EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Unit D2 – Medical Products: quality, safety, innovation

HAEMOVIGILANCE
ANNUAL SARE REPORT 2024

(Data collected from 01/01/2023 to 31/12/2023 and submitted to the European Commission in 2024)

Co-funded by the European Union

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Contents

INTRODUCTION

Blood transfusion is a vital medical procedure that supports a wide range of healthcare specialties, saving millions of lives across Europe each year. However, as with any substance of human origin, transfusions carry inherent risks, including disease transmission, immune incompatibilities and other potential adverse reactions. To ensure patient and donor safety, the European Union (EU) has established a comprehensive framework of safety and quality measures under EU Blood Legislation[1]. Despite these safeguards, adverse reactions and events can still occur, making haemovigilance a critical component of transfusion medicine.

Haemovigilance encompasses the entire transfusion chain, from donor selection and blood collection to the clinical application of blood components. It aims to systematically identify, assess and mitigate risks through corrective and preventive action (CAPA), ensuring continuous improvement in transfusion practices. Through national haemovigilance and surveillance systems, EU Member States (MS) are required to report Serious Adverse Reactions (SAR) and Serious Adverse Events (SAE) annually to the European Commission (EC), in line with legislative obligations. SAR refer to transfusion-related incidents that result in actual harm to donors or recipients, whereas SAE involve incidents that could compromise the quality or safety of blood components but do not necessarily cause harm.

Since 2012, voluntary reporting of donor-related SAR has been included in the EU's haemovigilance framework, further strengthening the commitment to comprehensive transfusion safety monitoring.

This report presents an analysis of SARE (Serious Adverse Reactions and Events) data for the year 2023 submitted to the EC by 30 European countries.
It introduces several refinements to the methodology and data presentation, aimed at enhancing clarity, comparability and overall insight into haemovigilance trends across Europe.

By identifying and addressing transfusion-related risks, haemovigilance plays a pivotal role in protecting both donors and recipients, ensuring the continued safety and efficacy of blood transfusion practices.

[1] Article 8 of Directive 2005/61/EC provides that MS shall submit to the EC an annual report, by 30 June of the following year, on the notification of SARE received by the NCA using the formats in Part D of Annex II and Part C of Annex III.

EXECUTIVE SUMMARY

30 Reporting Countries

26 EU MS plus Iceland, Liechtenstein, Norway and the UK (Northern Ireland)

Number of collections
Whole blood: 16,068,007 *(n = 26)*
Apheresis: 7,286,075 *(n = 25)*

Donation rate (median) per 1,000 population
34.4 (Whole blood)
2.6 (Apheresis)

Number of establishments
3,244 *(n = 29)*

Units issued
20,824,019 *(n = 30)*

Units transfused
16,213,234 *(n = 23)*

Units processed
23,700,556 *(n = 26)*

Recipients transfused*
2,850,968 *(n = 20)*

Serious Adverse Reactions (SAR)

3,170
Number in recipients SAR (IL 1-3) *(n = 28)*

19.6
Total SAR (IL 1-3) incidence rate per 100,000 units transfused

1,490
Number in recipients SAR (IL 2-3) *(n = 25)*

9.2
Total SAR (IL 2-3) incidence rate per 100,000 units transfused

3,534
Number in donors *(n = 22)*

16.0
Total SAR incidence rate per 100,0000 whole blood collections

13.1
Total SAR incidence rate per 100,0000 apheresis collections

5 Most prevalent types of SAR (IL 2-3)

1. Anaphylaxis/hypersensitivity (25.4%)
2. FNHTR (24.6%)
3. TACO (14.4%)
4. Immunological haemolysis (13.3%)
5. Other (11.7%)

21
Fatalities *(n=9)*

Serious Adverse Events (SAE)

2,294
Number of SAE *(n = 25)*

9.7
Total SAE incidence rate per 100,000 units processed

4 Most prevalent types of SAE by specification

1. Human error (42%)
2. Equipment failure (17%)
3. Component defect (16%)
4. Other (14%)

*Note: *recipients transfused was obtained with the sum of number of recipients for each type of BC (i.e. WB, RBC, platelets and plasma) from 18 countries (2,680,761 – see Table 2) plus the number of recipients from EE and EL (170,207) which only reported the overall number (i.e. regardless of type of BC).*

METHODOLOGY

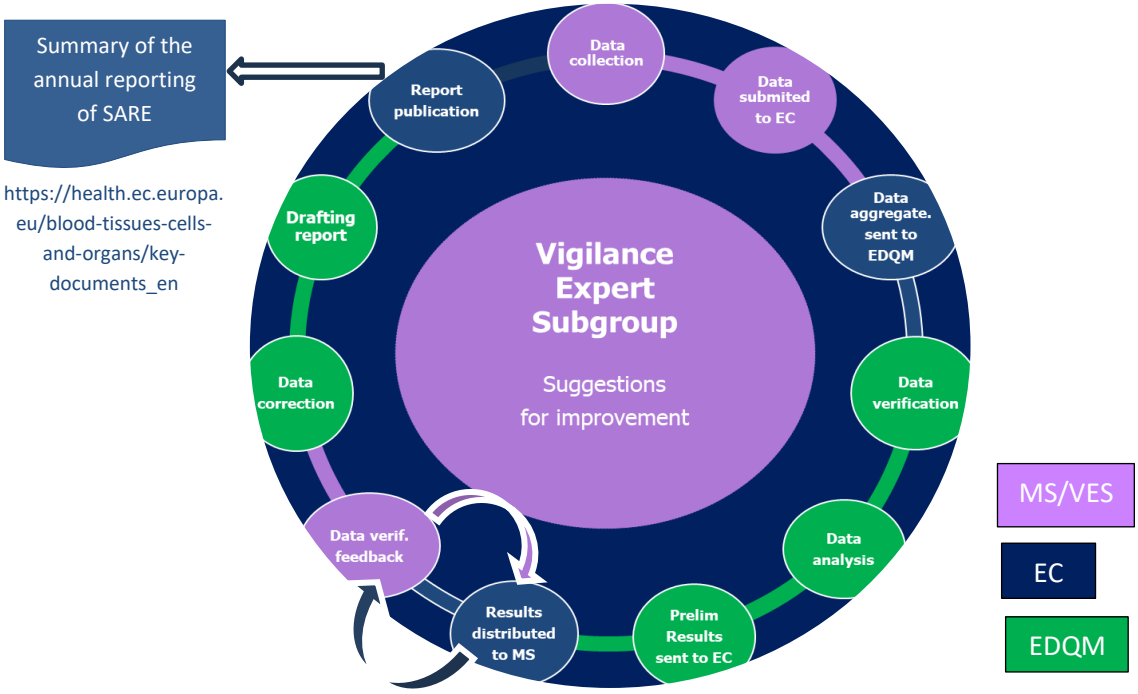
Data collection and analysis

This report provides a summary of the national data submitted to the EC by all EU MS except Malta and four non-EU countries (Iceland, Liechtenstein, Norway and UK (Northern Ireland)) pertaining to the reporting period from 1 January to 31 December 2023.

In 2023, the EC provided national competent authorities (NCAs) with improved tools to facilitate a standardised online data reporting approach:

1) ***An electronic reporting form (version 2024)***
2) ***The Common Approach, version 2024***, which complements the electronic reporting form and provides updated user instructions for data compilation.

The reporting countries and the Vigilance Expert Subgroup (VES) verified the preliminary results of the EDQM's analysis and interpretation of SARE data for 2023.
The process for issuing SARE reports (sequence of steps and involved parties) is presented in the image below.



Data reporting completeness

The annual data on SARE for blood and blood components were reported by 26 EU MS and four non-EU countries that submitted their national data on a voluntary basis (Iceland, Liechtenstein, Norway, and UK (Northern Ireland)), comprising aggregated data from 3,244 reporting establishments (RE). Refer to Annex 2. Reporting establishments per capita (pmp) for the geographical distribution of RE in Europe.

Regarding the percentage of reports received, 21 reporting countries confirmed receipt of 100% of reports, six countries received 80-99% of the expected data and one country 50-80%. Two countries were not able to provide any information.

Denominator data

- The total number of **units of blood/blood components (BC)** (i.e. whole blood (WB), red blood cells (RBC), platelets, and plasma) **transfused** annually was used as the denominator to calculate SAR incidence and fatality incidence per 100,000 units transfused.
  - 77% (23 of 30) countries reported this denominator.
  - This approach is compatible with those of the World Health Organization (WHO), US Food & Drug Administration (FDA) and the Canadian Transfusion Transmitted Injuries Surveillance System (TTISS), but not Serious Hazards of Transfusion (SHOT) which uses the denominator 'per 10,000 units BC issued'
- The total number of **units blood/BC processed** annually was used as the denominator to calculate SAE incidence per 100,000 units processed.
  - 87% (26 of 30) countries reported this denominator.
- The total **number of WB collections** was used as the denominator to calculate SAR incidence in WB donors per 100,000 donations.
  - 87% (26 of 30) countries provided this denominator.
  - This approach is compatible with SHOT, and the Australian National Blood Authority (NBA), for example.
- The total **number of apheresis collections** was used as the denominator to calculate SAR incidence in apheresis donors per 100,000 donations.
  - 83% (25 of 30) countries provided this denominator.
  - This approach is compatible with SHOT, and the Australian NBA, for example.

Limitations

- **Data variability**: incomplete reporting and inherent variations in reporting accuracy and quality must be considered during the interpretation of the results of SARE analysis.
- **Data coverage**: variations in the number of reporting countries year-over-year may influence total counts and calculated metrics. Whenever possible, data were normalised to account for these differences and, for transparency, the number of countries reporting each year is included alongside key metrics. Key raw data for each MS are also listed in the Annexes.

Updates and improvements

This year's SARE report incorporates several methodological improvements to enhance the accuracy, clarity and interpretability of haemovigilance data. These refinements align the report more closely with international best practices in haemovigilance and ensure a more robust assessment of transfusion safety trends.

Key updates include:

- More detailed benchmarking and trend analysis across multiple years (2017–2023) with clearer breakdowns by BC, type of reaction, donor type, etc. focusing on year-over-year changes while accounting for variations in the number of reporting countries.
- Refined statistical analysis, presenting total SAR and SAE incidence across Europe as well as the median SAR and SAE incidence per country to improve comparability across different reporting countries.
- Geographical distribution maps to enhanced data visualisation.
- Introduction of percentage change calculations, for larger baseline values, for understanding relative variations between 2022 and 2023. For small baseline values, absolute change calculations are used instead.

RESULTS

The outcomes of the data analysis are quantitative and qualitative indicators intended to provide information necessary for interpretation and conclusions regarding the safety of transfusion within the European space.

The SARE results are presented in four sections, each including the overall results and, where feasible, separate results for each type of BC (i.e. WB, RBC, platelets, plasma and more than one BC (MTOC)):

1. Activity dataset
    a. Yearly trends in blood collections, units issued, units transfused, units processed and recipients transfused (2017–2023)
    b. Geographic distribution of blood collections, units issued, units transfused and recipients transfused
    c. Overview of volume of activity by type of BC; comparative analysis with 2022
    d. Country-specific trends (2022 vs. 2023) in units transfused by type of BC
2. SAR in recipients
    a. Yearly trends in SAR and fatalities by imputability (2017–2023)
    b. Geographic distribution of SAR by imputability
    c. Yearly trends in SAR by type of BC (2017–2023)
    d. SAR incidence by type of BC
    e. Overview of SAR and fatalities by type of BC; comparative analysis with 2022
    f. Yearly trends in SAR and fatalities by type of reaction (2017–2023)
    g. Overview of SAR and fatalities by type of reaction; comparative analysis with 2022
    h. Investigation of fatalities
3. SAE
    a. Yearly trends in SAE (2017–2023)
    b. Geographic distribution of SAE
    c. Country-specific trends (2022 vs. 2023) in SAE
    d. Overview of SAE by activity step
    e. Yearly trends in SAE by specification (2017–2023)
    f. Overview of SAE by specification
4. SAR in donors
    a. Yearly trends in SAR (2017–2023)
    b. Geographic distribution of SAR in donors
    c. Overview of SAR in WB donors by type of reaction; comparative analysis with 2022
    d. Overview of SAR in apheresis donors by type of reaction; comparative analysis with 2022

1 Activity Dataset

Key findings

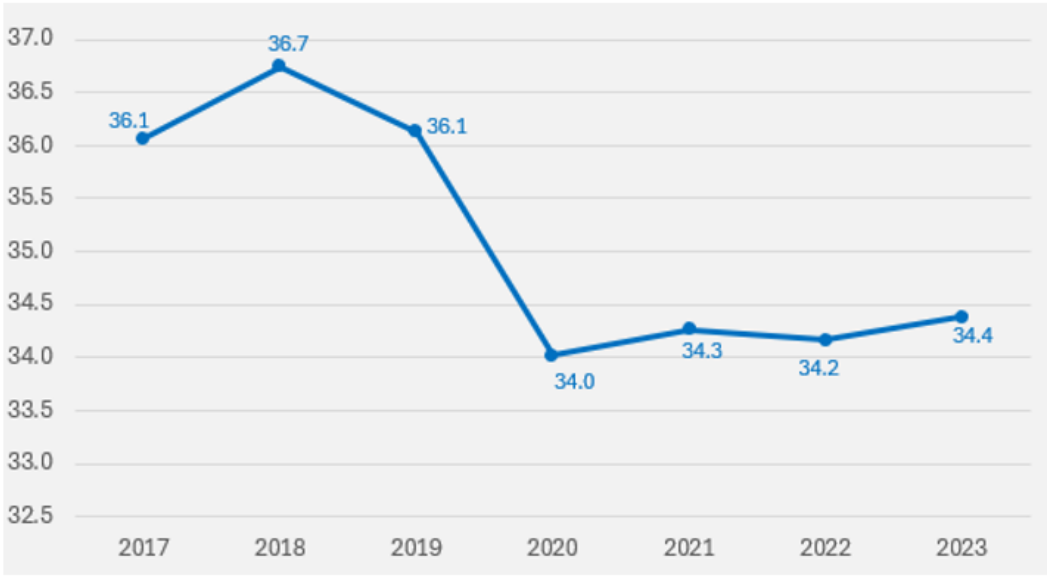
- Bood donation rates ranged from 21 to 76 per 1,000 population for WB (median 34.4); and from 0.4 to 128 per 1,000 population for apheresis (median 2.6).
- A downward trend in the European transfusion rate continues to be observed. There was a 10% decrease in plasma units transfused.

1.1 Yearly trends (2017–2023)

1.1.1. Blood collection

Considering the demographic data[2] of the reporting countries, Figure 1 presents the **WB donation** rate (median) per 1,000 population across all reporting countries for each year from 2017 to 2023.

A downward trend is observed for WB collections from 2018 to 2020, stabilising in the subsequent years.

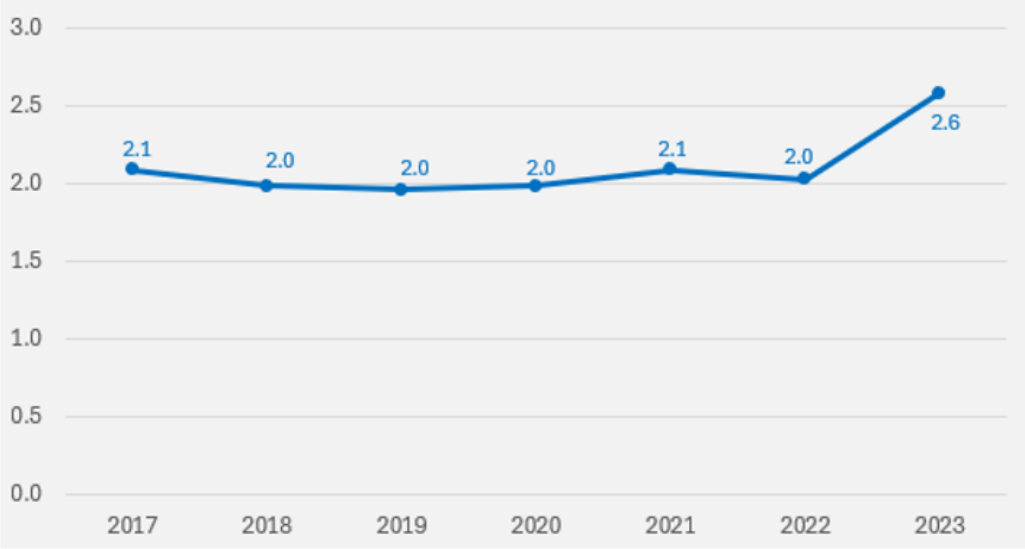


n	27	24	25	26	28	26	26

Figure 1. Whole blood donation rate (median) per 1,000 population; 2017–2023

Figure 2 presents the **apheresis donation** rate (median) per 1,000 population among reporting countries for each year from 2017 to 2023. The trend is relatively stable between 2017 and 2022, with a slight increase in 2023.

[2] https://ec.europa.eu/eurostat/ (Population on 1January – total; following Brexit, UK = Northern Ireland only)

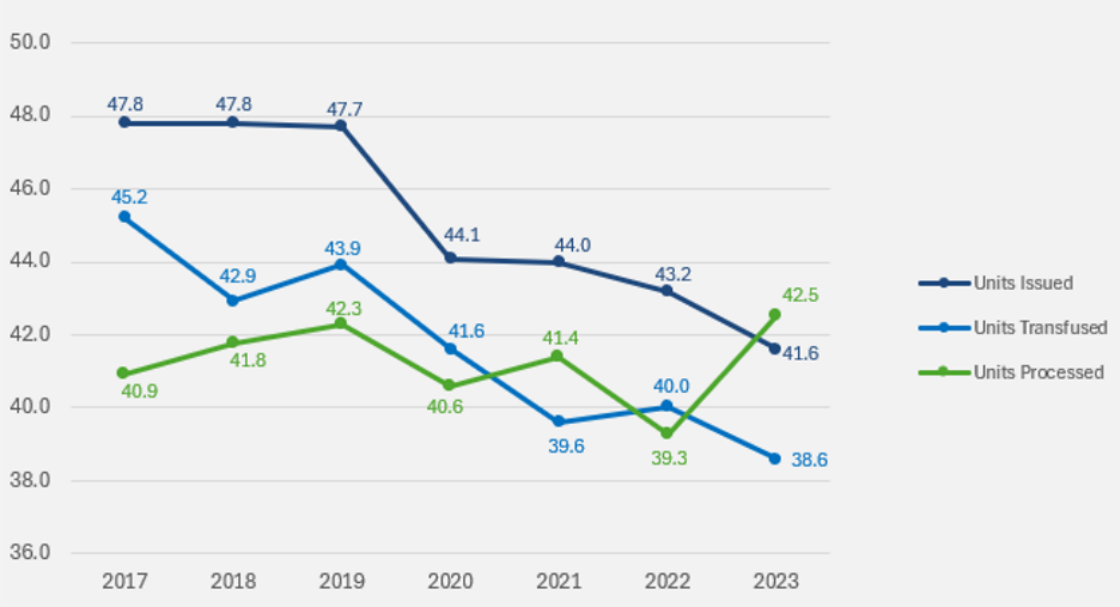


n	27	25	26	27	28	26	25

Figure 2. Apheresis donation rate (median) per 1,000 population; 2017–2023

1.1.2. Blood/BC units issued, transfused and processed

Figure 3 shows the rates (median) of units issued, transfused and processed per 1,000 population across all reporting countries for each year from 2017 to 2023. There is a general downward trend in units issued and units transfused. For units processed, there is a noticeable increase in 2023.

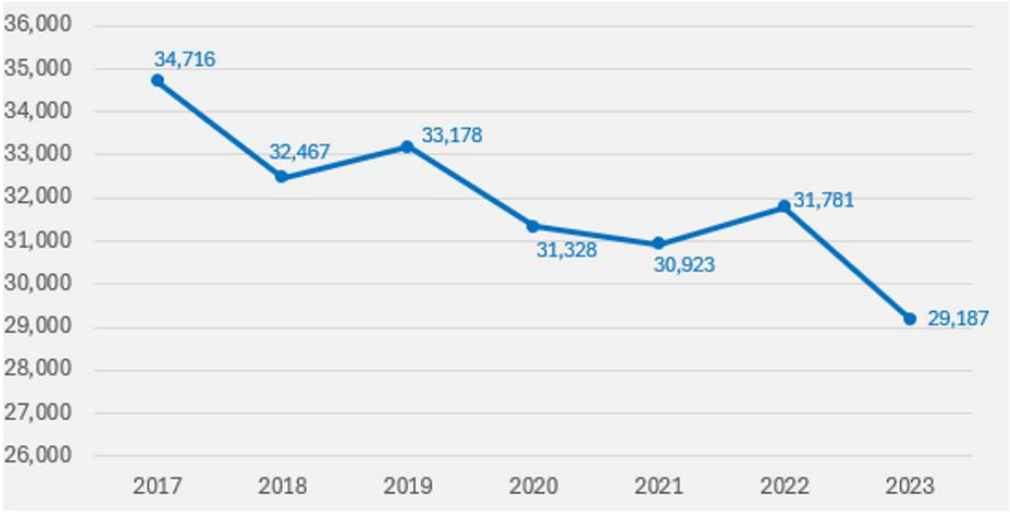


n(issued)	29	28	27	29	30	30	30
n(transfused)	24	23	22	24	26	24	23
n(processed)	28	24	25	28	28	27	26

Figure 3. Rates (median) of units issued, transfused and processed per 1,000 population; 2017–2023

1.1.3. Units transfused per type of BC

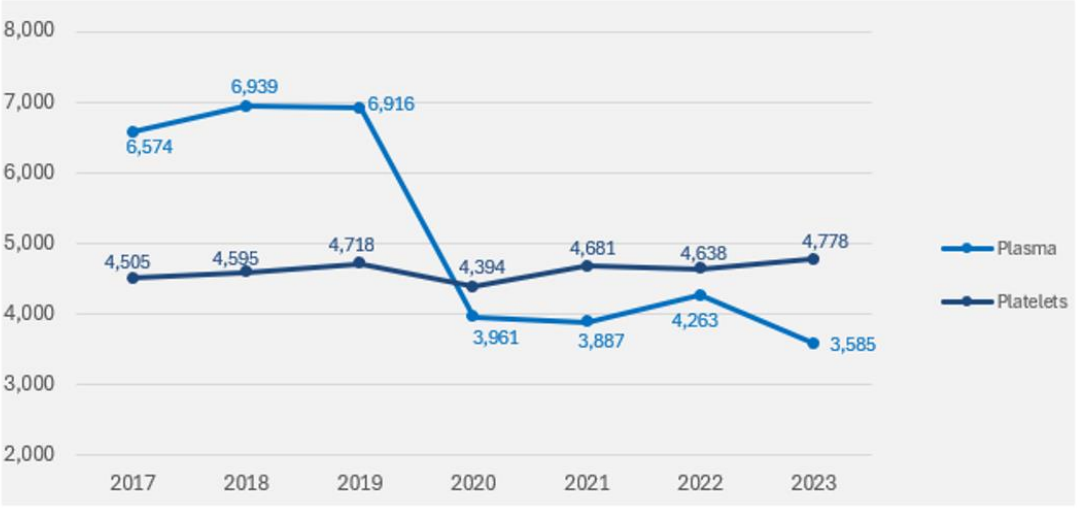
Figure 4 shows the rate (median) of units of **RBC** transfused per one million population (pmp) across all reporting countries for each year from 2017 to 2023. There is a general downward trend, although with varying slopes and some fluctuations.



n	24	22	22	24	25	24	23

Figure 4. Transfusion rate (median) of units of RBC pmp; 2017–2023

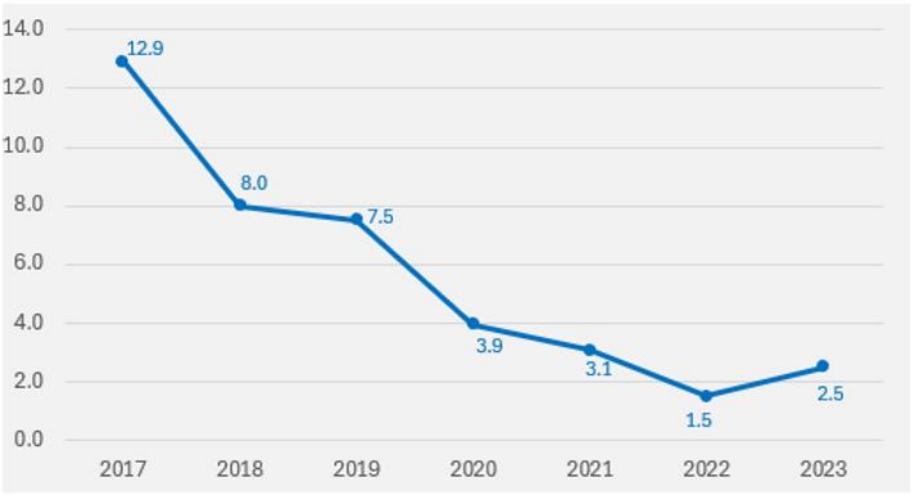
Figure 5 presents the transfusion rates (median) of units of **plasma** and **platelets** pmp across all reporting countries for each year from 2017 to 2023. Plasma data show a sharp decline in 2020 (possibly related to the COVID-19 pandemic), stabilising at a lower level in the following years. Platelet data remain more stable with a slight upward trend after 2020.



n (Plasma)	23	22	22	24	26	23	23
n (Platelets)	24	23	21	24	26	24	23

Figure 5. Transfusion rates (median) of units of platelets and plasma pmp; 2017–2023

Figure 6 displays the transfusion rate (median) of units of **WB** pmp across reporting countries for each year from 2017 to 2023. There was a continuous decline between 2017 and 2022, with a minor increase in 2023.

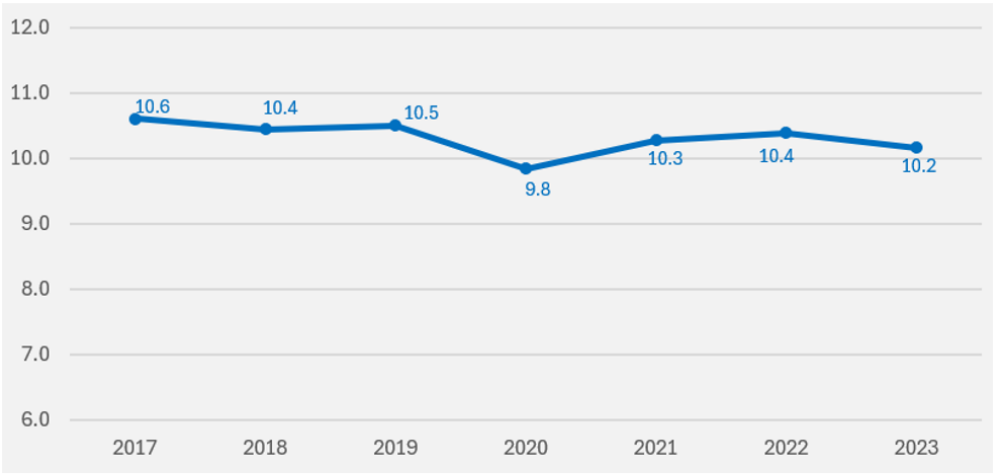


n	9	12	12	12	11	13	10

Figure 6. Transfusion rate (median) of units of whole blood pmp; 2017–2023
Note: n excludes countries that reported zero whole blood units

1.1.4. Recipients transfused

Figure 7 displays the rate (median) of recipients transfused (regardless of type of BC) per 1,000 population among reporting countries for each year from 2017 to 2023. A stable trend is evident throughout the seven-year period.



n	17	16	13	16	16	18	17

Figure 7. Rate (median) of recipients transfused per 1,000 population; 2017–2023

1.2. Geographic distribution

1.2.1. Blood collection

Twenty-six countries (AT, BE, BG, HR, CY, CZ, DK, EE, FI, FR, DE, EL, IS, IE, IT, LV, LT, NL, NO, PL, PT, SK, SI, ES, SE and UK(NI)) reported a total of 16,068,007 WB collections in 2023. This was a slight increase over the previous year, when 15,576,875 collections were reported by 25 countries.

In terms of apheresis collection, 25 countries (all the above minus SE) reported a total of 7,286,075 collections. Likewise, this was slightly higher than the previous year (6,376,960).

Considering the demographic data[3] of the reporting countries in 2023, the WB and apheresis collection rates per 1,000 population are shown in Figure 8 and Figure 9, respectively.

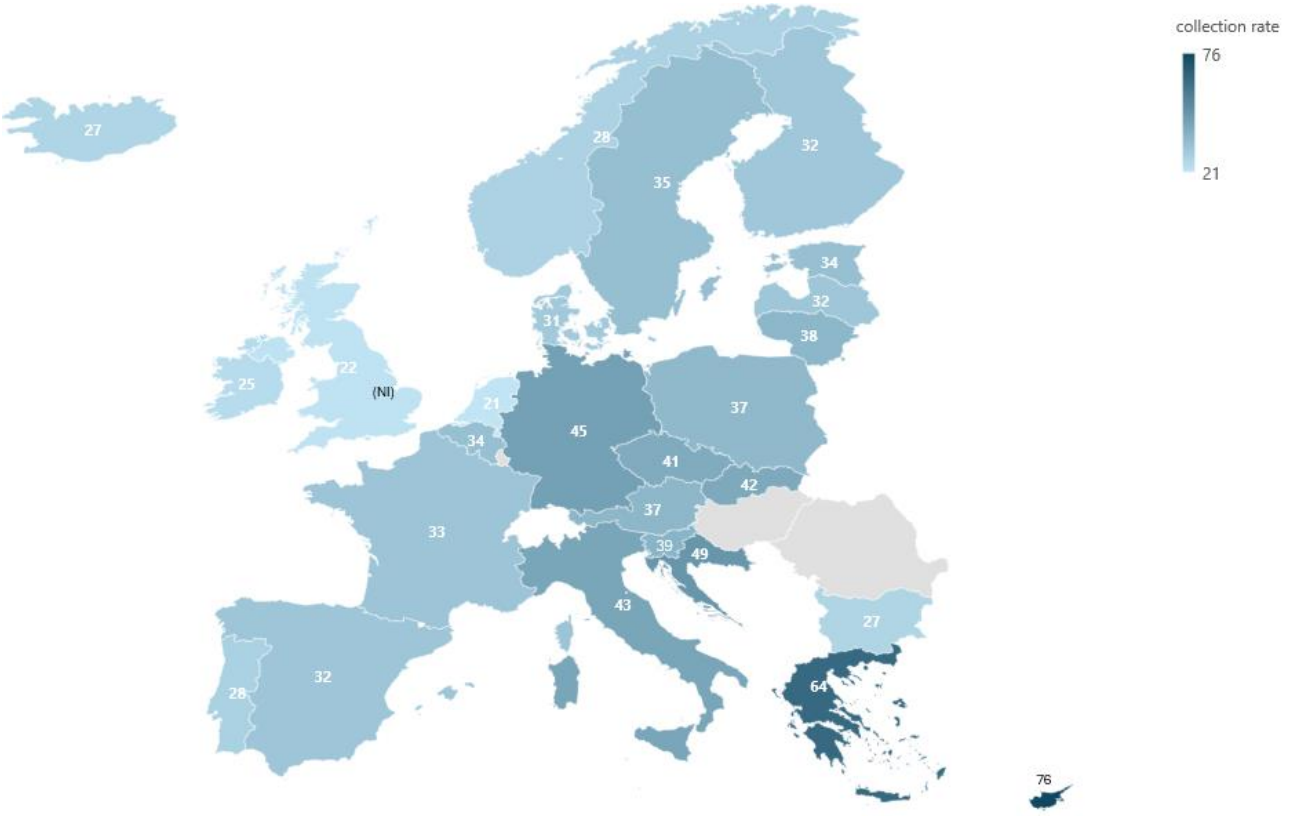


Figure 8. Whole blood collection rates in Europe per 1,000 population in 2023

The WB donation rate (median) was 34.4 donations per 1,000 population [range 21(NL) - 76(CY)], similar to the 2022 rate (34.2).

[3] https://ec.europa.eu/eurostat/ (Population on 1January – total; following Brexit, UK = Northern Ireland only)

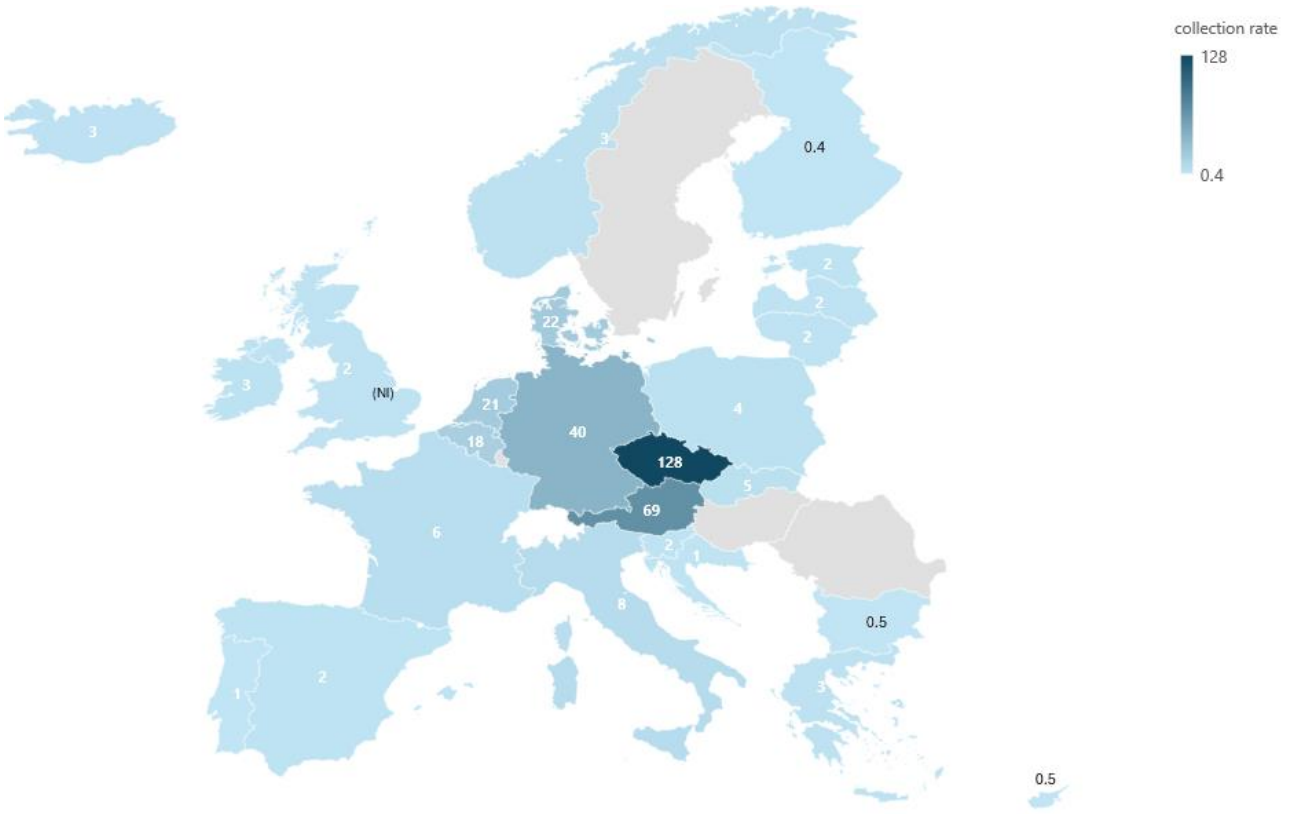


Figure 9. Apheresis collection rates in Europe per 1,000 population in 2023

The apheresis donation rate (median) was 2.6 donations per 1,000 population [range 0.4(FI) - 128(CZ)], which was marginally higher than the 2022 rate (2.0).

1.2.2. Blood/BC units issued and units transfused

Regarding the **units of blood/BC issued**, 27 countries (AT, BE, BG, HR, CY, CZ, DK, EE, FI, FR, DE, EL, HU, IS, IE, IT, LV, LT, LU, NL, PL, PT, RO, SK, SI, SE and UK(NI)) provided data. The three remaining countries (LI, NO and ES) did not report the number of units issued but provided 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 20,824,019 issued units of blood/BC were reported in 2023, a slight reduction in comparison with 2022 (21,394,422).

Figure 10 presents the issuance rates of blood/BC units per 1,000 population in Europe [range 4(LI) - 103 (CY)].

In 2023, the European issuance rate (median) of blood/BC units was determined to be 41.6/1,000 population, slightly lower than the 43.2/1,000 population reported in 2022.

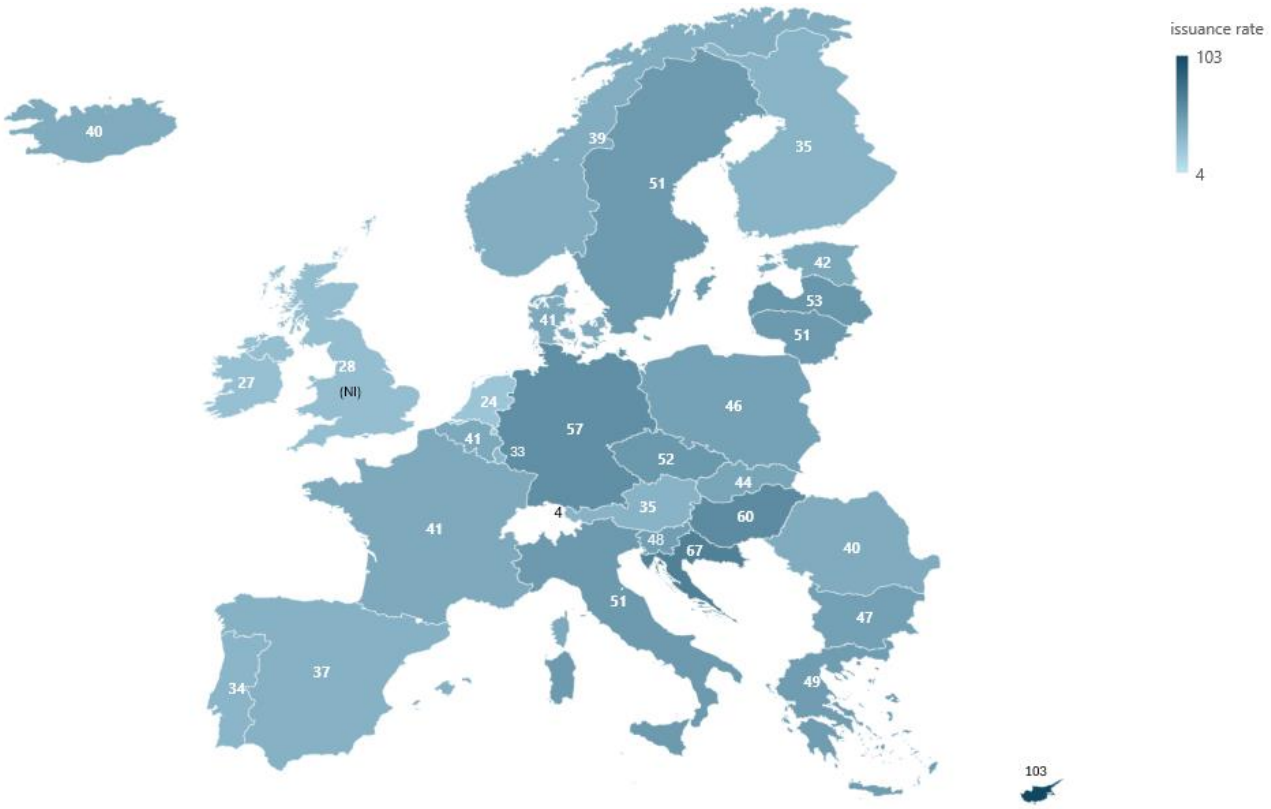


Figure 10. Issuance rates of blood/BC units in Europe per 1,000 population in 2023

Concerning **units of blood/BC transfused**, a total of 16,213,234 units were reported by 23 countries (AT, BE, BG, HR, CY, CZ, DK, EE, FR, DE, EL, IS, IE, IT, LI, LU, NL, NO, PT, RO, ES, SE and UK(NI)). This value is slightly lower in comparison with 2022 (17,197,676), which is due to absence of data from SK and lower volumes reported by FR, DE and RO.

Figure 11 shows the transfusion rates of blood/BC units per 1,000 population in Europe [range 4(LI) - 100 (CY)].

In 2023, the European transfusion rate (median) of blood/BC units was determined to be 38.6/1,000 population, slightly lower than the 40.0/1,000 population reported in 2022.

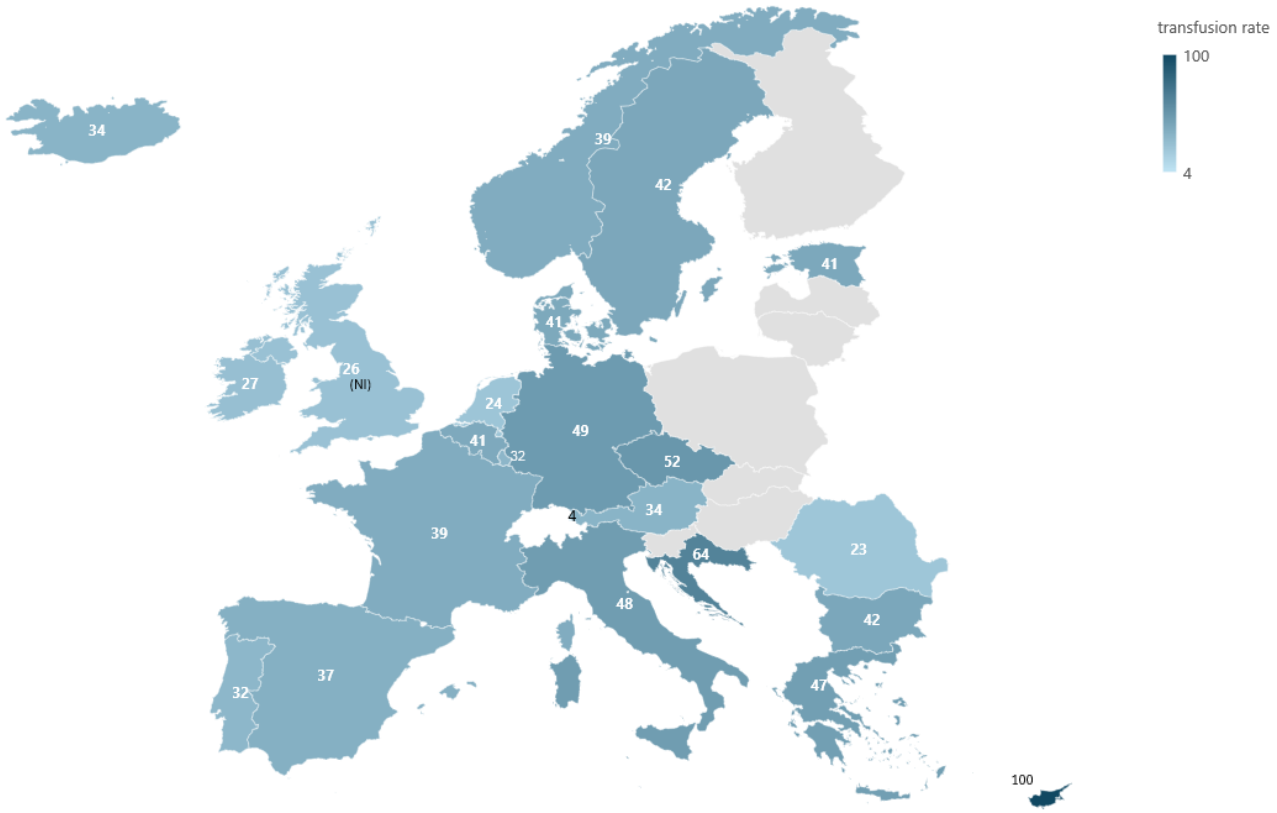


Figure 11. Transfusion rates of blood/BC units in Europe per 1,000 population in 2023

1.2.3. Recipients transfused

According to data reported by 17 countries (BE, BG, HR, CY, CZ, DK, EE, FR, EL, IS, IT, LI, LU, PT, ES, SE and UK(NI)) 2,502,392 patients were transfused in 2023 **regardless of the type of BC**. This is a slightly lower value than in 2022 (2,719,497) due to the absence of data from RO and SK.

Rates of recipients transfused per 1,000 population in Europe are displayed in Figure 12 [range 2(LI and UK(NI)) – 28(CY)].

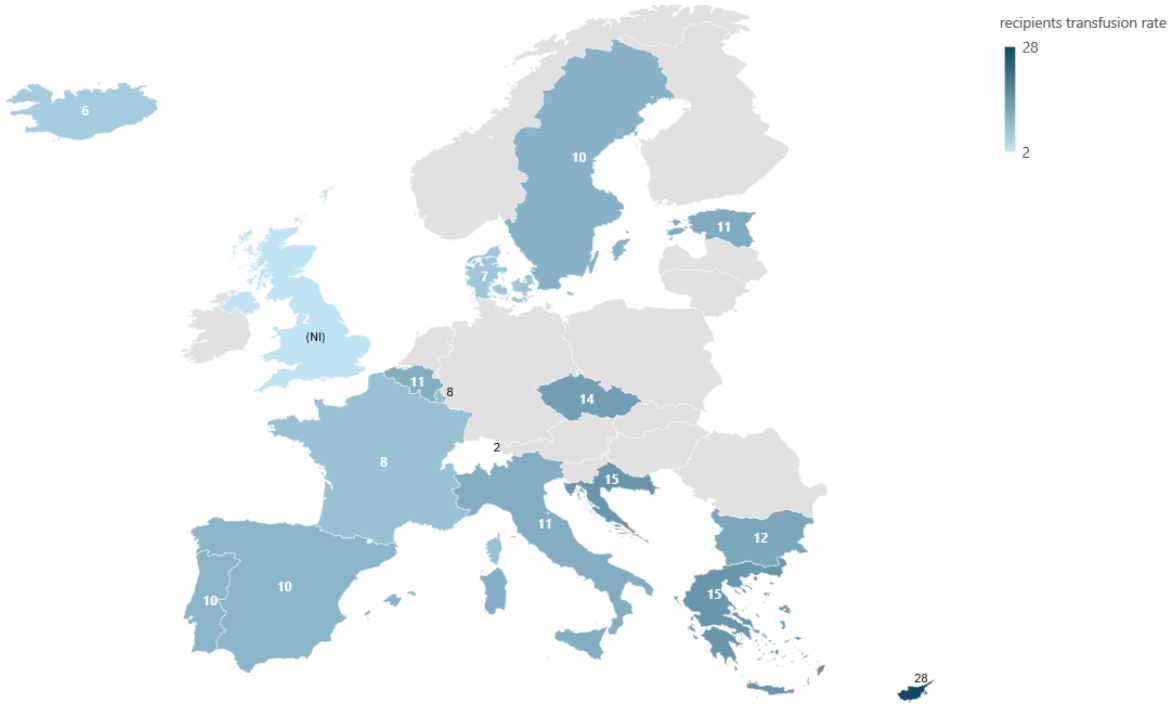


Figure 12. Rates of recipients transfused (regardless of the type of BC) in Europe per 1,000 population in 2023

The European rate (median) in 2023 was determined to be 10.2 patients transfused/1,000 population, similar to the 2022 rate (10.4).

1.3. Overview of volume of activity by type of BC

1.3.1. Distribution of number of units issued and transfused, and recipients

Overall data collected in 2023 for number of units issued and transfused, and recipients by type of BC is shown in Figure 13.

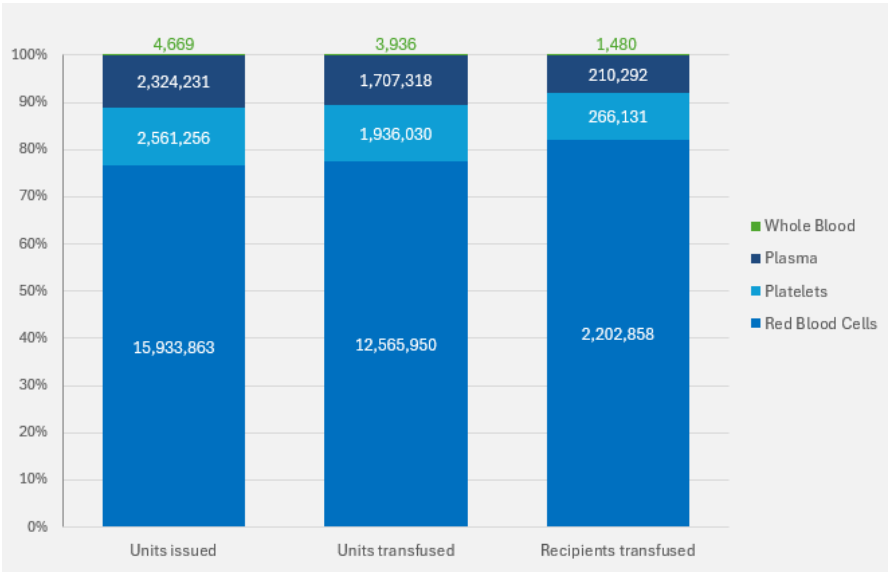


Figure 13. Percentage distribution of total number of units issued, transfused and recipients by type of BC in 2023

1.3.2. Comparative data

As shown in Table 1 and Table 2, RBC continue to be the most issued and transfused type of BC. In comparison with 2022, there was a 21% decrease in the number of plasma units issued and a 10% decrease in the number of plasma units transfused.

Total Number of **Units Issued**	2023	2022	% Change
Red Blood Cells	15,933,863	15,906,955	+0.2
Platelets	2,561,256	2,544,166	+1
Plasma	2,324,231	2,938,963	-21
Whole Blood	4,669	4,338	+8
n (RBC)	30	30	
n (Platelets)	30	30	
n (Plasma)	30	30	
n (Whole Blood)	25	27	

Total Number of **Units Transfused**	2023	2022	% Change
Red Blood Cells	12,565,950	13,311,076	-6
Platelets	1,936,030	1,989,210	-3
Plasma	1,707,318	1,893,485	-10
Whole Blood	3,936	3,905	+1
n (RBC)	23	24	
n (Platelets)	23	24	
n (Plasma)	23	23	
n (Whole Blood)	22	25	

Table 1. Summary of total number of units issued and transfused by type of BC; 2023 vs. 2022

Total Number of **Recipients transfused**	2023	2022	% Change
Red Blood Cells	2,202,858	2,281,248	-3
Platelets	266,131	269,975	-1
Plasma	210,292	221,567	-5
Whole Blood	1,480	1,583	-7
n (RBC)	18	19	
n (Platelets)	18	19	
n (Plasma)	18	19	
n (Whole Blood)	18	21	

Table 2. Summary of total number of recipients transfused by type of BC; 2023 vs. 2022

Transfusion rates pmp	**2023 (median)**	**2022 (median)**
Red Blood Cells	29,187	31,781
Platelets	4,778	4,638
Plasma	3,585	4,263
Whole Blood	2.5	1.5

Table 3. Summary of transfusion rates (median) pmp by type of BC; 2023 vs. 2022

1.4. Country-specific trends (2022 vs. 2023) by type of BC

Considering the demographic data[4] of the reporting countries in 2022 and 2023, the rate of units transfused pmp was calculated for each reporting country and for each type of BC (RBC, platelets, plasma and WB).

1.4.1. RBC transfusion

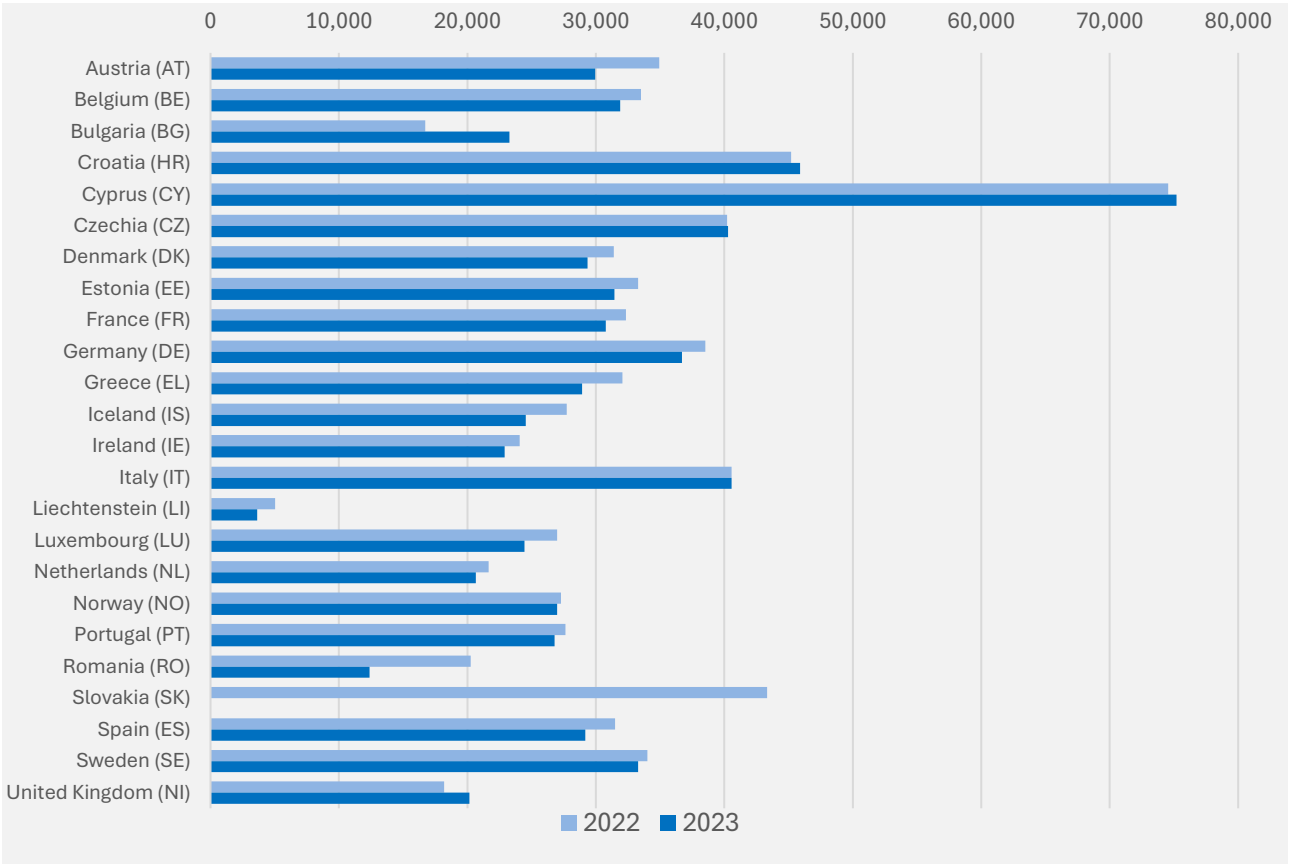


Figure 14. Transfusion rates of RBC units pmp per country; 2022 vs. 2023

[4] https://ec.europa.eu/eurostat/ (Population on 1January – total; following Brexit, UK = Northern Ireland only)

1.4.2. Platelet transfusion

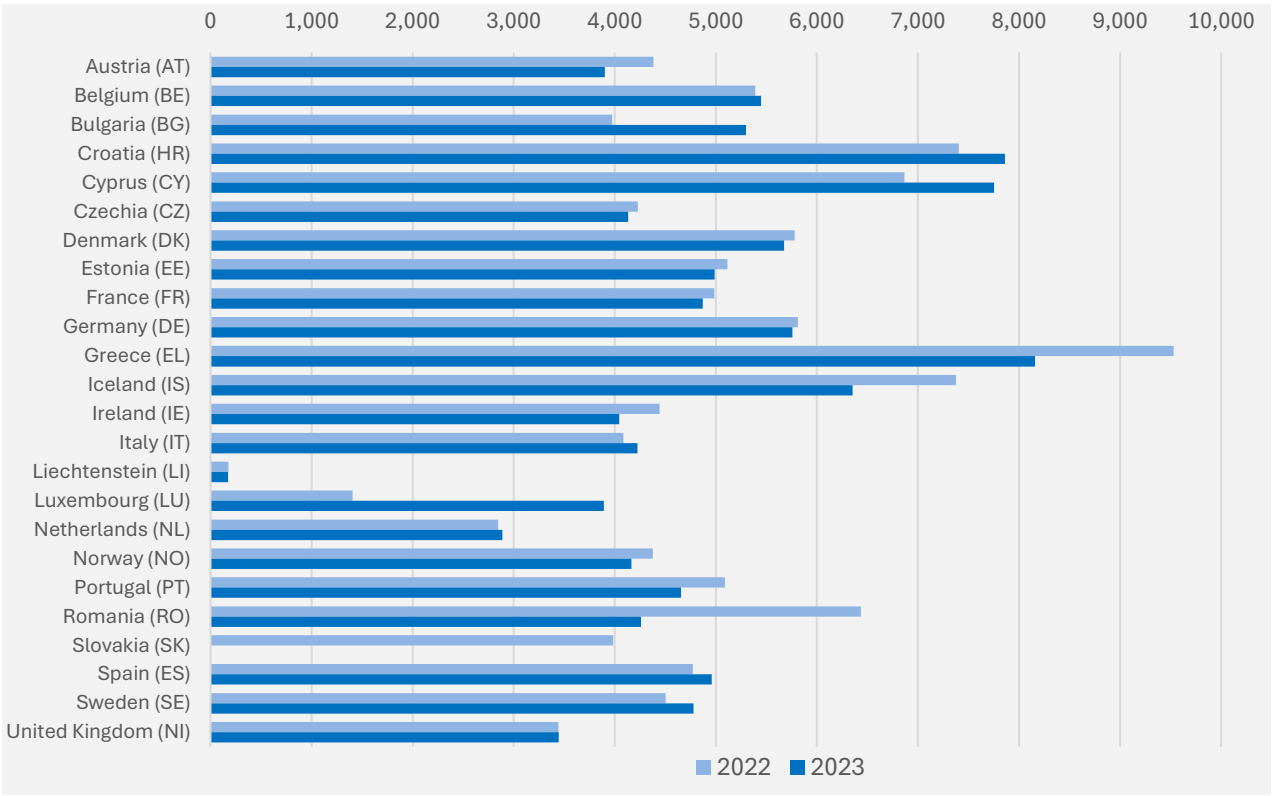


Figure 15. Transfusion rates of platelet units pmp per country; 2022 vs. 2023

1.4.3. Plasma transfusion

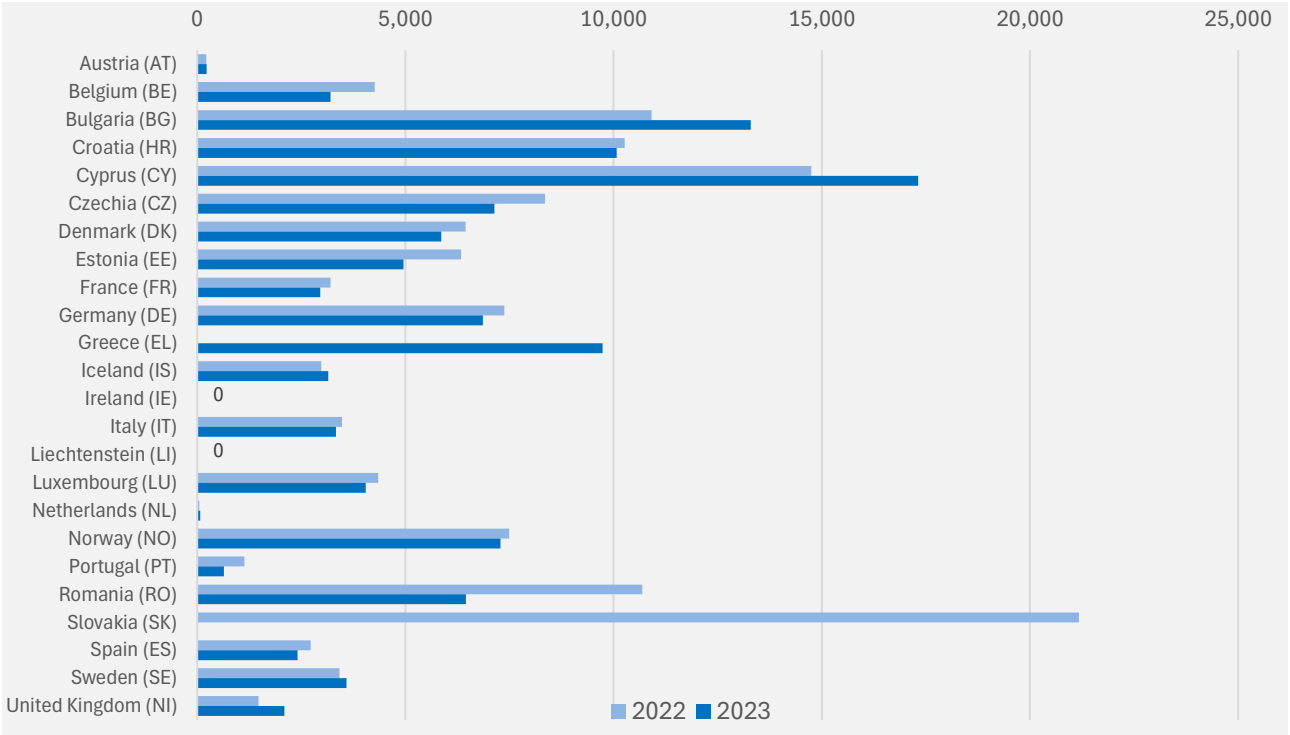


Figure 16. Transfusion rates of plasma units pmp per country; 2022 vs. 2023

1.4.4. WB transfusion

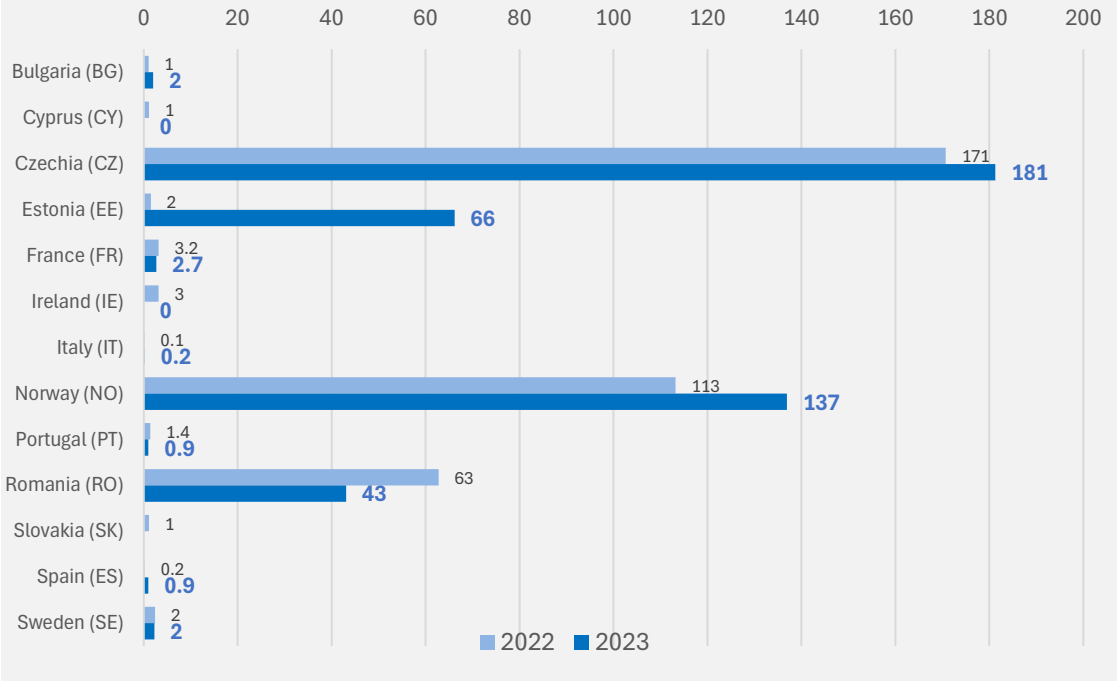


Figure 17. Transfusion rates of WB units pmp across reporting countries*; 2022 vs. 2023

**Note: in 2022, AT, HR, DK, FI, DE, EL, HU, LV, LI, LU, NL and UK(NI) reported 0 units of WB transfused. In 2023: AT, HR, CY, DE, EL, IS, IE, LV, LI, LU, NL and UK(NI) reported 0 units of WB transfused.*

2 Serious Adverse Reactions in Recipients

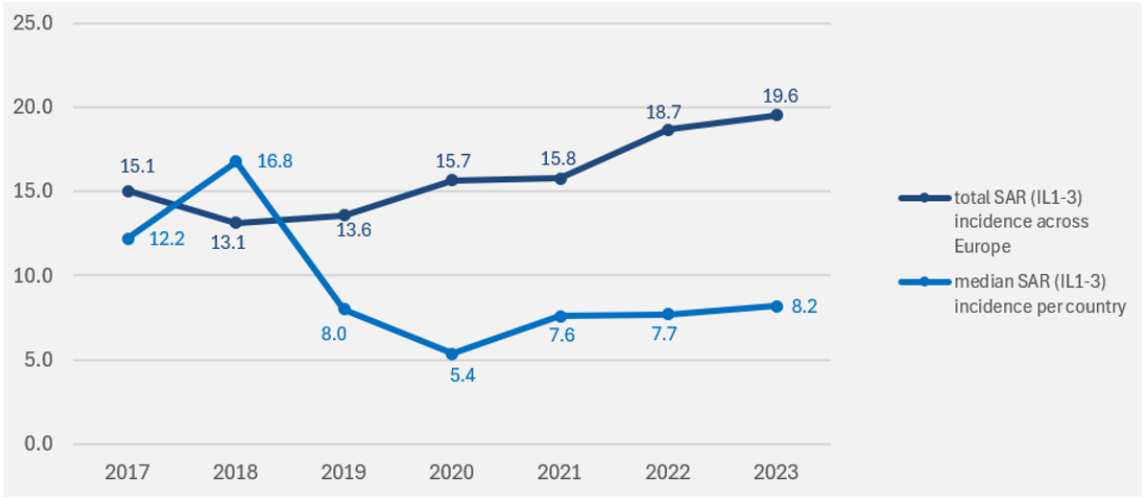
Key findings

- Total SAR (IL 2-3) incidence remained stable, occurring at a rate of 9.2/100,000 units transfused, while median SAR (IL 2-3) incidence per country showed a clear downward trend.
- Platelets consistently have the highest SAR (IL 2-3) incidence.
- The risk of death related to transfusion in Europe remains low (median 0.21/100,000 units transfused). Transfusion-associated circulatory overload (TACO) and immunological haemolysis continue to be the leading causes of transfusion-related deaths in Europe.
- In comparison with 2022, anaphylaxis/hypersensitivity and immunological haemolysis (IL 2-3) cases increased by 34% and 46%, respectively, while unclassified SAR ('other') decreased by 57%.
- Reporting requirements (fully or partially) for fatalities in recipients as stated in the ***Common Approach*** were met in 67% of cases (vs 22% in 2022). The exact infectious pathogen was also provided in 9 out of 30 transfusion-transmitted bacterial infection (TTBI) cases reported compared to none in 2022.

2.1 Yearly trends (2017–2023) by imputability

2.1.1 SAR (IL 1-3)

Figure 18 presents the yearly trends in SAR (imputability of possible, probable or certain) incidence from 2017 to 2023 using two complementary metrics: (1) total SAR (IL 1-3) incidence per 100,000 units of blood/BC transfused and (2) the median SAR (IL 1-3) incidence across all reporting countries. The first measure provides a region-wide perspective on the overall burden of SAR (IL 1-3) in transfusion safety, while the second trend illustrates the typical SAR (IL 1-3) incidence experienced by individual countries.



n	24	23	22	23	26	24	23

Figure 18. Yearly trends in SAR (IL 1-3) incidence: total SAR incidence/100,000 units transfused and median SAR (IL 1-3) incidence per country; 2017–2023

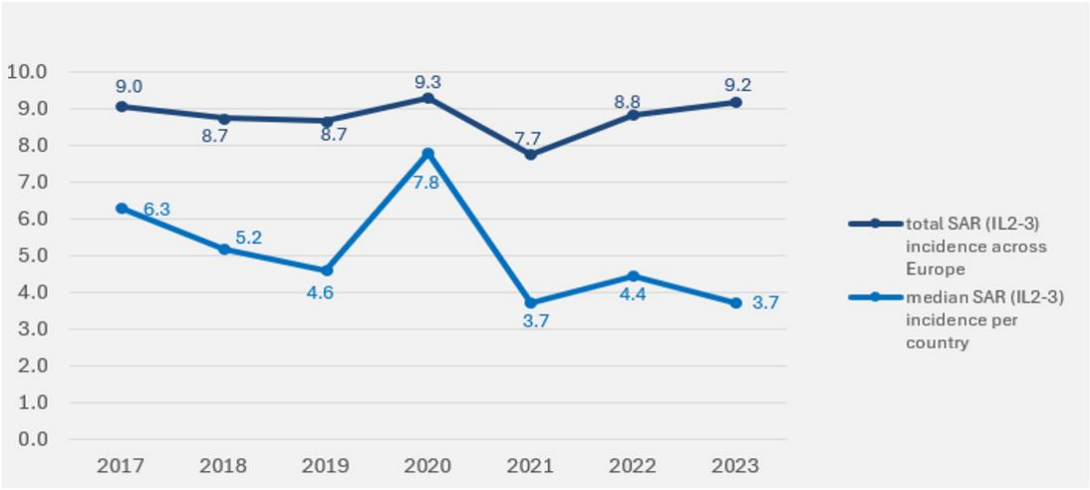
Note: only countries (n) that reported both SAR cases (including zero) and number of units of blood/BC transfused were included in the median SAR incidence calculations; for total SAR incidence refer to Annex 1.

Between 2017 and 2023, the total SAR (IL 1-3) incidence per 100,000 transfused units in Europe increased, rising from 15.1 in 2017 to 19.6 in 2023. However, the median SAR incidence per reporting country followed a different trajectory, decreasing from 16.8 in 2018 to 5.4 in 2020, before stabilising at around 7.6–8.2 from 2021 onward. This suggests that while a few countries with high SAR

incidence have contributed to the increase in total SAR rates, most countries report consistently lower SAR incidence levels.
The variability between the total and median incidence highlights differences in haemovigilance practices across Europe. The decline in median SAR incidence from 2018 to 2020 may indicate reduced reporting in certain countries or shifts in transfusion safety. The steady increase in total SAR incidence from 2021 to 2023 suggests either a real increase in SAR cases or improved detection and reporting following the COVID-19 pandemic.

2.1.2 SAR (IL 2-3)

Figure 19 presents the yearly trends in SAR (imputability of likely/probable or certain) incidence from 2017 to 2023 using two complementary metrics: (1) total SAR (IL 2-3) incidence per 100,000 units of blood/BC transfused and (2) the median SAR (IL 2-3) incidence across all reporting countries. The first measure provides a region-wide perspective on the overall burden of SAR (IL 2-3) in transfusion safety, while the second trend illustrates the typical SAR (IL 2-3) incidence experienced by individual countries.



n	24	23	22	24	26	24	24

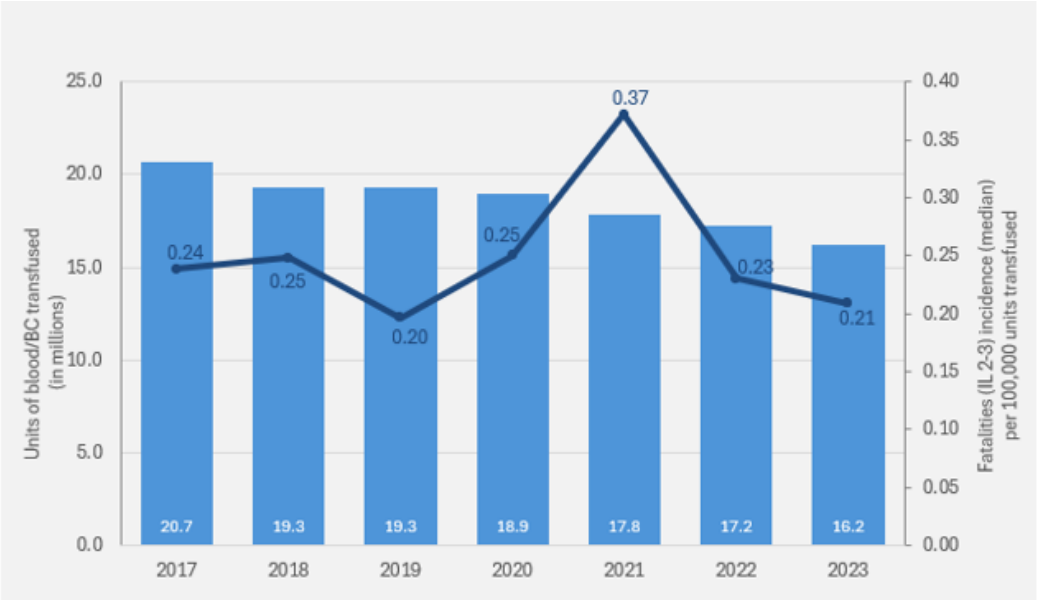
Figure 19. Yearly trends in SAR (IL 2-3) incidence: total SAR incidence/100,000 units transfused and median SAR (IL 2-3) incidence per country; 2017–2023
Note: only countries (n) that reported both SAR cases (including zero) and number of units of blood/BC transfused were included in the median SAR incidence calculations; for total SAR incidence refer to Annex 1.

Between 2017 and 2020, the total incidence of SAR (IL 2-3) per 100,000 transfused units remained relatively stable (~9), dropping to 7.7 in 2021 and increasing to 9.2 in 2023. However, the median SAR incidence per country declined from 6.3 in 2017 to 3.7 in 2023, indicating a downward trend in the typical SAR burden reported by individual countries. This suggests that while overall SAR incidence remains stable, most countries are experiencing lower SAR rates, with a few high-reporting countries influencing the total SAR burden.

A notable spike in the median incidence in 2020 (7.8) suggests a temporary reporting anomaly, possibly linked to COVID-19-related factors. The overall decline in the median SAR incidence per country may reflect improvements in transfusion safety, but potential under-reporting cannot be excluded.

2.1.3 Fatalities (IL 2-3)

Figure 20 shows the trend in transfusion-related deaths reported from 2017 to 2023.



n	7	7	8	9	9	7	9

Figure 20. Fatalities (IL 2-3) incidence (median) per 100,000 units transfused; 2017–2023

Deaths where it was likely/probable or certain that the reaction was caused by the blood (imputability 2 or 3) continue to be rare, with an incidence (median) ranging from 0.20 to 0.37/100,000 units transfused.

2.2 Geographic distribution by imputability

2.2.1 SAR (IL 1-3)

Figure 21 shows the SAR (IL 1-3) incidence rates per 100,000 units of blood/BC transfused across all reporting countries.

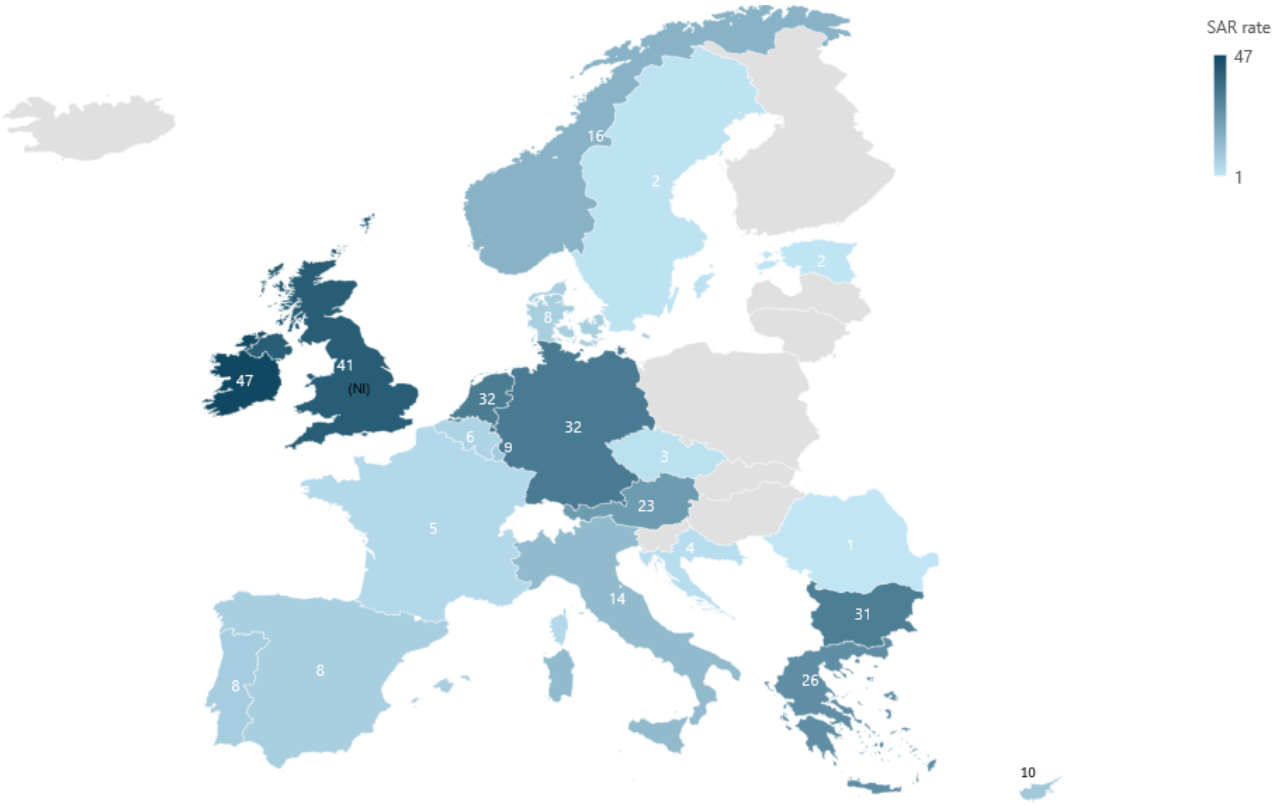


Figure 21. SAR (IL 1-3) incidence rates per 100,000 units transfused in Europe in 2023

Note: countries (FI, HU, LV, LT, PL, SK and SI) that reported SAR cases but did not report the number of units of blood/BC transfused (so incidence could not be calculated) as well as countries reporting zero SAR (IS and LI) are shown in grey.

SAR (IL 1-3) incidence ranged from a minimum of 1 (RO) to a maximum of 47 (IE) among reporting countries with a median of 8.2 SAR/100,000 units transfused, marginally higher than the 7.7 SAR/100,000 units transfused reported in 2022.

2.2.2 SAR (IL 2-3)

The SAR (IL 2-3) incidence rates per 100,000 units of blood/BC transfused across all reporting countries were determined (Figure 22).

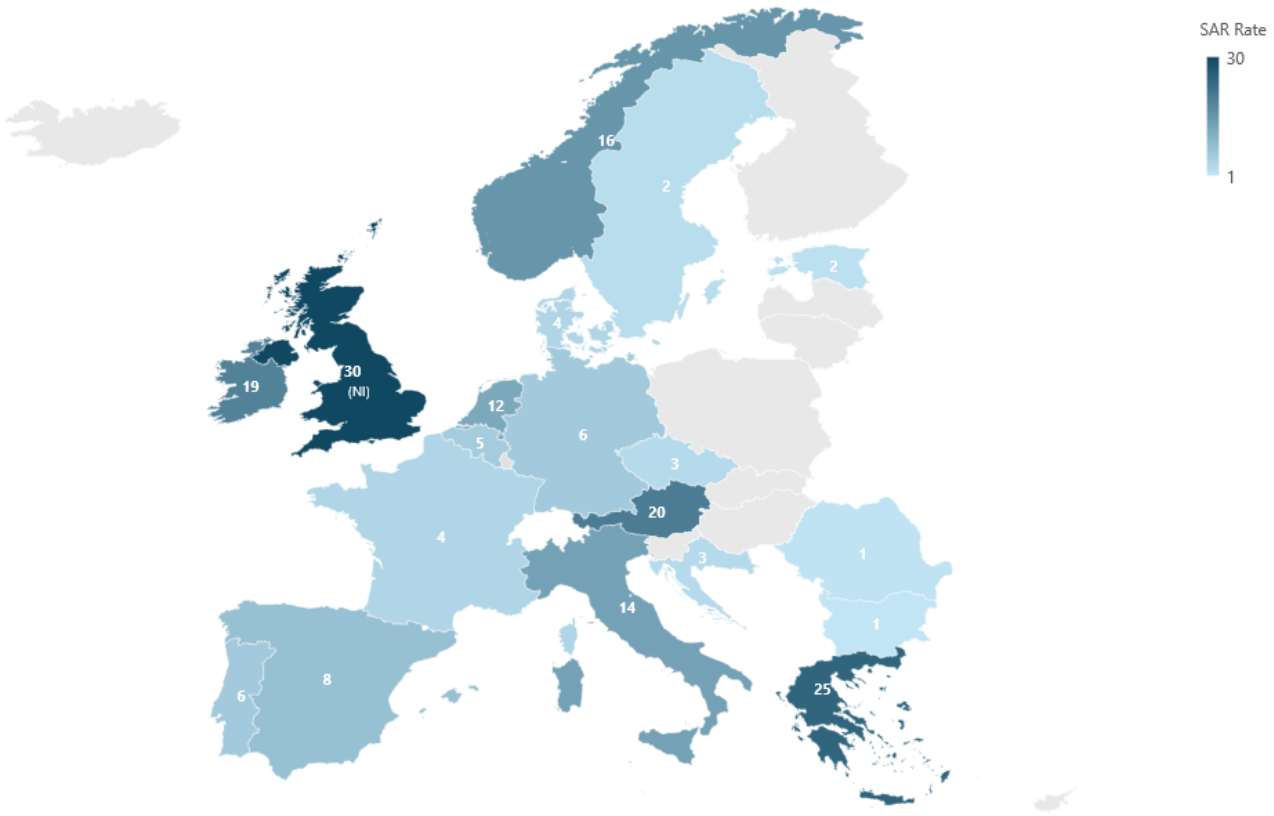


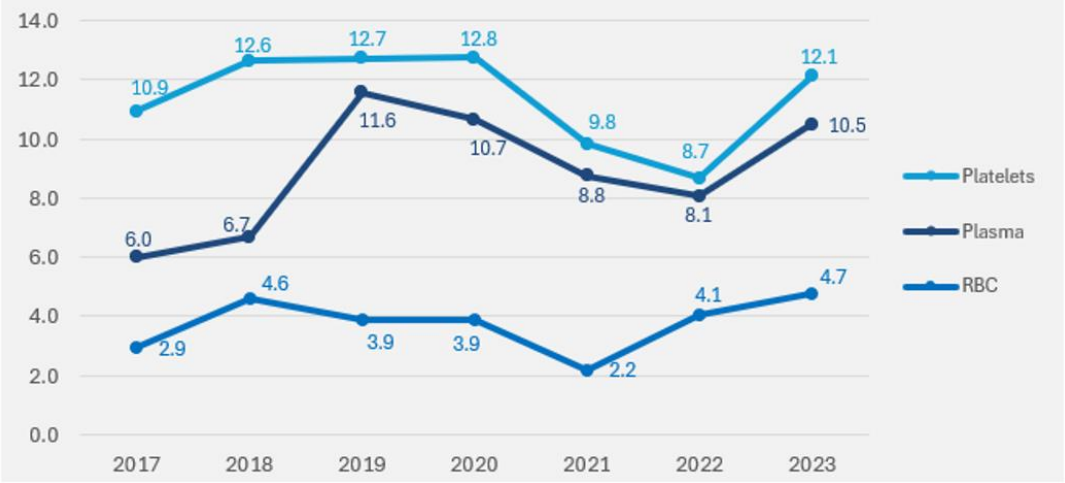
Figure 22. SAR (IL 2-3) incidence rates per 100,000 units transfused in Europe in 2023
Note: countries (FI, HU, LV, PL, SK and SI) that reported SAR cases but did not report the number of units of blood/BC transfused (so incidence could not be calculated) as well as countries reporting zero SAR (CY, IS, LI, LT and LU) are shown in grey.

SAR (IL 2-3) incidence in Europe varied from 1 (BG and RO) to 30 (UK(NI)), with a median of 3.7 SAR/100,000 units transfused, marginally lower than the 4.4 SAR/100,000 units transfused reported in 2022.

2.3 Yearly trends (2017–2023) by type of BC

2.3.1 SAR (IL 2-3)

Figure 23 presents the yearly trends in the median SAR (IL 2-3) incidence per 100,000 units transfused from 2017 to 2023 for each type of BC.



n(Platelets)	18	17	15	20	18	18	17
n(Plasma)	15	14	14	14	10	11	12
n(RBC)	24	22	22	24	25	21	23

Figure 23. Median SAR (IL 2-3) incidence per 100,000 units transfused for each type of BC; 2017–2023

Note 1: only countries that reported both SAR cases and the corresponding number of units transfused per BC were included in the median incidence calculations.

Note 2: n includes countries reporting zero SAR (IL 2-3) cases for RBC, but these are excluded for platelets and plasma.

Between 2017 and 2023, the median SAR (IL 2-3) incidence per country varied significantly depending on the BC. Platelet transfusions consistently showed the highest SAR incidence, with a peak at 12.8 in 2020, a drop in 2021 and 2022 and a return to 12.1 in 2023. Plasma SAR incidence increased sharply between 2017 and 2019, reaching 11.6, before stabilising between 8.1 and 10.5 in recent years. RBC transfusions had the lowest median SAR (IL 2-3) incidence per country, with minor fluctuations between 2.9 and 4.7.

These trends highlight the well-documented higher risk of transfusion reactions associated with platelet and plasma transfusions compared to RBC. The fluctuations in SAR incidence may reflect differences in haemovigilance reporting systems, clinical practices and the number of reporting countries per component. In particular, the decrease in plasma SAR incidence after 2019 coincides with a drop in the number of reporting countries, which may have influenced observed trends.

2.3.2 Fatalities (IL 2-3)

As seen in previous years, RBC components are associated with a higher number of fatalities (Figure 24).

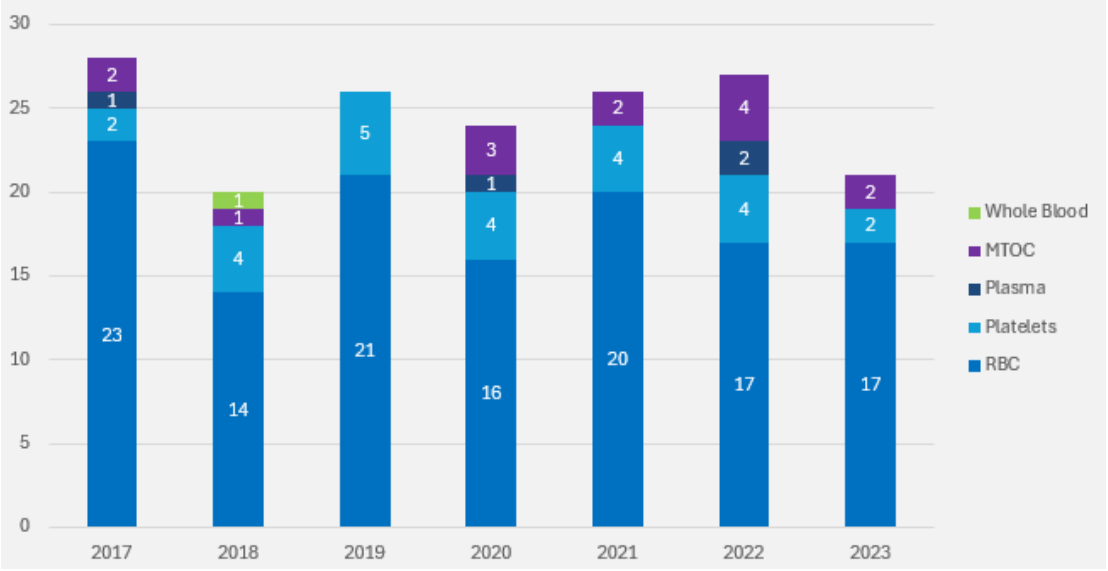


Figure 24. Summary of total number of fatalities (IL 2-3) by type of BC; 2017–2023

2.4 SAR (IL 2-3) incidence by type of BC

SAR (IL 2-3) incidence per 100,000 units transfused per country for each type of BC is displayed in Figure 25. In general, countries reported a higher SAR (IL 2-3) incidence associated with the transfusion of platelets or plasma than with RBC.

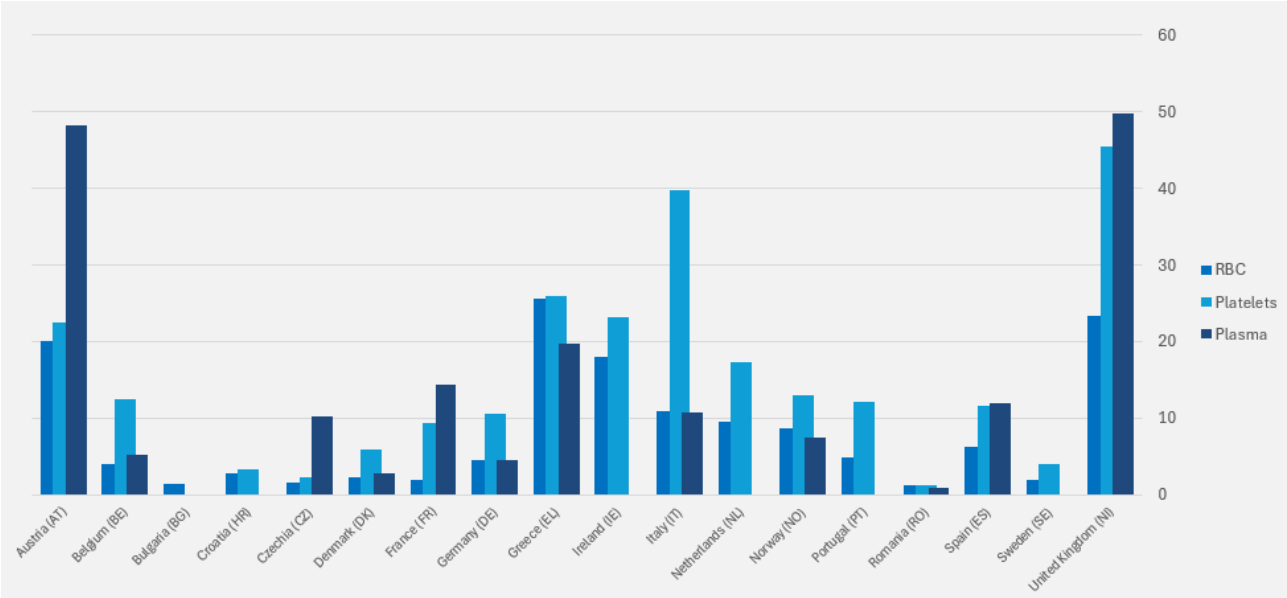


Figure 25. SAR (IL 2-3) incidence/100,000 units transfused for each type of BC per country in 2023

Note: FI, HU, LV, PL, SK and SI also reported SAR but did not provide number of units transfused so incidence could not be calculated. No SAR were reported by CY, IS, LI, LT or LU.

2.5 Overview of SAR and fatalities by type of BC

2.5.1 Distribution of number of SAR and fatalities

Overall data collected in 2023 for number of SAR and fatalities by IL1-3 and IL 2-3 and by type of BC are shown in Figure 26.

The majority of the reported **SAR (IL 2-3)** were associated with transfusions of RBC (65%), followed by platelets (21%) and plasma (10%).

Twenty-one **SAR (IL 2-3)** resulted in death. In terms of the type of BC involved, 17 fatalities were associated with RBC transfusion (81%), two with platelet transfusion (9.5%) and two with more than one BC transfused (MTOC) (9.5%).

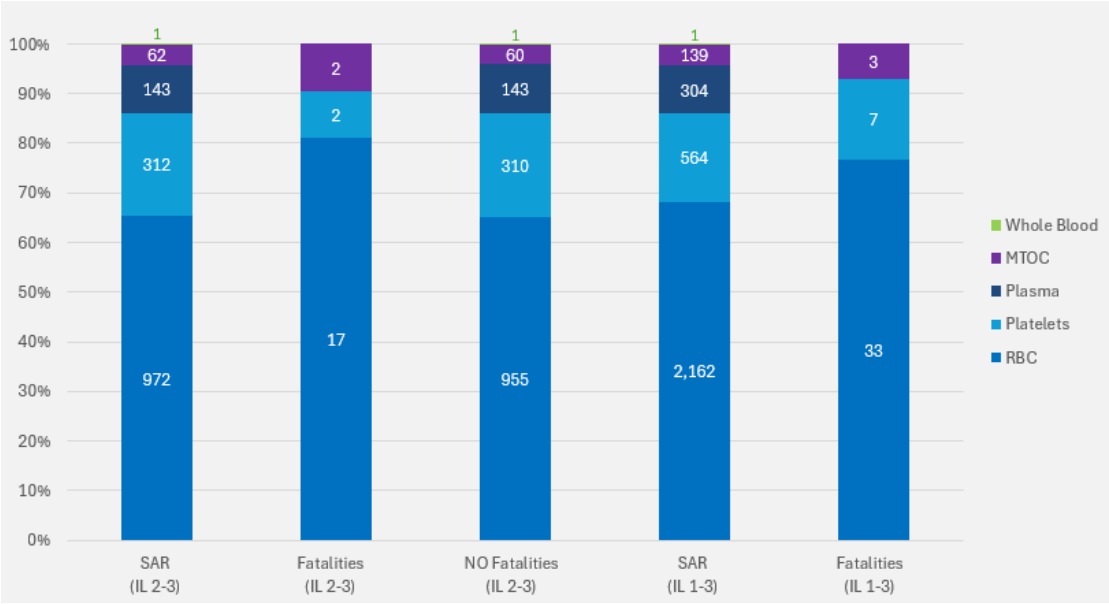


Figure 26. Percentage distribution of total number of SAR and fatalities by IL 1-3 and IL 2-3 and by type of BC in 2023

2.5.2 Comparative data

As shown in Table 4, in 2023 the total number of **SAR (IL 1-3)** reported was 3,170, comparable with 2022. Regarding **SAR (IL 2-3)**, the number of cases for platelets and plasma decreased by around 20%, whereas it increased by 38% for MTOC.

Total Number of **SAR (IL 1-3)**	**2023**	2022	**% Change**
Red Blood Cells	2,162	2,051	**+5**
Platelets	564	672	**-16**
Plasma	304	266	**+14**
MTOC	139	94	**+48**
Whole Blood	1	0	*
TOTAL	**3,170**	3,083	**+3**

* New value in 2023

n (RBC)	26	25
n (Platelets)	26	27
n (Plasma)	20	19
n (MTOC)	14	15
n (Whole Blood)	1	0

Total Number of **SAR (IL 2-3)**	**2023**	2022	**% Change**
Red Blood Cells	972	906	**+7**
Platelets	312	389	**-20**
Plasma	143	176	**-19**
MTOC	62	45	**+38**
Whole Blood	1	0	*
TOTAL	**1,490**	1,516	**-2**

* New value in 2023

n (RBC)	24	25
n (Platelets)	21	24
n (Plasma)	16	14
n (MTOC)	12	11
n (Whole Blood)	1	0

Table 4. Summary of total number of SAR (IL 1-3) and (IL 2-3) by type of BC; 2023 vs. 2022

Forty-three fatalities (IL 1-3) in recipients were reported in 2023, three fewer than in 2022. Overall, the number of fatalities per type of BC remained relatively constant (Table 5).

Total Number of **Fatalities (IL 1-3)**	2022	**2023**	**Absolute Change**
Red Blood Cells	34	33	-1
Platelets	4	7	+3
Plasma	2	0	-2
MTOC	6	3	-3
Whole Blood	0	0	0
TOTAL	46	**43**	**-3**

n (RBC)	8	11
n (Platelets)	2	3
n (Plasma)	2	0
n (MTOC)	3	1
n (Whole Blood)	0	0

Total Number of **Fatalities (IL 2-3)**	2022	**2023**	**Absolute Change**
Red Blood Cells	14	17	+3
Platelets	3	2	-1
Plasma	2	0	-2
MTOC	4	2	-2
Whole Blood	0	0	0
TOTAL	23	**21**	**-2**

n (RBC)	7	9
n (Platelets)	2	2
n (Plasma)	2	0
n (MTOC)	2	1
n (Whole Blood)	0	0

Table 5. Summary of total number of fatalities (IL 1-3) and (IL 2-3) by type of BC; 2023 vs. 2022

2.5.3 Fatalities by imputability level

Eleven countries (BE, FI, FR, DE, EL, IT, NL, PT, RO, ES and SE) reported a total of 43 fatalities in recipients. Of these, 22 fatalities were classified imputability 1 while 21 were assigned imputability 2 or 3. A summary of fatalities by imputability level and by type of BC is presented in Table 6.

Country (#SAR)	RBC	Platelets	Plasma	MTOC
Belgium (1)	1 IL2			
Finland (1)	1 IL1			
France (4)	2 IL2 2 IL3			
Germany (21)	8 IL1 2 IL2 3 IL3	4 IL1 1 IL2		1 IL1 2 IL2
Greece (2)	1 IL2 1 IL3			
Italy (1)	1 IL2			
Netherlands (7)	6 IL1	1 IL1		
Portugal (2)	1 IL1 1 IL2			
Romania (1)	1 IL2			
Spain (2)	1 IL2	1 IL2		
Sweden (1)	1 IL2			

Table 6. Summary of total number of fatalities by IL and by type of BC in 2023

2.6 Yearly trends (2017–2023) by type of reaction

According to the ***Common Approach***, 2024 edition, transfusion reactions are classified in a similar way to International Society of Blood Transfusion (ISBT) criteria (Table 7).

Immunologically related SAR	Cardiovascular and metabolic problems	Transfusion-transmitted infection (TTI)
• Transfusion-related acute lung injury (TRALI) • Anaphylaxis/hypersensitivity • Febrile non-haemolytic transfusion reaction (FNHTR) • Immunological haemolysis (due to ABO incompatibility/due to other alloantibody) • Post-transfusion purpura (PTP) • Transfusion-associated graft-versus-host disease (Ta-GvHD) --- • Non-immunological haemolysis	• Circulatory overload (TACO) • Hypotensive transfusion reaction • Transfusion-associated dyspnoea (TAD)	• Bacterial • Viral (HBV, HCV, HIV-1/2, other) • Parasitical (malaria, other) • Fungal • Prion
Other *(reactions which do not meet the criteria for a defined category)*		

Table 7. Types of reportable transfusion reactions

2.6.1 SAR (IL 2-3)

Table 8 shows the percentages of total SAR (IL 2-3) by the top 5 reaction types and Figure 27 shows the trend in reporting from 2017 to 2023. The upward trend for uncategorised reactions 'other' has reversed in 2023. Anaphylaxis/hypersensitivity reporting remains high.

Type of Reaction	2017	2018	2019	2020	2021	2022	2023
Other	29.4	26.2	9.6	27.7	29.9	27.0	11.7
FNHTR	24.0	22.8	16.3	20.4	24.2	23.0	24.6
Anaphylaxis/ hypersensitivity	15.6	19.6	42.3	21.7	15.7	18.6	25.4
TACO	13.0	16.6	16.8	16.3	13.4	13.2	14.4
Immunological haemolysis	9.8	7.9	8.0	6.9	8.4	9.0	13.3

Table 8. Percentages of total SAR (IL 2-3) by the top 5 reaction types; 2017–2023

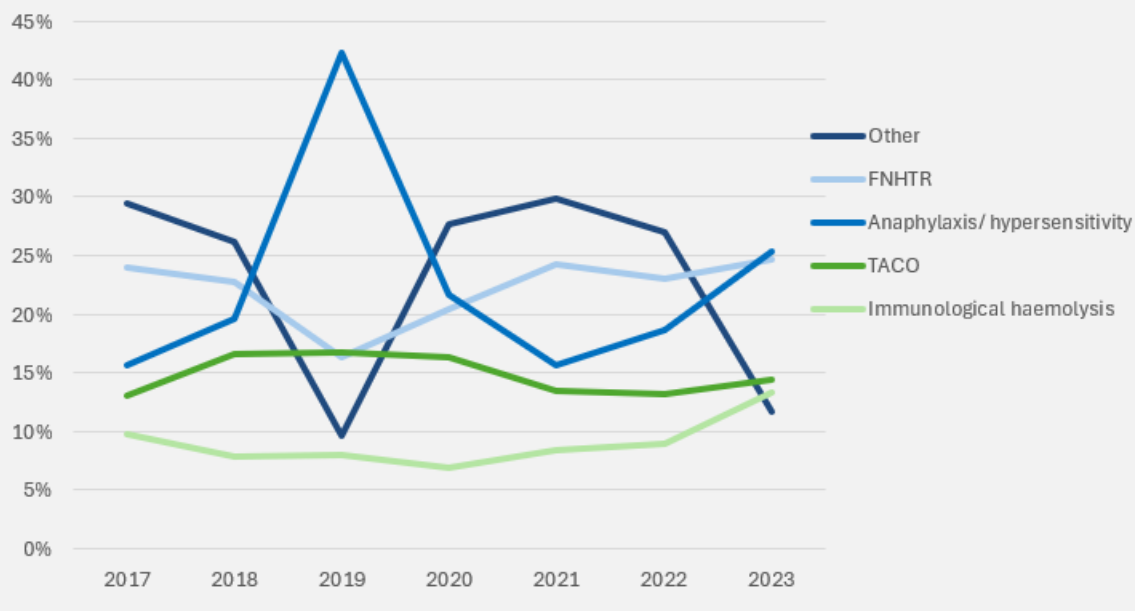


Figure 27. Yearly trends in percentage of total SAR (IL 2-3) by the top 5 reaction types; 2017–2023

2.6.2 Fatalities (IL 2-3)

Table 9 shows the number of transfusion-related deaths by type of reaction from 2017 to 2023.

Type of Reaction	2017	2018	2019	2020	2021	2022	2023
TACO	6	6	7	12	8	4	4
Immunological haemolysis	9	4	10	3	11	9	9
TRALI	1	3	3	5	2	9	3
Other	6	3	1	1	1		2
TTBI	2	2	1	1	3	4	3
Non-immunological haemolysis	1	1	1	1			
PTP		1					
TTVI	1		2	1			
TAD	1						
Anaphylaxis/ hypersensitivity	1					1	
TTPI			1				

Table 9. Summary of total number of fatalities (IL 2-3) by type of reaction; 2017–2023

2.7 Overview of SAR and fatalities by type of reaction

2.7.1 SAR (IL 2-3)

As shown in Figure 29, the most common type of transfusion reaction in 2023 was anaphylaxis/hypersensitivity (25.4%), followed by FNHTR (24.6%) and TACO (14.4%).

In comparison with 2022, anaphylaxis/hypersensitivity and immunological haemolysis cases increased by 34% and 46%, respectively, while unclassified SAR ('other') decreased by 57%, indicating an improvement in classification accuracy. Nevertheless, the definition of reactions still needs to be revisited given the list of SAR (IL 2-3) cases classified as 'other' (Figure 29).

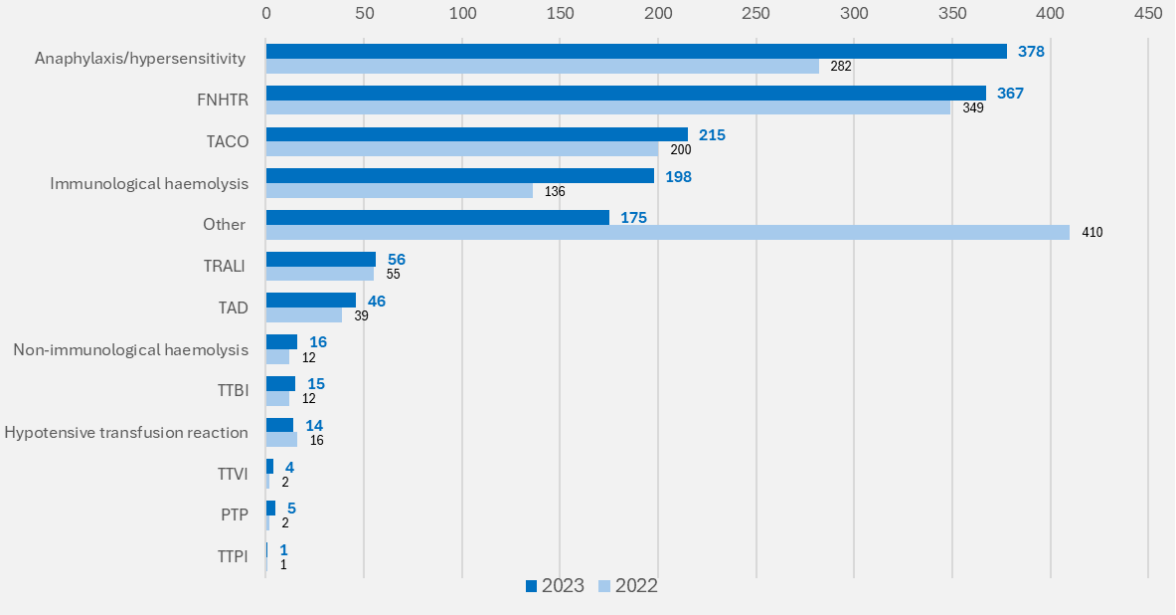


Figure 28. Distribution of SAR (IL 2-3) by type of reaction; 2023 vs. 2022

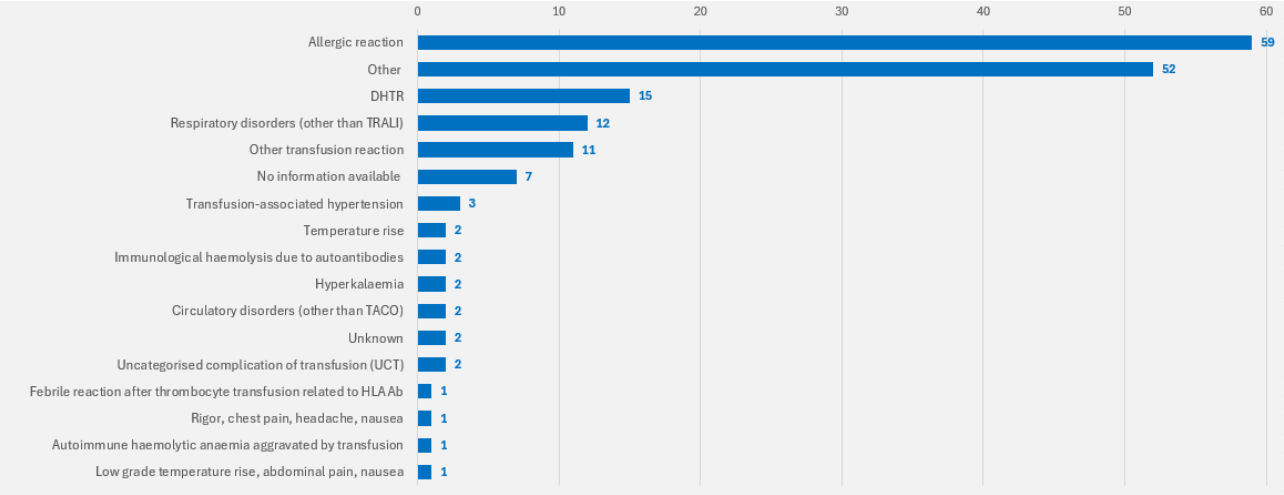


Figure 29. Distribution of SAR (IL 2-3) classified as 'other'; 2023 vs. 2022

A detailed summary of the top 5 transfusion reaction types by type of BC for 2023 vs. 2022 is displayed in Table 10 and Table 11.

Top 5 Reaction Types	RBC			Platelets		
	2022	2023	Absolute Change	2022	2023	Absolute Change
Anaphylaxis/hypersensitivity	74	133	+59	123	140	+17
FNHTR	272	276	+4	69	71	+2
TACO	174	170	-4	8	12	+4
Immunological haemolysis	a) 65 b) 50	a) 65 b) 108	a) 0 b) +58	a) 4 b) 0	a) 1 b) 10	a) -3 b) +10
Other	166	103	-63	156	52	-104
n (Anaphylaxis/hypersensitivity)	14	15		19	17	
n (FNHTR)	11	11		7	6	
n (TACO)	18	20		8	7	
n (Immunological haemolysis)	a) 16 b) 15	a) 14 b) 20		a) 4	a) 1 b) 2	
n (Other)	13	10		7	7	

Table 10. Summary of top 5 SAR (IL 2-3) types in RBC and platelets; 2023 vs. 2022
Note: the data exclude fatalities (IL 2-3); a) due to ABO incompatibility; b) due to other alloantibody

Top 5 Reaction Types	Plasma			MTOC		
	2022	2023	Absolute Change	2022	2023	Absolute Change
Anaphylaxis/hypersensitivity	67	89	+22	17	16	-1
FNHTR	5	15	+10	3	5	+2
TACO	10	9	-1	4	19	+15
Immunological haemolysis	a) 6	a) 3	-3	b) 2	b) 2	0
Other	79	14	-65	9	4	-5
n (Anaphylaxis/hypersensitivity)	12	14		6	6	
n (FNHTR)	3	4		2	3	
n (TACO)	5	5		4	7	
n (Immunological haemolysis)	a) 4	a) 1		b) 2	b) 2	
n (Other)	3	4		2	4	

Table 11. Summary of top 5 SAR (IL 2-3) types in plasma and MTOC; 2023 vs. 2022
Note 1: the data exclude fatalities (IL 2-3); a) due to ABO incompatibility; b) due to other alloantibody.
Note 2: one TACO case was reported for WB in 2023, none in 2022.

2.7.2 Transfusion-transmitted infection (TTI)

A report was classified as a TTI if the investigation revealed:
The recipient(s) had evidence of infection post transfusion with BC, there was no evidence of infection prior to transfusion, no evidence of an alternative source of infection, and either:
a. at least one component received by the infected recipient(s) was donated by a donor who had evidence of the same transmissible infection or
b. at least one component received by the infected recipient was shown to contain the agent of infection.

In this section the spectrum of TTIs is covered, namely bacterial (TTBI), viral (TTVI) and parasitical (TTPI) transmissions.
A total of 41 TTI cases (30 TTBIs, 9 TTVIs and 2 TTPIs), including 5 fatalities (due to TTBI) were reported in 2023 (Table 12).

Type of TTI	# SAR (IL 1-3)		
	2022	2023	Absolute Change
TTBI	26	30	+4
TTVI	5	9	+4
TTPI	1	2	+1
TOTAL	**32**	**41**	**+9**
n (TTBI)	4	7	
n (TTVI)	4	2	
n (TTPI)	1	2	

Type of TTI	# Fatalities (IL 1-3)		
	2022	2023	Absolute Change
TTBI	4	5	+1
TTVI	0	0	
TTPI	0	0	
TOTAL	**4**	**5**	**+1**
n (TTBI)	1	2	

Table 12. Summary of TTIs; 2023 vs. 2022

As presented in Table 13, out of the 41 cases, twenty-one were assessed as IL1, eight as IL2 and twelve as IL3. Of the 30 TTBI cases, five resulted in death: one following transfusion of RBC (IL2) and four associated with platelets (two IL1 and two IL2).

Type of TTI	RBC		Platelets		Plasma		MTOC	
	No fatalities & IL	Fatalities & IL	No fatalities & IL	Fatalities & IL	No fatalities & IL	Fatalities & IL	No fatalities & IL	Fatalities & IL
TTBI	**13** 7 IL1 1 IL2 5 IL3	**1** 1 IL2	**11** 5 IL1 3 IL2 3 IL3	**4** 2 IL1 2 IL2			**1** 1 IL1	
TTVI	**5** 2 IL1 3 IL3		**3** 3 IL1		**1** 1 IL3			
TTPI	**2** 1 IL1 1 IL2							

Table 13. Summary of TTIs by type of BC and by IL in 2023

The exact infectious pathogen was provided in 9 out of 30 TTBI cases reported (Table 14) compared to none in 2022.

Country (#SAR)	RBC	Platelets	MTOC
	Infectious Pathogen	Infectious Pathogen	Infectious Pathogen
Belgium (1)	*Cutibacterium acnes*		
France (3)	(1) *Serratia marcescens* (1) *Yersinia enterocolitica*	(1) *Bacillus cereus*	
Germany (22)	(1) *Staphylococcus haemolyticus*	(1) *Klebsiella oxytoca* (1) 1x *S. aureus* and *S. lugdunensis*, 1x *S. aureus* and *S. xylosus* (1) *Bacillus cereus*	?
Greece (1)	?		
Spain (1)		*Staphylococcus saprophyticus* *	
Sweden (1)	?		
Northern Ireland (1)		?	

Table 14. Summary of TTBIs by type of BC and by country in 2023
Note: the Spanish case occurred in 2022, but the investigation was only finalised in 2023.*

With regard to TTVIs, one HCV and eight HEV cases were reported. With regard to TTPIs, one case of Parvovirus B19 (mistakenly classified as a parasite) and one unspecified parasite were reported. In all these cases, no additional comments were provided.

Country (#SAR)	RBC	Platelets	Plasma
	Viral Subtype	Viral Subtype	Viral Subtype
Czechia (1)	HCV		
France (6)	(2) Other: HEV	(3) Other: HEV	(1) Other: HEV
Germany (1)	Other: HEV		
Spain (1)	Other: HEV*		

Country (#SAR)	RBC
	Parasitical Subtype
Germany (1)	Other: Parvovirus B19
Hungary (1)	Other: No Information

Table 15. Summary of TTVIs and TTPIs by type of BC and by country in 2023
Note: the Spanish case occurred in 2022, but the investigation was only finalised in 2023*

2.7.3 Fatalities

Eleven countries (BE, FI, FR, DE, EL, IT, NL, PT, RO, ES and SE) reported a total of 43 fatalities in recipients in 2023. The distribution of fatalities by IL and by type of reaction is presented in Figure 30.

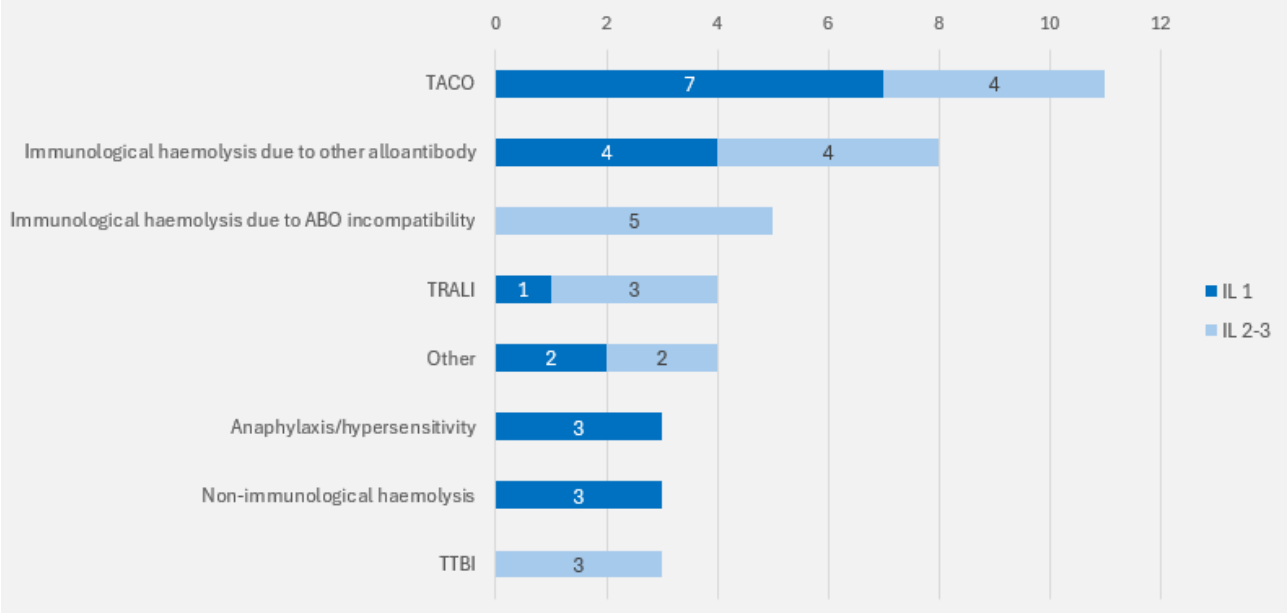


Figure 30. Distribution of fatalities by IL and by type of reaction in 2023

Of these fatalities, 21 were assigned IL 2 or 3, the majority of which were associated with immunological haemolysis due to ABO incompatibility (5), followed by immunological haemolysis due to other alloantibody (4), TACO (4), TRALI (3) and other (2). Sixteen fatalities were associated with transfusion of RBC and two with transfusion of MTOC. No fatalities associated with the transfusion of platelets or plasma were reported in 2023 (Table 16).

Type of Reaction	RBC			Platelets			Plasma			MTOC		
	2022	2023	Absolute Change	2022	2023	Absolute Change	2022	2023	Absolute Change	2022	2023	Absolute Change
Immunological haemolysis	a) 7 b) 1	a) 5 b) 4	a) -2 b) +3				a) 1	0	a) -1			
TACO	4	4	0									
TRALI	3	1	-2	1	0	-1	1	0	-1	4	2	-2
Other	0	2	+2									
Anaphylaxis/hypersensitivity				1	0	-1						

Table 16. Summary of fatalities (IL 2-3) by type of reaction and by type of BC in 2023
Note: the data exclude fatalities (IL 2-3) due to TTBI; a) due to ABO incompatibility; b) due to other alloantibody.

2.8 Investigation of fatalities

Investigating fatalities helps pinpoint errors and safety gaps in the transfusion process. Consequently, documenting these incidents in a thorough and complete way is crucial for quality assurance and can lead to changes in processes, systems and policies to improve transfusion safety.

The ***Common Approach***, 2024 edition, states: "Concerning reports where an SAR is confirmed to be fatal, any relevant information should be reported, 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."

In 2023, the requirements were met (fully or partially) for 29 out of 43 cases reported (67%). This was significantly higher than in 2022 (22%), highlighting an increased effort by MS to comply with the ***Common Approach***.
The following examples of selected fatality cases show the different ways in which transfusion errors can arise.

Example: Incorrect blood component transfused (ICBT)

An 83-year-old female patient with diabetes was reported with high fever and severe anaemia. Two days after admission, she presented with symptoms of septicaemia unresponsive to therapy with antibiotics. She was then transfused with one unit of red cells group A(+) and within 15 minutes after transfusion of about 50 mL she presented acute pain and severe haemolytic crisis.

Investigation performed: the patient was transfused with the wrong blood (her own blood group was O+).

Root cause: no confirmation of the patient's group was performed before transfusion by the responsible staff.

CAPA: conduct positive patient identification prior to administration of the component.

Example: Process not accurately described in the SOP

The patient was female and 72 years old. She was admitted to the healthcare facility with a diagnosis of mitral and aortic prosthesis stenosis and underwent double replacement of the valve prostheses. There was no need for the patient to undergo any transfusion.

Investigation performed: an incompatible ABO pre-storage leukocyte-depleted RBC unit destined for another patient was mistakenly transfused.

Root cause: there was a gap in the transfusion safety procedures that appears to have been overlooked and which, if followed at all stages, would have prevented the error from occurring. The training of personnel on transfusion therapy appeared to be insufficiently focused and was not explicitly mentioned in the SOP.

CAPA:
• the Blood Establishment must create and document an audit plan for the health facility;
• the SOP should detail control steps at the patient's bedside, including identification, data verification and documentation, with responsibility taken by the two operators performing the checks;
• implement both theoretical and practical training for all health professionals involved in transfusion activities.

Example: Non-compliance with SOP

The patient, a 66-year-old female, was hospitalised for multiple comorbidities (lumbar discitis, paraparesis, sepsis with vertebral starting point, severe anaemia, leukopenia, dilated cardiomyopathy, repeated myocardial infarctions in APP, pulse hypertension, CIC, moderate mitral insufficiency, COPD Gold stage II, chronic lymphocytic thyroiditis, dyslipidaemia, previous resections, internal haemorrhoids, carotid atheromatosis, hysterectomy in APP, clinical indications for transfusion – haemoglobin (5.7 g/dL). Two units of erythrocyte concentrate were transfused to the patient (one unit of leucocyte-depleted erythrocyte concentrate and one unit of non-leucodepleted erythrocyte concentrate).

Investigation performed: the first unit was transfused according to compatibility (saline test, enzyme test, indirect Coombs' test), but for the second transfused unit the indirect Coombs' test was not performed. The patient's pre-transfusion serum samples were tested by the County Regional Blood Transfusion Centre; after this test, it was found that the second transfused unit was not compatible with the indirect Coombs' test.

Root cause/Conclusions:
• the need to retrain the personnel involved in the transfusion activity;
• the need for personnel involved in transfusion activity to comply with transfusion work procedures and protocols.
The autopsy results showed that there were no typical signs of post-transfusion haemolytic reaction (haemorrhagic pleural or pericardial effusion, cerebral/integumentary haemorrhagic petechiae, spontaneous bleeding).

CAPA:
• the obligation to carry out compatibility tests by micromethod;
• supplement the staff of the Blood Transfusion Unit of the hospital;
• retrain personnel involved in the transfusion activity;
• enforce compliance with the procedures and working protocols by the personnel involved in the transfusion activity according to the legislation in force. For failure to comply, a contravention sanction will be applied.

Example: TACO Case study IL 2

A 93-year-old female patient with a history of valvular heart disease with aortic stenosis, hypertension and chronic renal failure was admitted to the emergency room at 06:36 for chest pain, dyspnoea and agitation. The patient presented with anaemia (haemoglobin of 47 g/L); prescription and transfusion of 1 unit of standard RBC, leucodepleted (initial flow rate 70 mL/hour) started at 11:00. The patient repeatedly used the call button and was monitored approximately every 10 minutes by the nurse. She was very agitated and needed to be reassured. At 11:50, transfusion was stopped early because of acute respiratory distress with O_2 saturation of 83%, polypnea and sweating. The patient had no alertness problems and no fever, but there was ideomotor slowing. The nurse noted that the bag appeared to have been transfused abnormally quickly, given the programmed flow rate; 40 mg diuretic was prescribed. There was no clear improvement and at 12:30 the patient suffered a sudden cardiorespiratory arrest (TACO), followed by death, which was confirmed by the doctor in charge.

CAPA:
• reminder of transfusion rates to emergency nurses;
• assess the relevance of emergency and night-time transfusions;
• adjust the transfusion rate using a pump and introduce a prescription rate by the prescriber on Cursus.

3 Serious Adverse Events

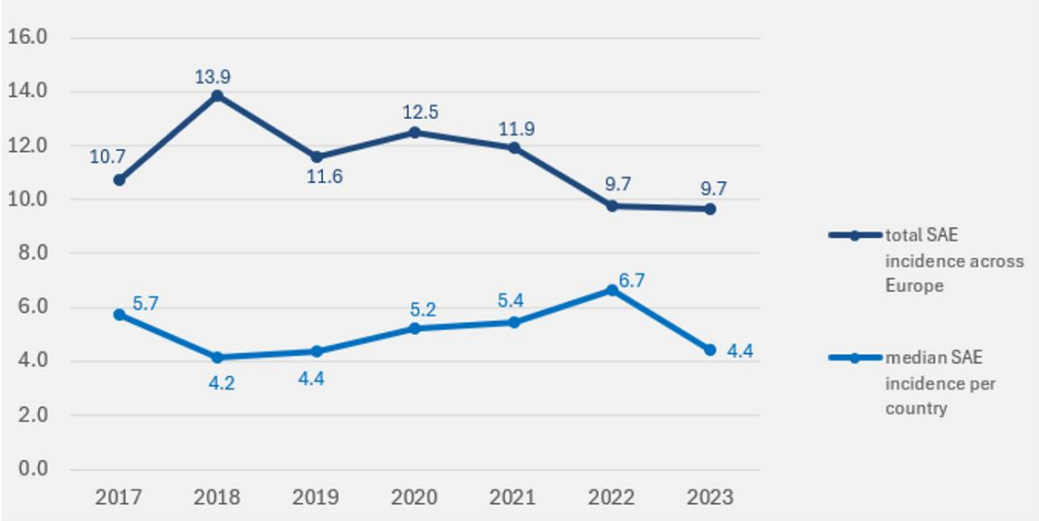
Key findings

- Total SAE incidence continues to decrease, reaching 9.7/100,000 units processed. Median SAE incidence per country followed a similar trend but declined more sharply in 2023 (4.4).
- Similar to 2022, SAE classified as 'other' were the most frequent (37%), followed by those attributed to storage (16%), issue (9%), whole blood collection and donor selection (both 8%).
- Human error, although decreasing, remains the top cause of SAE. In particular, 75% of events reported were related to staff making an incorrect decision or skipping steps in a process (vs 66% in 2022).

3.1 Yearly trends (2017–2023)

SAE occur at all stages of the transfusion cycle, from donor selection to clinical services, but the only available denominator is number of units of blood/BC processed, which is not optimal. Due to the lack of appropriate data, SAE incidence rates were calculated in relation to number of units of blood/BC processed, irrespective of where the events were identified/occurred.

Figure 31 presents the yearly trends in SAE incidence from 2017 to 2023 using two complementary metrics: (1) total SAE incidence per 100,000 units of blood/BC processed and (2) the median SAE incidence across all reporting countries. The first measure provides a region-wide perspective on the safety and efficiency of the whole transfusion chain, while the second trend illustrates the typical SAE incidence experienced by individual countries.



n	20	21	20	24	24	24	25

Figure 31. Yearly trends in SAE incidence: total SAE incidence/100,000 units processed and median SAE incidence per country; 2017–2023

Note: only countries that reported at least one SAE case and the number of units processed were included in the median SAE incidence calculations; for total SAE incidence refer to Annex 1.

Between 2017 and 2023, the total incidence of SAE per 100,000 processed units showed an overall declining trend, peaking at 13.9 in 2018 before steadily decreasing to 9.7 in 2023. The median SAE incidence per country followed a similar pattern, fluctuating between 4.2 and 6.7 until 2022, before dropping to 4.4 in 2023. This suggests a general reduction in SAE occurrence across Europe.

The number of reporting countries increased from 20 in 2017 to 25 in 2023, meaning the decline in SAE incidence is unlikely to be due to reduced reporting. Instead, this trend may reflect improvements in haemovigilance monitoring, process optimisations and changes in transfusion practices. The decline in both total and median SAE incidence suggests a real improvement in transfusion safety rather than reporting inconsistencies.

3.2 Geographic distribution

During 2023, 23,700,556 blood units were processed according to data provided by 26 countries (AT, BE, BG, HR, CY, CZ, DK, EE, FI, FR, DE, EL, IS, IE, IT, LV, LT, NL, NO, PL, PT, SK, SI, ES, SE and UK(NI)). This was a slight increase in comparison with the previous year (22,943,682).

A total of 2,294 SAE were reported in 2023 by 25 countries (AT, BE, BG, HR, CY, CZ, DK, EE, FI, FR, DE, EL, IS, IE, IT, LV, NL, NO, PL, PT, SK, SI, ES, SE and UK(NI)), marginally higher than in 2022 (2,235).

SAE incidence rates per 100,000 units of blood/BC processed across all reporting countries were determined (Figure 32).

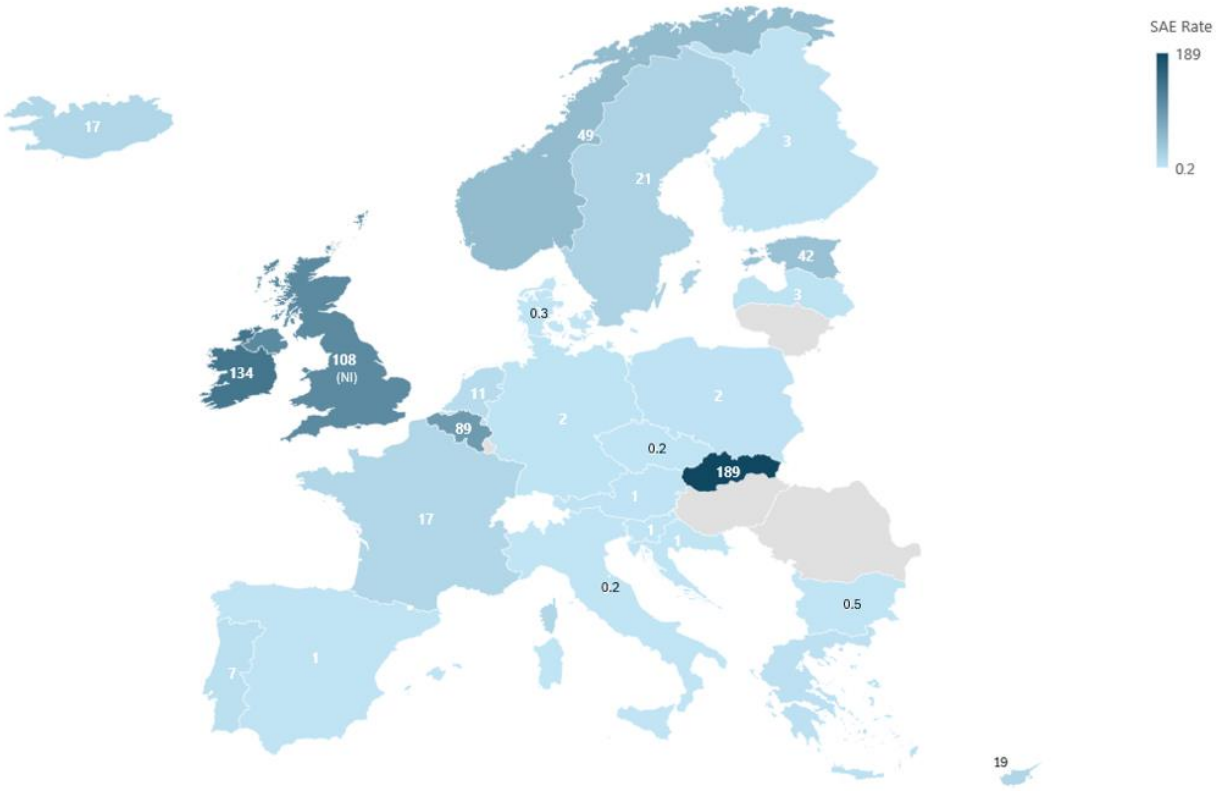


Figure 32. SAE incidence rates per 100,000 units processed in Europe in 2023
Note: countries reporting zero SAE cases (HU, LI, LT, LU and RO) are shown in grey.

As shown in Figure 32, there was a wide range of SAE incidence rates, with the lowest being 0.2 (CZ, IT) and the highest reaching 189 (SK). The median was 4.4 SAE/100,000 units processed, which was 34% lower than the previous year (6.7).

3.3 Country-specific trends (2023 vs. 2022)

Figure 33 compares the SAE incidence rates per reporting country in 2023 with 2022.

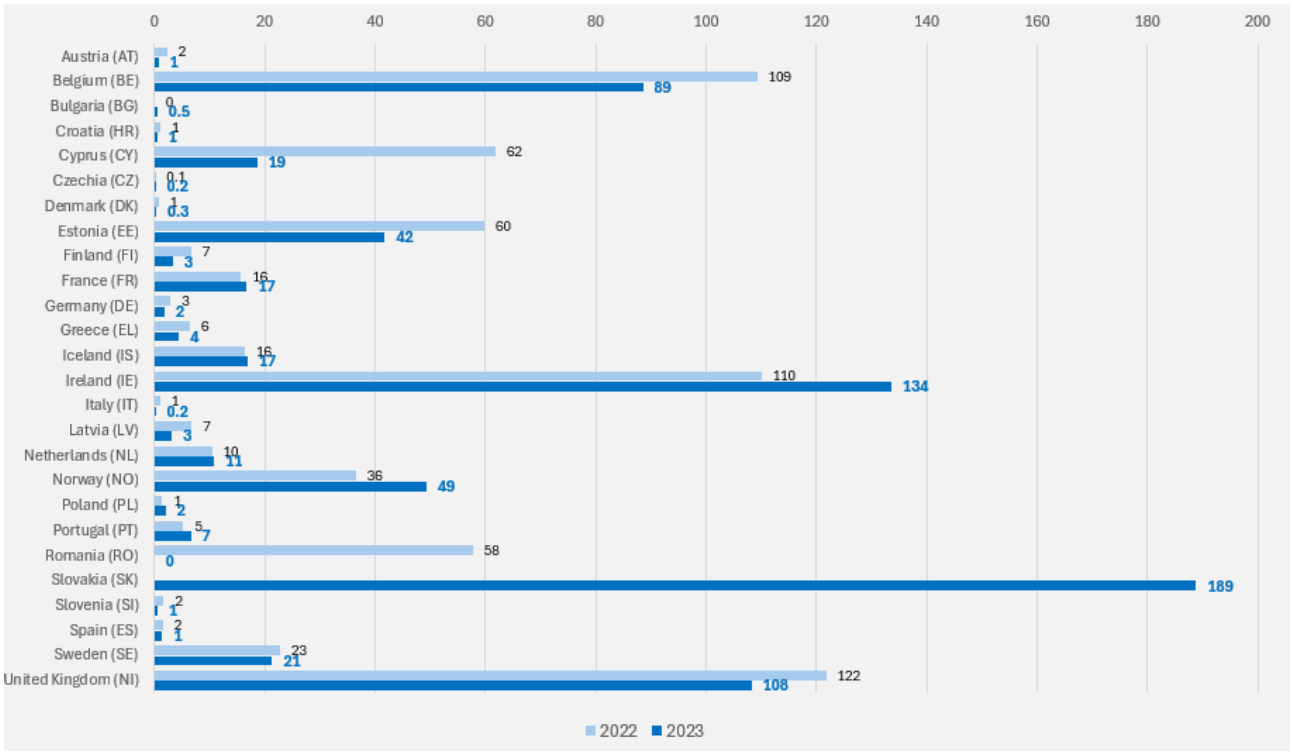


Figure 33. SAE incidence rates per 100,000 units processed per country; 2022 vs. 2023

Note: in 2022, SK also reported SAE but did not provide number of units processed so incidence could not be calculated. No SAE were reported by HU, LI, LT, LU or RO in either year.

3.4 Overview of SAE by activity step

As per the ***Common Approach***, 2024 edition, the activity steps, i.e. where/when in the transfusion chain an SAE could occur or be identified, include donor selection, WB and apheresis collection, testing, processing, storage, distribution, component selection, compatibility testing/cross matching, issue and other. EU legislation[5] on blood applies up to the **issue** of the BC for transfusion, after which the clinical legal sphere applies. Bedside treatment prior to and after transfusion is therefore the exclusive responsibility of MS.

Similar to the previous year, SAE classified as 'other' were the most frequent (37%), followed by those attributed to storage (16%), issue (9%), WB collection and donor selection (both 8%), as shown in Figure 34.

[5] 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.

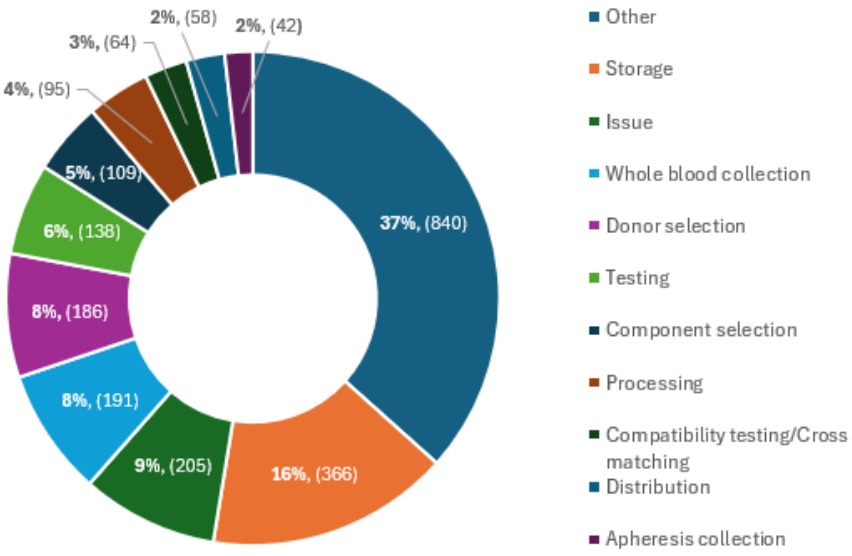


Figure 34. Percentage distribution of SAE by activity step (and absolute numbers) in 2023

Discrepancies between countries in terms of how activity steps are assigned persist; 840 out of 2,294 SAE were reported under the activity step 'other', of which 145 were not activity steps but rather event types/specifications. The distribution by country of SAE classified as 'other' vs the ten defined activity steps in the ***Common Approach*** is presented in Figure 35.

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.

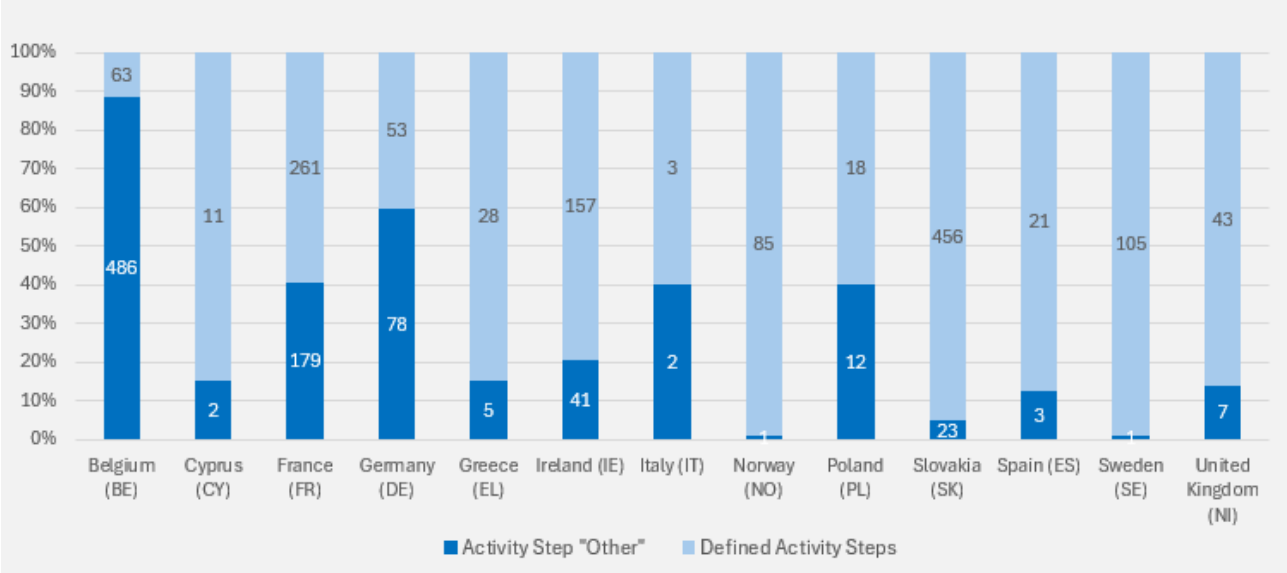


Figure 35. Percentage distribution of SAE classified as 'other' vs the ten defined activity steps in the ***Common Approach*** per country (and absolute numbers) in 2023

3.5 Yearly trends by specification (2017–2023)

According to the ***Common Approach***, 2024 edition, the specifications (i.e. causes) that can be associated with a specific event include component defect, equipment failure, materials, system failure, human error and other. Figure 36 shows the yearly trends in percentage of total SAE by type of specification from 2017 to 2023.

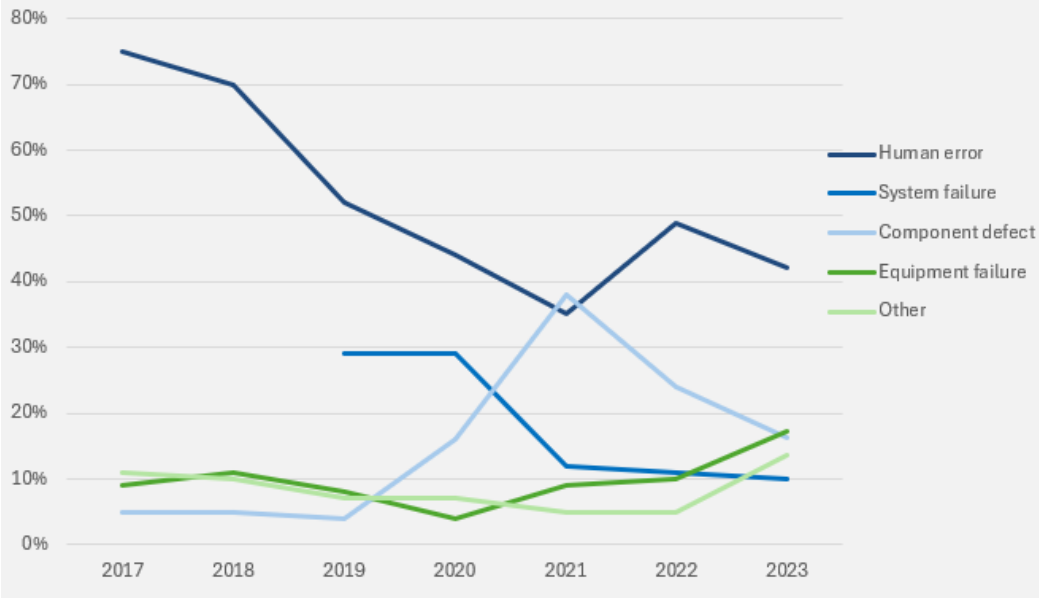


Figure 36. Yearly trends in percentage of total SAE by specification; 2017–2023
Note: the specification 'system failure' was only added in 2019; the specification 'materials' is not shown above (<4%)

Between 2017 and 2023, the causes of SAE have shifted significantly. Human error, which was responsible for over 70% of SAE in 2017, has steadily declined to around 40% in 2023, likely due to improved haemovigilance measures, enhanced training and increased automation. However, it remains the leading cause of SAE, emphasising the need for continued efforts in procedural safety.

Component defects saw a notable increase between 2019 and 2021 before declining, suggesting a temporary issue in product quality or reporting. Similarly, system failures peaked around 2019–2020, but have decreased since 2021, indicating the successful implementation of more reliable transfusion management systems.

In contrast, equipment failure and other causes have gradually increased, reaching their highest levels in 2023. The overall trend highlights a shift from human-related to system and equipment-related issues, reinforcing the need for continuous monitoring, investment in automation and infrastructure improvements.

3.6 Overview of SAE by specification

Similar to 2022, the most commonly reported SAE in 2023 were related to human error (42%), followed by equipment failure (17%), component defect (16%) and other (14%) (Figure 37). The number of SAE classified as human error decreased by 12% while 'other' saw a significant increase (5% in 2022).

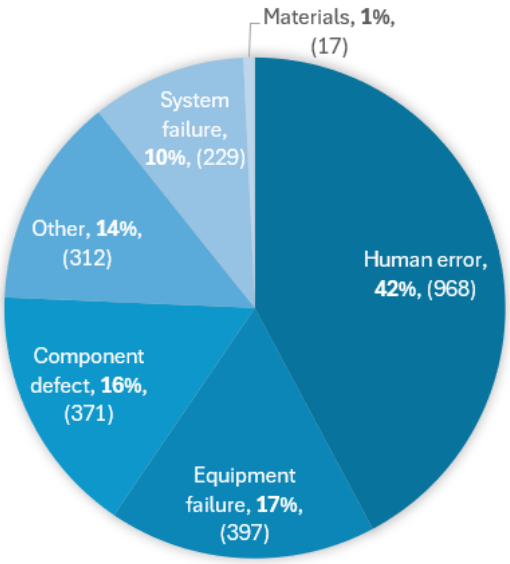


Figure 37. Percentage distribution of SAE by specification (and absolute numbers) in 2023

Regarding events assigned the cause 'human error', the specific type of error/failure was also reported (Figure 38). In 2023, 75% of events reported were related to staff making an incorrect decision or skipping steps in a process (vs 66% in 2022), whereas only 2% were related to staff having knowingly followed the wrong procedure (vs 14% in 2022).

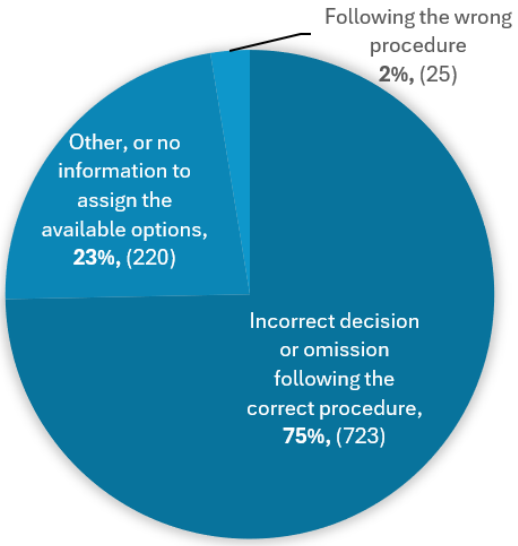


Figure 38. Percentage distribution of SAE classified as human error by type of error (and absolute numbers) in 2023

The distribution of the 968 SAE classified as human error by activity step is presented in Figure 39.

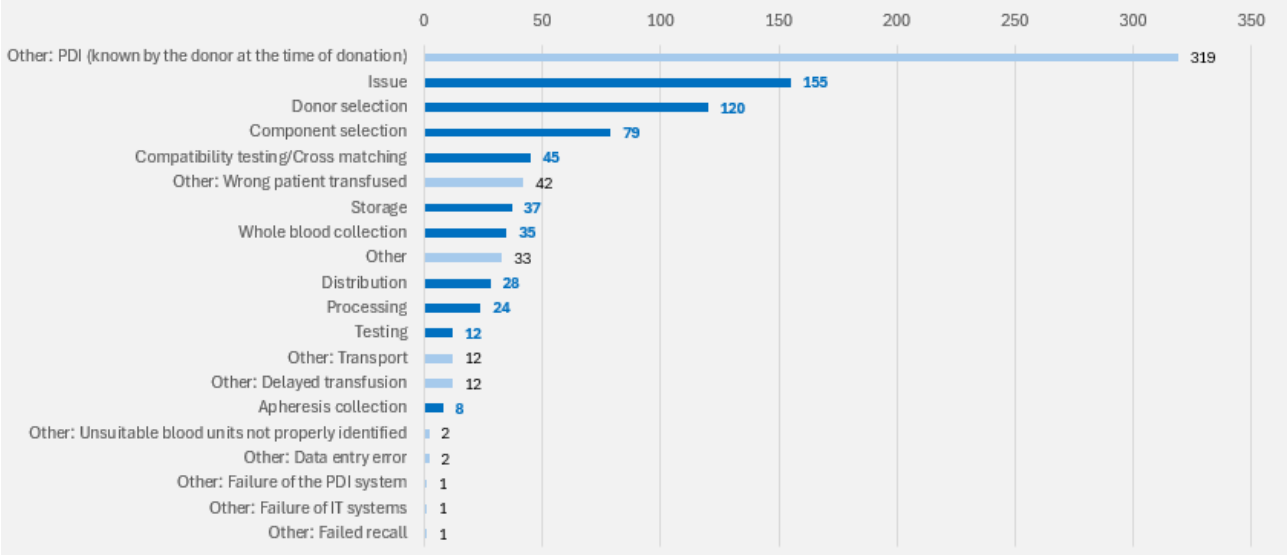


Figure 39. Distribution of SAE classified as human error by activity step in 2023

*Note 1: the steps coloured dark blue are mentioned in the **Common Approach** while those in light blue are "other" activity steps entered as free text.*

Note 2: Several cases captured under 'wrong patient transfused' and 'delayed transfusion' do not meet the criteria for SAE, as they occurred in clinical services. However, it is difficult to determine their number, so they have nonetheless been included.

As shown in Figure 39, the majority of the SAE classified as human error fall into the issue and donor selection categories. For more details, refer to Annex 10. Examples of SAE; specification (cause) human error.

Additional details/comments on the SAE reported were provided for 80% of SAE (1,832 out of 2,294), a significant increase in comparison with the previous year (22%). However, the reported SAE information remains insufficient and often unclear, preventing a detailed analysis. Additionally, the SAE specification was not always properly assigned.

The percentage distribution of SAE by specification for each reporting country is displayed in Figure 40.

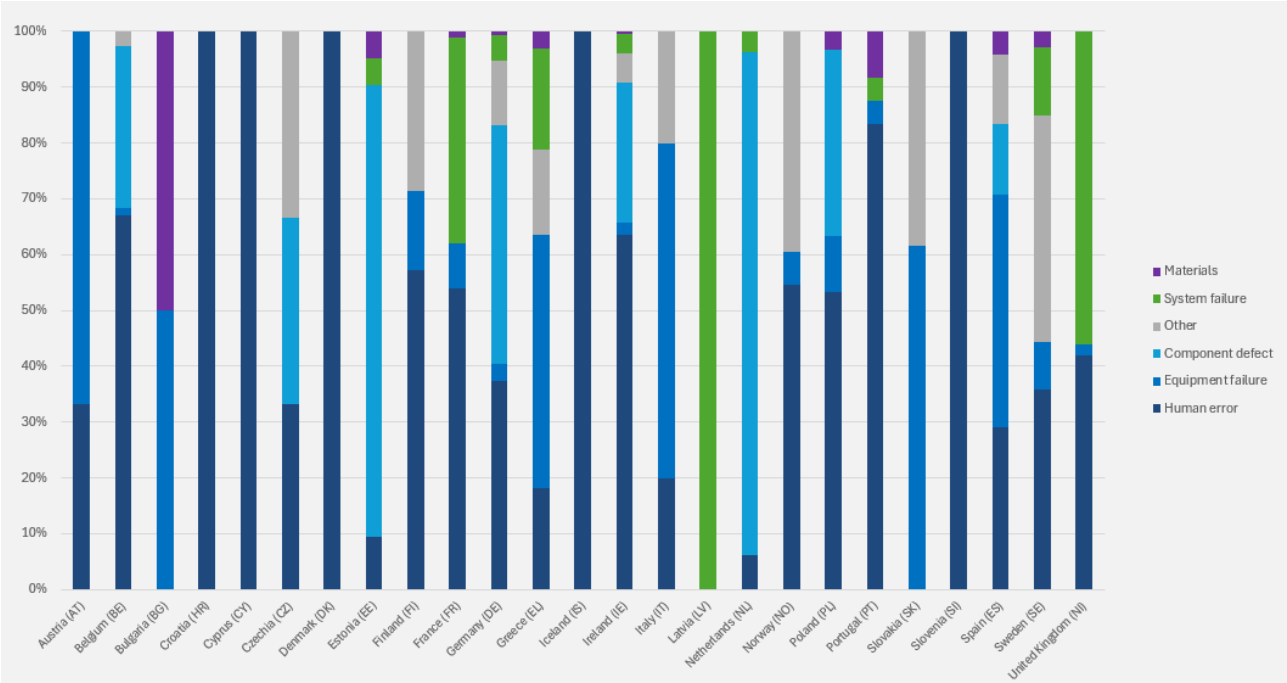


Figure 40. Percentage distribution of SAE by specification per country in 2023

3.7 International benchmarking

I. WHO Global Status Report on Blood Safety and Availability 2021 (data 2018) [1]: Key Points

Global haemovigilance overview:

- Approximately 128 countries had some form of national haemovigilance system.
- Significant variability exists in implementation quality and coverage worldwide.

SAR:

- Globally recognised SAR include TACO and TRALI, with TACO increasingly recognised as the predominant risk following TRALI reduction efforts.
- Reporting rates and recognition of reactions are significantly higher in higher-income countries, indicating under-reporting in resource-limited settings.

	Serious adverse reaction	Total number of components transfused/issued	Incidence
Africa (n=5)	214	1 457 280	14.7
Americas (n=7)	1 045	5 654 075	18.5
South-East Asia (n=3)	1 395	2 722 070	51.2
Europe (n=31)	2 634	27 238 559	9.7
Eastern Mediterranean (n=4)	409	4 070 358	10.0
Western Pacific (n=12)	795	11 892 266	6.7
Total (n=62)	6492	53 034 608	12.2

Table 17. Incidence of SAR (per 100,000 units transfused) by WHO region (Table 31 from [1])

Key global challenges:

- Persistent global under-reporting of serious adverse transfusion reactions.
- Lack of universally applied definitions and standards.
- Resource constraints limiting full implementation and effectiveness of haemovigilance systems, especially in lower-income regions.

Global recommendations:

- Adoption of standardised international definitions (ISBT definitions).
- Stepwise implementation of national haemovigilance systems encouraged by WHO guidelines.
- Promotion of international data sharing platforms, e.g. the International Surveillance of Transfusion-Associated Reactions and Events (ISTARE) database, to enhance global haemovigilance capacity and response.

II. International haemovigilance findings

Region / Country	Reported SARE (recent data)	Key Challenges	Key Recommendations
Canada [2] [3]	2022: 866 ATRs; 62 life-threatening, 12 deaths; TACO (36%) most common severe reaction.	Under-resourced system; fragmented provincial reporting; delayed national reports.	Secure sustained funding; modernise and standardise reporting nationally.
Australia [4]	2021–22: 659 adverse events; 75 serious; TACO (~36%) and severe anaphylaxis (~21%) prominent.	Variability in reporting across states; under-reporting of near-misses and non-severe reactions.	Standardise reporting tools; improve education on reactions; enhance Patient Blood Management.
Asia (India, Malaysia) [5-7]	India: Increasing reports; mainly mild (FNHTR/allergic); serious cases (TACO/TRALI) low (<1%). Malaysia (2022-23): Similar trends; mandatory reporting improving coverage. Overall serious reactions in Asia estimated low (e.g. 1 in 10^4 – 10^5 transfusions).	Partial coverage; fragmented reporting; under-diagnosis of complex reactions; limited IT infrastructure.	Increase participation; mandatory reporting; training; standardised definitions; electronic reporting platforms.
United States [8-12]	NHSN (2014–22): ~63,900 errors, few serious reactions. Fatalities (FDA 2017-21 data): TACO (~32%), TRALI (~21%).	Voluntary, limited participation in national system; inconsistent reporting standards; under-diagnosis (e.g. TACO).	Broaden hospital participation; standardise definitions; implement electronic safeguards; promote Patient Blood Management.
Africa (South Africa & region) [13]	South Africa: 2022 ~261 serious events (IBCT ~31%). Limited data elsewhere, primarily severe cases reported.	Identification errors prevalent; widespread under-reporting; infrastructure challenges.	Training on patient ID; standardised reporting forms; promote near-miss reporting; establish haemovigilance in healthcare frameworks.
New Zealand [14]	2023: 581 ATR; common reactions include: FNHTR, allergic reactions and pulmonary complications (TACO and TRALI) Reports of errors and near misses increased to 101 in 2023. Most common error type: Wrong Blood in Tube (WBIT).	Variability in reporting consistency across hospitals; increase in WBIT errors; under-reporting of mild reactions and near misses.	Improving education and training programmes on managing transfusion reactions; focus areas in 2024: reducing TACO incidents and managing WBIT through national meetings and expert involvement.
UK [15]	2023: 83% (3,184 reports) were attributed to avoidable errors. 1,366 near-miss events (39% of all reports). 38 deaths (15 TACO); increase in IBCT reports.	Increased workload and staffing shortages leading to errors; communication failures; inadequate IT systems.	Enhance training and competency; improve communication protocols; upgrade IT systems; encourage reporting of near misses and adverse events to promote a safety culture.

Table 18. Summary of international haemovigilance findings

Each region shows common themes: TACO and human error-related events (e.g. misidentifications) are key causes of serious transfusion harm, yet strong haemovigilance practices lead to targeted interventions (such as TRALI risk reduction and standardised procedures) that improve safety.

Regions differ in system maturity, e.g. North America, Europe and Australia have advanced systems capturing detailed data, whereas many Asian and African nations are scaling up their programmes. Notably, all regions identify under-reporting and inconsistent reporting as challenges, underscoring the need for training and a safety culture.

The recommendations universally call for better reporting (wider, standardised and more timely) and preventive actions (from clinical education to policy changes) based on haemovigilance findings. International bodies such as WHO and ISBT provide a framework to harmonise these efforts, so that ultimately transfusion safety continues to improve worldwide through shared learning and vigilance.

4 Severe Adverse Reactions in Donors

Key findings

- SAR in apheresis donors increased by 44% in comparison with 2022.
- Total SAR incidence was 16.0/100,000 WB donations and 13.1/100,000 apheresis donations, while the median SAR incidence in both types of donors was much lower (7.8 and 4.5, respectively).
- The most common reactions were vasovagal in both donor types.

According to Directive 2005/61/EC, SAR in donors are not reportable unless they impact the quality and safety of the BC. In the interest of transparency in donor vigilance and to facilitate international comparison, the EC encourages MS to submit these reactions on a voluntary basis.
In general, SAR in donors should be reported if they were likely/probably or certainly caused by the donation (IL 2 or 3). Concerning reports where SAR in donors are confirmed to be fatal, all cases should be reported where a fatality was possibly, probably or certainly related to the donation (i.e. IL 1, 2 or 3).

4.1 Yearly trends (2017–2023)

Figure 41 presents the yearly trends in SAR incidence in **WB donors** from 2017 to 2023 using two complementary metrics: (1) total SAR incidence in donors per 100,000 units of WB collections (2) the median SAR incidence in WB donors across all reporting countries. The first measure provides a region-wide perspective on the overall burden of SAR in the whole chain of blood donor care, while the second trend illustrates the typical SAR incidence in WB donors experienced by individual countries.

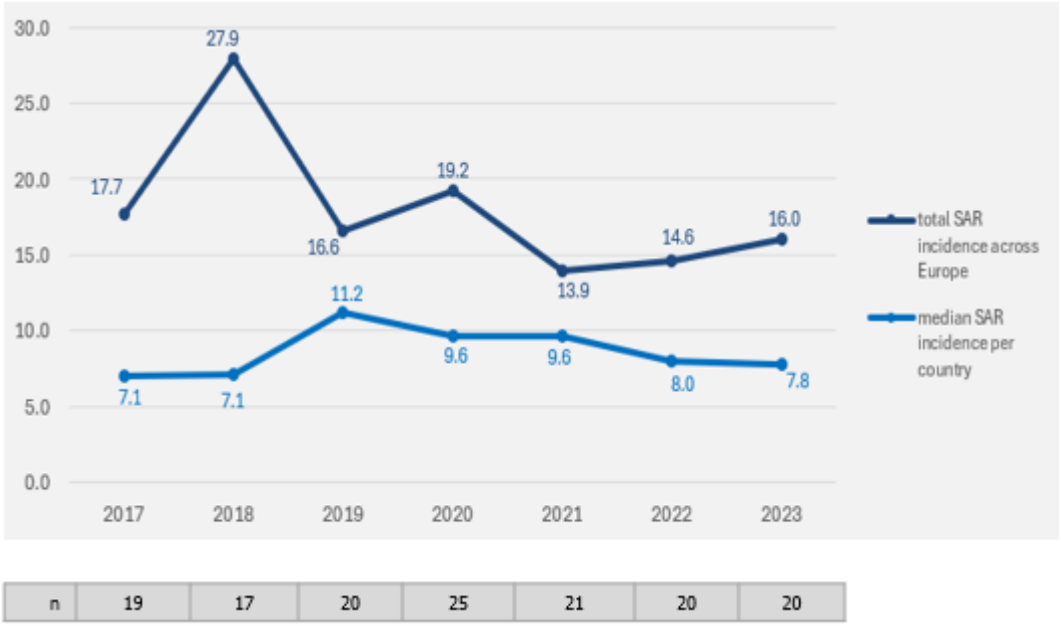


Figure 41. Yearly trends in SAR incidence in WB donors: total SAR incidence/100,000 WB collections and median SAR incidence per country; 2017–2023

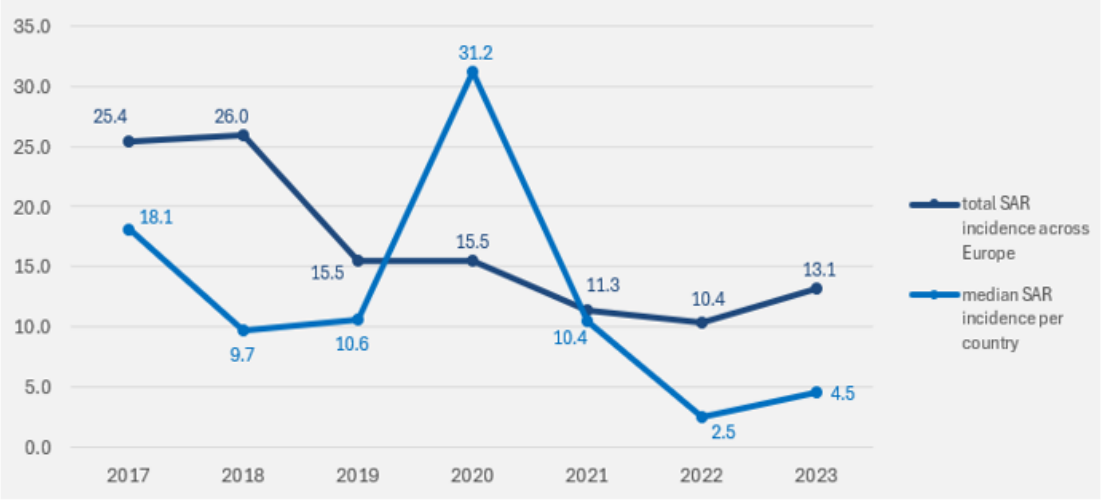
Note: only countries that reported at least one SAR case and the corresponding number of WB collections were included in the median SAR incidence calculations; for total SAR incidence refer to Annex 1.

Between 2017 and 2023, total SAR incidence among WB donors showed a sharp increase in 2018 (27.9 per 100,000 donations) before declining, later followed by a steady increase from 2021

onward. The median SAR incidence per country followed a more stable pattern, peaking at 11.2 in 2018 and then declining to 7.8 in 2023.

The 2018 peak in total SAR incidence suggests a temporary increase in reported donor adverse reactions, likely driven by a few countries rather than a Europe-wide trend. Since 2020, both total and median SAR incidence have remained more stable, aligning with more consistent reporting practices. The increase in reporting countries in 2020 (from 20 to 25) coincides with a decline in total SAR incidence, indicating that newly reporting countries may have had lower SAR rates.

Figure 42 presents the yearly trends in SAR incidence in **apheresis donors** from 2017 to 2023, using two complementary metrics: (1) total SAR incidence in donors per 100,000 units of apheresis collections (2) the median SAR incidence in apheresis donors across all reporting countries. The first measure provides a region-wide perspective on the overall burden of SAR in the whole chain of blood donor care, while the second trend illustrates the typical SAR incidence in apheresis donors experienced by individual countries.



n	13	12	13	15	14	11	12

Figure 42. Yearly trends in SAR incidence in apheresis donors: total SAR incidence/100,000 apheresis collections and median SAR incidence per country; 2017–2023

Note: only countries that reported at least one SAR case and the corresponding number of apheresis collections were included in the median SAR incidence calculations; for total SAR incidence refer to Annex 1.

Between 2017 and 2023, the total SAR incidence among apheresis donors showed a general decline, from 26.0 in 2018 to 13.1 in 2023.

The median SAR incidence per country followed a more dramatic downward trend, declining from 18.1 in 2017 to 9.7 in 2018, and again from 31.2 in 2020 to 2.5 in 2022, before slightly increasing to 4.5 in 2023. This suggests that while total SAR incidence remains relatively stable, the majority of countries report consistently low SAR rates, with a few high-incidence countries influencing the overall trend.

The drop in reporting countries from 14 in 2020 to 11 in 2021–2023 coincides with the decrease in median SAR incidence. This suggests that countries with historically higher SAR incidence may no longer be reporting, potentially influencing observed trends.

4.2 Geographic distribution

Twenty-two countries (AT, BE, BG, HR, CY, CZ, DK, EE, FR, DE, EL, IS, IE, IT, NL, NO, PL, PT, RO, SK, SI and SE) reported on a voluntary basis, a total of 3,534 SAR in donors in 2023. This was a 9% increase in comparison with 2022 (3,245 SAR).

As shown in Figure 43, there was a wide range of SAR incidence rates in WB donors, with the lowest being 1 (AT, HR) and the highest reaching 111 (NO). The median was 7.8 SAR in WB donors/100,000 WB collections, which was similar to the previous year (8.0).

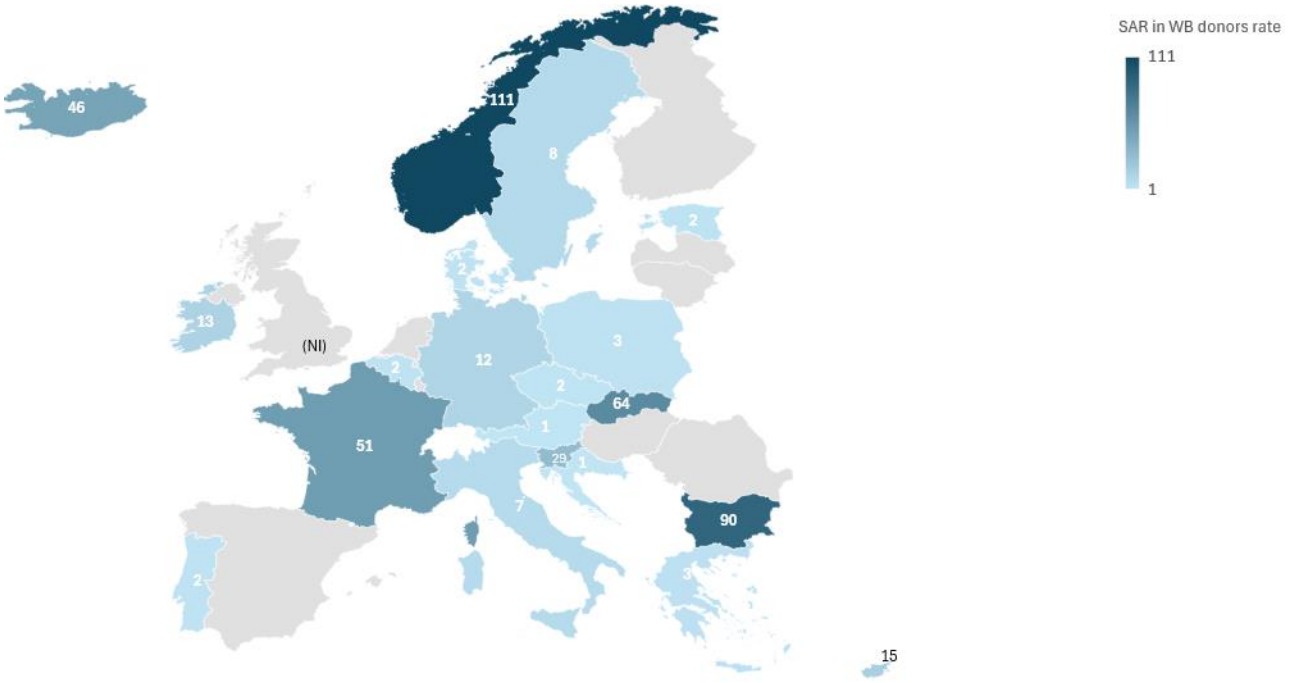


Figure 43. SAR incidence rates in WB donors per 100,000 WB collections in Europe in 2023
Note: incidence is shown only for countries that reported at least one SAR case and the corresponding number of WB collections.

Similarly, there was a wide range of SAR incidence rates in apheresis donors (Figure 44), with the lowest being 0.5 (BE) and the highest reaching 172 (FR). The median was 4.5 SAR in apheresis donors/100,000 apheresis collections, which was slightly higher than in 2022 (2.5).

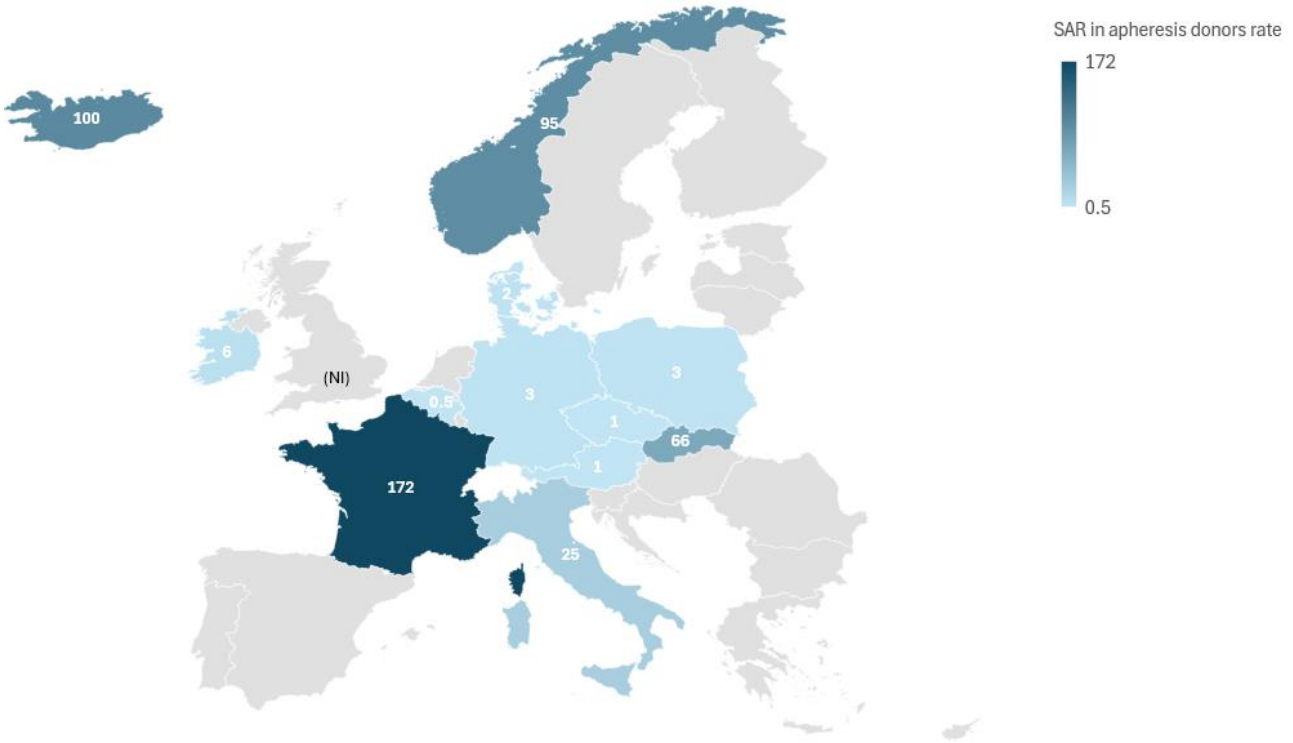


Figure 44. SAR incidence rates in apheresis donors per 100,000 apheresis collections in Europe in 2023
Note: incidence is shown only for countries that reported at least one SAR case and the corresponding number of apheresis collections.

4.3 Overview of SAR in WB donors by type of reaction

4.3.1 Distribution of number of SAR

Twenty-one countries (AT, BE, BG, HR, CY, CZ, DK, EE, FR, DE, EL, IS, IE, IT, NO, PL, PT, RO, SK, SI and SE) reported a total of 2,573 SAR in donors in relation to WB collections (16,068,007). This was a slight increase over the previous year when 2,271 SAR were reported, also by 21 countries.

In line with international trends and previous years, vasovagal circulatory reactions (commonly known as fainting) accounted for the majority of donor reactions (81%), followed by other (9.8%), nerve injury/irritation (8.8%) and major cardiovascular event or death (0.4%) (Figure 45).
There were no fatalities among the 11 cases of major cardiovascular events (CVE) reported by AT, FR, DE and IE.

For more details, refer to Annex 11. Additional information on SAR in donors.

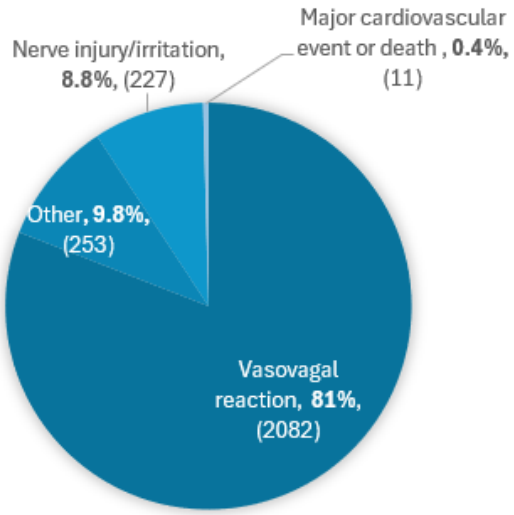


Figure 45. Percentage distribution of SAR in WB donors by type of reaction (and absolute numbers) in 2023
Note: no SAR cases were reported for citrate reactions or allergic reactions.

The percentage distribution of SAR in WB donors by type of reaction for each reporting country is displayed in Figure 46.

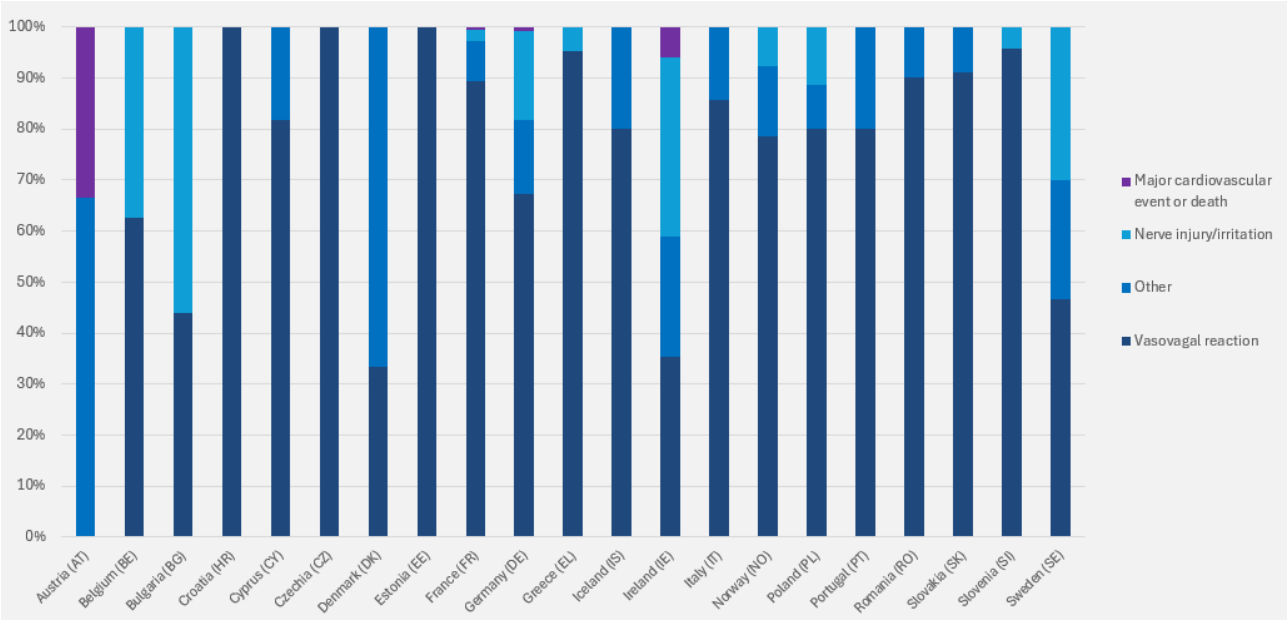


Figure 46. Percentage distribution of SAR in WB donors by type of reaction per country in 2023

4.3.2 Comparative data

The number of donor reactions by type for each reporting country is presented comparatively for 2022 and 2023 in Table 19.

Country	Vasovagal reaction		Absolute Change	Other		Absolute Change	Nerve injury/irritation		Absolute Change	Major CVE up to 24h after donation		Absolute Change
	2022	2023		2022	2023		2022	2023		2022	2023	
Austria (AT)	4	0	-4	0	2	+2				0	1	+1
Belgium (BE)	4	5	+1				4	3	-1			
Bulgaria (BG)	71	68	-3				72	87	+15			
Croatia (HR)	3	1	-2									
Cyprus (CY)	13	9	-4	0	2	+2	1	0	-1			
Czechia (CZ)	0	7	+7									
Denmark (DK)	6	1	-5	1	2	+1	1	0	-1			
Estonia (EE)	30	1	-29									
France (FR)	988	1,022	+34	97	88	-9	33	26	-7	2	6	+4
Germany (DE)	244	295	+51	61	63	+2	18	77	+59	5	3	-2
Greece (EL)	40	20	-20				1	1	0			
Iceland (IS)	6	4	-2	0	1	+1						
Ireland (IE)	2	6	+4	1	4	+3	2	6	+4	0	1	+1
Italy (IT)	163	161	-2	40	27	-13						
Netherlands (NL)	1	*					2	*				
Norway (NO)	144	135	-9	20	24	+4	14	13	-1			
Poland (PL)	30	28	-2	7	3	-4	1	4	+3			
Portugal (PT)	2	4	+2	0	1	+1						
Romania (RO)	88	145	+57	0	16	+16						
Slovakia (SK)	0	133	+133	0	13	+13						
Slovenia (SI)	15	23	+8				3	1	-2			
Spain (ES)							1	0	-1			
Sweden (SE)	18	14	-4	9	7	-2	3	9	+6			
Total	**1,872**	**2,082**	**+210**	**236**	**253**	**+17**	**156**	**227**	**+71**	**7**	**11**	**+4**
n	20	20		8	14		14	10		2	4	

Table 19. SAR in WB donors by country and type of reaction; 2023 vs. 2022

Note: NL did not report SAR by type of collection in 2023 (1 vasovagal reaction and 3 nerve injury/irritation).*

4.4 Overview of SAR in apheresis donors by type of reaction

4.4.1 Distribution of number of SAR

Twelve countries (AT, BE, CZ, DK, FR, DE, IS, IE, IT, NO, PL and SK) reported a total of 957 SAR in donors following apheresis collections (7,286,075). This was a 44% increase in comparison with the previous year when 664 SAR were reported by 11 countries.

The distribution of apheresis donor reactions in 2023 followed a similar pattern to the previous year (Figure 47).

Three countries (AT, FR and DE) reported six cases of major CVE with no fatalities. For more details, refer to Annex 11. Additional information on SAR in donors.

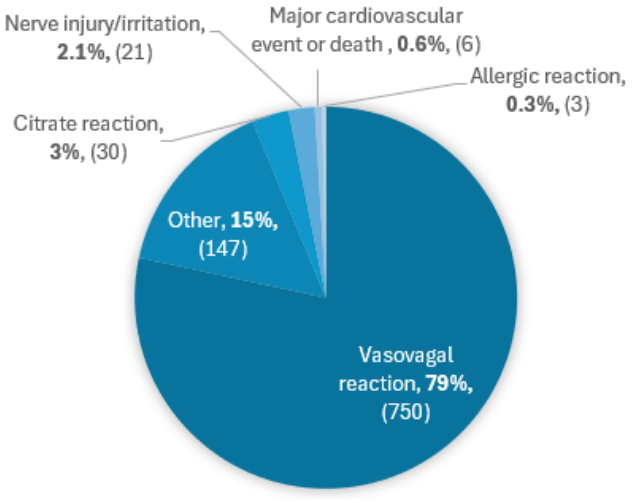


Figure 47. Percentage distribution of SAR in apheresis donors by type of reaction (and absolute numbers) in 2023

The percentage distribution of SAR in apheresis donors by type of reaction for each reporting country is displayed in Figure 48.

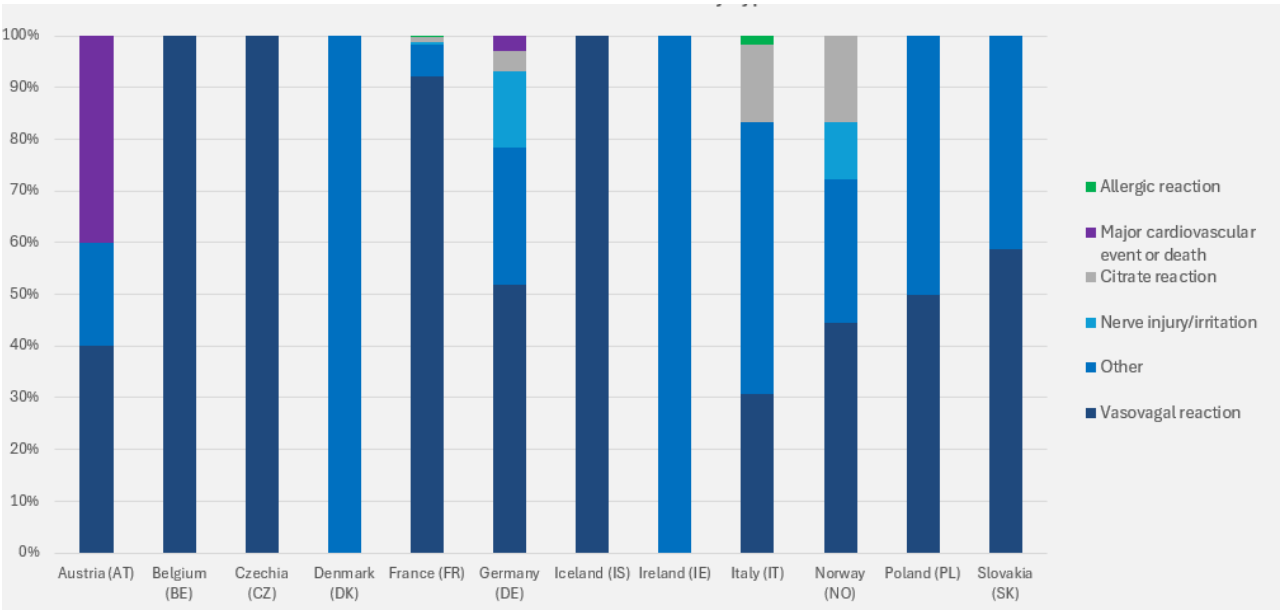


Figure 48. Percentage distribution of SAR in apheresis donors by type of reaction per country in 2023

4.4.2 Comparative data

The number of donor reactions by type for each reporting country is presented comparatively for 2022 and 2023 in Table 20.

Country	Vasovagal reaction		Absolute Change
	2022	2023	
Austria (AT)	4	2	-2
Belgium (BE)	1	1	0
Czechia (CZ)	5	7	+2
Denmark (DK)	1	0	-1
France (FR)	395	631	+236
Germany (DE)	38	53	+15
Greece (EL)	14	0	-14
Iceland (IS)	0	1	+1
Ireland (IE)			
Italy (IT)	35	35	0
Netherlands (NL)	1	*	
Norway (NO)	13	8	-5
Poland (PL)	3	2	-1
Slovakia (SK)	0	10	+10
Total	**510**	**750**	**+240**
n	11	10	

Country	Other		Absolute Change
	2022	2023	
Austria (AT)	1	1	0
Belgium (BE)			
Czechia (CZ)	2	0	-2
Denmark (DK)	0	3	+3
France (FR)	22	41	+19
Germany (DE)	20	27	+7
Greece (EL)			
Iceland (IS)			
Ireland (IE)	0	1	+1
Italy (IT)	57	60	+3
Netherlands (NL)			
Norway (NO)	5	5	0
Poland (PL)	1	2	+1
Slovakia (SK)	0	7	+7
Total	**108**	**147**	**+39**
n	7	9	

Country	Nerve injury/irritation		Absolute Change
	2022	2023	
Austria (AT)			
Belgium (BE)			
Czechia (CZ)			
Denmark (DK)	2	0	-2
France (FR)	4	4	0
Germany (DE)	2	15	+13
Greece (EL)	1	0	-1
Iceland (IS)			
Ireland (IE)			
Italy (IT)	1	0	-1
Netherlands (NL)	2	*	
Norway (NO)	0	2	+2
Poland (PL)			
Slovakia (SK)			
Total	**12**	**21**	**+9**
n	6	3	

Country	Citrate reaction		Absolute Change
	2022	2023	
Austria (AT)			
Belgium (BE)			
Czechia (CZ)	1	0	-1
Denmark (DK)			
France (FR)	7	6	-1
Germany (DE)	2	4	+2
Greece (EL)			
Iceland (IS)			
Ireland (IE)			
Italy (IT)	9	17	+8
Netherlands (NL)			
Norway (NO)	2	3	+1
Poland (PL)			
Slovakia (SK)			
Total	**21**	**30**	**+9**
n	5	4	

Country	Major CVE up to 24h after donation		Absolute Change
	2022	2023	
Austria (AT)	0	2	+2
Belgium (BE)			
Czechia (CZ)			
Denmark (DK)			
France (FR)	4	1	-3
Germany (DE)	3	3	0
Greece (EL)			
Iceland (IS)			
Ireland (IE)			
Italy (IT)			
Netherlands (NL)			
Norway (NO)			
Poland (PL)			
Slovakia (SK)			
Total	**7**	**6**	**-1**
n	2	3	

Country	Allergic reaction		Absolute Change
	2022	2023	
Austria (AT)			
Belgium (BE)			
Czechia (CZ)			
Denmark (DK)			
France (FR)	2	1	-1
Germany (DE)			
Greece (EL)			
Iceland (IS)			
Ireland (IE)			
Italy (IT)	3	2	-1
Netherlands (NL)			
Norway (NO)			
Poland (PL)	1	0	-1
Slovakia (SK)			
Total	**6**	**3**	**-3**
n	3	2	

Table 20. SAR in apheresis donors by country and by type of reaction; 2023 vs. 2022

Note: NL did not report SAR by type of collection in 2023 (1 vasovagal reaction and 3 nerve injury/irritation).*

CONCLUSIONS

This year's report reflects significant improvements in the analysis and presentation of haemovigilance data, enabling more precise tracking of transfusion-related adverse reactions and events. By refining the methodology and introducing more detailed benchmarking, the report provides a clearer, more actionable assessment of transfusion safety trends across Europe.

The Haemovigilance Annual SARE Report 2024 continues to recognise the commitment of MS to this initiative, with 30 European countries submitting their reports, representing a total of 3,244 transfusion establishments.

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

1. Summary of Key Findings

- The data indicate that total SAR (IL 2-3) and SAE incidence has remained stable and declined, respectively, over the last seven years, suggesting ongoing improvements in transfusion safety.
- SAR (IL 2-3) incidence by BC (RBC, platelets, plasma) continues to show variability, highlighting the importance of component-specific haemovigilance measures.
- The most commonly reported reactions in recipients included anaphylaxis/hypersensitivity, FNHTR and TACO, while unclassified SAR ('other') saw a 57% decrease in comparison with the previous year, indicating an improvement in classification accuracy.
- A total of 41 TTIs were reported in 2023 (nine more than in 2022). The exact infectious pathogen was provided in nine out of 30 TTBI cases reported compared to none in 2022.
- Human error remains the leading cause of SAE, but its decrease over time suggests improvements in training and automation. Most human errors occurred during issue and donor selection, often due to failures in patient identification and non-compliance with SOPs. On the other hand, the rising trend of equipment-related failures suggests that transfusion facilities may require enhanced maintenance and investment in new technologies.
- Overall, European haemovigilance data are consistent with known effects observed worldwide.
- WB donors continue to show higher SAR rates than apheresis donors; the most frequently reported were vasovagal reactions.

2. Challenges and Areas for Improvement

- Inconsistencies in reporting in different countries make year-on-year comparisons complex and require standardisation efforts.
- Some countries continue to report high SAE incidence rates than others. While this may reflect differences in donor selection or processing practices, it may also indicate more comprehensive haemovigilance systems and greater reporting completeness, highlighting variability in national surveillance capacities.
- The low quality of data regarding the cause of events remains a concern. This is due to the incomplete and unclear information provided by MS as well as the lack of more granular classification of events in subcategories.

3. Future Recommendations

- Encourage greater alignment in reporting criteria and methodology across countries to ensure more accurate comparisons.
- Support full reporting compliance across all MS to minimise data gaps and inconsistencies.
- Reinforce the importance and value of providing descriptive data to improve quality of TTI investigations (e.g. moment of symptom onset, exact pathogen responsible for infection, treatment, at home or in hospital and patient outcome).
- Maintain focus on human error reduction through continuous efforts in training, procedural verification and digital tracking systems.
- As fatalities remain rare but highly significant, continuous surveillance and thorough investigation are essential to further minimise transfusion-related risks. A meaningful analysis requires a description of the reaction in context (from detection until a final resolution), clear course of action, impact on the patient, results of investigation, CAPA and lessons learned.
- While blood donation is generally safe, implementing better post-donation support, i.e. encouraging all donors to report any discomfort or arm symptoms they experience during or after donation as well as stressing the need for continuous training for phlebotomists will improve donor experience and reduce vasovagal reactions.

The Haemovigilance Annual SARE Report 2024 underscores the critical role of a robust haemovigilance system in ensuring the safety and effectiveness of blood transfusions across Europe. The insights presented in this report enable countries to assess their own transfusion safety measures in comparison with others. Through ongoing vigilance, enhanced protocols and a continued commitment to haemovigilance, the EU healthcare system can further strengthen outcomes for both donors and patients.

List of Abbreviations

Ab	Antibodies
Ag	Antigens
ATR	Acute Transfusion Reaction
BC	Blood Component
CAPA	Corrective and Preventive Action
CVE	Cardiovascular Event
EC	European Commission
EDQM	European Directorate for the Quality of Medicines & HealthCare
EU	European Union
DHTR	Delayed Haemolytic Transfusion Reaction
FDA	Food and Drug Administration
FNHTR	Febrile Non-Haemolytic Transfusion Reaction
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HEV	Hepatitis E Virus
IBCT	Incorrect Blood Component Transfused
ISBT	International Society of Blood Transfusion
IL	Imputability Level
MTOC	More Than One Blood Component
MS	Member States
NBA	National Blood Authority
NCA	National Competent Authorities
NHSN	National Healthcare Safety Network
PDI	Post-Donation Information
PMP	Per Million Population
PTP	Post-Transfusion Purpura
RBC	Red Blood Cells
RE	Reporting Establishments
SAE	Serious Adverse Events
SAR	Serious Adverse Reactions
SARE	Serious Adverse Reactions and Events
SOP	Standard Operating Procedure
SHOT	Serious Hazards of Transfusion – UK haemovigilance programme
TACO	Transfusion-Associated Circulatory Overload
TAD	Transfusion-Associated Dyspnoea
TRALI	Transfusion-Related Acute Lung Injury
TTBI	Transfusion-Transmitted Bacterial Infection
TTI	Transfusion-Transmitted Infection
TTISS	Transfusion Transmitted Injuries Surveillance System – Canada haemovigilance programme
TTPI	Transfusion-Transmitted Parasitical Infection
TTVI	Transfusion-Transmitted Viral Infection
VES	Vigilance Expert Subgroup
WB	Whole Blood
WBIT	Wrong Blood in Tube
WHO	Word Health Organization

AT	Austria
BE	Belgium
BG	Bulgaria
HR	Croatia
CY	Cyprus
CZ	Czechia
DK	Denmark
EE	Estonia
FI	Finland
FR	France
DE	Germany
EL	Greece
HU	Hungary
IS	Iceland
IE	Ireland
IT	Italy
LV	Latvia
LI	Liechtenstein
LT	Lithuania
LU	Luxembourg
NL	Netherlands
NO	Norway
PL	Poland
PT	Portugal
RO	Romania
SK	Slovakia
SI	Slovenia
ES	Spain
SE	Sweden
UK	United Kingdom
UK(NI)	Northern Ireland

List of Figures

List of Tables

List of Annexes

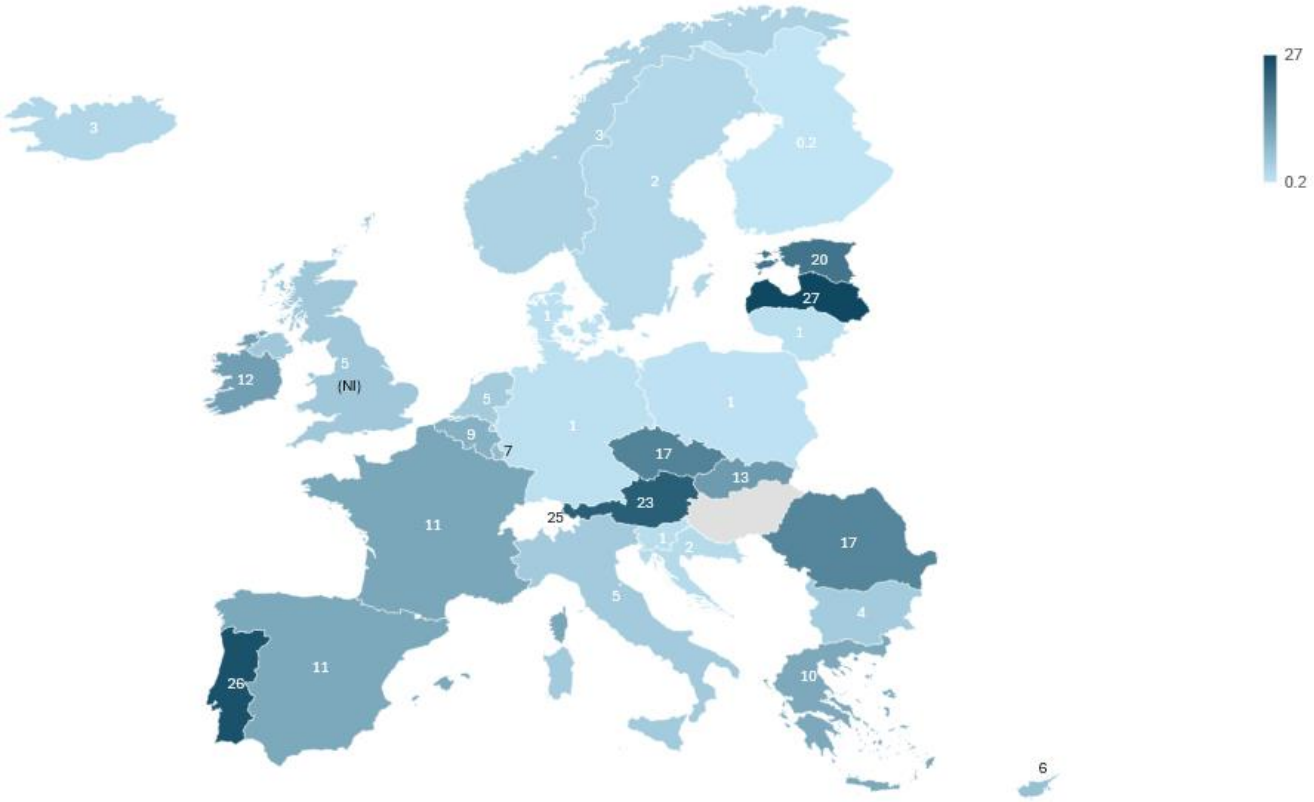
Annex 1. Executive summary (2017–2023)

Parameter	2018 (Data 2017)		2019 (Data 2018)		2020 (Data 2019)		2021 (Data 2020)		2022 (Data 2021)		2023 (Data 2022)		2024 (Data 2023)	
	n	Number	n	Number	n	Number	n	Number	n	Number	n	Number	n	Number
Reporting Establishments	28	4,028	28	3,834	27	4,009	30	3,617	30	3,307	30	3,346	29	**3,244**
Blood/BC Units Issued	29	25,093,906	28	22,922,191	27	22,863,135	29	22,104,136	30	20,633,199	30	21,394,422	30	**20,824,019**
Blood/BC Units Transfused	24	20,674,603	23	19,310,224	22	19,334,629	24	18,919,004	26	17,808,869	24	17,197,676	23	**16,213,234**
Recipients Transfused*	19	3,522,623	19	3,262,767	17	3,228,635	19	3,167,732	20	2,912,307	22	3,094,799	20	**2,850,968**
SAR (IL 1-3)	28	3,114	27	2,538	27	2,625	28	2,967	27	2,814	28	3,216	28	**3,170**
Total SAR (IL 1-3) **incidence** (per 10^5 units transfused)		15.1		13.1		13.6		15.7		15.8		18.7		**19.6**
SAR (IL 2-3)	26	1,871	24	1,687	26	1,674	26	1,756	24	1,379	27	1,516	25	**1,490**
Total SAR (IL 2-3) **incidence** (per 10^5 units transfused)		9.0		8.7		8.7		9.3		7.7		8.8		**9.2**
Fatalities (IL 2-3)	8	28	7	20	10	26	9	24	11	25	9	27	9	**21**
Blood/BC Units Processed	28	27,244,855	24	19,978,403	25	22,525,782	28	24,129,477	28	22,961,648	27	22,943,682	26	**23,700,556**
WB Collections	27	17,866,384	24	17,174,443	25	17,407,743	26	16,510,040	27	16,242,768	26	15,576,875	26	**16,068,007**
Apheresis Collections	27	5,772,463	24	5,387,919	25	5,789,033	26	5,502,403	27	6,035,995	26	6,376,960	25	**7,286,075**
SAE	20	2,920	23	2,770	22	2,604	24	3,018	24	2,734	25	2,235	25	**2,294**
Total SAE **incidence** (per 10^5 units processed)		10.7		13.9		11.6		12.5		11.9		9.7		**9.7**
SAR in WB Donors	21	3,166	21	4,795	22	2,882	26	3,174	21	2,262	21	2,271	21	**2,573**
Total SAR **incidence** in WB donors (per 10^5 collections)		17.7		27.9		16.6		19.2		13.9		14.6		**16.0**
SAR in Apheresis Donors	15	1,469	16	1,399	15	900	15	851	15	684	11	664	12	**957**
Total SAR **incidence** in apheresis donors (per 10^5 collections)		25.4		26.0		15.5		15.5		11.3		10.4		**13.1**

Methodological details: *the total SAR incidence in recipients (or in donors) was calculated by dividing the number of reported SAR by the number of blood/BC units transfused (or by the number of collections) and then expressing the result per 100, 000 units transfused (or per 100,000 collections). It is important to note that fewer countries reported data on units transfused (or number of collections) than those reporting SAR cases in recipients (or in donors). Although this difference may affect the absolute incidence values, the consistency of the reporting gap over time allows for reliable analysis of overall trends. The total SAE incidence was calculated by dividing the number of SAE by the number of blood/BC units processed, with the result expressed per 100,000 units processed. It is important to note that in this case, a slightly larger number of countries provided data on the number of units processed compared to those reporting SAE cases. Although this results in a broader denominator, the trend analysis remains robust as the reporting pattern is consistent over time. This disclosure allows for a better understanding of the potential limitations or biases in the incidence calculation.*

Note: **recipients transfused was obtained with the sum of number of recipients for each type of BC (i.e. WB, RBC, platelets and plasma) from countries which reported per type of BC plus the number of recipients from countries which only reported the overall number (i.e. regardless of type of BC).*

Annex 2. Reporting establishments per capita (pmp)



Note: HU reported data not available.

Annex 3. Data Supplement - Rate of whole blood and apheresis collections per 1,000 population in the last seven years
(Refer to Figure 1, Figure 2, Figure 8 and Figure 9)

Data Year	2017		2018		2019		2020		2021		2022		2023	
Country	Rate WB	Rate Apheresis	Rate WB	Rate Apheresis	Rate WB	Rate Apheresis	Rate WB	Rate Apheresis	Rate WB	Rate Apheresis	Rate WB	Rate Apheresis	Rate WB	Rate Apheresis
Austria (AT)	40	60	40	56	39	72	47	40	33	47	45	56	37	69
Belgium (BE)	39	15					37	19	37	18	36	17	34	18
Bulgaria (BG)	24	0	25	0	25	0	23	1	24	1	25	0	27	0
Croatia (HR)	48	1	47	1	48	2	44	1	48	1	48	1	49	1
Cyprus (CY)	66	0	73	0	73	0	71	0	75	0	76	0	76	0
Czechia (CZ)	41	69	40	71	40	74	40	83	43	101	43	115	41	128
Denmark (DK)	10	25					34	16	33	17	33	20	31	22
Estonia (EE)	39	3	38	3	38	3	37	2	36	2	36	2	34	2
Finland (FI)	37	0	37	0	36	0	34	0	33	0	33	0	32	0
France (FR)	37	6	36	7	36	6	35	6	35	5	34	5	33	6
Germany (DE)	48	33	47	32	45	34	44	33	45	34	43	35	45	40
Greece (EL)		2		1		2		1				2	64	3
Hungary (HU)					39	2								
Iceland (IS)							27	2	28	2	30	2	27	3
Ireland (IE)	27	2	26	2	27	2	25	2	25	2	26	2	25	3
Italy (IT)	43	7	43	7	43	7	41	8	43	8	43	7	43	8
Latvia (LV)	25	1	27	2	28	3	27	3	30	1	31	1	32	2
Liechtenstein (LI)														
Lithuania (LT)	33	2	34	2	36	2	32	2	34	2	36	2	38	2
Luxembourg (LU)	36	5	37	3			29	6	62	7	28	5		
Malta (MT)	35	1			35	1			31	1				
Netherlands (NL)	24	17	25	18	24	19			24	20	23	20	21	21
Norway (NO)	34	3	33	3	32	3	31	3	31	3	31	3	28	3
Poland (PL)	32	2	32	2	32	2	29	3	34	3	34	3	37	4
Portugal (PT)	31	1	30	1	28	0	27	1	29	1	29	1	28	1
Romania (RO)	21	0	21	0	22	0	16	0	39	1	21	0		
Slovakia (SK)	40	1	39	1	41	1	35	1	35	1			42	5
Slovenia (SI)	42	2	40	2	39	2	36	1	39	2	39	1	39	2
Spain (ES)	35	2	34	2	34	2	33	2	34	2	34	2	32	2
Sweden (SE)	41		40	0	39	0	36	0	37	0	36		35	
United Kingdom (	27	2	26	1	25	1	23	2	21	2	21	2	22	2
Median	**36.1**	**2.1**	**36.7**	**2.0**	**36.1**	**2.0**	**34.0**	**2.0**	**34.3**	**2.1**	**34.2**	**2.0**	**34.4**	**2.6**

Note: following Brexit, UK = Northern Ireland only

Annex 4. Data Supplement - Rate of units issued, transfused and processed per 1,000 population in the last seven years

(Refer to Figure 3, Figure 10 and Figure 11)

Data Year	2017			2018			2019			2020			2021			2022			2023		
Country	Rate units issued	Rate units transfused	Rate units processed	Rate units issued	Rate units transfused	Rate units processed	Rate units issued	Rate units transfused	Rate units processed	Rate units issued	Rate units transfused	Rate units processed	Rate units issued	Rate units transfused	Rate units processed	Rate units issued	Rate units transfused	Rate units processed	Rate units issued	Rate units transfused	Rate units processed
Austria (AT)	47	41	53	44	43	46	42	37	45	43	37	44	36	35	46	41	40	45	35	34	43
Belgium (BE)	47	47	54							45	44	56	45	44	55	43	43	53	41	41	52
Bulgaria (BG)	47	42	24	44	39	25	45	40	25	42	35	53	37	30	43	43	32	57	47	42	63
Croatia (HR)	65	56	49	68	57	48	66	60	49	60	58	44	66	63	49	65	63	49	67	64	50
Cyprus (CY)	125	82	65	93	20	71	90	88	71	92	88	70	98	94	74	99	96	75	103	100	75
Czechia (CZ)	54	54	110	54	53	111	53	52	115	52	51	123	54	54	144	53	53	158	52	52	169
Denmark (DK)	89	102	30	48	48		45	45		45	44	116	44	44	113	44	44	116	41	41	110
Estonia (EE)	65	52	42	52	50	41	51	50	40	49	48	39	48	47	39	45	45	38	42	41	37
Finland (FI)	40		43	41		43	40		42	38		40	38		39	37		38	35		37
France (FR)	47	44	103	45	43	43	45	42	43	44	42	41	44	42	44	43	41	39	41	39	38
Germany (DE)	67	58	69	56	56	61	55	55	79	53	53	77	60	60	78	59	52	78	57	49	85
Greece (EL)	66	63	69	60	43	67	61	56	75	50	46	85				56	42	59	49	47	71
Hungary (HU)	64			65			62		99	55			55	22		56			60		
Iceland (IS)										37	31	29	39	36	31	43	38	32	40	34	30
Ireland (IE)	30	30	32	29	29	32	29	29	26	27	27	24	29	28	25	29	29	28	27	27	28
Italy (IT)	51	49	50	51	49	50	51	49	50	49	47	49	50	49	51	53	48	51	51	48	51
Latvia (LV)	35	35	40	48	48	29	48	47	31	44	44	30	49	48	31	52		32	53		34
Liechtenstein (LI)													6	6		5	5		4	4	
Lithuania (LT)	51		35	53		36	53		38	48		34	45		36	51		38	51		40
Luxembourg (LU)	48	47	41	45	41	40				37	36	35	38	37	70	36	33	33	33	32	
Malta (MT)	62	44	36	60	43		57	41	36				45	35	31						
Netherlands (NL)	27	25	41	27	25	43	27	26	42	26	23	47	26	25	43	25	25	43	24	24	42
Norway (NO)	39	39	37	42	42	36	41	41	35	31	31	34	39	39	34	39	39	34	39	39	31
Poland (PL)	42		34	42		34	42		34	37		32	42		38	43		37	46		41
Portugal (PT)	38	35	32	37	33	31	36	34	29	34	32	28	36	34	30	36	34	37	34	32	34
Romania (RO)	35	34	21	37	35	21	38	35	22	31	30	17	35	34	40	40	37	22	40	23	
Slovakia (SK)	53	53	41	48	48	40	54	54	42	60	60	36	62	62	36	68	68		44		47
Slovenia (SI)	56		89	52		88	50		86	46		78	48		82	49		84	48		84
Spain (ES)	40	40	36	40	40		39	39		38	38	34	40	40	36	39	39	36	37	37	35
Sweden (SE)	57	48	59	55	48	56	55	46	55	49	42	48	52	43	49	52	42	47	51	42	47
United Kingdom (I	36	31	28	34	30	27	34	31	26	31	28	25	26	24	23	25	23	23	28	26	24
Median	**47.8**	**45.2**	**40.9**	**47.8**	**42.9**	**41.8**	**47.7**	**43.9**	**42.3**	**44.1**	**41.6**	**40.6**	**44.0**	**39.6**	**41.4**	**43.2**	**40.0**	**39.3**	**41.6**	**38.6**	**42.9**

Note: following Brexit, UK = Northern Ireland only

Annex 5. Data Supplement - Rate of recipients transfused regardless of type of BC per 1,000 population in the last seven years
(Refer to Figure 7)

Data Year / Country	2017	2018	2019	2020	2021	2022	2023
Austria (AT)							
Belgium (BE)	11			11	12	11	11
Bulgaria (BG)	14	16	14	16	10	10	12
Croatia (HR)	16	15	20	15	17	18	15
Cyprus (CY)	70	83	31	37	20	25	28
Czechia (CZ)	16	15	15	14	15	14	14
Denmark (DK)					7	7	7
Estonia (EE)	11	11	12	11		12	11
Finland (FI)							
France (FR)	8	8	8	8	8	8	8
Germany (DE)							
Greece (EL)						12	15
Hungary (HU)							
Iceland (IS)				7	7	6	6
Ireland (IE)	4	5					
Italy (IT)	11	12	12	10	11	11	11
Latvia (LV)							
Liechtenstein (LI)				1			2
Lithuania (LT)	51	16					
Luxembourg (LU)	8	8		8	8	9	8
Malta (MT)	11	10	10		9		
Netherlands (NL)							
Norway (NO)							
Poland (PL)							
Portugal (PT)	11	10	10	10	10	11	10
Romania (RO)	9	9	9	7	8	9	
Slovakia (SK)						6	
Slovenia (SI)							
Spain (ES)	10	10	10	10	10	10	10
Sweden (SE)	10	11	11	10	10	10	10
United Kingdom (	7	7	7	6	1	2	2
Median	**10.6**	**10.4**	**10.5**	**9.8**	**10.3**	**10.4**	**10.2**

Note: following Brexit, UK = Northern Ireland only

Annex 6.1. Data Supplement - Rate of units transfused pmp by type of BC in the last seven years

(Refer to Figure 4, Figure 5 and Figure 6)

Data Year	2017				2018				2019				2020			
Country	Rate RBC transfused	Rate Platelets transfused	Rate Plasma transfused	Rate WB transfused	Rate RBC transfused	Rate Platelets transfused	Rate Plasma transfused	Rate WB transfused	Rate RBC transfused	Rate Platelets transfused	Rate Plasma transfused	Rate WB transfused	Rate RBC transfused	Rate Platelets transfused	Rate Plasma transfused	Rate WB transfused
Austria (AT)	36,469	4,501			37,886	4,496	548	9.1	35,820		702	0.2	36,122	4,245	716	0.0
Belgium (BE)	35,859	5,942	4,744										34,410	5,604	3,864	0.0
Bulgaria (BG)	24,425	4,403	13,001	46.4	21,980	3,924	12,746	14.9	22,369	4,748	12,424	14.3	20,298	3,934	10,900	10.2
Croatia (HR)	40,454	4,131	11,291		40,495	4,601	11,686	0.0	40,887	7,381	12,045	0.0	40,805	6,757	10,124	0.0
Cyprus (CY)	64,613	4,918	12,498			6,026	13,890	6.9	68,878	5,378	13,425	10.3	68,966	5,836	13,679	3.4
Czechia (CZ)	37,375	3,847	12,427	173.6	37,455	4,247	11,526	134.7	38,279	4,226	9,798	117.8	37,562	4,287	9,476	100.8
Denmark (DK)	33,874	22,045	7,594	38,321.2	33,739	6,586	7,244		32,947	6,233	6,289	0.0	32,286	5,837	6,287	0.0
Estonia (EE)	36,204	5,578	10,418	12.9	36,148	4,886	8,794		35,075	5,416	9,256		33,960	4,982	9,227	4.5
Finland (FI)												0.0				
France (FR)	34,805	4,510	4,561		34,488	4,750	4,258		33,827	4,748	3,773		33,396	4,836	3,360	
Germany (DE)	42,543	6,048	9,363		41,190	6,103	8,244		40,251	5,810	8,857		39,631	5,697	7,580	0.0
Greece (EL)	37,381	11,627	14,231		32,709	10,177		1.1	33,403	9,844	12,631	1.1	27,513	8,436	9,773	
Hungary (HU)																
Iceland (IS)													23,953	4,331	2,977	
Ireland (IE)	25,319	4,218	0		24,948	4,004	0	0.0	24,578	4,234	0	0.0	22,537	4,131	0	0.0
Italy (IT)	40,909	3,645	4,735	0.7	40,782	3,891	4,477	0.3	40,944	3,912	4,242	0.4	39,638	3,882	3,804	0.5
Latvia (LV)	24,038	3,832	6,765		25,421	4,423	17,929	0.0	25,610	4,226	16,729	0.0	25,195	3,812	14,884	0.0
Liechtenstein (LI)																
Lithuania (LT)																
Luxembourg (LU)	34,627	5,516	6,574		31,093	4,816	5,168	0.0					27,474	4,889	4,057	0.0
Malta (MT)	33,750	4,687	5,449		32,224	4,193	6,634	0.0	32,953	3,672	4,700					
Netherlands (NL)	21,758	2,744	67		22,283	3,137	73	0.0	22,713	3,027	73	0.0	20,558	2,338	54	
Norway (NO)	28,570	4,178	6,486	9.3	30,010	4,335	7,512	59.5	28,936	4,268	7,544	75.8	27,136	4,236	0	103.4
Poland (PL)																
Portugal (PT)	29,033	4,759	862	2.3	28,058	4,595	836	2.9	28,441	4,718	607	2.1	26,294	4,456	1,232	2.4
Romania (RO)	18,620	4,490	10,669	460.3	19,151	5,083	10,831	271.1	19,259	5,208	10,827	174.9	15,967	4,479	9,029	86.8
Slovakia (SK)	35,694	4,032	12,947	87.8	33,348	4,020	10,639	14.3	38,371	4,440	11,176	24.8	36,214	4,329	19,317	1.8
Slovenia (SI)																
Spain (ES)	32,077	4,786	3,583		31,671	4,854	3,434	0.7	31,414	4,523	3,243	0.4	30,370	4,564	2,978	0.4
Sweden (SE)	39,011	4,546	4,906		38,688	4,716	4,099	0.0	37,603	4,860	3,936	0.0	34,001	4,062	3,578	2.7
United Kingdom (I	24,054	4,173	3,013	0.9	23,449	4,037	2,956	0.9	23,557	4,104	2,906	4.7	21,276	3,685	2,573	4.9
Median	**34,716**	**4,505**	**6,574**	**12.9**	**32,467**	**4,595**	**6,939**	**8.0**	**33,178**	**4,718**	**6,916**	**7.5**	**31,328**	**4,394**	**3,961**	**3.9**

Note: outlier highlighted in red. Also, following Brexit, UK = Northern Ireland only

Annex 6.2. Data Supplement - Rate of units transfused pmp by type of BC in the last seven years

(Refer to Figure 4, Figure 5, Figure 6, Figure 14, Figure 15, Figure 16 and Figure 17)

Data Year	2021				2022				2023			
Country	Rate RBC transfused	Rate Platelets transfused	Rate Plasma transfused	Rate WB transfused	Rate RBC transfused	Rate Platelets transfused	Rate Plasma transfused	Rate WB transfused	Rate RBC transfused	Rate Platelets transfused	Rate Plasma transfused	Rate WB transfused
Austria (AT)	30,923	3,841	346	0.0	34,933	4,383	216	0.0	29,961	3,901	227	0.0
Belgium (BE)	34,949	5,668	3,739		33,517	5,389	4,263		31,883	5,447	3,200	
Bulgaria (BG)	15,762	3,787	10,638	3.1	16,718	3,976	10,910	1.0	23,275	5,299	13,294	2.0
Croatia (HR)	45,050	7,278	10,662	0.0	45,207	7,405	10,266	0.0	45,907	7,861	10,075	0.0
Cyprus (CY)	72,168	6,615	15,022	0.0	74,556	6,866	14,745	1.1	75,193	7,754	17,315	0.0
Czechia (CZ)	40,109	4,474	9,355	133.5	40,210	4,229	8,351	170.7	40,298	4,132	7,140	181.3
Denmark (DK)	31,226	6,067	6,409		31,395	5,781	6,442		29,360	5,677	5,857	
Estonia (EE)	33,495	5,282	8,094	4.5	33,285	5,116	6,337	1.5	31,440	4,988	4,957	66.2
Finland (FI)				0.0								
France (FR)	33,387	4,939	3,268	2.1	32,341	4,985	3,202	3.2	30,769	4,871	2,956	2.7
Germany (DE)	42,279	7,165	10,489		38,521	5,811	7,374	0.0	36,708	5,759	6,861	0.0
Greece (EL)		16,996	5,210		32,078	9,532		0.0	28,932	8,158	9,737	0.0
Hungary (HU)												
Iceland (IS)	27,091	5,564	3,650		27,729	7,375	2,982	0.0	24,553	6,354	3,151	0.0
Ireland (IE)	24,038	4,418	0	0.2	24,060	4,445	0	3.2	22,906	4,044	0	0.0
Italy (IT)	40,747	3,999	3,970	0.3	40,552	4,087	3,481	0.1	40,554	4,224	3,335	0.2
Latvia (LV)	28,310	4,500	15,317	0.0				0.0				0.0
Liechtenstein (LI)	5,505	77	77	0.0	5,037	178	0	0.0	3,623	175	0	0.0
Lithuania (LT)												
Luxembourg (LU)	28,789	4,881	3,803	0.0	26,993	1,407	4,345	0.0	24,440	3,893	4,049	0.0
Malta (MT)	26984	3892	3790									
Netherlands (NL)	22,225	2,957	42	0.0	21,650	2,848	51	0.0	20,645	2,890	70	0.0
Norway (NO)	27,450	4,406	7,538	102.6	27,278	4,378	7,491	113.2	26,987	4,165	7,284	136.9
Poland (PL)												
Portugal (PT)	27,879	4,893	1,099	1.1	27,627	5,091	1,135	1.4	26,780	4,655	645	0.9
Romania (RO)	18,258	5,579	10,270	41.4	20,252	6,437	10,693	62.8	12,372	4,260	6,449	43.1
Slovakia (SK)	37,606	4,425	20,469	0.0	43,341	3,983	21,173	1.1				
Slovenia (SI)												
Spain (ES)	31,961	4,853	2,927	0.2	31,484	4,774	2,727	0.2	29,187	4,961	2,408	0.9
Sweden (SE)	35,013	4,509	3,631	4.3	33,999	4,503	3,417	2.4	33,281	4,778	3,585	2.3
United Kingdom (	18,747	3,197	1,767	0.0	18,196	3,443	1,473	0.0	20,154	3,445	2,093	0.0
Median	**30,923**	**4,681**	**3,887**	**3.1**	**31,781**	**4,638**	**4,263**	**1.5**	**29,187**	**4,778**	**3,585**	**2.5**

Note: following Brexit, UK = Northern Ireland only

Annex 7. Data Supplement - SAR (IL 1-3), SAR (IL 2-3) and SAE incidence rates in the last seven years

SAR incidence rates per 100,000 units transfused (Refer to Figure 18, Figure 19, Figure 21 and Figure 22)

SAE incidence rates per 100,000 units processed (Refer to Figure 31, Figure 32 and Figure 33)

Data Year	2017			2018			2019			2020			2021			2022			2023		
Country	SAR (IL1-3) Rate	SAR (IL2-3) Rate	SAE Rate	SAR (IL1-3) Rate	SAR (IL2-3) Rate	SAE Rate	SAR (IL1-3) Rate	SAR (IL2-3) Rate	SAE Rate	SAR (IL1-3) Rate	SAR (IL2-3) Rate	SAE Rate	SAR (IL1-3) Rate	SAR (IL2-3) Rate	SAE Rate	SAR (IL1-3) Rate	SAR (IL2-3) Rate	SAE Rate	SAR (IL1-3) Rate	SAR (IL2-3) Rate	SAE Rate
Austria (AT)	25	12	1	25	14	3	2	2	2	152	17	1	38	22	3	16	7	2	23	20	1
Belgium (BE)	28	14	47							3	16	97	4	3	101	17	12	109	6	5	89
Bulgaria (BG)	9	0	0	24	0	2	17	0	1	29	0	0.3	18	1	0.4	17	0	0	31	1	0.5
Croatia (HR)	7	5	3	4	4	1	6	5	2	4	7	3	6	5	2	4	3	1	4	3	1
Cyprus (CY)	24	0	0	163	0	173	1	1	5	374	0	3	17	0	2	25	1	62	10	0	19
Czechia (CZ)	4	2	1	3	2	1	1	1	0.5	2	2	0.5	3	3	0.2	4	3	0.1	3	3	0.2
Denmark (DK)	0	0	0	4	2		7	5		10	8	0.3	4	2	1.4	7	4	1	8	4	0.3
Estonia (EE)	68	68	54	33	32	65	27	27	67	75	20	80	14	13	92	8	8	60	2	2	42
Finland (FI)			3			0.4			4			2			7			7			3
France (FR)	5	3	10	5	3	24	5	3	17	5	3	15	4	2	16	4	3	16	5	4	17
Germany (DE)	10	4	2	11	5	2	12	5	3	0	4	3	11	4	4	19	5	3	32	6	2
Greece (EL)	14	8	1	22	16	0.1	17	13	0.2	0	15	2.2				21	13	6	26	24	4
Hungary (HU)									0				13	7				0			0
Iceland (IS)										18	0	28	0	0	27	0	0	16	0	0	17
Ireland (IE)	42	23	90	33	20	83	39	22	93	443	25	100	54	39	106	58	33	110	47	19	134
Italy (IT)	25	25	3	20	20	2	20	20	1	2	21	1	41	20	0	46	23	1	14	14	0
Latvia (LV)	3	3	4	25	8	7	3	3	5	0	2	9	3	3	3			7			3
Liechtenstein (LI)			0										0	0		0	0	0	0	0	0
Lithuania (LT)						0			0			0			0			0		0	0
Luxembourg (LU)	7	7	0	0	0	4				2,513	9	0	4	0	0	5	0	0	9	0	0
Malta (MT)	30	20	0	24	20		133	74	0				0	0	0						
Netherlands (NL)	27	11	13	26	11	14	20	9	12	31	18	11	24	12	11	25	9	10	32	12	11
Norway (NO)	20	10	45	5	4	33	8	8	52	8	14	42	16	16	47	5	5	36	16	16	49
Poland (PL)			2			2			2			3			3			1			2
Portugal (PT)	9	5	16	10	5	16	8	4	9	8	4	14	9	6	11	5	2	5	8	6	7
Romania (RO)	1	1	0	0	0	0	0	0	0	3	1	0	2	1	90	1	1	58	1	1	0
Slovakia (SK)	136	31	0	53	21	0	100	18	0	2	11	0	71	18	0	42	19				189
Slovenia (SI)			3			2			1			2			3			2			1
Spain (ES)	5	5	12	6	6		5	5		3	4	7	4	4	0	5	5	2	8	8	1
Sweden (SE)	1	1	8	2	2	12	2	2	17	27	4	23	4	4	24	3	3	23	2	2	21
United Kingdom (	21	12	57	17	11	66	21	15	67	5	17	66	24	13	140	25	16	122	41	30	108
Median	**12.2**	**6.3**	**5.7**	**16.8**	**5.2**	**4.2**	**8.0**	**4.6**	**4.4**	**5.4**	**7.8**	**5.2**	**7.6**	**3.7**	**5.4**	**7.7**	**4.4**	**6.7**	**8.2**	**3.7**	**4.4**

Note: outlier highlighted in red. Also, following Brexit, UK = Northern Ireland only

Annex 8. Data Supplement - SAR (IL 2-3) incidence/100,000 units transfused for each type of BC in the last seven years

(Refer to Figure 25)

Data Year	2017			2018			2019			2020			2021			2022			2023		
Country	SAR RBC Rate	SAR Platelets Rate	SAR Plasma Rate	SAR RBC Rate	SAR Platelets Rate	SAR Plasma Rate	SAR RBC Rate	SAR Platelets Rate	SAR Plasma Rate	SAR RBC Rate	SAR Platelets Rate	SAR Plasma Rate	SAR RBC Rate	SAR Platelets Rate	SAR Plasma Rate	SAR RBC Rate	SAR Platelets Rate	SAR Plasma Rate	SAR RBC Rate	SAR Platelets Rate	SAR Plasma Rate
Austria (AT)	7	10		13	20	0	1		0	14	26		20	41		6	8	52	20	22	48
Belgium (BE)	11	27	2	0	0	0				13	39	9	2	2	7	11	19	8	4	12	5
Bulgaria (BG)	0	0	3	2	5	9	0	0	0	0	0	0	1	0	0	1			1	0	0
Croatia (HR)	3	6	0		0	0	4	3	6	7	4	5	5	4	0	3	7		3	3	0
Cyprus (CY)	0	0	0	2	4	2	2	0	0	0	0	0	0	0	0	1			0	0	0
Czechia (CZ)	1	0	5	2	0	2	1	0	2	1	2	7	1	0	7	3	2	6	2	2	10
Denmark (DK)	0	0	0	40	0	9	4	3	11	4	12	16	2	3	0	4	6	3	2	6	3
Estonia (EE)	88	14	22	2	8	11	28	14	8	18	0	8	16	0	0	9			0	0	0
Finland (FI)																					
France (FR)	1	9	6	4	9	2	2	5	12	1	4	15	2	7		2	6	13	2	9	14
Germany (DE)	3	5	1	15	11		4	8	3	3	7		4	5	1	4	12	3	5	11	5
Greece (EL)	2	0	0				13	10	14	19	10	9				10	12		26	26	20
Hungary (HU)														1	10						
Iceland (IS)										0	0	0	0	0	0				0	0	0
Ireland (IE)	144	99		12	67		15	53		25	29		30	89		29	53		18	23	
Italy (IT)	0	55	47	11	81	38	11	92	41	11	96	43	11	87	42	15	84	36	11	40	11
Latvia (LV)	0	0	8	6	47	0	6	0	0	2	14	0	2	23	0						
Liechtenstein (LI)													0	0	0				0	0	
Lithuania (LT)																					
Luxembourg (LU)	0	61	0	0	0	0				0	65	0	0	0	0				0	0	0
Malta (MT)	13	93	0	7	0	95	86	0	43				0	0	0						
Netherlands (NL)	6	30	87	8	26	0	8	21	80	14	44	106	8	31	0	8	22		9	17	0
Norway (NO)	11	9	0	3	13	3	8	18	0	10	18		16	29	7	4	8		9	13	7
Poland (PL)																					
Portugal (PT)	3	10	11	4	13	0	4	6	0	4	4	0	5	10	9	2	6		5	12	0
Romania (RO)	0	1	1	0	1	0	0	0	0	0	1	1	1	4	0	1	2		1	1	1
Slovakia (SK)	24	9	24	20	14	24	4	50	43	9	25	12	14	75	13	23	37	9			
Slovenia (SI)																					
Spain (ES)	4	12	6	5	12	11	3	13	5	2	7	13	3	9	6	4	9	6	6	12	12
Sweden (SE)	1	2	2	2	4	5	1	4	12	3	5	5	1	6	16	2	8	3	2	4	0
United Kingdom (I	7	18	8	9	24	5	12	28	8	13	32	17	14	16	0	14	15	36	23	45	50
Median	**2.9**	**10.9**	**6.0**	**4.6**	**12.6**	**6.7**	**3.9**	**12.7**	**11.6**	**3.9**	**12.8**	**10.7**	**2.2**	**9.8**	**8.8**	**4.1**	**8.7**	**8.1**	**4.7**	**12.1**	**10.5**

Note: following Brexit, UK = Northern Ireland only

Annex 9. Data Supplement - SAR incidence/100,000 collections for WB and apheresis donors in the last seven years

(Refer to Figure 41, Figure 42, Figure 43 and Figure 44)

Data Year	2017		2018		2019		2020		2021		2022		2023	
Country	SAR in WB Rate	SAR in Apheresis Rate	SAR in WB Rate	SAR in Apheresis Rate	SAR in WB Rate	SAR in Apheresis Rate	SAR in WB Rate	SAR in Apheresis Rate	SAR in WB Rate	SAR in Apheresis Rate	SAR in WB Rate	SAR in Apheresis Rate	SAR in WB Rate	SAR in Apheresis Rate
Austria (AT)	0.9	1.5	0.0	0.8	1.4	0.8	0.5	1.7	1.3	0.7	1.0	1.0	0.9	0.8
Belgium (BE)	40.7	14.9					47.2	27.9	5.6	3.3	1.9	0.5	2.0	0.5
Bulgaria (BG)	104.9	0.0	84.3	0.0	74.8	0.0	88.9	0.0	52.9	0.0	84.7	0.0	89.5	0.0
Croatia (HR)	119.0	201.7	95.0	1000.4	159.8	0.0	134.8	20.0	110.2	20.4	1.6	0.0	0.5	0.0
Cyprus (CY)	1.8	0.0	7.9	0.0	21.9	0.0	14.3	0.0	4.5	0.0	20.4	0.0	15.4	0.0
Czechia (CZ)	0.9	0.0	1.4	0.3	0.0	1.4	0.9	1.2	0.4	0.4	0.0	0.7	1.6	0.5
Denmark (DK)	20.8	0.0					9.6	6.6	2.1	10.3	4.1	2.5	1.6	2.3
Estonia (EE)	0.0	0.0	0.0	0.0	4.0	0.0	20.4	0.0	10.3	33.3	63.2	0.0	2.1	0.0
Finland (FI)	0.0	0.0	0.5	0.0	0.5	0.0	1.1	0.0	0.5	0.0	0.0	0.0	0.0	0.0
France (FR)	40.9	142.6	41.0	128.2	48.3	127.6	45.1	121.6	40.1	128.0	47.8	134.0	51.3	171.7
Germany (DE)	9.0	3.7	8.4	4.5	8.6	3.3	8.5	3.2	7.6	2.3	9.2	2.2	11.6	3.1
Greece (EL)		0.0		13.1		41.6		39.1				92.3	3.1	0.0
Hungary (HU)														
Iceland (IS)							91.3	0.0	0.0	715.1	53.2	0.0	46.1	99.6
Ireland (IE)	4.7	10.0	7.1	0.0	12.1	10.6	6.5	0.0	10.9	10.6	3.8	0.0	12.9	5.9
Italy (IT)	17.8	130.8	17.4	80.8	11.4	39.1	11.9	31.2	9.6	21.1	7.9	24.6	7.3	25.0
Latvia (LV)	0.0	0.0	0.0	0.0	0.0	0.0	1.9	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Liechtenstein (LI)											0.0	0.0		
Lithuania (LT)	0.0	0.0	0.0	0.0	2.0	0.0	1.1	0.0	0.0	0.0			0.0	0.0
Luxembourg (LU)	0.0	0.0	0.0	0.0	0.0	0.0	2008.7	0.0						
Malta (MT)	2220.4	476.2			1.0	0.9			0.0	0.0				
Netherlands (NL)	1.2	1.8	1.4	1.6	20.4	53.0			0.7	3.5	0.8	0.9		
Norway (NO)	3.9	0.0	1.7	6.3	3.5	5.6	85.7	106.6	78.2	149.4	107.1	114.9	110.7	94.9
Poland (PL)	5.2	25.5	4.2	5.3	12.3	0.0	3.4	6.3	3.6	3.2	2.9	4.1	2.6	2.8
Portugal (PT)	11.0	0.0	11.3	15.8			7.8	36.0	4.3	0.0	0.7	0.0	1.7	0.0
Romania (RO)	0.0	2086.7					24.9	77.2	12.4	0.0	21.7	0.0		
Slovakia (SK)	62.7	18.1	919.9	4665.2	86.4	66.4	39.9	54.8	47.0	40.4	0.0	0.0	64.0	66.5
Slovenia (SI)	7.0	0.0	2.4	19.4	11.0	0.0	9.3	35.8	19.5	0.0	21.9	0.0	29.3	0.0
Spain (ES)	4.0	1.4	6.0	26.0	11.7	40.2	0.1	0.0	0.0	0.0	0.1		0.0	0.0
Sweden (SE)	7.1		8.7		8.9		10.1		11.3		8.0		8.2	
United Kingdom (	0.0	49.6	2.5		2.3	3.6	2.4	0.0	0.0	0.0	0.0	0.0		
Median	**7.1**	**18.1**	**7.1**	**9.7**	**11.2**	**10.6**	**9.6**	**31.2**	**9.6**	**10.4**	**8.0**	**2.5**	**7.8**	**4.5**

Note: outliers highlighted in red. Also, following Brexit, UK = Northern Ireland only

Annex 10. Examples of SAE; specification (cause) human error

Specification	SAE examples
Human error - Incorrect decision or omission following the correct procedure (723 SAE)	• No information provided (374 SAE) • Wrong BC selected (70 SAE) • BC issued to wrong patient (65 SAE) • Multiple successive failures in wrong patient transfused: error of identity of patient in prescribing BCs, failures of communication between the staff taking care of the patient and the staff issuing BCs, error in checking patient identity during issuing of these BCs in the blood establishment or in the hospital blood bank, error in checking patient identity in the clinical area (on receipt of BC and/or at bedside) (42 SAE) • Labelling error, labelling mix-up (17 SAE) • Physician did not implement amended exclusion criteria (13 SAE) • Multiple successive failures in delayed transfusion: delay in prescribing BCs, failures of communication between the staff taking care of the patient and the staff issuing BCs, delay in issuing of these BCs, delay in their transport/shipment from the blood establishment or from the hospital blood bank to the transfusion healthcare area and delay in the transfusion procedure (12 SAE) • Donors accepted despite meeting exclusion criteria, e.g. travel risk, interval between donations (10 SAE) • Quarantined blood incorrectly stored in the area designated for released BC (10 SAE) • Too much blood collected (10 SAE) • Loss of units due to incorrect storage or open system (9 SAE) • Platelet microbial contamination possible at venipuncture • Expired BC issued • Quarantined BC issued • BC issued without adequate documentation • Data entry errors • Incomplete testing • Loss of traceability • Failure to give irradiated product • Loss of units due to incorrect transport procedure • Sample processing error
Human error - Other, or no information to assign the above options (220 SAE)	• No information provided (145 SAE) • Incomplete information given to patients (34 SAE) • Labelling error, labelling mix-up (11 SAE) • Mix-up of products; issue of a product out of shelf life (7 SAE) • Lab mix-up of blood for screening tests; test reagent out of shelf life (4 SAE)
Human error - Following the wrong procedure (25 SAE)	• Component labelling error (10 SAE) • Component collection error (3 SAE) • Incorrect registration of donor • Blood units which were not transfused to patients returned to hospital blood bank by clinic without being marked as unsuitable • Failed recall • Data entry error • Incorrect blood component issued

Annex 11. Additional information on SAR in donors

Country and # SAR	WB vs Apheresis Donation	Comments
Country A (8 SAR)	37.5% (3) WB 62.5% (5) Apheresis	• WB donation: 1 cardiovascular event - possible imputability 2 other donor reactions: deep venous thrombosis • Apheresis donation: 2 cardiovascular events: (1 TIA, 1 arterial circulatory disorder) - possible imputability 1 'Other' donor reaction: deep muscle venous thrombosis (imputability was noted as "not assessable)
Country B (11 SAR)	100% WB	• 'Other' category: 2 cases were loss of consciousness - one of them was transferred to the Emergency Room of the hospital and was later released
Country C (1 SAR)	100% WB	1 donor fell and hit his head during vasovagal reaction after donation while exiting the blood centre. Donor left blood establishment on his own after an hour had passed (no lacerations), but later (20:00) turned to ER, with feeling dizzy, nausea and light sensitive eyes. ER physician ordered a head CT and saline was infused. Report did not include a diagnosis, but a head CT indicates doctor suspected concussion. Donor was sent home after 5,5 hours (01:30) in the ER. 48 h after donation donor was feeling well. 5 days after the donation donor was feeling well. Deemed this grade 3
Country D (540 SAR)	81% (438) WB 19% (102) Apheresis	• 2 cases of myocardial infarction were reported: One in a 49-year-old male donor during thrombocyte apheresis and one in a 57-year-old male donor shortly after plasmapheresis (both assessed as possibly related) • 1 case of apoplexy in a 73-year-old male donor was reported in the evening after an otherwise complication-free blood whole donation (assessed as unlikely related) • 1 case of tachycardia 3 hours after donation and one case of unspecified cardiac symptoms was reported (both assessed as possibly related) • 1 case of pulmonary embolism with unknown embolic source was reported in a 49-year-old female donor one month after complication-free blood donation (assessed as unlikely related)
Country E (190 SAR)	90% (172) WB 10% (18) Apheresis	• WB 'Other' category: another pain in arm: 8, another local reaction: 11, another systemic reaction: 5 • Apheresis 'Other' category: another pain in arm: 2, another local reaction: 3, another systemic reaction: 1
Country F (39 SAR)	90% (35) WB 10% (4) Apheresis	• WB 'Other' category: severe vein damage which required further treatment, tendon injury
Country G (5 SAR)	100% WB	• WB 'Other' category relates to a case of superficial thrombophlebitis
Country H (30 SAR)	100% WB N/A (Apheresis)	• WB 'Other' category: 4 artery puncture, 1 large hematoma, 1 skin reaction to disinfectant used + 1 atrial fibrillation 4 days after donation of granulocytes

Country and # SAR	SAR Rate (calculated by country)	SAR by Gender	Type of Donor	WB vs Apheresis Donation	Comments
Country I (1826 SAR)	173.0 SARs reports/100,000 apheresis donations (395,445 apheresis donations)) than in whole blood donation 51.6 SARs reports/100,000 WB donations (2,213,210 WB donations)	68% SAR in female donors vs 32% in male donors	80% SAR in regular donors vs 20% in first-time blood donors	63% (1142) WB 37% (684) Apheresis	WB donation: • 6 major CVE: 4 superficial vein thrombosis and 2 deep vein thrombosis • 88 SARs reported in the category 'Other': 46 haematoma, 12 anaemia, 8 arterial punctures, 5 local pain (unspecified brachial pain), 4 tendon injury, 2 iron deficiency, 2 lymphangitis, 1 local allergic reaction, 1 local infection and 7 Uncategorised complication of donation (UCD) Apheresis donation: • 1 major cardiovascular event: a superficial vein thrombosis • 41 SARs reported in the category 'Other': 29 haematoma, 4 local pain (unspecified brachial pain), 1 anxiety attack, 1 haemolysis, 1 lymphangitis, 1 tendon injury, 4 Uncategorised complication of donation (UCD)
Country J (18 SAR) (One major case for 2023. The remaining 17 SARs include 8 from 2021, 4 from 2022 and 5 from 2023)	132,706 attempted WB donations and 8,546 attempted apheresis donations in the calendar year 2023 (total of 141,252 attempted donations)	10 donors are female and 8 are male. All donors were subsequently excluded from donation			17 donors were WB donors and 1 was a regular apheresis donor WB donation: • 1 major CVE within 24 hrs. of donation, in a male regular donor .This donor had complained of discomfort in his jaw and left arm on the day before he donated, but did not mention it at clinic. He complained of chest pain on the day after donating and consulted his GP 2 days later. He was admitted to hospital approx. 72 hrs. after donating and was diagnosed with a myocardial infarction, for which he had a stent inserted and made a good recovery. The imputability is unclear as he had undiagnosed cardiovascular disease and symptoms pre-donation. We have assigned an imputability of possible. • One of the donors who had a delayed vasovagal reaction after donation, lost consciousness while driving her car, resulting in a single vehicle road traffic accident; her car was overturned. She did not have any serious injury. She was admitted to hospital and was found to have underlying cardiovascular disease. Another donor who had a delayed vasovagal reaction fell and suffered a malleolar fracture that required surgical intervention. Both were female, regular blood donors. • Under the category of 'Other' we are reporting 3 cases of painful arms, all of which persisted for more than 12 months after donation; and 1 case of a donor who complained of pain at the site in her finger where the test for haemoglobin was carried out. Apheresis donation: • This donor developed a deep venous thrombosis in the arm from which she had donated, within 2 weeks of her donation. She had no symptoms on the day of 2-week noted tenderness in the days following donation. She had taken 2 flights during the 2-week period that were 2.5 hours each. Her clinical team advised that they felt that her donation was a contributory factor to her DVT. We therefore assigned an imputability of probable to this incident.

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