# Donor Haemovigilance

# 6

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## Definitions:

**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).**

## Key messages

- Donor complications can occur despite best care, and some may have serious impact on donors
- While donor selection criteria help in ensuring donor and donation safety, decision-making depends on whether the condition was known, disclosed or evident before blood donation
- Delayed bleeding and bruising are the most commonly noted complications in donors >70 years and these donors have lower rates of vasovagal events compared to younger donors
- Staff dealing with blood donors should have adequate knowledge about potential complications and be able to identify and manage them promptly on session
- Improving donor experience with measures to reduce risk of complications related to blood donation along with prompt recognition and management of complications is vital

## Abbreviations used in this chapter

| | |
|---|---|
| **AABB** | Association for the Advancement of Blood & Biotherapies |
| **ADL** | Activities of daily living |
| **BSQR** | Blood Safety and Quality Regulations |
| **DAE** | Donor adverse event |
| **EBA** | European Blood Alliance |
| **ISBT** | International Society of Blood Transfusion |
| **IHN** | International Haemovigilance Network |
| **JPAC** | Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee |
| **NHSBT** | NHS Blood and Transplant |
| **NIBTS** | Northern Ireland Blood Transfusion Service |
| **OMC** | Outside medical care |
| **RTC** | Road traffic collision |
| **SAED** | Serious adverse event of donation |
| **SNBTS** | Scottish National Blood Transfusion Service |
| **UK** | United Kingdom |
| **VVR** | Vasovagal reactions |
| **WBS** | Welsh Blood Service |

## Recommendations

- All UK Blood Services should implement the 'Severity Grading Tool for Blood Donor Adverse Events' developed in 2020 by the AABB Donor Haemovigilance Working Group and endorsed by ISBT, IHN and EBA
- All UK Blood Services should benchmark donor haemovigilance data to improve practices and policies

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

# Introduction

Blood transfusions save lives and improve health. An adequate and reliable supply of safe blood needs a stable base of regular, voluntary, non-remunerated blood donors. The four UK Blood Services rely wholly on donations given by voluntary blood donors gifting their time and donations altruistically. Blood donation is an uneventful experience for most donors, but as with any clinical intervention, there are risks associated with it. Complications related to blood donations are adverse reactions and events with a temporal relation to a blood donation. Complications are broadly classified into two main categories: those with predominantly local symptoms and those with predominantly generalised symptoms. These are usually minor adverse events but, on occasion, may have lifelong consequences for the donor.

Good donor care not only involves the implementation of measures to minimise the risks to donors and the subsequent management of any adverse reactions, but it also requires informing donors of the material risks of blood donation.

The SAED reported by the four UK Blood Services are covered here. This year, adverse events in blood donors >70 years are discussed with further detail in the supplementary information on the SHOT website (https://www.shotuk.org/report-summary-and-supplement-2022/).

### Serious adverse events of donation

The UK Blood Services have implemented the 'Standard Surveillance of Complications Relating to Blood Donations' (Goldman et al. 2016). Each Blood Service records and monitors their own adverse events, including any SAED. SAED are those complications or events which result in a significant disability/ incapacity persisting for >1-year post donation, hospitalisation, interventions or rarely death. There are 10 SAED reporting categories, which are listed in Table 6.2. Assigning severity rating and imputability scoring (the strength of relation between donation and complication) is challenging, especially when information is incomplete. History taking and assessment are subjective and vary between clinicians. 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).

Recording imputability status for donor events, whilst not a mandatory requirement under BSQR (2005), is assessed and recorded for every SAED 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

Occasionally, the reported complication is clearly unrelated, or very unlikely to be related, to the donation event itself; for example, a donor developing abdominal pain relating to ovarian torsion requiring admission within 24 hours of donation.

# Data

A total of 1,816,191 whole blood and component donations were collected by the 4 UK Blood Services in 2022. This is summarised in the Table 6.1.

| Donations from 2022 | | NHSBT | SNBTS | WBS | NIBTS |
|---|---|---|---|---|---|
| Whole blood | Donations from male donors | 714,557 | 69,432 | 38,760 | 20,261 |
| | Donations from female donors | 738,152 | 79,963 | 43,918 | 19,661 |
| | Donations from new donors | 117,716 | 8,531 | 10,449 | 2,697 |
| | Donations from repeat donors | 1,334,993 | 140,864 | 72,229 | 37,225 |
| Apheresis | Donations from male donors | 68,478 | 7,204 | 2,300 | 3,298 |
| | Donations from female donors | 9,177 | 344 | 365 | 321 |
| | Donations from new donors | 6,017 | 0 | 56 | 0 |
| | Donations from repeat donors | 71,638 | 7,548 | 2,609 | 3,619 |
| **Total number of donations in 2022** | | **1,530,364** | **156,943** | **85,343** | **43,541** |

***Total number of donations in the UK from all the four UK Blood Services in 2022* = 1,816,191**

**Table 6.1: Cumulative donation data from the four UK Blood Services in 2022**

Table 6.2 summarises the number of SAED by category for all four UK Blood Services combined for period January 2022 – December 2022.

| **SAED category** ***All cases reported to the UK Blood Services included here irrespective of imputability or causality in relation to blood donation*** | **Total number (from all UK Blood Services)** | **NHSBT** | **SNBTS** | **WBS** |
|---|---|---|---|---|
| 01. Death within 7 days of donation | 2 | 2 | 0 | 0 |
| 02. Hospital admission within 24 hours of donation | 11 | 9 | 1 | 1 |
| 03. Injury resulting in a fracture within 24 hours of donation (including fractured teeth) | 8 | 6 | 1 | 1 |
| 04. Road traffic collision (RTC) within 24 hours of donation | 4 | 3 | 1 | 0 |
| 05a – Problems relating to needle insertion persisting for more than one year (this mainly includes suspected or confirmed nerve and tendon injuries) | 24 | 18 | 6 | 0 |
| 05b – Problems relating to needle insertion requiring hospitalisation/intervention (this mainly includes vascular complications) | 0 | 0 | 0 | 0 |
| 06. Acute coronary syndrome (ACS) diagnosed within 24 hours of donation | 5 | 3 | 1 | 1 |
| 07. Anaphylaxis | 0 | 0 | 0 | 0 |
| 08. Haemolysis | 0 | 0 | 0 | 0 |
| 09. Air embolism | 0 | 0 | 0 | 0 |
| 10. Other event | 1 | 0 | 1 | 0 |
| **Total reported SAED in 2022*** ***No SAED were reported from NIBTS in 2022** | **55** | 41 | 11 | 3 |

**Table 6.2: SAED by category in 2022 (all SAED included here irrespective of imputability)**

The 2 deaths reported following blood donation were due to coronary artery disease and were deemed to be unrelated to blood donation. One donor was in his late 60s and the other was >70 years old and both had donated several times before uneventfully and had not declared any underlying cardiac

problems or recent anginal symptoms. Ascherio et al. (2001) showed that there was no evidence of association between a history of blood donation and risk of coronary heart disease in a large cohort. Donors developing symptoms of cardiovascular disease contributed to 5 cases reported in 2022. None of these donors had declared any cardiovascular disease at screening. All these donors have been withdrawn from donating.

Table 6.3 details the total number of whole blood and component donations and the total number of SAED reported for each of the four UK Blood Services for period January 2022 - December 2022. This equates to 0.30 SAED per 10,000 donations or 1 SAED per 33,022 donations (irrespective of imputability). Table 6.3 also gives a summary of total number of SAED excluding imputability scores of 0a, 0b for 2022. This equates to 0.24 per 10,000 donations or 1 SAED per 42,237 donations.

**Table 6.3: Summary of total donations for the four UK Blood Services and total numbers of SAED for 2022**

| | NHSBT | SNBTS | WBS | NIBTS |
|---|---|---|---|---|
| Whole blood donations | 1,452,709 | 149,395 | 82,678 | 39,922 |
| Apheresis donations | 77,655 | 7,548 | 2,665 | 3,619 |
| **Total donations** | **1,530,364** | **156,943** | **85,343** | **43,541** |
| Total number of SAED in the calendar year 2022 | 41 | 11 | 3 | 0 |
| Total number of SAED excluding those scored with an imputability of 'unlikely' or 'not related to blood donation' | 33 | 9 | 1 | 0 |
| Rate of total SAED per 10,000 donations in UK for 2022 (all submitted reports irrespective of imputability) | | 0.30 | | |
| **Rate of SAED per 10,000 donations in UK for 2022 excluding those with imputability of 'unlikely' or 'not related to donation'** | | **0.24** | | |

## Comparison of trends with previous years

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

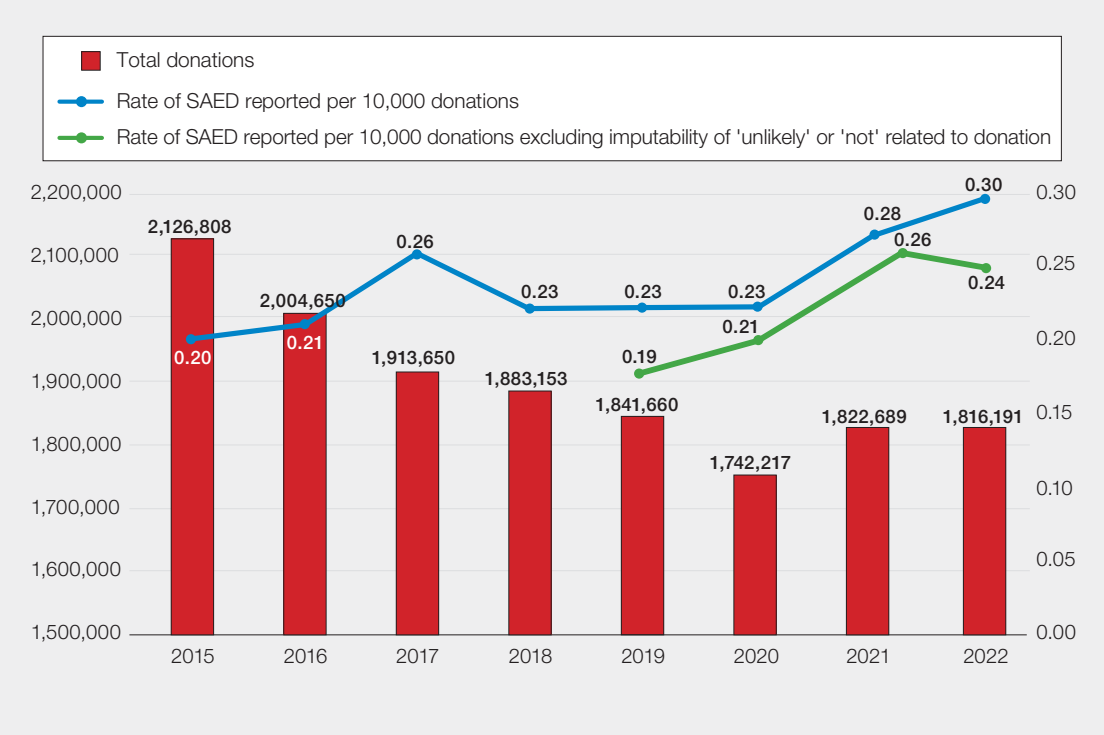


**Figure 6.1**
**Rate of SAED reported per 10,000 donations in the UK from 2015-2022**

*SAED=serious adverse event of donation*

Since 2015 there has been an overall upward trend in the rate of SAED. Improved reporting by better informed donors who are now reporting SAED that occurred in years prior to 2022 (these are included in the 2022 figures), and improved recording by UK Blood Services are key factors. There are additional factors that need to be considered such as staff turnover, training challenges, and effectiveness of measures implemented to reduce these severe events.

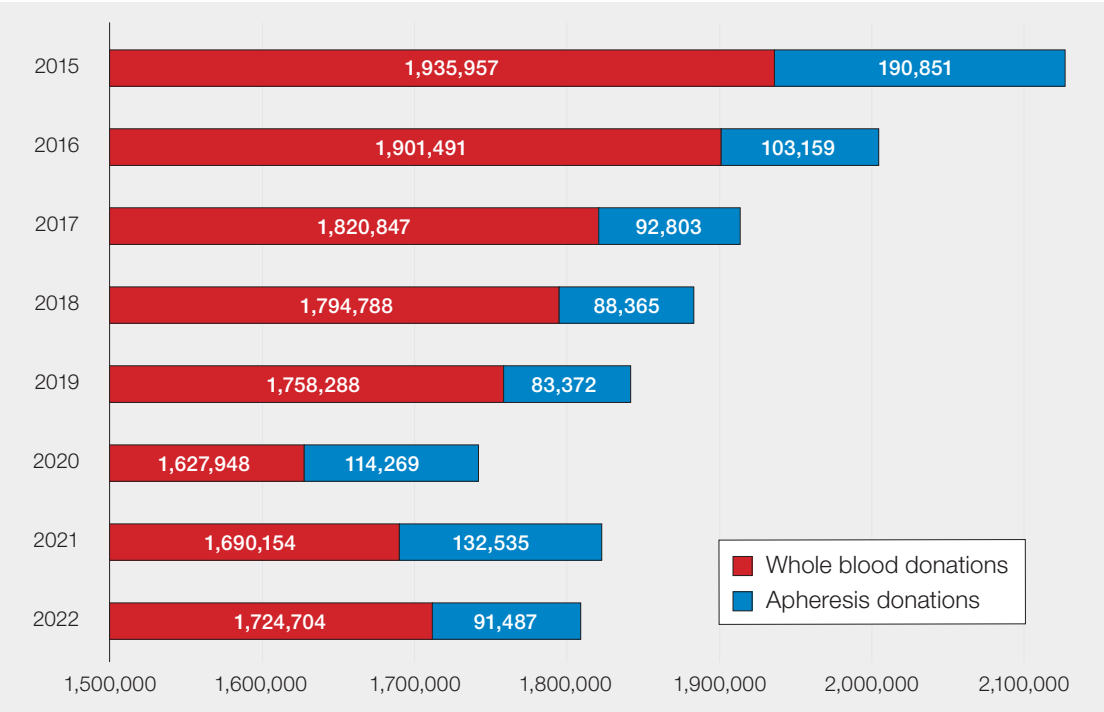


**Figure 6.2**
**Trends in the number of donations collected across the UK 2015-2022**

## Donor adverse event severity grading

The UK Blood Services have agreed to implement in 2023/24, the validated donor severity grading criteria developed by the AABB Donor Haemovigilance Working Group and endorsed by ISBT, IHN and EBA

(Link to document provided under 'Recommended resources') (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 6.4 below. SAED will be recorded according to the new grading criteria and will render the current categories, as outlined in Table 6.2, obsolete. This will lead to an increase in the number of SAED recorded in the UK once implemented.

**Table 6.4: 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)<br>***AND***<br>Short duration ≤2 weeks<br>***AND***<br>No limitation on activities of daily living (ADL)<br>***AND***<br>Resolved with no or minimal intervention | Arterial puncture, pressure bandage applied, resolved without intervention or sequelae<br>Vasovagal event that resolves with comfort care and/or oral hydration<br>Citrate reaction resolved with oral calcium or reduction in infusion rate |
| **Grade 2** | OMC, no hospitalisation<br>***OR***<br>Duration >2 weeks- ≤ 6 months<br>***OR***<br>Limitations on ADL for ≤2 weeks | Superficial thrombophlebitis resolved with oral antibiotics, no sequelae<br>Vasovagal event that requires transport to ED for IV hydration<br>Lacerations requiring sutures |
| **Grade 3** | Not life-threatening<br>***AND any of the following***<br>Hospitalisation<br>***OR***<br>Duration >6 months<br>***OR***<br>Limitations on ADL >2 weeks<br>***OR***<br>Require surgery<br>***OR***<br>Other serious complications (Category E) | Arteriovenous fistula requiring surgical repair<br>Fracture, dental injury, or concussion<br>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<br>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)*

## Donors >70

Since 2009, UK donors aged 70 and over have been able to donate blood, provided they have given a donation in the preceding two years. UK Blood Services are assessing adverse events data for this cohort, as part of a review of the age criteria within the JPAC Whole Blood and Component Donor Selection Guidelines. Among regular whole blood donors, the reported incidence of bruising and rebleeds was higher in donors aged over 70 years compared to those aged 25-70 years; however, vasovagal events and all types of arm pain occurred less often. Younger donors (aged under 25 years) were more likely to experience vasovagal events or arm pain, but less likely to rebleed. Further information regarding donor adverse events among donors of different age groups reported to all the UK Blood Services can be found in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2022/).

## Illustrative cases

### Case 6.1: Donor had a syncopal episode on session and later diagnosed to have Brugada syndrome

*A young male whole blood donor, in his 30s, experienced a syncopal episode which was thought to be an immediate vasovagal reaction following his first donation. He was suspected to have sustained a minor head injury following this syncope. He recovered sufficiently at session to be able to go home with family but had attended hospital since and following further investigations, was diagnosed with Brugada syndrome. The donor was withdrawn from future donations. The donor had commented he was grateful that due to his donation, his unidentified condition had been diagnosed.*

Syncope is a sudden temporary loss of consciousness associated with a loss of postural tone with spontaneous recovery. Syncope has a large differential diagnosis, is difficult to evaluate, and can be disabling. There are subsets of syncopal patients with a high risk of sudden death. Establishing the cause of syncope, deciding whether the patient needs to be admitted, and treating the causes of syncope effectively to reduce recurrences and potentially improve patient outcomes are the key issues to be addressed when managing patients with syncope. While vasovagal reactions are one of the common causes of syncope, other causes such as situational (micturition related, cough related, etc.), orthostatic hypotension, medications, cardiac and neurological causes can also cause syncope (Kapoor 2002; Grossman and Badireddy 2022).

VVR are among the most common complications of whole blood donation (Seheult et al. 2016). VVR is a general feeling of discomfort and weakness with anxiety, dizziness and nausea, which may progress to loss of consciousness. Donors can experience VVR due to several physiological reasons or due to underlying pathology which often comes to light during investigations of VVR. Syncope, or transient loss of consciousness, is the major cause of immediate morbidity of medical significance during blood donation and is the most severe of a spectrum of VVR, which range from mild pre-syncopal symptoms to severe reactions involving syncope. The overall prevalence of VVR in whole blood donors is estimated to be between 1.4 and 7% (moderate reactions) and between 0.1 and 0.5% (severe reactions) (Amrein et al. 2012). VVR have significant implications not only for the welfare of donors but also staff time and training, the management of donor sessions and perhaps more crucially on the retention of donors and security of the blood supply (France et al. 2004).

Brugada syndrome is a rare genetic disorder, affecting about 5 of every 10,000 people worldwide (Johns Hopkins Medicine n.d.). The condition can cause a very fast, abnormal heartbeat, but many people are unaware they have the syndrome, although some may experience syncope or a blackout, as illustrated by this donor (BHF 2022).

While neurally mediated syncope are frequent in patients with this syndrome similar to the general population, patients can have an arrhythmic syncope typically resulting from a self-terminating sustained ventricular tachycardia or paroxysmal ventricular fibrillation, potentially leading to sudden cardiac death. Distinguishing syncope due to malignant arrhythmias from a benign form is often difficult in these patients unless an electrocardiogram is recorded during the episode (Mascia et al. 2021).

Had the donor known of his condition prior to donation and reported to staff, he would have been deferred (JPAC 2019). However, as illustrated by this case, the donor was unaware of his underlying condition, and therefore could only be managed once he presented with the syncope at session, and subsequently with his hospital admission.

### Case 6.2: Delayed vasovagal reaction leading to a road traffic accident

*A female donor in her late 60s, gave a unit of whole blood at a community session. Donation was unremarkable. She left immediately after receiving a post-donation drink on the bed and drove away from the session. At some point she lost consciousness. A passer-by observed that her car drifted to the side and then scraped along a wall bordering the street, before coming to a gradual stop. The donor came round shortly afterwards and was unharmed. No one else was involved. After being assessed by paramedics the donor was allowed home.*

*The donor had successfully given many times with only one minor vasovagal episode at session several years earlier. She was not on any medication and had no recent medical treatment apart*

*from a COVID-19 booster four weeks earlier. On reflection, she noted that although she had not felt unwell after donation, she would have benefitted from taking longer to recover. In total she had been at the session for less than 30 minutes. In view of the severe delayed vasovagal reaction, she was deferred from future donation.*

Risk factors for delayed faints include being a new donor, female, young age and smaller stature (Kamel et al. 2010; Narbey et al. 2016). Increased risk has also been documented in older female donors (Narbey et al. 2016). Delayed vasovagal reactions carry a higher risk of injury to the donor and to those around them (Kamel et al. 2010; Narbey et al. 2016). Blood Services should ensure that all donors are aware of the risks and have the opportunity to wait at session after donation if needed.

**Case 6.3: Myocardial infarction within 24 hours of donation**

*A regular female donor in her 70s, had given 62 donations previously. She donated whole blood uneventfully following her health screen when no concerns were reported. The donor then called the Blood Service and reported that she had a myocardial infarction requiring two stents within 24 hours of donating. Prior to donating, the donor had noticed an increasing sense of heartburn type symptoms, the donor assumed this was related to her acid reflux so did not mention this to session staff as she felt well at the time of donation. Upon investigation the donor did have a family history of cardiovascular disease, but she was not known to have any cardiovascular disease. This donor has since been withdrawn from donating.*

Around 11.3% of the UK's population have cardiovascular disease, therefore a portion of blood donors may have underlying coronary artery disease (BHF 2021).

Current blood donor selection guidelines in the UK state that donors with ischaemic heart disease or angina, regardless of cause, must not donate (JPAC n.d.). Careful donor selection, thorough donor education and robust pre-donation assessment are critical to identify risk factors.

This case highlights the importance of educating blood donors to ensure they are aware to inform session staff of any change in health or new symptoms before donation, so that appropriate decisions can be made. This donor would not have been accepted if she had disclosed a recent increase in heartburn type symptoms.

## Conclusion

Blood Services should encourage donors to make early contact with the Blood Service 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 resources

**Severity grading tool for donor adverse events developed by AABB Donor Hemovigilance Working Group and endorsed by ISBT, IHN and EBA**
https://www.ihn-org.com/wp-content/uploads/2020/06/Tool_brochure_all_logos.pdf

**STRategies to Improve Donor ExperienceS (STRIDES) study (ISRCTN10412338)**
http://www.donorhealth-btru.nihr.ac.uk/studies/strides-study/

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BSQR (2005) The Blood Safety and Quality Regulations ISBN 0110990412; http://www.legislation.gov.uk/uksi/2005/50/contents/made [accessed 01 March 2023].

EU directives: https://ec.europa.eu/health/blood_tissues_organs/blood_en [accessed 30 March 2023] then click Blood Legislation and guidelines to expand list and select the option below:

Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC OJ L 33, 8.2.2003. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32002L0098 [accessed 30 March 2023].

Commission Directive 2005/61/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events (Text with EEA relevance)

OJ L 287M, 18.10.2006, p. 350–358 (MT) https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32005L0061&qid=1648656281267

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Kamel H, Tomasulo P, Bravo M et al. Delayed adverse reactions to blood donation. *Transfusion*. 2010;**50(3)**:556-65.

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Townsend M, Kamel H, Van Buren N, et al. Development and validation of donor adverse reaction severity grading tool: enhancing objective grade assignment to donor adverse events. *Transfusion*. 2020;**60(6)**:1231-1242. https://doi.org/10.1111/trf.15830. [accessed 27 April 2023].

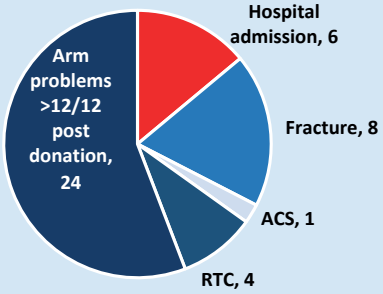
# Serious Adverse Events following Blood Donation reported to the UK Blood Services in 2022

In 2022 the UK Blood Services collected approximately 1.8 million donations (whole blood and apheresis)- this includes plasma collected for fractionation at NHSBT. Fifty five serious adverse events of donation (SAED) have been reported last year (this includes all categories of imputability and equates to 1 in 33,022 donations). Of the fifty five cases reported, 12 were not related to blood donation. The remaining forty three 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 2022

### SAED Categories

Excluding SAED's with an imputability of 0a and 0b.



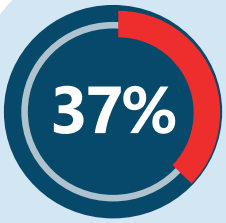

*RTC=road traffic collision*
*ACS= Acute coronary syndrome*

**SAED were seen in both female (23/43, 53.49 %) and male donors (20/43, 46.51%).**

**Five SAED were reported in first time donors, 3/5 of these being whole blood donors.**

**There were no reports of anaphylaxis, haemolysis or suspected air embolism due to component donation reported in 2022.**

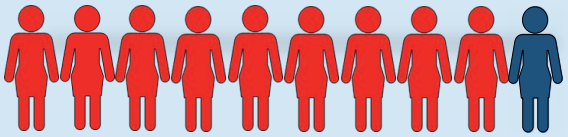
**All 8 fractures were related to delayed vasovagal reactions (DVVR). Female donors accounted for 6/8 of these cases. None of these cases were in first time donors.**




**16/43 SAED were as a direct result of a delayed vasovagal reaction. The break down of these cases include 4 RTC, 4 hospital admissions and 8 fractures.**


**24/43 SAED reported were related to persistent arm problems more than one year post donation.**
**Three were in component donors while all others were whole blood donors.**

**In general 9/10 donors who suffer an SAED are withdrawn from future donations**



### 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.**

**More than 1/3 of SAED's during 2022 were due to a delayed vasovagal event.**

**Whole blood and component donation is safe but complications do sometimes occur. The overall incidence of serious adverse events of donation (SAED) remains low. The rate of SAED in UK for 2022 is 0.24 per 10,000 donations taking into account the SAED where blood donation was deemed to have potentially contributed to the donor adverse event.**