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 2021 ANNUAL REPORTING OF SERIOUS ADVERSE REACTIONS AND EVENTS FOR BLOOD AND BLOOD COMPONENTS

(DATA COLLECTED FROM 01/01/2020 to 31/12 2020 AND SUBMITTED TO THE EUROPEAN COMMISSION IN 2021)

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1. INTRODUCTION

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, incompatibilities 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[1], these must be monitored and reported at national and EU level through vigilance and surveillance systems. For this purpose, the legislation defines Serious Adverse Reactions (SAR) as incidents observed during or after transfusion, which may be attributable to the quality and safety of blood components and where actual harm to a donor or recipient has occurred. Serious Adverse Events (SAE) are incidents which may affect the quality or safety of blood and blood components with a risk of harm, but where no harm has ultimately occurred.

In line with obligations defined in the EU legislation[2] EU Member States submit an annual report to the European Commission (hereinafter referred to as "the Commission") on the SAR which occurred in recipients of blood and blood components, and SAE which occurred at any stage in the chain from donation to clinical application. Since the year 2012 this report has also included information on SAR in donors of blood and blood components, submitted on a voluntary basis. A summary of all annual reports received from reporting European countries is made publicly available to the Competent Authorities, healthcare professionals, stakeholders and the general public.
The Vigilance Expert Subgroup, established in 2017 by the Commission in agreement with the Member States, has provided ongoing support and facilitated the development and improvement of the Serious Adverse Reactions and Events (SARE) reporting system by helping to redefine the Common Approach document and reporting template forms. Furthermore, the VES also contributed to the Commission's evaluation of the legal frameworks on blood, tissues and cells published in October 2019.[3]

Through a contribution agreement signed between the Commission and the Council of Europe/European Directorate for the Quality of Medicines & HealthCare (EDQM), SARE data analysis and drafting of the final summary reports has been assigned to the EDQM.

Thus, this report, prepared by the EDQM, summarises SARE data for the year 2020 (submitted to the Commission by 30 European countries), elaborates major findings, draws general conclusions and interprets trends in European transfusion services in terms of SARE occurrence and distribution (by category and type).

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

2. EXECUTIVE SUMMARY

The main findings for 2020 are listed below:

- Overall, 30 countries (26 EU Member States, Iceland, Liechtenstein, Norway and the United Kingdom) reported in the SARE annual exercise. Of these, 21 countries indicated receiving complete data from their reporting establishments[4].

- In relation to the units issued for transfusion[5], over **22.1 million units of blood or blood components** were reported by 30 countries. The data on patients who received a transfusion, reported by only 19 countries, indicate that more than **3.1 million patients** were transfused.

- In total, **2 967 Serious Adverse Reactions** (**SAR) in recipients** were reported with imputability levels 1-3. However, the focus of this report is the **1 756 SAR** that were likely, probably or certainly caused by the transfusion (imputability level 2 or 3). This number increased slightly in comparison with the previous reporting year. **Anaphylaxis/hypersensitivity**, **febrile non-haemolytic transfusion reaction (FNHTR)** and **transfusion-associated circulatory overload (TACO)** were the most commonly reported types of SAR.

- In 2020, there were **24 transfusion-related deaths** reported as likely, probably or certainly caused by the transfusion (imputability level 2 or 3). The data provided indicate that some of these reported transfusion-related deaths were not directly attributable to the quality and safety of blood components, but rather to failures in clinical practice or to unforeseeable reactions. However, only 3 countries provided final investigation results on reported donor deaths (Belgium, France and Ireland), while most investigation results were missing, incomplete or unclear, preventing interpretation and lessons learnt of whether (and how) the transfusion-related deaths could have been avoided and to what extent additional corrective measures were applied after the investigation.

- In total, **3 018 Serious Adverse Events (SAE)** were reported by 28 countries indicating a slight increase compared to the previous year. The majority of SAEs occurred due to **human error (44%)** and system failure (29%), which emphasizes the importance of conducting root cause analysis that led to their occurrence, and implementing appropriate corrective measures aimed at preventing such errors. Therefore, at the level of blood establishment, the key role of the QMS is to ensure that every case of non-compliance with the quality system is documented and investigated as part of the internal management of the quality system, and any occurrence of a major deviation (classified as SAE) is reported to the national and European surveillance system.
  It is important to note that SAE reporting rates vary considerably between countries. More than 70% of all SAE were reported by only 3 countries (UK, Belgium and France). This large discrepancy could be partially explained by uneven understanding of SAE definitions and

[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 noted that the data from 3 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.

specifications, as well as uneven systems of registering SAE which can lead to a significant degree of under-reporting or over-reporting. It should therefore 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. Raising awareness among all healthcare professionals of the importance of identifying, reporting and learning on underlying causes of such adverse events, remains essential for harm prevention.

- In addition, 28 countries voluntarily contributed to the reporting of SAR in blood donors. A total of **4 025 SAR** were reported among **blood donors**, slightly higher compared with the previous year. The availability of this data provides an opportunity to further analyse the risks and potential harm associated to blood donation and to implement more effective measures to reduce them. It is therefore of great importance to encourage countries to collect and report this data (even if it is not mandatory) to ensure the protection of those citizens who generously choose to help others by donating blood.

3. DATA COLLECTION AND ANALISYS

This report provides a summary of the data reported to the Commission during 2021 by **26 EU Member** States[6], Iceland, Liechtenstein, Norway and the United Kingdom pertaining to the reporting period from 1 January to 31 December 2020.

It also includes a comparison with the data from previous years and provides general conclusions drawn from the analysis performed.

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

3.1. ***An electronic reporting template, version 3.1.*** for national data collection and submission to a DG SANTE-hosted database.

3.2. ***The Common Approach, version 2021,*** for the definition of reportable SAR and SAE complementing the electronic reporting template.
The aim of the document, although not legally binding, is to provide recommendations and guidance to Member States when reporting. It 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.

Data for the year 2020 were submitted to the Commission in the reporting template, version 3.1. The Commission has assigned the task of data verification, analysis and elaboration of the summary results to the EDQM, based on the signed bilateral agreement. Therefore, SARE data submitted by Member States were analysed by the EDQM, and verified in close co-operation with the Commission (VES) and Member States.

[6]Malta did not report in this exercise

The report provides an interpretation of the data and a summary of the main findings for 2020, reviewed before publication by the designated blood authorities.

4. MAJOR FINDINGS

4.1. Data completeness

Annual data on SARE for blood and blood components were reported by 26 EU Member States and 4 non-EU countries, Iceland, Liechtenstein, Norway and the United Kingdom, comprising aggregated data from 3 617 reporting blood establishments.

Regarding data completeness, 21 countries confirmed full completeness of national data, while 8 countries received 75-99% of the expected data. One country was not able to provide information on the completeness of the national data. 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, and their interpretation.

In total, 26 EU Member States submitted their national annual report in compliance with the EU Directive requirement (Article 8. Directive 2005/61/EC); Malta did not meet this requirement.

Iceland, Liechtenstein, Norway and the United Kingdom submitted their national data on a voluntary basis, thus contributing to a broader picture of the quality and safety of European transfusion services.

Due to data incompleteness, this report provides only partial insights into SARE related to blood/blood components, rather than a comprehensive overview of the safety and quality of European transfusion services. Therefore, general conclusions extracted from this report should be interpreted with caution.

4.2. Denominators

4.2.1. Number of blood collections

Twenty-six countries (all but EL, HU, LI, NL) provided the total number of **whole blood collections** made during the year, amounting to **16 510 040**, a slight decrease compared with the previous year when 17 407 743 collections were reported by 25 countries.

In the case of **apheresis collection**, 27 countries (all but HU, LI, NL) provided the number of collections, amounting to **5 502 403** (5 789 033 were reported by 26 countries in 2019), as shown in *Figure 1*.

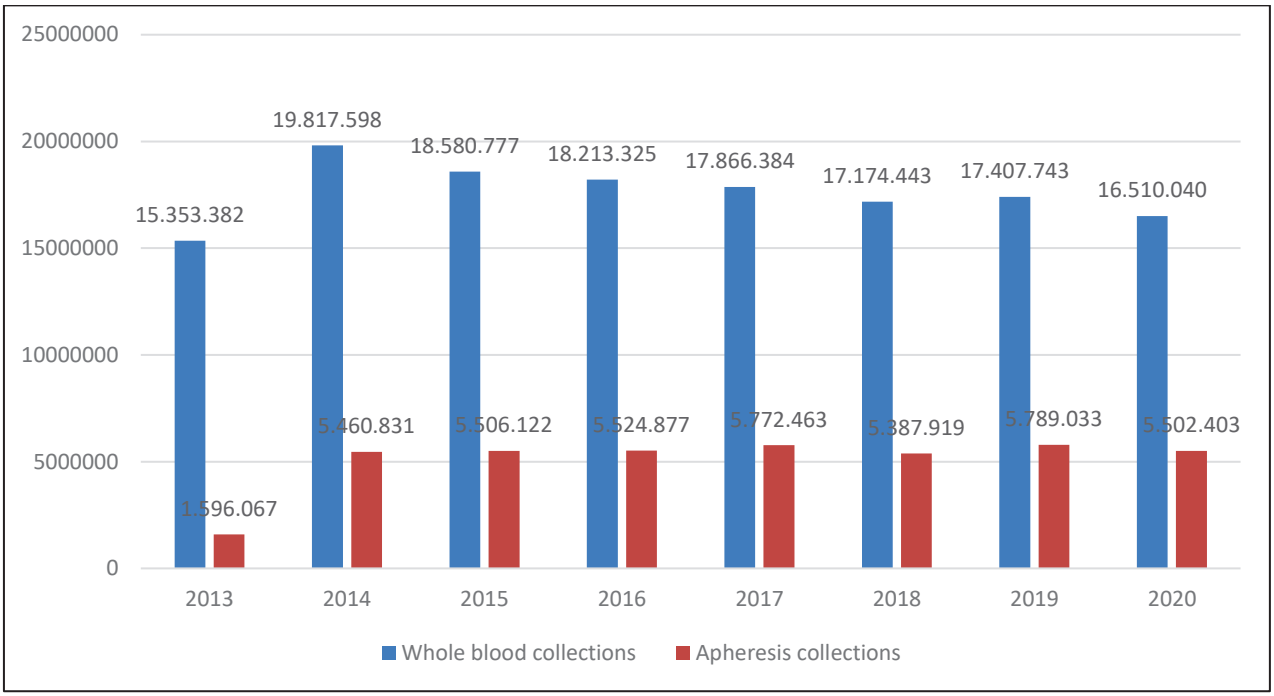

Figure 1. Total number of whole blood collections and apheresis collections: 2013-2020 comparative data.

4.2.2. Number of blood component units issued

Regarding the units of blood components issued**,** 26 countries (AT, BE, BG, HR, CY, CZ, DK, EE, FI, FR, EL, HU, IS, IE, IT, LV, LT, LU, NL, PL, PT, RO, SK, SI, SE and UK) provided data. Three of the remaining countries (DE, 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 as issued. One country (LI) did not provide data for either the number of units issued or the number of units transfused.

A total of **22 104 136 issued units** of blood and blood components were reported in 2020.

Figure 2 shows a breakdown of units issued by blood component type (including the transfused data from DE, ES and NO).

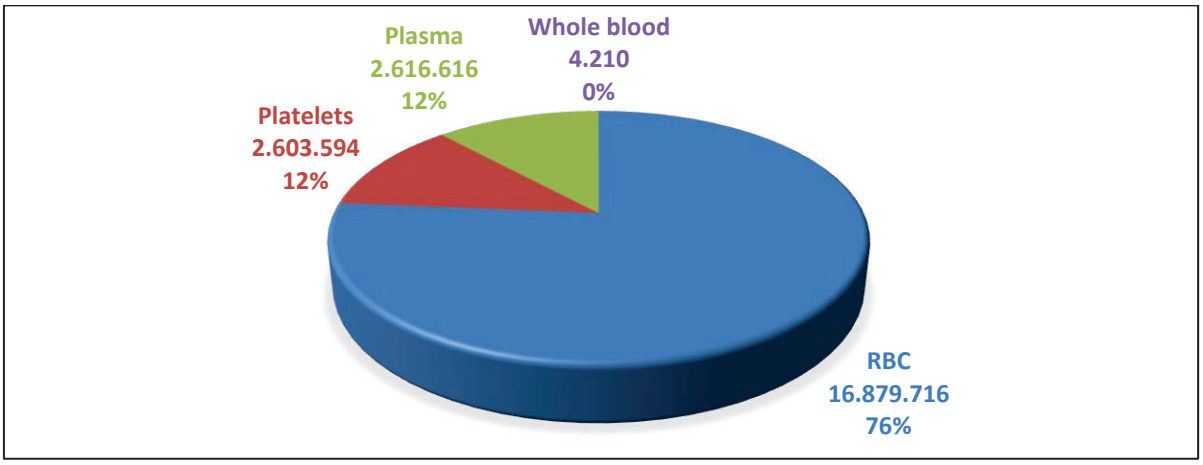

Figure 2. Units issued[7] per blood component type (absolute values and percentages); data 2020.

4.2.3. Number of blood component units transfused

Concerning the units of blood components transfused, **18 754 940** units were reported as transfused by 25 countries (AT, BE, BG, HR, CY, CZ, DK, EE, FR, DE, EL, HU, IS, IT, LV, LI, LU, NL, NO, PT, RO, SK, ES, SE, UK). Only 24 of these reported a detailed breakdown of units transfused by blood component type, as shown in *Figure 3*. The sum of the number of units transfused reported separately for each of the blood components within the scope of the SARE exercise according to the Common Approach equals **18 881 223** units transfused.

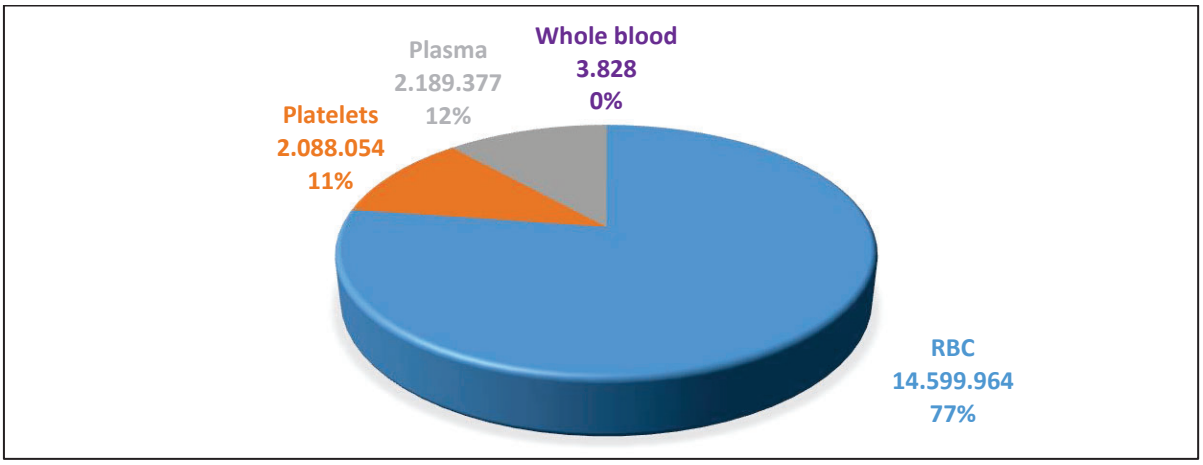

Figure 3. Units transfused per blood component (absolute values and percentages); data 2020.

4.2.4. Number of recipients transfused

According to data reported by 19 countries, **3 167 732** patients were transfused in 2020. This number includes 2 912 173 recipients transfused with specified blood components (as provided by 15 countries (AT, BE, HR, CY, CZ, FR, IS, IE, IT, LU, NL, PT, ES, SE and UK) and shown in *Figure 4*), and 255 559 recipients (reported by 4 countries BG, EE, LI and RO) whose type of blood component was not specified.

[7] Including data on units transfused from DE, ES and NO.

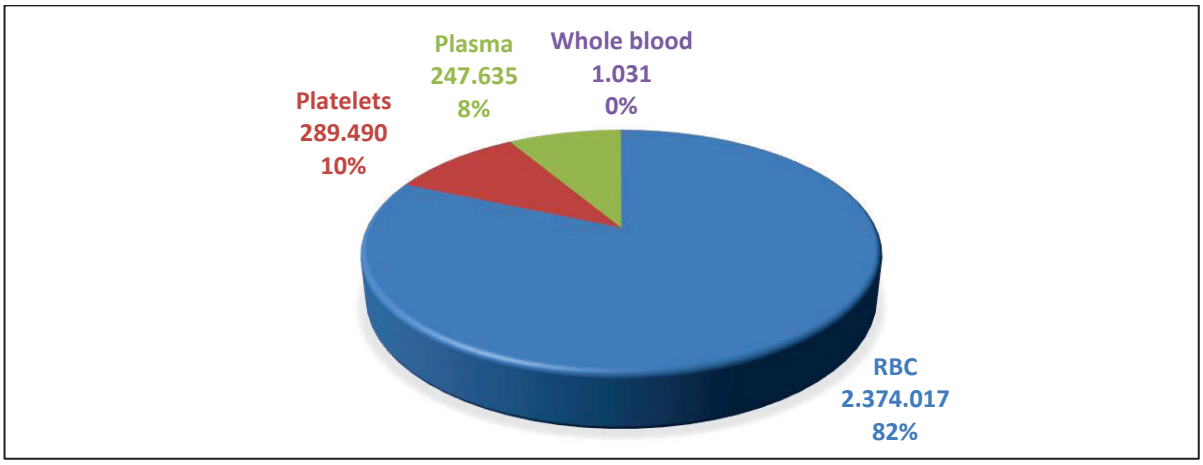

Figure 4. Recipients transfused per blood component; data 2020.

Taking into account the demographic data of the reporting countries on 1 January 2020[8], the incidence of issued and transfused blood components per million population are shown in *Figures 5, 6 and 7*.

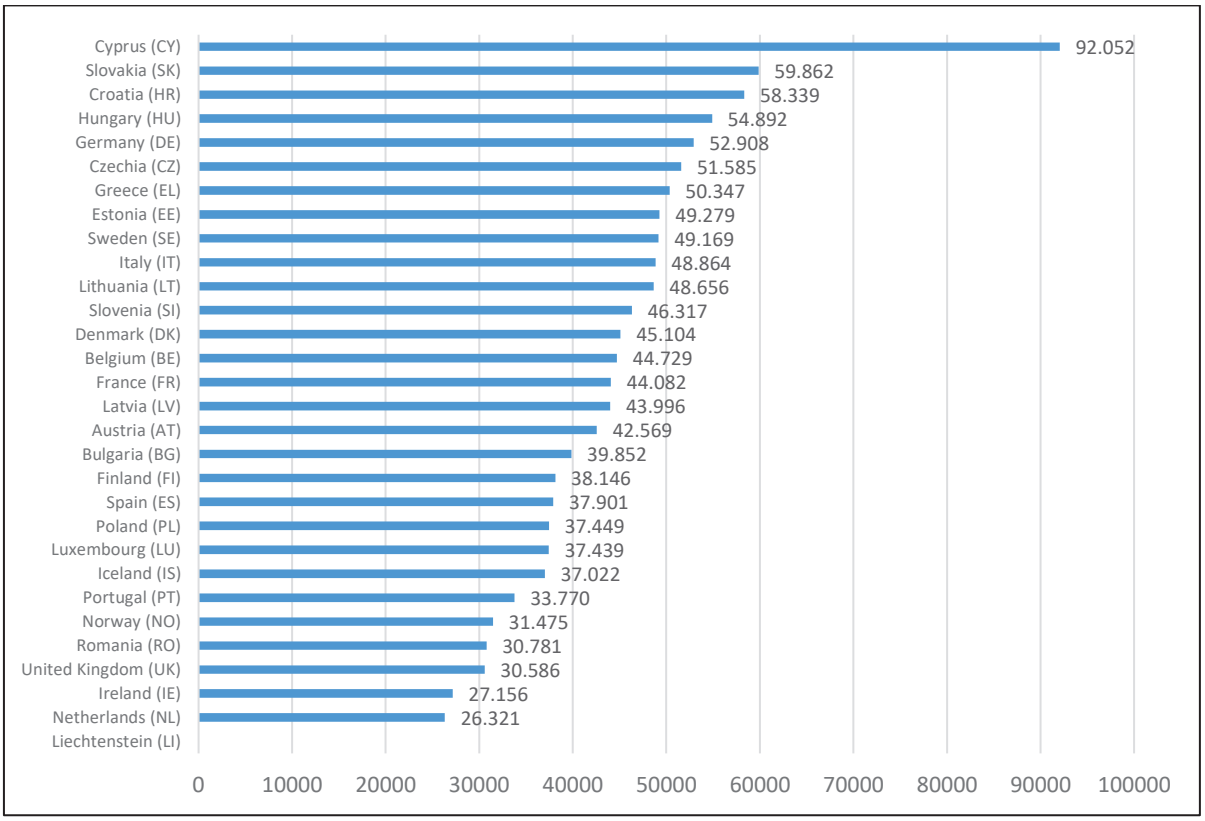

Figure 5. Number of blood units issued per million population; data 2020.

[8] https://ec.europa.eu/eurostat/web/population-demography/demography-population-stock-balance/database

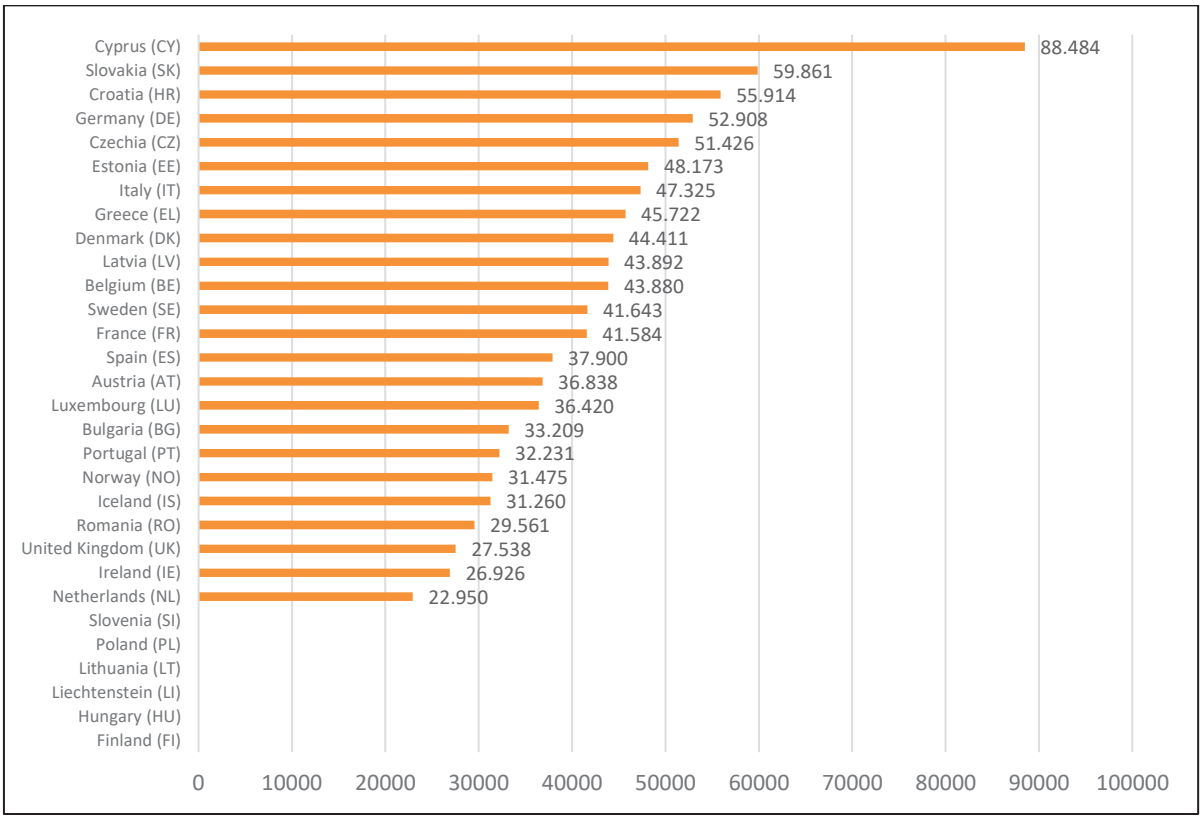

Figure 6. Number of blood units transfused per million population; data 2020.

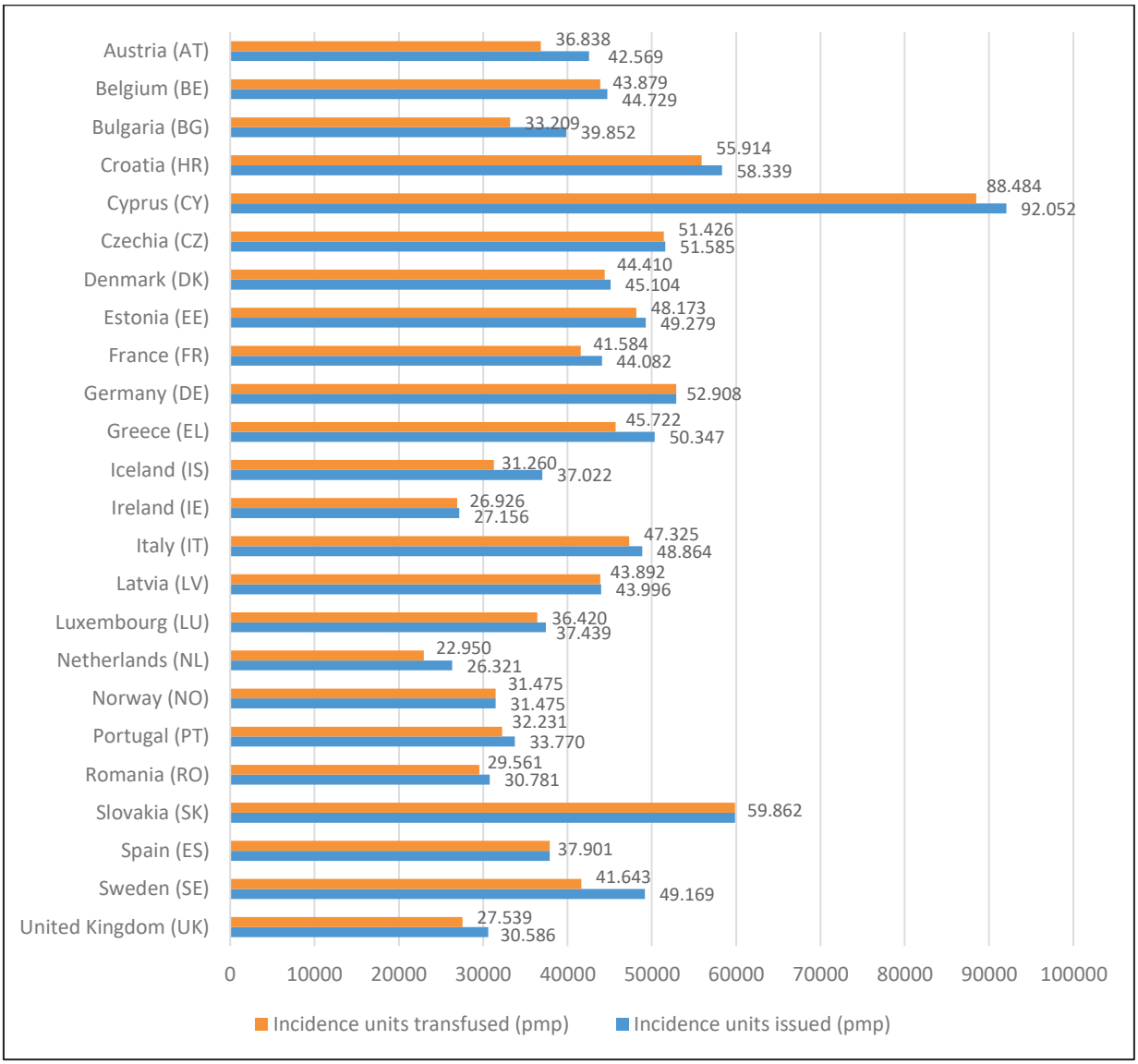

Figure 7. Number of units issued and transfused per million population; data 2020 (countries that did not provide data for both issued and transfused units have not been included in this graph).

4.3. Serious adverse reactions in recipients

4.3.1. General information

In 2020, a total of **2 967** SAR with imputability level of 1 to 3 were reported in the exercise. It should be noted that 9 countries (HR, IS, IT, LV, LI, LU, NO, ES 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[9].

During 2020, a total of **1 756** SAR at imputability level 2 or 3 were reported. Of those, 1 400 were submitted as level 2 and 356 were reported as level 3. Taking into account the data provided from those countries who were able to provide the number of SAR (imputability 2 or 3) and units transfused per blood component, there was an overall **incidence** of **8.99 SAR** per 100 000 units transfused. More information about this is given in section 3.3.3. This figure has decreased in comparison with the previous exercise. 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.

Out of the 1 756 SAR with imputability level 2 or 3, **24** resulted in death (16 deaths following red blood cell (RBC) transfusion, 4 following platelet transfusion, 1 following plasma transfusion and 3 following transfusion with more than one blood component).

The majority of the reported SAR were associated with transfusions of RBC, followed by platelets and plasma. The 1 756 SAR of imputability level 2 or 3 involved transfusion with the following blood components:

- **RBC**: 965 SAR (55%)
- **platelets:** 464 SAR (26%)
- **plasma**: 261 SAR (15%)
- **more than one blood component**: 65 SAR (3.7%)
- **whole blood**: 1 SAR (0.06%)

Figure 8 shows the percentage of SAR of imputability 2 or 3 per blood component:

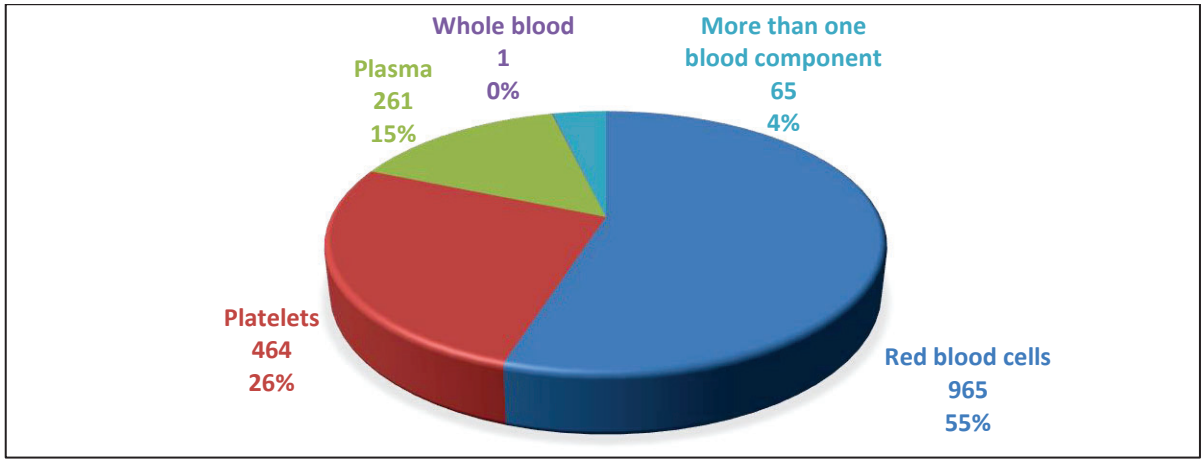

Figure 8. Percentage of SAR of imputability 2 or 3 per blood component type (absolute values and percentages); data 2020.

[9] Article 5, para 3a of Directive 2005/61/EC and Annex II Part B.

4.3.2. Incidence of SAR by type of blood component

As shown in *Table 1*, the risk associated with the transfusion of platelets is significantly higher compared to transfusion of other blood components (based on data from those countries who were able to provide the number of SAR and units transfused, per type of blood component). The incidence of SAR associated with transfusion of platelets (number of SAR associated with the transfusion of platelets per 100 000 units of platelets transfused) was 21.8, while for RBC it was 6.4.

Component type	Number of SAR (imputability 2 or 3) per 100 000 units transfused
Red blood cells	**6.40**
Platelets	**21.8**
Plasma	**11.1**
Whole blood	**0**

Table 1. Incidence of SAR of imputability 2 or 3 per 100 000 units transfused

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

4.3.3. SAR by type of reaction

Among the 1 756 reported SAR of imputability 2 or 3[10], different types of severe reactions were described. The most common type of reaction (out of those categorised) was **anaphylaxis/hypersensitivity** (22%), followed by **febrile non-haemolytic transfusion reaction** (20%) and **transfusion-associated circulatory overload** (16%).
The classification of all SAR of imputability 2 or 3 per type of reaction is summarised in *Figure 9*:

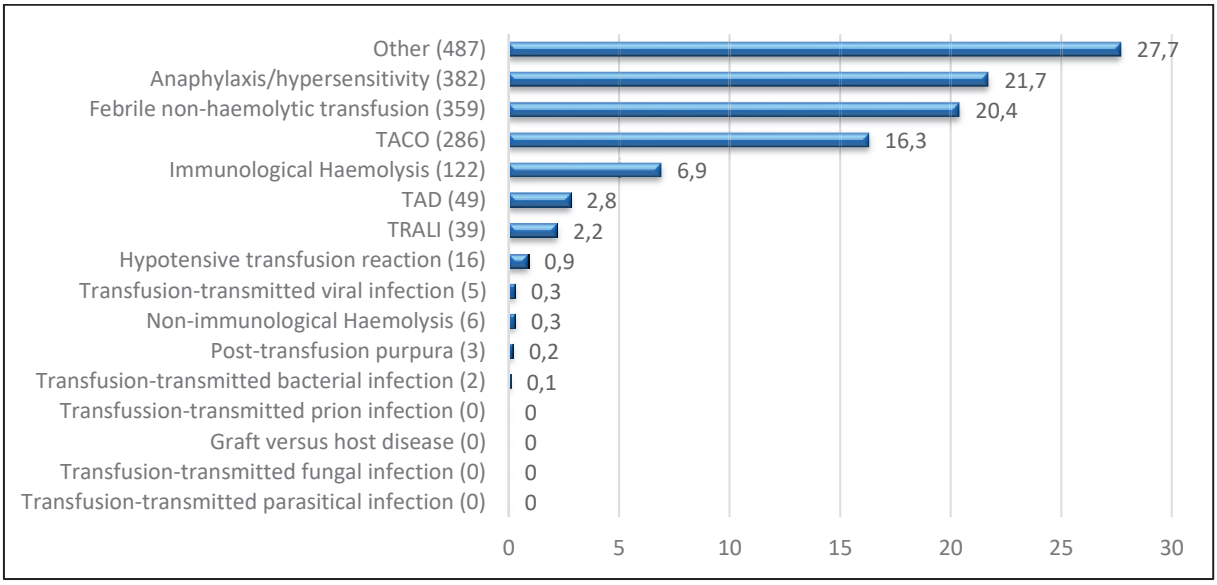

Figure 9. Distribution (number and percentage) of SAR of imputability 2 or 3, per type; data 2020.

[10] 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.

As shown in *Figure 9*, the category with the most reported SAR in recipients was "other" (28%) representing an increase of 65% compared to 2019. This raises concern over the accuracy and consistency of classifications by some countries.

4.3.4. Transfusion-related deaths

4.3.4.1. Type of SAR associated with death

Among the 1 756 SAR with imputability level 2 or 3, **24** resulted in **death**, representing an incidence of **13.7 deaths** per 1 000 SAR of imputability level 2 or 3.

Half of the reported deaths were associated with TACO, followed by TRALI (21%) and immunological haemolysis (12%). Transfusion-transmitted infections (TTI; 1 bacterial and 1 viral) accounted for 8% of deaths.

The complete distribution of deaths by type of SAR is as follows:

- **TACO** (12) - following RBC transfusion (8), platelet transfusion (1), and transfusion of more than one component (3)
- **TRALI** (5) - following RBC transfusion (3), platelet transfusion (1) and plasma transfusion (1)
- **Immunological haemolysis** (3) - following RBC transfusion, and due to other alloantibodies
- **Non-immunological haemolysis** (1) - following RBC transfusion
- **Bacterial infection** (1) – a *non-specified* bacterial infection transmitted via platelet transfusion
- **Viral infection** (1) - *hepatitis E* virus transmitted via platelet transfusion
- **Other** (1) **-** *uncategorised* adverse reaction following RBC transfusion

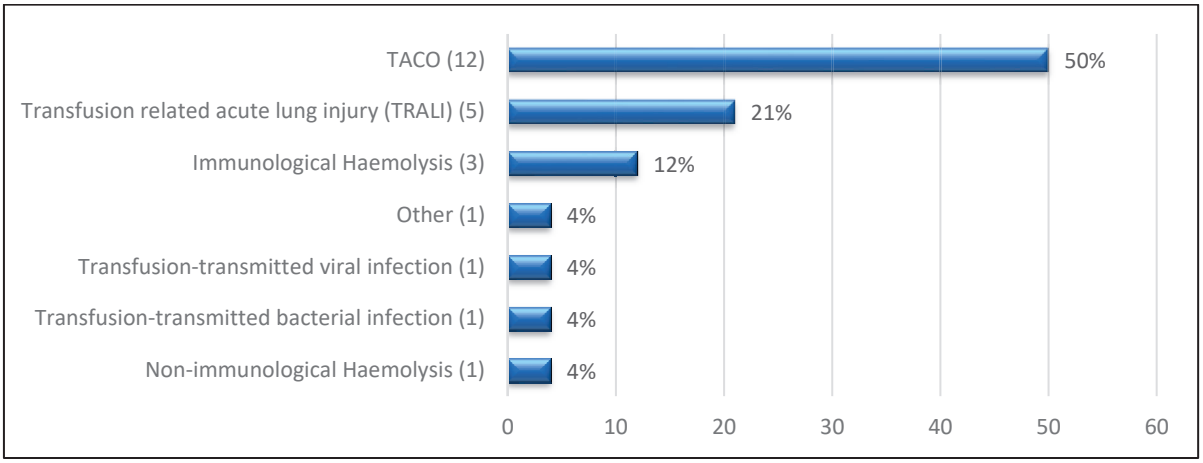

Figure 10. Deaths by SAR type (imputability level 2 or 3) in absolute values and percentages; data 2020.

In addition, **20 deaths** with imputability **level 1** were voluntarily reported by 5 countries (BE, FI, FR, NL and UK), most of which (80%) were associated with TACO, as shown in *Figure 11*.

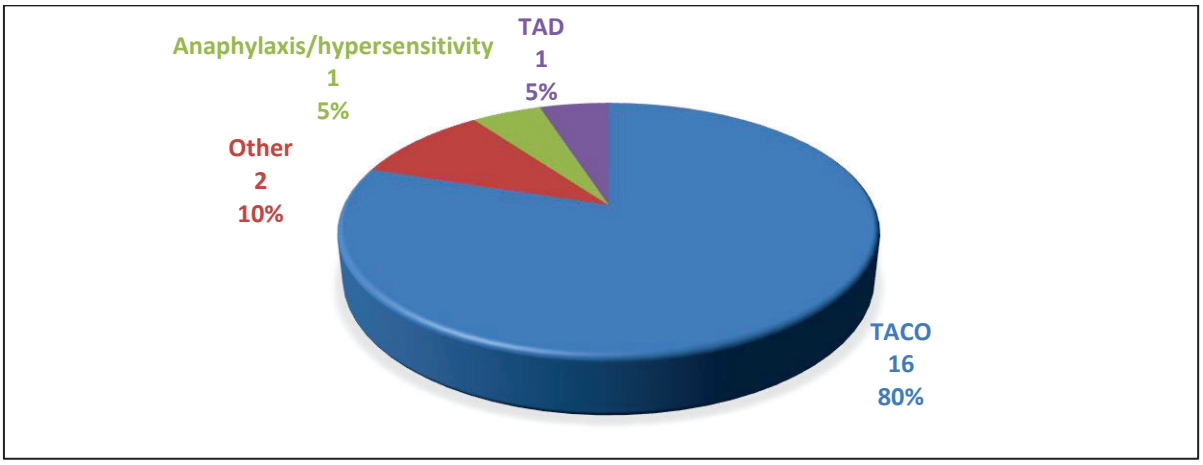

Figure 11. Deaths by type of SAR (imputability level 1) in absolute values and percentages; data 2020.

4.3.4.2. Death investigations

Among those reported SAR that resulted in death (imputability level 2 or 3) detailed investigation results were provided by only 3 countries (Belgium, France and Ireland).

4.3.5. International benchmarking

As in previous exercises, the Commission compares the results obtained from data submitted by participating European countries (EU, EEA, and the UK) with those of the **United States** published by the Food and Drug Administration (FDA). However, the data provided in the FDA report allow only basic comparisons of transfusion-related deaths, as this is the only category covered. According to the FDA report *Fatalities reported to FDA following blood collection and transfusion*[11], in 2020 there were 22 deaths classified as either *definitely* or *probably* related to transfusion. Among them, TACO and TRALI (along with anaphylaxis) were the most commonly reported reactions that led to death, which correlates with the information proved in this report indicating that TACO and TRALI were the most common types of SAR, among the 24 reported cases, that led to deaths classified as probably, likely or certainly associated with transfusion.

4.4. Serious Adverse Events

4.4.1. General information

The main denominator for SAE is the total number of **blood units processed**. During 2020, a total of **24 129 477** blood units were processed according to data provided by 28 countries (all except HU and LI). An overview of data on blood units processed over the reporting years is presented in *Figure 12*.

The number of SAE reported for 2020 was **3 018**. This figure was provided by 28 countries (all except HU and LI), of which, 4 countries (LT, LU, RO and SK) reported no SAE in 2020.

[11] Annual summary for fiscal year 2020: "Fatalities reported to FDA following blood collection and transfusion annual summary for FY2020" https://www.fda.gov/media/160859/download

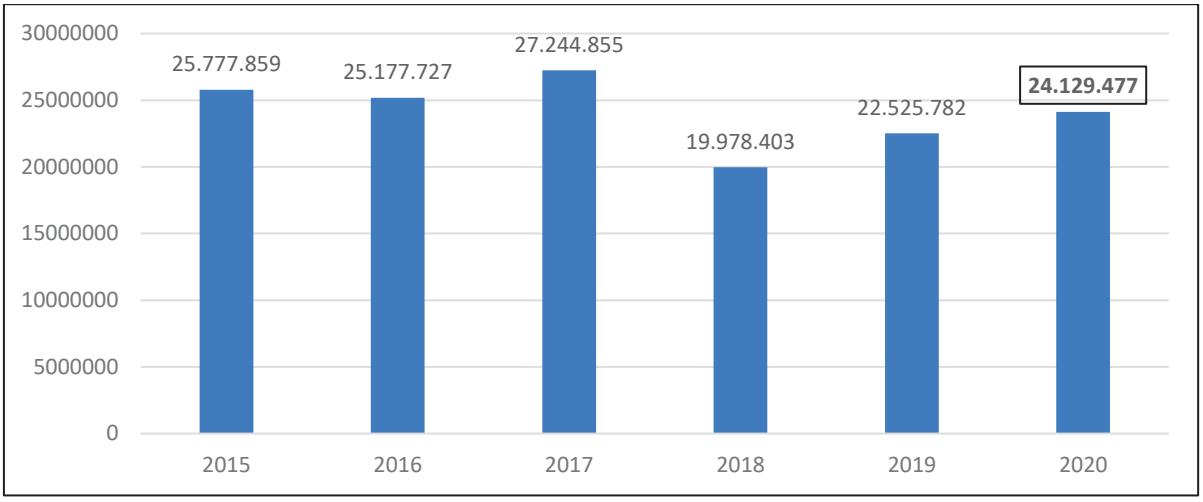

Figure 12. Total number of blood units processed: 2015-2020 comparative data.

It is worth noting that the number of SAE reported varied substantially between reporting countries, both in terms of incidence and the criteria for inclusion. In this exercise, 36% of all SAE were reported by one country, whereas around 10 countries reported less than 10 SAE each. Hence, an interpretation should be given with caution.

4.4.2. SAE by activity step

Since the 2019 SARE exercise, following a suggestion from the VES in collaboration with the Competent Authorities, new SAE activity steps have been incorporated in the reporting template: **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 blank), 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 more specific classification of SAE in the exercise.
The reporting countries have successfully adapted to these modifications to the activity steps, so this report reflects those changes.

Despite this, in 2020 **33%** of the 3 018 reported SAE were not associated with any specified activity steps (classified as "*other*", the category with the highest number of SAE). The number of SAE in this category has significantly increased compared to the previous year, when it represented only 18% of the total SAE. In addition, it was noted that 92% of all SAE classified as "other" were reported by only 3 countries for 2020. These data highlight a potential issue of accuracy in classification of SAE by type of activity step in certain countries.

Of the other SAE reported, 14% were attributed to the **donor selection** step, then **storage** and component selection, as shown in *Figure 13*.

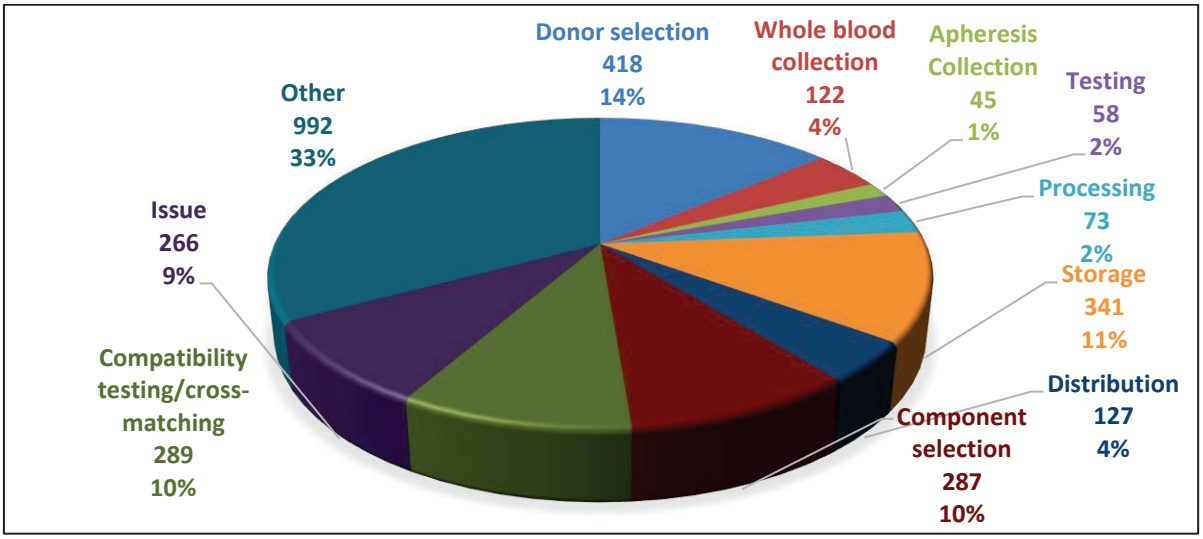

Figure 13. SAE per activity step (absolute numbers and percentages); data 2020.

4.4.3. SAE by type of event

SAE have traditionally been divided into 5 basic categories: human error, component defect, equipment failure, materials, and other (non-classified). As part of the ongoing improvements to the SARE exercise and data reporting, a new category of SAE, "system failure", was included following a suggestion by the VES in collaboration with the Competent Authorities. This was aimed at identifying SAE occurring when the quality management system (QMS) 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 most commonly reported SAE (44%) was "human error", followed by "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 improved the quality of the data reported. The complete breakdown of SAE by type is as follows:

- **Human error**: 1 339 SAE (44%)
- **System failure**: 882 SAE (29%)
- **Component defect**: 468 SAE (16%)
- **Equipment failure**: 124 SAE (4%)
- **Materials**: 6 SAE (0.2%)
- **Other:** 199 SAE (7%)

These data are shown in *Figure 14*.

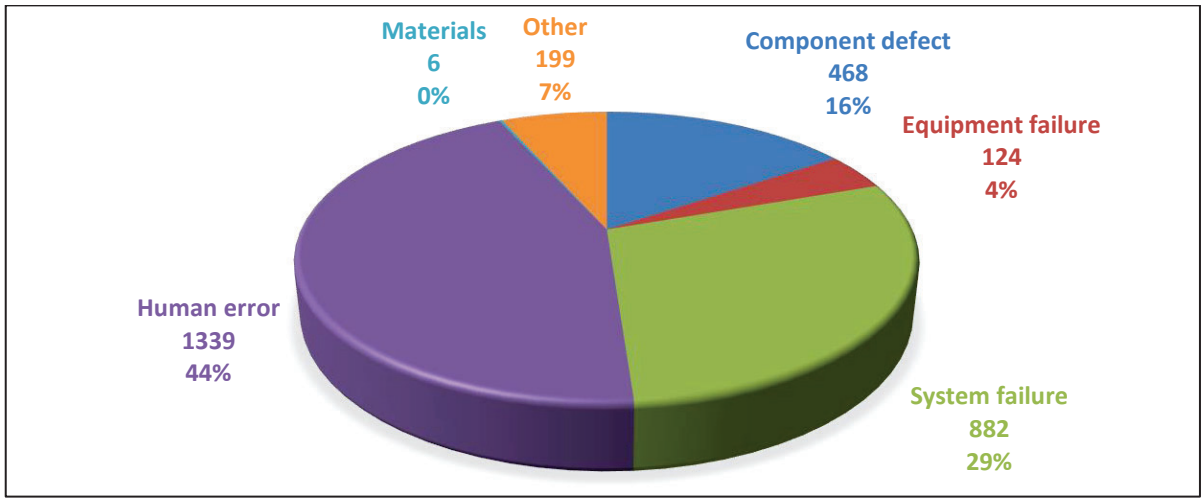

Figure 14. Distribution of SAE by type (absolute numbers and percentages); data 2020.

4.5. Serious adverse reactions 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[12]. However, acknowledging the value of data on SAR in donors, the Commission encourages Member States to submit these reactions on a voluntary basis. 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 should be reported where the fatality is possibly, probably or certainly related to the donation process (imputability 1, 2 or 3).
Twenty-eight countries (AT, BE, BG, HR, CY, CZ, DK, EE, FI, FR, DE, EL, IS, IE, IT, LV, LT, LU, NL, NO, PL, PT, RO, SK, SI, ES, SE and UK) reported, on a voluntary basis, a total of **4 025 SAR in donors**. This figure remains stable in comparison with the previous exercise, considering that 4 more countries have reported SAR in donors in this exercise. An overview of the comparative data from SARE exercises from 2016 to 2021 (2015-2020 data) is presented in *Figure 15*.

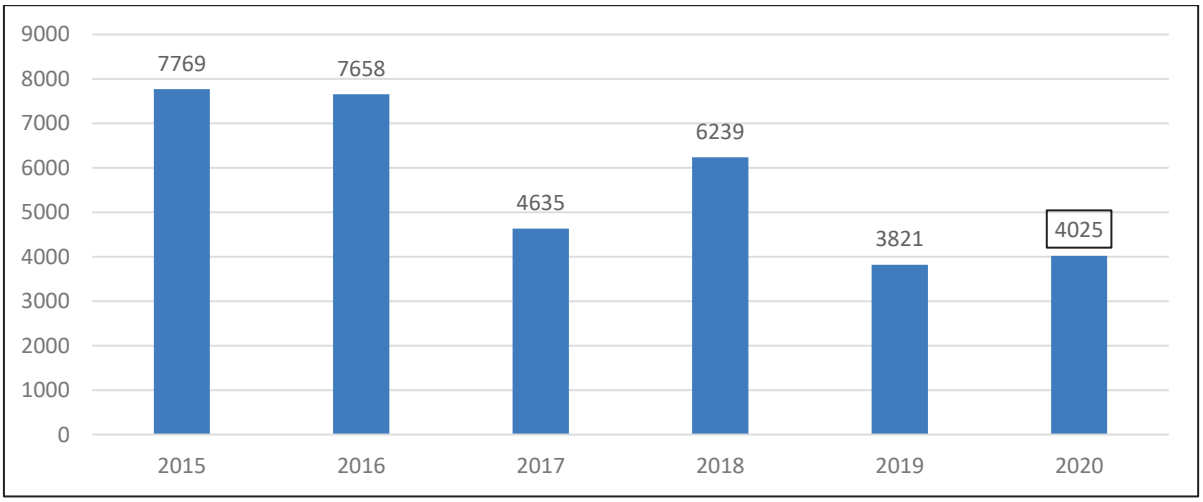

Figure 15. SAR in donors (absolute numbers): 2015-2020 comparative data.

[12]Article 5 of Directive 2005/61/EC.

Table 2 shows the number of SAR in donors per 100 000 collections (from those countries who were able to provide total numbers of whole blood collections and apheresis collections).

Collection type	Number of collections	SAR in donors	Number of SAR in donors per 100 000 collections (incidence)
Whole blood	16 510 040	3161	**191**
Apheresis	5 502 403	839	**15.2**
Total	**22 012 443**	**4000**	**242**

Table 2. Incidence of SAR in donors per 100 000 collections (absolute numbers); data 2020.

As shown in *Figure 16*, during *whole blood collection* **vasovagal reaction** was the most common type of reaction (66%), followed by "general" (data of subcategories are not available) and "other" reactions.

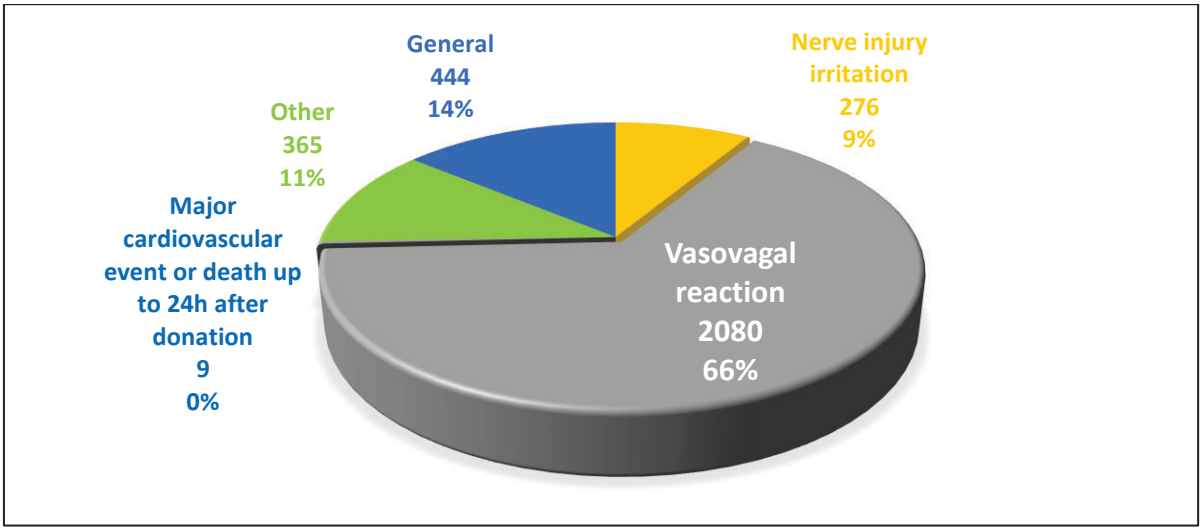

Figure 16. SAR in donors during whole blood collection (absolute numbers and percentages); data 2020

Distribution of SAR in donors during *apheresis collection* is shown in *Figure 17*.

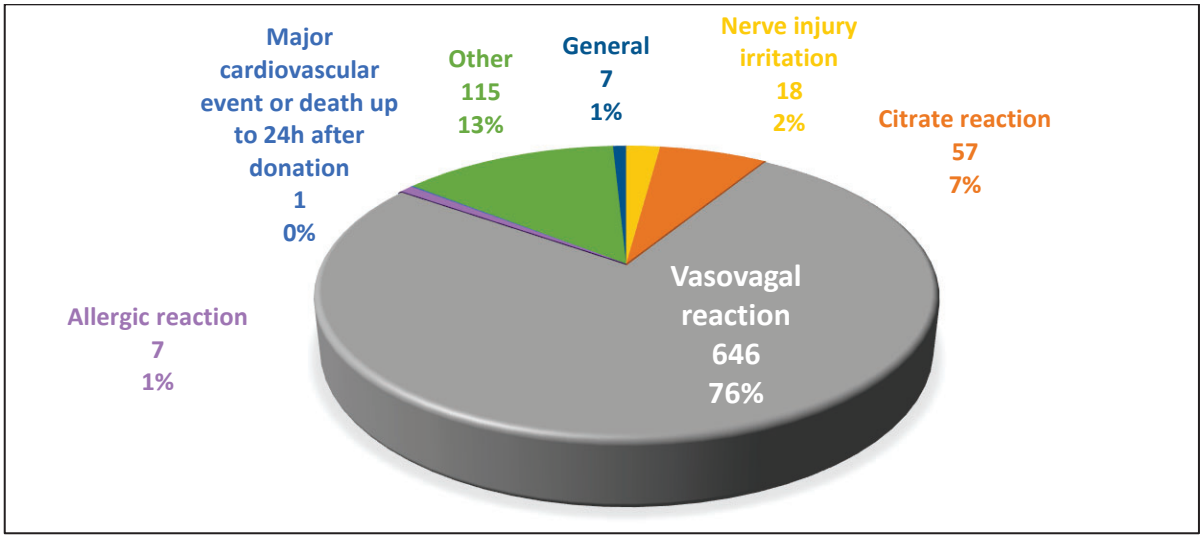

Figure 17. SAR in donors during apheresis collection (absolute numbers and percentages); data 2020.

It should be noted that, although the data is collected on a voluntary basis, there is variability between countries in the reporting of SAR in donors.

5. CONCLUSIONS

Thanks to the efforts of the Member States with the support of the Commission, VES and EDQM, the SARE exercise contributed to the improvement of the Member States' national surveillance and vigilance systems in the field of blood transfusion, especially in terms of accuracy and completeness of data. In addition, the SARE exercise contributed to better insight into the emergence of risks related to blood donation and transfusion, in Europe.

In this SARE exercise, as many as 30 European countries (a total of 3617 transfusion facilities) submitted reports, which indicates an increasing engagement and effort by European countries to further improve data reporting and safety monitoring.

However, there is still a significant degree of under-reporting, or even over-reporting, reflecting difficulties and inconsistency among countries in data collection and classification. Thus, in 2020 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 concerns about the data analysis and interpretation. For this reason, the general conclusions extracted from this report should be interpreted with caution.

In general, 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 vigilance and surveillance programmes.

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 Europe.

Annex 1. Overview of the 2012-2021 SARE reporting exercises (2011-2020 data)

	2012 (data 2011)		2013 (data 2012)		2014 (data 2013)		2015 (data 2014)		2016 (data 2015)		2017 (data 2016)		2018 (data 2017)		2019 (data 2018)		2020 (data 2019)		2021 (data 2020)	
	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	Countries reporting	Number
Units issued	29	24 821 809	27	25 129 344	27	24 043 766	27	25 717 028	26	25 324 888	29[13]	24 827 516	29[14]	25 093 906	28[14]	22 922 191	27[15]	22 863 118	30[15]	22 104 136
Units transfused	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	24	18 881 223
Recipients transfused	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	15	2 912 173
SAR (1-3)	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	30	2 967
SAR (2-3)	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	30	1 756
SAR death (2-3)	30	14	30	22	28	22	30	27	31	25	30	16	29	28	28	20	27	26	30	24
SAE	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	28	3 018
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	28	4 025

[13] 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.

[14] 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.

[15] This figure includes the data from the 3 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.