Donor Haemovigilance

5

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Key SHOT messages

- Serious adverse events of donation (SAED) are rare but do occur and may not always be preventable. These adverse events can be immediate or delayed and need to be recognised and managed promptly
- Vasovagal events resulting in donor hospitalisation or injury as well as nerve injuries post venepucture continue to be the most frequently reported SAED
- Donor education, vigorous donor selection processes, good clinical governance, effective staff training and competency assessments, clinical audits, robust data capture and analysis of donor adverse events with regular review of trends and management of adverse events and corrective actions taken along with benchmarking will all help in promoting donor safety
- Further research into interventions designed to prevent or reduce donor adverse events especially vasovagal events in blood donors is needed to enhance donor safety and ensure sustainability of blood supply

Background

Voluntary non-remunerated donors, donating regularly, are vital for the provision of safe and sufficient blood for transfusion. While blood donation is generally very safe, donor complications sometimes occur either during or after blood donation. Donor haemovigilance refers to the systematic monitoring of all adverse reactions, complications and incidents related to the care of the blood donor, with a view to improving quality and safety for all blood donors. The current European Blood Directives, issued and enforced between 2003 and 2005 (2002/98/EC and 2005/61/EC), provide the regulatory base of haemovigilance requirements for traceability and notification of serious adverse reactions and events (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.

Data

The following table summarises the whole blood and apheresis donations collected in the 4 UK Blood Services last year with a total of 2,004,650 donations (whole blood and components) collected.

Table 5.1: Donation data from the UK Blood Services 2016

Donations made in 2016		NHSBT	SNBTS	NIBTS	WBS
Whole blood	Donations from male donors	760,085	77,162	26,441	43,798
	Donations from female donors	844,252	85,877	22,353	41,523
	Donations from new donors	210,346	15,260	5,568	9,268
	Donations from repeat donors	1,393,991	147,779	43,226	76,053
Apheresis	Donations from male donors	77,166	9,657	4,594	2,662
	Donations from female donors	6,944	969	718	449
	Donations from new donors	9,753	0	18	120
	Donations from repeat donors	74,357	10,626	5,294	2,991
Total number of donations in 2016		**1,688,447**	**173,665**	**54,106**	**88,432**

Donor adverse events are recorded in the UK according to the revised 2014 'Standards for Surveillance of Complications Related to Blood Donation' drafted by the working group on donor vigilance of the International Society of Blood Transfusion (ISBT) working party on haemovigilance in collaboration with the International Haemovigilance Network (IHN) and the American Association of Blood Banks (AABB) Donor Haemovigilance Working Group (Goldman et al. 2016, ISBT 2014). These have helped harmonise reporting of donor adverse events in all the Blood Services. Serious adverse events of donation (SAED) are those which either result in donor hospitalisation, interventions or significant disability/incapacity persisting for >1-year post donation or rarely death. These are reported to the Medicines and Healthcare Products Regulatory Agency (MHRA) and investigated in a timely manner. The donor SAED are reportable if definitely, probably or possibly linked to donation.

Table 5.2 provides information related to the total number of donations, number of whole blood donations, component donations and total number of SAED reported by each of the UK Blood Services for the calendar year 2016.

Table 5.2: Summary of SAED from the 4 UK Blood Services for the calendar year 2016 (January to December)

	NHSBT	SNBTS	NIBTS	WBS
Whole blood donations	1,604,337	163,039	48,794	85,321
Apheresis/component donations	84,110	10,626	5,312	3,111
Total donations	1,688,447	173,665	54,106	88,432
Total number of donor SAED in the calendar year 2016	40	2	0	0
Rate of SAED per 10,000 donations in the UK	**This equates to a rate of 0.21 SAED per 10,000 donations or 1 SAED per 47,730 donations in the UK**			

Overall 42 SAED were reported from the 4 UK Blood Services for 2016. The two most common events were donors who required hospital admission and who experienced injury post donation resulting in fracture or broken teeth (n=13 in each category at a rate of 0.06 per 10,000 donations). Ten donors reported problems related to needle insertion persisting for more than a year (rate of 0.05 per 10,000 donations) with the majority being reported in male donors (n=8/10, 80.0%).

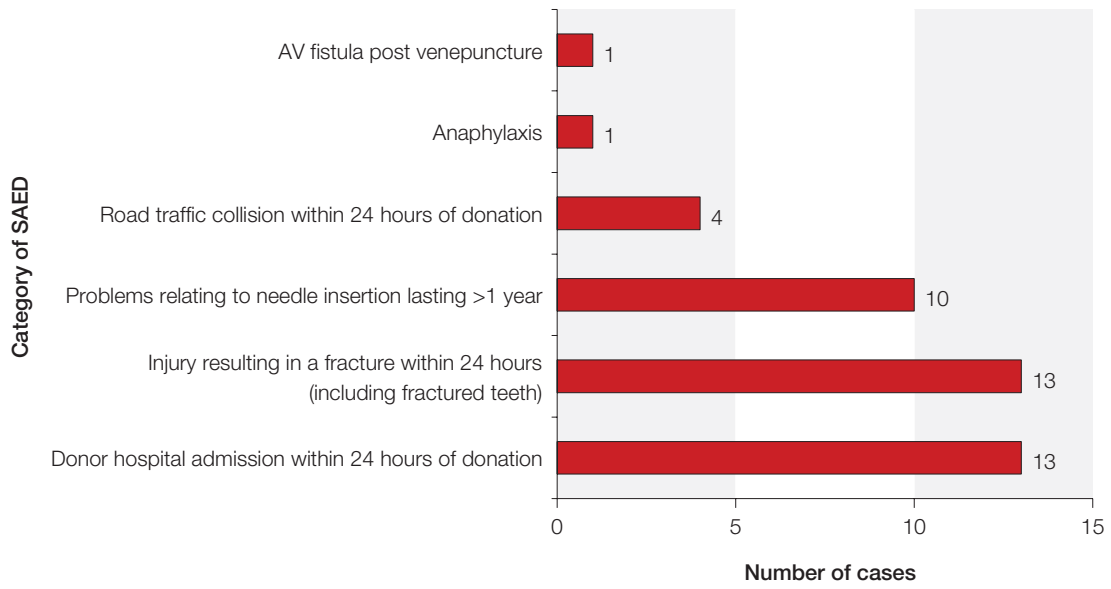

Figure 5.1 Reporting categories for the SAED reported from the 4 UK Blood Services in 2016 n=42

AV=arteriovenous

Note: One donor who sustained a fracture within 24 hours of donation also needed hospital admission and is reflected in the number of donors who sustained injury within 24 hours of donation

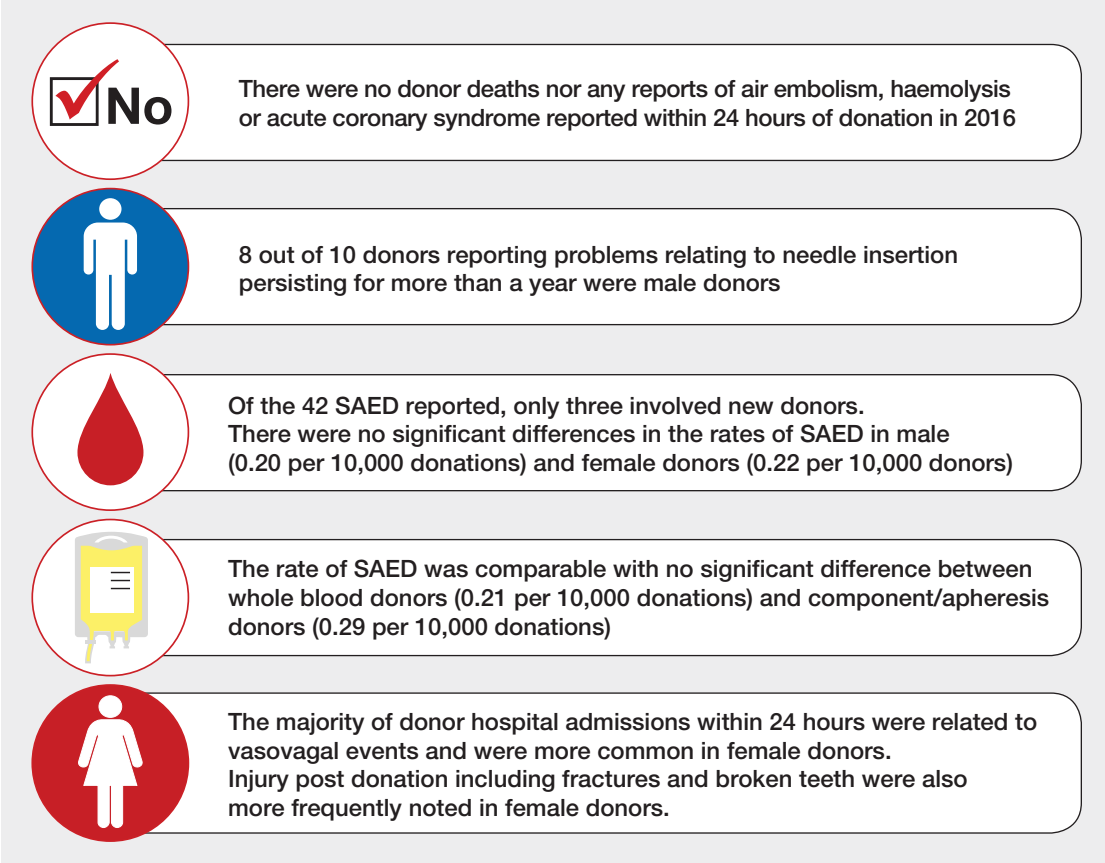

Figure 5.2: Summary with further details regarding the SAED reported in UK

There were no donation-related deaths. There were no reports of haemolysis or air embolism related to component donation nor any acute coronary syndrome within 24 hours of donation. It is also useful to note that of the 42 SAED reported, only three involved new donors. The majority, 39/42 (92.9%), were reported in whole blood donors while only 3 SAED occurred in component donors; however there was no significant difference in the rate of SAED in whole blood donors (0.21 per 10,000 donations) versus component donors (0.29 per 10,000 donations). There were no significant differences in the rate of SAED in male (0.20 per 10,000 donations) and female donors (0.22 per 10,000 donations).

The majority (n=10/13, 76.9%) of donor hospital admissions within 24 hours were related to vasovagal events and were more common in female donors (n=8). Of these, 7/10 (70.0%) donors suffered a delayed vasovagal event which is a well-recognised complication post donation. Injury post donation including fractures and broken teeth were also more frequently noted in female donors (n=9/13, 69.2%).

Case 5.1: Rare complication of AV fistula post venepuncture in a blood donor

A regular male donor fainted 4 minutes after venepuncture. The donation was stopped and the donor recovered uneventfully. He was contacted for follow up on the next day, when he reported that venepuncture had been more painful than usual and queried whether it had been an arterial puncture. Review of his session record showed that blood flow had not been faster than usual and he described no bruising, pain or swelling in his arm. Arterial puncture was therefore considered unlikely.

The donor called back the next day to report a 'buzzing' sensation in his arm, which he could also feel if he palpated the venepuncture site. He had no other symptoms, but described his arm as 'feeling funny'. He was advised to attend the emergency department (ED) where an AV fistula was diagnosed. The donor subsequently required surgery to close the fistula. The vascular surgeon who conducted the procedure reported that the brachial artery lay close behind the brachial vein and that during venepuncture the needle had passed through the back of the vein and into the artery. Retraction of the needle during venepuncture may have pulled the damaged arterial wall into the vein, allowing the fistula to develop. The arterial puncture was not recognised because the normal effects (fast flow, bruising post-donation) did not occur. The donor made an uneventful recovery from surgery. He has been advised not to donate in future.

The development of an AV fistula is an extremely rare complication of arterial puncture during blood donation, with only a handful of cases reported in the literature (Newman 2013). An AV fistula usually presents as an elongated pulsatile mass in the arm, associated with a palpable thrill and bruit. Phlebotomy-related AV fistulae are initially small but will generally increase in size over time and may only become symptomatic some time after venepuncture. Surgical repair is required, but is usually uncomplicated, with no long-term consequences.

In documented cases, donors have reported symptoms to the Blood Service days or weeks after venepuncture. Donors should be encouraged to make early contact with the Blood Service if they experience any arm complications, even if symptoms develop some time after the donation. Careful attention should also be given if a donor reports unusual or atypical symptoms, whether or not the donor has more obvious complications such as pain, bruising or paraesthesia.

Case 5.2: Donor with delayed faint requiring hospital admission within 24 hours post donation

A regular female whole blood donor had an uneventful donation and sustained a delayed faint 6-8 hours post donation and banged her head. She was admitted via the ED at the local hospital where blood tests, X-rays and a brain scan were all normal. The donor had a swollen jaw but recovered slowly. The donor had taken her pre- and post-donation drinks and had followed the advice regarding applied muscle tension (AMT) exercises. No bruise was recorded and the donor felt well before leaving the session venue. A root cause analysis confirmed that all standard NHSBT procedures were followed and nothing could be identified that needed to be addressed to be able to prevent this SAED.

Adverse events related to blood donation can occur during or after donation. Delayed complications are defined as complications which occur after the donor has left the donation venue. Delayed vasovagal reactions are a well-recognised but 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. Inadequate fluid intake post donation, prolonged standing, and high environmental

temperature are recognised factors increasing the risk of a delayed vasovagal reaction. Delayed reactions occur more frequently in female than male donors. Unlike immediate vasovagal reactions, the risk of a delayed reaction is not significantly higher in new 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, advice on maintaining post-donation fluid intake, and avoidance of known precipitating factors such as overheating and prolonged standing.

Case 5.3: Venepuncture-related persistent arm pain more than one year post donation

A regular male whole blood donor who had donated multiple times in the past without any adverse event, reported persistent problems with his donation arm >1 year post donation. He remembered the donation being uncomfortable but had no pain on needle insertion or removal. The donation was stopped midway as a swelling was noted at the venepuncture site. The swelling and local bruising resolved fully over the next couple of weeks. However, the donor was left with a constant 'niggle' at the venepuncture site with pins and needles sensation and intermittent numbness along his inner forearm. His range of movement was fully preserved. He was investigated locally and informed that he had median nerve damage and received regular physiotherapy with some improvement in symptoms. The haematoma following needle insertion contributed to the initial nerve irritation and had been managed promptly and appropriately at the donation session. Traumatic venepunctures are known to be associated with nerve injury.

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. It is recognised that arm symptoms from needle-related complications may take several weeks or longer to resolve, and these complications are usually over-represented among reported cases where there is long-term morbidity following a blood donation. Despite adequate staff training and competency-assessment, nerve injuries may not be completely avoidable because nerve anatomy is variable and nerves cannot be palpated. Most nerve injuries resolve, but in a few cases, it may take months, and in rare instances there may be permanent injury. Nerve injuries are the most common cause of disability among donors. Nerve injury is usually immediately apparent with donors reporting a sharp, burning or electrical pain radiating to the lower arm or into the hand/fingers and in some cases also proximally. Donors may also experience paraesthesias. This must be recognised by staff who insert needles and when donors report severe pain, the needle should be removed immediately.

References

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EU Directives: http://ec.europa.eu/health/blood_tissues_organs/key_documents/index_en.htm#anchor0_more [accessed 10 March 2017] Then click Blood-Legislation and Guidelines to expand list and select each option below:

> 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** [2005] OJ L 256/32
>
> 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 [2003] OJ L33/30

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