Haemovigilance Report

2019

Danish **R**egistry of **T**ransfusion Risks (DART)

DSKI
Danish Society for Clinical Immunology

Member of the Haemovigilance Committee

Bitten Aagaard (Corresponding author)
M.D.
Dept. of Clinical Immunology; Aalborg University Hospital
Email: biaaj@rn.dk

Betina Sørensen
M.D.
Dept. of Clinical Immunology, Aarhus University Hospital

Rune Larsen
M.D.
Department of Clinical Immunology, Zealand University Hospital

Helene Martina Paarup
M.D.
Dept. of Clinical Immunology, Odense University Hospital

Mie Topholm Bruun
M.D.
Dept. of Clinical Immunology, Odense University Hospital

Christina Mikkelsen
M.D.
Dept. of Clinical Immunology, Copenhagen University Hospital

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Abbreviations

AHTR	Acute hemolytic transfusion reaction
Anti-HLA	Antibodies against HLA (human leucocyte antigen)
Anti-HNA	Antibodies against HNA (human neutrophil antigen)
AR	Allergic reaction
BNP	Brain natriuretic peptide
CI	Cardiac index
CF	confer
DART	Danish Registry of Transfusion Risks
DAT	Direct antiglobulin test
DHTR	Delayed hemolytic transfusion reaction
DSR	Delayed serologic reaction
ECHO	Echocardiography
EF	Ejection fraction
EIS	Electronic Identification System
FNHTR	Febrile non-hemolytic transfusion reaction
Hb	Hemoglobin
HC	Haemovigilance committee
HR	Heart rate
IBCT	Incorrect blood component transfused
IHD	Ischemic heart disease
IHN	International Haemovigilance Network
ISBT	International Society of Blood Transfusion
LDH	Lactate dehydrogenase
MAP	Mean arterial pressure
PTP	Post transfusion purpura
RBC	Red blood cells
TACO	Transfusion-associated circulatory overload
TAD	Transfusion-associated dyspnea
Ta-GVHD	Transfusion-associated graft-versus-host disease

TR	Transfusion reaction
TRALI	Transfusion-related acute lung injury
TTI	Transfusion-transmitted infection

Introduction

DART is the Danish National Haemovigilance Committee. Since 1999, the committee has received and analyzed data for serious adverse events and reactions associated with transfusion of blood components.

DART is a member of the Nordic Haemovigilance Group and IHN. DART reports the Danish annual results of adverse events and reactions associated with transfusion of blood components to IHNs haemovigilance Database (ISTARE).

In 2019, 15.9 adverse events and reactions per 100,000 transfused blood components were reported to DART. The number for the recent years, (2018: 9.5; 2017: 5.5; 2016: 7.1; 2015: 8.0/100,000 transfused blood components).

In tables representing 2019 data, only the adverse events and reactions reported in 2019 are mentioned, which means, AHTR, TTI, hypotensive TR, TAD, Ta-GVHD, PTP and UCT are excluded.

As a standard procedure, since 2014, DART has validated the submitted reports according to ISBTs definitions of adverse event and reaction and imputability. The validation resulted in exclusion of two reported adverse reactions (one DSR, which is not represented in the tables; and one report FNHTR, did not fulfil the definitions of adverse event and reaction according the ISBT definition).

The formula for reporting serious adverse events and reactions associated with transfusion of blood components to DART, and the guide to DART reporting are to find on the homepage of Danish Society of Clinical Immunology (DSKI).

Definitions

The terms for blood components RBC, platelets and plasma are defined by IHN.
Adverse events and reactions is used as a headline for:
An adverse event

An incident
An adverse reaction

The type of adverse events and reactions are defined by ISBT as in DARTs "Vejledning til DART indberetning" [Guide to DART reporting].
Severity (grade 1 – 4; resp. non-severe, severe, life-threatening and death).
Imputability (five grades; resp. definite, probable, possible, unlikely and excluded of adverse events and reactions are categorized according to ISBTs standards.

Specifications for blood components

In Denmark blood components are produced in respect to "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 include a very few numbers of RBC washed and – cryopreserved.
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 as the above-mentioned plasma but never frozen (shorter shelf life).

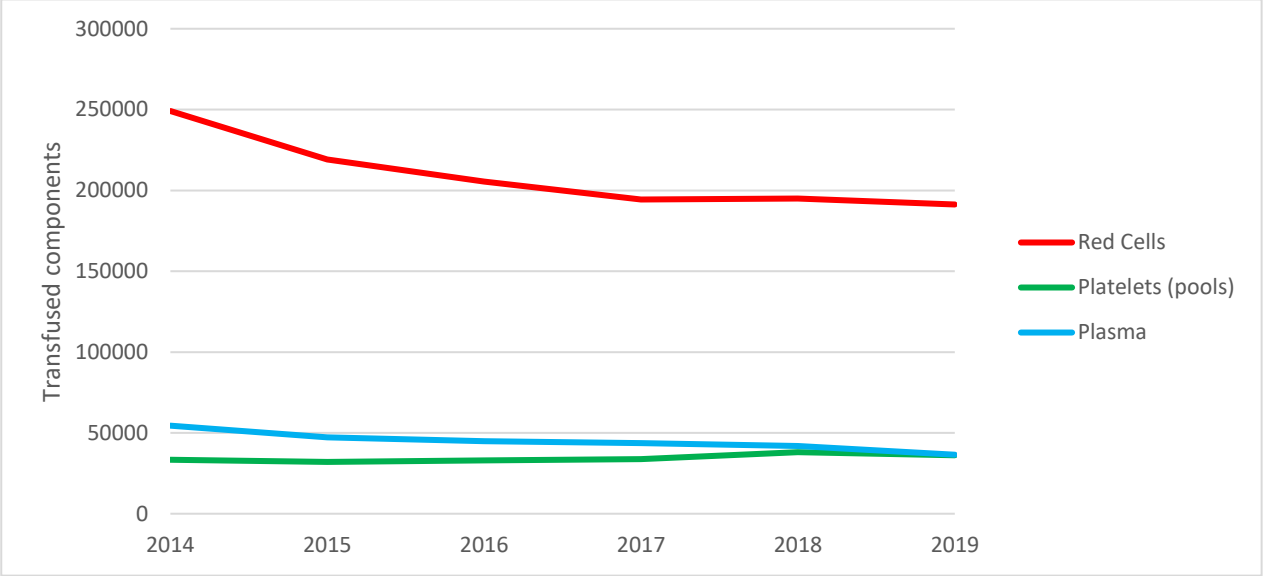
Blood Components Transfused

2019

Data of transfused blood components have been reported from the five regions.

Region	RBC	Platelets (pool)	Platelets (aphresis)	Plasma (whole blood)	Plasma (aphresis)	Total
Capital Region of Denmark	64,153	15,968	400	12,781	2,815	96,117
Region Zealand	25,286	2,254	390	2,098	945	30,973
Region of Southern Denmark	40,588	7,746	487	6,452	1,199	56,472
Central Denmark Region	41,885	6,040	253	6,340	443	54,961
North Denmark Region	19,381	2,385	266	3,357	85	25,474
Total	191,293	34,393	1,796	31,028	5,487	263,997

2014-2019



The number of transfused blood components is stable through the last three years.

Adverse events and reactions

2019 – Regionally

Region	Number	Number/100,000 transfused components
Capital Region of Denmark	8	8.3
Region Zealand	5	16.1
Region of Southern Denmark	3	5.3
Central Denmark Region	24	43.7
North Denmark Region	2	7.9
Total	42	15.9

The Central Denmark region has a marked increase in number of reported adverse events and reactions. The reason is a change in workflow regarding adverse reactions. A new version of the IT blood bank system was implemented in April 2019 and enabled the lab. technician to flag an adverse reaction. Weekly a deficiency list is extracted, and the responsible physician ensures fulfilling and reporting of the adverse reaction.

2019

Adverse events and reactions	Number	Number/100,000 transfused components
IBCT (wrong patient)	2	0.8
DHTR	15	5.7
AR	11	4.2
TRALI	1	0.4
TACO	6	2.3
FNHTR	7	2.7
Total	42	15.9

Cumulated table of reports – adverse events and reactions

2015-2019

Adverse events and reactions	Number/100,000 transfused component (absolute)					
	2015	**2016**	**2017**	**2018**	**2019**	**2015-2019**
Wrong patient	1.0 (3)	0.4 (1)	0	0.4 (1)	0	0.3
Wrong component	0.7 (2)	0.7 (2)	0.4 (1)	0.7 (2)	0.8 (2)	0.7
AHTR	0.3 (1)	0.4 (1)	0	0	0	0.1
DHTR	2.0 (6)	1.4 (4)	0	0.7 (2)	5.7 (15)	1.9
AR	1.0 (3)	2.1 (6)	1.1 (3)	1.5 (4)	4.2 (11)	1.9
TRALI	0.3 (1)	1.1 (3)	1.1 (3)	0.4 (1)	0.4 (1)	0.7
TACO	0.3 (1)	0.4 (1)	1.5 (4)	2.9 (8)	2.3 (6)	1.4
TTI	0.3 (1)	0	0	0	0	0.1
FNHTR	0.3 (1)	0.7 (2)	1.1 (3)	2.3 (6)	2.7 (7)	1.4
Hypotensive TR	0.7 (2)	0	0	0	0	0.1
TAD	0.3 (1)	0	0	0	0	0.1
UCT	0.7 (2)	0	1.1 (1)	0	0	0.2
Total	8.0 (24)	7.1 (20)	5.5 (15)	9.5 (25)	15.7 (42)	9.0

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
2015	0.8 (3)	0.5 (2)	1.3 (5)
2016	0.3 (1)	0.5 (2)	0.8 (3)
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)

Region	Fraction of transfused blood components validated electronically (%)	
	2018	2019
Capital Region of Denmark	0	0
Region Zealand	71	81
Region of Southern Denmark	31	37
Central Denmark Region	94	96
North Denmark Region	0	0
Mean	39	43

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

Erythrocyte antibodies detected in blood from patients with AHTR and DHTR in 2015-2019

Year	Number/100.000 transfused components (absolute)	
	AHTR	DHTR
2015	0.3 (1)	2 (6)
2016	0.4 (1)	1.4 (4)
2017	0	0
2018	0	0.7 (2)
2019	0	5.7 (15)

Specification of erythrocyte antibodies detected in blood from 15 patients with DHTR in 2019

Antibody	Jk^a	S	E	K	Fy^a	c	Fy^b	M
DHTR	4	1	5	2	1	4	1	2

Specification of erythrocyte antibodies detected in blood from patients with AHTR and DHTR in the period 2001-2019

Antibody	Jk^a	S	C	E	K	Jk^b	Fy^a	c	e	Fy^b	Lu^a	Bg	B	Cw	Wr^a	M	Other*
AHTR	3		1		2	2		1				1	1		3		3
DHTR	11	3	2	16	6	5	6	10	1	3	1			1		2	

*Two reactions the detected antibodies had unknown specificity, and one reaction where the only antibody identified was cold agglutinin

Allergic reaction (AR)

AR refers to grade 2-4 allergic reactions and the clinical presentation is an anaphylactic reaction cf. ISBT's definition

Year	Number/100,000 components transfused (absolute)			
	RC	Platelets	Plasma	Total
2015	0	3.1 (1)	4.2 (2)	1.0 (3)
2016	0.5 (1)	3.0 (1)	8.9 (4)	2.1 (6)
2017	0	3.0 (1)	4.6 (2)	1.1 (3)
2018	0	2.6 (1)	2.4 (1)	1.5 (4)*
2019	1.6 (3)	2.8 (1)	13.7 (5)	4.2 (11)*

* from 2018 AR observed in relation to transfusion of >1 type of blood component (ao. transfusion packages 4:4:1/5:5:2 RBC:Plasma:Platelets), only figure in the column "Total". In prior haemovigilance reports AR observed in relation to >1 type of blood component were allocated to the blood component most probable causing AR considering volume and type of blood components given.

Respiratory adverse transfusion reaction

Similarities in symptomatology has 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 regard them as close related.

Transfusion-related acute lung injury (TRALI)

Year	Number/100,000 components transfused (absolute)			
	RC	Platelets	Plasma	Total
2015	0.5 (1)	0	0	0.3
2016	1.0 (2)	0	2.2 (1)	1.1
2017	0.5 (1)	3 (1)	2.3 (1)	1.1
2018	0.5 (1)	0	0	0.4
2019	0	0	0	NA*/0.4 (1)

*Transfusion of granulocytes from a donor who prior had donated stem cells to the patient

Transfusion-associated circulatory overload (TACO)

Year	Number/100,000 components transfused (absolute)			
	RC	Platelets	Plasma	Total
2015	0.5(1)	0	0	0.3
2016	0.5(1)	0	0	0.3
2017	2.1(4)	0	0	1.5
2018	2.6(5)	5.3 (2)	2.4 (1)	2.9 (8)
2019	2.6 (5)	0	0	2.3 (6)*

* 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 only figure in the column "Total".

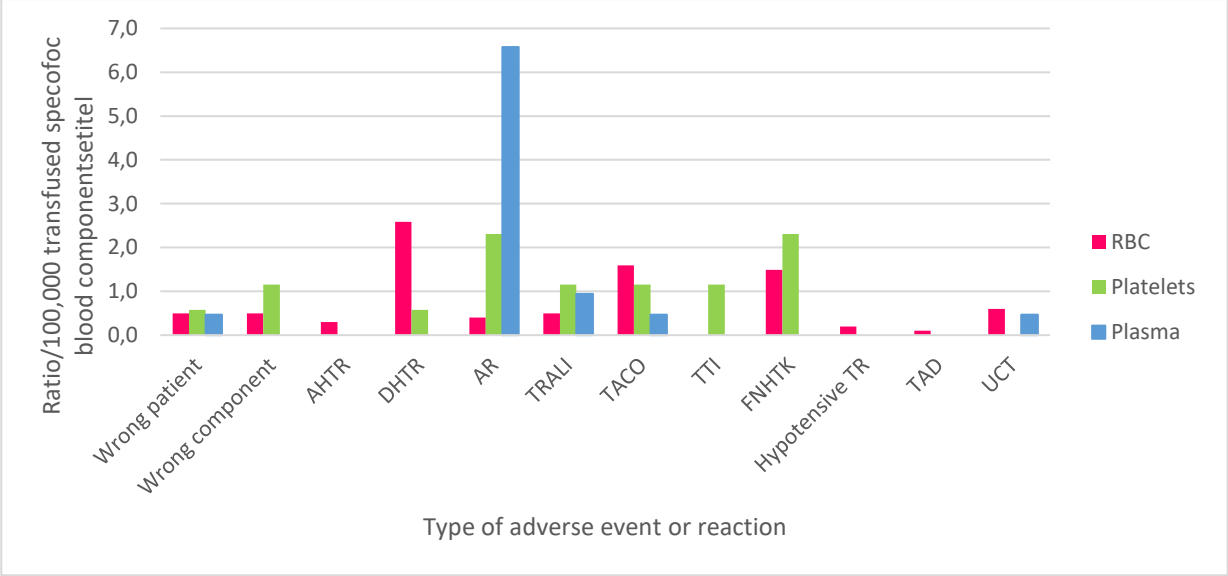
Adverse events and reactions in relation to blood component

2019

Adverse events and reactions	Number/100,000 components transfused (absolute)			
	RC	Platelets	Plasma	Total
IBCT (wrong patient)	0.5 (1)	0	2.7 (1)	0.8 (2)
DHTR	7.8 (15)	0	0	5.7 (15)
AR	1.6 (3)	2.8 (1)	13.7 (5)	4.2 (11)
TRALI	0	0	0	NA*/0.4 (1)
TACO	2.6(5)	0	0	2.3 (6)
FNHTR	2.1 (4)	8.3 (3)	0	2.7 (7)
Total	14.6 (28)	11.1(4)	16.4 (6)	15.9 (42)

*Transfusion of granulocytes from a donor who prior had donated stem cells to the patient

2015-2019

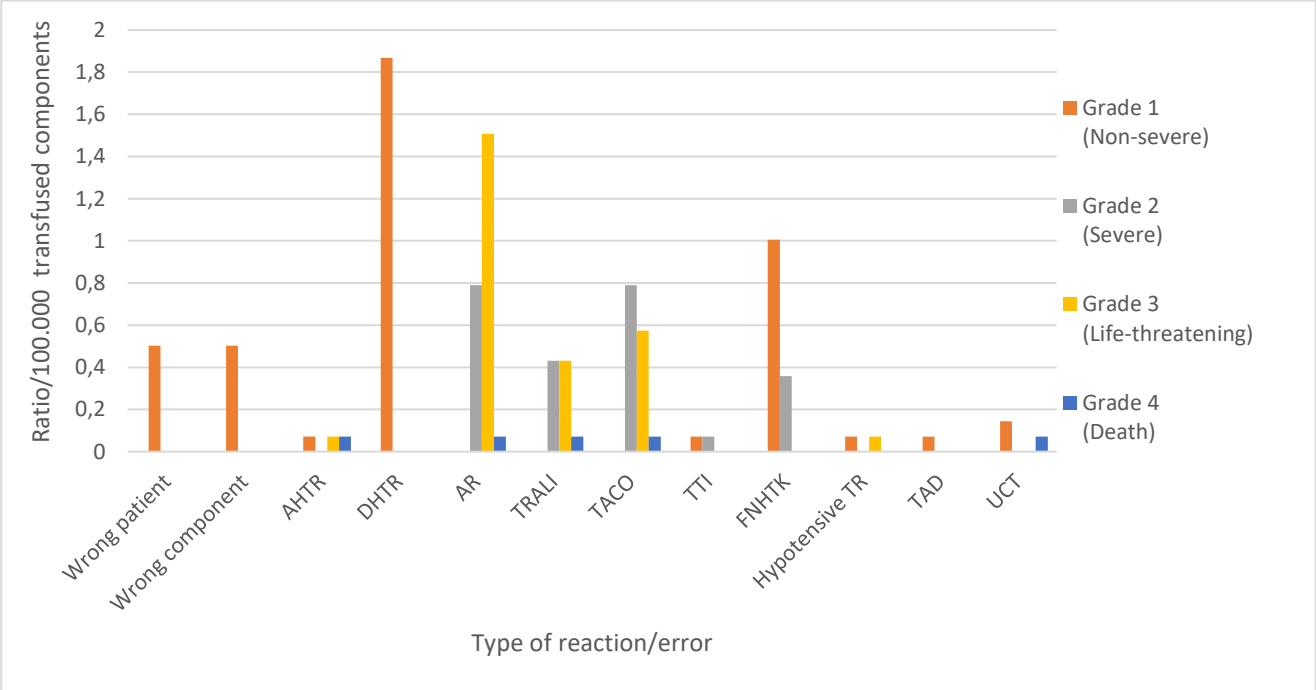


Severity

2019

Adverse event and reactions	Grade 1 (Non-severe)	Grade 2 (Severe)	Grade 3 (Life-threatening)	Grade 4 (Death)	Total
IBCT (wrong patient)	2	0	0	0	2
DHTR	15	0	0	0	15
AR	0	3	8	0	11
TRALI	0	1	0	0	1
TACO	0	1	5	0	6
FNHTR	5	2	0	0	7
Total	22	7	13	0	42
Ratio/100,000 components	8.3	2.7	4.9	0	15.9

2015-2019



Cases

For all cases (no. 1-42) listed below the terms severity and imputability refer to the definitions of ISBT (p. 10)

Incorrect blood component transfused (IBCT) – wrong patient

Pre-transfusion check at the bedside are compulsory, either by using a bar code-based electronic identification system (EIS) or by a standard two-person visual and verbal double-identification check of patient and blood component. This is to ensure blood components are administered to the right patient.

1) **Transfused component: RBC**
   Location: Central Denmark Region
   Severity: 1
   Recipient (AB RhD POS) was transfused with a component (A RhD NEG) released from the blood bank to another patient. This occurred as correct pre-transfusion identification control was neglected at the department. Half of the component was transfused before the mistake was realized. No transfusion reaction was reported.

2) **Transfused component: plasma**
   Location: Region Zealand
   Severity: 1
   A plasma component (A RhD POS) was given to the wrong patient. Correct pre-transfusion identification control was neglected. The blood type of the recipient was not known, and the patient declined any further investigation. No transfusion reaction was reported.

Delayed hemolytic transfusion reaction (DHTR)

3) **Age: 85 years old**
   Gender: male
   Transfused components: RBC
   Location: Central Denmark Region
   Severity: 1

Imputability: possible (notified as probable, secondly validated by HC as possible)
Screen test positive, specification revealed an anti-E, not previously detected. The patient had a marked unexplained reduction in Hb in the days prior to the positive screen test. Transfused with E-positive RBC two weeks earlier released as compatible to the patient due to a negative screen test.
Biochemical hemolytic parameters (not specified) negative, except the marked unexplained Hb reduction.

4) **Age: 61 years old**
Gender: female
Transfused components: RBC
Location: Central Denmark Region
Severity: 1
Imputability: possible (notified as probable, secondly validated by HC as possible)
Recipient with GI malignancy and anemia (3.5 mmol/l) was transfused 14 days ago. Discharged with a Hb 5.3 mmol/l and no active bleeding. At readmission, positive screen test specification revealed an anti-K not previously detected in this patient. Three RBC components transfused 14 days earlier were K-positive. Haemoglobinuria was noticed.
Biochemical hemolytic parameters (at the time for positive screentest) showed a decrease in Hb (5.3-3.5 mmol/l), a rise in haptoglobin (values not stated – steroid treatment) and LDH (value not stated) and a positive DAT (specification or strength not stated) were observed.

5) **Age: 71 years old**
Gender: female
Transfused components: RBC
Location: Central Denmark Region
Severity: 1
Imputability: possible (validated by HC to possible, not categorized in the report)
Admitted for a heart operation, transfused with three RBC components (one RBC Jk^a positive, two RBC Jk^a unknown) to a Hb level > 6.0 mmol/l. Eight days later a reduced Hb (4.7 mmol/l) was observed, plus a positive screentest specification revealed a not previously occuring anti-Jk^a.
A marked unexplained reduction in Hb prior to the positive screen test was observed. Biochemical hemolytic parameters (not specified) negative.

6) **Age: 75 years old**
Gender: male
Transfused components: RBC
Location: Central Denmark Region
Severity: 1

Imputability: possible (notified as probable, secondly validated by HC as possible)
A patient with a negative screen test was transfused with one E-positive and six c-positive RBC components over nine days. Ten days later a rapid unexplained reduction in Hb plus a positive screentest was observed. Specification revealed anti-c and anti-E.
Biochemical hemolytic parameters (not specified) negative.

7) Age: 71 years old
Gender: female
Transfused components: RBC
Location: Central Denmark Region
Severity: 1
Imputability: possible (notified as probable, secondly validated by HC as possible)
Known with colon cancer (not bleeding). Two weeks prior to an unexplained reduction in Hb (5.1 – 4.4 mmol/l) the patient was transfused with two c-positive RBC. At the time of Hb reduction a positive screentest was observed, specification revealed a not previously detected anti-c.
Biochemical hemolytic parameters were not performed.

8) Age: 15 years old
Gender: female
Transfused components: RBC
Location: Central Denmark Region
Severity: 1
Imputability: possible (notified as probable, secondly validated by HC as possible)
Nine days prior to a marked unexplained reduction in Hb (values not stated) the patient was transfused with two Fy^a-positive RBC components. At the time of Hb reduction a positive screentest was observed, specification revealed a not previously detected anti-Fy^a.
Biochemical hemolytic parameters (not specified) were negative.

9) Age: 81 years old
Gender: female
Transfused components: RBC
Location: Central Denmark Region
Severity: 1
Imputability: possible (notified as probable, secondly validated by HC as possible)
Recipient hospitalized because of necrotizing pancreatitis. Transfused with E-positive RBC components. Eleven days later a reduction in Hb (6.0 –> 5.1 mmol/l) was measured, a positive screentest was observed, specification revealed an anti-E not previously detected in this patient. The recipient became icteric.

Biochemical hemolytic parameters were positive. Bilirubin (63 µmol/l), LDH (299 U/L), P-Hb/(free Hb) (14 µmol/l) and a positive DAT (3+).

10) **Age: 75 years old**
Gender: male
Transfused components: RBC
Location: Central Denmark Region
Severity: 1
Imputability: probable
Recipient admitted to nephrectomy. Transfused with several M-positive RBC components in a period of 14 days. A routine screentest was positive, specification revealed a not previously detected anti-M.
Biochemical hemolytic parameters were positive. Hb reduced (7.1 – 6.0 mmol/l). A rise in bilirubin, LDH, P-Hb/(free Hb) and a positive DAT (values not stated).

11) **Age: 40 years old**
Gender: female
Transfused components: RBC
Location: Central Denmark Region
Severity: 1
Imputability: possible (notified as probable, secondly validated by HC as possible)
Recipient transfused with two RBC, both RBC components were Jk^a and c positive.
Seven days later a reduced Hb (value not stated) was observed, and a positive screentest specification revealed not previously detected anti- Jk^a and anti-c.
DAT positive (strength not stated), other biochemical hemolytic parameters were not performed.

12) **Age: 40 years old**
Gender: female
Transfused components: RBC
Location: Central Denmark Region
Severity: 1
Imputability: possible
Recipient transfused with two RBC components, both M-positive.
Four days later a reduced Hb (values not stated) was observed, plus a positive screentest, specification revealed a not previously detected anti-M.
DAT positive, other biochemical hemolytic parameters normal (values not stated).

13) **Age: 51 years old**
Gender: female
Transfused components: RBC
Location: Central Denmark Region
Severity: 1
Imputability: doubtful (notified as probable, secondly validated by HC as doubtful)
Recipient admitted because of GI bleeding, known with hepatic encephalopathy. Four weeks prior to admission the recipient was transfused with K-positive RBC components.
At admission a positive DAT (strength not stated) and a positive screentest were observed. Specification revealed a not previously detected anti-K. Biochemical hemolytic parameters were positive. Hb reduced (values not stated), increasing bilirubin (31 µmol/l), LDH (301 U/L) and haptoglobin normal (values not stated).

14) **Age: 63 years old**
Gender: male
Transfused components: RBC
Location: Central Denmark Region
Severity: 1
Imputability: possible
Five days prior to admission the recipient was transfused with two E positive RBC components.
At admission a positive DAT (strength not stated), a reduction in Hb and a positive screentest, specification revealed a not previously detected anti-E. Biochemical hemolytic parameters were normal (values not stated).

15) **Age: 64 years old**
Gender: male
Transfused components: RBC
Location: Central Denmark Region
Severity: 1 (notified as grade 2, secondly validated by HC as grade 1).
Imputability: possible
Recipient admitted because of cardiac disease. Eight days prior to admission the recipient was transfused with two Fyb and Jka positive RBC components (S antigen phenotype not known). At admission a reduction in Hb (6.0 – 5.3 mmol/l) and a positive screentest were observed. Specification revealed not previously detected anti- Fyb, - Jka and –S.
Biochemical hemolytic parameters were positive. Bilirubin (10 µmol/l), LDH (346 U/L), P-Hb/(free Hb) (6 µmol/l) and haptoglobin (< 0.06 g/l).

16) **Age: 73 years old**
Gender: male
Transfused components: RBC
Location: Central Denmark Region
Severity: 1 (notified as grade 2, secondly validated by HC as grade 1).
Imputability: possible
Recipient with a history irregular erythrocyte antibodies (anti-Kpa and –Jka). A routine crossmatch was positive, specification revealed an anti-E and –c. Reduction in Hb (5.1 – 4.5 mmol/l) in the days prior to the positive crossmatch (no bleeding). Transfused with E and c positive RBC components for four weeks before the positive crossmatch.
Biochemical hemolytic parameters: LDH (191 U/L), bilirubin (6 µmol/l), reticulocytes (32 x 109/l), haptoglobin (2.72 g/l). Positive DAT (strength not stated).

17) **Age: 89 years old**
Gender: female
Transfused components: RBC
Location: Capital Region of Denmark
Severity: 1 (notified as grade 2, secondly validated by HC as grade 1).
Imputability: probable (notified as definite, secondly validated by HC as probable).
Recipient with a history irregular erythrocyte antibodies (anti-Fya). A routine crossmatch was positive, specification revealed an anti-Jka. Reduction in Hb (6.4 – 4.4 mmol/l) in the days prior to the positive crossmatch (no bleeding). Transfused with nine RBC components (six Jka positive) within 17 days before the positive crossmatch.
Biochemical hemolytic parameters: LDH (397 U/L), bilirubin (20 µmol/l), reticulocytes (202 x 109/l), haptoglobin (1.72 g/l), P-Hb./(free Hb.) (5 µmol/l). Positive DAT (strength not stated).

Allergic reaction (AR)

18) **Age: 74 years old**
Gender: male
Transfused components: plasma
Location: Central Denmark Region
Severity: 3 (notified as grade 2, secondly validated by HC as 3)
Imputability: probable
Recipient admitted because of aortic dissection transfused with several blood components (RBC, platelets and plasma) during surgery. After the operation another plasma component was transfused; ten minutes

later the patient developed universal urticarial rash, hypotension (76/47 mmHg, initial values not stated) and desaturated (84%) despite respirator treatment.
Treatment: adrenaline, antihistamine and steroid were effective.
Analysis for delta-tryptase, IgA, anti-IgA were not requested.

19) Age: 53 years old
Gender: female
Transfused components: plasma
Location: Region Zealand
Severity: 3
Imputability: definite
Recipient known with liver cirrhosis, admitted because of hematemesis. Ten minutes after the transfusion begun, she developed hypotension (70 mmHg (systolic), initially 97/55 mmHg), universal maculopapular rash and angioedema.
Treatment: adrenaline, antihistamine and steroid were effective.
Delta-tryptase: no information; IgA: normal (2.6 g/l); anti-IgA: negative.

20) Age: 72 years old
Gender: male
Transfused components: RBC and plasma
Location: Central Denmark Region
Severity: 3
Imputability: definite (notified as probable, secondly validated by HC as definite)
Recipient with endocarditis, admitted to mitral valve replacement. Minutes after the transfusion begun, SvO_2 and CI were observed to decline. He developed hypotension (40 mmHg (MAP), initial BP/MAP not stated) and universal urticarial rash.
Treatment: adrenaline, antihistamine and steroid were effective.
Delta-tryptase: 23.4 µg/l (31-7.6 µg/l); IgA: normal (2.06 g/l); anti-IgA: no information.

21) Age: 24 years old
Gender: male
Transfused components: RBC, platelets
Location: North Denmark Region
Severity: 2
Imputability: probable
Patient with AML. Two minutes after completed platelet transfusion he developed universal urticarial rash and dyspnea, BP stable during TR.

Treatment: adrenaline, antihistamine and steroid were effective.

Delta-tryptase: not analyzed; IgA: normal (value not stated); anti-IgA: not analyzed.

22) Age: 65 years old

Gender: male

Transfused components: plasma

Location: Capital Region of Denmark

Severity: 3

Imputability: probable

Recipient known with bladder cancer admitted because of septic shock. During transfusion he developed hypotension (75 mmHg (systolic), initial values not stated) and desaturated (values not stated)

Treatment: adrenaline, antihistamine and steroid were effective.

Analysis for delta-tryptase, IgA, anti-IgA were not requested.

23) Age: 74 years old

Gender: male

Transfused components: platelets

Location: Central Denmark Region

Severity: 3 (primarily reported as grade 1, secondly validated by HC as grade 3)

Imputability: probable

Recipient known with AML admitted because of febrile neutropenia. During transfusion he developed universal urticarial rash, a rise in RF (value not stated), expiratory rhonchi, respiratory distress with need of oxygen therapy, hypotension (110 mmHg, initially 135 mmHg (systolic)).

Treatment: adrenaline, antihistamine and steroid were effective.

Delta tryptase: not analyzed; IgA: 1,88 g/l.

24) Age: 75 years old

Gender: male

Transfused components: plasma

Location: Region of Southern Denmark

Severity: 3

Imputability: probable

In the minutes after transfusion was initialized, the recipient developed universal urticarial rash, respiratory distress, desaturation (value not stated) and stridor breathing. Subsequently he had a cardiac arrest (successful resuscitation). Prior (shortly before, the exact elapsed time unknown) to transfusion the patient had an intravenous contrast injection for the purpose to scan.

Treatment: adrenaline, antihistamine and steroid were effective.

Delta tryptase: not analyzed; IgA: 0.69 g/l

25) Age: 50 years old
Gender: female
Transfused components: RBC
Location: Region of Southern Denmark
Severity: 2 (notified as 3, secondly validated by HC as 2)
Imputability: possible (notified as probable, secondly validated by HC as possible).
Recipient known with menometrorrhagia and atrial fibrillation (Marevan treatment). Admitted because of vaginal bleeding and anemia (Hb 4.7 mmol/l). Two minutes after the transfusion began, she developed tremor, respiratory distress, hypotension (80/50 - 115/71 mmHg), rise in HR (90) and desaturation (80%).
Treatment: oxygen and NaCl were effective.
Analysis for delta-tryptase, IgA, anti-IgA were not requested.

26) Age: 54 years old
Gender: male
Transfused components: plasma
Location: Capital Region of Denmark
Severity: 3
Imputability: probable
Recipient known with liver failure. Admitted to ascites puncture procedure. INR 3.6 (no medication). As the transfusion was completed, he developed angioedema and hypotension (50/40 mmHg initial values not stated) and desaturated (80%).
Treatment: adrenaline, antihistamine and steroid were effective.
Delta-tryptase: no information; IgA: 10.9 g/l.

27) Age: 82 years old
Gender: female
Transfused components: RBC
Location: Region Zealand
Severity: 3
Imputability: definite
Recipient known with myelodysplastic syndrome, admitted because of anemia. During transfusion (2/3 of the component was transfused) she developed hypotension (immeasurable, initial values 114/84 mmHg), respiratory distress and desaturation (value not stated).
Treatment: adrenaline, antihistamine and steroid were effective.
Delta-tryptase: not analyzed; IgA: 4.0 g/l.

28) **Age: 3 years old**

Gender: male

Transfused components: RBC

Location: Capital Region of Denmark

Severity: 2

Imputability: probable (notified as possible, secondly validated by HC as probable)

During transfusion (60 ml) the recipient developed universal urticarial rash, coughing, respiratory distress and desaturation (value not stated). No information about blood pressure.

Treatment: antihistamine and steroid were effective.

Tryptase: peak 6.07 µg/l (no baseline tryptase); IgA: not analyzed; anti-IgA: 0 kU/l.

Transfusion-related acute lung injury (TRALI)

29) **Age: 36 years old**

Gender: male

Transfused components: granulocyte

Location: Capital Region of Denmark

Severity: 2

Imputability: probable

Recipient known with AML (prior stem cell transplantation), admitted because of disseminated fungal infection. Transfused with granulocytes from the stem cell donor (mater). Six hours later he developed acute respiratory distress, desaturation (87%, initially 98%), a rise in RF (30). Blood pressure stable.

X-ray chest: bilateral infiltrations.

Anti-HLA I: anti-HLA-A23 was revealed in the patient (stem cell donor HLA-A1,3)

Anti-HNA: analysis not performed

Transfusion associated circulatory overload (TACO)

30) **Age: 76 years old**

Gender: male

Transfused components: RBC

Location: Central Region Denmark

Severity: 3 (notified as grade 1, secondly validated by HC as grade 3)

Imputability: probable (notified as uncategorized, secondly validated by HC as probable)

Patient known with ischemic heart disease, congestive heart failure, chronic obstructive lung disease and renal insufficiency received transfusion.

In the minutes after the transfusion was completed the patient suddenly developed severe respiratory distress and need of oxygen therapy, desaturated (84%) and increased RF 40/min. Tachycardia (88-110/min.) and a rise in blood pressure (150/91- 206/116 mmHg) were observed.
Treatment: diuretics were effectful although initializing slowly (50 minutes).
X-ray chest: No infiltrations, but pleural effusions bilateral.
ECHO: EF 30-40%.
Arterial gas puncture: metabolic acidosis, later a combined metabolic/respiratory acidosis.
Biochemical parameters: a light rise in troponins, BNP/pro-BNP not analyzed.

31) **Age: 68 years old**
Gender: male
Transfused components: RBC
Location: Capital Region of Denmark
Severity: 3 (notified as grade 2, secondly validated by HC as grade 3)
Imputability: probable
Patient known with IHD, admitted because of GI-bleeding (Hb 3.0 mmol/l). Within 12 hours transfused with three RBC components, 30 minutes after completed transfusion he developed respiratory distress and need of oxygen therapy, desaturated (84%) and RF 41/min. Tachycardia (88-110/min.). Blood pressure stable during TR.
Treatment: diuretics were effect full.
X-ray chest: lung oedema bilaterally.
ECHO: Non-cardiac lung oedema.

32) **Age: 41 years old**
Gender: female
Transfused components: RBC
Location: Capital Region of Denmark
Severity: 3
Imputability: possible (notified as probable, secondly validated by HC as possible)
Patient known with renal insufficiency admitted because of anemia (3.0 mmol/l). No known CHF. Duration of transfusion < 45 minutes and 15-30 minutes later the patient developed severe respiratory distress; a rise in blood pressure (180/92 - 202/109 mmHg) was observed.
Treatment: Increased diuretic treatment was effectful (the patient already had diuretic treatment before the TR).
X-ray chest: exacerbation of lung oedema bilaterally (mild lung oedema was observed before TR).
ECHO: no information

33) Age: 65 years old

Gender: male

Transfused components: RBC

Location: Region Zealand

Severity: 3

Imputability: probable

Recipient known with CHF, admitted because of anemia.

About two hours after transfusion was completed the patient suddenly developed severe respiratory distress, desaturation (value not stated), tachycardia (76-145/min.) and a rise in blood pressure (145/54-200 mmHg (systolic)).

Treatment: diuretics were effectful.

X-ray chest: lung oedema bilateral

ECHO: EF 40%.

BNP/pro-BNP not done.

34) Age: 43 years old

Gender: female

Transfused components: RBC, plasma

Location: Region Zealand

Severity: 3

Imputability: definite

Recipient admitted because of anemia (Hb 1.9 mmol/l). No known CHF. Within three days transfused with eight RBC components and one plasma unit. At day three the patient developed increasing respiratory distress.

No tachycardia or a rise in blood pressure was observed.

Treatment: diuretics were very effective, (withdrawal of 14 liters liquid).

X-ray chest: ARDS

ECHO: no signs of heart disease

BNP/pro-BNP not done.

35) Age: 85 years old

Gender: male

Transfused components: RBC

Location: Capital Region of Denmark

Severity: 2

Imputability: probable

Admitted because of vascular surgery. No known CHF. Transfusion of two components result in

sudden severe respiratory distress, a rise in RF (value not stated), tachycardia (73-95/min.) and a rise in blood pressure (163/53 – 198/68 mmHg).

Treatment: diuretics were effective.

X-ray chest: not done

ECHO: not done

BNP/pro-BNP: not analyzed (720 ng/l, two days before TR).

Febrile non-hemolytic transfusion reaction (FNHTR)

36) Age: 16 years old

Gender: female

Transfused components: platelets

Location: Central Region Denmark

Severity: 1 (notified as grade 2, secondly validated by HC as grade 1)

Imputability: probable (notified as possible, secondly validated by HC as probable)

One hour after completed transfusion she developed a rise in temperature > 2°C and > 39°C (37.6 – 40.8°C) and chills. No information about headache and nausea.

Post transfusion serological tests showed correct blood grouping, compatible components and negative DAT. Microbiological screening for microbial activity in the blood component was negative.

Treatment: None

37) Age: 90 years old

Gender: male

Transfused components: RBC

Location: Central Region Denmark

Severity: 1

Imputability: possible

A couple of hours after completed transfusion she developed a rise in temperature > 2°C, > 39°C (38.0 – 40.9°C). No information about headache, chills and nausea.

Post transfusion serological tests showed correct blood grouping, compatible components and negative DAT.

Treatment: None

38) Age: 39 years old

Gender: female

Transfused components: RBC

Location: Central Region Denmark

Severity: 1

Imputability: possible (notified as probable, secondly validated by HC as possible)
Recipient known with endometriosis, admitted for operation. One hour after transfusion began, she developed a rise in temperature > 2°C, > 39°C (37.1 – 39.4°C), chills, heart palpitations and felt severely unwell. No information about headache and nausea.
Post transfusion serological tests showed correct blood grouping, compatible components and negative DAT.
Treatment: None

39) **Age: 41 years old**
Gender: male
Transfused components: RBC
Location: Central Denmark Region
Severity: 1
Imputability: probable
Recipient admitted because of endocarditis and cerebral abscess, temperature stable (afebrile) for days. Within minutes after completed transfusion, he developed a rise in temperature > 2°C, > 39°C (37.4 – 39.5°C) and chills. No nausea and no information about headache.
Treatment: None

40) **Age: 55 years old**
Gender: female
Transfused components: platelets
Location: Central Region Denmark
Severity: 2
Imputability: possible
Recipient known with AML with neutro- and thrombocytopenia. After completed transfusion, she developed a rise in temperature > 2°C, > 39°C (37.7 – 40.9°C). No information about headache, chills or nausea.
Microbiological screening of the blood component was not possible as all was transfused.
Treatment: None

41) **Age: 73 years old**
Gender: male
Transfused components: RBC
Location: North Denmark Region
Severity: 2 (notified as grade 1, secondly validated by HC grade 2)
Imputability: probable
Two hours after completed transfusion the recipient developed a rise in temperature > 2°C, > 39°C (37.6 –

40.8°C) and chills. No headache or nausea.

Microbiological screening for microbial activity in the blood component was not possible (component possibly contaminated, recipient in quarantine because of infection)

Treatment: None

42) Age: 70 years old

Gender: female

Transfused components: platelets

Location: Region of Southern Denmark

Severity: 1

Imputability: probable (notified as uncategorized, secondly validated by HC as probable)

Recipient known with liver cirrhosis. Because of forthcoming operation and thrombocytopenia (57 x109/l) transfusion was needed. During transfusion she developed a rise in temperature > 2°C, > 39°C (36.7 – 40.2 °C), tachycardia (values not stated) and chills. No headache or nausea.

Microbiological screening for microbial activity in the blood component was not possible. The blood component was 5 days old and had a negative BACTalert.

Treatment: None