Donor Haemovigilance

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Definitions:

Donor haemovigilance is 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 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 (according to Article 3 (h) of Directive 2002/98/EC).

Key messages

- The overall incidence of serious adverse event of donation (SAED) remains low. The rate of SAED for 2019 was 0.23 per 10,000 donations
- Vasovagal events resulting in donor hospitalisation or injury along with arm problems in blood donors persisting for more than 12 months post venepuncture continue to be the most frequently reported SAED
- 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

BSQR	Blood Safety and Quality Regulations
DAE	Donor adverse events
DIL	Donor Information Leaflet
EU	European Union
ISBT	International Society of Blood Transfusion
NHSBT	National Health Service Blood and Transplant
NIBTS	Northern Ireland Blood Transfusion Service
SAED	Serious adverse event of donation
SNBTS	Scottish National Blood Transfusion Service
VVR	Vasovagal reaction
WBS	Welsh Blood Service

Recommendation

- Blood Services must take reasonable care to ensure that the blood donors are aware of any 'material risks' involved in donating blood

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

Introduction

The four UK Blood Services rely on blood donations given by voluntary blood donors gifting their time and donations altruistically. This ensures a sustainable blood supply for patients. 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 lifelong consequences for the donor. The overall incidence of the SAED for the UK Blood Services for January to December 2019 was 0.23 per 10,000 donations. This is low and has remained relatively static for 4 years.

Donor consent process in the UK Blood Services

The UK Blood Services have a duty of care to ensure all donors' donation journeys are as inconvenience free as possible. An essential part is ensuring donors are fully informed about the donation process, donation testing, donation use and the potential side effects of donation. Montgomery vs Lanarkshire 2015 (Chan et al. 2017) was a landmark legal case that changed the patient consent process fundamentally and specifically focussed on individualising the informed consent process. Donors are managed as a population and donor risk assessments are usually made using data generated from populations rather than individuals. It is therefore easy to apply similar criteria when consenting blood donors. It is imperative that the Blood Services consent donors in a way that aims to comply with Montgomery's principles as far as possible. Blood donors complete a health and lifestyle questionnaire prior to donating and this aims to screen out any donors with medical conditions that could be affected adversely by donating. Similarly, potential donors with medical conditions that would adversely affect any recipient of their blood component are screened out. This goes some way to individualising the consent process, but it is imperative that donors deemed medically fit to donate are informed of the possible adverse consequences of donation and consented in a way that complies as closely as possible with Montgomery's principles.

The WBS aims to achieve this by:

- Ensuring the 'Before You Donate' booklet is up to date. This document details the donation process, the tests performed on donations, how donations are used and the possible adverse consequences of donating blood or platelets (including incidences of donation related adverse events)
- Giving donors the opportunity to read all the information contained in the 'Before You Donate' booklet prior to attending a donation clinic. Donors at WBS are sent a link to the Blood Service website that details this information with the text or e-mail they are sent reminding them of their donation appointment. Donors will thus be familiar with the document content when arriving on donation clinic and not only read this information just prior to donating
- Having nominated 'Consent Champions' on every WBS donation clinic who deal with any consent queries and target first time donors to ensure they understand all the donation processes and possible consequences, thus individualising the consent process further
- Donors sign a consent form at the donation clinic confirming they have read and understood all the contents of the 'Before You Donate' booklet and had any queries answered

NIBTS has a specific leaflet entitled 'Risks of Blood Donation' which is provided to each donor when they present for donation. Donors are given time to read this (which contains up to date figures of the rate of adverse events in the UK), and they sign the consent section of the health check questionnaire indicating that they understand the nature of the donation process and the possible risks involved as set out in the leaflet. Documentation posted out to donors in advance of donation contains a link to the

NIBTS website which sets out the donation process (in writing and by short video) and again states the risks involved.

At NHSBT, donors are provided with the 'Welcome booklet' prior to their blood donation. This printed booklet is provided to each donor when they present for donation, either whole blood or component donation by apheresis and provides an overview about the donation process, tests performed on donations, information regarding risks and potential complications and how the donation and donor information is used. Donors are given time to read this (which contains up to date figures of the rate of adverse events at NHSBT) and get a chance to discuss with staff if they have any concerns or additional queries. They sign the consent section of the health check questionnaire indicating that they have understood the information provided and have had the chance to discuss this. This information is available and easily accessible online from the website https://www.blood.co.uk/the-donation-process/what-happens-on-the-day/ which donors access as well.

In SNBTS, all donors are asked to read the Donor Information Leaflet (DIL) before they give blood. The DIL includes information on the blood donation process, blood safety, microbiological testing, use of blood, and the nature and rate of donor adverse events (DAE). Figures included in the DIL are based on recent DAE rates recorded by SNBTS. During health screening, staff check that the donor has had an opportunity to read the DIL and discuss any questions or concerns the donor raises. Finally, before donation, the donor is asked to sign the 'Donor Declaration' on the session record. This includes a statement that they have read and understood the DIL. The DIL and further information about blood donation is also available on the Scotblood website.

All blood donors must be made aware of any 'material risks' involved in donating blood. A 'material risk' is one in which 'a reasonable person in the donor's position would be likely to attach significance to the risk, or the healthcare professional is or should reasonably be aware that the particular donor would be likely to attach significance to it' (BMA 2019 and Agnew 2015).

Serious adverse events of donation

The UK Blood Services have implemented the 'Standard for Surveillance of Complications Related to Blood Donation' issued by the International Society of Blood Transfusion (ISBT) (Goldman et al. 2016). The adverse events of donation can be divided into those that are **generalised** and affect the donor's body and those that are **localised** affecting the donor's arm. Presyncopal vasovagal reactions and bruises/haematomas are the most frequently observed adverse events in each category (Gavillet et al. 2013).

The current European Blood Directives, issued and enforced between 2003 and 2005 (2002/98/EC and 2005/61/EC), provide the regulatory bases of haemovigilance requirements for traceability and notification of serious adverse reactions and events (European Union (EU) Directives). The EU Directives were transposed into UK law through the Blood Safety and Quality Regulations (BSQR) 2005. These regulations ensure that all transfusion services have a system for receiving and registering reports of serious adverse reactions and serious adverse events related to quality and/or safety of blood or components for transfusion. SAED have been included in the donor haemovigliance chapter as part of the Annual Report from the SHOT UK haemovigilance scheme and are categorised in Table 6.2. This year category 5 (Problems relating to needle insertion persisting for more than one year) has been divided into two subcategories based on the main cause identified for the donor's arm problems.

Assigning severity and imputability (the strength of relation between donation and complication) can be difficult, especially when information is incomplete, and some terms, such as long-term pain and/or disability, are subjective. There are currently no uniformly agreed objective criteria to separate levels of severity or imputability and there is considerable variation in how this is recorded (Land et al. 2018).

Recording imputability for donor events in the UK, whilst not a mandatory requirement under BSQR, 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

It is clear, on occasion that the reported post-donation complication is unrelated or very unlikely to be related to the donation event itself. For example, a donor developing a complication relating to diverticulitis requiring admission within 24 hours of giving a donation. Hence the risk of SAED in the UK has been calculated using all reported cases in the first instance and in addition, risk after excluding those that are clearly not related to donation, see Table 6.3.

Data

A total of 1,841,660 whole blood and component donations were collected by the 4 UK Blood Services in 2019. This is summarised in the Table 6.1 below:

Table 6.1: Cumulative donation data from the 4 UK Blood Services for the period January to December 2019

Donations from 2019		NHSBT	SNBTS	NIBTS	WBS
Whole blood	Donations from male donors	708,740	66,196	22,516	44,781
	Donations from female donors	767,660	79,506	20,851	48,038
	Donations from new donors	138,134	12,512	5,168	9,137
	Donations from repeat donors	1,338,266	133,190	38,199	83,682
Apheresis	Donations from male donors	62,593	6,413	4,444	2,312
	Donations from female donors	6,315	407	523	365
	Donations from new donors	9,139	0	40	81
	Donations from repeat donors	59,769	6,820	4,927	2,596
Total number of donations in 2019		**1,545,308**	**152,522**	**48,334**	**95,496**

Table 6.2 summarises the number of SAED by category for all 4 UK Blood Services combined for the period January to December 2019. There was 1 death reported of a whole blood donor in his 50s who died unexpectedly 2 days post donation. The cause of death was reported as bilateral pulmonary embolism which was unrelated to blood donation. The donor had been well and reported no ongoing issues at time of his donation.

Table 6.2: SAED by category in 2019

SAED category	Total Number
01. Death within 7 days of donation	1
02. Hospital admission within 24 hours of donation	11
03. Injury resulting in a fracture within 24 hours of donation (including fractured teeth)	9
04. Road traffic collision (RTC) within 24 hours of donation	0
05a. Problems relating to needle insertion persisting for more than one year (this mainly includes suspected or confirmed nerve and tendon injuries)	18
05b. Problems relating to needle insertion requiring hospitalisation/intervention (this mainly includes vascular complications)	3
06. Acute coronary syndrome (ACS) diagnosed within 24 hours of donation	0
07. Anaphylaxis	0
08. Haemolysis	0
09. Air embolism	0
10. Other event	0
Total reported SAED in 2019	**42**

Table 6.3 details the total number of whole blood and component donations and the total number of SAED reported for each of the 4 UK Blood Services for 2019. This equates to 0.23 SAED per 10,000 donations or 1 SAED per 43,849 donations, similar to the previous 4 years. Table 6.3 also gives a summary of total number of SAED excluding imputability scores of 0a, 0b for 2019. This equates to 0.19 per 10,000 donations or 1 SAED per 52,619 donations.

	NHSBT	SNBTS	NIBTS	WBS
Whole blood donations	1,476,400	145,702	43,367	92,819
Apheresis/component donations	68,908	6,820	4,967	2,677
Total donations	**1,545,308**	**152,522**	**48,334**	**95,496**
Total number of SAED in the calendar year 2019	35	5	0	2
Rate of total SAED per 10,000 donations in UK for 2019 (all submitted reports irrespective of imputability)			0.23	
Total number of SAED excluding those cases unlikely or not related to blood donation	28	5	0	2
Rate of SAED per 10,000 donations in UK for 2019 excluding those cases unlikely or not related to donation			0.19	

Table 6.3: Summary of total donations for the 4 UK Blood Services and total numbers of SAED for 2019

Comparison with previous years

The four UK Blood Services have produced an annual summary report to SHOT of SAED recorded since 2015. The 2019 figures are similar to the previous 4 years.

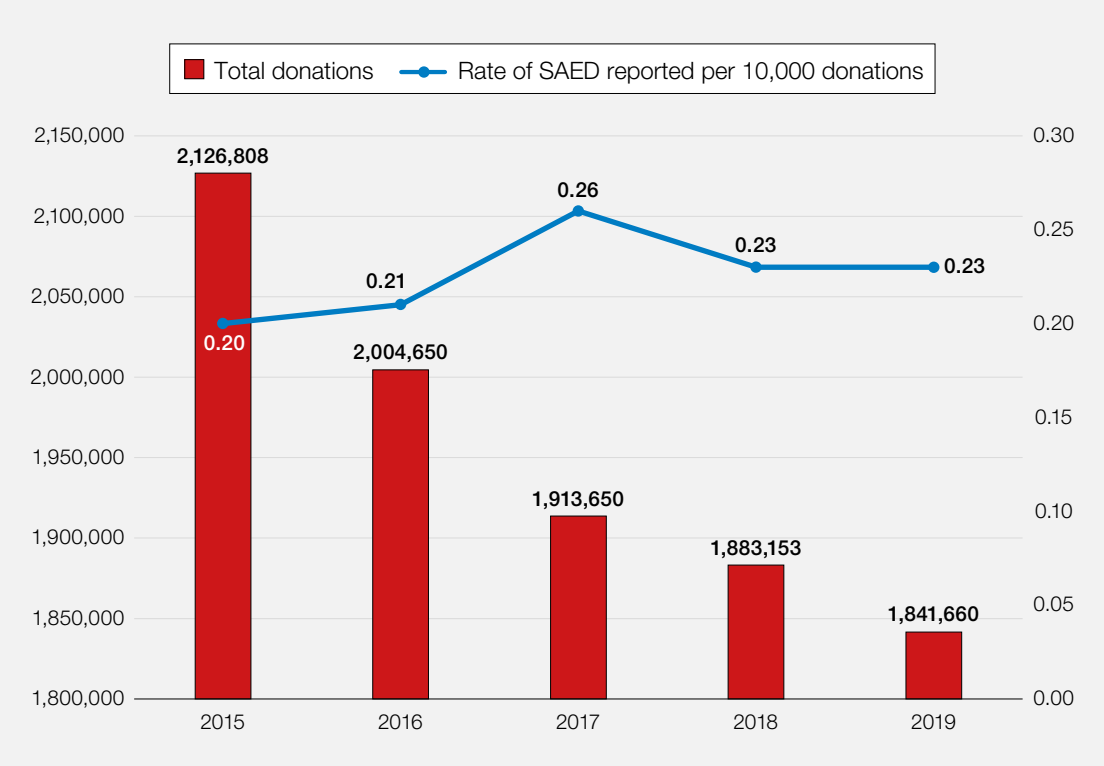
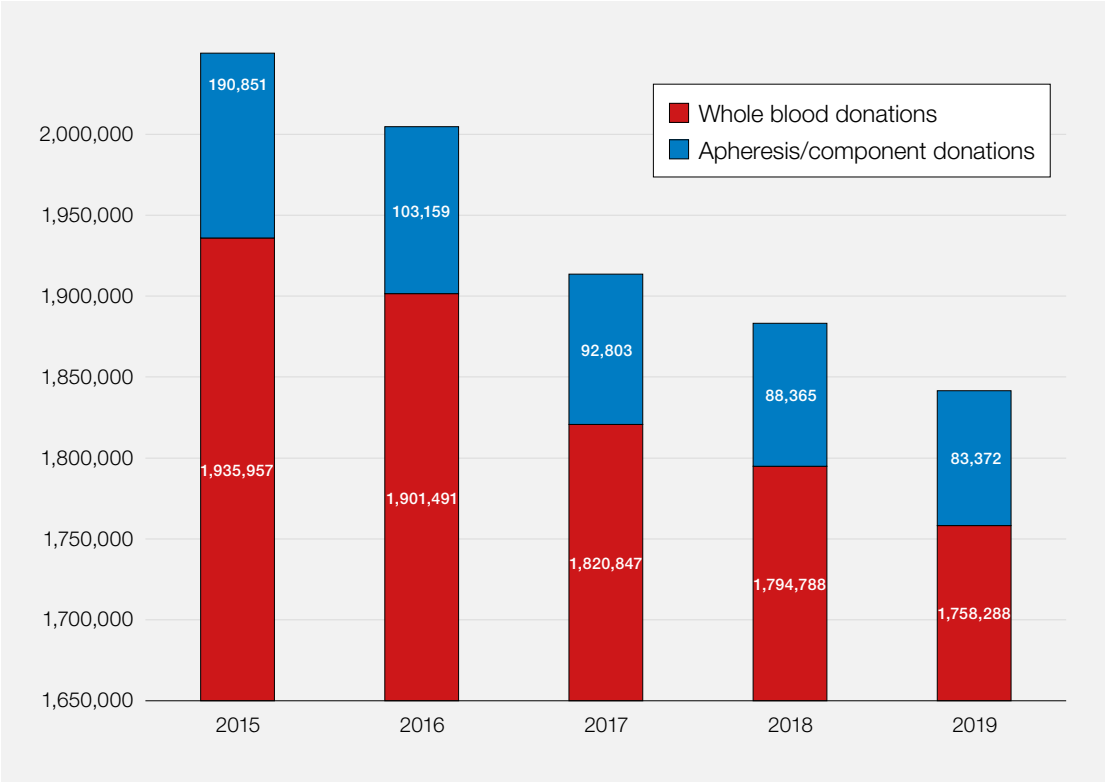


Figure 6.1: Rate of SAED reported per 10,000 donations in the UK from 2015-2019

Figure 6.2: Trend in number of donations collected in UK Blood Services 2015-2019



Illustrative case examples of SAED

Case 6.1: Development of a venous aneurysm/varix in the right cubital fossa - the site of repeated venepuncture for blood donation

A regular female donor in her 50s, contacted the WBS as she had developed an unexpected complication in her right arm. Her treating surgeon thought it was donation related. She last donated in January 2014, which she described as an uneventful donation. She however developed a lump at the venepuncture site several weeks post donation that slowly enlarged and pulsated on occasion. She saw her general practitioner, who initially prescribed symptomatic treatment but was referred to a vascular surgeon in January 2019 as the swelling was slowly enlarging. Of note is that this donor had no relevant past medical history, notably no history of a collagen vascular disorder.

Ultrasound showed that the swelling communicated with adjacent veins. She had the swelling surgically excised. At surgery it arose from the median cubital vein and contained thrombus. It was dissected clear of surrounding tissues, the feeding median cubital vein was ligated and divided proximally and distally and the swelling was removed. The surgeon's diagnosis was that of a venous aneurysm/varix at the site of repeated venepuncture for blood donation. At surgery, there was no association with the artery and thus the surgeon did not feel that she had developed an arteriovenous fistula at the time of venepuncture for blood donation.

This complication of blood donation is very rare. It is the first time that it has been described for SHOT. It is not mentioned in the standard definitions of donor adverse events developed by the ISBT Haemovigilance Working Party (Goldman et al. 2016), nor has it been found in a literature search.

How did this complication develop after an uneventful donation? A potential explanation is that at the time of venepuncture the needle damaged a venous valve, rendering it incompetent. This would allow the back flow of blood and the gradual enlargement of the segment of affected vein. The swelling may have become inflamed at times (i.e. developed a phlebitis) giving the donor the sensation of the swelling 'pulsating'. The swelling left untreated, would lead to the development of a varix or venous aneurysm as described by the donor's surgeon.

Case 6.2: Delayed faint in a regular whole blood donor resulting in ankle fracture

A regular female whole blood donor in her 60s who had donated over 25 times gave blood uneventfully. The donor's record had an instruction to give her extra rest after donation, following a delayed faint in 2017, so the donor remained at the donation session for 30 minutes. The donor felt light-headed whilst she was in a shop, so she left and went to a café for something to eat and drink. Whilst the donor was queueing to be served approximately 2 hours after her donation, she lost consciousness and fell to the floor. When the donor recovered, she attended a local ambulatory care centre where she was found to have a fracture to her left ankle. The donor has been withdrawn from blood donation.

A vasovagal reaction (VVR) is a general feeling of discomfort and weakness with anxiety, dizziness and nausea, which may progress to loss of consciousness. 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).

Both physiological and psychological factors may be important in VVR. The reaction is generated by the autonomic nervous system and further stimulated by psychological factors and the volume of blood removed, relative to the donor's total blood volume. VVR that occur after the donor has left the donation session are of concern, due to the potential for the donor to come to harm (Kamel et al. 2010). These are called delayed reactions and are a poorly understood complication of blood donation. They are thought to occur because of failure of the donor's normal compensatory reflexes to respond to the volume loss associated with donation. Occasional deaths have occurred because of accidents following delayed VVR. Inadequate fluid intake post donation, prolonged standing and high environmental temperature are recognised factors increasing the risk of a delayed VVR. Delayed reactions occur more frequently in female donors than male donors. Unlike immediate VVR, the risk of a delayed reaction is not significantly higher in first time and inexperienced donors compared to experienced and older donors. It is possible that experienced donors become less attentive about following advice to increase their fluid intake following donation, thereby increasing their risk of a delayed reaction.

Post-donation information must be provided to all donors. This should include the risk of delayed reactions and advice on prevention, in particular, on maintaining post-donation fluid intake, and avoidance of known precipitating factors such as overheating and prolonged standing. The mechanism for delayed VVR remains poorly understood. Understanding the physiological basis of such reactions may lead to the development of appropriate interventions to reduce their likelihood.

Case 6.3: Arterial puncture resulting in severe arm bruising in a regular whole blood donor

A regular female whole blood donor in her 40s who had donated several times previously, experienced pain on needle insertion. The donor did not inform staff of the discomfort that she experienced. The donation took around 4 minutes and no pain was experienced by the donor during the donation. The donor experienced pain on needle removal and was seen by a nurse who suspected an arterial puncture and was given care and advice. Later that day the donor's arm became painful and swollen, an ambulance was called, and she was taken to an emergency department. The donor was admitted overnight for observation due to severe bruising as a result of an arterial puncture. The donor was discharged the following morning. The donor has decided not to donate again.

Arterial puncture is a serious complication of donating blood with potentially long term, debilitating effects on the donor and necessitates timely recognition and appropriate management. The diagnosis of an arterial puncture is clinical and is based on a short collection time (≤3 minutes) or a combination of short collection time and bright red blood. Alternatively, the diagnosis could be based solely on a pulsating needle or pulsating tubing because the pulsation indicates that the needle is in the artery. A pulsating needle occurs in only about one-third of arterial puncture cases (Newman 2001).

Associated complications of arterial punctures include large bruises/haematomas and in severe cases compartment syndrome, arteriovenous fistula and brachial artery pseudoaneurysm with potentially long-term debilitating effects including permanent limb injury (Newman 2013). Because of the rapid blood flow, the risk of a large haematoma is increased and thereby risks of more serious pain and pressure syndromes listed above. Arterial punctures may also present as a needle falling out of the donor's arm. In the event of a needle falling out of an arm unless there is an obvious reason e.g. related to a needle manipulation it MUST be managed as an arterial puncture. As a precautionary measure to avoid vascular complications future donations will be taken from the other arm.

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.

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EU directives: http://ec.europa.eu/health/blood_tissues_organs/key_documents/index_en.htm#anchor0_more [accessed 08 June 2020] 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 08 June 2020].

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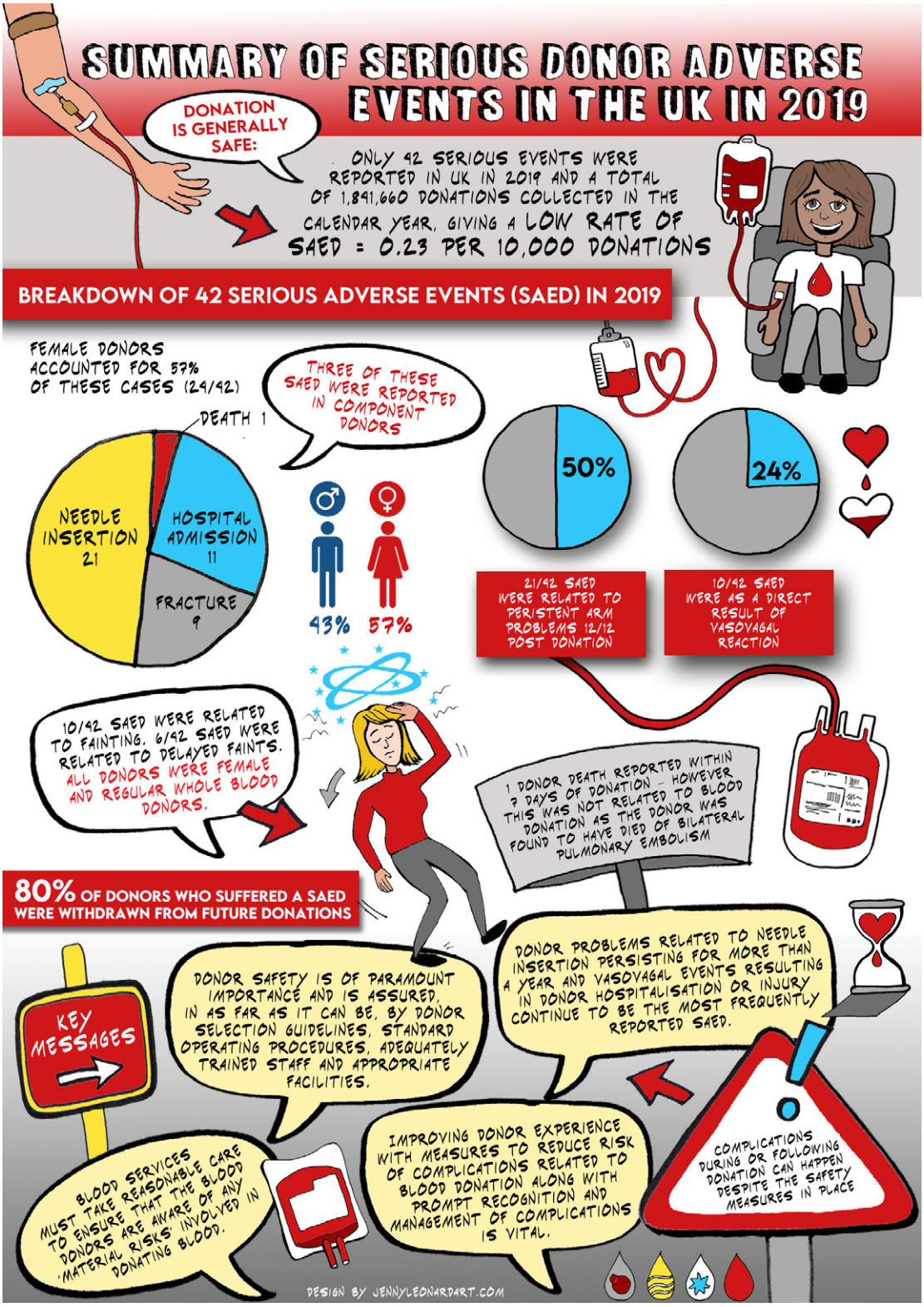

Figure 6.3: Summary of serious donor adverse events in the UK in 2019