
Haemovigilance Report

2021

Danish Registry of Transfusion Risks (DART)



DSKI
Danish Society for Clinical Immunology

Member of the Haemovigilance Committee

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Abbreviations

AHTR	Acute hemolytic transfusion reaction
Anti-HLA	Antibodies against HLA (human leucocyte antigen)
AR	Allergic reaction
BNP	Brain natriuretic peptide
CF	Confer
DART	Danish Registry of Transfusion Risks
DHTR	Delayed hemolytic transfusion reaction
DSKI	Danish Society of Clinical Immunology
FNHTR	Febrile non hemolytic transfusion reaction
HC	Haemovigilance Committee
HNA-Ab	Antibodies against HNA (human neutrophil antigen)
IBCT	Incorrect blood component transfused
IHN	International Haemovigilance Network
ISBT	International Society of Blood Transfusion
RBC	Red blood cells
TACO	Transfusion-associated circulatory overload
TAD	Transfusion-associated dyspnea
TRALI	Transfusion-related acute lung injury
TTI	Transfusion-transmitted infection

Introduction

The Danish Registry of Transfusions Risks (DART) is part of The Danish National Haemovigilance Committee under the auspices of the Danish Society of Clinical Immunology (DSKI). Since 1999, the committee has received and analyzed data for serious adverse events, - reactions, and errors associated with the transfusion of blood components.

DART is a member of IHN.

In 2021, 15.3 adverse events and reactions per 100,000 transfused blood components were reported to DART. The number for the recent years, (2020: 23.2; 2019: 15.9; 2018: 9.5; 2017: 5.5/100,000 transfused blood components).

In the tables representing 2021 data, only the adverse events, - reactions and errors reported in 2021 are mentioned.

The formula for reporting serious adverse events, - reactions, and errors associated with the transfusion of blood components, and the guide to DART reporting are to be found on the [DSKI](#) homepage.

Definitions

The terms for the blood components RBC, platelets and plasma are defined by the IHN.

Adverse events and reactions is the headline for the following:

An adverse event

An incident

An adverse reaction

The adverse events and reactions are defined and categorized according to ISBTs standards, that is: severity (grade 1 – 4) and imputability (grade 1 – 5).

Specifications for blood components

In Denmark blood components are produced in accordance with the "Guide to the preparation, use and quality assurance of blood components", EDQM current version.

RBC: Red Blood Cells, Leucocyte depleted in Additive Solution derived from whole blood donation. This includes a very few numbers of washed and cryopreserved RBC.

Platelets: Platelets, recovered, pooled, leucocyte-depleted, in additive solution derived from whole blood AND platelets, apheresis, leucocyte-depleted, in additive solution obtained by apheresis of a single donor.

Four regions used four buffy coats/pool platelets, one region used 6 buffycoats/two pool platelets.

Plasma: Plasma, fresh frozen prepared either from whole blood or from plasma obtained by apheresis of a single donor and frozen within 24 hours. Liquid plasma is akin the above-mentioned plasma but never frozen (shorter shelf life).

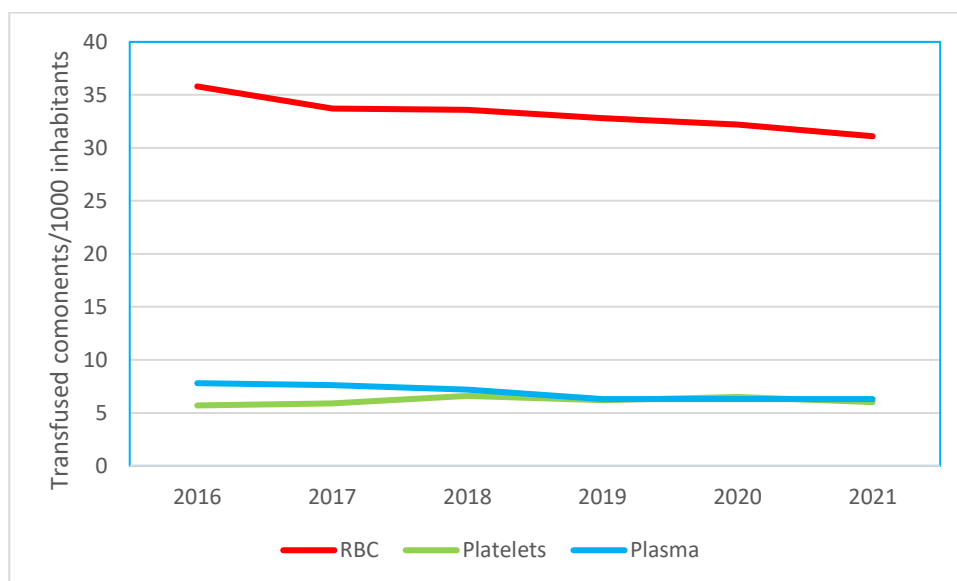
Blood Components Transfused

2021

Blood usage by region and blood component.

Region	RBC	Platelets (pool)	Platelets (apheresis)	Plasma (whole blood)	Plasma (apheresis)	Total
Capital Region of Denmark	61,447	15,436	816	14,034	3,928	95,661
Region Zealand	25,303	2,434	601	1,672	1,234	31,244
Region of Southern Denmark	35,867	7,357	478	5,677	869	50,248
Central Denmark Region	39,818	5,775	149	6,384	43	52,169
North Denmark Region	19,926	2,054	329	3,138	161	25,608
Total	182,361	33,056	2,373	30,905	6,235	254,930

2017-2021



For international standardization, the number of transfused blood components is shown per 1000 inhabitants. (Inhabitants per 4Q for the respective year, Statistics Denmark).

Adverse events and reactions

2021 – Regionally

Region	Number	Number/100,000 transfused components
Capital Region of Denmark	7	7.3
Region Zealand	2	6.4
Region of Southern Denmark	8	15.9
Central Denmark Region	16	30.7
North Denmark Region	6	27.3
Total	39	15.3

As in previous annual reports the Central Denmark region has reported the highest number of complications. Increased attention to complications of transfused blood components and educational initiative among staff are most likely part of the explanation.

2021

Adverse events and reactions	Number	Number/100,000 transfused components
IBCT (wrong patient)	1	0.4
IBCT (wrong component)	5	2.0
AHTR	5	2.0
DHTR	4	1.6
AR	6	2.4
TRALI	1	0.4
TACO	7	2.8
FNTHR	10	4.1
Total	39	15.3

Cumulated table of reports – adverse events and reactions

2017-2021

Adverse events and reactions	Number/100,000 transfused components (absolute)					
	2017	2018	2019	2020	2021	2017-2021
Wrong patient	0	0.4 (1)	0	1.1 (3)	0.4 (1)	0.4 (5)
Wrong component	0.4 (1)	0.7 (2)	0.8 (2)	0.8 (2)	2.0 (5)	0.9 (12)
AHTR	0	0	0	1.5 (4)	2.0 (5)	0.7 (9)
DHTR	0	0.7 (2)	5.7 (15)	2.7 (7)	1.6 (4)	2.1 (28)
AR	1.1 (3)	1.5 (4)	4.2 (11)	3.8 (10)	2.4 (6)	2.6 (34)
TRALI	1.1 (3)	0.4 (1)	0.4 (1)	1.9 (5)	0.4 (1)	0.8 (11)
TACO	1.5 (4)	2.9 (8)	2.3 (6)	4.6 (12)	2.8 (7)	2.8 (37)
TTI	0	0	0	0.4 (1)	0	0.1 (1)
FNHTR	1.1 (3)	2.3 (6)	2.7 (7)	6.1 (16)	4.1 (10)	3.2 (42)
UCT	0.4 (1)	0	0	0.4 (1)	0	0.2 (2)
Total	5.5 (15)	9.5 (25)	15.7 (42)	23.2 (61)	15.3 (39)	13.6 (181)

Adverse events and reactions listed by type

Incorrect blood component transfused (IBCT) - wrong patient/wrong component

Year	Number/100,000 transfused components (absolute)		
	Wrong patient	Wrong component	Total
2017	0	0.4 (1)	0.4 (1)
2018	0.4 (1)	0.7 (2)	1.1 (3)
2019	0.8 (2)	0	0.8 (2)
2020	1.1(3)	0.8(2)	1.9(5)
2021	0.4(1)	2.02(5)	2.4(6)

Region	Fraction of transfused blood components validated electronically (%)			
	2018	2019	2020	2021
Capital Region of Denmark	0	0	0	0
Region Zealand	71	81	81	81
Region of Southern Denmark	23	37	48	48
Central Denmark Region	94	96	96	96
North Denmark Region	0	0	0	0
Mean	39	43	45	45

The six reported IBCTs all occurred in the Region of Southern Denmark (one wrong patient and one wrong component) and Central Denmark Region (four reports of wrong components).

Acute hemolytic transfusion reaction (AHTR) and delayed hemolytic transfusion reaction (DHTR)

Red blood cell antibodies detected in blood from patients with AHTR and DHTR in 2017-2021.

Year	Number/100.000 transfused components (absolute)	
	AHTR	DHTR
2017	0	0
2018	0	0.7 (2)
2019	0	5.7 (15)
2020	14.5 (4)	2.7 (7)
2021	2.0 (5)	1.6 (4)

Specificity of red blood cell alloantibodies detected from 11 patients with AHTR or DHTR in 2021.

Antibody	Jk ^a	E	K	Jk ^b	IB	Other*
AHTR	1			2	1	1
DHTR	2	1	1			

*The detected antibody had unknown specificity

The screen test did not include erythrocytes for detection of an anti-IB antibody. Post-transfusion the plasma control turned out aberrant. Anti-IB, reacts at 4 and 20 degrees °C primarily.

Specificity of red blood cell alloantibodies detected from patients with AHTR and DHTR in the period 2001-2021.

Antibody	Jk ^a	S	C	E	K	Jk ^b	Fy ^a	c	e	Fy ^b	Lu ^a	Bg	B	Cw	Wr ^a	M	IB	Other*
AHTR	4		2		3	4		1	1			1	1	1	3		1	4
DHTR	17	3	2	19	9	5	8	10	1	3	1			1		2		

*For three reactions the detected antibodies had unknown specificity, and for one reaction the only antibody identified was cold agglutinin

Allergic reaction (AR)

AR refers to grade 2-4 allergic reactions with a clinical presentation of an anaphylactic reaction according to ISBT's definition.

Year	Number/100,000 components transfused (absolute)			
	RBC	Platelets	Plasma	Total
2017	0	3.0 (1)	4.6 (2)	1.1 (3)
2018	0	2.6 (1)	7.2 (3)	1.5 (4)
2019	1.6 (3)	2.8 (1)	13.7 (5)	4.2 (11)
2020	1.1 (2)	2.6 (1)	19.1 (7)	3.8 (10)
2021	1.7 (3)	2.8 (1)	5.4 (2)	2.4 (6)

Pulmonary adverse transfusion reactions

Similarities in symptomatology have inspired haemovigilance organizations (ISBT) to use a collective header for TRALI, TACO and TAD. As the reactions can be difficult to separate in the clinical ward, it makes sense to consider them as closely related.

Transfusion-related acute lung injury (TRALI)

Year	Number/100,000 components transfused (absolute)			
	RBC	Platelets	Plasma	Total
2017	0.5 (1)	3 (1)	2.3 (1)	1.1 (3)
2018	0.5 (1)	0	0	0.4 (1)
2019	0.4 (1)	0	0	0.4 (2)*
2020	1.6 (3)	2.6 (1)	0	1.9 (5)*
2021	0.5 (1)	0	0	0.4 (1)

*Two cases of TRALI were observed in relation to transfusion of granulocyte components. They are only represented in the column "Total"

Transfusion-associated circulatory overload (TACO)

Year	Number/100,000 components transfused (absolute)			
	RBC	Platelets	Plasma	Total
2017	2.1 (4)	0	0	1.5 (4)
2018	2.6 (5)	5.3 (2)	2.4 (1)	2.9 (8)
2019	2.6 (5)	0	0	2.3 (6)*
2020	5.3 (10)	5.3 (2)	0	4.6 (12)
2021	3.8 (7)	0	0	2.8 (7)

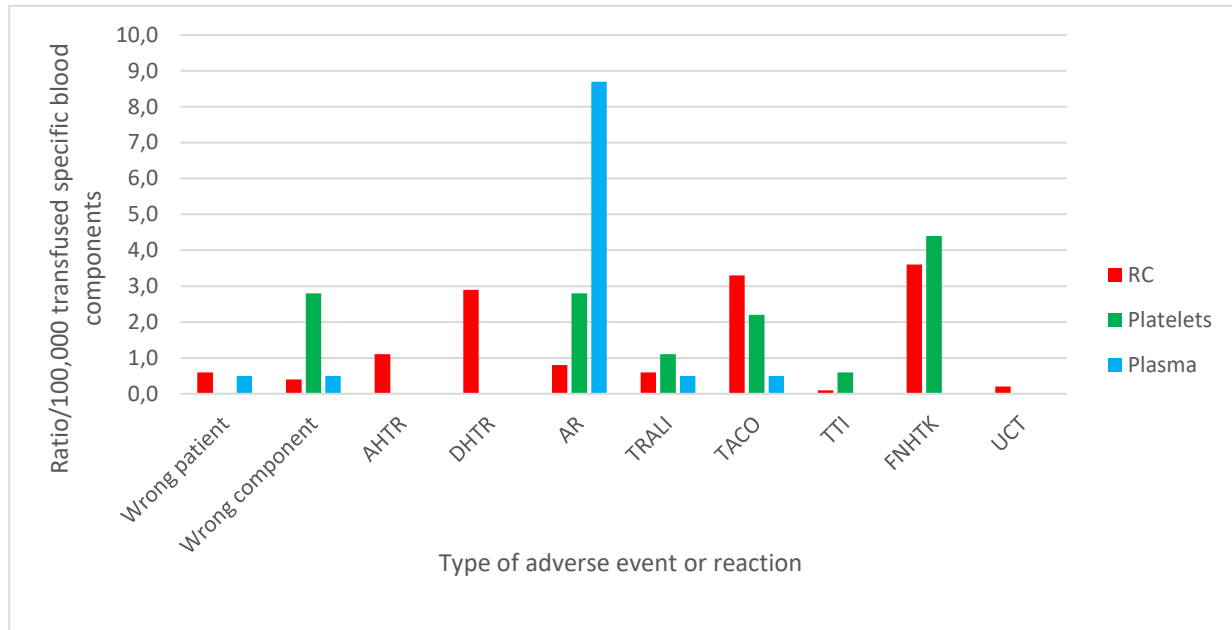
* In 2019 one of 6 TACO was observed in relation to transfusion of >1 type of blood component (ao. transfusion packages 4:4:1/5:5:2 RBC:Plasma:Platelets). The one TACO observed in relation to transfusion of >1 type of blood component is only represented in the column "Total".

Adverse events and reactions by blood component

2021

Adverse events and reactions	Number/100,000 components transfused (absolute)			
	RBC	Platelets	Plasma	Total
IBCT (wrong patient)	0.6(1)	0	0	0.4(1)
IBCT (wrong component)	1.1(2)	5.3(2)	2.8(1)	2.0(5)
AHTR	2.7(5)	0	0	2.0(5)
DHTR	2.2(4)	0	0	1.6(4)
AR	1.7(3)	2.8(1)	5.4(2)	2.4(6)
TRALI	0.6(1)	0	0	0.4(1)
TACO	4.0(7)	0	0	2.8(7)
FNHTR	4.9(9)	2.8(1)	0	4.0(10)
Total	17.5(32)	10.8(4)	8.5(3)	15.3(39)

2017-2021



Severity

2021

Adverse event and reactions	Grade 1 (Non-severe)	Grade 2 (Severe)	Grade 3 (Life-threatening)	Grade 4 (Death)	Total
IBCT (wrong patient)	0	1	0	0	1
IBCT (wrong component)	4	1	0	0	5
AHTR	1	4	0	0	5
DHTR	2	2	0	0	4
AR	0	1	5	0	6
TRALI	0	1	0	0	1
TACO	0	6	1	0	7
FNHTR	7	3	0	0	10
Total	14	19	6	0	39
Ratio/100,000 components	5,5	7,5	2,4	0,0	15,3

2017-2021



Cases

The presented cases are not exhaustive compared to the received reports. The cases presented are either representative reports for the type of adverse events/reactions/errors or have a more specific learning potential.

Incorrect blood component transfused (IBCT) – wrong patient

Indicator	Information
Age	18 – 65 years
Transfused components	RBC
Severity	3 (Life-threatening)
Wrong patient/- component	Wrong patient
ABO RhD blood type donor/component	A RhD positive

ABO RhD blood type patient	0 RhD negative
Description	<p>Acute cesarean section with findings of uterine rupture. An emergency blood component package is ordered. In the meantime, four A RhD pos. components from the emergency blood refrigerator were picked up. An electronic setup check is performed and the ProSang log shows that the following error message appears: "The blood component is not reserved for this patient. Contact the blood bank". The warning is forced, and the transfusion is completed.</p> <p>The patient develops chills, nausea and vomiting. The error is discovered and treatment with steroid and forced diuresis is started. In addition, blood samples are taken (haemolysis and free haemoglobin) and investigation for transfusion complications. The submitted A RhD pos. component is subsequently determined to be of blood type A2.</p>

Allergic reaction (AR)

Indicator	Information	
Age	18 – 65 years	
Transfused components	Platelets and cryoprecipitate	
Severity	3 (Life-threatening)	
Imputability	Probable (notified as possible, secondly validated by HC as probable)	
	Information	Specification

Blood Pressure	Hypotensive	From 124/89 to 86/49 mmHg
Respiratory insufficiency	Yes	No values reported
Angioedema	No	
Urticaria/universal erythema	Yes	
Medical treatment	Yes	Adrenalin, steroids and antihistamine
IgA	no information	
Anti-IgA	no information	
Tryptase	no information	
Description	<p>Patient admitted for surgery for compartment syndrome.</p> <p>During transfusion, a fulminant anaphylactic reaction develops with universal urticaria, dyspnoea with bronchospasm, tachycardia and hypotension. Treated with adrenaline, clemastine and solucortef.</p> <p>Adapts to the treatment.</p>	

Transfusion associated circulatory overload (TACO)

Indicator	Information	
Age	> 65 years	
Transfused components	16 RBC 10 plasma 1 cryoprecipitate 4 Platelets	
Severity	3 (Life-threatening)	
Imputability	Definite	
	Information	Specification

Respiratory insufficiency/hypoxemia	Yes	No values reported
Tachycardia	Yes	No values reported
Blood pressure	Hypertensive	From 158/60 to 197/69 mmHg
Acute/impairment of lung oedema	Yes	Not known
(Other) signs of positive fluid balance	No	
Medical treatment	Yes	Diuretics, nitroglycerin, trandate and venesection
x-ray chest (bilateral infiltrations)	Abnormal	Lung oedema
(Known) congestive heart failure (CHF)	Yes	
ECHO	No information	
BNP/pro-BNP	Not measured	
Description	Patient receiving apixaban for atrial fibrillation. Splenectomy performed due to traumatic splenic injury. Estimated bleeding was approximately 3500 ml. Treated medically and with venesection (due to "overtransfusion") and non-invasive ventilation with good effect.	

Transfusion-related acute lung injury (TRALI)

Indicator	Information	
Age	> 65 years	
Transfused components	RBC	
Severity	2 (Severe) reported as unknown, secondly validated by HC 2	
Imputability	possible	
	Information	Specification
Respiratory insufficiency/hypoxaemia	Yes	Saturation from > 90 to 75%
X-ray chest (bilateral infiltrations)	Yes	bilateral infiltrations
Circulatory overload	Yes	No specification
Other ALI disposing factors	Yes	No specification
Medical treatment	Yes	Diuretics had no effect
Anti-HLA/-HNA Ab donor	No	
Anti-HLA/-HNA-Ab patient	Not measured	
Description	<p>During transfusion of 2 RBC, the patient develops respiratory insufficiency with reduction in saturation, temperature rise and hypertension, interpreted as TACO.</p> <p>As treatment for this complication has no effect, TRALI/possible TRALI is suspected. The patient has competing factors and comorbidities that lead to discontinuation of treatment and the</p>	

	department has therefore announced that they do not want to take blood samples from the patient for TRALI investigation
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