



**SUMMARY OF THE 2020 ANNUAL REPORTING OF SERIOUS ADVERSE REACTIONS AND EVENTS  
FOR BLOOD AND BLOOD COMPONENTS  
(DATA COLLECTED FROM 01/01/2019 TO 31/12/2019)**

**1. EXECUTIVE SUMMARY**

Every year millions of European citizens benefit from blood transfusion as a result of different medical procedures supported by many healthcare specialities. However, the use of any substance of human origin carries some risk, particularly the possible transmission of diseases from the donor or other potential adverse effects to the recipient. These risks can be controlled and minimised by the application of a comprehensive set 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<sup>1</sup>, these must be monitored and reported at national and EU level through vigilance and surveillance programmes. For this purpose, the legislation defines Serious Adverse Reactions (SAR) as incidents where actual harm to a donor or patient has occurred, and Serious Adverse Events (SAE) as incidents where no harm has occurred but a risk of harm was detected.

Since 2008, in line with obligations defined in the legislation<sup>2</sup>, EU Member States, Iceland, Liechtenstein and Norway have submitted to the European Commission (hereinafter referred to as “the Commission”) annual vigilance reports on the notification of SAR which can occur in recipients of blood and blood components and SAE which can occur at any stage in the chain from donation to clinical application. Following the Directive, the Commission publishes an annual summary of the reports received, making it available to the Competent Authorities, healthcare professionals, stakeholders and the general public.

The Commission works with national Competent Authorities to standardise data collection procedures and to improve both the accuracy and the comparability of the information submitted on Serious Adverse Reactions and Events (SARE) at European level. 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. In addition, a Vigilance Expert Subgroup (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.

---

<sup>1</sup> 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.

<sup>2</sup> 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.

This report summarises the data submitted by the Member States during 2020 for the year 2019, draws general conclusions, and assesses the data in light of the information submitted in previous years.

The main findings of the 2020 reporting exercise are:

- Overall, 27 countries (25 EU Member States, Norway and the United Kingdom) reported in the SARE annual exercise. Of these, 21 countries indicated receiving complete data from their reporting establishments<sup>3</sup>.
- In relation to the number of units issued for transfusion<sup>4</sup>, over 22.8 *million units* of blood or blood components were reported by 27 countries. Partial data reported by 17 countries indicated that more than 3.2 *million patients were transfused*.
- Concerning *SAR in recipients*, 1 674 cases were reported for 2019 with imputability level 2 or 3 (likely, probably or certainly caused by the transfusion), which are the focus of further analysis in this report. Anaphylaxis, transfusion-associated circulatory overload (TACO) and febrile non-haemolytic transfusion reaction (FNHTR) were the most frequent SAR. The total number of SAR remains stable compared with previous exercises.
- The results also show that there were 26 *deaths* likely, probably or certainly resulting from blood transfusions in 2019. Compared with the previous exercises this number has increased slightly, but in general the figures remain stable. 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*, these amounted to 2 604 cases in 2019, reported by 27 countries. The reported figures have slightly decreased compared to the previous year, but in general terms they remain stable. Most of the SAE occurred due to human error (52%) and system failure (29%), which emphasises the importance of root-cause analysis to determine the best measures to avoid the repetition of SAE. It is important to note that SAE reporting rates vary considerably between countries.
- The reports submitted by 24 of the countries included information not only on recipients but also on *donors*, for whom 3 821 reactions were reported on a voluntary basis. It is important to collect these data and use them to further assess the underlying causes in order to better protect citizens who volunteer to donate blood.

---

<sup>3</sup> 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”.

<sup>4</sup> It should be noted that the data from 4 countries included only the units reported as transfused. It is evident that the number of units transfused must also have been issued prior to transfusion, and hence they have been included in the total.

## 2. DATA COLLECTION METHODOLOGY

This report provides a summary of the data reported to the Commission during 2020 by 25 EU Member States<sup>5</sup>, Norway and the United Kingdom<sup>6</sup> pertaining to the reporting period from 1 January to 31 December 2019. It also includes a comparison with the data from previous years and provides general conclusions determined from the analysis performed.

The Commission provided the following tools to the participating authorities to promote a standardised approach to data reporting:

- 1) An electronic reporting template (template version 3.0) to be sent to a DG SANTE-hosted database.
- 2) The Common Approach document (version 6) 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 recommendations and guidance to Member States when reporting. The Common Approach has been regularly updated to improve the data reporting methodology and clarify points of ambiguity. This has resulted in a gradual increase in the quality and accuracy of the data collected from Member States.

Since December 2018 the Commission and the Council of Europe/European Directorate for the Quality of Medicines & HealthCare (EDQM) signed a grant agreement for the latter to carry out the verification and analysis of the SARE data reported by Member States and the drafting of the summary report of the SARE exercise.

At the end of 2020 and the beginning of 2021, the EDQM started contacting reporting countries, when needed, in order to clarify and verify the accuracy of the reported data. Subsequently, the EDQM performed a detailed analysis of the verified information in close co-operation with the Commission and Member States, and drafted this report.

Before publishing this summary report, the data and analysis were disseminated and revised by the designated Competent Authorities for Blood.

## 3. MAIN FINDINGS OF THE 2020 DATA COLLECTION

### 3.1. General comments

Country reports were received from 25 EU Member States, Norway and the United Kingdom, comprising aggregated data from 4 009 reporting facilities.

It should be noted that not all countries were able to provide 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.

---

<sup>5</sup> Belgium did not submit data in this exercise. Luxembourg submitted their data after the deadline, and consequently they have not been included in this analysis.

<sup>6</sup> The withdrawal of the United Kingdom from the European Union included a transition period which ended on 31 December 2020, so their data has been included in this report. More info: [https://ec.europa.eu/info/sites/default/files/brexit\\_files/info\\_site/substances\\_of\\_human\\_origin\\_en.pdf](https://ec.europa.eu/info/sites/default/files/brexit_files/info_site/substances_of_human_origin_en.pdf)

Regarding data completeness, 21 countries reported receiving complete data, 5 countries received 85-99% 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 provide a comprehensive picture of SARE for blood and blood components. Therefore, general conclusions extracted from this report should be interpreted with caution.

**3.2. Denominators**

Twenty-five EU Member States, Norway and the United Kingdom submitted their national data, thereby complying with the annual report submission requirement established by Article 8 of Directive 2005/61/EC.

Regarding the **units of blood components issued**, 23 countries (AT, BG, CY, CZ, EE, EL, FI, FR, HR, HU, IE, IT, LT, LV, MT, NL, PL, PT, RO, SE, SI, SK and UK) provided data. The 4 remaining countries (DE, DK, ES and NO) did not report the number of units issued, but did provide the number of units transfused. As in previous exercises, it is considered that all units transfused must have previously been issued, hence the numbers for units transfused have been included in the total number of units reported issued.

A total of 22 863 118 units of blood and blood components were reported as issued in 2019. Figure 1 show the breakdown of units issued by component type (including the transfused data from DE, DK, ES and NO).

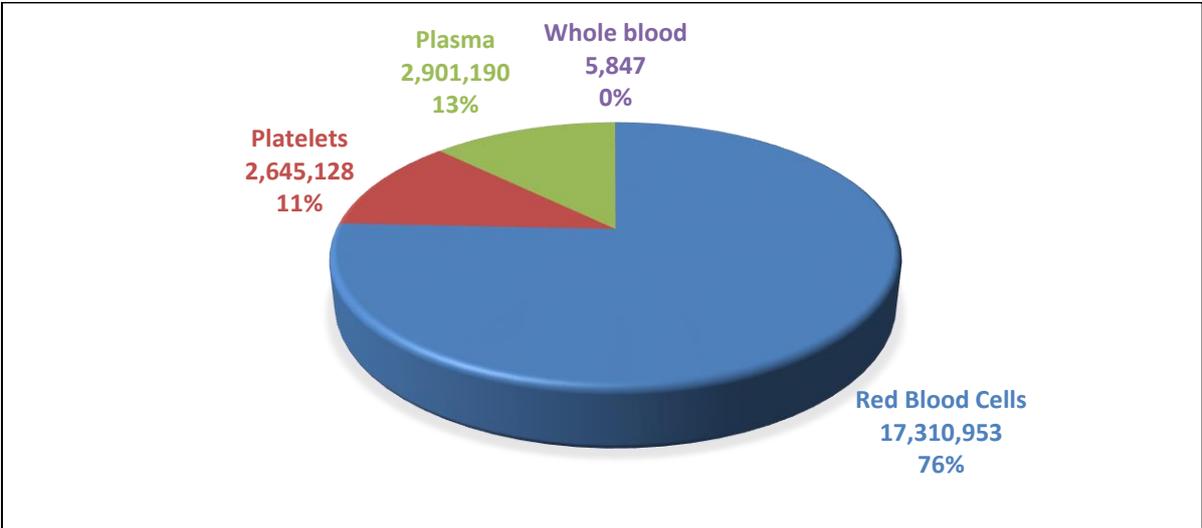


Figure 1: Units issued<sup>7</sup> per blood component (absolute values and percentages); data 2019.

Twenty-five countries (all but DK and EL) also provided the total number of whole blood collections made during the year, amounting to 17 407 743. In the case of apheresis collection, 26 countries (all but DK) provided the number of collections during the year, amounting to 5 789 033. Both figures are similar to those provided in previous exercises.

<sup>7</sup> Including data on units transfused from DE, DK, ES and NO.

Concerning the **units of blood components transfused**, 19 334 629 units were reported as transfused by 22 countries (AT, BG, CY, CZ, DE, DK, EE, EL, ES, FR, HR, IE, IT, LV, MT, NL, NO, PT, RO, SE, SK and UK). The data for units transfused per blood component are depicted in Figure 2.

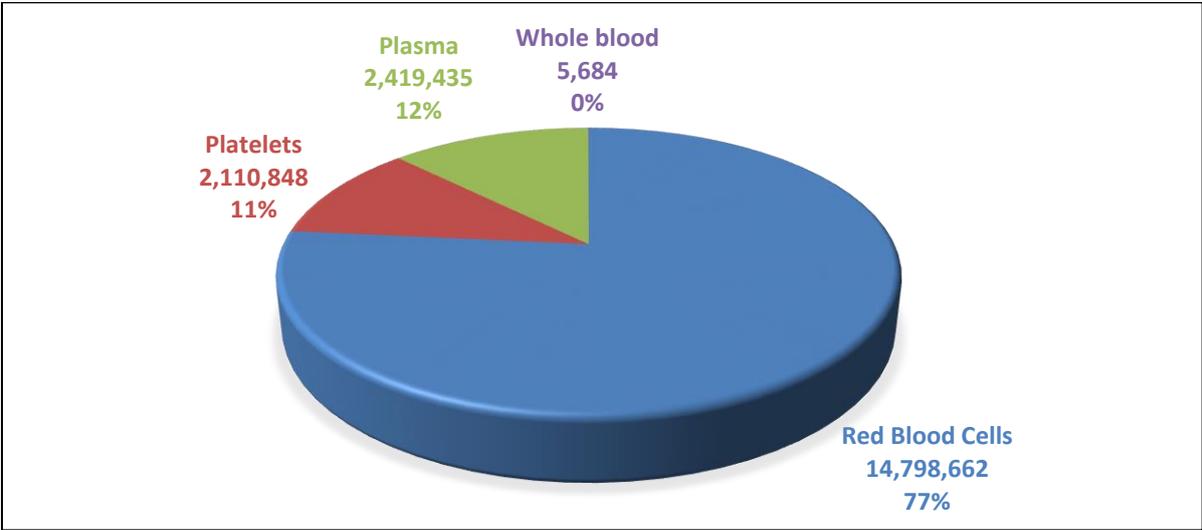


Figure 2. Units transfused per blood component; absolute values and percentages); data 2019.

Regarding **recipients transfused**, 3 228 635 patients were transfused in 2019 according to the reports. These are partial figures provided by 14 countries (AT, CY, CZ, DK, FR, IE, IT, HR, MT, NL, PT, ES, SE and UK) reporting a total of 2 954 750 recipients transfused by blood component type (Figure 3) and 3 countries (BG, EE and RO) which reported the total number of recipients regardless of component type transfused, amounting to 273 885.

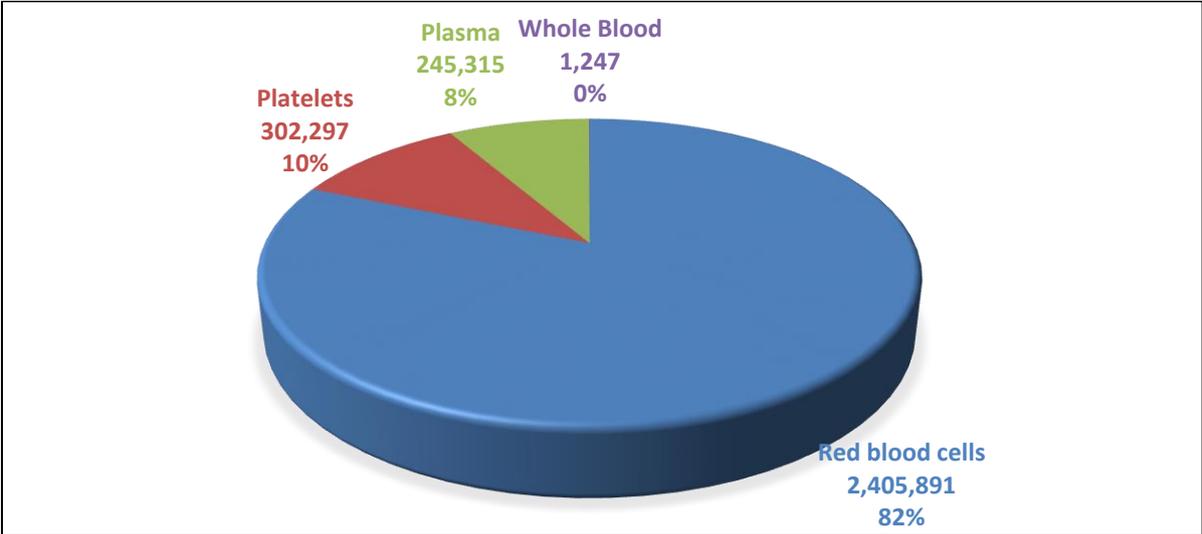


Figure 3. Recipients transfused per blood component; data 2019.

### 3.3. Serious Adverse Reactions in recipients

#### 3.3.1. Information by country

In 2019, a total of 2 625 SAR with imputability level of 1 to 3 were reported in the exercise. It should be noted that 7 countries (CY, EE, ES, IT, LV, NO and SE) did not report any SAR of imputability level 1.

Directive 2005/61/EC prescribes that reporting establishments must notify the Competent Authority of all relevant information about at least SAR of imputability level 2 or 3. According to 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<sup>8</sup>.

During 2019, a total of 1 674 SAR at imputability level 2 or 3 were reported. Of those, 1 303 were submitted as level 2 and 371 were reported as level 3.

Of the SAR reported, 26 resulted in death (21 deaths following red blood cell transfusion and 5 to platelet transfusion).

Taking into account the data provided from those countries who were able to provide the number of SAR and units transfused per blood component, overall there were 12 061 units transfused per SAR of imputability level 2 or 3. More information about this is given in section 3.3.2. This figure remains stable in comparison with previous exercises. However, these figures should also be interpreted with caution, as many reports are still partial and there are differences between countries when reporting denominators and SAR.

#### 3.3.2. Information by blood component

Of the 1 674 SAR of imputability level 2 or 3 reported:

- 902 SAR were related to **red blood cells**
- 456 SAR were related to **platelets**
- 251 SAR were related to **plasma**
- 8 SAR were related to **whole blood**
- 57 SAR were related to **more than one blood component**

Figure 4 and Table 1 show the percentage of SAR and number of units transfused per blood component per SAR (from those countries who were able to provide the number of SAR and units transfused per blood component), respectively.

---

<sup>8</sup> Article 5, para 3a of Directive 2005/61/EC and Annex II Part B.

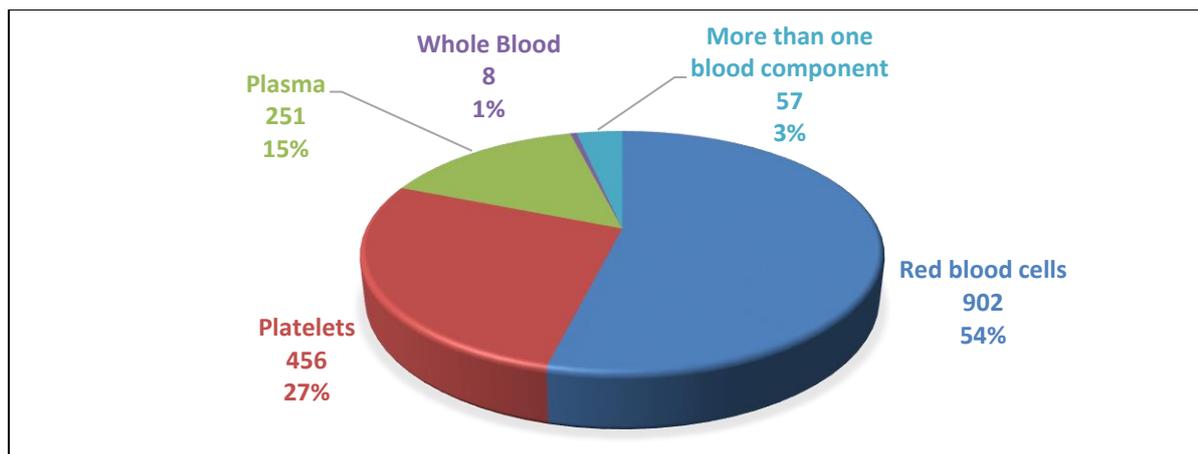


Figure 4. Percentage of SAR of imputability 2 or 3<sup>9</sup> per blood component (absolute values and percentages); data 2019.

Component type	Units transfused per SAR
Red blood cells	17 187
Platelets	4 786
Plasma	10 295
Whole blood	710

Table 1. Units per component type transfused per SAR (absolute numbers); data 2019.

As some participating countries reported partial data, these figures should be interpreted with caution.

### 3.3.3. Information by category of SAR

The 1 674 SAR (imputability level 2 or 3<sup>9</sup>) reported were classified as follows:

- Anaphylaxis/hypersensitivity: 708 cases
- Transfusion-associated circulatory overload (TACO): 281 cases
- Febrile non-haemolytic transfusion reaction (FNHTR): 273 cases
- Immunological haemolysis: 134 cases, of which
  - 24 cases due to ABO incompatibility and
  - 110 cases due to other alloantibodies
- Transfusion-related acute lung injury (TRALI): 29 cases
- Transfusion-associated dyspnoea (TAD): 27 cases
- Non-immunological haemolysis: 20 cases
- Transfusion-transmitted viral infection: 20 cases
- Transfusion-transmitted bacterial infection: 18 cases
- Post-transfusion purpura: 2 cases
- Transfusion-transmitted parasitic infection: 1 case
- Graft-versus-host disease: 1 case
- Other: 160 cases

<sup>9</sup> According to 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.

These data and the percentage of SAR per category are shown in Figure 5.

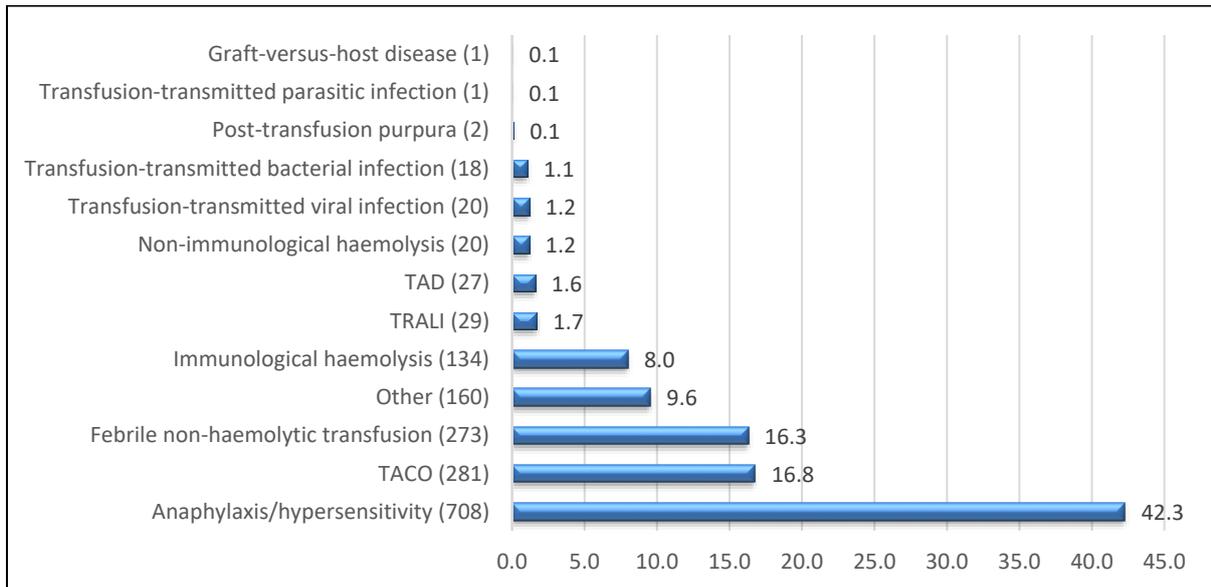


Figure 5. Number of SAR of imputability 2 or 3<sup>9</sup> per category (absolute values and percentages); data 2019.

### 3.3.4. Recipient deaths

Among the 1 674 cases of SAR reported of imputability level 2 or 3 there were 26 deaths, see Figure 6. These occurred as follows:

- 10 were associated with immunological haemolysis, representing 38% of all deaths reported. Of these, 4 were reportedly due to ABO incompatibility and 6 due to other alloantibodies; these deaths were associated with red blood cell transfusion in all cases.
- 7 were associated with TACO following red blood cell transfusion. This number represents 27% of all reported deaths.
- 3 were associated with TRALI following platelet transfusion. This number represents 12% of all reported deaths.
- 2 were associated with viral transmission (one transmission of parvovirus B19 and one of HBV) following platelet transfusion in one case and red blood cell transfusion in the other. This number represents 8% of all reported deaths.
- 1 was associated with non-immunological haemolysis following red blood cell transfusion. This number represents 4% of all reported deaths.
- 1 was associated with transmitted bacterial infection following platelet transfusion. This number represents 4% of all reported deaths.
- 1 was associated with transmitted parasitic infection (malaria) following red blood cell transfusion. This number represents 4% of all reported deaths.
- 1 was reported under the “other” category following the transfusion of red blood cells. This number represents 4% of all reported deaths.

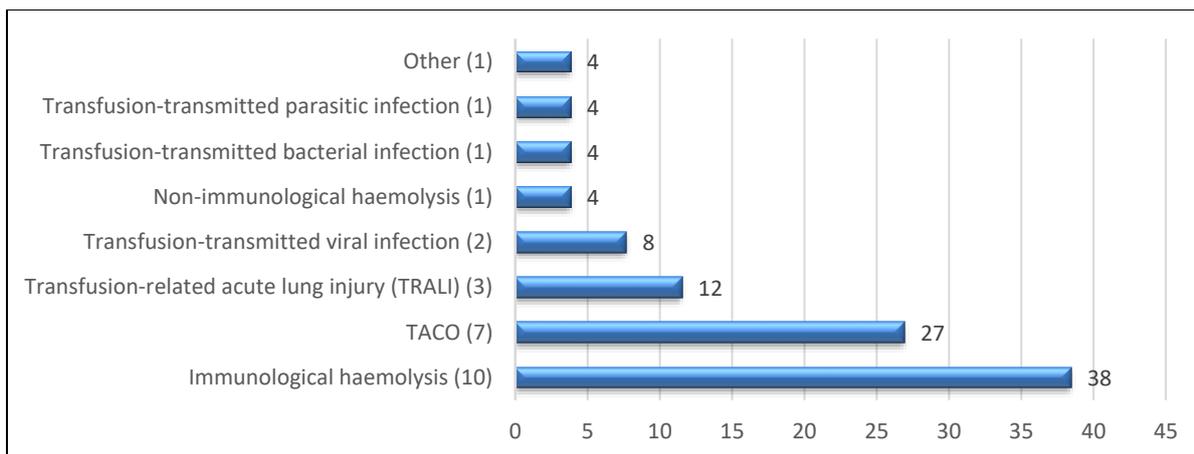


Figure 6. Deaths reported by SAR type of imputability level 2 or 3<sup>9</sup> (absolute values and percentages); data 2019.

EU Directive 2005/61/EC does not require countries to provide data concerning SAR of imputability level 1. This level means that evidence is insufficient to attribute adverse reactions either to the quality and safety of blood and blood components or to alternative causes.

In this exercise, 4 countries (FI, HU, NL and UK) voluntarily reported 9 deaths within this level (4 related to red blood cell transfusion, 1 related to plasma and 4 related to transfusion of more than one blood component); these data are shown in Figure 7. Although these are partial data, and should therefore be interpreted with caution, it was deemed appropriate to include them within this section, as the safety of transfused patients is considered essential by the Commission and all reporting countries.

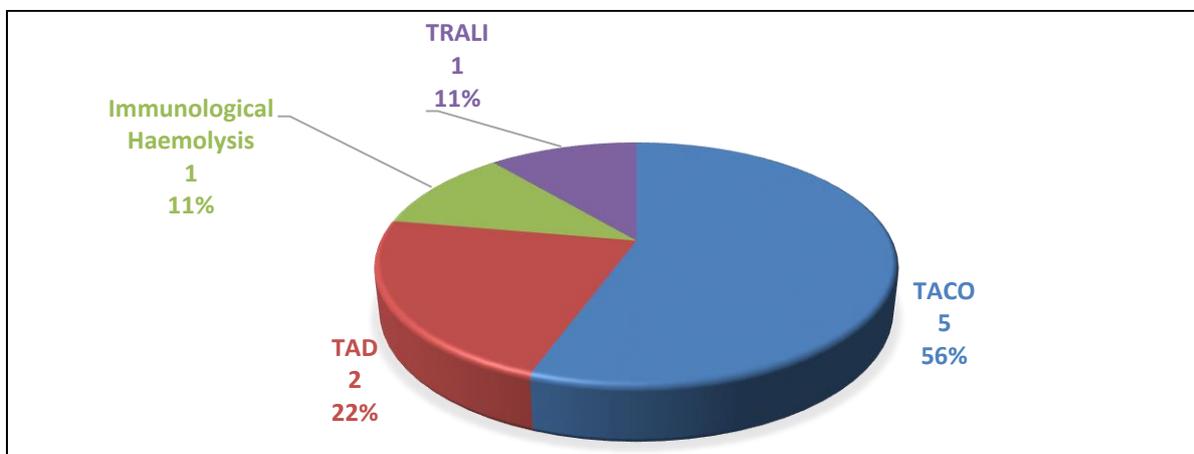


Figure 7. Deaths reported by SAR type of imputability level 1 (absolute values and percentages); data 2019.

As in previous exercises, the Commission compares the results obtained with those reported by the United States Food and Drug Administration (FDA), which publishes an annual summary of “Fatalities reported to FDA following blood collection and transfusion”<sup>10</sup>. The figures provided in that report allow some general comparisons to be made with the annual vigilance reports on SARE submitted by EU and

<sup>10</sup> Annual summary for fiscal year 2019: “Fatalities reported to FDA following blood collection and transfusion annual summary for FY2019” <https://www.fda.gov/media/147628/download>

EEA countries to the Commission. During 2019 there were 20 transfusion-related fatalities reported to the FDA. TACO and haemolytic transfusion reactions (non-ABO) were the most reported fatalities. In Europe, the information submitted in the SARE reporting exercise for 2020 (data from 2019) indicates similar results, where the highest number of deaths related to the transfusion of blood and blood components were due to immunological haemolysis and TACO.

**3.4. Serious Adverse Events**

**3.4.1. Information by country**

The total number of SAE reported for 2019 was 2 604. This figure was provided by 27 countries. Of these, 4 countries (LT, MT, RO and SK) reported no SAE in this exercise.

As regards the denominator for SAE, the *total number of units processed*, a total of 22 525 782 units were processed during 2019. This figure was provided by 25 countries (all except DK and ES). An overview of comparative data by reporting year is presented in Figure 8.

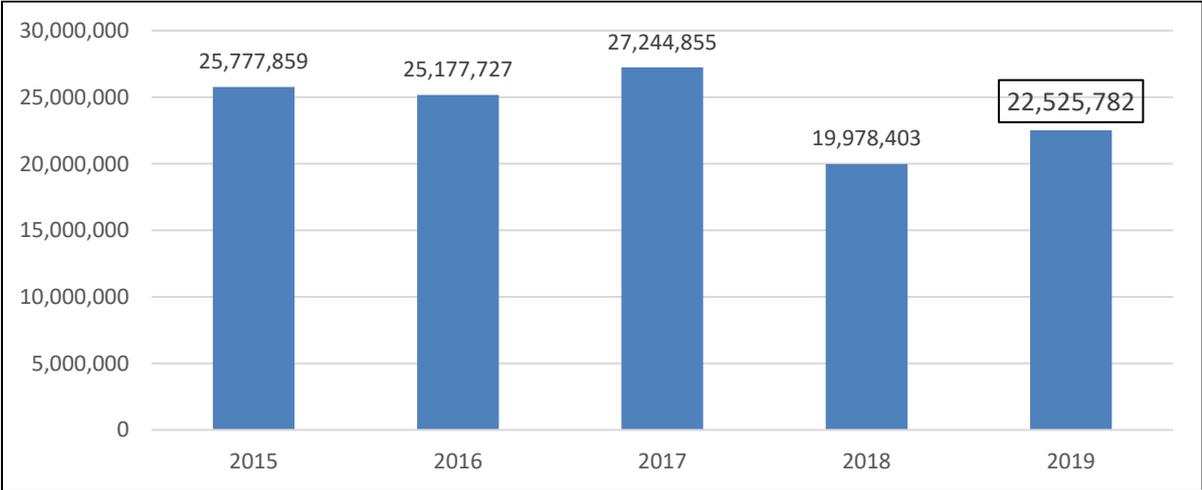


Figure 8. Total number of blood units processed: 2015-2019 comparative data.

Considering this figure as the denominator for SAE, the probability of a SAE occurring was once for every 8 650 units of blood components processed.

It is worth noting that the number of SAE reported varied substantially between reporting countries, both in terms of rates and the criteria for inclusion. In this exercise, one country reported 45% of all SAE whereas around 10 countries reported less than 10 SAE each. Hence, interpretations should be given with caution.

**3.4.2. Information by type of SAE**

In the previous exercise, following a suggestion from the VES in collaboration with the Competent Authorities, new SAE activity steps were incorporated. These were: component selection (i.e. the selection of the appropriate component by the blood establishment or hospital blood bank based on the recipient’s needs), compatibility testing/cross-matching (referring to procedures for serological investigation of the intended recipient's blood group and compatibility testing carried out before

transfusion by a blood establishment or hospital blood bank) and issue (which refers to the provision of blood or blood components by a blood establishment or a hospital blood bank for transfusion to a recipient). The aim of these modifications was to obtain a clearer classification of SAE in the exercise.

Of the 2 604 SAE reported, incidents were linked to the following activity steps:

- **Donor selection:** 346 SAE
- **Whole blood collection:** 207 SAE
- **Apheresis collection:** 50 SAE
- **Testing of donations:** 60 SAE
- **Processing:** 133 SAE
- **Storage:** 342 SAE
- **Distribution:** 126 SAE
- **Component selection:** 319 SAE
- **Compatibility testing/cross-matching:** 294 SAE
- **Issue:** 258 SAE
- **Other activity steps:** 469 SAE

These data are presented in Figure 9.

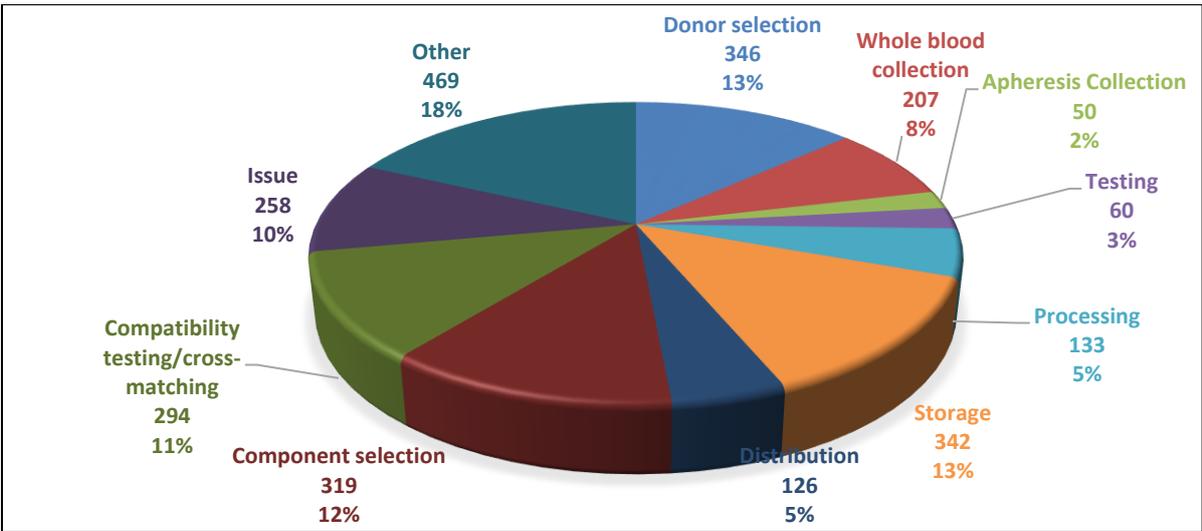


Figure 9. SAE per activity step (absolute numbers and percentages); data 2019.

The main reported activity step was the "other" category (18%) followed by donor selection (13%) and storage (13%). The reporting countries have adapted to the modifications included in the template, and in this exercise the proposed new activity steps are starting to reflect those changes.

**3.4.3. Information by specification of SAE**

As part of the ongoing objective to harmonise the reporting of SAE, a new specification “system failure” was included in this reporting exercise following a suggestion by the VES in collaboration with the Competent Authorities. This category is aimed at identifying SAE occurring when the quality management system fails due to insufficient training or education, high workload or pressure,

incompetent staffing or insufficient staff skill-mix, or inadequate processes, procedures or documentation; the category “human error” should be used once an investigation has ruled out failure of the system.

The 2 604 SAE were attributed to one of the following specifications:

- **Component defect:** 106 SAE
- **Equipment failure:** 198 SAE
- **System failure:** 750 SAE
- **Human error:** 1 368 SAE
- **Materials:** 11 SAE
- **Other:** 171 SAE

These data are shown in Figure 10.

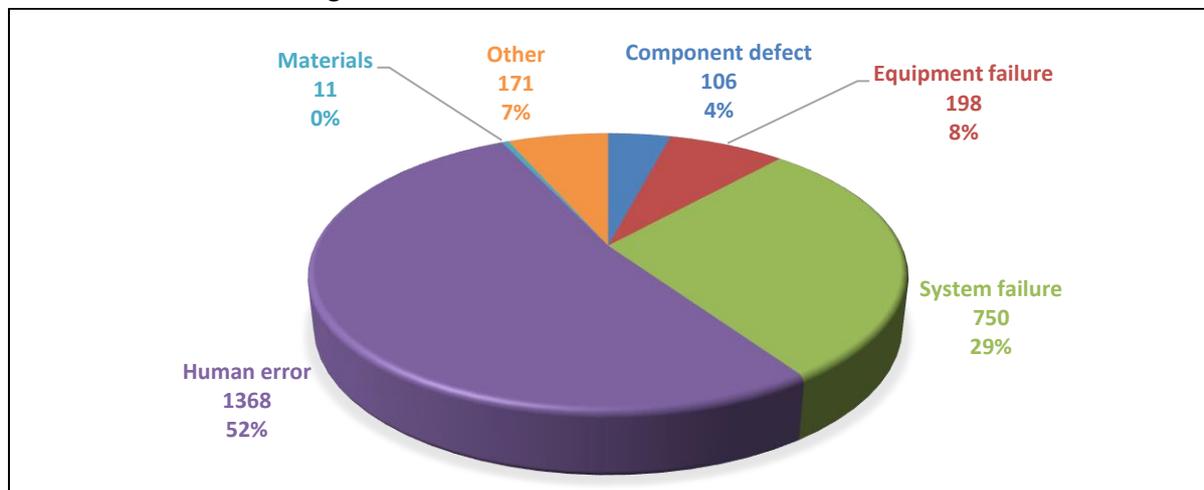


Figure 10. SAE by specification (absolute numbers and percentages); data 2019.

The majority of the SAE (52%) were reported within the category of human error, followed by the new category “system failure”, which accounted for 29% of all reported events. It should be noted that the number of reported SAE due to human error, although still high, has decreased in comparison with previous exercises. This reflects the efforts made by reporting countries to adapt to the new classification suggested by the VES, which has enabled to improve the quality of the data reported.

### 3.5. SAR in donors

According to Directive 200/61/EC, SAR in donors are not reportable unless they impact on the quality and safety of the blood components<sup>11</sup>. However, acknowledging the value of data on SAR in donors, the Commission invites Member States to submit these reactions on a voluntary basis, and thus a specific section “SAR in donors of blood or blood components” can be found in the reporting template. In general, SAR in donors should be reported if they were certainly or probably caused by the donation (imputability 2 or 3). However, for donor fatalities, all cases of imputability 1, 2 or 3 should be reported where the fatality is possibly, probably or certainly related to the donation process.

<sup>11</sup> Article 5 of Directive 2005/61/EC.

Twenty-four countries (AT, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, IE, IT, LT, NL, NO, PL, PT, RO, SE, SI, SK and UK) reported, on a voluntary basis, a total of 3 821 SAR in donors. This figure has decreased in comparison with previous exercises, reflecting that the modifications to the reporting template are helping the harmonisation of these data. An overview of the comparative data from SARE exercises from 2016 to 2020 (2015-2019 data) is presented in Figure 11.

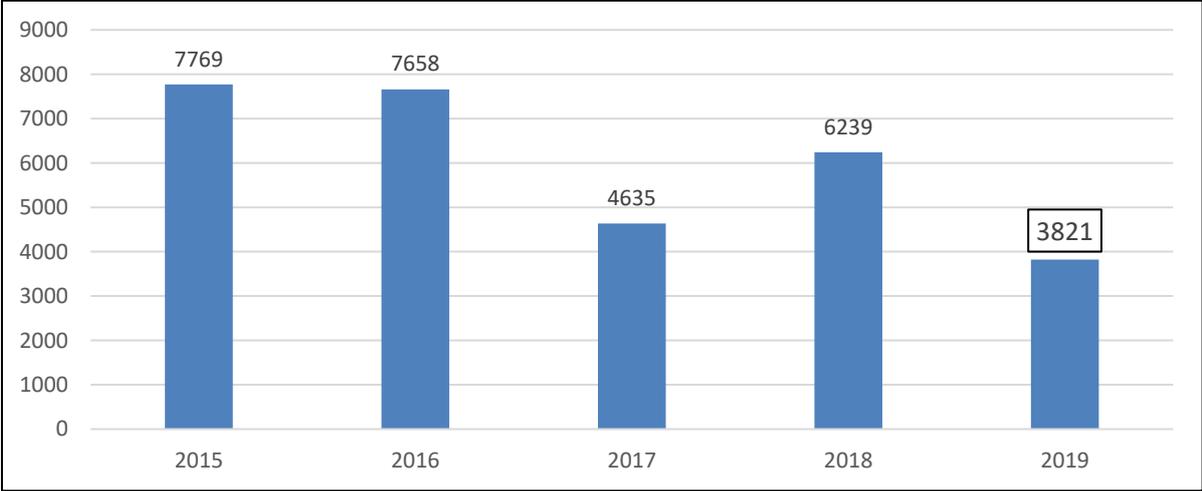


Figure 11. SAR in donors (absolute numbers): 2015-2019 comparative data.

As shown in Figure 12, during *whole blood collection* the main SAR in donors reported were vasovagal reactions followed by "other" and nerve injury irritation, whereas during *apheresis collection* the main SAR reported were vasovagal reactions followed by the "other" category and citrate reaction, see Figure 13.

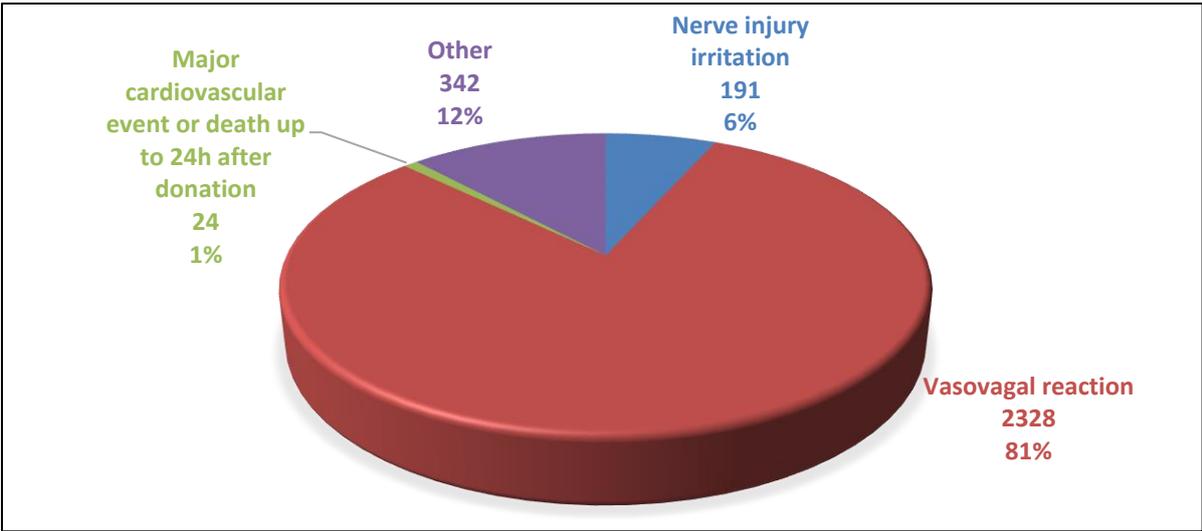


Figure 12. SAR in donors during whole blood collection (absolute numbers and percentages); data 2019.

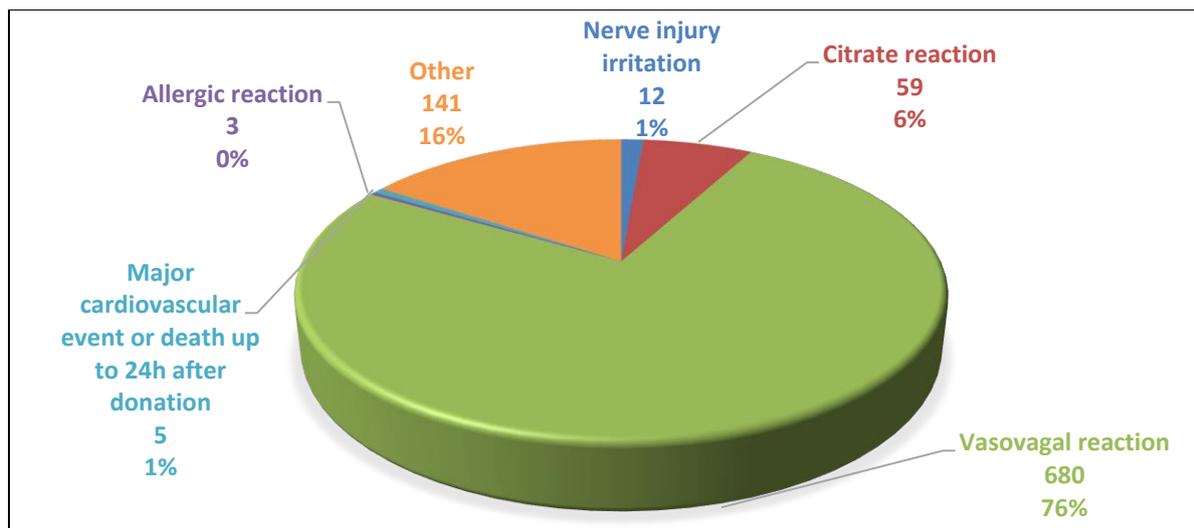


Figure 13. SAR in donors during apheresis collection (absolute numbers and percentages); data 2019.

It should be noted that, although the data is collected on voluntary basis, there is variability between countries in the reporting of SAR in donors. Due to this heterogeneity, reactions in donors notified by one Member State were not able to be included in Figures 12 or 13 due to the unavailability of information on the type of donation (i.e. apheresis or whole blood).

No donor deaths were reported during 2019.

#### 4. CONCLUSIONS

Taking into account the trends of previous SARE exercises, vigilance systems and national data collection in the field of haemovigilance are improving year after year. However, there are areas that still require further work and harmonisation, as not all countries were able to provide 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.

In the SARE 2020 annual reporting exercise, complete data was provided by 78% of the reporting countries (i.e. 21 out of 27) and a further 5 countries contributed 85-99% of the expected data. This reflects the continuous work of the EDQM, the VES and the Commission to improve data collection, assist those countries which have difficulties in collecting reliable data and improve the data analysis. Further improvement of the situation would require additional efforts from Member States to adapt and obtain more accurate and complete activity data from blood establishments. The creation of new categories within the SARE exercise facilitates more consistent reporting, which ultimately contributes to the collection of more reliable and comparable data.

The *number of SAR* in recipients (imputability level 2 or 3) reported for 2019 was 1 674. This figure has increased slightly in comparison with the previous reporting exercise but overall the numbers remain stable. Anaphylaxis/hypersensitivity and TACO were the most frequent SAR. The vast majority of the reported SAR were related to the transfusion of red blood cells (54%) and platelets (27%).

The number of *deaths* likely or certain to have resulted from blood transfusion in 2019 was 26. This figure has increased slightly compared with previous exercises. Immunological haemolysis and TACO were the most reported SAR that led to death. However, it should be noted that of the 26 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.

Quality management systems are aimed at preventing errors and maintaining a consistent standard of agreed specification. However, occasionally, residual risks or procedural errors may result in failures or situations in which donors or recipients are unintentionally exposed to risk. Instances of non-compliance with the quality system should be documented and investigated as part of the internal quality system management. On occasion, however, a particular non-compliance incident may be of such importance that it should be considered as SAE and reported through the European vigilance system. In the case of *number of SAE*, the reported figures have decreased slightly compared with previous exercises, but remain within the same range. It should be noted that, on an individual Member State basis, a higher number of reported SAE may not necessarily indicate an increased incidence of SAE but rather a more reliable and accurate reporting system, whereas a lower number may indicate under-reporting. The majority of SAE reported were due to human error and system failure, which highlights the importance of performing root-cause analysis to determine the ultimate cause of these SAE. Raising awareness among healthcare professionals of the importance of reporting, analysing and learning from these events is essential.

The number of SAR in donors reported for 2019 was 3 821. This number has decreased compared with previous exercises. This is probably due to a modification included in this category for the previous exercise, allowing the reporting countries to have a more harmonised approach. The main SAR in donors during both whole blood and apheresis collection were vasovagal reactions followed by the "other" category. This exercise has increased awareness in Member States of the importance of monitoring the safety and quality of donor care. 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.

Generally, 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 agreement signed with the Commission, the EDQM has been responsible for carrying out the verification and analysis of the blood and tissues and cells SARE exercises and for drafting the final summary reports. This collaboration has greatly contributed to improving the EU SARE exercise by helping refine the Common Approach document and reporting template forms. In addition, in January 2017, the Vigilance Expert Subgroup was established by the Commission, in agreement with the Member States. The objective of this subgroup is to support the development and improvement of the SARE reporting system both at national and Commission level.

Furthermore, the work of the VES also contributed to the Commission's evaluation of the legal frameworks on blood, tissues and cells, published in October 2019.<sup>12</sup>

The SARE exercise allows Member States to improve their vigilance requirements and data collection in the field of blood transfusion while taking the opportunity to share experience and knowledge with other European countries. Member States are making efforts to improve their vigilance systems and the quality and accuracy of data submitted to this exercise. However, there is still a significant degree of under-reporting and over-reporting by some Member States, thus, general conclusions extracted from this report should be interpreted with caution. 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.

Annex 1. Overview of the 2011-2020 SARE reporting exercises (2010-2019 data).

---

<sup>12</sup> [https://ec.europa.eu/health/blood\\_tissues\\_organs/policy/evaluation\\_en](https://ec.europa.eu/health/blood_tissues_organs/policy/evaluation_en)

	2011		2012		2013		2014		2015		2016		2017		2018		2019		2020	
	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 <sup>13</sup>	24 827 516	29 <sup>13</sup>	25 093 906	28 <sup>14</sup>	22 922 191	27 <sup>14</sup>	22 863 118
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	24	19 310 224	22	19 334 629
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	19	3 262 767	17	3 228 635
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	28	2 538	27	2 625
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	28	1 687	27	1 674
SAR death (2-3)	30	20	30	14	30	22	28	22	30	27	31	25	30	16	29	28	28	20	27	26
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	28	2 770	27	2 604
SAR in donors					18	2 494	23	2 470	20	3 723	23	7 769	23	7 658	23	4 635	24	6 239	24	3 821

<sup>13</sup> This figure includes the data from the 2 countries that reported only the number of units transfused. It was considered that the number of units transfused must also have been issued prior to transfusion.

<sup>14</sup> This figure includes the data from the 4 countries that reported only the number of units transfused. It was considered that the number of units transfused must also have been issued prior to transfusion.