



Haemovigilance Annual Report 2025

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Haemovigilance Annual Report 2025

Evaluation of haemovigilance
reports in 2025

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Editorial

Reporting transfusion reactions and serious incidents associated with blood transfusions, as well as quality defects and adverse events connected with blood donations, remains an essential tool for ensuring and continuously improving transfusion safety. Equally valuable are the findings from transfusion errors and near misses. The reports submitted in connection with haemovigilance provide Swissmedic with important information for identifying risks at an early stage, monitoring developments and, where necessary, taking appropriate action to protect patients and blood donors.

The vital importance of a functioning reporting system was confirmed yet again in 2025. The reports received not only enable individual events to be analysed, but also provide valuable insights into trends and challenges in everyday transfusion medicine. The ongoing recording and analysis of these data plays a significant role in further strengthening the safety of blood products across the entire supply chain.

The reporting numbers for 2025 confirm the heightened awareness of haemovigilance in Switzerland. The number of reports of transfusion reactions remains at a high level and underlines the established reporting culture prevailing in the transfusion centres. As regards serious incidents, changes in the reporting numbers, including in the context of the revised reporting requirements for grade 1 near misses, need to be taken into account, as a result of which the reporting obligation now focuses more closely on the more important safety-related events. This development helps to ensure that the available resources are targeted at the analysis of key risks and the resulting implementation of effective preventive measures.

The persons responsible for haemovigilance in blood transfusion services, hospitals and clinics play a crucial role in this process. They ensure that relevant events are identified, carefully investigated and reported to Swissmedic in accordance with the legal requirements. Their commitment forms the basis for high-quality data collection, enabling a thorough assessment at national level of the reported events.

At the same time, Swissmedic continues to refine the haemovigilance system, with the aim of making the reporting processes as user-friendly and efficient as possible, further enhancing the quality of the reports, and driving forward the digitalisation of the reporting system.

Swissmedic would like to thank everyone involved for their important contribution to the safety of blood donations and blood transfusions. Thank you for your interest. We hope you find this Annual Report to be an interesting and informative read.

Christian Schärer, Inspection Management and Blood Surveillance, Swissmedic

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.

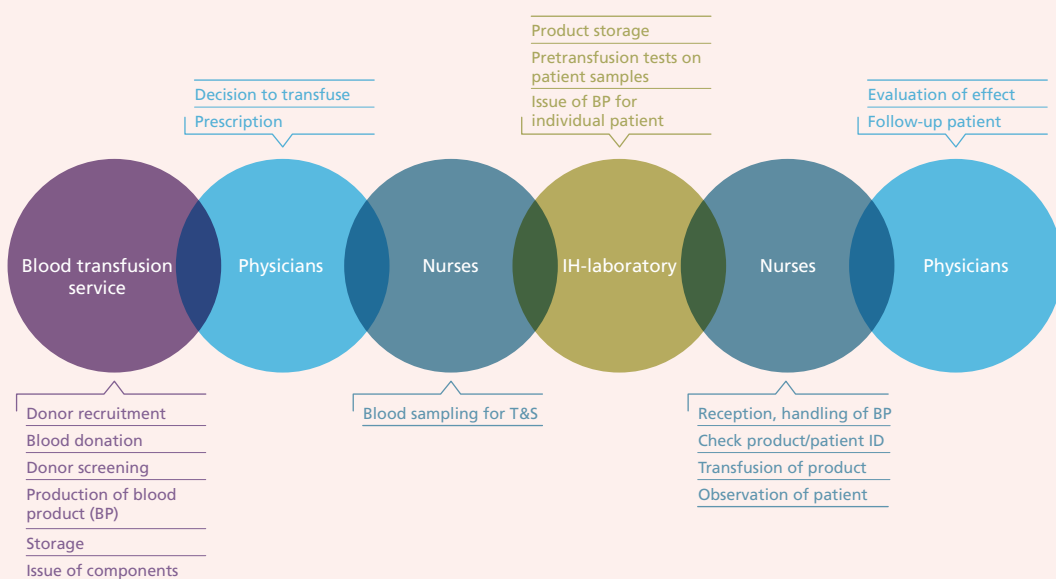
National haemovigilance system

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 under-reported. The risks described in this report should therefore be understood as minimum figures.



2 Number of transfusions and reporting rates

2.1 Number of transfusions

In 2025, a total of 263,995 blood products were supplied for transfusion in Switzerland, representing a 1.1% decline compared with 2024 (266,916 products) (Table 1). The decline is primarily attributable to the reduction in the number of supplied packed red blood cell units, from 203,832 to 200,596 (-1.6%). A reduction was also evident in the number of fresh frozen plasma units (quarantined or pathogen-inactivated), which fell from 25,092 to 23,857 (-4.9%). By contrast, the number of units of platelet concentrates rose from 37,992 to 39,542 (+4.1%).

After reaching a peak of 283,712 in 2021, supplied blood products continued the declining trend observed in recent years. In 2025, the total number of transfused products was 6.9% below the figure for 2021. This trend is predominantly attributable to the ongoing decline over several years in the number of transfused packed red blood cell units.

The transfusion figures are based on the number of labile blood products 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 2021 – 2025					
Blood product	2021	2022	2023	2024	2025
pRBC	217,049	214,197	211,546	203,832	200,596
PC	38,898	39,182	40,112	37,992	39,542
FFP	27,765	26,917	24,137	25,092	23,857
Total	283,712	280,296	275,795	266,916	263,995

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

A total of 6,838 reports were registered in the Swiss national haemovigilance system in 2025 (Table 2). Donor reactions (individual and collective reports) accounted for the largest proportion, with 3,061 reports (45% of all reports), followed by transfusion reactions (2,370 reports; 35%), serious incidents (1,255 reports; 18%), reports of protective measures (142 reports; 2.1%) and 10 reports of quality defects. The statistics include reports received by the end of February 2026 at the latest; later reports will be included in the statistics for 2026. The reports of quality defects are primarily processed with a focus on the institution concerned and are not currently analysed on an annual basis.

The number of reports of transfusion reactions remained largely stable compared to 2024, at 2,370 versus 2,389 reports (-0.8%). The number of transfusion reactions reported over the 10-year period from 2016 to 2025 (Figure 1) has increased by 33% (2016: 1,777 reports; 2025: 2,370 reports). There was only a small decrease in donor reactions, at 3,061 reports compared to 3,210 reports in 2024 (-4.6%). As regards “serious incidents”, the reporting system was revised in 2024, for example in respect of the reporting obligations for grade 1 near misses (reporting obligation no longer applies) and the categorisation of events. Overall, the number of reported serious incidents fell by 41% in 2025 compared with the previous year (from 2,122 to 1,255 reports), mainly as a result of the omission of grade 1 near misses.

Another significant reduction, of 73%, was observed in the number of reported protective measures – predominantly due to the decline in parvovirus B19 infections in blood donors in 2025. Further details can be found in the corresponding sections ([section 4 “Serious incidents”](#); [section 6 “Protective measures in case of infections”](#)). Overall, the number of reports fell by 17%, from 8,249 to 6,838 reports, primarily due to the aforementioned change in the reporting of “serious incidents”.

These changes in the absolute number of reports are also reflected in the reporting rate per 1,000 transfusions (Figure 2): The total reporting rate (transfusion reactions and serious incidents) fell from 16.9 to 13.7 reports/1,000 Tf (-19%). This decline in the reporting rate is mainly attributable to the aforementioned lower number of reported serious incidents. Despite this declining reporting rate, the volume of reports has remained at a high level over the past few years, which indicates that haemovigilance reporting has become firmly established in the institutions involved. The reporting rates for the various categories are discussed in the respective sections.

Table 2
Haemovigilance
reports: Total
numbers

Haemovigilance reports: Total numbers for 2025	
Type of report	n
Transfusion reactions	2,370
Serious incidents	1,255
Protective measures	142
Donor reactions	3,061
Quality defects	10
Total	6,838

Figure 1
Reports of transfusion
reactions and serious
incidents by year

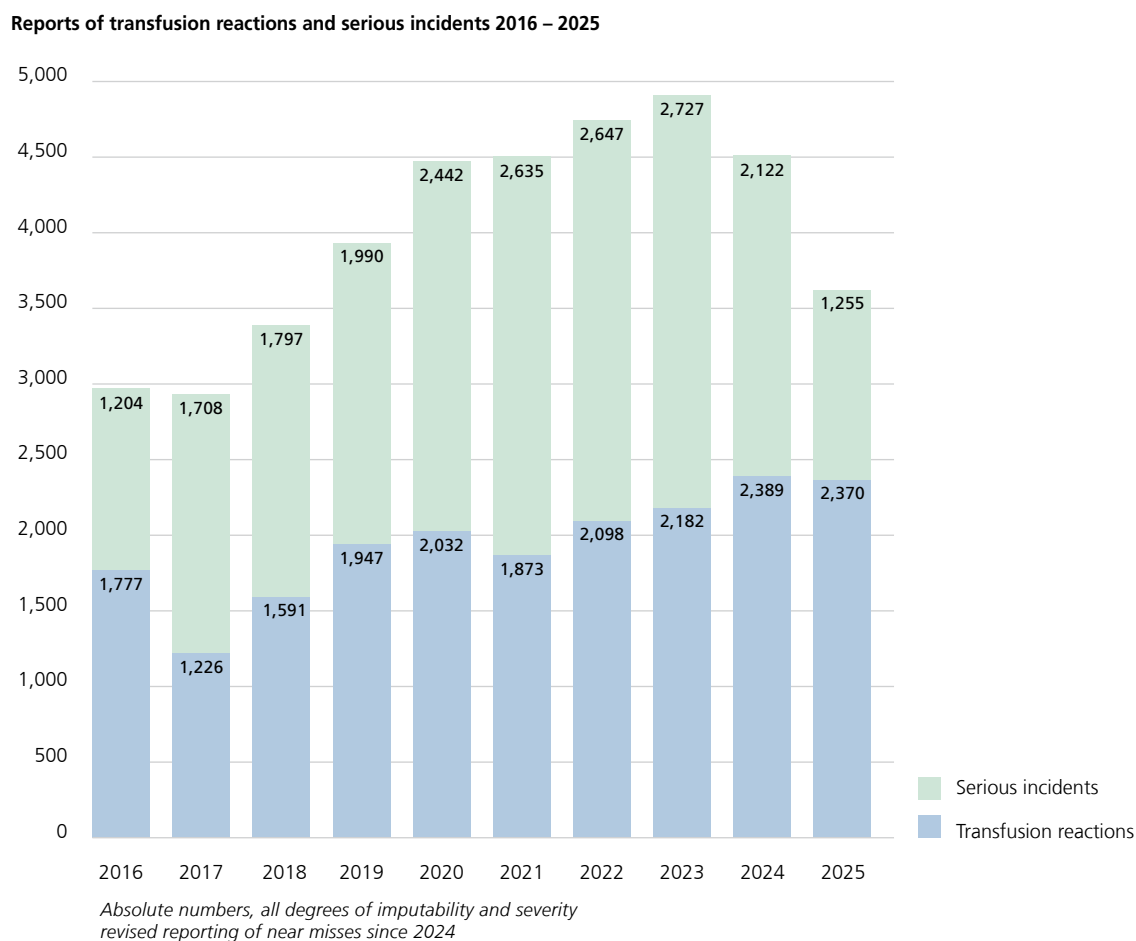
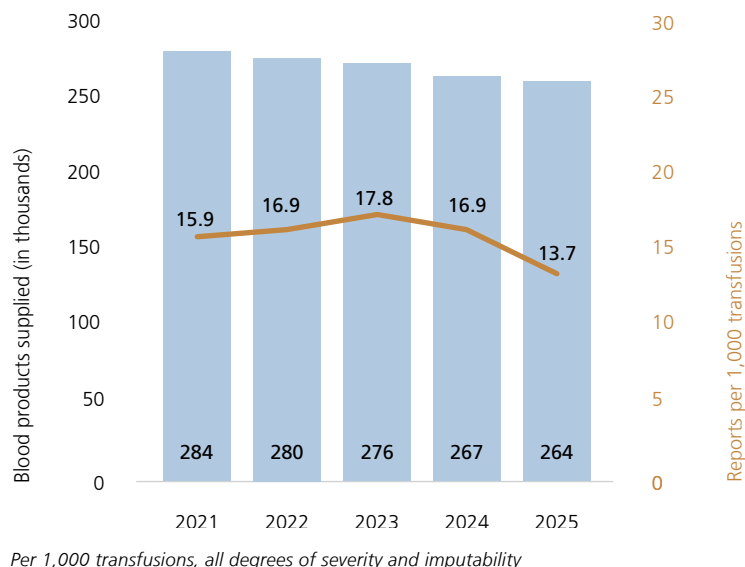


Figure 2

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

Reporting rate for haemovigilance reports 2021 – 2025



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 (excluding haemolytic reactions) after transfusion are detected as laboratory findings. Since this differs from the typical procedure for detecting other transfusion reactions, these reports are listed in total and excluding allo-immunisations. When evaluating the absolute numbers, it should be borne in mind that treatments (and thus transfusions) administered to patients outside a particular canton are not included, and that the reference figure is the number of inhabitants in the stated regions.

Northwest Switzerland had the highest reporting rate based on the number of inhabitants, with 51 reports per 100,000 inhabitants. This is followed by the Lake Geneva region, with 35, and Espace Mittelland, with 30 reports per 100,000 inhabitants. The lowest reporting rates were observed in Eastern Switzerland (10) and the Zurich region (11) – although both regions recorded an increase compared with 2024 (Table 3, Figure 3).

The regional distribution remained largely unchanged, even when allo-antibodies are excluded from the analysis. Here too, the highest reporting rate was observed for Northwest Switzerland, with 18 reports/100,000 inhabitants, followed by the Lake Geneva region (15 reports/100,000 inhabitants). Central Switzerland had the lowest reporting rate excluding allo-antibodies, with 1.7 reports/100,000 inhabitants.

Table 3

Reports of transfusion reactions: Distribution by major region

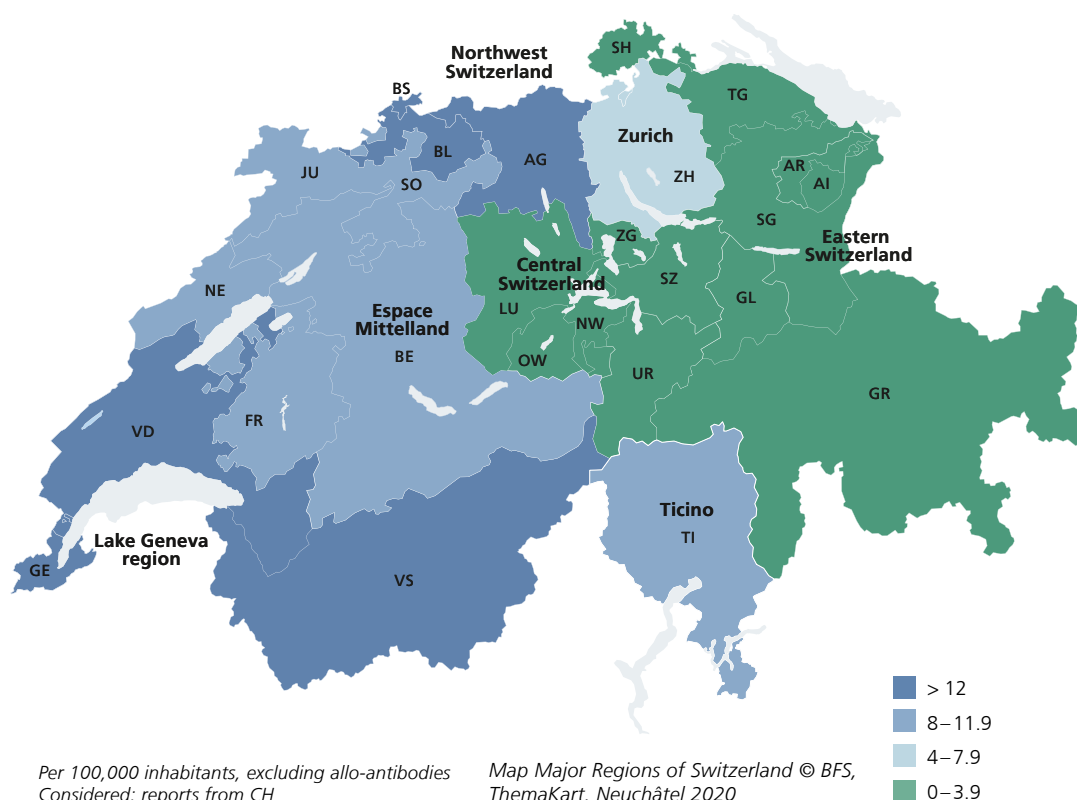
Transfusion reactions by major region in 2025

Major region	Canton	Reports in absolute numbers		Reports per 100,000 inhabitants*	
		Total	excluding allo-AB	Total	excluding allo-AB
Lake Geneva region	GE, VD, VS	610	268	35	15
Espace Mittelland	BE, SO, FR, NE, JU	597	163	30	8.3
Northwest Switzerland	BS, BL, AG	627	221	51	18
Zurich	ZH	176	114	11	7.0
Eastern Switzerland	SG, TG, AI, AR, GL, SH, GR	127	49	10	3.9
Central Switzerland	UR, SZ, OW, NW, LU, ZG	189	15	22	1.7
Ticino	TI	44	34	12	9.5

*Source: Federal Statistical Office (FSO)²

Figure 3

Reports of transfusion reactions: Distribution by major region



Regional differences were also evident in 2025 in the reporting of serious incidents (Table 4, Figure 4). The Lake Geneva region had the highest reporting rate based on the number of inhabitants, with 34 reports/100,000 inhabitants. The reporting rates for the other major regions ranged from 5.1 to 13 reports/100,000 inhabitants. The reporting rates for all regions were below those for 2024 – with regional differences partly attributable to a staggered implementation of the change in the reporting of near misses.

Table 4

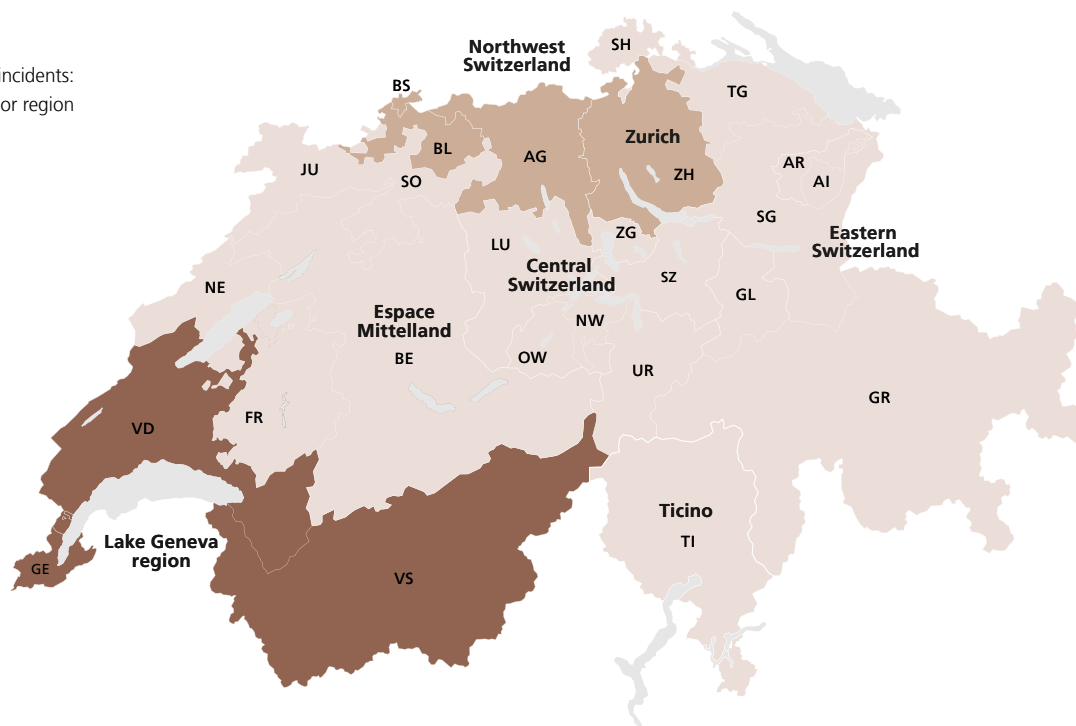
Reports of serious incidents:
Distribution by major region

Serious incidents by major region in 2025			
Major region	Canton	Reports in absolute numbers	Reports per 100,000 inhabitants*
Lake Geneva region	GE, VD, VS	601	34
Espace Mittelland	BE, SO, FR, NE, JU	136	6.9
Northwest Switzerland	BS, BL, AG	155	13
Zurich	ZH	216	13
Eastern Switzerland	SG, TG, AI, AR, GL, SH, GR	57	4.6
Central Switzerland	UR, SZ, OW, NW, LU, ZG	68	7.9
Ticino	TI	22	6.1

*Source: Federal Statistical Office (FSO)²

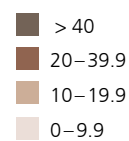
Figure 4

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



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.*

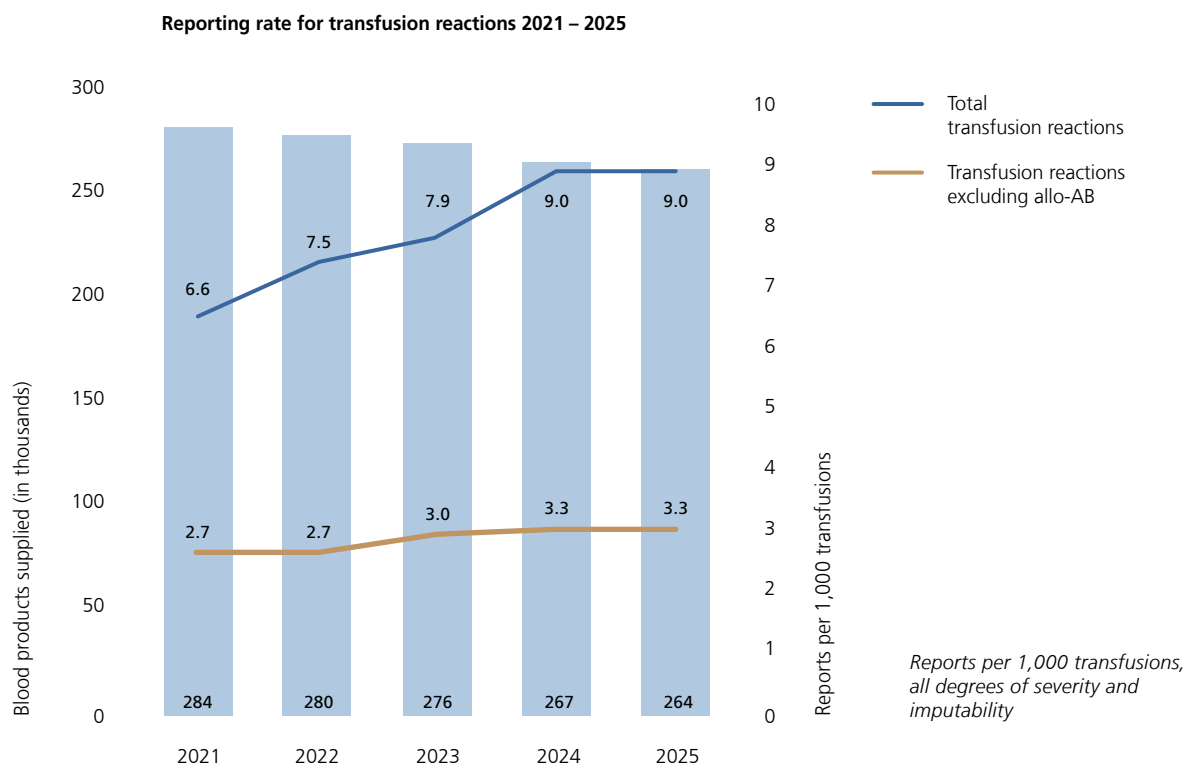
3.2 Reported data

3.2.1 Transfusion reactions: Reporting rate

The reporting rate for transfusion reactions remained unchanged in 2025 compared with 2024, at 9.0 reports per 1,000 transfusions. The same applies to the rate of transfusion reactions excluding allo-immunisations (3.3/1,000 Tf) and the reporting rate for allo-immunisations (5.7/1,000 Tf).

Figure 5

Reporting rate for transfusion reactions by year



3.2.2 Transfusion reactions: Categories

In 2025, 2,370 transfusion reactions were reported to Swissmedic. Figures 6 and 7 show their distribution by category, in each case in absolute numbers and as a reporting rate per 100,000 transfusions. All degrees of severity and imputability were considered. The frequency distribution of transfusion reactions remains unchanged overall compared with previous years: allo-immunisations represented the most frequently reported category, with 1,506 cases (64% of all reported transfusion reactions) (reporting rate 570/100,000 Tf; 1:175), followed by febrile non-haemolytic transfusion reactions (FNHTR) (19% of all transfusion reactions, 168/100,000 Tf; 1:595). With 179 cases (8%), allergic reactions formed the third most frequently reported category (68/100,000 Tf; 1:1,475).

The following were reported in the other categories: 46 cases of transfusion-associated circulatory overload (TACO) (17/100,000 Tf; 1:5,740), 18 hypotensive reactions (7/100,000 Tf; 1:14,670), 19 cases of transfusion-associated dyspnoea (TAD) (7/100,000 Tf; 1:13,900) and 5 TRALI (1.9/100,000 Tf; 1:52,800). The figures for TACO, TAD and TRALI represent a slight increase on the previous year (see also Table 5).

One transfusion-transmitted infection (TTI) was reported in 2025 – this involved a bacterial TTI and is described as a case study (Table 10). The transmission of parvovirus B19 by blood products no longer occurs (2024: 3 cases, see also: [6.2.2. Protective measures: Parvovirus B19](#)).

One report worth mentioning concerns post-transfusion purpura (PTP) – this was the third such case reported in Switzerland since the national haemovigilance system was set up in 2002. In this event, severe thrombocytopenia (<10 G/l; the platelet counts had been normal prior to the transfusion) occurred within 24 hours of the transfusion of a unit of packed red blood cells. Although the time to onset was unusually short, no other plausible reasons for this acute drop could be found in the comprehensive investigation of this case. Treatment with IVIG, based on the tentative diagnosis (PTP/immunological cause), caused the platelet counts to return to normal. The case is being monitored, and the event is currently classed as grade 3 with an imputability of possible.

Haemolytic transfusion reactions (HTR) accounted for 14 reports (5/100,000 Tf: 1:18,860): 12 acute and 2 delayed reactions. Imputability was assessed as “unlikely” for 2 of the acute HTR (see also [Table 7](#)). Allo-antibodies were considered to be responsible for the haemolysis in 6 cases. The following allo-antibodies were involved in the case of the acute HTR: anti-Co^b, anti-Sc1 (see also [Table 14: IBCT case studies](#)), anti-Vw, unspecified antibody against a private antigen; the delayed HTR were caused by anti-Jk^a and anti-Jk^a together with anti-Fy^b (In both cases, boosting of pre-existing allo-antibodies is likely based on the temporal course).

The other cases involved HTR in the context of cold agglutinins (see also [Table 10: Case studies](#)), a hyperhaemolysis syndrome in a patient with known haemoglobinopathy (beta-thalassaemia major), and a deterioration of pre-existing autoimmune haemolysis after a pRBC transfusion. In one case, an acute HTR was observed after a pRBC transfusion in a female patient with myelodysplastic syndrome as the underlying disease. The immunohaematology test results were negative. An acute HTR occurred in the context of a liver transplant with minor ABO incompatibility (O in B) and passenger lymphocyte syndrome after the transfusion of a unit of pRBC with blood group B.

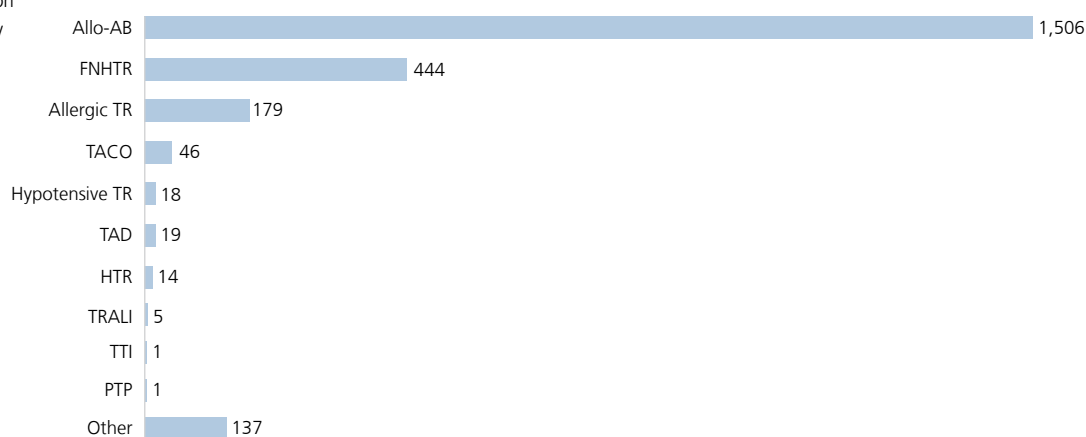
Although these are rare events, these cases serve as a reminder of the importance of a patient's transfusion history (previously known antibodies?) and the immunohaematology tests prior to transfusion and following a transfusion reaction. The possibility of haemolysis still needs to be considered even if the immunohaematology test results are normal.

Otherwise, 137 reactions that could not be classified in any of the defined ISBT categories were reported (52/100,000; 1:1,920). These include numerous reports (n=77) of febrile reactions that did not meet the criteria for an FNHTR and were therefore classed as "Other" (Figure 6, Figure 7, Table 6).

Figure 6

Number of transfusion reactions by category

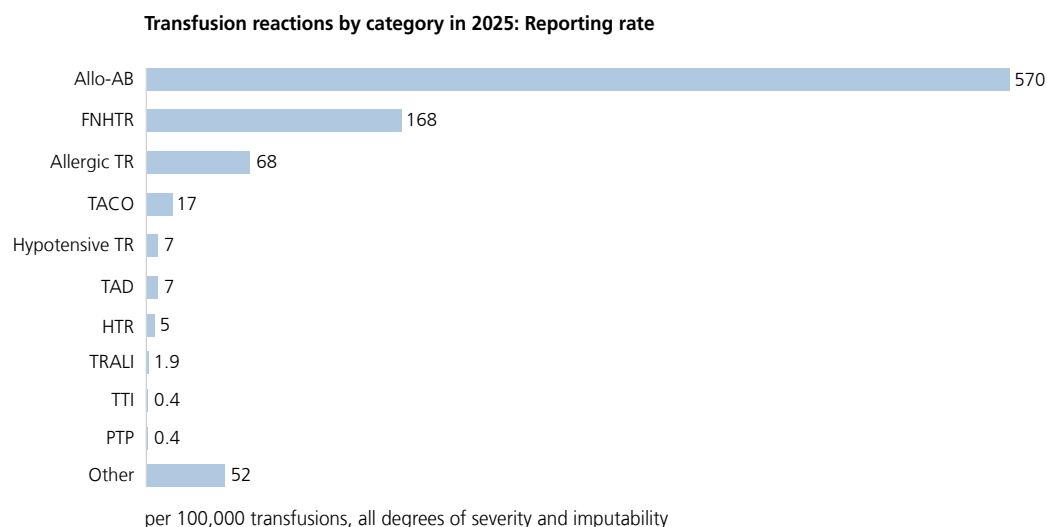
Transfusion reactions by category in 2025: Absolute numbers



Absolute numbers, all degrees of severity and imputability

Figure 7

Reporting rate for
transfusion reactions
by category



As previously mentioned, transfusion-associated circulatory overload (TACO) and transfusion-related acute lung injury (TRALI) increased slightly in 2025 – these transfusion reactions are two of the leading causes of morbidity and mortality and typically represent serious complications³.

Following a decline in TACO cases to 36 reports in 2023, the number of TACO reports remained largely unchanged in 2024 and then rose to 46 reports in 2025. Despite this increase, the number of reported TACO events continued to remain below the 2021 figure. As regards TRALI, one or two cases a year were reported between 2022 and 2024 (reporting rate < 1/100,000 Tf), and the reporting rate in 2025 was at the same level as in 2021, at approximately 2/100,000 Tf. These trends will need to be monitored over the next few years.

Table 5
TACO/TRALI
by year

TACO / TRALI 2021 – 2025				
	TACO		TRALI	
	Reports	Reporting rate	Reports	Reporting rate
2021	62	22	6	2.1
2022	39	14	2	0.7
2023	36	13	1	0.4
2024	37	14	1	0.4
2025	46	17	5	1.9

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

3.2.3 Transfusion reactions: Severity and imputability

Most of the 2,370 reports in 2025 were classified as severity grade 2 (1,710 cases, 72%) (Table 6). This was primarily attributable to the high number of allo-immunisations which, at 1,506 reports, accounted for 64% of all transfusion reactions and were assigned to severity grade 2. 600 reports (25%) were classified as not serious (grade 1). Life-threatening transfusion reactions were rare (grade 3: n=57, 2.4%), while two proved fatal (grade 4; 0.1%) (further details of these two groups can be found in [section 3.2.5](#)).

Table 6
Transfusion
reactions
by severity

Transfusion reactions by severity in 2025						
	n.e.	1	2	3	4	Total
Allo-immunisation	0	0	1,506	0	0	1,506
FNHTR	0	343	96	5	0	444
Allergic TR	0	120	42	17	0	179
TACO	0	2	30	13	1	46
TAD	0	8	8	3	0	19
Hypotensive TR	0	4	11	3	0	18
HTR	0	5	5	3	1	14
TRALI	0	0	0	5	0	5
TTI	0	0	0	1	0	1
PTP	0	0	0	1	0	1
Other	1	118	12	6	0	137
Total	1	600	1,710	57	2	2,370

Severity 1: non-severe, 2: severe/permanent damage,
3: life-threatening, 4: death; n.e.: not evaluable
Absolute numbers, all degrees of imputability

Imputability was rated as "possible" or higher for 1,584 of the 2,370 transfusion reactions (Table 7): a possible link was assumed for 740 reports (31%) (imputability 2). 633 cases (27%) were classed as "probable" (imputability 3), while 211 reports (8.9%) were rated as certainly related to the transfusion (imputability 4). In 149 reports (6.3%), the imputability was evaluated as unlikely (imputability 1). Imputability could not be evaluated adequately in 637 reports (27%), all of which involved allo-immunisations.

Table 7

Transfusion reactions
by imputability

Transfusion reactions by imputability in 2025						
	n.e.	1	2	3	4	Total
Allo-immunisation	637	7	279	414	169	1,506
FNHTR	0	99	270	73	2	444
Allergic TR	0	4	53	91	31	179
TACO	0	4	25	15	2	46
TAD	0	3	10	6	0	19
Hypotensive TR	0	1	8	8	1	18
HTR	0	2	3	4	5	14
TRALI	0	1	1	3	0	5
TTI	0	0	1	0	0	1
PTP	0	0	1	0	0	1
Other	0	28	89	19	1	137
Total	637	149	740	633	211	2,370

Imputability 1: unlikely, 2: possible, 3: probable, 4: certain, n.e.: not evaluable
Absolute numbers, all degrees of severity

3.2.4 Transfusion reactions: Age groups and gender

In 2025, the patient's age was specified in 860 transfusion reactions (excluding allo-immunisations) (Table 8). The highest number of reports was recorded in the over-70 age group (n=345), followed by the age group of 51 to 70 years (n=252). 69% of all reports involved these two age groups, which is in line with the distribution in previous years. The distribution by gender was largely balanced. A total of 435 transfusion reactions were reported in men and 409 in women. Gender was not specified in 16 cases.

Table 8

Transfusion reactions
by age group and gender

Transfusion reactions by age group and gender in 2025*				
Age groups	Number of reports	Male	Female	Not specified
0–10	85	53	26	6
11–18	31	21	9	1
19–30	47	17	30	0
31–50	100	40	60	0
51–70	252	138	112	2
> 70	345	166	172	7
Total	860	435	409	16

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

3.2.5 Transfusion reactions: Life-threatening and fatal events

In 2025, a total of 44 life-threatening transfusion reactions with an imputability of at least possible were reported (Figure 8). Allergic transfusion reactions accounted for the most common category, with 17 reports, followed by TACO (n=13). This matches the distribution of 2024, although the absolute numbers for both categories were higher. The number of life-threatening TRALI in 2025 was higher than in previous years (n=4), representing the highest number of grade 3/4 reactions in the period from 2021 to 2025. Also reported were three cases of severe hypotensive transfusion reactions, a figure that has remained largely stable. The number of life-threatening haemolytic transfusion reactions (HTR) rose to 3 cases, compared with one case reported in each of the years 2023 and 2024. All three cases involved acute HTR. The two cases classed as “other”, since the criteria were not met for inclusion in a specific ISBT category, involved the occurrence of pronounced haemodynamic instability. Less common categories and the imputability evaluations of the cases are described in Figure 8 and Table 9.

Fatal transfusion reactions are rare, with two such events reported in 2025. Similarly to the ISBT definitions, transfusion reactions are only classified as fatal (grade 4) if the imputability for the death is evaluated as at least possible⁴. The occurrence of fatal transfusion reactions in 2025 corresponded to a reporting rate of 0.76/100,000 Tf (1:132,000). The two events involved one acute HTR and one TACO. Both events are described in detail in Table 10.

Also because of the increased number of TACO cases observed last year, we would once again strongly emphasise the existing recommendations to assess 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. In this context, the TACO checklist published in the 2026 version of the [“Guidelines for quality assurance in transfusion practice”](#) may prove helpful^{3, 5}.

Figure 8
Life-threatening or fatal
transfusion reactions by year

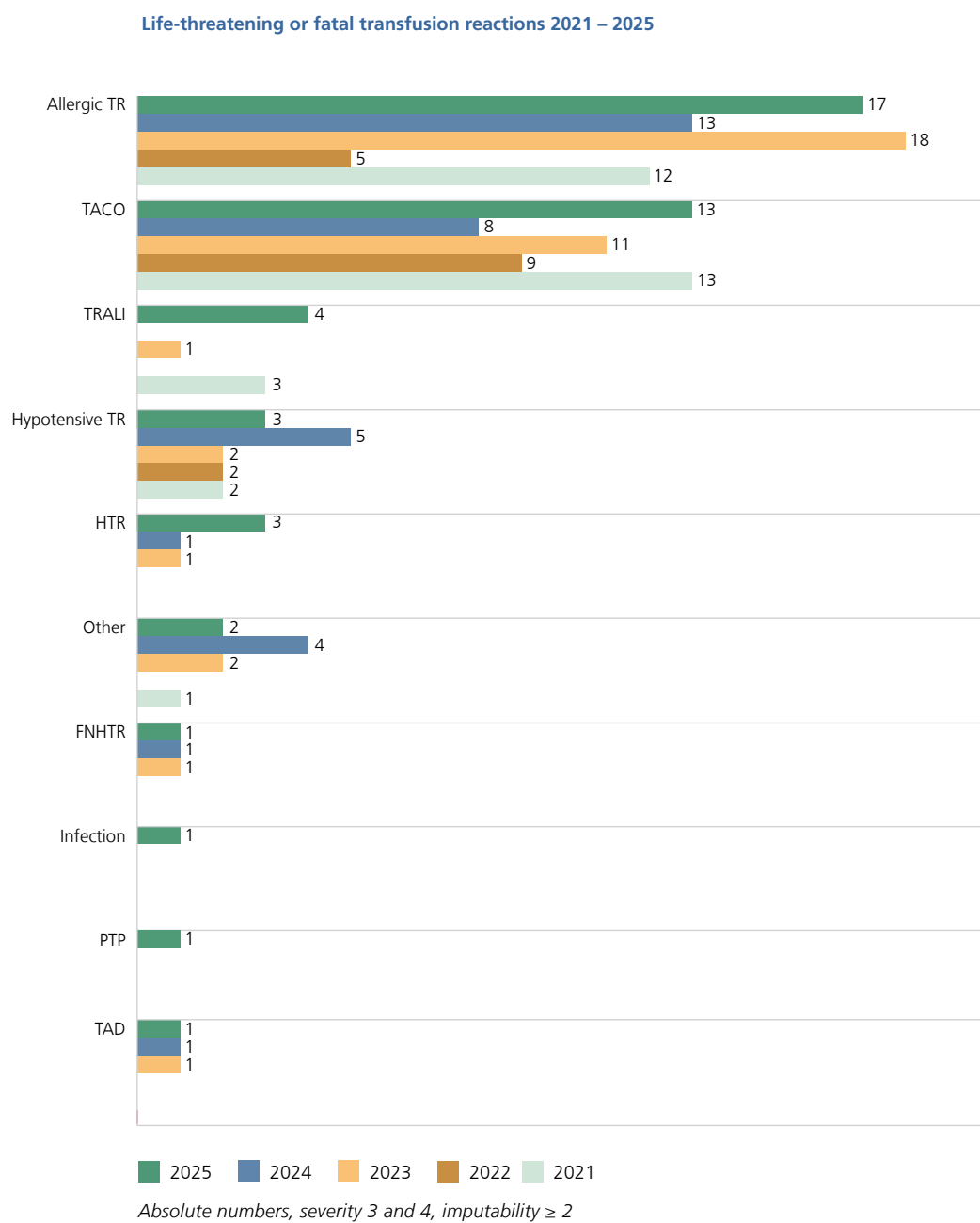


Table 9

Life-threatening and fatal transfusion reactions

Life-threatening and fatal transfusion reactions in 2025				
	Possible	Probable	Certain	Total
Allergic	6	10	1	17
TACO	9	3	1	13
TRALI	1	3	0	4
Hypotensive TR	1	2	0	3
HTR	2	1	0	3
Other	2	0	0	2
FNHTR	1	0	0	1
Infection	1	0	0	1
PTP	1	0	0	1
TAD	0	1	0	1
Total	24	20	2	46

Absolute numbers, severity 3 and 4, imputability ≥ 2

Table 10

Case studies of transfusion reactions

Transfusion reactions
Classification: Acute HTR, imputability: possible

Female patient, > 80 years, with a history of heart disease, hospitalised due to progressive acute pancreatitis, complicated by intracranial haemorrhage. Two units of packed red blood cells were transfused due to multifactorial anaemia. About one hour after the end of the transfusion of the second unit of packed red blood cells, the patient became haemodynamically unstable and experienced severe abdominal pain radiating to the legs. Clinical examination revealed diffuse marbling of the lower limbs and abdomen. An emergency CT scan of the abdomen did not show any evidence of active bleeding, thromboembolism or aortic dissection. Nor were there any signs of circulatory overload or pulmonary infiltrates. The patient was transferred to the intensive care unit, where her clinical condition rapidly deteriorated with the onset of central cyanosis. The patient died the same day. Immunohaematology testing revealed a blood group of B RhD pos, a positive antibody screen with non-specific reactivity, and a positive direct antiglobulin test (DAT) for C3d. Further investigations confirmed the presence of cold agglutinins. The biochemical tests did not reveal any clear increase in haemolysis parameters, although the haemoglobin did not rise following the transfusion. There was no evidence of a transfusion error. The cause of the clinical deterioration and death could not be conclusively established, and an autopsy was not performed. The most likely cause was considered to be the underlying acute abdominal condition, while progression of the intracranial haemorrhage was also a possible factor. However, a transfusion-related haemolytic transfusion reaction with the presence of cold agglutinins and an unwarmed transfusion could not be ruled out and may have (partly) influenced the clinical outcome. The transfusion reaction was ultimately evaluated as an acute haemolytic transfusion reaction (HTR), severity grade 4, imputability: possible.

Classification: TACO, imputability: possible

Female patient, > 90 years, with advanced cognitive impairments and multiple cardiovascular and renal comorbidities; hospitalised after a fall with suspected upper gastrointestinal bleeding and severe anaemia (Hb < 70g/l). In view of the increased risk of circulatory overload (TACO screening), the transfusion of a unit of packed red blood cells was started at a slow drip rate. A few minutes after the start of the transfusion, the patient developed increasing dyspnoea with oxygen desaturation and hypertension. The clinical findings were consistent with acute pulmonary oedema. The transfusion was interrupted and diuretic treatment initiated. An attempt to resume the transfusion about two hours later, since it was urgently indicated, had to be discontinued due to persistent hypertension and a newly-occurring fever of 38°C. Radiological investigation revealed a left-sided pleural effusion and signs of infection, but no bilateral infiltrates. Despite further therapeutic measures in accordance with the wishes of the patient and her family, the patient died the next day.

The criteria for a transfusion-associated circulatory overload (TACO) are satisfied in this case, with acute respiratory symptoms (dyspnoea and hypoxia), new onset of hypertension and clinically diagnosed pulmonary oedema. The chronological link to the transfusion is clear, although only a small amount of pRBC was actually transfused. Since an acute cardiac decompensation unrelated to the transfusion, particularly in a context of severe anaemia and pre-existing heart disease, cannot be ruled out, the imputability of the case was assessed as possible. Since this patient had an increased risk of developing TACO, preventive measures were taken (screening, slow transfusion, close monitoring and immediate diuretic treatment). The transfusion reaction was ultimately evaluated as TACO, severity grade 4, imputability: possible.

Classification: Bacterial TTI, imputability: possible

Female patient, > 70 years, with an underlying haematological disorder, receiving outpatient care (medical practice). On arrival the patient was afebrile, her CRP level was not elevated (white blood cell counts were not meaningful given the underlying condition). Since she had chronic thrombocytopenia, two units of platelet concentrates were transfused via a peripheral vein using a Venflon cannula newly inserted for the transfusions. On completion of the second unit, the patient developed a fever of > 39°C, chills, hypotension, tachycardia and hypoxia. Since initial treatment on site with steroids, hydration and oxygen failed to stabilise the patient and she remained febrile, she was transferred to a hospital by ambulance. Blood cultures were taken in the hospital emergency department, while the two units of platelet concentrates had been sent by the treating practice to another laboratory, where cultures were also taken from both packs (which had to be opened and rinsed since the transfusion had been completed). *Staphylococcus epidermidis* and *Staphylococcus warneri* were subsequently found in all cultures (with the additional detection in the blood products, after enrichment, of *Streptococcus mitis* and *Streptococcus oralis*), and the resistance profiles matched, where comparable. The infection markers

(including CRP) in this patient subsequently rose. Further tests revealed the puncture site of a recently performed bone marrow aspiration as a possible alternative source of infection, and there were also radiological and clinical signs of pulmonary oedema. Empirical antibiotic therapy had already been started on admission, and this was extended on receipt of the blood culture test results. Treatment with diuretics was also administered, whereupon the patient's condition improved.

Both of the platelet concentrate units originated from apheresis donations from two different donors taken on different days at different sites (and therefore with different apheresis equipment). Pathogen inactivation was performed with the same product batch of the inactivation process. The transfusion set was identified and was still within its shelf life.

An infection of the patient with *Staphylococcus epidermidis* and *Staphylococcus warneri* is plausible based on the clinical presentation and laboratory test results, and this was treated accordingly by the medical team. The symptoms of the infection appeared directly after the transfusion of the second unit of platelet concentrates. The findings were also consistent with the picture of cardiopulmonary decompensation.

The matching positive bacteriological result in both units of platelet concentrates is unusual: since the two apheresis donations had been taken at different times and locations, contamination of both products during the donations themselves is implausible. One possible explanation would be contamination of the first transfused unit, which secondarily (transfusion set) led to contamination of the second unit. While contamination during processing (same batch of the pathogen inactivation set) would be possible in principle, the relevant tests have not revealed any evidence to this effect. Contamination during collection of the cultures (rinsing and opening), contamination by the patient's blood (backflow, other cause of infection) or the transfusion set itself are possible alternative explanations. Overall, the event must be evaluated as a transfusion-transmitted bacterial infection, imputability "possible". Although a transfusion-associated circulatory overload (TACO) is possible in principle as a (contributory) cause of the pulmonary oedema, the findings are primarily explained by a septic reaction.

General comment

In Switzerland, all platelet concentrates must be treated with pathogen-reduction procedures (requirement of the Medicinal Products Licensing Ordinance (MPLO), Art. 38, para. 3). This has led to a significant decline in bacterial infections caused by platelet transfusions. Nevertheless, bacterial infections can still occur even after pathogen inactivation, as is also confirmed by international publications⁶. Contamination of materials used in platelet collection that are capable of surviving pathogen inactivation is another possibility, as published by the FDA in 2023: [Posttransfusion sepsis attributable to bacterial contamination in platelet collection set manufacturing, United States](#)⁷.

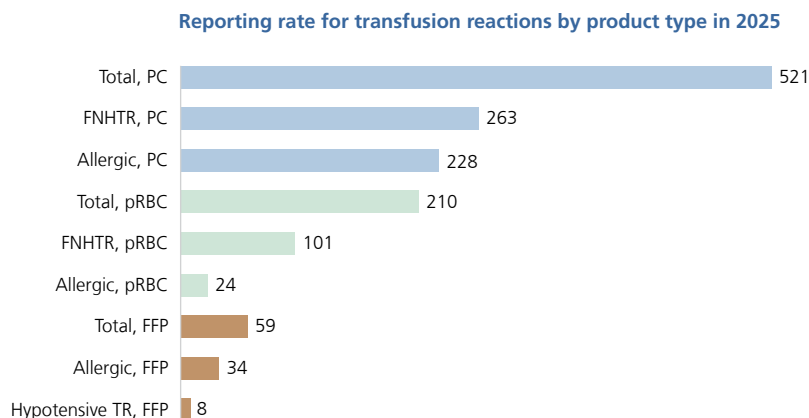
The possibility of bacterial contamination must always be considered in a patient with a corresponding clinical picture, particularly if a high fever (temperature rise to $> 39^{\circ}\text{C}$), chills and/or circulatory impairment compatible with septic shock are present. Corresponding tests (blood cultures from patient and blood product) are important not only for the correct treatment of the patient, they can also reveal potential sources of infection or contamination during the manufacture of blood products (and thereby ensure the safety of all transfused patients).

3.2.6 Product-specific risks

The frequency and type of transfusion reactions vary according to the type of product. Figure 9 shows the reporting rate (event/100,000 Tf) for the most common transfusion reactions. The evaluation considers reports with an imputability of at least “possible” (≥ 2) and covers all degrees of severity. Only those transfusion reactions that were clearly attributable to a particular product type were included. Allo-immunisations are not included in the evaluation since these reports often do not mention any triggering blood product, or the imputability of a particular transfusion is not certain. As in previous years, most reported events involved platelet concentrates (PC), at a rate of 521/100,000 Tf. The most common reaction types were febrile non-haemolytic transfusion reactions (FNHTR) (263/100,000 Tf) and allergic transfusion reactions (228/100,000 Tf). The overall reporting rate for packed red blood cells (pRBC) was 210/100,000 Tf: here too, FNHTR (101/100,000 Tf) and allergic transfusion reactions (24/100,000 Tf) were reported most frequently. The overall reporting rate for fresh frozen plasma (FFP) was 59/100,000 Tf: allergic transfusion reactions (34/100,000 Tf) and hypotensive transfusion reactions (8/100,000 Tf) were the most common categories. As regards FFP, the fact that other product types (pRBC, PC) were also transfused in many events involving plasma needs to be taken into account. As a result, these events cannot be attributed to a specific product and all the stated figures should be viewed as minimum values.

Figure 9

Reporting rate for transfusion reactions by product type



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

3.2.7 Allo-immunisations

Allo-immunisations continue to account for the majority of transfusion reactions. The formation of allo-antibodies signifies a permanent disadvantage for the affected patients since the choice of compatible blood components can be limited for future transfusions. Since complications may also arise in connection with pregnancies, allo-immunisations are classified as “serious” (grade 2). The events presented here include all newly occurring allo-antibodies. In the event of haemolysis as a result of allo-immunisation, this is additionally recorded as an HTR (see also Figures 5 and 6).

A total of 1,648 allo-antibodies were reported in 2025 (Figure 10, Table 11). As in previous years, antibodies belonging to the Rhesus system formed the most common group, accounting for 42% of all reported allo-antibodies with 684 reports. Within the Rhesus system, anti-E was the most frequently reported allo-antibody (n=354, 52% of RH antibodies), followed by anti-D (n=92, 13% of RH antibodies) – this is worth mentioning since identical RhD statuses are generally ensured for transfusions in Switzerland with the aim of preventing immunisation⁸.

In contrast with previous years, more antibodies in the MNS system (n=236, 14%) were reported compared to those in the Kell system (n=232, 14%). The difference is small, but it continues a trend seen in recent years: in 2017, for example, the difference between the two blood group systems was 8% (19% for the Kell system vs. 11% for the MNS system). Although no definite reason for this shift has been established, the antigen status KEL1 (“K”) is indicated on all packed red blood cell units in Switzerland, a practice that may support a KEL1-identical transfusion practice.

Allo-antibodies in the Lutheran, Kidd and Lewis systems each accounted for between 5.6% and 8.1% of reports. Antibodies in the Duffy, Diego and P1PK systems were reported less frequently. All other blood group systems were each responsible for less than 1% of reported allo-antibodies.

Figure 10

Allo-antibodies
by blood group system

Allo-antibodies by blood group system in 2025

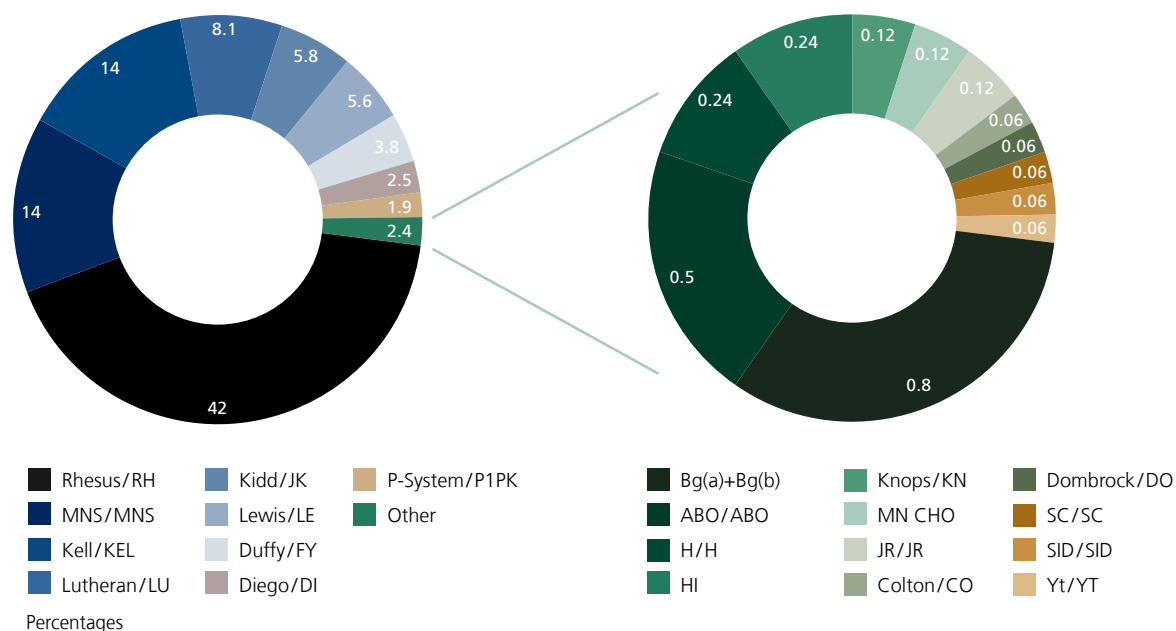


Table 11

Allo-antibodies
by blood group system

Allo-antibodies by blood group system in 2025					
Blood group system	n	%	Blood group system	n	%
Rhesus/RH	684	42	Bg(a)+Bg(b)*	13	0.8
MNS/MNS	236	14	ABO/ABO	8	0.5
Kell/KEL	232	14	H/H	4	0.24
Lutheran/LU	134	8.1	Anti-HI*	4	0.24
Kidd/JK	95	5.8	Knops/KN	2	0.12
Lewis/LE	93	5.6	MN CHO	2	0.12
Duffy/FY	62	3.8	JR/JR	2	0.12
Diego/DI	41	2.5	Colton/CO	1	0.06
P system/P1PK	31	1.9	Dombrock/DO	1	0.06
Other	40	2.4	SC/SC	1	0.06
Total	1,648	100**	SID/SID	1	0.06
			Yt/YT	1	0.06

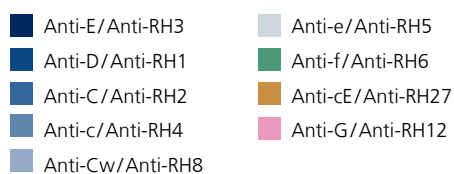
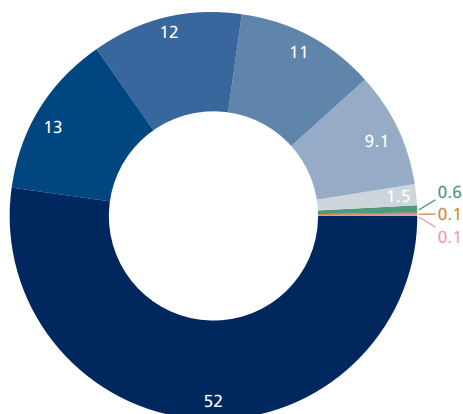
According to ISBT⁹

*No data were found for these antibodies
in the ISBT reference table

**Discrepancies in totals are due to rounding

Figure 11
Allo-antibodies
in the Rhesus system

Allo-antibodies in the Rhesus system in 2025



Percentages

Table 12
Allo-antibodies
in the Rhesus system

Allo-antibodies in the Rhesus system in 2025		
Antibodies	n	%
Anti-E/Anti-RH3	354	52
Anti-D/Anti-RH1	92	13
Anti-C/Anti-RH2	83	12
Anti-c/Anti-RH4	77	11
Anti-Cw/Anti-RH8	62	9.1
Anti-e/Anti-RH5	10	1.5
Anti-f/Anti-RH6	4	0.6
Anti-cE/Anti-RH27	1	0.1
Anti-G/Anti-RH12	1	0.1
Total	684	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.

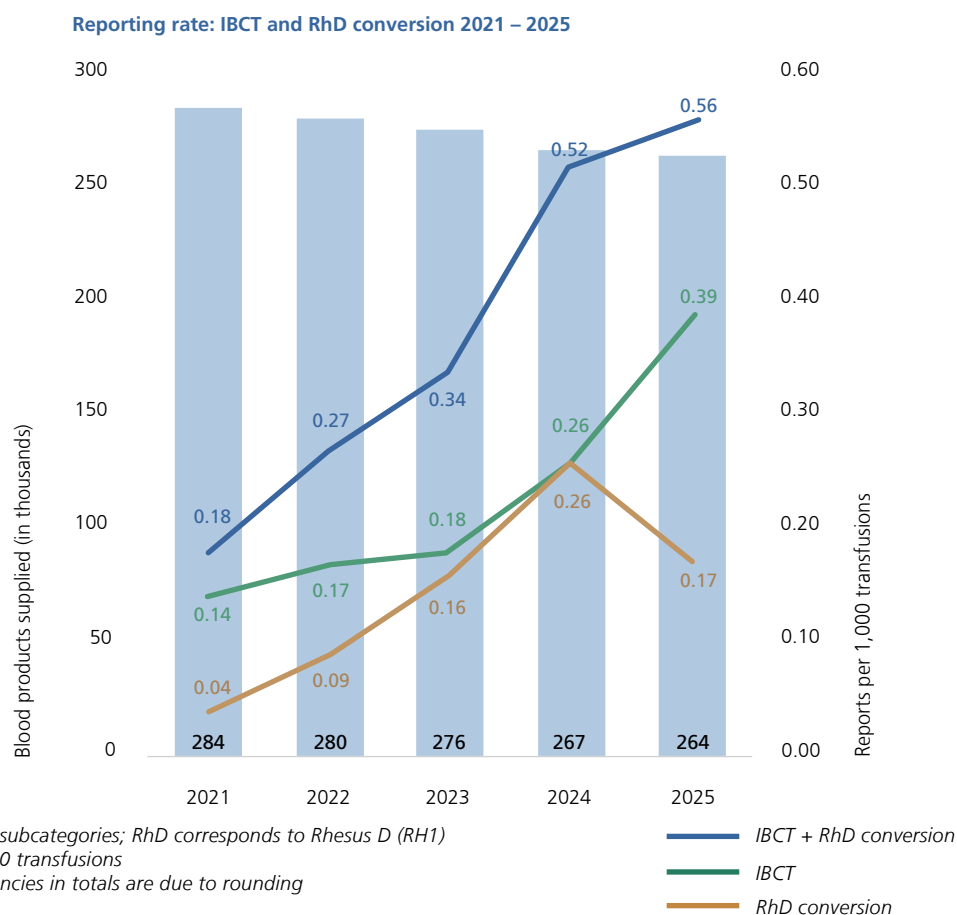
4.2 IBCT

4.2.1 IBCT: Reporting rate

The progression of the reporting rate for IBCT and Rhesus D conversions is shown in Figure 12: the reporting rate for IBCT rose compared with previous years, while the reporting rate for Rhesus D conversions fell slightly, to the levels seen in 2022 and 2023 (overall reporting rate: 0.56/1,000 Tf).

Figure 12

Reporting rate for IBCT and Rhesus D conversions by year



4.2.2 IBCT: Subclassification

IBCT in the subcategory HSE accounted for the majority of reports in 2025 (n=51; 50% of IBCT), followed by IBCT-SRNM (n=23, 22%) (Table 13). The number of HSE errors increased significantly compared with previous years: these errors predominantly occurred during administration and specifically involved an excessively rapid transfusion rate in patients at increased risk of TACO (breaches of the hospital's internally defined guidelines). We view this in particular as a sign of the increased awareness of the TACO risk (see also 3.2.5). Reviewing the effectiveness of, and compliance with, a hospital's own transfusion guidelines is an important step towards further improving transfusion safety.

The number of WCT has remained largely unchanged compared with 2024 (n=8, 8% of all IBCT; 2024: n=9, 13% of all IBCT), although there were 3 ABO/RhD-incompatible transfusions (2024: n=1). Two of these events are described in detail as case studies ([4.2.4, Table 14](#)). Four transfusions happened to be ABO-compatible by chance, and in one case a wrong product was transfused (a unit of pRBC that did not match the blood component selected by the LIS was dispensed and transfused (labelling of an incorrect unit of pRBC)). The distribution among the subcategories is shown in Table 13 / Figure 13.

The number of reports in the category of RBRP, Right Blood, Right Patient, remained almost unchanged. These are 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.

The category ADU includes an event that concerned an undertransfusion due to a shortage of compatible pRBC units – such reports are rare nowadays. We would like to raise readers' awareness of the need to report shortages that lead to patient harm and/or that significantly affect the treatment. Such events may involve specific blood groups or, for example, the lack of O RhD neg pRBC. The event is described as a case study ([4.2.4](#)).

Table 13
Subclassification
of IBCT

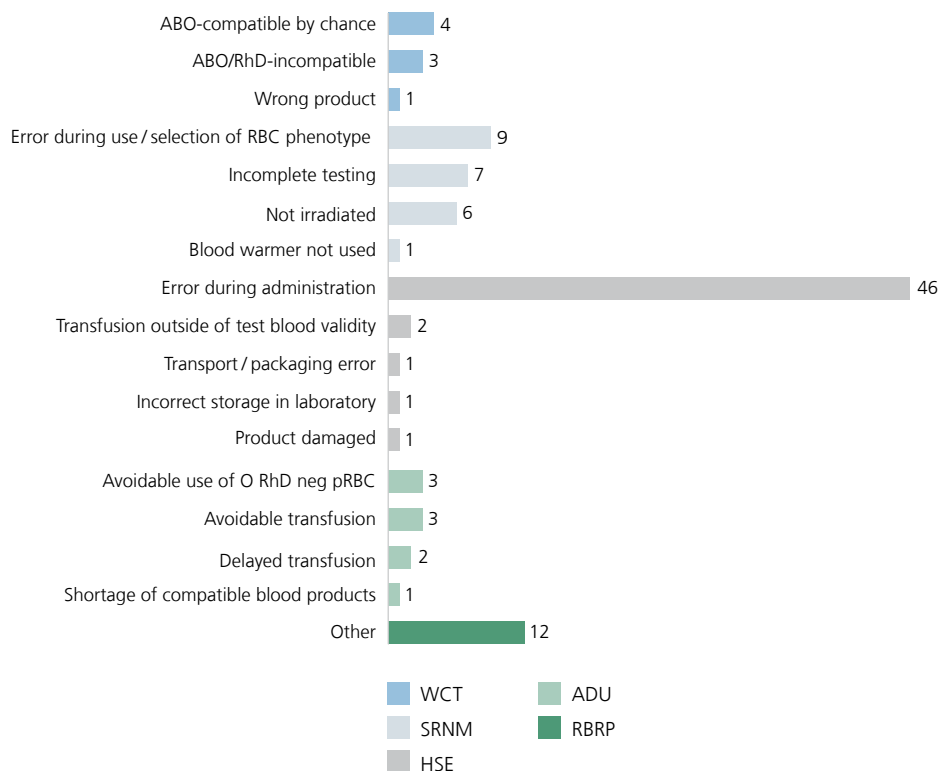
Subclassification of transfusion errors / IBCT in 2025			
WCT	Wrong component transfused		8
	ABO/RhD-incompatible	3	
	ABO-compatible by chance	4	
	Wrong product	1	
SRNM	Specific requirements not met		23
	Blood warmer not used	1	
	Error during use / selection of RBC phenotype	9	
	Not irradiated	6	
	Incomplete testing	7	
HSE	Handling and storage errors		51
	Error during administration	46	
	Error during transport/packaging	1	
	Incorrect storage in laboratory	1	
	Product damaged	1	
	Transfusion outside of test blood validity	2	
ADU	Avoidable, delayed or under / overtransfusion		9
	Shortage of compatible blood products	1	
	Avoidable transfusion	3	
	Avoidable use of O RhD neg pRBC	3	
	Delayed transfusion	2	
RBRP	Right blood, right patient		12
Total			103

Absolute numbers, IBCT classification adapted to SHOT definitions ¹⁰

Figure 13

IBCT: Subclassification

IBCT subclassification in 2025



Absolute numbers

WCT: Wrong component transfused

SRNM: Specific requirements not met

HSE: Handling and storage errors

ADU: Avoidable, delayed or under / overtransfusion

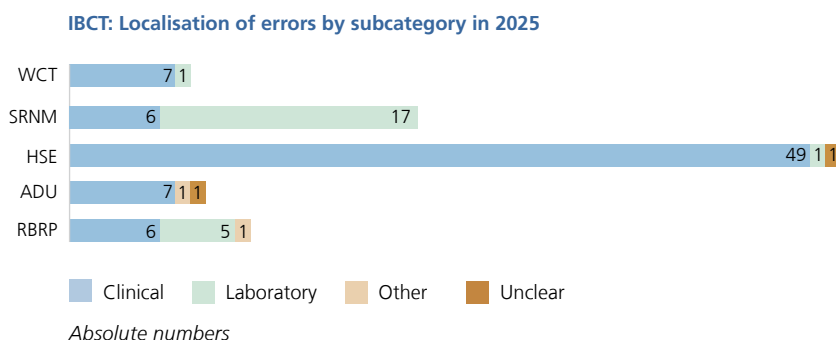
RBRP: Right blood, right patient

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, immunohaematology laboratory/blood store, other (e.g. manufacturer as the localisation of errors) subdivided by IBCT subcategory. A further analysis of the localisation of errors in the transfusion chain (point in process) can be found in section, [4.4 Localisation of errors](#) in the transfusion chain (point in process).

Figure 14

IBCT: Localisation
of errors
by subcategory



4.2.4 IBCT: Case studies

The selected IBCT case studies 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: Day shift

In an emergency department, packed red blood cells were ordered for two different female patients. Patient X: BG O RhD neg, age > 70 years; Patient Y: BG O RhD pos; different first names and surnames. The pRBC unit for patient Y was delivered and accepted in the expectation that it was for patient X. Although it was checked by two people, the check did not include the patient's name, and the patient's identity was not confirmed at the bedside. The hospital did not employ digital patient identification. The pRBC unit for patient Y (RhD pos) was transfused to patient X. The mix-up was only noticed after the end of the transfusion when someone looked for the pRBC unit for patient Y. A high stress level at the time of the error was reported.

No side effects occurred during the transfusion and initial follow-up checks did not show any haemolysis, although the patient did subsequently develop the allo-antibodies anti-D and anti-C.

This was a case of IBCT-WCT, and the transfusion happened to be compatible by chance in terms of ABO, but incompatible from the RhD standpoint. A transfusion side-effect also occurred (allo-immunisation). The error occurred during administration of the blood product: the patient's name had not been checked. This type of error occurs repeatedly in ABO-incompatible or randomly compatible transfusions, and expectations (pRBC is expected to arrive for one's "own" patient) and a high workload often play a role. Checking the patient's identity at the bedside by two people is essential for safe transfusion.

The process must become so established – particularly in high-stress situations – that it becomes and remains a fixed part of the routine. The use of digital patient identification as a second pair of eyes (the system does not tire or become distracted) or the use of a structured checklist, as described in the 2026 edition of the “Guidelines for quality assurance in transfusion practice”⁵ can be helpful in such cases.

IBCT-WCT

Localisation of the deviation in the transfusion chain: Administration

Time: Night shift

Female patient, > 70 years, BG A RhD pos, suffered a cardiac arrest due to upper gastrointestinal bleeding. After an initially successful resuscitation, she was transferred to a central hospital while still in an unstable condition. Resuscitation was resumed, and the massive transfusion protocol was initiated. For massive transfusions, units of pRBC O RhD neg and plasma AB (3 units) were stored in the intensive care unit, and further units were supplied from the IH laboratory. Blood products that had already been assigned to patients were also stored on site.

However, instead of the emergency plasma (BG AB), three plasma units that were being stored for other patients (blood groups: AB, A, B) were retrieved for the transfusion. All three units were transfused. No-one noticed that the units were labelled for other patients and that the plasma BG B was incompatible. The mistake was discovered when the blood units were recorded in the patient's records.

Due to the complexity of the clinical situation (resuscitation), the acute compatibility of the incompatible plasma BG B could not be adequately assessed. No haemolysis was evident when the laboratory test results were checked, most likely due to dilution effects associated with massive transfusion (a total of 23 blood units were transfused), and the isoagglutinin titre of the product was not known. The patient subsequently died, partly as a result of severe hypoxic brain damage, and the death was not attributed to the transfusion error.

This was a case of IBCT-WCT (ABO-incompatible transfusion), and the occurrence of a transfusion reaction could not be conclusively evaluated.

“Emergency” blood units (even if stored on site) must be clearly separated from other blood units. In addition to physical separation, colour coding can also prove helpful. Since the units are typically used in stressful situations, the established system must be clear and simple to use, particularly for these scenarios, and checking the units (blood group) is also important in such circumstances.

IBCT-ADU

Localisation of the deviation in the transfusion chain: Other (lack of resources)

Time: Day shift

Male patient, > 75 years, with uncontrolled urogenital bleeding and severe anaemia with an urgent need for transfusion. In terms of immunohaematology, he had a history of anti-Sc1 allo-antibody (Sc1 (Scianna) negative phenotype). Although compatible packed red blood cells were sought, none were available (worldwide shortage, high-frequency antigen, > 99% of the global population is Sc1-pos). Following a comprehensive assessment and consideration of the options, the clinical care team opted for transfusion of a unit of pRBC with the Sc1-pos phenotype supplemented by medication with IVIG and steroids. Nevertheless, haemolysis still occurred. Since he also had pre-existing generalised vascular disease, the untreatable severe anaemia resulted in multiple organ infarcts. The patient subsequently died as a result of the uncontrollable and untreatable anaemia.

The event was classed as an IBCT-ADU under the subgroup of "undertransfusion". No avoidable error occurred during the treatment process since the decision to transfuse a unit of Sc1-positive pRBC with corresponding concomitant medication was a deliberate clinical decision. However, a necessary transfusion could not be administered (or not adequately), and "undertransfusion" was the outcome. The incompatible transfusion and missing transfusions, even though they were indicated, were blamed on a shortage of compatible pRBC units. The localisation of the deviation was therefore classified as "other". The recording of such events is important since it transparently highlights the existence of resource shortages and their consequences in Switzerland.

IBCT-ADU

Localisation of the deviation in the transfusion chain: Request

Time: Day shift

Female patient, > 70 years, BG O RhD pos, hospitalised. In terms of immunohaematology, she had a history of anti-C and anti-Fy^a allo-antibodies, and a valid test blood sample was available. The ward requested a unit of O RhD neg pRBC without testing. Although the immunohaematology laboratory pointed out the presence of the allo-antibodies, the doctor in charge insisted that the order be implemented. The transfusion medicine specialist for the IH laboratory was not on duty at the time of the event. A unit of O RhD neg pRBC was accordingly dispensed and transfused. No acute side effects occurred.

Subsequent investigation revealed that the unit of pRBC happened to be negative for C and Fy^a, and no haemolysis occurred. The internal review concluded that waiting for a unit of pRBC to be tested would have been clinically acceptable (the transfusion was not indicated as an emergency).

This event involved an IBCT-ADU, subgroup “avoidable” (avoidable use of untested O RhD neg pRBC). The root cause of the error was the original request for untested pRBC despite the fact that sufficient time was available for testing and the regular dispensing of a pRBC unit. Any transfusion of untested O RhD neg pRBC poses an increased risk to the patient, since compatibility is ensured only for the ABO blood group and RhD. Such a transfusion must therefore be reserved for defined emergency situations (“risk-benefit analysis”). At the same time, stocks of RhD neg pRBC must be kept for these scenarios. The description of O RhD neg pRBC as “universal blood” or “always suitable” can certainly cause confusion in this context, and it is important to make all personnel involved in transfusions aware of the risks of these transfusions and their correct use.

The reporting hospital also reviewed the consultation options for the laboratory staff.

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. Their classification and the reporting obligation are published in the 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 decreased and amounted to 1.5/1,000 Tf in 2025, compared to 9.6/1,000 Tf before the revision (2023).

As regards events in severity grades 2 and 3, the total number of reported events also fell in 2025 (n=344; 2024: n=463) (Table 15). This decline can be partly explained by uncertainties in distinguishing between grade 1 and grade 2 events and, consequently, the applicable reporting obligation.

Figure 15
Near misses:
Reporting rate
by year

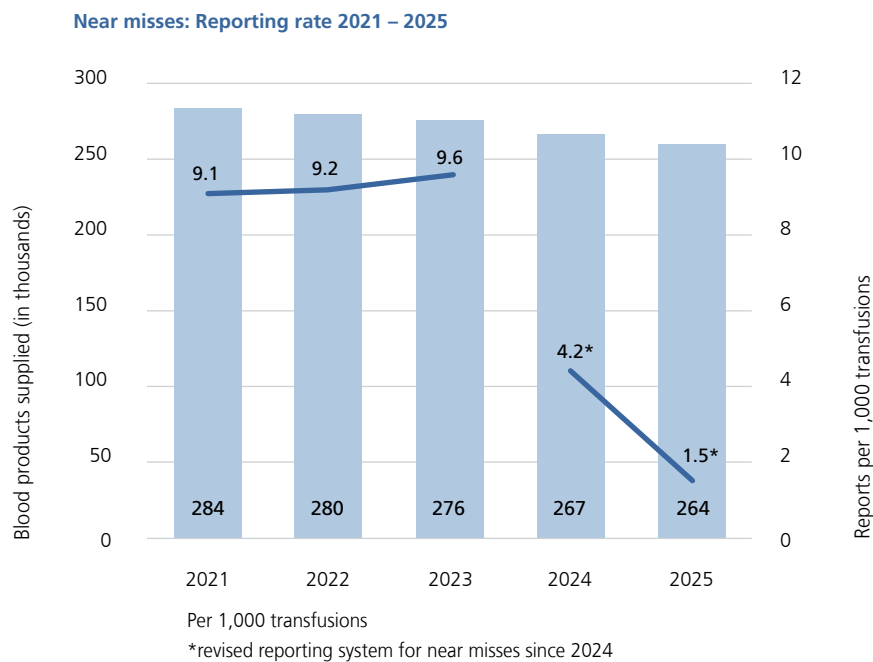


Table 15
Near misses
by severity

Severity of near misses in 2025	
1 Non-serious*	49
2 Serious	174
3 Very serious	170
Total	393

*revised reporting system for near misses since 2024

4.3.2 Near misses: Localisation and discovery

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. A similar picture to 2024 emerged in 2025, with approximately 77% of near misses occurring during clinical preparation. The “very serious events” that occurred during clinical preparation (n=150, 44% of all near misses), predominantly involved “wrong blood in tube” events (n=135, 2024: 168; see Figure 18). Localisation of errors classed as “other” included a previously treating department (missing documentation/antibodies), the manufacturer (quality defect in a blood product) and an external blood store (incorrect order). In one case, a mistake occurred during patient admission (patient registration at the hospital): the electronic patient records of two different patients were merged, and the patient was accordingly assigned to a (previously determined) incorrect blood group.

The number of “WBIT” cases fell slightly compared to the previous year, but still remained high. All these cases involved blood samples that were analysed in the laboratory as regular test samples, but that contained blood from another patient. The cases underline the absolute necessity to perform **two independent ABO blood group determinations**. As an alternative to a second blood sample, the results of previous blood group determinations (documented in the LIS or with a valid blood group card) count as “second” test results⁸. Routinely asking about a blood group card – and forwarding the card to the laboratory – can help both to reduce unnecessary blood sample collections and ensure that information about externally determined allo-antibodies is forwarded.

Figure 16

Near misses:
Severity and
localisation of
the error

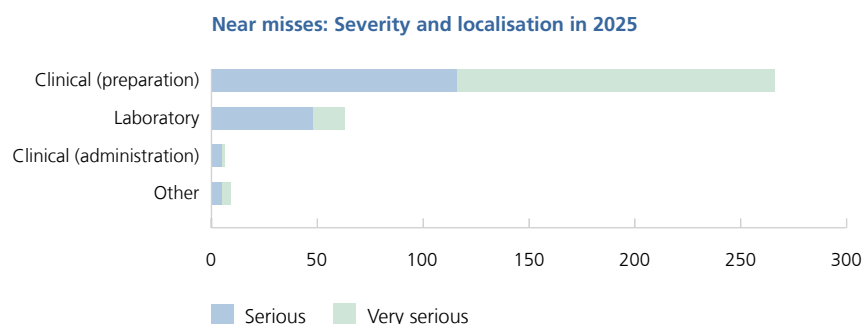


Table 16

Near misses:
Severity
and localisation
of the error

Near misses: Severity and localisation in 2025

Localisation of the error	Severity of the error		
	Serious	Very serious	Total
Clinical (preparation)	116	150	266
Laboratory	48	15	63
Clinical (administration)	5	1	6
Other	5	4	9
Total	174	170	344

Absolute numbers, severity grade ≥ 2

Figure 17

Near misses:
Discovery and localisation
of the error

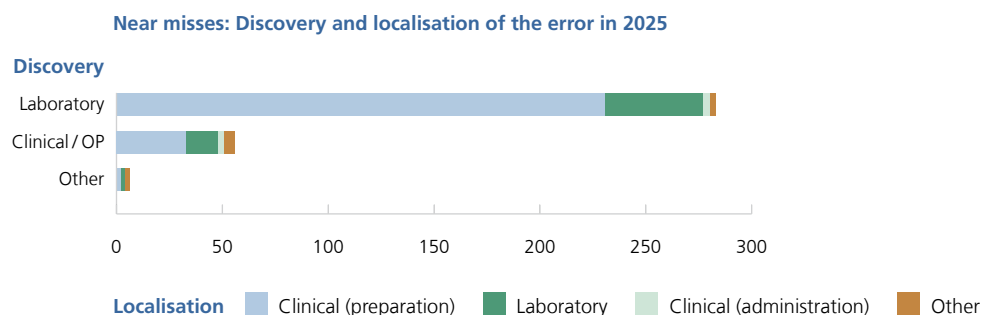


Table 17

Near misses:
Discovery and localisation
of the error

Near misses: Discovery and localisation of the error in 2025

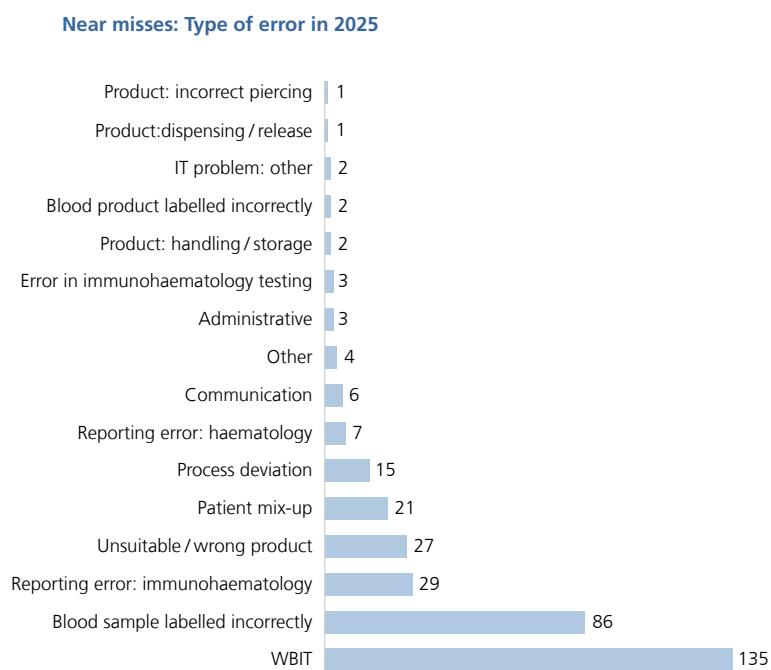
Discovery of the error	Localisation of the error				Total
	Clinical (preparation)	Laboratory	Clinical (administration)	Other	
Laboratory	231	46	3	3	283
Clinical/OP	33	15	3	5	56
Other	2	2	0	1	5
Total	266	63	6	9	344

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 2025, deviations that led to IBCT most frequently involved the prescribing of blood products (n=47), representing a significant increase compared with previous years (2024: n=7). These primarily involved the prescribing of an excessively rapid transfusion rate for patients at increased risk of TACO and who subsequently experienced an IBCT-HSE.

The second most common localisation of error was in administration (n=18; 2024: n=12), followed by the selection of blood products (n=10) and testing (n=7) (Figure 19). In 5 IBCT cases, the localisation of the error could not be assigned with certainty or was outside the transfusion chain: these included, for example, the transfusion of a unit of pRBC in which clots were discovered during the transfusion, the transfusion of an incorrectly identified patient (wristband, IBCT-RBRP), and the transfusion of an incompatible pRBC due to the inability to procure a compatible one (no communication error, all efforts exhausted, shortage situation (see also [4.2.4 case studies](#)).

“Error prior to ordering” constitutes a newly listed category (3 cases): these typically involve communication errors (failure to forward information) before the transfusion decision: In two cases, a failure to forward information led, respectively, to incorrect transfusion and incorrect testing: in the first case, externally known allo-antibodies (and transfusions) were not communicated, resulting in an IBCT-SRNM; in the second case, the transfusion requirement for a patient with a complex, extended phenotype was not communicated preoperatively despite comments from the laboratory - no pre-ordering was possible and the red blood cells with the necessary phenotype were not available (IBCT-SRNM).

If we just look at the IBCT-WCT, the errors arose predominantly during administration (n=5), similar to previous years' figures. A patient mix-up occurred in four of these cases (patient's identity was not checked at the bedside, transfusion of a unit of pRBC to the wrong patient). In one case, units were selected from blood products stored on site (intensive care unit) that were not intended for the patient. Two of these events are described as case studies ([4.2.4 IBCT: Case studies](#)).

In comparison, by far the largest number of grade 2 and 3 near misses occurred in the context of obtaining samples (preparation), followed by prescribing and testing. This is in line with the figures reported for the previous year and continues to underline the importance of careful (receiving) checks in the laboratory. There was a decline in the number of near misses occurring in connection with administration (and discovered before transfusion).

Figure 19 IBCT: Point in process

IBCT: Localisation of errors in the transfusion chain in 2025

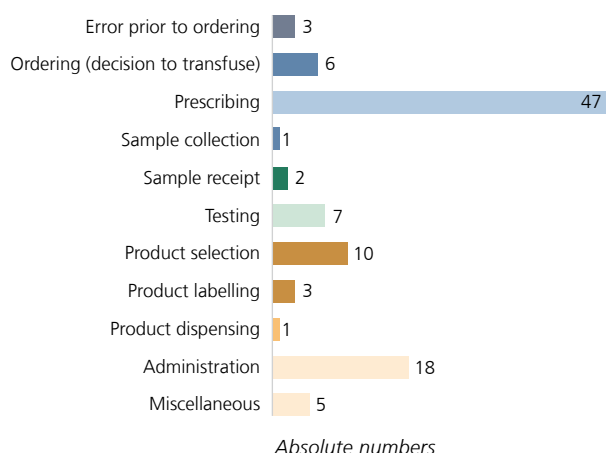


Figure 20 IBCT-WCT: Point in process

IBCT-WCT: Localisation of errors in the transfusion chain in 2025

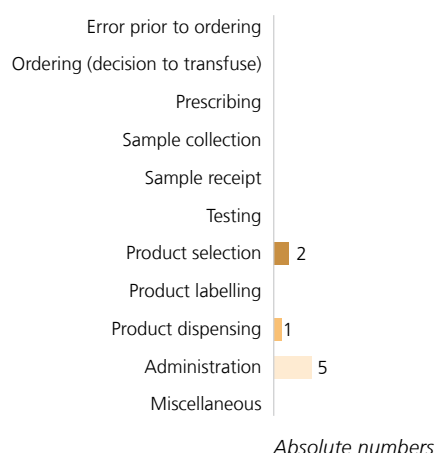
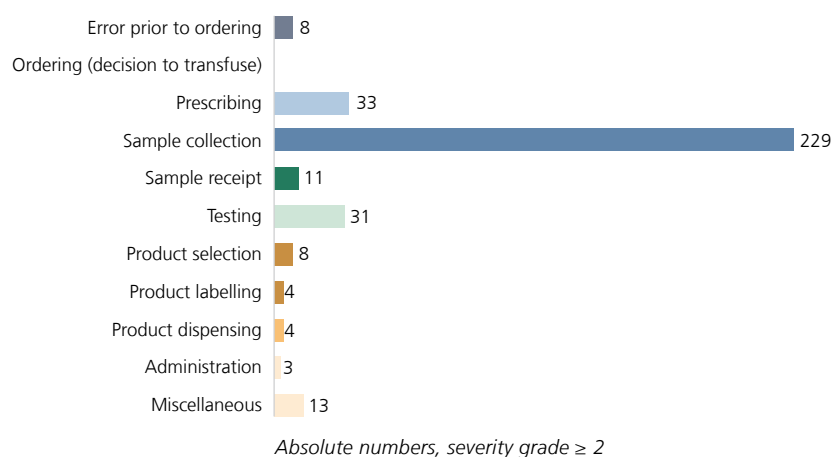


Figure 21 Near misses: Point in process

Near misses: Localisation of errors in the transfusion chain in 2025



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 2025 identified “human error/individual error” as the main cause of the incident, which was the same percentage as the previous year. In 61% of the reports 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). Technical errors were not reported as a cause of IBCT in 2025 (previous year: 20% of IBCT). In this connection, we would highlight the reporting obligations for medical devices (including in vitro diagnostic medical devices) - further information can be found under: [Materiovigilance reporting system](#). Defective test cells used for antibody screening had resulted in numerous IBCT cases in 2024.

The failure to follow an adequate SOP accounted for 73% 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 implement SOPs correctly in practice – including 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 factors¹¹.

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 possible⁵. Of those IBCT cases that could be assigned to a particular shift, 32% occurred during a night/late or weekend shift (17% of all IBCT; Figure 24). The proportion of transfusion errors occurring during the day shift remained largely stable (day shift in 2025: 37%; 2024: 36%; 2023: 29%). In an ideal situation, aids and processes exist to help staff handle rarely performed tasks and other stress factors (e.g. night shift, reduced staffing) and thus avoid errors. The implementation of digital (non-fatigable) checks is one possible option here.

The relevance of environmental factors is examined within the context of “Human Factors and Ergonomics” – in this connection we would refer interested readers to the information materials issued by SHOT (Serious Hazards of Transfusion), available online at: [Human Factors and Ergonomics \(HFE\) - Serious Hazards of Transfusion](#). Focusing on “human error” without addressing environmental factors is not helpful, either for the personnel involved or for patient safety.

Figure 22 IBCT: Causes
IBCT: Causes in 2025

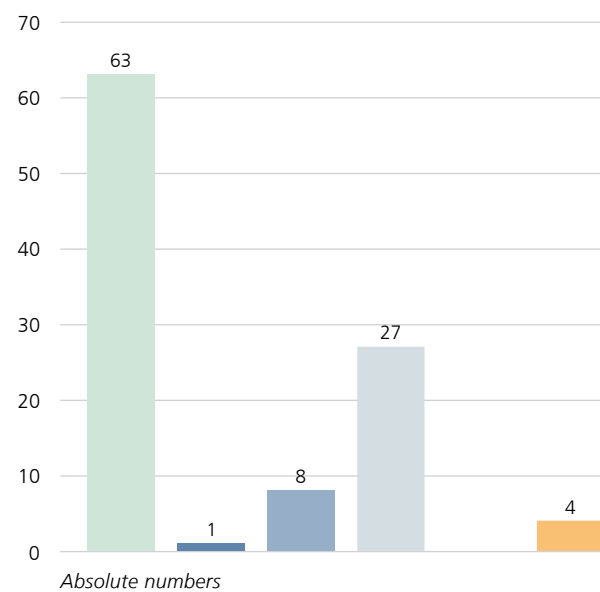
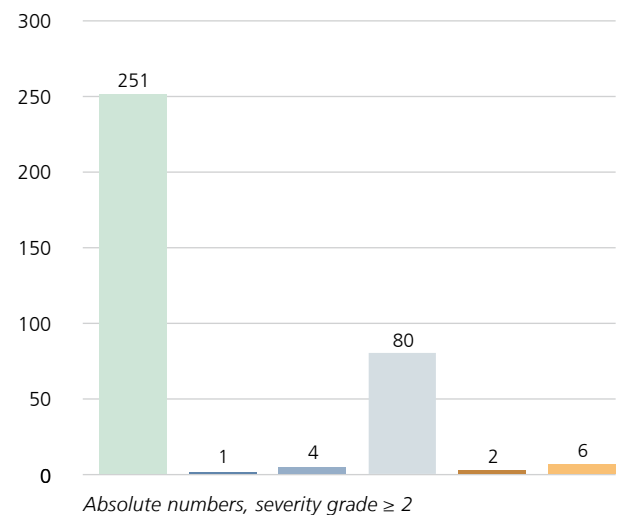


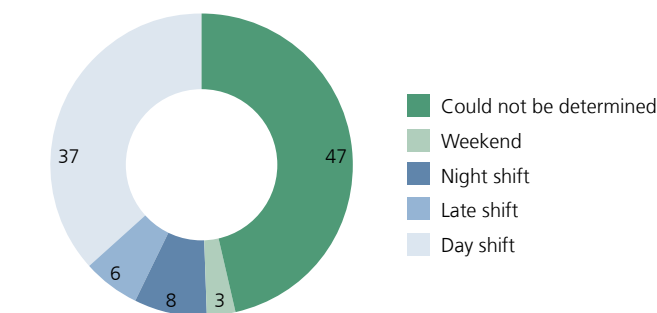
Figure 23 Near misses: Causes
Near misses: Causes in 2025



- SOP not available
- SOP available, not followed
- SOP available and followed but not adequate for this case
- Information/communication/documentation
- Human error, individual error
- Technical error
- Could not be assigned

Figure 24
IBCT : Shifts

IBCT: Shifts in 2025



Percentages
Discrepancies in totals are due to rounding

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. While the number of reports remains largely unchanged compared to the previous year (n=701, 2024: n=707), specific patient-related reasons were ascertained for more events. The main reasons were “medical condition rules out a transfusion” and “transfusion no longer indicated”. This more detailed information is helpful in identifying areas for improvement and reviewing procedures (e.g. checking the patient's clinical condition before retrieving the blood product from the laboratory). As in the previous year, only a small number of the situations were described by the reporters themselves as an “emergency situation” (incl. massive transfusions) (n=79, 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 persistently large number of “cancellations” given as the reason for discarding products (n=418, 60% 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).

The checklist for pre-transfusion checks published in the new edition of the “Guidelines for quality assurance in transfusion practice” can also help minimise possible sources of wastage⁵.

Table 18

Discarded blood products:
incorrect storage
and handling

Discarded blood products: incorrect storage and handling in 2025		
Orders / modified requirement		425
Cancellation with no further details	418	
Wrong product ordered	7	
Temperature monitoring		112
Incorrect storage outside the blood store (e.g. outside the refrigerator, unmonitored refrigerator)	61	
Cold chain interrupted with temperature monitoring	37	
Cold chain interrupted, temperature monitoring unclear	7	
Cold chain interrupted without temperature monitoring	4	
Temperature monitoring available: defective (e.g. technical error of the temperature logger/forgotten)	3	
Patient-related reasons		86
Transfusion no longer indicated	26	
Medical condition rules out a transfusion	24	
Patient died/treatment discontinued	14	
Patient refused transfusion	9	
Patient mix-up	7	
Venous access not possible	6	
Other		78
Product defective/incorrect handling (e.g. error when piercing the product, material defect, clot in FFP)	58	
Information unclear / wrong (transfusion would have been possible)	9	
Quality defects in the product	8	
Storage error in the blood store	2	
Product delivered to wrong place	1	
Total		701

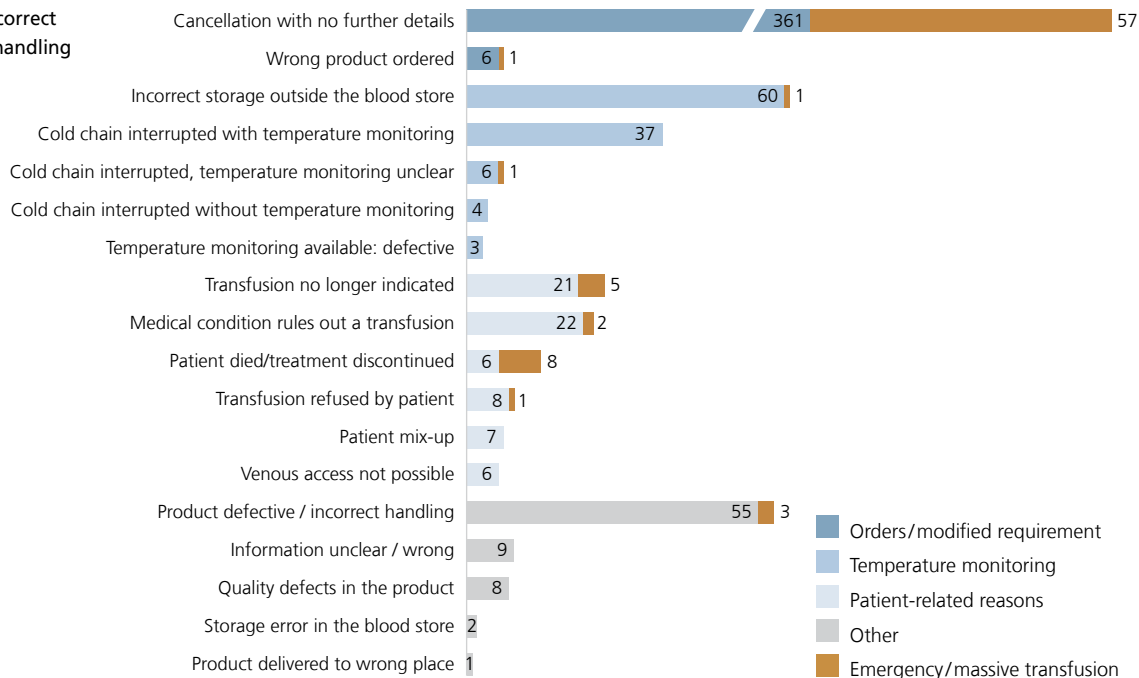
Absolute numbers

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

Discarded blood products – incorrect storage and handling in 2025



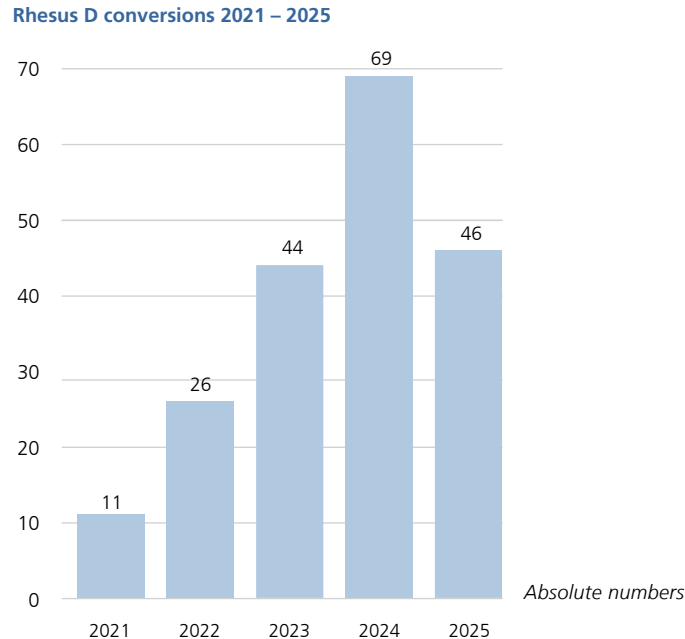
Absolute numbers

Only reportable events are shown. Reports concerning the expiry of products in stock are not included

4.6.2 Rhesus D conversion

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 are presented in the “Recommendations on the handling of blood products in the Rhesus D negative blood group”⁸. These provide for exceptions in special cases, particularly massive transfusions^{12, 8}. At the same time, if supply shortages exist (no compatible pRBC RhD neg available), a Rhesus D conversion is unavoidable. Despite compliance with guidelines, Rhesus D conversion remains a “serious incident” and should be reported as such. The reported data should also be used to assess the resource situation and the consequences of shortages for transfusion safety in Switzerland. In 2025 there was an overall reduction, back to the 2023 level, in the number of reported Rhesus D conversions (Figure 26). This trend will need to be monitored over the next few years.

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



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 2014²⁹. 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, Issue 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 (73%), and 88% of all reactions were mild. These were assessed as grade 3 events in 21 cases, and the causal connection with the blood donation was evaluated as at least possible in 20 of these donations (19 whole blood donations, 1 apheresis donation). 15 of the grade 3 events were “vasovagal reactions” – usually fainting with a need for further medical attention in the emergency department. Unfortunately, in one of these events the fainting patient fell onto the back of the head and lost consciousness. An intracranial haematoma was subsequently diagnosed and required surgical evacuation. The incident occurred on a very hot summer day. Relevant local symptoms occurred in four events, including one arm vein thrombosis and two extensive haematomas with prolonged local symptoms. No cardiovascular reactions of any severity occurred in 2025.

In relation to the total number of blood donations performed (blood donations in 2025: 252,703), severe/life-threatening donor reactions (grade 3) were very rare, although their absolute number was higher than in previous years (Table 20). However, it should be noted that in 12 of the grade 3 events (all vasovagal reactions), the only reason for classification as grade 3 was a brief visit to the emergency department, rather than the harm caused by the reaction itself.

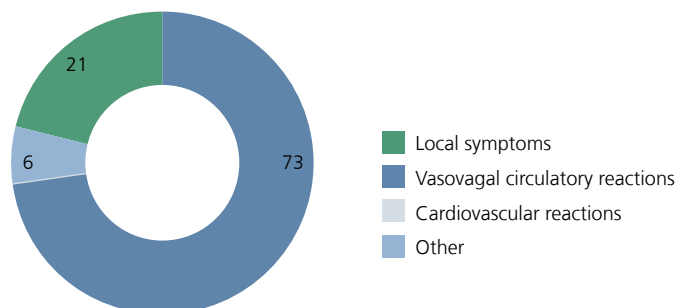
Table 19
Donor reactions:
Type and severity

Donor reactions in 2025					
Severity	Grade 1	Grade 2	Grade 3	Grade 4	Total
A Local symptoms	594	50	4	0	648
B Vasovagal circulatory reactions	1,971	254	15	0	2,240
C Specific adverse effects related to apheresis	139	17	1	0	157
D Allergic reactions	2	0	0	0	2
E Cardiovascular reactions	0	0	0	0	0
F Other serious adverse effects	11	2	1	0	14
Total	2,717	323	21	0	3,061

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 2025



all degrees of imputability and severity
Discrepancies in totals are due to rounding; no cardiovascular reactions in 2025

Table 20
Grade 3/4 donor reactions
by year

Grade 3/4 donor reactions in 2021 – 2025					
	2021	2022	2023	2024	2025
Local symptoms	0	1	1	4	4
Vasovagal circulatory reactions	6	6	10	9	15
Cardiovascular reactions	1	3	3	2*	0
Other	1	0	3	1	2
Total	8	10	17	13	21

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.

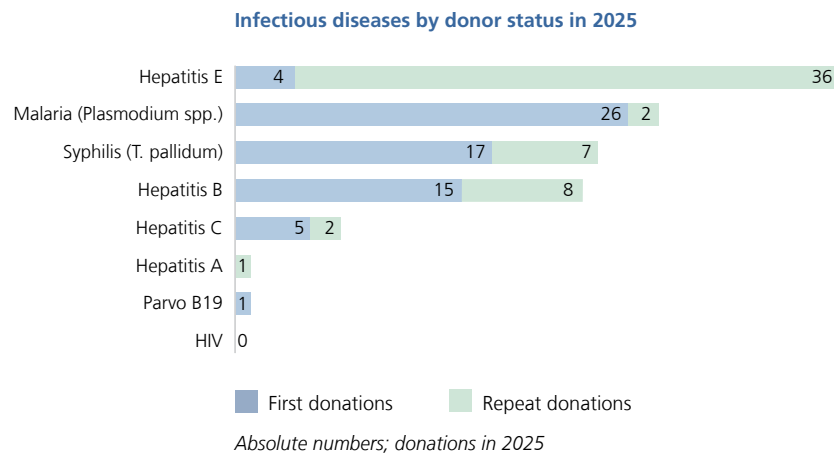
6.2 Reported data

6.2.1 Protective measures: Infectious diseases

In 2025, a total of 142 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 significant reduction compared to the previous year (2024: n=526, 2023: n=241) is attributable to the marked decline in parvovirus B19 infections, which had already become apparent in the second half of 2024 (Figure 30, see also 6.2.2). Apart from that, the infection numbers were largely unchanged compared with the previous year. Figure 28 breaks down these numbers by first-time donors and repeat donors. Only events in which blood was donated are listed here. So-called “diagnostic blood samples” taken to ascertain donor suitability (e.g. as a result of information in the donor's history) are not mentioned. No blood donation tested positive for HIV in 2025 (2024: n=1). Syphilis cases were largely stable, remaining at the level of previous years (2025: n=24; 2024: 29; 2023: 24). This stabilisation at an elevated level reflects the trend observed across Switzerland, which is monitored by the Federal Office of Public Health¹³. The number of blood donations testing positive for hepatitis B and C was also in line with previous years.

Figure 28

Infectious diseases
in blood donors:
first or repeat donation



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 the beginning of spring, with transmission mainly via the respiratory tract ¹⁴. 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 – 2025 (Figure 30): The trend for the disease figures is in line with observations in other European countries ¹⁵.

A significant decline in the reported numbers occurring back in the second half of 2024 has continued in 2025: only one blood donation tested positive for parvovirus B19 and – unlike in 2024 – no transmission of infections occurred. For further details please refer to the [Haemovigilance Annual Report 2024](#) and the information issued by Swissmedic on this topic: [“Increase in parvovirus B19 infections and impact on treating high-risk patients”](#) ¹⁶.

Figure 29
Parvovirus B19:
positive blood
donations

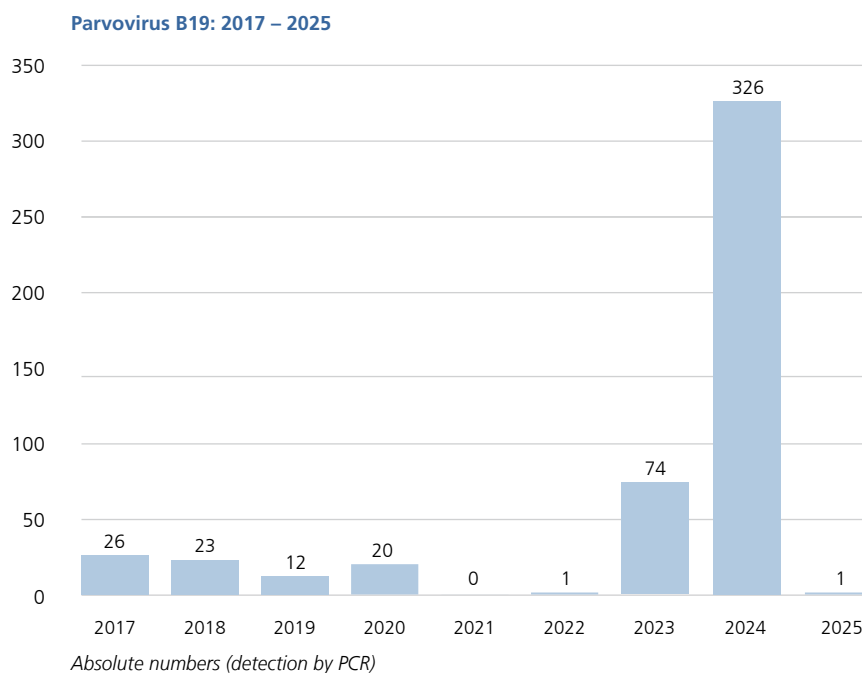
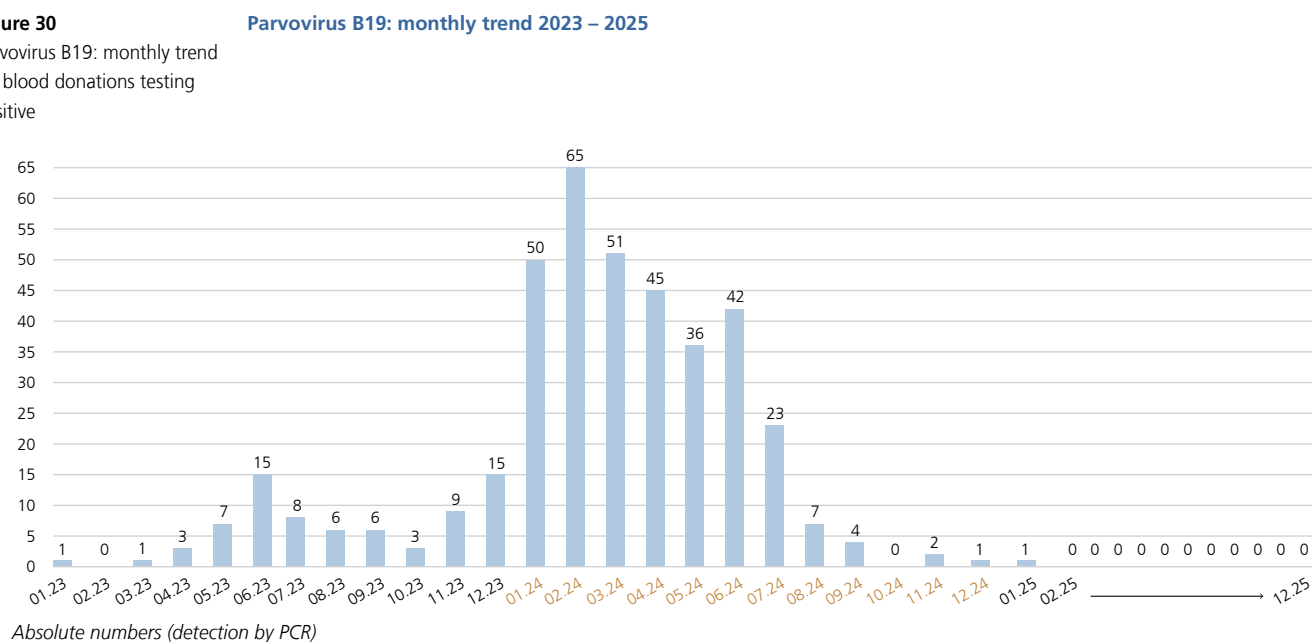


Figure 30
Parvovirus B19: monthly trend
for blood donations testing
positive



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 ST-SRC coordinating office 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 2025			
Infection markers	Case reports	Transfusion-related infections diagnosed	Ongoing
HBV	8	-	1
HEV	4	-	1
HIV	-	-	-
HCV	1	-	-

Absolute numbers, procedures concluded: 11

Thirteen donor-related look-backs were performed in 2025 (Table 21). No diseases transmitted by a blood product manufactured in Switzerland were identified (two procedures ongoing). The same applies to the ongoing donor-related look-backs mentioned in the 2024 Annual Report: here too, no transmission of infection was detected in any of these cases. Furthermore, four look-backs were performed due to Creutzfeldt-Jakob disease (CJD) (blood donated before onset of the disease). There is no screening blood test for this prion disease, and there is no indication of transmission.

6.3.2 Patient-related look-backs

No patient-related look-backs (PLB) were performed in 2025.

7 Abbreviations

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

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