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# Haemovigilance Report

## 2020

**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
EIS	Electronic Identification System
FNHTR	Febrile non hemolytic transfusion reaction
HNA-Ab	Antibodies against HNA (human neutrophil antigen)
IBCT	Incorrect blood component transfused
IHN	International Haemovigilance Network
ISBT	International Society of Blood Transfusion
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
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 IHN.

In 2020, 23.2 adverse events and reactions per 100,000 transfused blood components were reported to DART. The number for the recent years, (2019: 15.9 2018: 9.5; 2017: 5.5; 2016: 7.1/100,000 transfused blood components).

In tables representing 2020 data, only the adverse events and reactions reported in 2020 are mentioned.

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 [\(DSKI\)](#) homepage -"retningslinier".

## 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](#)".

Severity (grade 1 – 4) and imputability (five grades) 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).

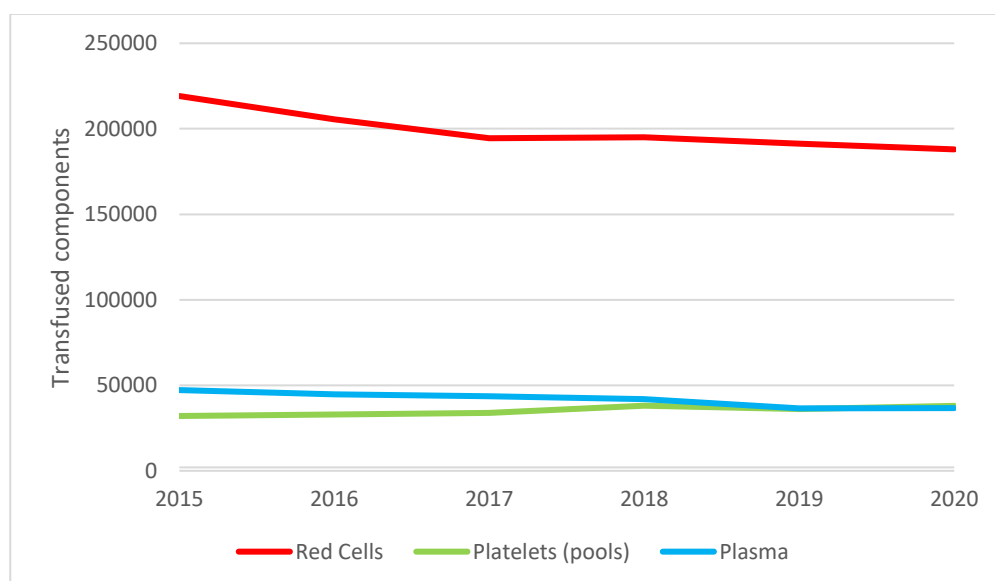
## Blood Components Transfused

### 2020

Blood usage by region and blood component.

Region	RBC	Platelets (pool)	Platelets (apheresis)	Plasma (whole blood)	Plasma (apheresis)	Total
Capital Region of Denmark	63,250	16,565	919	12,819	3,308	96,861
Region Zealand	25,413	2,522	493	1,935	962	31,325
Region of Southern Denmark	37,020	7,373	558	5,694	1,053	51,698
Central Denmark Region	42,741	6,846	302	7,205	525	57,619
North Denmark Region	19,534	2,188	265	2,921	186	25,094
<b>Total</b>	<b>187,958</b>	<b>35,494</b>	<b>2,537</b>	<b>30,574</b>	<b>6,034</b>	<b>262,597</b>

### 2015-2020



The number of transfused blood components seems to drop from 2015 and onward.

## Adverse events and reactions

### 2020 – Regionally

Region	Number	Number/100,000 transfused components
Capital Region of Denmark	9	9.3
Region Zealand	1	3.2
Region of Southern Denmark	12	23.2
Central Denmark Region	30	52.1
North Denmark Region	9	35.9
<b>Total</b>	<b>61</b>	<b>23.2</b>

As in previous reports the Central Denmark region differs markedly from the other regions in the number of reports. Increased attention to complications of blood component transfusion and an IT blood bank system “flagging” possible adverse events and reactions are most likely a part of the explanation.

### 2020

Adverse events and reactions	Number	Number/100,000 transfused components
IBCT (wrong patient)	3	1.1
IBCT (wrong component)	2	0.8
AHTR	4	1.5
DHTR	7	2.7
AR	10	3.8
TRALI	5	1.9
TACO	12	4.6
TTI	1	0.4
FNTHR	16	6.1
Unclassified	1	0.4
<b>Total</b>	<b>61</b>	<b>23.2</b>

## Cumulated table of reports – adverse events and reactions

### 2016-2020

Adverse events and reactions	Number/100,000 transfused components (absolute)					
	2016	2017	2018	2019	2020	2016-2020
<b>Wrong patient</b>	0.4 (1)	0	0.4 (1)	0	1,1(3)	0,2
<b>Wrong component</b>	0.7 (2)	0.4 (1)	0.7 (2)	0.8 (2)	0.8(2)	0.5
<b>AHTR</b>	0.4 (1)	0	0	0	1.5 (4)	0.3
<b>DHTR</b>	1.4 (4)	0	0.7 (2)	5.7 (15)	2.7 (7)	1.7
<b>AR</b>	2.1 (6)	1.1 (3)	1.5 (4)	4.2 (11)	3.8 (10)	2.1
<b>TRALI</b>	1.1 (3)	1.1 (3)	0.4 (1)	0.4 (1)	1.9 (5)	0.8
<b>TACO</b>	0.4 (1)	1.5 (4)	2.9 (8)	2.3 (6)	4.6 (12)	1.9
<b>TTI</b>	0	0	0	0	0.4 (1)	0.1
<b>FNHTR</b>	0.7 (2)	1.1 (3)	2.3 (6)	2.7 (7)	6.1 (16)	2.1
<b>UCT</b>	0	1.1 (1)	0	0	0.4 (1)	0.1
<b>Total</b>	7.1 (20)	5.5 (15)	9.5 (25)	15.7 (42)	23.2 (61)	9.8

The number of reported adverse events and reaction in 2020 is for certain categories (AHTR, TRALI and TACO) ascending compared to previous years cf. the tables below for the specific adverse event and reaction.



## 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
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)
2020	1.1(3)	0.8(2)	1.9(5)

The fraction of IBCT in 2020 has nearly doubled. No procedure has changed, and the most evident reason ascribes to the uncertain statistic due to few absolute numbers reported.

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

The five reported IBCT all occurred in the Region of Southern Denmark and Central Denmark Region. The Haemovigilance Committee regard the uneven reporting as a consequence to the fact, that the chance of realizing an IBCT is far more obvious for the staff when electronical validation is applied.

## 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 2016-2020.

Year	Number/100,000 transfused components (absolute)	
	AHTR	DHTR
2016	0.4 (1)	1.4 (4)
2017	0	0
2018	0	0.7 (2)
2019	0	5.7 (15)
2020	1.5 (4)	2.7 (7)

Specificity of red blood cell alloantibodies detected in blood from 11 patients with AHTR or DHTR in 2020.

Antibody	Jk <sup>a</sup>	S	C	E	K	Jk <sup>b</sup>	Fy <sup>a</sup>	c	e	Fy <sup>b</sup>	Lu <sup>a</sup>	Bg	B	Cw	Wr <sup>a</sup>	M	Other*
AHTR			1		1				1					1			
DHTR	4			2	2		2										

Specificity of red blood cell alloantibodies detected in blood from patients with AHTR and DHTR in the period 2001-2020.

Antibody	Jk <sup>a</sup>	S	C	E	K	Jk <sup>b</sup>	Fy <sup>a</sup>	c	e	Fy <sup>b</sup>	Lu <sup>a</sup>	Bg	B	Cw	Wr <sup>a</sup>	M	Other*
AHTR	3		2		3	2		1	1			1	1	1	3		3
DHTR	15	3	2	18	8	5	8	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 refer 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)			
	RBC	Platelets	Plasma	Total
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)	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)

## Pulmonary adverse transfusion reactions

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)			
	RBC	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	0.4 (1)	0	0	0.4(2)*
2020	1.6(3)	2.6(1)	0	1.9(5)*

\*Transfusion of granulocytes, only figure in the column "Total"

### Transfusion-associated circulatory overload (TACO)

Year	Number/100,000 components transfused (absolute)			
	RBC	Platelets	Plasma	Total
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)*
2020	5.3(10)	5.3(2)	0	4.6(12)

\* 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".

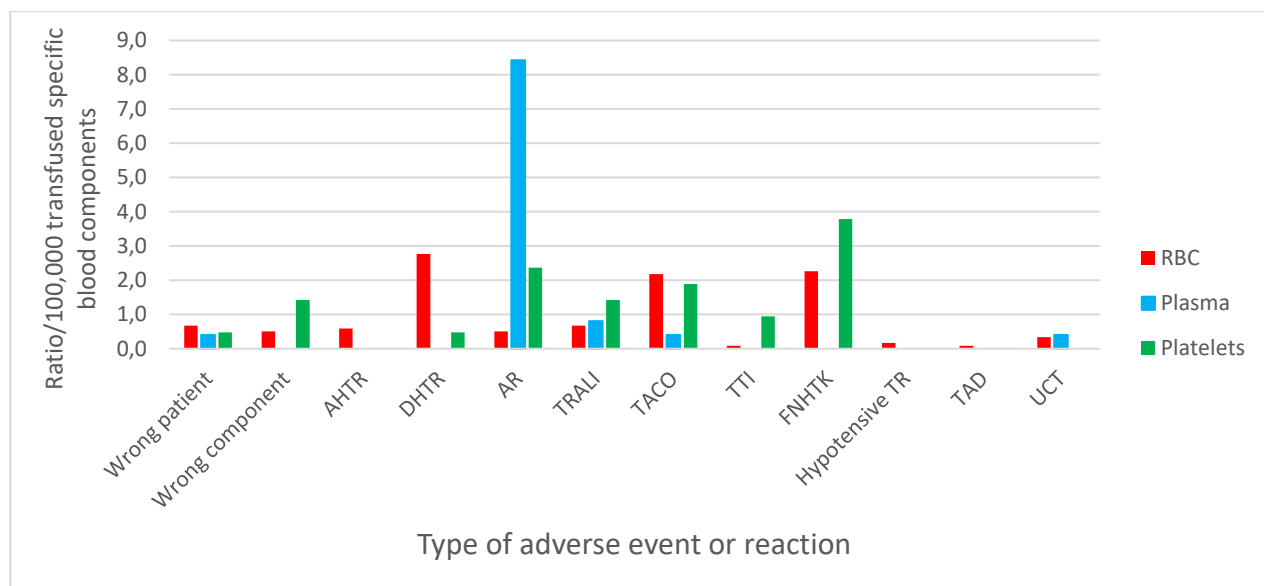
## Adverse events and reactions by blood component

### 2020

Adverse events and reactions	Number/100,000 components transfused (absolute)			
	RBC	Platelets	Plasma	Total
IBCT (wrong patient)	1.6(3)	0	0	1.1(3)
IBCT (wrong component)	0	5.3(2)	0	0.8(2)
AHTR	2.1(4)	0	0	1.5(4)
DHTR	3.7(7)	0	0	2.7(7)
AR	1.1(2)	2.6(1)	19.1(7)	3.8(10)
TRALI	1.6(3)	2.6(1)	0	1.9(5)*
TACO	5.3(10)	5.3(2)	0	4.6(12)
FNHTR	6.4(12)	10.5(4)	0	6.1(16)
AHTR	2.1(4)	0	0	1.5(4)
DHTR	3.7(7)	0	0	2.7(7)
TTI	0.5(1)	0	0	0.4(1)
Unclassified	0.5(1)	0	0	0.4(1)
<b>Total</b>	<b>23.4(44)</b>	<b>23.7(9)</b>	<b>19.1(7)</b>	<b>23.2(61)</b>

\*TRALI in a patient transfused with granulocytes, only figure in the column "Total"

### 2016-2020

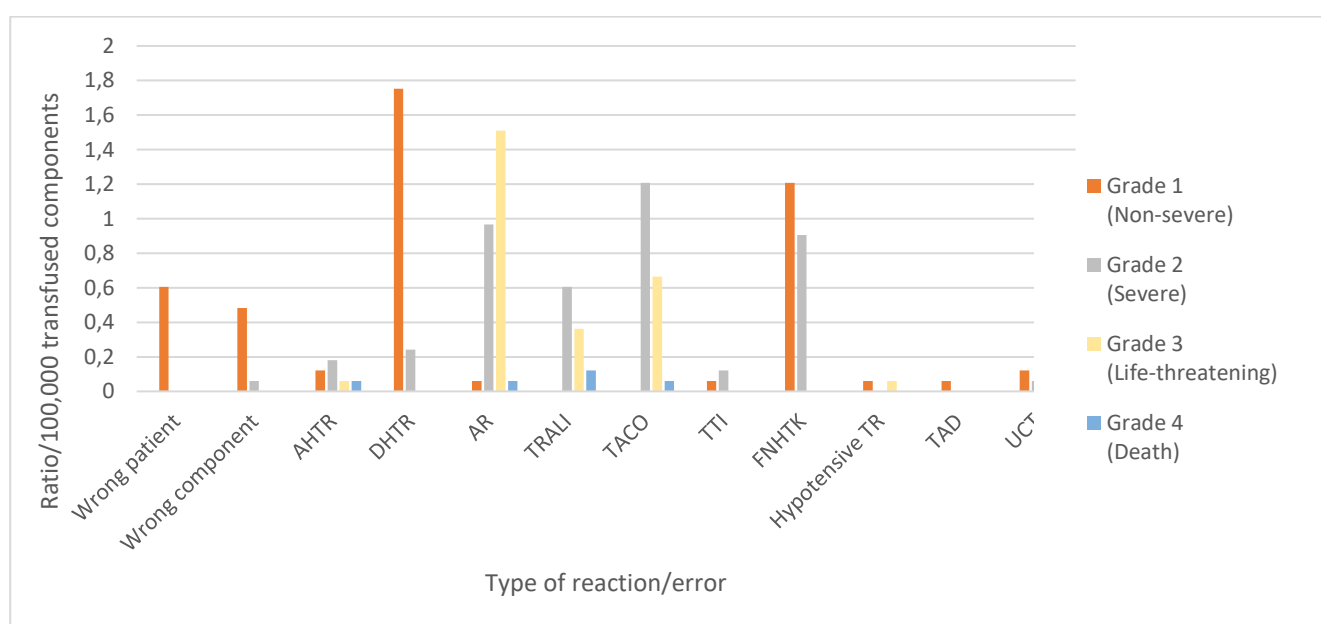


## Severity

### 2020

Adverse events and reactions	Grade 1 (Non-severe)	Grade 2 (Severe)	Grade 3 (Life-threatening)	Grade 4 (Death)	Total
IBCT (wrong patient/component)	3	0	0	0	5
DHTR	3	4	0	0	7
AR	1	5	4	0	10
AHTR	1	3	0	0	4
TRALI	0	4	0	1	5
TACO	0	9	3	0	12
FNHTR	6	10	0	0	16
TTI	0	1	0	0	1
Unclassified	0	0	0	0	1
Total	14	36	7	1	61
Ratio/100,000 components	5.3	13.7	2.7	0.4	23.2

### 2016-2020



## Cases

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

### **Incorrect blood component transfused (IBCT) – wrong patient**

<b>Indicator</b>	<b>Information</b>
<b>Age</b>	< 6 months
<b>Transfused components</b>	RBC
<b>Severity</b>	1
<b>Wrong patient/- component</b>	Wrong patient
<b>ABO RhD blood type donor/component</b>	0 RhD negative
<b>ABO RhD blood type patient</b>	Not known
<b>Description</b>	Recipient (Twin-A) was transfused with part of a component released from the blood bank to another patient (Twin-B). This occurred as correct pre-transfusion identification control was neglected at the department. No transfusion reaction was reported.

**Acute hemolytic transfusion reaction (AHTR)**

Indicator	Information	
Age	>65 years	
Transfused components	RBC	
Severity	4	
Imputability	Unlikely	
	Information	Specification
Chest/back/flank pain	No information	-
Dark urine/oligouri	No information	-
Icterus	No information	
Blood Pressure	No information	-
Temperature	No information	-
Biochemical hemolytic parameters	Not measured	-
Description	<p>Four 0 RhD negative RBC were transfused without pre-transfusion testing of the patient because of acute need of blood. Post-transfusion analyses revealed multiple irregular antibodies (anti-e, anti-K and possible anti-C). All four RBC were highly incompatible with the patient.</p> <p>The patient dies shortly after the transfusions, probably due to other causes (imputability: unlikely). No haemolysis parameters were required.</p>	

**Allergic reaction (AR)**

Indicator	Information	
Age	18 – 65 years	
Transfused components	FFP	
Severity	Life-threatening	
Imputability	possible	
	Information	Specification
Blood Pressure	Hypotensive	No exact values reported
Respiratory insufficiency	No information	Before/After (saturation)
Angioedema	No information	
Urticaria/universal erythema	Yes	
Medical treatment	Yes	Adrenalin, steroids and antihistamine
IgA	Yes	1,51 g/l
Anti-IgA	not measured	
Tryptase	no information	
Description	<p>Institutio cordis. Successful resuscitation though circulatory unstable. CT scan shows bleeding from the liver.</p> <p>The patient developed even through hypotension and urticarial rash. Treatment for anaphylaxis was effect full. Continuous treatment with adrenalin was necessary to keep up an adequate blood pressure.</p>	



## Transfusion-related acute lung injury (TRALI)

Indicator	Information	
Age	>65 years	
Transfused components	RC	
Severity	4	
Imputability	Possible	
	Information	Specification
Respiratory insufficiency/hypoxemia	Yes	Oxygen saturation 99% (no oxygen treatment) reduced to 90% (12 L/oxygen/min) Respiration rate 35/min
X-ray chest (bilateral infiltrations)	Abnormal	Bilateral infiltrations
Circulatory overload	No	
Other ALI disposing factors	Yes	CABG (>five years before adverse reaction)
Medical treatment	Yes	Oxygen treatment
Anti-HLA/-HNA Ab donor	Negative	
Anti-HLA/-HNA Ab patient	Negative	
Description	<p>Known with myelodysplastic syndrome (MDS) and ischemic heart disease.</p> <p>Receive one RC component as treatment for MDS in day hospital. Well-being at discharging. Five hours later acute admission to emergency room with severe respiratory insufficiency (see specification for desaturation). Supporting</p>	

	treatment incl. diuretics without any effect. About eight hours after emergency admission Institio cordis.
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## Transfusion associated circulatory overload (TACO)

Indicator	Information	
Age	> 65 years	
Transfused components	Platelet, RBC	
Severity	Life-threatening	
Imputability	Definite	
	Information	Specification
Respiratory insufficiency/hypoxemia	Yes	Oxygen saturation before not mentioned but drops to 80 %
Tachycardia	Yes	From 88 to 130
Blood pressure	Hypertensive	From 103/57 to 240/140
Acute/impairment of lung oedema	Yes	Not known
(Other) signs of positive fluid balance	Yes	Peripheral oedema, increasing weight
Medical treatment	Yes	Diuretics with normalization of blood pressure and oxygen saturation
x-ray chest (bilateral infiltrations)	Abnormal	Lung oedema

<b>(Known) congestive heart failure (CHF)</b>	No	NA
<b>ECHO</b>	No information	NA
<b>BNP/pro-BNP</b>	Not measured	NA
<b>Description</b>	Patient admitted with cytopenia and bleeding. Signs of positive fluid balance before the actual transfusion in relation to peripheral oedema and a higher weight than normal. Is transfused with first a unit of platelets and then a unit RBC. During the transfusion with RBC, the patients develops respiratory insufficiency, tachycardia and rattling. Is treated with diuretics, nitro-glycerine and oxygen with effect. Chest x-ray in accordance to lung oedema.	