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# SECTION 1

### 

**July 2016 – June 2017**

# AUSTRALIAN HAEMOVIGILANCE DATA

### Acknowledgements

This report is published on behalf of the states and territories who voluntarily provided data to the national system. The National Blood Authority (NBA) thank them for their contributions and ongoing commitment to haemovigilance.

Appreciation is also extended to the members of the Haemovigilance Advisory Committee (HAC) for their advice on improvements in adverse event reporting and analysis of the data for this report.

### Caveat

Reporting of haemovigilance data to the national haemovigilance program is voluntary and data validation is not performed in all instances in Australia.

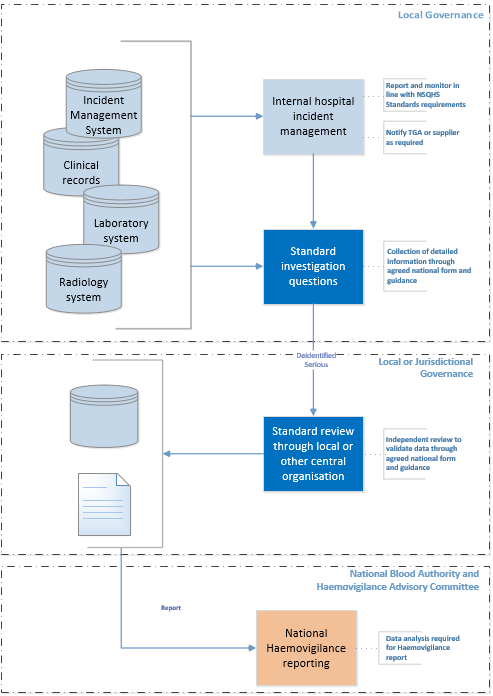
When using the data from this report it is important to note that it has quality issues in relation to data completeness, standardisation and relevance.

Notwithstanding these limitations, the NBA is publishing this data as an aid to relevant analysis and to maintain the time series of data published during the last ten years.

* Data in this report are in accordance with the National Blood Authority National Haemovigilance Data Dictionary (NHDD) 2010
* Data contributions vary across years and between states/territories.
* Near misses and denominator data (number of transfusions) are not collected and reported at national level.
* All the adverse events in this report are reported cases rather than confirmed cases.
* The definitions for the adverse events in the 2010 NHDD, Appendix I align with those used by the International Haemovigilance Network (IHN) and International Society Blood Transfusion (ISBT). However, it is not expected that they are applied rigorously.
* The national data set accepts the categorisation assigned by the contributing jurisdiction and the reviewing clinicians, regardless of minor differences to definitions.

Collection and reporting process

* Data is provided to the national haemovigilance program according to each jurisdiction’s review and reporting requirements.
* Data is reconciled by the Blood Service.
* State and territory health departments aggregate and de-identify data and report to the NBA.



### Summary of findings for 2016-17

Table 1: Adverse events by state, 2016-17



Notes

1.      All TTIs were suspected but not confirmed bacterial infections

2.      Number of patients or transfusion episodes is unavailable

3.      STIR uses a higher level temperature threshold for the reporting of FNHTR

Table 2: Adverse events by imputability score, 2016-17



Notes

1.      All TTIs were suspected but not confirmed bacterial infections

2.      Number of patients or transfusion episodes is unavailable

3.      STIR uses a higher level temperature threshold for the reporting of FNHTR

Table 3: Adverse events by blood product, 2016-17



Notes

1.      All TTIs were suspected but not confirmed bacterial infections

2.      Number of patients or transfusion episodes is unavailable

3.      STIR uses a higher level temperature threshold for the reporting of FNHTR

Table 4: Adverse events by clinical outcome severity, 2016-17



Notes

1.      All TTIs were suspected but not confirmed bacterial infections

2.      Number of patients or transfusion episodes is unavailable

3.      STIR uses a higher level temperature threshold for the reporting of FNHTR

Table 5: Reported adverse events by sex, 2016-17



Notes

1.      Limited sex data available for NSW

2.      Number of patients or transfusion episodes is unavailable

Table 6: Adverse events by age and sex, 2016-17



Notes

1.      Limited sex data available for NSW

2.      Number of patients or transfusion episodes is unavailable

Table 7: Serious adverse events by outcome severity and imputability score, 2016-17



Notes

1.        Not assessable and excluded/unlikely imputability scores are not included in the analysis

2.        Outcome severity with unknown outcomes, minor and no morbidities are not included in the analysis

3.        Number of patients or transfusion episodes is unavailable

**Cumulative results for 2012-13 to 2016-17**

Table 8: Adverse events by state, 2012-13 to 2016-17



Notes

1.       ACT reported zero adverse events for 2013–14 and 2014–15

2.       QLD did not contribute data for 2012–13

3.       WA did not contribute data from 2012–13 to 2014–15

4.       Number of patients or transfusion episodes is unavailable

5.       STIR uses a higher level temperature threshold for the reporting of FNHTR and cases are validated by an expert group prior to finalisation of the report

Table 9: Adverse events by hospital type, 2012-13 to 2016-17



Notes

1.       ACT reported zero adverse events for 2013–14 and 2014–15

2.       QLD did not contribute data for 2012–13

3.      WA did not contribute data from 2012–13 to 2014–15

4.      Only VIC, QLD and WA contributed private hospital data

5. Number of patients or transfusion episodes is unavailable

6. Private hospitals include private free-standing day hospital and other private hospitals (exclude private free standing day hospitals)

Table 10: Australian adverse event data, 2012-13 to 2016-17



Notes

1.       ACT reported zero adverse events for 2013–14 and 2014–15

2.       QLD did not contribute data for 2012–13

3.     WA did not contribute data from 2012–13 to 2014–15

4.      Only VIC, QLD and WA contributed private hospital data

5. All TTIs were suspected but not confirmed bacterial infections

6.      Number of patients or transfusion episodes is unavailable

\*Australian Red Cross Blood Service (2015), Blood Component Information: An extension of blood component labels

Table 11: Serious adverse events by state, 2012-13 to 2016-17



Notes

1.       ACT reported zero adverse events for 2013–14 and 2014–15

2.       QLD did not contribute data for 2012–13

3.       WA did not contribute data from 2012–13 to 2014–15

4.       Number of patients or transfusion episodes is unavailable

5.       STIR uses a higher level temperature threshold for the reporting of FNHTR and cases are validated by an expert group prior to finalisation of the report

Table 12: Serious adverse events, 2012-13 to 2016-17



Notes

1.       ACT reported zero adverse events for 2013–14 and 2014–15

2.       QLD did not contribute data for 2012–13

3.      WA did not contribute data from 2012–13 to 2014–15

4.      All TTIs were suspected but not confirmed bacterial infections

5.      Number of patients or transfusion episodes is unavailable

Table 13: Serious adverse events by product, 2012-13 to 2016-17



Notes

1.       ACT reported zero adverse events for 2013–14 and 2014–15

2.       QLD did not contribute data for 2012–13

3.      WA did not contribute data from 2012–13 to 2014–15

4.      All TTIs were suspected but not confirmed bacterial infections

5.      Number of patients or transfusion episodes is unavailable

Table 14: Serious adverse events by transfusion time, 2012-13 to 2016-17



Notes

1.       SA did not report transfusion time data from 2012–13 to 2014–15

2.       ACT reported zero adverse events for 2013–14 and 2014–15

3.       QLD did not contribute data for 2012–13

4.      WA did not contribute data from 2012–13 to 2014–15

5.      Number of patients or transfusion episodes is unavailable

Table 15: Serious adverse events by week day/weekend, 2012-13 to 2016-17



Notes

1.       ACT reported zero adverse events for 2013–14 and 2014–15

2.       QLD did not contribute data for 2012–13

3.      WA did not contribute data from 2012–13 to 2014–15

4.      Number of patients or transfusion episodes is unavailable

Table 16: Serious adverse events by age group, 2012-13 to 2016-17



Notes

1.       ACT reported zero adverse events for 2013–14 and 2014–15

2.       QLD did not contribute data for 2012–13

3.      WA did not contribute data from 2012–13 to 2014–15

4.      Number of patients or transfusion episodes is unavailable

**Febrile non haemolytic transfusion reaction (FNHTR)**

Table 17: FNHTR data summary, 2016-17



Notes

1.        NSW did not report the facility location data and limited reporting of sex data

2.        Number of patients or transfusion episodes is unavailable

Table 18: FNHTR clinical outcome severity by imputability, 2016-17



**Allergic reaction**

Table 19: Allergic reaction data summary, 2016-17



Notes

1.        NSW did not report the facility location data and limited reporting of sex data

2.        Number of patients or transfusion episodes is unavailable

Table 20: Allergic reaction clinical outcome severity by imputability, 2016-17



**Transfusion-associated circulatory overload (TACO)**

Table 21: TACO data summary, 2016-17



Notes

1.        NSW did not report the facility location data and limited reporting of sex data

2.        Number of patients or transfusion episodes is unavailable

Table 22: TACO clinical outcome severity by imputability, 2016-17



**Incorrect blood component transfused (IBCT)**

Table 23: IBCT data summary, 2016-17



Notes

1.        NSW did not report the facility location data and limited reporting of sex data

2.        Number of patients or transfusion episodes is unavailable

Table 24: IBCT clinical outcome severity by imputability, 2016-17



Table 25: Contributory factors cited in IBCT, 2012-13 to 2016-17



Notes

1.       Contributory factors are not reported for SA

2.        \* refers to potentially avoidable human errors

**Anaphylactic or anaphylactoid reaction**

Table 26: Anaphylactic or anaphylactoid reaction data summary, 2016-17



Notes

1.        NSW did not report the facility location data and limited reporting of sex data

2.        Number of patients or transfusion episodes is unavailable

Table 27: Anaphylactic or anaphylactoid reaction clinical outcome severity by imputability, 2016-17



**Delayed haemolytic transfusion reaction (DHTR)**

Table 28: DHTR data summary, 2016-17



Notes

1.        NSW did not report the facility location data and limited reporting of sex data

2.        Number of patients or transfusion episodes is unavailable

Table 29: DHTR clinical outcome severity by imputability, 2016-17



**Acute haemolytic transfusion reaction (AHTR)**

Table 30: AHTR data summary, 2016-17



Notes

1.        NSW did not report the facility location data and limited reporting of sex data

2.        Number of patients or transfusion episodes is unavailable

Table 31: AHTR clinical outcome severity by imputability, 2016-17



**Transfusion-transmitted infection (TTI)**

Table 32: TTI data summary, 2016-17



Notes

1.        NSW did not report the facility location data and limited reporting of sex data

2.        Number of patients or transfusion episodes is unavailable

Table 33: TTI clinical outcome severity by imputability, 2016-17



**Transfusion related acute lung injury (TRALI)**

Table 34: TRALI data summary, 2016-17



Notes

1.        NSW did not report the facility location data and limited reporting of sex data

2.        Number of patients or transfusion episodes is unavailable

Table 35: TRALI clinical outcome severity by imputability, 2016-17



**Contributory Factors**

Table 36: Contributory factors data summary, 2016-17



Notes

1.        Contributory factors are not reported for SA

2.        \* refers to potentially avoidable human errors

Table 37: Contributory factors cited by adverse event and by clinical outcome severity, 2016-17



Notes

1.        Contributory factors are not reported for SA

2.       \* refers to potentially avoidable human errors



# SECTION 2

**July 2016 – June 2017**

# DONOR HAEMOVIGILANCE DATA

### Executive Summary

Donor vigilance is the systematic monitoring of adverse reactions and incidents in blood donor care with a view to improving quality and safety for blood donors. Australia contributed to a joint initiative by the International Society for Blood Transfusion (ISBT), the International Haemovigilance Network (IHN) and the AABB to standardise donor haemovigilance definitions internationally. In 2014, agreement was reached on standard definitions and this report is the second to be published using these definitions. Appendix 1 shows the correlation between the classification of events using ISBT definitions and the Blood Service’s historic definitions.

Historical data in this report has been updated to incorporate this delayed reporting of adverse reactions by blood donors returning to donate; this is usually prompted by the donor wellness question which prompts donors to report previous reactions. The donor may report reactions months or even years after it occurred.

Between 1 July 2016 and 30 June 2017 there were just over 1.33 million donations, including 0.71 million whole blood donations, 0.59 million plasmapheresis donations and 0.04 million plateletpheresis donations. There were 40,995 donor adverse events reported. The overall reported rate of donation related adverse events has seen a slight decrease from 311/10,000 donations for the previous 12 months to 308/10,000 donations. The event numbers in this in this report are accurate as at 6 October 2017.

July 2016 – June 2017

SECTION 2

### Donation adverse event trends

Whilst blood donation is generally a safe process, there are recognised donor complications which can occur. Donor haemovigilance systems permit evaluation of the impact of changes in donation procedures and also of the success of interventions designed to further improve donor safety. The implementation of these systems has permitted real time reporting, and enabled detailed analysis, which has improved understanding of impacts of blood donation, changes in collection procedures and in donor selection criteria on the safety of donors.

Since the introduction of electronic reporting in 2010, the accuracy and completeness of the information reported has improved steadily. Several changes have been implemented resulting in a progressive increase in the number of donation reactions reported. These changes include the introduction of the “donor wellness check” in 2011 which has resulted in improved reporting of delayed donor reactions and phlebotomy injuries which become apparent after the donor leaves the donor centre. In late 2012 mandatory reporting of all citrate reactions in plasmapheresis and plateletpheresis donors was introduced, resulting in a significant increase in the number of reports of plateletpheresis reactions and modest increase in plasmapheresis donor reactions. In November 2013 refinements to the reporting system made it possible to report more than one type of donation reaction for each donation; this has resulted in an increase in the number of phlebotomy injuries which occurred in association with a faint or pre-faint. Since 2015, a program of staff education and compliance monitoring has resulted in improved reporting compliance.

These changes have enabled detailed analysis, which has improved understanding of the true impacts of blood donation on donor health, and the effects of changes in collection procedures and in donor selection criteria on the safety of donors. It has enabled identification donor groups at highest risk of donation reactions, which permits targeted intervention programs to reduce the risk and severity of reactions in these high risk groups.

There have been significant changes in the number and types of collections undertaken over the past 5 years. Whilst the total number of collections each year has remained relatively stable, there has been an 18% reduction in the number of whole blood collections and a 37% increase in plasmapheresis collections. The number of plateletpheresis collections each year has remained relatively stable, although the number of platelet doses collected has increased as a result as an increase in the number of double dose platelet collections, and a decline in the number of single dose platelet collections. In 2012-13, 32% of platelet collections were single dose collections; in 2016 ‑17, the proportion of single platelet collections fell to 21% of all platelet collections.

Table 38: Total number of collections by donation type, 2012-13 to 2016-17

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Collections | 2012-13 | 2013-14 | 2014-15 | 2015-16 | 2016-17 |
| Whole Blood | 858,594 | 783,346 | 747,684 | 718,341 | 705,587 |
| All apheresis procedures | 464,289 | 518,579 | 549,671 | 602,713 | 624,870 |
| *Plasmapheresis* | 427,945 | 482,857 | 509,269 | 564,640 | 587,444 |
| *Plateletpheresis* | 36,344 | 35,722 | 40,402 | 38,073 | 37,426 |
| Total collections | **1,322,883** | **1,301,925** | **1,297,355** | **1,321,054** | **1,330,457** |

There were 40,995 adverse events reported in 2016-17, giving an incidence of 3.08%. The overall reported rate of donation related adverse reactions has been stable for the past 2 years at 1:32. Events that occur in the donor centre are termed immediate events. Events which occur after the donor has left the donor centre are classified as delayed events.

Immediate vasovagal reactions are the most commonly reported adverse donation reactions, with an incidence of 1.9%. The majority of donors experience dizziness, weakness, sweating and nausea; only 7% of immediate reactions are associated with loss of consciousness. Vasovagal reactions can occur during or after the donation (sometimes as long as 6-8 hours following the donation).

Delayed vasovagal reactions are less common than immediate reactions occurring in only 0.27% of donors. Twelve percent of delayed reactions are associated with loss of consciousness. This represents a significant risk to the donor who is not under observation at the time of the event. Whilst most donors recover rapidly from a vasovagal reaction, a small number of individuals experience protracted symptoms despite appropriate immediate management and a very small number of donors sustain injuries when they faint. These donors may require hospital treatment. In 2016-17, hospital referral was required in 0.06% (6 in every 10,000) of donations.

Local phlebotomy site injuries caused by needle insertion are the next most common category of donation complication. The most frequently reported phlebotomy injuries include bruising, local pain and nerve irritation; less frequent but potentially more serious local complications include direct nerve injury, local thrombosis, tendon injury and arterial puncture.

Total donation-associated events and serious donation-related events are shown in Figure 1 below.

Figure 1: Total donation-associated events, 2012–13 to 2016–17

The incidence of the different types of adverse events for all donations is shown in Table 39**.** The rate of adverse reactions is stable overall. There has been a minor decrease in the overall frequency of vasovagal reactions compared to the previous year. This increase has been in non-syncopal reactions occurring on-site. There has been a significant decrease (P<0.0001) in the number of delayed reactions reported in 2016-17.

The incidence of phlebotomy injuries is stable, as is the rate of apheresis specific complications.

In early 2017, following the introduction of a new skin disinfection product (chlorhexidine 2% in isopropyl alcohol) because of the withdrawal of the previously used skin disinfection product (1% chlorhexidine) from the Australian market, reports of localised allergic skin reactions have increased significantly. The reactions remain very infrequent, and alternative skin disinfection is available for donors who experience a localised allergic reaction.

Table 39: Donation-associated events by category and frequency, 2012-13 to 2016-17 (per 10,000 donations)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Donor Event** | **2012–13** | **2013–14** | **2014-15** | **2015-16** | **2016-17** |
|  | **Systemic events** | | | | |
| Immediate vasovagal reaction | 195 | 183 | 183 | 191 | 190 |
| Delayed vasovagal reaction | 29 | 34 | 34 | 31 | 27 |
| Localised allergic reaction | 0.4 | 0.5 | 0.5 | 0.4 | 0.9 |
| Generalised (anaphylactic) reaction | 0 | 0.1 | 0.1 | 0 | 0 |
| Acute cardiac symptoms\* | 0.4 | 0.7 | 0.8 | 0.8 | 0.7 |
| Cardiac arrest | 0 | 0 | 0 | 0 | 0 |
| Transient ischaemic attack (TIA) | 0 | 0 | 0 | 0 | 0 |
| Cerebrovascular accident | 0 | 0 | 0 | 0 | 0 |
|  | **Local arm injuries** | | | | |
| Haematoma | 12 | 14 | 15 | 15 | 15 |
| Other arm pain | 5 | 12 | 17 | 17 | 18 |
| Nerve injury | 3 | 4 | 5 | 6 | 6 |
| Delayed bleeding | 0.3 | 0.6 | 1 | 1 | 1 |
| Superficial Thrombophlebitis | 0.3 | 0.3 | 0.3 | 0.4 | 0.4 |
| DVT | 0.1 | 0 | 0.1 | 0 | 0 |
| Compartment syndrome | 0 | 0 | 0 | 0 | 0 |
|  | **Apheresis specific events** | | | | |
| Citrate reaction | 10 | 32 | 34 | 46 | 45 |
| Infiltration | 0.1 | 0.7 | 0.7 | 1.2 | 1.2 |
| Haemolysis | 0 | 0.1 | 0.1 | 0 | 0 |
| Air embolism | 0 | 0 | 0 | 0 | 0 |
|  | **Other events** | | | | |
| Other events\*\* | 2 | 3 | 3 | 2 | 2 |
| **Total events** | **257** | **286** | **295** | **311** | **308** |

Notes

1. \* donors who experience palpitations /angina/acute myocardial infarction within 24 hours of donation. Each case is evaluated to determine underlying risk factors
2. \*\* includes non-cardiac chest pain, injuries sustained in falls during fainting, headaches occurring during or

after donation, cramps, nausea or abdominal pain occurring during or immediately following a procedure,

onset of wheeze or asthma during or after a donation, marked or prolonged fatigue following a donation.

### Adverse events by donation type

1. *Whole Blood –* Whole blood donation is associated with the highest frequency of pre-syncopal and syncopal reactions (“vasovagal reactions”). All but a very small number of first-time donors make a whole blood donation; the risk of vasovagal reactions in both male and female first time donors of all ages is almost twice that of donors of the same age and gender who have made only one previous donation. Between 60 and 70% of donors return to donate after their first donation, however, in the subset of donors who experience an adverse reaction, only 30% subsequently return to donate; thus, the lower rate of adverse reactions in returning donors is due, at least in part to selection bias.
2. *Plasmapheresis* – Plasma donation is associated with the lowest rate of donation complications of all donation types. All plasma donors receive 500mL normal saline as part of the donation protocol, which significantly reduces the impact of volume taken during the donation. Despite the continued growth of the plasma donor panel, the rate of pre-faints, faints and phlebotomy injuries is stable, and the incidence of citrate reactions has fallen as a result of the introduction of routinely offering all plasma and platelet donors oral calcium supplements before each donation.
3. *Plateletpheresis* – Platelet collections take significantly longer than plasma collections, platelet donors do not receive saline compensation and they are exposed to significantly higher doses of citrate anticoagulant than plasma donors. As a consequence, platelet donors experience significantly higher rates of both citrate reactions and pre-syncopal vasovagal reactions than plasma donors. In addition, platelet donors are more likely to develop significant bruising and other phlebotomy injuries as a result of the longer duration of platelet donation.

Table 40 shows annual rates of all adverse events by donation type from 2012-13 to 2016-17.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 40: Adverse event reaction rate by procedure, 2012-13 to 2016-17 (per 10,000 donations)   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | **Procedure** | | **2012–13** | **2013–14** | **2014-15** | **2015-16** | **2016-17** | | **Whole Blood** | 319 | | 333 | 352 | 361 | 368 | | **All apheresis procedures** | 152 | | 217 | 217 | 252 | 241 | | ***Plasmapheresis*** | 124 | | 163 | 182 | 216 | 209 | | ***Plateletpheresis*** | 480 | | 947 | 655 | 778 | 737 | | **Total procedures** | **257** | | **286** | **295** | **311** | **308** | |  |

Table 41: Donation associated events by reaction type and injury, 2016-17

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  | **Rate/10,000 donations** | | |
|  |  |  | | | **Whole Blood** | **Plasmapheresis** | **Plateletpheresis** |
|  |  |  | | | **(n=705,587)** | **(n=587,444)** | **(n=37,426)** |
| Immediate vasovagal reaction | Without LOC | Without injury | | | 257.93 | 80.71 | 130.93 |
| With injury | | | 0.51 | 0.1 | 0 |
| With LOC | Without injury | | | 18.93 | 5.57 | 3.21 |
| With injury | | | 1.39 | 0.22 | 0.27 |
| Delayed vasovagal reactions | Without LOC | Without injury | | | 32.03 | 13.28 | 7.75 |
| With injury | | | 1.2 | 0.27 | 0 |
| With LOC | Without injury | | | 4.21 | 1.04 | 0 |
| With injury | | | 0.69 | 0.19 | 0 |
| Blood outside vessel | Haematoma | | | | 15.67 | 12.48 | 51.84 |
| Arterial puncture | | | | 0.57 | 0 | 0 |
| Delayed bleeding | | | | 1.39 | 1.21 | 0.8 |
| Arm pain | Nerve injury/irritation | | | | 8.28 | 3.78 | 5.34 |
| *Other arm pain* | | | | 21.7 | 14.35 | 20.57 |
| Related to apheresis | Citrate reaction | | | |  | 69.13 | 507.13 |
| Haemolysis | | | |  | 0 | 0 |
| Air Embolism | | | |  | 0 | 0 |
| Infiltration | | | |  | 2.42 | 5.34 |
| Infection/ inflammation/ allergic reaction | Local allergic reaction | | | | 0.82 | 1.04 | 0.27 |
| Generalised (anaphylactic) reaction | | | | 0.03 | 0.07 | 0 |
| Thrombophlebitis | | | | 0.3 | 0.43 | 0.8 |
| Other | Cardiac | | Cardiac arrest | | 0 | 0 | 0 |
| Acute myocardial infarction | | 0.04 | 0 | 0 |
| Acute cardiac symptoms | | 0.72 | 0.71 | 0.53 |
| Cerebrovascular accident | | | | 0.01 | 0 | 0 |
| Transient ischaemic attack | | | | 0 | 0 | 0 |
| DVT | | | | 0 | 0.02 | 0 |
| Other | | | | 1.36 | 2.09 | 2.67 |
| **Total** | | | | | **368** | **209** | **737** |

### Serious complications of blood donation

Serious complications related to blood donation are defined as events resulting in any of the following:

* hospitalisation if it is attributable to the reaction, based on the evaluation of hospital medical staff
* attendance at a healthcare facility to manage a complication and to prevent ongoing impairment
* involvement in an accident (with or without significant injury) if the accident was probably or definitely related to the donation
* death following a donation complication if the death was probably, possibly or definitely related to the donation.

During 2016-2017, 826 donors attended hospital and 1,001 attended their general practitioner (GP) for donation related complications (Table 42). There were no donation associated deaths. The majority of hospital attendances are by donors directly referred from the donor centre, either because of an injury sustained in a fall during a vasovagal reaction or because a donor is very slow to recover from a vasovagal reaction. Donors experiencing chest pain are generally referred for assessment in the Emergency Department. 30 donors with chest pain were referred to hospital between July 2016 and June 2017 of whom 9 were admitted for cardiac investigations; all had been previously well but had risk factors for coronary disease. One donor suffered a myocardial infarct approximately 7 hours following a whole blood donation and required a single stent inserted and 2 whole blood donors were found to have coronary artery disease following hospital referral for chest pain. During follow up, feedback from the donors’ treating cardiologists indicated that blood donation was unlikely to be the cause of the cardiac events in these donors. Of the remaining donors referred for chest pain the diagnosis was anxiety (in 17 donors) or no definitive diagnosis was made (for 22 donors). Most hospital attendances are brief presentations to the Emergency Department, and admission to hospital is rare. A number of donors self-refer to hospital following a delayed vasovagal reaction.

Attendance at GPs may be initiated by donors who have experienced a delayed faint, or more frequently, because of arm pain due to a large haematoma or nerve irritation. Rare causes of arm pain requiring medical treatment are venous thrombosis (11 donors) and superficial thrombophlebitis (38 donors).

Table 42: Summary of external medical referrals, 2016-17

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Number of hospital referrals | Hospital referral rate/ 10,000 donations | Number of GP referrals | GP referral rate/ 10,000 donations |
| Whole Blood | 579 | 8 | 652 | 9 |
| Plasmapheresis | 238 | 4 | 324 | 6 |
| Plateletpheresis | 9 | 2 | 25 | 7 |
| Total | **826** | **6** | **1,001** | **8** |

Hospital referral rates have fallen steadily in whole blood donors since 2014 -15 and has remained stable in apheresis donors. (Refer to **Table 43** below).

Table 43: The rate per 10,000 donations and total numbers of adverse donor reactions (in bracket) requiring hospital attendance, 2012-13 to 2016-17

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Procedure** | **2012–13** | **2013–14** | **2014-15** | **2015-16** | **2016-17** |
| **Whole Blood** | 4 (348) | 5 (356) | 10 (761) | 9 (653) | 8 (579) |
| **All apheresis procedures** | 8 (124) | 3 (136) | 4 (226) | 4 (247) | 4 (247) |
| ***Plasmapheresis*** | 2 (105) | 2 (120) | 4 (191) | 4 (224) | 4 (238) |
| ***Plateletpheresis*** | 5 (19) | 4 (16) | 9 (35) | 6 (23) | 2 (9) |
| **Total procedures** | **4 (472)** | **4 (492)** | **7 (955)** | **7 (900)** | **6 (826)** |

The majority of donors attending hospital are whole blood donors. There have not been any significant changes in whole blood collection procedures or in the demographics of the whole blood donor pool which would account for the significant increase in hospital referrals. The increase is attributable mainly to transfer donors to hospital if their recovery from a vasovagal reaction is slow (more than 60-70 minutes), recognising that early administration of intravenous fluids is the most effective means of treating this group of donors. In keeping with good clinical practice, the majority of donors who complain of chest pain are referred to hospital.

### Donor gender and age and adverse reactions to donation

The frequency of donation associated events is higher in younger blood donors and in female blood donors. There is a steady reduction in the likelihood of a donation reaction with increasing age (See Table 44 and Table 45 below). The majority of the donation reactions in younger donors are characterised by brief dizziness, associated with sweating and nausea, usually lasting for less than 15 minutes. The higher rate of adverse events in this age group was one of the reasons that prompted a decision to increase the minimum age for blood donation from 16 to 18 years.

Table 44: Adverse donation reactions in female donors by age, including odds ratio, 2016-17

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Age group** | **Number of events** | **Total donors in age group** | **Frequency** | **Rate/1,000 donations** | **Odds ratio (95% CI)** |
|
| 16-17 | 1,371 | 7,875 | 1:7 | 174.10 | 4.5829 (4.3176-4.8646) |
| 18-20 | 1,958 | 29,237 | 1:15 | 66.97 | 1.5346 (1.4632-1.6095) |
| 21-23 | 4,047 | 39,485 | 1:10 | 102.49 | 2.6223 (2.5316-2.7164) |
| 24-30 | 5,619 | 90,465 | 1:16 | 62.11 | 1.4719 (1.4278-1.5175) |
| 31-40 | 4,077 | 94,385 | 1:23 | 43.20 | 0.9239 (0.8929-0.9561) |
| 41-50 | 3,202 | 99,203 | 1:31 | 32.28 | 0.649 (0.6250-0.6739) |
| 51-60 | 3,291 | 111,462 | 1:34 | 29.53 | 0.5778  (0.5567-0.5997) |
| 61-70 | 2,053 | 82,047 | 1:40 | 25.02 | 0.4937 (0.4717-0.5169) |
| 71+ | 153 | 9,976 | 1:65 | 15.34 | 0.3213 (0.2737-0.3771) |
| **Total** | **25,771** | **564,137** | **1:22** | **45.68** |  |

Table 45: Adverse donation reactions in male donors by age, including odds ratio, 2016-17

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Age group** | **Number of events** | **Total donors in age group** | **Frequency** | **Rate/1,000 donations** | **Odds ratio (95% CI)** |
|
| 16-17 | 514 | 4,762 | 1:9 | 107.94 | 5.9653 (5.4357-6.545) |
| 18-20 | 1,043 | 26,066 | 1:25 | 40.01 | 2.069 (1.9405-2.2060) |
| 21-23 | 1,903 | 33,423 | 1:18 | 56.94 | 3.157 (3.0050-3.3166) |
| 24-30 | 3,337 | 94,800 | 1:28 | 35.20 | 1.9495 (1.8749-2.0271) |
| 31-40 | 3,153 | 120,620 | 1:38 | 26.14 | 1.355 (1.3023-1.4099) |
| 41-50 | 2,191 | 137,872 | 1:63 | 15.96 | 0.7375 (0.7046-0.7720) |
| 51-60 | 1,910 | 173,872 | 1:91 | 10.99 | 0.4639 (0.4421-0.4869) |
| 61-70 | 1,095 | 133,002 | 1:121 | 8.23 | 0.3507 (0.3297-0.3731) |
| 71+ | 78 | 21,371 | 1:274 | 3.65 | 0.1713 (0.1371-0.2142) |
| **Total** | **15,224** | **745,201** | **1:49** | **20.43** |  |

The higher incidence of reactions in young donors and female donors is consistent with international experience.

### Current strategies to reduce the risk of adverse events

1. Donor selection criteria:
   1. An increase in the minimum weight to 50kg, and a minimum total blood volume of 3,333ml, was implemented in 2015.
   2. Permanent deferral of donors who are at significant risk of experiencing a recurrence of serious adverse reactions.
2. Interventions which reduce the risk of an adverse donation reaction
   1. Provide advice to donors on strategies to minimise the risk of a reaction during and after donation on [donateblood.com.au](file:///C:\Users\bbell\Desktop\NBA%20REPORT\NBA%20HAEMOVIGILANCE%20REPORT_15_16_partial271016.docx) (rest and fluid intake, avoidance of strenuous physical activity and alcohol post donation).
   2. Provision of specific information cards to donors at the time of an adverse event detailing immediate management and preventative actions relevant to subsequent donations.
   3. Use of a mid-donation saline protocol for plasma donors which includes the administration of 500ml of saline to reduce the risk of vasovagal reactions.
   4. Using a stepwise approach to increasing collection volume for plasmapheresis donors donating plasma for fractionation based on nomograms\* for percent Total Blood Volume.
   5. Using a stepwise approach for plasmapheresis donors donating Clinical Fresh Frozen Plasma with end saline also based on a nomogram for Total Blood Volume.
   6. Since December 2016, all plasma- and plateletpheresis donors have been routinely provided with 900mg of elemental calcium in a palatable peppermint lozenge. This has resulted in a significant, sustained reduction in the incidence of citrate reactions in platelet donors and female plasma donors.
3. Haemovigilance and Clinical Governance activities
   1. Communication with comparable international blood services to ensure ‘best practice’ protocols.
   2. Regular adverse events data review and trend analysis is conducted by the Donor Haemovigilance Team, with reporting provided at donor centre, state and national level.
   3. Formal clinical governance processes including review of staff scope of practice and training, the conduct of clinical audits, robust data capture and analysis of adverse events, regular management and external review of donor adverse event trends with corrective action taken as required.

\*A nomogram is a chart or graph used to show relationships between several variables (such as height and weight) to enable a third value (the collection volume, which is based on the total blood volume) to be read directly at the intersection point of the first 2 values.

# APPENDIX 1

Appendix 1: International Society of Blood Transfusion (ISBT) definitions



# ABBREVIATIONS

AABB American Association of Blood Banks

ABO The human red cell ABO blood group system

ACT Australian Capital Territory

AHTR Acute haemolytic transfusion reaction (other than ABO incompatibility)

ATR Acute transfusion reactions

DHTR Delayed haemolytic transfusion reaction

DVT Deep vein thrombosis

FNHTR Febrile non haemolytic transfusion reaction

GP General Practitioner

HAC Haemovigilance Advisory Committee

HBsAg Hepatitis B surface antigen

HBV Hepatitis B virus

HCV Hepatitis C virus

HIV Human Immunodeficiency virus

HTC Haemophilia Treatment Centre

HTLV Human T-cell lymphoma virus

IBCT Incorrect blood component transfused

IHN International Haemovigilance Network

ISBT International Society for Blood Transfusion

LOC Loss of consciousness

NAT Nucleic acid testing

NBA National Blood Authority

NHDD National Haemovigilance Data Dictionary

NSW New South Wales

NT Northern Territory

PTP Post transfusion purpura

QLD Queensland

SA South Australia

STIR Serious Transfusion Incident Reporting

TACO Transfusion-associated circulatory overload

TAS Tasmania

TIA Transient ischaemic attack

TRALI Transfusion-related acute lung injury

TTI Transfusion-transmitted infection

vCJD Variant Creutzfeldt-Jakob disease

VIC Victoria

VVR Vasovagal reaction

WA Western Australia

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