EUROPEAN COMMISSION
DIRECTORATE GENERAL FOR HEALTH AND FOOD SAFETY

Directorate B - Health systems, medical products and innovation
B4 – Medical products: quality, safety, innovation

SUMMARY OF THE 2018 ANNUAL REPORTING OF SERIOUS ADVERSE REACTIONS AND EVENTS FOR BLOOD AND BLOOD COMPONENTS

(Data collected from 01/01/2017 to 31/12/2017 and submitted to the European Commission in 2018)

EXECUTIVE SUMMARY

Blood transfusion is an essential medical procedure supporting many different healthcare specialities across the European Union (EU), with millions of EU citizens receiving donated blood and blood components every year. However, the use of any substance of human origin carries some risk, notably the potential for the transmission of disease from the donor. These risks can be minimised by the application of safety and quality measures as laid down in the EU Blood legislation. Despite these measures, rare adverse outcomes can occur, and in line with the legislation[1], these must be monitored and reported at national and EU level through vigilance and surveillance programmes.

Since 2008, in line with obligations defined in the legislation[2], the EU Member States, Iceland, Liechtenstein and Norway have submitted to the European Commission (henceforth referred to as 'the Commission') annual vigilance reports on the notification of Serious Adverse Reactions (SAR) and Serious Adverse Events (SAE). For this purpose, definitions of SAR and SAE are provided in the EU legislation[3] (SAR are incidents where actual harm to a donor or patient has occurred; SAE are incidents where no harm has occurred but a risk of harm was detected). The Commission, in turn, publishes this annual summary of the reports received, making it available to the Competent Authorities, healthcare professionals and the general public.

The Commission works with national Competent Authorities to verify the consistency and clarity of the information submitted on Serious Adverse Reactions and Events (SARE) and to improve the data collection procedure. The completeness and comparability of the data collected in the blood field has improved over the years. The SARE exercise has also facilitated the development and consolidation of the Member States' national vigilance programmes. A Vigilance Expert Sub-Group (VES, a subgroup to the Competent Authorities on Substances of Human Origin Expert Group) was established by the Commission in 2017 with the aim of supporting the development and improvement of the SARE reporting system.

[1] 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.
[2] Article 8 of Directive 2005/61/EC provides that Member States shall submit to the Commission an annual report, by 30 June of the following year, on the notification of serious adverse reactions and events (SARE) received by the competent authority using the formats in Part D of Annex II and C of Annex III.
[3] Article 3 of Directive 2002/98/EC

This report summarises the data submitted by the Member States during 2018, for the year 2017, and draws general conclusions, comparing the information with data submitted in previous years. The key results of the 2018 reporting exercise are:

- Overall, 29 countries (28 EU Member States and Norway) reported in the SARE annual exercise. Of these, 21 countries indicated receiving complete data from their reporting establishments[4].

- In relation to the number of units issued for transfusion and/or transfused[5], 25.1 *million units* of blood or blood components were reported by 29 countries. Partial data reported by 19 countries indicated that over 3.5 *million patients* were transfused.

- Concerning *SAR in recipients*, 1,871 cases were reported for 2017 with imputability level 2 or 3 (likely or certain to have been caused by the transfusion), which are the focus of further analysis in this report. The total number of SAR has slightly increased compared with previous exercises. Febrile non-haemolytic transfusion reaction and anaphylaxis were the most frequent SAR.

- The results also show that there were 28 *deaths* likely or certainly resulting from blood transfusions in 2017. Compared with previous exercises this number has moderately increased. It is worth noting that the majority of deaths were not directly attributable to the quality and safety of blood components, but rather to clinical practice or to unforeseeable reactions.

- Concerning *SAE*, which amounted to 2,920 cases for 2017, the reported figures have also slightly increased compared to those of the previous year. Most of the SAE are reported as being due to human error (75%). This emphasises the importance of root-cause analysis to determine the best measures to avoid the repetition of SAE. It is also noted that SAE reporting rates vary considerably between countries.

- The reports submitted by 23 of the countries included information not only on recipients but also *donors*, for whom 4,635 reactions were reported on a voluntary basis. Although not legally mandated, it is considered important to collect these data and to further assess the underlying causes in order to better protect those citizens who volunteer to donate blood and thus make transfusion possible.

Before publishing the summary report, the data contained in this report was presented at the meeting of the Competent Authorities for Blood and Blood Components in June 2019. This gave the reporting

[4] Article 1 of Directive 2005/61/EC defines a "reporting establishment" as "the blood establishment, the hospital blood bank or facilities where transfusion takes place that reports serious adverse reactions and/or serious adverse events to the competent authority".

[5] It should be taken into account that in the data from 2 countries, only the units reported as transfused, not those issued, were reported. It is evident that the number of units transfused must also have been issued prior to transfusion.

countries the opportunity to interact and share experience and knowledge on haemovigilance, hence supporting the development of their national systems and improving the safety of blood transfusion.

1. DATA COLLECTION METHODOLOGY

This document provides a summary report of the data collected at a Member State level during 2017 (from 1st January to 31st December) and submitted to the Commission in 2018 by Norway and all EU Member States. It also includes a comparison with the data from previous years and draws general conclusions. The Commission provided the following tools to the participating authorities to promote a standardised approach to data reporting:

1) An electronic reporting template to be sent to a DG SANTE-hosted database. The electronic reporting template used in 2018 (for 2017 data) was version 2.6.3;

2) The Common Approach document for the definition of reportable SAR and SAE ("Common Approach") attached to the electronic reporting template. The aim of the document, although not legally binding, is to provide guidance to Member States when reporting. First published in 2008, the Common Approach has been regularly updated to clarify points of ambiguity and inconsistency. This has in turn resulted in a gradual increase in the quality and accuracy of the data collected from the Member States. In 2018, version 5.4 of the Common Approach document was available to those countries reporting 2017 SARE data.

In December 2018 a grant agreement was signed between the Commission and the Council of Europe/European Directorate for the Quality of Medicines & HealthCare (EDQM) to carry out the verification and analysis of the SARE exercise. Therefore, at the beginning of 2019, the EDQM started contacting reporting countries when needed in order to clarify and verify the accuracy of the data, and performed the detailed analysis of the information presented in this report.

2. MAIN FINDINGS OF THE 2018 DATA COLLECTION

3.1. General comments

For the 2018 exercise (data reported at Member State level in 2017), the electronic reporting template was slightly modified following the recommendations of the VES. A revised version of the Common Approach document was also issued, paying special attention to the modifications in the template.
In this exercise, a new category '*donor selection'* was included in activity steps when submitting SAE. This gave the opportunity to reporting countries to submit any SAE that may occur when the donor selection or evaluation is performed and that may have an impact on the quality and safety of the blood or blood components. In addition, although information on SAR in donors is voluntarily reported, a new categorisation of types of SAR in donors was included with the intention of harmonising the information submitted by the reporting countries and provide a more informative view of donation risks across the EU.

Country reports were received from all 28 EU Member States and Norway, comprising aggregated data from 4,028 reporting facilities. Not all countries provided complete data on all denominators (i.e. blood units issued, blood units transfused and number of recipients), raising questions about the availability

and accuracy of the data. Despite this, denominator data have improved overall in comparison with previous exercises.

Regarding data completeness, 21 countries reported receiving complete data, 7 countries received 85-98% of the expected data, and one country was not able to provide this information. Although data quality has continued to improve, the data presented here are considered partial and still do not represent the entire picture. Therefore, conclusions should be interpreted with caution.

3.2. Denominators

All 28 EU Member States and Norway submitted replies to the questionnaire, thereby complying with the annual report submission requirement established by Article 8 of Directive 2005/61/EC.

As regards the **units of blood components issued,** 27 Member States (AT, BE, BG, CY, CZ, DE, DK, EE, EL, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK and UK) provided data. The two remaining countries (ES and NO) did not report the number of units issued, but did provide the number of units transfused. As all units transfused must have first been issued, their numbers for units transfused have been included in the total number of units reported issued. A total of 25,093,906 units of blood and blood components were reported as issued in 2017. Figure 1 and Table 1 show the breakdown of units issued by component type (including the transfused data from ES and NO).

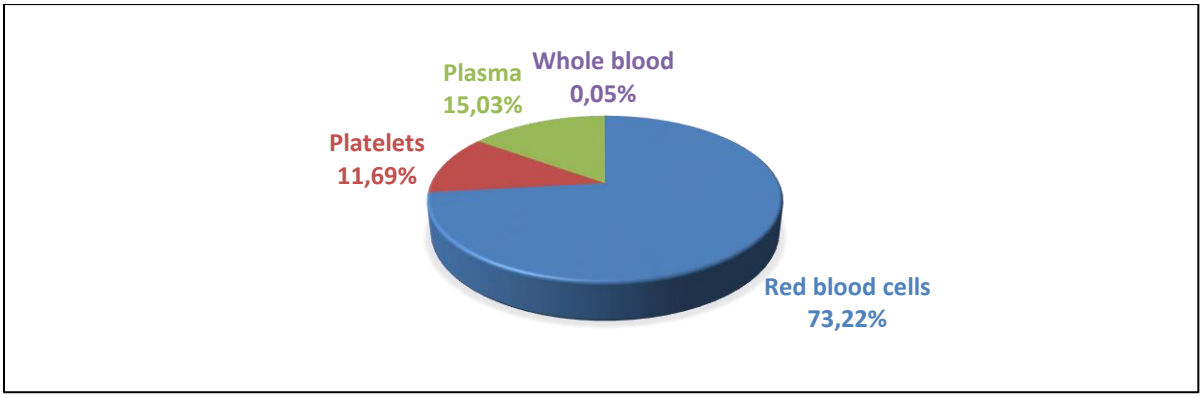

Figure 1: Units issued[6] (per blood component); data 2017.

Component type	Units issued
Red Blood Cells	18,374,971
Platelets[7]	2,934,371
Plasma	3,772,062
Whole blood	12,502
Total	**25,093,906**

Table 1. Number of units issued per blood component; data 2017.

Twenty-seven countries (all but EL and HU) also provided the total number of whole blood collections made during the year, amounting to 17,866,384. In the case of apheresis collection, 27 countries (all

[6] Including data on units transfused from ES and NO.
[7] Note that one platelet unit is normally prepared from several donations.

but HU and SE) provided the number of collections during the year, amounting to 5,772,463. Both figures are similar to the numbers provided in previous exercises.

Concerning the **units of blood components transfused**, there were 20,674,603 units reported as transfused by EU and EEA countries (AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FR, HR, IE, IT, LU, LV, MT, NL, PT, RO, SE, SK, UK and NO). The data for units transfused per blood component is shown in Figure 2 and Table 2.

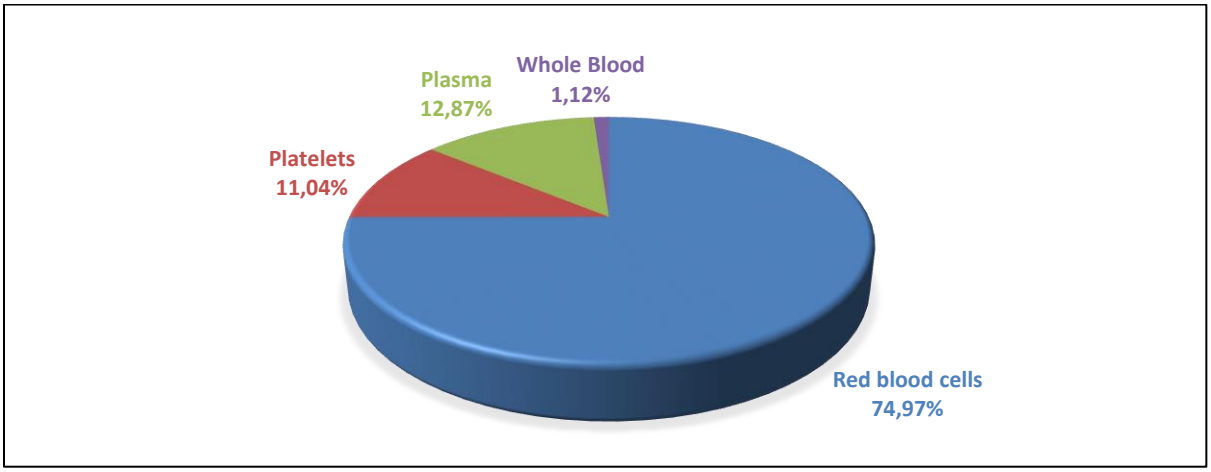

Figure 2. Units transfused (per blood component); data 2017.

Component	Units transfused
Red Blood Cells	15,499,783
Platelets[5]	2,281,466
Plasma	2,661,188
Whole blood	232,166
Total	**20,674,603**

Table 2. Number of units transfused per blood component; data 2017.

Regarding **recipients transfused**, 3,522,623 patients were transfused in 2017 according to the reports. These are partial figures provided by 19 countries (AT, BE, BG, CY, CZ, EE, ES, FR, IE, IT, HR, LT, LU, MT, NL, PT, RO, SE and UK) that either reported the number of recipients transfused by blood component type or the total number of recipients regardless of component type. The breakdown of the transfused recipients is shown in Figure 3 and Table 3.

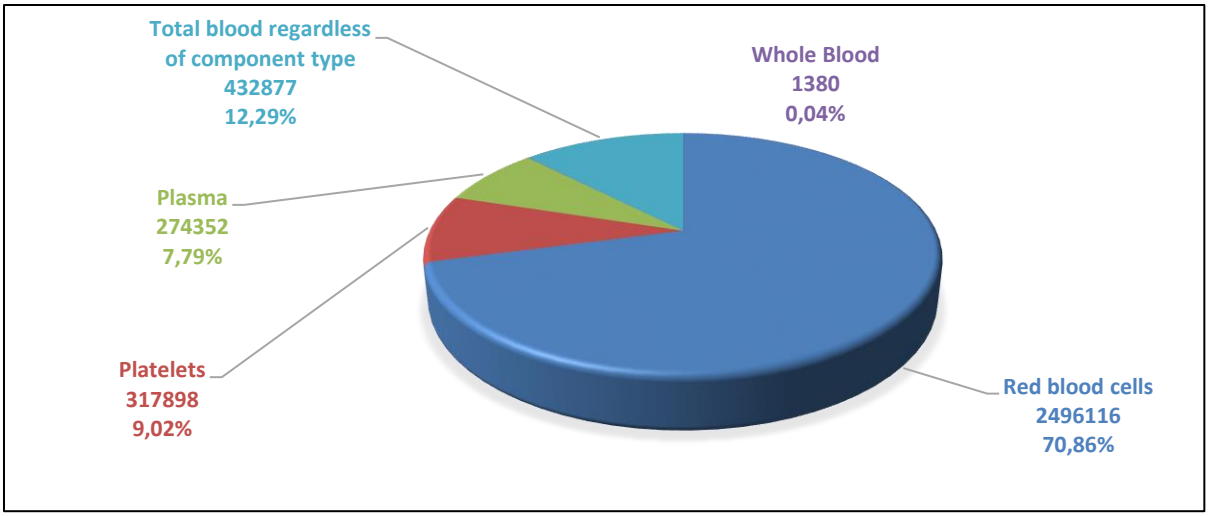

Figure 3. Recipients transfused per blood component; data 2017.

Component	Recipients transfused
Red Blood Cells	2,496,116
Platelets	317,898
Plasma	274,352
Whole blood	1,380
Total blood regardless of component type[8]	432,877
Total	**3,522,623**

Table 3. Number of recipients transfused per blood component; data 2017.

3.3. Serious Adverse Reactions

3.3.1. Information by country

In 2017, a total of 3,114 SAR with imputability level of 1 to 3 were reported in the exercise. However, eight countries (DK, EE, ES, IT, LT, LU, RO and SE) did not report any SAR of imputability level 1.

Directive 2005/61/EC provides that reporting establishments notify to the Competent Authority all relevant information about SAR of imputability level 2 or 3. Following the Directive, level 2 should be considered where it is likely or probable that the evidence is in favour of attributing the adverse reaction to the blood or blood component and level 3 is considered when it is certain that there is conclusive evidence for attributing it to the blood transfusion[9].

During 2017, a total of 1,871 SAR at imputability level 2 or 3 were reported. Of those, 28 resulted in death (23 deaths linked to red blood cell transfusion, 2 to platelet transfusion, 2 to plasma transfusion and 1 to transfusion with more than 1 component).

For the countries that provided data for the number of SAR and units transfused per blood component, there were 11,050 units transfused per SAR of imputability level 2 or 3.

[8] Two countries were not able to provide the number of recipients transfused per type of component, but provided the total number of patients transfused regardless of the type of component.
[9] Article 5, para 3a of Directive 2005/61/EC.

These figures should also be interpreted with caution as many reports are still partial and differences between countries do not necessarily indicate a safer system in one Member State compared to the other. In fact, a higher number of SAR reported may indicate a more reliable and accurate reporting system, and a lower number of SAR may indicate underreporting.

3.3.2. Information by blood component

Of the 1,871 SAR of imputability level 2 or 3 reported:

- 1,085 SAR were related to **red blood cells**
- 467 SAR were related to **platelets**
- 264 SAR were related to **plasma, and,**
- 55 SAR were related to **more than one blood component.**

Figure 4 and Table 4 show the percentage of SAR and number of units transfused per blood component per SAR respectively.

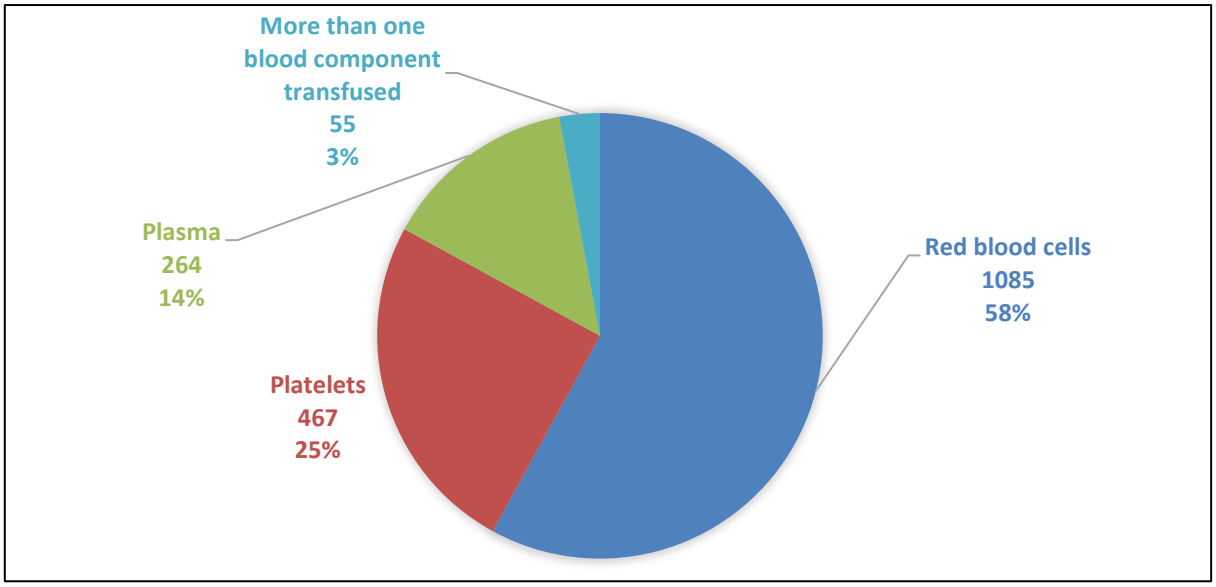

Figure 4. Percentage of SAR (imputability 2-3) per blood component; data 2017.

Component type	Units transfused per SAR
Red Blood Cells	14,285
Platelets	4,885
Plasma	10,080

Table 4. Units per component type transfused per SAR; data 2017.

3.3.3. Information by category of SAR

The 1,871 SAR (imputability level 2 or 3) reported were classified as follows:

- Febrile non-haemolytic transfusion reaction (FNHTR): 449 cases

- Anaphylaxis/hypersensitivity: 292 cases
- Transfusion-associated circulatory overload (TACO): 244 cases
- Immunological haemolysis: 184 cases, of which
    - 67 cases due to ABO incompatibility and
    - 117 cases due to other alloantibodies
- Transfusion-associated dyspnoea (TAD): 58 cases
- Transfusion-related acute lung injury (TRALI): 48 cases
- Transfusion-transmitted viral infection: 21 cases (3 hepatitis A, 4 hepatitis B, 12 hepatitis E, 1 hepatitis C and 1 Parvovirus B19)
- Transfusion-transmitted bacterial infection: 16 cases
- Non-immunological haemolysis: 8 cases
- Graft versus host disease: 1 case
- Other: 550.

The percentage of SAR per category is shown in Figure 5.

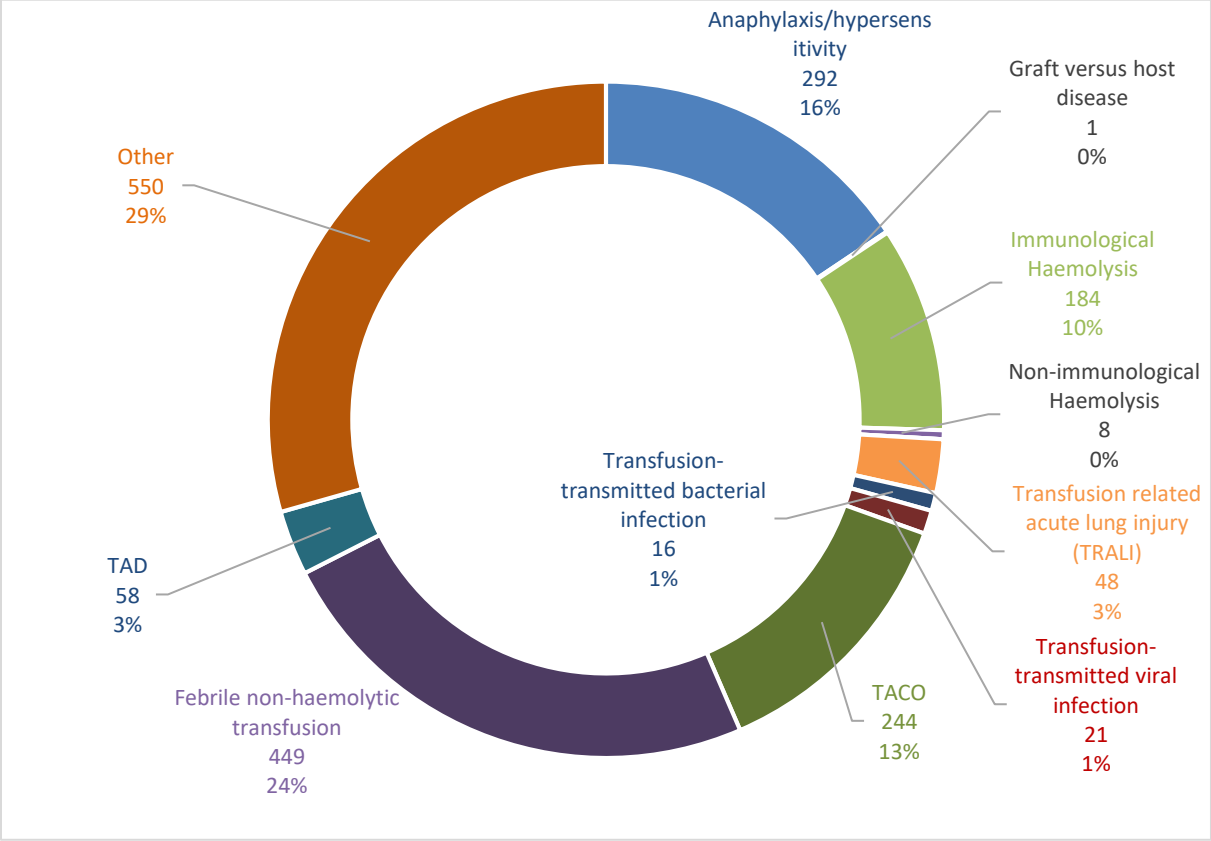

Figure 5. Percentage of SAR (imputability 2-3) per category; data 2017.

3.3.4. Recipient deaths

Within the 1,871 cases of SAR of imputability level 2-3 reported there were 28 deaths, as follows (Figure 6.):

- 9 were associated with immunological haemolysis, representing 32.1% of all deaths reported. Of these, five were reportedly due to ABO incompatibility and 4 due to other alloantibodies, associated with red blood cell transfusion in all cases (17.8% and 14.3%, respectively, of all reported deaths)
- 1 was associated with non-immunological haemolysis following red blood cell transfusion. (3.6% of all reported deaths)
- 1 was associated with TRALI following red blood cell transfusion. (3.6% of all reported deaths)
- 2 were associated with bacterial transmission, 1 following red blood cell transfusion and 1 following platelet transfusion (7.1% of all reported deaths)
- 1 was associated with anaphylaxis/hypersensitivity following red blood cell transfusion(3.6% of all reported deaths)
- 1 was associated with viral transmission (HEV) following platelet transfusion(3.6% of all reported deaths)
- 6 were associated with TACO, 5 following red blood cell transfusion and 1 following more than 2 blood component transfused (21.4% of all reported deaths)
- 1 was associated with TAD following plasma transfusion (3.6% of all reported deaths
- 6 were reported under the "other" category, 5 following the transfusion of red blood cells, and one more than one component transfused (21.4% of all reported deaths.

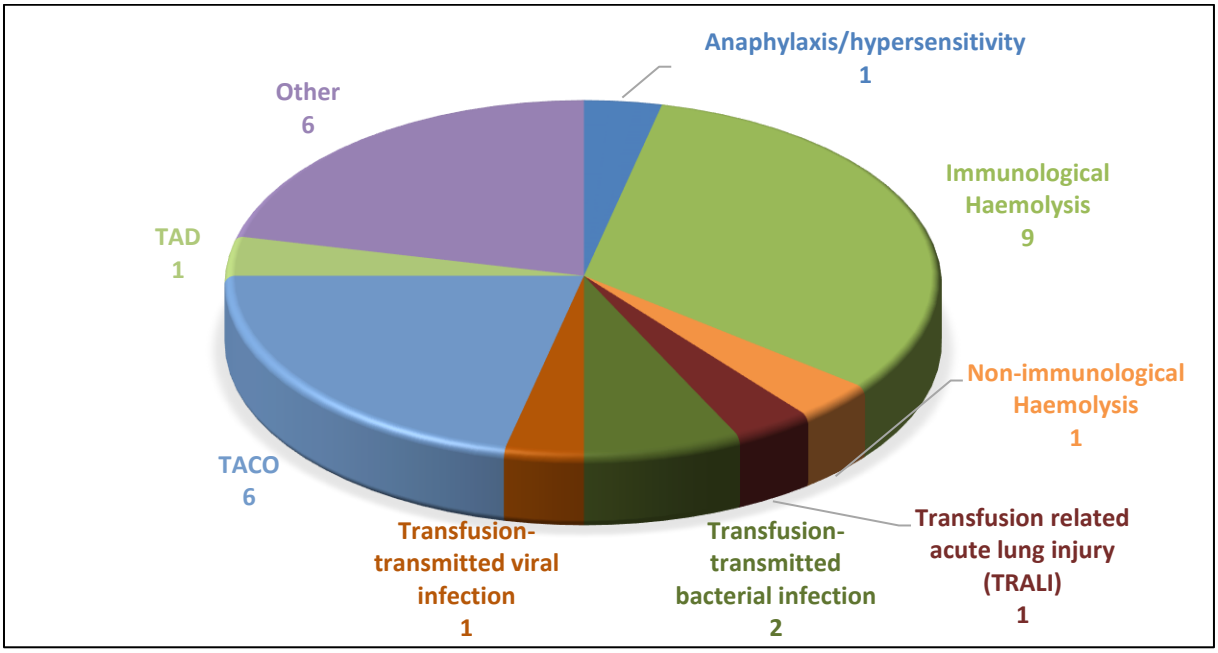

Figure 6. Fatalities reported by type of SAR (imputability 2-3); data 2017.

Directive 2005/61/EC does not require countries to provide data concerning serious adverse reactions of imputability 1. However, some countries voluntarily reported 37 deaths with this imputability level (26 related to red blood cell transfusion, 5 related to platelets, 4 related to plasma and 2 related to more than one blood component transfused). The main type of SAR reported in this category were TACO, anaphylaxis, and "*other*". Imputability 1 is assigned when evidence is insufficient for attributing adverse reactions either to the quality and safety of blood and blood components or to alternative causes. Although these are partial data, and should be interpreted with caution, it was deemed

appropriate to include them in this section, as safety of the transfused patients is considered paramount for the Commission and all reporting countries.

The United States Food and Drug Administration (FDA) publishes an annual summary of "Fatalities reported to FDA following blood collection and transfusion"[10]. The statistics provided in that report allow some broad comparisons to be made with the annual vigilance reports on SARE submitted by EU and EEA countries to the Commission. During 2017, there were 67 transfusion-related fatalities reported to the FDA. TRALI reactions and TACO caused the highest number of reported fatalities, followed by haemolytic transfusion anaphylaxis and bacterial and viral contamination. In Europe, the information submitted in the SARE reporting exercise for 2018 (data from 2017) shows similar results, the highest number of deaths related to the transfusion of blood and blood components was due to immunological haemolysis, bacterial contamination and other category.

3.3.5. SAR in donors

Twenty-three countries (AT, BE, BG, CY, CZ, DE, DK, EL, ES, FR, HR, IE, IT, MT, NL, NO, PL, PT, RO, SE, SI, SK and UK) reported, on a voluntary basis, a total of 4,635 SAR in donors.

In the context of non-mandatory reporting, variability between countries in the reporting of SAR in donors is significant. Unlike SAR in recipients, countries are not requested to report the imputability level of SAR in donors. Therefore, the criteria applied for including a particular type of donor SAR, or not, are not standardised. On the recommendation of the VES, two new sub-categories were added in this section to improve the value of the data collected.

As shown in Figure 7, during whole blood collection, the main SAR in donors reported were vasovagal reactions followed by "other", nerve injury irritation and major cardiovascular event or death up to 24h after donation. The SAR reported during apheresis collection, were more heterogeneous. A small number of countries were not able to report the SAR in donors by category and those figures were categorised as 'undefined'.

[10] Annual summary for 2017: "Fatalities reported to FDA following blood collection and transfusion annual summary for FY2017"
https://www.fda.gov/media/124796/download

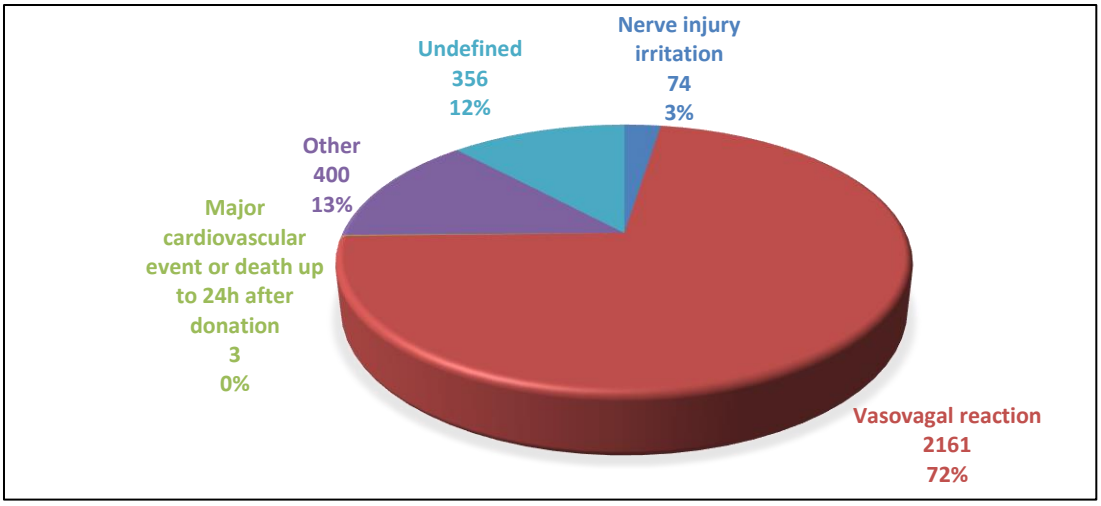

Figure 7. SAR in donors during whole blood collection.

Figure 8 shows that the main SAR in donors reported during apheresis collection were reported in the vasovagal reaction category, followed by “other”, undefined, nerve injury irritation, citrate reaction, allergic reaction and major cardiovascular event or death up to 24h after donation.

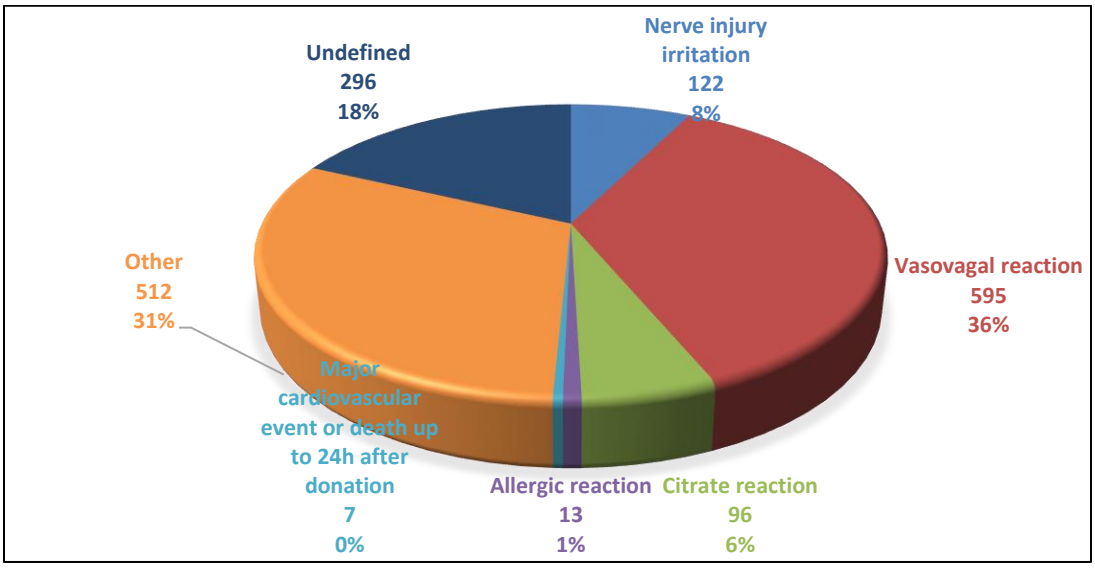

Figure 8. SAR in donors during apheresis.

Three deaths were reported by the reporting countries, one following apheresis donation, one following whole blood donation and one within 7 days after the donation without further information. In all cases, the investigations performed by the countries involved concluded that the death of the donor was not attributable to the donation. In the interest of providing complete information, the Commission and Member States considered that those cases should, nonetheless, be mentioned in this report.

3.4. Serious Adverse Events

3.4.1. Information by country

SAE were reported by 29 countries; the total number of SAE reported for 2017 was 2,920. It should be noted that nine countries (BG, CY, DK, HU, LT, LU, MT, RO and SK) reported that in 2017 there had been no reportable SAE. Those nine countries accounted for 1,166,566 units processed in 2017.

As regards the denominator for SAE, the total number of units processed, 28 countries (all but HU) reported a total of 27,244,855 units processed during 2017. Overall, considering this figure as denominator for SAE of those countries who reported any SAE in this exercise, the probability of SAE occurs with every 89,925 units of blood components processed.

It is noted that the number of SAE reported varied significantly between reporting countries, both in terms of rates and the criteria for inclusion. In this exercise, three countries submitted 69% of all SAE whereas 7 countries reported less than 10 SAE each. This suggests that further improvements should be made to the reporting criteria, with the collaboration of the Competent Authorities, to achieve a greater comparability of data, and interpretations should be given with caution.

3.4.2. Information by type of SAE

Overall, of the 2,920 SAE reported, incidents were linked to the following activity steps:

- **Whole blood collection**: 466 SAE
- **Apheresis collection**: 47 SAE
- **Donor selection:** 128 SAE
- **Testing of donations**: 129 SAE
- **Processing**: 99 SAE
- **Storage**: 331 SAE
- **Distribution**: 302 SAE
- **Materials:** 19 SAE
- **Other activity steps:** 1399 events (48% of reported SAE).

The new activity step, *donor selection*, was included in the reporting template, at the suggestion of the VES in order to obtain a more informative classification of SAE in the exercise. These data are presented in Figure 9.

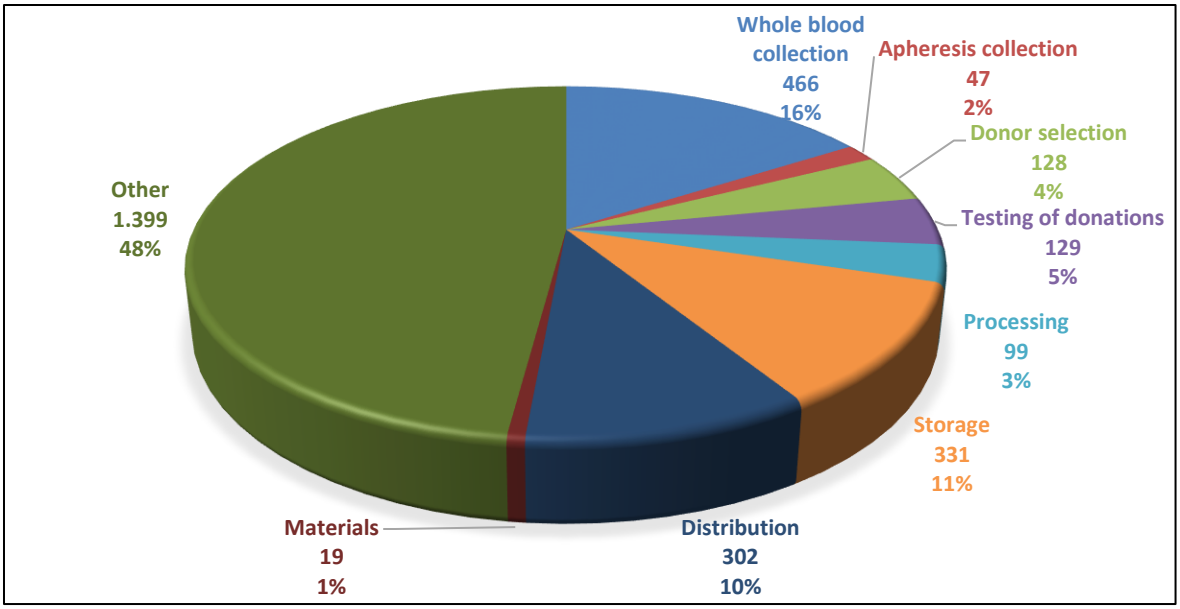

Figure 9. SAE per activity step; data 2017.

3.4.3. Information by specification of SAE

The 2,920 SAE were attributed to one of the following specifications:

- **Human Error**: 2,183 SAE
- **Equipment failure**: 279 SAE
- **Product defect**: 147 SAE
- **Other:** 311 SAE

These data are shown in Figure 10.

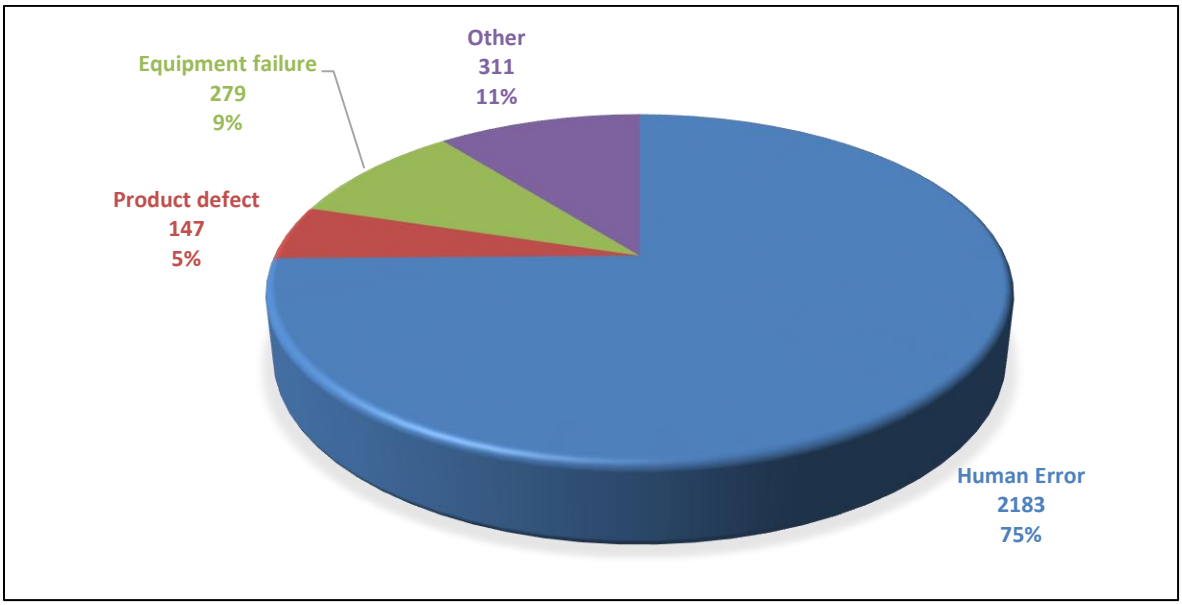

Figure 10. SAE by specification; data 2017.

The vast majority of the SAE (75%) were reported in the category of *Human error* without any further detail, and the process step most associated with SAE was the *Other* category. In order to facilitate improvement through learning from vigilance, consideration should be given to gathering more information in future exercises to better understand the causes of SAE reported in this exercise.

3. COMPARISON OF SARE REPORTING 2011-2017

Table 5 gives an overview of SARE reporting for 2011 to 2018 (data from 2010 to 2017).
In general, the numbers for each denominator have fluctuated from year to year: 23–25 million units issued, 12–21 million units transfused (with a slight decrease in the current exercise) and 2–4 million recipients transfused, which has slightly increased this year.

The number of SAR (at imputability level 2 or 3) reported increased from 2011 to 2014 (data from 2010 to 2013), decreased during the next 2 years, and now remains stable around 1,800 SAR. The same trend occurs for SAR of imputability 1 to 3, which has slightly increased in this latest exercise.
The number of deaths has remained relatively stable, in the range of 20-28, showing the efficacy of the measures implemented in the different vigilance systems by Member States.

For SAE, the numbers reported have varied over the years; this is probably the result of improved reporting by establishments and better awareness and training of staff involved in the process.

Finally, although SAR in donors is voluntarily reportable, the number has been increased over the years, reflecting the awareness in reporting countries of the importance of ensuring the safety of the healthy EU citizens who voluntarily decide to donate their blood and blood components to help others.

	2011		2012		2013		2014		2015		2016		2017		2018	
	Countries reporting	Number	Countries reporting	Number	Countries reporting	Number	Countries reporting	Number	Countries reporting	Number	Countries reporting	Number	Countries reporting	Number	Countries reporting	Number
Units issued	26	22,817,166	29	24,821,809	27	25,129,344	27	24,043,766	27	25,717,028	26	25,324,888	29[11]	24,827,516	29[11]	25,093,906
Units transfused	19	16,718,258	17	12,311,691	20	13,351,948	22	16,564,817	25	21,425,047	25	21,443,125	25	20,910,579	24	20,674,603
Recipients transfused	11	2,298,304	16	2,964,839	19	3,595,155	20	3,216,938	18	4,190,835	18	4,246,978	20	3,134,944	19	3,522,623
SAR (1-3)	30	2,449	30	3,133	30	3,519	30	2,831	30	2,441	31	2,587	30	2,950	29	3,114
SAR (2-3)	30	1,259	30	1,574	30	1,831	30	1,739	30	1,410	31	1,349	30	1,737	29	1,871
SAR death (2-3)	30	20	30	14	30	22	28	22	30	27	31	25	30	16	29	28
SAE	28	16,360	25	4,113	28	2,953	30	2,972	30	4,460	24	2,338	30	2,599	29	2,920
SAR in donors					18	2,494	23	2,470	20	3,723	23	7,769	23	7,658	23	4,635

Table 5. Overview of the 2011-2018 SARE reporting exercises (2010-2017 data).

[11] This figure includes the data from the 2 countries that reported only number of units transfused. It was considered that the number of units transfused must also have been issued prior to transfusion.

4. CONCLUSIONS

In the SARE 2018 annual reporting exercise, complete data (88 to 100%) was provided by 96% of the reporting countries (i.e. 28 out of 29). This represents a steady improvement in reporting by Member States compared to previous exercises. It also reflects the continuous work by the EDQM, the VES, the Member Statesand the Commission to improve data collection, to assist those countries which have difficulties in collecting reliable data and to improve the data analysis.

The *number of SAR* in recipients (imputability level 2 or 3) reported for 2017 was 1,871. This figure has slightly increased in comparison with the previous reporting exercise. Febrile non-haemolytic transfusion reactions (FNHTR) and anaphylaxis were the most frequent SAR. The majority of the SAR were related to the transfusion of red blood cells and platelets. However, as noted in previous exercises, considering that the data reported are partial, year-on-year comparisons should be interpreted with caution.

The number of *deaths* likely or certain to have resulted from blood transfusion in 2017 was 28. This figure has increased compared with previous years. It should be noted that of the 28 deaths reported, the majority were not attributable to the quality and safety of the blood component, but rather to clinical practice or to unforeseen reactions including anaphylaxis/hypersensitivity.

In the case of *number of SAE*, the reported figures have increased compared with previous exercises. It is noted that, on an individual Member State basis, a higher number of reported SAE may not necessarily imply an increased incidence of SAE but rather indicate a more reliable and accurate reporting system whereas a lower number may indicate underreporting. The large number of SAE reported as due to human error highlights the importance of performing root-cause analysis to determine why mistakes are made and to implement adequate preventive and corrective measures. It also demonstrates the need to create awareness among healthcare professionals of the importance of reporting and analysing those events.

The process step most associated with SAE was in the *Other activity steps* category. Reporting of SAE has revealed that there is a need to further clarify and improve the collection of SAE data overall to ensure that the reporting criteria are consistently applied.

Voluntary *reporting on donors*, which was introduced in 2012 and undertaken by a majority of countries in this reporting exercise, highlights the importance of also creating awareness about the safety of donors. Overall, the number of SAR for 2017 was 4,635. The main SAR in donors during whole blood collection were vasovagal reactions. During apheresis collection, the main SAR in donors were submitted in the vasovagal reactions category, the *other* category and nerve injury irritation. Performing this exercise has allowed Member States to increase awareness of the importance of monitoring the safety and quality of care of donors, those citizens who make transfusion medicine possible. The availability of these data provides the opportunity for further assessment of the underlying reasons for donor reactions and for the implementation of preventive measures to reduce them, assuring the safety of those EU citizens who generously decide to help others by donating blood.

Overall, the available data indicate that reporting is consistent with known effects and expected trends, with no new safety concerns regarding blood and blood components identified from national monitoring programmes.

Since 2017, through a contractual arrangements signed with the Commission, the EDQM is responsible for carrying out the verification and analysis of the blood and tissues and cells SARE exercises and drafting the final summary reports. Due to the expertise of the EDQM in the field of biovigilance and with international data collection activities, this collaboration has greatly contributed to improving the EU SARE exercise by helping refine the Common Approach document and reporting templates, increasing the quality of the data reported by the Member States through extensive data curation and verification and deeper data analysis and interpretation.

In addition, in January 2017, a Vigilance Expert Sub-group (a sub-group to the Competent Authorities on Substances of Human Origin Expert Group) was established by the Commission, in agreement with the Member States. The objective of this sub-group is to support the development and improvement of the SARE reporting system both at national and European Commission level. In addition, its work had also contributed to the evaluation of the legal frameworks on blood, tissues and cells, published in October 2019[12].

Finally, at European level the SARE exercise has allowed Member States to share experience and knowledge on haemovigilance. Individual countries should continue to use this exercise to evaluate the safety of their national blood sectors and to identify where issues occur and need to be addressed in order to improve the safety and quality of blood components across the EU.

[12] https://ec.europa.eu/health/blood_tissues_organs/policy/evaluation_en