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Haemovigilance
Annual Report 2024

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Haemovigilance
Annual Report 2024

Evaluation of haemovigilance reports in 2024

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Editorial

Reporting transfusion reactions, quality defects and side effects experienced during donation is as important as ever. The same applies to the findings from transfusion errors and near misses. Each year, the haemovigilance reports provide Swissmedic with important data and findings, enabling transfusion safety to be further improved and new risks identified in good time.

By way of example, last year in Switzerland, as in other European countries, a significant increase in parvovirus B19 was observed in blood donations, which Swissmedic was also able to identify from the haemovigilance reports. A transfusion-transmitted parvo B19 infection was even suspected in three patients receiving transfusions. Thanks to haemovigilance, Swissmedic could inform the transfusing doctors about the possible risk and precautions associated with the transfusions in high-risk patients.

The persons responsible for haemovigilance in blood transfusion services, hospitals and clinics play a crucial role in fulfilling the obligation to report. They are Swissmedic's contacts in these institutions and responsible for ensuring that the right investigations are carried out on site and the necessary information is forwarded to Swissmedic. A steady rise in reports, as observed once again in 2024, is evidence of the strong awareness of the importance of haemovigilance. We are very pleased by this!

Nevertheless, Swissmedic believes in the importance of continuing to develop the reporting obligation. We want to focus more closely on key observations, optimise forms accordingly, update information sheets and, last but not least, undertake the preparatory work for the growing digital transformation of the reporting system. Exciting times.

Swissmedic would specifically like to thank all reporters for their important and tireless dedication to the improvement of transfusion safety. Thank you for your interest. We hope you find this Annual Report to be a stimulating read.

Christian Schärer, Head of Inspection Management and Blood Surveillance

1 Introduction

The Haemovigilance Annual Report provides a regular update on facts and developments relating to transfusion safety in Switzerland. The main focus of the report is vigilance reporting from the different parts of the transfusion process. The underlying/employed definitions and classifications of the events and the legal aspects are provided as "background".

Haemovigilance

Haemovigilance is a surveillance system which covers the entire transfusion chain. It records and analyses unexpected and adverse events (such as donor reactions, blood-borne infections in blood donors, transfusion reactions, transfusion errors and near misses) before, during and after the administration of labile blood products.

The objective of haemovigilance is to prevent the occurrence or repetition of these events and to improve the safety of transfusion therapy.

Analysis and evaluation of reported data provide an up-to-date overall picture of safety in the transfusion chain and of the nature and dimension of the expected risks. The investigation of events can provide additional information about the causes of avoidable transfusion incidents and show where improvements are necessary and possible.

Legal basis and responsibilities

According to Art. 58 of the Therapeutic Products Act (TPA, SR 812.21), Swissmedic is responsible for monitoring the safety of therapeutic products, including blood and blood products as defined in Art. 4 para. 1 TPA. To this end, it collects and evaluates reports as stipulated in Art. 59 TPA in particular and institutes the necessary administrative actions.

The holder of a licence for activities with blood or labile blood products must appoint a person who is responsible for haemovigilance in accordance with Art. 28 para. 1 of the Medicinal Products Licensing Ordinance (MPLO, SR 812.212.1). This obligation applies particularly to manufacturers of labile blood products, i.e. specifically the blood transfusion services, but also to establishments that are authorised to store blood.

Art. 65 para. 4 of the Therapeutic Products Ordinance (TPO, SR 812.212.21) requires institutions which use labile blood products to set up a quality assurance system for the use of labile blood products in keeping with the current state of medical science and technology. According to this definition, this applies to all institutions which perform transfusions of labile blood products, and hospitals and doctors' practices in particular. These institutions designate a person who is responsible for fulfilling the reporting duty.

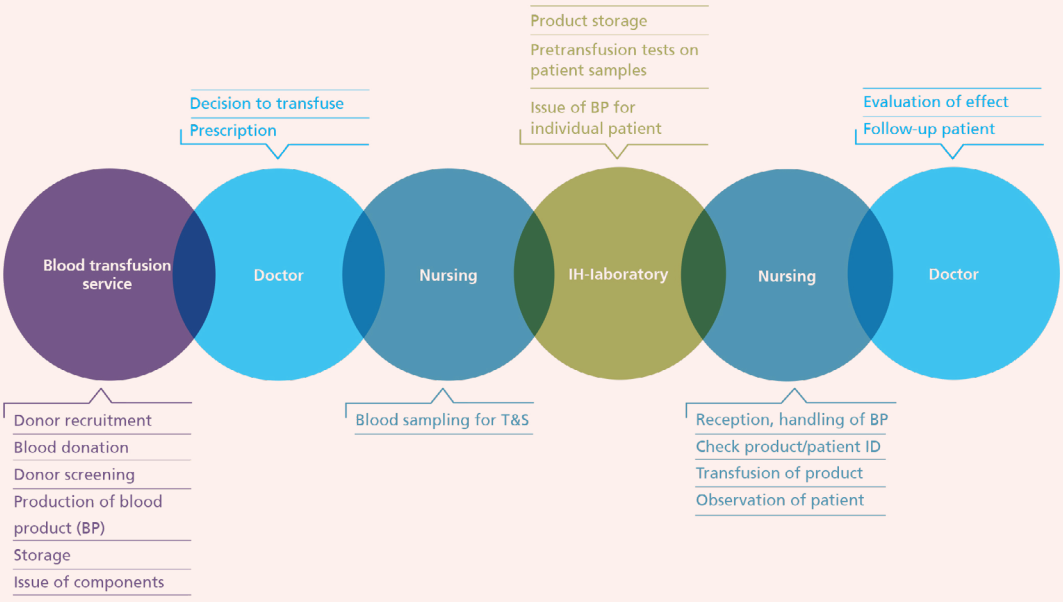
National haemovigilance system

The national haemovigilance system covers the whole of Switzerland. Under the Therapeutic Products Act, all institutions which transfuse (users), store and manufacture blood products have an obligation to report transfusion reactions, transfusion errors, near misses and quality defects. These reports are submitted via a duly appointed responsible person. Both users and manufacturers are also obliged to set up a quality assurance system.

Swissmedic records reports centrally and performs validation as necessary. The report assessment included in the statistics is the same as the final evaluation by Swissmedic Haemovigilance. If an analysis of individual cases identifies a need for action in the form of improved measures, corresponding proposals are requested from the affected institutions and reviewed.

The Swiss haemovigilance system is based on spontaneous reporting; it is what is known as a passive monitoring system. Active monitoring by the national system, such as in cohort studies for example, does not currently take place. Information about the number of blood components supplied for transfusion is provided by Swiss Transfusion SRC (Swiss Red Cross), enabling a relative risk assessment and international comparisons to be made.

As with all passive monitoring systems, it can be assumed that the figures are underreported. The risks described in this report should therefore be understood as minimum figures.



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2 Number of transfusions and reporting rates

2.1 Number of transfusions

In 2024, a total of 266,916 blood products were supplied for transfusion in Switzerland, representing a 3.2% decline compared with 2023. The declining overall trend is therefore continuing (2020 was an exception due to the COVID-19 pandemic) (Table 1). The transfusion figures are based on the number of blood components supplied as shown in the annual statistics of Swiss Transfusion SRC [1] and will be referred to below as transfusions or transfused products.

Table 1
Transfusions in Switzerland by year

Number of transfusions in Switzerland 2010–2024					
Blood product	**2020**	**2021**	**2022**	**2023**	**2024**
pRBC	212,947	217,049	214,197	211,546	203,832
PC	35,715	38,898	39,182	40,112	37,992
FFP	26,681	27,765	26,917	24,137	25,092
Total	**275,343**	**283,712**	**280,296**	**275,795**	**266,916**

pRBC: packed red blood cells
PC: platelet concentrate
FFP: fresh frozen plasma (quarantined (FFPq) or pathogen-inactivated (FFPpi))

Data source: blood products supplied, Blood Transfusion Service of the Swiss Red Cross [1]

2.2 Reporting numbers and rates

In 2024, Swissmedic received a total of 4,511 haemovigilance reports relating to transfusion reactions (TR) and "Serious incidents" (transfusion errors (IBCT)/near misses/Rhesus D conversions/destruction of blood products due to errors in their handling or storage). A further 3,210 reports of donor reactions (incl. collective reports) and protective measures were also received (Table 2). The statistics include reports received by the end of February 2025 at the latest; later reports will be included in the statistics for 2025.

In 2024, 9% more TR were reported than in 2023. As regards "serious incidents", the reporting system was revised, for example in respect of the reporting obligations for grade 1 near misses, which no longer need to be reported. Overall, this has resulted in a 22% reduction in the number of reported serious incidents. The number of reported transfusion errors/IBCT (excluding Rhesus D conversions) rose from 48 to 69 – further details can be found under 4.2 IBCT.

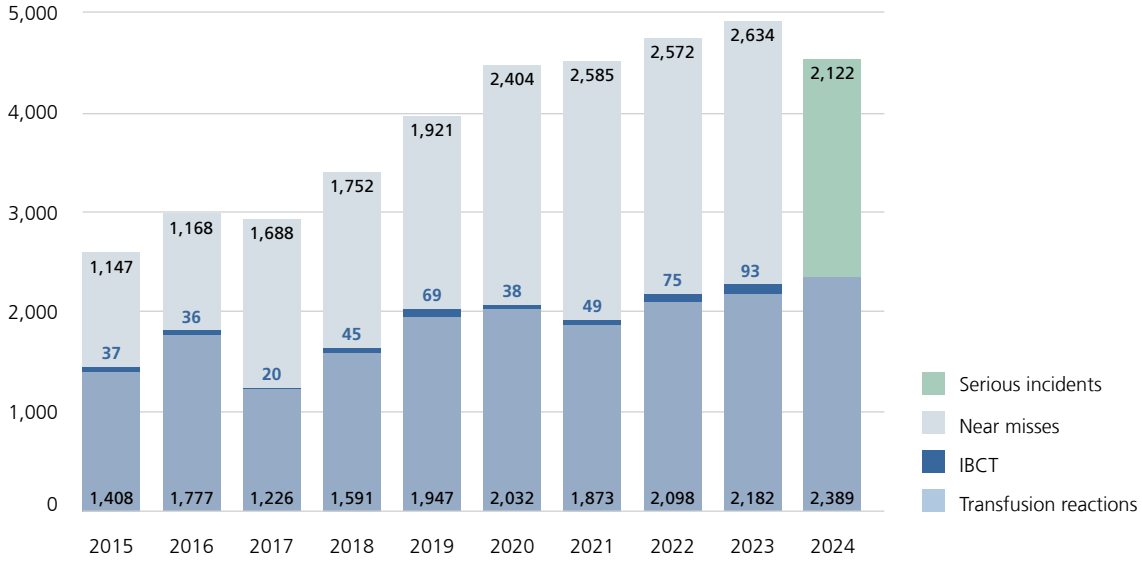
Table 2
Haemovigilance reports: Total numbers

Haemovigilance reports: Total numbers for 2024	
Type	**2024**
Transfusion reactions (TR)	2,389
Serious incidents*	2,122
Protective measures	528
Donor reactions	3,210

** revised reporting of near misses since 2024*

Figure 1
Reports of transfusion reactions and serious incidents by year

Reports of transfusion reactions and serious incidents 2015–2024

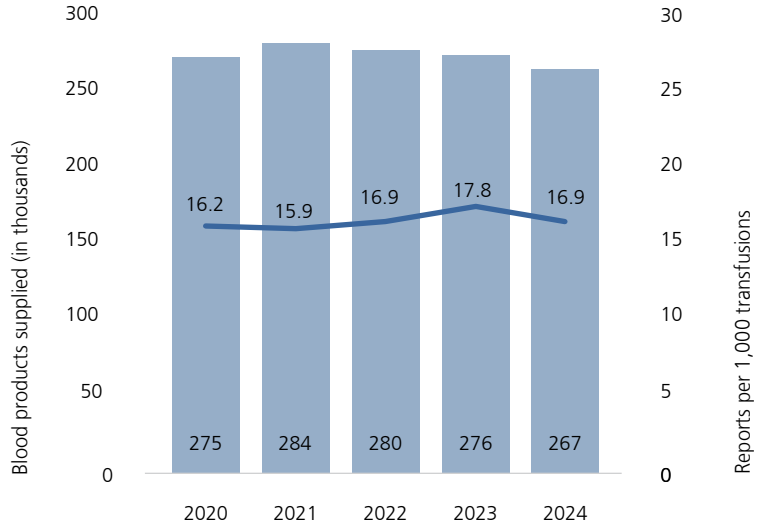


Absolute numbers, all degrees of imputability and severity

Swissmedic calculates the reporting rate per 1,000 transfusions (Tf) on the basis of the total number of reports. The total reporting rate fell slightly in 2024 compared with 2023 (16.9/1,000 Tf in 2024 versus 17.8/1,000 Tf in 2023). This is attributable particularly to the changed reporting obligation for near misses (grade 1 NM do not need to be reported). Increases were observed in all cases for the reporting rates for transfusion reactions, IBCT and Rhesus D conversions (details can be found in the corresponding sections: 3 Transfusion reactions, 4.2 IBCT and 4.3 Near misses).

Figure 2
Reporting rate for haemovigilance reports (transfusion reactions, serious incidents)

Reporting rate for haemovigilance reports 2020–2024



Per 1,000 transfusions, all degrees of severity and imputability

2.3 Reporting rates: Major regions

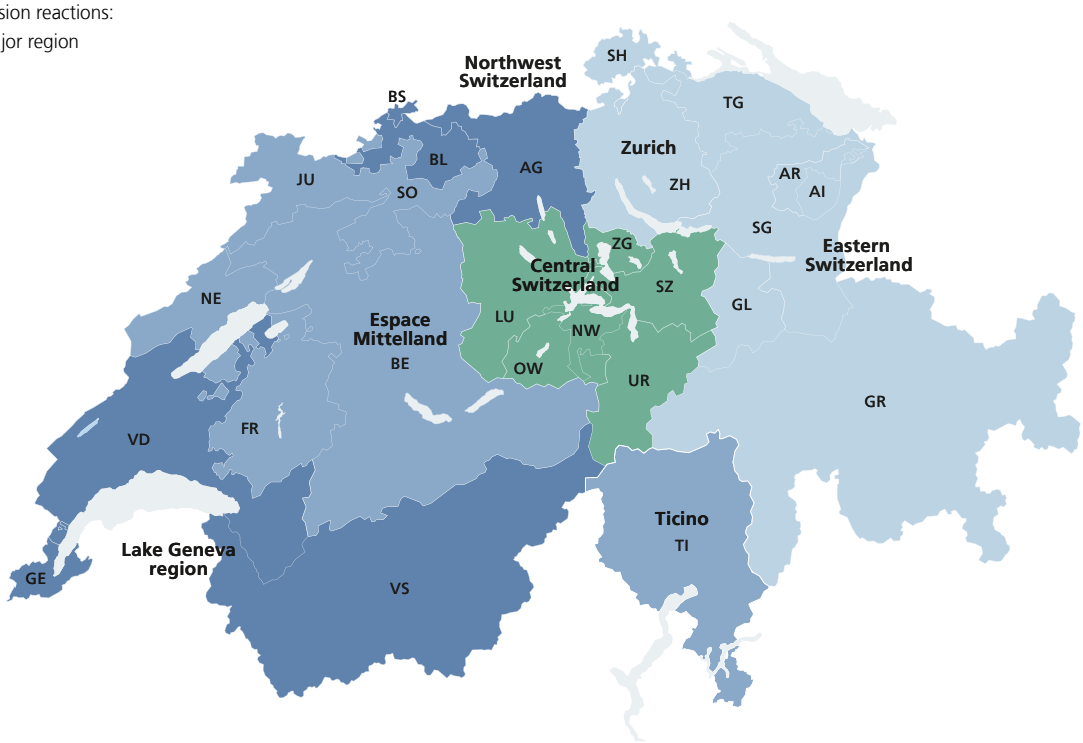
There are relevant fluctuations in the regional reporting rates for the different events based on the number of inhabitants (events reported per 100,000 inhabitants). The absolute reporting numbers and reporting rates per 100,000 inhabitants for transfusion reactions and serious incidents are shown below. Among the transfusion reactions, allo-immunisations (other than haemolytic reactions) after transfusion are detected as laboratory findings and thus differ fundamentally from other TR. For this reason TR are shown in total and excluding reports of allo-immunisation.

Table 3
Reports of transfusion reactions: Distribution by major region

Transfusion reactions by major region in 2024

		Reports in absolute numbers		Reports per 100,000 inhabitants	
Major region	**Canton**	**Total**	**excluding allo-AB**	**Total**	**excluding allo-AB**
Lake Geneva region	GE, VD, VS	613	281	35.3	16.2
Espace Mittelland	BE, SO, FR, NE, JU	650	155	33.4	8.0
Northwest Switzerland	BS, BL, AG	709	238	57.8	19.4
Zurich	ZH	126	83	7.8	5.2
Eastern Switzerland	SG, TG, AI, AR, GL, SH, GR	67	49	5.4	4.0
Central Switzerland	UR, SZ, OW, NW, LU, ZG	173	28	20.2	3.3
Ticino	TI	50	35	14.0	9.8

Figure 3
Reports of transfusion reactions: Distribution by major region



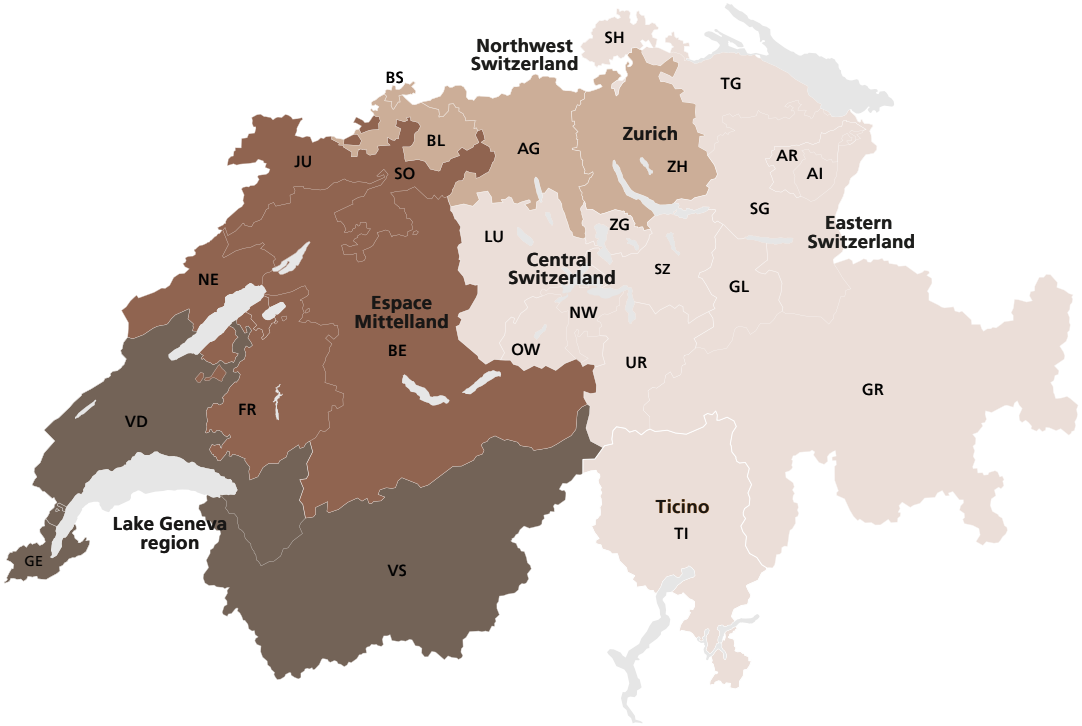
Per 100,000 inhabitants, excluding allo-antibodies
Considered: reports from CH

Map Major Regions of Switzerland © BFS, ThemaKart, Neuchâtel 2020

Table 4
Reports of serious incidents: Distribution by major region

Serious incidents by major region in 2024			
Major region	**Canton**	**Reports in absolute numbers**	**Reports per 100,000 inhabitants**
Lake Geneva region	GE, VD, VS	865	49.8
Espace Mittelland	BE, SO, FR, NE, JU	657	33.8
Northwest Switzerland	BS, BL, AG	129	10.5
Zurich	ZH	311	19.4
Eastern Switzerland	SG, TG, AI, AR, GL, SH, GR	70	5.7
Central Switzerland	UR, SZ, OW, NW, LU, ZG	68	8.0
Ticino	TI	20	5.6

Figure 4
Reports of serious incidents: Distribution by major region



Per 100,000 inhabitants
Considered: reports from CH

Map Major Regions of Switzerland © BFS, ThemaKart, Neuchâtel 2020

- > 40
- 20–39.9
- 10–19.9
- 0–9.9

3 Transfusion reactions

3.1 Background

Definitions

Transfusion reactions (TR) are undesirable or unexpected events related to the administration of labile blood products. Art. 63 para. 2 TPO requires these events to be reported to Swissmedic. TR are classified in a similar way to the ISBT criteria on the basis of the available information (see below) *[a, *b]. Reactions which do not meet the criteria for a defined category are summarised as "Other".

Transfusion reactions: Categories similar to ISBT

Immunologically-related TR	Cardiovascular and metabolic problems	Infections
• Transfusion-related acute lung injury (TRALI)* • Allergic TR • Febrile, non-haemolytic TR (FNHTR)* • Allo-immunisations • Haemolytic TR (HTR), acute and delayed • Post-transfusion purpura (PTP) • Transfusion-associated graft-versus-host disease (Ta-GvHD)	• Circulatory overload (TACO) • Hypotensive TR • Transfusion-associated dyspnoea (TAD) • Haemosiderosis • Hyperkalaemia, hypocalcaemia • Other	• Bacterial • Parasitic • Viral • Prions • Fungal

* *non-immunological mechanisms for these transfusion reactions are also under consideration*

Severity and imputability

The severity of a transfusion reaction is evaluated independently of its possible connection with the transfusion (imputability).

Severity of transfusion reactions	
Grade 1	**Non-severe** no treatment necessary/no permanent damage without therapy
Grade 2	**Severe** relevant or lasting damage (including allo-immunisation); hospitalisation required or prolonged; therapy necessary to prevent permanent damage If the following symptoms or findings are present, a transfusion reaction should be classified at least as severe: • Allo-immunisations • Fever > 39°C and > 2°C increase • Dyspnoea/hypoxia (other than a very mild form), pulmonary oedema • Loss of consciousness, drop in blood pressure (other than a very mild form) • Suspected haemolytic transfusion reaction • Suspected bacterial contamination/infection as a result of the transfusion • Timely intervention is necessary to avoid permanent damage or a life-threatening course
Grade 3	**Life-threatening** patient may die without relevant medical intervention, e.g. intubation, vasopressors, transfer to intensive care unit
Grade 4	**Death** grade 4 should only be used if imputability with the transfusion is at least "possible" (i.e. not if the relationship is purely temporal); otherwise: grading according to the type of the TR

The severity of a transfusion reaction is evaluated independently of its possible connection with the transfusion (imputability). For example, suspected cases of circulatory overload (TACO) with relevant dyspnoea should be classified as severe – and should remain so – even if the imputability is classified as "unlikely" in the final evaluation.

Imputability, i.e. the causal connection between transfusion and reaction, is evaluated according to its probability in a similar way to the ISBT criteria*[a]. Cases for which the information is not available or is insufficient are classified as "not evaluable".

Imputability

Imputability (causal connection between transfusion and reaction)		
0	not evaluable	There is insufficient or contradictory information and it is impossible to obtain supplementary information or check
1	unlikely	The reaction is definitely/more likely to be due to other causes
2	possible	The reaction can be explained both by the transfusion and by other causes
3	probable	The reaction does not appear to be due to another cause
4	certain	In all probability the reaction was caused by the transfusion

**a Working Party on Haemovigilance, ISBT, IHN, AABB. Proposed standard definitions for surveillance of non-infectious adverse transfusion reactions. 2013.*
**b Working party on Haemovigilance, ISBT, IHN, AABB. Transfusion-associated circulatory overload (TACO): revised definition. 2018.*

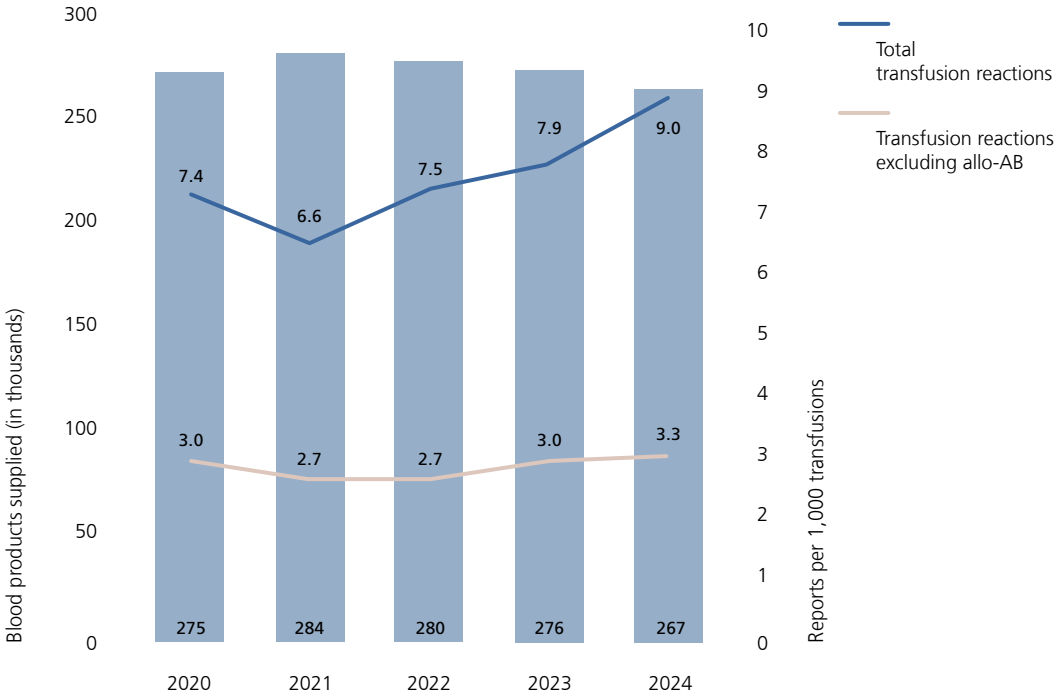
3.2 Reported data

3.2.1 Transfusion reactions: Reporting rate

Compared with the previous year, the reporting rate for TR in 2024 was 13% higher (9.0/1,000 Tf) and the reporting rate for TR excluding allo-antibodies was 9% higher (3.3/1,000 Tf) (Figure 5). Overall, there has been a rising trend in recent years in the total reporting rate for TR. In 2024, this was attributable to an increase in both the reported allo-antibodies and TR excluding allo-antibodies.

Figure 5
Reporting rate for transfusion reactions by year

Reporting rate for transfusion reactions 2020–2024



Reports per 1,000 transfusions, all degrees of severity and imputability

If we look at the frequencies of the various TR per 100,000 transfusions (all degrees of severity and imputability), the incidences are 194/100,000 (1:515) for FNHTR and 52/100,000 (1:1,920) for allergic TR. TACO were reported with a frequency of 14/100,000 (1:7,200) and TRALI with a frequency of 0.4/100,000 (1:265,000).Allo-immunisations were reported with a frequency of 569/100,000 (1:176) in 2024, compared to 491/100,000 (1:204) in 2023. The reporting rate in the category "Other" was 45/100,000 (1:2,200). These include numerous reports (n = 61) of febrile reactions that do not meet the ISBT criteria for an FNHTR and were therefore classed as "Other" (Figure 6, Figure 7, Table 6). In 2024, there were three suspected cases of parvovirus B19 infections transmitted via transfusions (see section 6.2.2 for further information).

Figure 6
Number of transfusion reactions by category

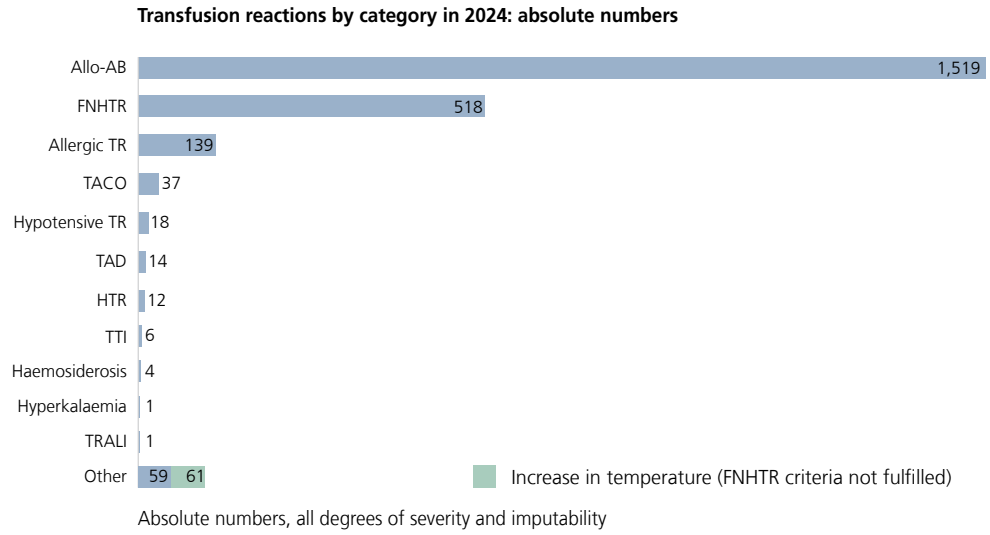
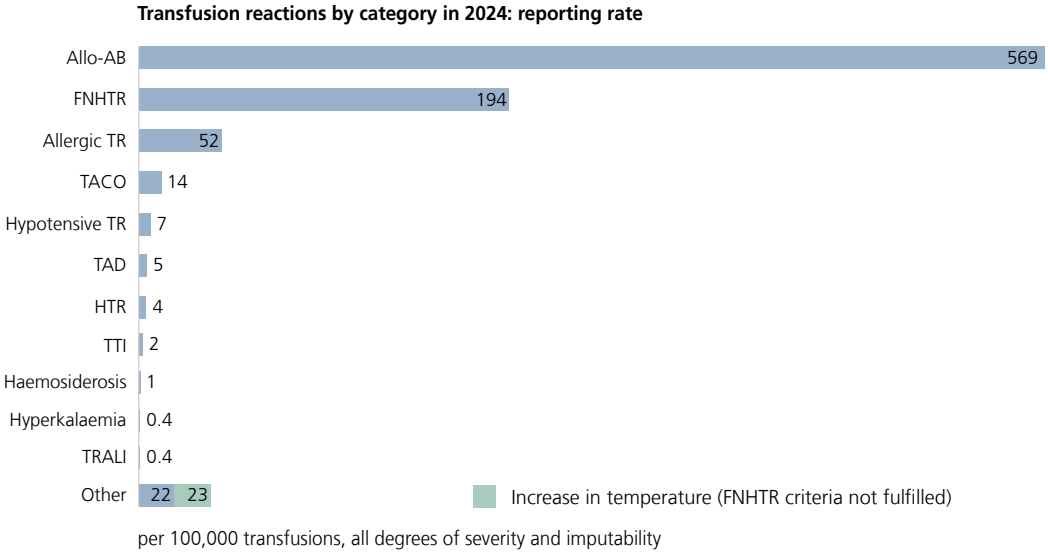


Figure 7
Reporting rate for transfusion reactions by category



TR also include transfusion-associated circulatory overload (TACO) and transfusion-associated acute lung injury (TRALI). These TR are among the main causes of morbidity and mortality and constitute typically serious complications [2]. The reported events over the past three years have been comparable in terms of both the absolute numbers and reporting rates. There is a downward trend in the number of life-threatening or fatal TACO reports (Table 5, Figure 8).

Table 5
TACO/TRALI by year

TACO / TRALI 2020–2024

	TACO		TRALI	
	Reports	Reporting rate	Reports	Reporting rate
2020	88	32	3	1.1
2021	62	22	6	2.1
2022	39	14	2	0.7
2023	36	13	1	0.4
2024	37	14	1	0.4

Absolute numbers and reporting rate per 100,000 transfusions, all degrees of severity and imputability

Table 6
Transfusion reactions by severity

Transfusion reactions by severity in 2024

	1	2	3	4	Total
Allo-immunisation	0	1,519	0	0	**1,519**
FNHTR	415	98	5	0	**518**
Allergic TR	87	38	14	0	**139**
TACO	3	26	8	0	**37**
Hypotensive TR	7	5	6	0	**18**
TAD	6	7	1	0	**14**
HTR	1	9	1	1	**12**
TTI	0	6	0	0	**6**
Haemosiderosis	4	0	0	0	**4**
TRALI	0	0	1	0	**1**
Hyperkalaemia	0	1	0	0	**1**
Other	101	13	6	0	**120**
Total	**624**	**1,722**	**42**	**1**	**2,389**

Severity 1: non-severe, 2: severe/permanent damage, 3: life-threatening, 4: death
Absolute numbers, all degrees of imputability

3.2.2 Transfusion reactions: Age groups and gender

In 2024, the numbers of TR observed in women and men were almost identical. The number of reported transfusion reactions is still increasing significantly after the age of 50.

Table 7
Transfusion reactions by age group and gender

Transfusion reactions by age group and gender in 2024*				
Age groups	**Number of reports**	**Male**	**Female**	**Unknown**
0–10	77	34	39	4
11–18	40	17	22	1
19–30	35	16	19	0
31–50	117	53	64	0
51–70	267	129	133	5
>70	333	176	155	2
Total	**869**	**425**	**432**	**12**

Absolute numbers, transfusion reactions excluding allo-AB, all degrees of severity and imputability
**reports including a date of birth are considered*

3.2.3 Transfusion reactions: Imputability

Table 8
Transfusion reactions by imputability

Transfusion reactions by imputability in 2024					
	1	**2**	**3**	**4**	**Total**
Allo-immunisation	3	75	594	847	**1,519**
FNHTR	108	319	81	10	**518**
Allergic TR	5	38	74	22	**139**
TACO	2	18	10	7	**37**
Hypotensive TR	3	8	7	0	**18**
TAD	0	10	4	0	**14**
HTR	1	4	4	3	**12**
TTI	4	0	1	1	**6**
Haemosiderosis	0	0	0	4	**4**
TRALI	1	0	0	0	**1**
Hyperkalaemia	0	0	1	0	**1**
Other	37	63	20	0	**120**
Total	**164**	**535**	**796**	**894**	**2,389**

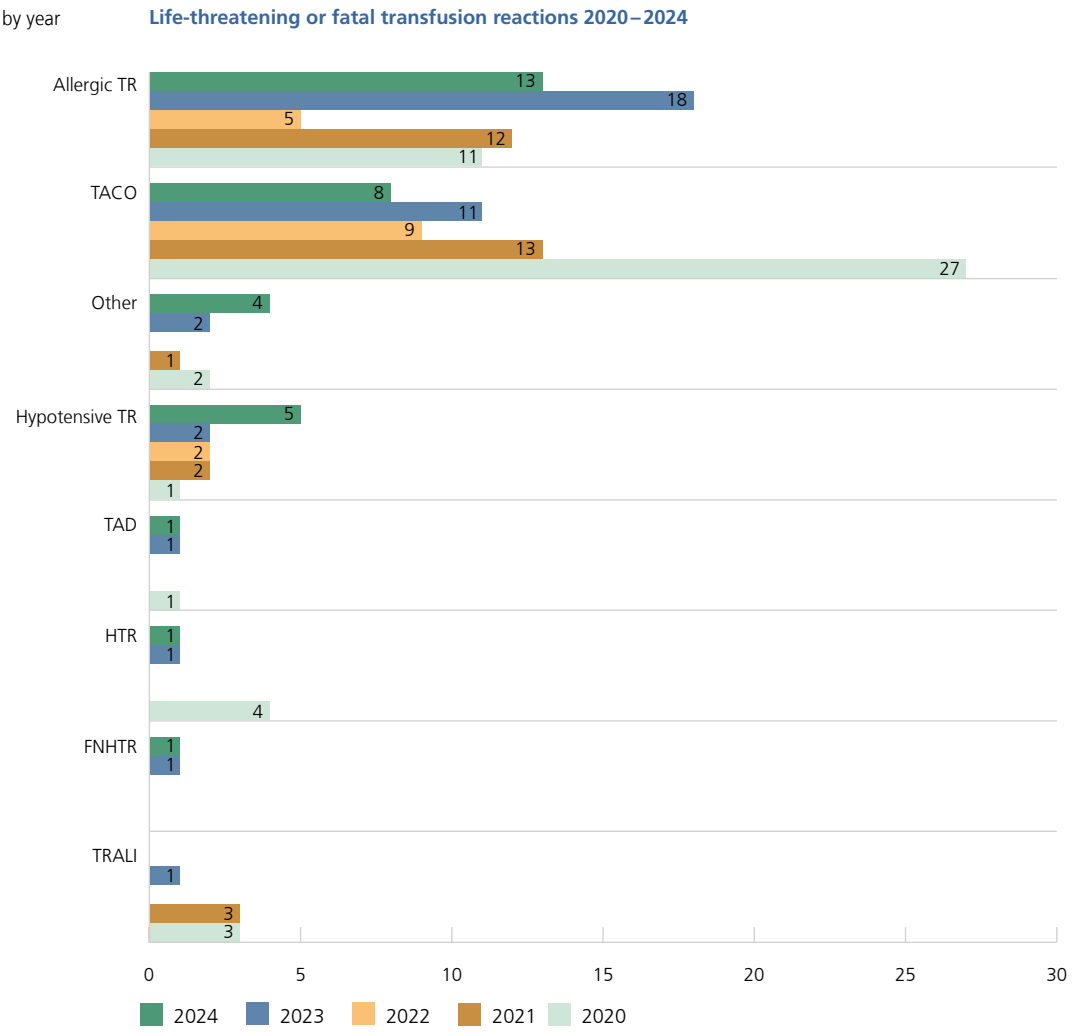
Imputability 1: unlikely, 2: possible, 3: probable, 4: certain
Absolute numbers, all degrees of severity

3.2.4 Transfusion reactions: Life-threatening and fatal events

In 2024, 870 TR (excluding allo-AB) were reported, representing an increase of approx. 5% compared with 2023. In 709 of these cases (approx. 81%), the imputability in relation to the transfusion was assessed as at least "possible" (≥ 2). Within this group (imputability at least "possible"), there were 33 life-threatening and one fatal TR (Table 9). TACO (n=8) and allergic TR (n=13) remain the most frequent causes of life-threatening or fatal transfusion reactions (Figure 8). The reporting rate for fatal transfusion reactions in 2024 was 0.37/100,000 (1:267,000).

The TACO reports for the years 2020–2024 are on a downward trend. While this is very encouraging, the next few years will reveal the extent to which this trend continues. In this year's report, we would once again urgently refer to the existing recommendations to screen patients for the risk of TACO and, if applicable, aim for a slow transfusion rate (e.g. 1 ml/kg body weight/h) and consider preventive diuretic treatment [2, 3].

Figure 8
Life-threatening or fatal transfusion reactions by year



Absolute numbers, severity 3 and 4, imputability ≥ 2

Table 9
Life-threatening and fatal transfusion reactions

Life-threatening and fatal transfusion reactions in 2024

	Possible	Probable	Certain	Total
Allergic	4	7	2	**13**
TACO	4	3	1	**8**
Hypotensive TR	3	2	0	**5**
Other	3	1	0	**4**
TRALI	0	0	0	**0**
FNHTR	1	0	0	**1**
HTR	1	0	0	**1**
TAD	1	0	0	**1**
Total	**17**	**13**	**3**	**33**

Absolute numbers, severity 3 and 4, imputability ≥ 2

Similarly to the ISBT definitions, transfusion reactions are only classified as deaths (grade 4) if imputability is evaluated as at least possible [4]. In 2024 there was one report of a fatal transfusion reaction, a clinically complex situation in which the definitive causal link between the death and the transfusion was difficult to assess. Since this reflects clinical reality, the case is described in more detail as a case study.

Table 10
Case studies of fatal incidents

Deaths
Acute HTR, imputability: possible

Female patient, age group > 80 years, multiple disorders, hospitalised with traumatic femoral and vertebral body fractures (following a fall) and pressure ulcers. Concomitant conditions included acute kidney injury, severe hypernatraemia, severe anaemia and advanced aortic stenosis. At the time of admission, the patient was assessed as unfit for anaesthesia and she was not capable of giving consent. Conservative treatment was initiated; transfusion with a unit of packed red blood cells was prescribed for the anaemia (Hb < 70 g/l).

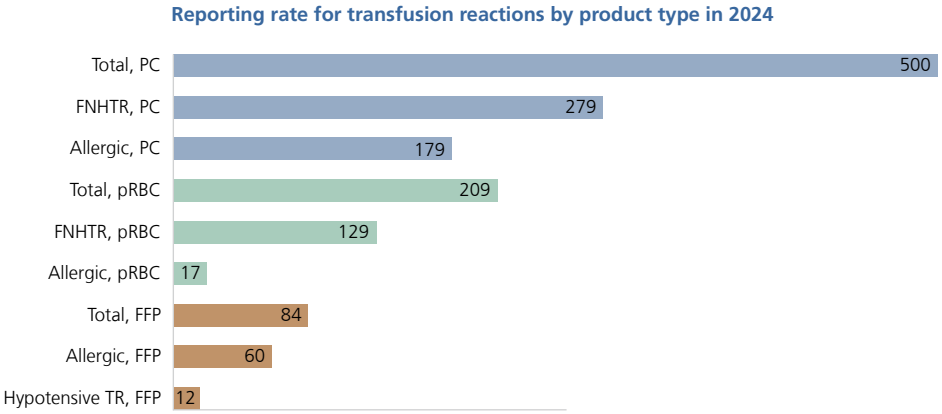
As the result of a patient mix-up the patient received an ABO-incompatible transfusion (A to O, see case study 4.2.4). The mix-up was soon noticed (transfusion volume approx. 25 ml), and the transfusion was discontinued. There was no immediate change in the vital parameters of this patient with pre-existing hypotension and requiring oxygen. The patient was unable to comment on her symptoms. In view of the incompatible transfusion, infusion therapy (hydration) and diuretic treatment were initiated. Laboratory tests showed haemolysis with slightly raised creatinine and bilirubin levels (comparison with previous results not possible). Other haemolysis parameters (LDH, haptoglobin) could not be interpreted (haemolysis in the sample), and no urinalysis was performed.

Her clinical situation subsequently worsened (approx. 7 hours after the transfusion) with respiratory deterioration and the appearance of pulmonary oedema. The treatment was not escalated and therefore no further laboratory diagnostic tests were carried out. The patient died the next day. An autopsy was not performed.

The transfusion reaction itself was assessed as an acute haemolytic transfusion reaction as a result of an ABO-incompatible transfusion. The haemolysis observed in the post-transfusion blood sample supports this assessment. A causal evaluation of the subsequent clinical development is extremely difficult – whether the aHTR itself or the measures initiated as a result of the transfusion error (infusion therapy and diuretics in a patient with severe aortic valve stenosis and pre-existing acute kidney injury) affected the clinical course to any relevant extent must ultimately remain unanswered. A cause of death that is unrelated to the TR is also possible. The TR was finally classified as an aHTR, grade 4, imputability: possible.

3.2.5 Product-specific risks

Figure 9
Reporting rate for transfusion reactions by product type



Per 100,000 Tf, all degrees of severity, imputability ≥ 2; excluding allo-AB, only TR unequivocally assignable to a product type are included
pRBC: packed red blood cells, PC: platelet concentrate,
FFP: fresh frozen plasma (FFPq / FFPpi)

The frequency and type of transfusion reactions vary according to the type of product. This evaluation included reports in which it was possible to assign the reaction unequivocally to a specific product type. Allo-immunisations have been excluded: most allo-immunisation reports do not mention a triggering blood product, or the imputability with a transfusion is not certain (e.g. in women). Allo-immunisations are therefore considered separately (see 3.2.6).

The highest reporting rates were observed for platelet concentrates (PC), particularly in connection with FNHTR (279/100,000) and allergic reactions (179/100,000). For packed red blood cells (pRBC), FNHTR were reported at a rate of 129/100,000 and allergic reactions much less frequently, at 17/100,000. The most common reactions involving fresh frozen plasma (FFP) were allergic TR (60/100,000) and hypotensive TR (12/100,000).

3.2.6 Allo-immunisations

Allo-immunisations accounted for the bulk of the transfusion reactions with severity 2. Allo-antibody formation means a permanent disadvantage for the affected patient since, for example, a limited choice of compatible blood components will be available for any future transfusions, or complications could occur during pregnancy.

Antibodies belonging to the Rhesus system are the most commonly reported allo-immunisations (43%), followed in second and third places by antibodies against the KEL and MNS systems (Table 11, Figure 10).This distribution is the same as in previous years. Anti-E (anti-RH3) is the most common allo-antibody within the Rhesus system, accounting for 50% (Table 12, Figure 11).

Figure 10
Allo-antibodies by blood group system

Allo-antibodies by blood group system in 2024

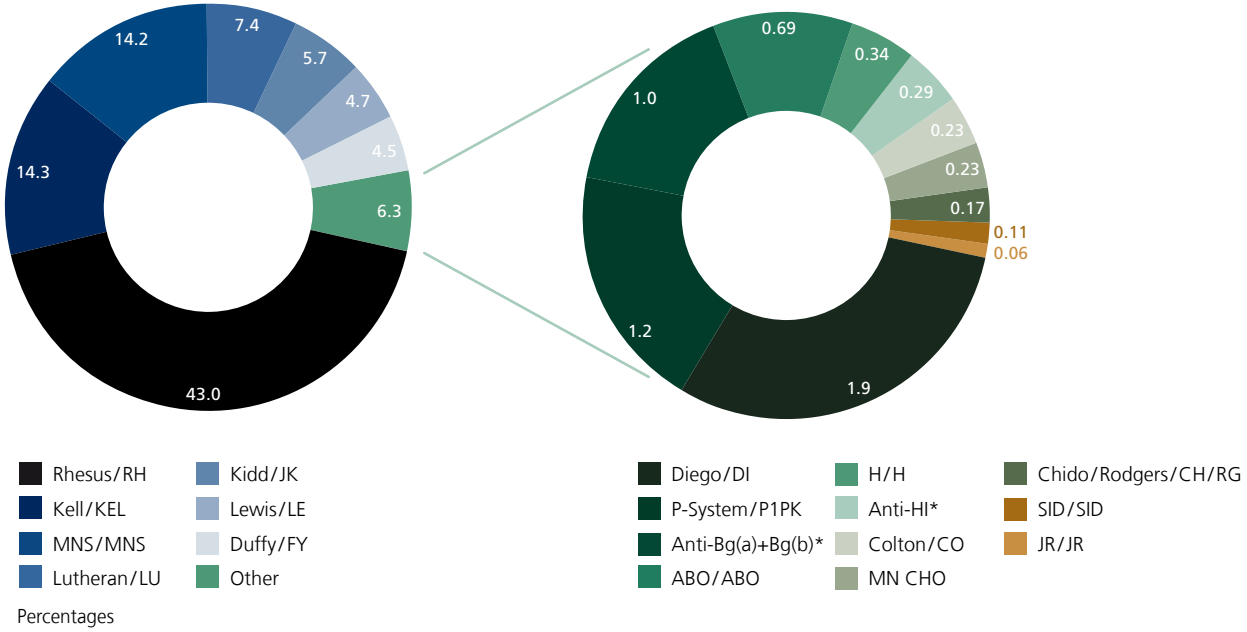


Table 11
Allo-antibodies by blood group system

Allo-antibodies by blood group system in 2024

Blood group system	n	%
Rhesus/RH	748	43.0
Kell/KEL	249	14.3
MNS/MNS	247	14.2
Lutheran/LU	128	7.4
Kidd/JK	100	5.7
Lewis/LE	82	4.7
Duffy/FY	78	4.5
Other	109	6.3
Total	**1,741**	**100°**

Blood group system	n	%
Diego/DI	33	1.9
P-System (P1PK)	21	1.2
Anti-Bg(a)+Anti-Bg(b)*	18	1.0
ABO/ABO	12	0.69
H/H	6	0.34
Anti-HI*	5	0.29
Colton/CO	4	0.23
MN CHO	4	0.23
Chido/Rodgers/CH/RG	3	0.17
SID/SID	2	0.11
JR/JR	1	0.06

According to ISBT[4]
** No data were found for these AB in the ISBT reference table*
° Discrepancies in totals are due to rounding

Figure 11
Allo-antibodies
in the Rhesus system

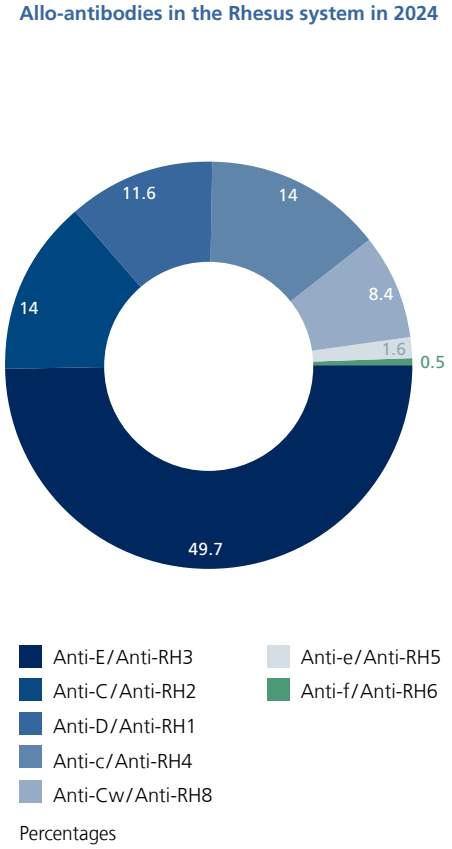


Table 12
Allo-antibodies
in the Rhesus system

Allo-antibodies in the Rhesus system in 2024		
Antibodies	**n**	**%**
Anti-E/Anti-RH3	372	49.7
Anti-C/Anti-RH2	87	11.6
Anti-D/Anti-RH1	105	14.0
Anti-c/Anti-RH4	105	14.0
Anti-Cw/Anti-RH8	63	8.4
Anti-e/Anti-RH5	12	1.6
Anti-f/Anti-RH6	4	0.5
Total	**748**	**100°**

°*Discrepancies in totals are due to rounding*

4 Serious incidents

4.1 Background

Definitions

Serious incidents in haemovigilance are typically transfusion errors and serious "errors without harm" (near misses), but may also be other events which constitute a relevant direct or indirect hazard for the patient. Transfusion errors are defined as events in which a blood component is transfused into a patient for whom it is not intended, not suitable, compatible by chance or not necessary, or in whom transfusion was delayed to a relevant extent. The term "IBCT" (incorrect blood component transfused) has become internationally established for this event. If errors or deviations from regulations and guidelines which could have resulted in a transfusion error or a transfusion reaction are discovered before the transfusion takes place, this is known as a "near miss".

Analyses of serious events help to identify sources of error and safety gaps in the transfusion chain. If a near miss happens, this provides an opportunity to investigate which safety precautions were effective. Reports of these events are therefore an important element of quality assurance, the aim being to prevent future incidents by establishing specific measures and to improve patient safety.

Mandatory reporting

Art. 63 TPO requires anyone who uses or dispenses medicinal products professionally, or is entitled to do so, to report to Swissmedic observations of serious or previously unknown facts which endanger drug safety. This Article also covers transfusion errors. Equally, Art. 59 para. 3 TPA requires serious or previously unknown adverse effects and incidents, observations of other serious or previously unknown facts and quality defects that are of significance for drug safety to be reported. According to Art. 4 para. 1 let. a TPA, blood and blood products are also medicinal products. The explanatory report on the Therapeutic Products Ordinance published in September 2018 states the following: "Observations of serious facts are incorporated for the first time following the revision of Article 59 paragraph 3 TPA. This specifically addresses situations in which erroneous use of a medicinal product was avoided but which favour errors in use and could lead to substantial damage to health. […]. Where blood products are concerned, transfusion errors that are barely avoided must also be reported." Here the Ordinance explicitly addresses near misses.

Classifications

The causes of an incorrect blood product being transfused can occur at any point in the transfusion chain: during the initial prescription, while taking blood samples, in the immunohaematology laboratory, when the product is dispensed or during the actual transfusion. Safety precautions are established to prevent transfusion errors, e.g. two blood group determinations from independent samples or the four-eyes principle. If a transfusion error occurs notwithstanding the precautions, the source of the error must be identified so that the control mechanisms can be improved. Near misses can also occur at any place in the transfusion chain and can potentially result in a transfusion error or a transfusion reaction in the recipient. However, by definition, they are identified prior to transfusion.

Swissmedic bases its classification of IBCT and near misses on the categories of the British haemovigilance system SHOT (Serious Hazards of Transfusion) [°a], so that data are comparable internationally. In addition to the error category, the place in the transfusion chain at which the deviation occurred and – where possible – the cause and type of error (e.g. communication, knowledge gaps, inadequate SOP) are also recorded.

IBCT

IBCT classifications adapted from SHOT [°b]
WCT: Wrong component transfused

Cases in which the wrong type of product (e.g. platelet concentrate instead of pRBC) or a blood product that was ABO-incompatible was transfused (this also includes cases in which the change in ABO blood group after a stem cell transplantation was not taken into account). Equally, transfusion of a suitable product in the wrong patient (e.g. due to a prescribing error) or transfusion of an unsuitable product in a premature baby/neonate (specific requirements not met) are also recorded in this category. Mistakes and errors in which the transfusion was ABO/RhD-compatible solely by chance are included in a similar way to ABO-incompatible transfusions.

- Incorrect ABO/RhD blood group
- ABO-compatible by chance
- Wrong patient, wrong type of product (also: wrong specification for neonates)

SRNM: Specific requirements not met

If a patient needs a blood product with particular specifications (in accordance with current guidelines or a doctor's prescription) and does not receive it because of an error, this constitutes an SRNM. Product specifications that may be affected are, for example, an extended RBC phenotype (e.g. in the context of allo-immunisation or haemoglobinopathy), irradiation or washing of a product, CMV negativity, HLA typing (for platelet concentrates) or warming of the blood product (e.g. if cold antibodies are present). An SRNM also exists if (e.g. in the immunohaematology laboratory) SOPs have not been followed and products are released before the necessary diagnostic procedures (including internal quality controls) have been completed.

Error concerning "specific requirements", e.g.

- Allo-antibodies
- Irradiation/washing of a blood product
- CMV negativity
- HLA compatibility (platelet concentrate)
- Extended RBC phenotype (e.g. haemoglobinopathies)
- Use of blood warmers (e.g. cold antibodies)

Laboratory aspects

- Product released in spite of incomplete/inadequate diagnostics
  - Expired T&S
  - Internal quality control not available

HSE: Handling and storage errors

If a blood product is selected and tested correctly but its quality and safety are compromised due to errors in handling or storage, this constitutes an HSE. These include, for example, interruption of the cold chain, storage for too long or incorrectly after the product has been dispensed (e.g. platelet concentrate without a shaker), errors in thawing a plasma product, transfusion although the bag is damaged, use of an incorrect giving set or transfusion of a product after its shelf life has expired.

- Storage:
  - Cold chain interrupted
  - Platelet concentrate stored cold
- Incorrect thawing
- Incorrect giving set, unsuitable Infusomat
- Damaged product bag (quality defect?)
- Shelf life exceeded

ADU: Avoidable, delayed or under / overtransfusion

ADU is the term used to describe errors in the quantity and timing of transfusions:

Avoidable transfusions: Transfusions in which the indication was incorrect, e.g. due to incorrect laboratory results (such as false low haemoglobin or platelet counts), errors in transmitting results or incorrect clinical decisions. The term also covers the avoidable use of emergency products (O RhD neg "untested").

Delayed transfusions: Clinically indicated transfusions which were not given or were given with a relevant delay. These include, for example, the delayed provision of blood products in an emergency situation or relevant delays in patient care (e.g. postponement of a date for surgery, rescheduling an outpatient appointment for another day).
Over / undertransfusion: Transfusion of too large or too small a quantity of a product, e.g. due to incorrect prescription or the malfunction of an infusion pump.

- Transfusion with an incorrect indication (e.g. due to incorrect Hb measurement, prescribing error)
- Incorrect quantity transfused
- A relevant delay in transfusion (e.g. the necessary postponement of surgery, patient rescheduled for another day)

RBRP: Right blood, right patient

Incidents in which the transfusion was correct but there were relevant errors in identifying, prescribing or selecting the blood products. In these situations there was a very high risk of patient harm and the error was identified only after the transfusion – the transfusion was administered "correctly by chance".

- Incorrect labelling
- Inadequate testing
- Missing prescription
- Missing patient identification when this is required (e.g. ID bracelet)

Cases of IBCT always involve (unintentional) errors in the transfusion process. Deliberate clinical decisions (e.g. deciding which product to use in complex clinical situations, in emergencies) are ***not*** *considered to be transfusion errors (see examples).*

Near misses

Typical examples are mix-ups at any place in the transfusion chain (blood taken from the wrong patient, labelling with the incorrect patient name). In this context the term WBIT (wrong blood in tube) is used to refer to a T&S sample on which label and patient do not match and this is not initially discovered on receipt in the laboratory (the mix-up is not discovered until after the sample has been received by the laboratory), or the mix-up occurs in the laboratory. Errors like this (discovered, for example, because the blood group is not the same as one that is already known) are a major risk for ABO/RhD-incompatible transfusion.

Other examples are ordering / dispensing a product for the wrong patient or wrong type of product. Unnecessary orders (e.g. due to incorrect laboratory results) also count as near misses if they lead to an order for blood products.

Examples of near misses

WBIT Wrong blood in tube
- Label / patient do not match, discovered after receipt of the sample in the laboratory / occurring in the laboratory

Incorrect orders
- For the wrong patient
- Wrong product specification, e.g. antibodies not considered
- Blood product labelled incorrectly

Error in immunohaematology results
- Incorrect transfusion recommendation (e.g. release after T&S if compatibility testing is indicated; allo-antibodies not considered)
- Incorrect information about test results, such as allo-antibodies

Storage
- Product entered in the LIS with wrong blood group information
- Expired product dispensed

Other
- Error in manually transferring laboratory results (e.g. wrong ABO blood group transferred)
- Findings relevant for transfusion medicine not passed on (e.g. allo-antibodies not communicated)
- Error in laboratory information system

Severity of near misses

Near misses are subdivided according to their hazard potential, and these usually involve a mix-up or the existence of the potential for use by mistake.

Severity of near misses (hazard potential)		
		Examples
Grade 1*	– Formal error – No potential for use by mistake – Non-serious hazard potential	– Missing initials/signature – Inadequate/missing labelling – Incorrect Hb/Tc determination **without** a product being ordered
Grade 2	Potential for use by mistake exists / serious hazard potential	– Another patient's date of birth – Relabelling/subsequent labelling of blood samples – A blood product ordered on the basis of incorrect laboratory results – Communication error concerning allo-antibodies, irradiation
Grade 3	Use by mistake occurred / very serious hazard potential	– WBIT – Discrepant BG determinations – **Order** for the wrong patient – Relevant error in immunohaematology results (e.g. incorrect transfusion recommendations)

**Do not have to be reported to Swissmedic (from 2024)*

Other serious incidents

In addition to IBCT and near misses, other incidents that are relevant to transfusion safety can also occur, including in particular:

– RhD-positive blood transfused to an RhD-negative recipient Rhesus D conversion
– Handling / storage errors with discarded blood products

Both of these types of incidents must also be reported – further details can be found in the corresponding information sheet: "Reporting a serious incident relating to the handling of labile blood products"

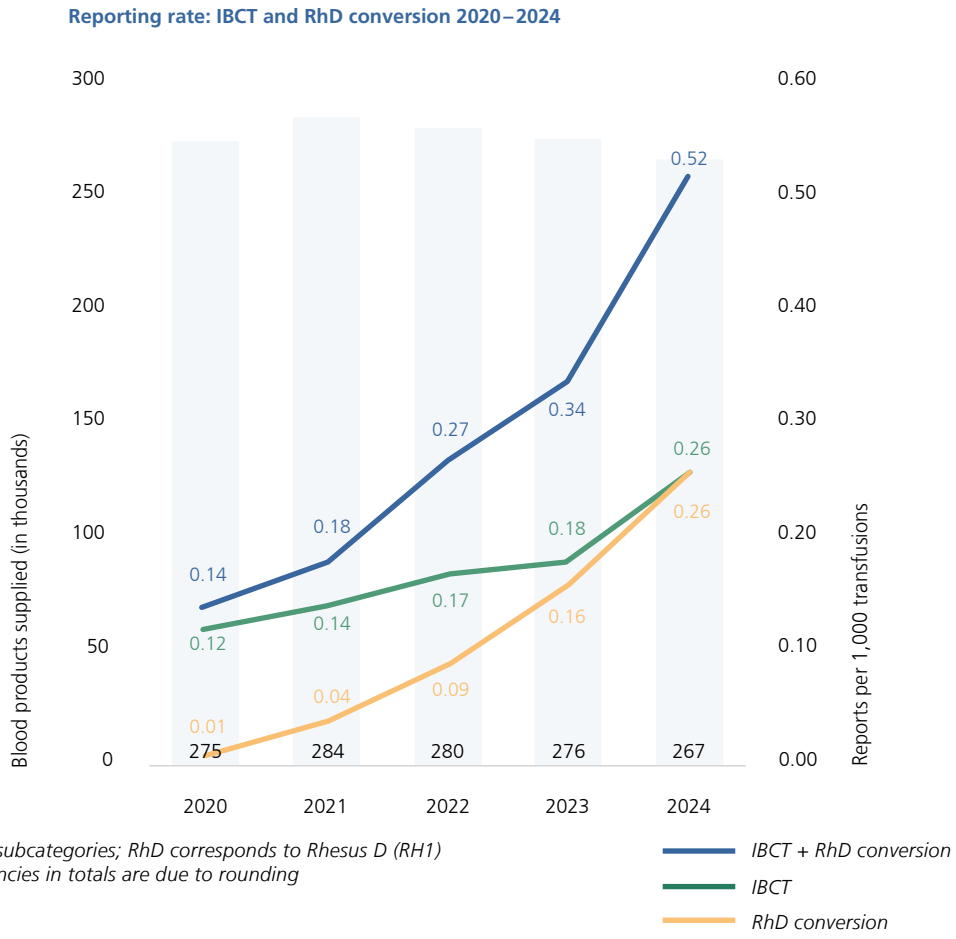
[a] *S. Narayan (ed.), D. Poles et al., on behalf of the SHOT Steering Group. The 2022 Annual SHOT report. 2023. 978-1-9995968-5-9.*
[b] *SHOT. SHOT Definitions. UK: Serious Hazards of Transfusion, 2022.*

4.2 IBCT

4.2.1 IBCT: Reporting rate

The progression of the reporting rate for IBCT (incl. Rhesus D conversions) is shown in Figure 12: the reporting rate continued to rise compared to previous years, both overall and for the two subgroups (total: 0.52/1,000).

Figure 12
Reporting rate for IBCT and RhD conversions by year



All IBCT subcategories; RhD corresponds to Rhesus D (RH1)
Discrepancies in totals are due to rounding

4.2.2 IBCT: Subclassification

As in the previous year, IBCT-SRNM accounted for the majority of reported transfusion errors in 2024 (n=32; 46% of IBCT) (Table 13). With effect from this year, incidents involving "conversion of the Rhesus D phenotype" will no longer be included in the group of IBCT-SRNM, but will be shown separately (see 4.6.2). Transfusions despite incomplete immunohaematology testing are the most common incident in the IBCT-SRNM group (n=12; 38% of SRNM), followed by errors in taking into account and/or selecting the extended red blood cell phenotype (n=11; 34%). The number of WCT rose slightly in relation to

2023 and was largely stable compared with recent years (n=9; 13% of all IBCT; 2023: n=8; 2022: n=14). One ABO-incompatible transfusion was reported in 2024, and this is described in more detail in the case studies (4.2.4). Seven transfusions were ABO-compatible by chance, all of which involved a mix-up of the patient during administration. The distribution among the subcategories is shown in Table 13 / Figure 13. Examples of IBCT reported in 2024 can be found in Table 14.

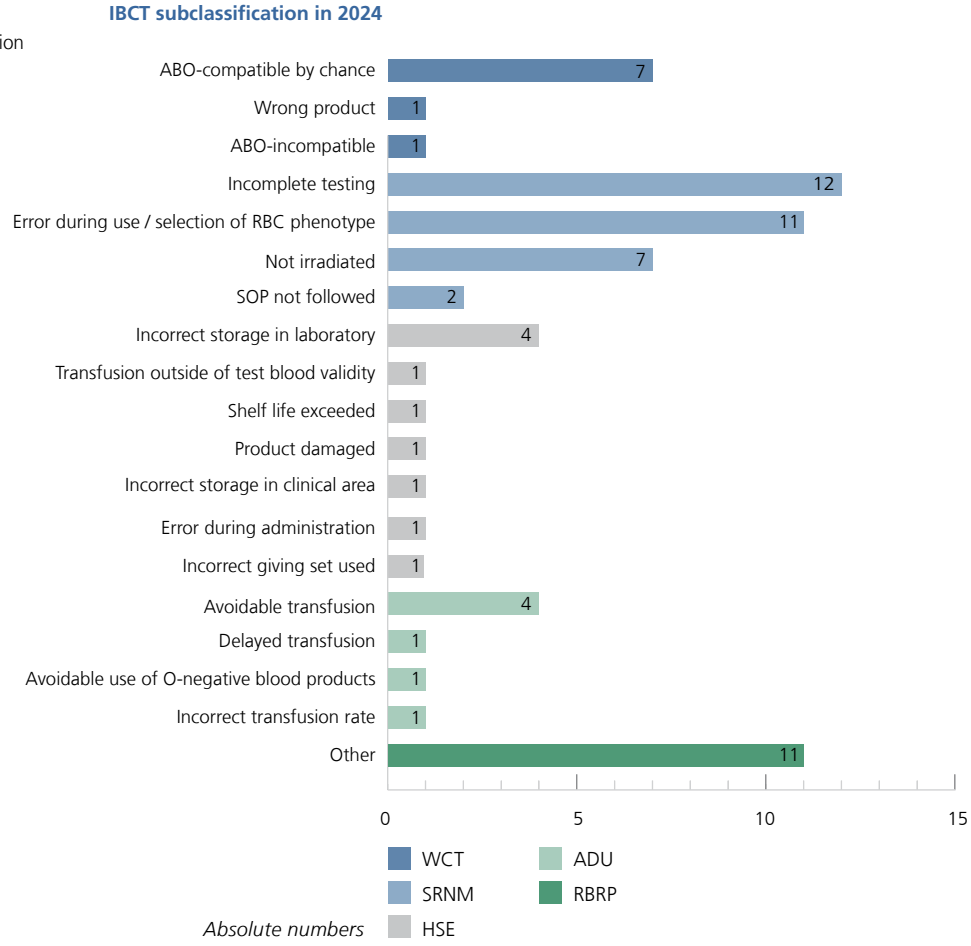
There was an increase in the number of reports in the category of RBRP, Right Blood, Right Patient, – as incidents in which the right blood product was transfused to the right patient, but serious deviations that jeopardised safety occurred during the transfusion process. This always involves a situational assessment that takes into account the specific processes on site. An example of an IBCT-RBRP is explained in the case studies (Table 14).

Table 13
Subclassification of IBCT

Subclassification of transfusion errors / IBCT in 2024			
WCT	**Wrong component transfused**		**9**
	ABO/RhD-incompatible	1	
	ABO-compatible by chance	7	
	Wrong product	1	
SRNM	**Specific requirements not met**		**32**
	Error during use / selection of RBC phenotype	11	
	Not irradiated	7	
	SOP not followed	2	
	Incomplete testing	12	
HSE	**Handling and storage errors**		**10**
	Incorrect giving set used	1	
	Error during administration	1	
	Incorrect storage in laboratory	4	
	Incorrect storage in clinical area	1	
	Product damaged	1	
	Shelf life exceeded	1	
	Transfusion outside of test blood validity	1	
ADU	**Avoidable, delayed or under / overtransfusion**		**7**
	Incorrect transfusion rate	1	
	Avoidable	4	
	Avoidable use of O-negative pRBC	1	
	Delayed	1	
RBRP	**Right blood, right patient**		**11**
Total			**69**

Absolute numbers, IBCT classification adapted to SHOT definitions [5]

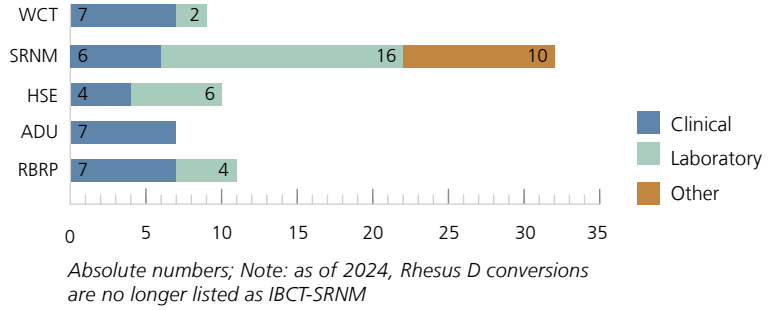
Figure 13
IBCT subclassification



4.2.3 IBCT: Localisation of error

The analysis of errors which have led to transfusion errors can help to increase the knowledge of process deviations and to improve processes. Figure 14 shows the localisation of errors (clinical area or immunohaematology laboratory/blood store) subdivided by IBCT subcategory. A further evaluation of the localisation of errors in the transfusion chain (point in process) can be found at 4.4 Localisation of errors in the transfusion chain (point in process)

Figure 14
Localisation of IBCT



4.2.4 IBCT: Case studies

The examples of the selected IBCT cases show the different ways in which transfusion errors can arise. They should in particular encourage practitioners to reflect on their own practices.

Table 14
IBCT case studies

Case studies: Transfusion errors
IBCT-WCT

Localisation of the deviation in the transfusion chain: Administration
Time: Late shift

During a late shift, a deputising nurse (high workload) assumed responsibility for administering a pRBC transfusion. The pRBC unit was checked in the preparation room following the four-eyes principle. In the patient's room, the nurse read out the female patient's name and date of birth on the blood group card, and the patient confirmed these details. A patient armband is used in the hospital, but this was not checked; digital compatibility checking of transfusions is not possible. The pRBC transfusion was started (pRBC blood group A). Soon afterwards, a second nurse entered the patient's room to carry out a haemoglobin check. In the following discussion it emerged that the patient who was being transfused was not the patient for whom the pRBC unit was intended.

Since the blood group of the transfused patient was A, this was a transfusion error that was ABO compatible by chance. No transfusion reaction occurred.

Possible contributory factors:
High workload and responsibility assumed for the transfusion by a deputising nurse who did not know the patient; the need to actively ask for the patient's name and date of birth (instead of stating yes/no) is repeatedly stressed – in this case this omission actually resulted in the transfusion error as the patient answered "yes" to a different identity.

IBCT-WCT

Localisation of the deviation in the transfusion chain: Administration
Time: Day shift

Female patients X and Y were hospitalised on the same ward (different rooms). Packed red blood cells were ordered for both patients: Pt. X: blood group O, 1 unit of pRBC; Pt. Y: blood group A, 2 units of pRBC. The patients were looked after by different nurses. For pt. Y, the second unit of pRBC ordered was delivered in a transport cool box to the ward, where it was initially kept (in the cool box).

The nurse responsible for pt. X discovered the transport cool box and assumed that it contained the pRBC for pt. X. She took the unit of pRBC and carried out a check in the preparation room following the four-eyes principle – however, only the match between the pRBC unit and the delivery note (number) was checked, not the match with the patient's identity. The transfusion of the pRBC was started for pt. X without a further check at the patient's bedside (pRBC: BG A, pt: BG O). The hospital did not have the option of electronic patient identification / digital compatibility checking; a checklist exists, but was not used correctly. The patient herself was cognitively impaired. After a short time (approx. 10 min.), the nurse responsible for pt. Y discovered the empty transport box in the office and realised that the pRBC unit for pt. Y was missing. The mix-up was subsequently discovered, and the transfusion was stopped. This was an ABO-incompatible transfusion (IBCT-WCT); the clinical course of this event is explained in Table 10.

Possible contributory factors:
Simultaneous but independent ordering of pRBC units for different patients (expectation) →, this is where communication within the team (awareness that different pRBC units will arrive) or a direct handover of the transport box with checking/mention of the patient's name can help; patient's impaired ability to communicate.

The point in process at which the initial error in these two "IBCT-WCT" events occurred was the administration, specifically the identification of the patient (patient mix-up). Since no further checking options existed after this process step, this mistake led directly to the transfusion error.

In both events, the four-eyes check conducted in the office, incompletely in one case, failed. Checking at the patient's bedside did not take place or was inadequate. Both incidents highlight the need to check the patient's identity and match the blood product to the patient. Electronic patient identification and digital compatibility checking at the patient's bedside can further enhance safety here - as can the consistent and practised use of a checklist.

RBRP

Localisation of the deviation in the transfusion chain: Patient admission
Time: Day shift

Patient X was brought to the emergency department by paramedics, at which time he was unable to provide his personal details, and no identification documents were available. The administration took the patient's name and date of birth from the information provided by the paramedics (date of birth 19XX). Patient labels, including laboratory labels for blood testing, were printed with these details, the analyses were completed and a unit of pRBC with these details was supplied. Meanwhile, the administration staff received an identification document and realised that the documented date of birth was not correct (19YY); although the details were corrected in the IT system, they were not forwarded directly to the responsible nurses.

The transfusion was supplied with the wrong date of birth, and this discrepancy was not noticed since the pRBC unit itself, the accompanying delivery note and the initially printed patient labels all showed the date of birth 19XX. The discrepancy between the dates of birth was noticed (after the transfusion) in the laboratory and was subsequently corrected.

This incident belongs to the error category "Right blood, right patient"

The point in process at which the initial error in this event occurred was when the patient's details were being recorded. The following steps were performed correctly using the incorrect date of birth. Since all labels showed the identical (incorrect) date of birth and the patient was unable to provide any clear details himself, the checks did not reveal any discrepancies, nor were there any delays. The pRBC, test blood and patient matched ("RBRP"). Nevertheless, a sample of test blood or unit of pRBC labelled with an incorrect date of birth still poses a risk. Examples of the potential consequences of a "wrong identity" in relation to the transfusion chain include: previous results cannot be taken into account (e.g. allo-antibodies), the patient may be assigned to the wrong previous results (for a different patient); delays in the transfusion may occur if a discrepancy with the patient's details / details in the hospital IT system is subsequently discovered. If the discrepancy is not corrected in all IT systems (interface problem), the traceability of the transfusion can no longer be guaranteed.

ADU

Patient X was referred by his GP to a hospital outpatient clinic for a pRBC transfusion for severe anaemia. The Hb level reported to the hospital was < 60 g/l, although this had been measured approx. 4 weeks previously. The appointment for the transfusion was arranged at very short notice since the date of the Hb measurement was either not known or was not consciously noted. On admission to the hospital outpatient clinic, his Hb level was determined, a sample of test blood was taken and a unit of pRBC was prescribed and ordered all at the same time. The unit of pRBC was delivered and the transfusion was started immediately. After some time (approx. 45 min of transfusion), the message was received to discontinue the transfusion because the newly determined Hb level was > 100 g/l. The transfusion was terminated, no transfusion reaction occurred.

This incident was an "avoidable" transfusion (ADU).

Possible contributory factors:
The hospital's internal procedures require the Hb level to be checked before a transfusion decision is made. Since the junior doctor responsible had only been working at the hospital for a short time at that point, he was inexperienced and unsure about the procedures ("Inexperience / new employee"). Various communication levels and interfaces existed at the same time: urgent registration, organisation of an unscheduled appointment, presentation specifically for a pRBC transfusion only (external treating doctor); external Hb result.

The point in process at which the initial error in this event occurred was the transfusion decision itself, which was made on the basis of an Hb level that was no longer current at the time of the transfusion. Typically, the transfusion decision itself is not checked by structured "safety barriers".

Location details are provided if they are relevant to an understanding of the example.

4.3 Near misses

4.3.1 Near misses: Reporting rates

The reporting system for near misses was revised in 2024. Grade 1 near misses were defined as near misses with no potential for use by mistake and/or only low hazard potential and no longer need to be reported to Swissmedic. The classification and reporting obligation were published in a new information sheet ("Reporting a serious incident relating to the handling of labile blood products"). Applying this classification, the total number and reporting rate for near misses fell compared to the previous year and was 4.2/1,000 Tf in 2024 compared to 9.6/1,000 Tf in 2023). As regards events in severity grades 2 and 3, the total number of reported events fell slightly in 2024 (n= 463; 2023: n=500) (Table 15).

Figure 15
Near miss reporting rate by year

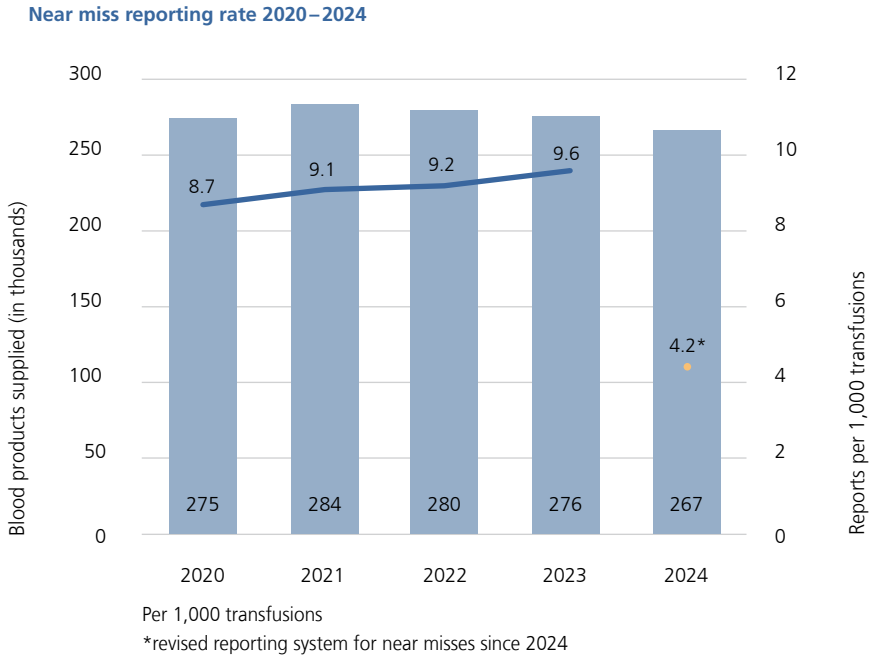


Table 15
Near misses by severity

Severity of near misses in 2024	
1 Non-serious	654
2 Serious	245
3 Very serious	218
Total	**1,117**

Absolute reporting numbers
**revised reporting system for near misses since 2024*

4.3.2 Near misses: Localisation and discovery

As in 2023, the evaluation of near misses this year focused on reportable serious and very serious events (grades 2 and 3).

The localisation of near misses and the localisation of their discovery are shown below in the same way as for the evaluation of IBCT. While the picture is similar to that for 2023, the number of very serious near misses occurring during clinical preparation has increased (n=189, 41% of the total). These predominantly involved "wrong blood in tube" incidents (n= 168, see Figure 18). The proportion of near misses whose localisation is described as "other" has increased – these include cases in which patient mix-ups occurred during admission (hospital IT system): one mix-up was not reported to the immunohaematology laboratory (lack of interface) and was only discovered by the accounts department; a further mix-up was noticed by a pharmacist who was supposed to be dispensing other medicines (incorrect date of birth). The accounts department also discovered a case in which a blood sample was inadvertently assigned in the LIS to the wrong patient.

If these cases had not been discovered, an incorrect ABO blood sample would have remained in the LIS. These and many other "WBIT" cases underline **the absolute necessity to perform two independent ABO blood group determinations**.

The localisation of near misses and the localisation of their discovery are shown below in the same way as for the evaluation of IBCT.

Figure 16
Near misses: Severity and localisation of the error

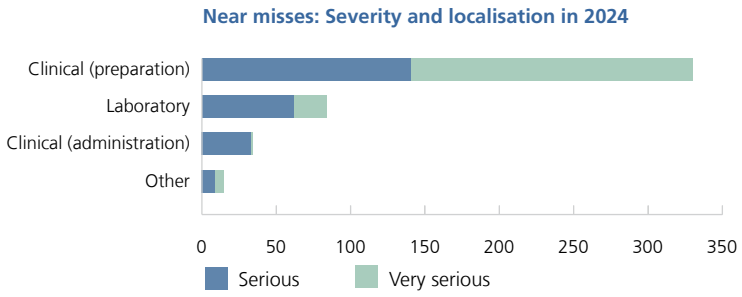


Table 16
Near misses: Severity and localisation of the error

Near misses by severity and localisation of the error 2024

	Severity of the error		
Localisation of the error	Serious	Very serious	**Total**
Clinical (preparation)	141	189	**330**
Laboratory	62	22	**84**
Clinical (administration)	33	1	**34**
Other	9	6	**15**
Total	245	218	**463**

Absolute numbers, severity grade ≥ 2

Figure 17
Near misses: Discovery and localisation of the error

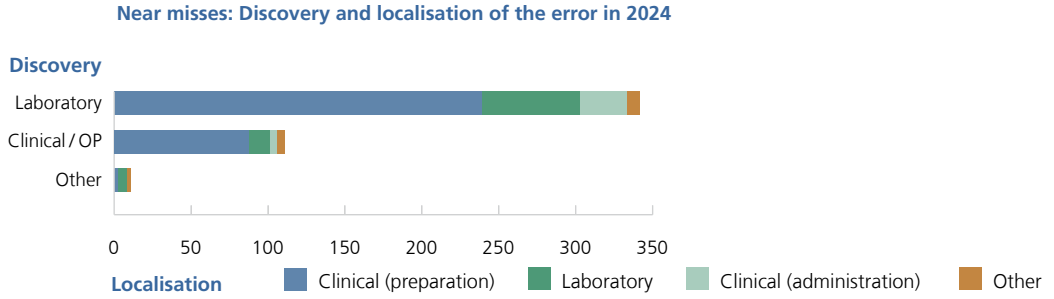


Table 17
Near misses: Discovery and localisation of the error

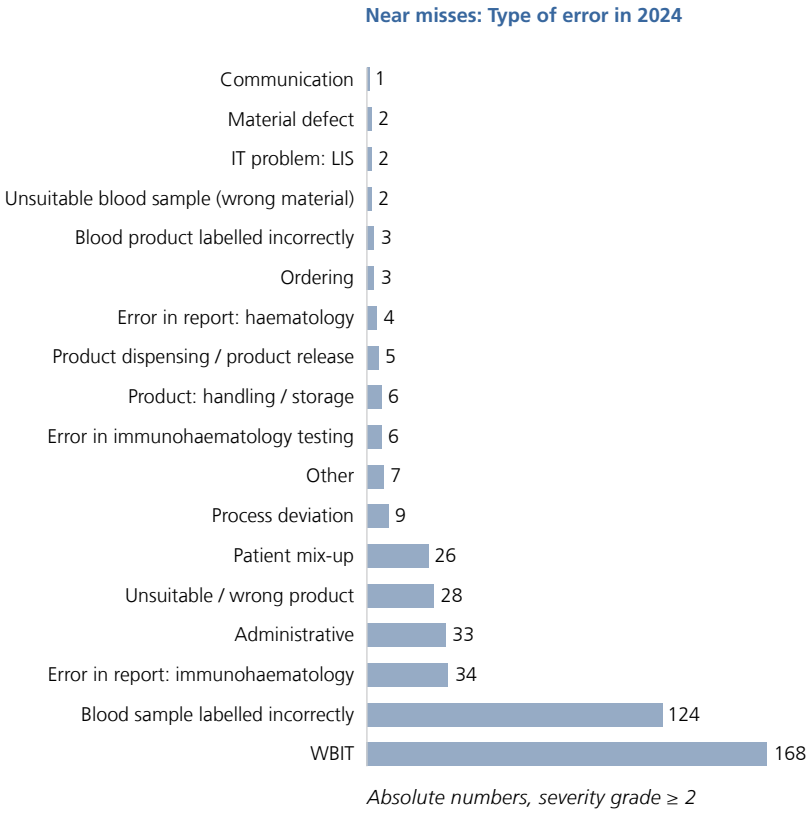
Near misses: Discovery and localisation of the error in 2024

	Localisation of the error				
Discovery of the error	Clinical (preparation)	Laboratory	Clinical (administration)	Other	**Total**
Laboratory	239	64	30	8	**341**
Clinical / OP	88	14	4	5	**111**
Other	3	6	0	2	**11**
Total	**330**	**84**	**34**	**15**	**463**

Absolute numbers, severity grade ≥ 2

4.3.3 Near misses: Type of error

Figure 18
Near misses: Type of error



Absolute numbers, severity grade ≥ 2

4.4 Localisation of error in the transfusion chain (point in process)

Clusters of errors at a specific point in the transfusion chain (point in process) are indicative of particularly critical process points. Looking at IBCT, clusters indicate that decisions in these areas are being reviewed using few or ineffective (safety) checks (lack of safety barriers). It is therefore worthwhile to compare the localisation distribution of IBCT (errors that were not identified) and near misses (errors that were identified). Deviations that were identified (near misses) probably have more effective safety checks.

In 2024, deviations that led to IBCT most frequently involved the testing of blood products (n=16), representing a significant increase compared to 2023 (n=6). Other frequent sources of error were the selection/dispensing of the blood products and the administration, followed by the transfusion decision itself (order) and prescription (prescribing process, e.g.: prescribed for the wrong patient) (Figure 19). The increase in IBCT caused during the "testing" step is largely attributable to the use of a defective test cell for antibody screening (medical device error) and led to IBCT-SRNM before the manufacturer realised or was informed (see also "Figure 22 Causes of IBCT"). Other errors in relation to testing included: Transfusion of blood group "A" products with just a single BG determination, error in the immunohaematology result (failure to mention a possible allo-AB), transfusion without the necessary compatibility testing (multiple allo-AB and haemoglobinopathy) after a specific order and misunderstandings between suppliers and the transfusing hospital. If we just look at the IBCT-WCT, the error arose predominantly during administration (n=5): a patient mix-up occurred in all cases (all "ABO-compatible by chance"), with the transfusion of a unit of pRBC to an incorrect patient (see also 4.2.4 IBCT: Case studies).

In comparison, by far the most grade 2 and 3 near misses occurred in the context of obtaining samples (preparation) – this is in line with the figures reported for the previous year and underlines the importance of checks in the laboratory.

Figure 19 IBCT – point in process

IBCT: Localisation of errors in the transfusion chain in 2024

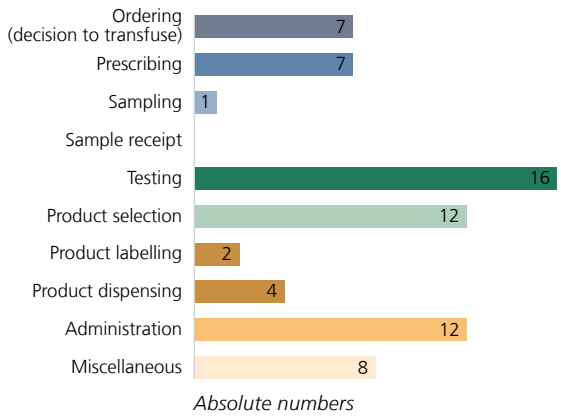


Figure 20 IBCT-WCT – point in process

IBCT-WCT: Localisation of errors in the transfusion chain in 2024

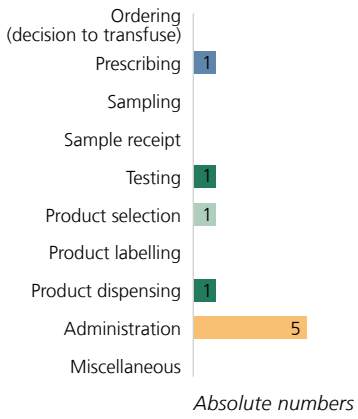
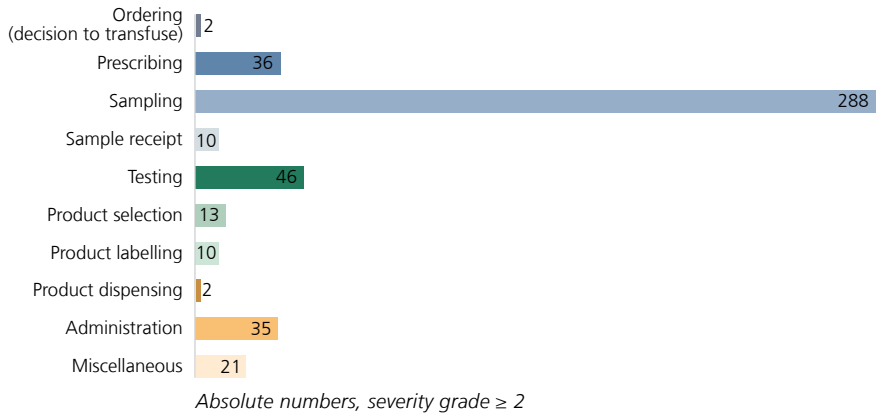


Figure 21 Near misses – point in process

Near misses: Localisation of errors in the transfusion chain in 2024



4.5 Further evaluations

The discovery, processing and reporting of transfusion errors is evidence of a functioning quality management system – we would expressly like to thank all reporters for their commitment to improving transfusion safety. A structured incident analysis should be performed, taking all the process factors into account. 26% of the IBCT reports in 2024 identified "human error/individual error" as the main cause of the incident. In 45% the main cause was failure to follow an existing and adequate SOP. Far rarer was the scenario in which an SOP was either inadequate or not available (n=1 in each case). There was a substantial increase over the previous year in the number of technical errors as the cause (n=14, 20% of IBCT): these involved problems in IT systems (errors in the assignment of the extended Rhesus phenotype due to an error in the laboratory IT system), errors in temperature monitoring during storage, which were not detected in time due to an inadequate alarm system, and errors in the testing of patient samples caused by defective

test cells. In many steps, correct transfusions depend on the correct operation of in vitro diagnostic medical devices (IVD), and the prompt detection of IVD errors is important for the safety of the transfused patients. On this issue, please also note the applicable reporting obligations associated with materiovigilance (more information at: Materiovigilance reporting system)

The failure to follow an adequate SOP accounted for 75% of near misses. Figure 22 and Figure 23 show the distribution of causes of IBCT and near misses.

The rare mention of missing or inadequate SOPs suggests that quality assurance systems are effectively implemented. At the same time, the reported data show how challenging it is to be able to correctly implement SOPs in practice – in all stressful situations. If SOPs are commonly not followed, in addition to providing training and raising awareness, it is necessary to review the processes and instructions themselves.

While the existence and contribution of human, individual errors is undeniable, it is important to consider these errors as part of (and in some cases the consequence of) existing processes and surrounding factors[6]. The workload and staffing differ from one situation and one shift to the next. The "Guidelines for quality assurance in transfusion practice" issued by the Swiss "Quality Assurance in the Use of Blood Products" working group recommend that transfusions should not be performed at night if possible[7]. 26% of the IBCT (Figure 24) occurred during a night/late or weekend shift. Compared to previous years, the proportion of transfusion errors occurring during the day shift remained largely stable (day shift in 2024: 36%; 2023: 29%; 2022: 41%) (Figure 24). In an ideal situation, aids and processes exist to help staff handle rarely performed activities and other stress factors (e.g. night shift, reduced staffing) and thus avoid errors. The implementation of digital (non-fatiguable) checks is one possible option here.

Figure 22
Causes of IBCT

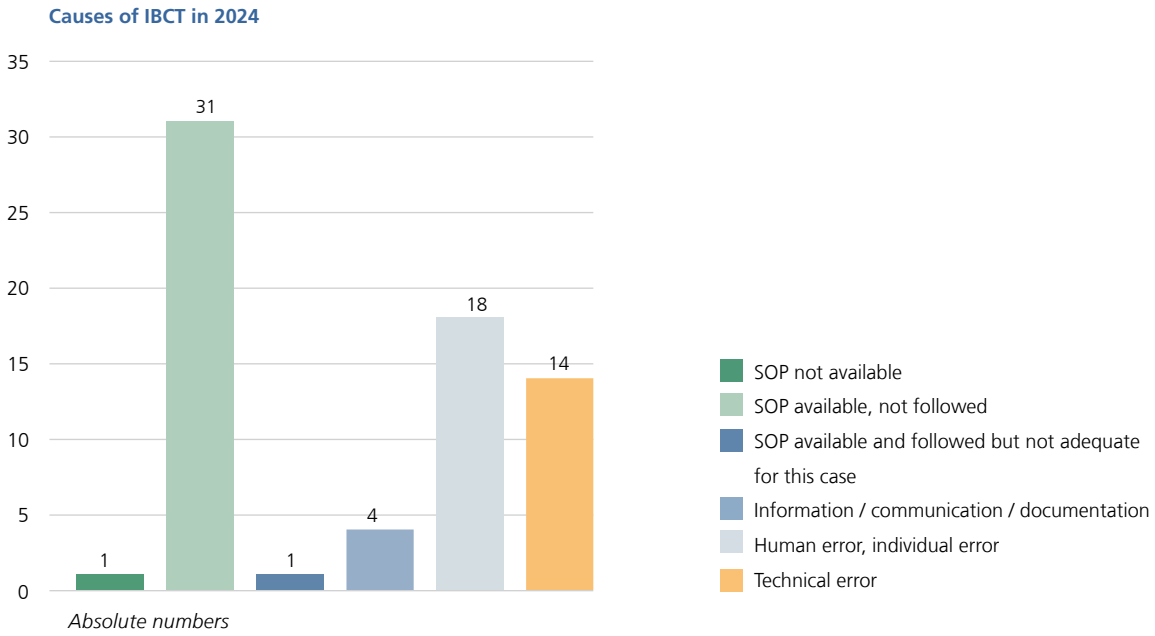


Figure 23
Causes of near misses

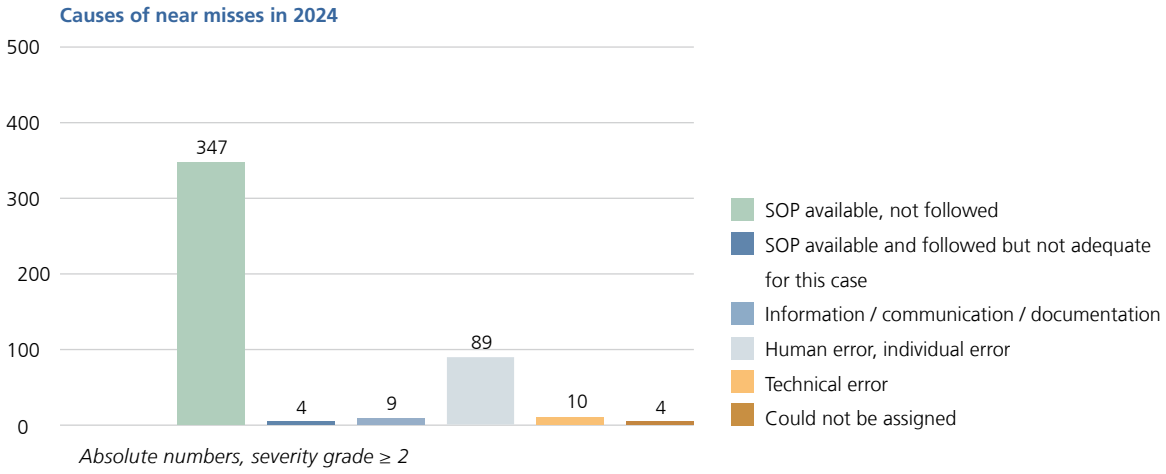
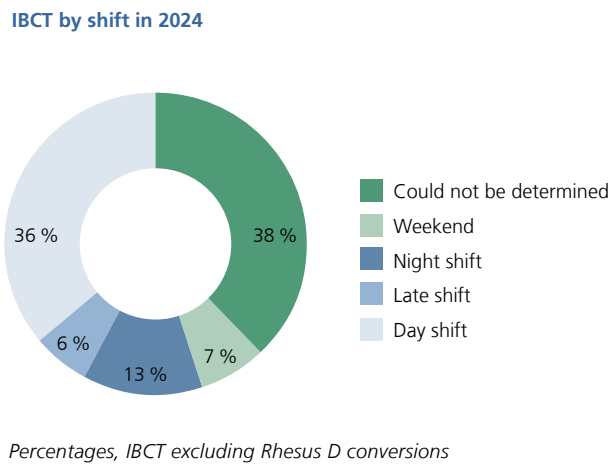


Figure 24
Occurrence of IBCT by shift



4.6 Other serious incidents

4.6.1 Discarded blood products – incorrect storage and handling

If they are not detected, errors in the handling or storage of blood products can put patients at risk. More often than not, they lead to the product being discarded which, from the standpoint of scarcity of resources and the ethical responsibility to the donors, should be prevented at all costs. Errors that lead to the destruction of blood products are therefore classified as serious incidents. Events in which products are destroyed during storage, i.e. without process errors, do not have to be reported. Table 18 shows the reasons stated by the reporters for the products having been discarded: in all cases, the table shows the reported "main reason" that led to the product being discarded. This means that – where noted – the clinical situation / reason for the modified requirement is stated. In all the cases listed under "Orders/modified requirement" and "Patient-related reasons", the blood products could not be returned to the blood store. Cases in which no information was given about the background (e.g. the reason for cancellation) are shown under the corresponding storage problem (e.g. temperature monitoring). There was no double-counting of reports. The reports are intended to give an overview of common causes of discarded blood products in Switzerland and help identify possible areas for improvement.

It is striking that, for example, only a small number of the situations were described by the reporters themselves as an "emergency situation" (incl. mass transfusions) (n=73, 11% of reports). In the context of temperature monitoring, a basic distinction can be made between users who use certified monitoring systems for transport/storage outside the blood store (temperature loggers, etc.) and users who dispense the products without such controls. Overall, an interrupted cold chain or inadequate monitoring is the most frequent reason for the destruction of packed red blood cells. Here, the use of certified transport boxes or temporary storage in validated refrigerators (if the need is unclear) can enable more products to remain in use. The large number of "cancellations" given as the reason for discarding products (n=389, 55% of all events) shows the importance of suitable and rapid communication channels in the transfusion chain (rapid and simple information for the transfusion laboratory, raising awareness among staff of the relevance of the information).

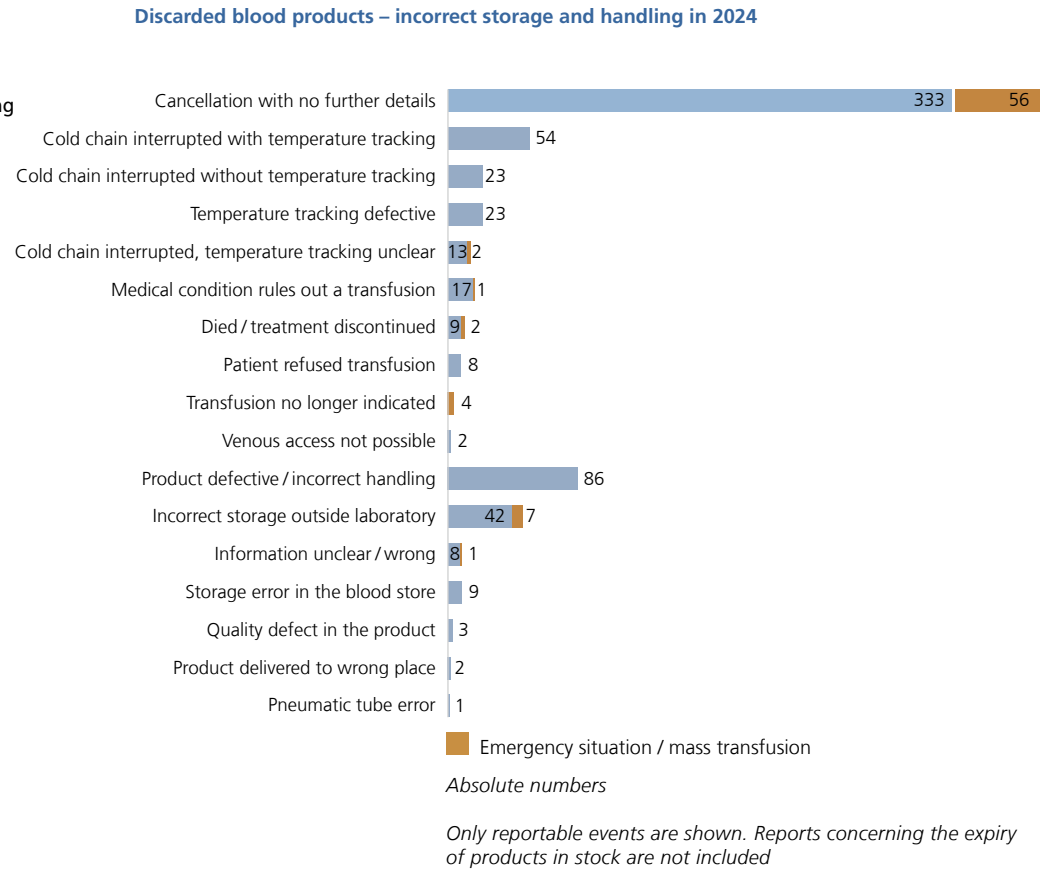
Table 18
Discarded blood products – incorrect storage and handling

Discarded blood products – incorrect storage and handling in 2024		
Orders / modified requirement		**389**
Cancellation with no further details	389	
Temperature monitoring		**164**
Cold chain interrupted with temperature monitoring	54	
Incorrect storage outside the blood store (e.g. outside the refrigerator, unmonitored refrigerator)	49	
Cold chain interrupted without temperature monitoring	23	
Temperature monitoring available: defective (e.g. technical error of the temperature logger / forgotten)	23	
Cold chain interrupted, temperature monitoring unclear	15	
Patient-related reasons		**44**
Medical condition rules out a transfusion	18	
Patient died / treatment discontinued	11	
Patient refused transfusion	8	
Transfusion no longer indicated	4	
Venous access not possible	2	
Patient mix-up	1	
Other		**110**
Product defective / incorrect handling (e.g. error when piercing the product, material defect, clot in FFP)	86	
Information unclear / wrong (transfusion would have been possible)	9	
Storage error in the blood store	9	
Quality defects in the product	3	
Product delivered to wrong place	2	
Pneumatic tube error	1	
Total		**707**

Absolute numbers

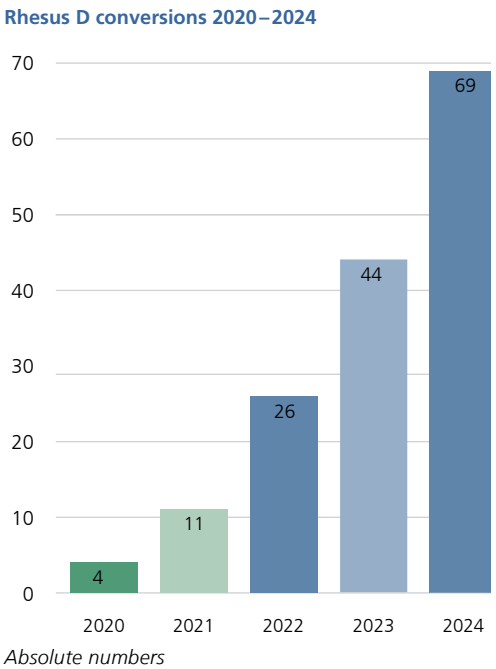
The table only shows reportable events. Reports concerning the expiry of products in stock are not included

Figure 25
Discarded blood products – incorrect storage and handling



4.6.2 Rhesus D conversion

Figure 26
Rhesus D conversion: Course over the last 5 years



The transfusion of a unit of pRBC with the phenotype RhD pos to a recipient whose own blood group is RhD neg, known as Rhesus D conversion, is associated with the risk of anti-RhD allo-immunisation. One way to avoid this scenario is to ensure that the RhD statuses are identical if possible during pRBC transfusions. The current transfusion medicine recommendations in Switzerland provide for exceptions, particularly mass transfusions [8, 9]. At the same time, if supply shortages exist (no compatible pRBC RhD neg available), a rhesus D conversion is unavoidable. Despite compliance with guidelines and alternatives, Rhesus D conversion remains a "serious incident" and should be reported as such. The reported data should also be used to assess the resources situation and the consequences of shortages for transfusion safety in Switzerland. From Swissmedic's perspective, the rise in case numbers shown in Figure 26 is primarily attributable to improved reporting compliance, although a relevant number of necessary conversions is apparent. Further evaluations will follow in future as the data pool improves.

5 Donor reactions

5.1 Background

Mandatory reporting

In accordance with Art. 58 para. 1 TPA, Swissmedic and the other authorities responsible for enforcing the Therapeutic Products Act monitor the legitimate manufacture, distribution, dispensing and promotion of therapeutic products within the scope of their responsibilities. They perform periodic inspections to establish whether the conditions for licensing are still being met. Swissmedic's responsibility for inspections relating to blood and blood products is set out in Art. 60 para. 2 let. b TPA.

The regional blood transfusion services (RBTS) report all grade 1–4 donor reactions cumulatively to Swissmedic and to Swiss Transfusion SRC once a year. Severe grade 3 and 4 donor reactions must also be reported individually to Swissmedic (on a separate form) within 15 days, as stipulated in Art. 62 TPO and Art. 63 para. 3 TPO.

Classifications

Swissmedic classifies donor reactions using the classification developed by the Donor Haemovigilance working groups of the ISBT, IHN and AABB in 2014°[a]. This enables reactions to be recorded in a standardised manner and facilitates international comparison of donor haemovigilance data. Reactions are classified into symptom-related categories and degrees of severity; in addition, imputability between donation and incident is evaluated. A detailed classification is provided on the Swissmedic website (Haemovigilance: Forms / Information sheets).

Classification of donor reactions	
A	Local symptoms
B	Generalised symptoms/vasovagal circulatory reactions
C	Specific adverse effects related to apheresis
D	Allergic reactions
E	Cardiovascular reactions
F	Other serious adverse effects

adapted from °a

Severity of donor reactions	
Grade 1	**mild** – Localised symptoms – Mild symptoms – Spontaneous/rapid recovery – No medical intervention necessary
Grade 2	**moderate** – Localised but more extensive – More severe or more persistent symptoms – Functional impairment – Recovery delayed – Possibly intervention such as infusion required – Possibly medical treatment
Grade 3	**severe / life-threatening** – Medical intervention necessary to prevent permanent damage or to save life (resuscitation) – Admission to emergency department/hospitalisation required – Duration of symptoms > 1 year after donation
Grade 4	**Death**

°a Townsend, M., Kamel, H., Van Buren, N. et al. Development and validation of donor adverse reaction severity grading tool: enhancing objective grade assignment to donor adverse events. Transfusion. 60, 2020, Bd. 6.

5.2 Reported data

Since 2021 Swissmedic has published the reported data for all donor reactions, i.e. both serious (single reports) and non-serious (collective reports). This is done in the interest of transparency in donor vigilance and is intended to facilitate international comparison. As in previous years, vasovagal circulatory reactions accounted for the majority of donor reactions, 91% of all reactions were mild. Of the grade 3 events, the causal connection with the blood donation was evaluated as at least possible for a total of 12 donations, all whole blood donations (two first-time donors); nine of the grade 3 events were "vasovagal reactions", mostly fainting with a need for further medical attention in the emergency department. Relevant local symptoms occurred in three events, including two arm vein thromboses and one temporary damage probably to nerve structures. Unfortunately, one death occurred following a blood donation in 2024: a male donor (age group 60–65) was found lifeless a few hours after a complication-free whole blood donation. There were no infringements of donor suitability, and the authorities did not suspect any negligence by a third party. The connection with the blood donation was finally evaluated as "not evaluable". In relation to the total number of blood donations performed (260,349 in 2024) [1] severe/life-threatening donor reactions (grade 3) were very rare.

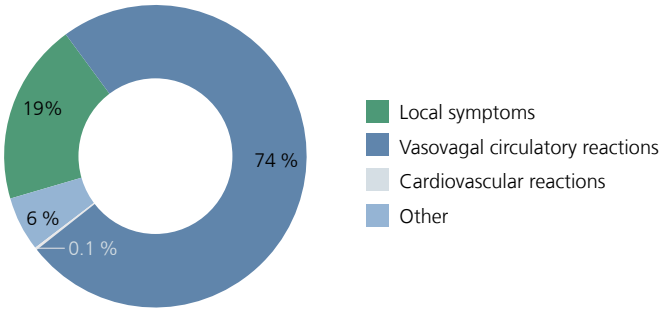
Table 19
Donor reactions: Type and severity

Donor reactions in 2024					
Severity	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**	**Total**
A Local symptoms	556	64	4	0	**624**
B Vasovagal circulatory reactions	2,164	207	9	0	**2,380**
C Specific adverse effects related to apheresis	178	12	0	0	**190**
D Allergic reactions	4	0	0	0	**4**
E Cardiovascular reactions	0	1	1	1	**3**
F Other serious adverse effects	6	2	1	0	**9**
Total	**2,908**	**286**	**15**	**1**	**3,210**

Absolute numbers; grades 1 and 2: collective reports, grades 3 and 4: direct reports to Swissmedic, all degrees of imputability

Figure 27
Donor reactions: Causes

Donor reactions in 2024



Percentages, all degrees of imputability
Discrepancies in totals are due to rounding

Table 20
Grade 3/4 donor reactions by year

Grade 3/4 donor reactions in 2020–2024

	2020	2021	2022	2023	2024
Local symptoms	0	0	1	1	4
Vasovagal circulatory reactions	12	6	6	10	9
Other	2	2	3	6	3*
Total	**14**	**8**	**10**	**17**	**16**

All degrees of imputability * of which one grade 4

6 "Protective measures" in case of infections

6.1 Background

Mandatory reporting

If it is found that the donor did not fulfil the criteria for donor suitability during the donation, the tests for communicable diseases were not performed correctly or the donor has been discovered to have a blood-borne disease, Art. 37 para. 1 MPLO requires the person who holds a licence for activities involving blood and labile blood products to take the necessary protective measures without delay.

According to Art. 37 para. 4 MPLO, institutions which administer blood and labile blood products to patients (generally hospitals and doctors' practices) must, on request, provide the manufacturers with the relevant information concerning use of the labile product to facilitate investigations (involvement in the "look-back" procedure, see below).

Reportable incidents

Reports which describe protective measures usually concern infection markers identified in donors who test positive. They also include the documentation of any further investigations triggered by this finding with respect to earlier donations by the same person and/or other blood donors in some cases (known as the "look-back" procedure).

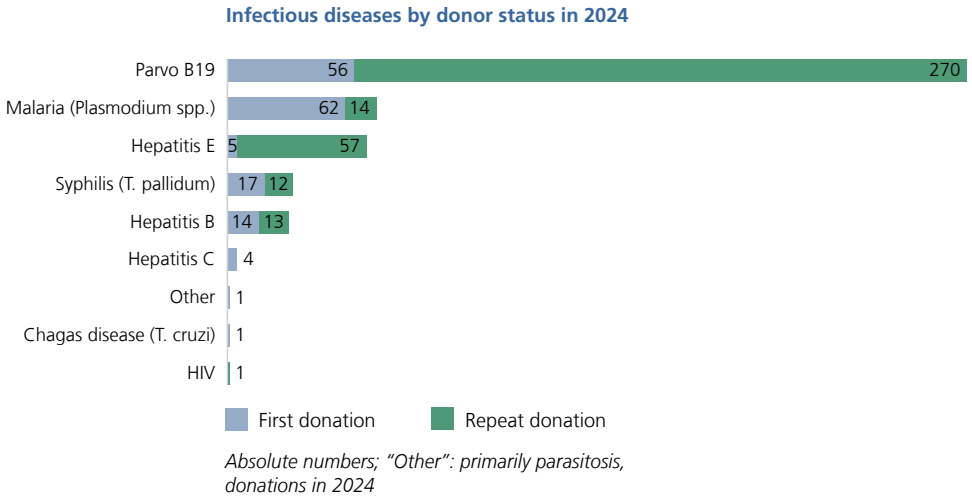
The responsible blood transfusion service reports the infection markers, the measures implemented and the data for the donated blood products to Swissmedic. The exposure risk must also be reported for certain infection markers. For repeat donors, the data from the last-but-one donation must also be provided, and it must be stated whether a look-back procedure was initiated.

6.2 Reported data

6.2.1 Protective measures: Infection markers

In 2024, a total of 526 reports were received concerning infections in blood donors and corresponding protective measures. Furthermore, two reports concerned protective measures as a result of the failure to fulfil the donor suitability criteria (Figure 28). This rise in the reporting numbers compared with previous years (2023: n=241; 2022: n=146) is due to a substantial increase observed, since the second half of 2023, in infections with parvovirus B19 (Figure 30). Further details are provided in section 6.2.2. Apart from that, the infection numbers were largely unchanged compared to the previous year. The cases of malaria involved mainly first-time donors who were tested specifically as they had a corresponding personal history. There was also an increase in syphilis cases (2024: 29; 2023: 24, 2022: 14) – this reflects a trend also being observed in the population at large [10].

Figure 28
Infectious diseases in blood donors: first or repeat donation



Absolute numbers; "Other": primarily parasitosis, donations in 2024

6.2.2 Protective measures: Parvovirus B19

Parvovirus B19 (Parvo B19) is a non-enveloped DNA virus. Infections with the virus are often asymptomatic or may cause erythema infectiosum (fifth disease). In high-risk patients, such as people with certain blood diseases, immunosuppressed people or pregnant women, infection can have serious consequences including aplastic crisis or hydrops fetalis. Epidemics of the infection typically occur at the end of winter and start of spring, with transmission mainly via the respiratory tract [11]. During an epidemic, non-immune contacts are infected in 50% of cases. Seroprevalence in the population is high and increases with age, exceeding 60% in the over-50s. In Switzerland, Parvo B19 does not need to be reported to the FOPH.

Cases of parvo B19 declined considerably during the COVID-19 pandemic – very probably as a result of the behavioural measures that were put in place – followed by a significant increase in the winter of 2023/2024. Figure 29 shows the trend for absolute reported numbers for parvo B19 in recent years, with monthly figures for 2023–2024 (Figure 30): The trend for the disease figures is in line with observations in other European countries [12]. In the second half of 2024 there was a significant decline in the reported numbers (Figure 30).

During an infection with parvo B19, the virus can be detected in the blood of the patient and transmission via blood products is possible in principle. Consequently, anyone suffering from a parvo B19 infection (or showing symptoms of the disease without a clear diagnosis) may not give blood temporarily. In Switzerland, everyone who donates blood is also currently tested for the presence of parvovirus B19. Due to the short shelf life and to ensure supplies of platelet concentrate in particular, these products must sometimes be released for distribution before all parvo B19 test results are available. Pathogen inactivation is also carried out in all platelet concentrates during production. While this process is effective with low viral titres, it is only of limited effectiveness with high viral titres due to the nature of the virus [13].

In 2024, in a total of six transfused units of platelet concentrates (all buffy coat platelet concentrates) and one of packed red blood cells, parvovirus B19 was detected in the donated blood by PCR testing. In all cases, the user was immediately informed upon detection. The investigations of the transfused patients revealed three cases in which a transfusion-transmitted infection (TTI) was suspected – in subsequent investigations, the imputability was classified as certain, probable and unlikely, respectively, in the three cases. No transmission of infection was detected in any of the other cases.

Due to the general rise in parvo B19 infections and the higher numbers of blood donors testing positive, the Swiss blood transfusion services increased the testing frequency in 2024 so that, in the event of a positive result, the affected blood products can be destroyed or recalled quickly (usually within a few days). For particularly vulnerable patients

it is also possible to order blood products with a confirmed test result. The reader's attention is also drawn to the information issued by Swissmedic on this topic: "Increase in parvovirus B19 infections and impact on treating high-risk patients" [14].

Figure 29
Parvovirus B19: positive blood donations

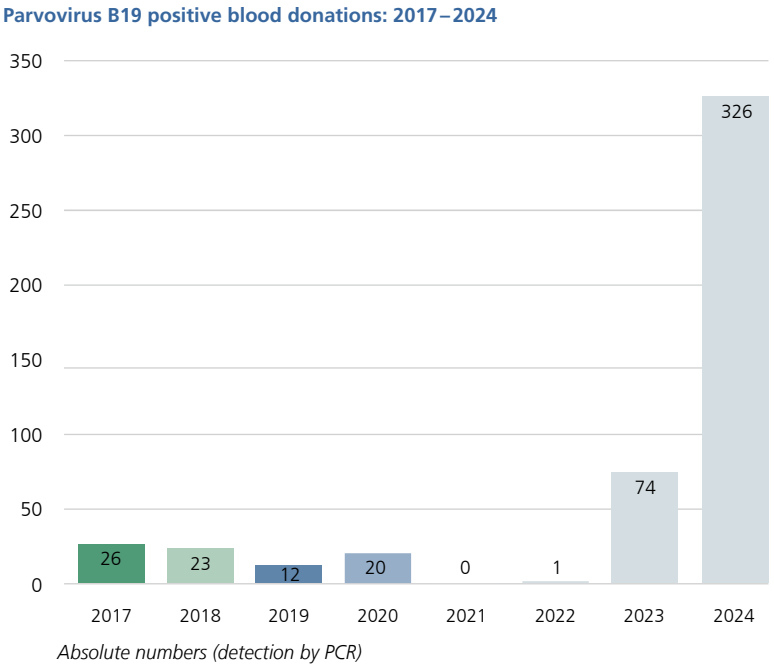
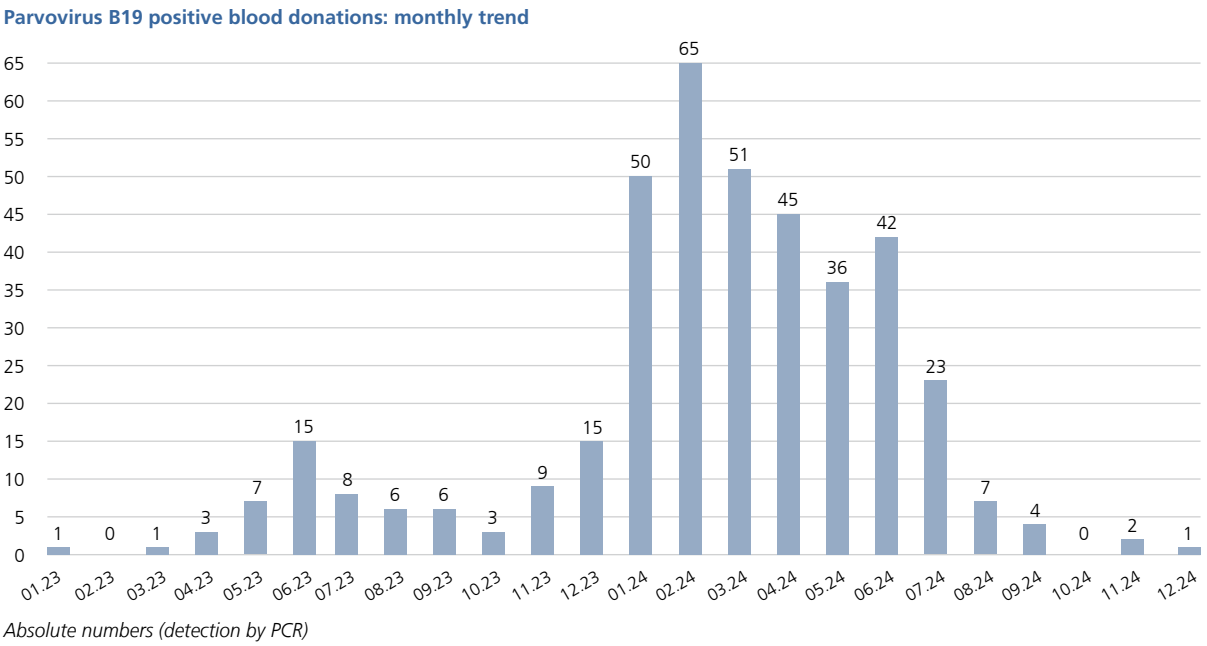


Figure 30
Monthly trend for blood donations testing positive for parvovirus



6.3 Look-back procedures

Look-backs are performed to investigate the transmission of infections in blood products. The procedure may focus on the donor (confirmed diagnosis of a blood-borne infection in a repeat donor) or the patient (confirmed diagnosis of a blood-borne infection in a recipient of blood products). The investigations are coordinated by the Look Back coordinating office SRK CH and performed using algorithms specific to each infection.

6.3.1 Donor-related look-backs

Table 21
Donor-related look-backs

Donor-related look-backs in 2024			
Infection markers	**Case reports**	**Transfusion-related infections diagnosed**	**Ongoing**
HBV	8	-	2
HEV	4	-	1
HIV	1	-	1
HCV	0	-	-

Absolute numbers, procedures concluded: 9

13 donor-related look-backs were performed in 2024, one of which involved an HIV infection (Table 21). No diseases transmitted by a blood product were identified (four procedures ongoing). The same applies to the ongoing donor-related look-backs mentioned in the 2023 Annual Report: here too, no transmission of infection was detected in any of these cases. No look-backs were triggered as a result of Creutzfeldt-Jakob Disease (CJD) (blood donated before onset of the disease).

6.3.2 Patient-related look-backs

One patient-related look-back was initiated in 2024 as a result of HCV infection. Transmission of this infection by the transfused blood products was ruled out.

Table 22
Patient-related look-backs

Patient-related look-backs in 2024			
Infectious disease	**Case reports**	**Result: Infection ruled out**	**Result: Infection not ruled out**
HIV	0	-	-
HBV	0	-	-
HCV	1	1	-
HEV	0	-	-

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7 Abbreviations

°C	degrees Celsius
AB	antibodies
ABO	ABO blood group system
ADU	avoidable, delayed or under/overtransfusion
Ag	antigen
Allo-AB	allo-antibodies
AR	Annual Report
Art.	Article
BD/BTS	blood donation/blood transfusion service
BG	blood group
BP	blood pressure
CH	Switzerland
CHD	coronary heart disease
CJD	Creutzfeldt Jakob Disease
COPD	chronic obstructive pulmonary disease
DLB	donor-related look-back
e.g.	for example
F	female
FFP	fresh frozen plasma
FFPpi	fresh frozen plasma, pathogen-inactivated
FFPq	fresh frozen plasma, quarantined
FNHTR	febrile non-haemolytic transfusion reaction
h	hour
HBV	hepatitis B virus
HCV	hepatitis C virus
HEV	hepatitis E virus
HIV	human immunodeficiency virus
HLA	human leukocyte antigen
HSE	handling and storage errors
HTR	haemolytic transfusion reaction
HV	haemovigilance
i.e.	in other words
IBCT	incorrect blood component transfused
ID	identification
ISBT	International Society of Blood Transfusion
IT	information technology
L	litre
let.	letter
M	male
ml	millilitre
ml/kg BW	millilitres per kilogram body weight
MPLO	Medicinal Products Licensing Ordinance
n	Number
NM	Near misses
para.	paragraph
PC	platelet concentrate (PCa: apheresis-derived; PCb: whole blood-derived)
pg	picogram
PLB	patient-related look-back
pRBC	packed red blood cells
PTP	post-transfusion purpura
RBRP	right blood, right patient
res	resuscitation
RH	rhesus
RPHv	Responsible Person for Haemovigilance
SHOT	Serious Hazards of Transfusion (United Kingdom's haemovigilance scheme)
SOP	standard operating procedure
SRC	Swiss Red Cross
SRNM	specific requirements not met
ST-SRC	Swiss Transfusion SRC
T&S	type and screen (to define blood group and detect irregular antibodies)
T. cruzi	Trypanosoma cruzi (causative agent in Chagas disease)
TACO	transfusion-associated circulatory overload
TAD	transfusion-associated dyspnoea
Ta-GvHD	transfusion-associated graft versus host disease
Tf	transfusion
TPA	Therapeutic Products Act
TPO	Therapeutic Products Ordinance
TR	transfusion reaction
TRALI	transfusion-associated acute lung injury
TTI	transfusion transmissible infections
WBIT	wrong blood in tube
WCT	wrong component transfused
AI	Appenzell Innerrhoden
AR	Appenzell Ausserrhoden
BE	Bern
BL	Basel-Land
BS	Basel-Stadt
FR	Fribourg
GE	Geneva
GL	Glarus
GR	Graubünden
JU	Jura
Lu	Lucerne
NE	Neuchâtel
NW	Nidwalden
OW	Obwalden
SG	St. Gallen
SH	Schaffhausen
SO	Solothurn
SZ	Schwyz
TG	Thurgau
TI	Ticino
UR	Uri
VD	Vaud
VS	Valais
ZG	Zug
ZH	Zurich

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8 List of figures

Figures

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Tables

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9 Bibliography

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