# Donor Haemovigilance

# 7

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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).**

## Abbreviations used in this chapter

| | |
|---|---|
| **AABB** | Association for the Advancement of Blood & Biotherapies |
| **DV** | Delayed vasovagal reaction |
| **EBA** | European Blood Alliance |
| **GP** | General practitioner |
| **ISBT** | International Society of Blood Transfusion |
| **IHN** | International Haemovigilance Network |
| **JPAC** | Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee |
| **MHRA** | Medicines and Healthcare products Regulatory Agency |
| **NHSBT** | National Health Service Blood and Transplant |
| **NIBTS** | Northern Ireland Blood Transfusion Service |
| **PfM** | Plasma for Medicine |
| **PLT** | Platelets |
| **SAED** | Serious adverse event of donation |
| **SDC** | Serious donor complication |
| **SNBTS** | Scottish National Blood Transfusion Service |
| **UK** | United Kingdom |
| **WBS** | Welsh Blood Service |

## Recommendations

- All UK Blood Services should work collaboratively to ensure best practice in the prevention and management of donor adverse events is developed and shared. Measures such as the implementation of the severity grading tool and the development of standard questions for donor adverse event follow up will facilitate this aim
- Effective donor education has a key role in reducing the frequency and severity of adverse events. All donors should be educated to speak up if they feel unwell or experience arm symptoms during and after donation

- Staff dealing with blood donors should have adequate knowledge about potential complications and be able to identify and manage them promptly on session

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


## Introduction

Blood donation in the UK is a voluntary non-remunerated act that is essential to support patient care across all disciplines. Although generally safe, complications do sometimes occur. Appropriate donor care includes giving donors information about the material risks of blood donation, implementing measures to minimise those risks, and providing appropriate clinical management for any adverse reactions which occur.

## Serious adverse events of donation

SAED are complications or events where a donor experiences serious harm, or very rarely, result in donor death. The ten SAED categories are listed in Table 7.2. SAED are also given an imputability score, as follows:

3. Definite or certain link to donation

2. Probable or likely link to donation

1. Possible link to donation

0a. Link to donation unlikely

0b. Link to donation excluded


## Data from 2023

### UK donations

A total of 1,808,690 donations were collected by the four UK Blood Services in 2023 (Table 7.1). As well as whole blood and component donations, this includes 24,104 plasma donations collected by NHSBT for the manufacture of medicinal products.

| Donations from 2023 | | NHSBT | SNBTS | WBS | NIBTS | UK |
|---|---|---|---|---|---|---|
| Whole blood | Donations from male donors | 738,706 | 69,392 | 38,193 | 21,638 | 867,929 |
| | Donations from female donors | 698,272 | 78,797 | 40,606 | 21,004 | 838,679 |
| | Donations from new donors | 171,635 | 7,892 | 6,020 | 3,207 | 188,754 |
| | Donations from repeat donors | 1,265,343 | 140,297 | 72,779 | 39,435 | 1,517,854 |
| | **Total whole blood donations** | **1,436,978** | **148,189** | **78,799** | **42,642** | **1,706,608** |
| Apheresis | Donations from male donors | PLT 58,541 PfM 16,386 | 6,293 | 2,061 | 3,189 | 86,470 |
| | Donations from female donors | PLT 6,805 PfM 7,718 | 328 | 384 | 377 | 15,612 |
| | Donations from new donors | PLT 8,807 PfM 9,874 | 0 | 85 | 0 | 18,766 |
| | Donations from repeat donors | PLT 56,539 PfM 14,230 | 6,621 | 2,360 | 3,566 | 83,316 |
| | **Total apheresis donations** | **PLT 65,346 PfM 24,104** | **6,621** | **2,445** | **3,566** | **102,082** |
| **Total number of donations in 2023** | | **1,526,428** | **154,810** | **81,244** | **46,208** | **1,808,690** |

**Table 7.1: Cumulative donation data from the four UK Blood Services in 2023 (n=1,808,690)**

*NHSBT=National Health Service Blood and Transplant; SNBTS=Scottish National Blood Transfusion Service; WBS=Welsh Blood Service; NIBTS=Northern Ireland Blood Transfusion Service; UK=United Kingdom; PfM=Plasma for Medicine; PLT=platelets*

Table 7.2 summarises the number of SAED by category for all four UK Blood Services combined for the period January 2023 to December 2023.

| SAED category | 2023 | | | | | 2022 |
|---|---|---|---|---|---|---|
| | NHSBT[1] | SNBTS | WBS | NIBTS | UK | UK |
| 01 Death within seven days of donation | 0 | 0 | 0 | 0 | **0** | **2** |
| 02 Hospital admission within 24 hours of donation | 2 | 0 | 1 | 0 | **3** | **11** |
| 03 Injury resulting in a fracture within 24 hours of donation (including fractured teeth) | 7 (includes 4 with DV[2]) | 2 (includes 2 with DV[2]) | 0 | 0 | **9** | **8** |
| 04 Road traffic collision within 24 hours of donations | 0 | 0 | 0 | 0 | **0** | **4** |
| 05a Problems relating to needle insertion persisting for more than one year (this mainly includes suspected or confirmed nerve and tendon injuries) | 23 | 7 | 3 | 1 | **34** | **24** |
| 05b Problems relating to needle insertion requiring hospitalisation/intervention (this mainly includes vascular complications) | 0 | 0 | 0 | 0 | **0** | **0** |
| 06 Acute coronary syndrome diagnosed within 24 hours of donation | 2 | 0 | 0 | 0 | **2** | **5** |
| 07 Anaphylaxis (component donation) | 1 | 0 | 0 | 0 | **1** | **0** |
| 08 Haemolysis (component donation) | 0 | 0 | 0 | 0 | **0** | **0** |
| 09 Air embolism (component donation) | 1 | 0 | 0 | 0 | **1** | **0** |
| 10. Other event related to donation resulting in:<br>• Hospital admission,<br>• Intervention, or<br>• Disability or incapacity lasting more than one year and not included above | 3 | 0 | 0 | 0 | **3** | **1** |
| **Total reported SAED** | **39** | **9** | **4** | **1** | **53** | **55** |

**Table 7.2: SAED by category in 2023 (All SAED included here irrespective of imputability)**

*1 Data includes 3 imputability 0a SAED (1x category 02 Hospital admission; 2x category 06 Acute coronary syndrome), all reported by NHSBT*
*2 DV: delayed vasovagal reaction – i.e., a vasovagal reaction occurring after the donor has left the donation session*

*NHSBT=National Health Service Blood and Transplant; SNBTS=Scottish National Blood Transfusion Service; WBS=Welsh Blood Service; NIBTS=Northern Ireland Blood Transfusion Service; UK=United Kingdom; SAED=serious adverse events of donation*

As in 2022, problems related to venepuncture lasting more than one year (category 05a) account for the majority of SAED and are typically due to nerve injury, although 2 cases from NHSBT were suspected to be tendon injuries. Arm pain events have increased in 2023, but the reasons behind this are not clear. Improved awareness and reporting may be a factor. It should be noted, that of the 34 cases reported, 25 donors developed symptoms (pain or paraesthesia) immediately at venepuncture but only 13 informed session staff at the time. In 10 of these cases, the needle was withdrawn, but in 3 cases donation continued. Further details about the category 05a SAED are given in the data tables in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2023/).

## Learning point

- Donors must be encouraged to speak up if they experience pain or paraesthesia at the time of venepuncture. Donation should be stopped, and the needle carefully withdrawn if the donor has immediate symptoms suggestive of nerve or tendon injury

Table 7.3 summarises the total number of donations and SAED reported for each of the four UK Blood Services in 2023. The rate of SAED was 0.29 per 10,000 donations, irrespective of imputability, or 0.28 per 10,000 donations excluding imputability scores of 0a or 0b.

**Table 7.3: Summary of total donations for the four UK Blood Services and total numbers of SAED for 2023**

| | NHSBT | SNBTS | WBS | NIBTS |
|---|---|---|---|---|
| Total donations (whole blood and apheresis) | 1,526,428 | 154,810 | 81,244 | 46,208 |
| Total number of SAED in the calendar year 2023 | 39 | 9 | 4 | 1 |
| Total number of SAED excluding those scored with an imputability of 'unlikely' or 'not related to blood donation' | 36 | 9 | 4 | 1 |
| Rate of total SAED per 10,000 donations in UK for 2023 (all submitted reports irrespective of imputability) | | 0.29 | | |
| **Rate of SAED per 10,000 donations in UK for 2023 excluding those with imputability of 'unlikely' or 'not related to donation** | | **0.28** | | |


## Comparison of trends with previous years

The four UK Blood Services have produced an annual summary report to SHOT of SAED recorded since 2015.

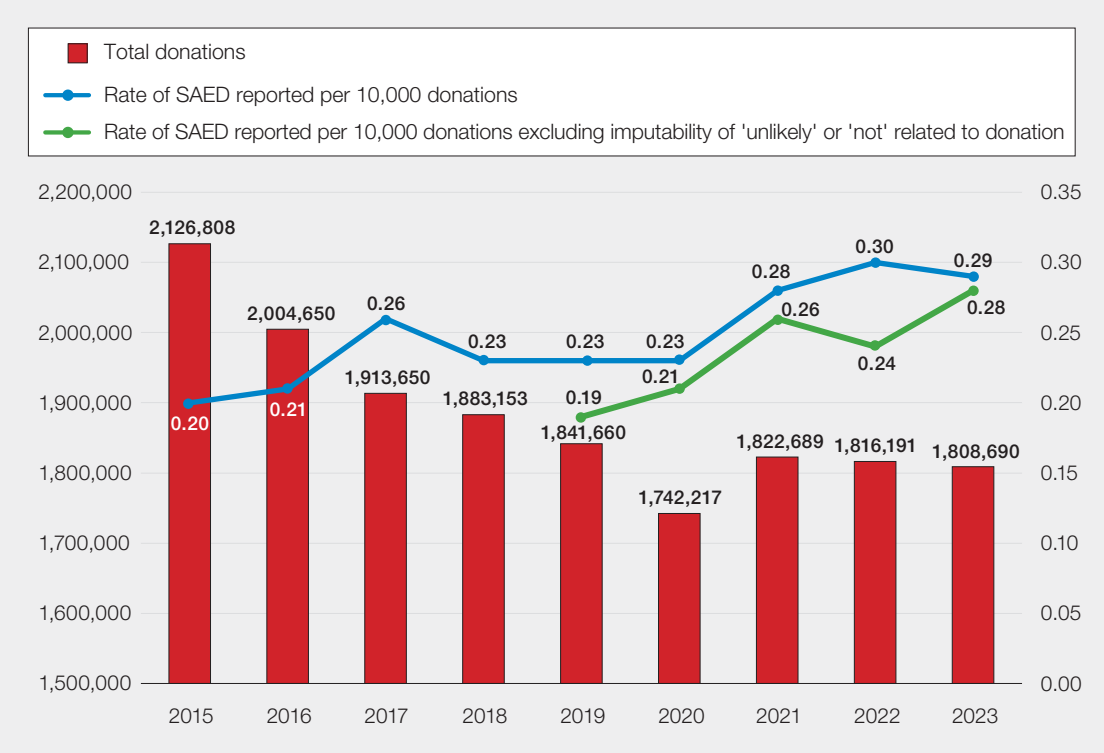


**Figure 7.1: Rate of SAED reported per 10,000 donations in the UK 2015-2023**

*SAED=serious adverse event of donation; UK=United Kingdom*

Overall SAED rates are unchanged from 2022, but this masks a rise in rates for SAED with imputability 1-3 to 0.28 per 10,000 donations (from 0.24 per 10,000 donations in 2022). This rise may reflect better reporting, but other factors should be considered, and appropriate actions taken to reduce the frequency and severity of donor adverse events. Areas to address include donor education, staff training, monitoring of donor adverse events, regular audits with improvements to the session environment and procedures. Shared learning across the four UK Blood Services promotes adoption of best practices and facilitates improvements.

## Implementation of donor adverse event severity grading

The UK Blood Services have agreed to implement the validated donor severity grading criteria developed by the AABB Donor Haemovigilance Working Group and endorsed by ISBT, IHN and EBA (Townsend, et al., 2020). Donor adverse events will be recorded according to the new grading criteria which rate severity of donor adverse events by grades 1-5, with 1 through 5 being associated with mild, moderate, severe, life-threatening and death. Any event of grade 3 or above will be reported as a SDC. Once implemented by all the 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 and recorded than in previous years.

Individual UK Blood Services are implementing severity grading over different timescales. During this transition period, services may record either SDC or SAED. It is hoped that by 2025, the new system will be fully implemented across the UK.

## Plasma for Medicine project

Since April 2021, NHSBT has been collecting both sourced and recovered plasma for the purpose of manufacturing PfM. In October 2020, a comprehensive review of the evidence to reassess the safety of UK plasma to manufacture plasma-derived medicinal products was undertaken, and the results presented to the Commission on Human Medicines (MHRA, 2021). In April 2021, under the advisement of the MHRA, the Government directed NHSBT to recommence the collection of plasma, to produce lifesaving medicines, for the benefit of UK patients. Based on the scientific review, blood regulators and operators have been urged to take account of the safety profile when considering fractionation

of UK plasma, and to revise their guidelines on the deferral of donors who have lived in, or received a transfusion in, the United Kingdom (Thomas, et al., 2023).

As with whole blood donations, PfM is an invasive procedure that can result in donor adverse events, and therefore, as for other blood donations, requires careful monitoring and management of donors during their donation. Adverse events related to donors feeling faint or losing consciousness are consistently reported at 1.4%. This is similar to rates seen in whole blood donors. Bruising is the most common adverse event in plasma donors and rates are higher than in either whole blood or apheresis platelet donors (5.0% in PfM donors vs 0.9% whole blood and 2.5% platelet). Further details and relevant graphs can be accessed in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2023/).

## Illustrative case

**Case 7.1: Venepuncture-related pain and paraesthesia but no abnormalities on electromyography or nerve conduction studies**

*A regular male whole blood donor, who had donated fifteen times previously, reported persistent problems with his donation arm when he returned to donate five months later. The donor remembered experiencing a sharp pain at the time of needle insertion but this improved during the donation process and this was not reported to staff. A full donation was taken. Post donation, minor bruising in the right antecubital fossa and the medial aspect of right forearm was experienced. Since donation, the donor described having a painful cramp and tingling sensation when holding a phone to his ear for long periods or when lifting weights. The donation arm was painful with elbow flexion but not at rest. He occasionally woke in the mornings with discomfort in his arm if his hand or elbow came under his weight. There was no loss of power or coordination, no swelling, or lump.*

*The donor was subsequently assessed by his GP for numbness in his right thumb/thenar eminence and pain on elbow flexion against resistance. He was seen by a consultant neurologist and a clinical neurophysiologist, 10 months after donation. Neurological examination, electromyography and nerve conduction studies were all normal. He also had a normal magnetic resonance imaging scan of his right forearm. The donor has been withdrawn from future blood donations.*

Venepuncture-related arm problems do occur and can have debilitating long-term effects due to ongoing pain and restricted function. Needle-related complications include haematoma, arterial puncture, and painful arm, which may result from nerve irritation through a haematoma or from direct injury to a nerve or other structure (Working Group on Donor Vigilance of the ISBT Working Party on Haemovigilance, 2014). Peripheral nerve injuries are defined by a persistent burning, shooting, electrical-type pain or paraesthesia in a specific nerve distribution, which begins immediately while the needle is in situ, or can be delayed for several hours thereafter. Published evidence suggests that 30–70 donors per 100,000 donations will develop a nerve injury (Newman, 2013; Sorensen, et al., 2008). Of these around 5 per 100,000 may develop long-term symptoms.

Donation staff must be aware of these possible complications and advise donors accordingly during acquisition of informed consent. Some donors may be reluctant to report any venepuncture-related pain or discomfort. It is therefore important that staff check with the donor if they have any of these symptoms, as the needle should be removed immediately to minimise the risks of any long-term injury. Guidance for the management of donors who do sustain a possible nerve injury is available on the JPAC website (See 'Recommended resources' at the end of this chapter).

This donor had several investigations, all of which were normal. There is some evidence that nerve injury can still be present despite normal nerve conduction studies. A recent study by Kang et al. (2023) focused on the limitations of electrophysiological tests as diagnostic tools. Individuals for whom normal data were obtained in the nerve conduction studies were eventually diagnosed with nerve swelling on ultrasonography. These false-negative results imply that electrophysiological tests cannot be used as an independent method for diagnosing or determining the clinical severity of venepuncture-related nerve injuries. Assessment of clinical symptoms alongside knowledge of cutaneous nerve distribution

provides significant indicators for inferring nerve damage. In cases where electrophysiological tests are normal, ultrasonography may reveal morphological damage to the corresponding nerves and should be considered.

## Conclusion

While blood donation is generally very safe, donor complications sometimes occur either during or after blood donation. Most of these are non-severe and resolve promptly but are still unpleasant for the donor. SAED occur infrequently and may result in long-term or permanent disability or injury to the donor. Preventing these adverse events must be a priority and when donor complications do occur, they should be managed promptly and appropriately. Continuing donor haemovigilance and embedding lessons learnt from surveillance helps improve quality and safety for all blood donors.

Blood Services should encourage donors to make early contact with the clinical team if they experience any complications so that they can be appropriately investigated and managed. Post-donation information must be provided to all donors. This should include the risk of delayed reactions, when to seek medical advice and guidance on prevention. 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**
Post-donation management of blood donors with nerve injury related to donation V2.pdf (transfusionguidelines.org)

## References

Kang, M. S. et al., 2023. Clinical, Electrophysiological, and Sonographic Findings in Patients With Nerve Injury After Vessel Puncture. *Journal of Clinical Neurology,* 19(4), pp. 371-375. doi: 10.3988/jcn.2022.0285.

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Sorensen, B. S., Johnsen, S. P. & Jorgensen, J., 2008. Complications related to blood donation: a population-based study. *Vox Sanguinis,* 94(2), pp. 132-137. https://doi.org/10.1111/j.1423-0410.2007.01000.x.

Thomas, S. et al., 2023. Safety profile of plasma for fractionation donated in the United Kingdom, with respect to variant Creutzfeldt–Jakob disease. *Vox Sanguinis,* 118(5), pp. 341-413. doi: https://doi.org/10.1111/vox.13416.

Townsend, M. et al., 2020. Development and validation of donor adverse reaction severity grading tool: enhancing objective grade assignment to donor adverse events. *Transfusion,* 60(6), pp. 1231-1242. https://doi.org/10.1111/trf.15830.

Working Group on Donor Vigilance of the International Society of Blood Transfusion (ISBT) Working Party on Haemovigilance, 2014. *Standards for Standard for Surveillance of Complications Related to Blood Donation,* s.l.: Association for the Advancement of Blood & Biotherapies (aabb).

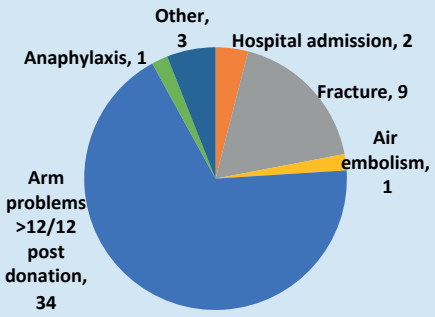
# Serious adverse events following blood donation reported to the UK Blood Services in 2023

In 2023 the UK Blood Services collected approximately 1.8 million donations (whole blood and apheresis); this includes plasma collected for fractionation at NHSBT. Fifty-three serious adverse events of donation (SAED) have been reported last year and includes all categories of imputability; this equates to a rate of 0.29 per 10,000 donations, or 1 in 34,126 donations. Of the 53 cases reported, 3 were not related to blood donation. The remaining 50 cases are described below. Serious adverse events are very rare but do occur and can have a significant impact on donor health and donor retention. UKBTS are planning implementation of the internationally validated donor adverse events severity grading criteria over the next year.

## Breakdown of serious adverse events in 2023

### SAED categories

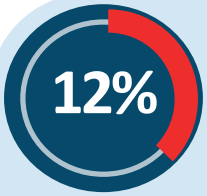
Excluding SAED with an imputability of 0a and 0b




SAED were seen in both female (30/50, 60%) and male donors (20/50, 40%).
3 SAED were reported in first time donors, all of these being whole blood donors.

6/9 fractures were related to delayed vasovagal reactions. Female donors accounted for all of these cases. None were first time donors.

There were no reports of any deaths or road traffic collisions, or haemolysis due to component donation, reported in 2023.




6/50 SAED were as a direct result of a delayed vasovagal reaction.


34/50 SAED reported were related to persistent arm problems more than one year post donation.
All were whole blood donors.

47/50 donors were withdrawn from future donations. 3 donors were not withdrawn. This includes 2 donors with arm pain who were allowed to return if donating from their other arm.

3/50 SAED were in component donors (1 platelets, 2 plasma for medicine). The rate of apheresis SAED is 1 in 34,027 donations, similar to the overall SAED rate.

### Key messages

Blood Services must ensure that blood donors are aware of any 'material risks' involved in donating blood and the measures that need to be taken to reduce risk of these complications.

Effective donor education has a key role in reducing the frequency and severity of adverse events.

Whole blood and component donation is safe but complications do sometimes occur. The overall incidence of SAED remains low. The rate of SAED in UK for 2023 is 0.28 per 10,000 donations taking into account the SAED where blood donation was deemed to have potentially contributed to the donor adverse event.