ask the donor for their SAAB this information can be used to determine haemoglobin limits, blood volume and selection of blood components.
 - c. For donors who do not disclose their SAAB a haemoglobin limit of 125 to 180 g/L is proposed for whole blood donation, blood volume should be assessed with the formula for females, and plasma rich components* should not be manufactured from donations collected from these donors, with consideration of HLA and HNA antibody testing before platelet donation.
 - *Plasma rich components from whole blood donations include FFP, cryoprecipitate, red cells in plasma, red cells for neonatal exchange transfusion and whole blood (with or without platelets).
 - d. If services choose to ask for gender identity and transgender history, similar criteria could be used for non-binary donors and any donor who reports a transgender history.

Recommendations

- Blood Services should develop donor selection processes that include transgender and non-binary donors.
- Asking donors their Sex Assigned at Birth can inform decisions about Hb screening, whole blood donation frequency, blood volume estimation and safe component manufacture.
- As an alternative, Blood Services can ask donors about their gender identity and transgender history. In a similar fashion this can inform decisions about Hb screening, whole blood donation frequency, blood volume estimation and safe component manufacture, although it may mean fewer donations will be identified as suitable for the manufacture of plasma rich components.
- If donors are on stable gender affirming hormone therapy, haemoglobin screening targets can be modified to take account of the expected changes in their haemoglobin.
- The rationale for asking such questions should be explained to donors and supported by donor information resources and staff training.
- It is essential to recognise individual identity, and donors should not be asked SAAB in isolation. Donors must not be put under pressure to report their SAAB, gender identity or transgender history. Donor questionnaires and systems must provide options for donors who choose not to disclose this information.
- Proposals for managing donors and donations by SAAB or gender identity are presented in tables 2 and 3.
- At this point, no final recommendation can be made about the appropriate blood volume equation for donors on hormone therapy to support their transition. A further task to consider this question will be added to the SACCSD workplan.
- This document focuses on whole blood and component donors, the draft change notifications include criteria for plasmapheresis donors.

Tables

Table 1: Current donor selection and donation management by Donor Sex

Donor sex	Hb limits (g/L) for WB donation	Donations per year (WB)	Blood volume equation	Plasma rich components for transfusion?
Male	135 – 180	4	Male	Yes
Female	125 - 165	3	Female†	No

Table 2: Donor selection and donation management by SAAB

SAAB	Hb limits (g/L) for WB donation	Donations per year (WB)	Blood volume equation	Plasma rich components for transfusion?
Male	135 – 180	4	Male	Yes
Female	125 - 165	3	Female†	No
Not disclosed	125 – 180	3	Female†	No

Table 3: Donor selection and donation management by gender and transgender history

Gender	Transgender history?	Hb limits (g/L) for WB donation	Donations per year (WB)	Blood volume equation	Plasma rich components for transfusion?
	No	135 – 180	4	Male	Yes
Man	Yes	125 - 165	3	Female†	No
	Not declared	125 - 180	3	Female†	No
	No	125 - 165	3	Female†	No
Woman	Yes	135 – 180	4	Male	Yes
	Not declared	125 - 180	3	Female†	No
	No	125 – 180	3	Female†	No
Non-binary or not disclosed	Yes	125 – 180	3	Female†	No
	Not declared	125 – 180	3	Female†	No

[†] used to assess whole blood donors under 20 years of age⁷



٧1

Glossary

AFAB	Acronym meaning Assigned Female at Birth. AFAB people may or may not identify as female some or all of the time.8
АМАВ	Acronym meaning Assigned Male at Birth. AMAB people may or may not identify as male some or all of the time.8
Apheresis	A type of blood donation where a machine is used to only collect specific parts of the donor's blood. This means that other parts of the donor's blood are given back to the donor.
BSQR	The Blood Safety and Quality Regulations 2005.
Components	Blood is separated into individual parts (components) so patients can be given the type of treatment they need. The four main components are plasma, red blood cells, white blood cells and platelets.
Cryoprecipitate	A frozen blood component used to prevent or control bleeding.
FFP	FFP is an acronym meaning 'Fresh Frozen Plasma', which is a blood component used to prevent or stop bleeding.
Gender Identity	A person's innate sense of their own gender, whether male, female or something else (see non-binary below), which may or may not correspond to the sex assigned at birth.9
Haemoglobin	The red coloured protein in blood cells which transports oxygen around the body.
HLA and HNA antibodies	Antibodies which target white blood cells.
Neonatal exchange transfusion	A transfusion received by newborn babies during which the baby's own red cells are removed and replaced by donor cells. This is most often needed when babies have severe jaundice.
Non-binary	An umbrella term for people whose gender identity doesn't sit comfortably with 'man' or 'woman'. Non-binary identities are varied and can include people who identify with some aspects of binary identities, while others reject them entirely.9
Person with a trans history	Someone who identifies as male or female or a man or a woman, but was assigned the opposite sex at birth. This is increasingly used by people to acknowledge a trans past ⁹ .
Plasma	The straw-coloured part of blood which contains clotting factors and antibodies.
Red cells	Red blood cells. These cells contain haemoglobin which carries oxygen.
SACCSD	Standing Advisory Committee on Care and Selection of Donors which reports to the Joint UKBTS Professional Advisory Committee (JPAC).

v₁

The Red Book	The short name for the Guidelines for the Blood Transfusion and Tissue Transplantation Services in the UK. The guidelines reflect an expert view of current best practice, provide specifications for blood components, and sets standards for collecting, testing and manufacturing blood components.
Transgender	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, transsexual, gender-queer (GQ), gender-fluid, non-binary, gender-variant, crossdresser, genderless, agender, nongender, third gender, bi-gender, trans man, trans woman, trans masculine, trans feminine and neutrois.9

References

- 1. SNBTS TopBox Survey 2022.
- Chapter 7, Guidelines for the Blood Transfusion Services in the UK, available at Specifications for blood components http://www.transfusionguidelines.org/red-book/chapter-7 (last accessed 20/03/2024)
- 3. Personal communication, L McLintock.
- Statement 12.9 within Coleman, E., Radix, A. E., Bouman, W.P., et al (2022). Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. International Journal of Transgender Health, 23(S1), S1-S260. https://doi.org/10.1080/26895269.2022.2100644 (last accessed 20/03/2024)
- Inclusive content Sex, gender and sexuality https://service-manual.nhs.uk/content/inclusive-content/sex-gender-and-sexuality
 (last accessed 20/03/2024)
- 10 ways to step up as ally to non-binary people
 https://www.stonewall.org.uk/about-us/news/10-ways-step-ally-non-binary-people
 (last accessed 20/03/2024)
- WB-DSG Donor weight entry <u>www.transfusionguidelines.org/dsg/wb/guidelines/we003-donor-weight</u> (last accessed 20/03/2024)
- SafeZone Terminology, Office of Equity, Diversity, and Inclusion, National Institutes of Health. www.edi.nih.gov/people/sep/lgbti/safezone/terminology (last accessed 20/03/2024)
- List of LGBTQ+ terms, Stonewall.org.uk. <u>www.stonewall.org.uk/list-lgbtq-terms</u> (last accessed on 20/03/2024)

50000

Dr Stephen Thomas
Professional Director