6 Donor Haemovigilance

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Definition:

Donor haemovigilance: the systematic monitoring of adverse reactions and incidents in the whole chain of blood donor care, with a view to improving quality and safety for blood donors.

Serious adverse reaction: An unintended response in a donor or in a 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 (according to Article 3 (h) of Directive 2002/98/EC).

Recommendations

- Blood Services must ensure that donors are aware of the importance of reporting all adverse events of donation, especially those that occur after the donor has left the donation session
- All United Kingdom (UK) Blood Services should continue to work collaboratively to ensure best practice in the prevention and management of donor complications is developed and shared. Measures such as the development of standard questions for donor adverse event follow up and guidance documents will facilitate harmonisation of practices
- Previous recommendations relating to donor/staff education and benchmarking to inform improvements continue to be pertinent

Action: All staff involved in care and management of blood donors

Key messages

- Ensuring blood donor safety is of paramount importance and is assured, in as far as it can be, by donor selection guidelines, standard operating procedures, adequately trained staff and appropriate facilities. Despite these measures, various adverse events and reactions can and do occur during and after blood donation
- Implementation of the severity grading criteria for donor complications is in progress across the UK. The rate of serious adverse events of donation (SAED) and serious donor complications (SDC) in 2024 was 0.43 per 10,000 donations in the UK or 1 SAED/SDC per 23,479 donations approximately. This figure needs to be interpreted with caution due to the changes in recording donor complications
- Arm pain related to needle insertion and vasovagal events continue to be the most frequently reported serious donor complications
- Blood Services have a duty to take reasonable care to ensure that donors are aware of 'material risks' of blood donation

Introduction

This chapter presents data from the four UK Blood Services on SAED and SDC (grade 3 and higher as per the severity grading criteria), with illustrative cases and recommendations for donor care and safety. Reports from each Blood Service along with denominator data have been presented. Blood donation is usually an uneventful experience for most donors, but as with any clinical intervention, there are risks associated with blood donation. These are usually minor adverse events but, on occasion, may potentially have moderate to severe consequences for the donor. Good donor care involves implementation of measures to minimise the risks of blood donation to donors as well as timely recognition and appropriate management of any complication. Ensuring donor safety also requires informing donors of the material risks of blood donation.

Implementation of severity grading of all blood donor adverse events

All the UK Blood Services record donor complications as per the 'Standard Surveillance of Complications Relating to Blood Donations' (Goldman, et al., 2016). Staff overseeing donor care in each Blood Service record, monitor and investigate the donor adverse events reported appropriately. Until recently, all UK Blood Services were recording serious complications as SAED which are events that result in a significant disability/incapacity persisting for >1-year post donation, hospitalisation, interventions or rarely death. There have been 10 SAED reporting categories, and those reported in the UK in 2024 are listed in Table 6.3.

The UK Blood Services have been implementing severity grading of donor adverse events following the release of validated donor severity grading criteria. These were developed by the Association for the Advancement of Blood & Biotherapies (AABB) Donor Haemovigilance Working Group and endorsed by the International Society of Blood Transfusion (ISBT), International Haemovigilance Network (IHN) and European Blood Alliance (EBA) (Townsend, et al., 2020). This helps rate severity of donor adverse events by grades 1-5, with 1 through 5 being roughly associated with mild, moderate, severe, life-threatening and death as described in Table 6.1. Any event of grade 3 or above will be reported as an SDC. Once implemented by all UK Blood Services, the reporting of SDC will replace the previous SAED categories. It is anticipated that the new grading system will result in more SDC being reported than SAED in previous years.

The Welsh Blood Service (WBS) went live with incorporating severity grading of donor complications in January 2024 and National Health Service Blood and Transplant (NHSBT) went live in October 2024. Training and education of staff, regular review of practices and feedback loops were instrumental in ensuring smooth implementation. The Scottish National Blood Transfusion Service (SNBTS) and Northern Ireland Blood Transfusion Service (NIBTS) are in the process of implementing this soon. Due to the staggered implementation across the UK, a summary of the SAED/SDC reported by each Blood Service has been provided separately in this chapter.

Table 6.1: Validated severity grading criteria for donor adverse events

Severity grade	General factors to consider in assigning severity. Donor adverse event (DAE) severity tool	DAE examples
Grade 1	No outside medical care (OMC) ***AND*** Short duration ≤2 weeks ***AND*** No limitation on activities of daily living (ADL) ***AND*** Resolved with no or minimal intervention	Arterial puncture, pressure bandage applied, resolved without intervention or sequelae Vasovagal event that resolves with comfort care and/or oral hydration Citrate reaction resolved with oral calcium or reduction in infusion rate
Grade 2	OMC, no hospitalisation ***OR*** Duration >2 weeks- ≤ 6 months ***OR*** Limitations on ADL for ≤2 weeks	Superficial thrombophlebitis resolved with oral antibiotics, no sequelae Vasovagal event that requires transport to ED for IV hydration Lacerations requiring sutures
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)	Arteriovenous fistula requiring surgical repair Fracture, dental injury, or concussion Transient ischaemic attack and other cardiovascular events, which are not life-threatening
Grade 4*	Immediate medical intervention required to prevent death	Loss of consciousness with fall and intracranial bleed Anaphylaxis requiring intubation or tracheostomy
Grade 5*	Death	Death

*Grade 4 and Grade 5 are not shown in the severity grading tool of blood donor adverse events.

Based on the severity grading tool developed by the AABB Donor Haemovigilance Working Group (https://www.ihn-org.com/wp-content/uploads/2020/06/Tool_brochure_all_logos.pdf)

Imputability

Assigning imputability scoring (the strength of relation between donation and complication) is challenging, especially when information is incomplete or unavailable. History taking and donor assessment over the telephone varies between clinicians with often inconsistent information available to make a reasonable assessment. There are currently no uniformly agreed objective criteria to record levels of imputability and there is considerable variation in how this is recorded (Land, et al., 2018). There is an international working group currently working on developing a scoring matrix for imputability which would help ensure consistency and objectivity in determining this for significant events. Imputability for the SAED and SDC reported in 2024 have not been included in this chapter.

Data from 2024

UK donations

A total of 1,807,914 donations were collected by the four UK Blood Services in 2024 (Table 6.2). This includes whole blood and component donations, as well as plasma donations collected for the manufacture of medicinal products.

Table 6.2: Cumulative donation data from the four UK Blood Services in 2024

Donations from 2024		NHSBT	SNBTS	WBS	NIBTS
Whole blood donations	Donations from male donors	738,393	67,678	38,828	20,592
	Donations from female donors	689,259	77,358	41,086	20,754
	Donations from new donors	180,576	8,346	4,953	3,766
	Donations from repeat donors	1,247,076	136,690	74,961	37,580
Apheresis (includes plateletpheresis, plasmapheresis and PfM donations)	Donations from male donors	79,780	8,112	2,039	2,873
	Donations from female donors	19,434	942	400	386
	Donations from new donors	23,329	1	77	0
	Donations from repeat donors	75,885	9,053	2,362	0
Total number of donations in 2024		**1,526,866**	**154,090**	**82,353**	**44,605**

PfM=Plasma for Medicine

Table 6.3 summarises the number of SAED by category for Scotland and Northern Ireland for the period January 2024 to December 2024, and England until the end of September 2024. This table includes all cases reported in 2024 irrespective of the degree of imputability.

Table 6.3: SAED by category reported to SNBTS (Jan-Dec 2024), NIBTS (Jan-Dec 2024) and NHSBT (Jan-Sept 2024) (All SAED included here irrespective of imputability)

SAED category	NHSBT	SNBTS	NIBTS	Total number
01. Death within 7 days of donation	0	0	0	**0**
02. Hospital admission within 24 hours of donation	8	2	0	**10**
03. Injury resulting in a fracture within 24 hours of donation (including fractured teeth)	7	1*	0	**8**
04. Road traffic collision within 24 hours of donation	1	1*	0	**2**
05a. Problems relating to needle insertion persisting for more than one year (this mainly includes suspected or confirmed nerve and tendon injuries)	20	3	0	**23**
05b. Problems relating to needle insertion requiring hospitalisation/ intervention (this mainly includes vascular complications)	0	0	0	**0**
06. Acute coronary syndrome diagnosed within 24 hours of donation	3	1	0	**4**
07. Anaphylaxis	0	0	0	**0**
08. Haemolysis	1	0	0	**1**
09. Air embolism	0	0	0	**0**
10. Other event	4	0	0	**4**
Total reported SAED in 2024	**44**	**8**	**0**	**52**

** SNBTS: Donation in 2023, reported to SNBTS in 2024*

Note: All events reported in 2024 to WBS were recorded under the new system incorporating severity grading, see SDC Table 6.4

There were no SAED reported to NIBTS in 2024.

SDC (grade 3 and above as per the severity grading criteria) reported to WBS (Jan-Dec 2024) and NHSBT (Oct-Dec 2024) are listed in Table 6.4.

Table 6.4: SDC (grade 3 or above) by category reported to WBS (Jan-Dec 2024) and NHSBT (Oct-Dec 2024)

SDC category	NHSBT	WBS	Total number
Blood outside vessel	0	1*	1
Arm pain	7	3**	10
Localised infection/inflammation of vein or soft tissue	1	0	1
Other major blood vessel injury	0	0	0
Vasovagal reactions	10***	0	10
Related to apheresis	0	0	0
Allergic reaction	0	0	0
Other serious complication	3****	0	3
Other	0	0	0
Total reported SDC in 2024	**21**	**4**	**25**

**WBS: 1 x haematoma leading to nerve irritation or inflammation*
***WBS: 1 x donation in 2022, captured as SDC in 2024*
****NHSBT: 1 x grade 4 following a delayed vasovagal reaction*
*****NHSBT: 1 x pulmonary embolism, 2 x myocardial infarction*

Table 6.5 summarises the total number of donations and SAED and SDC reported for each of the four UK Blood Services in 2024. The rate of SAED/SDC was 0.43 per 10,000 donations, irrespective of imputability. While this is higher than 0.3 per 10,000 donations reported previously, it must be interpreted with caution due to the changes in recording of donor complications. Trends in the subsequent years and the learning from incident investigations and operational insights will inform improvement actions. It is recognised that there is variation in the number/rate of SAED/SDC reported from each Blood Service. Factors contributing to this are being explored through a Joint UK Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (JPAC)/SHOT working group and may include variable reporting thresholds and donor demographics among other factors. With regular collaboration and communication, the teams are working towards a better harmonisation across the UK Blood Services.

Table 6.5: Summary of total donations for the four UK Blood Services and total numbers of SAED/SDC for 2024

	NHSBT	SNBTS	WBS	NIBTS
Whole blood donations	1,427,652	145,036	79,914	41,346
Apheresis donations including PfM	99,214	9,054	2,439	3,259
Total donations	**1,526,866**	**154,090**	**82,353**	**44,605**
	Total donations in the UK: 1,807,914			
Total number of SAED/SDC in the calendar year 2024	**SAED:** 44 **SDC:** 21	**SAED:** 8	**SDC:** 4	0
Rate of total SAED/SDC per 10,000 donations in UK for 2024 (all submitted reports irrespective of imputability)	**0.43***			

**The new SDC is wider than the earlier 10 SAED categories, caution must be exercised when looking at trend over the years as this figure is not strictly comparable to the rate from previous years*

Illustrative cases

Case 6.1: Transient red urine in a post source plasmapheresis donation

A regular donor attended for a routine source plasma donation. The donor, who had been donating source plasma since 2021 had a history of successful donations without complications. During

the 7th cycle of the donation process, the haemoglobin (Hb) detector alarm was triggered on the plasmapheresis machine, indicating the presence of red blood cells in the plasma. Staff observed red discolouration in the tubing, (referred to as Hb in harness, which indicates a potential red cell spill or haemolysis: the breakdown of red blood cells). The donation was terminated without returning the remaining red cells to the donor.

The donor remained well and asymptomatic whilst in the care of the plasma centre but later reported observing blood in their urine. The donor declined the request to attend their general practitioner (GP) surgery as the symptoms had subsequently resolved and they were in good health. Due to the presentation of reported symptoms by the donor, it was believed the likely cause of red urine was haemoglobinuria (the clearance of haemolysis breakdown products through the kidneys). The donor was temporarily deferred but remains eligible to donate in the future.

Haemolysis can occur due to kinks in the lines of the apheresis disposable or other mechanical obstructions resulting in damage to the red blood cells (Vrielink, 2014).

If haemolysis is suspected (due to the presence of pink plasma or detection of Hb in the plasma collection line), the plasmapheresis procedure must be stopped without the return of any red cells remaining in the disposable harness. This is to avoid the risk of damaged cells being given back to the donors. Neyrink et al. (2018) suggest staff should inform the donor about the possibility of red colouring of the urine (haemoglobinuria) as part of their post donation advice.

Haemolysis is a known but rare complication of plasmapheresis donation. Whilst some data reports an occurrence rate of 0.14 per 100,000 apheresis procedures, Pink, et al. (2022) concur there is little evidence or literature reporting the frequency of haemolysis events or the outcome for affected plasmapheresis donors.

Case 6.2: Two donors with arm pain lasting more than 12 months since venepuncture

Two regular whole blood donors reported persisting arm pain for more than 12 months following their donation. The first case was a returning donor who reported the last donation was more painful than usual with accompanying slow flow. The donor could not recall whether they reported their symptoms to session staff at the time of donation and only reported it to the Blood Service 4 years later. At that time, a full donation was obtained, no needle adjustments or pain at session were recorded and it was noted to have been an uneventful donation. The donor reported developing a large haematoma with significant bruising and associated nerve symptoms (tingling and numbness) to their hand. The haematoma resolved without any further intervention and the donor was reviewed by their GP who did not recommend any further investigations or treatment.

The second donor was a regular donor who reported that a needle adjustment was performed soon after venepuncture due to slow flow; this caused them pain, but they did not report this to staff. The donor could not recall whether staff enquired regarding their wellbeing following the adjustment. A full donation was obtained. The donor reported that they continued to experience pain in the antecubital fossa with no other neurological symptoms. The donor received ultrasonic treatment to help alleviate symptoms.

Donating blood is generally considered to be safe (Veldhuizen, et al., 2012). There are however recognised complications of donation (Goldman, et al., 2016). These include well-defined venepuncture-related arm complications, e.g., bruising and nerve-related irritation/injury, which can affect donors to a varying degree, sometimes in the long-term.

From Case 6.2, it is observed that neither donor reported their initial symptoms of arm pain at donation when it became apparent. Various reasons may influence the donor to not report complications. This includes lack of awareness or unfamiliarity with complications, normalisation of symptoms, fear of being deferred, and other social or cultural factors.

Donor education therefore forms a vital part of the blood donation and consenting process. Donors should be made aware of what to expect and what to do in the event of any complication during or after donation. This is important, not only to ensure prompt management of the donor and ensuring their

safety, but also optimising the donor base by maximising return rate of donors (Wiersum-Osselton, et al., 2014). It is well recognised that donors who experience a venepuncture-related complication may either opt not to return or even be withdrawn from donation due to the complication.

Addressing gaps in staff knowledge and improving staff awareness about potential complications and management is equally important. This includes the observation of donors during the venepuncture and donation process, including noticing non-verbal cues, e.g., facial expression and restlessness, especially in the absence of any verbal reports by the donor.

When a donation rate is slow, a needle adjustment may occasionally be required. Staff should confirm with the donor regarding any discomfort before and after needle adjustments. They should also be vigilant for any signs of donor discomfort and act promptly to ensure donor safety. It is essential to stop a donation in the event of any symptoms, to help minimise risk of injury and possible long-term complications.

Conclusion

Staff should provide post-donation information to all donors. This should include the risk of delayed reactions, when to seek medical advice and guidance on prevention. Donors should be encouraged to make early contact with the Blood Service if they experience any complications. This will ensure appropriate clinical advice and management. Understanding these complications and predisposing risk factors will help lead to the development of appropriate interventions to reduce their likelihood, as well as better donor selection criteria to ensure donor safety.

Recommended resource

Post-donation management of blood donors with nerve injury related to donation
https://www.transfusionguidelines.org/document-library/documents/post-donation-management-of-blood-donors-with-nerve-injury-related-to-donation-v2-pdf

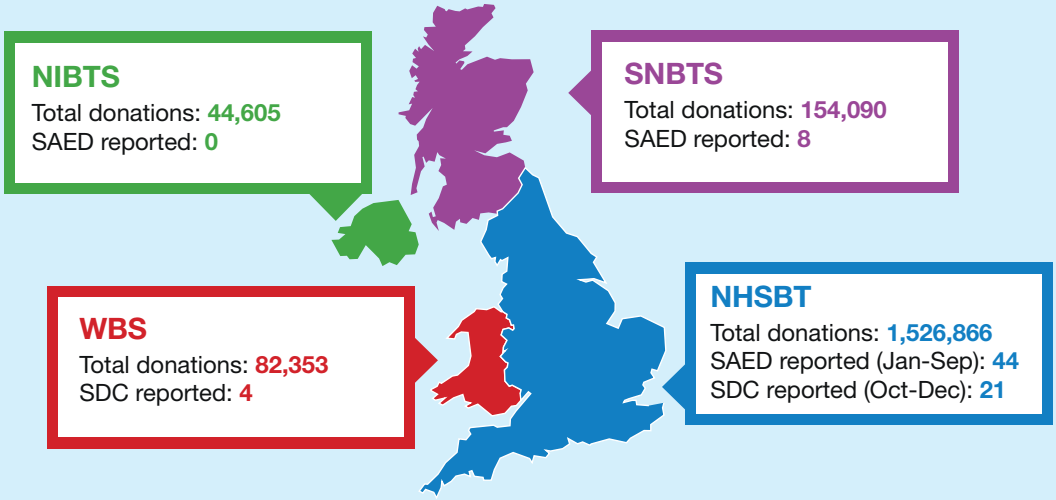
Serious adverse events following blood donation reported to the UK Blood Services in 2024

2024 has seen the gradual transition of the UK Blood Services away from serious adverse events of donation (SAED) which focused on grouping based on category to serious donor complications (SDC) which focuses on impact to the donor based on severity. The introduction of donor severity grading for adverse events also allows for a benchmarking via a uniform standard for all UK Blood Services and internationally.

SAED (Pre 2024)
- Serious adverse event of donation
- Focused on grouping by category

Transition (2024)
- SAED phased out
- SDC introduced

SDC (From 2024)
- Serious donor complications
- Focuses on impact to individual



NHSBT=National Health Service Blood and Transplant; NIBTS=Northern Ireland Blood Transfusion Service; SNBTS=Scottish National Blood Transfusion Service; WBS=Welsh Blood Service

Key messages:

1. The rate of serious donor complications in the UK is one SAED/SDC per 23,479 donations
2. Arm pain from needle insertion and vasovagal reactions remain the most common complications reported
3. Donor complications can occur despite best care, and some may have serious impact on donors
4. Improving donor experience with measures to reduce risk of complications related to blood donation along with prompt recognition and management of complications is vital
5. Blood Services must ensure that all donors are aware of the importance of reporting all adverse events of donation so the donor can be appropriately managed, and the adverse events can be recorded, monitored and appropriate actions taken to improve donor safety