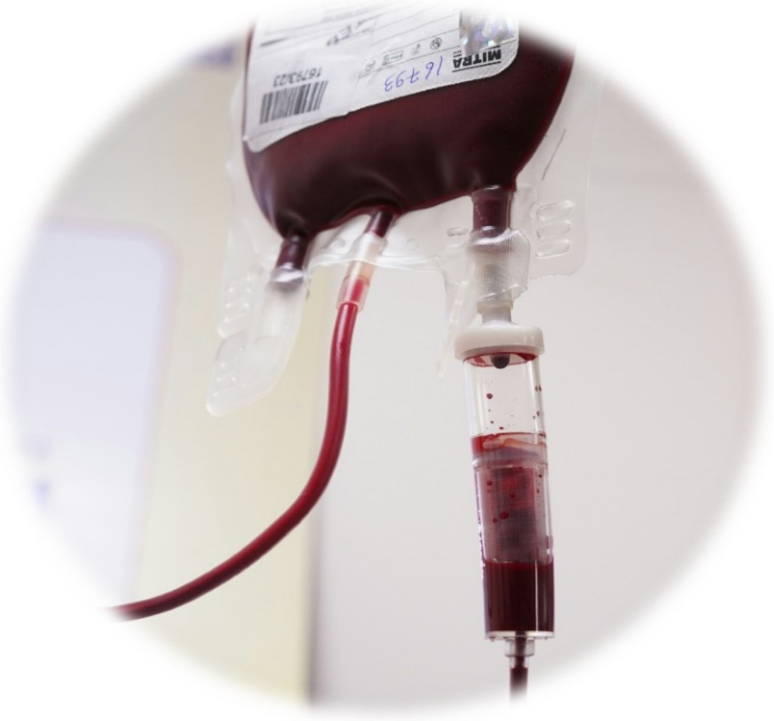
EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Unit D2 – Medical Products: quality, safety, innovation



HAEMOVIGILANCE
ANNUAL SARE REPORT 2025

(Data collected from 01/01/2024 to 31/12/2024 and submitted to the European Commission in 2025)

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 the role of haemovigilance in transfusion medicine essential.

Haemovigilance encompasses a series of surveillance procedures that monitor the entire transfusion process, from blood donation and processing to transfusion and patient follow-up. According to the World Health Organization (WHO), haemovigilance aims to continuously improve the quality of the transfusion chain through corrective and preventive measures, ultimately enhancing donor and patient safety and reducing wastage.

Through national haemovigilance 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.

The 2025 Haemovigilance Report provides an in-depth analysis of SARE (Serious Adverse Reactions and Events) data for the year 2024 submitted to the EC by 28 European countries, highlighting key findings, trends and challenges faced in ensuring safe and effective blood transfusions in Europe.

[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

Haemovigiliance 2025 Highlights

28 Countries
25 EU MS plus Iceland, Norway and the UK (Northern Ireland)

3 190 reporting establishments

Donation activity rate (median):
31.8 WB collections per 1 000 pop ↓ 8%
2.5 apheresis collections per 1 000 pop

1 360 SAR (IL 2-3) (n=25) ↓ 9%

~2.6 M units of plasma issued (n=23) ↑ 13%

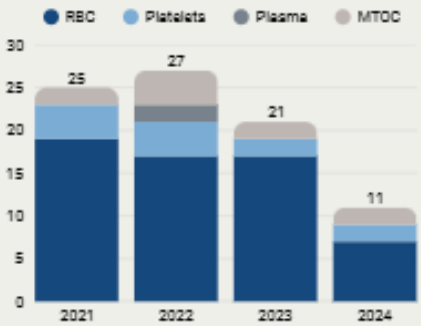
~16.5 M units transfused (n=23)

~ 3 M patients transfused (n=21)

8.3 SAR (IL 2-3) per 100 000 units transfused
[median: 5.2] ↑ (+1.5)

RBC, platelet and plasma transfusion rates pmp (median) ↘

- **Reaction profile unchanged:**
  - FNHTR (most frequent)
  - Anaphylaxis/hypersensitivity
  - TACO (increasing trend)
- Platelets continue to show the highest SAR incidence
- 14 TTIs (IL 2-3) (6 less than in 2023)



11 fatalities (IL 2-3) ↘
(n=5)

4 764 SAE ↑ 108% *(driven by RO's data)*
(n=25)

19.5 SAE per 100 000 units processed *(Excluding RO, total=6.4)*
[median: 6.4]

- Root cause pattern shifted: component defect (60%) overtook human error (14%)
  (Excluding RO, human error remains the leading cause (38%))

2 260 SAR in donors ↓ 36%*
*(*driven primarily by FR's scope update)*

4 fatalities in donors
(first ever reported)

METHODOLOGY

Data collection and analysis

This report provides a summary of the national data submitted to the EC by all EU MS (except Hungary and Malta) and three non-EU countries (Iceland, Norway and UK (Northern Ireland)) pertaining to the reporting period from 1 January to 31 December 2024.

As in previous years, the EC provided national competent authorities (NCA) with the following tools to facilitate a standardised online data reporting approach:

1) ***An electronic reporting form (version 2025)***
2) ***The Common Approach, version 2025 [1]***, which complements the electronic reporting form and provides updated user instructions for data compilation.

The sequence of steps comprised (and involved parties) from data collection to the publication of the final report are shown below.

Summary of the annual reporting of SARE for blood and blood components: https://health.ec.europa.eu/blood-tissues-cells-and-organs/key-documents_en

The preliminary results of the EDQM's SARE analysis (data 2024) were verified by the reporting countries and also presented at the annual meeting of the Vigilance and Traceability Working Group (previously known as VES, the Vigilance Expert Subgroup) of the SoHO Coordination Board during the 27–28th April 2026.

Data reporting completeness

The annual data on SARE for blood and blood components were reported by 25 EU MS and three non-EU countries that submitted their national data on a voluntary basis, comprising aggregated data from 3 190 reporting establishments. Refer to Annex 2. Reporting establishments per capita (pmp) for their geographical distribution in Europe.

Regarding the percentage of reports received, 21 reporting countries confirmed receipt of 100% of reports, four countries received 80-99% of the expected data and two countries' 50-80%. One country was not able to provide any information. For more details, refer to **Annex 3. Completeness dashboard per metric per country.**

Denominator data

- The total number of **units of blood/blood components (BC) transfused** (i.e. the sum of whole blood (WB), red blood cells (RBC), platelets and plasma units) annually was used as the denominator to calculate SAR (IL 2-3) incidence per 100 000 units transfused.
  - 82% (23 of 28) countries reported this denominator.
- The total number of **units blood/BC processed** annually was used as the denominator to calculate SAE incidence per 100 000 units processed.
  - 100% (28 of 28) 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.
  - 93% (26 of 28) countries provided this denominator.
- The total **number of apheresis collections** was used as the denominator to calculate SAR incidence in apheresis donors per 100 000 donations.
  - 89% (25 of 28) countries provided this denominator.

Annex 3. Completeness dashboard per metric per country outlines whether each reporting country have denominator data valid for rate calculations.

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 indicators definitions

- **Transfusion rate per country in data year Y** is an indicator that reflects how frequently blood/BC are administered within a population, providing insight into national clinical practice patterns and overall demand for blood/BC. It is the total number of units of blood/BC transfused as a function of the size of the reference population and **expressed per one thousand population**.
  - How it is calculated: total number of units of blood/BC transfused x (1/population size) x 1 000.

    - The same logic is used for determining the issuance, processing, donation and recipient rates per country in data year Y.
- **Median per-country transfusion rate in data year Y** represents the typical level of transfusion activity across reporting countries, expressed as the middle value of national transfusion rates for that data year.
    - How it is calculated: the transfusion rate (per 1 000 population) is calculated for each reporting country of said data year Y and then the median is taken.
    - The median is independent of the number of reporting countries and fairly robust against extreme values (e.g., countries with abnormally high or low transfusion rates).
    - The same logic is used for determining the median per-country issuance, processing, donation and recipient rates in data year Y.
- **RBC transfusion rate per country in data year Y** is the number of units of RBC transfused as a function of the size of the reference population and **expressed per one million population (pmp)**.
    - How it is calculated: number of units of RBC transfused x (1/population size) x 10^6.
    - The same logic is used for determining the WB, platelets and plasma transfusion rates per country in data year Y.
- **Median per-country RBC Transfusion rate in data year Y** represents the typical level of transfusion activity of RBC across reporting countries, expressed as the middle value of national RBC transfusion rates for that data year.
    - How it is calculated: the RBC transfusion rate (pmp) is calculated for each reporting country of said data year Y and then the median is taken.
    - The same logic is used for determining the median per-country WB, platelets and plasma transfusion rates per country in data year Y.
- **Total SAR incidence in data year Y** is an indicator of the overall burden of SAR within the transfusion system across Europe of said data year Y, reflecting its general safety performance; **expressed per 100 000 units of blood/BC transfused**; best for international comparisons.
    - How it is calculated: total number of SAR cases reported divided by the total number of units of blood/BC transfused × 100 000.
    - The numerator (total number of reported SAR) and the denominator (total number of units of blood/BC transfused) includes different sets of countries. Specifically, some countries report the number of SAR cases but do not provide the corresponding denominator, or some countries report the number of units transfused but report zero SAR. As a result, the total pooled incidence rate may not represent a strictly matched country set and should be interpreted alongside median per-country rates and denominator completeness table to properly assess trends and comparability across the EU.
    - The same logic is used for determining the total fatalities (IL 2-3) incidence (expressed per 100 000 units of blood/BC transfused), total SAE incidence (expressed per 100 000 units of blood/BC processed) and total SAR incidence in WB or apheresis donors (expressed per 100 000 WB or apheresis collections, respectively).
- **Median per-country SAR incidence in data year Y** is an indicator of the "typical" SAR rate across reporting countries of said data year Y, serving as a benchmark for comparing transfusion safety performance and identifying which countries have higher or lower incidence than this central value; **expressed per 100 000 units of blood/BC transfused.**

- How it is calculated: the SAR rate is calculated for each reporting country (only those countries where **both** SAR and units of blood/BC transfused are available) and then the median is taken.
- The median is independent of the number of reporting countries and fairly robust against extreme values (e.g., countries with abnormally high or low SAR incidence).
- The same logic is used for determining the median per-country SAE incidence in data year Y (expressed per 100 000 units of blood/BC processed) and the median per-country SAR incidence in WB or apheresis donors (expressed per 100 000 WB or apheresis collections, respectively).

Updates and improvements

The 2025 edition of the SARE report incorporates some structural and methodological updates aimed at improving transparency, comparability, regulatory clarity and the analytical utility of the reported data:

- A critical update is the structural separation of SAR in recipients by imputability level. The data analyses now explicitly isolate "**in-scope" SAR (IL 2-3)**, which are legally mandated under EU reporting directives, from "voluntary" SAR (IL 1) (see Annex 7). This structure empowers NCA and external reviewers to filter, compare and aggregate statutory metrics with high precision and confidence.
- A **completeness dashboard per metric per country** has been introduced (see Annex 3). This provides immediate visibility into the integrity of the denominator data, clearly highlighting where data gaps may compromise incidence analysis. Additionally, the methodology chapter has been complemented through a new, dedicated key indicators **definitions section** that explicitly details how median and total incidence rates are calculated.
- Another major update is the **qualitative thematic analysis** of the free-text narrative data (comments) submitted alongside SAE reports, covering all specification categories**.** This approach is essential in order to highlight failure modes, systemic vulnerabilities and reporting quality gaps.
- For major chapters, the introduction text has been extended, particularly for SAE. This expansion aims to reduce interpretative ambiguity and data variability that stems from inconsistent national reporting practices.
- A "***key countries shaping the landscape***" box, including brief national notes from countries, when available, across different metrics, clarifying whether differences reflect system maturity, system maturity, national clinical practice patterns, or recent changes in reporting methodology.

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[2])):

1. Activity dataset
    a. Yearly trends in donation (WB and apheresis), issuance, transfusion, processing and recipient rates (2021–2024)
    b. Geographic distribution of donation, issuance, transfusion and recipient rates
    c. Overview of volume of activity by type of BC; comparative analysis with 2023
    d. Country-specific trends (2023 vs. 2024) in transfusion rates by type of BC
2. SAR (IL 2-3) in recipients
    a. Yearly trends in SAR (IL 2-3) incidence (2021–2024)
    b. Geographic distribution of SAR (IL 2-3) incidence
    c. Yearly trends in median per-country SAR (IL 2-3) incidence by type of BC (2021–2024)
    d. Country-specific trends (2023 vs. 2024) in SAR (IL 2-3) incidence by type of BC
    e. Overview of SAR (IL 2-3) and fatalities (IL 2-3) by type of BC; comparative analysis with 2023
    f. Yearly trends in SAR (IL 2-3) and fatalities (IL 2-3) by type of reaction (2021–2024)
    g. Overview of SAR (IL 2-3) and fatalities (IL 2-3) by type of reaction; comparative analysis with 2023
    h. Fatalities (IL 2-3) in recipients – case studies
3. SAE
    a. Yearly trends in SAE incidence (2021–2024)
    b. Geographic distribution of SAE incidence
    c. Country-specific trends (2023 vs. 2024) in SAE incidence
    d. Overview of SAE by activity step
    e. Yearly trends in SAE by specification (2021–2024)
    f. Overview of SAE by specification (including Qualitative Thematic Analysis)
4. SAR in donors
    a. Geographic distribution of SAR incidence in WB and apheresis donors
    b. Country-specific trends (2023 vs. 2024) in SAR incidence in WB and apheresis donors
    c. Overview of SAR by type of reaction in WB and apheresis donors; comparative analysis with 2023
    d. Fatalities in donors

Note 1: wherever **N/A** is mentioned throughout the text it means **data not available**.
Note 2: key raw data for each MS for the period 2021–2024 are listed in the **Annexes 8–13**.

[2] More Than One Component (MTOC) reflects exposure to multiple component categories over the reporting period, irrespective of timing or clinical episode.

1 Activity Dataset

Key findings

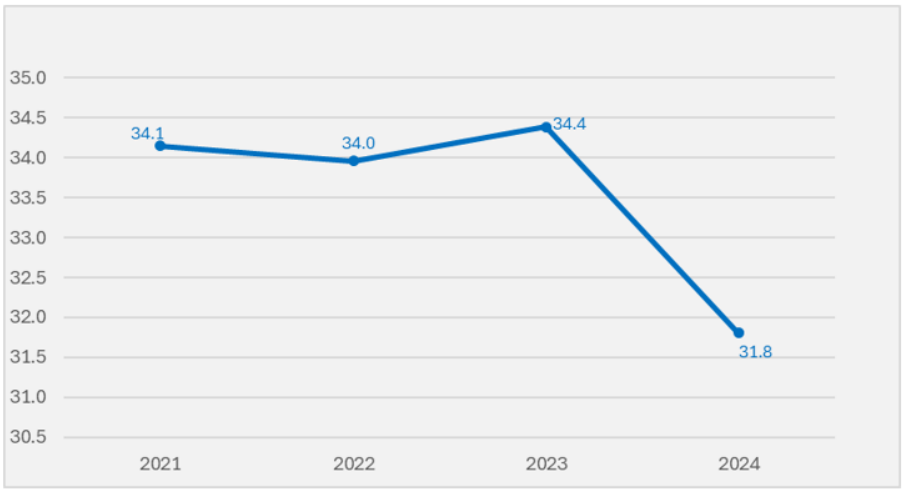
- WB donation rate (median) declined 8% (31.8 vs 34.4 in 2023) while the apheresis' remained stable (2.5 vs 2.6).
- RBC, platelets and plasma transfusion rates (median) decreased slightly across all BC types except WB.
- Plasma issuance volume increased by 13% in comparison with 2023.
- Recipient numbers increased across all BC types.

1.1 Yearly trends (2021–2024)

1.1.1. Donation (Whole Blood and Apheresis) rates

Considering the demographic data[3] of the reporting countries, Figure 1 presents the median of country-specific **WB donation/collection** rate (per 1 000 population) across all reporting countries from 2021 to 2024.

Between 2021 and 2023, the median WB donation rate remained stable at approximately 34 donations per 1 000 population. In 2024, however, a marked decrease to 31.8 was observed (an 8% drop compared with 2023).



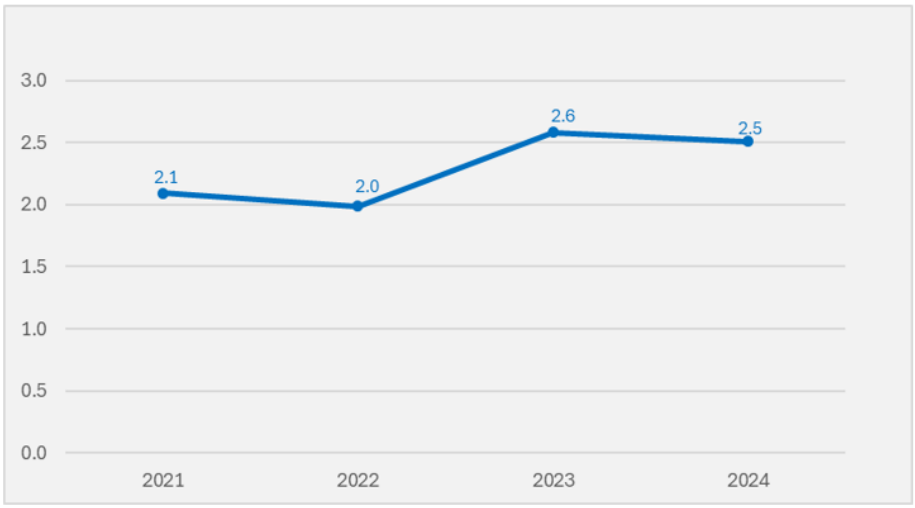
n	28	26	26	26

Figure 1. Yearly trend in whole blood donation rate (median per-country) per 1 000 population; 2021–2024

Figure 2 presents the median of country-specific **apheresis donation** rate (per 1 000 population) among reporting countries from 2021 to 2024.

The median per-country apheresis donation rate remained broadly stable between 2021 and 2024, fluctuating within a narrow range.

[3] https://ec.europa.eu/eurostat/ (Population on 1January Y+1 – total)

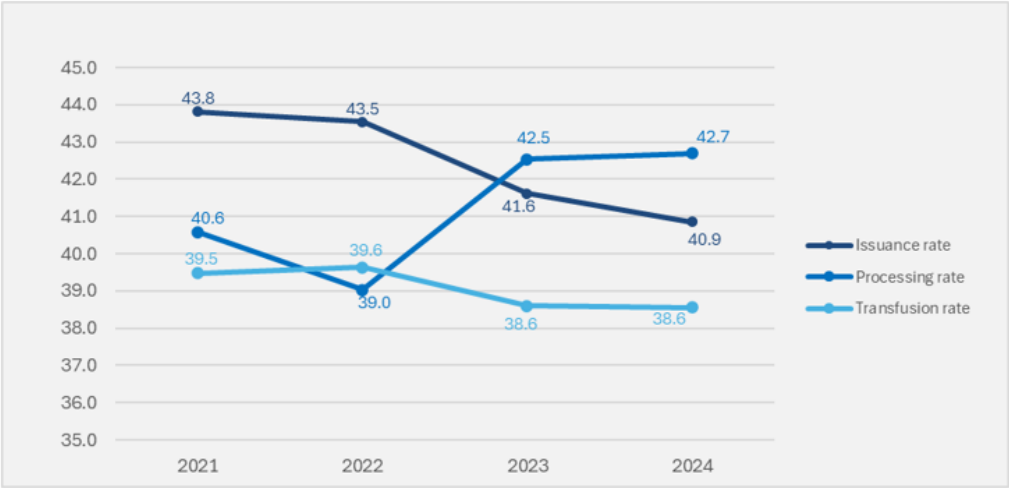


n	28	26	25	25

Figure 2. Yearly trend in apheresis donation rate (median per-country) per 1 000 population; 2021–2024

1.1.2. Blood/BC issuance, transfusion and processing rates

Figure 3 shows the median of country-specific blood/BC issuance, transfusion and processing rates (per 1 000 population) across all reporting countries from 2021 to 2024.



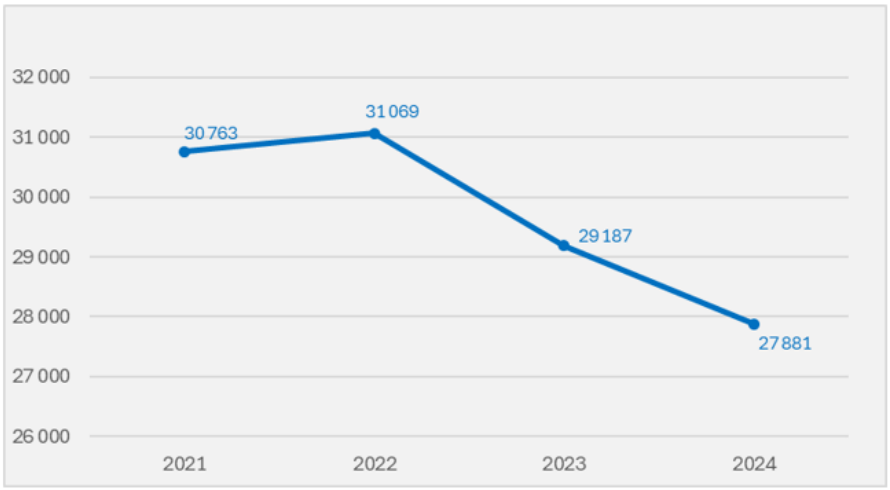
n(issuance)	30	30	30	28
n(processing)	28	27	26	28
n(transfusion)	26	24	23	23

Figure 3. Yearly trends in blood/BC issuance, processing and transfusion rates (median per-country) per 1 000 population; 2021–2024

The downward trend in **issuance rates** from 2021 to 2024 is paralleled by overall stable **transfusion rates**, suggesting that the reduction in issued units is primarily driven by improved inventory management and wastage reduction practices rather than a decline in clinical demand. Between 2021 and 2024, the median **processing rate** showed an overall upward trajectory.

1.1.3. Transfusion rates per type of BC

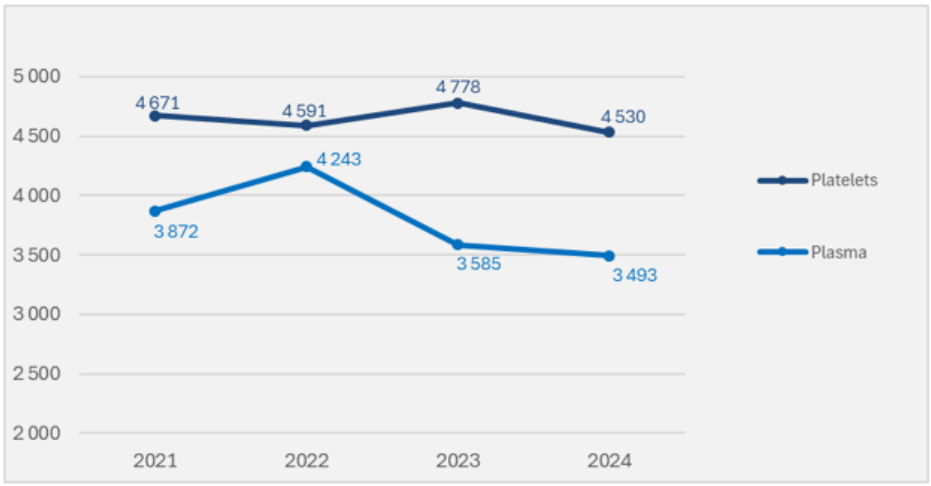
Figure 4 shows the median of country-specific **RBC** transfusion rate (per one million population, pmp) across all reporting countries from 2021 to 2024. There has been a continuous decline in RBC transfusion rate from 2022 onwards.



n	25	24	23	23

Figure 4. Yearly trend in RBC transfusion rate (median per-country) pmp; 2021–2024

Figure 5 presents the median of country-specific **platelets** and **plasma** transfusion rates (pmp) across all reporting countries from 2021 to 2024.

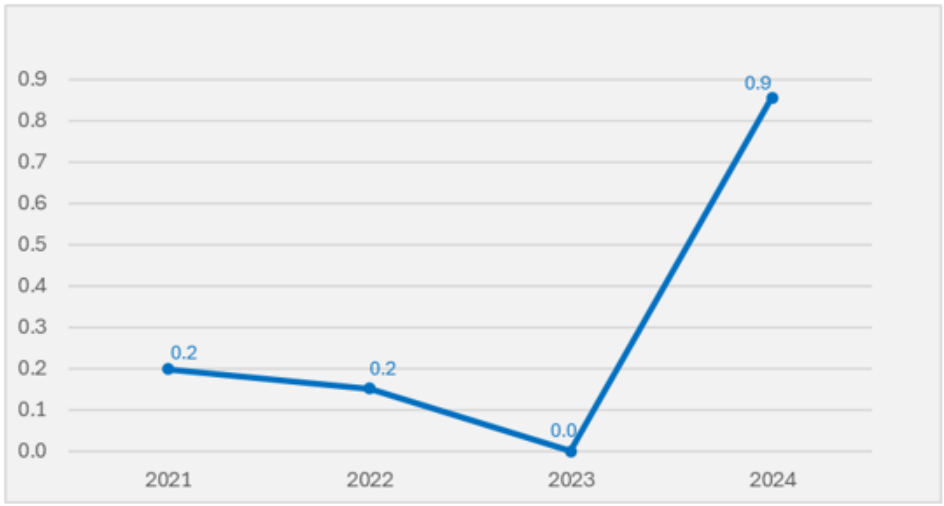


n(platelets)	26	24	23	23
n(plasma)	26	23	23	24

Figure 5. Yearly trends in platelet and plasma transfusion rates (median per-country) pmp; 2021–2024
Note: for plasma, n includes countries that reported zero units and consequently a transfusion rate of zero.

Between 2021 and 2024, the median **platelet** transfusion rate remained relatively stable, fluctuating within a narrow range, with a modest peak at 4 778 in 2023. In contrast, the median **plasma** transfusion rate shows more marked fluctuations. After increasing initially from 3 872 in 2021 to 4 243 in 2022, it declined significantly in 2023, stabilising at lower level in 2024.

Figure 6 displays the median of country-specific **WB** transfusion rate (pmp) across reporting countries from 2021 to 2024. From 2021 to 2023, the trend was fairly stable with a pronounced increase in 2024.



n	21	25	22	19

Figure 6. Yearly trend in WB transfusion rate (median per-country) pmp; 2021–2024
Note: n includes countries that reported zero units and consequently a zero rate.

1.1.4. Summary by type of BC (2023 vs. 2024)

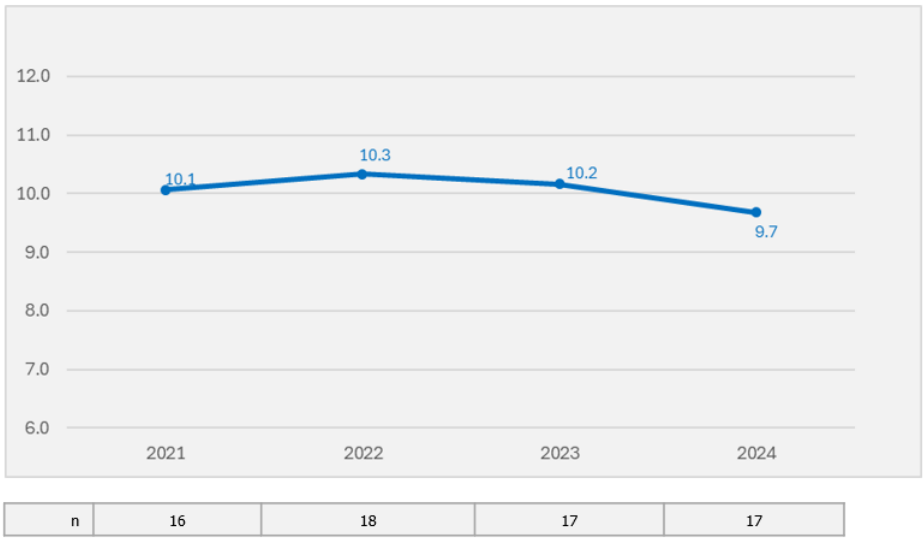
As shown in Table 1, in comparison with 2023, the transfusion rates (median) decreased slightly across all types of BC except for WB.

Table 1. Summary of transfusion rates (median per-country) pmp by type of BC; 2023 vs. 2024

Type of BC	2023 (median rate pmp)	2024 (median rate pmp)
RBC	29 187	27 881
Platelets	4 778	4 530
Plasma	3 585	3 493
WB	0.0	0.9

1.1.5. Recipient rate

Figure 7 displays the median of country-specific recipient (**regardless of type of BC**) rates (per 1 000 population) among reporting countries from 2021 to 2024. In general, recipient data has been plateauing from 2021 until 2023, with a marginal decrease in 2024.



n	16	18	17	17

Figure 7. Yearly trend in recipient rate regardless of type of BC (median per-country) per 1 000 population; 2021–2024

1.2. Geographic distribution

1.2.1. Donation (Whole Blood and Apheresis) rates

Twenty-six countries (AT, BE, BG, HR, CY, CZ, DK, EE, FI, FR, DE, EL, IS, IE, IT, LV, LU, NL, NO, PL, PT, RO, SI, ES, SE and UK(NI)) reported a total of 15 679 193 **WB collections** in 2024. This was a minor decrease over the previous year, when 16 068 007 collections were also reported by 26 countries.

In terms of **apheresis collections**, 25 countries (all the above minus SE) reported a total of 7 590 344 collections, representing a 4% increase compared to the 7 286 075 collections in 2023.

Considering the demographic data[4] of the reporting countries in 2024, the WB and apheresis collection rates per 1 000 population are shown in Figure 8 and Figure 9, respectively.

The WB donation rate (median) was 31.8 donations per 1 000 population [range 21(UK(NI)–76(CY)], similar to the 2023 rate (34.4).

The apheresis donation rate (median) was 2.5 donations per 1 000 population [range 0.3(CY, EL)–137(CZ)], similar to the 2023 median (2.6).

[4] https://ec.europa.eu/eurostat/ (Population on 1January Y+1 – total)

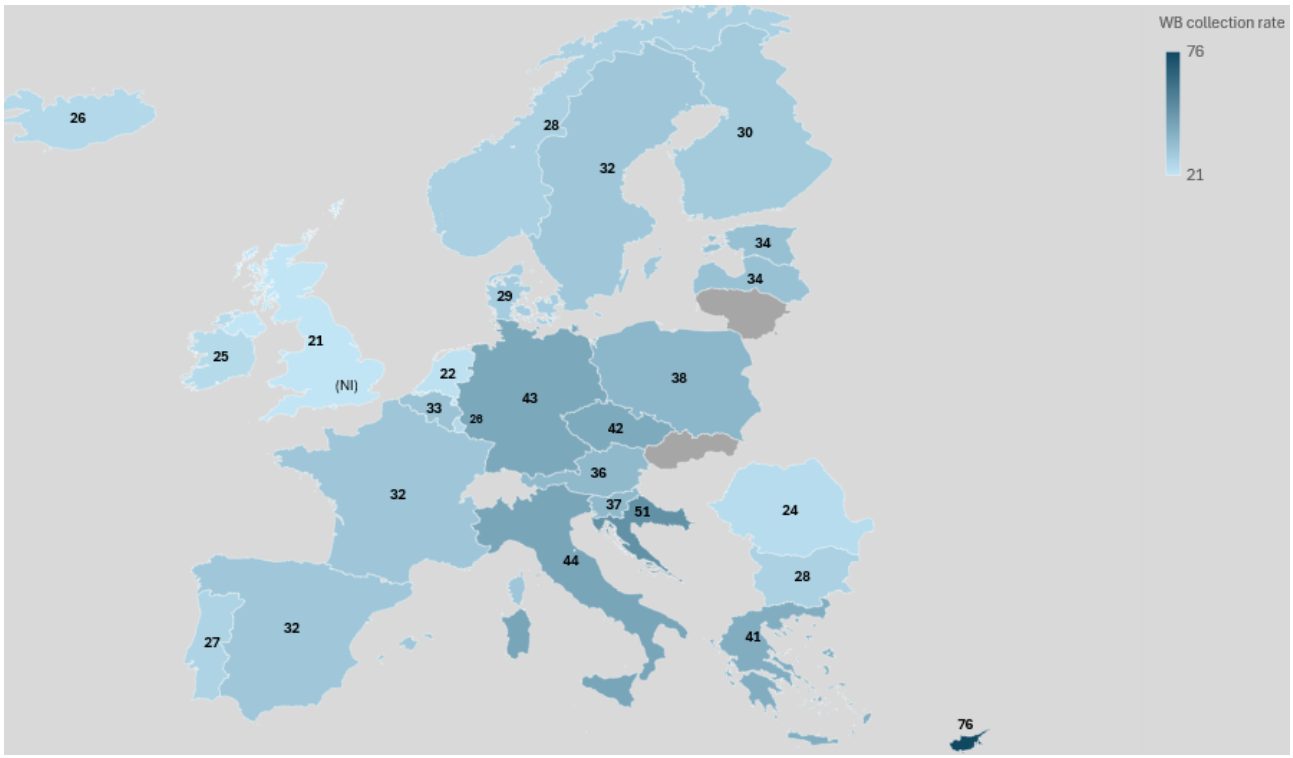


Figure 8. WB collection rates in Europe per 1 000 population in 2024

Note: LT and SK reported data N/A (shown above in dark grey).

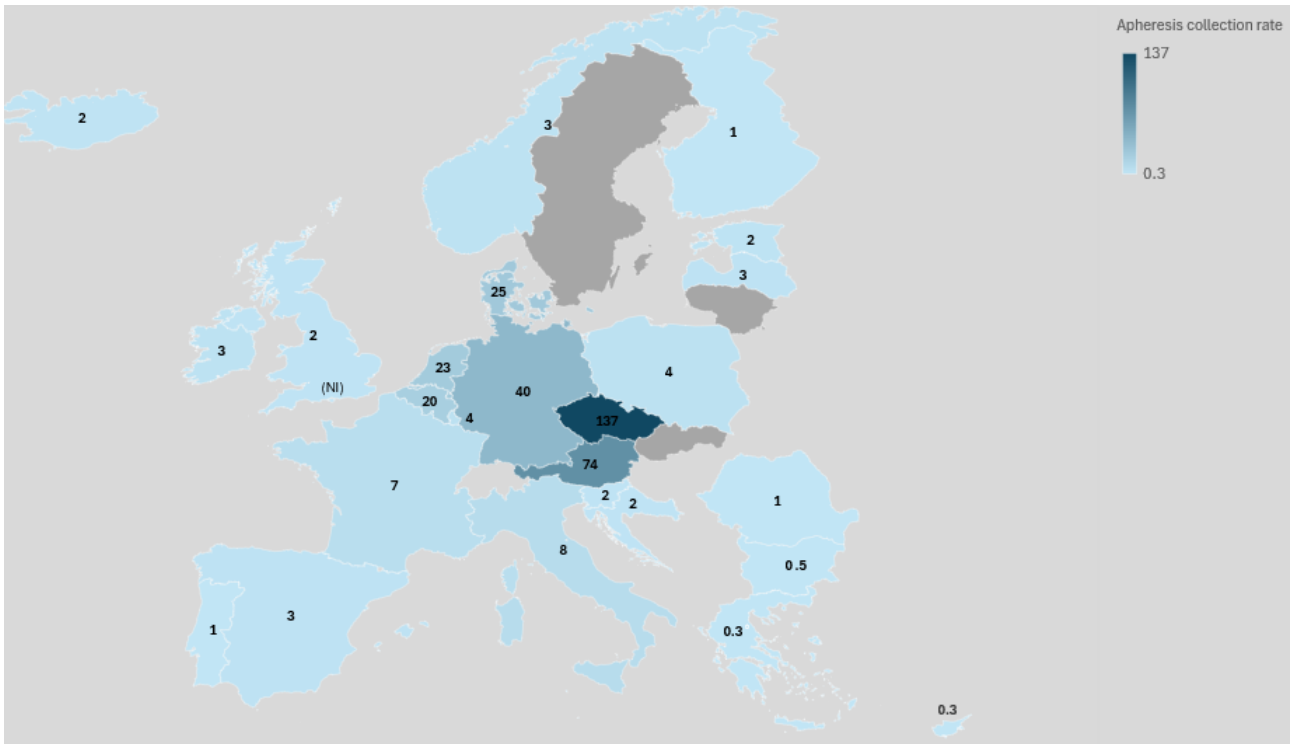


Figure 9. Apheresis collection rates in Europe per 1 000 population in 2024

Note: LT, SK and SE reported data N/A (shown above in dark grey).

1.2.2. Blood/BC issuance and transfusion rates

In 2024, 26 countries (AT, BE, BG, HR, CY, CZ, DK, EE, FI, FR, DE, EL, IS, IE, IT, LV, LT, LU, NL, PL, PT, RO, SK, SI, SE and UK(NI)) provided data for **units of blood/BC issued**. NO and ES reported N/A for 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 20 467 219 **units issued of blood/BC** were reported in 2024, similar to 2023 (20 824 019).

Figure 10 presents the blood/BC issuance rates per 1 000 population in Europe [range 23(NL)–138 (CY)].

In 2024, the European issuance rate (median) of blood/BC units was determined to be 40.9/1 000 population, marginally lower than the 41.6/1 000 population reported in 2023.

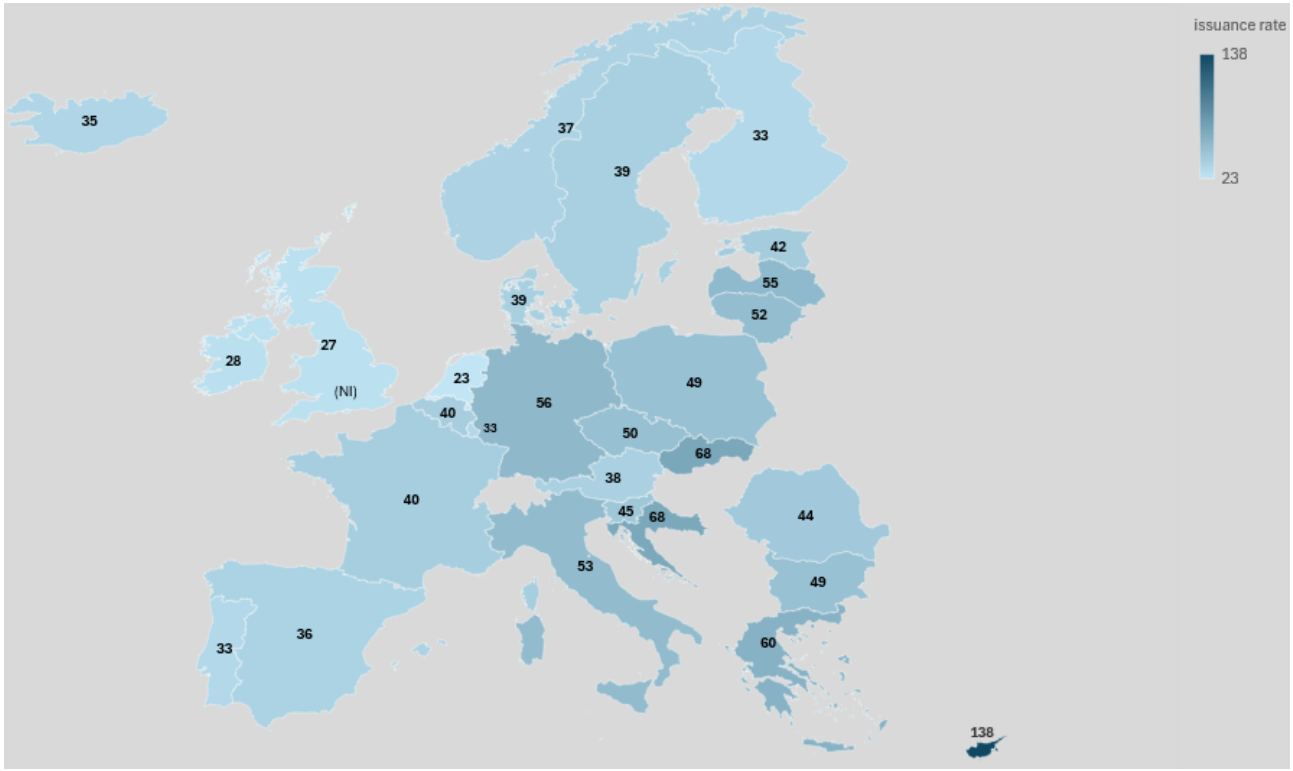


Figure 10. Blood/BC issuance rates in Europe per 1 000 population in 2024

Concerning **units of blood/BC transfused**, a total of 16 478 412 units were reported by 23 countries (AT, BE, BG, HR, CY, CZ, DK, EE, FR, DE, EL, IS, IE, IT, LU, NL, NO, PT, RO, SK, ES, SE and UK(NI)). This value is comparable with 2023 (16 213 234) also reported by 23 countries.

Figure 11 shows the transfusion rates of blood/BC units per 1 000 population in Europe [range 23(NL)–107(CY)].

In 2024, the European blood/BC transfusion rate (median) was determined to be 38.6/1 000 population, the same as reported in 2023.

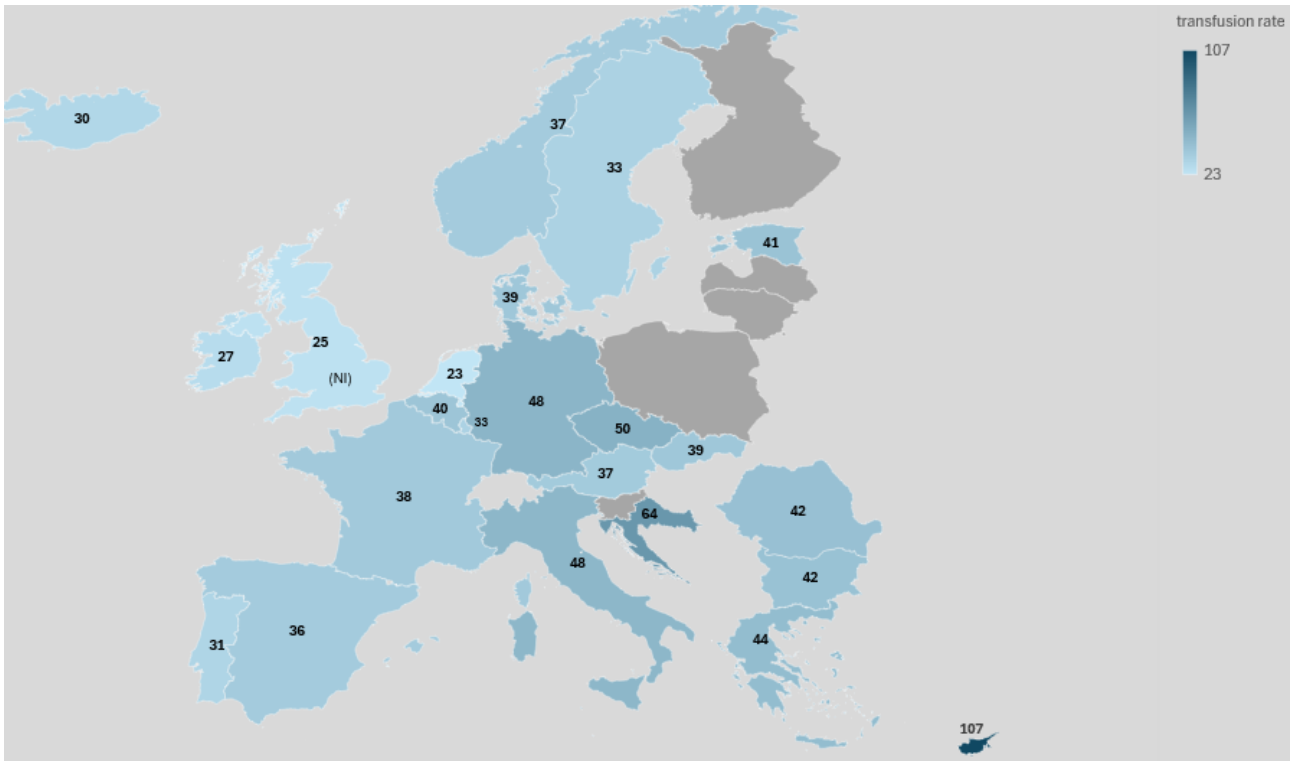


Figure 11. Blood/BC transfusion rates in Europe per 1 000 population in 2024
Note: FI, LV, LT, PL and SI reported data N/A (shown above in dark grey).

Comparing with 2023, a new transfusion rate was reported for SK (37) and there was a significant increase for RO (rate 42 vs 23 in 2023).

1.2.3. Recipient rates

According to data reported by 17 countries (BE, BG, HR, CY, CZ, DK, EE, FR, EL, IS, IT, LU, PT, RO, ES, SE and UK(NI)) 2 530 113 patients were transfused in 2024 **regardless of the type of BC**, comparable with 2023 (2 502 392).

Recipient rates per 1 000 population in Europe are displayed in Figure 12 [range 2(UK(NI)–25(CY)].

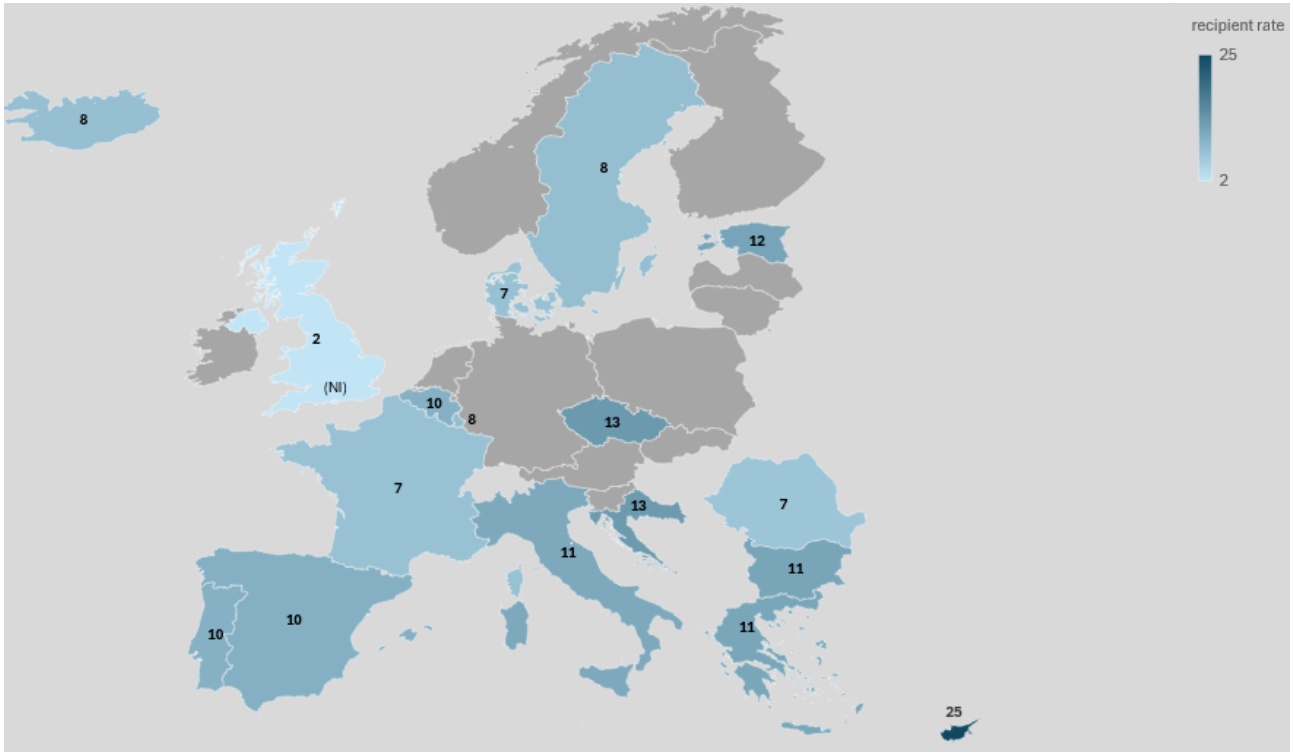


Figure 12. Recipient rates (regardless of the type of BC) in Europe per 1 000 population in 2024
Note: AT, FI, DE, IE, LV, LT, NL, NO, PL, SK and SI reported data N/A (shown above in dark grey).

The European rate (median) in 2024 was determined to be 9.7 patients transfused/1 000 population, slightly lower than the 2023 rate (10.2).

Key countries shaping the landscape

- Apheresis collection rate in CZ reached 137 per 1 000 population (far above the median 2.5).
- CY issuance and transfusion rates were among Europe's highest (issuance 138 per 1 000; transfusion 107 per 1 000), indicating high per-capita utilisation.

1.3. Overview of volume of activity by type of BC

Overall data collected in 2024 for number of units issued, units transfused and recipients by type of BC (excluding MTOC) is shown Table 2 and

Table *3*.

RBC continue to be the most issued and transfused type of BC by far. In comparison with 2023, there was a 13% increase in the number of plasma units issued. Regarding number of units transfused, the values were similar to those recorded in 2023, except for WB.

The number of recipients transfused increased across all types of BC, reflecting sustained clinical demand.

Table 2. Summary of total number of units issued and transfused by type of BC; 2023 vs. 2024

Total Number of **Units Issued**	2023	2024	% Change
RBC	15 933 863	15 413 314	-3
Platelets	2 561 256	2 430 261	-5
Plasma	2 324 231	2 619 750	+13
WB	4 669	3 894	-17
n (RBC)	30	28	
n (Platelets)	30	28	
n (Plasma)	30 (including 2 reporting zero)	28 (including 2 reporting zero)	
n (WB)	25 (including 12 reporting zero)	22 (including 7 reporting zero)	

Total Number of **Units Transfused**	2023	2024	% Change
RBC	12 565 950	12 758 561	+2
Platelets	1 936 030	1 992 202	+3
Plasma	1 707 318	1 724 288	+1
WB	3 936	3 361	-15
n (RBC)	23	23	
n (Platelets)	23	23	
n (Plasma)	23 (including 2 reporting zero)	24 (including 2 reporting zero)	
n (WB)	22 (including 12 reporting zero)	19 (including 7 reporting zero)	

Table 3. Summary of total number of recipients transfused by type of BC; 2023 vs. 2024

Total Number of **Recipients transfused**	2023	2024	% Change
RBC	2 202 858	2 320 512	+5
Platelets	266 131	294 558	+11
Plasma	210 292	249 752	+19
WB	1 480	1 547	+5
n (RBC)	18	18	
n (Platelets)	18	18	
n (Plasma)	18 (including 2 reporting zero)	19 (including 2 reporting zero)	
n (WB)	18 (including 12 reporting zero)	17 (including 7 reporting zero)	

1.4. Country-specific trends (2023 vs. 2024) by type of BC

Considering the demographic data[5] of the reporting countries in 2023 and 2024, the transfusion rates pmp were calculated for each reporting country and for each type of BC (excluding MTOC).

1.4.1. RBC transfusion

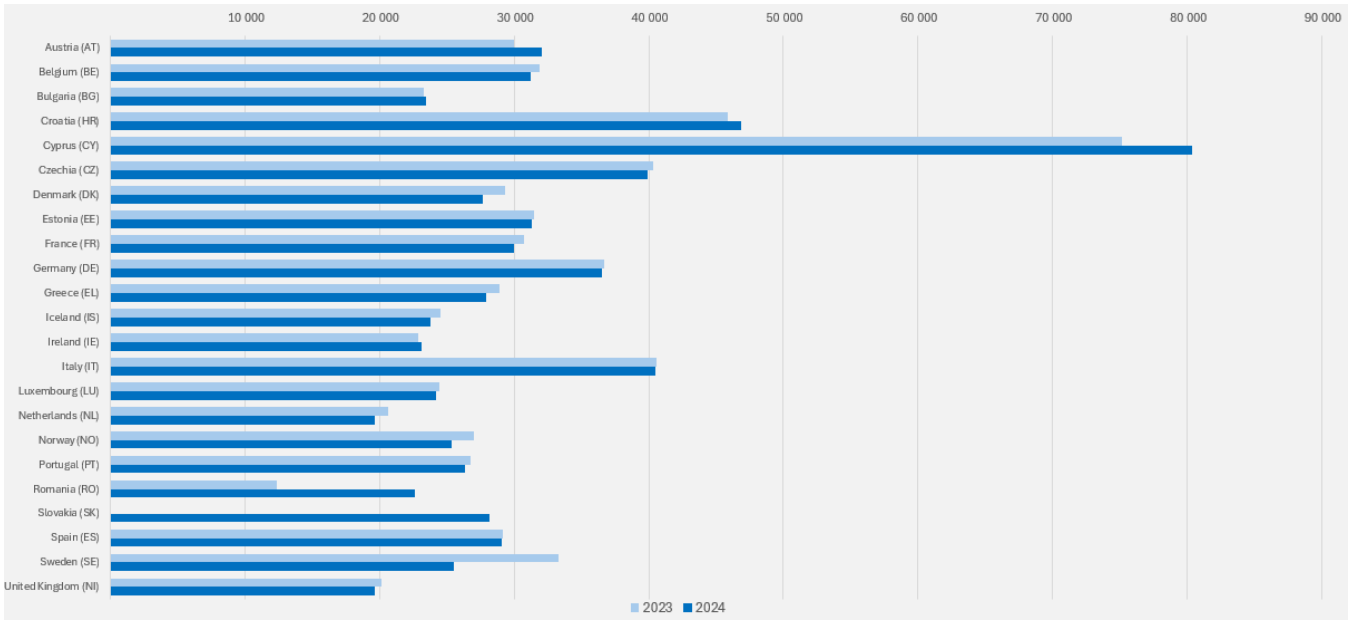


Figure 13. RBC transfusion rates pmp per country; 2023 vs. 2024
Note: FI, LV, LT, PL and SI reported data N/A in both 2023 and 2024 (not shown above).

1.4.2. Platelet transfusion

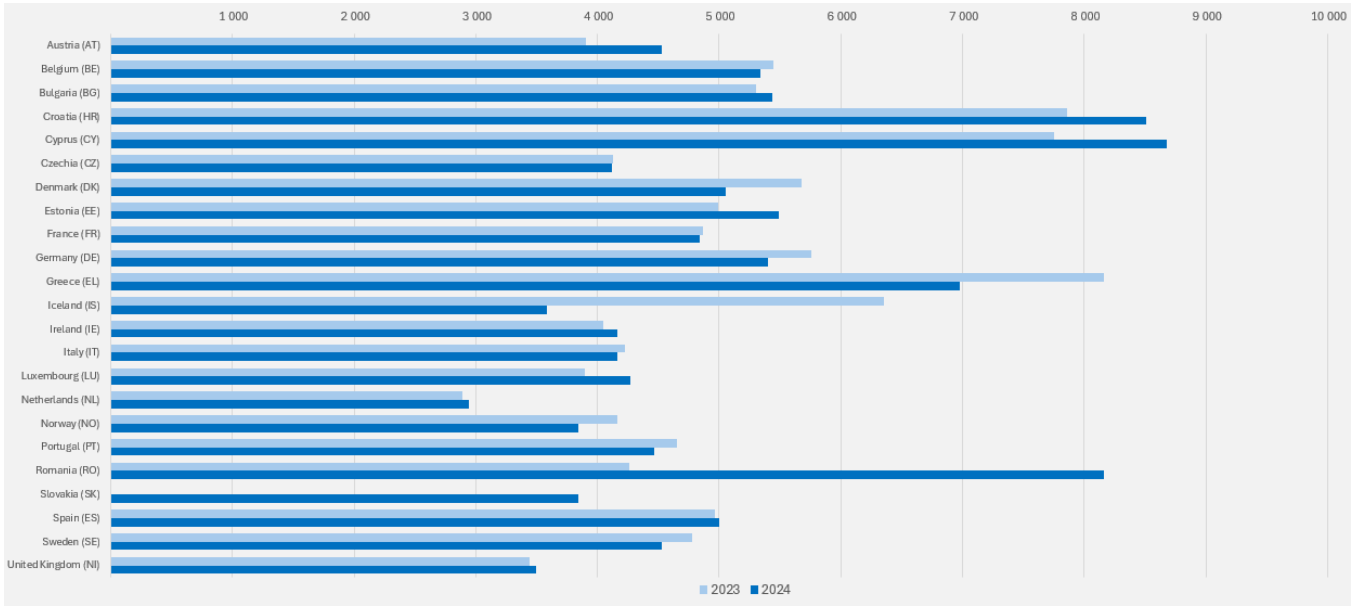


Figure 14. Platelet transfusion rates pmp per country; 2023 vs. 2024
Note: FI, LV, LT, PL and SI reported data N/A in both 2023 and 2024 (not shown above).

[5] https://ec.europa.eu/eurostat/ (Population on 1January Y+1 – total)

1.4.3. *Plasma transfusion*

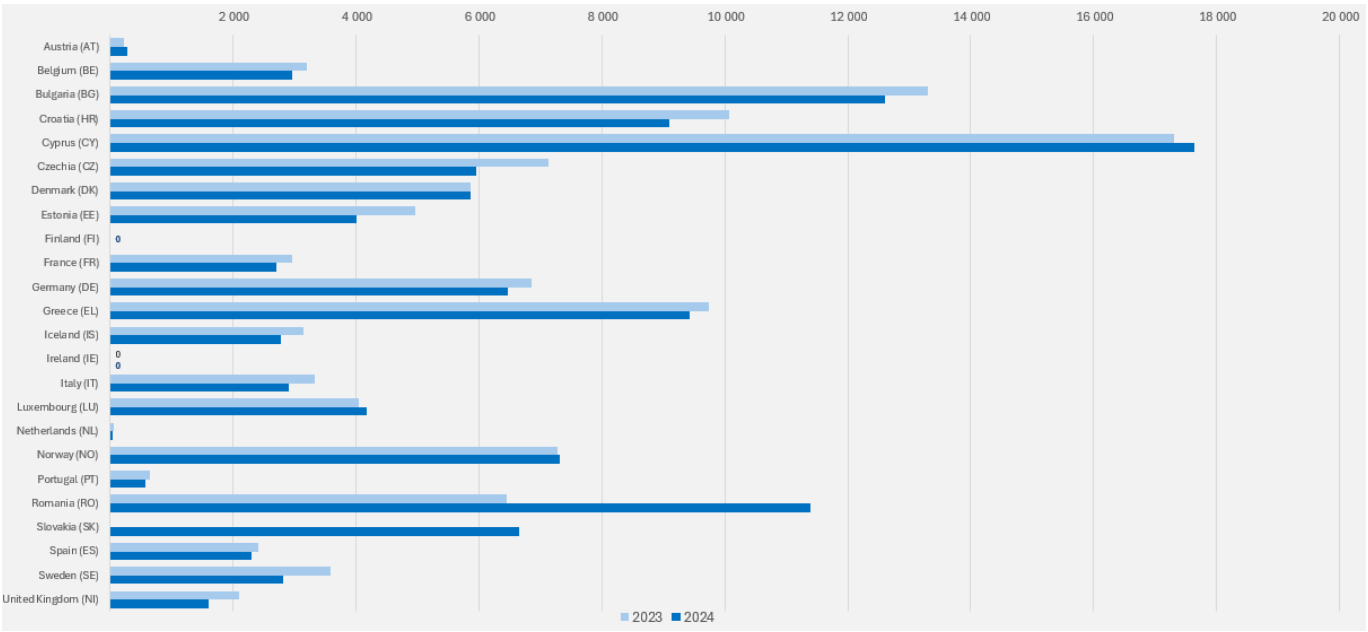


Figure 15. Plasma transfusion rates pmp per country; 2023 vs. 2024

Note: LV, LT, PL and SI reported data N/A in both 2023 and 2024 (not shown above). FI reported data N/A in 2023.

1.4.4. *WB transfusion*

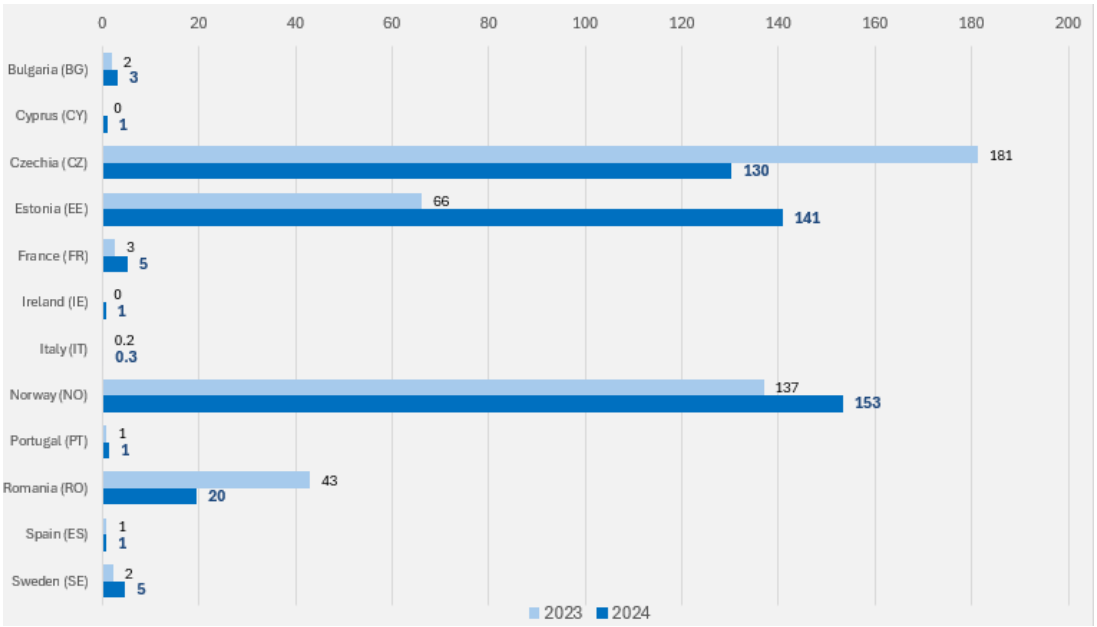


Figure 16. WB transfusion rates pmp per country; 2023 vs. 2024

Note: in 2023, AT, HR, CY, DE, EL, IS, IE, LV, LI, LU, NL and UK(NI) reported 0 units and consequently a zero rate (not shown above). In 2024, AT, BE, HR, CY, EL, IS, NL and UK(NI) reported 0 units of WB transfused and consequently a zero rate (not shown above).

2 Serious Adverse Reactions in Recipients (Mandatory)

Key findings

- In 2024, a total of 1 360 SAR (IL 2-3) were reported across 16.5 million units of blood/BC transfused. This represents a 9% decrease in reporting compared to 2023 (1 490 reports), translating to a total SAR (IL 2-3) rate of 8.3 per 100 000 units transfused.
- Platelets consistently show the highest median SAR (IL 2-3) incidence, followed by RBC and plasma.
- FNHTR, anaphylaxis/hypersensitivity and TACO remain the three dominant reaction types.
- TTI burden decreased: 14 reported (6 less than in 2023). 83% of TTBI cases had pathogen identification (vs 47% in 2023).
- 11 fatalities (IL 2-3), the lowest in four years, with RBC involved in 7/11 cases. Fatality proportion: 0.81% of SAR (IL 2-3).
- While general compliance with fatality (IL 2-3) reporting is evident, harmonisation of detail remains necessary, particularly regarding component preparation, investigations and CAPA documentation.

A **serious** adverse reaction refers to an unintended response, including a communicable disease, in the recipient associated with the transfusion of blood/BC that is **fatal**, **life-threatening**, **disabling or incapacitating**, or which results in, or prolongs, hospitalisation or morbidity.

Insignificant (*no harm to the recipient*) and non-serious reactions (*mild clinical consequences. No hospitalisation. No anticipated long-term consequence/disability*) are not reportable.

SAR are also assessed for **imputability** which refers to the likelihood that the blood transfusion directly caused the observed adverse reaction.
The seriousness of a transfusion reaction is evaluated independently of its possible connection with the transfusion.

The imputability criteria are detailed in the table below:

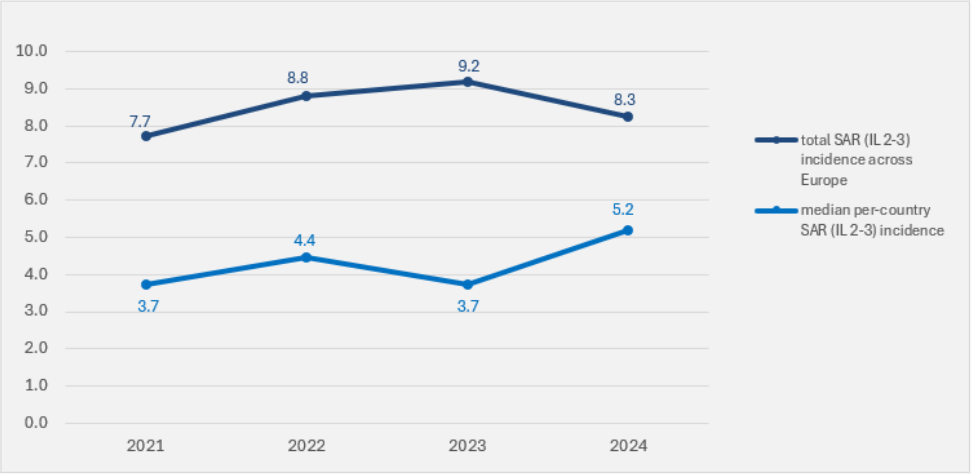
Table 4. Definition of imputability levels

Imputability Level (IL)		Explanation
Not Assessable		When there is insufficient data for the imputability assessment.
0	Excluded	When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to alternative causes.
	Unlikely	When the evidence is clearly in favour of attributing the adverse reaction to causes other than the blood/BC.
1	Possible	When the evidence is indeterminate for attributing adverse reaction either to the blood/BC or to alternative causes.
2	Likely, Probable	When the evidence is clearly in favour of attributing the adverse reaction to the blood/BC.
3	Certain	When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to the blood/BC.

In order to make the boundary between regulatory/statutory obligations and voluntary safety-monitoring efforts explicit, this chapter includes information only on the number of **SAR IL 2-3** in line with article 5(3)(a) of Directive 2005/61/EC. For information on SAR IL 1, refer to **Annex 7. SAR IL 1 (Voluntary)**.

2.1 Yearly trends (2021–2024)

Figure 17 presents the yearly trends in SAR (imputability of likely/probable or certain) incidence from 2021 to 2024 using two complementary metrics: (i) the total SAR (IL 2-3) incidence per 100 000 units of blood/BC transfused and (ii) the median of country-specific SAR (IL 2-3) incidence rates (per 100 000 units transfused) 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	26	24	24	23

Figure 17. Yearly trends in SAR (IL 2-3) incidence: total SAR (IL 2-3) incidence/100 000 units transfused and median per-country SAR (IL 2-3) incidence/100 000 units transfused; 2021–2024

Note 1: total SAR (IL 2-3) incidences are calculated using all reported cases as the numerator and the sum of all reported units transfused (including countries reporting zero SAR) as the denominator. Countries not reporting denominator data but reporting SAR contribute to the numerator but not the denominator. Please refer to the completeness dashboard (Annex 3.) for coverage details.

Note 2: only countries (n) that reported both SAR cases (including zero) and the corresponding number of units of blood/BC transfused were included in the median per-country SAR incidence calculations.

Between 2021 and 2024, the total SAR (IL 2–3) incidence showed a modest upward trend, increasing from 7.7 in 2021 to a peak of 9.2 in 2023, before decreasing slightly to 8.3 in 2024. The median per-country SAR incidence followed a similar but more variable pattern: rising from 3.7 in 2021 to 4.4 in 2022, dipping again to 3.7 in 2023 and then increasing to 5.2 in 2024. These fluctuations suggest that while the overall European SAR burden remained relatively stable, country-level medians reveal greater year-to-year variability, possibly reflecting differences in reporting sensitivity, national vigilance practices, or small-number effects in countries with lower transfusion volumes.

2.2 Geographic distribution

The SAR (IL 2-3) incidence rates per 100 000 units of blood/BC transfused across all reporting countries were determined (Figure 18).

SAR (IL 2-3) incidence in Europe varied from 0 (BG, CY and IS) to 49 (IE), with a median of 5.2 SAR/100 000 units transfused, slightly higher than the 4.4 SAR/100 000 units transfused reported in 2023.

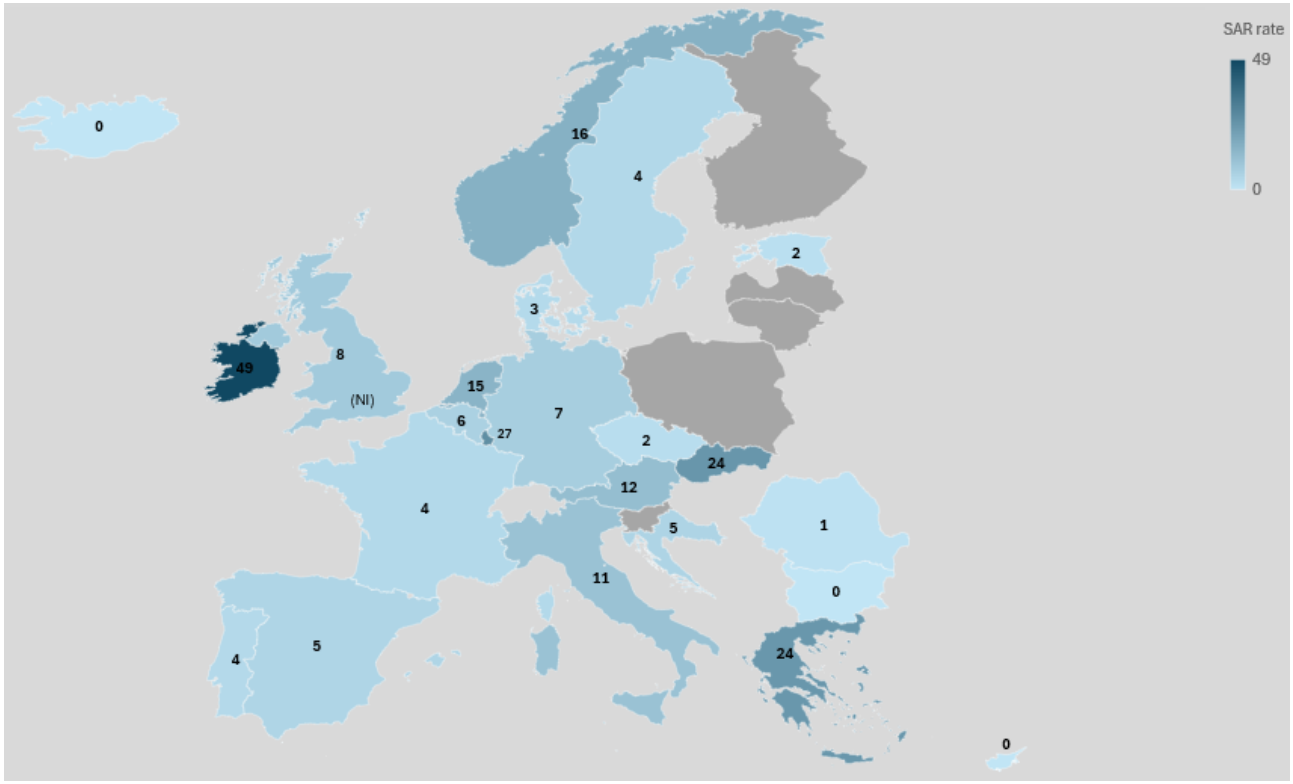


Figure 18. SAR (IL 2-3) incidence rates per 100 000 units transfused in Europe in 2024
Note: countries (FI, LV, LT, PL and SI) that reported SAR cases but reported N/A for the number of units of blood/BC transfused (so incidence could not be calculated) are shown in dark grey.

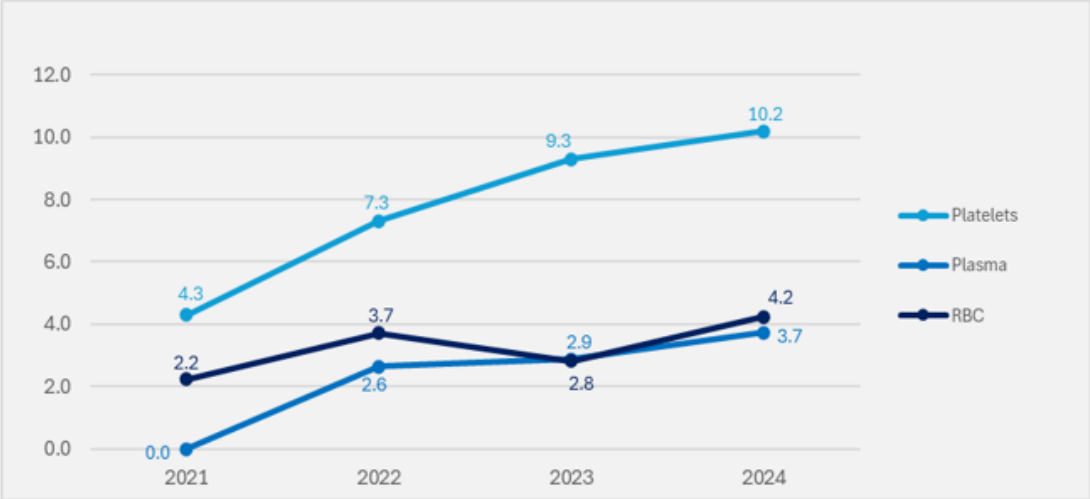
Comparing with 2023, there was a significant increase for LU and IE (27 and 49 vs 0 and 19, respectively). Additionally, NL, HR and SE reported moderate increases (15, 5 and 4 vs 12, 3 and 2 respectively) whereas AT, IT, PT and ES showed decreased incidence rates.

Key countries shaping the SAR picture
- IE reported the highest SAR (IL 2-3) incidence rate (49 per 100 000 units transfused).

2.3 Yearly trends (2021–2024) by type of BC

2.3.1 SAR (IL 2-3)

Figure 19 presents the yearly trends in the median per-country SAR (IL 2-3) incidence per 100 000 units transfused from 2021 to 2024 for each type of BC (excluding WB and MTOC).



n(platelets)	26	24	23	23
n(plasma)	25	21	21	22
n(RBC)	25	24	23	23

Figure 19. Yearly trends in SAR (IL 2-3) incidence (median per-country) per 100 000 units transfused of platelets, plasma and RBC; 2021–2024

Note 1: only countries (n) that reported both SAR cases (including zero) and the corresponding number of units of BC transfused were included in the median per-country SAR incidence calculations.

Note 2: median SAR incidence in WB is not shown above as only one country reported throughout the period (2021: 2 cases; 2022: 0; 2023: 1 case; 2024: 2 cases).

As consistently observed in prior years, platelet transfusions carry the highest median per-country SAR (IL 2-3) incidence rate, substantially exceeding that of RBC and plasma components. This is biologically expected given the immunogenically complex nature of platelet products.

Moreover, the RBC SAR (IL 2-3) rate has remained comparatively stable, while plasma SAR (IL 2-3) rate is exhibiting a modest upward trend.

2.3.2 Fatalities (IL 2-3)

Transfusion-associated fatalities remain exceptionally rare when measured against the sheer volume of blood/BC utilised. Among the transfusion-related deaths, the majority were due to the transfusion of RBC (largely proportional to their dominance in issuance and transfusion volumes), followed by platelets and then MTOC (Figure 20).

In 2024, the risk of death related to transfusion in Europe was 1 in approximately 1.5 million units of blood/BC transfused. Alternatively, this corresponds to a transfusion-related mortality rate of approximately 0.06 per 100 000 units transfused.

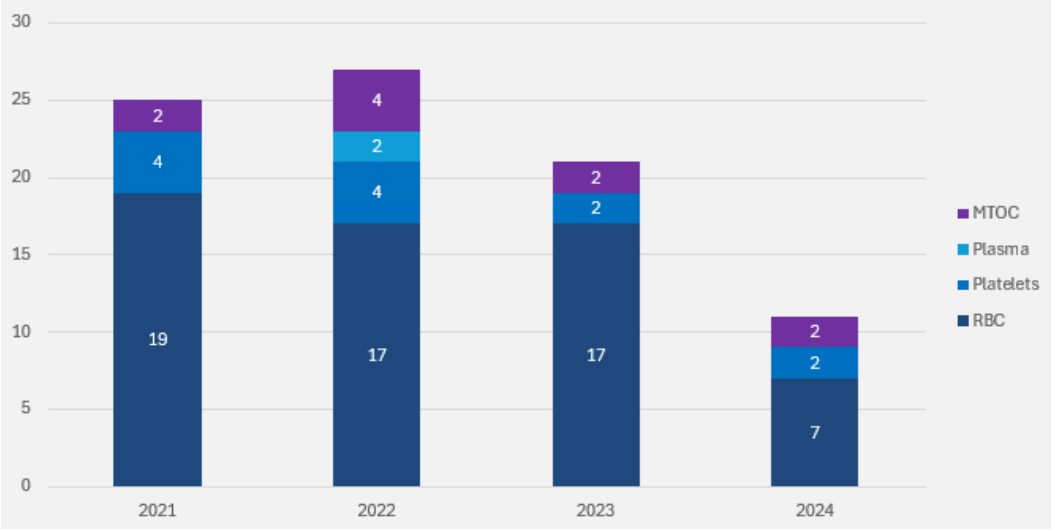


Figure 20. Summary of total number of fatalities (IL 2-3) by type of BC; 2021–2024
Note: no fatalities reported in WB.

2.4 Country-specific trends (2023 vs. 2024) by type of BC

SAR (IL 2-3) incidence rates per 100 000 units transfused per country for each type of BC (excluding MTOC) in 2023 and 2024 is presented in Table 5.

Table 5. SAR (IL 2-3) incidence rates/100 000 units (RBC, platelets or plasma) transfused per country; 2023 vs. 2024

Country	RBC			Platelets			Plasma		
	2023	2024	Absolute change	2023	2024	Absolute change	2023	2024	Absolute change
Austria (AT)	20	12	-8	22	12	-10	48	0	-48
Belgium (BE)	4	5	+1	12	13	+1	5	6	+1
Bulgaria (BG)	1	0	-1	0	0	0	0	0	0
Croatia (HR)	3	5	+2	3	9	+6	0	3	+3
Czechia (CZ)	2	2	0	2	0	-2	10	5	-5
Denmark (DK)	2	1	-1	6	7	+1	3	6	+3
Estonia (EE)	0	2	+2	0	0	0	0	0	0
France (FR)	2	3	+1	9	8	-1	14	10	-4
Germany (DE)	5	6	+1	11	15	+4	5	6	+1
Greece (EL)	26	12	-14	26	58	+32	20	36	+16
Ireland (IE)	18	43	+25	23	79	+56	-	-	-
Italy (IT)	11	8	-3	40	35	-5	11	8	-3
Luxembourg (LU)	0	30	+30	0	34	+34	0	0	0
Netherlands (NL)	9	14	+5	17	17	0	0	0	0
Norway (NO)	9	4	-5	13	28	+15	7	7	0
Portugal (PT)	5	3	-2	12	6	-6	0	0	0
Romania (RO)	1	1	0	1	1	0	1	1	0
Slovakia (SK)	*	19	-	*	58	-	*	28	-
Spain (ES)	6	4	-2	12	10	-2	12	5	-7
Sweden (SE)	2	4	+2	4	2	-2	0	7	+7
United Kingdom (NI)	23	5	-18	45	30	-15	50	0	-50

Note 1: CY and IS reported zero SAR across the different types of BC in both 2023 and 2024 (not shown above).
Note 2: SAR incidence rates in WB not shown above (2023 (IT): 1 SAR reported; 2024 (NO): 2 SAR reported).
*Note 3: *in 2023, SK reported N/A for number of units transfused so incidence could not be calculated.*
*Note 4: highlighted in **red** are changes that represent a **potential real concern**. These countries show multiple SARs (not just 1–2), large transfusion denominators (so rates are stable), sharp increases beyond what small-number variation can explain. Highlighted in **green** are **true improvements** not strongly influenced by small denominators or low SAR counts.*

The comparative data for countries which also reported SAR (IL 2-3) but were missing denominator data (resulting in the impossibility of calculating the incidence rate) are shown in Table 7.

Table 6. Number of SAR (IL 2-3) per country reporting missing denominator data in RBC, platelets and plasma; 2023 vs. 2024

RBC

Country	2023	2024	Absolute change
Finland (FI)	4	7	+3
Latvia (LV)	1	0	-1
Lithuania (LT)	0	1	+1
Poland (PL)	53	54	+1
Slovenia (SI)	6	6	0

Platelets

Country	2023	2024	Absolute change
Finland (FI)	0	6	+6
Latvia (LV)	0	0	0
Lithuania (LT)	0	0	0
Poland (PL)	11	6	-5
Slovenia (SI)	3	4	+1

Plasma

Country	2023	2024	Absolute change
Finland (FI)	0	-	-
Latvia (LV)	1	0	-1
Lithuania (LT)	0	0	0
Poland (PL)	9	9	0
Slovenia (SI)	1	3	+2

2.5 Overview of SAR (IL 2-3) and fatalities (IL 2-3) by type of BC

Overall data collected in 2024 for number of SAR (IL 2-3) and fatalities (IL 2-3) by type of BC are shown in Table 7.

In 2024, the total number of SAR (IL 2-3) reported was 1 360, slightly lower than in 2023. Of the total 1 360 SAR (IL 2-3) reported, 77% were attributed to IL 2 and 23% to IL 3 (vs 75% and 25% in 2023, respectively).

Eleven fatalities (IL 2-3) were reported in recipients in 2024, ten less than in 2023.

Table 7. Summary of total number of SAR (IL 2-3) and fatalities (IL 2-3) by type of BC; 2023 vs. 2024

Total Number of SAR (IL 2-3)	2023	2024	% Change
RBC	972	821	-16
Platelets	312	334	+7
Plasma	143	142	-1
MTOC	62	61	-2
WB	1	2	*(absolute change +1)*
TOTAL	**1 490**	**1 360**	**-9**
n (RBC)	24	24	
n (Platelets)	21	21	
n (Plasma)	16	15	
n (MTOC)	12	10	
n (WB)	1	1	

Total Number of Fatalities (IL 2-3)	2023	2024	Absolute Change
RBC	17	7	-10
Platelets	2	2	0
Plasma	0	0	0
MTOC	2	2	0
WB	0	0	0
TOTAL	**21**	**11**	**-10**
n (RBC)	9	4	
n (Platelets)	2	1	
n (Plasma)	0	0	
n (MTOC)	1	2	
n (WB)	0	0	

2.5.1 SAR (IL 2-3) by type of BC per country

The distribution of number of SAR (IL 2-3) by type of BC per reporting country is shown in Figure 21.

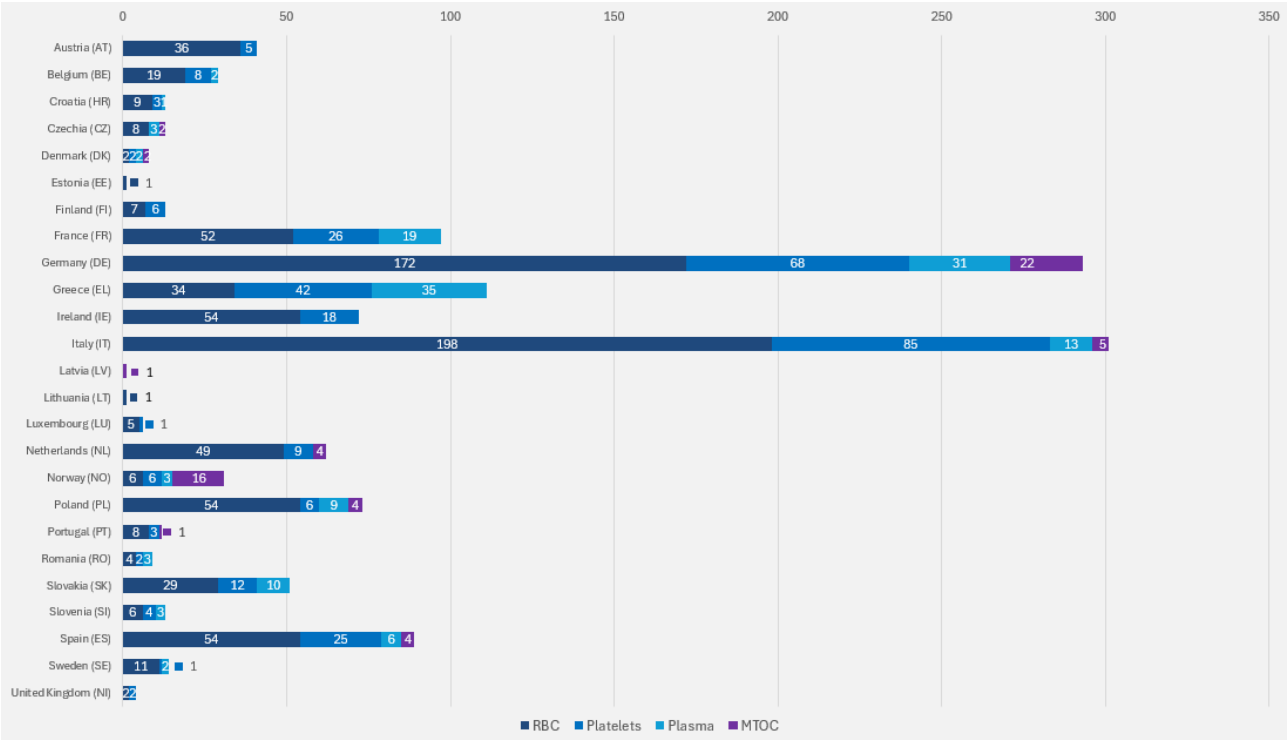


Figure 21. Number of SAR (IL 2-3) by type of BC per country in 2024
Note 1: also 2 SAR for WB from NO were reported (not shown above).
Note2: BG, CY and IS reported zero SAR (not shown above).

2.5.2 Fatalities (IL 2-3) by type of BC per country

Regarding the eleven fatalities (IL 2-3) reported, the country reporting them is detailed in Table 8.

Table 8. Summary of total number of fatalities (IL 2-3) by type of BC per reporting country in 2024

Country (#)	RBC	Platelets	MTOC
Belgium (1)	1		
Finland (1)	1		
France (4)	2	2	
Germany (4)	3		1
Norway (1)			1

Note: zero fatalities reported in plasma and WB.

2.6 Yearly trends (2021–2024) by type of reaction

Transfusion reactions are classified as shown in Table 9. International Society of Blood Transfusion (ISBT) definitions are used (except for transfusion transmitted infections – see 2.7.2).

Refer to Annex 4. Definitions of the reportable types of transfusable reactions.

Table 9. Types of reportable transfusion reactions

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	• Transfusion-associated cardiovascular overload (TACO) • Hypotensive transfusion reaction • Transfusion-associated dyspnoea (TAD)	• Bacterial (TTBI) • Viral (TTVI) ○ HBV, HCV, HIV-1/2, other • Parasitical (TTPI) ○ malaria, other • Fungal (TTFI) • Prion (TTPRI)
Other *(reactions which do not meet the criteria for a defined category)*		

2.6.1 SAR (IL 2-3)

Table 10 shows the percentages of total SAR (IL 2-3) by the main reaction types and Figure 22 shows the trend in reporting from 2021 to 2024.

Table 10. Percentages of total SAR (IL 2-3) by the main reaction types; 2021–2024

Main Types of Reaction	2021	2022	2023	2024
Other	29.9	27.0	11.7	10.4
FNHTR	24.2	23.0	24.6	26.1
Anaphylaxis/ hypersensitivity	15.7	18.6	25.4	25.7
TACO	13.4	13.2	14.4	16.7
Immunological haemolysis	8.4	9.0	13.3	10.4
TAD	3.0	2.6	3.1	3.5
TRALI	2.7	3.6	3.8	3.8

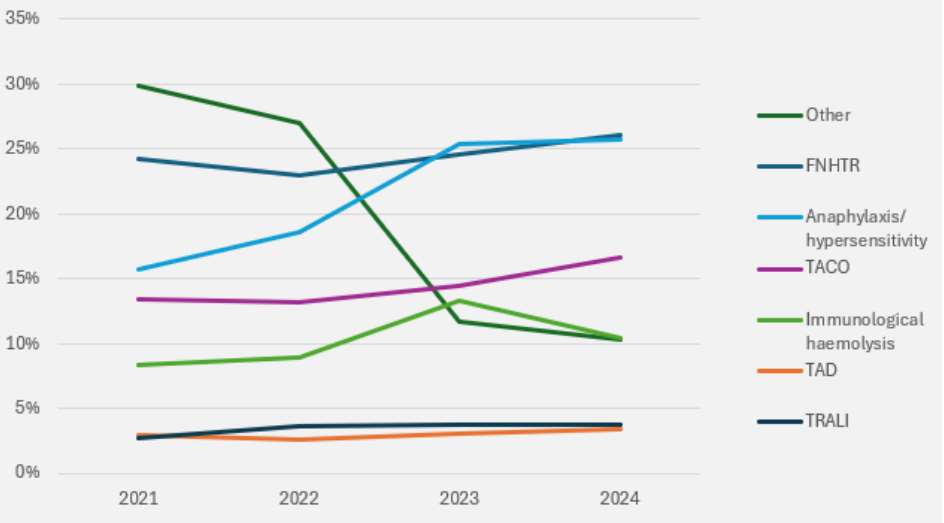


Figure 22. Yearly trends in percentage of total SAR (IL 2-3) by the main reaction types; 2021–2024

This distribution by the main reaction types has remained largely consistent across the 2021–2024 period, confirming that FNHTR and anaphylaxis/hypersensitivity continue to dominate the European haemovigilance landscape. These group of unpredictable and largely unpreventable reactions accounted for 52% of all SAR (IL 2-3) in 2024.
As been noted in UK's Serious Hazards of Transfusion (SHOT) recent reports [2] harm can be minimised by ensuring that treatment given and investigations performed are correctly targeted to the type of reaction. This means using the patient's symptoms and signs to distinguish febrile from allergic reactions.

TACO as the third most frequent type of reaction keeps increasing gradually.
Unlike FNHTR or antibody-mediated reactions, TACO is a largely preventable complication of transfusion practice. Haemovigilance signals derived from SHOT indicate that TACO is a direct physiological consequence of administering fluid volume at a rate or volume that a compromised cardiopulmonary system cannot process. SHOT has heavily emphasized the need for pre-transfusion TACO risk assessments. [3]
The persistent occurrence of TACO indicates that challenges remain in assessing patient risk and selecting appropriate transfusion parameters, even though the blood product itself is safe.

2.6.2 Fatalities (IL 2-3)

Table 11 shows the number of transfusion-related deaths by type of reaction from 2021 to 2024.

Table 11. Summary of total number of fatalities (IL 2-3) by type of reaction; 2021–2024

Type of Reaction	2021	2022	2023	2024	TOTAL
Immunological haemolysis	11	9	9	3	**32**
TACO	8	4	4	2	**18**
TRALI	2	9	3	1	**15**
TTBI	3	4	3	1	**11**
Other	1	0	2	1	**4**
Anaphylaxis/ hypersensitivity	0	1	0	2	**3**
Hypotensive transfusion reaction	0	0	0	1	**1**
TOTAL	**25**	**27**	**21**	**11**	-
% of total SAR (IL 2-3)	**1.81**	**1.78**	**1.40**	**0.81**	-

As shown in Table 11, the number of fatalities (IL 2-3) were at their lowest in 2024, comparing to previous years.
Overall, in the 2021–2024 period, immunological haemolysis, TACO and TRALI were the leading causes of deaths, with a total of 32, 18 and 15 cases, respectively.

2.7 Overview of SAR (IL 2-3) and fatalities (IL 2-3) by type of reaction

2.7.1 SAR (IL 2-3)

As shown previously in Table 10, in 2024, FNHTR was the most prevalent type of reaction (26.1%) followed by anaphylaxis/hypersensitivity (25.7%) and TACO (16.7%).

Table 12. Summary of total number of SAR (IL 2-3) by type of reaction; 2023 vs. 2024

Type of Reaction	2023 position	# SAR 2024 (+/- 2023)
FNHTR	2	355 (-12)
Anaphylaxis/ hypersensitivity	1	350 (-28)
TACO	3	227 (+12)
Immunological haemolysis	4	142 (-56)
Other	5	141 (-34)
TRALI	6	52 (-4)
TAD	7	47 (+1)
Hypotensive transfusion reaction	10	16 (+2)
Non-immunological haemolysis	8	14 (-2)
TTVI	12	8 (+4)
TTBI	9	6 (-9)
PTP	11	2 (-3)
TTPI	13	0 (-1)
TOTAL	-	**1 360** (-130)

Note: zero SAR reported for Ta-GvHD, TTFI and TTPRI in both 2023 and 2024.

In general, the number of cases reported across the different types of reactions decreased in comparison with 2023, apart from TACO and TTVI, which increased slightly (Table 12).

Figure 23 shows the distribution of SAR (IL 2-3) classified as 'other'.

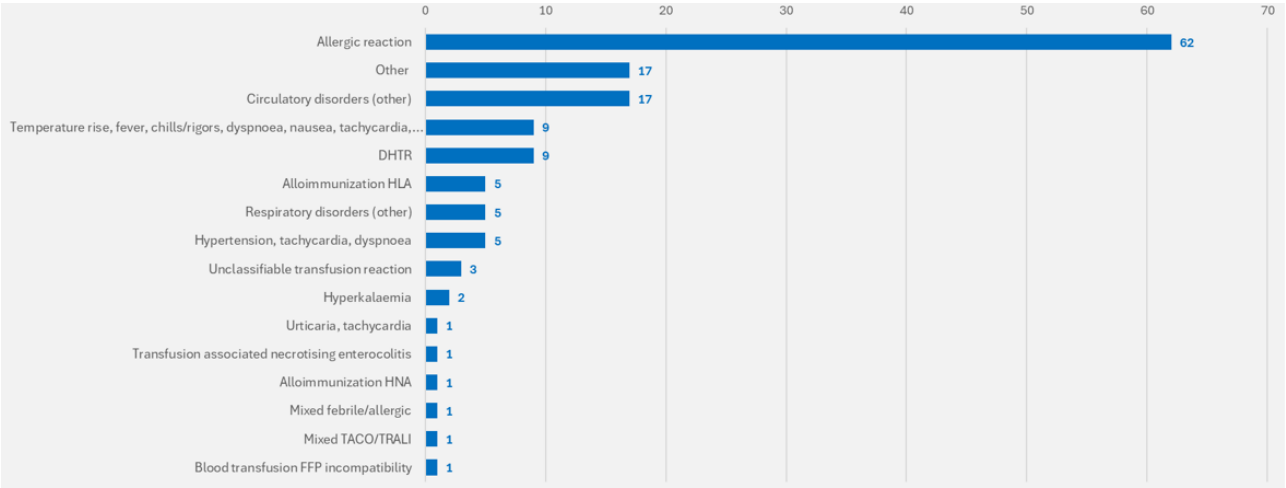


Figure 23. Distribution of SAR (IL 2-3) classified as 'other' in 2024

A detailed summary of the top 5 transfusion reaction types by type of BC for 2023 vs. 2024 is displayed in Table 13 and Table 14.

Table 13. Summary of number of SAR (IL 2-3) (excluding fatalities) by the top 5 reaction types in WB, RBC and platelets; 2023 vs. 2024

Top 5 Reaction Types	WB			RBC			Platelets		
	2023	2024	Absolute Change	2023	2024	Absolute Change	2023	2024	Absolute Change
Anaphylaxis/hypersensitivity	0	1	+1	133	100	-33	140	135	-5
FNHTR	0	0	0	276	224	-52	71	110	+39
TACO	1	0	-1	170	200	+30	12	10	-2
Immunological haemolysis	0	0	0	a) 65 b) 108	a) 62 b) 68	a) -3 b) -40	a) 1 b) 10	a) 3 b) 1	a) +2 b) -9
Other	0	1	+1	103	83	-20	52	34	-18
n (Anaphylaxis/hypersensitivity)	0	1		15	16		17	19	
n (FNHTR)	0	0		11	15		6	8	
n (TACO)	1	0		20	19		7	7	
n (Immunological haemolysis)	0	0		a) 14 b) 20	a) 11 b) 17		a) 1 b) 2	a) 3 b) 1	
n (Other)	0	1		10	14		7	7	

Note: a) due to ABO incompatibility; b) due to other alloantibody

As presented in Table 13, overall, there was a reduction in the number of SAR (IL 2-3) observed in the top 5 reaction types in WB, RBC and platelets. Nevertheless, there were 30 more TACO cases reported in RBC and 39 more FNHTR cases reported in platelets.

Table 14. Summary of SAR (IL 2-3) (excluding fatalities) by the top 5 reaction types in plasma and MTOC; 2023 vs. 2024

Top 5 Reaction Types	Plasma			MTOC		
	2023	2024	Absolute Change	2023	2024	Absolute Change
Anaphylaxis/hypersensitivity	89	91	+2	16	21	+5
FNHTR	15	14	-1	5	7	+2
TACO	9	6	-3	19	9	-10
Immunological haemolysis	a) 3	a) 1	-2	b) 2	b) 4	+2
Other	14	17	+3	4	5	+1

n (Anaphylaxis/hypersensitivity)	14	14		6	6
n (FNHTR)	4	3		3	4
n (TACO)	5	4		7	6
n (Immunological haemolysis)	a) 1	a) 1		b) 2	b)1
n (Other)	4	3		4	3

Note: a) due to ABO incompatibility; b) due to other alloantibody.

2.7.2 Transfusion-Transmitted Infections (TTIs)

As per SHOT definition, a case is classified as a TTI if the investigation revealed:
The recipient 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** at least one component received by the infected recipient was donated by a donor who had evidence of the same transmissible infection.
- **or** at least one component received by the infected recipient was shown to contain the agent of infection.

Overall, the total number of confirmed TTIs (IL 2-3) decreased substantially, from 20 in 2023 to 14 in 2024, driven primarily by a marked reduction in TTBI (Table 15).

Table 15. Summary of TTIs (IL 2-3) by type of TTI; 2023 vs. 2024

Type of TTI	2023	2024	Absolute Change
TTBI	15	6	-9
TTVI	4	8	+4
TTPI	1	0	-1
TOTAL	20	**14**	**-6**

n (TTBI)	7	4
n (TTVI)	3	3
n (TTPI)	1	0

Note: zero TTFI and TTPRI cases reported in both 2023 and 2024.

As presented in Table 16, RBC-related TTIs declined across all infection categories, with a notable reduction in TTBI (-6). In contrast, TTIs associated with platelets increased slightly, rising from 8 to 10, mainly due to an increase in TTVI (+5) despite reductions in bacterial TTIs (-3). Although absolute numbers remain small, this shift highlights platelets as a continuing area of vigilance.

Table 16. Summary of TTIs (IL 2-3) by type of TTI and by type of BC; 2023 vs. 2024

Type of TTI	RBC			Platelets			Plasma			MTOC		
	2023	2024	Absolute Change	2023	2024	Absolute Change	2023	2024	Absolute Change	2023	2024	Absolute Change
TTBI	7	1	-6	8	5	-3						
TTVI	3	2	-1	0	5	+5	1	0	-1	0	1	+1
TTPI	1	0	-1									
TOTAL	**11**	**3**	**-8**	**8**	**10**	**+2**	**1**	**0**	**-1**	**0**	**1**	**+1**

Note 1: zero TTFI and TTPRI cases reported in both 2023 and 2024.
Note 2: zero TTIs reported in WB in both 2023 and 2024.

The exact infectious pathogen was provided in 5 out of 6 (83%) TTBI cases reported (Table 17), a notable improvement from 47% in 2023. This improvement in pathogen characterisation reflects the value of standardised post-investigation reporting and should be encouraged across all reporting countries. Where pathogen identification remains incomplete, reporting establishments are encouraged to document at minimum the genus and route of contamination, as this information is essential for corrective action and benchmarking against international contamination databases such as the European Centre for Disease Prevention and Control (ECDC) pathogen surveillance systems and ISBT's bacterial contamination working group data.

Table 17. Summary of the infectious pathogen reported in TTBIs by type of BC per country in 2024

Country (#SAR)	RBC	Platelets
France (1)		(1) *Staphylococcus ureilyticus*
Germany (3)	(1) *E. coli*	(2) *Bacillus cereus*
Greece (1)		(1) N/A
Spain (1)		(1) *E. coli*

Note: the Spanish case occurred in 2023, but the investigation was only finalised in 2024.

Regarding TTVIs, the exact infectious pathogen was provided in all reported cases (the same as in 2023). As presented in Table 18, of the 8 TTVIs, five were reported in platelets, two in RBC and one in MTOC.

Table 18. Summary of the infectious pathogen reported in TTVIs by type of BC per country in 2024

Country (#SAR)	RBC	Platelets	MTOC
Finland (4)	(1) Other: HEV	(3) Other: HEV	
France (1)		(1) Parvo-B19	
Germany (3)	(1) Parvo-B19	(1) Parvo-B19	(1) Parvo-B19

2.7.3 Fatalities (IL 2-3)

As mentioned previously, five countries (BE, FI, FR, DE and NO) reported a total of 11 fatalities (IL 2-3) in recipients in 2024. Of these fatalities, six were assigned IL2 and five IL3. The type of reaction associated with these fatalities is captured in Table 19 and the comparison with 2023 data is shown in Table 20.

Table 19. Summary of number of fatalities by type of reaction and by IL 2 or 3 in 2024

Type of Reaction	# IL 2	# IL 3
TACO	2	
Anaphylaxis/ hypersensitivity	2	
Immunological haemolysis due to ABO incompatibility		2
Other (DHTR)		1
TTBI		1
Immunological haemolysis due to other alloantibody		1
TRALI	1	
Hypotensive transfusion reaction	1	
TOTAL	**6**	**5**

Table 20. Summary of number of fatalities (IL 2-3) by type of reaction and by type of BC; 2023 vs. 2024

Type of Reaction	RBC			Platelets			MTOC		
	2023	2024	Absolute Change	2023	2024	Absolute Change	2023	2024	Absolute Change
Immunological haemolysis	a)5 b)4	a)2 b)1	a)-3 b)-3						
TACO	4	1	-3				0	1	+1
TRALI	1	0	-1				2	1	-1
TTBI	1	0	-1	2	1	-1			
Anaphylaxis/hypersensitivity	0	1	+1	0	1	+1			
Hypotensive transfusion reaction	0	1	+1						
Other	2	1	-1						

Note: no fatalities were reported in plasma and WB in both 2023 and 2024.

As shown in Table 20, in comparison with 2023, 2024 saw a reduction in fatalities associated with both TACO and immunological haemolysis, namely in RBC. This has contributed to the overall reduction in recipient fatalities from 21 to 11.

2.8 Fatalities (IL 2-3) in recipients – case studies

The ***Common Approach***, 2025 edition [1], states: "Concerning reports where an SAR is confirmed to be fatal, any relevant information should be reported, such as:
(i) a brief description of patient details (if possible: gender, age, initial illness, clinical indications for transfusion etc.);
(ii) a brief description of the occurrences that led to the fatality. **In the case of a TTI, state the pathogen (species) which was demonstrated (NEW)**;
(iii) a list of transfused units of blood/BC; for each unit, any relevant information regarding the preparation of the implicated component(s) (leucodepletion, apheresis...);
(iv) the conclusions and follow-up actions (corrective and preventive), if appropriate."

Overall, the quality and completeness of fatality reporting in 2024 varied significantly across countries. Most reports contained adequate clinical descriptions. However, the level of detail regarding component preparation, transfusion chronology, root cause assessment and corrective/preventive actions was not uniform.
Several countries provided high-quality narratives that met all (or nearly all) ***Common Approach*** requirements, including clear patient history, detailed timelines, component-specific technical information and explicit conclusions. Other reports lacked essential elements, particularly transfused component characteristics, preparation details and documented corrective and preventive actions (CAPA). The variability in reporting may suggest that, while many NCA have well-established fatality investigation pathways, others may benefit from further guidance and harmonisation to ensure consistent adherence to the ***Common Approach***.

For transparency and learning, a small number of representative cases are then presented below to support clinical learning across the European haemovigilance network.

Case 1: Severe Anaphylaxis (RBC), IL2

- **(i) Patient details:** 66-year-old patient, with a following medical history: diabetes type II, hypertension, heart disease, endocarditis (aortic valve replacement), cerebral vascular accident and chronic obstructive pulmonary disease; Chronic alcoholism, active smoking.
- **(ii) Events leading to the fatality:** He was admitted to hospital with anaemia due to gastrointestinal bleeding (melena), of unspecified cause. Hb was 72 g/L. Immediate clinical manifestations from the first ml transfused with facial oedema, macroglossia, respiratory discomfort and grunting without skin manifestations. Immediate medical management of the upper airway obstruction was unsuccessful, followed by rescue tracheostomy (because intubation had failed) and continued ventilation and cardiopulmonary resuscitation for 30 minutes without success.
- **(iii) List of transfused units:** One RBC prescribed.
- **Investigation:** No known allergic history, eczema of both legs. The patient had already been transfused without adverse reactions. Post mortem biomarkers showed histamine >100 nmol/L (standard <10 nmol/L) and tryptase 10.1 µg/L (below 11 µg/L but above the 95th percentile of 8.4 µg/L). The donor of RBC is a regular donor. No medication taken. No adverse reaction had occurred with BC derived from other donations.
- **(iv) Conclusions and Follow-up actions:** Hypoxia would appear to be the main cause of the cardiorespiratory arrest.

Key compliance strengths: Full patient history; biomarker data; donor history

Case 2: Other (delayed haemolytic transfusion reaction (DHTR)), RBC, IL3

- **(i) Patient details:** A 23-year-old patient with homozygous sickle cell disease, treated with hydroxyurea (baseline Hb 80g/L) and Oxbryta (voxelotor) since July 2023, with a following medical history: multiples vaso-occlusives crises, acute thoracic syndrome, cerebral vasculopathy, cholecystitis and osteomyelitis. Transfusion history with in 2023, no antibody identified. He was receiving several doses of rituximab. The last dose was in January 2024. He was transfused in March 2024 before a haemopoietic stem cell transplantation with two phenotyped and matched RBC, each preceded by a blood exchange.
- **(ii) Events leading to the fatality:** At day 5 after transfusion, onset of vaso-occlusive crisis of both hips, and Hb level was 94 g/L with biological signs of haemolysis (intermediate DHTR risk), no new antibodies identified. Hb A 3.3%, Hb S 63.4%. He was hospitalised in the continuous medical monitoring department for further management. At day 6 after transfusion, in the morning, clinical deterioration, renal failure with acidosis and severe hyperkalaemia. Treated with Eculizumab and renal dialysis. Unfavourable neurological and respiratory outcome (acute respiratory distress) requiring intubation in the afternoon. Thoracic angioscan showed bilateral parenchymal condensation. Cardiogenic shock (right heart) developed during the night, with no response to vasopressor amines. Haemolysis parameters progressively worsened with increasing renal failure, and the Hb level rose to 50 g/L. At day 7 after transfusion, there was a sudden haemodynamic deterioration with severe hypotension. A follow-up transthoracic ultrasound revealed a major acute pulmonary heart with systolic failure of the left ventricle. The patient died a few hours later in multivisceral failure despite maximum resuscitation.
- **(iii) List of transfused units:** Two phenotyped and matched RBC, each preceded by a blood exchange.
- **(iv) Conclusions and Follow-up actions: (not mentioned)**

Points for consideration: Do hospitals have sickle cell disease-specific transfusion protocols? and are they being applied?
It also illustrates the difficulty of attributing causality when no new antibodies are detected, which has direct implications for imputability scoring.

Case 3: Suspected TACO (RBC), IL2

- **(i) Patient details:** (M, 84 years): History: Patient known by palliative support team: AML + aortic valve stenosis.
- **(ii) Events leading to the fatality:**
  - General malaise (palliative; AML)
  - Hypertension: before transfusion 162/66, after 15' 173/81, stop transfusion at 12:21 213/86
  - Temp: before transfusion 37°C, after 15' 36.9°C, stop transfusion 37.8°C + shivering
  - Shivering fever again in the evening: temp at 18:00: 38.2°C and 19:25 38.4°C
  - At 20:00: oxygen administration (sat 87%)
  - At 20:45: patient deceased
- **(iii) List of transfused units: (not mentioned)**
- **(iv) Conclusions and Follow-up actions:** Still haemolysis? Acute pulmonary edema? Due to underlying disease?

Key deficiencies: ✕ Component details missing; ✕ Limited clinical narrative: hypertension and shivering described, but no detailed examination findings, fluid balance, imaging or lab outcomes; ✕ No CAPA documented.

Points for consideration: TACO is typically preventable, but insufficient information prevents drawing conclusions about transfusion rate, volume or monitoring. It also illustrates the blurred line between TACO, TAD, and disease progression.

Case 4: Hypotensive transfusion reaction (RBC), IL2

Female (80 years old) had acute bleeding and also suspected to have septic shock. Patient died less than 24 hours from the transfusion. Patient's IgA levels were found to be normal. Microbial culture was performed on the remains of the RBC unit and there was no growth. It is unlikely that the patient's symptoms were due to contaminated RBC unit.

Key deficiencies: ✕ Very brief description, insufficient detail on transfusion sequence or clinical deterioration; ✕ No transfused component preparation details; ✕ No CAPA documented.

Point for consideration: This case highlights how missing detail prevents proper classification (e.g., distinguishing between septic shock, hypotension or coexisting clinical causes).

3 Serious Adverse Events (Mandatory)

Key findings

- In 2024, 4 764 SAE were reported, a 108% increase compared to the 2 294 SAE recorded in 2023, driven almost entirely by Romania (67% of all SAE).
- European total SAE incidence doubled to 19.5 per 100 000 units processed, up from 9.7 in 2023, once again, driven by Romania's dataset. However, the median per-country value was consistent with previous years.
- Activity steps most associated with SAE: storage (42%), WB collection (17%) and processing (15%).
- Root cause pattern shifted: component defect (60%) overtook human error (14%) due to Romanian reporting. Furthermore, a substantial proportion of its records contained insufficient detail which severely limits qualitative analysis. (NOTE: excluding Romania, human error remained the leading cause (38%)).
- Type of human error: 78% of human error SAE were incorrect decisions/omissions while following correct procedures, rather than knowingly following wrong procedures (5%); most occurred at issue and donor selection.

Only adverse events (AE) considered ***serious***, i.e., when they **may** put in danger blood donors or recipients of blood/BC, or they **may** have a negative impact on blood donation or on transfusion of patients are reportable to the EC.

Early identification, analysis and evaluation of SAE provide an up-to-date overall picture of safety in the transfusion chain and of the nature and dimension of the expected risks. Investigation of these events can provide additional information about the causes of avoidable transfusion incidents and show where improvements are necessary and possible.

Deviations from standard operating procedures (SOPs) in reporting establishments, or other AE which have implications for the quality and safety of blood/BC, should be reported to the EC only when one or more of the criteria described in Table 21 applies.

Table 21. Criteria for inclusion of SAE

Scenario	Examples
Inappropriate blood/BC have been issued/distributed for use, even if not used	- BC distributed for use with incorrect blood group labels, - BC distributed for use without the mandatory donor testing results, - BC issued with incorrect cross-matching information, - BC distributed for use despite a post-donation notification from the donor implying a disease transmission risk, - BC distributed/issued for use despite having been stored at temperatures outside the required range, - BC issued by the hospital blood bank (HBB) without specific characteristics requested by the treating physician (e.g., irradiation, cytomegalovirus (CMV) negative).
The AE resulted in loss of any irreplaceable highly matched (i.e. recipient specific) blood/BC	- BC prepared for a patient with highly specific and urgent needs lost due to a storage or processing error, - BC of a very rare group collected for a specific recipient and lost due to a storage or processing error.
The AE resulted in the loss of a significant quantity of unmatched blood/BC – a significant quantity is considered a loss that will have a negative impact (delay or cancellation) on treatment or surgery	- in a BE, an undetected cold-room breakdown with the consequent discard of number of red cell concentrates (RCC) creating a problem to respond to requests for RCC from hospitals, - a failure of the virology testing equipment results in 50% of a large blood establishment (BE) (supplying many hospitals) platelet stock expiring without being cleared for issue.

The AE could have implications for other patients or donors because of shared practices, services, supplies or donors (e.g., repeated event inside or outside the BE/HBB)	- a defect is detected in a haemoglobin testing device known to be used by other BE – no harm caused to donors due to parallel testing by a different method.
The AE could significantly impact the blood transfusion system (e.g., by jeopardising the confidence of blood donors or recipients)	- confidential donor information is accidentally made publicly accessible, - donations are collected, in error, from underage donors.

The term "near miss event"[6] is not defined in the Blood Directive but is a commonly used term. A near-miss is functionally a free lesson, an error that occurred in the chain but was caught by chance or secondary checks right before patient harm occurred. If 'near miss events' meet the criteria listed in the table above, they are reportable as SAE.

When a SAE results in a reportable SAR in a blood recipient or donor, only the SAR, not the SAE, should be reported.

3.1 Yearly trends (2021–2024)

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 24 presents the yearly trends in SAE incidence from 2021 to 2024 using two complementary metrics: (i) total SAE incidence per 100 000 units of blood/BC processed and (ii) the median of country-specific SAE incidence rates (per 100 000 units processed) 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.

[6] According to SHOT, near miss events are "an error or deviation from standard procedures or policies that is discovered before the start of the transfusion and that could have led to a wrong transfusion or a reaction in a recipient if transfusion had taken place." https://www.shotuk.org/reporting/ (accessed 31 March 2026)

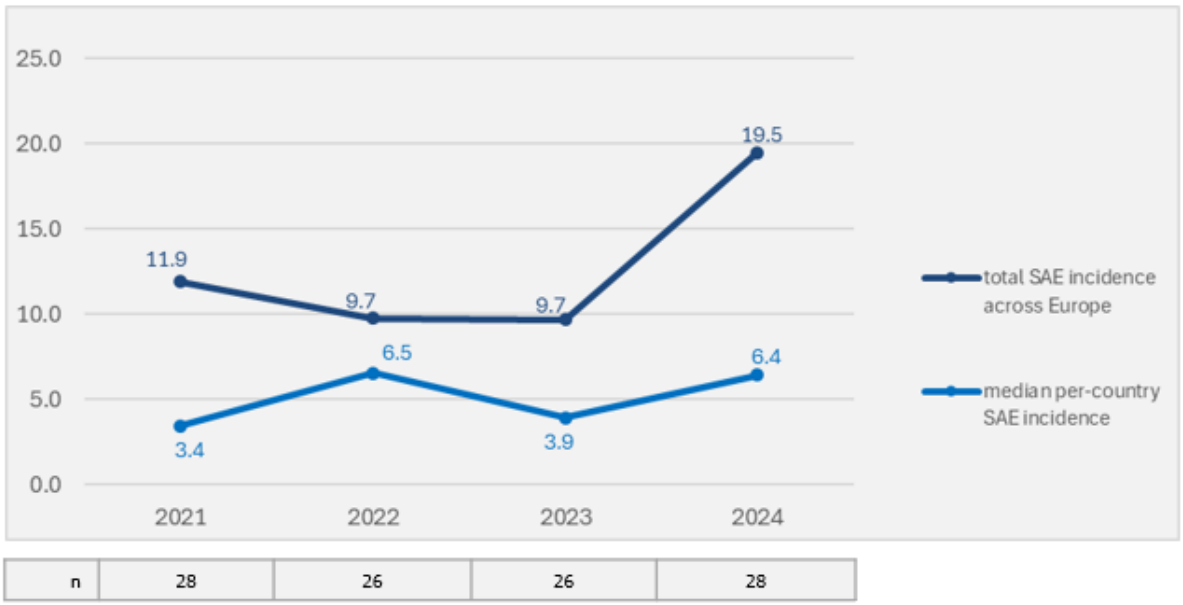


Figure 24. Yearly trends in SAE incidence: total SAE incidence/100 000 units processed and median per-country SAE incidence/100 000 units processed; 2021–2024

Note 1: total SAE incidences are calculated using all reported cases as the numerator and the sum of all reported units processed (including countries reporting zero SAE) as the denominator. Countries not reporting denominator data but reporting SAE contribute to the numerator but not the denominator. Please refer to the completeness dashboard (Annex 3.) for coverage details.

Note 2: only countries (n) that reported both SAE cases (including zero) and the corresponding number of units of blood/BC processed were included in the median per-country SAE incidence calculations.

Figure 24 shows that between 2021 and 2023, both the total and median per-country SAE incidence rates were generally stable. The sharp increase in 2024, with the total incidence more than doubling relative to 2023, is attributable to the SAE dataset submitted by Romania. When examined at the median country level, SAE patterns remained stable and consistent with previous years.

When Romania's contribution is excluded, the total SAE incidence for 2024 falls from 19.5 to 6.4 per 100 000 units processed, a figure lower than the 2023 total of 9.7, suggesting no deterioration in the overall safety performance.

3.2 Geographic distribution

24 423 977 blood units were processed in 2024 according to data provided by 28 countries. This was a slight increase in comparison with the previous year (23 700 556 reported by 26 countries).

A total of 4 764 SAE were reported in 2023 by 25 countries (AT, BE, HR, CY, CZ, DK, EE, FI, FR, DE, EL, IE, IT, LV, LU, NL, NO, PL, PT, RO, SK, SI, ES, SE and UK(NI)), representing a 108% increase in comparison with 2023 (2 294). This alarmingly shift can be explained by Romania's data, which alone accounts for 67% of the total number of SAE reported.

SAE incidence rates per 100 000 units of blood/BC processed across all reporting countries were determined (Figure 25). There was a wide range of SAE incidence rates, with the lowest being 0 (BG, IS and LT) and the highest reaching 332 (RO). The median was 6.4 SAE/100 000 units processed.

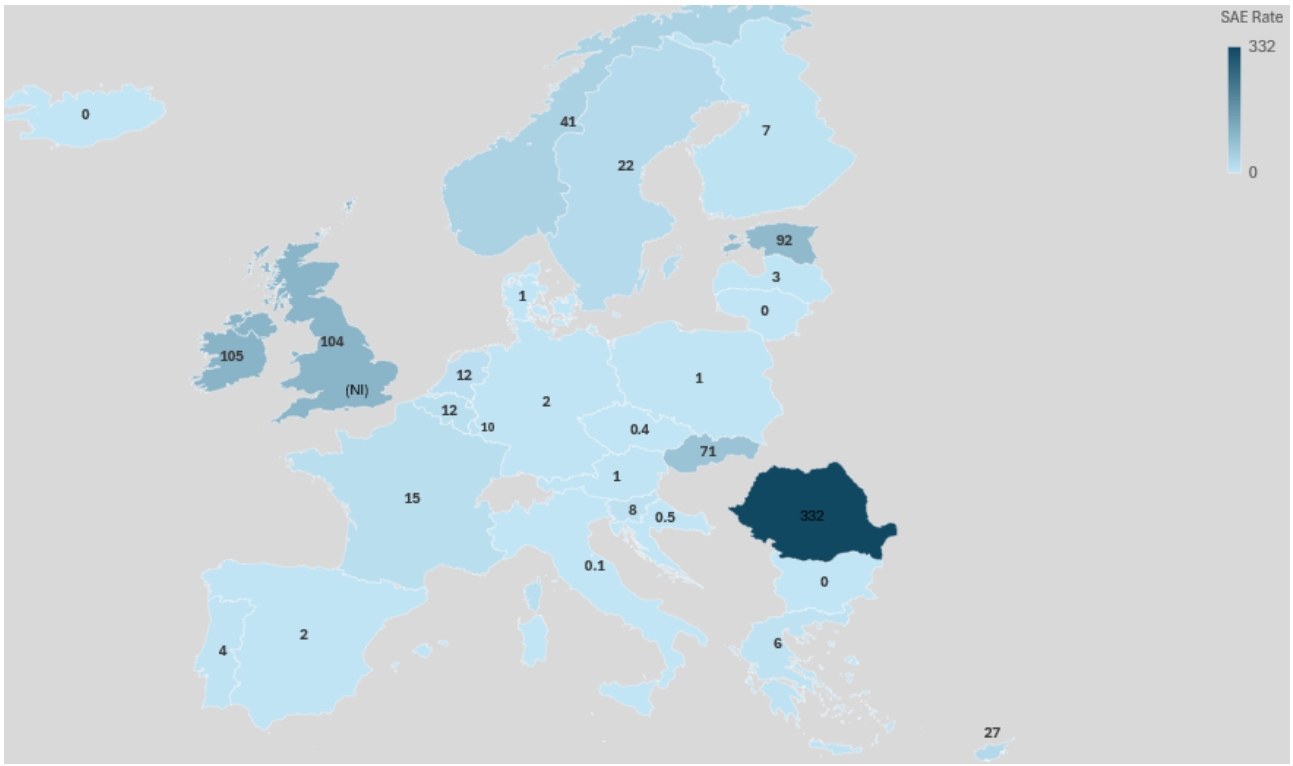


Figure 25. SAE incidence rates per 100 000 units processed in Europe in 2024

3.3 Country-specific trends (2023 vs. 2024)

Figure 26 compares the SAE incidence rates (per 100 000 units processed) per country in 2024 with 2023.

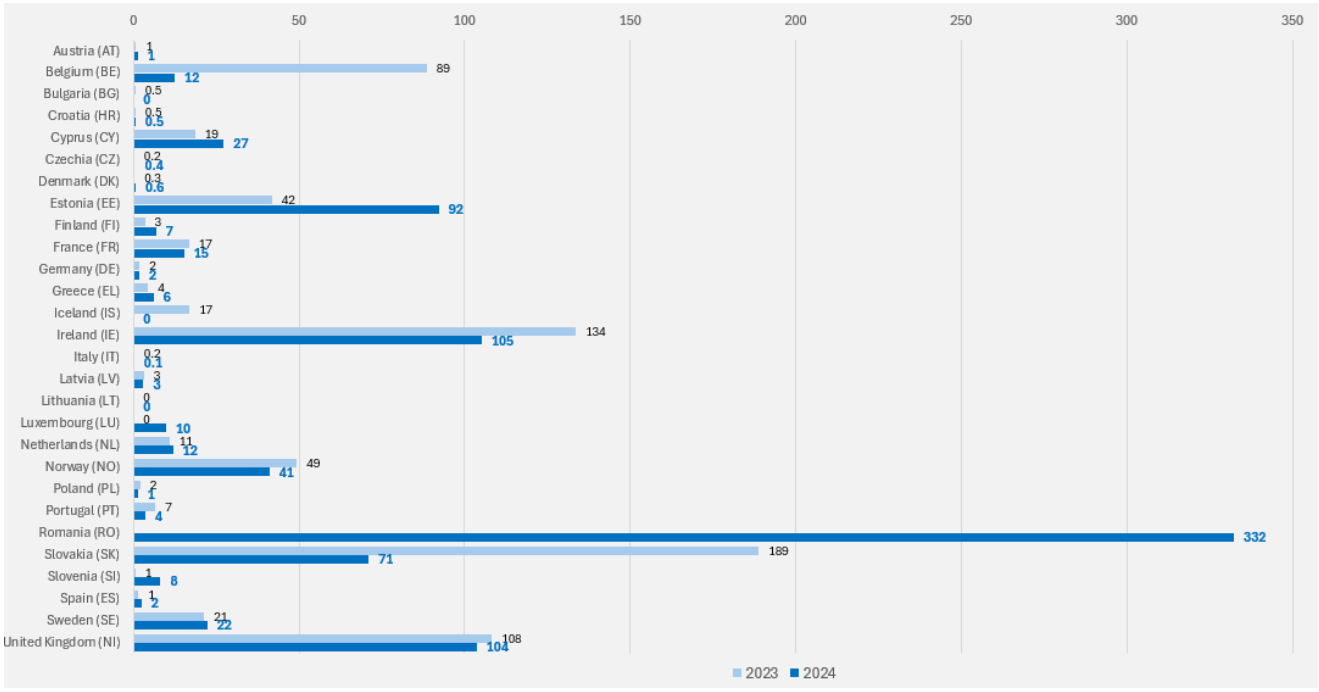


Figure 26. SAE incidence rates per 100 000 units processed per country; 2023 vs. 2024

As presented in Figure 26, Romania reported the highest incidence rate (vs. N/A in 2023). Furthermore, there was a significant rate increase for EE and SI in comparison with 2023, while BE, IE and SK showed a clear improvement.

Key countries shaping process safety picture

- RO reported an extremely high SAE incidence of 332 per 100 000 units processed.
- Comment RO: "*In 2023, there were limitations in our reporting system that led to underreporting or incomplete documentation of events. For this reason, "N/A" was indicated for that year. Starting in 2024, we implemented a revised SAE reporting protocol, along with additional training sessions for personnel involved in the identification and reporting of adverse events. The reporting criteria have been broadened to include cases previously considered minor or ambiguous, in alignment with updated haemovigilance recommendations*."

3.3.1 Overview of SAE per country

The number of SAE reported per country is shown in Figure 27.

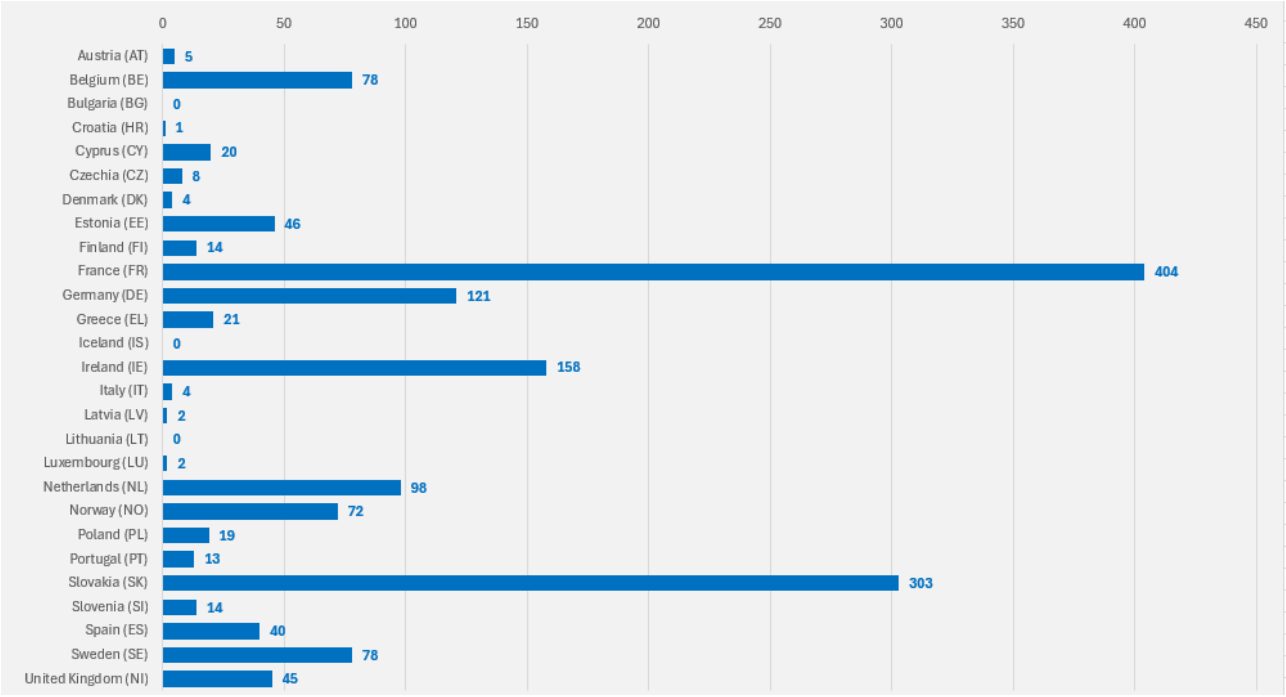


Figure 27. Number of SAE per country in 2024
Note: outlier RO (SAE= 3 194) not shown above.

3.4 Overview of SAE by activity step

Clusters of errors at a specific point in the transfusion chain are indicative of particularly critical process points. As per the ***Common Approach***, 2025 edition [1], there are nine crucial points (activity steps) where errors might happen in the transfusion process. Their definitions are explained in the table below.

Table 22. Definitions of activity steps for SAE

Activity Step	Definition
1. Donor selection	the evaluation carried out to avoid collecting blood from donors with increased risk of complications and to avoid risk of TTI or other adverse reactions in the recipient. (exclusive to BE)
2. WB and apheresis collection	the act of collection of WB or apheresis donations. (exclusive to BE)
3. Testing	the act of testing blood donations to meet the requirements of Directive 2002/98/EC Annex IV, as well as supplementary national requirements. This includes donor testing as well as BC testing. (exclusive to BE)
4. Processing	the process of transforming donations of WB and apheresis donations into issuable components intended for transfusion. This also involves secondary processing such as irradiation. (exclusive to BE)
5. Storage	the act of storing blood/BC at BE or HBB and the written SOPs to ensure maintenance of quality and safety from the time blood/BC are released from a BE and distributed to an HBB. (exclusive to BE)
6. Distribution	the act of delivery of blood/BC to other BE, HBB and manufacturers of blood and plasma derived products. It does not include the issuing of blood/BC for transfusion. (exclusive to BE)
7. Component selection	the selection of the appropriate component based on the recipient's needs. This occurs before issue. (BE or HBB)
8. Compatibility testing/Cross-matching	procedures of blood group serological investigations of the intended recipient and compatibility testing with donor red cells, carried out before transfusion. It includes procedures for (electronic) compatibility verification in facilities where "Type and Screen" is used for eligible patients. (BE or HBB)
9. Issue	the process of linking the correctly selected component to the correct patient and patient records and the labelling of that component, to maintain traceability. (BE or HBB)
Other	any other activity or parameter in the process that can affect the quality and safety of the component that may harm a patient.

EU legislation[7] 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.

However, practical experience demonstrates that this boundary can be blurred because the two legal spheres are closely interconnected in operational terms. For example, BC may be received by clinical staff at the hospital and stored minutes or even hours prior to the transfusion in a fridge next to the clinical area that is monitored by the HBB. These dark grey zones cause uncertainty over which SAE should be reported under the Blood Directives.

Storage, even after issue to a clinical area, falls within the scope of the Blood Directive and any SAE that occur during this time are therefore reportable. For example, a unit of blood may be stored incorrectly on a ward and then returned to the blood fridge for use at a later time, or a unit of blood may be incorrectly packaged for distribution to another hospital when a patient is transferred.

[7] 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.

SAE which **are not reportable** include:
• an incorrect result of compatibility testing performed by the BE/HBB due to a misidentification of the recipient's blood sample (e.g., wrong blood in tube (WBIT) from a clinical area and detected in the lab);
• correctly cross-matched and labelled BC that are issued by the HBB for the correct patient and transfused to the wrong patient.

In 2024, the most common SAE occurred during storage (42%), followed by WB collection (17%) and processing (15%) as shown in Figure 28. This distribution is quite different from the previous year where SAE classified as 'other' were the most frequent (37%), followed by those attributed to storage (16%) and issue (9%).

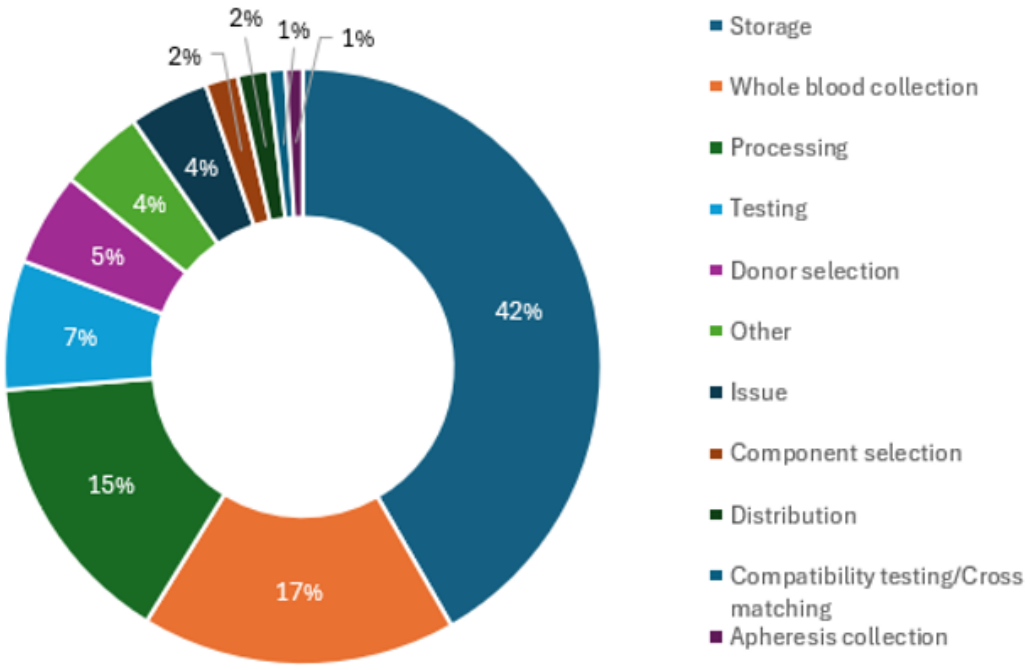


Figure 28. Percentage distribution of SAE by activity step in 2024

As shown in Table 23, a dramatic increase was observed in the number of SAE assigned to storage, primarily driven by Romania's data which accounts for 95% of the total number of SAE associated with storage.
Furthermore, 218 SAE were classified as 'other', representing a 74% drop (equivalent to 622 less reports) in comparison with 2023. This significant improvement demonstrates NCA's effort in promoting uniform classification.

Table 23. Summary of total number of SAE by activity step; 2023 vs. 2024

Activity Step	2023 position	# SAE 2024 (+/- 2023)
Storage	2	1 987 (+1 621)
Whole blood collection	4=	812 (+621)
Processing	7	715 (+620)
Testing	5	334 (+196)
Donor selection	4=	241 (+55)
Other	1	218 (-622)
Issue	3	206 (+1)
Component selection	6	84 (-25)
Distribution	9=	79 (+21)
Compatibility testing/Cross matching	8	44 (-20)
Apheresis collection	9=	44 (+2)
TOTAL	-	**4 764 (+2 470)**

Of the total 4 764 SAE reported, 218 were assigned to the activity step 'other'. Details of these entries are presented in Figure 29. In addition, the distribution per country of SAE classified as 'other' vs the nine defined activity steps is presented in Figure 30.

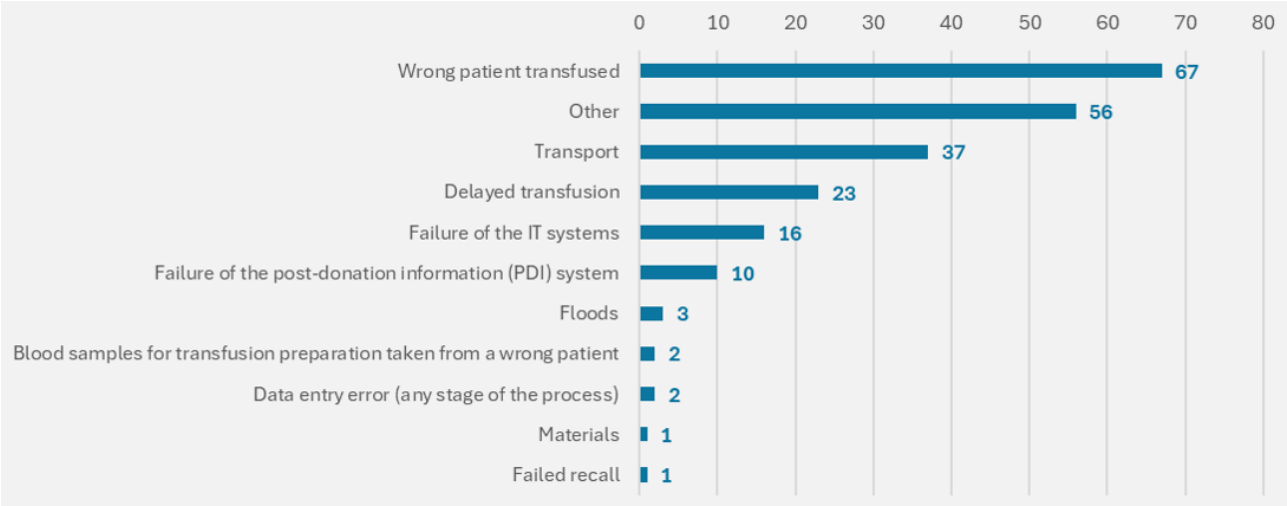


Figure 29. Distribution of SAE classified with the activity step 'other' in 2024

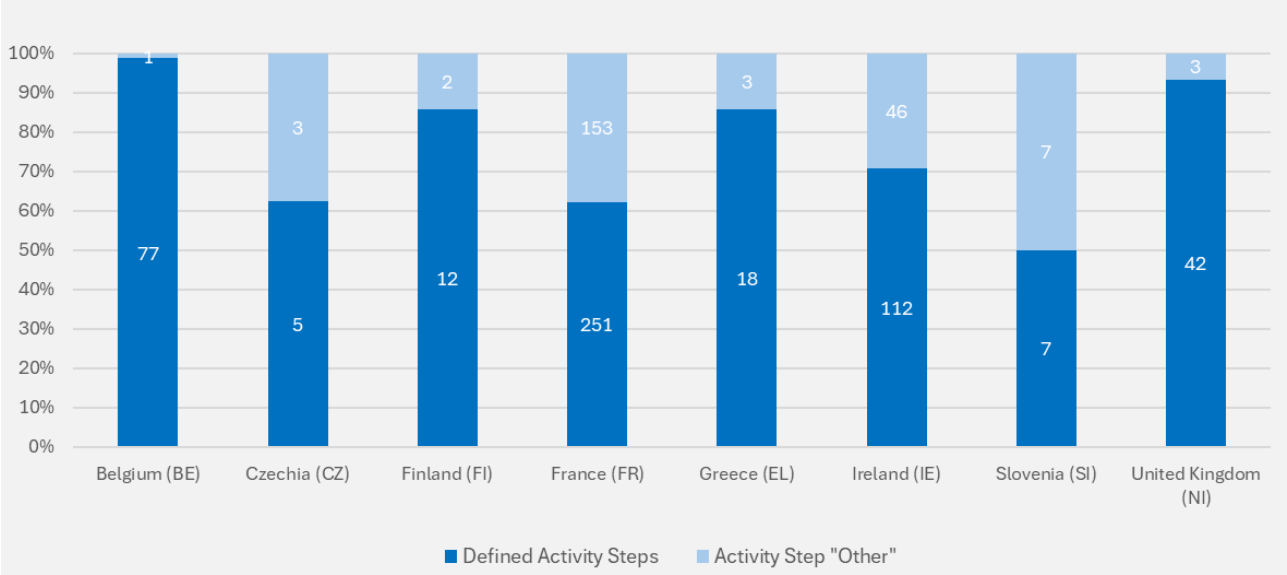


Figure 30. Percentage distribution (and absolute numbers) of SAE classified as 'other' vs the nine defined activity steps per reporting country in 2024

In order to continuing incentivizing reclassification, the per-country 'other' share 2023 vs. 2024 is presented in Table 24.

Table 24. Percentage of SAE classified with activity step 'other' per reporting country; 2023 vs. 2024

	'Other' (%)		
Country	2023	2024	Trend
Belgium (BE)	89	1	↓
Cyprus (CY)	15	0	↓
Czechia (CZ)	0	38	NEW
Finland (FI)	0	14	NEW
France (FR)	41	38	↓
Germany (DE)	60	0	↓
Greece (EL)	15	14	↓
Ireland (IE)	21	29	↑
Italy (IT)	40	0	↓
Norway (NO)	1	0	↓
Poland (PL)	40	0	↓
Slovakia (SK)	5	0	↓
Slovenia (SI)	0	50	NEW
Spain (ES)	13	0	↓
United Kingdom (NI)	14	7	↓

3.5 Yearly trends by specification (2021–2024)

According to the ***Common Approach***, 2025 edition [1], the specifications (i.e. error causes) that can be associated with a specific event include component defect, equipment failure, materials, system failure, human error and other. Their definitions are explained in the table below.

Table 25. Definitions of specifications (causes) for SAE

Specification	Definition
Component defect	when the blood/BC that has been issued for use does not meet the quality and safety requirements set in Annex V of the Directive 2004/33/EC due to an undetectable parameter.
Equipment failure	when it was caused by any instruments or machinery that did not function as required at any stage from the collection to the distribution of blood and BC. ➢ if the equipment failed because of inappropriate use, or the failure was not detected/ prevented by incorrect human action, these should be reported as human error. ➢ failures of medical devices, whether or not they met the criteria for SAE notification, should be reported under medical device legislation.
Materials	when it was caused by any material (bags, preservation solutions, etc.) from collection to distribution of blood/BC. ➢ if the SAE was caused by inaccurate human handling of the material, these should be reported as human error.
System failure	when the quality management system fails. **Type of error:** • insufficient training or education • high workload or pressure, incompetent staffing or insufficient skill-mixes of staffing • inadequate processes, procedures or documentation • other, or no information to assign the above options
Human error	when it resulted from an inappropriate or undesirable human decision or behaviour that reduces, or has the potential of reducing, effectiveness, quality, safety, or system performance. SAE should only be categorised as human error once investigation has ruled out failure of the system. **Type of error:** • incorrect decision or omission following the correct procedure • following the wrong procedure • other, or no information to assign the above options
Other	when it cannot be classified in the specifications listed above.

Figure 31 shows the yearly trends in percentage of total SAE by type of specification from 2021 to 2024.

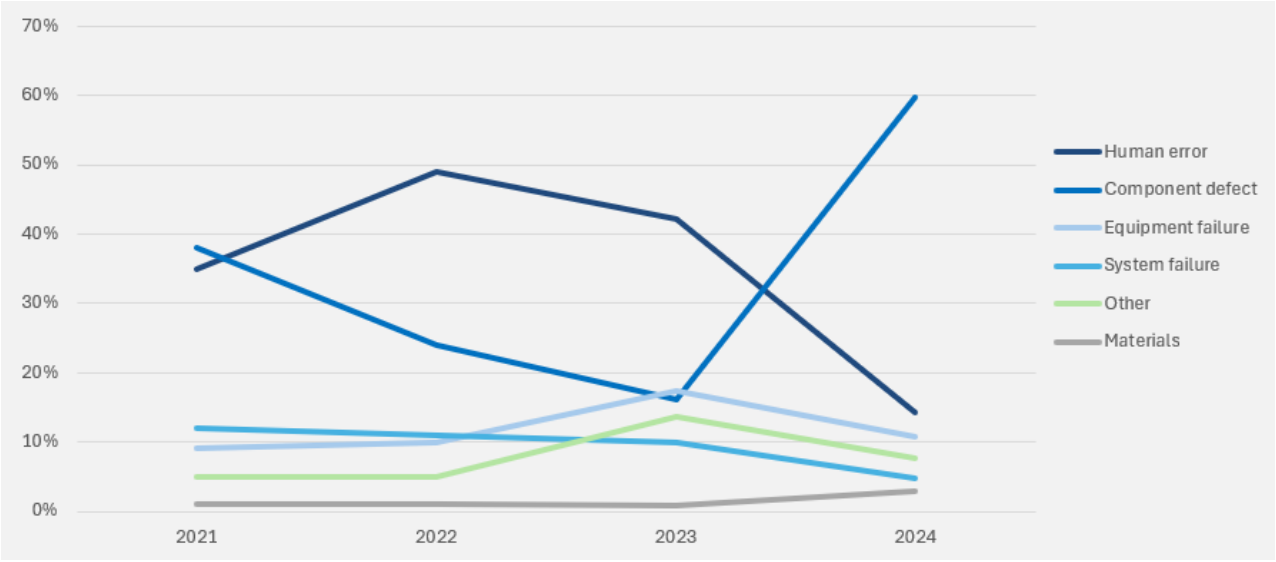


Figure 31. Yearly trends in percentage of total SAE by specification; 2021–2024

From 2021 to 2023, human error consistently represented the dominant root cause category, accounting for approximately 40–50% of all SAE per year. This is consistent with international benchmarking data: the SHOT annual report [2] has repeatedly identified human factors, particularly incorrect decisions, omissions in procedure and communication failures, as the primary driver of near-miss and serious transfusion events.

Equipment failure and component defect maintained relatively stable and comparatively lower shares over the same period. The clear change of pattern in 2024, with component defect rising to 60% and human error falling to 14%, is almost entirely attributable to the Romanian's data, which classifies the large majority of its reported SAE under component defect and equipment failure categories. Without Romania's contribution, the 2024 specification distribution would be substantially consistent with prior years, reinforcing the conclusion that this shift reflects a reporting system difference rather than a genuine European-wide change in root cause patterns.

3.6 Overview of SAE by specification

As presented in Figure 32 and Table 26, in 2024, the most predominant root causes identified were component defect (60%), human error (14%) and equipment failure (11%). This picture differs significantly from the previous year — human error (42%), equipment failure (17%) and component defect (16%). As already mentioned, the main reason for this change is due to the data reported by Romania which accounts for 92% of the total number of SAE associated with component defect and 80% of the total number of SAE associated with equipment failure.

Excluding Romania's contribution, the distribution of SAE by specification in 2024 would revert to a pattern closely aligned with 2023: human error would remain the predominant root cause (38%), followed by 'other' (18%), system failure (15%) and component defect (14%).

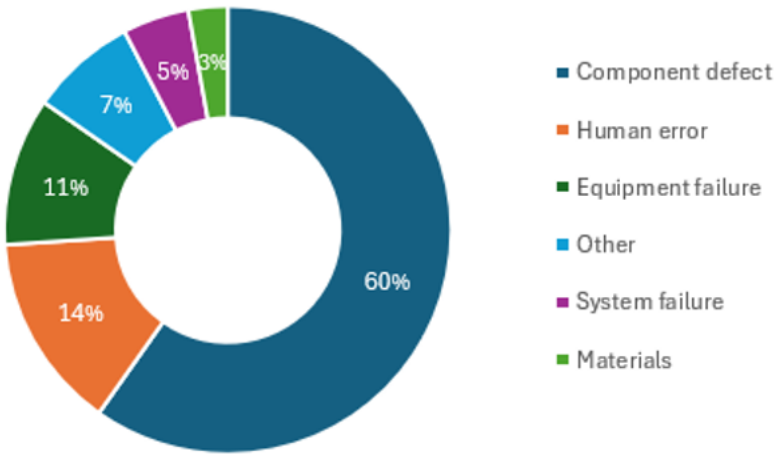


Figure 32. Percentage distribution of SAE by specification in 2024

Table 26. Summary of total number of SAE by specification; 2023 vs. 2024

Specification	2023 position	# SAE 2024 (+/- 2023)
Component defect	3	2 848 (+2 477)
Human error	1	675 (-293)
Equipment failure	2	510 (+113)
Other	4	367 (+55)
System failure	5	229 (0)
Materials	6	135 (+118)
TOTAL	-	4 764 (+2 470)

Figure 33 disaggregates the root cause (specification) profile within each activity step, revealing important patterns in where different types of failure concentrate. Human error is predominant in the issue and component selection steps, consistent with the well-established vulnerability of these process points to staff identification errors. Component defect concentrates in storage, WB collection and processing steps, while equipment failure is distributed across storage and processing.

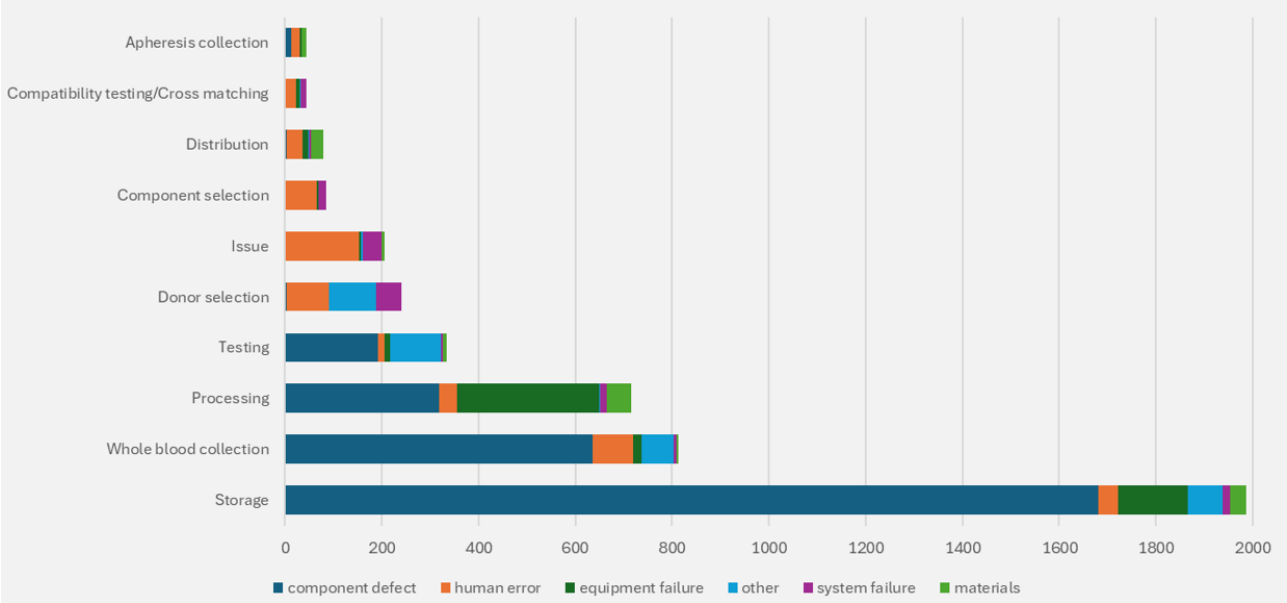


Figure 33. Distribution of SAE for the defined activity steps by specification in 2024

Of the 218 SAE assigned to the 'other' activity step, the majority were attributed to human error and system failure causes, suggesting that many of these events involve process gaps that span multiple defined activity steps or fall outside the canonical transfusion chain defined in the Blood Directive framework (Figure 34).

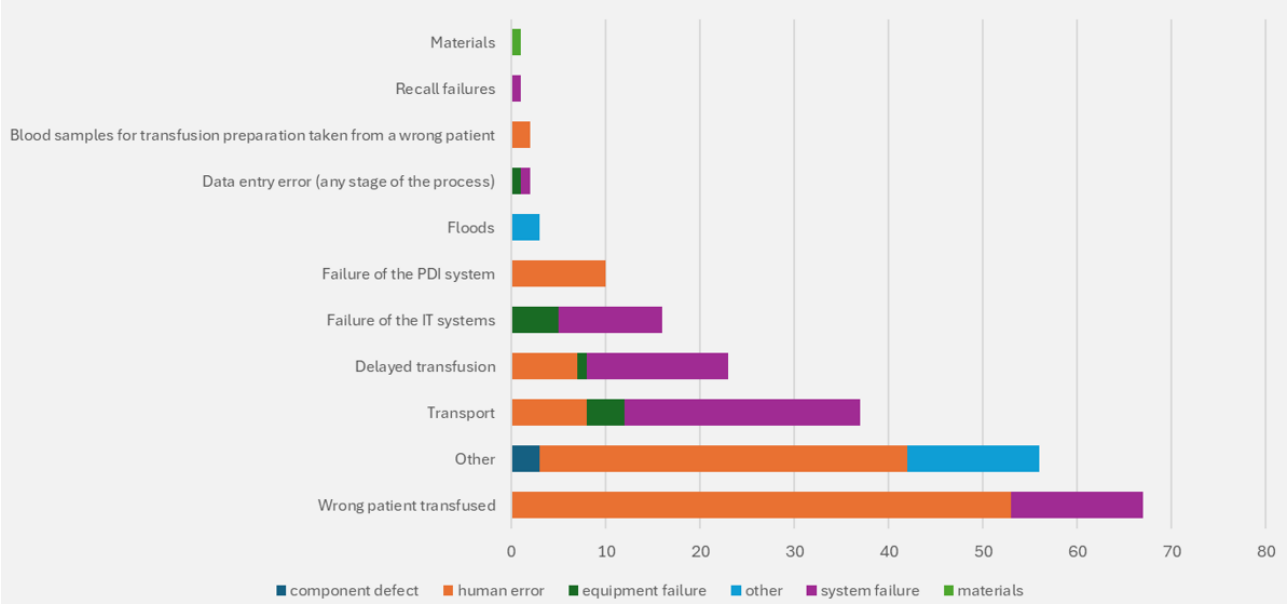


Figure 34. Distribution of SAE assigned to 'other' activity step entries by specification in 2024

Regarding events assigned the cause 'human error', the specific type of error/failure was also reported (Figure 35 and Table 27). In 2024, 78% of events reported were related to staff making an incorrect decision or skipping steps in a process (vs 75% in 2023), whereas only 5% were related to staff having knowingly followed the wrong procedure (vs 2% in 2023).

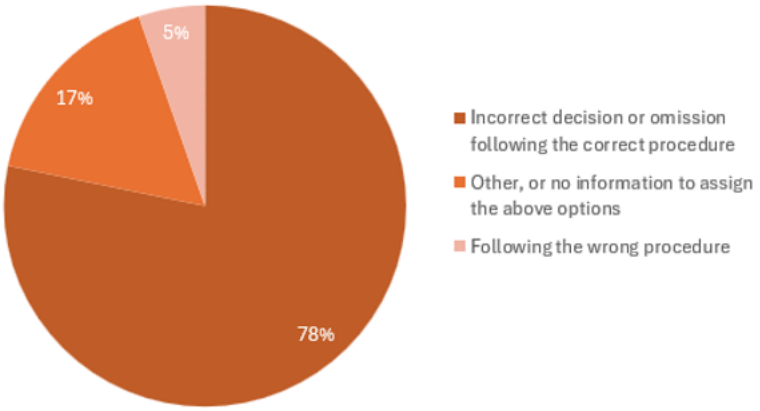


Figure 35. Percentage distribution of SAE classified as 'human error' by type of error in 2024

Table 27. Summary of total number of SAE classified as 'human error' by type of error; 2023 vs. 2024

Type of Error	2023 position	# SAE 2024 (+/- 2023)
Incorrect decision or omission following the correct procedure	1	528 (-195)
Other, or no information to assign the available options	2	111 (-109)
Following the wrong procedure	3	36 (+11)
TOTAL	-	**675 (-293)**

The percentage distribution of SAE by specification for each reporting country is displayed in Figure 36.

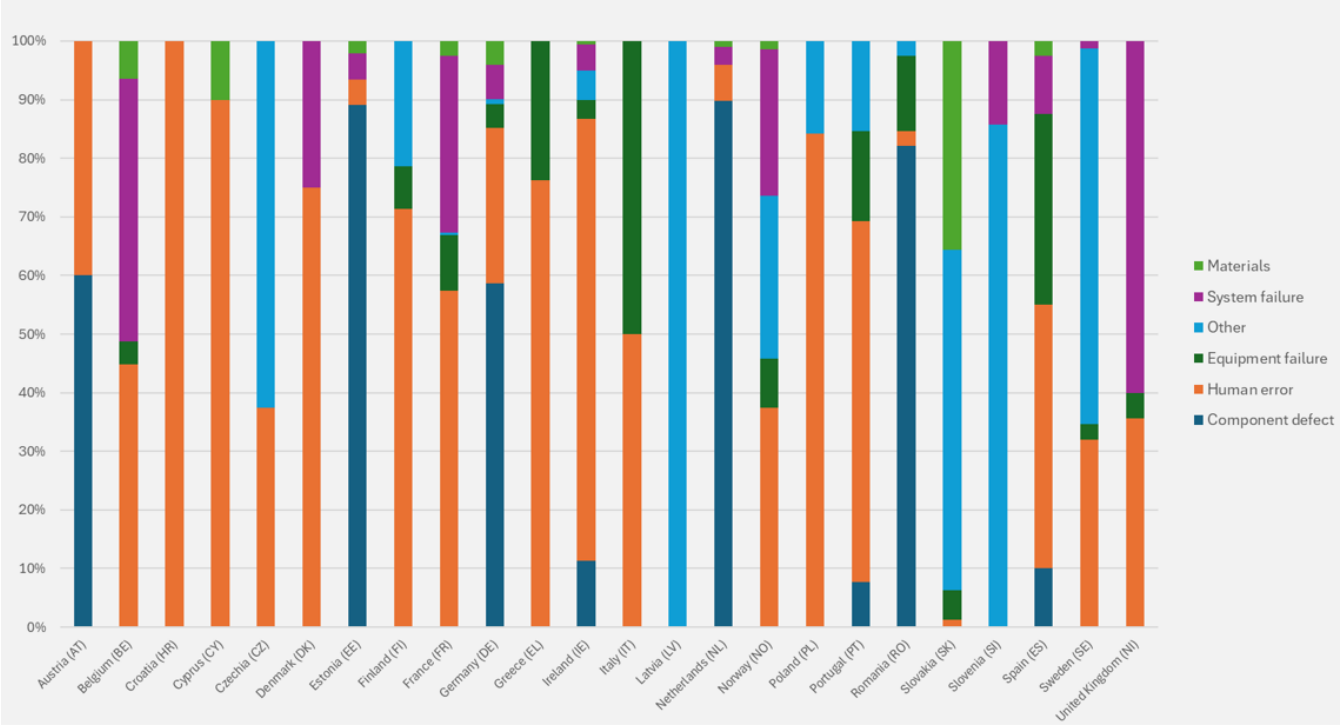


Figure 36. Percentage distribution of SAE by specification per country in 2024
Note: countries reporting zero SAE cases (BG, IS and LT) are not shown above.

Key countries shaping process safety picture

- Comment RO: "*In 2023, there were limitations in our reporting system that led to underreporting or incomplete documentation of events. For this reason, "N/A" was indicated for that year. Starting in 2024, we implemented a revised SAE reporting protocol, along with additional training sessions for personnel involved in the identification and reporting of adverse events. The reporting criteria have been broadened to include cases previously considered minor or ambiguous, in alignment with updated haemovigilance recommendations.*"
- Excluding Romania's contribution, the distribution of SAE by specification in 2024 would revert to a pattern closely aligned with 2023: human error would remain the predominant root cause (38%), followed by 'other' (18%), system failure (15%) and component defect (14%).

3.6.1 Qualitative Thematic Analysis

Using the data presented in **Annex 5. Additional information on SAE by specification**, a qualitative thematic analysis was carried out.

Theme 1: Under-Documentation

This is the single most important theme. The majority of SAE in the two of the largest specification categories (component defect and equipment failure) are analytically invisible as "no additional information provided" or "N/A" represents the largest entry by case count:

- Component defect: 2 626 + 15= 2 641 of 2 848 cases (93%)
- Equipment failure: 423 +12= 435 of 510 cases (85%)

Theme 2: Patient Identification and Wrong-Patient Events

Across human error and system failure categories, wrong-patient and ICBT events emerge as a persistent multi-level failure mode, appearing in several entries:

- 67 cases of wrong patient transfused under human error — described as a combination of identity failures across prescribing, laboratory communication, HBB checking and bedside verification
- 11 cases of transfusion/issue of incorrectly labelled component
- 9 cases of ICBT due to insufficient or no bedside check
- 9 cases of ICBT due to incorrect product allocation during issue
- 8 cases of WBIT, labelling error, donor mix-up
- 14 cases of wrong patient transfused under system failure — same multi-layered failure description

Theme 3: Donor Disclosure Integrity

A cluster of entries across component defect, human error, other and system failure categories all point to an underlying vulnerability: the blood safety system depends heavily on donors providing complete and accurate health information and this dependency is frequently not met.

Relevant entries include:

- 58 cases (component defect): PDI known at time of donation but not disclosed by donor, or information that led to later refusal may have affected prior donations, including newly diagnosed malignancy and *Borrelia infection*
- 50 cases (other): Donor did not provide correct or full information at donation
- 30 cases (human error): Unreported recent travel to malaria- or Chagas-endemic areas, largely due to donor omission and insufficient emphasis during the pre-donation interview
- 26 cases (human error): Donor accepted despite information available for exclusion; insufficient donor deferral
- 33 cases (system failure): Donor eligibility violations
- 3 cases (other): Patient hid therapy/diagnosis information; BCs distributed for use
- 3 cases (human error): Donor had too poor language skills to adequately understand consent forms
- 1 case (system failure): Different procedure for accepting donor regarding medical declaration form

Taken together, these entries describe a spectrum of failures ranging from deliberate concealment by the donor, to language and literacy barriers preventing informed participation in the screening process, to inconsistencies in how medical declaration forms are administered. These cases are not donor failures alone; they reflect a screening environment that does not create adequate conditions for honest self-disclosure, whether due to time pressure, lack of private interview space, language barriers or social expectations.

Theme 4: IT and Software Failures

IT-related failures appear across multiple specification categories, often without adequate description and some likely misclassified. However, the entries that do contain detail are quite educational:

- 2 cases (system failure): Typing errors when entering positive infection parameters were interpreted as negative by the electronic data processing (EDP) system due to poor programming
- 3 cases (component defect): Insufficient deferral period after risk of infection due to incorrect programming in EDP
- 36 cases (system failure): IT system and transport failures, flagged as subject to systematic maintenance checks and procedure reminders (*suggesting known, recurring issues*)
- 2 cases (equipment failure): IT-software error and machine malfunction

- 1 case (equipment failure): Incorrect D weak declaration as D negative due to EDP misprogramming
- 1 case (equipment failure): Omission of alloantibody screening test of donors due to EDP misprogramming
- 1 case (system failure): Failure to provide irradiated units after introduction of a new lab system
- 1 case (materials): Units pathogenically reduced but exposure report had incorrect date due to a system date change

The EDP programming error that caused positive infection results is a finding of particular concern as the staff member entered the data correctly, but a software validation failure inverted a safety-critical result. This type of hidden system failure is particularly dangerous because it can affect multiple samples before detection and may not be identified through routine individual case review.

Theme 5: Component Integrity Classification

The materials category is dominated by burst blood bags and plasma chylostasis (combined: 112 of 135 cases, 83%) and several entries in other categories describe similar failures:

- 49 cases: Burst blood bag
- 33 cases: Burst blood bag with plasma chylostasis
- 30 cases: Plasma chylostasis *(alone)*
- 7 cases (other): Leaking packs, clots in unit, minor sediment, haemolysed units
- 11 cases (equipment failure): Burst blood bag

Chylostasis (lipaemic plasma) is not a manufacturing defect in the conventional sense; it reflects donor metabolic status at the time of donation (typically high triglyceride levels due to recent fatty meal) and is a known quality issue in plasma components. Its frequency in the materials category alongside burst bags suggests possible misclassification.

The classification boundary between component defect, materials and equipment failure requires clarification in the ***Common Approach*** guidance, particularly for burst bag events and component appearance deviations.

Theme 6: Emerging and Environmental Risks

- 2 cases: National epidemiological situation increased HEV cases linked to sausage consumption; additional testing initiated; positive cases found on archive samples that had already been transfused
- 3 cases: Extensive floods (presumably affecting storage, distribution or establishment operations)
- 24 cases: Covid and Herpes Zoster in donor selection

The HEV cluster is particularly instructive. It describes a food-borne outbreak that translated into a blood safety risk because HEV-viraemic donors donated during the incubation period before the epidemiological signal was identified and additional testing was introduced. The retrospective identification of positive cases in already-transfused archive samples indicates that recipient lookback was initiated, a positive finding in terms of haemovigilance response, but the case illustrates the inherent lag between a community infection event and a blood safety system response. This is the type of emerging risk scenario that national haemovigilance systems are structurally poorly equipped to detect prospectively and it underscores the importance of blood safety authorities maintaining active surveillance links with national infectious disease and public health agencies.

The flood events, while small in number, represent a type of risk (infrastructure and environmental disruption) that is largely absent from standard SAE reporting frameworks but likely to grow in relevance as climate-related events increase in frequency across Europe.

Theme 7: Thin Evidence of CAPA

Across all specification categories, explicit reference to CAPA is rare. Where CAPA language does appear, it takes the following forms:

- "Subject to systematic equipment maintenance checks and systematic reminders of the procedures" (equipment failure, system failure)
- "A systematic reminder is carried out for staff who have not respected PDI procedures" (human error)
- "Additional blood donation testing was started" following HEV cluster (other)

The most implicit CAPA signals come from the multi-layered wrong-patient event descriptions, which acknowledge systemic process complexity, but even here, no corrective actions are described and the narrative stops at failure description rather than resolution.

4 Severe Adverse Reactions in Donors (Voluntary)

Key findings

- 2 260 SAR in donors were reported (36% drop vs 2023).
- Vasovagal reactions dominate (77% in WB, 54% in apheresis).
- France's scope update (only grades 3–4 reported) significantly reduced overall donor SAR frequency.
- For the first time, 4 fatalities were reported in donors (1 in WB and 3 in apheresis).

An adverse donor reaction is described as unintended response in a donor associated with the collection of blood/BC which can happen acutely during the donation process or delayed after the donor has left the donation site.

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.

Reactions in donors are reportable only if they were **serious** in nature.

The ***Common Approach***, 2025 edition [1], states that "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 Geographic distribution

Twenty-three countries (AT, BE, BG, CY, CZ, DK, EE, FI, FR, DE, EL, IS, IE, IT, LU, NL, NO, PL, PT, RO, SK, SI and SE) reported on a voluntary basis, a total of 2 260 SAR in donors in 2024. This was a 36% decrease in comparison with 2023 (3 530 SAR).

As shown in Figure 37, there was a wide range of SAR incidence rates in WB donors, with the lowest being 0 (AT, HR, LV and ES) and the highest reaching 122 (NO).

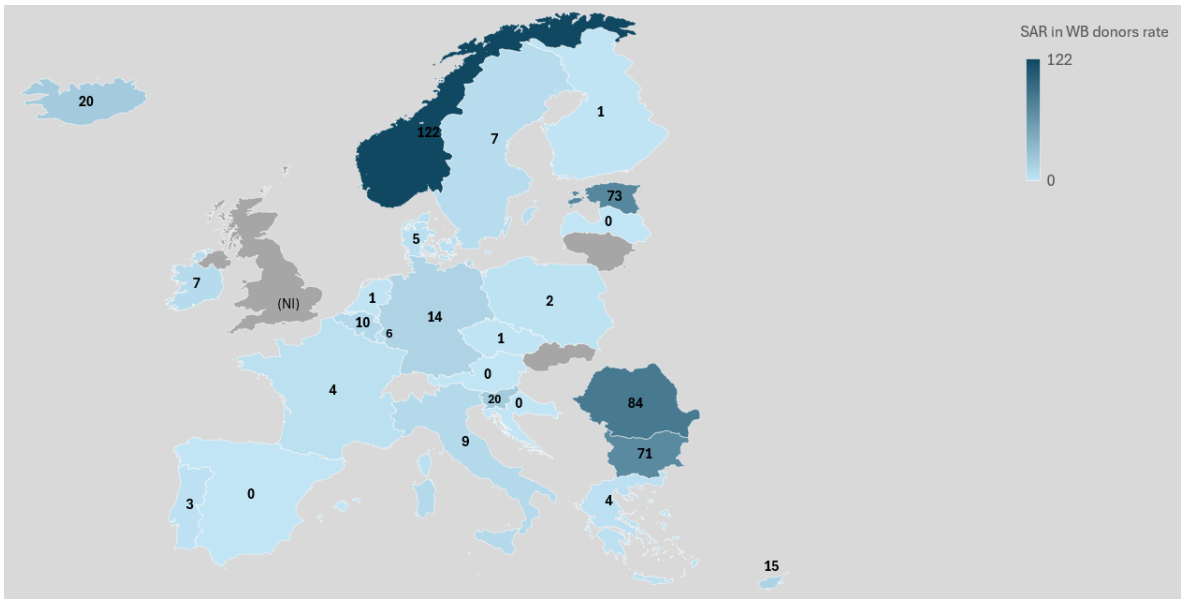


Figure 37. SAR incidence rates in WB donors per 100 000 WB collections in Europe in 2024
Note: LT and SK reported N/A for the number of WB collections, so they appear above in dark grey; UK(NI) reported N/A for the number of SAR, also shown above in dark grey.

Similarly, there was a wide range of SAR incidence rates in apheresis donors (Figure 38), with the lowest being 0 (BG, HR, CY, FI, EL, IS, IE, LV, PT and RO) and the highest reaching 171 (NO).

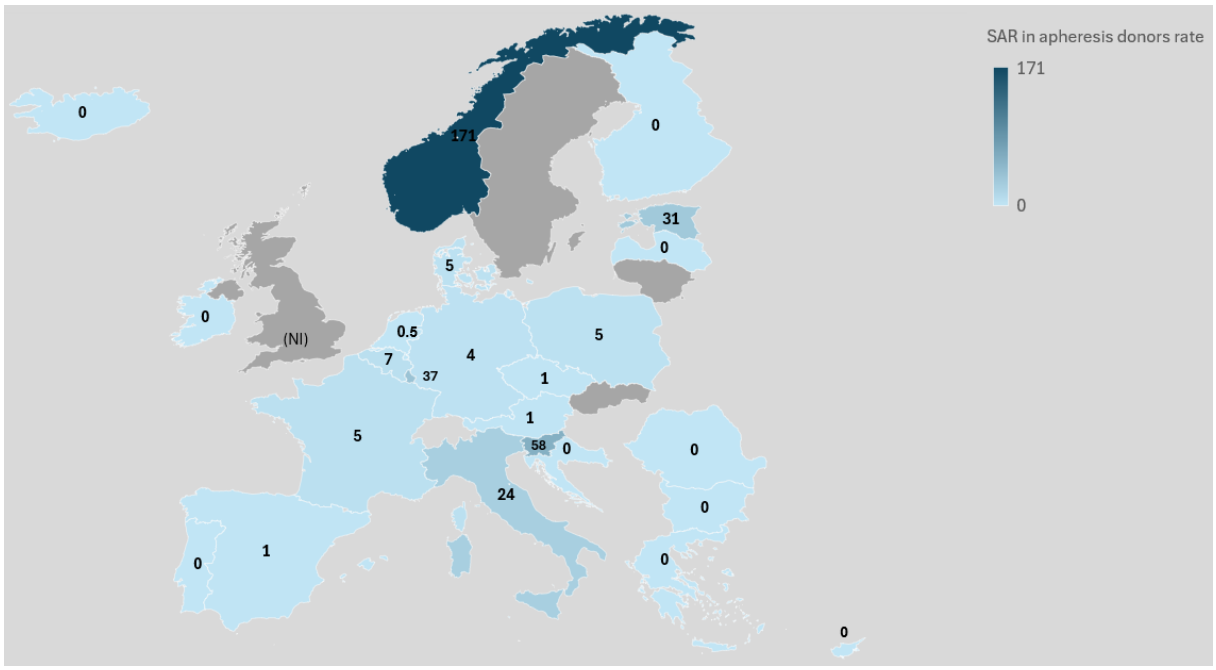


Figure 38. SAR incidence rates in apheresis donors per 100 000 apheresis collections in Europe in 2024
Note: LT and SK reported N/A for the number of apheresis collections, so they appear above in dark grey; SE and UK(NI) reported N/A for the number of SAR, also shown above in dark grey.

4.2 Country-specific trends (2023 vs. 2024)

Figure 39 compares the SAR incidence rates in WB donors (per 100 000 WB collections) per country in 2024 with 2023.

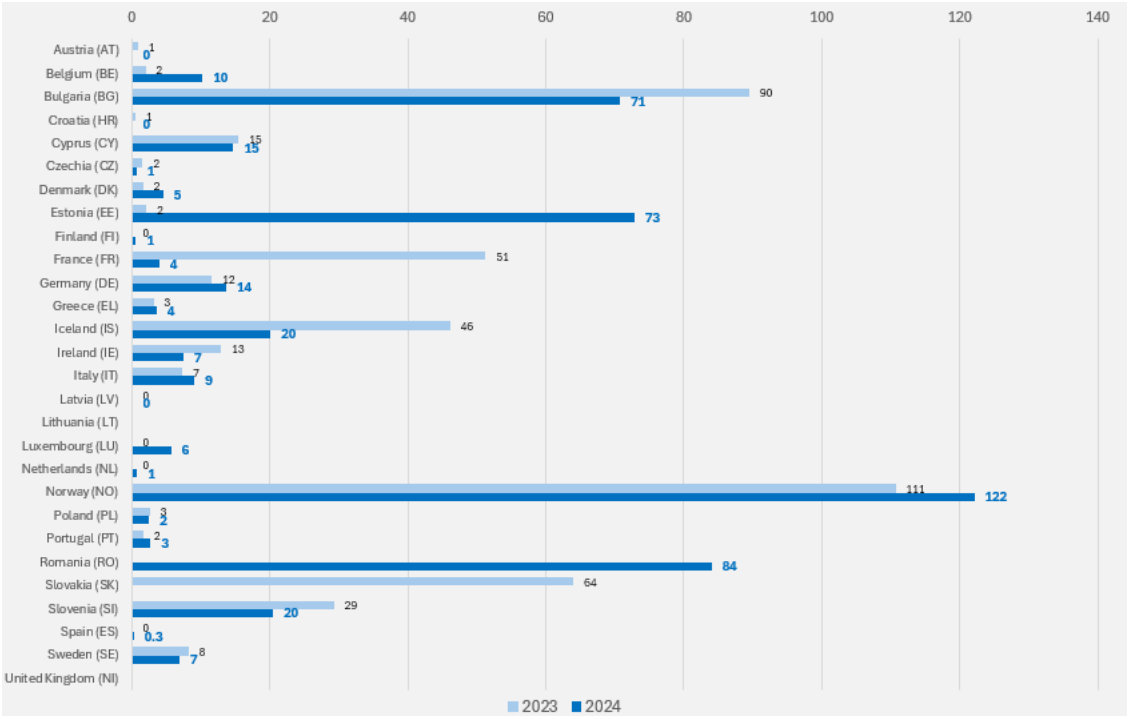


Figure 39. SAR incidence rates in WB donors per 100 000 WB collections per country; 2023 vs. 2024
Note 1: for FR, rates are not comparable due to change in the reporting scope (only grade 3 (severe) and grade 4 (death) reported in 2024 vs all grades in 2023).
Note 2: LT reported N/A for the number of WB collections in both 2023 and 2024. In 2023, RO reported SAR cases but N/A for the number of WB collections. In 2024, SK reported SAR cases but N/A for the number of WB collections. UK(NI) reported N/A for the number of SAR in both 2023 and 2024.

As shown in Figure 39, BE and EE had significant increases in the SAR incidence rate in comparison with 2023, while FR had a large drop explained by a change in the national reporting scope, which restricted submitted donor SAR to grade 3 (severe) and grade 4 (fatal) reactions only, in contrast to all grades reported in prior years. This methodological change substantially reduces the comparability of French donor SAR data between 2023 and 2024, and caution should be exercised when interpreting France's apparent improvement.

The comparison of SAR incidence rates in apheresis donors (per 100 000 apheresis collections) between 2024 and 2023 is presented in Figure 40.

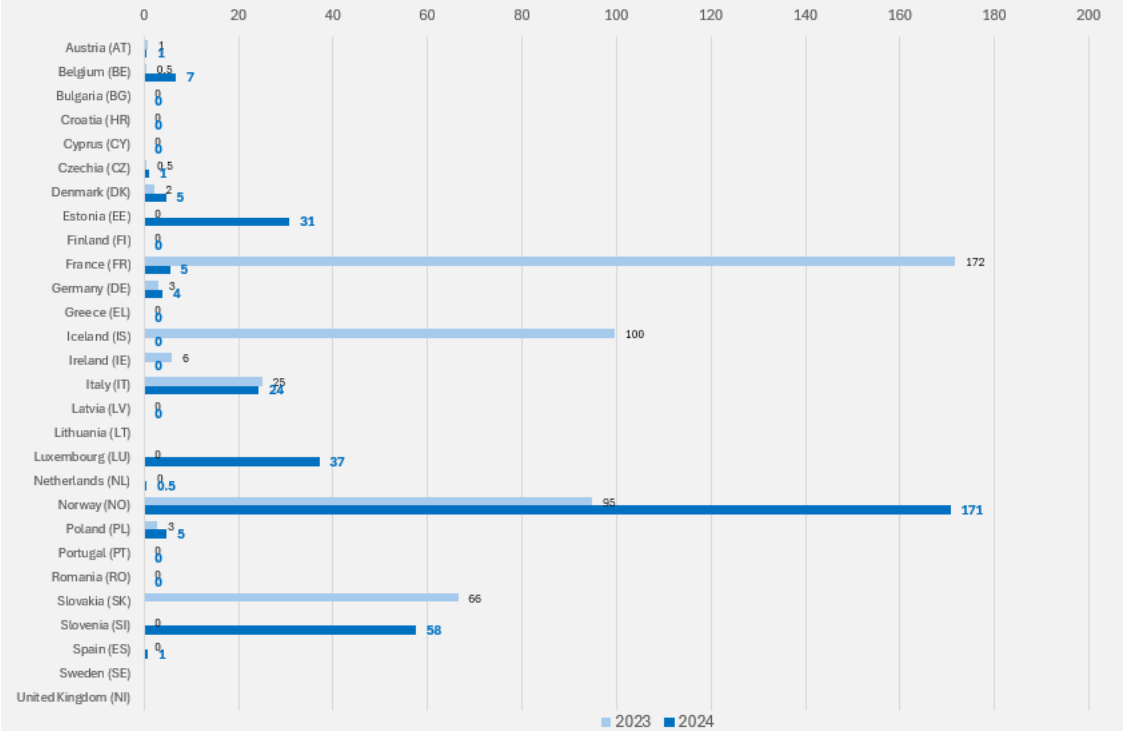


Figure 40. SAR incidence rates in apheresis donors per 100 000 apheresis collections per country; 2023 vs. 2024

Note 1: for FR, rates are not comparable due to change in the reporting scope (only grade 3 (severe) and grade 4 (death) reported in 2024 vs all grades in 2023).

Note 2: LT reported N/A for the number of apheresis collections in both 2023 and 2024. In 2024, SK reported SAR cases but N/A for the number of apheresis collections. SE reported N/A for both the number of SAR and the number of apheresis collections in both 2023 and 2024. UK(NI) reported N/A for the number of SAR in both 2023 and 2024.

Key countries shaping the donor safety picture

- Comment FR: "*from the 2nd of January 2024, the reporting of SAR donors focus on the most serious adverse reactions: only grades 3 (severe) and 4 (death) needs to be reported to the NCA (grades 1 and 2 are notified, traced and analysed at local level of BE). This allows also the harmonization of French data with European and international modalities, for greater comparability of data between countries, particularly EU MS.*"

4.2.1 Overview of SAR in donors by type of donor per country

The distribution of number of SAR by type of donor per reporting country is shown in Figure 41.

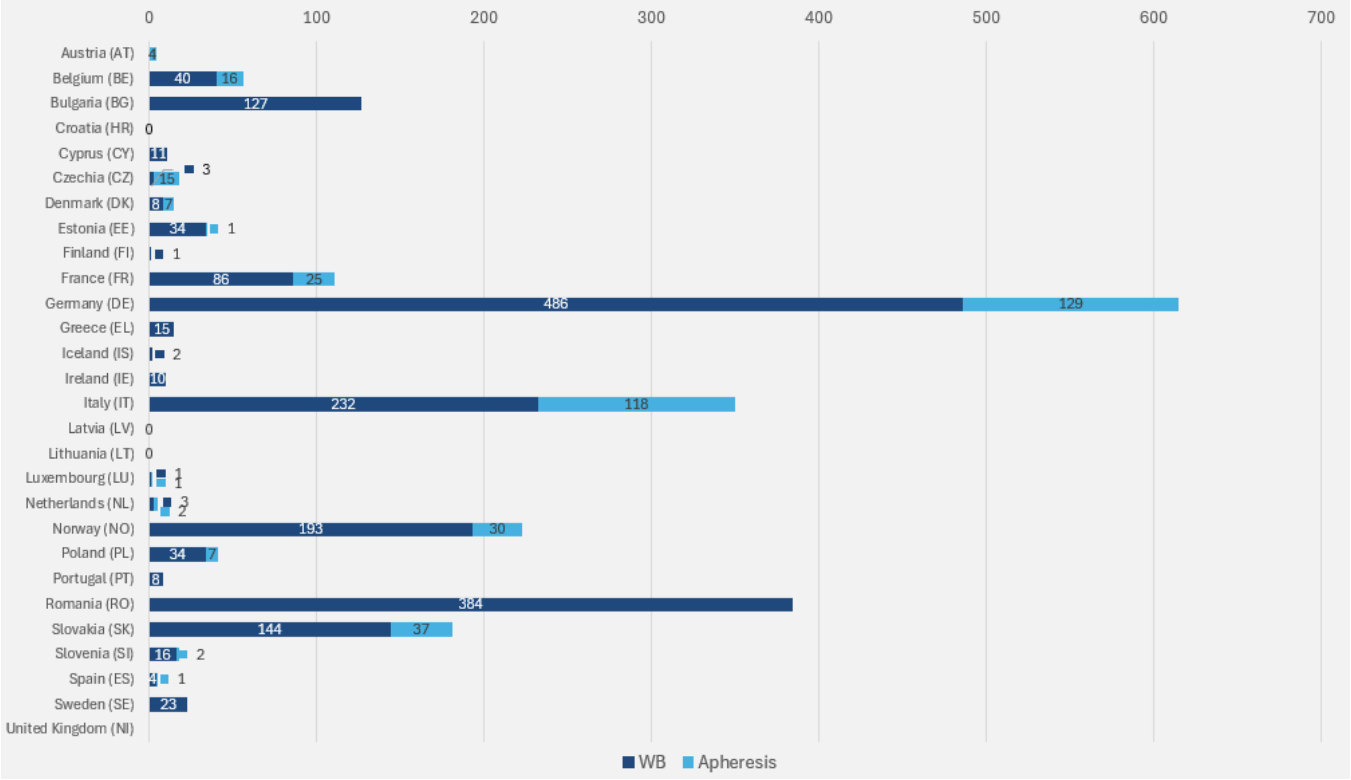


Figure 41. Number of SAR in donors by type of donor per country in 2024
Note: UK(NI) reported data N/A.

4.3 Overview of SAR in donors by type of reaction

SAR in donors are classified as per table below.

Table 28. Classification of donor reactions

Type of Reaction
Vasovagal reaction
Citrate reaction *(specific to apheresis)*
Allergic reaction
Nerve injury/irritation
Haematoma **NEW!**
Major cardio-or cerebrovascular event (CCVE) up to 24 hours after donation
Other
General *(only if data for the reactions listed above are not available)*

Note 1: haematoma is reserved for donors in whom haematoma was present without (serious) nerve injury/irritation
Note 2: for major CCVE an imputability assessment should be made.

4.3.1 SAR in WB donors

Twenty-three countries (BE, BG, CY, CZ, DK, EE, FI, FR, DE, EL, IS, IE, IT, LU, NL, NO, PL, PT, RO, SK, SI, ES and SE) reported a total of 1 865 SAR in donors in relation to WB collections (15 679 193). This represents a 28% decrease in comparison with the previous year when 2 573 SAR were recorded by 21 countries.

As presented in Figure 42, in 2024, vasovagal reactions accounted for the majority of donor reactions (77%), followed by nerve injury/irritation (12%) and other (6%). This is a similar distribution to the one observed in 2023.
Vasovagal reaction is known to be the most common SAR that happened to donors during or after the blood donation process has completed. Donors may experience either acute or delayed feeling of dizziness usually associated with nausea, sweating and general discomfort; and maybe associated with bradycardia and hypotensive episodes.

For more details related to 'other' and major CCVE, refer to **Annex 6. Additional information on SAR in donors per reporting country**.

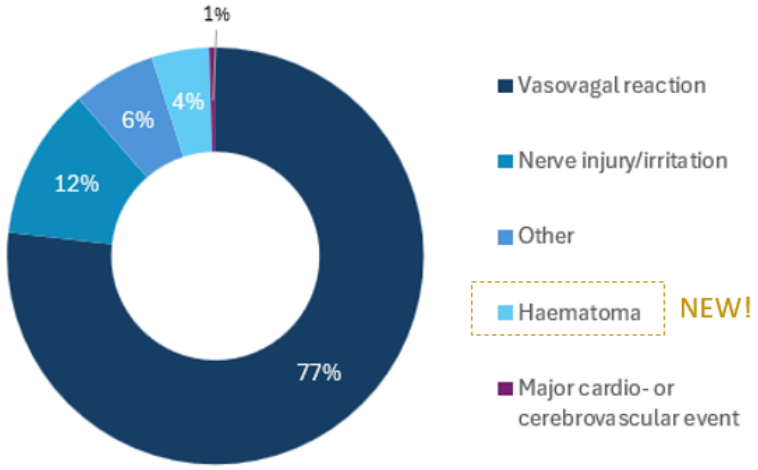


Figure 42. Percentage distribution of SAR in WB donors by type of reaction in 2024
Note: zero SAR cases reported for allergic reactions.

Table 29. Summary of total number of SAR in WB donors by type of reaction; 2023 vs. 2024

Type of Reaction	2023 position	# SAR 2024 (+/- 2023)
Vasovagal reaction	1	1 430 (-652)
Nerve injury/irritation	3	220 (-7)
Other	2	120 (-133)
Haematoma (NEW!)	-	83
Major cardio-or cerebrovascular event (CCVE) up to 24hours after donation	4	9 (-2)
General	-	3 (+3)
Allergic reaction	-	0
TOTAL	-	**1 865 (-708)**

The number of donor reactions by type for each reporting country is presented comparatively for 2023 and 2024 in Table 30.

Table 30. SAR in WB donors by type of reaction per country; 2023 vs. 2024

Country	Vasovagal reaction		Absolute Change	Nerve injury/irritation		Absolute Change	Other		Absolute Change	NEW! Haematoma	Major CCVE up to 24h after donation		Absolute Change	General		Absolute Change
	2023	2024		2023	2024		2023	2024		2024	2023	2024		2023	2024	
Austria (AT)							2	0	-2		1	0	-1			
Belgium (BE)	5	18	+13	3	11	+8	0	6	+6	5						
Bulgaria (BG)	68	77	+9	87	50	-37										
Croatia (HR)	1	0	-1													
Cyprus (CY)	9	8	-1	0	2	+2	2	1	-1							
Czechia (CZ)	7	1	-6				0	2	+2							
Denmark (DK)	1	6	+5	0	1	+1	2	1	-1							
Estonia (EE)	1	34	+33													
Finland (FI)							0	1	+1							
France (FR)	1 022	21	*	26	12	*	88	42	*	8	6	3	*			
Germany (DE)	295	333	+38	77	93	+16	63	24	-39	32	3	4	+1			
Greece (EL)	20	14	-6	1	1	0										
Iceland (IS)	4	2	-2				1	0	-1							
Ireland (IE)	6	3	-3	6	5	-1	4	2	-2	N/A	1	0	-1			
Italy (IT)	161	209	+48				27	9	-18	14						
Luxembourg (LU)											0	1	+1			
Netherlands (NL)														0	3	+3
Norway (NO)	135	135		13	31	+18	24	16	-8	11						
Poland (PL)	28	26	-2	4	7	+3	3	0	-3	1						
Portugal (PT)	4	5	+1				1	1	0	2						
Romania (RO)	145	383	+238				16	0	-16	1						
Slovakia (SK)	133	126	-7				13	9	-4	9						
Slovenia (SI)	23	15	-8	1	0	-1					0	1	+1			
Spain (ES)	0	4	+4													
Sweden (SE)	14	10	-4	9	7	-2	7	6	-1							
n	20	20		10	11		14	13		9	4	4		0	1	

*Note 1: * for FR, data between years is not comparable due to change in the reporting scope (only grade 3 (severe) and grade 4 (death) reported in 2024).*
Note 2: LV and LT reported zero SAR both in 2023 and 2024 (not shown above); UK(NI) reported data N/A both in 2023 and 2024 (not shown above).
Note 3: zero SAR cases reported for allergic reactions in both 2023 and 2024.

In comparison with the previous year, the total number of vasovagal reactions in WB donors decreased substantially (Table 29). This is primarily due to France's revised reporting scope (only grade 3 and 4 events reported in 2024, versus all grades in 2023).

The percentage distribution of SAR in WB donors by type of reaction for each reporting country is displayed in Figure 43.

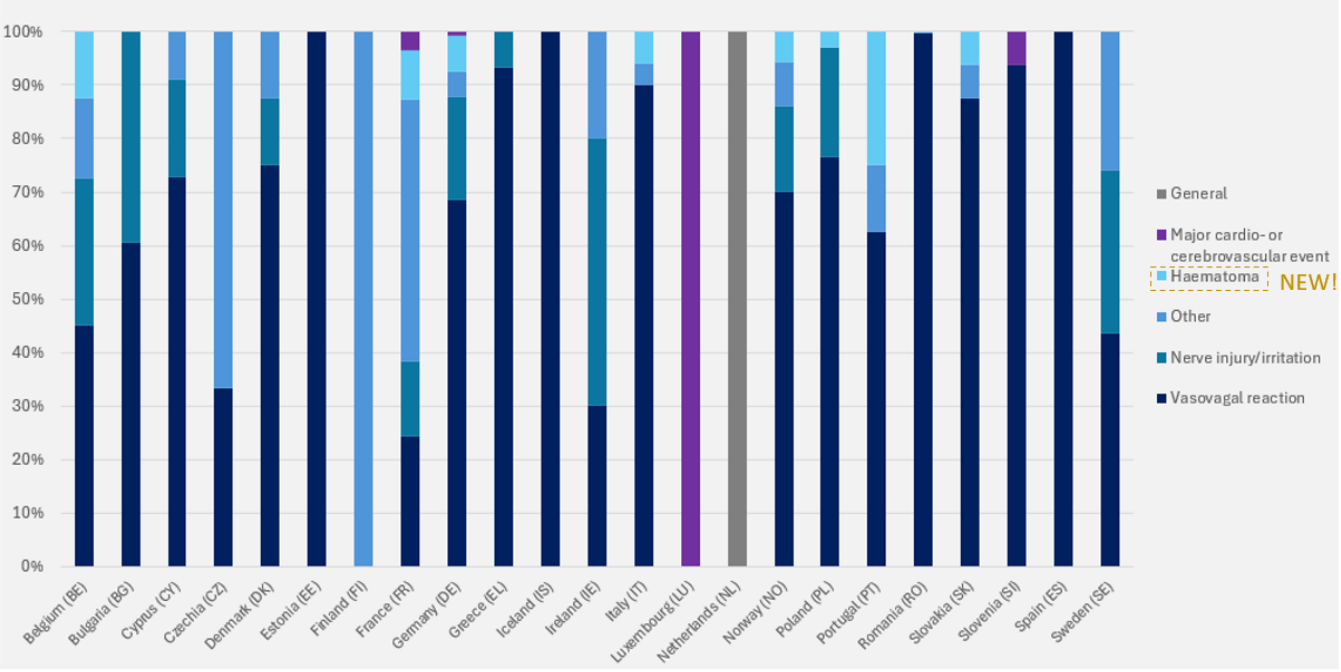


Figure 43. Percentage distribution of SAR in WB donors by type of reaction per country in 2024
Note 1: AT, HR, LV and LT reported zero SAR (not shown above); UK(NI) reported data N/A (not shown above).
Note 2: zero SAR cases reported for allergic reactions.

4.3.2 SAR in apheresis donors

Fifteen countries (AT, BE, CZ, DK, EE, FR, DE, IT, LU, NL, NO, PL, SK, SI and ES) reported a total of 395 SAR in donors following apheresis collections (7 590 344). This was a 59% reduction in comparison with the previous year when 957 SAR were reported by 12 countries.
The distribution of apheresis donor reactions in 2024 is shown in Figure 44.

For more details related to 'other' and major CCVE, refer to **Annex 6. Additional information on SAR in donors per reporting country**.

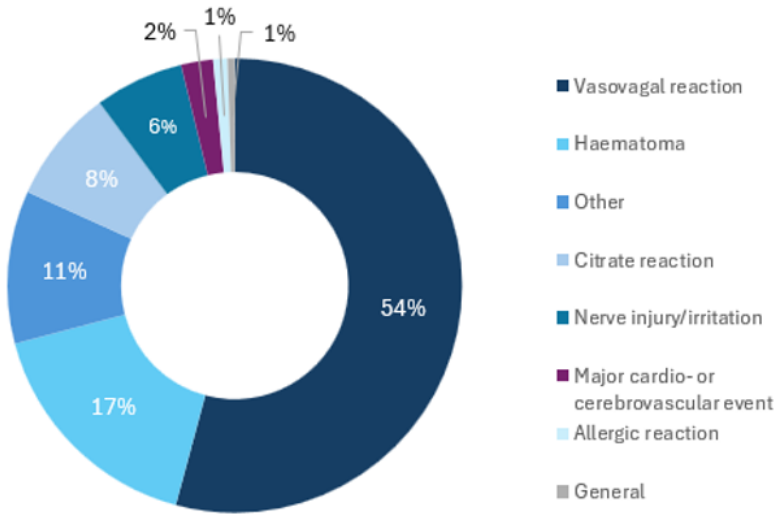


Figure 44. Percentage distribution of SAR in apheresis donors by type of reaction in 2024

Table 31. Summary of total number of SAR in apheresis donors by type of reaction; 2023 vs. 2024

Type of Reaction	2023 position	# SAR 2024 (+/- 2023)
Vasovagal reaction	1	214 (-536)
Haematoma (NEW!)	-	66
Other	2	43 (-104)
Citrate reaction	3	32 (+2)
Nerve injury/irritation	4	25 (+4)
Major cardio-or cerebrovascular event (CCVE) up to 24hours after donation	5	9 (+3)
Allergic reaction	6	4 (+1)
General	-	2 (+2)
TOTAL	-	**395 (-562)**

The number of donor reactions by type for each reporting country is presented comparatively for 2023 and 2024 in Table 32.

Table 32. SAR in apheresis donors by type of reaction per country; 2023 vs. 2024

NEW!

Country	Vasovagal reaction		Absolute Change	Haematoma	Other		Absolute Change	Citrate reaction		Absolute Change	Nerve injury/irritation		Absolute Change
	2023	2024		2024	2023	2024		2023	2024		2023	2024	
Austria (AT)	2	3	+1		1	1							
Belgium (BE)	1	8	+7		0	3	+3				0	4	+4
Czechia (CZ)	7	5	-2		0	9	+9	0	1	+1			
Denmark (DK)	0	2	+2	2	3	2	-1				0	1	+1
France (FR)	631	10	*	6	41	6	*	6	1	*	4	1	*
Germany (DE)	53	77	+24	12	27	9	-18	4	8	+4	15	15	
Iceland (IS)	1	0	-1										
Ireland (IE)				N/A	1	0	-1						
Italy (IT)	35	66	+31	33	60	2	-58	17	14	-3	0		
Luxembourg (LU)								0	1	+1			
Netherlands (NL)													
Norway (NO)	8	13	+5	3	5	8	+3	3	6	+3	2	0	-2
Poland (PL)	2	4	+2	1	2	0	-2				0	2	+2
Slovakia (SK)	10	24	+14	9	7	3	-4	1	0	+1			
Slovenia (SI)											0	2	+2
Spain (ES)	0	1	+1										
Sweden (SE)													
n	10	11		7	9	9		4	6		3	6	

Country	Major CCVE up to 24h after donation		Absolute Change	Allergic reaction		Absolute Change	General		Absolute Change
	2023	2024		2023	2024		2023	2024	
Austria (AT)	2	0	-2						
Belgium (BE)				0	1	+1			
Czechia (CZ)									
Denmark (DK)									
France (FR)	1	1	*	1	0	*			
Germany (DE)	3	8	+5						
Iceland (IS)									
Ireland (IE)									
Italy (IT)				2	3	+1			
Luxembourg (LU)									
Netherlands (NL)							0	2	+2
Norway (NO)									
Poland (PL)									
Slovakia (SK)									
Slovenia (SI)									
Spain (ES)									
Sweden (SE)							N/A	N/A	
n	3	2		2	2		0	1	

Note 1: BG, HR, CY, FI, EL, IS, LV, LT, PT and RO reported zero SAR in both 2023 and 2024 (not shown above); UK(NI) reported data N/A in both 2023 and 2024 (not shown above).
*Note 2: * for FR, data between years is not comparable due to change in the reporting scope (only grade 3 (severe) and grade 4 (death) reported in 2024)*

In comparison with the previous year, the total number of vasovagal reactions in apheresis donors decreased substantially in 2024 (Table 31). As noted in Table 32, this change is not directly comparable with 2023 data due to France's revised reporting scope, as mentioned before. In 2023, French vasovagal reactions accounted for 84% of the European total for apheresis donors; their effective removal from the 2024 total accounts for the majority of the observed reduction.

The percentage distribution of SAR in apheresis donors by type of reaction for each reporting country is displayed in Figure 45.

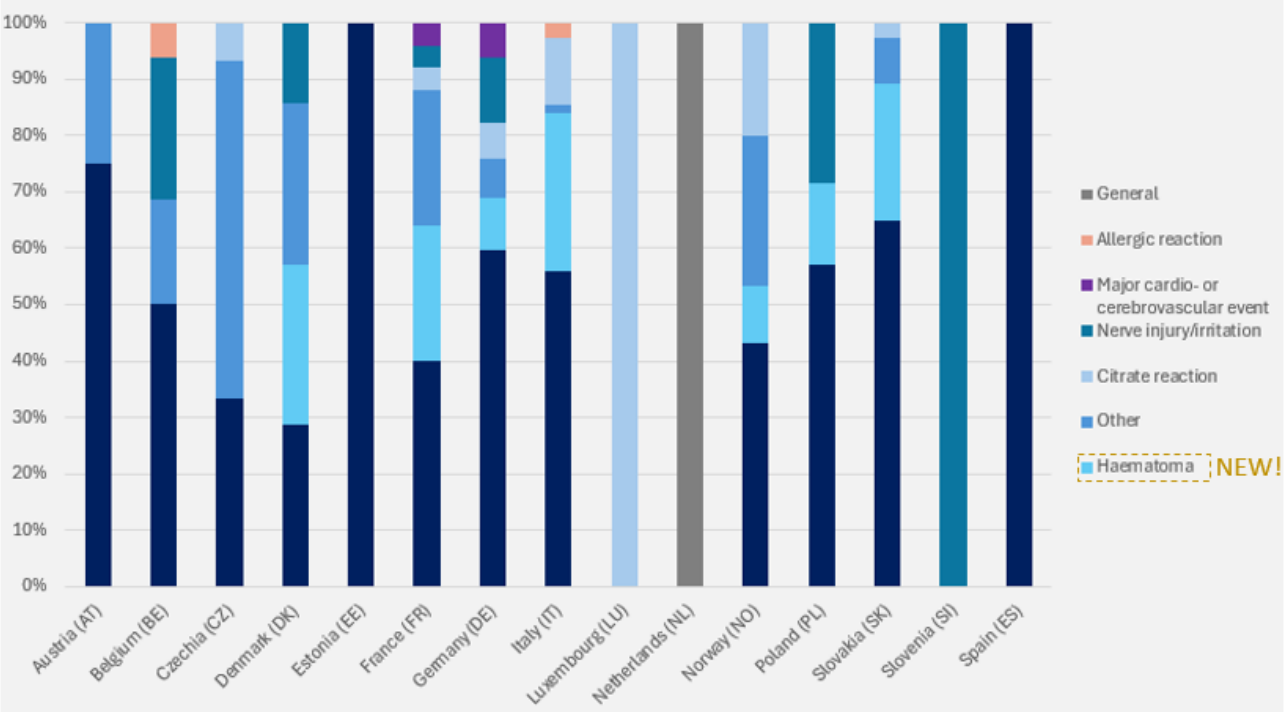


Figure 45. Percentage distribution of SAR in apheresis donors by type of reaction per country in 2024
Note: BG, HR, CY, FI, EL, IS, IE, LV, LT, PT and RO reported zero SAR (not shown above); SE and UK(NI) reported data N/A (not shown above).

4.4 Fatalities in donors

In 2024, four fatalities (1 in WB and 3 in apheresis) were reported in donors. This is a significant finding given that no donor fatalities were reported in previous years. The four cases have been presented alongside some points for consideration at the Vigilance & Traceability Working Group annual meeting (27th–28th April 2026).

CONCLUSIONS

Haemovigilance, the systematic surveillance of transfusion-related adverse reactions and events, is fundamental to the continuous improvement of blood safety across Europe. The 2025 SARE Report, drawing on data submitted by 28 countries for the 2024 reporting period, provides the most comprehensive picture of European transfusion safety to date.

The findings presented below should be interpreted in the context of the methodological limitations outlined in this report, in particular the variability in reporting completeness, the evolving composition of the contributing country set and the structural impact of Romania's dataset on aggregate metrics.

A. Summary of Key Findings

1. Activity Data

- The WB donation rate (median) declined 8% while the apheresis' remained stable.
- Transfusion activity across Europe remained broadly stable in 2024. Approximately 16.5 million units of blood/BC were transfused across reporting countries, with the median per-country transfusion rate (38.6 per 1 000 population) consistent with 2023.
- RBC continue to represent the dominant component type by volume, though a 13% increase in plasma units issued relative to 2023 is of note.
- The total number of recipients transfused increased across all types of BC, reflecting sustained clinical demand.

2. SAR (IL 2-3)

- The total number of SAR (IL 2-3) in recipients was 1 360 in 2024, representing a decrease of approximately 9% compared to the previous year. The total SAR (IL 2-3) incidence remains consistently low and fairly stable. Platelets consistently show the highest median SAR (IL 2 3) incidence, followed by RBC and plasma.
- FNHTR, anaphylaxis/hypersensitivity and TACO accounted for the three most prevalent reaction categories, a distribution that has remained consistent since 2022 and is aligned with data from established haemovigilance systems including SHOT.
- The most clinically significant finding of the 2024 reporting cycle is the reduction in recipient fatalities (IL 2-3) to 11, the lowest annual figure in the 2021–2024 period and ten fewer than in 2023. Over this period, immunological haemolysis (32 deaths), TACO (18 deaths) and TRALI (15 deaths) remain the three leading cumulative causes of transfusion-related mortality. This is a pattern consistent with fatality profiles reported by the FDA and the International Haemovigilance Network (IHN), reinforcing that these reaction types represent the primary preventable mortality burden in high-income transfusion systems globally.
- Fourteen TTIs (IL 2-3) were reported in 2024, six fewer than in 2023, with bacterial infections predominantly associated with platelet components, which is consistent with international surveillance data on platelet contamination risk. The proportion of TTBI cases with pathogen-level identification improved substantially, from 47% in 2023 to 83% in 2024, representing a meaningful quality improvement in post-investigation reporting.

3. SAE

- The total number of SAE increased dramatically (108%), translating into a total SAE incidence of 19.5 per 100 000 units processed (vs 9.7 in 2023), driven primarily by Romania's reporting update approach. However, at the median country level, SAE patterns remained fairly stable. When Romania's contribution is excluded, the total incidence falls to 6.4, comparable with previous years.
- Procedurally, Romania's dataset, which alone accounts for 67% of all reported events, altered the specification distribution (component defect rising from 16% to 60% of all SAE). Excluding Romania's contribution, human error continued to feature as the leading cause (38% vs 42% in 2023).
- Analysis of SAE narrative data across all specification categories reveals that the majority of reported events, particularly within component defect (93%) and equipment failure (85%), were submitted without any accompanying detail, making them as analytically invisible. Where narrative data were available, wrong-patient and ICBT events consistently emerged as multi-layer system failures (covering prescribing, laboratory communication and bedside verification) while a recurring cluster of donor disclosure failures, ranging from deliberate non-disclosure to language and literacy barriers exposed a structural over-reliance on donor self-reporting as the primary safety screen.

4. SAR in Donors (Voluntary)

- A 36% reduction in donor SAR was observed (primarily driven by France's scope update). The most frequently reported type of SAR were vasovagal reactions. France historically contributed the majority of vasovagal reactions reported in WB and apheresis donors; its exclusion of grades 1 and 2 cases in 2024 lowers the European aggregate while concealing true comparability with prior years for this parameter.
- Four donor fatalities were reported for the first time in 2024.

B. Major Challenges and Points for Consideration

- A persistent gap in European haemovigilance is the lack of complete denominator data which limits incidence comparability.
- Despite widespread awareness and clear mitigation guidelines, TACO remains stubbornly persistent as one of the leading causes of transfusion-related mortality. **Point for consideration:** An example of best practice is the SHOT pre-transfusion TACO risk assessment [3]. Therefore, compliance with TACO prevention protocols could ideally be incorporated as an audit metric within national haemovigilance programmes.
- Fatality narratives remain a critical source of learning. While general compliance with ***Common Approach*** is evident, harmonisation of detail remains necessary. **Point for consideration:** Case narratives, when shared, are far more valuable when they include enough contextual detail to support a preventability judgement. Elements that tend to make this possible include whether pre-transfusion risk assessment was performed, whether known mitigations or patient-specific protocols were available and applied, and what possible contributory factors were identified. SHOT [2] illustrates this approach well, with a dedicated chapter on deaths and per-category fatality narratives that cover human-factor and contributory factor analysis.

- **Point for consideration:** Minimum documentation standards for SAE submissions should be strengthened. A case reported without any accompanying narrative or root cause information should not be considered a complete submission.
- A SAE finding of particular concern is a documented software programming error in which positive infectious disease parameters were interpreted as negative by the data entry system due to poor programming logic. This is a latent system failure with the potential to affect multiple donations before detection. **Point for consideration:** Competent authorities should enquire whether a formal software incident report was filed with the relevant medical device regulatory authority in addition to the haemovigilance reporting. IT system changes, including software updates, new laboratory information system implementations and interface changes should be subject to mandatory prospective validation protocols before go-live.

The 2024 data demonstrate meaningful progress across several aspects of transfusion safety, including a record low number of recipient fatalities and reductions in both TTIs and SAR. However, persistent gaps in the completeness of SAE reporting, the ongoing preventable burden of TACO and immunological haemolysis, and the concerns highlighted by donor fatality data underscore the need for sustained and coordinated action. Strengthened efforts in staff training, as well as the harmonisation of practices and reporting standards across (inter)national haemovigilance systems remain essential.

List of Abbreviations

AE	Adverse Event
ALI	Acute Lung Injury
AML	Acute Myeloid Leukaemia
AHTR	Acute Haemolytic Transfusion Reaction
BC	Blood Component
BE	Blood Establishment
BNP	B-Type Natriuretic Peptide Levels
CAPA	Corrective and Preventive Actions
CCVE	Cardio-or Cerebrovascular Event
CMV	Cytomegalovirus
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
EDQM	European Directorate for the Quality of Medicines & HealthCare
EDP	Electronic Data Processing
EU	European Union
DHTR	Delayed Haemolytic Transfusion Reaction
FDA	Food and Drug Administration
FNHTR	Febrile Non-Haemolytic Transfusion Reaction
HBB	Hospital Blood Bank
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HEV	Hepatitis E Virus
HPA	Human Platelet Antigen
IBCT	Incorrect Blood Component Transfused
IHN	International Haemovigilance Network
IL	Imputability Level
ISBT	International Society of Blood Transfusion
MTOC	More Than One Blood Component
MS	Member States
N/A	Not Available
NCA	National Competent Authorities
PDI	Post-Donation Information
PMP	Per One Million Population
PTP	Post-Transfusion Purpura
RBC	Red Blood Cells
RCC	Red Cell Concentrates
SAE	Serious Adverse Events
SAR	Serious Adverse Reactions
SARE	Serious Adverse Reactions and Events
SOP	Standard Operating Procedure
SHOT	UK's Serious Hazards of Transfusion
TACO	Transfusion-Associated Circulatory Overload
TAD	Transfusion-Associated Dyspnoea
TRALI	Transfusion-Related Acute Lung Injury
TTBI	Transfusion-Transmitted Bacterial Infection
TTFI	Transfusion-Transmitted Fungal Infection
TTI	Transfusion-Transmitted Infection
TTPRI	Transfusion-Transmitted Prion Infection
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
MT	Malta
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

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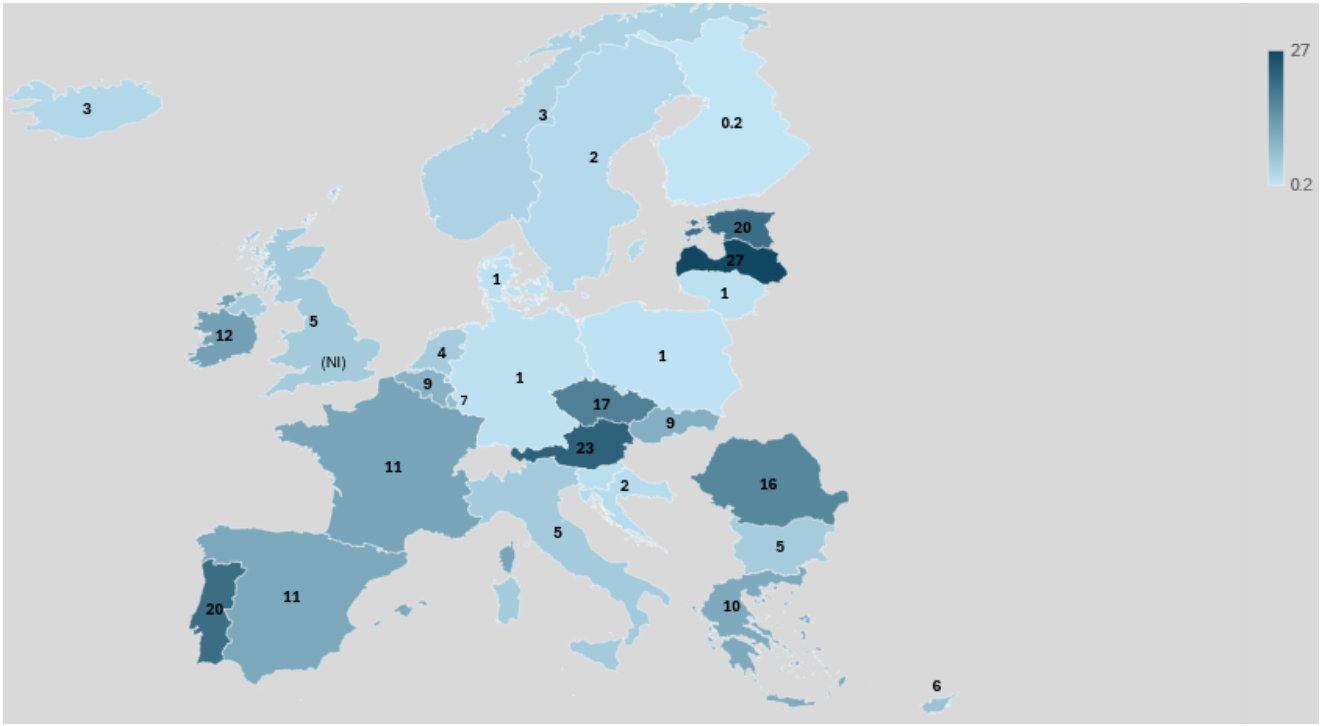
Annex 1. Executive summary (2021–2024)

Parameter	2022 (Data 2021)		2023 (Data 2022)		2024 (Data 2023)		2025 (Data 2024)	
	n	Number	n	Number	n	Number	n	Number
Reporting Countries		30		30		30		**28**
Reporting Establishments	30	3 307	30	3 346	29	3 244	28	**3 190**
Blood/BC Units Issued	30	20 633 199	30	21 394 422	30	20 824 019	28	**20 467 219**
Blood/BC Units Transfused	26	17 808 869	24	17 197 676	23	16 213 234	23	**16 478 412**
Recipients Transfused*	20	2 912 307	22	3 094 799	20	2 850 968	21	**2 998 676**
SAR (IL 1) (Voluntary)	23	1 435	21	1 700	21	1 680	20	**1 457**
SAR (IL 2-3)	24	1 379	27	1 516	25	1 490	25	**1 360**
Total SAR (IL 2-3) incidence (per 10^5 units transfused)		7.7 [median= 3.7]		8.8 [median= 4.4]		9.2 [median= 3.7]		**8.3 [median=5.2]**
Fatalities (IL 2-3) in recipients	11	25	9	27	9	21	5	**11**
Total Fatalities (IL 2-3) incidence (per 10^5 units transfused)		0.14		0.16		0.13		**0.06**
Blood/BC Units Processed	28	22 961 648	27	22 943 682	26	23 700 556	28	**24 423 977**
WB Collections	27	16 242 768	26	15 576 875	26	16 068 007	26	**15 679 193**
Apheresis Collections	27	6 035 995	26	6 376 960	25	7 286 075	25	**7 590 344**
SAE	24	2 734	25	2 235	25	2 294	25	**4 764**
Total SAE incidence (per 10^5 units processed)		11.9 [median= 3.4]		9.7 [median= 6.5]		9.7 [median= 3.9]		**19.5 [median= 6.4]**
SAR in Donors (Voluntary)	23	2 946	23	2 935	23	3 530	22	**2 260**
SAR in WB Donors	21	2 262	21	2 271	21	2 573	23	**1 865**
SAR in Apheresis Donors	15	684	11	664	12	957	15	**395**
Fatalities in Donors	0	0	0	0	0	0	3	**4**

*Note 1: the observed **SAE increase in 2024 is primarily due to Romania's data***
*Note 2: *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). In 2024, it results from 19 countries (2 866 369) plus the number of recipients from EE and EL (132 307) which only reported the overall number.*
Note 3: for details on how total incidence was calculated refer to section 'Key indicators definitions' in Methodology. This disclosure allows for a better understanding of the potential limitations or biases in the incidence calculation.

Annex 2. Reporting establishments per capita (pmp)



Annex 3. Completeness dashboard per metric per country in 2024

	General completeness				Component level completeness											
						Units Issued				Units Transfused						Number of Collections - Denominator available for SAR incidence in Donors?	
Country	% Reports Received	% Number of Units Issued	% Number of Recipients	% Number of Units Transfused	Number of Recipients regardless of BC	WB	RBC	Platelets	Plasma	WB	RBC	Platelets	Plasma	Denominator available for SAR (IL 2-3) incidence?	Units Processed - Denominator available for SAE incidence?	WB	Apheresis
Austria (AT)	88	100	96	100	N/A	Yes (0)	Yes	Yes	Yes	Yes (0)	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Belgium (BE)	100	100	100	100	Yes	Yes (0)	Yes	Yes	Yes	Yes (0)	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Bulgaria (BG)	99	99	90	96	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Croatia (HR)	100	100	99	99	Yes	Yes (0)	Yes	Yes	Yes	Yes (0)	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Cyprus (CY)	100	100	100	100	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Czechia (CZ)	100	100	100	100	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Denmark (DK)	100	100	100	100	Yes	N/A	Yes	Yes	Yes	N/A	Yes	Yes	Yes	Yes, but incomplete	Yes	Yes	Yes
Estonia (EE)	100	100	100	100	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Finland (FI)	100	100	N/A	N/A	N/A	N/A	Yes	Yes	Yes (0)	N/A	N/A	N/A	Yes (0)	No	Yes	Yes	Yes
France (FR)	100	100	100	100	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Germany (DE)	99	N/A	N/A	N/A	N/A	N/A	Yes	Yes	Yes	N/A	Yes	Yes	Yes	Yes, but incomplete	Yes	Yes	Yes
Greece (EL)	67	87	61	80	Yes	Yes (0)	Yes	Yes	Yes	Yes (0)	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Iceland (IS)	100	100	100	100	Yes	Yes (0)	Yes	Yes	Yes	Yes (0)	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Ireland (IE)	100	100	70	100	N/A	Yes	Yes	Yes	Yes (0)	Yes	Yes	Yes	Yes (0)	Yes	Yes	Yes	Yes
Italy (IT)	100	100	100	100	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Latvia (LV)	100	100	N/A	N/A	N/A	N/A	Yes	Yes	Yes	N/A	N/A	N/A	N/A	No	Yes	No	No
Lithuania (LT)	100	100	N/A	N/A	N/A	Yes	Yes	Yes	Yes	N/A	N/A	N/A	N/A	No	Yes	Yes	Yes
Luxembourg (LU)	100	100	100	100	Yes	N/A	Yes	Yes	Yes	N/A	Yes	Yes	Yes	Yes, but incomplete	Yes	Yes	Yes
Netherlands (NL)	94	100	77	100	N/A	Yes (0)	Yes	Yes	Yes	Yes (0)	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Norway (NO)	100	N/A	N/A	100	N/A	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Poland (PL)	100	100	N/A	N/A	N/A	Yes	Yes	Yes	Yes	N/A	N/A	N/A	N/A	No	Yes	Yes	Yes
Portugal (PT)	100	100	100	100	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Romania (RO)	100	100	100	100	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Slovakia (SK)	76	80	N/A	75	N/A	Yes	Yes	Yes	Yes	N/A	Yes	Yes	Yes	Yes, but incomplete	Yes	No	No
Slovenia (SI)	100	100	N/A	N/A	N/A	N/A	Yes	Yes	Yes	N/A	N/A	N/A	N/A	No	Yes	Yes	Yes
Spain (ES)	N/A	N/A	N/A	N/A	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Sweden (SE)	100	100	100	100	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
United Kingdom (NI)	100	100	33	100	Yes	Yes (0)	Yes	Yes	Yes	Yes (0)	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Note 1: HU, MT and LI did not report in 2024.
Note 2: N/A- data not available; Yes(0)- country reported 0 units.

Annex 4. Definitions of the reportable types of transfusable reactions

Term	Definition
Transfusion-related acute lung injury (TRALI)	In patients with no evidence of acute lung injury (ALI) prior to transfusion, TRALI is diagnosed if a new ALI is present: • Acute onset • Hypoxemia - PaO2/FiO2 < 300 mm Hg or - Oxygen saturation is < 90% on room air or - Other clinical evidence • Bilateral infiltrates on frontal chest radiograph • No evidence of left atrial hypertension (i.e. circulatory overload) • No temporal relationship to an alternative risk factor for ALI during or within 6 hours of completion of transfusion. Neither presence of anti-HLA or anti-HNA antibodies in donor(s) nor confirmation of cognate antigens in recipient is required for diagnosis.
Anaphylaxis/hypersensitivity	There is anaphylaxis when, in addition to mucocutaneous systems there is airway compromise or severe hypotension requiring vasopressor treatment (or associated symptoms like hypotonia, syncope). The respiratory signs and symptoms may be laryngeal (tightness in the throat, dysphagia, dysphonia, hoarseness, stridor) or pulmonary (dyspnoea, cough, wheezing/bronchospasm, hypoxemia). Such a reaction usually occurs occurring during or very shortly after transfusion.
Febrile non-haemolytic transfusion reaction (FNHTR)	Only the most serious cases of FNHTR should be accounted for: Fever (≥39ºC oral or equivalent AND a change of ≥2ºC from pre-transfusion value) and/or chills/rigors.
Immunological haemolysis	• **due to ABO incompatibility:** acute haemolytic transfusion reaction (AHTR) caused by transfusion of ABO-incompatible RBCs, mediated by naturally occurring antibodies. • **due to other alloantibody:** haemolytic transfusion reaction caused by recipient alloantibodies to non-ABO antigens (e.g., Rh, Kidd, Kell), presenting as an acute or delayed haemolytic transfusion reaction.
Post-transfusion purpura (PTP)	PTP is characterized by thrombocytopenia arising 5-12 days following transfusion of cellular blood components with findings of antibodies in the patient directed against the Human Platelet Antigen (HPA) system.
Transfusion-associated graft-versus-host disease (Ta-GvHD)	TA-GvHD is a clinical syndrome characterised by symptoms of fever, rash, liver dysfunction, diarrhoea, pancytopenia and findings of characteristic histological appearances on biopsy occurring 1-6 weeks following transfusion with no other apparent cause. The diagnosis of TA-GvHD is further supported by the presence of chimerism.
Transfusion-associated cardiovascular overload (TACO)	Patients classified with TACO (surveillance diagnosis) should exhibit the following during or up to 12 hours after transfusion* • At least one required criterion (i.e., A and/or B) • With a total of at least 3 or more criteria (A to E) *Required criteria (A and/or B) A. Acute or worsening respiratory deterioration and/or B. Evidence of acute or worsening pulmonary oedema based on: - clinical physical examination, and/or - radiographic chest imaging and/or other non-invasive assessment of cardiac function Additional criteria C. Evidence for cardiovascular system changes not explained by the patient's underlying medical condition, including development of tachycardia, hypertension, jugular venous distension, enlarged cardiac silhouette and/or peripheral oedema

	D. Evidence of fluid overload including any of the following: a positive fluid balance; clinical improvement following diuresis E. Supportive result of a relevant biomarker, e.g., an increase of B-type natriuretic peptide levels (BNP) or N-terminal-pro brain natriuretic peptide) NT-pro BNP to greater than 1.5 times the pre-transfusion value
Hypotensive transfusion reaction	This reaction is characterized by hypotension defined as a drop in systolic blood pressure of ≥ 30 mm Hg occurring during or within one hour of completing transfusion and a systolic blood pressure ≤ 80 mm Hg. Most reactions do occur very rapidly after the start of the transfusion (within minutes).
Transfusion-associated dyspnoea (TAD)	TAD is characterized by respiratory distress within 24 hours of transfusion that do not meet the criteria of TRALI, TACO, or allergic reaction. Respiratory distress should not be explained by the patient's underlying condition or any other known cause.
Non-immunological haemolysis	Haemolysis due to physical, chemical, or mechanical factors, without involvement of immune antibodies. Common causes include: - Mechanical damage (e.g., improper warming, small-bore needles, infusion pumps) - Thermal injury (overheating/freezing of RBC) - Osmotic injury (hypotonic solutions) - Chemical exposure (incompatible IV fluids, drugs) - Storage or transport conditions causing RBC membrane damage

Annex 5. Additional information on SAE by specification

Specification	SAE Examples/Comments	# SAE
Component defect **60%** (2 848 out of 4 764)	• ***No additional information provided***	2 626
	• Platelet units found to have positive bacterial screening after "negative to date" distribution, the units from the donations had already been transfused	88
	• PDI that was known at the time of donation but not mentioned by the donor OR information that led to the donor's refusal but may have influenced the quality of former donations (e.g. newly diagnosed malignant disease or *Borellia* infection)	58
	• **Non available information (N/A)**	15
	• Repeat donor tested positive for HCV	14
	• Insufficient deferral period after risk of infection due to incorrect programming in EDP	3
Human error **14%** (675 out of 4 764)	• **Non available information (N/A)**	129
	• ***No additional information provided***	101
	• Wrong patient transfused: resulting from a combination of multiple successive failures during the same BC prescription process. The failures are combined from the error of identity of patient in prescribing BCs, failures of communication between the staff taking care of the patient and the staff issued BCs, the error in checking of identity patient in issuing of these BCs in the BE or in the HBB, the error in checking of identity patient in the clinical area (at the reception of BCs and/or at bedside). 10% occurred in urgent settings, none occurred during night shifts (8 PM to 8 AM); 16% occurred during week-end or public holidays. When a SAR ABO incompatibility results from a 'wrong patient transfused', they are not included in this category. They are reported only as SAR ABO incompatibility.	67
	• Most reported SAEs were related to unreported recent travel to malaria- or Chagas-endemic areas, largely due to donor omission and insufficient emphasis during the pre-donation interview, although no TTIs occurred and all post-donation testing was negative. Less frequently, procedural omissions (such as missed Hb testing or shortened inter-donation intervals) were reported, none of which resulted in adverse consequences, and all events were followed by systematic reminders of existing procedures.	30
	• Donor accepted despite info for exclusion; insufficient donor deferral	26
	• Delayed transfusion (DT): resulting from a combination of multiple successive failures during the same BC prescription process. The failures are combined from the delay in prescribing BCs, failures of communication between the staff taking care of the patient and the staff issuing BCs, the delay in issuing these BCs, the delay in their transport/shipment from the BE or from the HBB to the transfusion healthcare area and the delay in the transfusion procedure. This DTs occur mainly in urgent settings (20%) and in in non-urgent settings (medical and intensive care units 12%, emergency department 13% and obstetrics 4%. And among DTs in urgent settings, 3% occurred during night shifts (8 PM to 8 AM).	23
	• Lack of concentration	20
	• Overcollection due to plasma bag not hanging freely (2), doctor mistakenly prescribed too large collection volume(5), overcollection due to incorrect setting on device (6)	13
	• Transfusion/Issue of incorrectly labelled component	11
	• Failure of the PDI system: they are due to non-application of procedures. A systematic reminder is carried out for staff who have not respected these procedures	10
	• Transfusion on an invalid sample	10
	• ICBT e.g. due to insufficient or no bedside check	9
	• ICBT due to incorrect product allocation during issue	9
	• WBIT, labelling error, donor mix-up	8
	• Error in blood component transportation	8
	• Wrongful registration of the blood donor	5
	• Incorrect blood component issued by blood bank	5
	• Incorrect labelling after irradiation, Errors during irradiation, omission of quality control	4
	• FFP units which were not transfused to patients returned to HBB by clinic without marked as unsuitable. HBB realized that the specific FFP units were not suitable for transfusion and after preventive and corrective actions the units were discarded.	3
	• Microbe contamination in platelet product (which were not transfused), possibly due to venipuncture step	3
	• The donor had too poor language skills. They did not adequately understand what they signed on	3

Specification	SAE Examples/Comments	# SAE
Equipment failure **11%** (510 out of 4 764)	• ***No additional information provided***	423
	• These rare SAEs are subject to systematic equipment maintenance check and systematic reminders of the procedures and the need to respect them	38
	• **Non available information (N/A)**	12
	• Burst blood bag	11
	• Missing or invalid positive controls for infection serology	3
	• Incorrect weight indication on the weigher/mixer resulting in too much blood volume being taken	2
	• IT-software error and machine malfunction	2
	• Inadequate blood typing reagents	2
	• Weld failure	2
	• Incorrect weak D declaration as D negative due to EDP misprogramming	1
	• Omission of alloantibody screening test of donors due to EDP misprogramming	1
	• Overfilling of EC, probably due to defective scale	1
	• The machine drew to much plasma	1
Other **7%** (367 out of 4 764)	• ***No additional information provided***	83
	• Positivity ALT during testing	70
	• The donor did not provide correct or full information at the donation	50
	• Collapse during whole blood collection	40
	• Covid, Herpes Zoster in donor selection	24
	• Rupture veins during whole blood collection	17
	• Positivity NCT during testing	11
	• The interview form used is inadequate	9
	• Positive viral- or microbiological tests came back after donation	8
	• The transfused component doesn`t meet the requirements (incorrect blood antigen determined)	7
	• Leaking pack noted on arrival to hospital x 3, Clots observed in unit x 1, Minor red cell sediment in ports, not significant to transfusion and no patient impact x 1, Leak noted in unit pre-transfusion x 1, Unit haemolysed x 1	7
	• Positivity anti HCV during testing	4
	• Patient hid the information about the therapy he receives/his diagnosis. Blood components were distributed for use	3
	• Extensive floods	3
	• National epidemiological situation changed (increased amount of HEV cases due to sausages); additional blood donation testing was started, and positive cases were found on archive samples; the blood products were already transfused	2

Specification	SAE Examples/Comments	# SAE
System failure **5%** (229 out of 4 764)	• Failure of the IT systems/ Transport: these rare SAEs are subject to systematic equipment maintenance check and systematic reminders of the procedures and the need to respect them	36
	• **Non available information (N/A)**	34
	• Donor eligibility violations	33
	• Delayed transfusion: resulting from a combination of multiple successive failures during the same BC prescription process (...)	15
	• Wrong patient transfused: resulting from a combination of multiple successive failures during the same BC prescription process (...)	14
	• Little knowledge about rules and procedures	12
	• ***No additional information provided***	9
	• Lack of routines/internal procedure	3
	• Stress	3
	• Typing errors when entering positive infection parameters were interpreted as negative by EDP due to poor programming	2
	• BCs issued without specific characteristics - irradiation and/or CMV	2
	• Errors due to delayed process validation	1
	• Different procedure for accepting donor regarding medical declaration form	1
	• Failure to provide irradiated units after introduction of new lab-system	1
	• Issue of donor-incompatible plasma for patient with planned kidney transplant	1
Materials **3%** (135 out of 4 764)	• Burst blood bag	49
	• Burst blood bag, plasma chylostasis	33
	• Plasma chylostasis	30
	• Faulty pipette tips or faulty positive controls led to invalid test results	2
	• **Non available information (N/A)**	1
	• ***No additional information provided***	1
	• Faulty lot number of serological immunoassay cards	1
	• The units were pathogenically reduced but the exposure report had an incorrect date due to a date change in the system	1
	• Wrong result of the phenotype resulting from a default reagent	1
	• False positive results due to faulty reagent lot number	1

Annex 6. Additional information on SAR in donors per reporting country

Country (# SAR)	WB vs Apheresis Donation	Comments (related to 'Other' and Major CCVE)
Belgium (56)	71% (40) WB 29% (16) Apheresis	• WB 'Other category': 4 thrombophlebitis; 1 tendon-muscle injury; 1 erysipelas • Apheresis 'Other' category: 3 thrombophlebitis
Cyprus (11)	100% WB	'Other' category: after removing the needle from the donor's arm, the blood flow could not stop, and he was transferred to the Emergency Room of the hospital and later released.
Czechia (18)	17% (3) WB 83% (15) Apheresis	• WB 'Other category': 2 vasovagal reaction with fall and laceration • Apheresis 'Other' category: 3 spasm and hypotension due to replacement of physiological saline and citrate; 1 tissue infection (*Str. pyogenes*); 2 vasovagal reaction with spasm; 3 vasovagal reaction with fall and laceration
Finland (1)	100% WB	'Other' category: 28 hours after whole blood donation, donor experienced chest pain during strenuous labour, which resulted in hospitalisation, myocardial infarction and operation (balloon angioplasty with stent) and diagnosing of coronary artery disease. The donor had been without cardiac symptoms before the event and had been in follow-up due to high cholesterol levels. Blood donation and the resulting dehydration and lowered haemoglobin may have been contributing factors leading to the cardiovascular event. The donor's coronary artery disease had probably been developing for a long time but was asymptomatic and undiagnosed. Seriousness: Serious; Severity: Grade 3 (classified using the AABB Severity Grading Tool of Blood Donor Adverse Events: category E; acute cardiac symptoms; myocardial infarction --> diagnosis medically confirmed); Imputability: 1/possible
Germany (615)	79% (486) WB 21% (129) Apheresis	• WB 'Other category': 9 thrombophlebitis; 1 inflammatory tissue reaction; 1 phlegmon; 7 venous thrombosis; 1 pseudoaneurysm; 1 allergic reaction; 1 unclear neurological symptoms; 1 cerebral seizure; 1 anaemia; 1 traffic accident after donation • Apheresis 'Other' category: 2 thrombophlebitis; 1 phlegmon; 1 cyst formation in the crook of the elbow; 3 haemolysis; 1 unclear neurological symptoms; 1 status epilepticus
Italy (350)	66% (232) WB 34% (118) Apheresis	• WB 'Other category': 5 post-donation accident-related head trauma and 4 thrombophlebitis • Apheresis 'Other' category: 2 thrombophlebitis
Luxembourg (2)	50% (1) WB 50% (1) Apheresis	• A donor presented for WB donation, filled in the pre-donation questionnaire and got a medical consultation before the donation. No contraindication for a blood donation was detected (normal physiological parameters, negative answer on exceptional bleedings). A bag of WB had been collected without any problems. By performing the hemogram, the laboratory technician found on the same day a haemoglobin result of 6.5 g/l. He was immediately informed by the BTC about the result and said that he was in a good shape and had not detected any fatigue. During the phone call, he said that he has slight bleeding due to haemorrhoids since approximately 1 year. He was informed to contact as soon as possible his treating medical doctor. He did a consultation at an emergency department, got two blood transfusions of RBC. Unfortunately, we are unaware of the etiology.
Netherlands (5)	no distinction can be made based on donation type	'Other' category: 4 vasovagal reactions and 1 venipuncture related/thrombophlebitis
Norway (223)	87% (193) WB 13% (30) Apheresis	• WB 'Other category': 1 local allergic reaction; 6 other systemic reactions, 9 reactions with local pain in the arm not judged to be due to nerve irritation • Apheresis 'Other' category: 6 local pain reactions not judged to be due to nerve irritation; 2 systemic reactions
Portugal (8)	100% WB	'Other' category: 1 brachial artery pseudoaneurysm
Slovenia (18)	89% (16) WB 11% (2) Apheresis	WB: 1 Major CCVE up to 24 hours after donation: The donor suffered an acute myocardial infarction in the evening around 11 pm. The imputability assessment: probably, likely
Sweden (23) (2 cases from 2023)	(23) WB N/A Apheresis	WB 'Other category': 3 artery puncture; 3 skin reaction and received antibiotics

Country (# SAR)	SAR Rate (calculated by country)	SAR by Gender	Type of Donor	WB vs Apheresis Donation	Comments
France (111)	4.2 SARs per 100 000 donations (2 650 837 donations) or 0.7 SARs per 10 000 blood donors (1 557 675 donors)	75% in women vs 25% in men	85% regular blood donors vs 15% first-time blood donors (regardless of inclusion criteria)	77% (86) WB 23% (25) Apheresis 45% occurred in fixed site of BE vs 55% in mobile collection site	• WB Major CCVE event (3 SAR): 2 superficial vein thrombosis, 1 deep vein thrombosis. All occurred in current women donors • WB 'Other category': 18 iron deficiencies, 16 anaemia, 2 arterial punctures, 2 tendon injuries, 1 arteriovenous fistula, 1 local infection, 1 lymphangitis and 1 uncategorised complication of donation (atypical chest pain) • Apheresis Major CCVE (1 SAR): 1 superficial vein thrombosis, occurred in a current male donor • Apheresis 'Other category': 3 lymphangitis, 1 anaemia, 1 iron deficiency, 1 tendon injury
Ireland (10) (2 from 2022, 2 from 2023 and 6 from 2024)	133 996 attempted WB donations and 8 339 attempted apheresis donations in the calendar year 2024 (total of 142 335 attempted donations). The rate of SARs for WB and apheresis donations was therefore 1 in 14 234 attempted donations.	5 donors are female and 5 are male		100% WB	• 3 SARs classified as vasovagal reactions, 1 was an immediate vasovagal reaction without injury, 2 were delayed vasovagal reactions with injury. ➢ The immediate vasovagal reaction occurred in a 46-year-old male donor with a history of 8 previous donations. He briefly lost consciousness for about 2 minutes. During this period, he appeared to stop breathing and had no detectable pulse, prompting clinic staff to start CPR and use a portable AED. The AED detected electrical activity (no shock advised), and the donor quickly regained consciousness. He was transported to hospital where tests confirmed there was no cardiac arrest. The donor recovered completely, was discharged the next morning, and advised to follow up with his GP. He is now permanently excluded from donating blood. ➢ The two donors who had delayed vasovagal reactions were regular female donors; one was 51 years of age and was unconscious for > 60 seconds without seizure-like activity or incontinence; the second donor was 61 years of age and was unconscious for < 60 seconds and did not have seizure-like activity or incontinence. Both donors were admitted to hospital for overnight observations. The 51-year-old donor received 3 litres of intravenous fluid due to hypotension. Both donors made a full recovery and are permanently excluded from donating. • 5 SARs classified as nerve injury/nerve irritation, 4 of these were nerve injuries on needle insertion and 1 was a nerve irritation. Symptoms lasted longer than 12 months in all 5 cases. • 'Other' category: 2 cases of painful arms, in both donors, symptoms persisted for more than 12 months after donation.

Annex 7. SAR IL 1 (Voluntary)

6.1 Overview of SAR (IL 1) and fatalities (IL 1) by type of BC (2023 vs. 2024)

Total Number of SAR (IL 1)	2023	2024	% Change
RBC	1 190	1 092	-8
Platelets	252	194	-23
Plasma	161	100	-38
MTOC	77	71	-8
WB	0	0	-
TOTAL	**1 680**	**1 457**	**-13**

n (RBC)	20	19
n (Platelets)	17	13
n (Plasma)	11	11
n (MTOC)	7	9
n (WB)	0	0

Total Number of Fatalities (IL 1)	2023	2024	Absolute Change
RBC	16	14	-2
Platelets	5	3	-2
Plasma	0	1	+1
MTOC	1	3	+2
WB	0	0	-
TOTAL	**22**	**21**	**-1**

n (RBC)	4	5
n (Platelets)	2	3
n (Plasma)	0	1
n (MTOC)	1	3
n (WB)	0	0

6.2 Overview of SAR (IL 1) by type of reaction (2023 vs. 2024)

Type of Reaction	2023 position	# SAR 2024 (+/- 2023)
FNHTR	2	484 (-10)
Anaphylaxis/hypersensitivity	1	445 (-204)
Other	3	200 (+15)
TACO	4	150 (-11)
TAD	5	59 (-4)
Immunological haemolysis	8	40 (+15)
TRALI	7	39 (+5)
Hypotensive transfusion reaction	10	18 (+10)
TTBI	9	12 (-3)
PTP	12=	6 (+5)
Non-immunological haemolysis	6	3 (-36)
TTVI	11	1 (-4)
TTPI	12=	0 (-1)

6.3 Overview of TTIs (IL 1)

Type of TTI	2023	2024	Absolute Change
TTBI	15	12	-3
TTVI	5	1	-4
TTPI	1	0	-1
TOTAL	21	**13**	**-8**

n (TTBI)	1	2
n (TTVI)	2	1
n (TTPI)	1	0

Note: zero TTFI and TTPRI cases reported in both 2023 and 2024.

6.4 Overview of TTIs (IL 1) by type of BC; 2023 vs. 2024

Type of TTI	RBC			Platelets			MTOC		
	2023	2024	Absolute Change	2023	2024	Absolute Change	2023	2024	Absolute Change
TTBI	7	7	0	7	4	-3	1	1	0
TTVI	2	1	-1	3	0	-3			
TTPI	1	0	-1						
TOTAL	10	**8**	**-3**	10	**4**	**-6**	1	**1**	**0**

Note 1: zero TTFI and TTPRI cases reported in both 2023 and 2024.
Note 2: zero TTIs reported in plasma or WB in both 2023 and 2024.
*Note 3: in 2024, **TTBI**: **RBC**- (1) Serratia marcescens et Proteus mirabilis; (1) E.coli; (1) Bacillus cereus; (1) Streptococcus mitis and Streptococcus oralis; (3) Klebsiella oxytoca, E. coli and Staphylococcus haemolyticus; **Platelets**- (1) Staphylococcus warneri, (1) Staphylococcus hominis and Staphylococcus epidermidis, (1) Bacillus cereus, (1) Streptococcus dysgalactiae; **MTOC**- (1) Staphylococcus aureus. **TTVI**: **RBC**- (1) HEV.*

6.5 Overview of fatalities (IL 1) by type of BC and per reporting country; and by type reaction (2023 vs. 2024)

Country (#)	RBC	Platelets	Plasma	MTOC
Belgium (3)	2		1	
Finland (2)	1			1
France (2)	2			
Germany (8)	7	1		
Netherlands (3)	2			1
Poland (2)		1		1
Portugal (1)		1		

Type of Reaction	2023	2024	Absolute change
TACO	7	8	+1
Anaphylaxis/ hypersensitivity	3	4	+1
Other	2	2	0
TTBI	2	2	0
Immunological haemolysis due to other alloantibody	4	1	-3
TRALI	1	1	0
Hypotensive transfusion reaction	0	1	+1
TAD	0	1	+1
Non-immunological haemolysis	3	1	-2

Two TTBI (IL 1) fatalities were reported:

- A severely ill patient with extensive comorbidity and pre-existing sepsis deteriorated rapidly after RBC transfusion. Bacterial culture from one RBC unit later showed growth of *Yersinia enterocolitica*, a pathogen well recognised for proliferating at refrigerated temperatures. Imputability remained IL1 due to possible reverse contamination from the patient.
- A patient developed septic shock shortly after transfusion of pooled platelets. *Bacillus cereus* was isolated from both recipient blood cultures and one platelet unit. Imputability was IL1 because strain comparison or resistance profile was not performed.

Annex 8. Data Supplement – Donation rates of WB and apheresis per 1 000 population in the last four years

(Refer to Figure 1, Figure 2, Figure 8 and Figure 9)

Data Year	2021		2022		2023		2024	
Country	Rate WB	Rate Apheresis	Rate WB	Rate Apheresis	Rate WB	Rate Apheresis	Rate WB	Rate Apheresis
Austria (AT)	33	47	44	55	37	69	36	74
Belgium (BE)	37	18	35	17	34	18	33	20
Bulgaria (BG)	23	1	26	0.4	27	0.5	28	0.5
Croatia (HR)	48	1	48	1	49	1	51	2
Cyprus (CY)	74	0.2	72	0.4	76	0.5	76	0.3
Czechia (CZ)	43	100	42	112	41	128	42	137
Denmark (DK)	33	17	33	20	31	22	29	25
Estonia (EE)	36	2	35	2	34	2	34	2
Finland (FI)	33	0	33	0.4	32	0.4	30	1
France (FR)	35	5	34	5	33	6	32	7
Germany (DE)	44	34	43	35	45	40	43	40
Greece (EL)				2	64	3	41	0.3
Hungary (HU)								
Iceland (IS)	28	2	29	2	27	3	26	2
Ireland (IE)	25	2	25	2	25	3	25	3
Italy (IT)	43	8	43	7	43	8	44	8
Latvia (LV)	30	1	30	1	32	2	34	3
Liechtenstein (LI)								
Lithuania (LT)	34	2	36	2	38	2		
Luxembourg (LU)	61	7	27	4			26	4
Malta (MT)	30	1						
Netherlands (NL)	24	19	22	20	21	21	22	23
Norway (NO)	31	3	30	3	28	3	28	3
Poland (PL)	34	3	35	3	37	4	38	4
Portugal (PT)	29	1	29	1	28	1	27	1
Romania (RO)	39	1	21	0.4			24	1
Slovakia (SK)	35	1			42	5		
Slovenia (SI)	39	2	39	1	39	2	37	2
Spain (ES)	34	2	34	2	32	2	32	3
Sweden (SE)	36	0	36		35		32	
United Kingdom (NI)	21	2	21	2	22	2	21	2
Median	**34.1**	**2.1**	**34.0**	**2.0**	**34.4**	**2.6**	**31.8**	**2.5**

Note: cells highlighted in dark grey refer to countries not reporting for that data year while cells highlighted in light dark grey refer to countries reporting data N/A.

Annex 9. Data Supplement – Issuance, transfusion and processing rates per 1 000 population in the last four years
(Refer to Figure 3, Figure 10 and Figure 11)

Data Year	2021			2022			2023			2024		
Country	Issuance Rate	Transfusion Rate	Processing Rate	Issuance Rate	Transfusion Rate	Processing Rate	Issuance Rate	Transfusion Rate	Processing Rate	Issuance Rate	Transfusion Rate	Processing Rate
Austria (AT)	36	35	46	40	39	44	35	34	43	38	37	43
Belgium (BE)	45	44	55	42	43	52	41	41	52	40	40	53
Bulgaria (BG)	35	29	41	45	34	60	47	42	63	49	42	55
Croatia (HR)	67	63	49	66	63	49	67	64	50	68	64	52
Cyprus (CY)	97	93	73	95	92	72	103	100	75	138	107	75
Czechia (CZ)	54	54	143	52	51	154	52	52	169	50	50	179
Denmark (DK)	43	43	113	43	43	114	41	41	110	39	39	109
Estonia (EE)	48	47	39	44	44	37	42	41	37	42	41	36
Finland (FI)	38		39	36		38	35		37	33		37
France (FR)	44	42	44	43	40	39	41	39	38	40	38	39
Germany (DE)	60	60	78	59	52	78	57	49	85	56	48	82
Greece (EL)				56	42	60	49	47	71	60	44	33
Hungary (HU)	55	22		56			60					
Iceland (IS)	39	36	30	41	37	31	40	34	30	35	30	28
Ireland (IE)	29	28	25	28	27	27	27	27	28	28	27	28
Italy (IT)	50	49	51	53	48	51	51	48	51	53	48	52
Latvia (LV)	49	49	31	52		31	53		34	55		36
Liechtenstein (LI)	6	6		5	5		4	4				
Lithuania (LT)	45		36	50		37	51		40	52		84
Luxembourg (LU)	38	37	68	35	32	32	33	32		33	33	30
Malta (MT)	44	34	31									
Netherlands (NL)	26	25	43	25	24	42	24	24	42	23	23	46
Norway (NO)	39	39	34	39	39	33	39	39	31	37	37	31
Poland (PL)	41		37	45		38	46		41	49		42
Portugal (PT)	36	34	30	35	33	36	34	32	34	33	31	34
Romania (RO)	35	34	40	39	37	22	40	23		44	42	50
Slovakia (SK)	63	63	36	69	69		44		47	68	39	79
Slovenia (SI)	48		82	49		84	48		84	45		80
Spain (ES)	40	40	36	38	38	36	37	37	35	36	36	34
Sweden (SE)	52	43	49	52	42	47	51	42	47	39	33	33
United Kingdom (NI)	26	24	23	25	23	23	28	26	24	27	25	23
Median	**43.8**	**39.5**	**40.6**	**43.5**	**39.6**	**39.0**	**41.6**	**38.6**	**42.5**	**40.9**	**38.6**	**42.7**

Note: cells highlighted in dark grey refer to countries not reporting for that data year while cells highlighted in light dark grey refer to countries reporting data N/A.

Annex 10. Data Supplement – Recipient rates regardless of type of BC per 1 000 population in the last four years

(Refer to Figure 7 and Figure 12)

Data Year / Country	2021	2022	2023	2024
Austria (AT)				
Belgium (BE)	12	11	11	10
Bulgaria (BG)	10	11	12	11
Croatia (HR)	17	19	15	13
Cyprus (CY)	20	24	28	25
Czechia (CZ)	15	14	14	13
Denmark (DK)	7	7	7	7
Estonia (EE)		11	11	12
Finland (FI)				
France (FR)	8	8	8	7
Germany (DE)				
Greece (EL)		13	15	11
Hungary (HU)				
Iceland (IS)	7	6	6	8
Ireland (IE)				
Italy (IT)	11	11	11	11
Latvia (LV)				
Liechtenstein (LI)			2	
Lithuania (LT)				
Luxembourg (LU)	7	8	8	8
Malta (MT)	9			
Netherlands (NL)				
Norway (NO)				
Poland (PL)				
Portugal (PT)	10	10	10	10
Romania (RO)	8	9		7
Slovakia (SK)		6		
Slovenia (SI)				
Spain (ES)	10	10	10	10
Sweden (SE)	10	10	10	8
United Kingdom (NI)	1	2	2	2
Median	**10.1**	**10.3**	**10.2**	**9.7**

Note: cells highlighted in dark grey refer to countries not reporting for that data year while cells highlighted in light dark grey refer to countries reporting data N/A.

Annex 11. Data Supplement – Transfusion rates pmp by type of BC (except MTOC) in the last four years

(Refer to Figure 4, Figure 5, Figure 6, Figure 13, Figure 14, Figure 15 and Figure 16)

Data Year	2021				2022				2023				2024			
Country	RBC Transfusion Rate	Platelets Transfusion Rate	Plasma Transfusion Rate	WB Transfusion Rate	RBC Transfusion Rate	Platelets Transfusion Rate	Plasma Transfusion Rate	WB Transfusion Rate	RBC Transfusion Rate	Platelets Transfusion Rate	Plasma Transfusion Rate	WB Transfusion Rate	RBC Transfusion Rate	Platelets Transfusion Rate	Plasma Transfusion Rate	WB Transfusion Rate
Austria (AT)	30 763	3 821	345	0.0	34 450	4 323	213	0.0	29 961	3 901	227	0.0	32 022	4 526	283	0.0
Belgium (BE)	34 760	5 637	3 719		33 160	5 331	4 217		31 883	5 447	3 200		31 258	5 337	2 968	0.0
Bulgaria (BG)	15 055	3 617	10 161	2.9	17 732	4 217	11 572	1.1	23 275	5 299	13 294	2.0	23 492	5 436	12 607	3.3
Croatia (HR)	45 409	7 336	10 747	0.0	45 341	7 427	10 296	0.0	45 907	7 861	10 075	0.0	46 900	8 510	9 089	0.0
Cyprus (CY)	71 474	6 551	14 878	0.0	71 070	6 545	14 056	1.1	75 193	7 754	17 315	0.0	80 372	8 679	17 632	1.0
Czechia (CZ)	40 025	4 465	9 335	133.2	39 056	4 107	8 111	165.8	40 298	4 132	7 140	181.3	39 889	4 116	5 958	130.3
Denmark (DK)	31 049	6 032	6 373		31 081	5 723	6 377	0.0	29 360	5 677	5 857		27 641	5 058	5 859	
Estonia (EE)	33 452	5 276	8 084	4.5	32 454	4 988	6 179	1.5	31 440	4 988	4 957	66.2	31 290	5 494	4 017	140.9
Finland (FI)				0.0				0.0							0	
France (FR)	33 316	4 929	3 261	2.0	32 149	4 955	3 183	3.1	30 769	4 871	2 956	2.7	30 000	4 843	2 710	5.3
Germany (DE)	42 237	7 158	10 478		38 576	5 819	7 384	0.0	36 708	5 759	6 861	0.0	36 529	5 404	6 467	
Greece (EL)					32 219	9 574		0.0	28 932	8 158	9 737	0.0	27 881	6 976	9 428	0.0
Hungary (HU)		16 930	5 190													
Iceland (IS)	26 554	5 454	3 577		26 906	7 157	2 894		24 553	6 354	3 151	0.0	23 775	3 587	2 778	0.0
Ireland (IE)	24 070	4 425	0	0.2	23 095	4 267	0	3.0	22 906	4 044	0	0.0	23 125	4 162	0	0.7
Italy (IT)	40 889	4 013	3 984	0.3	40 575	4 090	3 483	0.1	40 554	4 224	3 335	0.2	40 453	4 167	2 913	0.3
Latvia (LV)	28 574	4 542	15 459	0.0				0.0				0.0				
Liechtenstein (LI)	5 470	76	76	0.0	4 990	176	0	0.0	3 623	175	0	0.0				
Lithuania (LT)																
Luxembourg (LU)	28 313	4 800	3 740	0.0	26 363	1 374	4 243	0.0	24 440	3 893	4 049	0.0	24 171	4 273	4 167	
Malta (MT)	26 774	3 862	3 760													
Netherlands (NL)	22 079	2 937	42	0.0	21 382	2 813	51	0.0	20 645	2 890	70	0.0	19 669	2 941	41	0.0
Norway (NO)	27 278	4 378	7 491	101.9	26 962	4 328	7 404	111.9	26 987	4 165	7 284	136.9	25 345	3 842	7 308	153.4
Poland (PL)																
Portugal (PT)	27 993	4 913	1 103	1.1	27 195	5 011	1 117	1.3	26 780	4 655	645	0.9	26 352	4 468	579	1.5
Romania (RO)	18 411	5 625	10 356	41.7	20 239	6 433	10 686	62.7	12 372	4 260	6 449	43.1	22 663	8 159	11 393	19.6
Slovakia (SK)	37 780	4 445	20 563	0.0	43 389	3 988	21 196	1.1					28 192	3 843	6 656	
Slovenia (SI)																
Spain (ES)	31 939	4 850	2 925	0.2	31 057	4 709	2 690	0.2	29 187	4 961	2 408	0.9	29 073	4 997	2 307	0.9
Sweden (SE)	34 769	4 478	3 606	4.3	33 775	4 473	3 394	2.4	33 281	4 778	3 585	2.3	25 503	4 530	2 809	4.8
United Kingdom (NI)	18 675	3 185	1 760	0.0	18 102	3 425	1 465	0.0	20 154	3 445	2 093	0.0	19 688	3 499	1 598	0.0
Median	**30 763**	**4 671**	**3 872**	**0.2**	**31 069**	**4 591**	**4 243**	**0.2**	**29 187**	**4 778**	**3 585**	**0.0**	**27 881**	**4 530**	**3 493**	**0.9**

Note: cells highlighted in dark grey refer to countries not reporting for that data year while cells highlighted in light dark grey refer to countries reporting data N/A.

Annex 12. Data Supplement - SAR (IL 2-3) and SAE incidence rates in the last four years

SAR (IL 2-3) incidence rates per 100 000 units transfused (Refer to Figure 17 and Figure 18)

SAE incidence rates per 100 000 units processed (Refer to Figure 24, Figure 25 and Figure 26)

Data Year	2021		2022		2023		2024	
Country	SAR (IL2-3) Rate	SAE Rate	SAR (IL2-3) Rate	SAE Rate	SAR (IL2-3) Rate	SAE Rate	SAR (IL2-3) Rate	SAE Rate
Austria (AT)	22	3	7	2	20	1	12	1
Belgium (BE)	3	101	12	109	5	89	6	12
Bulgaria (BG)	1	0.4	0	0	1	0	0	0
Croatia (HR)	5	2	3	1	3	1	5	0
Cyprus (CY)	0	2	1	62	0	19	0	27
Czechia (CZ)	3	0.2	3	0.1	3	0.2	2	0.4
Denmark (DK)	2	1	4	1	4	0.3	3	1
Estonia (EE)	13	92	8	60	2	42	2	92
Finland (FI)		7		7		3		7
France (FR)	2	16	3	16	4	17	4	15
Germany (DE)	4	4	5	3	6	2	7	2
Greece (EL)			13	6	24	4	24	6
Hungary (HU)	7							
Iceland (IS)	0	27	0	16	0	17	0	0
Ireland (IE)	39	106	33	110	19	134	49	105
Italy (IT)	20	0.3	23	1	14	0	11	0
Latvia (LV)	3	3		7		3		3
Liechtenstein (LI)	0		0		0			
Lithuania (LT)		0		0		0		0
Luxembourg (LU)	0	0	0		0		27	10
Malta (MT)	0	0						
Netherlands (NL)	12	11	9	10	12	11	15	12
Norway (NO)	16	47	5	36	16	49	16	41
Poland (PL)		3		1		2		1
Portugal (PT)	6	11	2	5	6	7	4	4
Romania (RO)	1	90	1	58	1		1	332
Slovakia (SK)	18	0	19			189	24	71
Slovenia (SI)		3		2		1		8
Spain (ES)	4	0.4	5	2	8	1	5	2
Sweden (SE)	4	24	3	23	2	21	4	22
United Kingdom (NI)	13	140	16	122	30	108	8	104
Median	**3.7**	**3.4**	**4.4**	**6.5**	**3.7**	**3.9**	**5.2**	**6.4**

Note: cells highlighted in dark grey refer to countries not reporting for that data year while cells highlighted in light dark grey refer to countries reporting denominator data N/A (so incidence could not be calculated).

Annex 13. Data Supplement - SAR (IL 2-3) incidence rates/100 000 units transfused for each type of BC (excluding MTOC) in the last four years *(Refer to Figure 19)*

Data Year	2021			2022			2023			2024		
Country	SAR (IL2-3) RBC Rate	SAR (IL2-3) Platelets Rate	SAR (IL2-3) Plasma Rate	SAR (IL2-3) RBC Rate	SAR (IL2-3) Platelets Rate	SAR (IL2-3) Plasma Rate	SAR (IL2-3) RBC Rate	SAR (IL2-3) Platelets Rate	SAR (IL2-3) Plasma Rate	SAR (IL2-3) RBC Rate	SAR (IL2-3) Platelets Rate	SAR (IL2-3) Plasma Rate
Austria (AT)	20	41	0	6	8	52	20	22	48	12	12	0
Belgium (BE)	2	2	7	11	19	8	4	12	5	5	13	6
Bulgaria (BG)	1	0	0	1	0	0	1	0	0	0	0	0
Croatia (HR)	5	4	0	3	7	0	3	3	0	5	9	3
Cyprus (CY)	0	0	0	1	0	0	0	0	0	0	0	0
Czechia (CZ)	1	0	7	3	2	6	2	2	10	2	0	5
Denmark (DK)	2	3	0	4	6	3	2	6	3	1	7	6
Estonia (EE)	16	0	0	9	0	0	0	0	0	2	0	0
Finland (FI)												
France (FR)	2	7	5	2	6	13	2	9	14	3	8	10
Germany (DE)	4	5	1	4	12	3	5	11	5	6	15	6
Greece (EL)				10	12		26	26	20	12	58	36
Hungary (HU)		1	10									
Iceland (IS)	0	0	0	0	0	0	0	0	0	0	0	0
Ireland (IE)	30	89		29	53		18	23		43	79	
Italy (IT)	11	87	42	15	84	36	11	40	11	8	35	8
Latvia (LV)	2	23	0									
Liechtenstein (LI)	0	0	0	0	0		0	0				
Lithuania (LT)												
Luxembourg (LU)	0	0	0	0	0	0	0	0	0	30	34	0
Malta (MT)	0	0	0									
Netherlands (NL)	8	31	0	8	22	0	9	17	0	14	17	0
Norway (NO)	16	29	7	4	8	0	9	13	7	4	28	7
Poland (PL)												
Portugal (PT)	5	10	9	2	6	0	5	12	0	3	6	0
Romania (RO)	1	4	0	1	2	0	1	1	1	1	1	1
Slovakia (SK)	14	75	13	23	37	9				19	58	28
Slovenia (SI)												
Spain (ES)	3	9	6	4	9	6	6	12	12	4	10	5
Sweden (SE)	1	6	16	2	8	3	2	4	0	4	2	7
United Kingdom (NI)	14	16	0	14	15	36	23	45	50	5	30	0
Median	**2.2**	**4.3**	**0.0**	**3.7**	**7.3**	**2.6**	**2.8**	**9.3**	**2.9**	**4.2**	**10.2**	**3.7**

Note 1: cells highlighted in dark grey refer to countries not reporting for that data year while cells highlighted in light dark grey refer to countries reporting denominator data N/A (so incidence could not be calculated).
Note 2: also for WB- 2021 (NO) SAR rate of 362; 2023 (IT) SAR rate of 10 000; 2024 (NO) SAR rate of 233.

Annex 14. References

[1] Common Approach, version 2025; https://health.ec.europa.eu/document/download/ca7b4156-6b55-4768-9c06-4ce59e77d69b_en?filename=btco_2025_blood_common-approach_en.pdf

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[3] 2024 Annual SHOT Report, Chapter 20a Transfusion-Associated Circulatory Overload (TACO) n=188, https://www.shotuk.org/wp-content/uploads/2025/07/20a.-Transfusion-Associated-Circulatory-Overload-TACO-2024.pdf