Change Notification for the UK Blood Transfusion Services

Date of Issue: 07 October 2024 **Implementation:** to be determined by each Service

No. 28 – 2024

Donor Adverse Events – Severity Grading

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. Chapter 5.10	○	○	○	○	○	○	●
2. Chapter 5.13	○	○	○	○	○	○	●
3. Chapter 5 – Appendix I	○	○	○	○	○	○	●

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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~~

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

Chapter 5: Collection of a blood or component donation

(no changes to sections 5.1 – 5.9)

~~***5.10: Adverse reactions in donors***~~

~~*The care of all donors at blood collection venues should incorporate research-based therapeutic interventions to reduce the risk of adverse events of donation.*~~

~~*All adverse reactions in donors should be documented and reported according to standard protocols. It is recommended that as a minimum data are collected and reviewed on all donor adverse events of donation using the International Haemovigilance Network (IHN) definitions of complications related to blood donation.*[3] *The blood services in the UK have also agreed definitions for Serious Adverse Events of Donation (SAEDs, see Appendix I). This will allow comparison over time and between services of event rates, and monitoring of the effectiveness of any interventions to reduce event rates. SAEDs should be investigated with root cause analysis or similar tools to ensure that proper preventative and corrective actions are implemented.*~~

~~*Serious adverse reactions occurring in donors during or post-donation must be reported to the Competent Authority according to the Blood Establishment protocol.*~~

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5.10: Donor Adverse Events

5.10.1: Definitions

Term		Definition
DAE	Donor Adverse Event	An event where harm occurs to a donor as a result of the blood donation process.
SDC	Serious Donor Complication	A DAE which is graded at Grade 3 or above using the Severity Grading Tool.
SAED	Serious Adverse Event of Donation	A DAE which meets the previous severity criteria agreed by the UK Blood Services.

A donor adverse event (DAE) which is graded as either a serious donor complication (SDC) or a serious adverse event of donation (SAED) meets the Medicines and Healthcare products Regulatory Agency (MHRA) definition of a Serious Adverse Reaction: *"An unintended response in a donor or in patient associated with the collection or transfusion of blood or blood components that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity."*

5.10.2: DAE classification, investigation, and reporting

DAEs are classified according to the categories included in the Standard for Surveillance of Complications Related to Blood Donation (2014)[3]. In 2023/24, the UK Blood Services agreed to implement the validated donor severity grading criteria developed by the AABB Donor Haemovigilance Working Group and endorsed by ISBT, IHN and EBA[4,5]. This records the severity of donor adverse events by Grades 1-5, with 1 through 5 being roughly associated with mild, moderate, severe, life-threatening and death. Further details of DAE classification, grading and assignment of imputability scores are given below (see sections 5.10.3 – 5.10.5).

Management of all SDCs or SAEDs should include appropriate incident investigation to ensure that proper preventative and corrective actions are implemented. This supports optimal learning from reported incidents.

The Blood Safety and Quality Regulations (BSQR) mandate that blood establishments report serious adverse events or reactions, including those which occur in donors. Each Blood Service is therefore required to submit an annual report to the MHRA covering any DAE which are classified as SDCs. During the transition period for introduction of the Severity Grading Tool, Services may alternatively choose to report using the previous SAED categories (see 5.10.6).

Blood Services must also ensure that:

- All DAEs are documented and reported according to standard procedures.
- For DAEs which are Grade 3-5 (or identified as SAEDs), written procedures are in place documenting expected donor follow up.
- Processes are in place for investigation of appropriate DAE. This should include those of Grade 3-5 or SAEDs. Any investigation should apply human factors and systems thinking principles. Lessons learnt should be shared widely.

The care of all donors at blood collection venues should incorporate research-based therapeutic interventions to reduce the risk of adverse events of donation.

Blood Services are encouraged to collect all DAE data in a format which will allow analysis of DAE trends over time both within and between services (benchmarking). This will also enable monitoring of the effectiveness of any interventions to reduce event rates.

A summary of the serious donor adverse events reported in the 4 UK Blood Services is included in the donor haemovigilance chapter in each Annual SHOT Report – these can be accessed here: **https://www.shotuk.org/shot-reports/**

5.10.3: Classification of Donor Adverse Events

(based on Standard for Surveillance of Complications Related to Blood Donation[3])

Code	Description
A	**Complications mainly with local symptoms**
A.1	Complications mainly characterised by the occurrence of blood outside the vessels • Haematoma (bruise) • Arterial puncture • Delayed bleeding (rebleeding)
A.2	Complications mainly characterised by pain • Nerve injury/irritation • Other painful arm
A.3	Localised infection/inflammation
A.4	Other major blood vessel injury • Deep vein thrombosis • Arteriovenous fistula • Compartment syndrome • Brachial artery pseudoaneurysm
B	**Complications mainly with generalised symptoms: vasovagal reactions**
	• Without loss of consciousness • With loss of consciousness Recording of the additional subcategories below is recommended. • With or without injury • Occurring at the donation site or after the donor has left the donation site
C	**Complications related to apheresis**
	• Citrate reaction • Haemolysis • Air embolism • *Infiltration (only relevant for procedures using volume replacement)*
D	**Allergic reactions**
	• Allergy • Generalised allergic reaction / anaphylaxis
E	**Other serious complications related to blood donation**
	Major cardiovascular event such as acute cardiac symptoms, myocardial infarction, cardiac arrest, transient ischaemic attack, cerebrovascular accident, death
F	**Other complications**
	Systemic reactions or complications which do not fit into any of the categories listed above

5.10.4: Donor Adverse Event Severity Grading

(based on Severity Grading Tool for Blood Donor Adverse Events[5])

Severity Grade	Criteria
Grade 1	Did not require intervention from an external Health Care Practitioner (HCP) ***AND*** Duration ≤2 weeks ***AND*** No limitation on Activities of Daily Living (ADL) ***AND*** Resolved with no or minimal intervention
Grade 2	Required intervention from an external HCP, no hospitalisation ***OR*** Duration >2 weeks and ≤6 months ***OR*** Limitations on ADL ≤2 weeks
Grade 3	Not life-threatening ***AND any of the following*** Hospitalisation ***OR*** Duration >6 months ***OR*** Limitations on ADL >2 weeks ***OR*** Require surgery ***OR*** Other serious complications (Category E)
Grade 4	Immediate medical intervention required to prevent death
Grade 5	Death

When assessing DAEs, assign the highest applicable severity grade. The Severity Grading Tool should be referenced for guidance on specific DAE categories.

5.10.5 Donor Adverse Event Imputability Scoring

Imputability in the context of blood donation means the likelihood that a DAE can be attributed to the donation. Imputability is scored according to the criteria below based on the SHOT Definitions (2023)[6].

Score	Imputability	Definition
N/A	Not Assessable	When there is insufficient data for imputability assessment.
0a	Excluded	When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to causes other than the blood or blood components or where the evidence is clearly in favour of alternative causes.
0b	Unlikely	
1	Possible	When the evidence is indeterminate for attributing the adverse reaction either to the blood or blood component or where there may be alternative causes.
2	Likely / Probable	When the evidence is clearly in favour of attributing the adverse reactions to the blood or blood component.
3	Certain	When there is conclusive evidence beyond reasonable doubt attributing the adverse reactions to the blood or blood component.

5.10.6: Serious Adverse Events of Donation

Prior to implementation of the Severity Grading Tool, DAE were classified as Serious Adverse Events of Donation (SAEDs) if they fell into one of the categories listed in the table below. Mapping of SAED categories to the new classification and grading system is also shown. Note that if reporting under SAED criteria, fewer adverse events will be included.

During the transition phase for introduction of the Severity Grading Tool, services may continue to use SAED classifications for reporting of serious adverse reactions to SABRE and SHOT.

Code	SAED Category	Mapped to Classification and Severity Grading Tool
01	Death within seven days of donation	Any category, Grade 5
02	Hospital admission within 24 hours of donation	Any category, Grade 3 or 4
03	Injury resulting in a fracture within 24 hours of donation (including fractured teeth)	B, Grade 3
04	Road traffic collision within 24 hours of donations	B*, Grade 3 or 4 *If due to vasovagal reaction
05a	Problems relating to needle insertion persisting for more than one year (this mainly includes suspected or confirmed nerve and tendon injuries)	A (usually A.2), Grade 3
05b	Problems relating to needle insertion requiring hospitalisation/intervention (this mainly includes vascular complications)	A (usually A.4), Grade 3 or 4
06	Acute coronary syndrome diagnosed within 24 hours of donation	E, Grade 3 or 4
07	Anaphylaxis (component donation)	D, Grade 3 or 4
08	Haemolysis (component donation)	C, Grade 3 or 4
09	Air embolism (component donation)	C, Grade 3 or 4
10	Other event related to donation resulting in: Hospital admission, Intervention, or Disability or incapacity lasting more than one year and not included above	F, Grade 3 or 4

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(no changes to sections 5.11 – 5.12)

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

Chapter 5: Collection of a blood or component donation

5.13: References

1. Statutory Instrument 2005 No. 50. The Blood Safety and Quality Regulations 2005. Available at **www.legislation.gov.uk**

2. Joint UKBTS Professional Advisory Committee's (JPAC) Whole Blood and Component Donor Selection Guidelines. Available at **www.transfusionguidelines.org**

~~*3. Working Group on Donor Vigilance of the International Society of Blood Transfusion Working Party on Haemovigilance (2014). Standards for the Surveillance of Complications Related to Blood Donation.*~~

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3. Working Group on Donor Vigilance of the International Society of Blood Transfusion Working Party on Haemovigilance (2014). Standard for Surveillance of Complications Related to Blood Donation. Available at **https://www.aabb.org/docs/default-source/default-document-library/resources/donor-standard-definitions.pdf**
(Last accessed 04 Sept 2024)

4. Townsend M, Kamel H, Van Buren N, Wiersum-Osselton J, Rosa-Bray M, Gottschall J, Rajbhandary S. Development and validation of donor adverse reaction severity grading tool: enhancing objective grade assignment to donor adverse events. *Transfusion*. 2020 Jun;60(6):1231-1242. Available at **https://onlinelibrary.wiley.com/doi/10.1111/trf.15830**
(Last accessed 04 Sept 2024)

5. AABB Donor Hemovigilance Working Group (2020) Severity Grading Tool for Blood Donor Adverse Events, A User Brochure. Available at **https://www.aabb.org/docs/default-source/default-document-library/resources/severity-grading-tool-for-donor-adverse-events.pdf**
(Last accessed 04 Sept 2024)

6. SHOT Definitions 2023. Pg 20 Imputability, Available at **https://www.shotuk.org/wp-content/uploads/myimages/SHOT-Definitions-2023-FINAL-VERSION.pdf**
(Last accessed 04 Sept 2024)

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

Chapter 5: Collection of a blood or component donation

Appendix 1: Serious Adverse Events of Donation – UK Blood Services Definitions

*This appendix will be **removed**. Its information is now included in the main text.*