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 2019 ANNUAL REPORTING OF SERIOUS ADVERSE REACTIONS AND EVENTS FOR BLOOD AND BLOOD COMPONENTS (DATA COLLECTED FROM 01/01/2018 TO 31/12/2018)

1. 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 possible transmission of infectious diseases from the donor 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[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], 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 Serious Adverse Reactions (SAR) which may occur in recipients of blood and blood components and Serious Adverse Events (SAE) which may occur in the chain from donation to clinical application.

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.

This report summarises the data submitted by the Member States during 2019 for the year 2018 and assesses the data in light of the information submitted in previous years.
The main results of the 2019 reporting exercise are:

[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.

- Overall, 28 countries (27 EU Member States and Norway) reported in the SARE annual exercise. Of these, 20 countries indicated receiving complete data from their reporting establishments[3].

- In relation to the number of units issued for transfusion[4], 22.9 *million units* of blood or blood components were reported by 28 countries. Partial data reported by 19 countries indicated that over 3.3 *million patients were transfused*.

- Concerning *SAR in recipients*, 1 687 cases were reported for 2018 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 decreased compared with previous exercises. This is partly explained by the fact that no data were received from one Member State that had reported in previous exercises. Febrile non-haemolytic transfusion reaction and anaphylaxis were the most frequent SAR.

- The results also show that there were 20 *deaths* likely or certainly resulting from blood transfusions in 2018. Compared with previous exercises this number has moderately decreased. This decrease may also be explained by the lack of information of the Member State that reported in previous exercises. 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 2 770 cases in 2018, reported by 26 countries. The reported figures have also slightly decreased compared to those of the previous year. Most of the SAE occurred due to human error (70%), 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 6 239 reactions were reported on a voluntary basis. It is important to collect these data and to further assess the underlying causes in order to better protect citizens who volunteer to donate blood, thus making transfusion possible.

2. DATA COLLECTION METHODOLOGY

This document provides a summary report of the data collected during 2018 (from 1 January to 31 December) and submitted to the Commission in 2019 by Norway and 27 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:

[3] 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".

[4] It should be taken into account that in the data from 4 countries, only the units reported as transfused have been included. It is evident that the number of units transfused must also have been issued prior to transfusion.

1) An electronic reporting template to be sent to a DG SANTE-hosted database. The electronic reporting template used in 2019 (for 2018 data) was version 2.6.5;

2) The Common Approach document (version 5.5) for the definition of reportable SAR and SAE ("Common Approach") attached to the electronic reporting template. The aim of the document is to provide guidance to Member States when reporting. First published in 2008, the Common Approach has been regularly updated to improve the data reporting methodology and clarify points of ambiguity. This has in turn resulted in a gradual increase in the quality and accuracy of the data collected from Member States.

In 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 beginning of 2020, the EDQM started contacting reporting countries when needed in order to clarify and verify the accuracy of the reported data, and performed the detailed analysis of the information presented in this report.

Before publishing this summary report, the data contained were presented at the meeting of the Competent Authorities for Blood and Blood Components in February 2020 and disseminated among Competent Authorities for verification. This gave the reporting 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.

3. MAIN FINDINGS OF THE 2019 DATA COLLECTION

3.1. General comments

For the 2019 exercise (data reported in 2018), the electronic reporting template was slightly modified following the recommendations of the Vigilance Expert Sub-Group (a sub-group of the Competent Authorities on Substances of Human Origin Expert Group). This group was created by the Commission, and also involves representatives of the EDQM in charge of the SARE exercise. It has the aim of supporting the development and improvement of the SARE reporting system.

For this exercise, *materials* has been moved from the activity step list to the SAE specific list. In addition, new activity steps where a SAE may occur have been incorporated. These are *component selection, compatibility testing/cross-matching* and *issue.*

Country reports were received from 27 EU Member States and Norway, comprising aggregated data from 3 834 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.

Regarding data completeness, 20 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

represent a comprehensive picture of SARE for blood and blood components. Therefore, conclusions should be interpreted with caution.

3.2. Denominators

27 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.

Regarding the **units of blood components issued,** 24 Member States (AT, BG, CY, CZ, EE, EL, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK and UK) provided data. The four remaining countries (DE, DK, 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 previously been issued, their numbers for units transfused have been included in the total number of units reported issued. A total of 22 922 191 units of blood and blood components were reported as issued in 2018. This figure is lower than that of previous years, probably due to the lack of reporting on the number of issued units by a country with very high activity that was reporting this number in the past; in addition to the already mentioned lack of submission of data from a Member State that was reporting in previous years. Figure 1 and Table 1 show the breakdown of units issued by component type (including the transfused data from DE, DK, ES and NO).

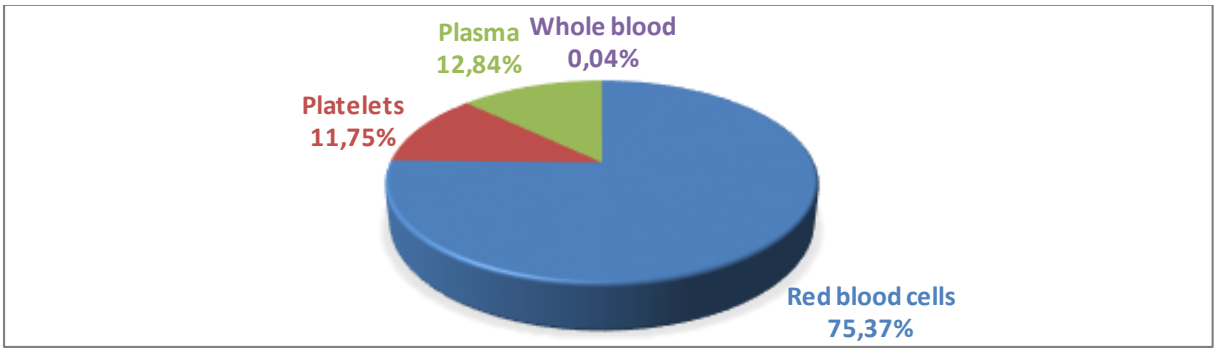

Figure 1: Units issued[5] (per blood component); data 2018.

Component type	Units issued
Red blood cells	17 276 260
Platelets[6]	2 694 324
Plasma	2 943 508
Whole blood	8 099
Total	**22 922 191**

Table 1. Number of units issued per blood component; data 2018.

Twenty-four countries (all but DK, EL, HU and MT) also provided the total number of whole blood collections made during the year, amounting to 17 174 443. In the case of apheresis collection, 25

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

countries (all but DK, HU and MT) provided the number of collections during the year, amounting to 5 387 919. Both figures are similar to the numbers provided in previous exercises.

Concerning the **units of blood components transfused**, there were 19 310 224 units reported as transfused by EU and EEA countries (AT, BG, CY, CZ, DE, DK, EE, EL, ES, FR, HR, IE, IT, LT, LU, LV, MT, NL, PT, RO, SE, SK, UK and NO). The data for units transfused per blood component are depicted in Figure 2 and Table 2.

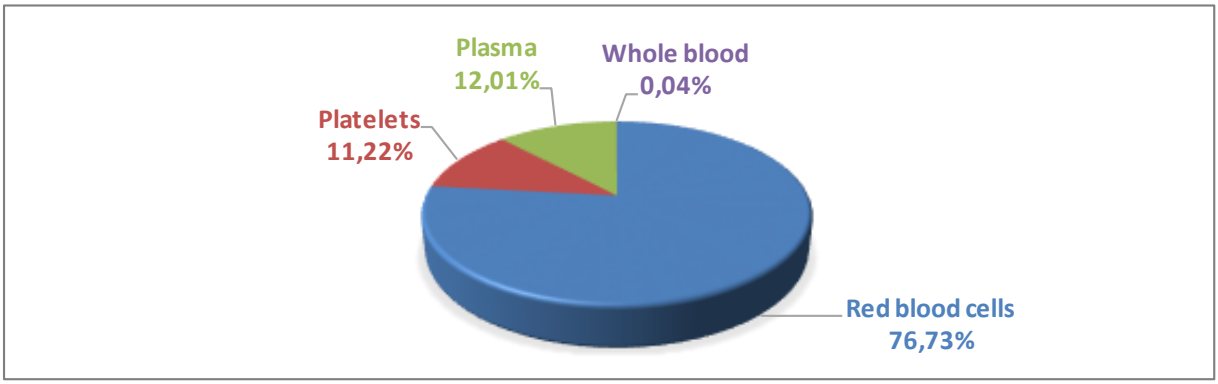

Figure 2. Units transfused (per blood component); data 2018.

Component	Units transfused
Red blood cells	14 817 559
Platelets[5]	2 165 675
Plasma	2 319 530
Whole blood	7 460
Total	**19 310 224**

Table 2. Number of units transfused per blood component; data 2018.

Regarding **recipients transfused**, 3 262 767 patients were transfused in 2018 according to the reports. These are partial figures provided by 19 countries (AT, BG, CY, CZ, EE, EL, ES, FR, IE, IT, HR, LT, LU, MT, NL, PT, RO, SE, UK) which 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.

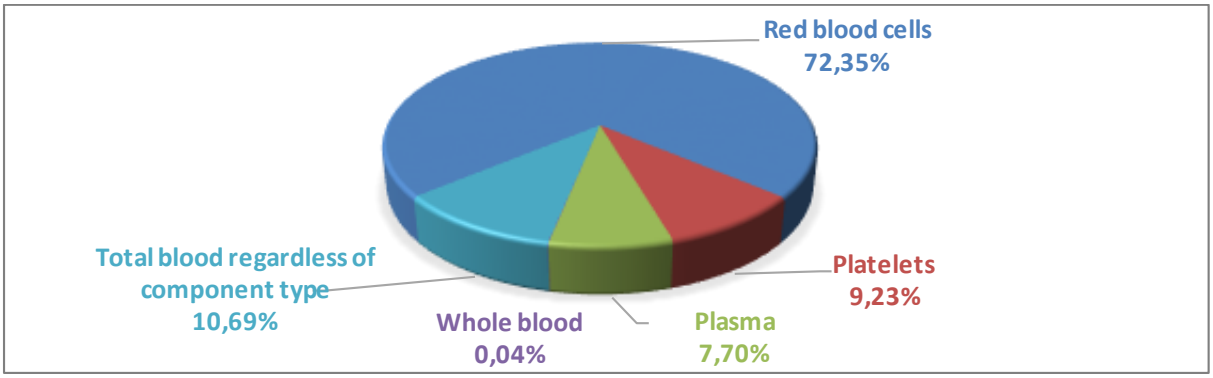

Figure 3. Recipients transfused per blood component; data 2018.

Component	Recipients transfused
Red blood cells	2 360 679
Platelets	300 994
Plasma	251 235
Whole blood	1 191
Total blood regardless of component type[7]	348 668
Total	**3 262 767**

Table 3. Number of recipients transfused per blood component; data 2018.

3.3. Serious Adverse Reactions in recipients

3.3.1. Information by country

In 2018, a total of 2 538 SAR with imputability level of 1 to 3 were reported in the exercise. However, 6 countries (ES, HR, IT, LU, RO and SE) did not report any SAR of imputability level 1.

Directive 2005/61/EC establishes that reporting establishments must notify the Competent Authority of 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[8].

During 2018, a total of 1 687 SAR at imputability level 2 or 3 were reported. Of these, 20 resulted in death (13 deaths linked to red blood cell transfusion, 5 to platelet transfusion, 1 to whole blood transfusion and 1 to transfusion with more than one blood component).

For the countries that provided data for the number of SAR and units transfused per blood component, there were 12 031 units transfused per SAR of imputability level 2 or 3.

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 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 1 687 SAR of imputability level 2 or 3 reported:

- 975 SAR were related to **red blood cells**
- 434 SAR were related to **platelets**
- 234 SAR were related to **plasma**
- 1 SAR was related to **whole blood**

[7] Five 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.
[8] Article 5, para 3a of Directive 2005/61/EC.

- 43 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.

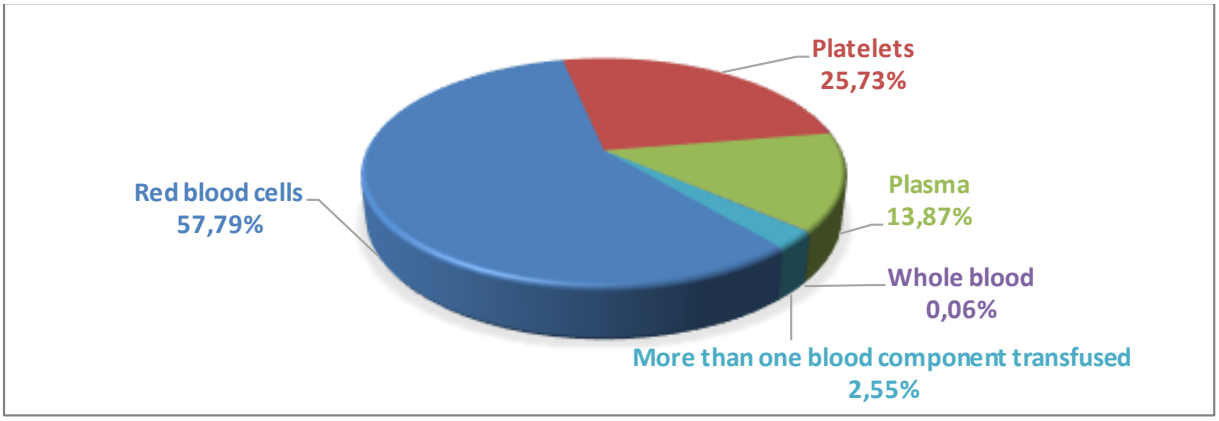

Figure 4. Percentage of SAR (imputability 2-3) per blood component; data 2018.

Component type	Units transfused per SAR
Red blood cells	15 950
Platelets	5 144
Plasma	10 838
Whole blood	7 460

Table 4. Units per component type transfused per SAR; data 2018.

3.3.3. Information by category of SAR

The 1 687 SAR (imputability level 2 or 3) reported were classified as follows:

- Febrile non-haemolytic transfusion reaction (FNHTR): 384 cases
- Anaphylaxis/hypersensitivity: 331 cases
- Transfusion-associated circulatory overload (TACO): 280 cases
- Immunological haemolysis: 134 cases, of which
  - 28 cases due to ABO incompatibility and
  - 106 cases due to other alloantibodies
- Transfusion-associated dyspnoea (TAD): 40 cases
- Transfusion-related acute lung injury (TRALI): 48 cases
- Transfusion-transmitted viral infection: 13 cases
- Transfusion-transmitted bacterial infection: 7 cases
- Non-immunological haemolysis: 6 cases
- Post-transfusion purpura: 2 cases
- Other: 442 cases

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

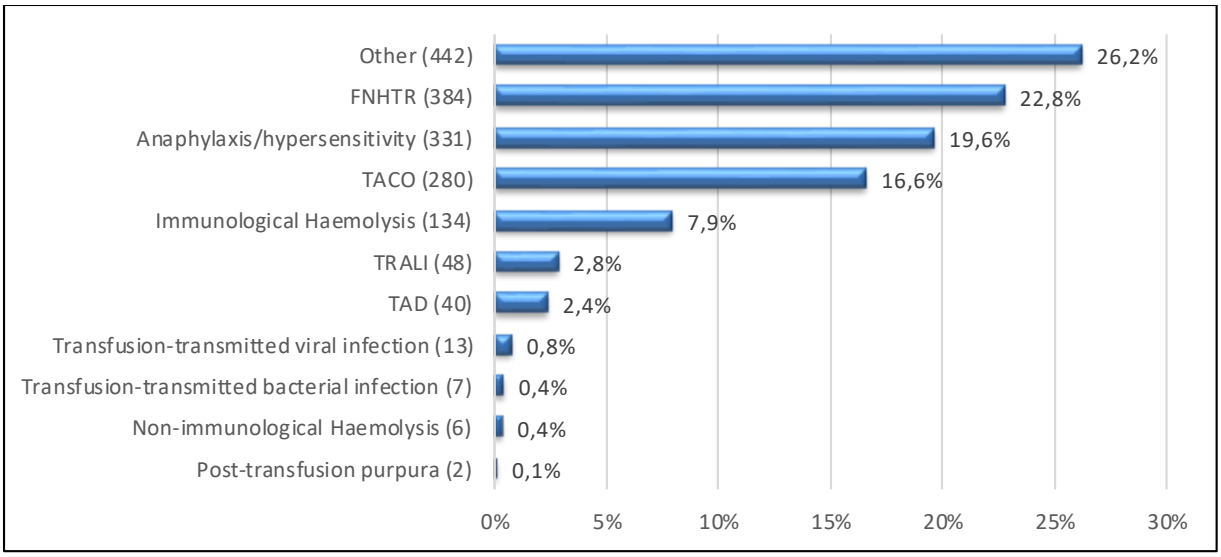

Figure 5. Percentage of SAR (imputability 2-3) per category; data 2018.

3.3.4. Recipient deaths

Among the 1 687 cases of SAR reported of imputability level 2-3 there were 20 deaths, as follows:

- 4 were associated with immunological haemolysis, representing 20% of all deaths reported. Of these, three were reportedly due to ABO incompatibility and 1 due to other alloantibodies; these deaths were associated with red blood cell transfusion in 3 cases and with transfusion of more than one blood component in the other case. These numbers represent 15% and 5% of all reported deaths, respectively.
- 1 was associated with non-immunological haemolysis following red blood cell transfusion. This number represents 5% of all reported deaths.
- 3 were associated with TRALI, one with red blood cell transfusion, another with platelet transfusion and the other one with transfusion of more than one blood component. This number represents 15% of all reported deaths.
- 6 were associated with TACO following red blood cell transfusion. This number represents 30% of all reported deaths.
- 2 were associated with bacterial transmission, both following platelet transfusion. This number represents 10% of all reported deaths.
- 1 was associated with post-transfusion purpura following whole blood transfusion. This number represents 5% of all reported deaths.
- 3 were reported under the “other” category, following the transfusion of red blood cells (2), and platelets (1). This number represents 15% of all reported deaths.

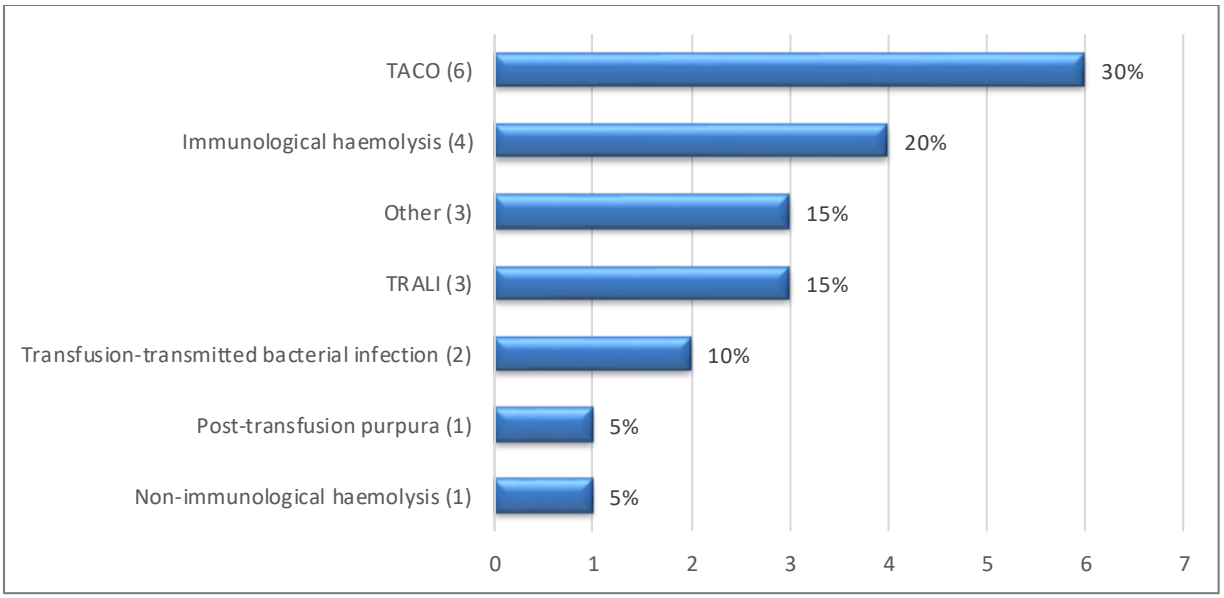

Figure 6. Type of SAR (imputability level 2-3); data 2018.

It should be highlighted that Directive 2005/61/EC does not require countries to provide data concerning SAR of imputability level 1. However, 3 countries (FR, NL and UK) voluntarily reported 12 deaths within this level (9 related to red blood cell transfusion, 1 related to platelets and 2 related to more than one blood component transfused); the type of SAR reported is shown in Figure 7. Imputability level 1 means that 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 within this section, as the safety of transfused patients is considered paramount by the Commission and all reporting countries.

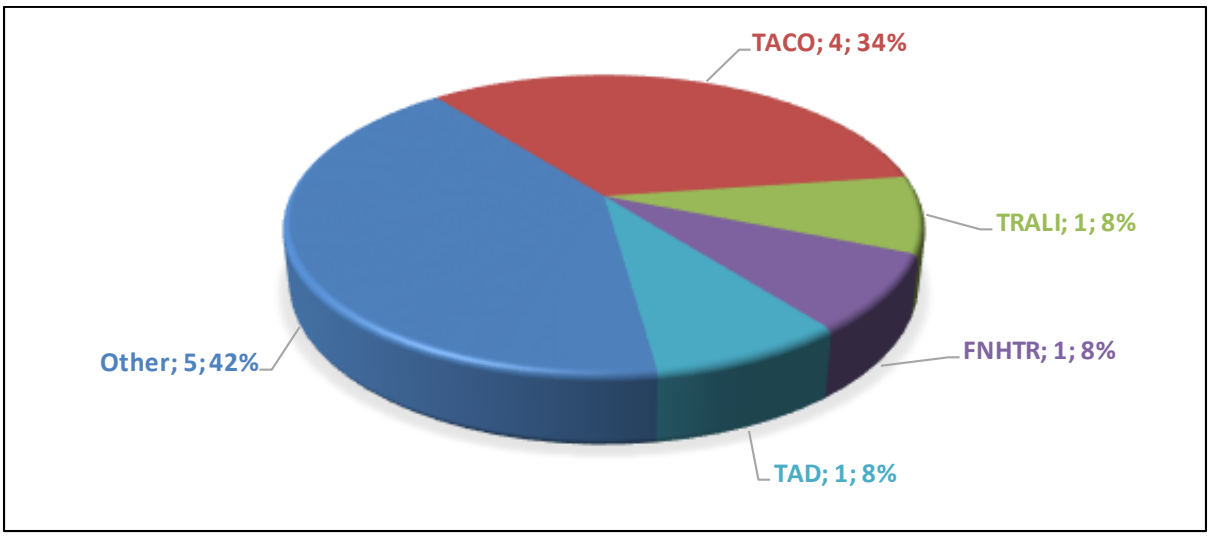

Figure 7. Type of SAR (imputability level 1); data 2018.

The United States Food and Drug Administration (FDA) publishes an annual summary of "Fatalities reported to FDA following blood collection and transfusion"[9]. 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 2018, there were 31 transfusion-related fatalities reported to the FDA. TACO and bacterial and viral contamination caused the highest number of reported fatalities, followed by haemolytic transfusion reactions, TRALI and anaphylaxis. In Europe, the information submitted in the SARE reporting exercise for 2019 (data from 2018) shows similar results, the highest number of deaths related to the transfusion of blood and blood components was due to TACO, immunological haemolysis, TRALI and other category.

3.4. Serious Adverse Events

3.4.1. Information by country

SAE were reported by 26 countries; the total number of SAE reported for 2018 was 2 770. It should be noted that two countries (SK and RO) reported that in 2018 there had been no reportable SAE. Those two countries accounted for 634 873 units processed in 2018.

As regards the denominator for SAE, the total number of units processed, 24 countries (all except DK, HU, MT and ES) reported a total of 19 978 403 units processed during 2018. Overall, considering this figure as denominator for SAE of those countries who reported any SAE in this exercise, the probability of a SAE occurring is once every 7 253 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, two countries reported 71% of all SAE whereas 8 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 2 770 SAE reported, incidents were linked to the following activity steps:

- **Whole blood collection**: 495 SAE
- **Component selection**: 350 SAE
- **Storage**: 318 SAE
- **Donor selection:** 250 SAE
- **Issue:** 225 SAE
- **Compatibility testing/cross-matching:** 201 SAE
- **Testing of donations**: 119 SAE
- **Distribution:** 105 SAE
- **Processing**: 71 SAE

[9] Annual summary for fiscal year 2018: "Fatalities reported to FDA following blood collection and transfusion annual summary for FY2018"
https://www.fda.gov/media/136907/download

- **Apheresis collection**: 47 SAE
- **Other activity steps:** 589 events (21% of reported SAE)

As mentioned previously, in this exercise, *materials* has been moved from the activity step list to the SAE specific list. In addition, new activity steps where a SAE may occur have been incorporated: *component selection, compatibility testing/cross-matching* and *issue*, at the suggestion of the Vigilance Expert Sub-group with the collaboration of the Competent Authorities, in order to obtain a clearer classification of SAE in the exercise. These data are presented in Figure 8.

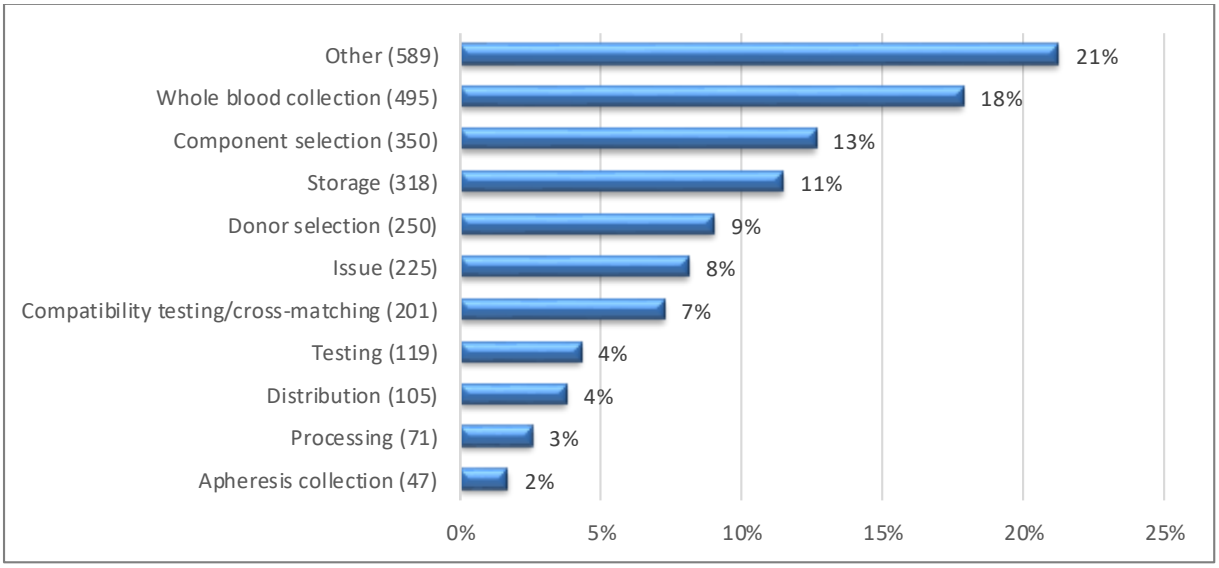

Figure 8. SAE per activity step; data 2018.

3.4.3. Information by specification of SAE

The 2 770 SAE were attributed to one of the following specifications:

- **Human error**: 1 950 SAE
- **Equipment failure**: 316 SAE
- **Component defect**: 125 SAE
- **Materials**: 111 SAE
- **Other:** 268 SAE

These data are shown in Figure 9.

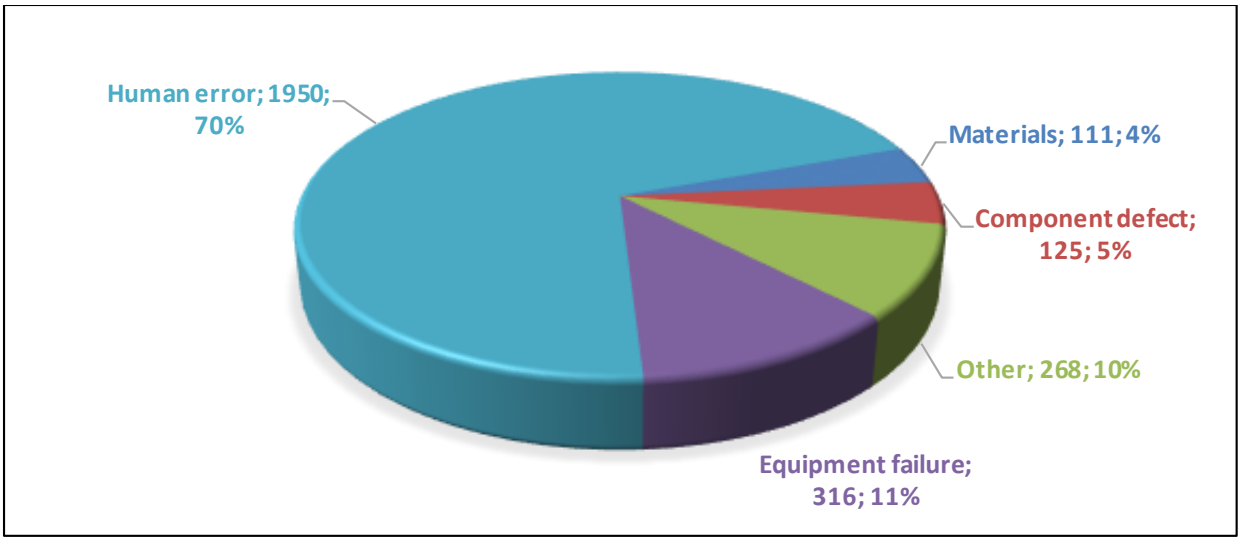

Figure 9. SAE by specification; data 2018.

The vast majority of the SAE (70%) were reported within 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 within the *Other* category.

3.5. SAR in donors

Several Member States and EEA collect information on SAR in donors at a national level. The Commission recognises the value of these data and invites Member States to submit these reactions on a voluntary basis. Accordingly, a specific box "SAR in donor of blood and blood components" can be found in the SARE template. In general, SAR in donors should be reported if they were definitely or probably caused by the donation (imputability 2 or 3). Concerning reports where SAR in donors are confirmed to be fatal, total number of fatalities should be reported. A table giving the most commonly reported types of SAR in donors is included in the template since 2018. If it was not possible to report donor reactions by these categories, Member States were invited to provide just the total number, leaving this table blank

Twenty-four countries (AT, BG, CY, CZ, DE, DK, EL, ES, FI, FR, HR, IE, IT, LU, MT, NL, NO, PL, PT, RO, SE, SI, SK and UK) reported, on a voluntary basis, a total of 6 239 SAR in donors.

It should be noted that there is considerable variability between countries in the reporting of SAR in donors. However, in contrast to SAR in recipients, countries are not requested to report the imputability level of SAR in donors and, as stated above, there is no legally binding requirement to report this denominator. Therefore, there are no homogeneous criteria for countries when reporting. Due to this heterogeneity in reporting, for the detailed analysis of the data, 45 reactions in donors notified by RO could not be taken into account as no details were provided on the reactions that occurred. In addition, 43 reactions in donors notified by UK could not be considered due to the unavailability of information on the type of donation (i.e. apheresis or whole blood).

As shown in Figure 10, 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*, whereas during apheresis collection the SAR reported were more heterogeneous.

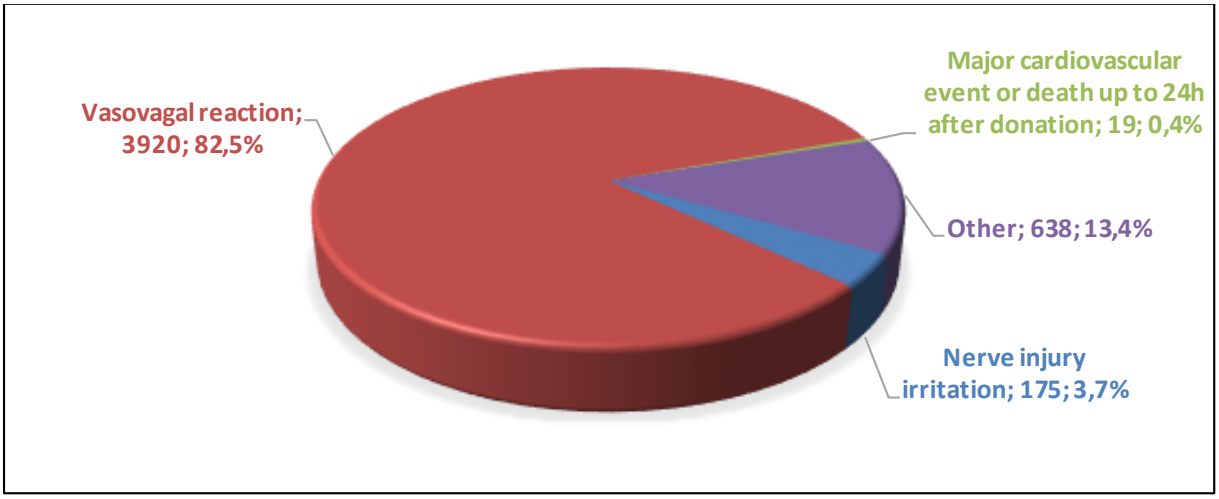

Figure 10. SAR in donors during whole blood collection; data 2018.

Figure 11 shows that the main SAR in donors reported during apheresis collection of blood components was *vasovagal reaction*, followed by those reported in the *other* category, followed by *citrate reaction, nerve injury irritation, major cardiovascular event or death up to 24h after donation* and *allergic reaction.*

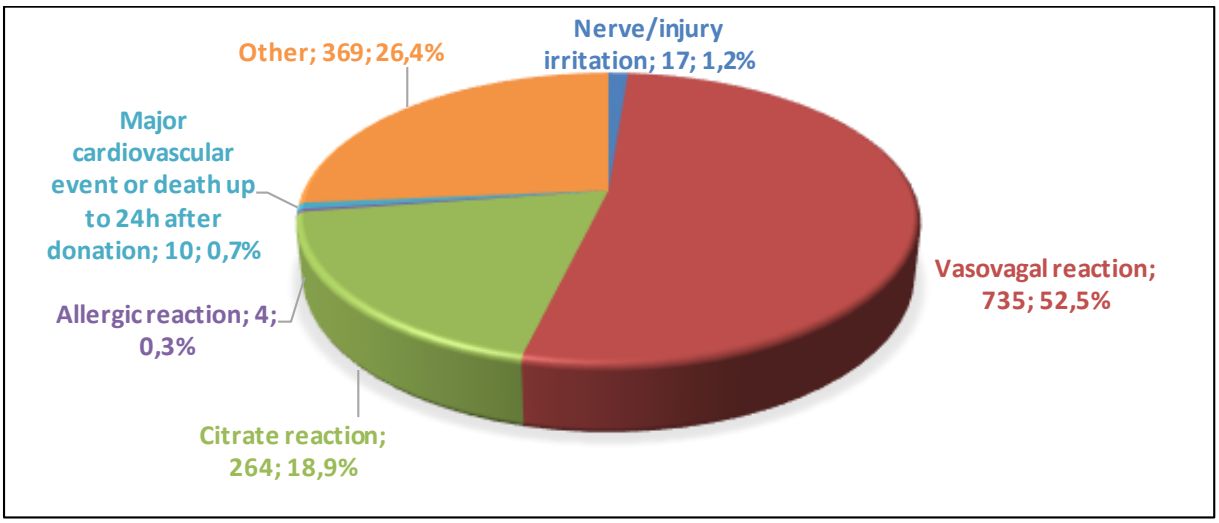

Figure11. SAR in donors during apheresis; data 2018.

No deaths were reported.

4. COMPARISON OF SARE REPORTING 2011-2018

Table 5 gives an overview of SARE reporting for 2011 to 2019 (data from 2010 to 2018).

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 decrease in the current exercise) and 2–4 million recipients transfused, which has slightly decreased this year compared with the previous one.

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 since then has remained stable at around 1 700 SAR. The same trend occurs for SAR of imputability 1 to 3, which has slightly decreased in this latest exercise. This reflects the efforts made by all participating countries to implement and improve their biovigilance systems year by year.

The number of deaths has remained relatively stable, at around 20-28, showing the efficacy of the safety and quality measures implemented in the different blood establishments among Member States.

For SAE, the numbers reported have varied over the years, probably as a 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 regularly been reported over the years, reflecting the increased awareness among countries of the safety of the healthy EU citizens who voluntarily decide to donate their blood in order to save others.

	2011		2012		2013		2014		2015		2016		2017		2018		2019	
	Countries reporting	Number	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[10]	24 827 516	29[10]	25 093 906	28[11]	22 922 191
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
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
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
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
SAR death (2-3)	30	20	30	14	30	22	28	22	30	27	31	25	30	16	29	28	28	20
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
SAR in donors					18	2 494	23	2 470	20	3 723	23	7 769	23	7 658	23	4 635	24	6 239

Table 5**.** Overview of the 2011-2019 SARE reporting exercises (2010-2018 data).

[10] 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.

[11] 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.

5. CONCLUSIONS

In the SARE 2019 annual reporting exercise, complete data (88 to 100%) were provided by 89% of the reporting countries (i.e. 25 out of 28). This represents continuity in reporting trends by Member States compared with previous exercises. It also reflects the continuous work carried out by the EDQM, the Vigilance Expert Sub-Group and the Commission to improve data collection, to assist those countries which have difficulties in collecting reliable data and to improve the data analysis. In the same line, Member States are doing efforts to adapt rapidly to the new modifications included in the template. The creation of new categories of SAE allows for a more homogeneous reporting, which ultimately contributes to collecting more reliable and comparable data.

The *number of SAR* in recipients (imputability level 2 or 3) reported for 2018 was 1 687. This figure has slightly decreased in comparison with the previous reporting exercise. It should be highlighted that FNHTR and anaphylaxis were the most frequent SAR, and the majority of the SAR were related to the transfusion of red blood cells and platelets. However, as mentioned in previous exercises, considering that the data reported are partial, year-on-year comparisons should be interpreted with caution. The information extracted from this figures will allow Member States to implement preventive and corrective measures in those situations where more SAR in donors are reported.

The number of *deaths* likely or certain to have resulted from blood transfusion in 2018 was 20. This figure has decreased compared with previous years. It should be noted that of the 20 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.

In the case of *number of SAE*, the reported figures have decreased compared with previous exercises. As mentioned in previous years, it should be taken into account 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 the ultimate cause of these SAE, the need for adequate training of the personnel and to implement adequate preventive and corrective measures. It is also important to create awareness among healthcare professionals of the importance of reporting, analysing and learning from those events.

Regarding the number of SAR in donors, the number reported for 2018 was 6 239. The main SAR in donors during both whole blood and apheresis collections were vasovagal reactions. The second most common type of reactions for both collections was the *Other* category. Performing this exercise has allowed Member States to increase awareness of the importance of monitoring the safety and quality of care for donors. As in the case of SAR in recipients, 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 agreement 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 for 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 improve 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 going deeper into the data analysis and interpretation.

In January 2017, the Vigilance Expert Sub-Group was established by the Commission. As mentioned before, this group was created with the aim of supporting the development and improvement of the SARE reporting system. The work of the Vigilance Expert Sub-Group has helped to improve and harmonise the exercise and support the development of national SoHO vigilance systems. The resulting outcomes of this work have contributed not only to the improvement of the SARE exercise and the development of vigilance systems in Member States but also to the evaluation by the Commission of the legal frameworks on blood, tissues and cells.[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