6 Donor Haemovigilance

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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 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) (BSQR 2005).

Abbreviations used in this chapter

AABB	Association for the Advancement of Blood & Biotherapies
ACS	Acute coronary syndrome
BSQR	Blood Safety and Quality Regulations
EBA	European Blood Alliance
ISBT	International Society of Blood Transfusion
IHN	International Haemovigilance Network
MRI	Magnetic resonance imaging
NHS	National Health Service
NHSBT	NHS Blood and Transplant
NIBTS	Northern Ireland Blood Transfusion Service
RTC	Road traffic collision
SAED	Serious adverse event of donation
SNBTS	Scottish National Blood Transfusion Service
STRIDES	STRategies to Improve Donor ExperienceS
UK	United Kingdom
VVR	Vasovagal reaction
WBS	Welsh Blood Service

Key messages

- The rate of SAED for January 2021 to December 2021 was 0.26 per 10,000 donations. The overall incidence of SAED remains low but the overall trend is upwards over the last 7 years
- Blood Services must ensure that all donors are aware of the importance of reporting all adverse events of donation so the donor can be appropriately managed, and the adverse events can be recorded, monitored and appropriate actions taken to improve donor safety

Recommendations

- Blood Services must ensure that blood donors are aware of any 'material risks' involved in donating blood as part of the consent process pre-donation
- Blood Services must ensure that donors are aware of the importance of reporting all adverse events of donation, especially those that occur after the donor has left the donation session
- All UK Blood Services to 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

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

Introduction

The UK Blood Services rely entirely on the goodwill of blood donors to ensure an adequate supply of blood components to the NHS. It is imperative that the Blood Services do everything possible to facilitate the recruitment of new blood donors and the repeated return of regular donors. All donors should be fully informed about the blood donation journey, clearly understand the donation procedure and be aware of adverse events of donation prior to signing their consent forms.

For most donors the donation process is uneventful but as with any clinical procedure there are risks associated with blood donation. These are usually minor adverse events but there is a potential risk of more serious adverse events which may have lifelong consequences for the donor. European legislation (European Blood directives 2002/98/EC AND 2005/61/EC), which has been subsequently transposed into UK law through the BSQR, mandates that donors are made aware of these risks and that good governance processes exist to identify and mitigate risks, thus improving donor and donation safety. This chapter covers serious complications of blood donation reported in the UK in 2021.

UK Blood Services have implemented the 'Standard surveillance of complications relating to blood donations' (Goldman et al. 2016) and individually record and monitor complications relating to blood donations referred to as adverse events of donation. SAED are those which either result in donor hospitalisation, interventions, significant disability/incapacity persisting for >1-year post donation or rarely death.

The incidence of SAED for the UK Blood Services for 2021 was 0.26 per 10,000 donations. This is low; however, an upward trend is noted over the last 7 years which could reflect better reporting and recording of these events across all the four UK Blood Services.

Serious adverse events of donation

The UK Blood Services have ten SAED reporting categories. These are listed in Table 6.2.

Assigning severity rating and imputability scoring (the strength of the relationship 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 separate levels of severity or 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, 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, it is clear that the reported complication is unrelated, or very unlikely to be related, to the donation event itself. For example, a donor developing a complication relating to gall stones requiring admission within 24 hours of donation. Hence the rate of SAED in the UK is calculated using all reported cases and by excluding those that are clearly not related to donation (Table 6.3).

Data

A total of 1,822,689 whole blood and component donations were collected by the four UK Blood Services in 2021. This is summarised in the Table 6.1 below:

Table 6.1: Cumulative donation data from the four UK Blood Services in 2021

Donations from 2021		NHSBT	SNBTS	NIBTS	WBS
Whole blood	Donations from male donors	711,925	64,392	20,653	37,981
	Donations from female donors	711,655	78,783	21,072	43,693
	Donations from new donors	131,938	9,161	2,792	6,470
	Donations from repeat donors	1,291,642	134,014	38,933	75,204
Apheresis	Donations from male donors	109,181	7,097	3,372	2,579
	Donations from female donors	9,067	402	407	430
	Donations from new donors	21,680	0	0	141
	Donations from repeat donors	96,568	7,499	3,779	2,868
Total number of donations in 2021		**1,541,828**	**150,674**	**45,504**	**84,683**

Total donations in the UK: 1,822,689

Table 6.2 summarises the number of SAED by category for all four UK Blood Services combined for 2021.

Table 6.2: SAED by category in 2021 (all SAED included here irrespective of imputability)

SAED category		Number of reported SAED
01.	Death within 7 days of donation	0
02.	Hospital admission within 24 hours of donation	9
03.	Injury resulting in a fracture within 24 hours of donation (including fractured teeth)	10
04.	RTC within 24 hours of donation	5
05a.	Problems relating to needle insertion persisting for more than one year (this mainly includes suspected or confirmed nerve and tendon injuries)	25
05b.	Problems relating to needle insertion requiring hospitalisation/intervention (this mainly includes vascular complications)	0
06.	ACS diagnosed within 24 hours of donation	1
07.	Anaphylaxis	0
08.	Haemolysis	0
09.	Air embolism	1
10.	Other event	0
Total reported SAED in 2021		**51**

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 during 2021. This equates to 0.28 SAED per 10,000 donations or 1 SAED per 35,739 donations when we include all SAED reported irrespective of imputability. Table 6.3 gives a summary of the total number of SAED excluding imputability scores of 0a and 0b for 2021. This equates to 0.26 per 10,000 donations or 1 SAED per 38,781 donations.

	NHSBT	SNBTS	NIBTS	WBS
Whole blood donations	1,423,580	143,175	41,725	81,674
Apheresis/component donations	118,248	7,499	3,779	3,009
Total donations	**1,541,828**	**150,674**	**45,504**	**84,683**
Total number of SAED reported in the calendar year 2021	43	5	0	3
Rate of total SAED per 10,000 donations (all submitted reports irrespective of imputability)		0.28		
Total number of SAED excluding those scored with an imputability of 'unlikely' or 'not related to blood donation'	40	4	0	3
Rate of SAED per 10,000 donations excluding those with imputability of 'unlikely' or 'not related to donation'		**0.26**		

Table 6.3: Summary of total donations for the four UK Blood Services and total numbers of SAED for 2021

Comparison of trends with previous years

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

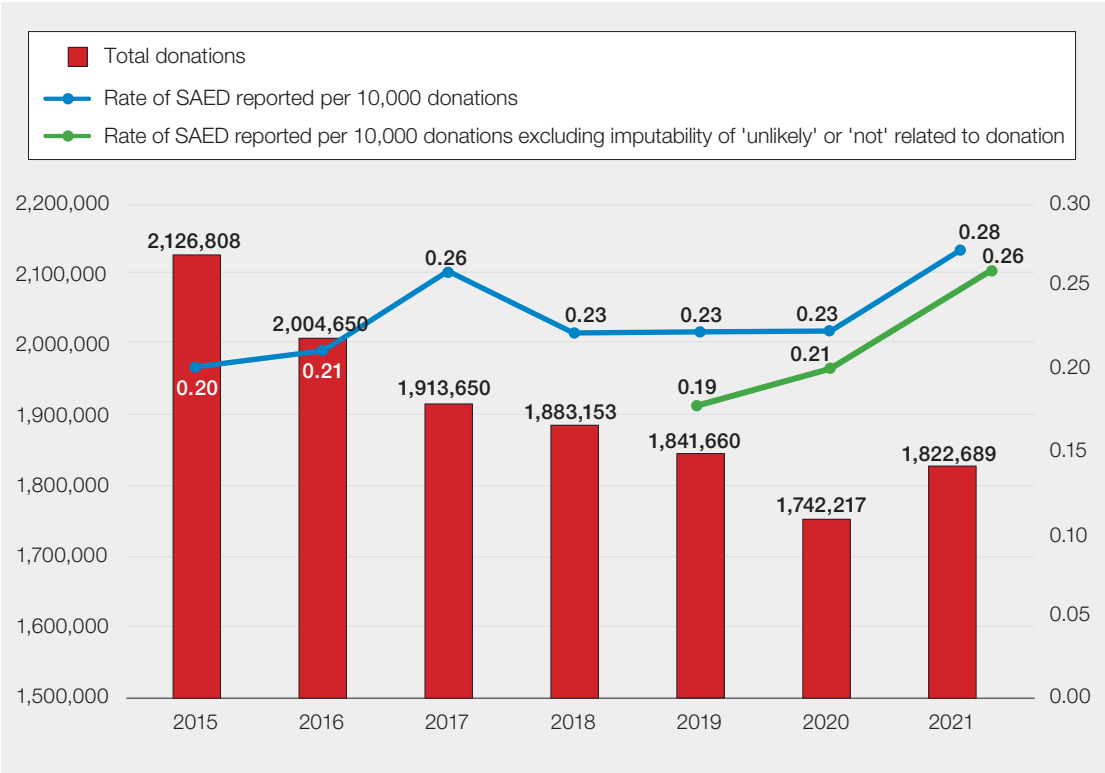
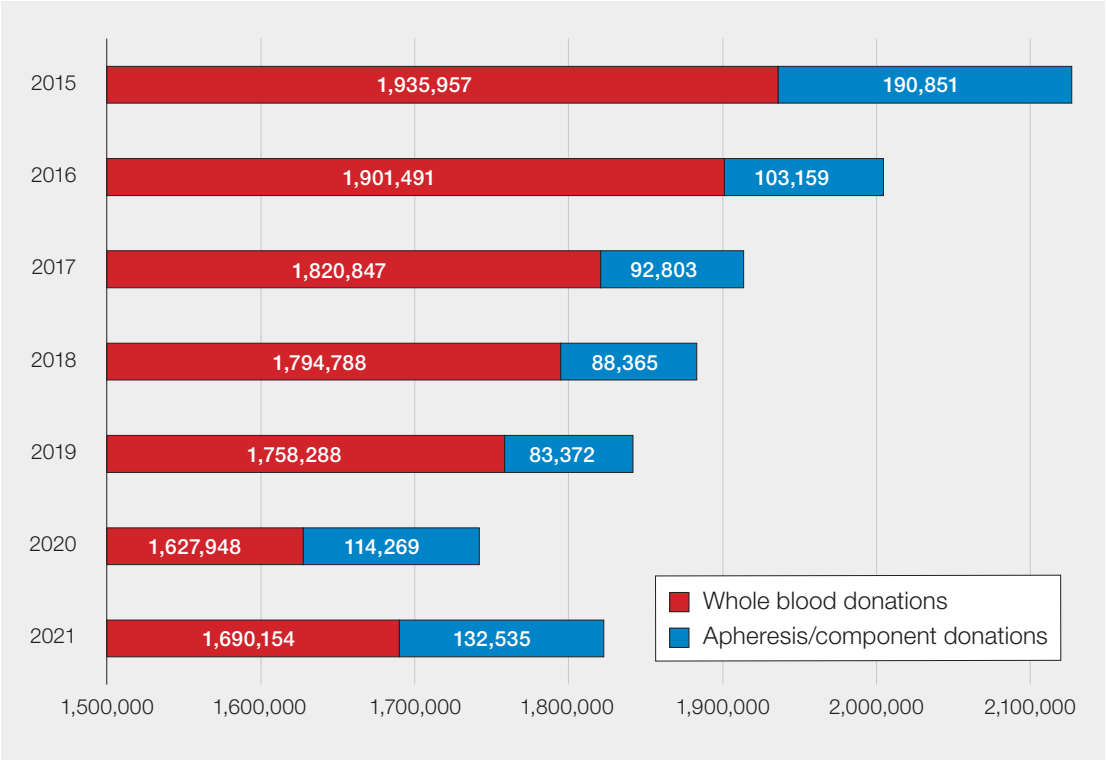


Figure 6.1: Rate of SAED reported per 10,000 donations in the UK from 2015-2021

Since 2015 there is 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 2021 (these are included in 2021's figures), and improved recording by UK Blood Services are key factors. Other contributory factors for the increasing trend in SAED reported include staff turnover, training challenges, and suboptimal measures implemented to reduce these severe events.

Figure 6.2: Trends in the number of donations collected across the UK 2015-2021



These numbers include COVID-19 convalescent plasma donations

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 (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. This tool will more accurately reflect the impact an adverse event has on a donor as it includes 'impact on activities of daily living' in the assessment. This may well lead to an increase in the number of SAED recorded in the UK.

Donor communications

It is essential that UK Blood Services collect data on all significant adverse events (immediate and delayed) related to donation. To achieve this, blood collection staff must be trained to log all donation-related adverse events in their organisations quality system.

Donors need to be aware of the importance of reporting adverse events that occur once they have left the donor centre (delayed events), so they can be given appropriate advice, signposted for appropriate management/follow up and the organisation can include this data in its quality statistics. Blood Services must ensure that appropriate follow up is given to all donors reporting an adverse event regardless of the mode of reporting: on donation clinic, via e-mail, in feedback/complaints and via the telephone contact centre. Py et al. (2016) found that the delayed adverse events are under-reported in standard donor haemovigilance systems and recommended that delayed reactions are included in all donor haemovigilance data.

It is not uncommon for a donor to report a significant delayed adverse event at their next attendance to donate, hence many months may have passed between the delayed adverse event and the Blood Service being made aware of it. Donors are also now reporting SAED which may have occurred in previous years. These events will be recorded in the year they are reported rather than in the year the

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

venepuncture occurred. Thus, both the donor and the Blood Service are at a disadvantage as this causes a delay in the donor seeking appropriate medical assessment which in turn may increase the likelihood of a donor developing long term complications impacting donor well-being and future donations.

Blood Services consent all donors prior to taking a donation by providing an information leaflet for donors which details the incidences of the variety of adverse events and requests that donors report any adverse events of donation and post donation illness information to the Blood Service. Donors are reminded of this request on booking a donation appointment, completion of a donation and Blood Services have this information on their websites. On occasion, however, some donors do not report delayed adverse events to the Blood Services promptly. Blood Services need to optimise their donor communications to try and reduce the numbers of adverse events that are reported long after the event itself. This helps to improve both donor health and donor retention.

Example of the information given to donors on the post donation thank-you card:

Thank you for giving blood today – the following notes are for your information.

- Have a drink and rest for at least 10 minutes
- For at least 2 hours, leave the dressing on your arm and do not smoke
- Today, drink plenty, avoid heavy lifting, unaccustomed exercise, using a sauna or steam room and alcohol

- If bleeding occurs, raise the arm and apply firm pressure on the site for at least 5 minutes
- If you feel faint or dizzy, lie down or sit with your head between your knees
- If you feel unwell, avoid hazardous activities
- If you become ill in the 2 weeks following your donation, please phone Welsh Blood Service on 0800 252266, 8:00am to 8:00pm Monday – Friday and 9:00am – 1:00pm on Saturdays
- At other times phone 01443 622000

Newman et al. (2003) obtained adverse reaction and donor arm injury information from 1000 randomly selected whole blood donors approximately 3 weeks after a whole blood donation. They found that adverse events and complaints after donation may be more common than previously thought and stated that a post-donation interview is a good tool for defining the blood donor's experience which can be used to evaluate and improve blood donor safety and comfort.

Tiwari et al. (2016) recognised that while blood donors experience both immediate and delayed adverse reactions, there is limited data on the incidence of delayed adverse reactions. They contacted donors 3 weeks after donation and concluded that delayed adverse reactions are more common than immediate adverse reactions and are of a different profile. They found that the post-donation interview provided an insight into donor experiences and was a valuable tool in donor haemovigilance.

Kaur et al. (2022) conducted a study to determine the incidence of delayed adverse reactions and explore how various epidemiological factors affect delayed adverse donor reactions. They concluded that donors do experience delayed adverse reactions which are often not reported to Blood Centres as they are mild. They note however that it is important that these delayed reactions are reported into the donor haemovigilance system so that preventative strategies can be formulated.

In practice conducting a post-donation interview with every blood donor in the UK is not feasible. It is therefore very important that Blood Services continue to inform and educate donors, making them aware that reporting all adverse events, immediate and delayed, is vital to ensure that appropriate advice and help can be offered in a timely manner and more data can be obtained on delayed adverse events to help formulate strategies to try and prevent them from occurring.

Update about STRategies to Improve Donor ExperienceS (STRIDES) study

Authors: Dr Amy McMahon, Scientific Study Coordinator, Cardiovascular Epidemiology Unit, Department of Public Health and Primary Care, University of Cambridge and Susan Mehenny NHSBT Lead – STRIDES Study & Our Future Health

The STRIDES study aims to improve donor experiences by finding an alternative intervention, or combination of interventions, to reduce VVR in whole blood donors. The STRIDES study is comparing four different interventions with current NHSBT practice to reduce VVR in blood donors including:

- Isotonic hydration before donation: 500mL isotonic drink vs. current 500mL plain water
- Time on donation chair after donation: 3-minutes before standing vs. current 2-minutes
- Modified applied muscle tension: new vs. current practice
- Psychosocial intervention: preparatory materials vs. current practice of nothing

To date, 1,241,439 donors are part of the STRIDES trial. In addition, 72,207 of those participants have provided additional blood samples for genetic and biochemical analyses and more in-depth questionnaire data relating to donor faints. The results of this study will determine if a change in current policy and strategies for faint prevention is required to safeguard all blood donors. The study is expected to be completed in autumn 2022 and some results expected to be released in 2023. Further information and updates can be found at the link provided in the 'Recommended resources' section.

Illustrative cases

Case 6.1: Delayed faint not declared until the next attendance to donate

A regular female donor in her 60s, who had given 46 donations previously, attended to donate again 8 months after her previous donation. At this attendance she declared that after her previous donation she was walking home and felt unwell, she became lightheaded which resulted in her falling and fracturing her elbow. She had not informed the Blood Service of this adverse event prior to her re-attendance as she was not sure if there was a causal link between her donation and the faint. She also did not wish to bother the Blood Service! This donor has since been withdrawn from further donation.

Discussion: Unlike immediate VVR or faint, the risk of a delayed faint occurring after the donor has left the session is not significantly higher in first time, inexperienced and younger donors compared to experienced, regular, and older donors. It is possible that experienced donors become complacent about following advice to increase their fluid intake following donation, thereby increasing their risk of a delayed reaction.

This case and the other SAED included in this chapter highlight the importance of ensuring blood donors are aware that they must feedback any post-donation information regarding adverse events or infections so that appropriate actions can be taken, and the donor advised appropriately. Post-donation information must be provided to all donors. This should include the risk of delayed reactions and advice on maintaining post-donation fluid intake, and avoidance of known precipitating factors such as overheating and prolonged standing. The mechanism for delayed faints remains poorly understood. Understanding the physiological basis of such reactions may lead to the development of appropriate interventions to reduce their likelihood. Prevention is important as blood donors who experience VVR are less likely to give blood again (Eder et al. 2012). Reducing adverse events improves donor retention. Therefore, it is important to understand and prevent adverse events related to blood donation and to improve blood donation safety.

Case 6.2: Tendon injury following venepuncture for blood donation

A female donor in her 50s, with one previous donation donated from the right (dominant) arm in September 2020. The donor described a sharp, severe pain at the insertion of the needle.

Although initially the pain seemed to be improving, it subsequently worsened, and the donor noted reduced function. The donor was referred and seen at a hospital outpatient clinic. An MRI scan demonstrated tendon injury. The specialist advised that the injury was secondary to venepuncture, to continue mobilising the arm and that recovery could take up to 2 years. The donor continues to have pain on flexion and reduced function/power in their right arm.

Discussion: As symptoms have persisted for more than a year, this event qualifies as a SAED (Problems relating to needle insertion lasting greater than 1 year).

Arm pain is a common event, occurring in around 10% of donors interviewed in one post-donation survey (Newman et al. 2003). This can be caused by nerve injury or non-neurological causes including haematoma formation, soft tissue injury or tendon injury. The donor's symptoms can help in the differential diagnosis. Tendon injury due to venepuncture can cause biceps tendonitis which presents with pain at the antecubital fossa exacerbated by supination of the forearm and flexion at the elbow. Reduced function with weakness affecting supination and flexion, as well as localised tenderness over the biceps tendon can occur (ASSH 2018). In contrast, pain due to nerve injury may result in sensory symptoms such as tingling, numbness or 'pins and needles' as well as motor symptoms such as weakness. Typically, the pain is described as sharp, burning, shooting or electrical, often radiating into the lower arm, hands, and fingers and occasionally into the upper arm.

Case 6.3: Suspected nerve irritation with persistent symptoms 12 months post donation

A first-time female whole blood donor in her 30s reported persistent ache and tingling in her donation arm and wrist 12 months post donation, following painful needle insertion.

During needle insertion into her left arm, she experienced sharp pain sensation from her forearm to her wrist. The donor did not mention the sharp pain during venepuncture to session staff as 'arm pain resolved during and immediately after donation'. She therefore made a full donation.

A few hours after leaving the session, she started to experience numbness in her left wrist and an 'electric shock sensation' from her forearm to her wrist on moving her arm. The donor reported this to Blood Service 2 days post donation and was appropriately advised on measures to take to alleviate symptoms by the clinical team and was also advised to call back in 3 weeks if no improvement. No further communications were received from the donor, and it was only an outbound call from the Blood Service a year later to discuss booking her next appointment to donate blood that the donor disclosed that she was still symptomatic and experiencing a dull ache in her left wrist which was also 'tender and tingly if touched'.

Due to persistent symptoms for at least 12 months, donor was advised by the clinical support team to seek medical review for further assessment and was withdrawn from future donations.

Discussion: Symptoms of nerve irritation may occur during venepuncture and can be due to direct injury to a nerve which is 'grazed' during venepuncture or compression on a nerve from surrounding haematoma or soft tissue swelling due to bruising (Goldman et al. 2016).

Up to 65% of donors report immediately apparent symptoms described as a sharp, lancinating burning or electrical pain that radiates to the lower arm or into the hand and fingers and in some cases also proximally (Newman et al. 2013). Symptoms of nerve irritation such as numbness, tingling, pins and needles, may develop and worsen over time or with certain positions and with certain arm motions.

It is recognised that in most cases, symptoms reported due to nerve irritation will usually resolve over a period of time. Resolution time is variable and could be days to weeks and months or even longer in rare cases. In rare cases, there may be residual long term or permanent symptoms in the affected donation arm. Nerve injuries are the most common cause of disability among donors. 70, 90, and 96% of venepuncture-related nerve injuries resolve within 1, 2 and 6 months, respectively. However, chronic disabling deficits have been reported at an incidence of 1 in 1.5 million phlebotomies. In 87% of patients who required ongoing care by a pain management specialist, some degree of permanent nerve damage continues to be experienced (Oven and Johnson 2017). Nerve injuries may not be completely avoidable because nerve anatomy is variable, and nerves cannot be palpated.

Minimising needle movement while in situ is probably also wise, however, taking the high anatomic variability into account, the risk of inadvertent nerve damage is still a possibility (Ramos et al. 2014).

Most donors will express some unusual discomfort and or symptoms such as severe sharp pain, numbness, paraesthesia or pins and needles because of nerve injury during venepuncture. This must be recognised and managed accordingly by staff when donors report such unusual symptoms during venepuncture or during donation and the donation discontinued with provision of appropriate post donation arm care advice to donor.

On this occasion, the donor did not report the symptoms she experienced during venepuncture and therefore went on to make a full donation. This could be because the donor was donating for the first time and self-deferred from donations.

It is therefore important for session staff to encourage all donors, especially first-time donors to report any unusual symptom during venepuncture and donation. Observation of donors for non-verbal clues of pain such as restlessness, facial expressions, and bracing is also important.

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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Eder AF, Notari EP, Dodd RY. Do reactions after whole blood donation predict syncope on return donation? *Transfusion* 2012;**52(12)**:2570-6. DOI: 10.1111/j.1537-2995.2012.03666.x

EU directives: https://ec.europa.eu/health/blood_tissues_organs/blood_en [accessed 04 May 2022] 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 04 May 2022].
>
> 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 [accessed 04 May 2022].

Goldman M, Land K, Robillard P, et al. Development of standard definitions for surveillance of complications related to blood donation. *Vox Sang*. 2016;**110(2)**:185-8. doi: 10.1111/vox.12323.

Kaur S, Mittal K, Kaur R, et al. Reporting of delayed adverse donor reactions in whole blood donors: Just the tip of an iceberg! *Transfus Clin Biol*. 2022;29(2):141-146. doi: 10.1016/j.tracli.2021.11.003.

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Newman B. Arm complications after manual whole blood donation and their impact. *Transfus Med Rev* 2013;**27(1)**:44-9. doi: 10.1016/j.tmrv.2012.05.002.

Oven SD and Johnson JD. Radial Nerve Injury after Venipuncture. *J Hand Microsurg*. 2017;**9(1)**:43-44. doi:10.1055/s-0037-1599220.

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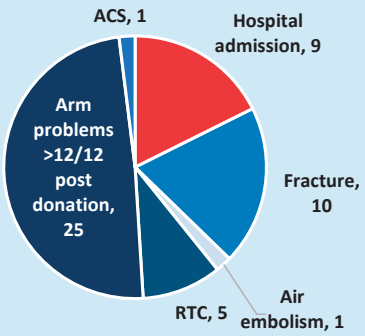
Townsend M, Kamel H, Van Buren N, et al. Development and validation of donor adverse reaction severity grading tool: enhancing objective grade assignment to donor adverse events. *Transfusion*. 2020;**60(6)**:1231-1242. https://doi.org/10.1111/trf.15830.

Serious Adverse Events following Blood Donation reported to the UK Blood Services in 2021

In 2021 the UK Blood Services collected approximately 1.8 million donations (whole blood and apheresis)- this includes plasma collected for fractionation at NHSBT. Fifty one serious adverse events of donation (SAED) have been reported last year (this includes all categories of imputability and equates to 1 in 35,739 donations). 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 2 years.

Breakdown of Serious Adverse Events in 2021

SAED Categories



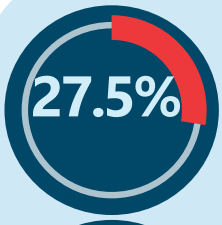
ACS=acute coronary syndrome
RTC=road traffic collision

SAED were seen in both female (25/51, 49%) and male donors (26/51, 51%).

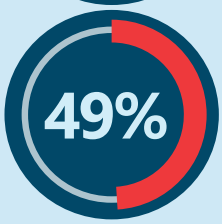
Five SAED were reported in first time donors, all whole blood with 3/5 of these being female donors.

There were no reports of anaphylaxis or haemolysis due to component donation reported in 2021. There was one suspected air embolism. No donor deaths reported relating to donation in 2021

All 10 fractures were related to vasovagal reactions (VVR), 3 immediate and 7 delayed reactions. 6/7 of these delayed VVR were in female donors. Two of these cases were in first time donors (both on session faints),

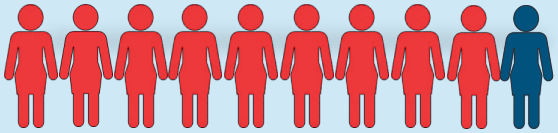


14/51 SAED were as a direct result of a delayed vasovagal reaction. The break down of these cases include 5RTC, 2 hospital admissions and 7 fractures.



25/51 SAED reported were related to persistent arm problems more than one year post donation. Only one was in an apheresis platelet donor while all others were whole blood donors. A suspected tendon injury accounted for one of these cases.

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. Blood Services must ensure that blood donors are aware of any 'material risks' involved in donating blood.

Vasovagal events, both immediate and delayed, 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. The overall incidence of serious adverse events of donation (SAED) remains low. The rate of SAED in UK for 2021 is 0.26 per 10,000 donations taking into account all SAED where blood donation was deemed to have potentially contributed to the donor adverse event.