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Haemovigilance
Annual Report 2022

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Evaluation of haemovigilance reports in 2022

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1 Editorial

After two years that were dominated by the SARS-CoV-2 pandemic, the healthcare situation for the year under review largely returned to normal. This also applies to the transfusion figures, which have shown a slight decline compared to the previous year, in line with the long-term trend. The backlog of elective surgical procedures that accumulated during the pandemic therefore appears to have been cleared.

A welcome development for haemovigilance is the fact that the total number of reports, particularly thanks to the reported transfusion reactions, has increased again compared to the previous year. As a result, the reporting rate has also improved – indicating an increased awareness of the importance of haemovigilance.

However, large regional differences in the reporting rates remain a striking feature. These differences apply both to reports relating to transfusion reactions and to near miss reports. The obvious explanation for these discrepancies lies in a differing awareness of reporting and possibly also in a different approach to dealing with errors. Swissmedic will increasingly highlight this problem and continue to step up the efforts to raise awareness of the importance of haemovigilance in these regions.

Swissmedic's message to everyone involved in the transfusion chain remains the same: Reports of transfusion errors and near misses are important for quality assurance and indicate good awareness of the significance of both haemovigilance and an established and progressive approach to dealing with errors for the benefit of patient safety.

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

Christoph Küng, Head of Safety of Medicines Division

2 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. Separate sections are dedicated to the definitions and classifications of each type of incident, e.g. transfusion reactions and adverse effects, transfusion errors (known as IBCT, incorrect blood component transfused) and near misses.

2.1 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.

2.2 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 transfu-

sions of labile blood products, and hospitals and doctors' practices in particular. These institutions designate a person who is responsible for fulfilling the reporting duty.

Where relevant, further specific legal obligations are described in the respective chapter.

2.3 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 (cf. 2.2). Both users and manufacturers are also obliged to set up a quality assurance system.

Swissmedic enters reports in the haemovigilance database and assigns a case-specific reference number. The notified data and measures are evaluated by a vigilance assessor and additional information is requested if necessary. The report assessment included in the statistics is the same as the final evaluation by the vigilance assessor. If this deviates to a relevant degree from the assessment by the reporting healthcare professional, the responsible person is consulted. 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 the Blood Transfusion Service of the 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.

3 Number of transfusions and reporting rates

3.1 Number of transfusions

In 2022, a total of 280,296 blood products were supplied for transfusion in Switzerland, representing a 1.2% decline compared with 2021 (Table 1). The transfusion figures are based on the number of blood components supplied as shown in the annual statistics of the Blood Transfusion Service of the Swiss Red Cross [1] and will be referred to below as transfusions or transfused products.

Table 1

Transfusions in Switzerland over the past five years

Blood product	2018	2019	2020	2021	2022
pRBC	221,100	220,481	212,947	217,049	214,197
PC	38,947	36,317	35,715	38,898	39,182
FFP	30,552	28,405	26,681	27,765	26,917
Total	**290,599**	**285,203**	**275,343**	**283,712**	**280,296**

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].

3.2 Reporting numbers and rates

In 2022, Swissmedic received a total of 4,744 haemovigilance reports relating to transfusion reactions and IBCT/near misses and a further 3,653 reports of donor reactions (incl. collective reports), and protective measures/quality defects (Table 2). The statistics include reports received by the end of January 2023 at least; later reports will be included in the statistics for 2023. Since the publication of donor reactions was modified in 2021 (to include all degrees of severity), the reported figures are not comparable with those published before 2021. Please refer to section 6 for further explanations.

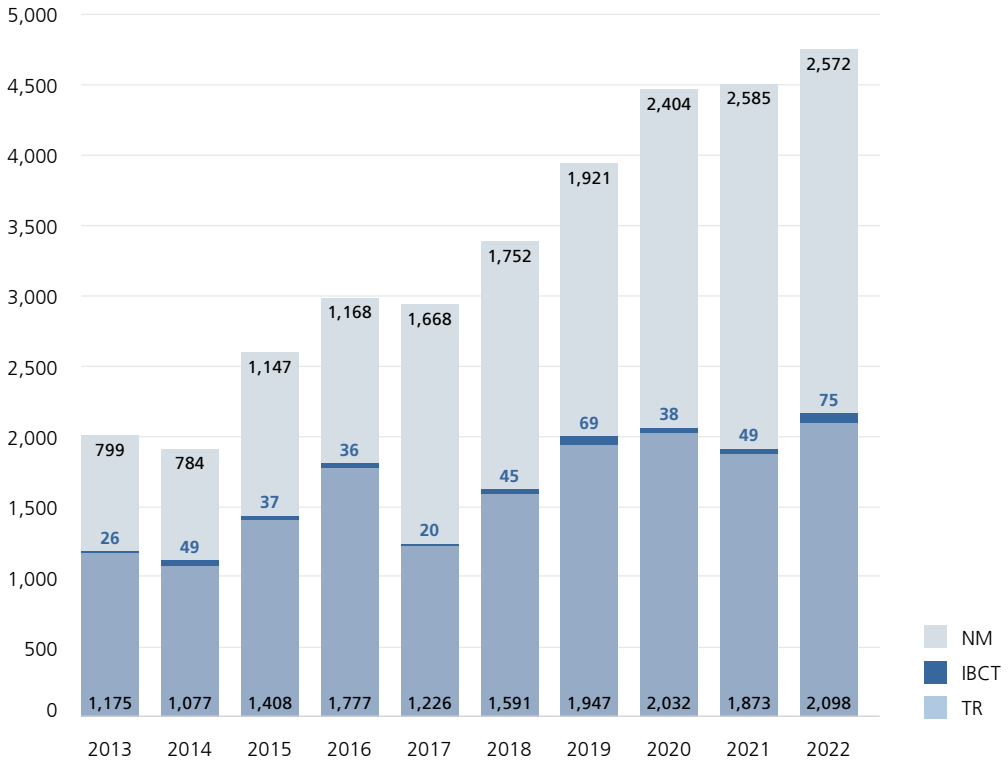
Table 2

Reports received in 2022	
Type	**Number of reports**
Transfusion reactions (TR)	2,098
Near misses (NM)	2,572
Transfusion errors / incorrect blood component transfused (IBCT)	75
Protective measures / Quality defects	145
Donor reactions*	3,508

** Publication of data reported for donor reactions modified from 2021*

In 2022, 12% more TR were reported than in 2021 (absolute reported figure). The number of NM remained roughly constant during the same period, while the number of transfusion errors has increased significantly (by approx. 51% compared to the previous year).

Figure 1
Haemovigilance reports
by year (2013–2022)



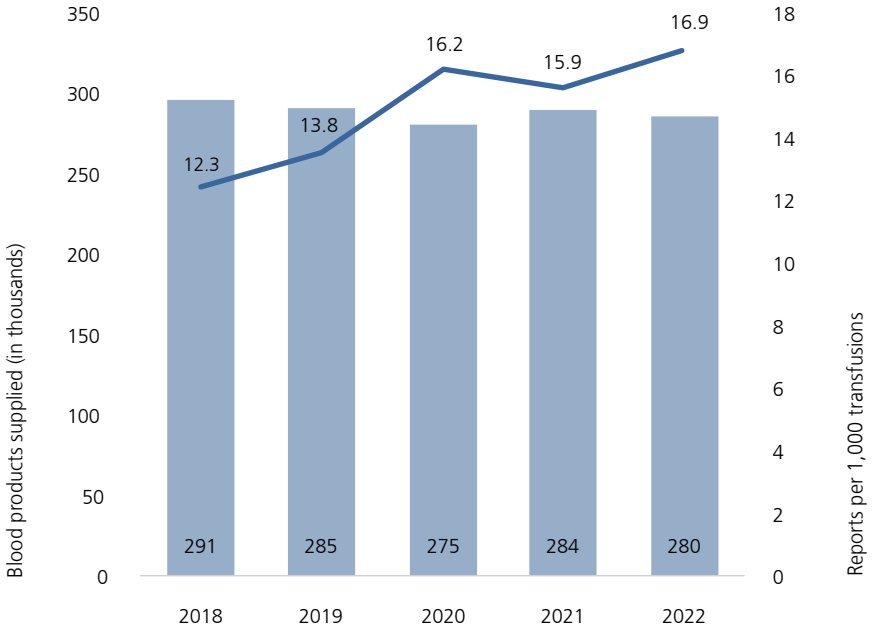
Near misses remain the most frequent haemovigilance reports.

Swissmedic calculates the reporting rate per 1,000 transfusions (Tf) on the basis of the total number of reports. The total reporting rate rose slightly in 2022 compared with 2021 (16.9/1,000 Tf in 2022 compared with 15.9/1,000 Tf in 2021), with increases in the reporting rates for transfusion reactions and IBCT. The number of near miss reports has remained stable (Figure 2).

The average reporting rate for TR over the previous five years (2018-2022) was 6.8/1,000 Tf (1:150); in 2022 it was 7.5/1,000 Tf (1:134).

The reporting rate for transfusion errors (IBCT) over the previous five years (2018-2022) was 0.20/1,000 Tf (1:5,460 Tf); in 2022 it was 0.26/1,000 Tf (1:3,788). Near misses and IBCT are discussed in detail in section 5.

Figure 2
Reporting rate (transfusion reactions, near misses and transfusion errors)



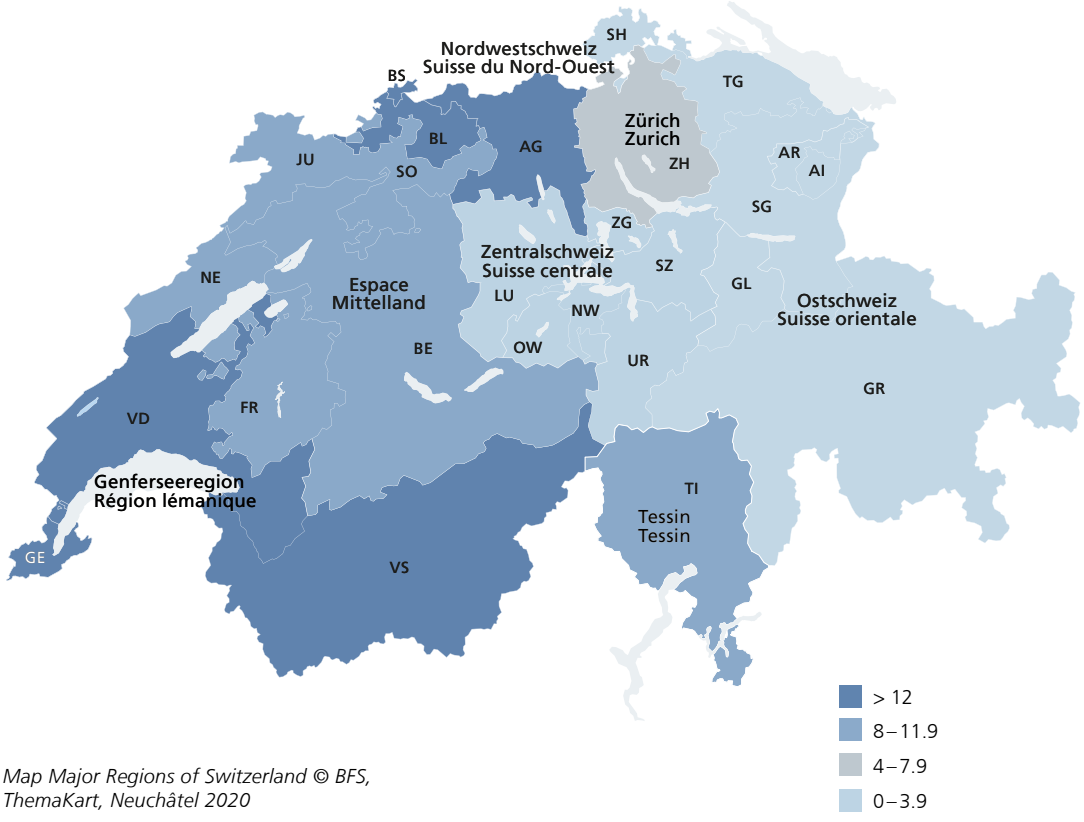
3.3 Reporting rates: Major regions

The Swiss hospitals have well-established haemovigilance systems. However, the regional reporting rates based on the number of inhabitants (TR reported per 100,000 inhabitants) vary widely. Allo-immunisations after transfusion are detected as a laboratory finding and without direct clinical symptoms (any haemolytic reactions are recorded separately), and they therefore differ fundamentally from other TR. The TR reporting rate is therefore shown as the total reporting rate and as the reporting rate excluding allo-AB. The highest reporting rates for TR (excluding allo-immunisations) were registered in Northwest Switzerland, the Lake Geneva region and Espace Mittelland (Table 3, Figure 3). Zurich, the Lake Geneva region and Espace Mittelland had the highest reporting rate for NM (Table 4, Figure 4). Central and Eastern Switzerland and Zurich had the lowest reporting rate for TR (excluding allo-immunisations), Ticino and Central and Eastern Switzerland the lowest reporting rate for NM. Shifts due to care provided outside a region are not illustrated since the reporting rates are calculated on the basis of the number of inhabitants. This must be taken into account when interpreting the data.

Table 3 Distribution of transfusion reactions by major region

		Reports		Reports per 100,000 inhabitants	
Major region	**Canton**	**Total**	**excluding allo-AB**	**Total**	**excluding allo-AB**
Lake Geneva region	GE, VD, VS	494	221	29.3	13.1
Espace Mittelland	BE, SO, FR, NE, JU	683	198	35.8	10.4
Northwest Switzerland	BS, BL, AG	602	162	50.5	13.6
Zurich	ZH	69	59	4.4	3.8
Eastern Switzerland	SG, TG, AI, AR, GL, SH, GR	63	51	5.2	4.2
Central Switzerland	UR, SZ, OW, NW, LU, ZG	150	31	18.0	3.7
Ticino	TI	36	24	10.2	6.8

Figure 3
Distribution of TR reports (excluding allo-AB) by major region



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

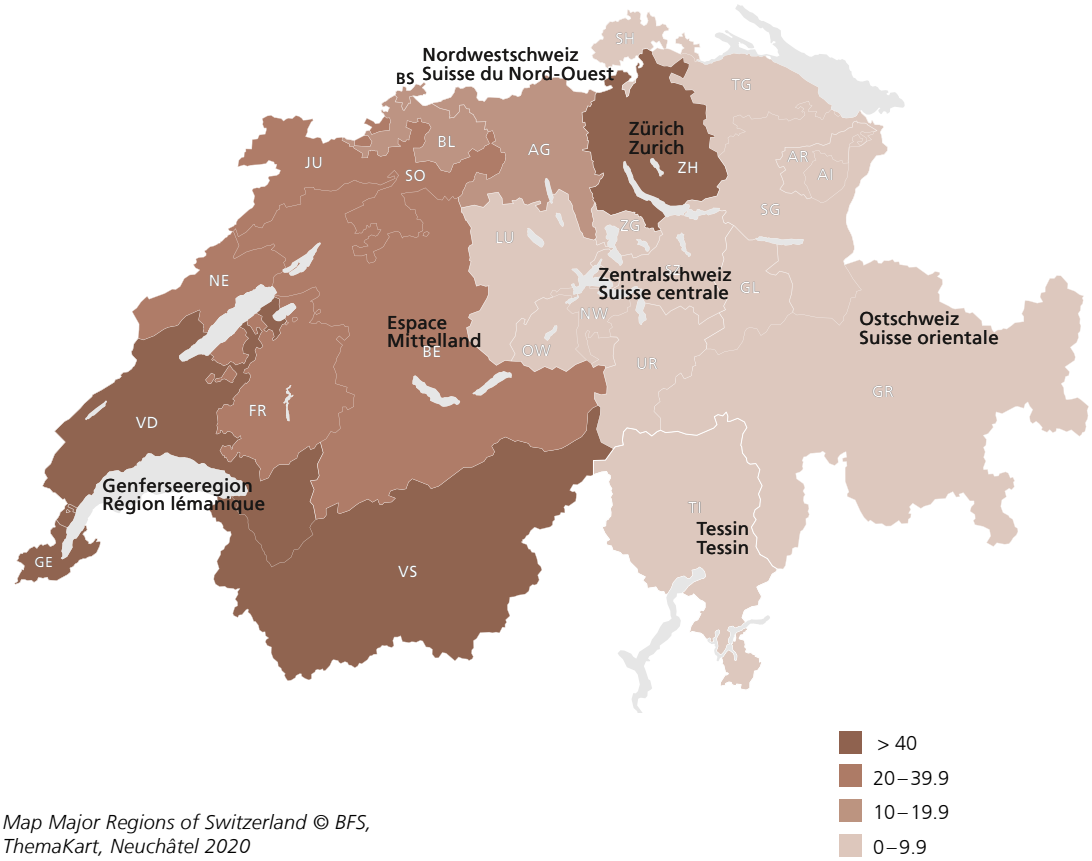
Table 4

Distribution of NM reports by major region

Major region	Canton	Reports	Reports per 100,000 inhabitants
Lake Geneva region	GE, VD, VS	690	40.9
Espace Mittelland	BE, SO, FR, NE, JU	533	27.9
Northwest Switzerland	BS, BL, AG	191	16.0
Zurich	ZH	1067	68.2
Eastern Switzerland	SG, TG, AI, AR, GL, SH, GR	59	4.9
Central Switzerland	UR, SZ, OW, NW, LU, ZG	28	3.4
Ticino	TI	24	6.8

Corrigendum: the version dated 21 February 2024 showed near miss data for 2021. The data has been corrected to the figures of 2022 .

Figure 4
Distribution of NM reports
by major region



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

4 Transfusion reactions

4.1 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 [2, 3] Table 5. Reactions which do not meet the criteria for a defined category are summarised as «Other».

Table 5

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

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

4.2 Severity and imputability

Table 6

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: graded according to the type of TR)

The severity of a transfusion reaction is evaluated independently of its possible connection with the transfusion (imputability). For example, suspected cases of volume 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 by Swissmedic according to its probability in a similar way to the ISBT criteria [2]. Cases for which the information is not available or is insufficient are classified as «not evaluable» (Table 7).

Table 7

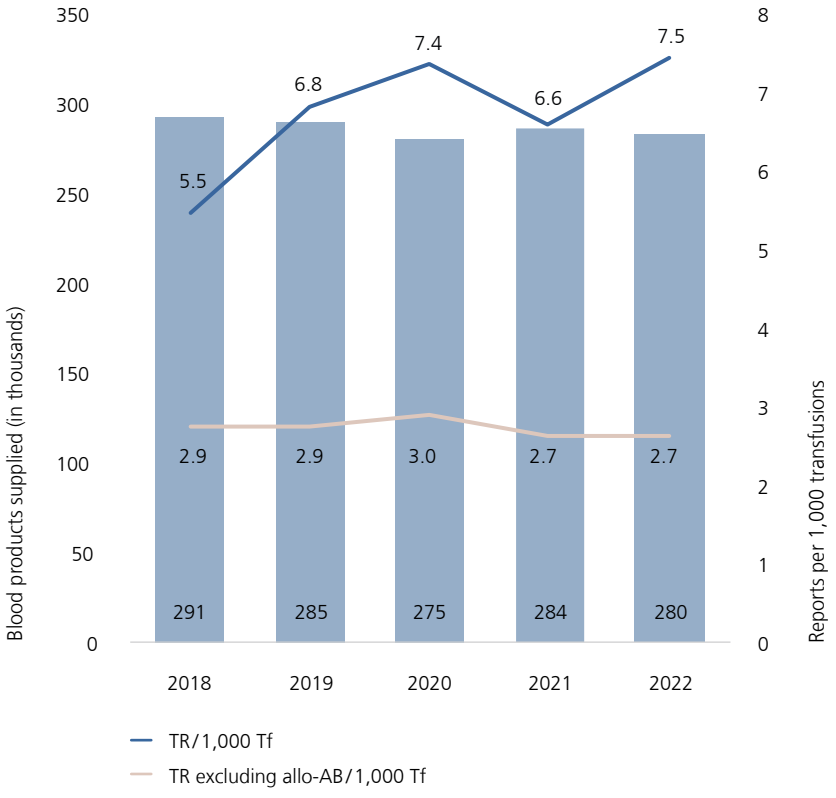
Imputability (causal connection between transfusion and reaction)		
0	not evaluable	There is insufficient or contradictory information and it is impossible to obtain supplementary information or check
1	unlikely	The reaction is definitely/more likely to be due to other causes
2	possible	The reaction 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

4.3 Reported data

4.3.1 Transfusion reactions: Reporting rate

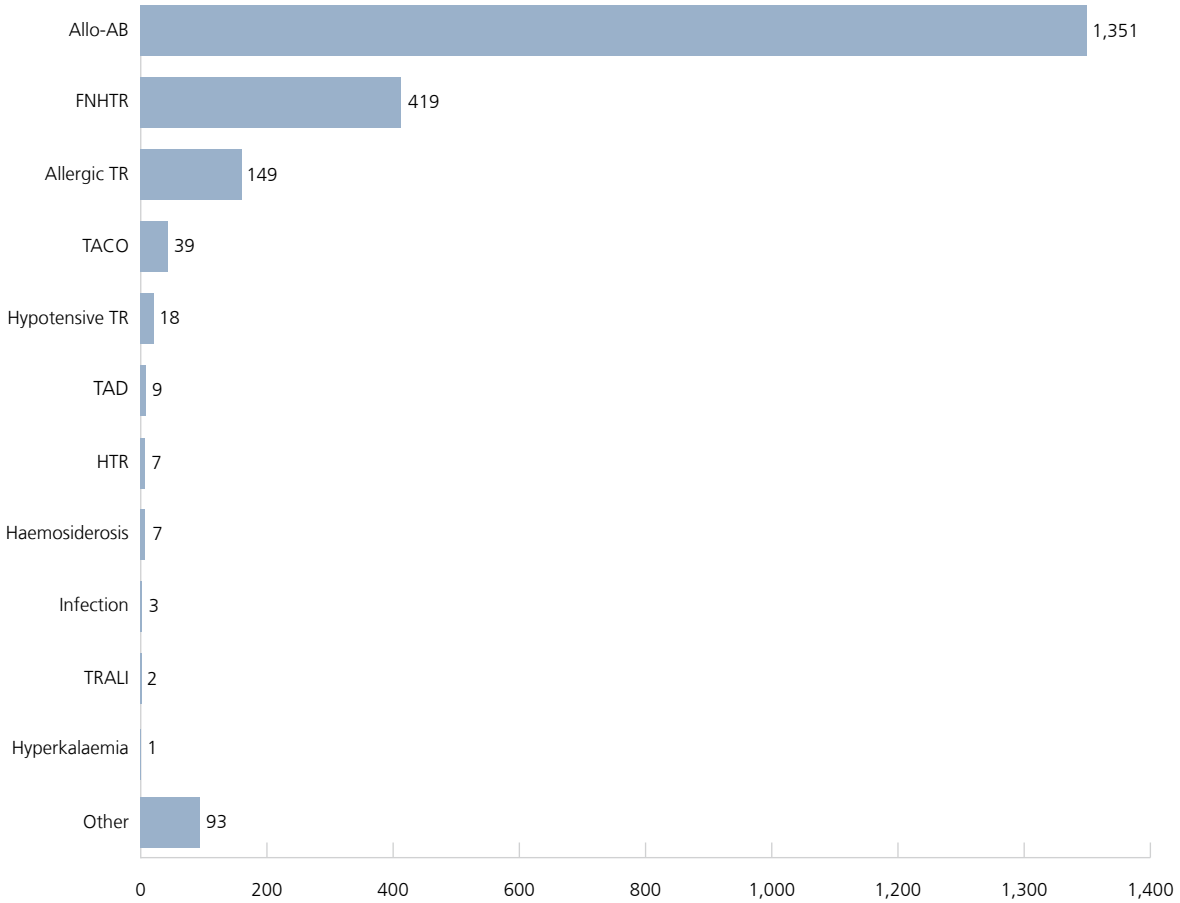
Compared with the previous year, the reporting rate for TR in 2022 was 12% higher (7.5/1,000 Tf) (Figure 5). This increase is attributable to the number of reported allo-immunisations – the reporting rate for TR without allo-immunisations (2.7/1,000 Tf) remained unchanged compared to the previous year. After allo-immunisations, FNHTR and allergic TR were the most frequently reported transfusion reactions.

Figure 5
Reporting rate for transfusion reactions



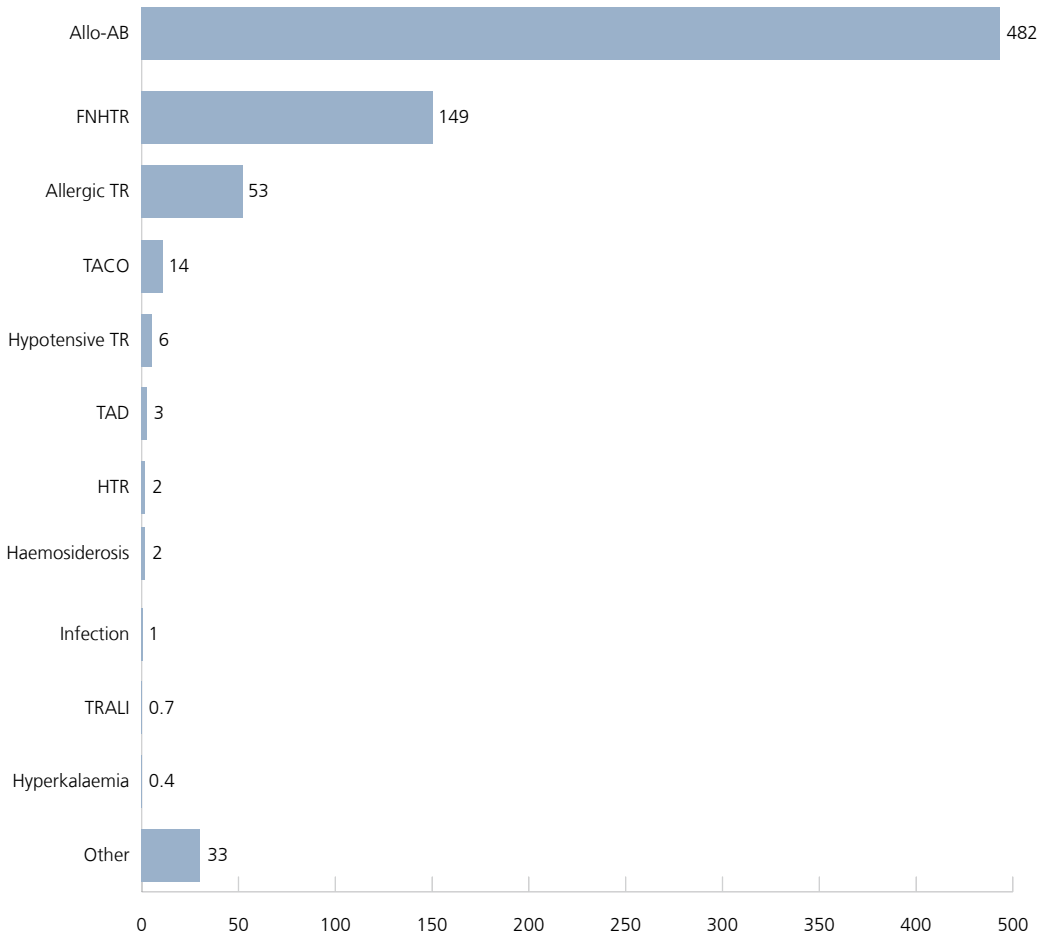
If we look at the frequencies of the various TR per 100,000 transfusions (all degrees of severity and imputability), the incidences are 149/100,000 (1:669) for FNHTR and 53/100,000 (1:1,881) for allergic TR. TACO were reported with a frequency of 14/100,000 (1:7,189), TRALI with a frequency of 0.7/100,000 (1:140,252). Allo-immunisations were reported with a frequency of 482/100,000 (1:134) in 2022, compared to 393/100,000 (1:151) in 2021. The reporting rate in the category «Other» was 33/100,000 (1:3,014) compared to 11/100,000 (1:9,457) – these include numerous reports (n=30) of febrile reactions that do not meet the ISBT criteria for an FNHTR and were therefore classed as «Other» (Figure 6, Figure 7, Table 8).

Figure 6
Transfusion reactions reported in 2022 by category (absolute figures)



A total of 2,098 transfusion reactions were reported in 2022

Figure 7
TR reported in 2022 by category
per 100,000 transfusions



Reporting rate for TR by category (TR per 100,000 transfusions) (including all degrees of severity and imputability)

Table 8

TACO/TRALI: Reports (absolute) per 100,000 transfusions				
	TACO		TRALI	
	Reports	Reporting rate	Reports	Reporting rate
2018	66	23	3	1.0
2019	48	17	8	2.8
2020	88	32	3	1.1
2021	62	22	6	2.1
2022	39	14	2	0.7

Table 9: The vast majority of the FNHTR had a mild course (grades 1 and 2, 99%; n=415); 95% of the allergic TR were also classified as grades 1 and 2 (n=142). 77% of the TACO were grades 1 and 2 (n=30), 18% were grade 3 (n=7), two TACO proved fatal (grade 4). In total, three fatal transfusion reactions (grade 4) were reported in 2022 – these fatalities are detailed in section 4.3.5.

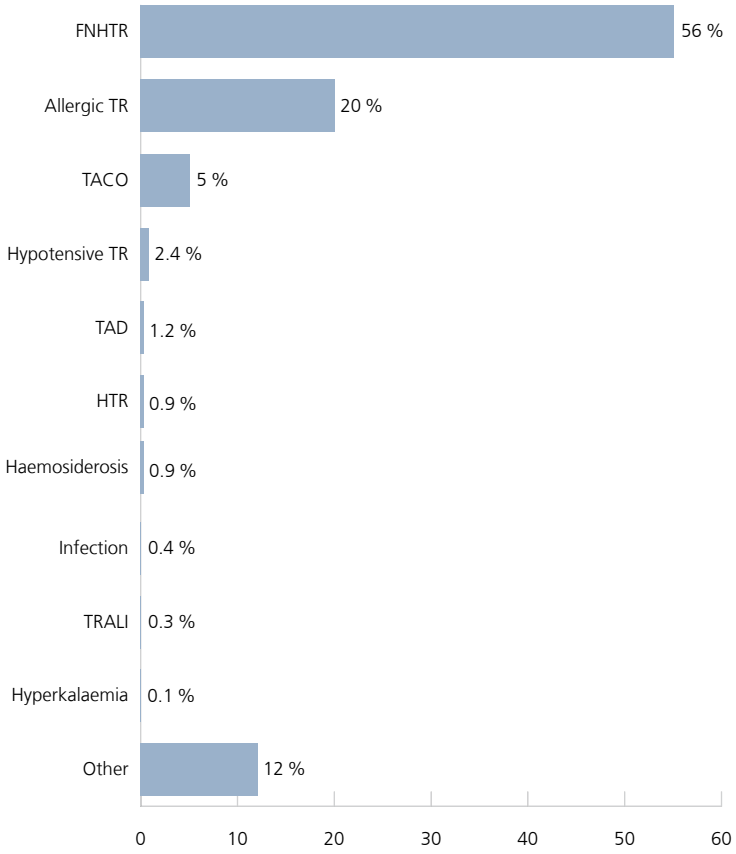
Table 9

Transfusion reactions by severity					
	1	2	3	4	Total
Allo-immunisation	0	1,351	0	0	**1,351**
FNHTR	266	149	4	0	**419**
Allergic TR	103	39	6	1	**149**
TACO	3	27	7	2	**39**
Hypotensive TR	7	8	3	0	**18**
TAD	4	5	0	0	**9**
HTR	1	5	1	0	**7**
Haemosiderosis	1	6	0	0	**7**
Infection	0	3	0	0	**3**
TRALI	1	1	0	0	**2**
Hyperkalaemia	0	1	0	0	**1**
Other	78	11	4	0	**93**
Total	**464**	**1,606**	**25**	**3**	**2,098**

Severity 1: non-severe, 2: severe/permanent damage, 3: life-threatening, 4: death.

If allo-immunisations are excluded, the majority of the 747 TR were accounted for by FNHTR (56%), allergic TR (20%), TACO (5%) and hypotensive TR (2.4%). 12% of the reports were classed in the category «Other» (Figure 8).

Figure 8
Distribution of transfusion reactions excluding allo-AB



4.3.2 Transfusion reactions: Age groups and gender

TR were observed more frequently in men than in women, a distribution that was already evident in previous years (Table 10). The number of reported transfusion reactions increases after the age of 50, a finding which applies to all types of transfusion reaction. However, the distribution patterns are different for each type of TR: TACO (95% > 50 years, 79% >70 years) and hypotensive TR (83% > 50 years, 50% > 70 years) occurred predominantly in older patients. By contrast, 52% of allergic reactions were experienced in the age group < 50 years (Figure 9).

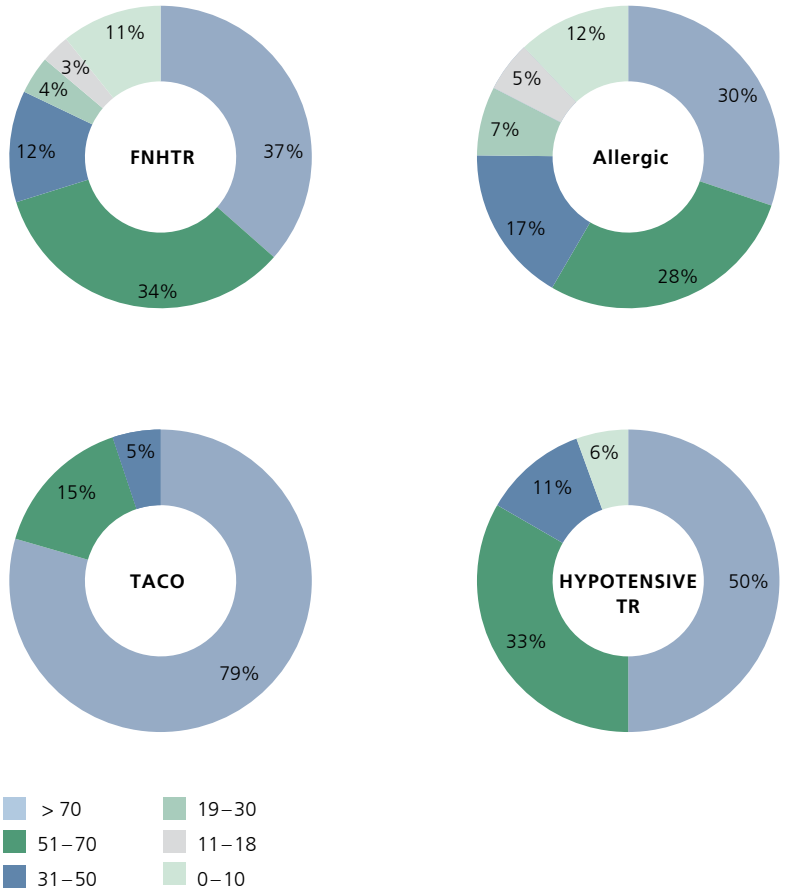
These data describe the absolute occurrence of transfusion reactions. Since there are no data on the transfusions performed by age group and gender, it is not possible to infer the incidence by age group and gender.

Table 10

Transfusion reactions by age group and gender				
Age groups	**Number of reports**	**Male**	**Female**	**Unknown**
0–10	72	38	28	6
11–18	26	16	9	1
19–30	30	13	17	0
31–50	93	36	57	0
51–70	227	131	95	1
>70	299	153	145	1
Total	**747**	**387**	**351**	**9**

Transfusion reactions reported in 2022 by age group and gender (excluding allo-AB)

Figure 9
The four most common transfusion reactions in 2022 by age group



4.3.3 Transfusion reactions: Imputability

Table 11

Transfusion reactions by imputability

	0	1	2	3	4	Total
Allo-immunisation	0	0	58	587	706	**1351**
FNHTR	0	75	275	63	6	**419**
Allergic TR	0	9	57	77	6	**149**
TACO	0	2	20	15	2	**39**
Hypotensive TR	0	2	6	9	1	**18**
TAD	0	0	7	2	0	**9**
HTR	0	3	0	2	2	**7**
Haemosiderosis	0	0	0	0	7	**7**
TRALI	0	1	1	0	0	**2**
TTI	0	1	2	0	0	**3**
Hyperkalaemia	0	0	0	0	1	**1**
Other	1	35	44	10	3	**93**
Total	**1**	**128**	**470**	**765**	**734**	**2098**

Number of transfusion reactions in 2022 by classification and imputability. The imputability of the allo-AB was classified as certain in the majority of cases (n=706). Excluding the allo-AB, the imputability of just 28 TR was classified as certain.
imputability 1: unlikely, 2: possible, 3: probable, 4: certain.

4.3.4 Transfusion reactions: Life-threatening and fatal events

In 2022, 747 TR were reported (excluding allo-AB). In 618 of these cases (approx. 83%), the imputability in relation to the transfusion was assessed as at least «possible». Within this group (imputability at least «possible»), there were 13 life-threatening and three fatal TR (Table 12). TACO (n=9) and allergic TR (n=5) remain the most frequent causes of life-threatening or fatal transfusion reactions (Figure 10). The incidence of fatal transfusion reactions was 1.1/100,000 transfusions (1:93,432) in 2022.

Figure 10
Grade 3–4 transfusion reactions with imputability ≥2 in the last 5 years

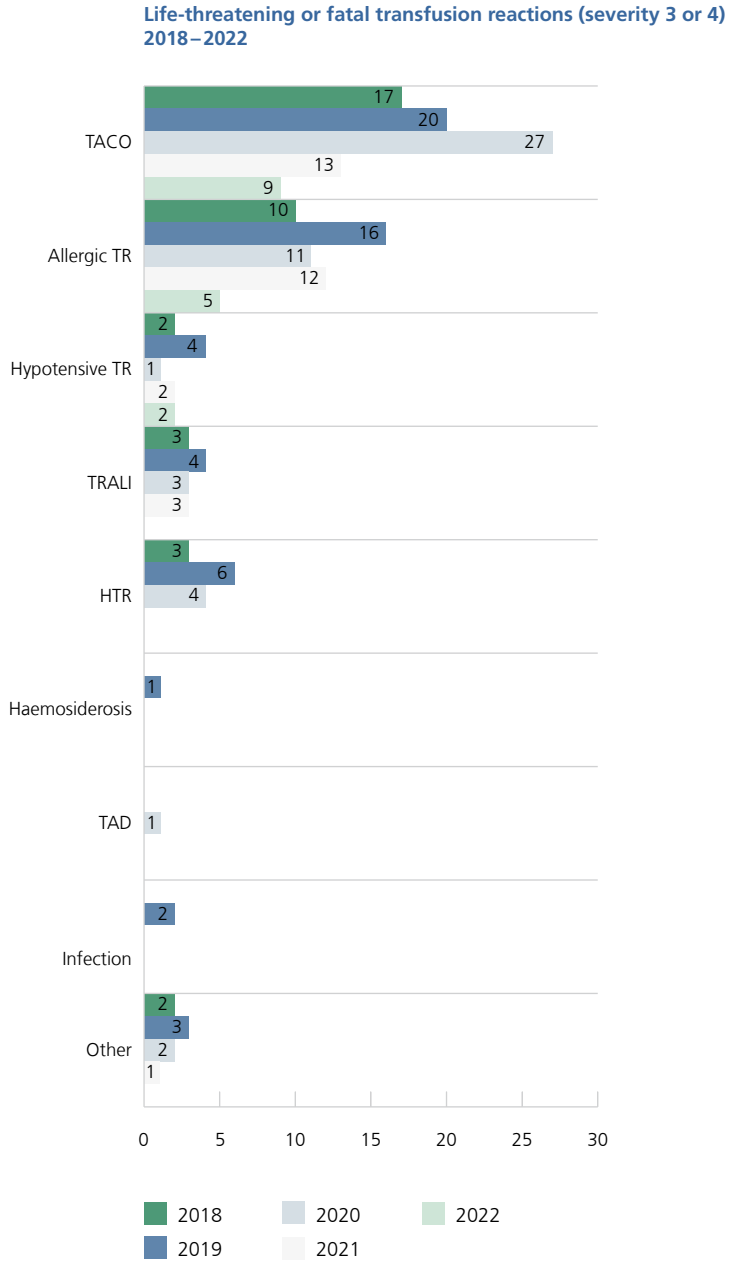


Table 12

Life-threatening and fatal transfusion reactions (severity 3 and 4) 2022 with imputability ≥2				
	Possible	Probable	Certain	Total
TACO	3	6	0	**9**
Allergic TR	3	2	0	**5**
Hypotensive TR	0	2	0	**2**
TRALI	0	0	0	**0**
Total	**6**	**10**	**0**	**16**

4.3.5 Deaths

A total of three fatal transfusion reactions were reported in 2022. Similarly to ISBT, transfusion reactions are only classified as deaths (grade 4) if imputability is evaluated as at least possible [2]. In this year also, two of the ultimately fatal reactions were TACO – in this connection we would once again urgently refer to the recommendation to screen patients for a TACO risk and, if applicable, aim for a slow transfusion rate (e.g. 1ml/kg body weight) and consider pre-emptive diuretic treatment [4, 5]. All three fatalities involved clinically complex situations in which the respective transfusion reactions cannot be viewed in isolation.

Table 13

Deaths
TACO: Imputability possible
Female patient, age group 30-50 years with a history of liver disease and chronic alcohol consumption and regular paracetamol use. Emergency referral with gastrointestinal bleeding and incipient haemorrhagic shock. On admission, she was severely anaemic (Hb < 50 g/L), thrombocytopenia (< 5x10 ^{9}/L) and elevated INR (>2). Following confirmation of lower GI bleeding and shock, several blood products (pRBC, PC, FFP) were transfused within 24 hours, supplemented by tranexamic acid. During this time, she suffered acute respiratory deterioration and required intubation. A chest X-ray showed pulmonary oedema as well as a unilateral pleural effusion. Echocardiography did not detect any structural heart disease. Diuretic treatment was initiated. Despite exhaustive intensive medical treatment, the patient's clinical progress was characterised by multiple organ failure with progressive liver failure, the bleeding and clotting situation could not be stabilised and the patient died. A post-mortem liver biopsy showed ASH/NASH, an autopsy was refused.

Since this case involved a clinically complex situation, it is difficult to make a clear distinction between her conditions and a transfusion reaction and assign the corresponding imputability. Overall, the picture is one of cardiogenic pulmonary oedema, possibly triggered by the transfusions, and the TACO criteria are formally met. In view of the overall clinical situations, other causes of the pulmonary oedema are possible. The extent to which the TACO was responsible for the multiple organ failure and, ultimately, the fatal outcome cannot be determined with certainty, but the severe and progressive liver disease was definitely unrelated to the transfusions. In conclusion, this case is classed as a TACO, imputability possible.

Allergy, anaphylaxis: Imputability possible

Male patient, age group > 70 years. Emergency surgery for an abdominal aortic aneurysm, aortic cross-clamping time > 80 min, with the transfusion of 2 units of FFP at the end of the operation due to disseminated intravascular coagulation. During the transfusion of the second unit of FFP, the patient became haemodynamically unstable and hypotensive, with indications of pulmonary obstruction, as well as a rash mainly affecting the trunk. Since an anaphylactic reaction was suspected, catecholamines, steroids and antihistamines were administered, but the hypotension failed to respond to this treatment and the patient subsequently went into shock. The scan images (CT angio) showed post-ischaemic lesions in several organs and low contrast uptake in the bowel areas; a surgical intervention was not an option. Colitis with bacterial translocation and septic shock was considered in the differential diagnosis as a cause of the patient's clinical condition (no pathogen detected). Despite intensive medical measures, the patient died a few hours after the surgery. An autopsy was not performed.

The presence of an allergic reaction to FFP is probable in this case (typical clinical presentation), although it is difficult to assess the extent to which this reaction contributed to the persistent shock and fatal outcome. Overall, the event was assessed as multifactorial shock (prolonged hypoperfusion and reperfusion, as well as hypotension in connection with an allergic TR and/or haemorrhage). The transfusion reaction itself was classified as allergic (anaphylactic), imputability possible.

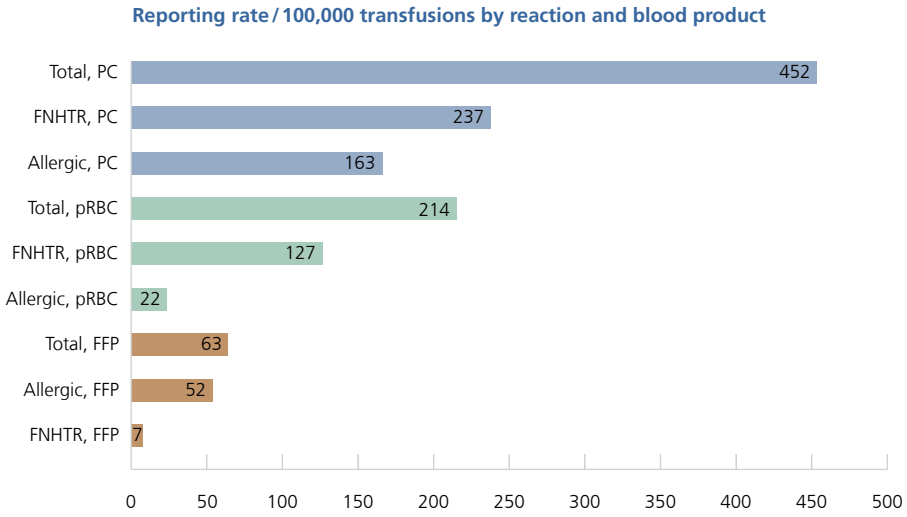
TACO: Imputability: possible

Male patient, age group >70 years with a history of advanced lung cancer, pulmonary emphysema, pulmonary fibrosis and heart disease. Since he was anaemic (Hb < 80 g/L) a unit of pRBC was transfused at a rate of > 4 ml/kg/h. After about half of the unit had been transfused, the patient experienced severe dyspnoea, tachypnoea and hypoxia (peripheral SpO2: < 60%, pre-transfusion: 81%). Clinical examination revealed a picture of acute pulmonary oedema with bubbling respiration and crackles over all lung fields. The patient was given immediate diuretic treatment and supportive measures. In view of the overall clinical situation, the treatment was not escalated (intubation/intensive medical care). A radiograph on the following day revealed, in addition to the known lung cancer, evidence of acute interstitial pneumonia and pleural effusion; the NTproBNP level was distinctly elevated (approx. 3,000 pg/ml). The initiated treatment produced temporary clinical stabilisation, but his condition subsequently deteriorated again. The patient died in the evening of the following day. An autopsy was not performed.

The acute clinical event during the transfusion met the criteria for a TACO, but the response to the diuretic treatment is difficult to assess (a transient improvement is described). The radiograph on the following day did not show pulmonary oedema (anymore?) – the patient's subsequent clinical progress should also be viewed in the context of the diagnosed pneumonia and cancer. The extent to which the possible TACO contributed to the patient's death is also difficult to establish here, and the imputability is classified as «possible».

4.3.6 Product-specific risks

Figure 11
TR rate by product type; imputability ≥ 2, all degrees of severity



Comparison of product-specific TR rates; excluding allo-AB (see text); only TR unequivocally assignable to a product type were included. pRBC: packed red blood cells, PC: platelet concentrate, FFP: fresh frozen plasma (FFPq / FFPpi).

The frequency and type of transfusion reactions vary according to the type of product. This evaluation included reports in which it was possible to assign the reaction unequivocally to a specific product type. Reactions which occurred after various types of product had been transfused were excluded, as were allo-immunisations: in most allo-immunisation reports a triggering blood product is not mentioned, or the imputability with a transfusion is not certain (e.g. in women). Allo-immunisations are therefore considered separately (cf. 4.3.7).

Transfusion of PC is associated with a high incidence of febrile and anaphylactoid reactions in the literature [6]. This picture was confirmed again in Switzerland in 2022: The transfusion of PC was associated with the highest rate of TR overall (452/100,000 transfusions), of which FNHTR (237/100,000) and allergic reactions (163/100,000) were the most common types of reaction.

The TR rate (214/100,000) for pRBC (excluding allo-AB) was slightly higher in 2022 than in 2021 (182/100,000). FNHTR (127/100,000) and allergic TR (22/100,000) were the most common types of reaction associated with pRBC too, although the incidences were lower than for PC.

The TR rate for FFP (63/100,000) was lower overall than the rates for pRBC and PC, and these mostly involved allergic reactions (52/100,000) and FNHTR (7/100,000).

4.3.7 Allo-immunisations

Allo-immunisations accounted for the bulk of the transfusion reactions with severity 2. Allo-antibody formation signifies a permanent disadvantage for the affected patients since, for example, a limited choice of compatible blood components will be available for any future transfusions, or complications could occur during pregnancy. As mentioned before, many of these reports do not state the causative blood product, or the imputability with a transfusion is not certain (e.g. allo-AB in women, which may also have been triggered by pregnancy). In view of the clinical relevance of allo-AB, we consider the totality of the reports (even if imputability was not certain). The rate of allo-AB / Tf (based on transfused pRBC and PC) was 482/100,000.

43% of the reported antibodies belong to the Rhesus/Rh system, followed by Kell antibodies, which accounted for 15%, and antibodies against the MNS system (13%) (Figure 12, Table 14). Anti-E antibodies (anti-RH3) are the most common antibodies within the Rh system, accounting for 49% (Figure 12, Table 15).

Figure 12
Allo-AB by BG system in %

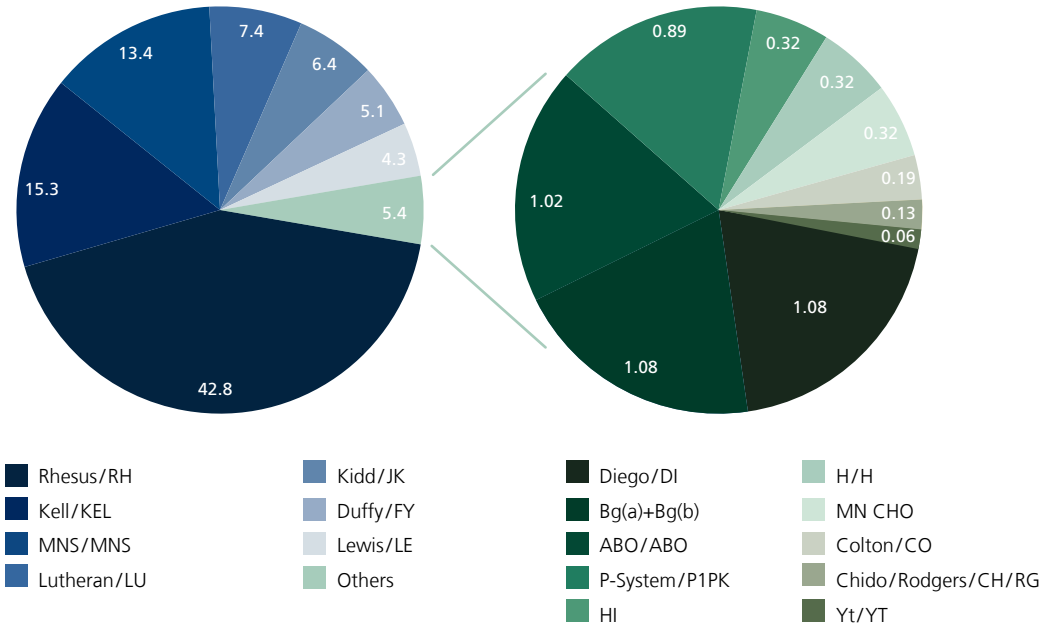


Table 14

Allo-AB reports by BG system (%)

Name (symbol)	n	%
Rhesus/RH	673	42.8
Kell/KEL	240	15.3
MNS/MNS	211	13.4
Lutheran/LU	116	7.4
Kidd/JK	101	6.4
Duffy/FY	80	5.1
Lewis/LE	67	4.3
Others	85	5.4
Total	**1573**	**100**

Name (symbol)	n	%
Diego/DI	17	1.08
Anti-Bg(a)+Anti-Bg(b)*	17	1.08
ABO/ABO	16	1.02
P-System (P1PK)	14	0.89
Anti-HI*	5	0.32
H/H	5	0.32
MN CHO	5	0.32
Colton/CO	3	0.19
Chido/Rodgers/CH/RG	2	0.13
Yt/YT	1	0.06

*According to ISBT [7] *(no data were found for these AB in the ISBT reference table)*

Figure 13
Allo-AB in the Rh system in %

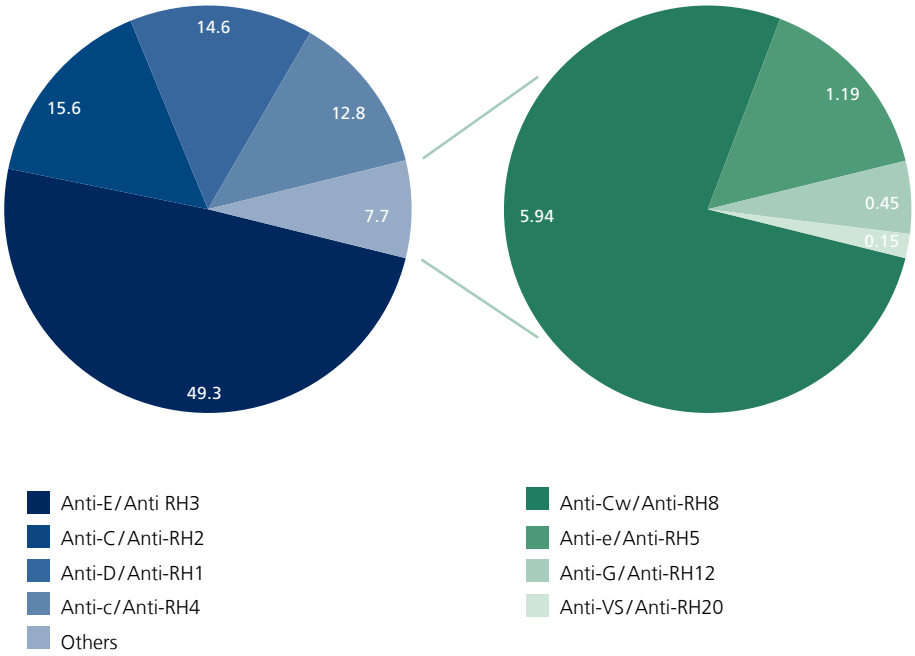


Table 15

Allo-AB in the Rh system (%)

Antibodies	n	%
Anti-E/Anti RH3	332	49.3
Anti-C/Anti-RH2	105	15.6
Anti-D/Anti-RH1	98	14.6
Anti-c/Anti-RH4	86	12.8
Others	52	7.7
Total	**673**	**100**

Antibodies	n	%
Anti-Cw/Anti-RH8	40	5.94
Anti-e/Anti-RH5	8	1.19
Anti-G/Anti-RH12	3	0.45
Anti-VS/Anti-RH20	1	0.15

5 Transfusion errors/IBCT and near misses

5.1 Definitions

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» event.

Analyses of IBCT and near misses help to identify sources of errors 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.

5.2 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.

5.3 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)[8] so that data are recorded internationally in a comparable manner. In addition to the error category (cf. Table 16), 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.

Table 16

Classification of IBCT adapted from SHOT[9]
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 (specifications 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 blood group • ABO/RhD-compatible by chance • Wrong patient (e.g. order) • 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. **If the deviation is the result of a deliberate clinical decision (e.g. because of an emergency situation), this is not an SRNM** (one exception here is the deliberate administration of Rhesus D-positive blood to Rhesus D-negative recipients in the context of a mass transfusion – this should be reported). 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.

- Alloantibodies
- 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
  – nternal quality control not available
- Deliberate Rhesus D conversion in the context of mass transfusion

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 without a shaker
- Incorrect thawing
- Incorrect giving set, unsuitable Infusomat
- Damaged product bag (quality defect?)
- Shelf life exceeded

Avoidable, delayed or under-/over-transfusion

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 values), errors in transmitting results or incorrect clinical decisions. The term also covers the avoidable use of emergency products (0 RhD neg).

Delayed transfusions: Clinically indicated transfusions which were not given or given with a relevant delay. These include, for example, the delayed provision of blood products in an emergency situation of relevant delays in patient care (e.g. postponement of a date for surgery, rescheduling an out-patient for another day).

Over-/under-transfusion: 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)

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 select in complex clinical situations, in emergencies) are not considered to be transfusion errors. The only exception here is the «Rhesus D conversion» in mass transfusions, which is considered a serious incident and reportable as such (see examples).

Table 17

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 which was not 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 products 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**. Moreover, errors in the process that lead to a blood product having to be discarded should be reported as a serious event.

WBIT: wrong blood in tube

- Label/patient do not match, discovered after receipt of the ample in the laboratory/occurring in the laboratory

Orders

- Wrong patient/wrong product/unnecessary (e.g. due to incorrect laboratory results)

Product selection/dispensing

- Wrong patient/wrong product
- Wrong product specification (cf. «SRNM»)

Relevant errors / deviations concerning:

- Product (quality defect?)
- Labelling
- Blood sample/material
- Error in result/finding

Discarded blood products

- Due to incorrect storage/handling

5.4 Severity

IBCT and near misses are also subdivided into grades of severity. As regards IBCT, a distinction is made primarily between the transfusion of a suboptimal product / incorrect transfusion procedure (usually categories SRNM, ADU, HSE) and uses by mistake (Table 18). Near misses are subdivided according to their hazard potential, and these usually involve the existence of the potential for use by mistake (Table 19).

Table 18

Severity of IBCT		
		Examples
Grade 1	Deliberate Rhesus D conversion in mass transfusion	
Grade 2	Transfusion with suboptimal prod-uct/ incorrect transfusion proce-dure	– Not irradiated / washed – Allo compatibility not considered – HLA antibodies not considered – CMV negativity – Incorrect quantity/time
Grade 3	Use by mistake occurred	– Wrong patient – Wrong product – ABO/RhD-incompatible/ABO-compatible by chance

If a transfusion error is fatal, the case is recorded as grade 4 in the transfusion reaction database and as grade 3 in the transfusion error database.

Table 19

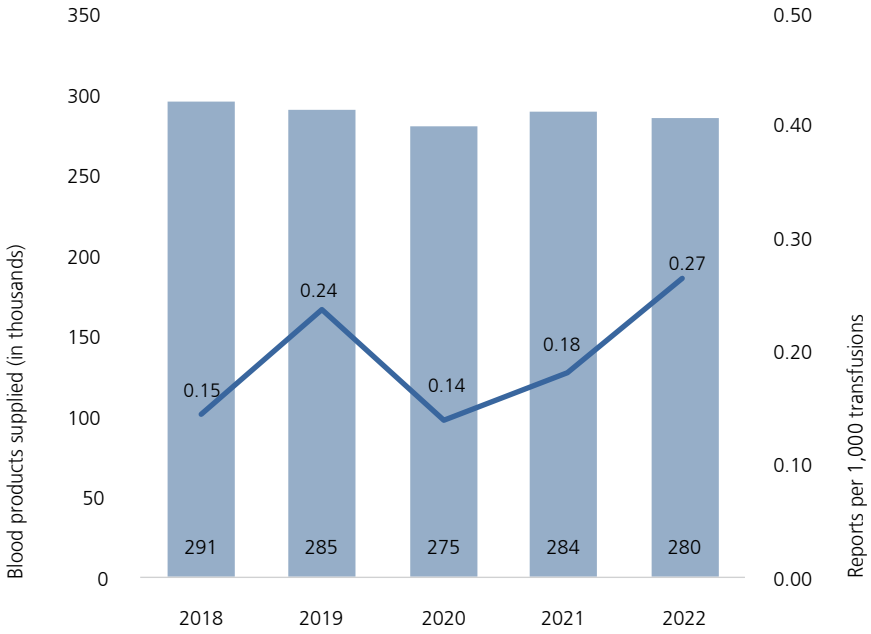
Severity of near misses (hazard potential)		
		Examples
Grade 1	Formal error **No** potential for use by mistake	– Missing initials/signature – Inadequate labelling
Grade 2	Potential for use by mistake **exists**	– Another patient's date of birth
Grade 3	Use by mistake **occurred** **Great** potential for a transfusion error	– WBIT – Discrepant BG determinations – Order for the wrong patient – Relevant error in finding

5.5 Reported data

5.5.1 IBCT: Reporting rate

There was a slight reduction in the number of blood products supplied in Switzerland for transfusions in 2022 compared with 2021 (Table 1). The reporting rate for IBCT continued to rise compared to previous years (0.27/1,000) (Figure 14).

Figure 14
IBCT reporting rate by year



5.5.2 IBCT: Subclassification

As in the previous year, SRNM account for the lion's share of reported IBCT (n=44; 59%) (Table 20). Most of the SRNM involved planned Rhesus D conversions (n=26; 59% of SRNM) and errors in taking into account the extended RBC phenotype (n=10; 23% of SRNM). The number of WCT increased both in relation to 2021 and the trend in recent years (n=14; 19% of all IBCT; 2021: n=5). There was one ABO-incompatible transfusion in 2022, and 10 transfusions were ABO/RhD-compatible by chance, representing a significant rise compared with previous years. These ABO/RhD-compatible by chance cases included three reports of mix-ups occurring during the transfusion (products tested and written up for other patients but transfused to a different patient) – however, the blood group of the patient and the product were compatible by chance. In two cases, there was a mix-up in the removal of the blood product from storage (refrigerator) (no writing on product / mix-up of product number). In one case a unit of packed red blood cells was transfused instead of a prescribed unit of platelet concentrate (prescription written for PC, order forwarded verbally by phone to the transfusion laboratory, but for a unit of

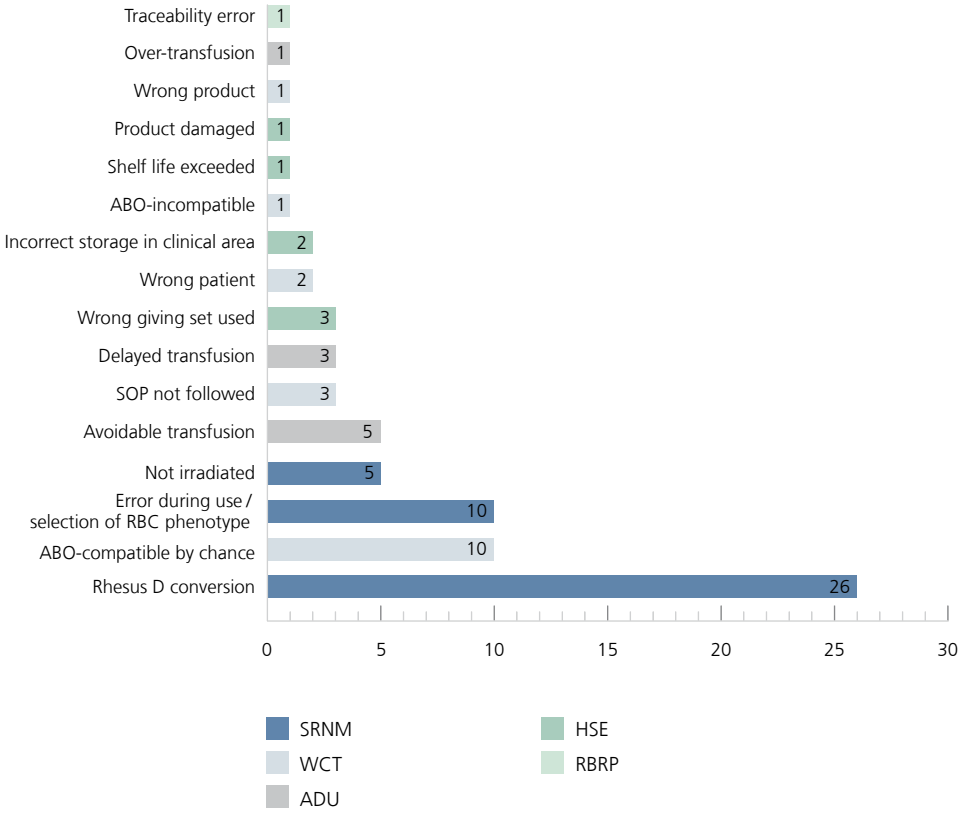
pRBC; the verbal order was carried out and the unit of packed red blood cells was supplied and transfused). Two reports concerned transfusions to the wrong patient (patient mix-up during the transfusion of a unit of PC; transfusion of patient-specific pRBC labelled blood group O neg to a different patient). Examples of IBCT reported in 2022 can be found in Table 21.

Table 20

Subclassification of transfusion errors / IBCT			
WCT	**Wrong component transfused**		**14**
	ABO-compatible by chance	10	
	ABO/RhD-incompatible	1	
	Wrong patient	2	
	Wrong product	1	
SRNM	**Specific requirements not met**		**44**
	Rhesus D conversion	26	
	Error during use/selection of RBC phenotype	10	
	Not irradiated	5	
	SOP not followed	3	
HSE	**Handling and storage errors**		**7**
	Shelf life exceeded	1	
	Product damaged	1	
	Incorrect giving set	3	
	Incorrect storage in clinical area	2	
ADU	**Avoidable, delayed or under-/over-transfusion**		**9**
	Delayed	3	
	Avoidable	5	
	Over-transfusion	1	
RBRP	**Right blood, right patient**		**1**
	Entered for wrong patient in LIS Traceability error	1	
Total			**75**

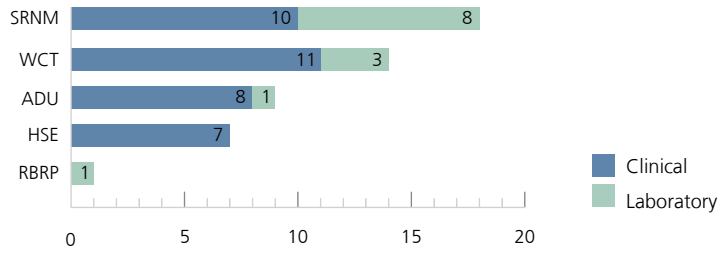
Transfusion errors were classified according to SHOT definitions [9]

Figure 15
IBCT subclassification



5.5.3 IBCT: Localisation of error

Figure 16
Localisation of IBCT (SRNM excluding Rhesus D conversions)



	Localisation by subclass				
	SRNM	**WCT**	**ADU**	**HSE**	**RBRP**
Clinical	10	11	8	7	0
Laboratory	8	3	1	0	1

The analysis of the localisation of the causes of IBCT disregarded cases with deliberate Rhesus D conversion (26 cases, cf. Table 20), since these situations did not involve an error in the process, and the instructions were followed on site.

When the other reports are viewed as a whole, the cause of IBCT was more often in the clinical area (73%); this likewise applied to the subcategories ADU and HSE. In contrast with the previous year, in 2022 the initial error for a WCT also occurred predominantly in the clinical area (79% of WCT). For the subcategory IBCT-SRNM (excluding Rhesus D conversions, see above), there was an almost balanced distribution between the clinical and laboratory areas. The initial error is recorded in the statistics, any further errors in the process (e.g. inadequate checking of an incorrect product) are not shown here.

Figure 17
IBCT – Point in Process

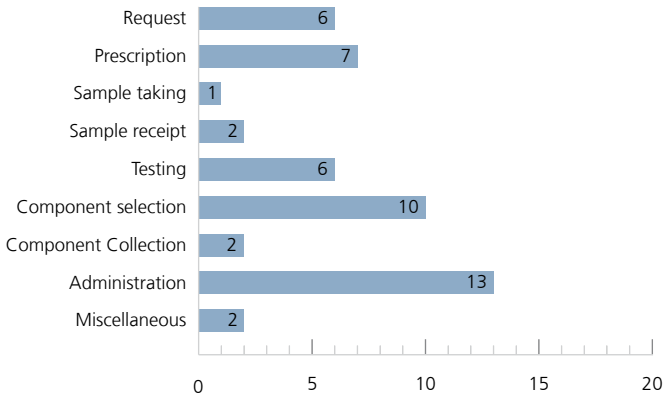


Figure 17 shows the detailed analysis of the point in the transfusion chain («point in process») where the initial error of the various IBCT occurred. The most common point in 2022 was the administration of the transfusion (n=13, 27% of IBCT); these transfusion errors included 6 IBCT-WCT (including the ABO-incompatible transfusion). The second most likely starting point in the reported transfusion errors was the product selection (laboratory/blood store) (n=10, 20% of IBCT), including four errors in the selection of the RBC phenotype. 12% (n=6) of the IBCT cases occurred at the start of the transfusion chain when the transfusion was decided, 14% (n=7) when the product was prescribed.

5.5.4 IBCT: Case studies

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

Table 21

Case studies: Transfusion errors
WCT: ABO-incompatible

Localisation of the deviation in the transfusion chain: Administration
Severity: 3
Place: Hospital
Time: Day shift

A unit of packed red blood cells was prescribed during the day shift for patient X. This was ordered and delivered to the ward. A qualified nurse was in charge of the ward and was assisted by a trainee. Because of an emergency situation on the neighbouring ward, another qualified nurse could not be called on to check the pRBC. The two-person check was therefore carried out by the nurse and the trainee in the ward office (pRBC, blood group card; BG: A RhD pos). The qualified nurse left the ward office with the pRBC. At this time patient Y pressed his bell. The nurse went with the pRBC to patient Y (patient with anaemia, but for whom no transfusion was prescribed) and started the transfusion for patient Y (blood group of pt. Y: O pos). A check to match the pRBC with the patient was not per-formed. On leaving the patient room, the nurse herself became aware of the patient mix-up and stopped the transfusion (small quantity transfused). No transfusion reaction occurred. The unit of pRBC was subsequently connected to a new transfusion giving set and patient X was transfused (note: this event was additionally listed as an IBCT-HSE).

WCT: ABO/RhD-compatible by chance

Localisation of the deviation in the transfusion chain: Blood store (dispensing)
Severity: 3
Place: Hospital, no 24h immunohaematology laboratory service. When the IH laboratory is not staffed, pRBC units are retrieved from the regular store by nurses (previously tested or, in emergen-cy situations, from an emergency store).
Time: Night shift

Patient X was admitted to the ward and a sample of blood was taken for testing. A few days later at night, an emergency transfusion of 2 units of pRBC was indicated and prescribed. Since the blood group was not determined twice, untested units of pRBC O RhD negative had to be transfused. The qualified nurse in charge on the night shift did not collect the pRBC from the emergency store (pRBC O RhD negative), but rather from the «regular» blood store (blood group O RhD positive).

Both stores were accessible, and the «regular» store did not have any access restriction. Both units of pRBC were transfused during the night. No transfusion reaction occurred, and subsequent testing showed that the products were compatible.

Notes: the patient's blood group was O RhD pos; since, at the time of the transfusion/ collection of the pRBC, no immunohaematology finding or blood group card was available, the compatibility (particular-ly with Rhesus D) had to be assessed by chance; dispensing of pRBC from the blood store (refriger-ator) is part of the blood storage, even if this was delegated here to a «user» (nurse)–the location of the error was therefore listed as «Blood store» (laboratory).

ADU: delayed

Localisation of the deviation in the transfusion chain: Laboratory
Severity: 3
Place: Hospital, 24h immunohaematology laboratory
Time: Night shift

Patient X was in haemorrhagic shock (uncontrolled bleeding) on the ICU, Hb < 50 g/l with an urgent need for transfusion; pRBC units were prescribed and ordered. Previous investigations had indicated that patient X had an alloantibody (anti-Jk(a)), and the current antibody screening test was positive. In view of the alloantibody, the dispensing of pRBC was refused by the laboratory; the laboratory technician on duty believed that the SOP did not permit the dispensing of pRBC if alloantibodies were present. The doctor treating the patient discussed this directly with the laboratory technician on duty. Even after this discussion, the dispensing of pRBC was refused, and the person in charge of the IH laboratory could not be contacted at night. Since the patient was in a life-threatening situation, he was transferred as an emergency to a central hospital, where he was transfused (time delay: several hours). The subsequent debriefing revealed that the SOP had not been interpreted correctly.

WCT: ABO/RhD-compatible by chance

Localisation of the deviation in the transfusion chain: Administration
Severity: 3
Place: Outpatient clinic
Time: Day shift

Units of packed red blood cells for several patients had been ordered in advance for outpatient trans-fusion and some of them had already been delivered to the outpatient clinic. One unit of pRBC for patient X was checked by two people in the ward office (2 nurses); the transfusion itself was then administered by a third nurse who had just arrived on shift.

She took the pRBC and started the trans-fusion for patient Y, but the patient's name and date of birth were not checked at the bedside (dissimi-lar name, different gender). The mix-up became apparent when a nurse returned from her break and noticed that the pRBC for patient X was missing. The transfusion was discontinued. Since the pRBC was compatible by chance, a transfusion reaction did not occur.

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

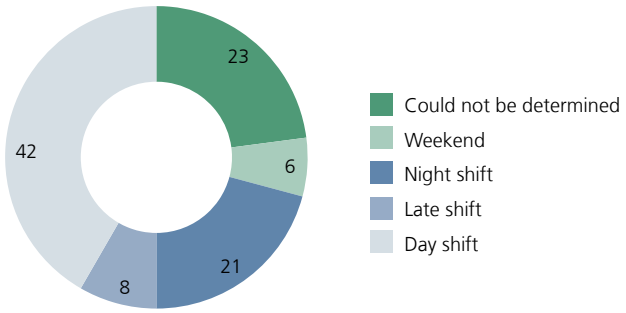
The discovery, processing and reporting of transfusion errors is a sign of a functioning quality management system – we would expressly like to thank all reporters for their commitment to improving transfusion safety. A structured incident analysis should be performed, taking all the process factors into account. 59% of the IBCT reports in 2022 identified «human error» (failure to follow an existing SOP, human error, individual error) as the main cause of the incident. While the existence and contribution of human, individual error is undeniable, it is important to consider these errors as part of (and in some cases the consequence of) existing processes and surrounding factors [10], with the aim of identifying factors that increase the likelihood of an error being made and finding options to improve safety. Activities that are only carried out rarely often involve a greater degree of uncertainty since they are not part of the daily routine. This may apply to activities that rarely arise in general, or to activities that can only be undertaken at certain times on a delegated basis. If other factors are added (e.g. night shift, reduced staffing), the risk of error is further increased. Two of the IBCT examples described occurred in such situations. It is important to identify these situations, train for them regularly and check for possible resources that could help. These could include flowcharts that provide clear overviews of certain scenarios (card, sign, etc.), technical measures (e.g. access restrictions: refrigerators (blood stores) that may not be used should be kept separate and protected against unauthorised access). Last but not least, the evaluation of the IBCT shows the importance of standardised procedures in transfusion practice that must be followed to the letter – e.g. the mandatory checking of the blood product at the patient's bedside [4].

5.5.5 IBCT: Shift work

The workload and human resources differ from one shift to another. The "Guidelines for quality assurance in transfusion practice" issued by the Swiss "Quality Assurance in the Use of Blood Products" working group recommend that transfusions should not be performed at night if possible [4].

It was possible to assign 78% of the IBCT reports in 2022 (SRNM excluding Rhesus D conversion) to a specific shift (2021: 71%). 41% of the IBCT (n=20) occurred during the day shift, 37% during other shifts or at the weekend (Figure 18). Compared to the previous year therefore, a slightly higher proportion of transfusion errors occurred during the day shift (day shift in 2021: 33%, 2022: 41%). Since no figures for the frequency with which transfusions are performed in the respective shifts are available, it is not possible to derive an error rate from this information. Considering that most activities are focused on the day shift (surgery, outpatient clinics, doctors' rounds), it is likely that more transfusions are performed during the day shift.

Figure 18
Occurrence of IBCT by shift (%)

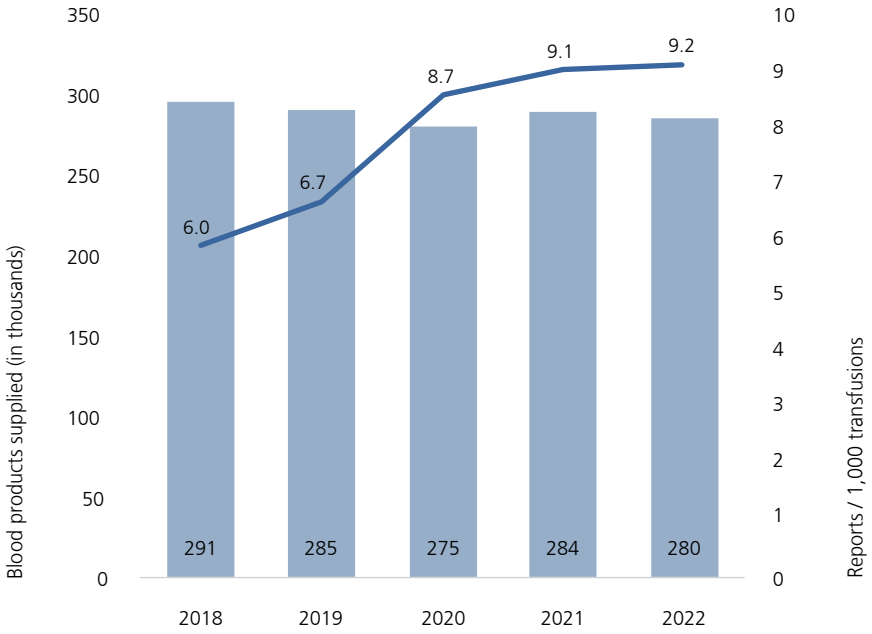


5.6 Near misses

5.6.1 Near misses: Reporting rates

The reporting rate for near misses rose slightly compared to previous years (9.2/1,000 blood products). The number of reporting centres also increased clearly compared to previous years (currently: n=71; 2021: n=47, 2020: n=44, 2019: n=54). In both points we assume that awareness is now greater and vigilance processes are being implemented more effectively at the centres.

Figure 19
NM reporting rate
by year



NM reporting rate. The reporting rate is calculated from the total number of reports per 1,000 transfusions (products supplied). The reporting rate rose slightly in 2022 (9.2 reports per 1,000 transfusions in 2022 versus 9.1 in 2021).

5.6.2 Near misses: Severity and localisation

Figure 20
NM by severity
and localisation

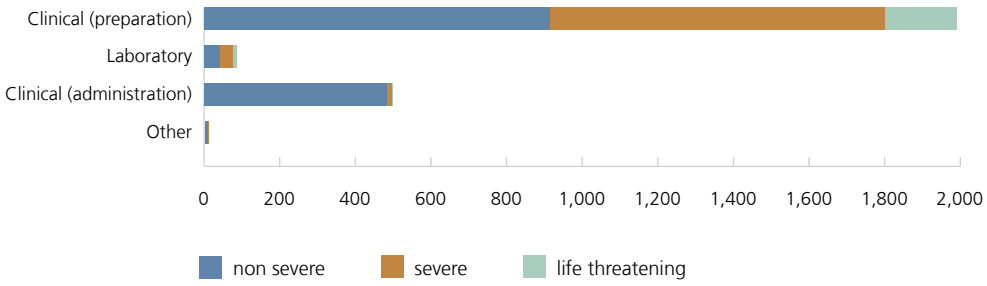


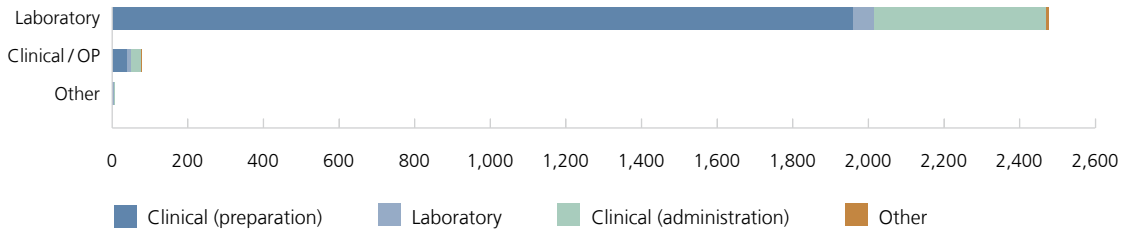
Table 22

	Near misses by severity and localisation of the deviation				
Severity	**Clinical (preparation)**	**Laboratory**	**Clinical (administration)**	**Other**	**Total**
1 Non-severe	916	43	480	7	**1,446**
2 Severe	886	32	14	2	**934**
3 Life-threatening	181	10	1	0	**192**
Total	**1,983**	**85**	**495**	**9**	**2,572**

Within the near miss reports, the proportion of non-severe events (grade 1) showed a further increase over previous years (56%; 2021: 47%) (Table 22). The majority of near misses occurred in the clinical area (preparation and administration, 96% in total). 94% of the grade 3 errors were localised in clinical preparation; this continues to represent a slightly higher proportion than in previous years.

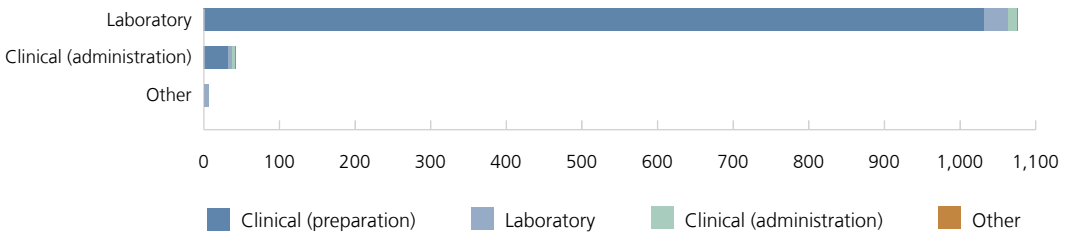
5.6.3 Discovery of near misses

Figure 21
Discovery of near misses
(all degrees of severity)



	Discovery of the error			
Localisation of the error	**Laboratory**	**Clinical / OP**	**Other**	**Total**
Clinical (preparation)	1,945	36	2	**1,983**
Laboratory	70	9	6	**85**
Clinical (administration)	468	25	2	**495**
Other	7	2	0	**9**
Total	**2,490**	**72**	**10**	**2,572**

Figure 22
Discovery of the error
(severity ≥ 2)



	Discovery of the error (severity ≥ 2)			
Localisation of the error	**Laboratory**	**Clinical / OP**	**Other**	**Total**
Clinical (preparation)	1,033	32	2	**1,067**
Laboratory	32	6	4	**42**
Clinical (administration)	11	4	0	**15**
Other	1	1	0	**2**
Total	**1,077**	**43**	**6**	**1,126**

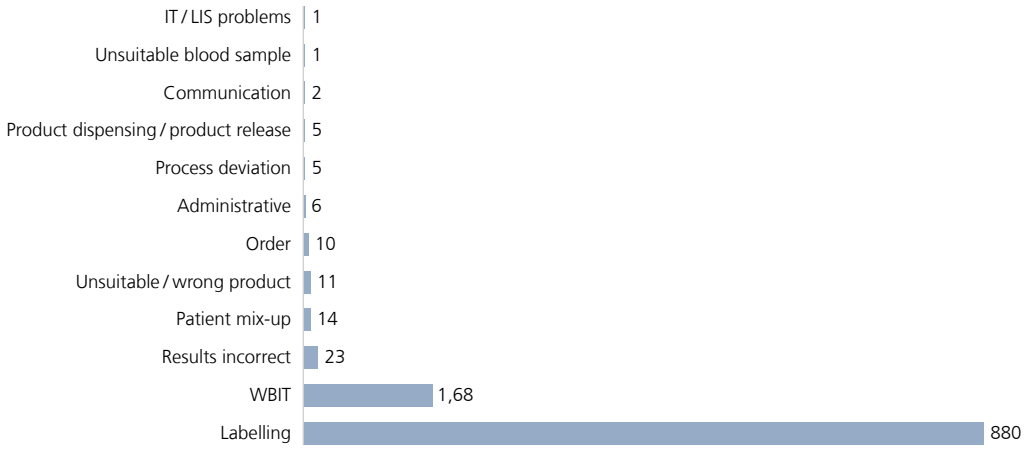
Localisation of the deviation (rows) and the localisation of the discovery of the deviation (columns). The majority of deviations are discovered in the laboratory.

97% of all near miss events were discovered in the laboratory. If the least serious events are considered on their own – i.e. events where there was a risk of mix-up (cf. Table 19) – this applied in 96% of the cases. Overall in 2022, 1,126 near misses of grades 2 and 3 were reported, corresponding to a slight decline compared to the previous year (2021: 1,363).

Near misses that were discovered in the laboratory include both cases when a blood sample was received (e.g. incorrect labelling, discrepancy between label and delivery note) and cases that were not noticed until the blood sample had been analysed (e.g. discrepancy between the blood group and previous findings in the context of WBIT). Here, the difference between the most common localisation of the error (clinical: preparation) and discovery (laboratory) illustrates the principle of sequential control (and the possibility of discovering an error) at each step of the process.

5.6.4 Near misses: Cause

Figure 23
NM (severity ≥ 2)
by cause



Incorrectly labelled blood samples account for 38% of all near misses and 78% of grade 2 or 3 near misses. These include e.g. blood samples with a discrepancy between the labelling of the blood tube and the delivery note, no labelling at all (also: barcode only), or handwritten changes on the label, which were discovered at the latest on receipt by the laboratory. These events involve the risk of a sample mix-up and, consequently, a transfusion error. They result in the need for a further blood sample to be collected – with corresponding extra work and possibly a delay in the transfusion.

The number of WBIT reports (wrong blood in tube) increased in 2022 compared to the previous year (2021: n=147; 2022: n=168). 89% of the WBIT were discovered in the laboratory; in 94% (n=158) of cases the blood collection was identified as the cause (mix-up of the patient or blood sample with wrong labels). In one case involving a pair of twins, the patient case was recorded under the twin brother and, as a result, incorrect labels for the blood sample were printed (emergency consultation). In four reported cases, there was a mix-up in the assignment / relabelling in the laboratory (mix-up in entry in the LIS, mix-up in the labelling of the analysis tubes). Also worth mentioning are three WBIT cases that were most likely attributable to identity theft (discrepancy in blood groups with repeated confirmation in each case as well as further suspicious factors locally) – the cause in these cases was not considered to lie primarily in the transfusion chain, but these cases were nevertheless listed as near misses because of the risk of a transfusion error.

In the absence of previous determinations in the same laboratory or a blood group card, WBIT can result in an ABO-incompatible transfusion and must be viewed especially critically. They underpin the need for the blood group to be determined twice from different blood samples. They also support the recommendation, even in emergency situations, to establish the ABO blood group only if the results of two independent blood group determinations, including a current confirmation, are available [11].

5.6.5 Near misses: Case studies

In the same way as reporting transfusion errors, reporting near misses is useful in analysing errors and should help to make the transfusion process safer. Errors are part of any real-life work situation, and the fact that they are discovered and followed-up is indicative of a functioning quality assurance process. The following case studies have been chosen by way of example and describe situations in which deviations occurred at very different places in the transfusion chain, but were still always discovered. Possible contributory factors are mentioned in these case studies. These are not conclusive but should be viewed as food for thought.

Table 23

Near misses
WBIT

Localisation of the deviation in the transfusion chain: Clinical/preparation
Severity: 3
Discovery of the discrepancy: check before transfusion

Patient X was to be transfused in a nursing home and the corresponding blood samples were collected (test blood) from this patient. However, labels from patient Y were affixed to the sample tubes. Since patient X had difficult vein conditions, the sample had to be collected by two nurses. Patients X and Y had the same last names and very similar first names with different dates of birth (same decade), and the incorrect labelling was not noticed during sample collection. The transfusion laboratory tested the blood (of patient X) and labelled the pRBC unit as being for patient Y in accordance with the labelling of the sample tubes and request form. When the pRBC was received in the nursing home, the staff noticed that no transfusion had been prescribed and no pRBC ordered for patient Y. Therefore, the mix-up was noticed, the pRBC unit was destroyed and a new blood sample was collected.

Contributory factors: Name similarity, distraction (concentration on the vein situation), known patients

WBIT

Localisation of the deviation in the transfusion chain: Clinical/patient recording
Severity: 3
Discovery of the discrepancy: Patient

Patient X was brought to the emergency department by paramedics. In accordance with the prior notification by the paramedics, a patient case was opened in the ED; this case was created under the known patient Y (same first and last names, day and month of birth identical, only the year of birth was different (same decade)). The first laboratory investigations, including a blood test, were created under this case, and a sample was identified with the corresponding labels and sent to the IH laboratory. The mix-up was discovered in the emergency department, and the laboratory, but not the immunohaematology laboratory (separate LIS), was informed. The IH tests were therefore car-ried out on the sample identified as patient Y and the results were saved under this name. A transfu-sion was not required. The error was discovered when patient Y received an invoice for the test but was unable to understand what had happened (no hospital stay at this time).

Contributory factors: Emergency situation, heavy workload, oral forwarding of information, name similarity, lack of interface with the transfusion laboratory (for forwarding information)

Product mix-up

Localisation of the deviation in the transfusion chain: Clinic/administration
Severity: 3
Discovery of the discrepancy: Clinical/Op

Planned intervention (early morning) in a patient with a clotting disorder and requiring the transfusion of platelets and plasma prior to the intervention. On the day before the intervention, a prescription was written on the ward for one unit of platelet concentrate and two units of FFP for the next day. However, only the order for the platelet concentrate was sent to the transfusion laboratory. During the night, a unit of PC was therefore dispensed and transfused, and the night shift nurses believed that this was a unit of FFP and confirmed the transfusion of a prescribed unit of FFP in the electronic medical history (no interface between the IT systems). During the preoperative checking of the pa-tient's medical history (anaesthesia, Op), the staff noticed that the patient was not transfused as prescribed (only one unit of FFP according to the medical history). The anaesthetist contacted the ward and transfusion laboratory. As a result of the differing details in the laboratory and medical his-tory, the investigations took time and the intervention had to be delayed. The mix-up was finally re-solved, and the patient was given two units of FFP before the intervention.

Contributory factors: Night shift; rare administration of transfusions on the ward/ lack of experience with blood products; use of abbreviations on prescriptions and on product labels; lack of interface between clinical information system and transfusion laboratory

5.6.6 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.

In 2022, n=464 discarded products were reported (2021: n=210) – we consider this to be due to improved reporting compliance. Table 24 presents the reasons for the discarding of products for the reported events. In all cases, the table shows the main reason resulting in the product being discarded as stated by the reporter. 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 products had to be discarded, but for which no background information was provided, are listed under the corresponding storage problem (e.g. «Temperature monitoring»). There was no double counting of reports (e.g. «Cancellation» and «Cold chain interrupted»). The reports are intended to give an overview of common causes of discarded blood products in Switzerland and help identify possible areas for improvement.

Table 24

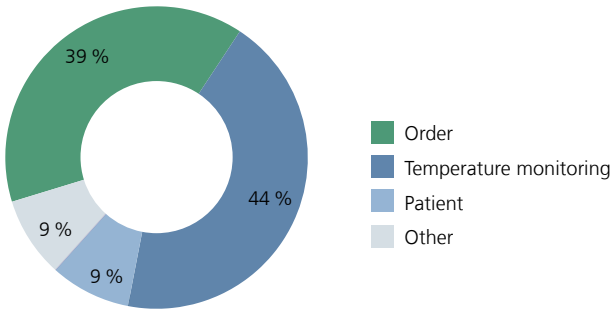
Causes of discarded blood products – storage and handling		
Orders / modified requirement		**181**
Cancellation	116	
Mass transfusion	19	
Emergency situation	31	
Order not collected (thawed FFP)	12	
Wrong product ordered	3	
Temperature monitoring		**203**
Cold chain interrupted	121	
Temperature monitoring available: defective (e.g. technical error of the temperature logger/forgotten)	50	
Incorrect storage outside the blood store (e.g. outside the refrig-erator, unmonitored refrigerator)	32	
Patient-related reasons		**40**
Patient febrile	7	
Venous access not possible	2	
Patient died	26	
Patient refuses transfusion	5	
Other		**40**
Information unclear/wrong (transfusion would have been possi-ble)	2	
Storage error in the blood store	1	
Product defective/incorrect handling (e.g. error when piercing the product, material defect, clot in FFP)	28	
Product expired	7	
Pneumatic tube error	2	
Total		**464**

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 platelet concentrates. The use of certified transport boxes or temporary storage in certified refrigerators (if the need is unclear) can help here in the ability to continue using more products.

In 116 events, the prescription of a blood product after it was dispensed by the transfusion laboratory was cancelled or someone had forgotten to forward the cancellation; in a further 12 cases, ordered (and correspondingly thawed) units of FFP were not collected for use. Both of these facts underline the importance of good communication between the user and transfusion laboratory/blood store. Possible areas for improvement here (apart from the controlled transport of products mentioned above) include structured processes / training, but also the use of digital resources (interfaces between the clinical area and transfusion laboratory, digital forwarding of a cancellation).

Separately recorded are clinical situations in which the transfusion requirement is very difficult to estimate in advance (mass transfusions, emergency situations; n = 50) and sufficient blood products are ordered in order to ensure best patient care. In these cases, the storage can be reviewed so that, if applicable, products can be returned to the blood store – particularly since these cases often involved pRBC of blood group O RhD negative.

Figure 24
Discarded blood products – storage and handling (%)



As a result of rounding, the percentages do not always add up to 100%

6 Donor reactions

6.1 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.

6.2 Classifications

Swissmedic classifies donor reactions using the classification developed by the Donor Haemovigilance working group of the ISBT, IHN and AABB in 2014 [12]. 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 (Table 25 and Table 26); in addition, imputability between donation and incident is evaluated (similarly to imputability in TR, cf. Table 7, section 4.2). A detailed classification is provided on the Swissmedic website (https://www.swissmedic.ch/swissmedic/en/home/humanarzneimittel/market-surveillance/haemovigilance.html: Forms/Classification).

Table 25

Classification of donor reactions (after ISBT [12])	
A	Local symptoms
B	Generalised symptoms/vasovagal circulatory reactions
C	Specific adverse effects related to apheresis
D	Allergic reactions
E	Other cardiovascular reactions
F	Other severe reactions

Table 26

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**

6.3 Reported data

In contrast to previous years, since 2021 Swissmedic has published the data not only for serious donor reactions and reactions notified in individual reports, but also for incidents classified as non-serious (grades 1 and 2), which are notified in collective reports. This change has been made in the interest of transparency in donor vigilance and is intended to facilitate international comparison.

A total of 3,508 donor reactions (whole blood and apheresis donations) were reported (Table 27). At 62%, and as in the previous year, vasovagal and circulatory symptoms accounted for the largest proportion of all reactions (Figure 25). 92% (n=3,211) of the incidents involved mild symptoms (mainly local symptoms or low-grade vasovagal reactions without injury or need for treatment). Ten incidents were classified as serious (grade 3), all involving whole blood donations; numerically speaking, this is the same order of magnitude as in previous years (Table 28). Six of these serious incidents were vasovagal circulatory reactions requiring emergency treatment (consequences of a fall or prolonged recovery). In one incident, severe bruising occurred at the puncture site (patient attended the emergency department the following day due to paraesthesia). Three incidents were classified as cardiovascular side effects, including angina symptoms during the blood donation and the occurrence of an ischaemic cerebrovascular accident on the day following a donation. One donor suffered a cardiac arrest and was briefly resuscitated during a blood donation; he regained consciousness and recovered completely from the incident while still in the blood donation centre; asystole as a result of a severe vagal reaction was considered as a possible explanation. All three individuals with cardiovascular incidents were repeat donors.

Overall, three of the ten incidents affected first-time donors (all vasovagal reactions), two affected donors were over 65 years of age (both cardiovascular incidents).

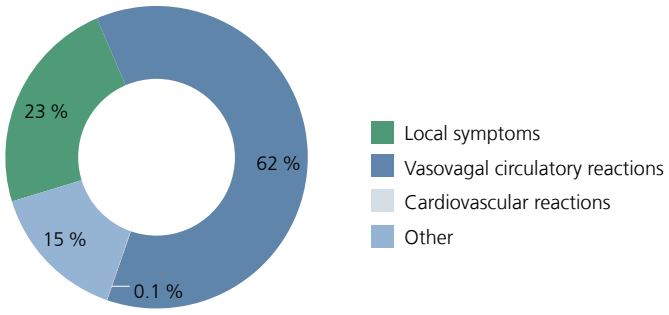
In relation to the total number of donors (total: 265,215; whole blood: 248,316; apheresis: 16,899), serious donor reactions in whole blood donors occurred with a frequency of 0.4/10,000 donors (no incident in apheresis donors in 2022 (2021: 0.6 /10,000 donors). These numbers are low and at a level comparable to that recorded in international donor haemovigilance data [13, 8].

Table 27

Donor reactions (total figures) 2022

Severity	Grade 1	Grade 2	Grade 3	Total
A Local symptoms	768	47	1	**816**
B Vasovagal circulatory reactions	1,937	224	6	**2,167**
C Specific adverse effects related to apheresis	197	14	0	**211**
D Allergic reactions	2	0	0	**2**
E Other cardiovascular reactions	0	0	3	**3**
F Other severe reactions	307	2	0	**309**
Total	**3,211**	**287**	**10**	**3,508**

Figure 25
Donor reactions in 2022



Vasovagal circulatory reactions are the most common adverse reaction.

Table 28

Grade 3/4 donor reactions in the last five years					
	2018	2019	2020	2021	2022
Local symptoms	1	2	0	0	1
Vasovagal circulatory reactions	15	18	12	6	6
Other	1	2*	2	2	3
Total	**17**	**22**	**14**	**8**	**10**

** of which one grade 4*

7 Protective measures/Quality defects

7.1 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). Furthermore, everyone involved in the transfusion chain is obliged to report quality defects in blood products (Art. 61 paras. 6 and 7 TPO and Art. 63 para. 1 let. c TPO).

7.2 Incidents during manufacture that must be reported

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.

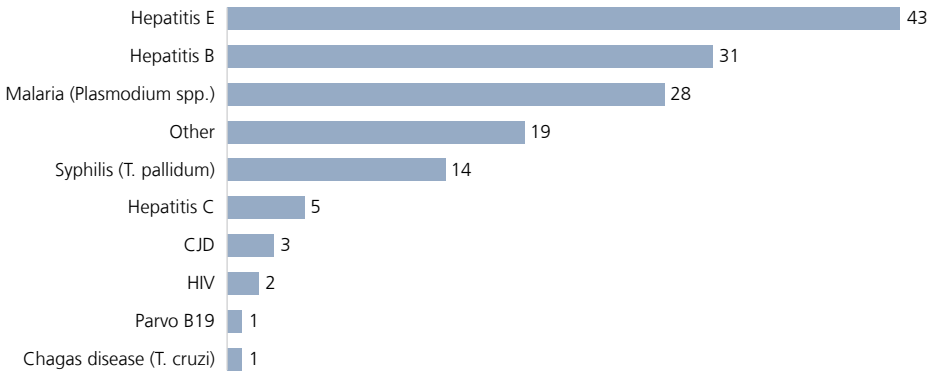
Generally speaking, a quality defect is considered to be present if a therapeutic product displays characteristics which do not correspond to the specifications authorised by Swissmedic, if manufacture is not compliant with the rules of Good Manufacturing Practice (GMP/GMG), or if new findings concerning the quality of the medicinal product emerge which could endanger the health of humans or animals. The same also applies to blood products. Further information and examples of the reporting of quality defects in labile blood products can be found on our website.

7.3 Reported data

7.3.1 Protective measures/Quality defects: total

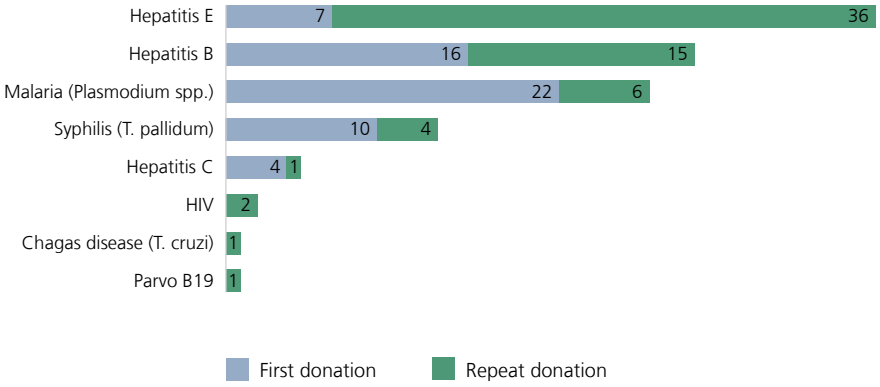
In 2022, a total of 146 reports were received concerning defects and corresponding protective measures (Figure 26). 138 of these reports involved infection markers which had tested positive (hepatitis E, hepatitis B, hepatitis C, HIV, Treponema pallidum, Plasmodium spp.). Three reports involved individuals who had contracted Creutzfeldt-Jakob disease and had donated blood in the past. The rest of the reports ("Other") were related to quality defects (n=4; including deviations in the authorisation for blood donation) and incidents in which a donor reported a SARS-CoV-2 infection after the blood donation (known as post-donation information).

Figure 26
Protective measures and quality defects in 2022



7.3.2 Protective measures / Quality defects: Infection markers

Figure 27
Positive infection markers in first-time or repeat donors in 2022



Infection markers									
Donation	**HEV**	**HBV**	**Malaria**	**Syphilis**	**HCV**	**HIV**	**T. cruzi**	**Parvo B19**	**Total**
First donation	7	16	22	10	4	0	0	0	**59**
Repeat donation	36	15	6	4	1	2	1	1	**66**
Total	**43**	**31**	**28**	**14**	**5**	**2**	**1**	**1**	**125**

As in the previous year, the most frequently detected infection marker in donors was hepatitis E, although the absolute number declined in absolute terms compared to 2021 and was back to the 2020 level (2021: n= 63, 2022: n= 43), followed by hepatitis B. The positive results for Plasmodium spp. (malaria) predominantly involved diagnostic blood samples from volunteer donors with a corresponding risk history.

7.4 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 B-CH coordinating office and performed using algorithms specific to each infection.

7.4.1 Donor-related look-backs

Table 29

Donor-related look-backs in 2022

Infection markers	Case reports	Transfusion-related infections diagnosed	Ongoing
HIV	2	0	1
HBV	14	0	2
HCV	1	-	1
HEV	1	0	0
Malaria	1	-	1
Chagas disease	1	-	1

Donor-related look-back CJD: cf. text

24 donor-related look-backs were performed in 2022 (Table 29). No diseases transmitted by a blood product were identified. Six look back procedures are not yet concluded at this time. In addition, three donor-related look-backs were performed for three donors who contracted Creutzfeldt-Jakob disease (CJD) (blood donated before onset of the disease). It is not possible to screen (test blood) for this prion disease, there is no indication of transmission.

7.4.2 Patient-related look-backs

No patient-related look-back procedures were performed in 2022

swissmedic

8 Abbrevations

°C	degrees Celsius
AB	antibodies
ABO	ABO blood group system
ADU	avoidable, delayed or under/overtransfusion
Ag	antigen
Allo-AB	alloantibodies
AR	Annual Report
Art.	Article
BD/BTS	blood donation/blood transfusion service
BG	blood group
CH	Switzerland
CJD	Creutzfeldt-Jakob disease
e.g.	for example
F	female
FFP	fresh frozen plasma
FFPq	fresh frozen plasma, quarantined
FFPpi	fresh frozen plasma, pathogen-inactivated
FNHTR	febrile non-haemolytic transfusion reaction
h	hour
HBV	hepatitis B virus
HCV	hepatitis C virus
HEV	hepatitis E virus
HIV	human immunodeficiency virus
HLA	human leukocyte antigen
HSE	handling and storage errors
HTR	haemolytic transfusion reaction
HV	haemovigilance
i.e.	in other words
IBCT	incorrect blood component transfused
ID	identification
ISBT	International Society of Blood Transfusion
IT	information technology
let.	letter
M	male
MPLO	Medicinal Products Licensing Ordinance
n	number
NM	near miss(es)
para.	paragraph
PC	platelet concentrates (PCa: apheresis-derived; PCb: whole blood-derived)
pRBC	packed red blood cells
PTP	post-transfusion purpura
RBRP	right blood, right patient
Rh	rhesus
RPHv	Responsible Person for Haemovigilance
SHOT	Serious Hazards of Transfusion (United Kingdom's haemovigilance scheme)
SOP	standard operating procedure
SRC	Swiss Red Cross
SRNM	specific requirements not met
T&S	type and screen (to define blood group and detect irregular antibodies)
T. cruzi	Trypanosoma cruzi (causative agent in Chagas disease)
TACO	transfusion-associated circulatory overload
TAD	transfusion-associated dyspnoea
Ta-GvHD	transfusion-associated graft versus host disease
Tf	transfusion
TPA	Therapeutic Products Act
TPO	Therapeutic Products Ordinance
TR	transfusion reaction
TRALI	transfusion-related acute lung injury
TTI	transfusion transmissible infections
WBIT	wrong blood in tube
WCT	wrong component transfused
AI	Appenzell Innerrhoden

AR	Appenzell Ausserrhoden
BE	Berne
BL	Basel-Land
BS	Basel-Stadt
FR	Fribourg
GE	Geneva
GL	Glarus
GR	Graubünden
JU	Jura
LU	Lucerne
NE	Neuchâtel
NW	Nidwalden
OW	Obwalden
SG	St. Gallen
SH	Schaffhausen
SO	Solothurn
SZ	Schwyz
TG	Thurgau
TI	Ticino
UR	Uri
VD	Vaud
VS	Valais
ZG	Zug
ZH	Zurich

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