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Haemovigilance Annual Report 2020

July 2021

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Evaluation of haemovigilance reports in 2020

Credits

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1 Editorial

2020 was dominated by the coronavirus and the ensuing global pandemic. In Switzerland and elsewhere, hospital resources were freed up for the resulting Covid patients, and elective surgical procedures were delayed.

Numerous transfusions still had to be performed, however, even though the last year followed the current trend with almost four percent fewer transfusions compared with the year before.

Despite this, the number of haemovigilance reports increased by 18% compared with the previous year, which was primarily due to near-miss reports. This rise in the reporting rate is pleasing from a transfusion quality perspective, as it shows that there is more awareness of the importance of haemovigilance and that reporting compliance has improved. People seem more aware that it is worth taking a closer look and systematically eliminating potential sources of error for the benefit of patient safety. The reporting haemovigilance officers and their institutions are thus demonstrating that they have an established and progressive approach to errors, and that quality management means more to them than just lip service. The fact that haemovigilance reporting is also one of the legal obligations set out in the Therapeutic Products Act (TPA), the Therapeutic Products Ordinance (TPO) and the Medicinal Products Licensing Ordinance (MPLO) is, for once, only mentioned in passing.

Thank you for your interest. We hope you find this report to be a stimulating read.

Christoph Küng
Head of Safety of Medicines Department

2 Introduction

The Haemovigilance Annual Report provides a regular update on facts and developments relating to transfusion safety. To produce a report that stands on its own, certain aspects and sections of text have been taken over from previous annual reports, particularly in the Introduction and Methods sections.

2.1 Haemovigilance

Haemovigilance is a surveillance system which covers the entire transfusion chain. It records and analyses expected and unexpected adverse events such as donor reactions, quality defects, 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.

Early identification, analysis and evaluation provide an up-to-date overall picture of safety in the transfusion chain and of the nature and dimension of the expected risks. Investigation of these events can provide additional information about the causes of avoidable transfusion incidents and show where improvements are necessary and possible.

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 Article 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.

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 (QA) 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.

2.2 Reporting pathways and how the national haemovigilance system functions

The national haemovigilance system covers the whole of Switzerland. Under the Therapeutic Products Act, all institutions that transfuse blood products (users) and the manufacturers of blood products have an obligation to report transfusion reactions, transfusion errors, near misses and quality defects. It is also mandatory for both users and manufacturers to set up a quality assurance system and to appoint a responsible person for haemovigilance (haemovigilance officer).

Swissmedic enters reports in the haemovigilance database and confirms receipt to the sender. At the same time, the sender is informed of the reference number assigned to the case. The clinical data and the actions taken are evaluated by a clinical reviewer. The Swissmedic reviewers obtain additional information from the reporters where necessary, or request further investigations, and carry out the final assessment.

If this assessment deviates significantly from the report sent by the professional, the haemovigilance officer is consulted, as is the initial reporter if the haemovigilance officer thinks this is necessary, to ensure that all the available information is taken into account adequately when the report undergoes its final evaluation.
If an analysis of individual cases identifies a need for action in the form of improved measures, corresponding proposals are discussed and reviewed in cooperation with the affected institutions.

The Swiss haemovigilance system is based on spontaneous reporting and can thus be termed a "passive" monitoring system. Active monitoring by the national system, such as in cohort studies for example, does not take place. The number of blood components supplied for transfusion is used for the quantitative evaluation of transfusion risks (with exposure data as the denominator).

Transfusion risks may be underestimated as a result of under-reporting, and for this reason the risks described in this report should be understood as minimum figures.

2.3 Definitions for HV reports

2.3.1 Transfusion reaction (TR)

Transfusion reactions are undesirable or unexpected events which may be related to the administration of labile blood products. Article 63 para. 2 TPO requires these events and all the relevant and available information to be reported to Swissmedic.

Table 1
Transfusion reactions (TR)

Transfusion reactions (TR)		
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) – Platelet refractoriness* – Transfusion-associated graft-versus-host disease (Ta-GvHD)	– Circulatory overload (TACO) – Hypotensive TR – Transfusion-associated dyspnoea (TAD) – Hemosiderosis – Severe hypothermia (mass transfusion) – Hyperkalaemia – Calcium deficiency –	– Bacterial – Parasitic – Prions – Viral – Fungal

* Non-immunological mechanisms underlying these transfusion reactions are also considered

2.3.1.1 Severity / imputability / mortality

Table 2
Severity of TR

Severity of TR	
Grade 1	Non-severe
Grade 2	Severe Permanent damage or permanent risk. 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 – Positive blood cultures in patient or blood product – Timely intervention is necessary to avoid permanent damage or a life-threatening course
Grade 3	Life-threatening
Grade 4	Death

The severity of a transfusion reaction is evaluated independently of its possible connection with the transfusion (imputability). For example, suspected cases of bacterial contamination or other infections should be classified as severe – and should remain so – even if the imputability is classified as 'unlikely' in the final evaluation.

Table 3
Imputability

Imputability (kausaler Zusammenhang zwischen Transfusion und Reaktion)		
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	probably	The reaction does not appear to be due to another cause
4	definite	In all probability the reaction was caused by the transfusion

Table 4
Mortality

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

2.3.2 Transfusion errors (incorrect blood component transfused / IBCT) and near misses (NM)

2.3.2.1 IBCT

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. Transfusion errors are defined as events in which a blood component was transfused into a patient for whom it was not intended, not suitable, compatible by chance or not necessary, or in whom transfusion was delayed.

The causes of an incorrect blood product being transfused can lie anywhere in the entire transfusion chain. An incorrect prescription, a blood sample being taken from the wrong patient or an error in the immunohaematology laboratory may be the origin of a transfusion error. Several checks, e.g. two blood group determinations from independent samples or the four-eyes principle, are incorporated into the process to prevent transfusion errors. If a transfusion error occurs nonetheless, these control mechanisms have failed.

Table 5
Examples of IBCT

IBCT	
WCT (Wrong component transfused)	– ABO-incompatible – ABO-compatible by chance – Non-allo-antibody-compatible blood product – Transfusion of avoidable untested O negative blood products – HLA-incompatible – Wrong product
SRNM (Specific requirements not met)	– Non-irradiated / non-washed blood products – Phenotype not observed – Deliberate Rhesus conversion in mass transfusions – SOP not followed
HSE (Handling and storage errors)	– Wrong equipment used – Transfusion after expiry of type & screen validity – Incorrect storage of blood product
ADU (Avoidable, delayed or under-/ over-transfusion)	– Transfusion volume not adapted – Delayed transfusion – Transfusion rate not adapted
RBRP (Right blood right Patient)	– Incorrect blood product ID

2.3.2.2 Near Miss

According to Art. 59 para. 3 TPA, any person who professionally dispenses therapeutic products or administers them to humans or who is entitled to do so as medical personnel must notify Swissmedic of any 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.

According to Art. 4 para. 1 let. a, 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 encourage errors in use and can lead to substantial damage to health. […] Where blood products are concerned, transfusion errors that are barely avoided must also be reported." Here the Ordinance addresses what are known as near misses. Practical experience has shown that the following cases, in particular, are likely to be near misses for haemovigilance purposes: wrong patient if names are nearly identical, wrong blood product ordered as a result of miscommunication, or blood products ordered on the basis of haemoglobin, platelet or coagulation values that are wrong due to pre-analytical factors.

These examples show that near misses are errors or deviations from regulations or guidelines which were discovered prior to transfusion and could have resulted in a transfusion error or a transfusion reaction in a recipient.

Reporting near misses also contributes to quality assurance and should protect other patients against the potential hazards identified in this way. In other words, the purpose of monitoring haemovigilance data and causes is to identify when and where in the transfusion chain errors typically occur. This enables future mistakes of this kind to be prevented by establishing specific measures.

Table 6
Examples of near misses

Near Miss
– Order form not initialled
– Sample tubes not labelled correctly or order form incomplete
– Minor discrepancy between tubes and order form
– Another patient›s date of birth
– Labels missing from sample tubes
– Handling & storage with products discarded
– Wrong sample tubes retrieved
– Different patient identification on sample tubes/form
– Blood taken from wrong patient and only discovered because of discrepancy in blood group / wrong blood in tube (WBIT)
– Blood product orders for the wrong patient
– Wrong blood product ordered
– Blood products ordered on the basis of haemoglobin, platelet or coagulation values that are wrong due to pre-analytical factors

2.3.2.3 Severity of IBCT and NM

Table 7
Severity of IBCT and NM

Severity of IBCT and NM	
Grade 1	**Non-severe** Formal error with no potential for use by mistake: – **Order form not initialled** – **Sample tubes not labelled correctly or order form incomplete** – **Minor discrepancy between tubes and order form** – **Deliberate Rhesus conversion in mass transfusions** – **Handling & storage with products discarded**
Grade 2	**Severe** Formal error with potential for use by mistake or transfusion error involving a suboptimal product – **Labels missing from sample tubes** – **Another patient›s date of birth** – **Patient ID on sample tube differs from that on form** – **Transfusion error with unconfirmed allo-AB compatibility according to the SOP**
Grade 3	**Life-threatening** Use by mistake occurred at some level in the transfusion chain – **Wrong blood in tube* (WBIT)** – **Discrepant BG determinations** – **Blood product orders for the wrong patient** – **Transfusion error ABO incompatible or ABO compatible only by chance** ***Wrong blood in tube (WBIT) means that the patient identification on the tube and order form does not match the patient whose blood is in the tube.**

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.

2.3.3 Donor reactions

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 the corresponding licences are still being met. Swissmedic's responsibility for inspections relating to blood and blood products is set out in Article 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 so that the adverse effects can be assigned to a regional blood transfusion service, which is important for Swissmedic inspection purposes. Serious (Grade 3 and 4) donor reactions must be notified to Swissmedic within 15 days using the Swissmedic form.

2.3.4 Quality defects

Art. 37 para. 1 MPLO requires the natural or legal person that holds a licence for activities involving blood and labile blood products to take necessary protective measures immediately, particularly if they discover 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. Reports of quality defects 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.

The blood transfusion service uses the Swissmedic form to report the donor's data, the positive infection markers and, if the donor is a repeat donor, the data from the last-but-one donation. The report must also state whether a look-back procedure (tracing procedure) has been started and the exposure risk must be described. In addition, the measures taken with respect to the donor must be stated and the blood products collected must be named.

However, quality defects and protective measures may also involve the users. On the one hand, Art. 37 para. 4 MPLO requires institutions (usually hospitals and doctors' practices) which administer blood and labile blood products to patients to provide relevant information about the use of the labile blood products if requested in order to assist with the manufacturers' investigations and on completion of the look-back procedure. On the other hand, quality defects in a product may not be identified until the product is used in a hospital. These defects must be reported to Swissmedic in accordance with Article 63 para. 1 let. c TPO. Quality defects must be reported immediately to the blood transfusion service since, in certain cases (e.g. if bacterial contamination of the blood product is suspected), further products from the donor may have to be blocked or recalled without delay.

Table 8
Incidents during manufacture that must be reported

Incidents during manufacture that must be reported
– Safety risks for blood donors: Incidents that pose a threat to the health of the blood donor.
– Donor and donation mix-ups
– Incorrect release, incorrect labels
– Release of out-of-specification blood products
– Defective materials or reagents. Incorrect testing
– Suspected quality defects
– Detection of a blood-borne infection in a blood donor

3 Reports received

3.1 Overview

Table 9
Reports in 2020

Type	Number of reports
Transfusion reactions	2 032
Transfusion errors / incorrect blood component transfused	38
Near misses (NM)	2 404
Donor reactions	26
Quality defects and protective measures	155
Total number of reports evaluated	4 655

Table 9 shows the number of reports involving labile blood products received in 2020. A total of 4 655 reports were received.

Figure 1
HV reports by year

Events reported by year (2011 to 2020)

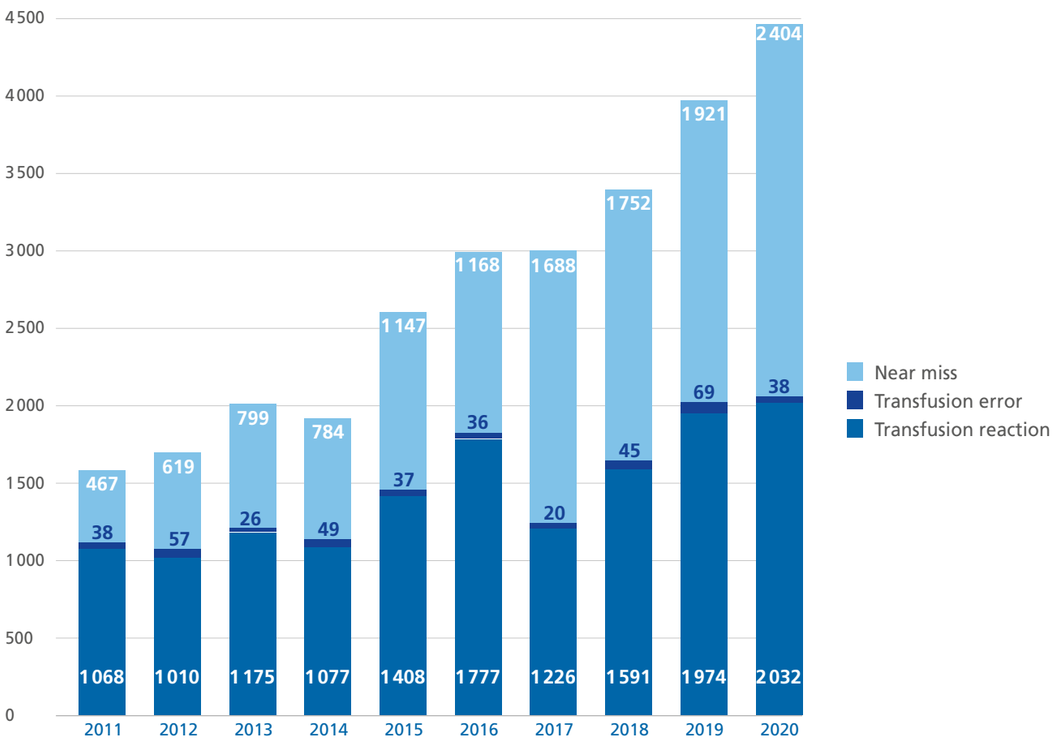


Figure 1 shows the number of HV reports received compared with previous years.

The increase in transfusion reactions from 1947 in 2019 to 2032 in 2020, is once again attributable to allo-immunisations. Near-miss reports also increased again, totalling 2404 in 2020.

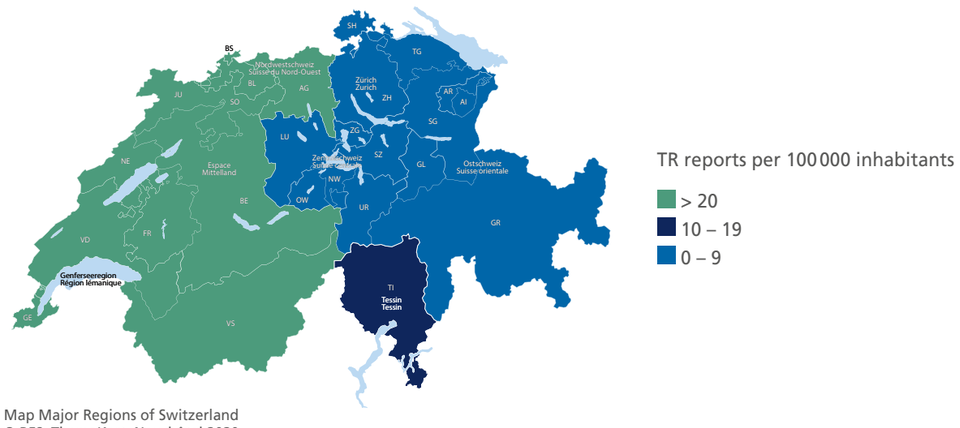
Table 10
Distribution of TR reports by major region

Transfusion reaction reports 2020 by region			
Major region	**Canton**	**Reports**	**Reports per 100 000 inhabitants**
Lake Geneva Region	VD, VS, GE	451	27.4
Espace Mittelland	BE, FR, SO, NE, JU	692	36.8
Northwestern Switzerland	BS, BL, AG	626	53.7
Zurich	ZH	116	7.5
Eastern Switzerland	GL, SH, AR, AI, SG, GR, TG	48	4.1
Central Switzerland	LU, UR, SZ, OW, NW, ZG	51	6.3
Ticino	TI	48	13.6

Considerable asymmetry exists in the reporting rates in the different major regions of Switzerland. While the haemovigilance systems are now well established in Switzerland's main cities, there is still a large divide in respect of the frequency and quality of reports. Various hospitals now possess internal online reporting systems, a user-friendly development that has a positive impact on willingness to report.

Figure 2
Distribution of reports by major region

Transfusionreaction reports by Major regions



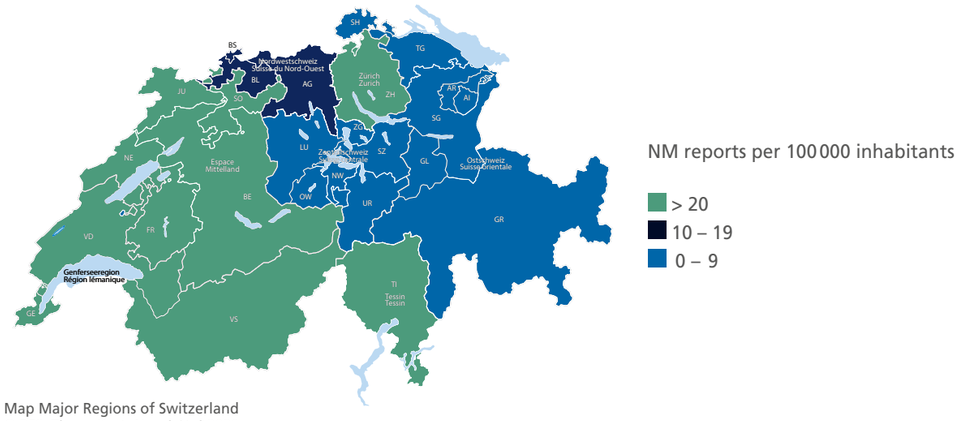
Map Major Regions of Switzerland
© BFS, ThemaKart, Neuchâtel 2020

Table 11
Distribution of reports by major region

Near Miss reports 2020 by region			
Major region	**Canton**	**Reports**	**Reports per 100 000 inhabitants**
Lake Geneva Region	VD, VS, GE	533	32.4
Espace Mittelland	BE, FR, SO, NE, JU	417	22.2
Northwestern Switzerland	BS, BL, AG	159	13.6
Zurich	ZH	1 230	79.9
Eastern Switzerland	GL, SH, AR, AI, SG, GR, TG	31	2.6
Central Switzerland	LU, UR, SZ, OW, NW, ZG	30	3.7
Ticino	TI	4	1.1

Figure 3
Distribution of NM reports by major region

Near miss reports by Major regions



Map Major Regions of Switzerland
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3.2 Number of transfusions and reporting rates

Table 12
Number of transfusions in Switzerland over the past 6 years

Number of transfusions in Switzerland over the past 6 years						
Blood components	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**
pRBC	248 647	239 890	226 276	221 100	220481	212947
PC	36 439	38 374	37 490	38 947	36317	35715
FFP	33 658	33 310	29 303	30 552	28405	26681
Total	318 744	311 574	293 069	290 599	285203	275343

pRBC: packed red blood cells (erythrocyte concentrates)
PC: platelet concentrates
FFP: fresh frozen plasma
Data source: Blood Transfusion Service of the Swiss Red Cross. (1)

Table 12 shows the number of transfusions given throughout Switzerland in the past 6 years. The 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).
The reporting rate can be calculated from the number of transfusions:

Figure 4
Reporting rate, all reports

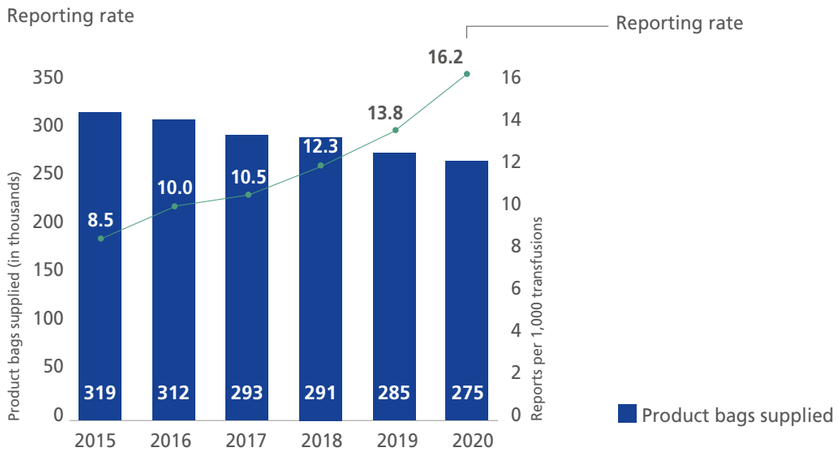


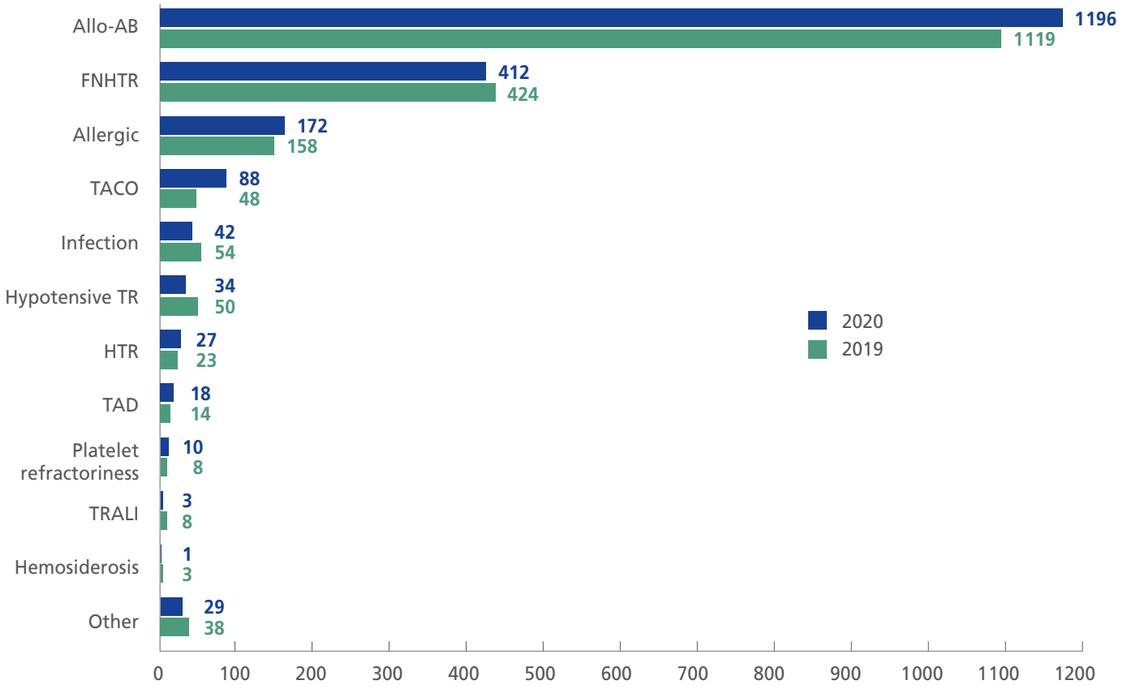
Figure 4 shows the overall reporting rate. The reporting rate is calculated from the total number of reports per 1000 transfusions (product bags supplied). The reporting rate rose again in 2020 despite there being fewer transfusions (16.2 reports per 1000 transfusions in 2020 versus 13.8 in 2019).

3.3 Transfusion reactions

3.3.1 Overview

Figure 5
TR reported in 2019/2020 by category

Transfusion reactions according to category



2032 transfusion reactions were reported in 2020. This chart takes all levels of severity and imputability into account. As in previous years, the reactions most frequently observed were allo-immunisations, FNHTR and allergic TR. These account for approx. 88% of all reported transfusion reactions.

Figure 6
TR reported in 2019/2020 by category per 1000 transfusions (excluding allo-AB)

Transfusion reactions according to category per 1000 transfusions

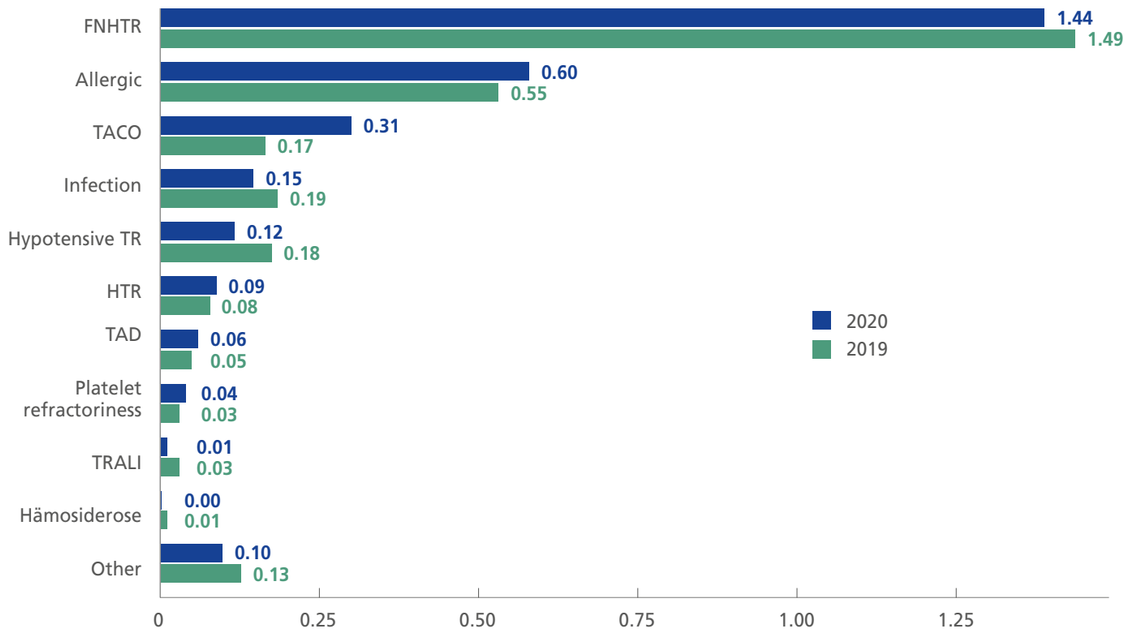


Figure 6 shows the ratio of TR by category, calculated according to the number of reactions per 1000 transfusions. The reports for allo-AB were not included here. There was a relative increase in TR reports during 2020 since the number of transfusions during the year decreased compared with the previous year.

3.3.2 TR by age group and gender

Table 13
Transfusion reactions by age group and gender

Transfusion reactions by age group and gender				
Age group (years)	Number of reports	Gender recipients		
		male	female	unknown
0-10	88	48	30	10
11-18	19	10	8	1
18-45	108	55	53	0
45-70	302	184	111	7
>70	316	178	132	6
Total	833	475	333	24

Table 13 shows the 833 transfusion reactions reported in 2020 by age group and gender. The reports for allo-AB have not been included.

Table 14
TACO by age group and gender

TACO-reports by age group and gender				
Age group (years)	Number of TACO-reports	Gender recipients		
		male	female	unknown
0-10	6	5	1	0
11-18	2	2	0	0
18-45	4	2	2	0
45-70	22	15	7	0
>70	54	25	28	1
Total	88	49	38	1

For self-explanatory reasons, the risk group accounts for the majority – 54 out of a total of 88 – TACO cases in 2020. As in the past, the cause is still the failure to adapt transfusion rates to existing risk factors.

Table 15
TR categories by age group and gender

Transfusion reactions according to categories by age group and gender																		
	0–10			11–18			18–45			45–70			>70			Total		
	M	F	unk	M	F	unk	M	F	unk	M	F	unk	M	F	unk	M	F	unk
FNHTR	**39**			**10**			**58**			**168**			**134**			**409**		
	17	17	5	4	5	1	32	26	0	101	62	5	78	52	4	232	162	15
Allergic TR	**34**			**6**			**34**			**57**			**41**			**172**		
	24	9	1	3	3	0	17	17	0	34	23	0	28	13	0	106	65	1
TACO	**6**			**2**			**4**			**22**			**54**			**88**		
	5	1	0	2	0	0	2	2	0	15	7	0	25	28	1	49	38	1
Infection	**4**			**0**			**2**			**16**			**20**			**42**		
	1	2	1	0	0	0	0	2	0	11	4	1	15	5	0	27	13	2
Hypotensive TR	**2**			**0**			**3**			**8**			**21**			**34**		
	1	1	0	0	0	0	2	1	0	5	3	0	11	9	1	19	14	1
HTR	**2**			**1**			**3**			**10**			**11**			**27**		
	0	0	2	1	0	0	1	2	0	3	6	1	6	5	0	11	13	3
TAD	**1**			**0**			**2**			**7**			**8**			**18**		
	0	0	1	0	0	0	1	1	0	6	1	0	5	3	0	12	5	1
Platelet re-fractoriness	**0**			**0**			**1**			**1**			**8**			**10**		
	0	0	0	0	0	0	0	1	0	0	1	0	0	8	0	0	10	0
TRALI	**0**			**0**			**0**			**3**			**0**			**3**		
	0	0	0	0	0	0	0	0	0	2	1	0	0	0	0	2	1	0
Hemosi-derose	**0**			**0**			**0**			**1**			**0**			**1**		
	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0
Other	**0**			**0**			**1**			**9**			**19**			**29**		
	0	0	0	0	0	0	0	1	0	7	2	0	10	9	0	17	12	0
Total	**88**			**19**			**108**			**302**			**316**			**833**		
	48	30	10	10	8	1	55	53	0	184	111	7	178	132	6	475	334	24

3.3.3 TR by imputability

Number of transfusion reactions in 2020 by classification and imputability

Table 16
TR by imputability

Imputability					
	1	2	3	4	Total
Allo-Immunisation	0	88	473	635	1 196
FNHTR	64	275	59	14	412
Allergic TR	0	43	99	30	172
TACO	0	21	52	15	88
Infection	39	3	0	0	42
Hypotensive TR	4	15	13	2	34
HTR	3	3	7	14	27
TAD	4	11	3	0	18
Platelet refractoriness	0	1	4	5	10
TRALI	0	2	1	0	3
Hemosiderosis	0	0	0	1	1
Other	8	20	0	1	29
Total	122	482	711	717	2 032

Imputability 1: unlikely, 2: possible, 3: probable, 4: certain.

3.3.4 TR by severity

Only those transfusion reactions with an imputability of 2, 3 or 4 (possible, probable or certain) are presented here.

Table 17
TR by severity

Severity					
	1	2	3	4	Total
Allo-Immunisation	0	1 196	0	0	1 196
FNHTR	281	67	0	0	348
Allergic TR	117	44	10	1	172
TACO	4	57	26	1	88
Hypotensive TR	2	27	1	0	30
HTR	2	18	4	0	24
TAD	1	12	1	0	14
Platelet refractoriness	4	6	0	0	10
Infection	0	3	0	0	3
TRALI	0	0	3	0	3
Hemosiderosis	1	0	0	0	1
Other	12	7	1	1	21
Total	424	1 437	46	3	1 910

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

3.3.5 Life-threatening or fatal (severities 3 and 4) transfusion reactions

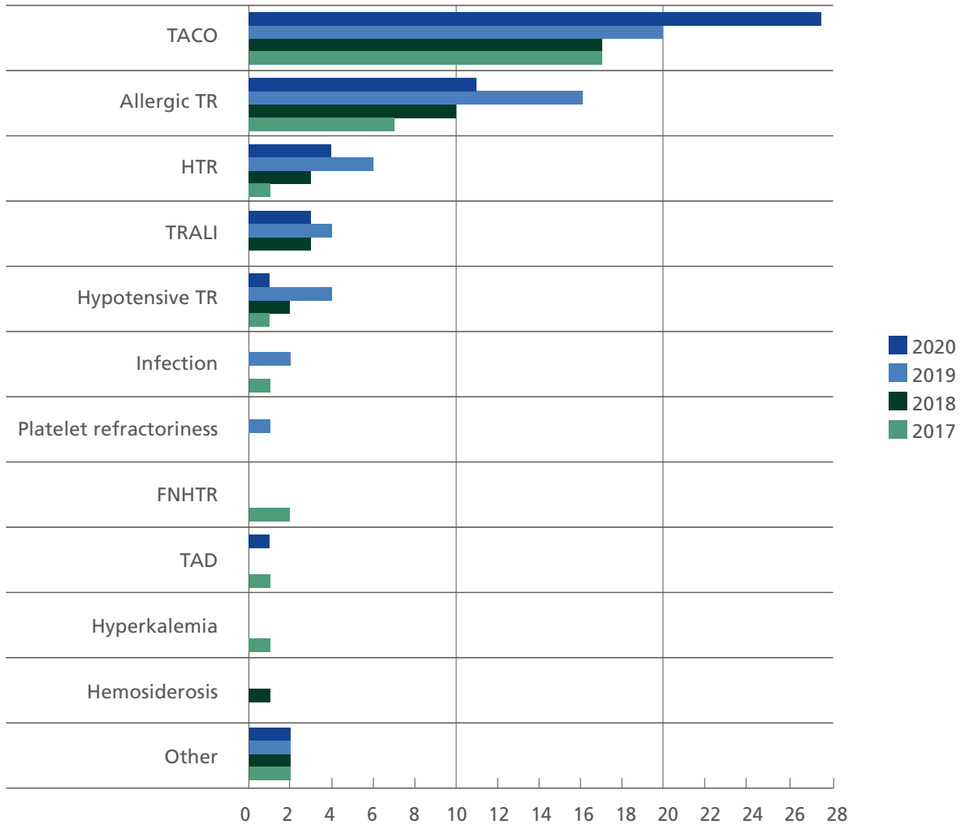
Table 18
Life-threatening or fatal TR (severities 3 and 4)

Life-threatening or fatal TR (severities 3 and 4)				
	possible	probable	definite	Total
TACO	2	15	10	27
Allergic TR	2	9	0	11
HTR	0	0	4	4
TRALI	2	1	0	3
Hypotensive TR	0	0	1	1
TAD	0	1	0	1
Other	2	0	0	2
Total	8	26	15	49

A total of 49 deaths and life-threatening transfusion reactions with an imputability of 2, 3 or 49 were reported in 2020.

Figure 7
Life-threatening or fatal TR

Transfusion reactions with severity 3 (life-threatening) or 4 (death) by year



By way of comparison: in 2020, 49 transfusion reactions with an imputability of 2, 3 or 4 (including 41 with an imputability of 3 or 4) were reported to Swissmedic, compared to 56 in 2019 (including 36 with an imputability of 3 or 4).

TACO (27) and allergic TR (11) remain the most frequent causes of life-threatening or fatal transfusion reactions.

3.3.6 Deaths

Table 19
Deaths in 2020

Imputability					
	1	2	3	4	Total
TACO	0	0	1	0	1
Allergic TR	0	0	1	0	1
FNHTR	1	0	0	0	1
HTR	1	0	0	0	1
Hypotensive TR	1	0	0	0	1
TAD	1	0	0	0	1
Other	2	1	0	0	3
Total	6	1	2	0	9

Imputability 1: unlikely, 2: possible, 3: probable, 4: certain.

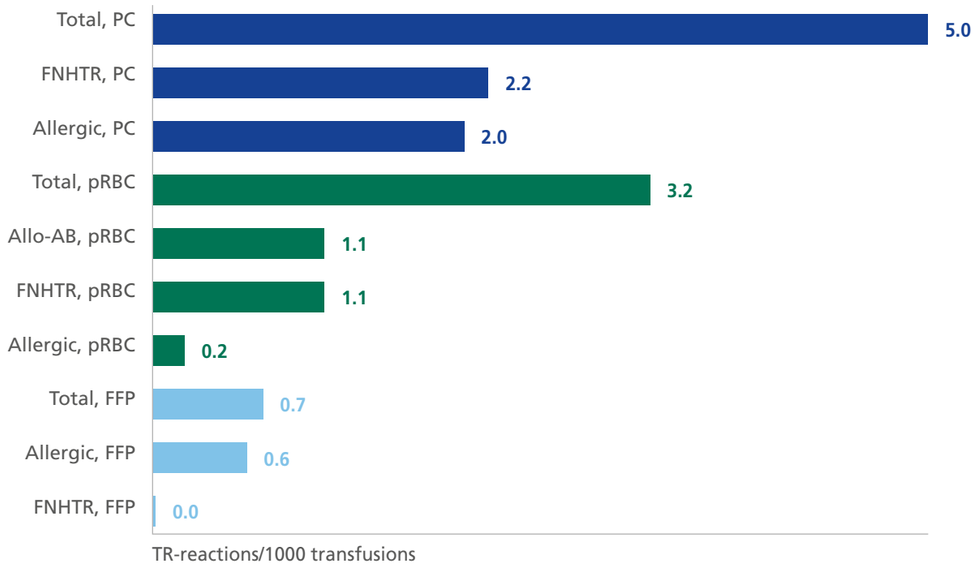
Table 19: Reported deaths in 2020 by diagnosis and imputability. A total of nine deaths were reported in 2020.

3.3.7 Product-specific risks

Reporting rates in 2020 per product, imputability of 2, 3 or 4 – all severities.

Figure 8
Reporting rate by component

Reporting rate according to reaction and blood component



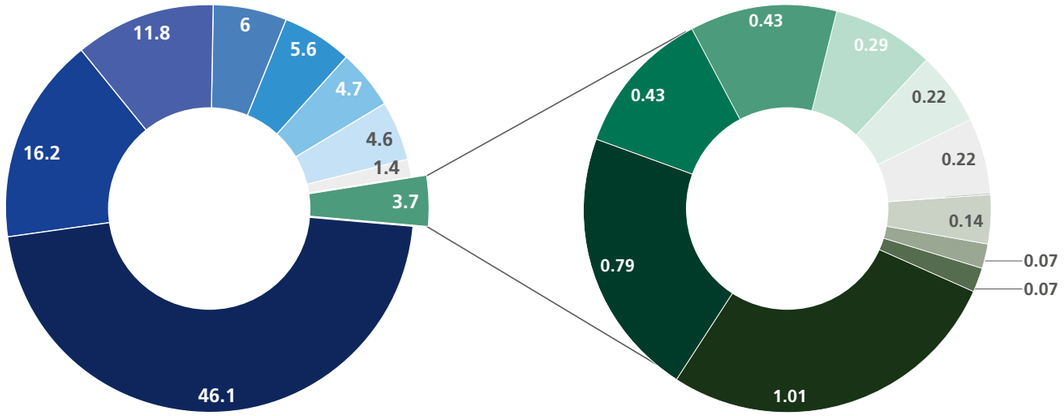
pRBC: packed red blood cells (erythrocyte concentrates)
PC: platelet concentrates
FFP: fresh frozen plasma

Figure 8 shows a comparison of the product-specific reporting rates. Platelet concentrates (PC) showed the highest reporting rate, with approx. five transfusion reactions per 1000 supplied PC bags. The most frequent reactions observed in 2020 for PC were FNHTR (2.2/1000) and allergic reactions (2.0/1000). While allergic reaction was also the commonest reaction seen with fresh frozen plasma (FFP), it occurred less frequently than with PC (0.6/1000). The reporting rate for packed red blood cells (pRBC) was 3.2/1000; the reactions that occurred most frequently were allo-AB (1.1/1000) and FNHTR (1.1/1000). In contrast to PC and FFP, allergic reactions were much rarer with pRBC (0.2/1000).

3.3.8 Allo-immunisations

Figure 9
Allo-AB by BG system in %

Allo-Immunisations by BG system (%)



- Rhesus (RH)
- Kell (KEL)
- MNS (MNS)
- Lutheran (LU)
- Kidd (JK)
- Lewis (LE)
- Duffy (FY)
- Diego (DI)
- Others
- Anti-Bg(a)+Anti-Bg(b)
- P-System (P1PK)
- Anti-HI
- MN CHO (M1)
- H (H)
- ABO (ABO)
- Chido/Rodgers (CH/RG)
- Sid (Sda)
- Yt (YT)
- Anti-Cs(a)

Table 20
Allo-AB reports by BG system

Name (Symbol)	ISBT	%
Rhesus (RH)	004	46.1
Kell (KEL)	006	16.2
MNS (MNS)	002	11.8
Lutheran (LU)	005	6.0
Kidd (JK)	009	5.6
Lewis (LE)	007	4.7
Duffy (FY)	008	4.6
Diego (DI)	010	1.4
Others		3.7
Total		100

Name (Symbol)	ISBT	%
Anti-Bg(a)+Anti-Bg(b)	*	1.01
P-System (P1PK)	003	0.79
Anti-HI	*	0.43
MN CHO (M1)	213002	0.43
H (H)	018	0.29
ABO (ABO)	001	0.22
Chido/Rodgers (CH/RG)	017	0.22
Sid (Sda)	901012	0.14
Yt (YT)	011	0.07
Anti-Cs(a)	205001	0.07

*By ISBT (2) (no data were found for this AB in the ISBT reference table)

Figure 10
Allo-AB in the Rh system in %

Allo-Immunisation in the RH system

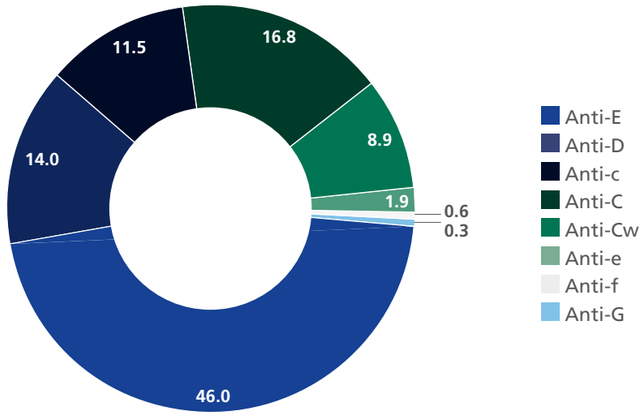


Table 21
Allo-immunisation in the Rh system

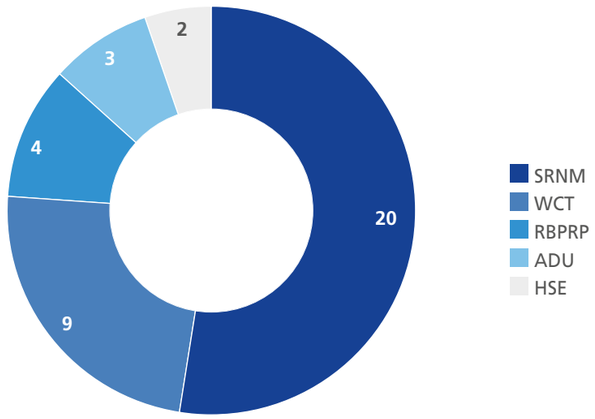
Allo-AB in the RH system		
Antibody	ISBT AG-NO.	%
Anti-E	004 003	46.0
Anti-D	004 001	14.0
Anti-c	004 004	11.5
Anti-C	004 002	16.8
Anti-Cw	004 008	8.9
Anti-e	004 005	1.9
Anti-f	004 006	0.6
Anti-G	004 012	0.3

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 a limited choice of compatible blood components will be available for any future transfusions.

3.4 IBCT

Grafik 11
IBCT

Transfusion errors classification



WCT: Wrong component transfused
SRNM: Specific requirements not met
HSE: Handling and storage errors
ADU: Avoidable, Delayed or Under-/ Over-transfusion
RBRP: Right blood right patient

According to SHOT definition. (3)

3.4.1 Subclassification of transfusion errors

Table 22
Subclassification of IBCT

Subclassification of IBPT				
Transfusion errors classification		**n**		**n**
IBPT (Incorrect blood product transfused)	WCT (Wrong component transfused)	9	ABO-incompatible	3
			ABO-compatible by chance	2
			Wrong product	4
	SRNM (Specific requirements not met)	20	Non-irradiated	6
			Failure to use phenotyped blood	9
			Rhesus D switch	4
			Failure to follow SOP	1
HSE (Handling and storage errors)		2	Wrong giving set used	1
			Inappropriate storage in clinical area	1
ADU (Avoidable, Delayed or Under-/ Over-transfusion)		3	Avoidable	2
			Delayed	1
RBRP (Right blood right patient)		4	Transposition of labels for same patient	3
			Miscellaneous	1
Total		38		38

Transfusion errors were classified according to SHOT definitions . (3)

3.4.2 Localisation of the error

Table 23
Localisation IBCT

Localisation of the error				
Transfusion errors classification		**Clinical**	**Laboratory**	**Total**
IBPT (Incorrect blood product transfused)	SRNM (Specific requirements not met)	8	12	20
	WCT (Wrong component transfused)	4	5	9
HSE (Handling and storage errors)		1	1	2
ADU (Avoidable, Delayed or Under-/ Over-transfusion)		2	1	3
RBRP (Right blood right patient)		2	2	4
Total		17	21	38

Figure 12
Localisation IBCT

Transfusion errors classification and location

	SRNM	WCT	RBRP	ADU	HSE
Clinical	8	4	2	2	1
Laboratory	12	5	2	1	1

3.5 Near Miss

Figure 13
NM reporting rate by year

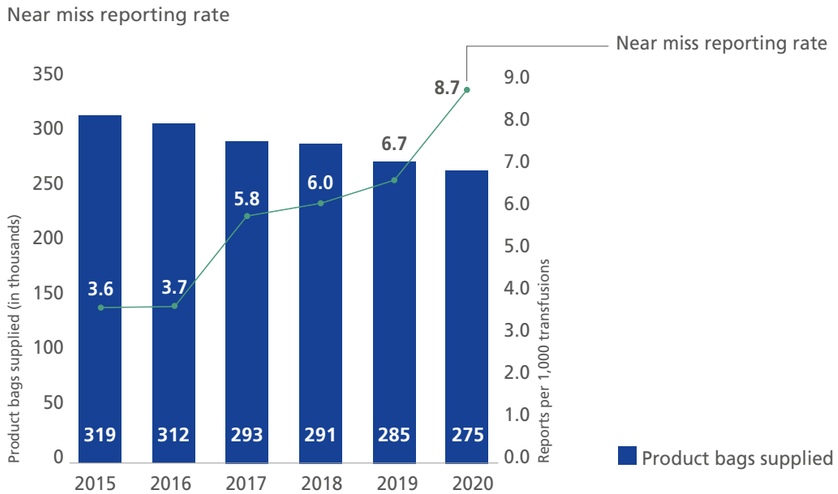


Figure 13 shows the reporting rate for NM. The reporting rate is calculated from the total number of reports per 1000 transfusions (product bags supplied). The reporting rate rose again in 2020 despite there being fewer transfusions (8.7 reports per 1000 transfusions in 2020 versus 6.7 in 2019).

3.5.1 NM by severity and localisation

Table 24
NM severity

NM by Severity	
Severity	**n**
Non-severe	1 052
Severe	1 171
Life-threatening	181
Total	**2 404**

Figure 14
NM severity

Near miss reports according to severity

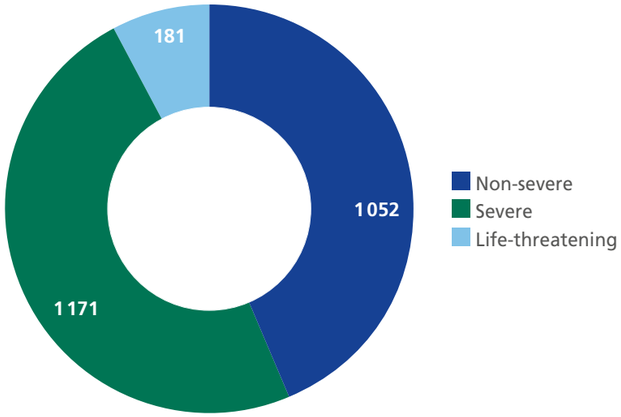
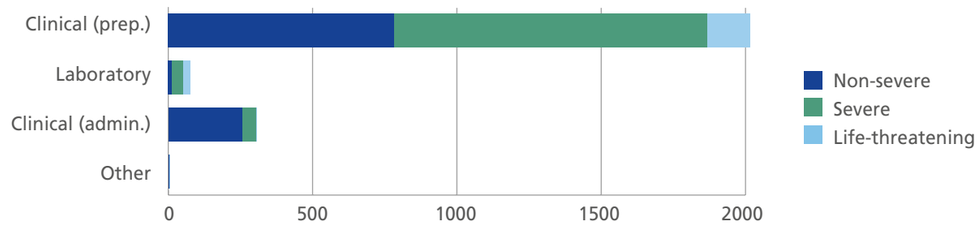


Figure 15
NM by severity and localisation

Near miss according to severity and localisation



Severity	Clinical (preparation)	Laboratory	Clinical (administration)	Other
Non-severe	783	12	255	2
Severe	1083	37	49	2
Life-threatening	150	26	3	2

3.5.2 NM discovery

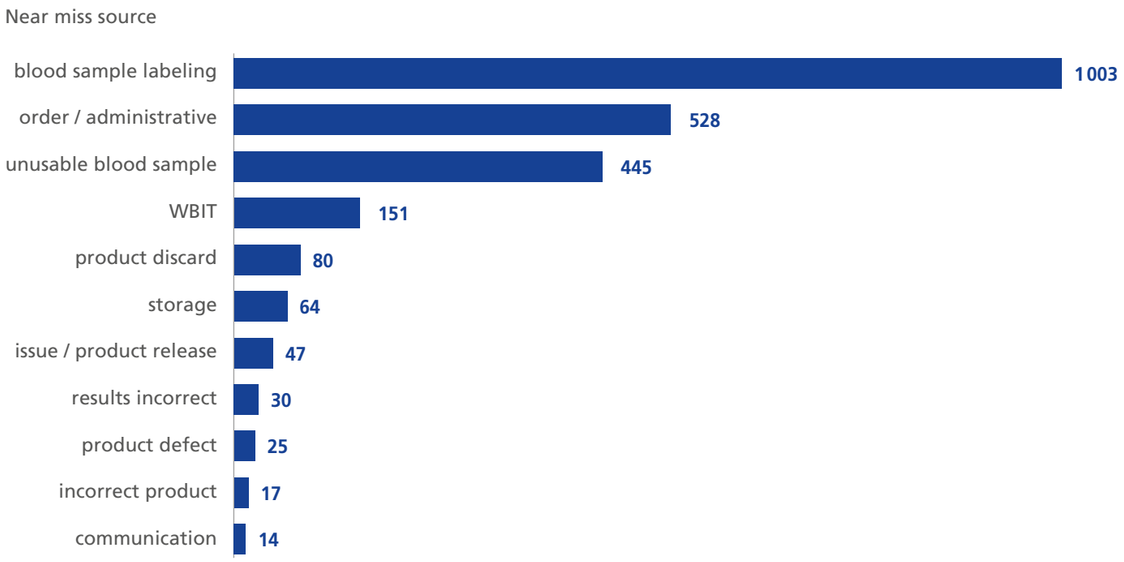
Table 25
NM discovery

NM discovery					
		Discovery of the deviation			
		Ward/Op	Laboratory	Other	Total
Stage at which the deviation occured	Clinical (preparation)	22	1992	2	2016
	Laboratory	12	62	1	75
	Clinical (administration)	17	289	1	307
	Other	2	4	0	6
Total		53	2347	4	2404

Table 25 shows the localisation of the deviation (rows) and the localisation of the discovery of the deviation (columns). The deviations were discovered in the laboratory.

3.5.3 NM incidents according to cause

Figure 16
NM according to cause



3.6 Donor reactions

3.6.1 Overview

Swissmedic received 26 reports in 2020.

Table 26
Donor reactions

Donor reactions				
Severity	**Local symptoms**	**Vasovagal reactions**	**Other**	**Total**
Non-severe	0	6	0	6
Severe	3	4	1	8
Life-threatening	0	12	2	14
Death	0	0	0	0
Total	3	22	3	28

Of the 26 cases, two involved more than one reaction, making a total of 28 reactions for 2020.

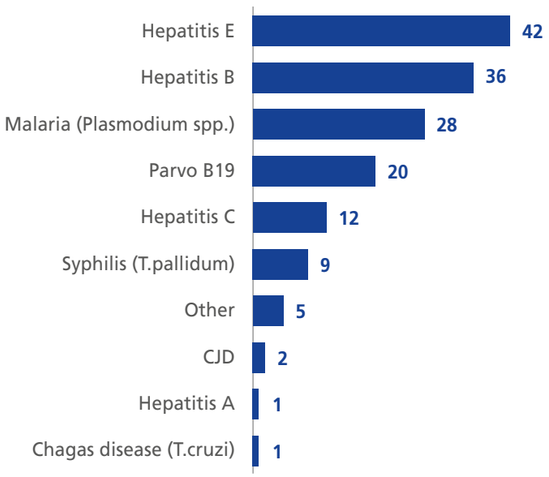
3.7 Quality defects and protective measures

3.7.1 Overview

In 2020, a total of 151 reports were received concerning protective measures for positive infection markers and quality defects. Two quality defects were reported in five donors

Figure 17
Quality defects and protective measures

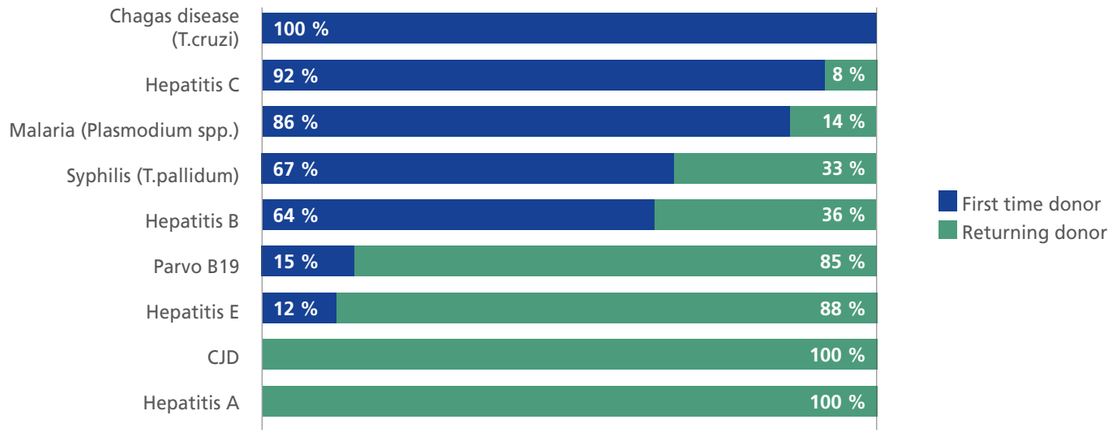
Quality defects and protective measures reports



3.7.2 Infection markers and donor status

Figure 18
Infection markers and donor status

Infectious marker according to donor status



3.8 Patient-specific look-back procedures

Table 27
Look-back procedures in 2020

Patient-specific Look-Back procedures			
Infectious marker	Number of cases	Excluded	Not Exluded
HCV	1	1	0

The donors tested negative in the look-back procedure.

4. Coronavirus

19 transfusion reactions were reported in patients with confirmed COVID-19 infection during 2020.

Table 28
Transfusion reactions in COVID-19 patients

Transfusion reactions by Covid-19 patients								
	Severity				Imputability			
	1	2	3	4	1	2	3	4
FNHTR	10	0	0	0	6	4	0	0
Allergic TR	1	0	1	0	0	0	2	0
TACO	0	4	0	0	0	3	0	1
HTR	0	0	0	1	0	1	0	0
TRALI	0	0	1	0	0	1	0	0
Other	1	0	0	0	0	1	0	0
Total	12	4	2	1	6	10	2	1

Severity 1: non-severe, 2: severe/permanent damage, 3: life-threatening, 4: death.
Imputability 1: unlikely, 2: possible, 3: probable, 4: certain.

Table 28 shows the reported transfusion reactions by classification, severity and causality.

Table 29
Convalescent plasma produced and supplied by major region

Produced and delivered convalescent plasma units by major regions			
Major region	Canton	Convalescent Plasma	
		Produced	Delivered
Lake Geneva Region	VD, VS, GE	68	20
Espace Mittelland	BE, FR, SO, NE, JU	124	46
Northwestern Switzerland	BS, BL, AG	195	64
Zurich	ZH	249	*
Ticino	TI	54	59**
Total		695	184

*Information not received by the close of the reporting year.
**18 additional products purchased from other RBTS and supplied.

695 units of convalescent plasma were produced in 2020, of which 184 units were supplied to hospitals. It is not known how much product was supplied in one major region.

Attachment

Abbreviations

%	percent
°C	degrees Celsius
AB	antibodies
ABO	ABO blood group system
para.	paragraph
ADU	avoidable, delayed or under/overtransfusion
PU	antigen
AG-NO.	Antigen number
AB	antibodies
Allo-AB	allo-antibodies
MPLO	Medicinal Products Licensing Ordinance
Art.	Article
BG	blood group
BD/BTS	blood donation/blood transfusion service
let.	letter
CH	Switzerland
CJD	Creutzfeldt-Jakob disease
pRBC	packed red blood cells
F	female
FFP	fresh frozen plasma
FFP	fresh frozen plasma
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
TPA	Therapeutic Products Act
HSE	handling and storage errors
HTR	haemolytic transfusion reaction
HV	haemovigilance
RPHv	haemovigilance officer
IBCT	incorrect blood component transfused
ID	identification
ISBT	International Society of Blood Transfusion
IT	information technology
AR	Annual Report
M	male
NM	near miss
PC	platelet concentrates
pRBC	packed red blood cells
PTP	post-transfusion purpura
RBRP	right blood right patient
RF	risk factors
Rh	rhesus
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
PC	platelet concentrates (PCa: apheresis-derived; PCb: whole blood-derived)
TR	Transfusion reaction
TRALI	transfusion-related acute lung injury
unk	unknown
TPO	Therapeutic Products Ordinance
WBIT	wrong blood in tube
WCT	wrong component transfused
e.g.	for example
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

List of figures

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