5 Donor Haemovigilance

Author: Dr. Shruthi Narayan, Consultant Donor Medicine, NHS Blood and Transplant (NHSBT)

With contributions from:

Phil Carter, Senior Nurse Practitioner, Clinical Support Team; NHS Blood and Transplant (NHSBT)

Dr. Angus Wells, Clinical Director Donors and Manufacturing, and Dr. Jayne Hughes; Scottish National Blood Transfusion Service (SNBTS)

Dr. Mark Bridgham, Locum Consultant Haematologist, Northern Ireland Blood Transfusion Service (NIBTS)

Dr. Janet Birchall, Medical Director, and Joan Jones, Head of Service Development; Welsh Blood Service (WBS)

Key messages

- Whole blood and component donation is generally safe but complications do occur sometimes
- Donors need a clear understanding of what, when and how to report adverse events
- Vasovagal events resulting in donor hospitalisation or injury and nerve injuries post venepuncture continue to be the most commonly reported serious adverse events of donation (SAED)

Background

Blood donations save lives and improve health. It is only through regular voluntary contributions from blood donors that we can ensure a safe and sustainable supply of blood to patients. Blood donation is safe for most donors but a small proportion may suffer an adverse event. Even a relatively minor adverse event can impact the donor experience and retention. In more severe cases, donors may suffer an injury or disability following donation. Donor haemovigilance, the systematic monitoring and surveillance of such adverse events, helps improve donor and overall transfusion safety.

Data

The following table summarises the whole blood and apheresis donations collected in the four UK Blood Transfusion Services last year with a total of 1,913,650 donations (whole blood and component) collected.

Donations from 2017		NHSBT	SNBTS	NIBTS	WBS
Whole blood	Donations from male donors	716,366	71,045	23,699	44,942
	Donations from female donors	819,707	80,997	20,029	44,062
	Donations from new donors	143,148	12,800	4,208	13,362
	Donations from repeat donors	1,392,925	139,242	39,520	75,642
Apheresis	Donations from male donors	68,618	9,349	3,992	2,082
	Donations from female donors	7,101	794	465	402
	Donations from new donors	168	0	112	71
	Donations from repeat donors	75,551	10,143	4,345	2,413
Total number of donations in 2017		**1,611,792**	**162,185**	**48,185**	**91,488**

Table 5.1: Cumulative data from the UK Blood Services 2017

All donor adverse events are recorded according to the revised 2014 'Standards for Surveillance of Complications Related to Blood Donation' (Goldman et al. 2016, ISBT 2014) which have helped harmonise reporting and permit benchmarking of the data in all the blood transfusion services.

SAED are those which either result in donor hospitalisation, interventions, significant disability/incapacity persisting for >1-year post donation or rarely death. SAED are investigated by the accountable Blood Service and reported to the Medicines and Healthcare Products Regulatory Agency (MHRA) in a timely manner. In addition, the donor SAED are classified as definitely, probably or possibly linked to donation. European legislation (European Blood Directives 2002/98/EC and 2005/61/EC) which has been subsequently transposed into UK law through the Blood Safety and Quality Regulations (BSQR) 2005 mandate submission of an annual overview of SAED and adverse events relating to the quality and/or safety of blood or components in donors and recipients.

The following caveats need to be considered in interpreting data in this report:

- All adverse events in this report are reported cases rather than confirmed cases
- We rely on donors reporting the delayed adverse events to Blood Services and these may be underreported if donors do not report and simply withdraw from future donations
- The adverse events definitions used for reporting in the four UK Blood Services has been consistent with current International Society for Blood Transfusion (ISBT) definitions only since 2016 hence data comparison prior to this must be done cautiously
- It is recognised that there is variation in the number/rate of SAED reported from each Blood Service but factors contributing to this have not been explored

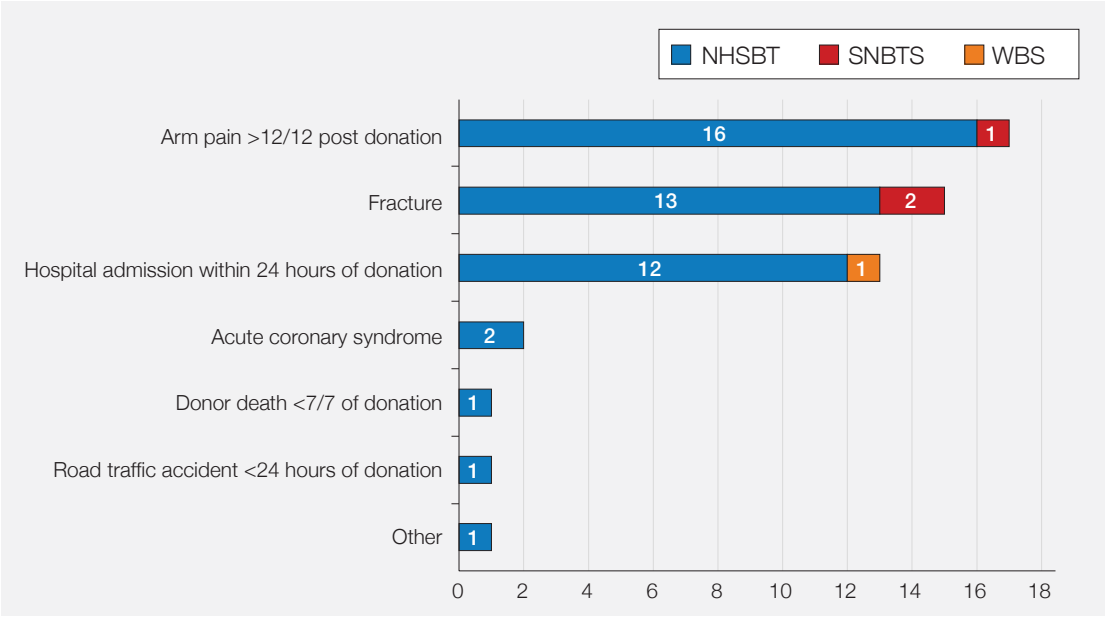
The following table provides information relating to the total number of donations, number of whole blood donations, component donations and total number of SAED reported by each of the UK Blood Transfusion Services for the calendar year 2017 (January-December).

	NHSBT	SNBTS	NIBTS	WBS
Whole blood donations	1,536,073	152,042	43,728	89,004
Apheresis/component donations	75,719	10,143	4,457	2,484
Total donations	1,611,792	162,185	48,185	91,488
Total number of donor SAED in the calendar year 2017	46	3	0	1
Rate of SAED per 10,000 donations in UK	**This equates to a rate of 0.26 SAED per 10,000 donations or 1 SAED per 38,273 donations in UK**			

Table 5.2: Summary of SAED from the four UK Blood Transfusion Services for the calendar year 2017 (Jan 2017–Dec 2017)

In total, there were 50 SAED reported, of which 46 were reported from NHSBT, 3 from SNBTS, 1 from WBS and none from NIBTS. The SAED reported from the four UK Blood Transfusion Services in 2017 fell into the following reporting categories:

Figure 5.1: SAED by category



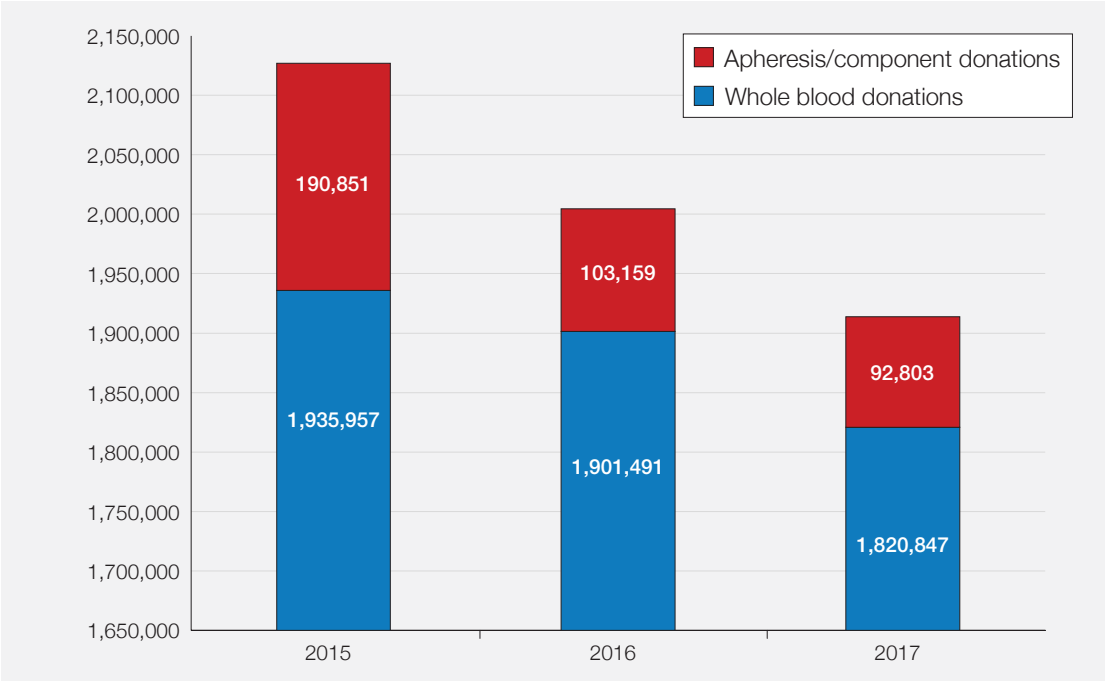
NHSBT=National Health Service Blood & Transplant; SNBTS=Scottish National Blood Transfusion Service; WBS=Welsh Blood Service

Trending data

There has been a steady reduction in the demand for blood in the last few years most likely resulting from effective implementation of Patient Blood Management and improved medical practices. A significant challenge to all the Blood Services is to maintain the right number and blood group mix of active donors to meet this overall decreasing demand coupled with a changing differential demand at the blood group level and to do so efficiently while retaining the goodwill of donors and maintaining high donor satisfaction.

Figure 5.2 demonstrates the steady fall in the number of donations collected in the UK.

Figure 5.2: Trend in whole blood and apheresis donations in the UK from 2015-2017



More SAED are being recorded which may reflect improved awareness through donor and staff education and therefore increased and more consistent reporting across the UK Blood Services. Donors are encouraged to get in touch if they experience problems post donation. Despite this the rate of SAED per 10,000 donations remains low.

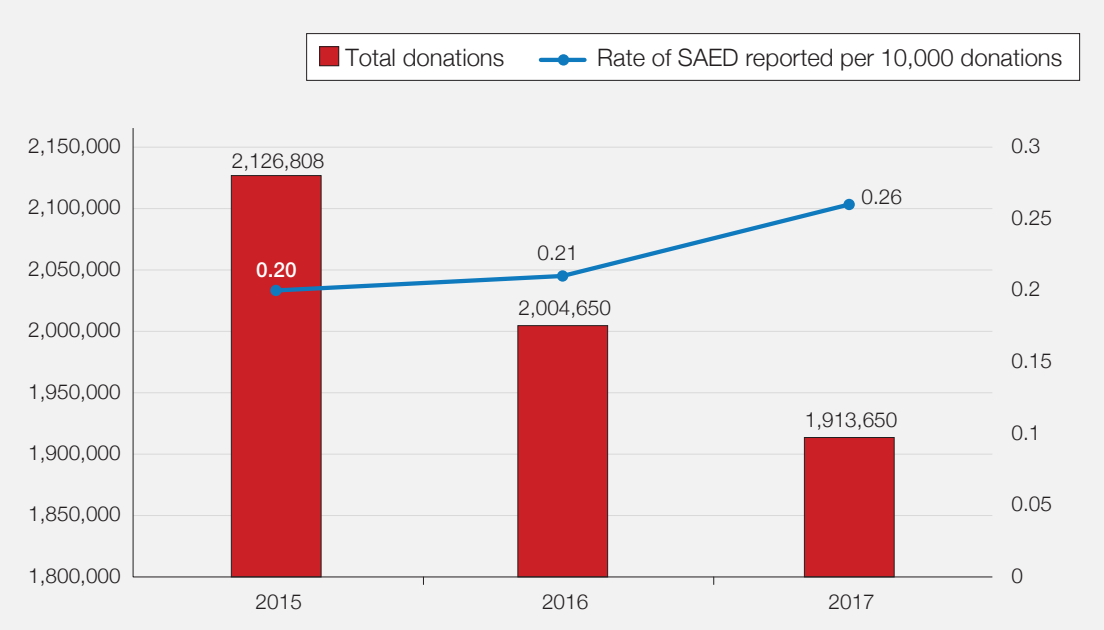


Figure 5.3: Trends in donations and reported rate of SAED in UK Blood Services

SAED=serious adverse event of donation

Case 5.1: Donor with delayed faint involved in road traffic collision within 24 hours of donation

A young female whole blood donor had an uneventful first donation. Following donation, the donor had a delayed faint whilst driving her car out of the venue car park. The donor was transferred to the local emergency department (ED) by ambulance. No injuries were sustained by the donor. The donor was found to be hypotensive and discharged from the ED following treatment with intravenous (IV) fluids. The donor has been withdrawn from blood donation. A root cause analysis confirmed that all standard procedures were followed and nothing could be identified that needed to be addressed to be able to prevent this SAED.

Adverse events relating 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 donors than in male donors. Off-site reactions, particularly in female donors, have been reported to be more likely to be associated with a fall, with head trauma, with other injury, and with the use of outside medical care (Kamel 2010).

Blood donation is safe, but a small proportion of donors have delayed and/or off-site reactions that have the potential to lead to serious injury. 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. Women are more likely than men to report delayed reactions. Delayed and off-site reactions lead to potentially preventable morbidity. Understanding the physiologic basis of such delayed reactions may lead to the development of appropriate interventions to reduce their likelihood.

Case 5.2: Venepuncture related persistent arm pain >1-year post donation

A female regular whole blood donor who had donated 11 times previously reported problems with her donation arm which had persisted for longer than 12 months post donation. The donor reported the venepuncture being painful and the donation being slow. The donation was discontinued appropriately before the full volume could be collected. The donor had local bruising for several days after donation and intermittent pain to the inner aspect of her elbow radiating down her wrist and up her upper arm. She also reported weakness in her arm when performing tasks. The donor is under the care of her general practitioner (GP) and may be referred to a specialist. The donor has been withdrawn from blood donation.

Peripheral nerve injuries have been described after venepuncture (Newman 2013). Nerves in the antecubital fossa classically lie on a plane just beneath, and in close proximity to, the veins, making them susceptible to injury during phlebotomy; also, it has been shown that there is a large range of anatomic variation, suggesting that even a non-traumatic, satisfactory venepuncture can directly damage these nerves. 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. Nerve injuries may not be completely avoidable because the nerve anatomy is variable and the nerves cannot be palpated. Most nerve injuries resolve, but in a small number of 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. Good phlebotomy technique can minimise the incidence of painful arms. 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 paraesthesiae. This must be recognised by staff who insert needles and in donors reporting severe pain, the needle should be removed immediately.

References

BSQR. The Blood Safety and Quality Regulations ISBN 0110990412; 2005. http://www.legislation.gov.uk/uksi/2005/50/contents/made [accessed 13th March 2018].

EU Directives: http://ec.europa.eu/health/blood_tissues_organs/key_documents/index_en.htm#anchor0_more [accessed 13th March 2018] Then click Blood-Legislation and Guidelines to expand list and select each 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 [2003] OJ L33/30. Available at http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32002L0098&from=EN [accessed 13th March 2018].

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. Available at http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32005L0061&from=EN [accessed on 13th March 2018].

Goldman M, Land K et al. Development of standard definitions for surveillance of complications related to blood donation. *Vox Sang* 2016;**110**:185–188.

ISBT. Standard for Surveillance of Complications Related to Blood Donation, 2014. http://www.isbtweb.org/working-parties/haemovigilance/ (click on definitions then Revised Standard 2014 Surveillance complications blood donation) [accessed 13th March 2018].

Kamel H, Tomasulo P et al. Delayed adverse reactions to blood donation. *Transfusion* 2010;**50**: 556-565.

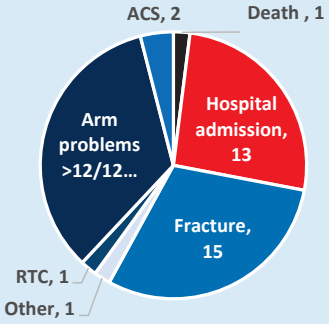
Newman B (2013). Arm Complications After Manual Whole Blood Donation and Their Impact, *Transfus Med Rev* 2013;**27(1):**44 – 49.

Serious Adverse Events following Blood Donation reported to the UK Blood Services in 2017

In 2017 the UK Blood Services collected approximately 1.9 million donations. Fifty serious adverse events of donation (SAED) have been reported last year (1 in 38,273 donations). Serious adverse events are very rare but do occur and can have a significant impact on donor health and donor retention

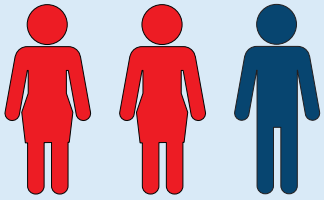
Breakdown of Serious Adverse Events in 2017

SAED Categories



ACS=acute coronary syndrome
RTC=road traffic collision

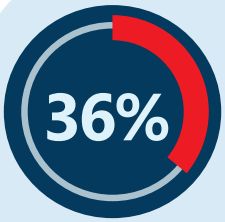
Female donors accounted for nearly 2/3 of SAED reported



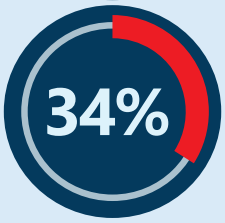
No reports of anaphylaxis, haemolysis or air embolism due to component donation reported in 2017

All 15 fractures were related to vasovagal reactions, 2 immediate and 13 delayed reactions

There was one report of a donor death <7 days of donation and two reports of acute coronary syndrome <24 hours of donation



18/50 SAED were as a direct result of a delayed vasovagal reaction



17/50 SAED were related to persistent arm problems more than one year post donation

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

Key Messages

Donors need a clear understanding of what, when and how to report adverse events

Vasovagal events resulting in donor hospitalisation or injury and nerve injuries post venepuncture continue to be the commonly reported SAED

Whole blood and component donation is safe but complications do sometimes occur