EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Medical Products and Innovation
Medical Products: Quality, Safety, Innovation

SUMMARY OF THE 2023 ANNUAL REPORTING OF SERIOUS ADVERSE REACTIONS AND EVENTS FOR BLOOD AND BLOOD COMPONENTS

(DATA COLLECTED FROM 01/01/2022 to 31/12/2022 AND SUBMITTED TO THE EUROPEAN COMMISSION IN 2023)

Table of Contents

List of Figures

List of Tables

List of annexes

1 INTRODUCTION

Every year millions of European citizens benefit from blood transfusion as a result of different medical procedures supported by many healthcare specialties. 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 reactions 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 reactions and events can occur and, in line with the legislation[1], these must be identified and reported at national and EU level (when appropriate) through national haemovigilance and surveillance systems. For the purpose of promoting an internationally harmonised approach to reporting such unintended reactions or events, the legislation defines Serious Adverse Reactions (SAR) as incidents observed throughout the transfusion cycle, 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 2012, this report has also included information on SAR in donors of blood and blood components, submitted on a voluntary basis.

This report summarises SARE data for the year 2022 submitted to the Commission by 30 European countries and includes major findings, general conclusions and 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.

2 EXECUTIVE SUMMARY

The main findings for 2022 compared to the previous two years are presented in the table below:

Parameter	2021 (Data 2020)	2022 (Data 2021)	2023 (Data 2022)
Reporting Countries	30 27 EU member states plus Iceland, Liechtenstein and Norway	30 26 EU member states plus Iceland, Liechtenstein, Norway and the United Kingdom (Northern Ireland)	**30** **26 EU member states** plus Iceland, Liechtenstein, Norway and the United Kingdom (Northern Ireland)
Number of establishments	3 617	3 307	**3 387**
Units issued	22 104 136 (30 countries)	20 633 199 (30 countries)	**21 393 810 units** (30 countries)
Units transfused	18 881 223 (24 countries)	17 808 869 (26 countries)	**17 197 062 units** (24 countries)
Transfusion recipients	3 167 732 (19 countries)	2 912 307 (20 countries)	**3 094 799 recipients** (22 countries)
SAR (IL1-3)	2 967 (28 countries)	2 814 (27 countries)	**3 216** (28 countries)
SAR (IL 2-3)	1 756 (26 countries)	1 379 (24 countries)	**1 516** (27 countries)
Most prevalent types of SAR	Anaphylaxis/hypersensitivity (21.7%) Febrile non-haemolytic transfusion reaction (FNHTR) (20.4%) Transfusion-associated circulatory overload (TACO) (16.3%) Other (27.7%)	Febrile non-haemolytic transfusion reaction (FNHTR) (24.2%) Anaphylaxis/hypersensitivity (15.7%) Transfusion-associated circulatory overload (TACO) (13.4%) Other (29.9%)	Febrile non-haemolytic transfusion reaction (FNHTR) (23%) Anaphylaxis/hypersensitivity (18.6%) Transfusion-associated circulatory overload (TACO) (13.2%) Other (27%)
Fatalities (SAR IL 2-3)	24 (9 countries)	25 (11 countries)	**27** (9 countries)
Units Processed	24 129 477 (28 countries)	22 961 648 (28 countries)	**22 943 682 units** (27 countries)
SAE	3 018 (24 countries)	2 734 (24 countries)	**2 235** (25 countries)
Most prevalent types of SAE by specification	Human error 1 339 (44%) System failure 882 (29%) Component defect 468 (16%) Equipment failure 124 (4%)	Component defect 1 037 (38%) Human error 974 (35%) System failure 332 (12%) Equipment failure 243 (9%)	Human error 1 099 (44%) Component defect 543 (24%) System failure 257 (11%) Equipment failure 216 (10%)
SAR in donors	4 025 5 (28 countries)	2 946 (23 countries)	**3 245** (23 countries)

- Similar to the previous year, **30 countries** comprising **26 EU member states** plus Iceland, Liechtenstein, Norway and the United Kingdom (Northern Ireland) contributed to the SARE exercise.

- Across the 30 countries, over **21.3 million units** of blood or blood components were **issued** for transfusion (compared to 20.6 in 2021 and 22.1 million in 2020). The data on recipients (reported by only 22 countries) indicates that more than **3.0 million patients** received at least one transfusion, totalling **17.1 million units transfused** (17.8 mil in 2021). Note: a patient who received more than one blood component is counted multiple times.

- In total, **3 216 SAR** in **recipients** (imputability levels 1-3) were reported by 28 countries. However, only **1 516 SAR** were probably or certainly caused by the transfusion (imputability level 2 or 3). This number is slightly higher than in the previous reporting year (1 379).

- Similar to 2021**, febrile non-haemolytic transfusion reaction (FNHTR)** (23%) was the most commonly reported type of SAR, followed by **anaphylaxis/hypersensitivity** (18.6%) and **transfusion-associated circulatory overload (TACO)** (13.2%). Uncategorised reactions (*Other*) remained the most prevalent (27%), signalling potentially inadequate classification (a persistent issue throughout the years).

- There were **27 fatalities** classified as probably or certainly caused by transfusion (imputability level 2 or 3). According to the data provided, some of these transfusion-related deaths could not be directly attributed to the quality and safety of blood components. Only three countries provided final investigation results on reported deaths (Belgium, Finland and France), while most investigation results were missing, incomplete or unclear, making it impossible to know if these deaths were preventable and what lessons, if any, could have been learned.

- In total, **2 235 SAE** were reported by 25 countries, indicating an 18% decrease compared to the previous year (2 734). The decrease was due to the UK no longer reporting as a whole. Eighty percent of all SAE were reported by six countries (Belgium, France, Romania, Germany, Ireland and Sweden), so it is important to note that SAE reporting varies considerably between countries.

- The number of **units processed** – **22.9 million** in 2022 – was used as denominator for the calculation of the incidence of SAE.

- The majority of **SAE** were attributed to **human error** (44%), followed by **component defect** (24%), **system failure** (11%) and **equipment failure** (10%). After a slight decrease in 2021, the proportion of events classified as human error increased again, as per the trend in past years.

- The number of **SAR in donors (3 245)**, voluntarily reported by 23 countries, was at approximately the same level as the previous year (2 946 SAR, 23 countries).

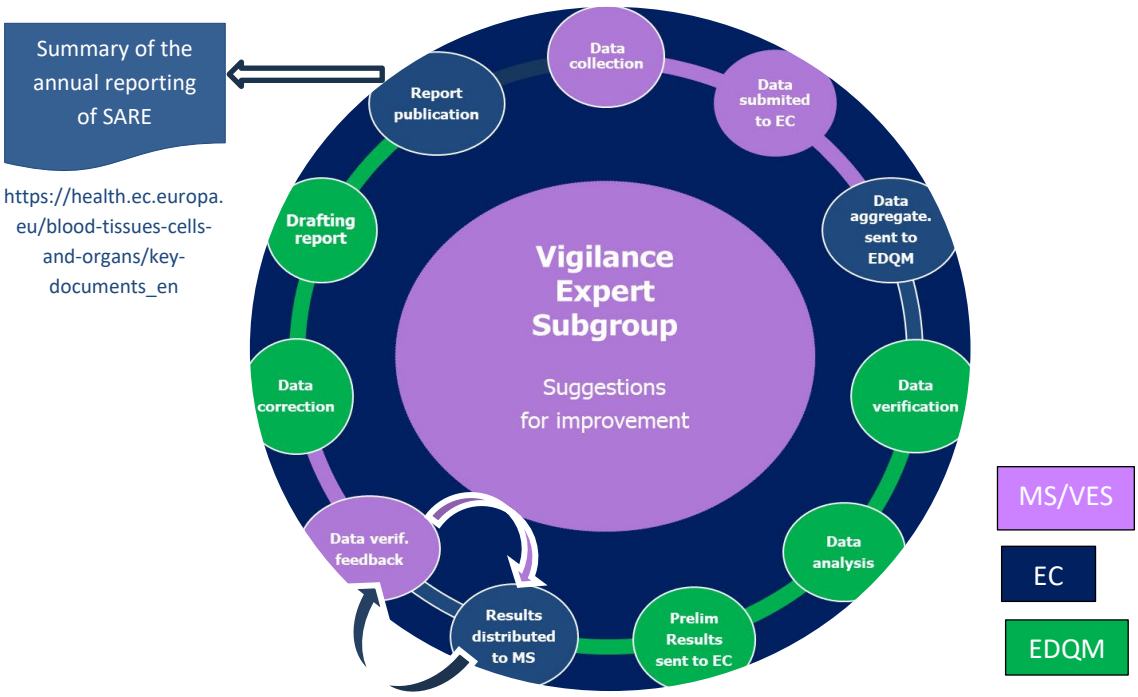
3 DATA COLLECTION AND ANALYSIS

This report provides a summary of the national data submitted to the Commission by all EU member states except Malta and four non-EU countries (Iceland, Liechtenstein, Norway and Northern Ireland) pertaining to the reporting period from 1 January to 31 December 2022. It also includes a comparison with the data from previous years and general conclusions.

In 2022, the Commission provided National Competent Authorities with improved tools to facilitate a standardised online data reporting approach:

1) ***An electronic reporting form (version 2023)***
2) ***The Common Approach, version 2023*** which complements the electronic reporting form and provides updated user instructions for data compilation.

The reporting countries and VES verified the preliminary results of the EDQM's analysis and interpretation of SARE data for 2022.
The process for issuing SARE reports (sequence of steps and involved parties) is presented in the image below.



4 MAJOR FINDINGS

4.1 Data completeness

The annual data on SARE for blood and blood components were reported by 26 EU member states and four non-EU countries (Iceland, Liechtenstein, Norway and Northern Ireland) comprising aggregated data from 3 387 reporting establishments. The UK ceased reporting as a whole in 2021 (the first year post-Brexit), which explains the reduction in the number of establishments compared to the previous two years.

Regarding percentage of reports received, 20 out of 30 reporting countries confirmed receipt of 100% reports, four countries received 98-99% of the expected data, one country, 91% and three countries, 65 – 85%. Two countries were not able to provide any information in this sense.

Incomplete data (especially in terms of denominators such as blood units issued, blood units transfused and number of recipients) affected the analysis and reliability of results.
Therefore, this report provides a partial insight into SARE related to blood/blood components, rather than a comprehensive view of the safety and quality of European transfusion services.

Non-EU countries (Iceland, Liechtenstein, Norway and Northern Ireland) submitted their national data on a voluntary basis, thus contributing to a broader picture of the quality and safety of European transfusion services.

4.2 Denominators

4.2.1 Number of blood collections

Twenty-six countries (AT, BE, BG, HR, CY, CZ, DK, EE, FI, FR, DE, IS, IE, IT, LV, LT, LU, MT, NL, NO, PL, PT, RO, SI, ES and NI) reported a total of 15 576 875 **whole blood collections** in 2022. This was slightly lower than the previous year when 16 242 768 collections were reported by 28 countries.

In terms of **apheresis collection**, 26 countries (all of the above plus EL and minus SE) reported a total of 6 376 960 collections.

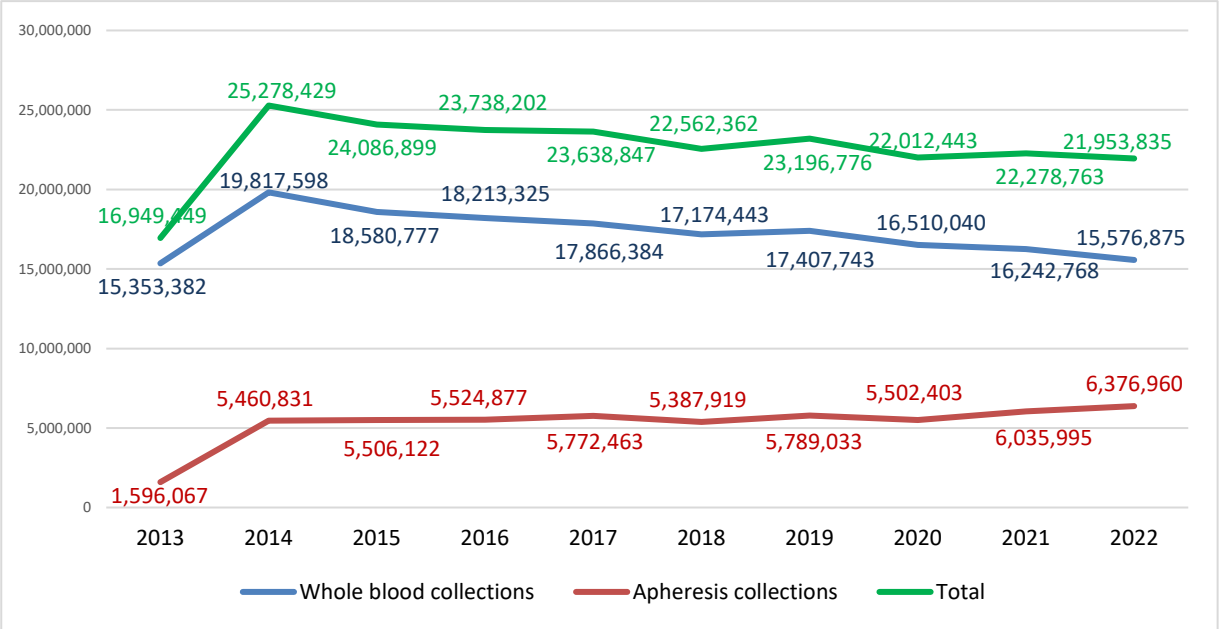


Figure 1. Whole blood, apheresis and total number of collections: 2013 – 2022 comparative data

4.2.2 Number of blood component units issued

Regarding the units of blood components issued**,** 27 countries (AT, BE, BG, HR, CY, CZ, DE, DK, EE, EL, FI, FR, IE, IS, IT, LV, LT, LU, MT, NL, PL, PT, RO, SK, SI, SE and NI) provided data. The three remaining countries (ES, LI 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.

A total of **21 393 810 issued units** of blood and blood components were reported in 2022. *Figure 2* shows a breakdown of units issued by type of blood component (including data on transfused units from ES, LI and NO).

The approach to COVID-19 convalescent plasma (CCP) reporting varies among countries; CCP units and related SAR were either included or excluded, where possible, from the regular plasma number of units issued. The inclusion of CCP in the analysis has a negligible impact due to the limited numbers involved (5 906 units issued, 4 909 units transfused and 1 551 recipients reported in 2021).

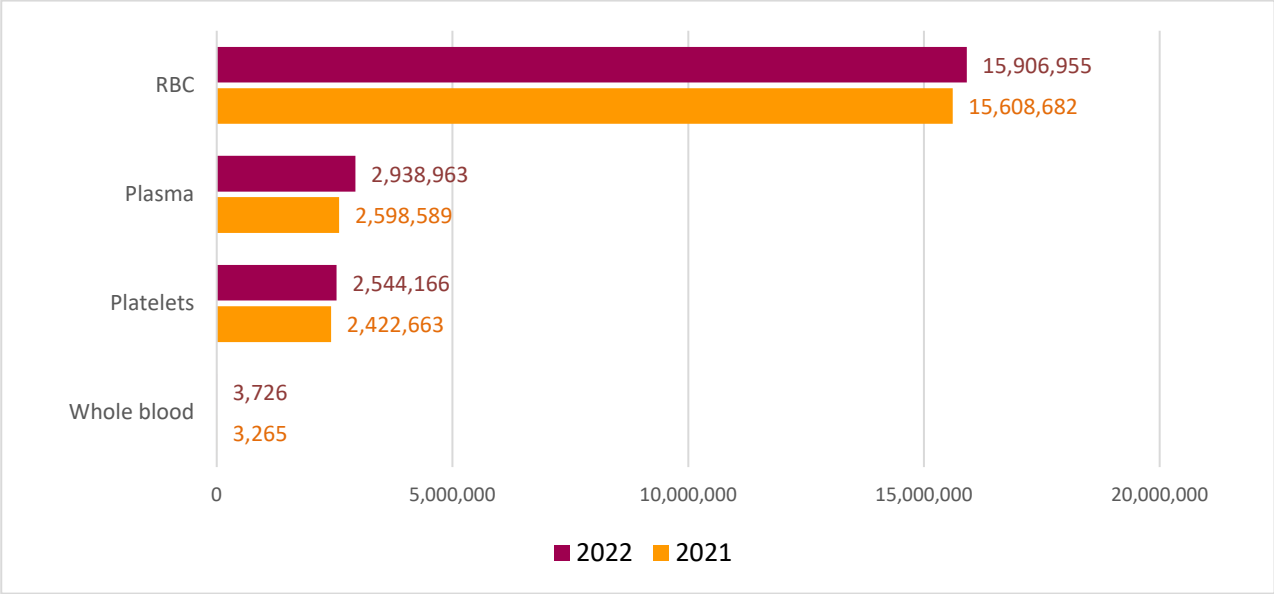


Figure 2. Units issued per blood component type; 2021 – 2022 comparative data

4.2.3 Number of blood component units transfused

Concerning the units of **blood components transfused**, a total of **17 197 062** units were reported as transfused by 24 countries (AT, BE, BG, CY, CZ, DE, DK, EE, ES, FR, EL, HR, IE, IS, IT, LI, LU, NL, NO, PT, RO, SK, SE and NI). The slightly lower number of units transfused in 2022 is due to a lower volume reported (DE, FR), no longer reporting (HU, LV) and fewer establishments reporting in some countries (DE, FR).

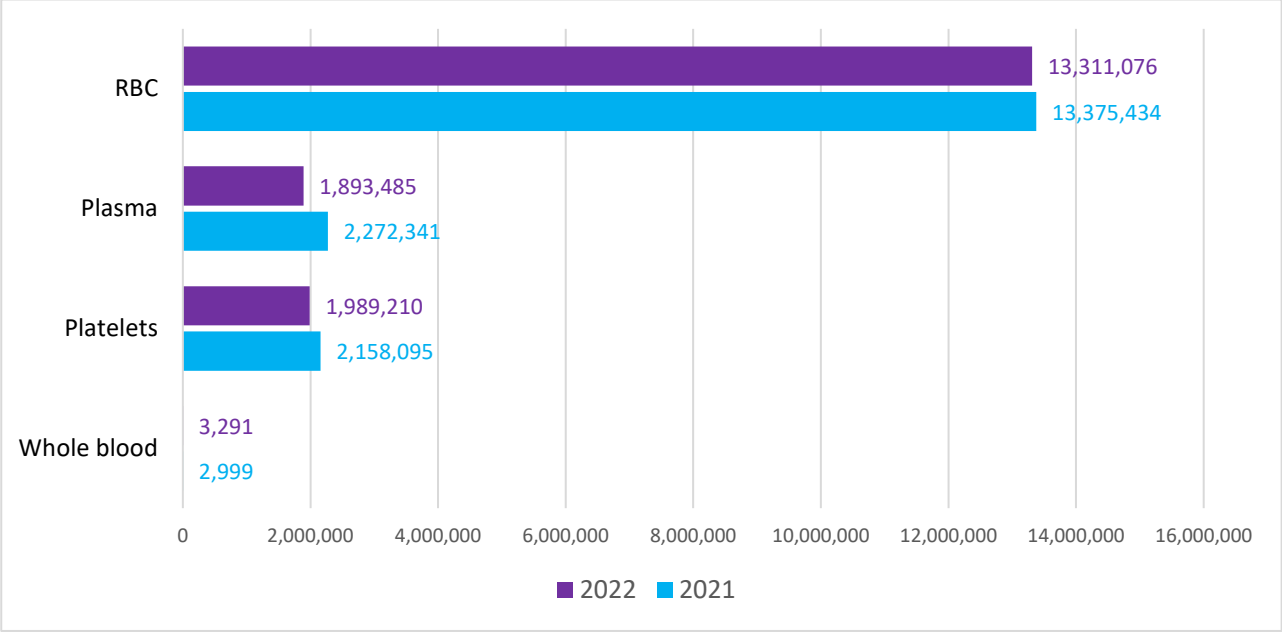


Figure 3. Units transfused per blood component; 2021 – 2022 comparative data

4.2.4 Number of blood component units issued and transfused by country

The number of units issued and transfused as reported by each country, compared with data from 2021, is presented in *Table 1*. Where only the number of units transfused was reported (ES, LI and NO), the units transfused were considered as units issued on the principle that the number of blood components issued was greater than or equal to the number of units transfused (only issued products are suitable for transfusion). The same data (in millions) is represented graphically in *Figure 4*.

Country	Number of units issued 2022	Number of units transfused 2022	Number of Units Issued 2021	Number of Units Transfused 2021	Difference issued	Difference transfused
Austria (AT)	**365 472**	**354 954**	323 548	313 628	**41 924**	**41 326**
Belgium (BE)	**498 757**	**501 521**	518 514	512 521	**-19 757**	**-11 000**
Bulgaria (BG)	**291 405**	**216 142**	238 582	197 206	**52 823**	**18 936**
Croatia (HR)	**252 538**	**242 853**	256 870	245 223	**-4 332**	**-2 370**
Cyprus (CY)	**90 013**	**87 004**	87 467	84 050	**2 546**	**2 954**
Czechia (CZ)	**560 162**	**556 974**	569 628	567 467	**-9 466**	**-10 493**
Denmark (DK)	**256 184**	**256 184**	254 611	255 219	**1 573**	**965**
Estonia (EE)	**59 952**	**59 584**	63 869	62 349	**-3 917**	**-2 765**
Finland (FI)	**202 696**		211 621		**-8 925**	**0**
France (FR)	**2 910 091**	**2 750 879**	3 005 234	2 817 261	**-95 143**	**-66 382**
Germany (DE)	**4 907 144**	**4 303 781**	4 983 716	4 983 716	**-76 572**	**-679 935**
Greece (EL)	**586 526**	**435 236**			**586 526**	**435 236**
Hungary (HU)	**541 383**		535 512	214 322	**5 871**	**-214 322**
Iceland (IS)	**16 025**	**14 330**	14 552	13 389	**1 473**	**941**
Ireland (IE)	**145 822**	**144 254**	145 501	144 185	**321**	**69**
Italy (IT)	**3 104 855**	**2 840 572**	2 964 204	2 885 769	**140 651**	**-45 197**
Latvia (LV)	**98 168**		92 038	91 115	**6 130**	**-91 115**
Liechtenstein (LI)	**205**	**205**	221	221	**-16**	**-16**
Lithuania (LT)	**142 159**		127 126		**15 033**	**0**
Luxembourg (LU)	**23 220**	**21 133**	24 237	23 785	**-1 017**	**-2 652**
Malta (MT)			23 059	17 892	**-23 059**	**-17 892**
Netherlands (NL)	**447 188**	**431 839**	457 317	440 791	**-10 129**	**-8 952**
Norway (NO)	**212 387**	**212 385**	212 938	212 938	**-551**	**-553**
Poland (PL)	**1 635 545**		1 615 651		**19 894**	**0**
Portugal (PT)	**372 793**	**350 455**	372 143	352 078	**650**	**-1 623**
Romania (RO)	**752 337**	**713 029**	674 654	655 704	**77 683**	**57 325**
Slovakia (SK)	**372 271**	**372 271**	341 234	341 234	**31 037**	**31 037**
Slovenia (SI)	**102 686**		101 897		**789**	**0**
Spain (ES)	**1 849 153**	**1 849 153**	1 883 734	1 883 734	**-34 581**	**-34 581**
Sweden (SE)	**548 144**	**438 169**	543 175	447 945	**4 969**	**-9 776**
UK (NI)	**48 529**	**44 155**	49 016	45 127	**-487**	**-972**
Total	**21 393 810**	**17 197 062**	20 691 869	17 808 869	**701 941**	**-611 807**

Table 1. Number of units issued and transfused by country (in millions); 2021 – 2022 comparative data

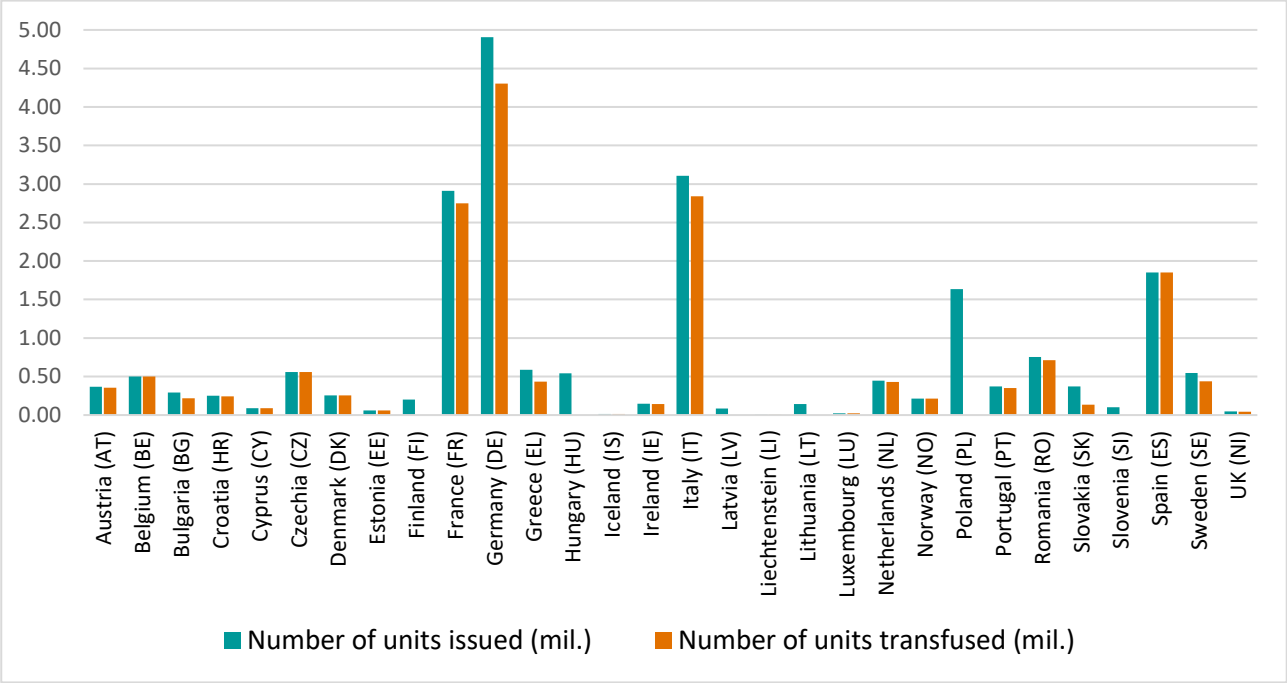


Figure 4. Number of units issued and transfused by country (million); data 2022

4.2.5 Number of recipients transfused

According to data reported by 22 countries (AT, BE, BG, HR, CY, CZ, DK, EE, EL, ES, FR, IS, IE, IT, LI, LU, NI, NL, PT, RO, SE and SK), **3 094 799** patients were transfused in 2022 (*Figure 5*). Three of these countries reported a total of 320 426 recipients for whom for the type of blood component transfused was not specified (EE 15 452, EL 130 403 and RO 174 571 units).

When interpreting these results, it should be noted that they do not reflect the fact that a given patient may have received more than one blood component; these patients were counted more than once.

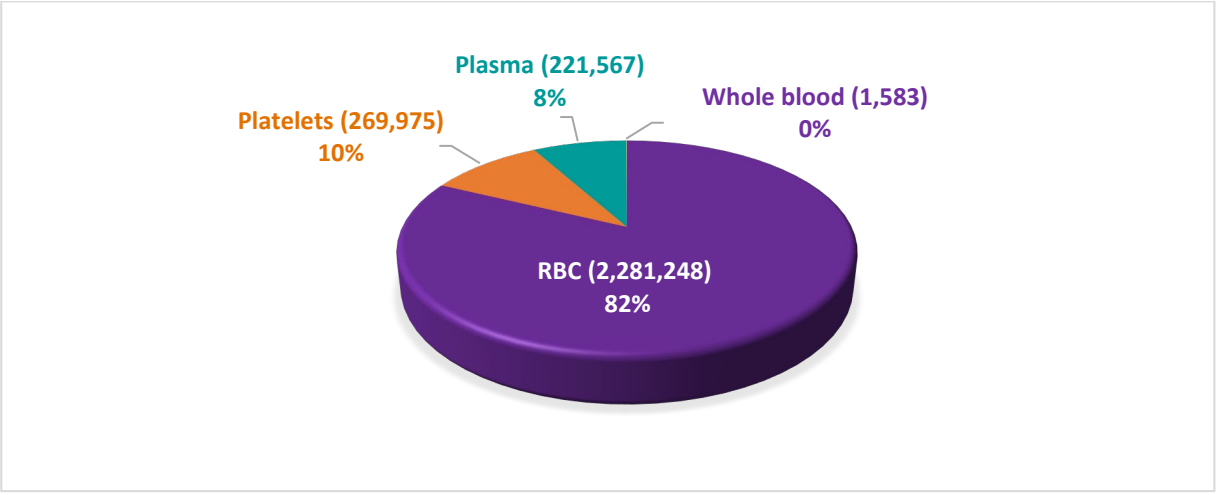


Figure 5. Recipients transfused per blood component; data 2022

Considering the demographic data of the reporting countries as of 1 January 2022[3], the incidence of issued and transfused blood components per 1 000 population is presented in *Figures 6 and 7.*

[3] https://ec.europa.eu/eurostat/web/population-demography/demography-population-stock-balance/database (Following Brexit, UK = Northern Ireland only)

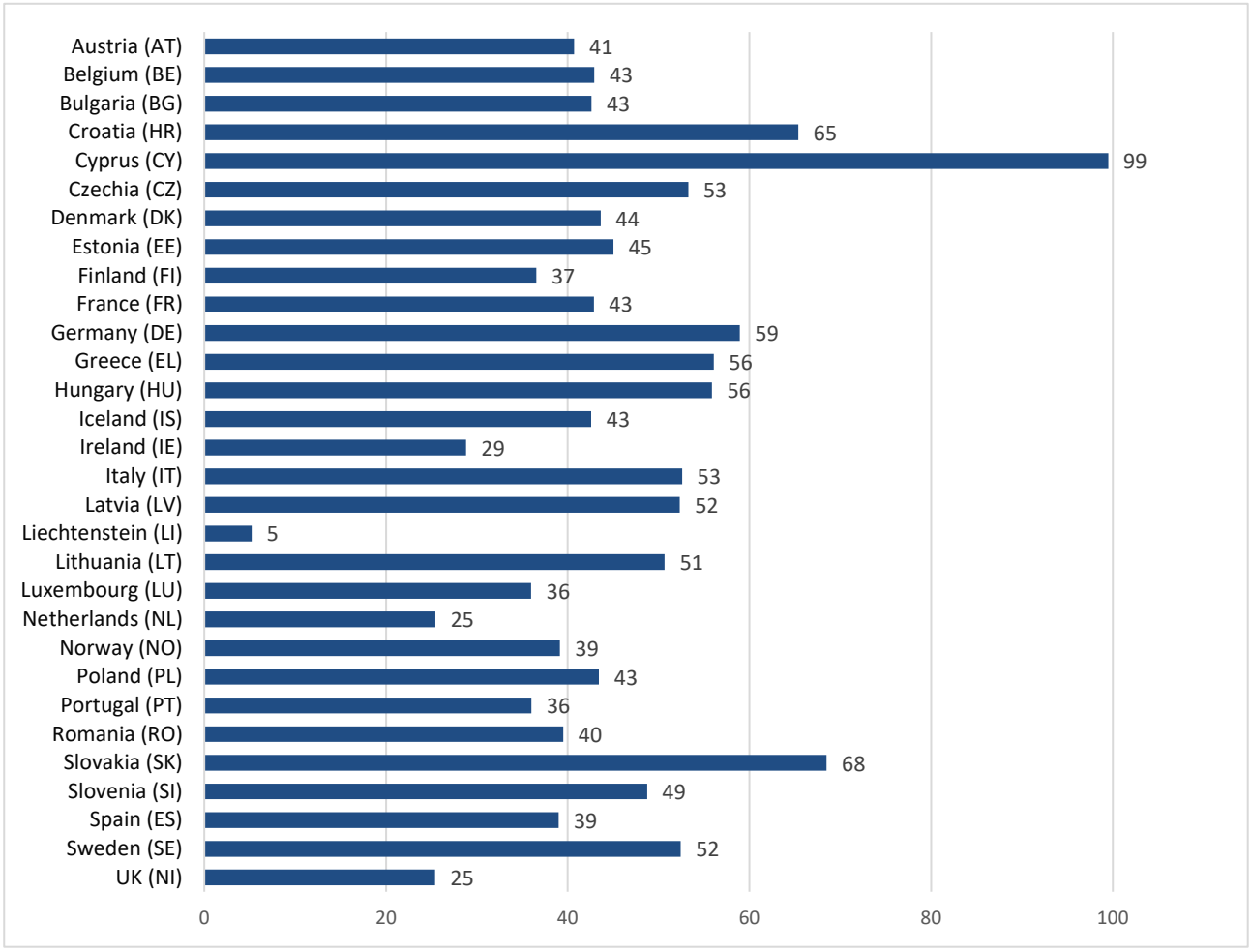


Figure 6. Number of blood units issued per 1 000 population; data 2022

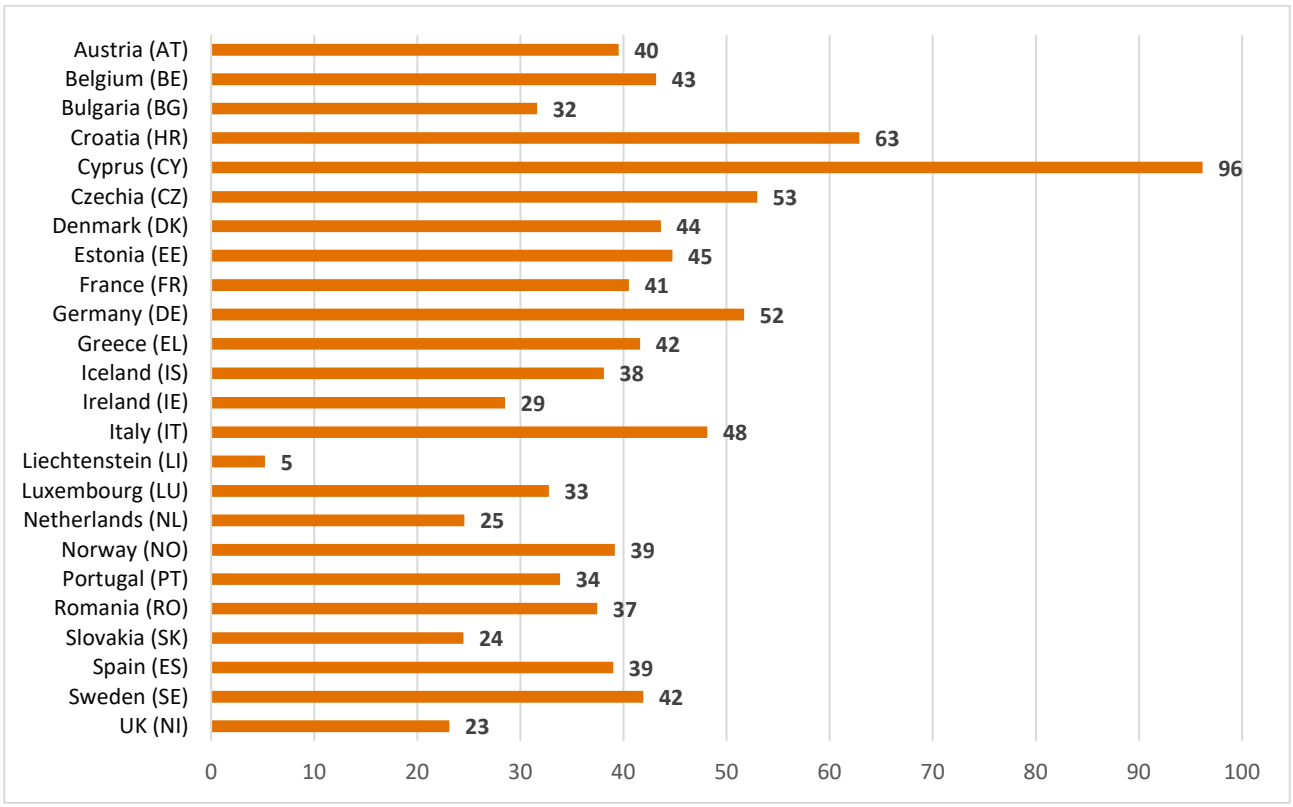


Figure 7. Number of blood units transfused per 1 000 population; data 2022

The incidence of blood component units transfused (per million population), calculated for each reporting country, is presented in *Table 2* below. Countries that did not provide data for at least one type of component were not included.

Country	RBC		Platelets		Plasma		WB	
	2022	2021	2022	2021	2022	2021	2022	2021
Austria (AT)	**34 933**	30 923	**4 383**	3 841	**216**	346		
Belgium (BE)	**33 517**	34 949	**5 389**	5 668	**4 263**	3 739		
Bulgaria (BG)	**16 718**	14 886	**3 976**	3 576	**10 910**	10 047	**1.0**	2.9
Croatia (HR)	**45 207**	43 451	**7 405**	7 020	**10 266**	10 283		
Cyprus (CY)	**74 556**	72 168	**6 866**	6 615	**14 745**	15 022	**1.1**	
Czechia (CZ)	**40 210**	40 109	**4 229**	4 474	**8 351**	9 355	**170.7**	133
Denmark (DK)	**31 395**	31 226	**5 781**	6 067	**6 442**	6 409		
Estonia (EE)	**33 285**	33 495	**5 116**	5 282	**6 337**	8 094	**1.5**	4.5
France (FR)	**32 341**	33 422	**4 985**	4 945	**3 202**	3 272	**3.2**	2
Germany (DE)	**38 521**	42 279	**5 811**	7 165	**7 374**	10 489		
Greece (EL)	**32,078**		**9,532**					
Iceland (IS)	**27,729**	27,091	**7,375**	5,564	**2,982**	3,650		
Ireland (IE)	**24,060**	24,328	**4,445**	4,472			**3.2**	0.2
Italy (IT)	**40,552**	40,747	**4,087**	3,999	**3,481**	3,970	**0.1**	0.3
Liechtenstein (LI)	**5 037**	5 505	**178**	77		77		
Luxembourg (LU)	**26 993**	28 789	**1 407**	4 881	**4 345**	3 803		
Malta (MT)	**-**	26 985	**-**	3 893	**-**	3 790		
Netherlands (NL)	**21 650**	22 225	**2 848**	2 957	**51**	42		
Norway (NO)	**27 278**	27 450	**4 378**	4 406	**7 491**	7 538		102.6
Portugal (PT)	**27 627**	28 139	**5 091**	4 939	**1 135**	1 109	**1.4**	1
Romania (RO)	**20 252**	18 258	**6 437**	5 579	**10 693**	10 270	**62.8**	41.4
Slovakia (SK)	**43 341**	37 606	**3 983**	4 425	**21 173**	20 469		
Spain (ES)	**31 484**	31 962	**4 774**	4 853	**2 727**	2 927	**0.2**	0.2
Sweden (SE)	**33 999**	35 013	**4 503**	4 509	**3 417**	3 631	**2.4**	4.3
UK (NI)	**18 196**	18 747	**3 443**	3 197	**1 473**	1 767		

Table 2. Incidence (number of units transfused per million population by blood component and by country); 2021 – 2022 comparative data

4.3 Serious adverse reactions in recipients

4.3.1 General information

The **incidence of SAR (imputability probable and certain)** in 2022 was **8.3 per 100 000 units transfused** (see section 4.3.2).

Twenty-seven SAR (imputability probable and certain) resulted in **death**. In terms of the type of blood component involved, 17 fatalities were associated with red blood cell (RBC) transfusion (63%), four with platelet transfusion (15%), four with transfusion of more than one blood component (15%) and two with transfusion of plasma (7%).

A summary is presented in *Figure 8*. **Note that SAR from countries that did not report the number of units transfused were excluded.**

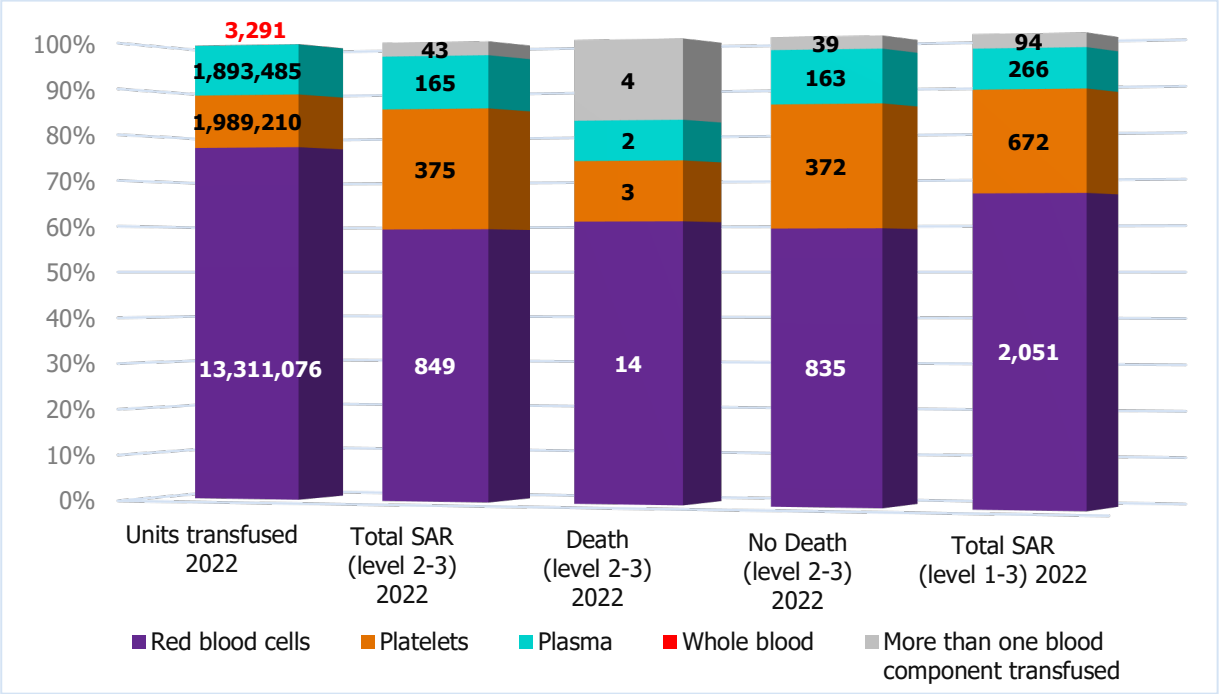


Figure 8. Number of SAR and fatalities by imputability level and by type of blood component; data 2022

The majority of the reported SAR (imputability level 2-3) were associated with transfusions of RBC, followed by platelets and plasma. The percentage of SAR by type of blood component is presented in *Figure 9*.

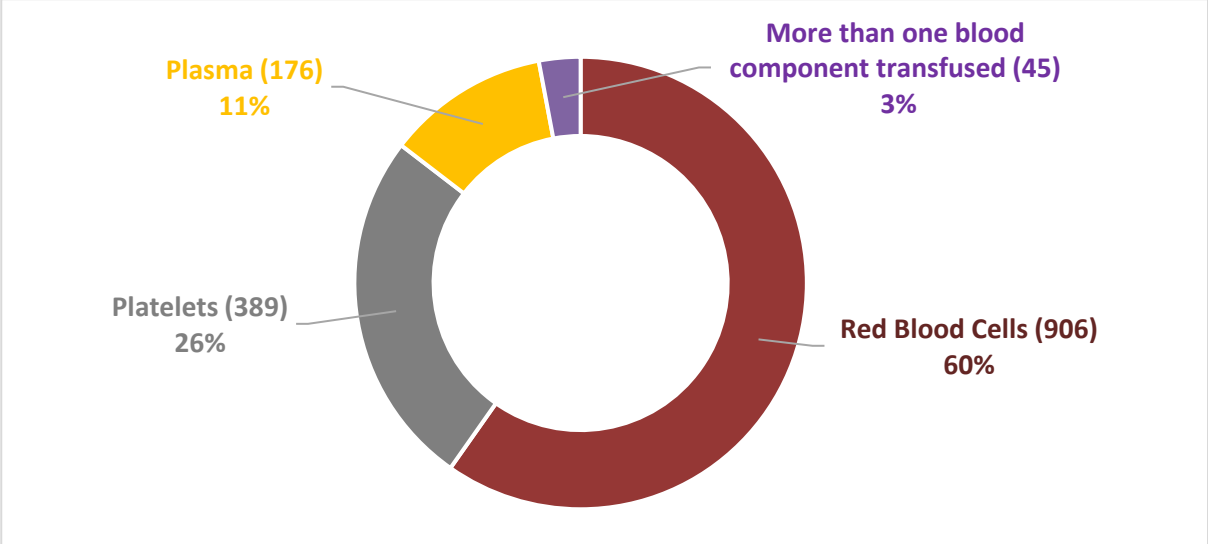


Figure 9. Data on SAR by blood component type; data 2022

The distribution of SAR imputability 1-3 and 2-3 by country and by blood component is presented in *Tables 3 & 4* and *Figures 10 & 11*.

Country	Red Blood Cells	Platelets	Plasma	More than one blood component transfused	Total # SAR
Austria (AT)	50	7	1		58
Belgium (BE)	65	12	5	2	84
Bulgaria (BG)	25	2	9		36
Croatia (HR)	6	2		1	9
Cyprus (CY)	12	5	5		22
Czechia (CZ)	14	1	5	1	21
Denmark (DK)	11	2	1	4	18
Estonia (EE)	4			1	5
Spain (ES)	54	20	8	3	85
Finland (FI)	12	4		1	17
France (FR)	49	31	37		117
Germany (DE)	585	136	44	54	819
Greece (EL)	52	22	17		91
Hungary (HU)	18	3	1		22
Ireland (IE)	64	17		2	83
Italy (IT)	824	367	105	16	1312
Latvia (LV)		1			1
Lithuania (LT)		1	1		2
Luxembourg (LU)		1			1
Netherlands (NL)	87	14		5	106
Norway (NO)	6	2		2	10
Poland (PL)	46	13	15	1	75
Portugal (PT)	11	5	1		17
Romania (RO)	4	2			6
Slovakia (SK)	113	19	26		158
Slovenia (SI)	10	4	1	1	16
Sweden (SE)	6	4	1	3	14
UK (NI)	9	1	1		11
Total	**2,137**	**698**	**284**	**97**	**3216**

Table 3. Number of SAR of imputability level 1-3 by country and type of blood component; data 2022

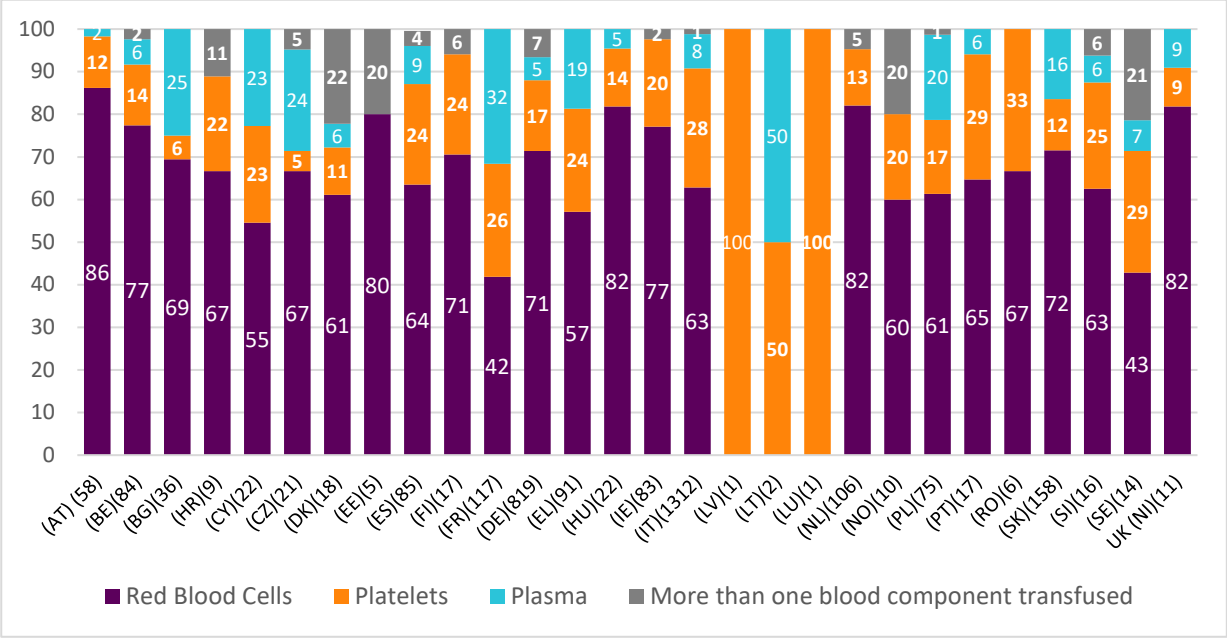


Figure 10. SAR imputability level 1-3 by country and type of blood component ; (percentages) data 2022

Country	Red Blood Cells	Platelets	Plasma	More than one blood component transfused	Total # SAR
Austria (AT)	20	3	1		24
Belgium (BE)	44	12	4	1	61
Bulgaria (BG)	1				1
Croatia (HR)	5	2			7
Cyprus (CY)	1				1
Czechia (CZ)	12	1	5	1	19
Denmark (DK)	7	2	1	1	11
Estonia (EE)	4			1	5
Spain (ES)	54	20	8	3	85
Finland (FI)	7	1			8
France (FR)	33	19	28		80
Germany (DE)	134	59	21	21	235
Greece (EL)	32	12	12		56
Hungary (HU)	11	3			14
Ireland (IE)	35	12			47
Italy (IT)	359	202	73	10	644
Latvia (LV)		1			1
Lithuania (LT)		1	1		2
Netherlands (NL)	29	11			40
Norway (NO)	6	2		2	10
Poland (PL)	33	7	10	1	51
Portugal (PT)	5	3			8
Romania (RO)	4	2			6
Slovakia (SK)	53	8	10		71
Slovenia (SI)	6	1		1	8
Sweden (SE)	6	4	1	3	14
UK (NI)	5	1	1		7
Total	**906**	**389**	**176**	**45**	**1,516**

Table 4. Number of SAR of imputability level 2-3 by country and type of blood component; data 2022

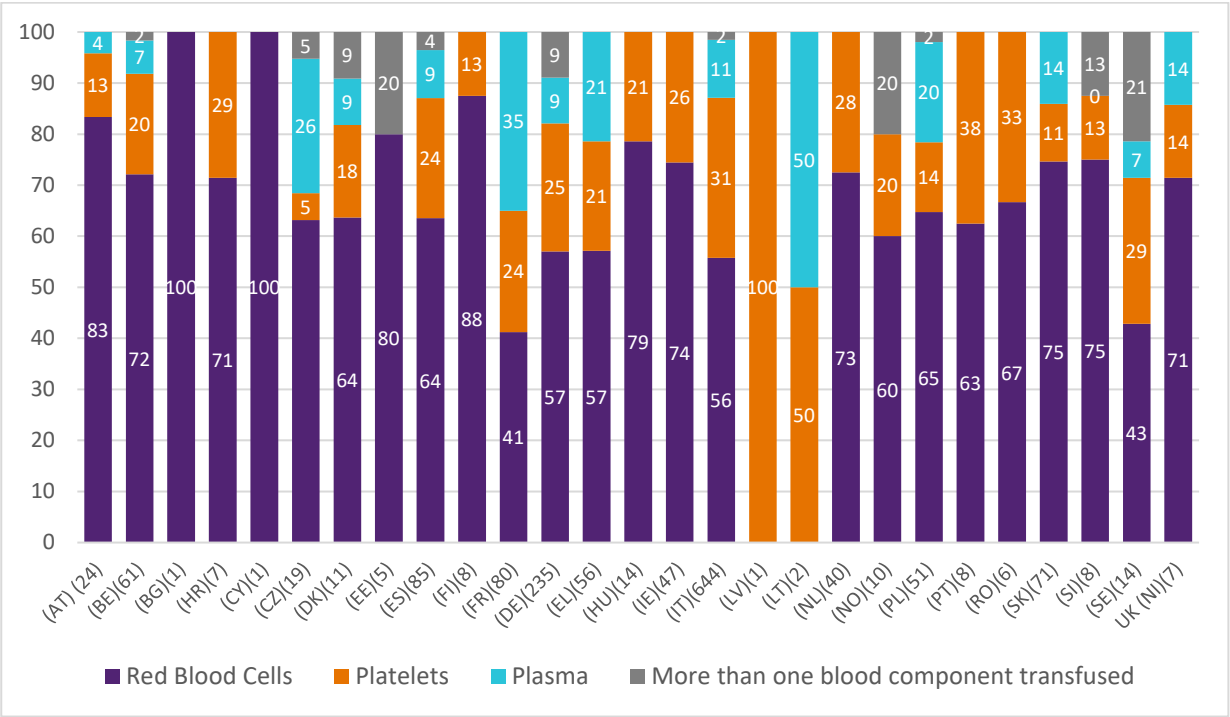


Figure 11. SAR imputability level 2-3 by country and type of blood component (percentages); data 2022

4.3.2 Incidence of SAR by type of blood component

As shown in *Table 3*, the risk associated with the transfusion of **platelets** is significantly higher compared to other blood components (based on data from those countries who provided the number of SAR and units transfused, per type of blood component).

Note that SAR from countries that did not report the number of units transfused have not been included (FI, HU, LT, LV, PL and SI).

Overall, the number of transfusion-associated SAR and fatalities in recipients reported every year remains relatively constant. In the last two years, the highest incidence of SAR with imputability established as probable and certain was associated with infusion of platelets and more than one transfused component. As for fatalities, the highest percentage was among patients who received more than one component.

Incomplete reporting and inherent variations in reporting accuracy must be considered in the interpretation of the results of SARE analysis. Notwithstanding these limitations, the risks associated with blood transfusion remain low due to advances in donor screening, improved testing, automated data systems and changes in transfusion practices.

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 **19.8**, **9.1** for plasma and **6.4** for RBC (*Table 5*).

As some participating countries reported partial data, the interpretation of these results should take into consideration this limitation.

Component type	**Units transfused** (reported by 24 countries)	**Total SAR (IL1-3)** (reported by 24 countries)	**Total SAR (IL2-3)** (reported by 24 countries)	**SAR (2-3) incidence (per 10^5 units transfused)**		**Fatalities (IL2-3)** (reported by 9 countries)	**Fatalities (%) among SAR IL2-3**		**Fatalities incidence (per 10^5 units transfused) 2022**	
				2022	2021		**2022**	2021	**2022**	2021
Red blood cells	13 311 076	2 051	849	**6.4**	5.4	14	**1.6%**	2.6%	**0.11**	0.14
Platelets	1 893 485	672	375	**19.8**	17.3	3	**0.8%**	1.1%	**0.16**	0.18
Plasma	1 818 743	266	165	**9.1**	7.2	2	**1.2%**	0%	**0.11**	0
Whole blood	3 291				66.7					
More than one blood component transfused		94	43			4	**9.30%**	4.6%		NA
Total	17 197 062	3 083	1 432	**8.3**	7.3	23	**1.6%**	1.7%	**0.13**	0.14

Table 5. Incidence of SAR by type of blood component; 2021 – 2022 comparative data

IL = Imputability Level

As shown in *Table 6*, the incidence of fatalities in the last four years as reported in the US FDA and SARE reports is comparable, with between 0.12 and 0.17 fatalities per 100 000 units transfused.

Resource	Fatalities (probable + definitive) incidence (per 100 000 units transfused)			
	FY** 2019	FY 2020	FY 2021	FY 2022
US FDA Report*	0.12	0.13	0.17	-
SARE Report	0.13	0.13	0.14	0.13

Table 6. Incidence of probable and definitive fatalities; 2019 – 2022 comparative data

*US FDA *Notification Process for Transfusion Related Fatalities and Donation Related Deaths* https://www.fda.gov/vaccines-blood-biologics/report-problem-center-biologics-evaluation-research/transfusiondonation-fatalities

** For the purposes of the US FDA Report, fiscal year (FY) = 1 October to 30 September the following year; for SARE, FY = 1 January to 31 December of the same year

4.3.3 SAR by type of reaction

As shown in *Figure 12*, the most common type of SAR in 2022 was **FNHTR** (23%), followed by **anaphylaxis/hypersensitivity** (18.6%) and **TACO** (13.2%). The distribution is the same as in 2021.

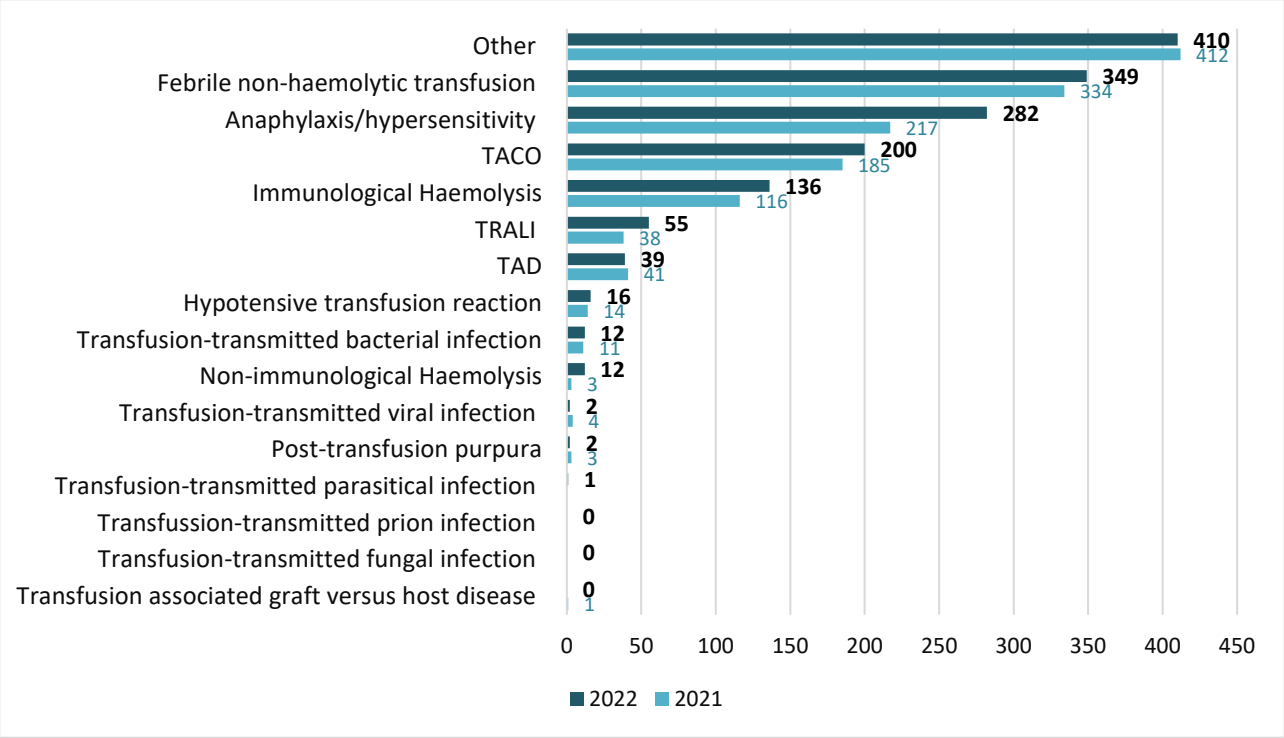


Figure 12. Distribution of SAR by type of reaction; 2021 – 2022 comparative data

As was the case in previous years, unclassified SAR remains the most prevalent group (27%). A list of the types of reactions in recipients classified as “others” is available in *Figure 13*. The definition of reactions needs to be revisited in order to address the potential issue of classification accuracy.

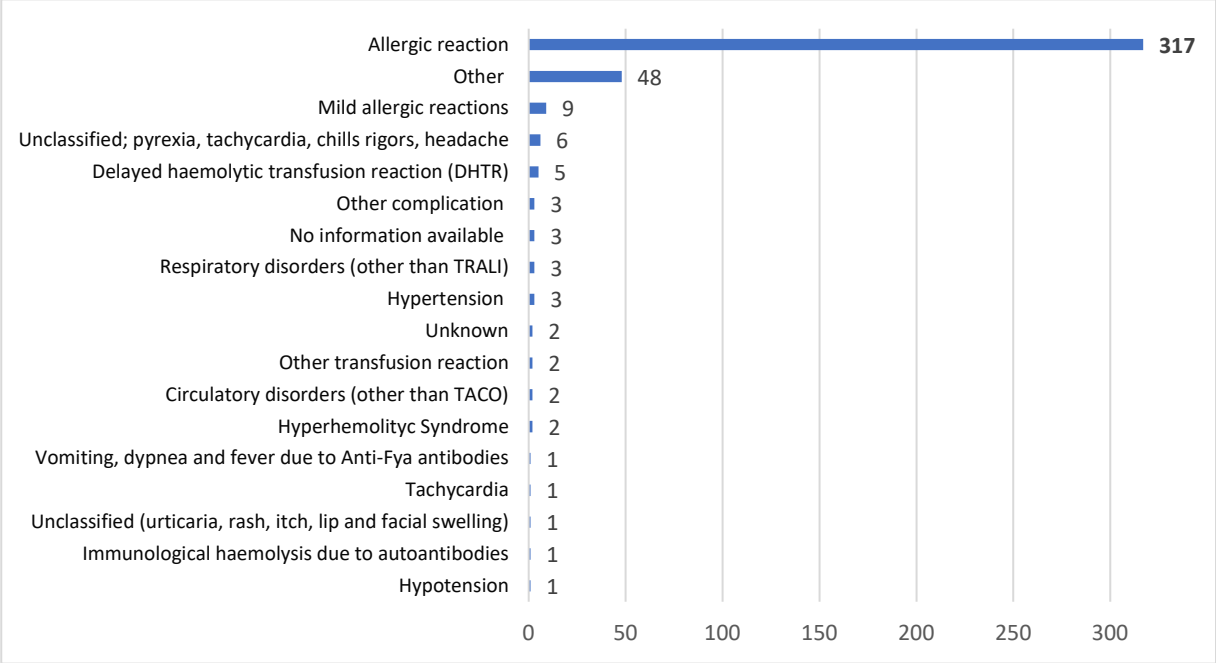


Figure 13. Distribution of SAR classified as “Others”, by subtype of other reaction; data 2022

A detailed presentation of SAR (imputability probable and certain) by type of reaction and type of blood component is available in *Table 7* below.

SAR type (Imputability Level 2 + 3)	Red blood cells		Platelets		Plasma		More than one blood component transfused		Whole blood		All		
	No Death	Death	No death	Death	No Death	Death	No Death	Death	No Death	Death	No Death	Death	Total
Febrile non-haemolytic transfusion reaction (FNHTR)	272		69		5		3				349		349
Anaphylaxis/hypersensitivity	74		123	1	67		17				281	1	282
TACO	174	4	8		10		4				196	4	200
Immunological haemolysis due to ABO incompatibility	115	8	4		6	1					125	9	134
Immunological haemolysis due to other allo-antibody							2				2		2
Non-immunological haemolysis	12										12		12
Post-transfusion purpura	1		1								2		2
Transfusion-related acute lung injury (TRALI)	30	3	8	1	3	1	5	4			46	9	55
Transfusion-transmitted bacterial infection	4	2	4	2							8	4	12
Transfusion-transmitted parasitical infection	1										1		1
Transfusion-transmitted fungal infection													
Transfusion-transmitted viral infection	1						1				2		2
Transfusion-transmitted prion infection													
Transfusion-associated graft-versus-host disease													
TAD	29		7		3						39		39
Hypotensive transfusion reaction	10		5		1						16		16
Other	166		156		79		9				410		410
Total	**889**	**17**	**385**	**4**	**174**	**2**	**41**	**4**	**0**	**0**	1 489	27	1 516

Table 7. Number of SAR (Imputability levels 2-3) by type of reaction and blood component; data 2022

Out of the 30 cases of transfusion-transmitted infections (TTI) reported in 2022, as presented in *Table 8*, 15 were assessed as imputability level 1 (IL1), 11 as IL2 and four as IL3. Except for three viral infections and one parasitical infection, all were bacterial infections. Of the 15 IL2 and IL3, four bacterial infections ended in death: two following transfusion of RBC (IL2) and two associated with platelets (one IL2 and one IL3).

The pathogen involved in the infections was specified for the viral infections only: one HBV, one HCV and one CMV. A recipient of RBC tested positive for HBV. The HBV infection was assessed as IL2 because the patient was not tested for HBV before blood transfusion; therefore, exposure to HBV prior to transfusion could not be ruled out. The investigation indicated that the repeat donor tested indeterminate for NAT screening (HIV, HBV, HCV) and positive for HBc antibody. The results of NAT screening for all previous donations were negative, but HBc and HBs antibodies were present.

Two blood recipients were tested for HBV (HBV Ag, HBe Ab, HBc Ab). One recipient tested 19 months after potentially infectious transfusion was positive for HBc Ab and negative for HBs Ag and HBe Ab. The HCV infection concerned a patient who received an RBC transfusion decades ago. Incomplete data prevented trace back.
No information was provided for the rest of the TTI, fatalities included.

TTI category	Total # of infection related SAR	Fatalities	RBC		Platelets		More than one component	
			No fatalities & IL	Fatalities & IL	No fatalities & IL	Fatalities & IL	No fatalities & IL	Fatalities & IL
TTBI	**26**	**4**	**13** 9 IL1 3 IL2 1 IL3	**2** 2 IL2	**9** 5 IL1 3 IL2 1 IL3	**2** 1 IL2 1 IL3	-	-
TTVI	**3**	**-**	**2** 1 HCV IL1 1 HBV IL2	-	-	-	**1** 1 CMV IL2	-
TTPI	**1**	**-**	**1** 1 Other IL3	-	-	-	**-**	-

Table 8. Transfusion-transmitted infections; data 2022

TTI = transfusion-transmitted infections
TTBI = transfusion-transmitted bacterial infection
TTVI = transfusion-transmitted viral infection
TTPI = transfusion-transmitted parasitical infection

4.3.4 Transfusion-related fatalities

4.3.4.1 Type of SAR associated with fatalities

Ten countries (BE, DE, DK, EL, ES, FI, FR, HU, NL and UK) reported a total of 46 fatalities in recipients in 2022. Of these, 27 were assigned **imputability level 2 and 3**, the majority of which were associated with TRALI (9) and immunological haemolysis due to ABO incompatibility (8), followed by bacterial infection (4), TACO (4), immunological haemolysis due to other allo-antibody (1) and anaphylaxis/hypersensitivity (1). Seventeen fatalities were related to transfusions of RBC, four to more than one component, four to platelets and two to plasma. A comparison with data from the previous year is presented in *Figure 14*.

- **TACO** (4) - following RBC transfusion
- **Immunological haemolysis due to ABO incompatibility** (8) – following RBC transfusion (7) and plasma (1)
- **Immunological haemolysis due to other alloantibodies** (1)- following RBC transfusion
- **Bacterial infection** (4) – *non-specified* bacterial infections transmitted via RBC (2) and platelet transfusion (2)
- **TRALI** (9) - following platelet transfusion (1), RBC transfusion (3), plasma (1) and more than one component transfusion (4)
- **Anaphylaxis/hypersensitivity** (1) - uncategorised adverse reaction following RBC transfusion

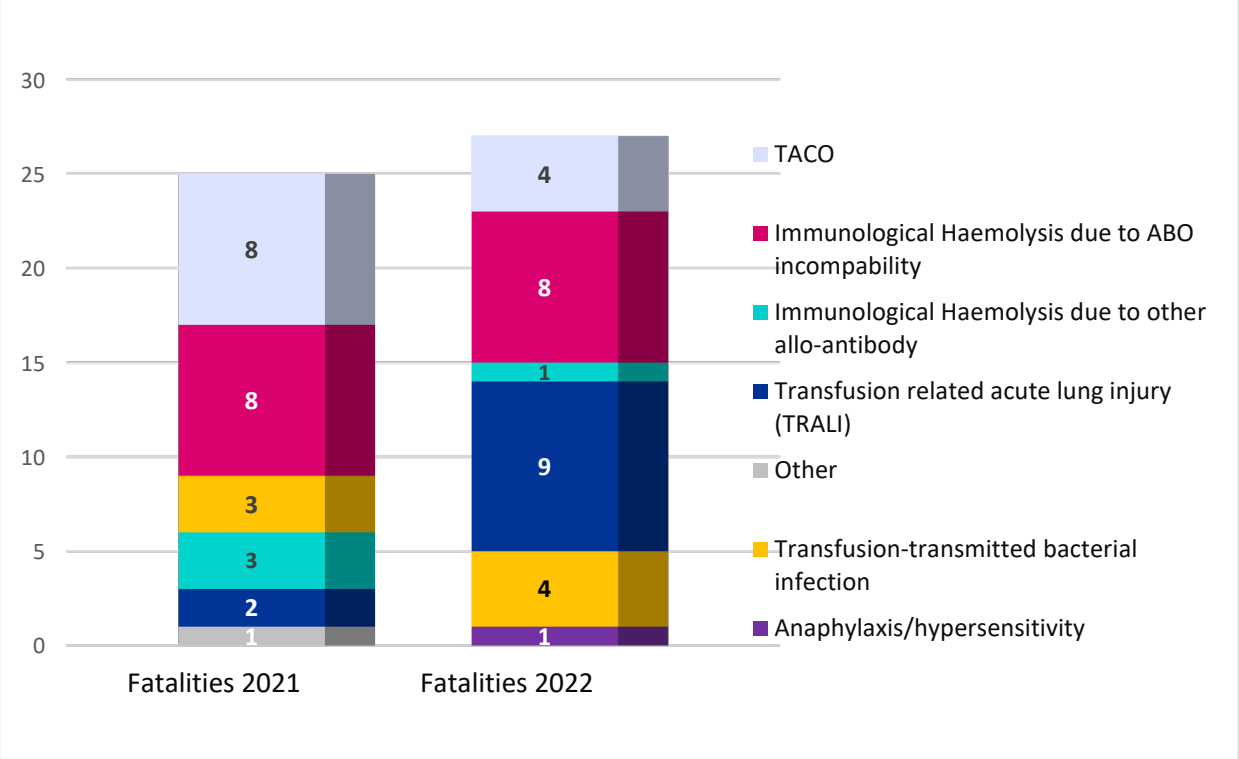


Figure 14. Fatalities by SAR type (imputability level 2-3); 2021 – 2022 comparative data

In addition, **19 fatalities** with **imputability possible** were reported by seven countries (DE, DK, FI, FR, HU, NL and UK), 58% of which were associated with TACO, as shown in *Figure 15*.

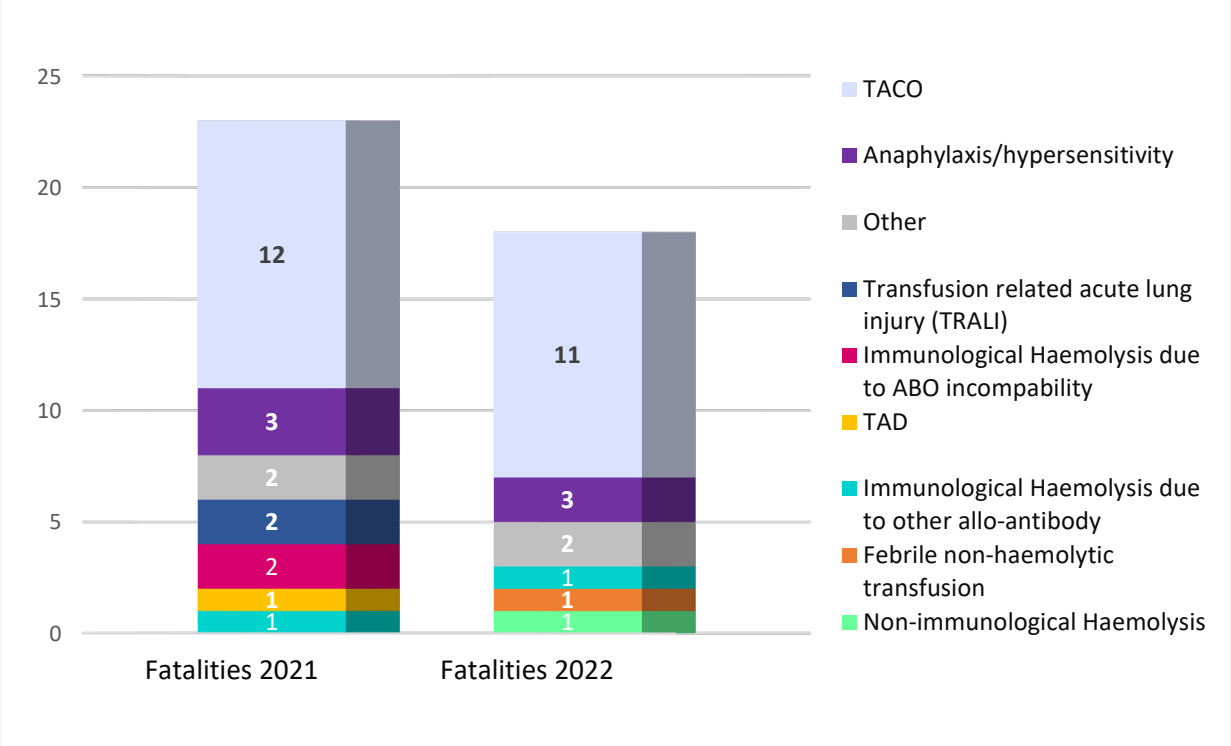


Figure 15. Fatalities by type of SAR (imputability level 1); 2021 – 2022 comparative data

4.3.4.2 Investigation of fatalities

The *Common Approach*, edition 2023, recommends: "Concerning reports where an SAR is confirmed to be fatal, any relevant information should be reported in the comments box, such as:
(1) a brief description of patient details (if possible: gender, age, initial illness, clinical indications for transfusion etc.),
(2) a brief description of the occurrences that led to the fatality,
(3) a list of transfused units of blood/blood components; for each unit, any relevant information regarding the preparation of the implicated component(s) (leucodepletion, apheresis...),
(4) the conclusions and follow-up actions (corrective and preventive), if appropriate."

The 13 SAR confirmed to have resulted in fatalities due to transfusion (IL3) were as follows:

- six cases of immunological haemolysis due to ABO incompatibility (transfusion of RBC (5) and plasma (1))
- three cases of TACO (transfusion of RBC)
- two cases of TRALI (transfusion of RBC (1) and plasma (1))
- one case of transfusion-transmitted bacterial infection (transfusion of platelets), and
- one case of immunological haemolysis due to allo-antibodies (RBC)

Only three countries (BE, FI and FR) submitted information regarding ten fatalities: three with IL1, three with IL2 and four with IL3. The reporting style differs among countries, some providing adequate context and investigative actions, some insufficient. The recommendations of the *Common Approach* remain largely unmet, especially with regard to the cause(s) that led to the fatal outcome and corrective and/or preventive actions, which are expected for IL3 fatalities but are rarely reported.

4.3.5 International benchmarking

On 4 April 2024, the MHRA issued the safety alert ***National Patient Safety Alert: Reducing risks for transfusion-associated circulatory overload (NatPSA/2024/004/MHRA)[4].*** Within the EU, TACO accounted for 13% of severe adverse events reported in 2022 and 2021, and 16% in 2020; in addition, TACO was identified as the cause of 58% of all fatalities (imputability levels 1-2-3) in 2022, and 15% of SAR IL2-3 (four fatalities due to TACO out of 27 SAR IL2-3). The MHRA states that "TACO is one of the most common causes of transfusion-related deaths in the UK and cases have increased substantially in recent years. Identifying risk factors for TACO prior to transfusion allows initiation of appropriate mitigating measures", and, very important, "TACO deaths are potentially preventable". Risk reduction measures recommended in this notice could benefit transfusion practices everywhere.

SHOT Annual Report 2022[5] - Key SHOT messages:

- "Safe staffing: Clinical and laboratory teams can function optimally only if adequately staffed and well-resourced. Staffing challenges in both clinical and laboratory areas are commonly cited as contributory in transfusion incidents and must be addressed urgently. Adequate numbers of appropriately trained staff must be available to ensure safe transfusions; there should be contingency planning for staffing levels below a minimum level and for times of high workload

[4] https://www.gov.uk/drug-device-alerts/national-patient-safety-alert-reducing-risks-for-transfusion-associated-circulatory-overload-natpsa-slash-2024-slash-004-slash-mhra
[5] https://www.shotuk.org/wp-content/uploads/myimages/SHOT-REPORT-2022-FINAL-Bookmarked-1.pdf

- Well-resourced systems: Healthcare leaders and management must ensure that staff have access to the correct IT equipment which is fit for purpose. Adequate financial resources are a must for safe and effective functioning of teams
- Addressing knowledge gaps, cognitive biases, and holistic training: Transfusion training with a thorough and relevant knowledge base in transfusion to all clinical and laboratory staff along with training in patient safety principles, understanding human factors and quality improvement approaches are essential. It is important that staff understand how cognitive biases contribute to poor decision-making so that these can be mitigated appropriately
- Patient safety culture: Fostering a strong and effective safety culture that is 'just and learning' is vital to ensure a reduction in transfusion incidents and errors, thus directly improving patient safety
- Addressing transfusion delays: Avoidable transfusion delays continue to contribute to patient deaths and measures recommended in the SHOT CAS alert (SHOT 2022) must be implemented to address these
- Addressing transfusion errors: Errors continue to be the source of most SHOT reports (83.1%). While transfusions are largely safe, errors can result in patient harm. Many of these are caused by poor communication and distraction. These must be investigated using human factors principles based incident investigations and appropriate mitigating measures implemented
- Learning from near misses: Reporting and investigating near misses helps identify and control risks before actual harm occurs, providing valuable opportunities to improve transfusion safety
- Shared care: Clear, timely and comprehensive communication between all teams and hospitals involved in patient care is vital in ensuring patient safety. Robust and transparent processes must be in place for safe and effective transfer of information at all points in the patient-care pathway**"**

Swissmedic Haemovigilance Annual Report 2022[6]: Similar to the situation at EU level, as reflected in this report, the most frequent transfusion reactions reported in Switzerland were FNHTR, allergic reactions and TACO. **"***If allo-immunisations are excluded, the majority of the 747 TR were accounted for by FNHTR (56%), allergic TR (20%), TACO (5%) and hypotensive TR (2.4%). 12% of the reports were classed in the category «Other»*"

Transfusion of platelets was associated with the highest rate of SAR, both in Switzerland and in the EU: *"Transfusion of PC is associated with a high incidence of febrile and anaphylactoid reactions in the literature 6. This picture was confirmed again in Switzerland in 2022: The transfusion of PC was associated with the highest rate of TR overall (452/100,000 transfusions), of which FNHTR (237/100,000) and allergic reactions (163/100,000) were the most common types of reaction."*

In terms of fatalities and near miss events, Swissmedic reinforces the need for diligent identification, reporting, and analysis of SAR/E: "*A total of three fatal transfusion reactions were reported in 2022. Similarly to ISBT, transfusion reactions are only classified as deaths (grade 4) if imputability is evaluated as at least possible. In this year also, two of the ultimately fatal reactions were TACO – in this connection we would once again urgently refer to the recommendation to screen patients for a TACO risk and, if applicable, aim for a slow transfusion rate (e.g. 1ml/kg body weight) and consider pre-emptive diuretic treatment 4, 5. All three fatalities involved clinically complex situations in which the respective transfusion reactions cannot be viewed in isolation.*

[6]Swissmedic Haemovigilance Annual Report 2022 available at https://www.swissmedic.ch/swissmedic/en/home/humanarzneimittel/market-surveillance/haemovigilance.html

The discovery, processing and reporting of transfusion errors is a sign of a functioning quality management system. A structured incident analysis should be performed, taking all the process factors into account. 59% of the IBCT reports in 2022 identified «human error» (failure to follow an existing SOP, human error, individual error) as the main cause of the incident. While the existence and contribution of human, individual error is undeniable, it is important to consider these errors as part of (and in some cases the consequence of) existing processes and surrounding factors 10, with the aim of identifying factors that increase the likelihood of an error being made and finding options to improve safety. Activities that are only carried out rarely often involve a greater degree of uncertainty since they are not part of the daily routine. This may apply to activities that rarely arise in general, or to activities that can only be undertaken at certain times on a delegated basis. If other factors are added (e.g. night shift, reduced staffing), the risk of error is further increased. It is important to identify these situations, train for them regularly and check for possible resources that could help. These could include flowcharts that provide clear overviews of certain scenarios (card, sign, etc.), technical measures (e.g. access restrictions: refrigerators (blood stores) that may not be used should be kept separate and protected against unauthorised access). Last but not least, the evaluation of the IBCT shows the importance of standardised procedures in transfusion practice that must be followed to the letter – e.g. the mandatory checking of the blood product at the patient's bedside.

97% of all near miss events were discovered in the laboratory…and include both cases when a blood sample was received (e.g. incorrect labelling, discrepancy between label and delivery note) and cases that were not noticed until the blood sample had been analysed (e.g. discrepancy between the blood group and previous findings in the context of WBIT). Here, the difference between the most common localisation of the error (clinical: preparation) and discovery (laboratory) illustrates the principle of sequential control (and the possibility of discovering an error) at each step of the process."

4.4 Serious adverse events

4.4.1 General information

The main denominator for SAE is the total number of **blood units processed**. During 2022, a total of **22 943 682** blood units were processed according to data provided by 27 countries (AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, IE, IS, IT, LT, LU, LV, NL, NO, PL, PT, RO, SE SI, and UK(NI)). An overview of data on blood units processed over the reporting years is presented in *Figure 16*.

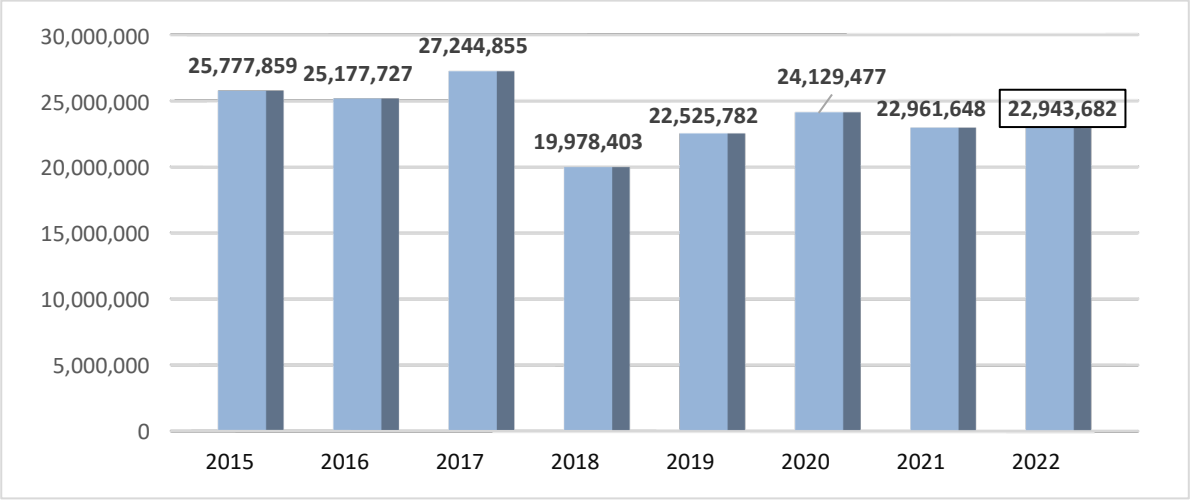


Figure 16. Total number of blood units processed: 2015-2022 comparative data

2 235 SAE were reported in 2022 by 25 countries (AT, BE, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, IE, IS, IT, LV, NL, NO, PL, PT, RO, SE, SI, SK and UK(NI)). As shown in *Figure 17,* the number of SAE reported varied substantially between reporting countries, similar to previous years. It is recommended to exercise caution when drawing conclusions from these data as 80% of SAE were reported by only six countries (BE, DE, FR, IE, RO and SE).

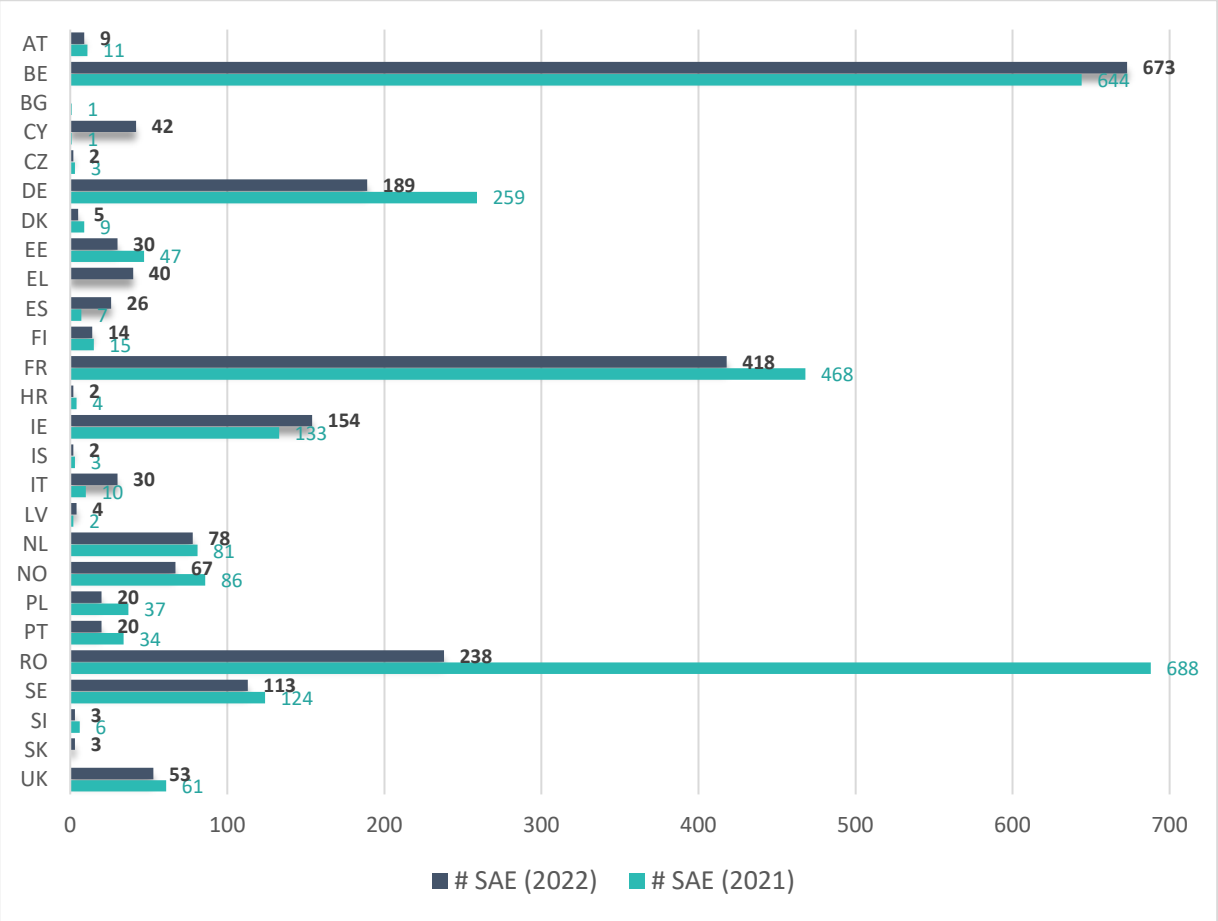


Figure 17. Number of SAE by country; 2021 – 2022 comparative data

4.4.2 Incidence of SAE

SAE occur at all stages of the transfusion cycle, from donor selection to clinical services, but the only available denominator is *number of units processed*, which is not optimal. Regardless, it has been used to calculate the incidence of SAE (per 100 000 units of blood/blood components processed).

The incidence of SAE per reporting country is presented in *Table 9* and *Figure 18* below.

Note: The 3 SAE reported by SK were not considered due to the fact that number of units processed was not reported and, therefore, incidence could not be calculated.

Country	# Units processed	# SAE (2022)	SAE/100 000 units processed 2022	SAE/100 000 units processed 2021
Austria (AT)	399 678	9	**2**	3
Belgium (BE)	616 377	673	**109**	101
Bulgaria (BG)	389 174		**0**	0.4
Croatia (HR)	189 458	2	**1**	2
Cyprus (CY)	67 942	42	**62**	1.5
Czechia (CZ)	1 662 587	2	**0**	0.2

Denmark (DK)	678 965	5	**1**	1.4
Estonia (EE)	50 157	30	**60**	91
Finland (FI)	212 135	14	**7**	7
France (FR)	2 665 302	418	**16**	16
Germany (DE)	6 501 815	189	**3**	4
Greece (EL)	619 940	40	**6**	
Iceland (IS)	12 190	2	**16**	27
Ireland (IE)	139 986	154	**110**	96
Italy (IT)	2 982 624	30	**1**	0.3
Latvia (LV)	59 433	4	**7**	3.4
Lithuania (LT)	106 980		**0**	0
Luxembourg (LU)	21 058		**0**	0
Netherlands (NL)	750 000	78	**10**	11
Norway (NO)	183 592	67	**36**	47
Poland (PL)	1 411 027	20	**1**	3
Portugal (PT)	379 487	20	**5**	11
Romania (RO)	412 431	238	**58**	90
Slovenia (SI)	177 166	3	**2**	3.5
Spain (ES)	1 714 696	26	**2**	0.4
Sweden (SE)	495 941	113	**23**	24
UK (NI)	43 541	53	**122**	140
Total	22 943 682	2 232	9.8	11.4

Table 9. Incidence of SAE per 100 000 units processed; 2021-2022 comparative data

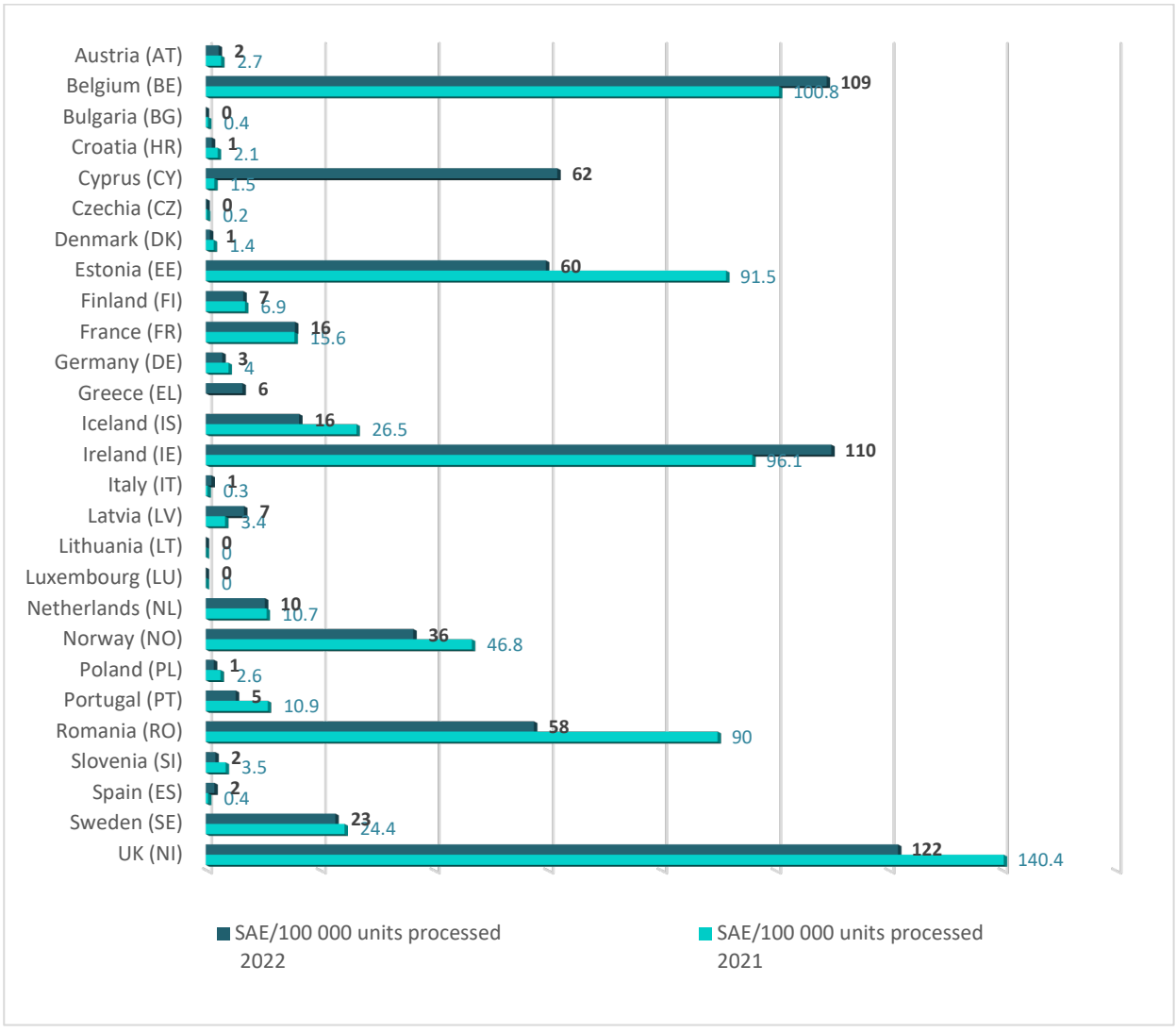


Figure 18. Incidence of SAE per 100 000 units processed; 2021 – 2022 comparative data

4.4.3 SAE by activity step

According to the *Common Approach*, version 2023, Annex II, the activity steps where SAE could occur or be identified include donor selection, whole blood apheresis collection, testing, processing, storage, distribution, component selection, compatibility testing/cross matching, issue and other.
Similar to the previous year, SAE classified as **other SAE** were the most represented (43%), followed by those attributed to **donor selection** and **storage** (each 11%), **issue** 9%) and whole blood collection (7%), as shown in *Figure 19*.

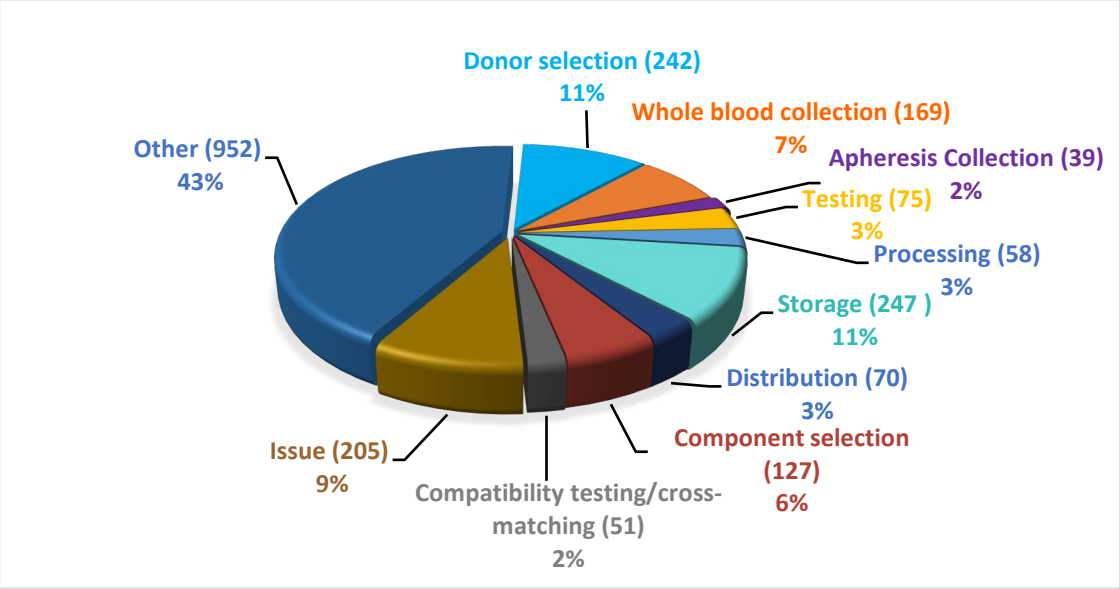


Figure 19. Distribution of SAE by activity step (absolute numbers and percentages); data 2022

Discrepancies between countries in terms of how activity steps are assigned persist; 952 (43%) of all SAE were reported under the activity step 'Other' and as SAE types instead of activity steps. The distribution by country of SAE attributed to activity steps **other** than the ten listed in the Common Approach, Annex II, is presented in *Figure 20.*

This raises the question of accuracy of classifying SAE by activity step, as well as issues of over/under reporting, but it may also be an indication that the activity steps need to be defined in line with current processes specific to blood establishments.

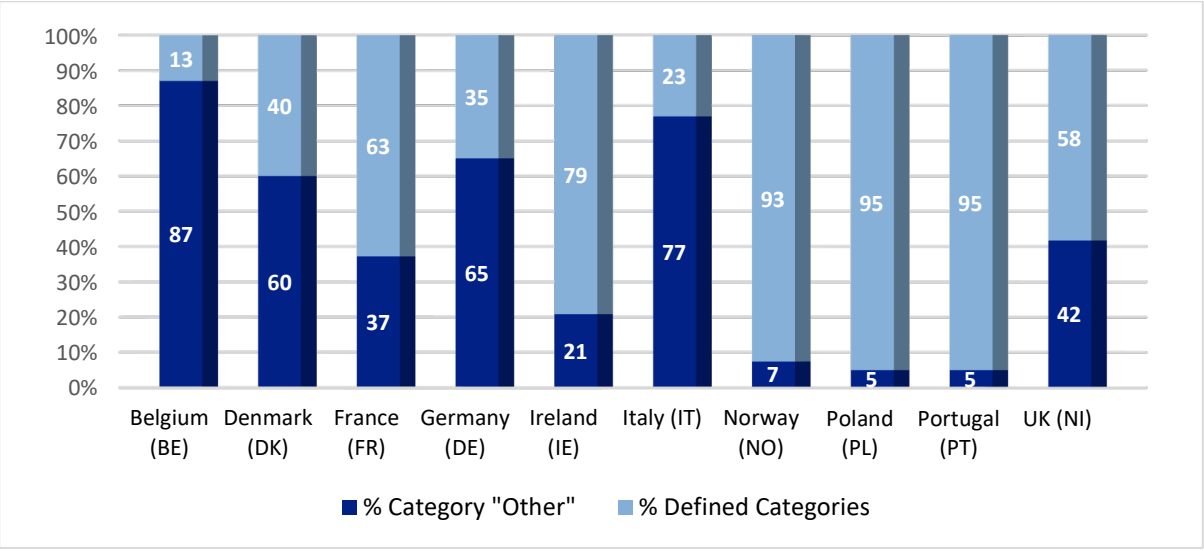


Figure 20. Percentage of SAE reported for activity steps other than the ten steps listed in the Common Approach, Annex II; data 2022

4.4.4 SAE by type of event

The most commonly reported SAE in 2022 were related to **human error** (49%), followed by component defect (24%), **system failure** (11%) and **equipment failure** (10%). The number of SAE classified as human error, increased again in 2022 after a downward trend in recent years.

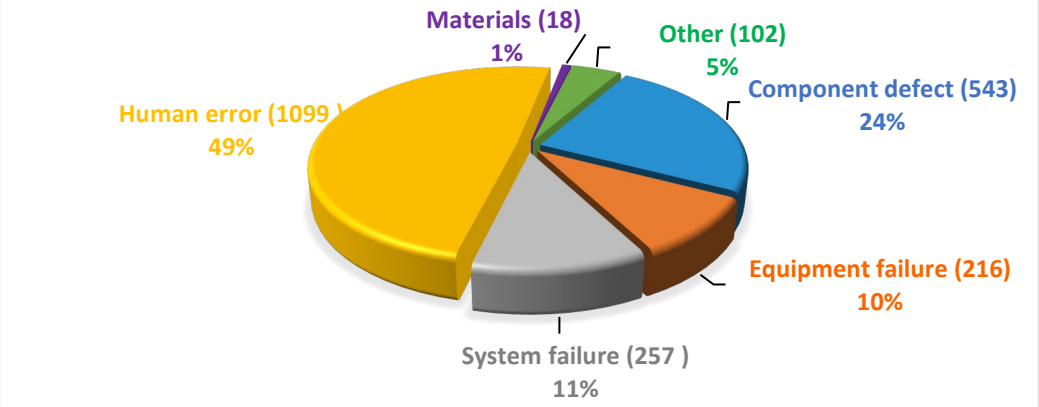


Figure 21. Distribution of SAE by type (absolute numbers and percentages); data 2022

Human error can occur at any stage in the transfusion chain, from donor selection to transfusion and patient follow-up. The distribution of the 1 099 SAE classified as human error by activity step is presented in *Figure 22*. Note that certain (sub)types of events were reported as activity steps, specifically failure of the post-donation system, post-donation information known by the donor at the time of donation, loss of transfusion, delayed transfusion and transfusion to wrong patients. These are currently not among the six types of events (specifications) included in the *Common Approach*, but are valid types of failures and could either be incorporated into the existing classification, or the list of specifications could be revisited/expanded to include other types of failure that member states currently have in place (national haemovigilance programmes).

The information on the SAE reported does not allow a detailed analysis as information was provided for only 22% of SAE (496 out of 2 235), was insufficient and not always clear. Examples of SAE reported as "*human error*" are provided in *Annex 1*. Another concern, in addition to the quality and quantity of information provided, is that the SAE specification was not always adequately assigned.

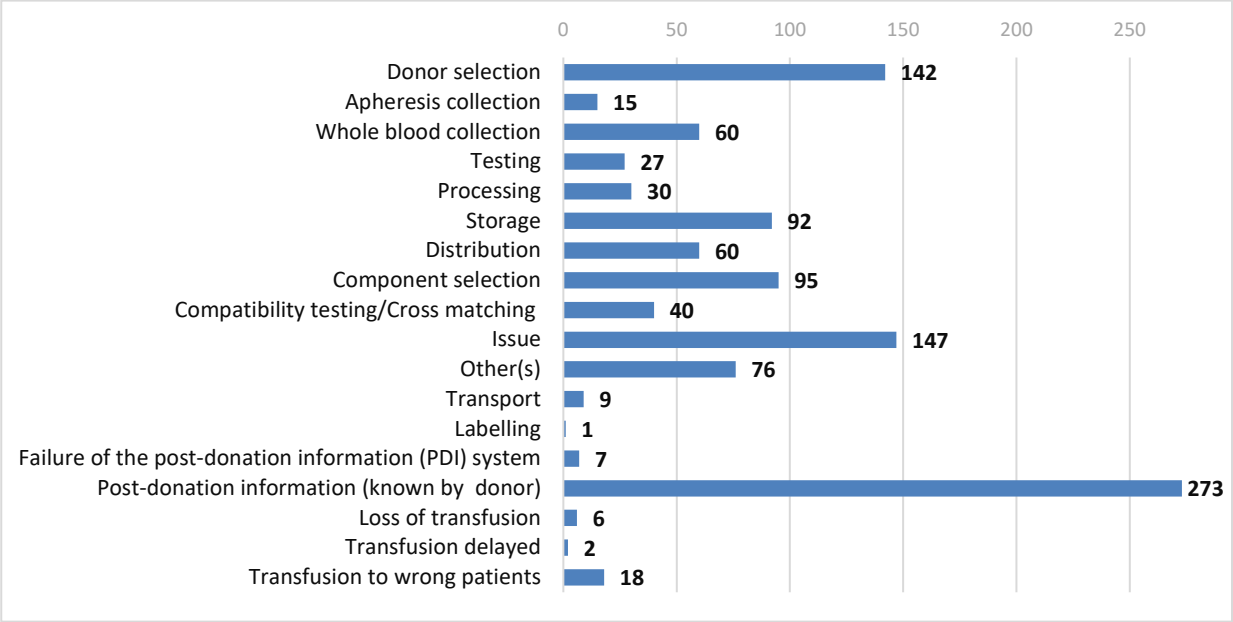


Figure 22. Distribution by activity step of SAE classified as human error; data 2022

A detailed presentation of SAE by type for each reporting country is available in *Figure 23* below.

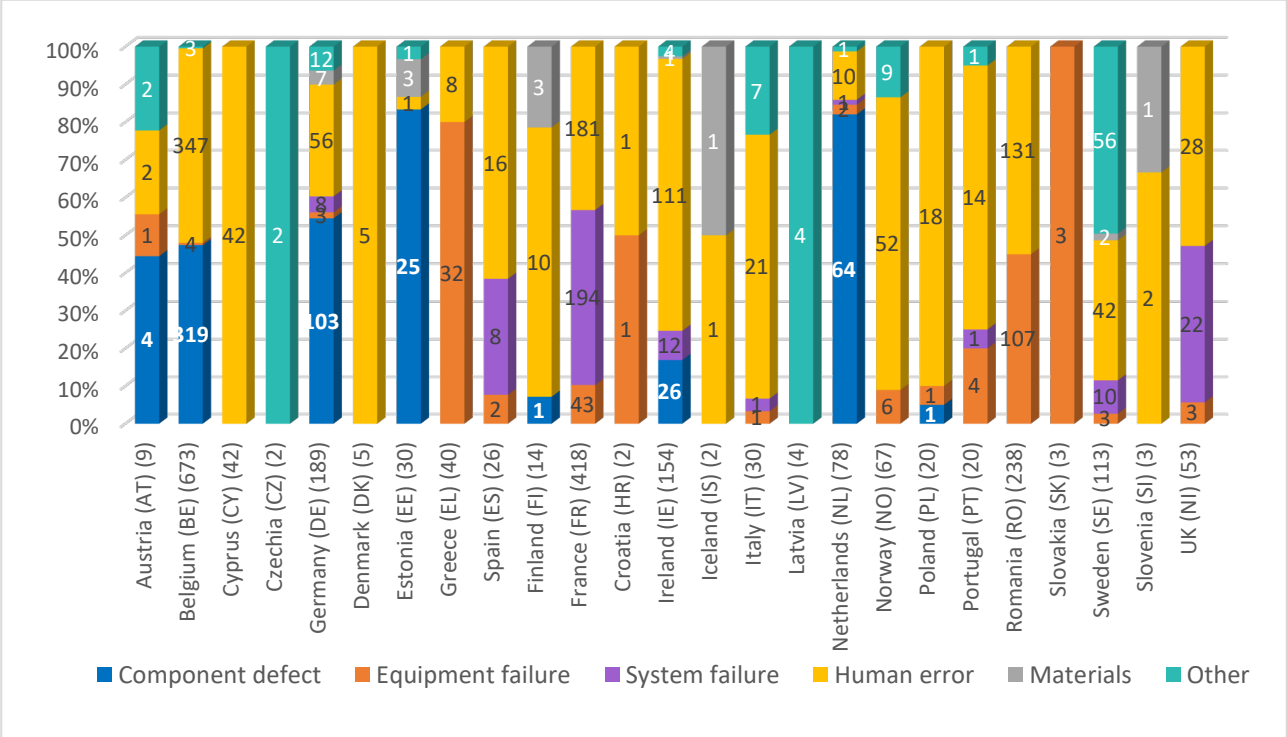


Figure 23. SAE by type and by country; data 2022

4.5 Severe adverse reactions in donors

According to Directive 200/61/EC, SAR in donors are not reportable unless they impact the quality and safety of the blood components[7]. However, as an acknowledgment of the value of data on SAR in donors, the Commission encourages member states to submit these reactions on a voluntary basis. Thus, a specific "SAR in donors of blood or blood components" section is included in the reporting template.

[7] Article 5 of Directive 2005/61/EC

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 a fatality was possibly, probably or certainly related to the donation process (imputability 1, 2 or 3).

Twenty-three countries (AT, BE, BG, HR, CY, CZ, DE, DK, EE, EL, ES, FR, IE, IS, IT, LU, NL, NO, PL, PT, RO, SI and SE) reported, on a voluntary basis, a total of **3 245 SAR in donors**. The comparative data from SARE exercises in the period 2016-2022 (2015-2021 data) is presented in *Figure 24*.

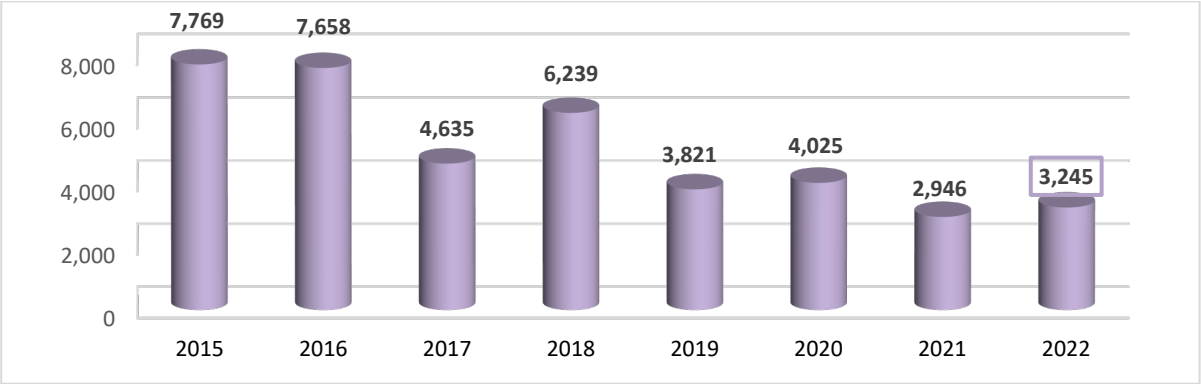


Figure 24. SAR in donors (absolute numbers): 2015-2022 comparative data

When interpreting data on SAR in donors, the following should be factored in:

- Reporting of SAR in donors is voluntary.
- Not all blood establishments follow up on donors who experienced an adverse reaction.

Figure 25 shows the number of SAR in donors per 100 000 collections: the same 23 countries as in 2021, except for Finland and Slovakia; fewer countries reported apheresis collections; the incidence of SAR was at comparable levels to 2021 for AT, FR, DE, IT, SI and SE.

Note that only countries that reported SAR in donors by type of collection were included in the analysis.

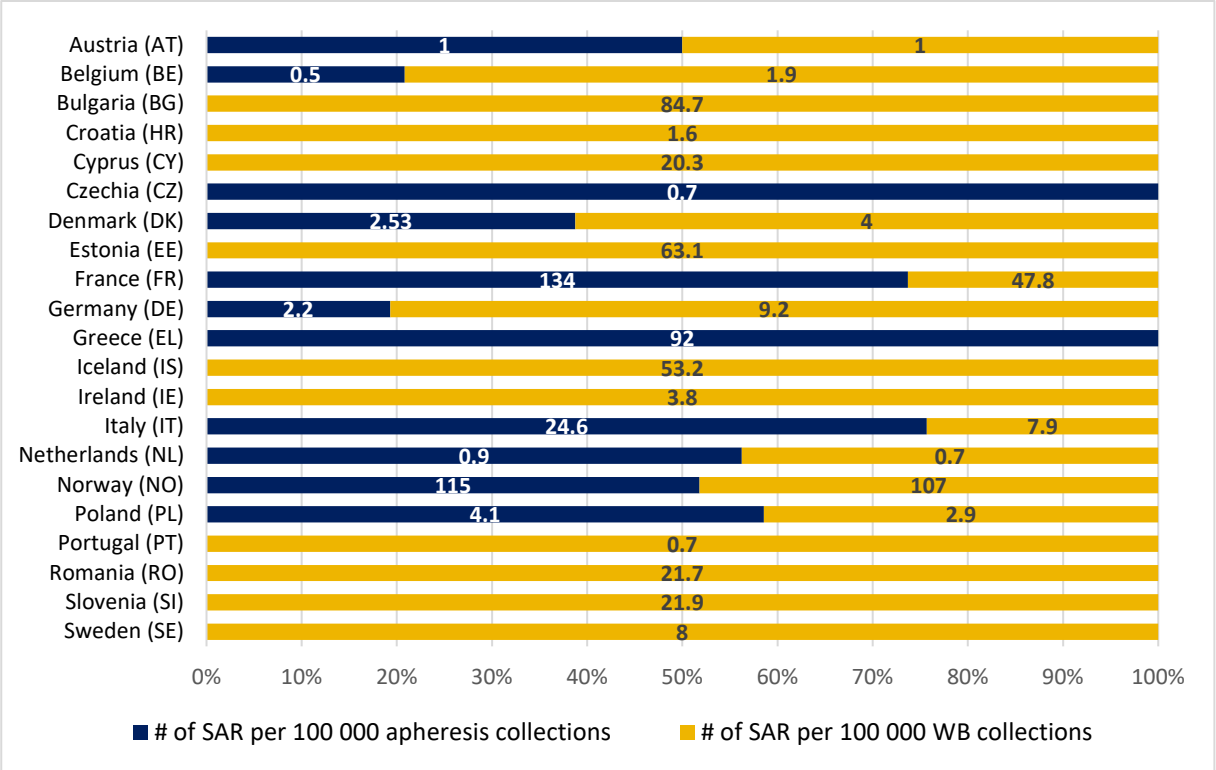


Figure 25. Incidence of SAR in donors per 100 000 collections (absolute numbers); data 2022

Twenty-one countries (AT, BE, BG, HR, CY, DE, DK, EE, EL, ES, FR, IE, IS, IT, NL, NO, PL, PT, RO, SI and SE) reported a total of **2 271 SAR in donors in relation to whole blood collection**. As shown in *Figure 26*, during *whole blood collection*, **vasovagal reaction** was the most common type of reaction (82%), followed by **other** (10%) and **nerve injury/irritation** (7%).

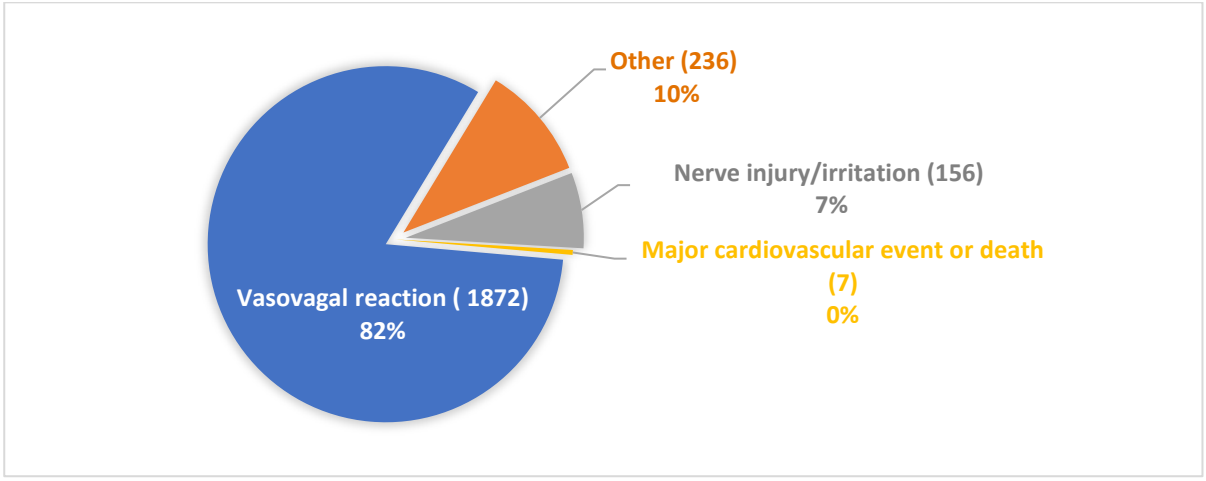


Figure 26. SAR in donors during whole blood collection (absolute numbers and percentages); data 2022

No fatalities were encountered among the ten cases of major cardiovascular events reported by FR, DE and HU.

Eleven countries (AT, BE, CZ, DE, DK, EL, FR, IT, NL, NO and PL) reported a total of **664 SAR in donors following apheresis collection.**

Three countries (CZ, FR and DE) reported four cases of major cardiovascular events with no fatalities.

Distribution of SAR in donors during *apheresis collection* is shown in *Figure 27*.

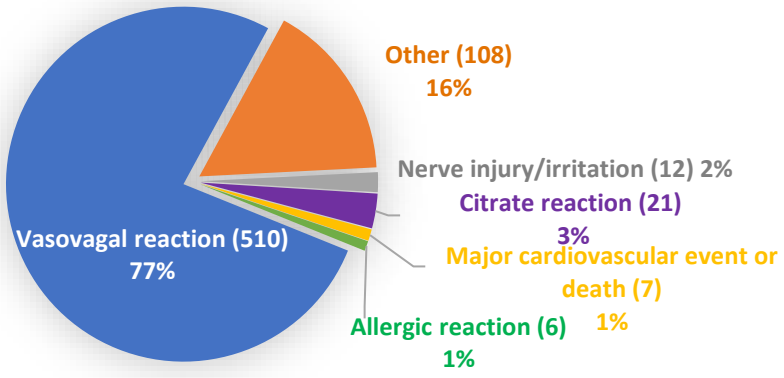


Figure 27. SAR in donors during apheresis collection (absolute numbers and percentages); data 2022

Additional information on SAR in donors

The types of SAR in donors per type of collection and per country are presented in *Figures 28* and *29* below.

Only countries that reported SAR in donors by type of collection were included in the analysis.

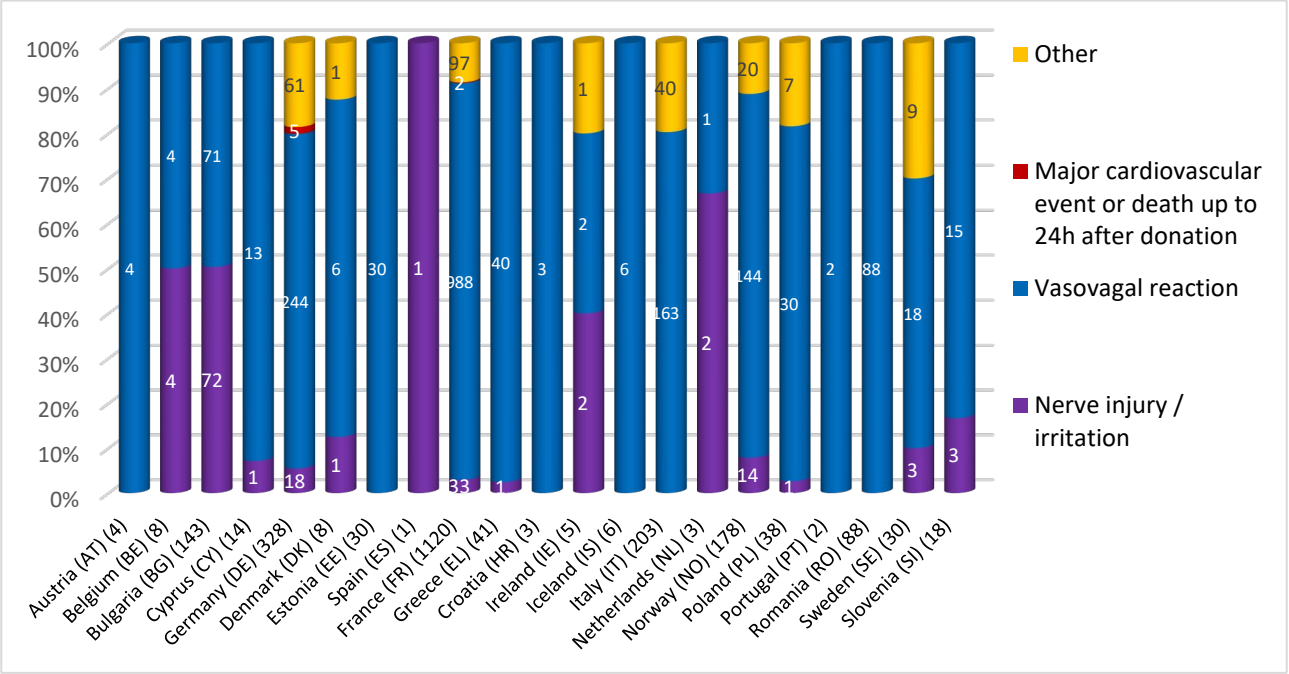


Figure 28. Number of SAR in donors by type (whole blood collection); data 2022

SAR in donors (whole blood collection) by type of reaction and reporting countries are presented comparatively for 2021 and 2022 in *Table 10.*

Country	Nerve injury / irritation		Vasovagal reaction		Major CV event or death up to 24h after donation		Other	
	2022	2021	2022	2021	2022	2021	2022	2021
Austria (AT)			4	4				
Belgium (BE)	4	6	4	8				10
Bulgaria (BG)	72	60	71	22		1		
Cyprus (CY)	1		13	3				
Czechia (CZ)				2				
Germany (DE)	18	17	244	142	5	6	61	115
Denmark (DK)	1		6	3			1	1
Estonia (EE)			30	5				
Finland (FI)								1
Spain (ES)	1							
France (FR)	33	44	988	793	2	6	97	114
Greece (EL)	1		40					
Croatia (HR)			3	202				3
Ireland (IE)	2	6	2	5			1	3
Iceland (IS)			6					
Italy (IT)		1	163	217			40	29
Netherlands (NL)	2		1	2				1
Norway (NO)	14	6	144	106			20	18
Poland (PL)	1	6	30	34			7	6
Portugal (PT)			2	13				
Romania (RO)			88	92				1
Slovakia (SK)				85				4
Sweden (SE)	3	6	18	30		1	9	6
Slovenia (SI)	3	1	15	13				2
Total	**156**	**153**	**1 872**	**1 781**	**7**	**14**	**236**	**314**

Table 10. SAR in donors by type of reaction and by country (whole blood collection); 2021 – 2022 comparative data

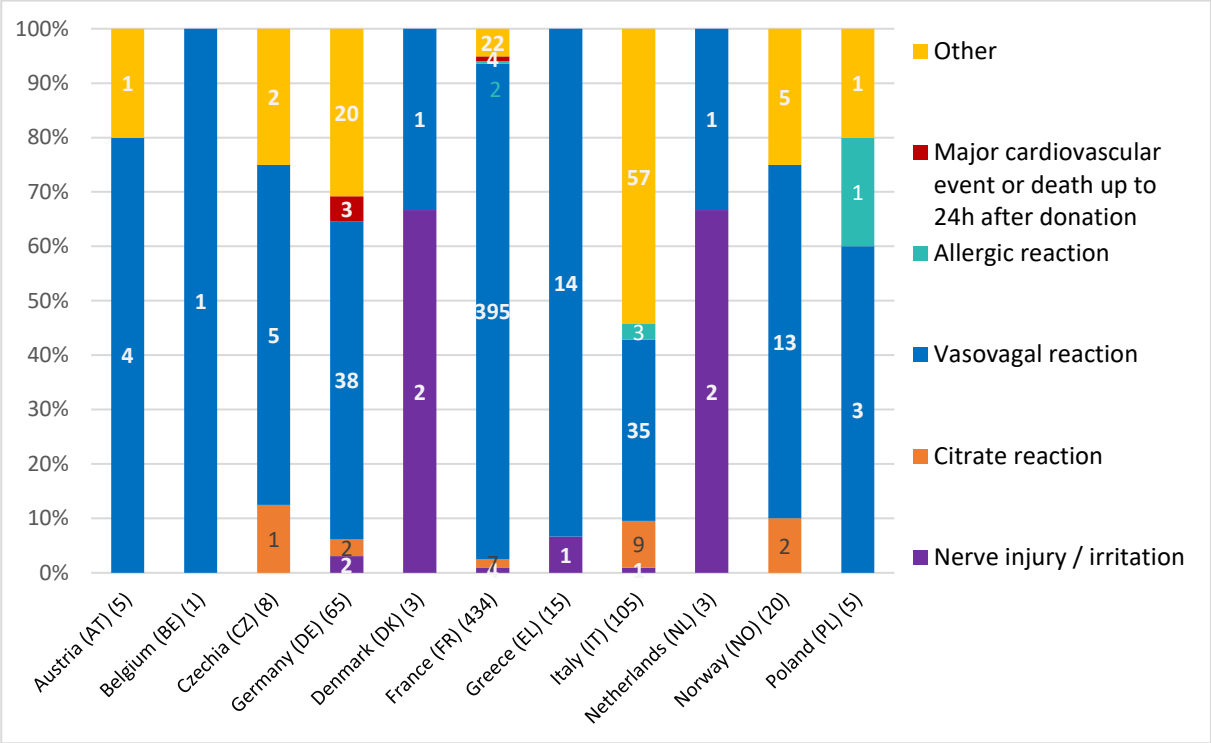


Figure 29. Number of SAR in donors by type (apheresis collection); data 2022

SAR in donors (apheresis collection) by type of reaction and reporting countries are presented comparatively for 2021 and 2022 in *Table 11.*

Country	Nerve injury / irritation		Citrate reaction		Vasovagal reaction		Allergic reaction		Major CV event or death up to 24h after donation		Other	
	2022	2021	2022	2021	2022	2021	2022	2021	2022	2021	2022	2021
Austria (AT)		1			4	2					1	
Belgium (BE)		1		1	1	4						1
Czechia (CZ)			1		5	2				1	2	1
Germany (DE)	2	5	2	4	38	27			3	1	20	28
Denmark (DK)	2			1	1	8						1
Estonia (EE)						1						
France (FR)	4	6	7	19	395	384	2	2	4	2	22	32
Greece (EL)	1				14							
Croatia (HR)												1
Ireland (IE)												1
Iceland (IS)						6						
Italy (IT)	1		9	10	35	34	3	2			57	50
Netherlands (NL)	2	1		1	1	4						6
Norway (NO)		1	2	2	13	18					5	5
Poland (PL)					3	3	1				1	1
Slovakia (SK)												3
Total	**12**	**15**	**21**	**38**	**510**	**493**	**6**	**4**	**7**	**4**	**108**	**130**

Table 11. SAR in donors by type of reaction and by country (apheresis collection); 2021 – 2022 comparative data

5 CONCLUSIONS

The SARE reporting exercises completed to date have resulted in a gradual improvement in the quality and accuracy of the data reported. In 2022, as many as 30 European countries submitted reports, which indicates commitment to the initiative. The total number of reporting establishments slightly increased (3 387 in 2022 vs 3 307 in 2021) which correlates with the slightly increased volume of activity in terms of the number of units issued (21 393 810 in 2022 vs 20 633 199 in 2021). Overall transfusion-related activities were comparable to the previous years, but not at pre-pandemic level**.**

However, as mentioned throughout this report, there is still a significant degree of inconsistency between countries in terms of data reporting rates, data completeness, classification and management of events:

- Reporting of denominators: 14 out 30 countries (47%) reported 100%, while nine countries (30%) did not report the number of recipients; 17 countries out of 30 (57%) reported 100%, while eight countries (27%) did not report the number of units transfused.
- Uncategorised SAR (*Other*) remain the most prevalent (27%).
- Human error (different interpretations)
- Lack of more granular classification
- No relevant information provided for 28 out of 30 TTI (93%) apart from type of blood component and imputability level.
- Requirements for reporting fatalities in recipients as stated in the *Common Approach* largely not met.
- 952 of all SAE (a 12% increase from 850 in 2021) were reported under the activity step 'Other', and as SAE types instead of activity step.
- An analysis of SAE beyond the six categories – specifications – as offered in the *Common Approach*, is not possible due to the lack of more granular classification of events in sub-categories for an in-depth understanding of areas of issues, and due to insufficient information reported.

In general, the major findings in this report indicate that European haemovigilance data are consistent with known effects and expected trends, with no new safety concerns regarding blood and blood components identified from national vigilance and surveillance programmes.

Interpretation of the analysis and results provided in this report should take into account the limitations of the reporting exercise, notably the completeness and quality of the data reported.

Annex 1. Examples of SAE; specification *human error*

Specification	SAE examples
Human error - Following the wrong procedure (66 SAE)	• Blood components returned to blood bank (not needed); destroyed due to storage in inappropriate conditions (35 SAE) • Labelling error (6 SAE) • Component collection error • Failed recall • Incorrect storage • Incorrect registration of donor in the BE's database
Human error - Incorrect decision or omission following the correct procedure (649 SAE)	• Donors accepted despite not meeting exclusion criteria, e.g. travel risk, interval between donations (13 SAE) • Special approval of senior donor omitted • Required screening tests not performed • Too much blood collected (6 SAE) • Wrong patient/bedside control not well performed (18 SAE) • Sample processing error (6 SAE) • Wrong component selected/assigned (10 SAE) • Blood components issued to wrong patients • Platelet microbial contamination possible at venipuncture • Quarantined blood incorrectly stored in the area designated for released blood components (8 SAE) • Data entry error • Units at the end of expiry date missing from inventory, possibly distributed or retrieved, but not recorded • Recording of transfusion omitted • Expired collection set used • Failure to provide antibody-compatible units • Labelling error, mix-up labelling • Incorrect storage
Human error - Other, or no information to assign the above options (67 SAE)	• Donors accepted despite not meeting exclusion criteria (8) • Too much blood collected • Improper sampling leading to haemolysis • Mix-up of test material (3) • Lack of communication

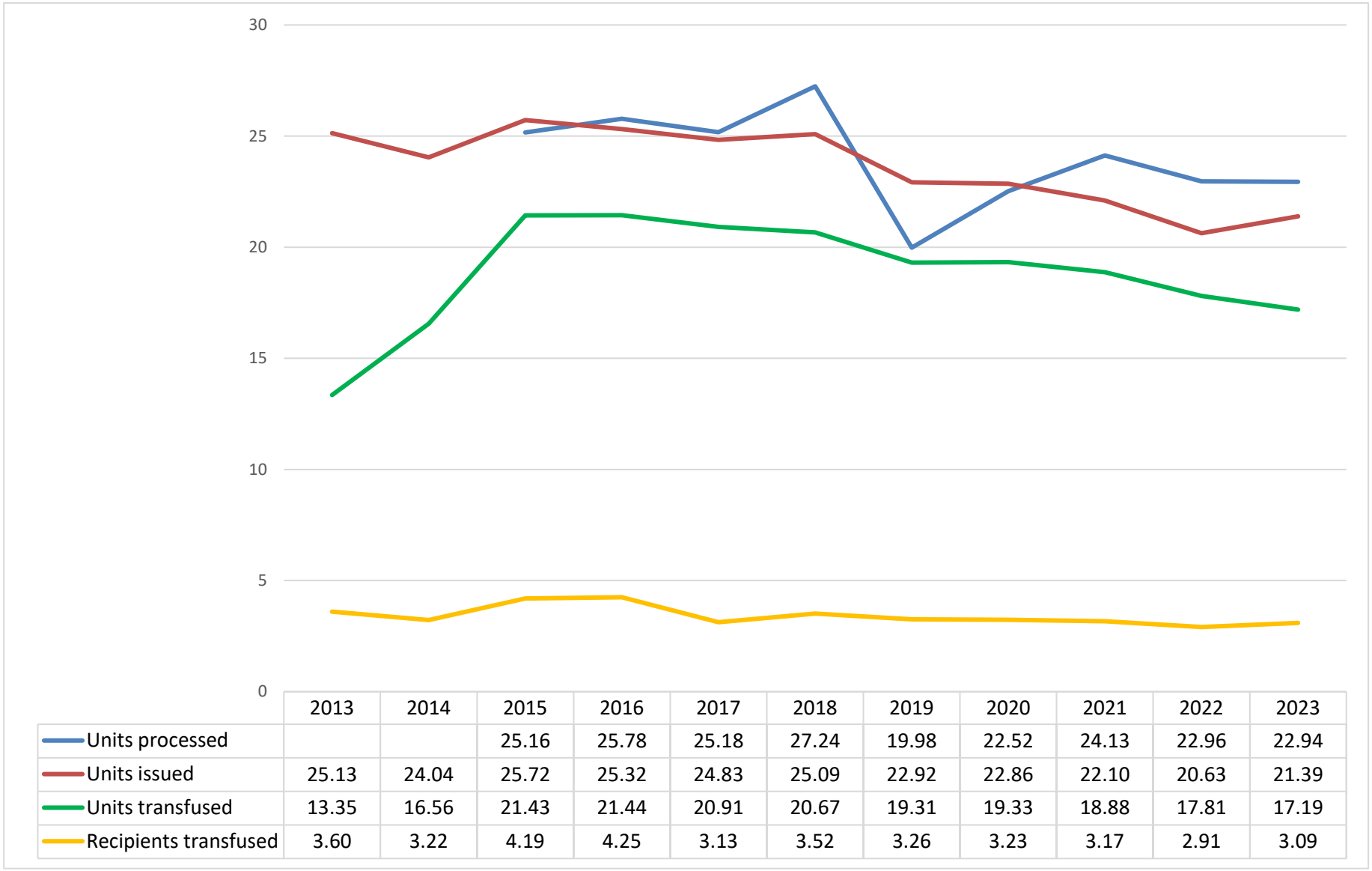
Annex 2. Additional information on SAR in donors

Country and SAR #	SAR Rate	SAR by Gender	Type of Donor	WB vs Apheresis Donation	SAR Type
Country A (9 SAR)				44% (4) of reported SAR occurred in whole blood donation and 55% (5) in apheresis donations.	• 6 vasovagal reactions with vulnus lacero-contusum • 2 vasovagal reactions with apnoea • 1 “other” SAR: thrombophlebitis
Country B (1 554 SAR IL 2-3)	58.3 SAR per 100 000 donations (2 665 302 donations) or 9.8 SAR per 10 000 blood donors (1 593 206 donors).	70% SAR in female donors vs 30% in male donors	71% SAR in regular donors vs 29% in first-time blood donors	72% of reported SAR occurred in whole blood donation and 28% in apheresis donations. Note: The incidence of SAR in donors is higher in apheresis (134 SAR reports / 100 000 apheresis donations (323 979 apheresis donations)) than in whole blood donation (48 SAR reports/100 000 whole blood donations (2 341 322 WB donations)).	The 97 SAR reported in the category "Other“ in whole blood donors include: - 54 hematomas - 12 local pain - 12 anaemias - 6 arterial punctures - 3 localised infections - 1 iron deficiency - 9 uncategorised complications of donations (UCD). The 22 SAR reported in the category "Other“ in apheresis donors, are: - 19 hematomas - 1 local pain, and - 2 uncategorised complications of donations (UCD).
Country C (198 SAR)	-	-	-	90% (178) of reported SAR occurred in whole blood donation and 10% (20) in apheresis donations.	20 SAR “Other” in WB group: - local pain (13) - other local reaction (6) - other systemic reaction (prolonged menstruation - 1) 5 SAR “Other” in apheresis group: - local pain (4) - other systemic reaction (1 deep vein thrombosis in leg followed by lung thrombus)

Country and SAR #	SAR Rate	SAR by Gender	Type of Donor	WB vs Apheresis Donation	SAR Type
Country D (5 SAR)	1 SAR in 27 986 attempted donations, 130 911 attempted whole blood donations and 9 018 attempted apheresis donations a (total of 139 929 attempted donations).	60% (3) SAR in female donors vs 40% (2) in male donors	80% (4) regular donors vs 20% (1) first-time donor	100% (5) of reported SAR occurred in whole blood donation.	• 2 cases of nerve injury on needle insertion (1 male and 1 female) • 2 severe immediate vasovagal reactions with loss of consciousness (LOC), both of whom sustained injury. - first-time female donor who had given a full donation and had LOC lasting < 60 seconds without fitting or incontinence, but headaches for a week and concussion; full recovery - regular blood donor; the LOC was associated with seizure-like movements; slow recovery with hypotension and admission to hospital for 2 nights (intravenous fluids). Donor investigated for an underlying CV cause, but none was found; full recovery. • 1 “Other” SAR - regular male donor, who donated without any apparent problems. He was well until 6 days after the donation when the donor developed pain in the antecubital fossa of the arm he had donated from. Condition deteriorated despite analgesia; donor diagnosed with septic arthritis (*Staphylococcus aureus*) in the elbow joint that required hospitalisation, 2 surgical procedures under general anaesthesia and intravenous antibiotics; imputability = probable

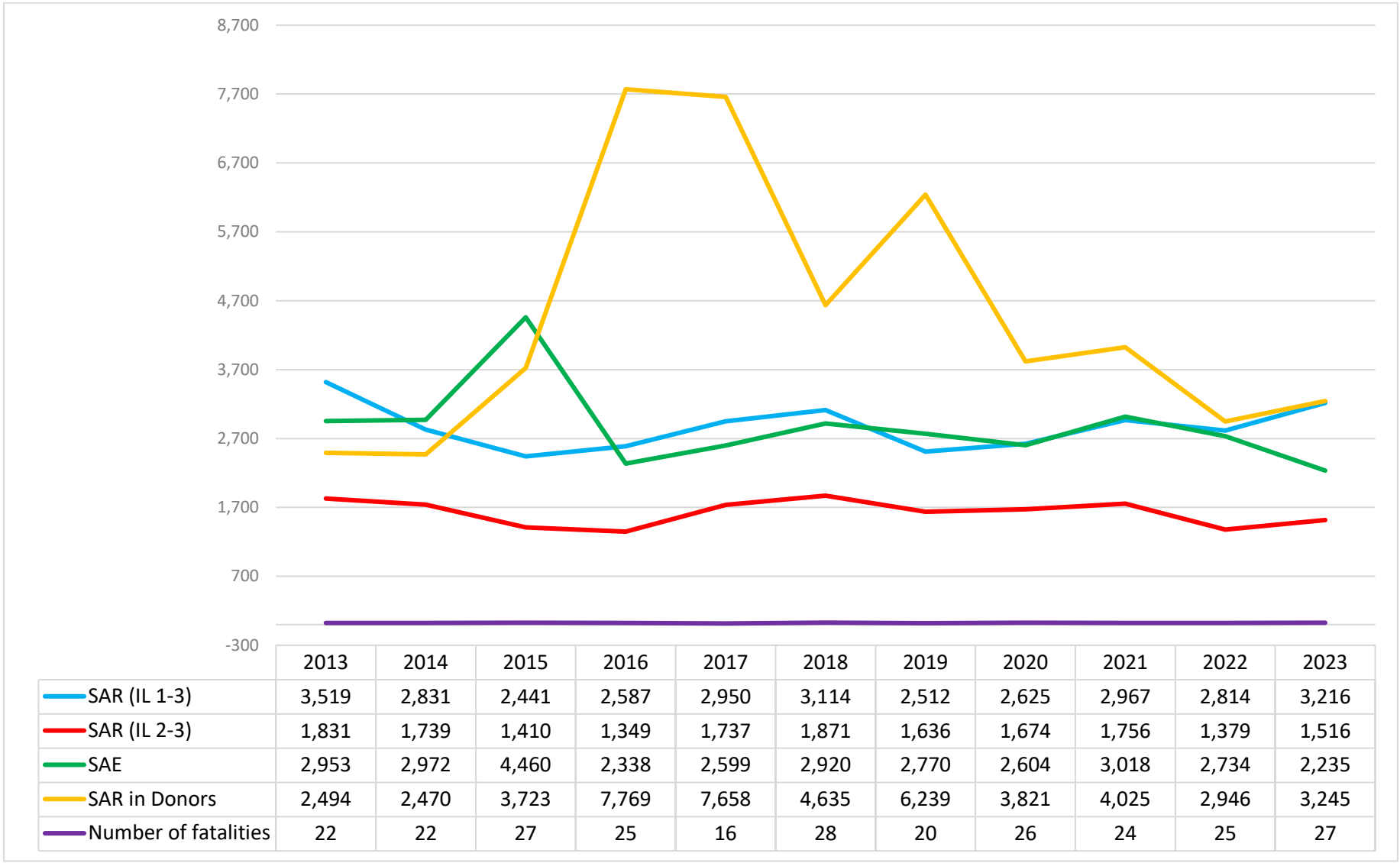
Country and SAR #	WB vs Apheresis Donation	SAR Type
Country E (43 SAR)	88% (38) of reported SAR occurred in whole blood donation and 12% (5) in apheresis donations.	1 “other” SAR = vein and artery injury requiring treatment
Country F (30 SAR)	Reports do not always specify whether the event occurred during whole blood donation or apheresis.	“Other” SAR: - 3 artery puncture - 3 painful haematoma - 1 migraine - 1 vasculitis - 1 haematoma after the bed’s armrest fell on the donor 4 additional SAR in donors occurred and were reported in 2022, but the cases were not closed at the time of reporting: 1 suspected artery puncture, 2 nerve injury/irritation + 1 vasovagal reaction.

Annex 3. Annual comparison (Years of exercises 2013-2023): number of units processed/issued/transfused/recipients (millions)



	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Units processed			25.16	25.78	25.18	27.24	19.98	22.52	24.13	22.96	22.94
Units issued	25.13	24.04	25.72	25.32	24.83	25.09	22.92	22.86	22.10	20.63	21.39
Units transfused	13.35	16.56	21.43	21.44	20.91	20.67	19.31	19.33	18.88	17.81	17.19
Recipients transfused	3.60	3.22	4.19	4.25	3.13	3.52	3.26	3.23	3.17	2.91	3.09

Annex 4. Annual comparison (Years of exercises 2013-2023): SAR (1-3), SAR (2-3), SAE, SAR in donors and fatalities



	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
SAR (IL 1-3)	3,519	2,831	2,441	2,587	2,950	3,114	2,512	2,625	2,967	2,814	3,216
SAR (IL 2-3)	1,831	1,739	1,410	1,349	1,737	1,871	1,636	1,674	1,756	1,379	1,516
SAE	2,953	2,972	4,460	2,338	2,599	2,920	2,770	2,604	3,018	2,734	2,235
SAR in Donors	2,494	2,470	3,723	7,769	7,658	4,635	6,239	3,821	4,025	2,946	3,245
Number of fatalities	22	22	27	25	16	28	20	26	24	25	27