

French haemovigilance annual report Year 2024 Executive summary

October 2025

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List of acronyms

ABOit	ABO-incompatible
AHTR	Acute Hemolytic Transfusion Reactions
AI	Alloimmunization
ANSM	<i>Agence Nationale de Sécurité du Médicament et des produits de santé</i> National Agency for the safety of Medicines and Health Products
AR	Adverse reaction
BC	Blood Component
BE	Blood establishment
CHV-ST	<i>Correspondants d'hémovigilance et de sécurité transfusionnelle</i> Haemovigilance and transfusion safety correspondents of hospitals, clinics and blood establishments
CRH-ST	<i>Coordonnateurs régionaux d'hémovigilance et de sécurité transfusionnelle</i> : Haemovigilance coordinators for the regional Public health agencies
CTSA	<i>Centre de Transfusion Sanguine des Armées</i> : French Army blood service
DHTR	Delayed Hemolytic Transfusion Reaction
DSAR	Donor serious adverse reaction
DSR	Delayed serologic reactions
DT	Delayed transfusion
EFS	<i>Etablissement Français du Sang</i> : French National blood Service
FEIGD	<i>Fiche d'effet indésirable grave donneur</i> : Blood donor serious adverse reaction form
FEIR	<i>Fiche d'effet indésirable receveur</i> : Recipient adverse reaction form
FIG	<i>Fiche d'incident grave</i> , Serious incident form
FIPD	<i>Fiche d'information post don</i> : Post-donation information form
FNHTR	Febrile non hemolytic transfusion reaction
HBB	Hospital blood bank
HEV	Hepatitis E virus
IBCT	Incorrect blood component transfused
IBCT	Incorrect blood component transfused
LBP	Labile blood products
MCE	Major cardiovascular events
NCA	National competent authority
NME-ABOit	Near-misses events of ABO-incompatible
NME-Ot	Near-misses events of Overtransfusion
NME-ABOit	Near-misses events of ABO-incompatible
P	Plasma
PC	Platelet concentrates
PDI	Post-donation information
PRP	Platelets, recovered, pooled

PRP-PR	Platelets, recovered, pooled, pathogen reduced
PR-APC	Pathogen reduction- apheresis-derived platelet concentrates
RBC	Red blood cells
PR-APC	pathogen reduction- apheresis-derived platelet concentrates
RBC	red blood cells

Edito/Context

This is the French Haemovigilance Annual Report Executive Summary for the data for fiscal year 2024. This report corresponds to the 22nd national haemovigilance report, relating to the entire transfusion chain, from blood collection to recipient (e.g. patient transfused) follow-up, and compiled from the reports of the haemovigilance and transfusion safety correspondents of facilities (hospitals and clinics) and blood establishments (CHV-ST).

This Executive Summary provides information on blood and blood components (B&BC) issued nationwide, all numerators are as follows: all adverse reactions (ARs) occurring in patients transfused, serious adverse reactions (SAR) occurring in blood donors, post-donation information (PDI), and any serious adverse event (SAE) occurring along the transfusion chain between blood donation and transfusion and which could jeopardize the quality of the blood components (e.g. labile blood products) or the safety of the blood donor or the recipient (including but not limited to near misses, blood components defects) and transfusion/donation data (denominators) as well as the calculation of incidences (numerators vs. denominators). It is intended to provide an overview of the main results and findings.

Created by the Public Health Code law nr. 93-5 (dated January 4, 1993), French haemovigilance is a key pillar to ensure the quality and safety of transfusion and blood donation. The National Agency for the safety of Medicines and Health Products (“Agence Nationale de Sécurité du Médicament et des produits de santé”, ANSM) is in charge of haemovigilance at a national level, comprising monitoring the reactions and events related to haemovigilance, updating the legislative framework to ensure a high level of quality for all labile blood products (e.g. blood components intended for transfusion), in accordance with international standards and adapting to new technology processes, and maintaining a robust haemovigilance system which plays a key role in public health and epidemiological surveillance.

The haemovigilance system contributes to an increase in scientific knowledge on haemovigilance reactions and events, the provision of tools for early detection of new risks and defects, and the assessment of the efficacy of preventive measures aimed at mitigating the risks and reducing their occurrence.

The French haemovigilance reporting system of reactions and events is mandatory. Depending on their seriousness, reactions and events are reported and analysed through a multi-level framework:

- hospitals and health facilities, both private and public, including army facilities ;
- blood donation sites/locations, at a local and regional level ;

Edito/Context

- French National blood Service (*“Etablissement français du sang”* EFS) and French Army blood service (*“Centre de transfusion sanguine des armées”* CTSA), in charge of supervising reported events at a sub-national level ;
- French Public Health Agency (*“Santé Publique France”* SPF), in charge of the infectious disease surveillance in blood donors ;
- Haemovigilance coordinators for the regional Public health agencies (*“Coordonnateurs régionaux d’hémovigilance et de sécurité transfusionnelle”*, CRH-ST), in charge of implementing the haemovigilance legal framework and good practices at a regional level ;
- ANSM, national competent authority (NCA), in charge, at a national level, of coordinating and implementing haemovigilance.

All reactions and events reported are directly registered in the electronic national reporting system called “e-FIT”, which is a secured web-based application dedicated to haemovigilance, created and maintained by the ANSM. e-FIT provides four types questionnaires or forms, for reporting adverse reactions and events, each dedicated to a specific reaction, event or information in compliance with the regulations:

- recipient adverse reaction form (*“Fiche d’effet indésirable receveur FEIR”* as defined in the July 2, 2020 ANSM Decision).
- blood donor serious adverse reaction form (*“Fiche d’effet indésirable grave donneur FEIGD”* as defined in the December 28, 2023 ANSM Decision) ;
- serious incident form, for all serious adverse events (SAEs) occurring in one or more steps of the transfusion chain (during the transfusion process), such as near-misses and quality defects (*“Fiche d’incident grave FIG”* as defined in the December 24, 2010 ANSM Decision) ;
- post-donation information form (*“Fiche d’information post-don FIPD”* for which the ANSM Decision is currently pending).

e-FIT also provides detailed data on blood collection (number of donors and donations) and transfusion (number of blood components issued, transfused, recalled and number of patients transfused, traceability rate etc.), which are the denominators used to calculate the incidence of adverse reactions and events.

Methods

Data collected via the e-FIT electronic system consist of reports of the 4 above mentioned types, reported before January 1, 2025 concerning reactions and events which occurred during the fiscal year 2024 (FEIR, FEIGD, FIG) or post-donation information that was discovered during the fiscal year 2024 (FIPD), (from the 1st of January up to and including the 31st of December). Only reactions and events reported as having “completed investigation” as of the February 4, 2025 are analysed in this report.

The number of labile blood products (LBP) issued and transfused, as well as data concerning blood donations and blood donors are also reported in the e-FIT system since 2015. These data are collected at a national level by the EFS and CTSA, and are reported in the e-FIT system by the ANSM after passing the data quality-control tests. They are further updated and supervised by the CRH-ST according to the latest information regarding traceability in the health facilities.

All data regarding LBP, blood donors and blood donations provided for the fiscal year 2024 are analysed in this report.

Adverse reactions (ARs), occurring in recipients of blood components and in blood donors, are graded according to their imputability and severity, regardless of the type of AR.

Imputability is scored as follows:

- imputability 0: excluded/unlikely
- imputability 1: possible
- imputability 2: likely, probable
- imputability 3: definite, certain
- imputability 9: not assessable (NA)

Severity is scored for recipients as follows:

- grade 1: non-severe
- grade 2: severe
- grade 3: life-threatening
- grade 4: death

Severity is scored for blood donors as follows:

- grade 1: mild
- grade 2: moderate
- grade 3: severe
- grade 4: death

Results

Labile blood products (see Appendix)

2,735,518 blood components (BC e.g; labile blood products, LBP) were issued in 2024 of which around 81% were red blood cell concentrates (RBC), 12% were platelet concentrates (PC) and 7% were plasma (P), and less than 0.1% were autologous blood components.

The traceability rate is 99.3% in 2024.

Among 2,668,921 blood donations (of which 2,650,862 were completed), 83% were whole blood donations and 17% were apheresis donations. Nationwide 1,557,675 donors donated blood, regardless of the blood collection type.

LBP were transfused to 520,872 recipients (50% female, 50% male), representing an average of 4.9 BC transfused per recipient. The transfusion rate in France represents 7.6 recipients per 1,000 inhabitants in 2024.

Reported Events and Reactions (see Appendix)

Regardless of the investigation status reported and the date of occurrence or discovery of the event, a global decrease of 0.6% in events is observed, compared with 2023:

- -0.5% for recipient ARs (FEIR),
- -22.1% for donor SARs (FEIGD)¹,
- -3.5% for SAEs (FIG),
- +3.6% for PDIs (FIPD).

Overall, 12,838 events or reactions were reported in 2024, regardless of the investigation status and their date of occurrence (or discovery), of which:

- 9,593 recipient ARs ;
- 141 blood donor SARs ;
- 1,108 SAEs ;
- 1,996 PDIs.

¹ Calculation based on comparison of grade 3 donors SARs in 2023 according to the new classification

Recipient Adverse Reactions

According to the French legislation, all recipient ARs have to be reported.

Among the 9,593 recipient ARs reported, 9,085 occurred in 2024 (95%), i.e. an incidence rate of 352 reactions per 100,000 BC transfused and 174 reactions per 10,000 recipients. Among all 9,085 adverse reactions occurred and reported in 2024, the investigation status of 9,013 was completed, as of 4 February 2025, and 90% of these were of grade 1 severity. Among them, 5,431 adverse reactions of imputability level probable (2) or certain (3) were analysed and summarised as follows (except Transfusion-related Acute Lung Injury (TRALI) and delayed hemolytic transfusion reaction (DHTR), for which the reactions summarised below were of imputability possible (1), probable or certain).

Concerning grade 4 adverse reactions, two deaths with strong causality were reported in 2024, one of them involving RBC, the other involving pathogen reduction- apheresis-derived platelet concentrates (PR-APC): 2 allergies (of imputability probable).

Delayed serologic reactions (DSR) (Alloimmunization (AI))

DSR represented the most frequent adverse reaction (66%), of which the overwhelming majority (99.0%) of grade 1 severity, mostly transfusion-related RBC (90%).

Allergic reactions

Allergic reactions were the second most frequently reported adverse reaction (10%), most of which of grade 1 severity (74%). In 2024, allergic reactions (all levels of severity) were reported mainly related to the transfusion of plasma, then platelets.

Febrile non hemolytic transfusion reaction (FNHTR)

FNHTR was the third most frequently reported adverse reaction (9%), almost all of which of grade 1 severity (98%). This adverse reaction is specific for transfusion, RBC and platelets being the most frequently involved.

Transfusion-associated circulatory overload (TACO)

TACO represented 5% of adverse reactions of imputability 2 or 3, i.e. an incidence rate of 9.9 TACO per 100,000 BC issued. The overwhelming majority (91%) were adverse reactions of grade 1 or 2 severity, and no death was reported in 2024 for this adverse reaction. TACO is mostly RBC transfusion-related. It is mainly reported in elderly recipients, especially over 70 old-years.

Acute Hemolytic Transfusion Reactions (AHTR)

Almost 4% of all adverse reactions, of imputability 2 and 3, consisted of AHTR, of which 27 were related to ABO incompatibility. Five ABO accidents were reported following RBC transfusion. 68% were platelets transfusion-related of which 74% were related to the HLA system.

Delayed Hemolytic Transfusion Reaction (DHTR)

DHTR in Sickle cell Disease (SCD) represented 0.6% of adverse reactions of imputability 1 to 3; i.e. an incidence rate of 1.7 per 100,000 BC issued. Among the reported DHTR, 9 were of grade 3, and one death has been reported. There is strong evidence that transfusion played a role in the death.

Transfusion-related Acute Lung Injury (TRALI)

TRALI represented 0.2% of adverse reactions of imputability possible, probable or certain, i.e. an incidence rate of 0.6 TRALI per 100,000 BC issued. Among the reported TRALI, two were defined as immunological TRALI (of imputability certain): one grade 3 involving platelets, recovered, pooled (PRP) and one grade 2 involving RBC.

Transfusion-transmitted bacterial infections (TTBI)

TTBI remain very rare. One TTBI (G3, n=1) was reported in 2024, involving PR-APC (*Staphylococcus ureilyticus*). Unfortunately, the clinical outcome was unfavourable. It is difficult to assess the role of the transfusion in the patient's death.

Transfusion-transmitted viral infections (TTVI)

For TTVI, all the reactions reported in 2024 were considered in this Executive Summary. One Hepatitis E virus (HEV) infection of imputability 2 or 3 and of grade 1 (BC not specified) and one parvovirus B19 infection of imputability 2 and of grade 1 (platelets, recovered, pooled, pathogen reduced (PRP-PR)) were reported. The estimated incidence rate is 0.07 TTVI per 100,000 BC issued, and 0.04 TTVI per 10,000 recipients.

Serious Adverse Reaction in Donors

According to the French legislation for 2024 fiscal year, donor SARs (grade 3 (severe) and grade 4 (death occurring within seven days after the donation) reactions) have to be reported as in the Donor SARs (DSAR) reportable to the European Commission on a voluntary basis.

Among the 141 reactions reported in 2024, the investigation of 123 reactions had been completed on February 4, 2025, with imputability 1 to 3 and not assessable, i.e. an incidence of 4.6 DSARs per 100,000 blood collections and 0.8 DSARs per 10,000 blood donors.

The **incidence of DSARs was higher after an apheresis donation** compared to whole blood, i.e. 6.5 versus 4.2 serious reactions per 100,000 blood collections respectively.

Serious adverse reactions were mostly reported in female blood donors, with an estimated rate of 7.2 serious adverse reactions per 100,000 blood collections compared to an estimated rate of 2.3 serious adverse reactions for male blood donors.

The incidence of DSARs observed in regular donors was slightly higher than that observed in first-time blood donors: 0.8 versus 0.7 per 10,000 blood donors (difference not statistically significant).

No death was reported in 2024. 40% of serious adverse reactions were found to have no medical consequence for the blood donor.

Vasovagal reaction

Vasovagal reaction is the most frequently reported diagnosis (28%), i.e. an estimated rate of 1.27 serious reactions per 100,000 blood collections. The incidence rate appears higher after apheresis donation (2.38 per 100,000 collections) than after whole blood donation (1.04 per 100,000 collections).

Local reactions

Local reactions (such as bruise, arterial puncture, nerve injury, tendon injury) are the second most frequently reported diagnosis (about 25%).

Anaemia or aggravation of anaemia

In 2024, 31,678 grade 2 of “anaemia” (according to the WHO definitions) or “aggravation of anaemia” type were notified and 16 of grade 3 were reported (FEIGD).

Venous and/or arterial thromboembolic adverse reactions

Venous and/or arterial thromboembolic adverse reactions are more serious but rarer and were reported in 3 blood donors in 2024. These 3 DSAR were superficial thrombophlebitis of the upper limb.

Major cardiovascular events (MCE)

Four major cardiovascular events (MCE) of grade 3 were reported: cardiac adverse events (no deaths reported in 2024), mainly after whole blood donation. These are two myocardial infarctions, one rhythm disorder and one other coronary syndrome. The imputability of the donation was rated as not assessable. No neurological or pulmonary-type adverse event was reported.

Serious Adverse Events (SAE)

According to the French legislation **only serious adverse events** have to be reported in France.

1,108 SAEs were reported in 2024. Among them, 1,019 occurred in 2024 (either 37 SAE per 100 000 BC issued), including 997 SAE reports having a “completed investigation” as of February 4, 2025 which have been analysed in detail. The incidence of transfusion-related SAEs was estimated as 11 SAEs per 100,000 BC transfused, transfusion-related SAEs represent 28% of all SAEs, regardless of the investigation status.

Most of SAEs occurred in hospital and healthcare facilities (74%) while 21 % SAEs occurred at blood donation sites/locations of blood establishments (BE) and the remaining 5% occurred in a third party (medical biology laboratory, BC transporter, etc.).

Each SAE reported can be linked to a series of failing steps (1 to 10) in the transfusion chain. However, only one failing step is identified for the majority (60%) of SAEs and in most cases, only one specification (e.g. contributing factor) is responsible for the failing step. The human error and system failure represent the most frequently (49%) reported contributing factors among all SAEs. This finding results in ample opportunities to improve and apply best practices in order to reduce the occurrence.

Potential risks represent the most reported (80%) grounds for reporting of SAEs, of which 52% are associated with a potential severe event.

Confirmed risks [(including: adverse reaction in patient, adverse reaction in blood donor (whatever the severity) and transfusion) are reported in 286 SAEs (29%), of which transfusion represents the main ground for reporting (90%).

Recipient re-sampling for biological analysis is the most frequently reported consequence (30%), before impact on BC traceability (12%) and BC wastage (12%).

Approximately 98.9% of all SAEs led to preventive measures.

The SAEs detailed below are sentinel SAEs.

Incorrect blood component transfused (IBCT) reported in 2024

This SAE category corresponds to all reported episodes where a patient was transfused with a blood component that did not meet the appropriate requirements or that was intended for another patient, even if

- the component was ABO compatible and/or
- even if only a small quantity of blood was transfused and/or
- there was no adverse reaction.

ABO-incompatible (ABOit) red cell transfusions are included in this category of IBCT. All cases where a red cells unit was transfused which was ABO incompatible even if only a small quantity of blood was transfused.

In 2024, 64 incorrect blood component transfused were reported, including 50 errors of RBC transfused (78%), i.e. an incidence rate of 2.43 SAE per 10⁵ BC transfused.

For the ABO RBC/ABO recipient phenotype pairs reported, the distribution was: 26% A/A, 31% O/O, 18% O/A and 1% B/B. In addition, 19% of transfused RBC were ABO incompatible, of which 5 were associated with ABO-incompatible (ABOit) red cell transfusions (2 of grade 1 non severe, 2 of grade 2 severe and 1 of grade 3 life-threatening). A 6th ABO incompatibility in CGR transfusion was reported in 2024, but the investigation was ongoing as of February 4, 2025.

These IBCT resulted in 108 having potential outcomes for transfused patients, mainly (in descending order): transfusion delayed and/or interruption of the transfusion protocol of the intended patient, control sampling and ABO incompatibility SAR for the patient transfused by mistake.

They are due to a succession of reported failures (169 in total, on average 2.6 failures per SAE). The steps involved in these IBCT are: final pre-transfusion patient identity checking at the bedside, patient identity checking at the time of reception of blood components in the clinical area, blood component issue step and the pre-transfusion performance and/or interpretation of the pre-transfusion ABO compatibility test at the patient's bedside.

Blood component issued to the wrong patient reported in 2024

This category of SAE concerns all events in which a blood component is issued for transfusion which, at that time, did not correspond to the correct patient and could lead to the transfusion of the wrong patient.

In 2024, 209 SAE of “blood component issued to the wrong patient” type were reported, 7.6 per 10⁵ BCs issued.

All of them were detected before the transfusion.

For the ABO RBC/ABO recipient phenotype pairs reported, the distribution was: 27% O/O, 20% O/A, 19% A/A, 5% O/B and 2% B/B. In addition, 27% of issued and non-transfused RBCs were ABO incompatible.

These errors resulted in 278 consequences for transfused patients, mainly (in descending order): need for control sampling, transfusion delayed and/or interruption of transfusion protocol and impact on BC traceability.

They are due to a succession of reported failures (326 in total, on average 1.6 failures per SAE).

One or more control steps worked properly in the care service/unit or in the blood establishments.

Near-misses events of ABO-incompatible (NME-ABOit) red cell transfusions reported in 2024

In 2024, 10 NME-ABOit red cells transfusions occurred and were reported, 0.45 per 10⁵ RBCs issued. There is likely underreporting.

All were detected before transfusion by ABO compatibility test at the patient's bedside.

The distribution of the ABO RBC/patient phenotype pair is: 50% A/O, 20% B/O, 20% B/A, and 10% A/B.

NME-ABOit red cells transfusions resulted in 26 outcomes for patients requiring transfusion and/or for RBCs issued.

These NME-ABOit red cells transfusions are due to a succession of failures: 35 in total, an average of 3.5 failures per SAE, mainly failures in patient identification (40%).

Delayed transfusion (DT) Reported in 2024

A total of 207 of these SAEs were reported, representing 19.1% of the total number of SAEs reported in 2024 with completed investigations. This represents 7.6 DTs for 10⁵ BC issued.

Of the reported DTs, RBCs were involved in approximately 78% of the reports, plasma in approximately 6%, and platelets in approximately 11%. 20% of DT occurred in emergency settings.

In all reported DTs, delayed patient care was associated in 75% of cases, but without serious outcomes. Morbidity related to DT was observed in 4% of reports. In 1.3%, three deaths were observed, but the reporting parties concluded that there was no causal link between these DTs and the concomitant deaths.

DTs are mainly due to failures in patient identification (52%), whether during the prescription of BCs and/or pre-transfusion testing (blood group determination, irregular antibody screen and/or compatibility testing etc...), the issuance of BCs, their transport and communication between the healthcare teams and those of issuing of blood establishments/hospital blood banks.

Overtransfusion Reported in 2024

A SAE "Overtransfusion" is the transfusion of a dose of BC that is inappropriate for the patient's needs and generally results in a haemoglobin or platelet count significantly outside the intended target range, whether or not there are clinical consequences.

In 2024, 34 SAEs of the "Overtransfusion" occurred and were reported, 1.3 per 10⁵ BCs transfused. The number of reports of this type is probably underreported. RBCs are involved in 68% of cases.

For the ABO RBC/ABO recipient phenotype pairs reported, the distribution was: 44% A/A, 22% O/O, 22% O/A and 11% AB/O.

These overtransfusion resulted in 78 consequences for transfused patients. They are due to a succession of reported failures: 90 in total, on average 2.6 failures per SAE mainly : patient identity checking at the different steps of the transfusion chain, BC medical prescription (mainly overprescribing) and issue (mainly issuing of surplus BCs).

Near-misses events of Overtransfusion (NME-Ot) Reported in 2024

A near miss of overtransfusion refers to a situation where an error or event is linked to an anomaly in the prescription of BC (overprescription) or issue of BC (error in the number of BC units issued) which was detected at a later step in the transfusion chain allowing the overtransfusion of the patient to be avoided.

In 2024, 40 NME-Ots occurred and were reported, 1.3 per 10⁵ BCs transfused. The number of reports of this type is probably underreported.

Neither the ABO phenotypes of the prescribed/issued BCs nor those of the patients were reported in the NME-Ots.

The steps involved in these NME-Ots are: BC medical prescription (mainly overprescribing) and issue (mainly issuing of surplus BCs).

Post-donation information (PDI)

Although post-donation informations (PDI) have been reported to the national competent authority since 2002, this reporting has only been mandatory since 2014.

Are reported in e-FIT: PDIs for which at least one blood component issued from a donation at risk is no longer in the Blood Establishment and the receiving facility (hospitals, clinics, etc.) need to be informed of the PDI.

Among the 1,996 PDIs reported, 1,949 have been detected and reported in 2024, regardless of the investigation status, i.e. an incidence rate of 73 PDIs per 100,000 blood collections, 73 PDIs per 100,000 blood donations and 12 PDIs per 10,000 blood donors. 1,880 PDIs having a “completed investigation” as of February 4, 2025 (96% of reported PDIs) were analysed. The overwhelming majority (88%) were reported by the blood donor himself or a family member.

One or more BC can be involved in one PDI. A total of 4,634 BCs (data from reporting forms) were reported among all PDIs, of which 40% were plasma, 36% were RBC and 23% were platelets. 89.7% of PDIs mention at least one RBC, 99.7% at least one plasma and 56.8% at least one platelet.

Following the PDI, 42% of the BC were already transfused (a majority of platelets, 83%) and 20% were destroyed (the majority of RBC, 64%).

90% of PDIs involved an infectious disease risk (confirmed infection in the donor or donor exposure to an infectious risk). Among the seroconversion PDI, the most reported were:

- Syphilis (n=116) with an incidence rate of 4.3 PDI per 100,000 blood collections;
- Infections by SARS-CoV-2 (n=43) with an incidence rate of 1.6 PDI per 100,000 blood collection;
- Infection by HEV (n=34) with an incidence rate of 1.3 PDI per 100,000 blood collections.

13 Parvovirus B19 infections were reported as PDIs in 2024, with an incidence of 0.5 PDI per 100,000 blood collections.

Among risks other than infectious risks, a medication (estimated rate 7.2 PDI per 100,000 blood collections) was the most frequently reported information. The most frequently reported medications were raloxifene, topiramate and valproic acid and derivatives, together accounting for almost 33% of medicine-related PDIs. They were often reported during the pre-donation interview to the subsequent donation (96%) and most blood donors (53%) reporting a medicine intake were aged 50 years old and over.

Refer to the whole report to put the data into perspective

Table 1: data of collection and transfusion activity, 2024 (denominators)

Blood recipients	
Total number of patients transfused regardless the type of component	520,872
Number of patients transfused per 1,000 inhabitants	7.6
Blood donors	
Total number of blood donors	1,557,675
% of blood donors in the general population in category of age 18-69 years	3.5%
% First time donors in the general population in category of age 18-69 years	0.6%
Blood donations	
Total number of blood collection	2,668,921
Total number of completed donations	2,650,862
Average number of blood donation per blood donor	1.71
Blood components issued	
Total number of units issued regardless the type of component	2,735,518
Average number of units issued per 1,000 inhabitants	39.9
Average number of RBC issued per 1,000 inhabitants	32.1
Average number of platelets (apheresis platelets+recovered pooled platelets) issued per 1,000 inhabitants	4.9
Average number of plasma issued per 1,000 inhabitants	2.9
Total number of units transfused regardless the type of component	2,577,973
Average number of blood components transfused per patient	4.9
Average number of units transfused per 1,000 inhabitants	37.6
Average number of RBC transfused per 1,000 inhabitants	30.0
Average number of platelets (apheresis platelets+recovered pooled platelets) transfused per 1,000 inhabitants	4.8
Average number of plasma transfused per 1,000 inhabitants	2.7
Number of blood component returned appropriately to the stock of blood establishment	115,441
Rate of blood component returned appropriately to the stock of blood establishments (BEs)	4.22%
Number of blood component wastage	20,568
Blood component wastage's rate	0.75%
Number of blood components not traced	18,356
BCs traceability's rate	99.3%

Table 1: data of collection and transfusion activity, 2024 (denominators) - continued

Medical facilities	
Number of transfusion facilities	1,322
Number of recipient ARs reporting establishments	776
Number of SAEs reporting establishments	312
Hospital blood banks activity	
Total number of hospital blood banks (HBBs)	617
Number of blood component distributed by BEs to HBBs	810,738
Rate of blood component distributed by BEs to HBBs	29.6%
Number of blood component issued by BEs to HBBs	266,415
Rate of blood component issued by BEs to HBBs	9.7%
Number of blood component issued by HBBs (emergency situations and routine issuing)	438,352
Rate of blood component issued by HBBs (emergency situations and routine issuing)	16.0%
Number of blood component issued by HBBs to their hospitals	420,881
Rate of blood component issued by HBBs to their hospitals	15.4%
Number of blood component issued by HBBs to another hospital (emergency situations)	12,865
Rate of blood component issued by HBBs to another hospital (emergency situations)	0.5%

Table 2: data of reporting activity occurred in 2024, reactions and events reported in 2024, regardless of the investigation (numerators)

Category of reporting	Number	Rate
Recipient adverse reactions (all severity grades and all imputability levels)	9 593	372.1 per 100,000 BCs transfused 184.2 per 10,000 recipients transfused
Serious adverse events (SAEs)	1 108	36.4 per 100,000 BCs issued 286 SAEs with transfusion 43.0 per 100,000 BCs transfused
Donor Serious adverse reactions (SARs all imputability levels)	141	5.3 per 100,000 blood collections 0.9 per 10,000 blood donors
Post-donations informations (PDIs)	1 996	75.3 per 100 000 blood collection 12.8 per 10 000 blood donors

Table 3: distribution of hospital blood banks by type of activity in 2024

	Activated in 2024	Inactivated in 2024	Active in 2024
Issuing Hospital blood bank (HBB) *	4	1	166
Relay HBB **	0	1	17
Vital Emergency HBB ***	4	4	214
Vital emergency and relay HBB	3	7	226
Total	11	13	623

*Blood bank localised in facility (hospital or clinic), approved by regional health competent authority, who stores and selects blood components compatible with the patient and issues them to him.

**Blood bank localised in facility (hospital or clinic), approved by regional health competent authority, who stores and transfers to the patient blood components previously issued by the blood establishment specifically for this patient

***Blood bank localised in facility (hospital or clinic), approved by regional health competent authority, who stores a limited stock of blood components and can issues, in vital emergency situations mainly to the patients of their hospitals, only RBCC of group O and/or plasma of group AB.

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