swissmedic

Haemovigilance
Annual Report 2023

swissmedic

Credits

Publisher
Swissmedic, Swiss Agency for Therapeutic Products
Inspectorates and Licences Division
Inspection Management and Blood Surveillance
Hallerstrasse 7
3012 Bern
Switzerland
haemovigilance@swissmedic.ch
haemovigilance.swissmedic@hin.ch
https://www.swissmedic.ch/haemovigilance

Editors / contacts
René Bulter, Subject Specialist
Julia Engels, Vigilance Assessor
Justine Brodard, Vigilance Assessor

Layout and typesetting
Swissmedic, Communication Division

ISSN 2813-3013

swissmedic

Haemovigilance
Annual Report 2023

Evaluation of haemovigilance reports in 2023

swissmedic

List of contents

Editorial **5**

1 Introduction **6**

2 Number of transfusions and reporting rates **8**
2.1 Number of transfusions 8
2.2 Reporting numbers and rates 8
2.3 Reporting rates: Major regions 10

3 Transfusion reactions **13**
3.1 Background 13
3.2 Reported data 15
3.2.1 Transfusion reactions: Reporting rate 15
3.2.2 Transfusion reactions: Age groups and gender 18
3.2.3 Transfusion reactions: Imputability 19
3.2.4 Transfusion reactions: Life-threatening and fatal events 19
3.2.5 Product-specific risks 23
3.2.6 Allo-immunisations 24

4 Serious incidents **27**
4.1 Background 27
4.2 IBCT 34
4.2.1 IBCT: Reporting rate 34
4.2.2 IBCT: Subclassification 34
4.2.3 IBCT: Localisation of error 36
4.2.4 IBCT: Case studies 37
4.3 Near misses 41
4.3.1 Near misses: Reporting rates 41
4.3.2 Near misses: Localisation and discovery 42
4.3.3 Near misses: Type of error 43
4.4 Localisation of error in the transfusion chain (point in process) 44
4.5 Further evaluations 45
4.6 Discarded blood products – incorrect storage and handling 47

5 Donor reactions **49**
5.1 Background 49
5.2 Reported data 50

6 "Protective measures" in case of infections **52**
6.1 Background 52
6.2 Reported data 52
6.2.1 Protective measures: Total 52
6.2.2 Protective measures: Infection markers 53
6.3 Look-back procedures 55
6.3.1 Donor-related look-backs 55
6.3.2 Patient-related look-backs 55

7 Abbreviations **56**

8 List of figures **57**

9 Bibliography **59**

swissmedic

Editorial

Although blood usage in Switzerland is falling steadily, the complexity of processes and the associated challenges are increasing. Since the introduction of the haemovigilance reporting requirement in 2002, the number of reports has grown constantly, showing that acceptance of the reporting system is good and that it is being used. This in turn is a sign of the strong awareness of the importance of haemovigilance. We are very pleased by this!

As an independent authority, Swissmedic plays a fundamental role in maintaining a functioning national blood transfusion service. Haemovigilance reports provide us with important data and findings, enabling further improvement of transfusion safety and application of scientifically founded donation criteria. In 2023, for example, this was possible with the approval of a proposal to standardise donation criteria, irrespective of sexual orientation. The careful selection of blood donors will remain a key pillar of blood safety in the future, not least due to the increasing prevalence of tropical pathogens.

Swissmedic's message to everyone involved in the transfusion chain remains the same: Reporting of transfusion reactions, quality defects and side effects experienced during donation continues to be important. The findings from transfusion errors and near misses also represent an established, progressive approach to dealing with errors for the benefit of patient safety. Errors can happen, but we should learn from them!

Digital transformation will help to simplify the complex processes along the transfusion chain and fulfilment of the obligation to report, thereby also optimising the efficiency of transfusion safety monitoring. We are happy to take on this challenge because we hope that it will bring major improvements for all concerned, not least the patients who require blood products.

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.

Christian Schärer, Head of 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.

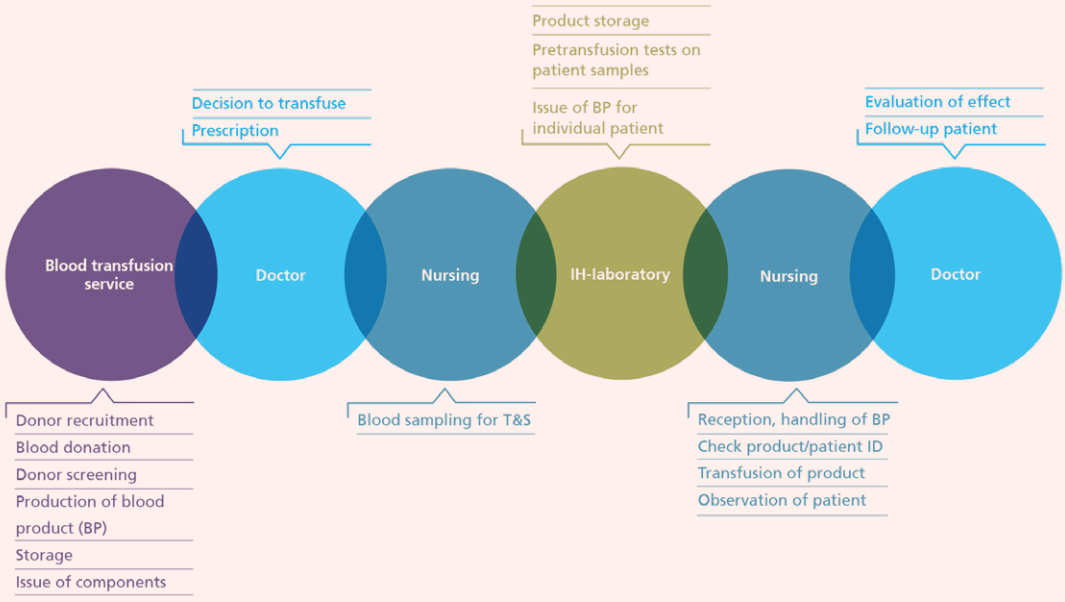
National haemovigilance system

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 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 underreported. 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 2023, a total of 275,795 blood products were supplied for transfusion in Switzerland, representing a 1.6% decline compared with 2022. The declining overall trend is therefore continuing (2020 is to be seen as an exception due to the COVID-19 pandemic) (Table 1). The transfusion figures are based on the number of blood components supplied as shown in the annual statistics of 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 by year

Number of transfusions in Switzerland 2019–2023					
Blood product	**2019**	**2020**	**2021**	**2022**	**2023**
pRBC	220,481	212,947	217,049	214,197	211,546
PC	36,317	35,715	38,898	39,182	40,112
FFP	28,405	26,681	27,765	26,917	24,137
Total	**285,203**	**275,343**	**283,712**	**280,296**	**275,795**

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

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

2.2 Reporting numbers and rates

In 2023, Swissmedic received a total of 4,909 haemovigilance reports relating to transfusion reactions (TR) and transfusion errors (IBCT/near misses) and a further 3,421 reports of donor reactions (incl. collective reports) and protective measures (Table 2). The statistics include reports received by the end of February 2024 the latest; later reports will be included in the statistics for 2024.

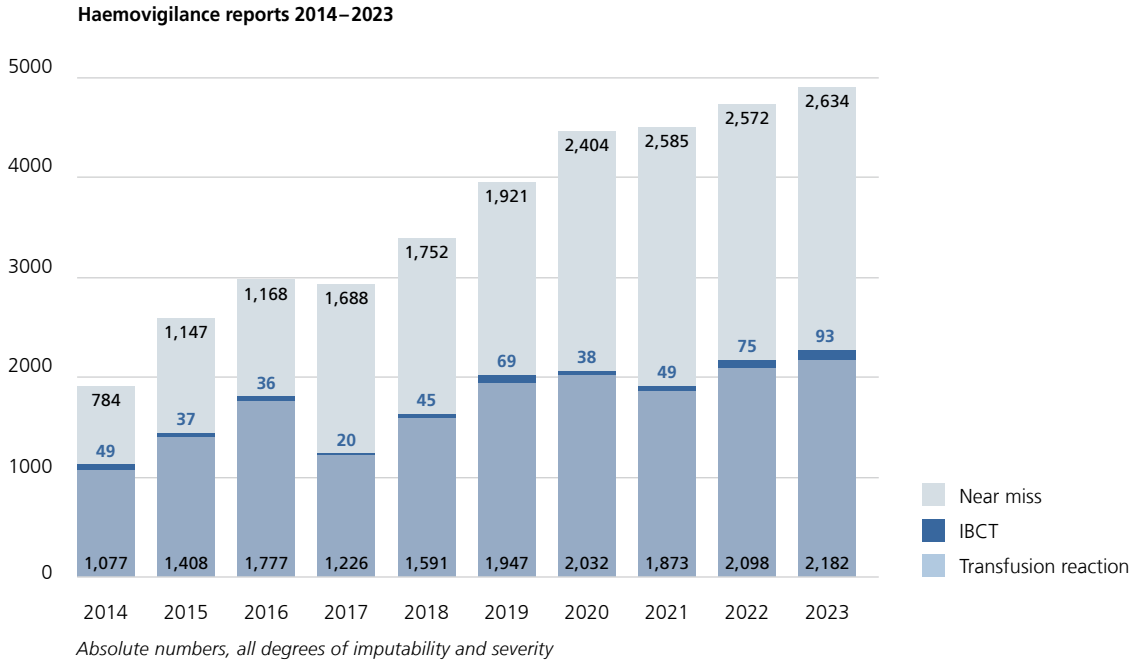
Table 2
Haemovigilance reports: Total numbers

Haemovigilance reports: Total numbers for 2023	
Type	**Number of reports**
Transfusion reactions (TR)	2,182
Near misses (NM)	2,634
Transfusion errors/incorrect blood component transfused (IBCT)	93
Protective measures	238
Donor reactions*	3,183

** Publication of data reported for donor reactions modified from 2021, individual and collective reports included*

In 2023, 4.0% more TR and 24% more transfusion errors were reported than in 2022. The number of near misses also increased during the previous years.

Figure 1
Haemovigilance reports by year

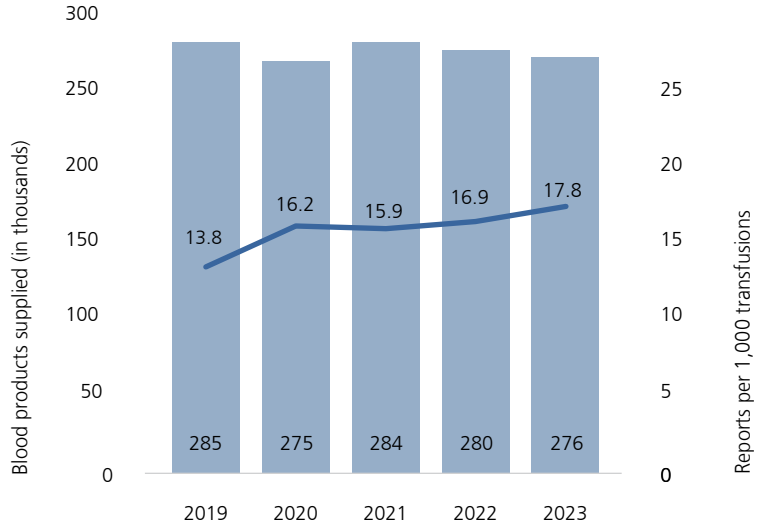


Absolute numbers, all degrees of imputability and severity

Swissmedic calculates the reporting rate per 1,000 transfusions (Tf) on the basis of the total number of reports. The total reporting rate rose slightly in 2023 compared with 2022 (17.8/1,000 Tf in 2023 compared with 16.9/1,000 Tf in 2022), with a slight increase in the reporting rate for transfusion reactions and IBCT (details are given in the corresponding section).

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

Reporting rate for haemovigilance reports 2019–2023



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

2.3 Reporting rates: Major regions

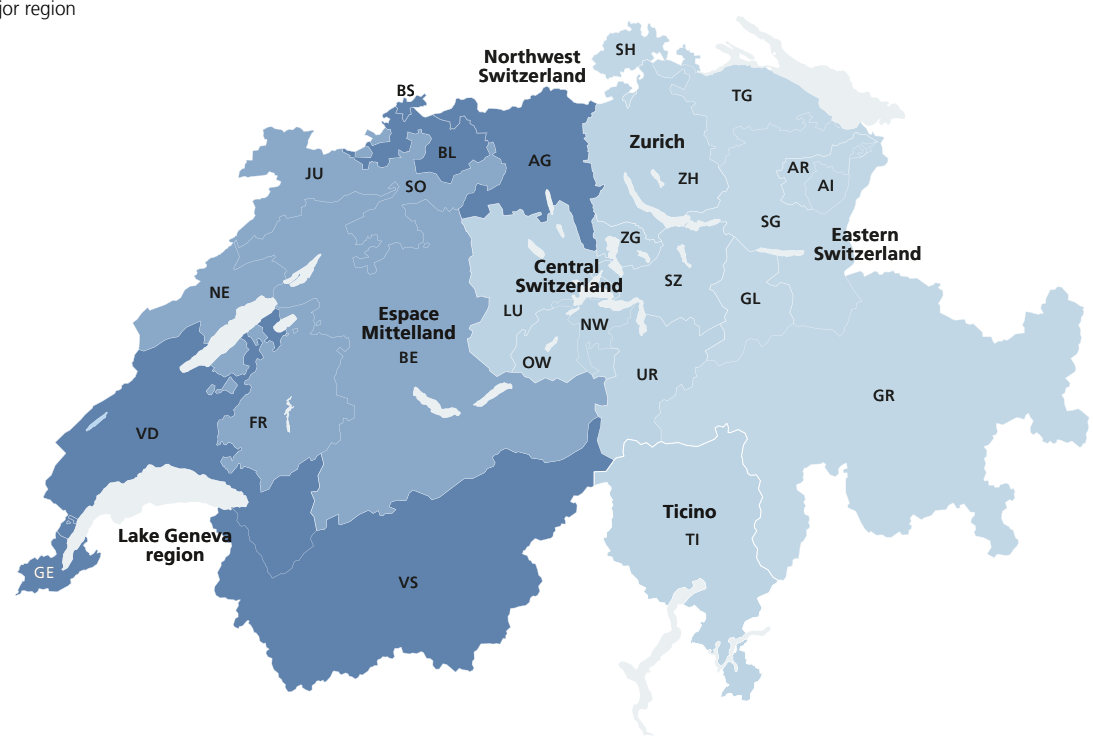
There are relevant fluctuations in the regional reporting rates for the different events based on the number of inhabitants (events reported per 100,000 inhabitants). The absolute reporting rates and reporting rates per 100,000 inhabitants for transfusion reactions and serious incidents (transfusion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

Table 3
Reports of transfusion reactions: Distribution by major region

Transfusion reactions by major region in 2023

		Reports in absolute numbers		Reports per 100,000 inhabitants	
Major region	**Canton**	**Total**	**excluding allo-AB**	**Total**	**excluding allo-AB**
Lake Geneva region	GE, VD, VS	435	249	25.6	14.6
Espace Mittelland	BE, SO, FR, NE, JU	661	163	34.4	8.5
Northwest Switzerland	BS, BL, AG	666	192	55.4	16.0
Zurich	ZH	102	95	6.5	6.0
Eastern Switzerland	SG, TG, AI, AR, GL, SH, GR	78	57	6.4	4.7
Central Switzerland	UR, SZ, OW, NW, LU, ZG	199	43	23.7	5.1
Ticino	TI	40	27	11.3	7.6

Figure 3
Reports of transfusion reactions: Distribution by major region



Per 100,000 inhabitants, excluding allo-antibodies

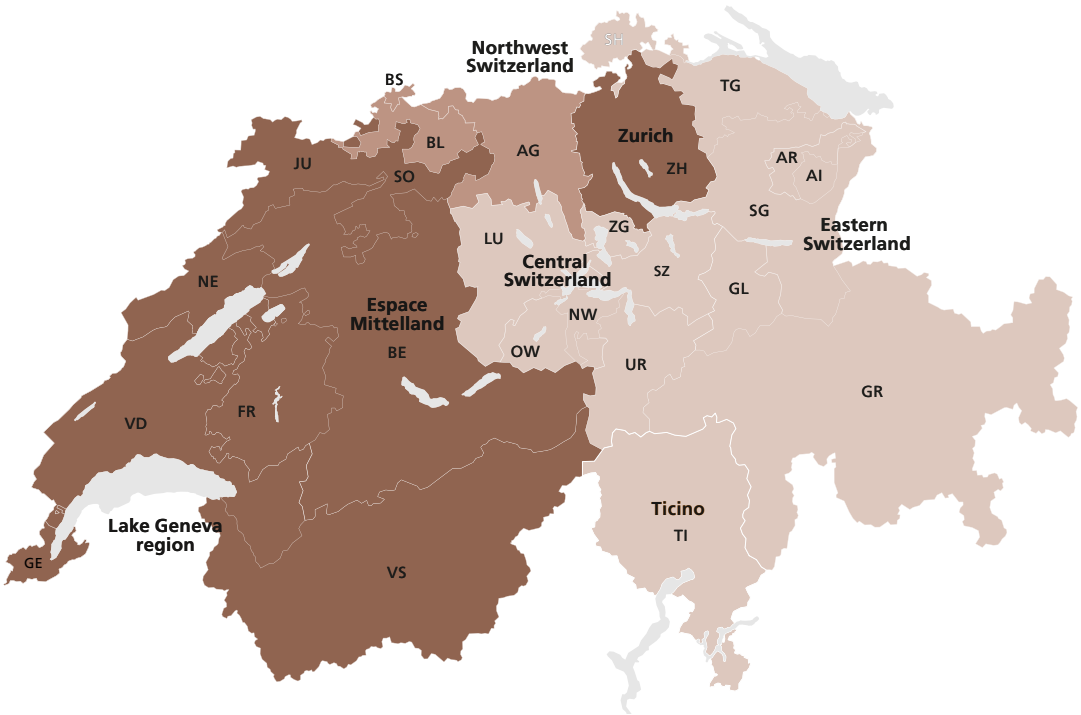
Map Major Regions of Switzerland © BFS, ThemaKart, Neuchâtel 2020

swissmedic

Table 4
Reports of serious incidents: Distribution by major region

Serious incidents by major region in 2023			
Major region	**Canton**	**Reports in absolute numbers**	**Reports per 100,000 inhabitants**
Lake Geneva region	GE, VD, VS	778	45.7
Espace Mittelland	BE, SO, FR, NE, JU	788	41.1
Northwest Switzerland	BS, BL, AG	162	13.5
Zurich	ZH	866	54.8
Eastern Switzerland	SG, TG, AI, AR, GL, SH, GR	58	4.8
Central Switzerland	UR, SZ, OW, NW, LU, ZG	53	6.3
Ticino	TI	16	4.5

Figure 4
Reports of serious incidents: Distribution by major region



Per 100,000 inhabitants

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 severity 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 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 according to its probability in a similar way to the ISBT criteria*[a]. Cases for which the information is not available or is insufficient are classified as "not evaluable".

Imputability

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

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

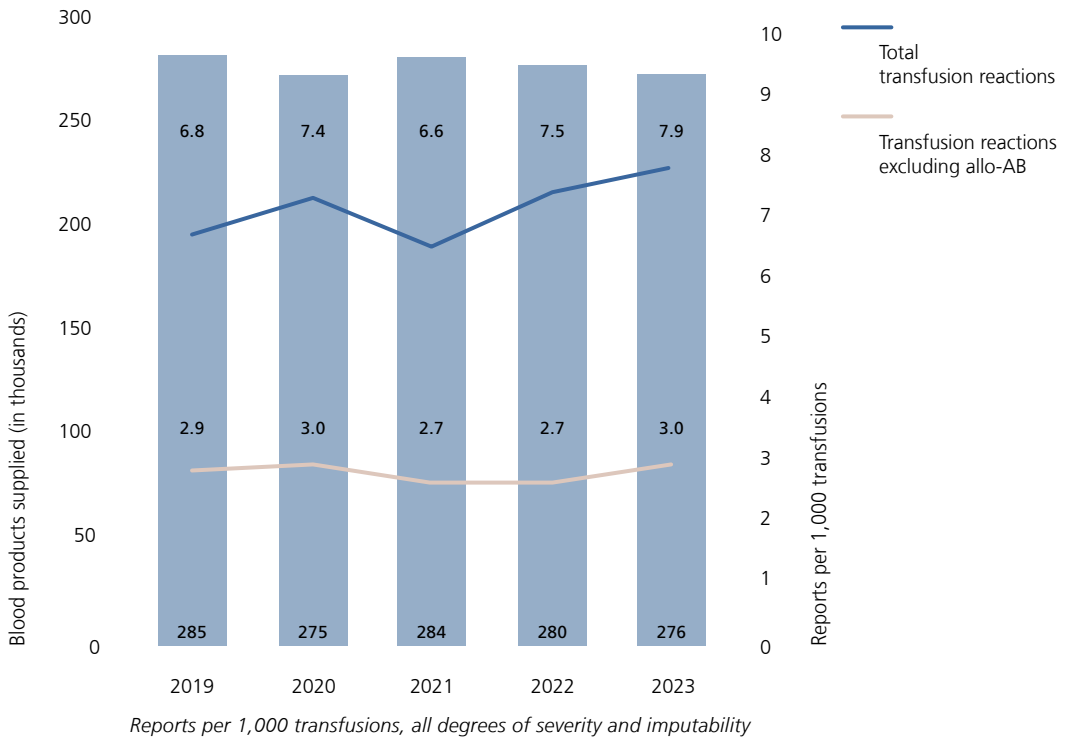
3.2 Reported data

3.2.1 Transfusion reactions: Reporting rate

Compared with the previous year, the reporting rate for TR in 2023 was 5% higher (7.9/1,000 Tf), and the reporting rate for TR excluding allo-antibodies 11% higher (3.0/1,000 Tf) (Figure 5). Overall there has been a slight uptrend in the total reporting rate for TR since 2019; the reporting rate for TR excluding allo-antibodies is largely steady.

Figure 5
Reporting rate for transfusion reactions by year

Reporting rate for transfusion reactions 2019–2023



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

Figure 6
Number of transfusion reactions by category

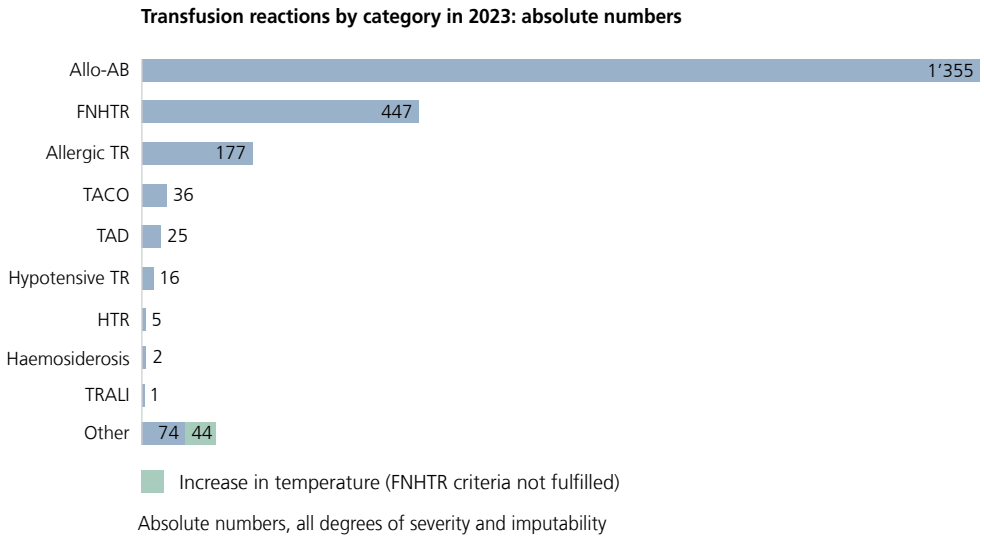
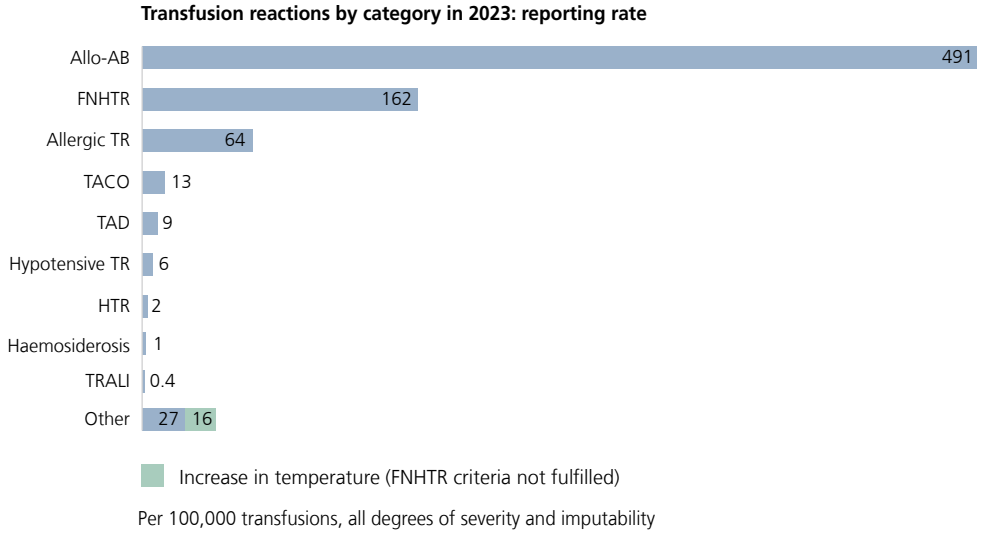


Figure 7
Reporting rate for transfusion reactions by category



TR also include transfusion-associated circulatory overload (TACO) and transfusion-associated acute lung injury (TRALI). These TR are typically serious complications and are among the main causes of morbidity and mortality [2]. The absolute number and the reporting rate of reported events in Switzerland were lower in 2023 than in previous years (Table 5). Unfortunately there was an increase in the number of life-threatening TACO, and both deaths reported in 2023 had to be evaluated as TACO (Table 5, Figure 8).

Table 5
TACO/TRALI by year

TACO/TRALI 2019–2023				
	TACO		TRALI	
	Reports	Reporting rate	Reports	Reporting rate
2019	48	17	8	2.8
2020	88	32	3	1.1
2021	62	22	6	2.1
2022	39	14	2	0.7
2023	36	13	1	0.4

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

Table 6
Transfusion reactions by severity

Transfusion reactions by severity in 2023					
	1	2	3	4	Total
Allo-immunisation	0	1355	0	0	**1355**
FNHTR	315	130	2	0	**447**
Allergic TR	116	42	19	0	**177**
TACO	2	23	9	2	**36**
TAD	13	11	1	0	**25**
Hypotensive TR	6	7	3	0	**16**
HTR	1	3	1	0	**5**
Haemosiderosis	0	2	0	0	**2**
TRALI	0	0	1	0	**1**
Infection	0	0	0	0	**0**
Hyperkalaemia	0	0	0	0	**0**
Other	96	13	9	0	**118**
Total	**549**	**1586**	**45**	**2**	**2182**

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

3.2.2 Transfusion reactions: Age groups and gender

In 2023, TR were observed slightly more frequently in women than in men (approx. 2%). This represents a shift compared with previous years, in which more TR reports concerned male patients than female patients (Table 7). The number of reported transfusion reactions is still increasing after the age of 50, a finding which applies to all types of transfusion reaction.

Table 7
Transfusion reactions by age group and gender

Transfusion reactions by age group and gender in 2023

Age groups	Number of reports	Male	Female	Unknown
0–10	76	38	32	6
11–18	31	13	17	1
19–30	38	9	28	1
31–50	98	34	60	4
51–70	262	140	117	5
>70	322	163	156	3
Total	**827**	**397**	**410**	**20**

Absolute numbers, transfusion reactions excluding allo-AB, all degrees of severity and imputability

3.2.3 Transfusion reactions: Imputability

Table 8
Transfusion reactions by imputability

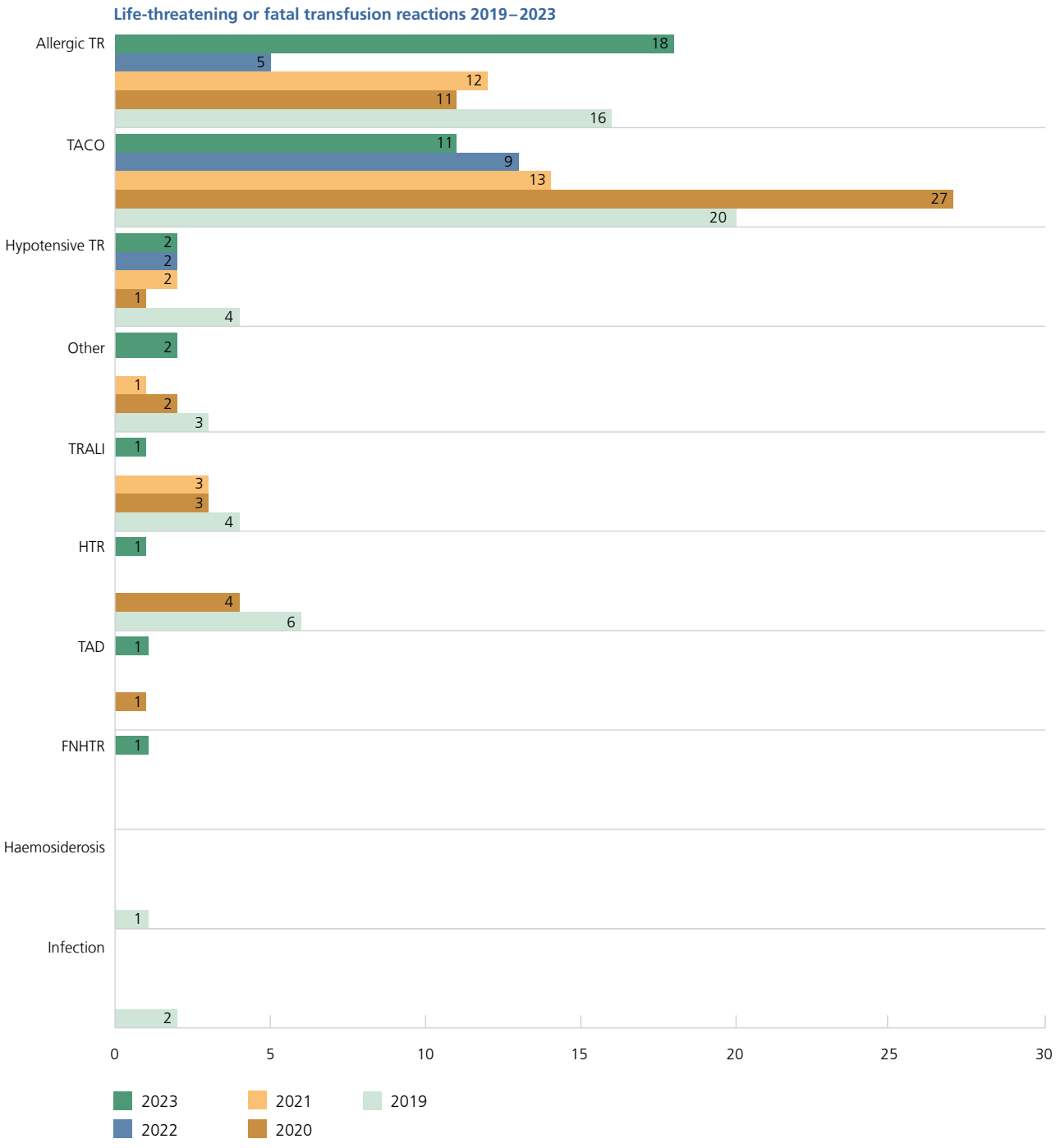
Transfusion reactions by imputability in 2023						
	0	**1**	**2**	**3**	**4**	**Total**
Allo-immunisation	0	0	62	558	735	**1355**
FNHTR	4	104	294	38	7	**447**
Allergic TR	0	13	64	85	15	**177**
TACO	0	1	19	11	5	**36**
TAD	0	3	18	4	0	**25**
Hypotensive TR	0	3	5	7	1	**16**
HTR	0	1	1	1	2	**5**
Haemosiderosis	0	0	0	0	2	**2**
TRALI	0	0	1	0	0	**1**
TTI	0	0	0	0	0	**0**
Hyperkalaemia	0	0	0	0	0	**0**
Other	2	40	60	13	3	**118**
Total	**6**	**165**	**524**	**717**	**770**	**2182**

Imputability 0: not evaluable, 1: unlikely, 2: possible, 3: probable, 4: certain
Absolute numbers, all degrees of severity

3.2.4 Transfusion reactions: Life-threatening and fatal events

In 2023, 827 TR (excluding allo-AB) were reported, representing an increase of approx. 11% compared with the previous year. In 656 of these cases (approx. 79%), the imputability in relation to the transfusion was assessed as at least "possible". Within this group (imputability at least "possible"), there were 35 life-threatening and two fatal TR (Table 9). TACO (n=11) and allergic TR (n=18) remain the most frequent causes of life-threatening or fatal transfusion reactions (Figure 8). The reporting rate for fatal transfusion reactions was 0.7/100,000 transfusions (1:137,898) in 2023.

Figure 8
Life-threatening or fatal transfusion reactions by year



Absolute numbers, severity 3 and 4, imputability ≥ 2

Table 9
Life-threatening and fatal transfusion reactions

Life-threatening and fatal transfusion reactions in 2023				
	Possible	Probable	Certain	Total
Allergic TR	5	11	2	**18**
TACO	8	2	1	**11**
Hypotensive TR	0	1	1	**2**
Other	1	1	0	**2**
TRALI	1	0	0	**1**
HTR	0	1	0	**1**
FNHTR	0	1	0	**1**
Total	**16**	**17**	**4**	**37**

Absolute numbers, severity 3 and 4, imputability ≥ 2

A total of two fatal transfusion reactions were reported in 2023. Similarly to the ISBT definitions, transfusion reactions are only classified as deaths (grade 4) if imputability is evaluated as at least possible [3]. Both fatal reactions were classified as TACO; there were also two TACO with a fatal outcome in 2022. In this connection we would once again urgently refer to the recommendation to screen patients for the risk of TACO and, if applicable, aim for a slow transfusion rate (e.g. 1 ml/kg body weight/h) and consider preemptive diuretic treatment [4, 5].

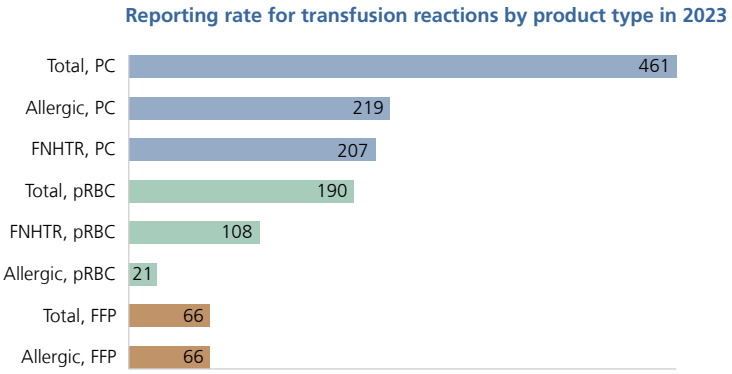
Table 10
Case studies of fatal incidents

Deaths
TACO: Imputability possible
Male patient, age group >80 years, multiple disorders, with known severe heart failure in the context of coronary heart disease and immunothrombocytopenia. On admission he was, among other things, severely anaemic (< 60 g/l) with thrombocytopenia (< $20x10^9$/l) and acute gastrointestinal bleeding. pRBC were transfused, vital parameters before transfusion: blood pressure 108/64 mm/Hg, pulse 70/min, SpO2 100%. The patient developed dyspnoea during the transfusion, vital parameters: BP 125/70 mmHg, pulse 120/min, SpO2 78%, no fever. Clinical examination showed pulmonary oedema, imaging revealed cardiopulmonary congestion. The patient was treated with oxygen, steroids and diuretics. Immunohaematological investigation showed no abnormalities. The patient's clinical status deteriorated in the hours following transfusion, with progressive pulmonary oedema. The patient had refused invasive ventilation in advance; he died of respiratory failure. The reported reaction fulfils the criteria for transfusion-associated circulatory overload (TACO) in the context of pre-existing risk factors (known heart failure and CHD). Very severe anaemia in the context of gastrointestinal bleeding and heart disease are other conceivable causes. In view of the clinical course, imputability with the transfusion of pRBC was classified as "possible" (TACO, grade 4, imputability possible).
TACO: Imputability possible
Male patient, age group 60–70 years, with advanced cancer, receiving combined radio-chemotherapy. Hospitalised for, among other things, exacerbation of severe chronic obstructive pulmonary disease (COPD). Unfavourable clinical course with global respiratory failure and anaemia (Hb 80–90 g/l). Packed red blood cells were transfused following deterioration of the patient's respiratory status. Initially slow transfusion (approx. 200 ml/> 2 hours), which was tolerated well. Clinical deterioration following an increase in the flow rate, with dyspnoea, drowsiness, pallor, sweating, signs of centralisation and a clinical picture of decompensated heart failure. The patient was transferred urgently to a different hospital. On arrival: BP 190/110 mmHg, pulse 110/min, SpO2 88% (3 l O2), no fever, clinical signs of central cyanosis. A chest X-ray showed cardiopulmonary congestion and pulmonary infiltrates. NTproBNP was distinctly elevated (2716 pg/ml). The patient was treated with oxygen and diuretics. He was admitted to the intensive care unit and non-invasive ventilation (NIV) was initiated. Following further clinical deterioration, invasive ventilation and endotracheal intubation were indicated; the patient had refused this procedure in advance (advance directive). He died the same day.

The reported reaction fulfils the criteria for transfusion-associated circulatory overload (TACO), the acute deterioration occurred during the transfusion. (Nosocomial) pneumonia was diagnosed at the same time as cardiac decompensation occurred; the former is also a possible cause of the symptoms, the patient had preexisting respiratory failure in the context of COPD. Imputability with the transfusion in this case was therefore classified as "possible" (TACO, grade 4, imputability possible).

3.2.5 Product-specific risks

Figure 9
Reporting rate for transfusion reactions by product type



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

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

3.2.6 Allo-immunisations

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

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

Figure 10
Allo-antibodies by blood group system

Allo-AB by blood group system in 2023

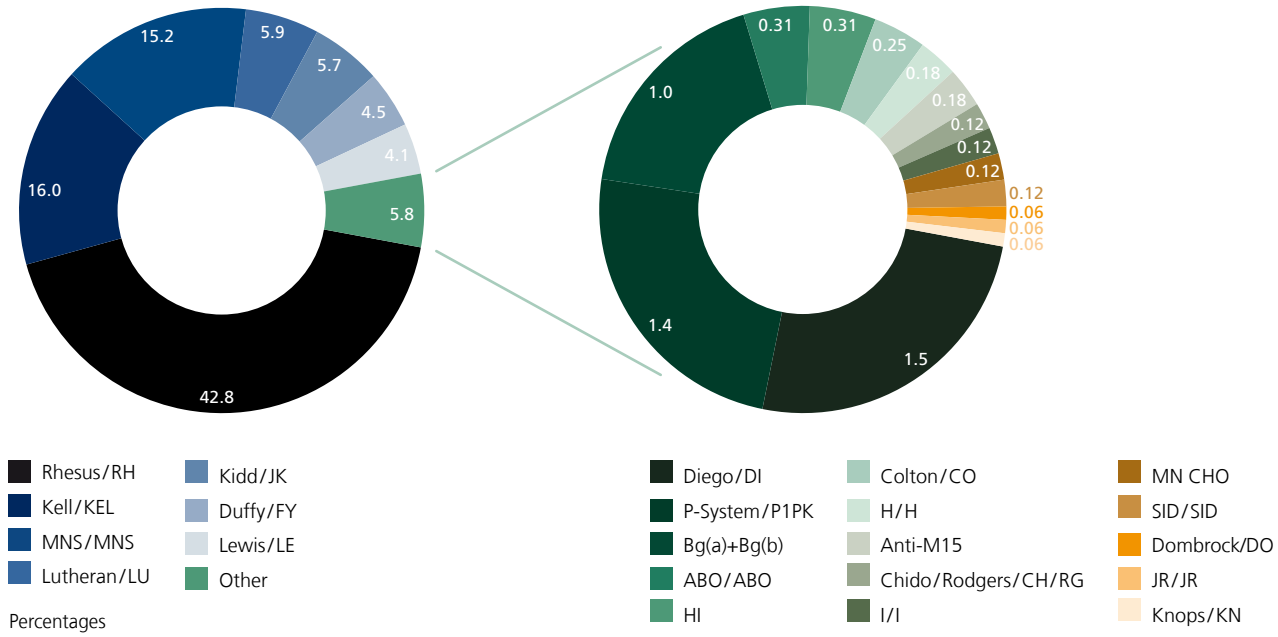


Table 11
Allo-antibodies by blood group system

Allo-antibodies by blood group system in 2023

Blood group system	n	%
Rhesus/RH	696	42.8
Kell/KEL	261	16.0
MNS/MNS	247	15.2
Lutheran/LU	96	5.9
Kidd/JK	92	5.7
Duffy/FY	74	4.5
Lewis/LE	66	4.1
Other	95	5.8
Total	**1627**	**100°**

Blood group system	n	%
Diego/DI	24	1.5
P-System (P1PK)	23	1.4
Anti-Bg(a)+Anti-Bg(b)*	17	1.0
ABO/ABO	5	0.31
Anti-HI*	5	0.31
Colton/CO	4	0.25
H/H	3	0.18
Anti-M15*	3	0.18
Chido/Rodgers/CH/RG	2	0.12
I/I	2	0.12
MN CHO	2	0.12
SID/SID	2	0.12
Dombrock/DO	1	0.06
JR/JR	1	0.06
Knops/KN	1	0.06

According to ISBT[6]
** No data were found for these AB in the ISBT reference table*
° Discrepancies in totals are due to rounding

Figure 11
Allo-antibodies
in the Rhesus system

Allo-antibodies in the Rhesus system in 2023

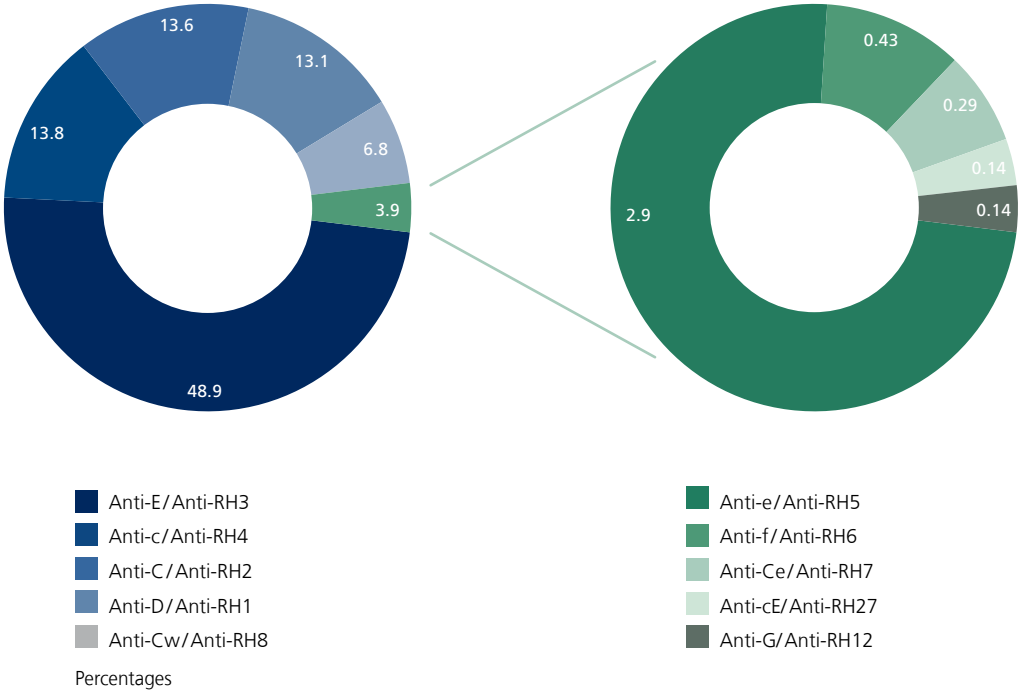


Table 12
Allo-antibodies
in the Rhesus system

Allo-antibodies in the Rhesus system in 2023

Antibodies	n	%
Anti-E/Anti-RH3	340	48.9
Anti-c/Anti-RH4	96	13.8
Anti-C/Anti-RH2	95	13.6
Anti-D/Anti-RH1	91	13.1
Anti-Cw/Anti-RH8	47	6.8
Others	27	3.9
Total	**696**	**100°**

Antibodies	n	%
Anti-e/Anti-RH5	20	2.9
Anti-f/Anti-RH6	3	0.43
Anti-Ce/Anti-RH7	2	0.29
Anti-cE/Anti-RH27	1	0.14
Anti-G/Anti-RH12	1	0.14

°*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 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.

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 recorded internationally in a comparable manner. 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 classifications adapted from SHOT[b]

IBCT classifications
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, 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
- Deliberate Rhesus D conversion in the context of mass transfusion (will be shown separately as a "serious incident" in the future)

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 without a shaker
- 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 values), errors in transmitting results or incorrect clinical decisions. The term also covers the avoidable or unjustified use of emergency products (O 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 or relevant delays in patient care (e.g. postponement of a date for surgery, rescheduling an out-patient 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).*

Examples of near misses

Near misses

Typical examples are **mix-ups** at any place in the transfusion chain (blood taken from the wrong patient, labelling with an 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 sample 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

Severity

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

Severity of IBCT		
		Examples
Grade 1	Deliberate Rhesus D conversion in mass transfusion	
Grade 2	Transfusion with suboptimal product/ incorrect transfusion procedure	– 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.

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

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

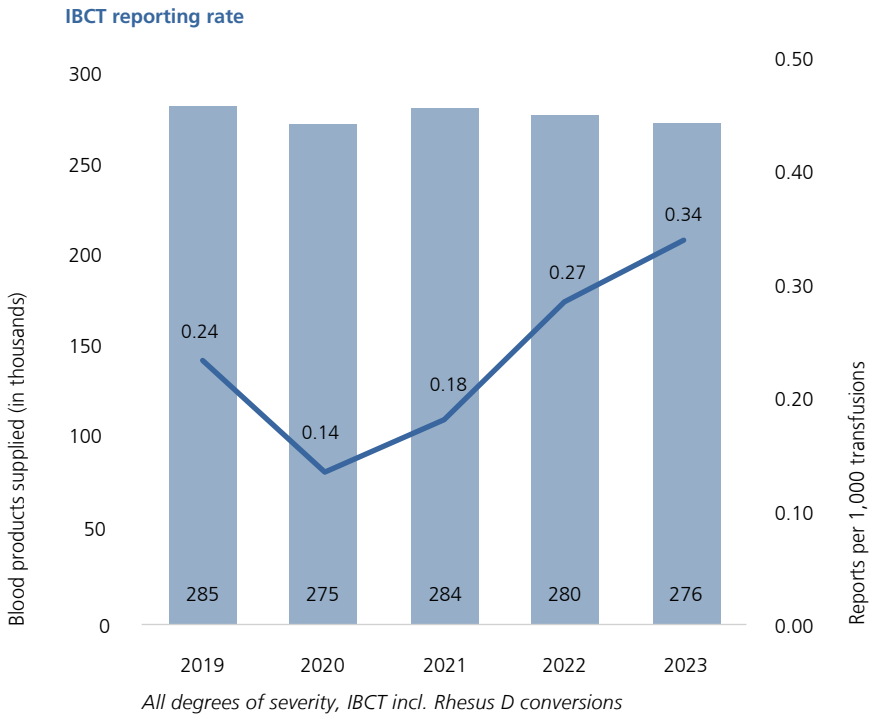
[a] S. Narayan (ed.), D. Poles et al., on behalf of the SHOT Steering Group. The 2022 Annual SHOT report. 2023. 978-1-9995968-5-9.
[b] SHOT. SHOT Definitions. UK: Serious Hazards of Transfusion, 2022.

4.2 IBCT

4.2.1 IBCT: Reporting rate

The progression of the reporting rate for IBCT (incl. Rhesus D conversions) is shown in Figure 12: the reporting rate continued to rise compared to previous years (0.34/1,000).

Figure 12
IBCT reporting rate by year



4.2.2 IBCT: Subclassification

As in the previous year, IBCT-SRNM accounted for the majority of reported transfusion errors in 2023 (n=64; 70% of IBCT) (Table 13). Most of these events involved conversion of the Rhesus D phenotype (Rhesus D conversions) (n=44; 69% of SRNM) and errors in taking into account the extended RBC phenotype (n=14; 22% of SRNM). The number of WCT declined slightly in relation to 2022 and was largely stable compared with recent years (n=8; 9% of all IBCT; 2022: n=14; 2021: n=5). The distribution among the subcategories is shown in Table 13/Figure 13. Examples of IBCT reported in 2023 can be found in Table 14.

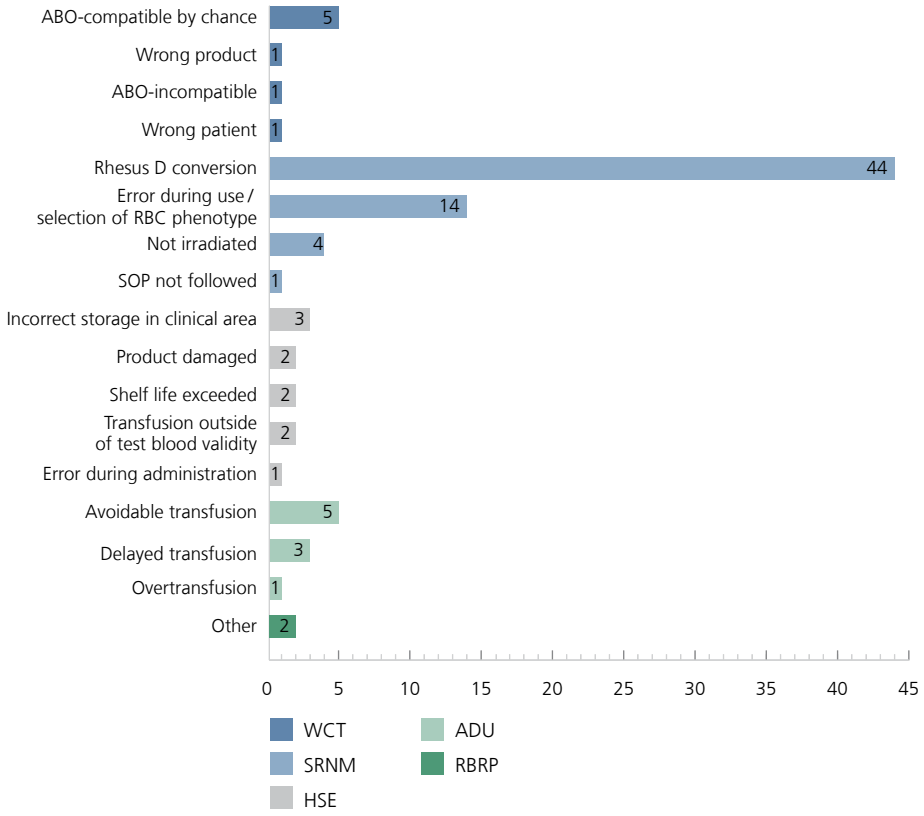
Table 13
Subclassification of IBCT

Subclassification of transfusion errors / IBCT in 2023			
WCT	**Wrong component transfused**		**8**
	ABO-compatible by chance	5	
	ABO/RhD-incompatible	1	
	Wrong patient	1	
	Wrong product	1	
SRNM	**Specific requirements not met**		**63**
	Rhesus D conversion	44	
	Error during use/selection of RBC phenotype	14	
	Not irradiated	4	
	SOP not followed	1	
HSE	**Handling and storage errors**		**10**
	Incorrect storage in clinical area	3	
	Shelf life exceeded	2	
	Product damaged	2	
	Transfusion outside of test blood validity	2	
	Error during administration	1	
ADU	**Avoidable, delayed or under/overtransfusion**		**9**
	Avoidable	5	
	Delayed	3	
	Overtransfusion	1	
RBRP	**Right blood, right patient**		**2**
	Sample labelling error	2	
Total			**92**

Absolute numbers, IBCT classification adapted to SHOT definitions [7]

Figure 13
IBCT subclassification

IBCT subclassification in 2023

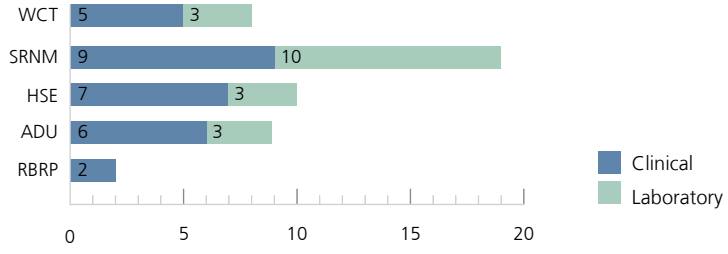


4.2.3 IBCT: Localisation of error

The analysis of errors which have led to transfusion errors can help to increase knowledge of process deviations and to improve processes. Figure 14 shows the localisation of errors (clinical area or immunohaematology laboratory/blood store) subdivided by IBCT subcategory. The analysis of the localisation of the causes of IBCT disregarded cases with deliberate Rhesus D conversion (44 cases, cf. Table 13) since these situations did not involve an error in the process, and the instructions were followed on site. A further evaluation of the localisation of errors in the transfusion chain (point in process) can be found at Localisation of errors in the transfusion chain (point in process).

Figure 14
Localisation of IBCT

IBCT: Localisation of errors by subcategory in 2023



Absolute numbers, IBCT-SRNM excluding Rhesus D conversions

4.2.4 IBCT: Case studies

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

Table 14
IBCT case studies

Case studies: Transfusion errors
IBCT-WCT

Localisation of the deviation in the transfusion chain: Prescription
Severity: 3
Time: Night shift

The anaesthesist on duty determined that Patient X (blood group 0) required transfusion of pRBC in the immediate post-operative period (recovery room) (not an emergency situation, intraoperative blood loss, no active source of bleeding). The responsible nurse was informed orally about the prescription. The doctor accidentally ordered the pRBC electronically for Patient Y (blood group A); at the time (night shift) he was responsible both for the recovery room and for patients in the operating theatre. The pRBC were tested for Patient Y and delivered to the recovery room with the corre-sponding documentation (Patient Y's blood group card, delivery note for pRBC). The check was performed with these documents in the ward office, it was not noticed that they had not been issued for Patient X. The pRBC were subsequently transfused into Patient X in accordance with the oral instructions. No check was performed at the pa-tient's bedside, the light was poor and the patient was sleepy after surgery. Patient X had an acute transfusion reaction (ABO-incompatible transfusion) with circulatory failure. The transfusion was stopped immediately and therapeutic measures incl. administration of vasopressors were initiated. The patient was subsequently stabilised.

The point in process at which this event occurred was the prescription for the wrong patient – this error cannot be identified in the laboratory and the blood was correctly noted and labelled for Patient Y prior to delivery. The four-eyes check failed prior to administration. The night shift with reduced staffing and a heavy workload, poor light-ing at the patient's bedside and an insufficiently responsive patient were contributory factors.

Corrigendum: the blood group information provided in the version dated 3 September 2024 has been corrected.

IBCT-HSE

Localisation of the deviation in the transfusion chain: Administration
Severity: 2
Time: Day shift

Patient X was receiving regular plasmapheresis (PEX) in the intensive care unit (plasma exchange, > 20 FFP each time). The FFP for PEX was always ordered in two stages, i.e. firstly half of the FFP was requested from the laboratory and delivered, the second half was delivered on further request. At the start of PEX the responsible nurse noted that there was one more FFP in the delivery than had been ordered. The pre-transfusion check (correct patient name/date of birth) was done using the four-eyes principle, all the FFP were assigned to the patient and were transfused during PEX. When the second half was requested, the laboratory denied having delivered more than had been ordered in the first delivery; the matter was initially not investigated further, the ordered number of FFP were supplied and transfused, there were no complications during PEX. The joint check (clinical/laboratory) after PEX had been completed showed that the extra FFP had been thawed three days earlier and issued for Patient X. Three days previously, PEX had been performed with one FFP less than had been ordered (the PEX team stated that less FFP had been received, no further investigations at this point). The FFP in question had presumably been at the bottom of the transport bag (not a validated transport box, dark, inside pockets), was overlooked and remained in the bag.

In this case the point in process at which the initial error occurred was administration – the error began on the day the previous plasmapheresis was carried out, on which the wrong (too low) number of FFP had not been queried or investigated. In this situation, checking the thawing date or the delivery note was not successful as a control mechanism, the high number of FFP probably makes the error more likely.

IBCT-WCT

Localisation of the deviation in the transfusion chain: Administration
Severity: 3
Time: Night shift

pRBC were prescribed for Patient X, the patient was hospitalised (not an emergency situation). The blood sample was taken in the morning but did not reach the laboratory until the afternoon. The presence of allo-antibodies meant that immunohaematological (IH) testing had to be done by another laboratory, which sent the IH result by e-mail in the early evening (information by telephone had not been requested on the form). The e-mail with the result was not noticed until that night, and the pRBC were tested for transfusion and released in the early hours of the morning. The nurse on the night shift was informed by telephone; the pRBC were checked in the ward office using the four-eyes principle. The nurse wanted to start the transfusion immediately, but was interrupted repeatedly by other urgent tasks (seriously ill, in some cases delirious patients). She finally started the infusion for Patient Y, a check was not performed at the patient's bedside. The error was noticed when Patient X was monitored and the transfusion was stopped. No transfusion reaction occurred, the transfusion was ABO-compatible "by chance" (patient's blood group: B, blood group of pRBC: O). New pRBC were requested for Patient X.

In this case the point in process at which the error occurred was administration. However, in this case there are numerous contributory factors: the arrival of the blood sample in the laboratory was delayed, there was a further delay in supplying the product because of allo-antibodies (had to be sent to an external laboratory). There was also a delay at this interface: communication of the result by telephone had not been requested but, according to the reporter, had usually been done anyway in the past ("habitual expectation"). Due to this chain of events, the pRBC were not supplied until that night, when staffing was reduced. The acute need to administer at night was not questioned (existing prescription), and the night-time transfusion was ultimately given to the wrong patient. A four-eyes check in the ward office is ineffective when this type of mix-up occurs; it is vital to perform it at the patient's bedside.

IBCT-HSE

Localisation of the deviation in the transfusion chain: Prescription
Severity: 1
Time: Early shift

Transfusion of pRBC and two units of PC was indicated for outpatient Patient X (results of immunohaematological testing available). The doctor on duty in the emergency department ordered the blood products for the following day. The products were ordered externally and delivered by courier early the next morning as ordered (there is no provision for storing PC at the hospital – direct administration). Patient X was not scheduled for a transfusion, it was unclear where the products had been delivered within the hospital, the doctor who had prescribed them was not at the hospital. After multiple queries it was established that the prescription had been issued on behalf of a specialist looking after the patient; the patient had an out-patient appointment with him that morning but no transfusion slot. The transfusion was given on a monitoring ward after several hours' delay; the PC had not been stored properly during this time, in view of the overall situation it was decided not to discard the product and to perform the transfusion. No transfusion reaction occurred.

This IBCT is mainly due to communication errors (interfaces) which are not specific to the transfusion chain. There are special requirements for storing blood products, and their shelf-life is very limited outside of these stores. These communication errors may result in products being destroyed (see also: Discarded blood products – incorrect storage and use).

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

4.3 Near misses

4.3.1 Near misses: Reporting rates

The reporting rate for near misses rose slightly again in 2023 (Figure 15). The majority of the 2,634 reports were due to non-serious events, approx. 7% of the events were classified as very serious (mix-ups occurred) (Table 15).

Figure 15
Near miss reporting rate by year

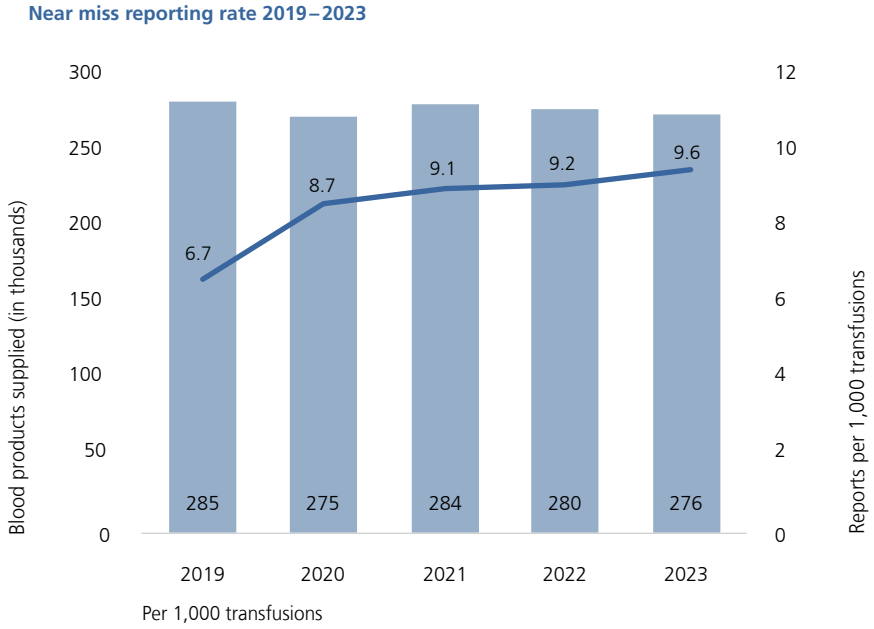


Table 15
Near misses by severity

Severity of near misses in 2023	
1 Non-serious	2,133
2 Serious	305
3 Very serious	195
Total	**2,633***

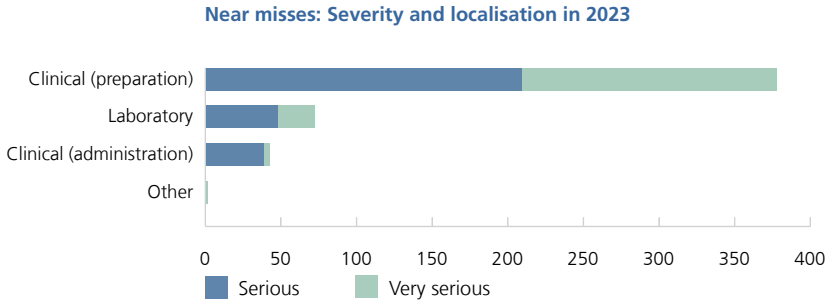
**Reported cases: 2,634, completed and evaluated cases: 2,633*
Absolute numbers

4.3.2 Near misses: Localisation and discovery

Evaluation of near misses this year focused on serious and very serious events (grade 2 and 3). The non-serious events mainly comprised labelling discrepancies with no danger of a mix-up (minor deviations in patients' names, no labelling at all, blood samples that could not be used for immunohaematology analysis). Products discarded as a result of storage and handling errors are described in more detail under 4.6.

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

Figure 16
Near misses: Severity and localisation of the error

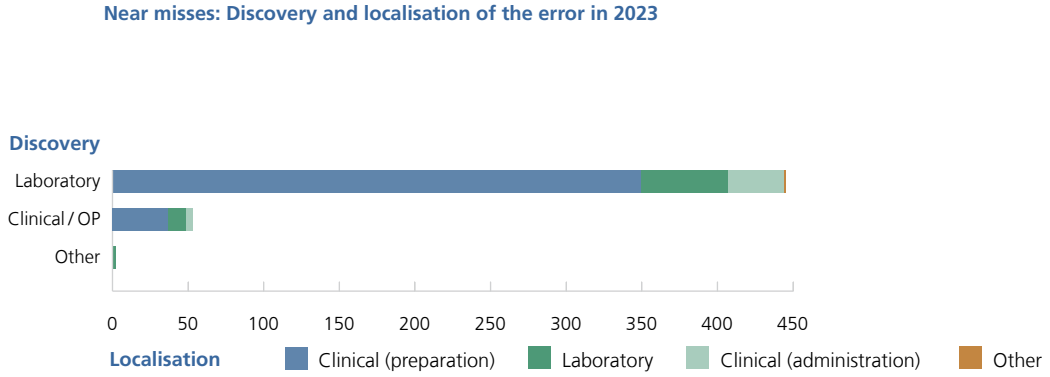


Near misses by severity and localisation of the error 2023

	Severity of the error		
Localisation of the error	Serious	Very serious	**Total**
Clinical (preparation)	220	167	**387**
Laboratory	47	24	**71**
Clinical (administration)	38	3	**41**
Other	0	1	**1**
Total	305	195	**500**

Near misses severity ≥ 2, absolute numbers

Figure 17
Near misses:
Discovery and localisation
of the error

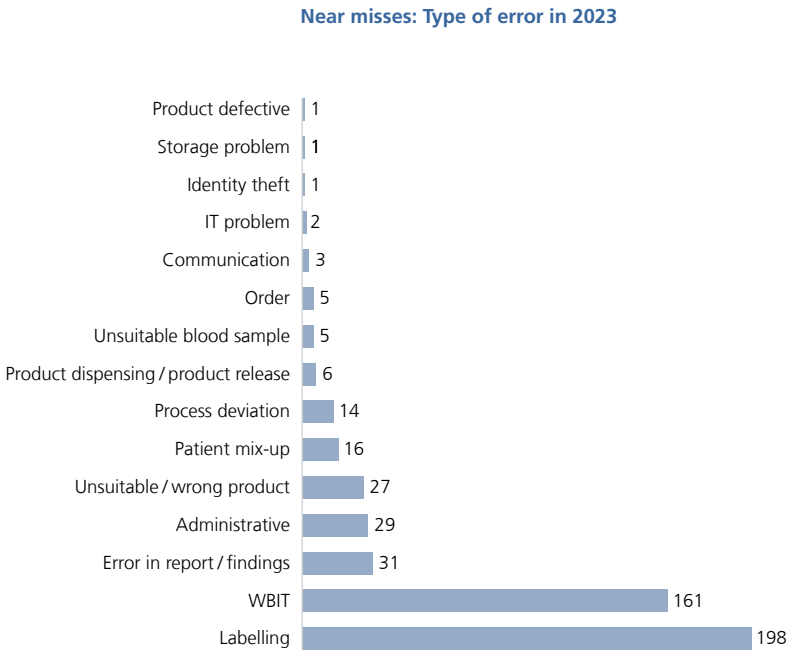


	Localisation of the error				
Discovery of the error	Clinical (preparation)	Laboratory	Clinical (administration)	Other	**Total**
Laboratory	350	57	37	1	**445**
Clinical / OP	37	12	4	0	**53**
Other	0	2	0	0	**2**
Total	**387**	**71**	**41**	**1**	**500**

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

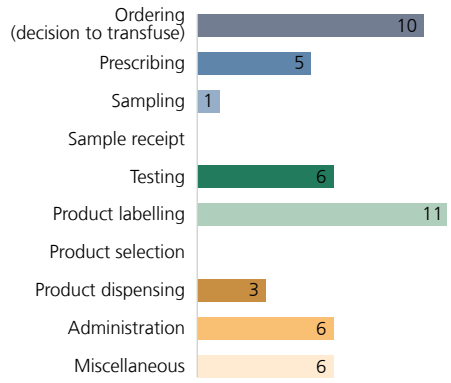
4.4 Localisation of error in the transfusion chain (point in process)

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 less effective (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.

Deviations involving IBCT were most frequently related to the transfusion decision itself (order) and the selection of products in the laboratory/blood store (Figure 19). In the (few) IBCT-WCT the error arose during prescription, selection of products in the laboratory and administration. In comparison, by far the most grade 2 and 3 near misses occurred in the context of obtaining samples (preparation)–this underlines the importance of checks in the laboratory.

Figure 19 IBCT–point in process

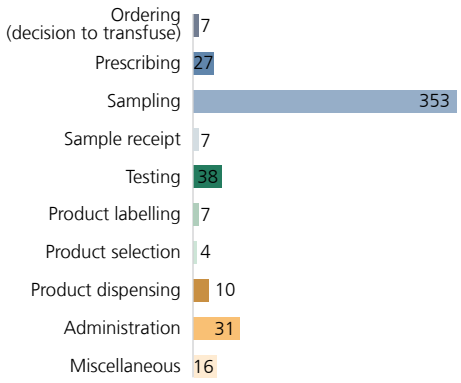
IBCT: Localisation of errors in the transfusion chain in 2023



Absolute numbers, IBCT excluding Rhesus D conversions

Figure 20 Near misses–point in process

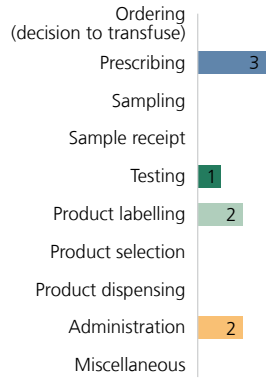
Near misses: Localisation of errors in the transfusion chain in 2023



Absolute numbers, severity grade ≥ 2

Figure 21 IBCT-WCT–point in process

IBCT-WCT: Localisation of errors in the transfusion chain in 2023



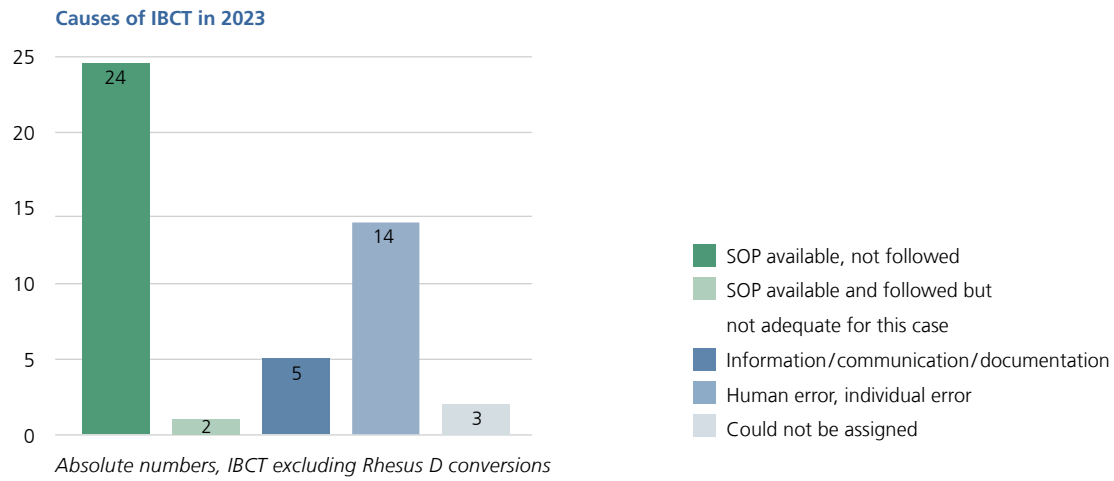
Absolute numbers

4.5 Further evaluations

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. 14% of the IBCT reports in 2023 identified "human error/individual error" as the main cause of the incident. In 24% the main cause was failure to follow an existing and adequate SOP. This factor accounted for 81% of near misses. Figure 22 and Figure 23 show the distribution of causes of IBCT and near misses. 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 [8]. If SOPs are commonly not followed, in addition to providing training and raising awareness, it is necessary to review the processes and instructions themselves. The workload and staffing differ from one situation and 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]. 41% of the IBCT (Figure 24) occurred during a night/late or weekend shift. Compared to previous years, a lower proportion of transfusion errors occurred during the day shift (day shift in 2023: 29%, 2021: 33%, 2022: 41%) (Figure 24).

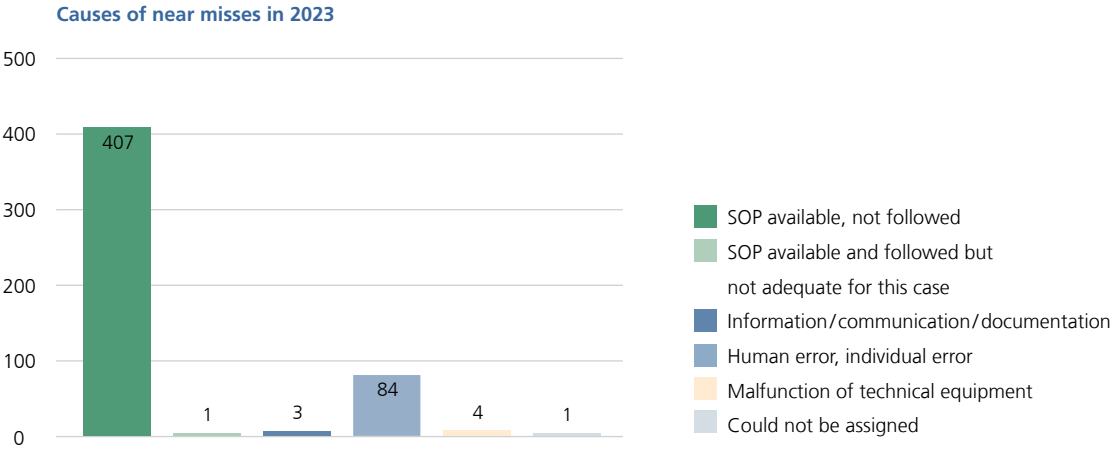
In an ideal situation, aids and processes exist to help staff handle rarely performed activities and other stress factors (e.g. night shift, reduced staffing) and thus avoid errors. The implementation of digital (non-fatiguable) checks is one possible option here.

Figure 22
Causes of IBCT



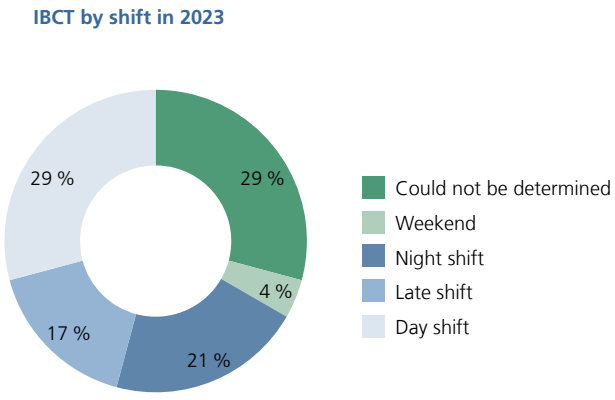
Absolute numbers, IBCT excluding Rhesus D conversions

Figure 23
Causes of near misses



Absolute numbers, severity grade ≥ 2

Figure 24
Occurrence of IBCT by shift



Percentages, IBCT excluding Rhesus D conversions

4.6 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. The number of reports in this area has increased substantially compared with previous years (n=772; 2022: n=464; 2021: n=210). We believe that this is the result of improved reporting compliance.

Table 16 shows the reasons stated by the reporters for the products having been discarded: in all cases the table shows the "main reason" given in the report that led to the product being discarded. This means that – where noted – the clinical situation/reason for the modified requirement is stated. In all the cases listed under "Orders/modified requirement" and "Patient-related reasons", the blood products could not be returned to the blood store. Cases in which no information was given about the background (e.g. the reason for cancellation) are shown under the corresponding storage problem (e.g. temperature monitoring). There was no double-counting of reports. The reports are intended to give an overview of common causes of discarded blood products in Switzerland and help identify possible areas for improvement. It is striking that, for example, only a small number of the situations were described by the reporters as an "emergency situation" (incl. mass transfusions) (n=55, 7% 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 certified refrigerators (if the need is unclear) can enable more products to remain in use. The large number of "cancellations" given as the reason for discarding products (n=242, 31% of all events) shows the importance of suitable and rapid communication channels in the transfusion chain (rapid and simple information for the transfusion laboratory, raising awareness among staff of the relevance of the information).

Table 16
Discarded blood products – storage and handling

Discarded blood products – storage and handling in 2023		
Orders / modified requirement		**298**
Cancellation	242	
Mass transfusion	37	
Emergency situation	18	
Order not collected (thawed FFP)	1	
Temperature monitoring		**161**
Cold chain interrupted	104	
Temperature monitoring available: defective (e.g. technical error of the temperature logger / forgotten)	27	
Incorrect storage outside the blood store (e.g. outside the refrigerator, unmonitored refrigerator)	30	
Patient-related reasons		**41**
Patient febrile / deterioration of general condition	22	
Venous access not possible	3	
Patient died	13	
Patient refused transfusion	3	
Other		**271**
Information unclear / wrong (transfusion would have been possible)	4	
Storage error in the blood store	2	
Product defective / incorrect handling (e.g. error when piercing the product, material defect, clot in FFP)	78	
Product thawed, not transfused	102	
Product expired	85	
Total		**771**

Absolute numbers

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 group of the ISBT, IHN and AABB in 2014°[a]. This enables reactions to be recorded in a standardised manner and facilitates international comparison of donor haemovigilance data. Reactions are classified into symptom-related categories and degrees of severity; in addition, imputability between donation and incident is evaluated. A detailed classification is provided on the Swissmedic website (www.swissmedic.ch/swissmedic/en/home/humanarzneimittel/market-surveillance/haemovigilance.html: Forms/Classification).

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

adapted from °a

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

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

5.2 Reported data

Since 2021 Swissmedic has published the reported data for all donor reactions, i.e. both serious (single reports) and non-serious (collective reports). This is done in the interest of transparency in donor vigilance and is intended to facilitate international comparison. As in previous years, vasovagal circulatory reactions accounted for the majority of donor reactions, 92% of all reactions were mild. Of the grade 3 events, the causal connection with the blood donation was evaluated as at least possible for a total of 12 donations, 11 of them whole blood donations (four first-time donors); eight of these grade 3 events were vasovagal reactions, mostly fainting with a need for further medical attention. One repeat donor developed symptomatic, tachycardic atrial fibrillation (initial diagnosis) the day after donating – a relationship with the donation was evaluated as possible. In relation to the total number of blood donations performed (263,702 in 2023) [1] severe/life-threatening donor reactions (grade 3) were very rare.

Table 17
Donor reactions:
Type and severity

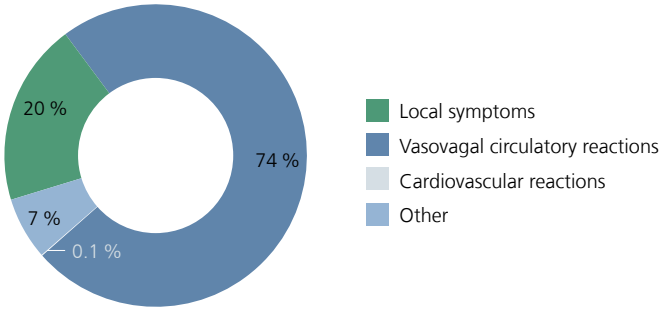
Donor reactions in 2023

Severity	Grade 1	Grade 2	Grade 3	Total
A Local symptoms	577	44	1	**622**
B Vasovagal circulatory reactions	2,162	173	10	**2,345**
C Specific adverse effects related to apheresis	176	11	0	**187**
D Allergic reactions	10	0	0	**10**
E Cardiovascular reactions	0	0	3	**3**
F Other serious adverse effects	13	0	3	**16**
Total	**2,938**	**228**	**17**	**3,183**

Absolute numbers; grade 1 and 2: cumulative reports,
grade 3: direct reports to Swissmedic, all degrees of imputability

Figure 25
Donor reactions:
Causes

Donor reactions in 2023



Percentages, all degrees of imputability

Table 18
Grade 3/4 donor reactions
by year

Grade 3/4 donor reactions in 2019–2023

	2019	2020	2021	2022	2023
Local symptoms	2	0	0	1	1
Vasovagal circulatory reactions	18	12	6	6	10
Other	2*	2	2	3	6
Total	**22**	**14**	**8**	**10**	**17**

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.

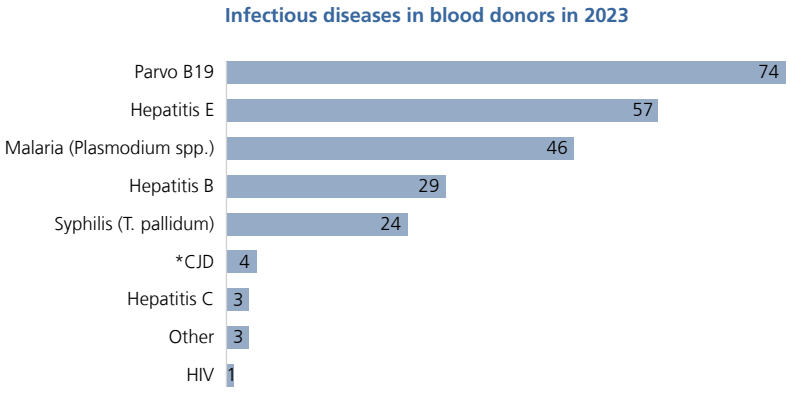
6.2 Reported data

6.2.1 Protective measures: Total

In 2023, a total of 241 reports were received concerning infections in blood donors and corresponding protective measures (Figure 26). The substantial increase compared with 2022 (n=146) is due in particular to a substantial increase in infections with parvovirus B19. Figure 28 shows the development of the absolute numbers reported in recent years: as reported internationally, case numbers decreased considerably during the COVID-19 pandemic – very probably as a result of the protective measures adopted (parvovirus B19 is transmitted via the respiratory tract). The increase continued in 2024 – the reader's attention is drawn also to the information issued by Swissmedic on this topic: Safety of blood and labile blood products [9].

Furthermore, the numbers of reported infections with hepatitis E and Plasmodium spp. (malaria) also increased slightly compared with the previous year. The cases of malaria involved mainly first-time donors who were tested specifically as they had a corresponding personal history. There was also an increase in syphilis cases (2023: 24, 2022: 14)–this reflects a trend also being observed in the population at large [10].

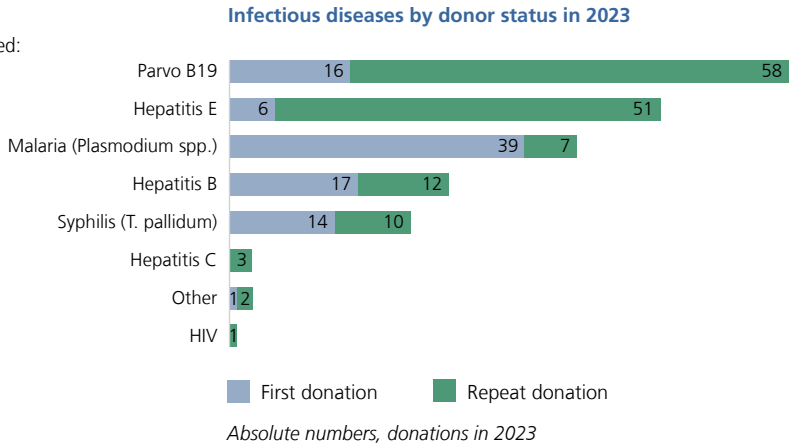
Figure 26
Infectious diseases in blood donors



*Absolute numbers; "Other": toxoplasmosis, viral infection without pathogen determination; *CJD: donations prior to 2023*

6.2.2 Protective measures: Infection markers

Figure 27
Infection markers detected: first or repeat donation



Absolute numbers, donations in 2023

Figure 28
Parvovirus B19: positive blood donations

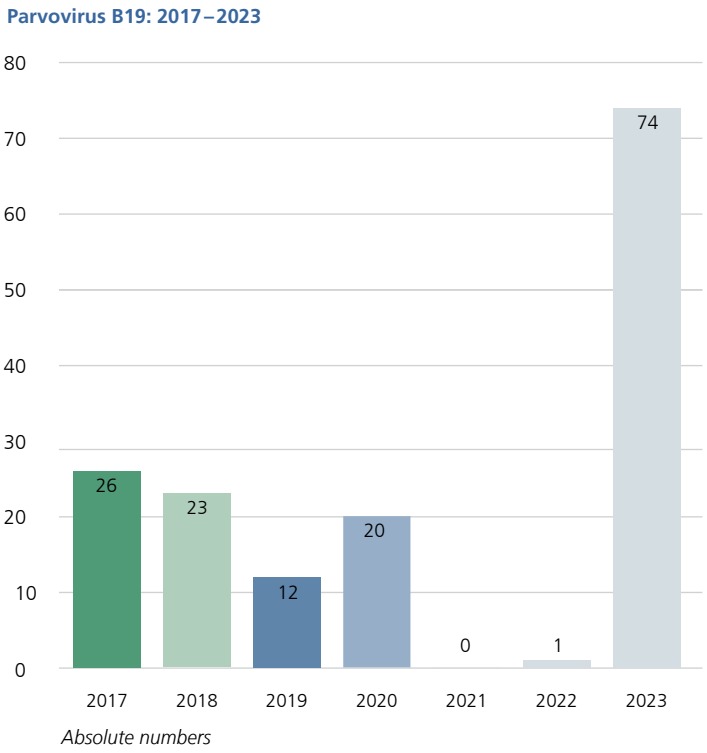


Table 19
Parvovirus B19-positive blood donations

Year	Parvo B19-positive*
2017	26
2018	23
2019	12
2020	20
2021	0
2022	1
2023	74

**detection by PCR*

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

6.3.1 Donor-related look-backs

Table 20
Donor-related look-backs

Donor-related look-backs in 2023			
Infection markers	**Case reports**	**Transfusion-related infections diagnosed**	**Ongoing**
HBV	8	0	3
HCV	0	-	-
HEV	4	0	-
HIV	0	-	-
Syphilis (T. pallidum)	2	0	1

Absolute numbers, procedures concluded: 14; donor-related look-backs CJD: see text

18 donor-related look-backs were performed in 2023, none of them involving infection with HCV or HIV (Table 20). No diseases transmitted by a blood product were identified (four procedures ongoing). The same applies to the ongoing donor-related look-backs mentioned in the 2022 Annual Report: here too, there were no cases in which an infection was shown to have been transmitted. Furthermore, a look-back was performed for four 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.

6.3.2 Patient-related look-backs

No patient-related look-back procedures (PLB) were performed in 2023.

swissmedic

7 Abbreviations

°C	degrees Celsius
AB	antibodies
ABO	ABO blood group system
ADU	avoidable, delayed or under/ overtransfusion
Ag	antigen
Allo-AB	allo-antibodies
AR	Annual Report
Art.	Article
BD / BTS	blood donation/blood transfusion service
BG	blood group
CH	Switzerland
CJD	Creutzfeldt-Jakob disease
COPD	chronic obstructive pulmonary disease
e.g.	for example
F	female
FFP	fresh frozen plasma
FFPpi	fresh frozen plasma, pathogen-inactivated
FFPq	fresh frozen plasma, quarantined
FNHTR	febrile non-haemolytic transfusion reaction
H	hour
HBV	hepatitis B virus
HCV	hepatitis C virus
HEV	hepatitis E virus
HIV	human immunodeficiency virus
HLA	human leukocyte antigen
HSE	handling and storage errors
HTR	haemolytic transfusion reaction
HV	haemovigilance
i.e.	in other words
IBCT	incorrect blood component transfused
ID	identification
ISBT	International Society of Blood Transfusion
IT	information technology
let.	letter
M	male
MPLO	Medicinal Products Licensing Ordinance
n	number
NM	near misses
para.	paragraph
PC	platelet concentrates (PCa: apheresis-derived; PCb: whole blood-derived)
PLB	patient-related look-backs
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-associated acute lung injury
TTI	transfusion transmissible infections
WBIT	wrong blood in tube
WCT	wrong component transfused
AI	Appenzell Innerrhoden
AR	Appenzell Ausserrhoden
BE	Bern
BL	Basel-Land
BS	Basel-Stadt
FR	Fribourg
GE	Geneva
GL	Glarus
GR	Graubünden
JU	Jura
LU	Lucerne
NE	Neuchâtel
NW	Nidwalden
OW	Obwalden
SG	St. Gallen
SH	Schaffhausen
SO	Solothurn
SZ	Schwyz
TG	Thurgau
TI	Ticino
UR	Uri
VD	Vaud
VS	Valais
ZG	Zug
ZH	Zurich

swissmedic

8 List of figures

Figures

Figure 1 9
Haemovigilance reports by year

Figure 2 10
Reporting rate for haemovigilance reports (transfusion reactions, serious incidents)

Figure 3 11
Reports of transfusion reactions: Distribution by major region

Figure 4 12
Reports of serious incidents: Distribution by major region

Figure 5 15
Reporting rate for transfusion reactions by year

Figure 6 16
Number of transfusion reactions by category

Figure 7 16
Reporting rate for transfusion reactions by category

Figure 8 20
Life-threatening or fatal transfusion reactions by year

Figure 9 23
Reporting rate for transfusion reactions by product type

Figure 10 25
Allo-antibodies by blood group system

Figure 11 26
Allo-antibodies in the Rhesus system

Figure 12 34
IBCT reporting rate by year

Figure 13 36
IBCT subclassification

Figure 14 36
Localisation of IBCT

Figure 15 41
Near miss reporting rate by year

Figure 16 42
Near misses: Severity and localisation of the error

Figure 17 43
Near misses: Discovery and localisation of the error

Figure 18 43
Near misses: Type of error

Figure 19 44
IBCT–point in process

Figure 20 44
Near misses–point in process

Figure 21 44
IBCT-WCT–point in process

Figure 22 46
Causes of IBCT

Figure 23 46
Causes of near misses

Figure 24 46
Occurrence of IBCT by shift

Figure 25 51
Donor reactions: Causes

Figure 26 53
Infectious diseases in blood donors

Figure 27 53
Infection markers detected: first or repeat donation

Figure 28 54
Parvovirus B19: positive blood donations

swissmedic

Tables

Table 1 8
Transfusions in Switzerland by year

Table 2 9
Haemovigilance reports: Total numbers

Table 3 11
Reports of transfusion reactions: Distribution by major region

Table 4 12
Reports of serious incidents: Distribution by major region

Table 5 17
TACO/TRALI by year

Table 6 17
Transfusion reactions by severity

Table 7 18
Transfusion reactions by age group and gender

Table 8 19
Transfusion reactions by imputability

Table 9 21
Life-threatening and fatal transfusion reactions

Table 10 22
Case studies of fatal incidents

Table 11 25
Allo-antibodies by blood group system

Table 12 26
Allo-antibodies in the Rhesus system

Table 13 35
Subclassification of IBCT

Table 14 37
IBCT case studies

Table 15 41
Near misses by severity

Table 16 48
Discarded blood products – storage and handling

Table 17 51
Donor reactions: Type and severity

Table 18 51
Grade 3/4 donor reactions by year

Table 19 54
Parvovirus B19-positive blood donations

Table 20 55
Donor-related look-backs

swissmedic

9 Bibliography

1
Blutspende SRK Schweiz. Jahresstatistik. Bern: Blutspende SRK Schweiz, 2023.

2
Roubinian, Nareg. TACO and TRALI: biology, risk factors, and prevention strategies. Blood Systems Research Institute, San Francisco, CA; Kaiser Permanente Northern California Medical Center: Hematology, 2018.

3
Working Party on Haemovigilance, ISBT, IHN, AABB. Proposed standard definitions for surveillance of non-infectious adverse transfusion reactions. 2013.

4
Schweizer Arbeitsgruppe für die Qualitätssicherung in der Anwendung von Blutprodukten. Leitfaden für die Qualitätssicherung in der Transfusionspraxis. 2017.

5
Robinson, S. Harris, A. et al. The administration of blood components: a British Society for Haematology Guideline. Transfusion medicine. 2018, Vol. 28, 1.

6
ISBT - International Society of Blood Transfusion. [Online] 2022. https://www.isbtweb.org/working-parties/red-cell-immunogene-ics-and-blood-group-terminology.

7
SHOT. SHOT Definitions. UK: Serious Hazards of Transfusion, 2022.

8
CIEHF. White Paper on Learning from Adverse Events. [Online] CIEHF, 2020. https://ergonomics.org.uk/resource/learning-from-adverse-events.html.

9
Swissmedic. [Online] https://www.swissmedic.ch/dam/swissmedic/en/dokumente/marktueberwachung/haemovigilance/zunahme-parvovirus-b19-infektionen.pdf.download.pdf/Increase%20in%20parvovirus%20B19%20infections%20and%20impact%20on%20treatin%20high-risk%20patients%20with%20blood%20products.pdf

10
Bundesamt für Gesundheit. Sexuell übertragene Infektionen und Hepatitis B/C in der Schweiz im Jahr 2022: eine epidemiologische Übersicht. [Online] https://www.bag.admin.ch/dam/bag/de/dokumente/mt/p-und-p/hiv-sti-statistiken-analysen-und-trends/hiv-sti-epizahlen-2022.pdf.download.pdf/hiv-sti-epizahlen-2022-de.pdf.

swissmedic

Schweizerisches Heilmittelinstitut
Institut suisse des produits thérapeutiques
Istituto svizzero per gli agenti terapeutici
Swiss Agency for Therapeutic Products

Swissmedic, Swiss Agency for Therapeutic Products
Inspectorates and Licences Division
Inspection Management and Blood Surveillance
Hallerstrasse 7
3012 Bern
Switzerland
haemovigilance@swissmedic.ch
haemovigilance.swissmedic@hin.ch
www.swissmedic.ch/haemovigilance

ISSN 2813-3013