5 Donor Haemovigilance

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Definitions:

Donor haemovigilance:

The systematic monitoring and surveillance of donor adverse events.

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

- Donor safety is of paramount importance and is assured, in as far as it can be, by donor selection guidelines, standard operating procedures, adequately trained staff and appropriate facilities. Despite these measures, various adverse events and reactions can and do occur during and after blood donation
- The rate of serious adverse events of donation (SAED) in 2018 was 0.23 per 10,000 donations in the United Kingdom (UK) or 1 SAED per 43,794 donations approximately. This rate is similar to previous Annual SHOT Reports. SAED are therefore very rare, making blood donation a generally safe process
- Donor problems related to needle insertion persisting for more than a year and vasovagal events resulting in donor hospitalisation or injury continue to be the most frequently reported SAED
- 70% of the donors who suffered a SAED were withdrawn from the active donor panel
- Blood Services have a duty to take reasonable care to ensure that donors are aware of 'material risks' of blood donation

This chapter presents data from the four UK Blood Services on SAED, with illustrative cases and recommendations for donor care. Numerator and denominator data for each Blood Service is also presented.

Background

Blood donation remains a voluntary, independent and altruistic act that is essential to patient care across several medical and surgical disciplines. Although generally safe, complications do sometimes occur. Keeping adverse consequences as low as possible is a duty of collection facilities with regards to quality of care and is vital to sustain adequate blood supply.

Good donor care not only involves the implementation of measures to minimise the risks to donors and the subsequent management of any adverse reactions, it also requires informing donors of the material risks of blood donation. The Montgomery v Lanarkshire case of March 2015 drew fresh attention to informed consent (Chan et al. 2017). Simply providing the information and getting a signature on the consent section of the health check questionnaire may not be enough to evidence proper consent. Blood Services have a responsibility to share the risks of donation with potential donors so that they are fully aware of what complications may ensue.

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. The actual knowledge of adverse reactions among blood donors is limited to a few publications issued from large surveys in the United States (2008), Denmark (2008), Japan (2009) and Switzerland (2011), which reported incidence rates varying from 0.82% to 3.48% (Gavillet et al. 2013). The collection of these data rely on donors notifying the Blood Service of any adverse reactions. Newman et al. (2013) suggested that minor and delayed events are likely to be under-reported, as an overall complication rate of 36% was found after systematically interviewing blood donors three weeks after collection.

Presyncopal reactions and haematomas represent most events, while severe complications are very rare (5-74 of 100,000 donations) (Gavillet et al. 2013). Adverse events reduce the likelihood of a second donation as only a quarter of donors who have suffered a syncope will return for future donation (France et al. 2004).

The wide variability of complication rates observed in these studies may reflect the lack of standardised reporting practice. The 2008 International Society of Blood Transfusion (ISBT) standard for surveillance of complications related to blood donation introduced a classification with descriptions of types of complications. Subsequent revisions were made to this document so that the definitions were easy to apply in a standardised way and they aligned with those used in the AABB donor haemovigilance system (Goldman et al. 2016, ISBT 2014). The current classification system, which has been implemented by all four UK Blood Services, allows for benchmarking for donor adverse events both internally in the UK and internationally. It also enables monitoring of the effectiveness of any interventions to reduce event rates. SAED should all be fully investigated with a root cause analysis or similar tool to ensure that proper preventative and corrective actions are implemented. 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) mandates that blood establishments notify the competent authority in their country of any serious adverse events or reactions. Each Blood Service therefore submits to the Medicines and Healthcare products Regulatory Agency (MHRA) an annual overview of SAED and adverse events related to the quality and/or safety of blood or components in donors and recipients.

Data

The following table summarises the whole blood and apheresis donations collected in the four UK Blood Services last year with a total of 1,883,153 donations (whole blood and components) collected.

Table 5.1: Cumulative data from the UK Blood Services 2018

Donations from 2018		NHSBT	SNBTS	NIBTS	WBS
Whole blood	Donations from male donors	689,467	68,316	23,392	50,662
	Donations from female donors	811,741	82,958	21,106	47,146
	Donations from new donors	168,342	14,380	5,119	11,586
	Donations from repeat donors	1,332,866	136,894	39,379	86,222
Apheresis	Donations from male donors	65,646	8,229	3,863	2,137
	Donations from female donors	7,170	567	387	366
	Donations from new donors	224	0	76	77
	Donations from repeat donors	72,592	8,796	4,174	2,426
Total number of donations in 2018		**1,574,024**	**160,070**	**48,748**	**100,311**

The following table 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 2018 (January - December).

Table 5.2: Summary of SAED from the 4 UK Blood Services for the calendar year 2018 (January - December)

	NHSBT	SNBTS	NIBTS	WBS
Whole blood donations	1,501,208	151,274	44,498	97,808
Apheresis/component donations	72,816	8,796	4,250	2,503
Total donations	1,574,024	160,070	48,748	100,311
Total number of donors SAED	**34**	**5**	**2**	**2**

Rate of SAED per 10,000 donations in the UK:

This equates to a rate of 0.23 SAED per 10,000 donations or 1 SAED per 43,794 donations approximately

In total, there were 43 SAED reported, of which 34 were reported from NHSBT, 5 from SNBTS, 2 from NIBTS and 2 from WBS. It is recognised that there is variation in the number/rate of SAED reported from each Blood Service. Factors contributing to this are being explored through a joint Joint UK Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (JPAC)/SHOT working group so that there is better harmonisation across the Blood Services. The SAED reported from the four UK Blood Services in 2018 fell into the following reporting categories:

SAED by category in 2018	
01. Death within 7 days of donation	1
02. Hospital admission within 24 hours of donation	12
03. Injury resulting in a fracture within 24 hours (including fractured teeth)	9
04. Road traffic collision (RTC) within 24 hours of donation	1
05. Problems related to needle insertion persisting for more than a year or requiring hospitalisation/intervention	16
06. Acute coronary syndrome (ACS) diagnosed within 24 hours of donation	1
07. Anaphylaxis	0
08. Haemolysis	0
09. Air embolism	1
10. Other event	2 (DVT*)
Total SAED in 2018 reported	**43**

**Deep venous thrombosis (both upper limb)*

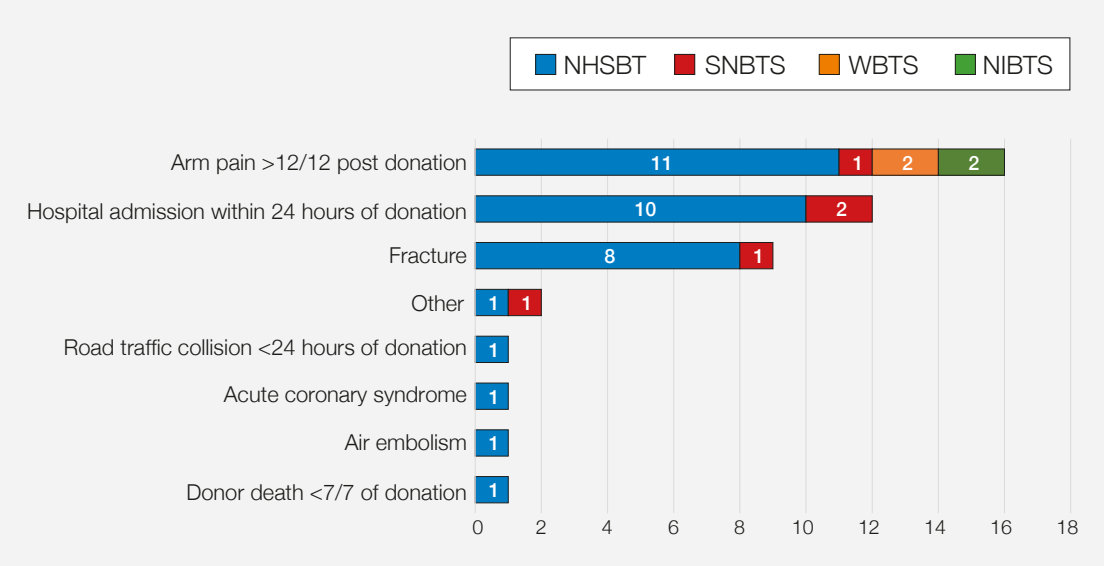


Figure 5.1: SAED by category in 2018

NHSBT=National Health Service Blood and Transplant; SNBTS=Scottish National Blood Transfusion Service; WBS=Welsh Blood Service; NIBTS=Northern Ireland Blood Transfusion Service

As illustrated above, the two most common events were donors who reported problems related to needle insertion persisting for more than a year (rate of 0.08 per 10,000 donations) and donors who required hospital admission within 24 hours of donation (rate of 0.06 per 10,000 donations). Two thirds of the hospital admissions were due to vasovagal reactions, and eight of the nine injuries resulting in fracture were due to vasovagal reactions.

There was one donation-related death. A regular platelet donor in their mid-60s died 4 days following an uneventful donation. The donor had previously donated over 200 times without any documented adverse events apart from one episode of bruising. The health check questionnaire raised no health concerns, there were no deviations from procedure, and no Blood Service fault was identified following investigation. This was supported by the post-mortem examination; cause of death was coronary artery atherosclerosis, resulting in a severe myocardial infarction.

Comparison with previous years

The four UK Blood Services have produced an annual summary report to SHOT of SAED recorded since 2015. The 2018 figures are similar to the previous three years:

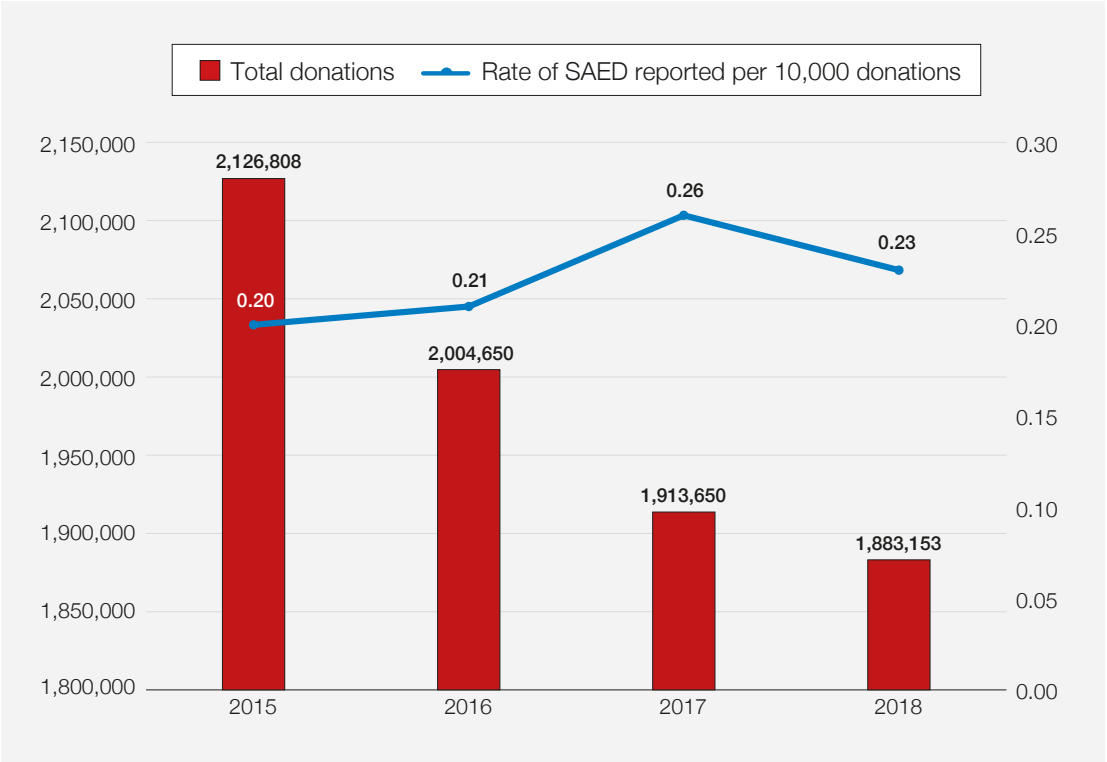
2015: 37 SAED; 0.20 SAED per 10,000 donations (1 per 50,000 donations)

2016: 42 SAED; 0.21 SAED per 10,000 donations (1 per 47,730 donations)

2017: 50 SAED; 0.26 SAED per 10,000 donations (1 per 38,273 donations)

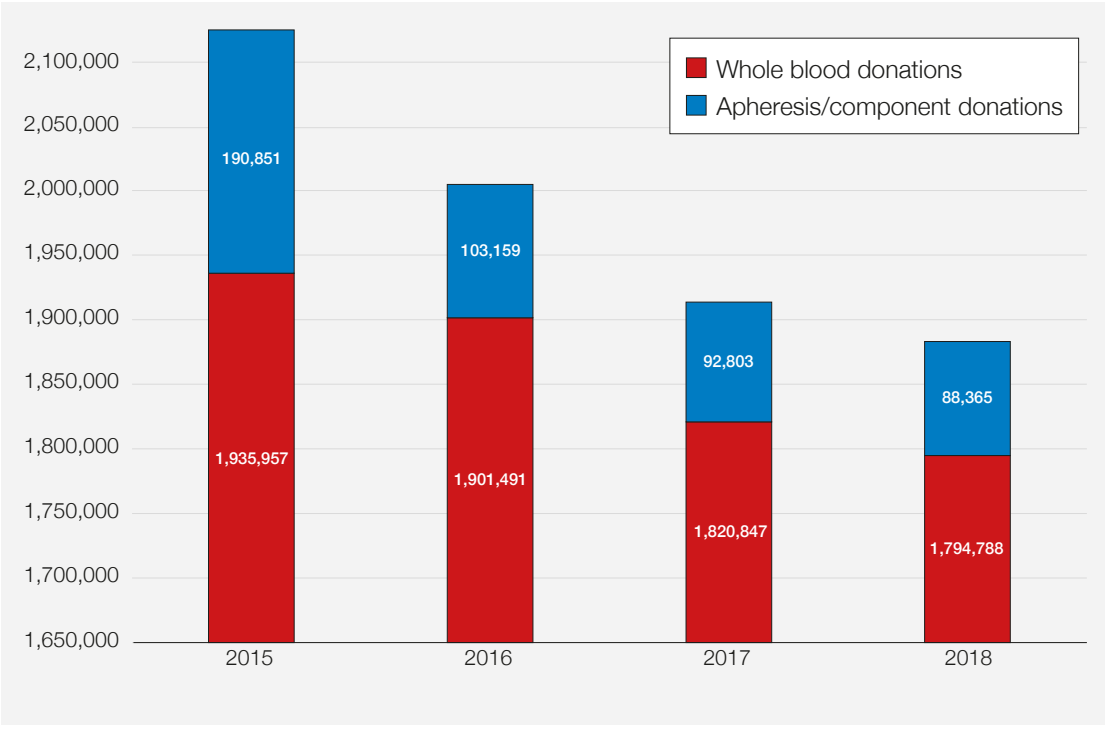
The trend in the rates of SAED reported per 10,000 donations in the last 4 years are illustrated in Figure 5.2.

Figure 5.2: Rate of SAED reported per 10,000 donations in the UK from 2015-2018



It is important to keep these events in proportion: approximately 2 million donations have been collected across the UK annually over these years and serious incidents are rare.

Figure 5.3: Trend in number of donations collected in the UK



Case examples of SAED

Case 5.1: Venepuncture-related persistent arm pain more than one-year post donation

A regular female whole blood donor who had donated 13 times previously without any adverse event, reported persistent problems with her donation arm >1-year post donation. She remembered the donation being initially slow. This prompted staff to reposition the needle, which immediately resulted in discomfort. The donor did not report this symptom at the time and a full donation was taken. The donor was left with a constant pain at the venepuncture site with an intermittent stinging sensation travelling up her arm towards her shoulder joint. Although her range of movement was preserved, she described her arm as heavy and occasionally supported it with a cushion. She had no local bruising. The donor was referred to a vascular surgeon and clinical neurophysiologist. A small neuroma was queried however this was excluded by a normal ultrasound scan. No evidence of a peripheral nerve lesion was evident on nerve conduction studies. The donor has been withdrawn from blood donation.

Venepuncture-related arm problems do occur and can have debilitating long term effects due to on-going pain and restricted function. 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 (ISBT 2014). Phlebotomy best practice has suggested that for venepuncture the inserted needle should be placed superficially, and the medial aspect of the antecubital fossa should be avoided. Minimizing 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). Peripheral nerve injuries are defined by a persistent burning, shooting, electrical-type pain or paraesthesia in a specific nerve distribution, which begins immediately while the needle is in situ, or can be delayed for several hours thereafter. Pain in the arm, without characteristics of nerve irritation, may be related to tissue injury, possibly due to a haematoma in the deeper tissues. Donation staff must be aware of these possible complications and advise donors properly during acquisition of informed consent. Some donors may be reluctant to report any venepuncture related pain or discomfort. It is therefore important that staff check with the donor if they have any of these symptoms, as the needle should be removed immediately to minimise the risks of any long-term injury.

Case 5.2: Rare complication of DVT post venepuncture

A regular female donor felt that her arm was a little tight and tender after giving blood; no bruising was noted. From 2 days post donation, her upper limb and ipsilateral chest wall became increasingly red, swollen, itchy, sore and heavy; the veins appeared prominent when compared with the left side (Urshel's sign). The donor was short of breath on minimal exertion. She contacted the Blood Service 1-week post donation and was advised to attend the emergency department urgently. An extensive upper extremity deep venous thrombosis (UEDVT) and pulmonary embolus (PE) were confirmed. She was discharged on Rivaroxaban and will likely remain on this, with follow up, for at least 6 months. The donor's only risk factor for UEDVT was use of the combined oral contraceptive pill (OCP), commencing a few weeks prior to this donation. The donor has been withdrawn from blood donation.

UEDVT as a complication of blood donation is extremely rare with only a small number of published cases reported in the literature. Donors most commonly presented with progressive arm pain, arm swelling, and a bruise (Newman et al. 2015). It is recognised and included in the international classification of adverse events of donation. UEDVT may involve the axillary, subclavian and brachial veins (Campbell et al. 2012). These account for up to 10% of all DVT (Flinterman et al. 2008), and occur with a rate of around 16 per 100,000 of the population per annum (Spencer et al. 2007). Donation in this instance, with associated decrease in blood volume, in an individual at slightly higher risk due to the combined OCP, appears to have affected Virchow's triad and triggered clot formation. Risk factors for UEDVT are like those for lower extremity DVT, with the notable exception of thrombophilic coagulation defects (Haba et al. 2017). PE is a complication in 5-8% of cases of UEDVT (of any cause) with mortality of 0.7% (Mintz et al. 2017). However, data suggests that the incidence of PE, especially subclinical PE, may in fact, be higher (up to 36%), as symptoms and signs can be minimal (Mintz et al. 2017). Post thrombotic syndrome can also complicate UEDVT in up to 13% of all cases of UEDVT (primary and secondary UEDVT) (Mintz et al. 2017).

Rare complications of blood donation, like DVT, can occur. Blood Services should encourage donors to make early contact with the Blood Service if they experience arm complications so that they can be appropriately investigated and managed.

Case 5.3: Delayed vasovagal reaction resulting in injury/fracture and hospitalisation within 24 hours post donation

A regular female whole blood donor who had donated over 30 times previously without any adverse event, reported that she had fainted on the evening following her donation. The donor gave a whole blood donation in the afternoon without any adverse event. The donor went out for a meal in the evening. During the meal the donor became warm and stood up to take her sweater off, the donor then lost consciousness falling forward onto her face. The donor sustained facial injuries including maxillae fractures. Surgery was performed the following day and the donor was discharged from hospital 2 days later. 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 physiologic 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 (Kamal 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.

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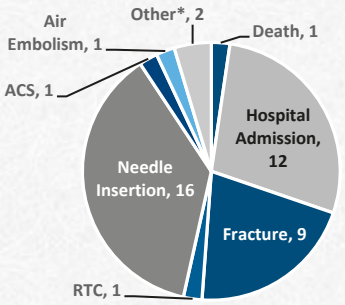
Figure 5.4: Summary of Serious Adverse Events following Blood donation reported to the UK Blood Services in 2018

Serious Adverse Events following Blood Donation reported to the UK Blood Services in 2018

In 2018 the UK Blood Services collected approximately 1.9 million donations. Forty three serious adverse events of donation (SAED) were reported (1 in 43,794 donations). Serious adverse events are very rare following blood donation but do occur and can have a significant impact on donor health and donor retention.

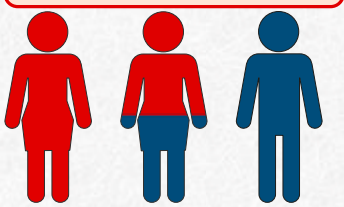
Breakdown of Serious Adverse Events in 2018

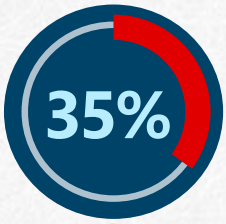
SAED Categories n=43



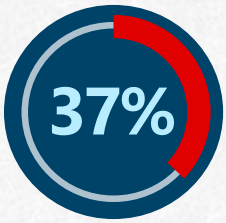
RTC=road traffic collision, ACS=acute coronary syndrome
**Other = Upper limb deep vein thrombosis*

Female donors accounted for 23/43 (53%) SAED





15/43 SAED were as a direct result of a vasovagal reaction



16/43 SAED were related to persistent arm problems 12/12 post donation

7/10 donors who suffered an SAED were withdrawn from future donations

2/43 SAED related to upper limb deep vein thrombosis following donation.

8/9 fractures were related to vasovagal reactions, 4 immediate and 4 delayed reactions.

1 report of a donor death <7 days of donation and 1 report of acute coronary syndrome <24 hours of donation.

Key Messages

Donor safety is of paramount importance and is assured, in as far as it can be, by donor selection guidelines, standard operating procedures, adequately trained staff and appropriate facilities.

Complications during or following donation can happen despite the safety measures in place

Arm problems relating to needle insertion persisting for more than a year and vasovagal events resulting in donor hospitalisation or injury continue to be the most frequently reported SAED