THE SLOVENIAN HAEMOVIGILANCE SYSTEM

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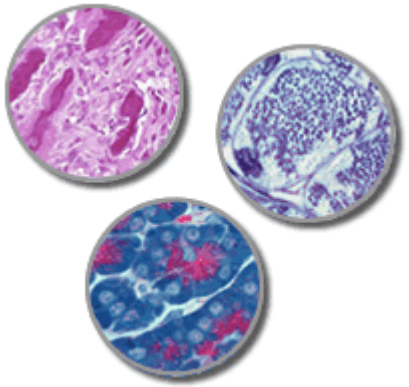
Zavod Republike Slovenije
za transfuzijsko medicino
Blood Transfusion Centre of Slovenia

VIGILANCE

HAEMOVIGILANCE

PHARMACOVIGILANCE

HISTOVIGILANCE



Haemovigilace

Haemovigilance is the set of surveillance procedures covering the **entire blood transfusion chain**, from the donation and processing of blood and its components, through to their provision and transfusion to patients, and including their follow-up. It includes the monitoring, reporting, investigation and analysis of adverse events related to the donation, processing and transfusion of blood, and taking action to prevent their occurrence or recurrence. The reporting systems play a fundamental role in enhancing patient safety by learning from failures and then putting in place system changes to prevent them in future.

Haemovigilance (IHN)

- A set of surveillance procedures of the whole transfusion chain intended to minimize adverse events or reactions in donors and recipients and to promote safe and effective use of blood components.

Haemovigilance

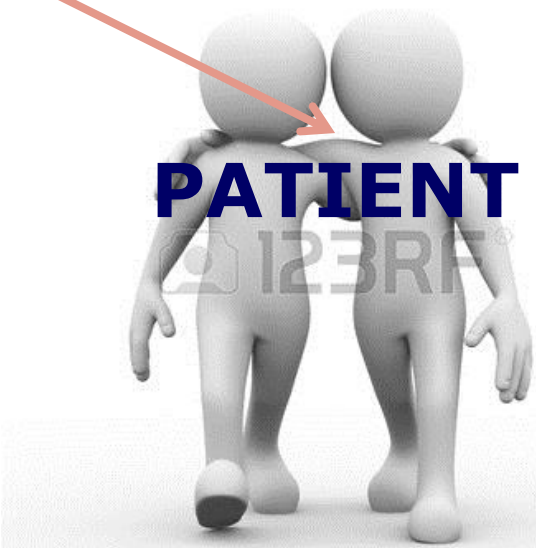
ADVERSE EVENTS

ADVERSE REACTIONS

BLOOD DONOR

COMPLICATIONS IN DONORS

PATIENT



Haemovigilance

„SEVER“ SAE = any untoward occurrence associated with the collection, testing, processing, storage and distribution of blood or blood components that might lead to death or life–threatening, disability or incapacitatiy conditions for patient or clinical results in, or prolonged hospitalisation or morbidity.

„SEVER“ SAR = An unintended response in a donor or in patient that is associated with the collection, or transfusion of blood components that is fatal, life-threateing, disabling or incapacitating, or clinical results in or prolonged hospitalisation or morbidity.

Goals of haemovigilance

= the overall aim of Haemovigilance is to improve transfusion safety

COMMISSION DIRECTIVE 2005/61/EC

of 30 September 2005

implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events

(Text with EEA relevance)

L 256/32 EN Official Journal of the European Union 1.10.2005

COMMISSION DIRECTIVE 2005/61/EC

of 30 September 2005

implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC [1], and in particular points (a) and (i) of the second paragraph of Article 29 thereof,

Whereas:

(1) Directive 2002/98/EC lays down standards of quality and safety for the collection and testing of human blood and blood components, whatever their intended purpose, and for their processing, storage and distribution when intended for transfusion so as to ensure a high level of human health protection.

(2) In order to prevent the transmission of diseases by blood and blood components and to ensure an equivalent level of quality and safety, Directive 2002/98/EC calls for the establishment of specific technical requirements dealing with traceability, a Community procedure for notifying serious adverse reactions and events and the notification

medicinal products for human use [3], Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components [4], and certain recommendations of the Council of Europe.

(5) Accordingly, blood and blood components imported from third countries, including those used as starting material or raw material for the manufacture of medicinal products derived from human blood and human plasma, intended for distribution in the Community, should meet equivalent Community standards and specifications relating to traceability and serious adverse reaction and serious adverse event notification requirements as set out in this Directive.

(6) It is necessary to determine common definitions for technical terminology in order to ensure the consistent implementation of Directive 2002/98/EC.

(7) The measures provided for in this Directive are in accordance with the opinion of the Committee set up by Directive 2002/98/EC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The network of Haemovigilance system in Slovenia

- JAZMP - Agency for Medicinal Products and Medical Devices of the Republic of Slovenia
- Haemovigilance Service (BTC of Slovenia)
- Hospitals, Blood establisments, Hospital Blood Banks
- Doctors, Medical staff
- Patients – recepients of Blood components

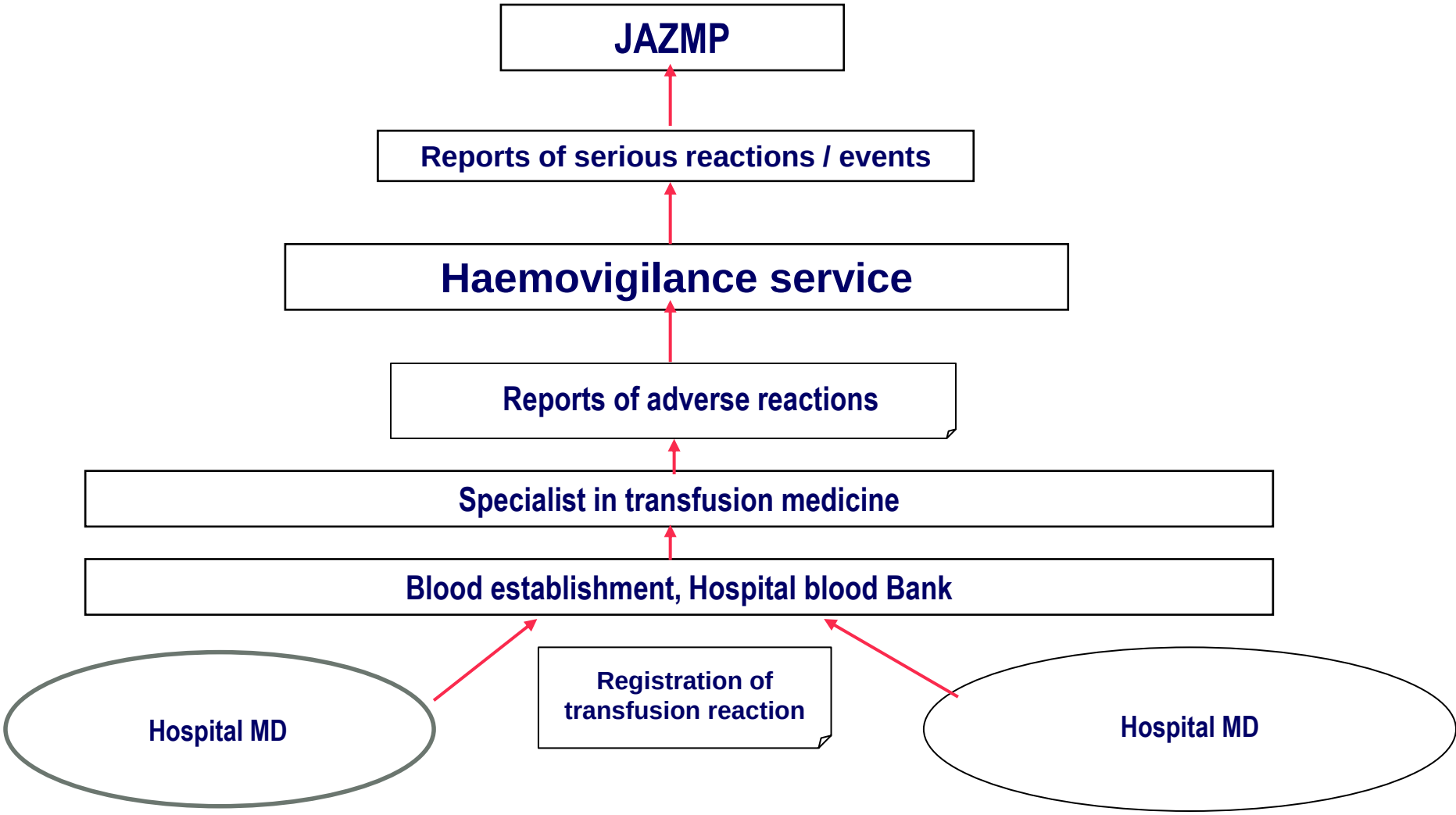
Registration and Reporting

of adverse reaction / events

- Form for registration of adverse reactions (M.D / Hospital)
- Form for reporting of adverse reaction (M.D. / transfusion medicine specialist)
- Form for rapid reporting of serious adverse reactions / events
- Form for yearly report

Haemovigilance policy

information channels

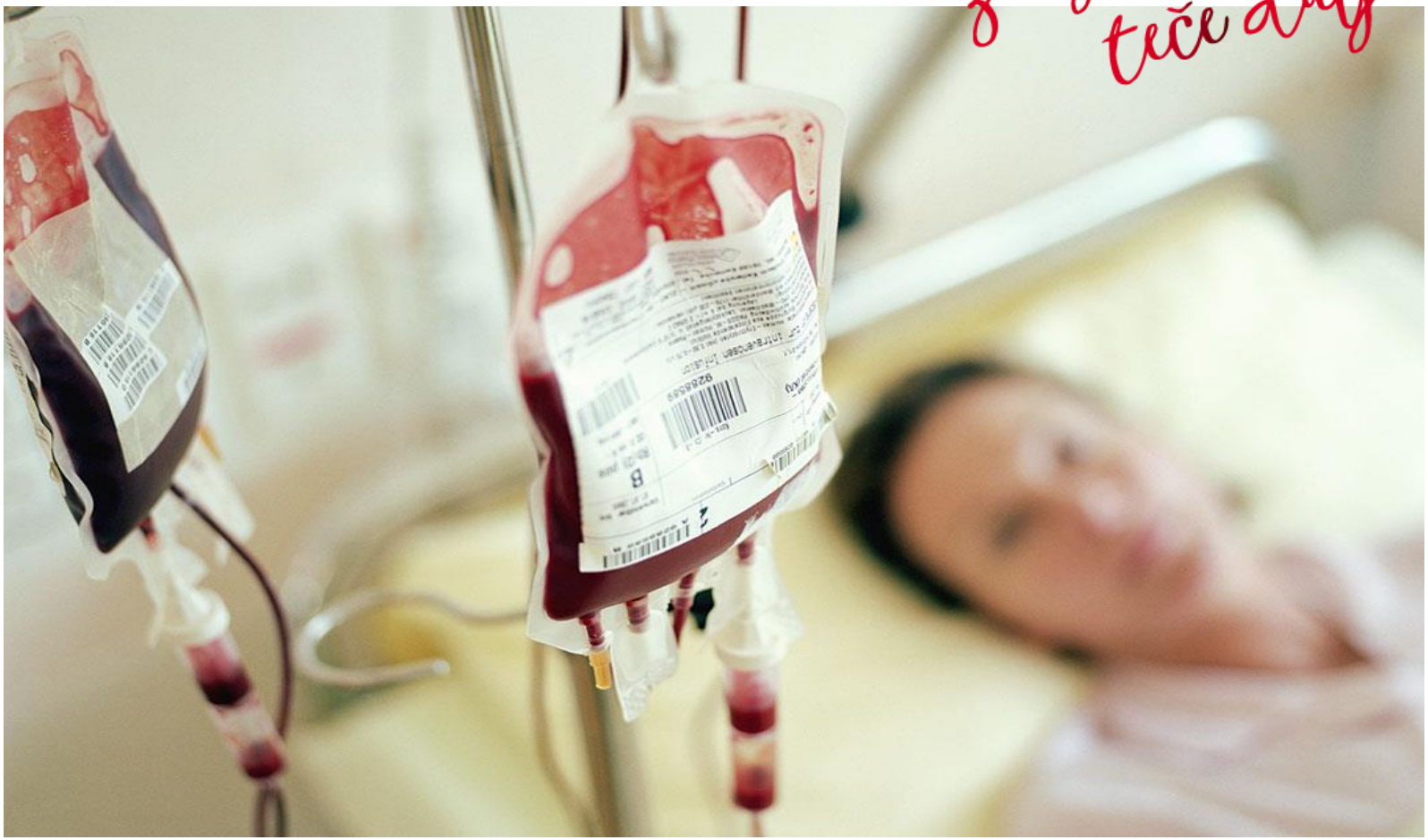



Avstrija
Madžarska
Italija
Hrvaška
Murska Sobota
Slovenj Gradec
Maribor
Jesenice
Celje
Ptuj
Trbovlje
Ljubljana
Nova Gorica
Novo mesto
Izola
H
H
H

HAEMOVIGILANCE / DATA

- SAR - patients
- SAE
- SAR – Blood donors

PATIENTS / recipients transfused



1.Form for registraton of adverse reactions

Zavod Republike Slovenije
za transfuzijsko medicino
Blood Transfusion Centre of Slovenia

Šlajmerjeva ulica 6, 1000 Ljubljana, Slovenija
Tel.: +386 (0)1 543-81-00, Fax: +386 (0)1 230-22-24
E-pošta: central@ztm.si, www.ztm.si

Številka naročilnice
№ 089350

Prijava neželene transfuzijske reakcije

Podatki o naročniku

Klinika:
Interni telefon:
Kontaktna oseba:
Zdravnik naročnik:
Datum naročila:
Ura naročila:

Podatki o bolniku/ci

Enotna matična številka občana (EMŠO):
Ime in priimek:
Datum rojstva:
Naslov:
Reg. št. zavezanca:
Šifra dejavnosti:

Vzorce bolnikove krvi obvezno označite s priloženimi črtnimi kodami! Glej navodilo za odvzem vzorcev krvi na hrbtni strani naročilnice.

Center za sprejem, shranjevanje in izdajo krvnih pripravkov, Tel.: 01/5438 111, preko UKC, int.: 38-62
Center za imunohematologijo, Tel.: 01/5438 169, preko UKC, int.: 28-72

1. Diagnoza:

2. Transfuzijska anamneza:
Bolnik(ca) je že prejel(a) transfuzijo krvi
☐ Da ☐ Ne ☐ Ni znano
Datum zadnje transfuzije:
Reakcije ob prejšnjih transfuzijah
☐ Da, opis reakcije:
☐ Ne

3. Nosečnost:
☐ Da ☐ Ne
Leto zadnje nosečnosti:

4. Številka krvne komponente:
Volumen transfundirane krvne komponente:
Vrsta krvne komponente, ki je povzročila reakcijo
☐ KE ☐ KT
☐ KTF ☐ SZP
☐ Drugo:

5. Laboratorijski izvidi:
☐ Hb pred transfuzijo
☐ Hb po transfuziji
☐ Haptoglobin
☐ Hemoglobinemija
☐ Nekonjugirani bilirubin
☐ LDH
☐ Retikulociti
☐ Levkociti
☐ Hemosiderin v urinu
☐ Hemoglobinurija
☐ Urobilinogen v urinu

6. Terapija po transfuzijski reakciji:

7. Znaki in simptomi ob transfuzijski reakciji:
☐ mrzlica
☐ porast telesne temperature (>1°C) pred: po:
☐ urtikarija
☐ drugi kožni izpuščaji, opis:
☐ rdečica obraza
☐ bledica
☐ cianoza
☐ zlatenica
☐ padec/porast krvnega tlaka pred: po:
☐ padec/porast srčne frekvence pred: po:
☐ težko dihanje
☐ porast frekvence dihanja pred: po:
☐ kašelj in/ali izkašljevanje
☐ pljučni edem
☐ bolečina v prsih
☐ bolečina v ledvenem predelu
☐ bolečina na mestu infuzije
☐ bolečine v mišicah
☐ krči
☐ oligurija/anurija
☐ hemoglobinurija
☐ nepojasnjen padec hemoglobina
☐ nenormalne krvavitve
☐ slabost
☐ bruhanje
☐ nezavest
☐ šok
☐ smrt
☐ drugo:

8. Sum na*:
☐ virusno okužbo
☐ bakterijsko okužbo

9. Povezanost s transfuzijo:
☐ izključena povezava (0)
☐ malo verjetna povezava (0)
☐ možna povezava (1)
☐ verjetna povezava (2)
☐ nedvomna povezava (3)

10. Stopnja:
☐ ni znakov (0)
☐ takojšnje pojavljanje brez znakov življenske ogroženosti in polne razvitosti (1)
☐ takojšnje pojavljanje znakov z življensko ogroženostjo (2)
☐ dolgotrajna obolelost (3)
☐ smrt bolnika (4)

* Potrebno je izpolniti dodatni obrazec. *Prijava suma na potransfuzijsko okužbo*, ki ga pridobite na ZTM

Podpis in žig zdravnika (obvezno!)

VZOREC B120001490A

NAROČILNICA B120001490A

Sprejem naročila na ZTM

Zap. št.:

Datum:

Sprejem v laboratoriju

Sprejel:

Datum/ura:

2. Form for reporting of adverse reactions on a yearly basis to JAZMP (competent authority)

POROČILO O NEŽELENEM ŠKODLJIVEM UČINKU TRANSFUZIJE

BOLNIK

Začetnici imena in priimeka: .....
Spol: M Ž
Datum rojstva: .....
Identifikacijska št.: .....
Datum transfuzije: .....
Nastanek reakcije po transfuziji: ..... min ..... ur ..... dni

KRVNI PRIPRAVEK

Številka pripravka: .....
Mesto izdaje: ☐ ZTM ☐ transfuzijski oddelek ☐ bolnišnica (depo)

Vrsta pripravka: ☐ eritrociti ☐ trombociti ☐ plazma ☐ granulociti ☐ alogenski ☐ avtologni

Način priprave: ☐ iz polne konzervirane krvi ☐ afereza ☐ SD obdelava ☐ odstranjeni levkociti ☐ obsevanje ☐ antigensko skladna ☐ odstranjena plazma ☐ CMV negativna ☐ karantena ☐ drugo (opišite): .....

SIMPTOMI IN KLINIČNI / BIOLOŠKI ZNAKI REAKCIJE

Znaki	pred	po
Temperatura	.....	.....
Krvni pritisk (mm Hg)	.....	.....
Pulz	.....	.....
Hemoglobinurija		
Srčna aritmija		
Drugo:		

Simptomi (1)
☐ slabo počutje
☐ mrzlica
☐ srbenje
☐ urtikarija
☐ rdečica
☐ izpuščaj
☐ zlatenica
☐ drugo: .....

Simptomi (2)
☐ bolečine v križu
☐ bolečine v prsih
☐ bolečine v trebuhu
☐ slabost/bruhanje
☐ težko dihanje
☐ akutna odpoved ledvic
☐ šok
☐ nezavest
☐ drugo: .....

Biološki
☐ pozitiven DCT
☐ hiperbilirubinemija
☐ ALT > 2N
☐ refraktarnost na transfuzijo
☐ drugo: .....

ZAKLJUČKI ALI SINDROM *(le eden za vsako poročilo)*:

Imunološki
Hemoliza - Ab0
Hemoliza - nepričakovana protitelesa
Imunizacija:
ERI Granulociti
HLA IgA
Trombociti
PTP
Alergija
Anafilaktična reakcija
TRALI

Okužba
Bakterijska okužba komponente
Bakterija(e) .....
HIV
HBV
HCV
CMV
Drugi povzročitelj: _____

Drugo
Nehemolitična febrilna TR
S transfuzijo povezana GVHD
Pljučni edem (srčna odpoved, preobremenitev)
Hemosideroza

STOPNJA
0. *ni znakov*
1. *takojšnje pojavljanje brez znakov življ. ogroženosti ali polne razvitosti*
2. *takojšnje pojavljanje znakov z življ. ogroženostjo*
3. *dolgotrajna obolelost*
4. *smrt bolnika*

POVEZANOST
0. *ni povezave*
1. *možna povezava*
2. *verjetna povezava*
3. *zanesljiva povezava*

DRUGE POMEMBNE KLINIČNE INFORMACIJE, TERAPIJA:

IZID ZDRAVLJENJA:

Potek transfuzije
kraj:
☐ operacijska dvorana
☐ enota za intenzivno terapijo
☐ bolnišnični oddelek
☐ pediatrični oddelek
☐ dnevna bolnišnica
☐ drugo:

čas:
☐ redni delovni čas
☐ dežurstvo: podnevi ponoči
☐ konec tedna

Transfundiran napačen pripravek: DA NE
Napaka se je zgodila:
☐ laboratorij za predtransfuzijsko testiranje
☐ transfuzijska služba
☐ izdaja, prenos na bolnišnični oddelek
☐ drugo: .....

Vključena tudi:
☐ materiovigilanca
☐ farmakovigilanca
☐ laboratorijski reagenti

POROČEVALEC - zdravnik

Ime in priimek:
Ustanova:
Naslov:
Telefon ali GSM, E-mail:
Datum poročanja:
Podpis:

Reporting to JAZMP

- Severe adverse reactions in patients (SAR) who recive blood
- Severe adverse reactions in blood donors
- Severe adverse events

registration within 24 hours or as soon as possible

- Annual report / all SAR (patients blood donors) and all SAE

Adverse acute reactions / patients :

(within 24 hours after transfusion)

Type of reaction	Description	Presentation
Acute hemolytic	Rare reaction, red cell incompatibility	Chills, fever, hemoglobinuria, hypotension, renal failure with oligouria, DIC, back pain, anxiety
Allergic	Common reaction to transfusion, antibody to donor plasma proteins	Urticaria, pruritus, flushing
Anaphylactic	Rare reaction, antibody to donor plasma proteins (including IgA, haptoglobin, C4, cytokines)	Hypotension, urticaria, bronchospasm, local oedema, anxiety
Febrile, nonhemolytic	Common reaction to transfusion, accumulated cytokines in platelet unit, antibody to donor WBCs.	Fever, chills, headache, vominting
Sepsis	Rare, bacterial contamination	Fever, chills, hypotension
TRALI	Rare reaction, WBC antibodies in donor (occasionally in recipient), other WBC-activating agents in components	Hypoxemia, respiratory failure, hypotension, fever, bilateral pulmonary oedema

Adverse acute reactions /patients:

TACO	**Circulatory volume overload**	**Dyspnea, orthopnea, cough, tachycardia, hypertension, headache**
TAD	Rare transfusion reaction, pulmonary distress	dyspnea
Hypotension	Rare transfusion reaction, hypotension associated with ACE inhibition	hypotension

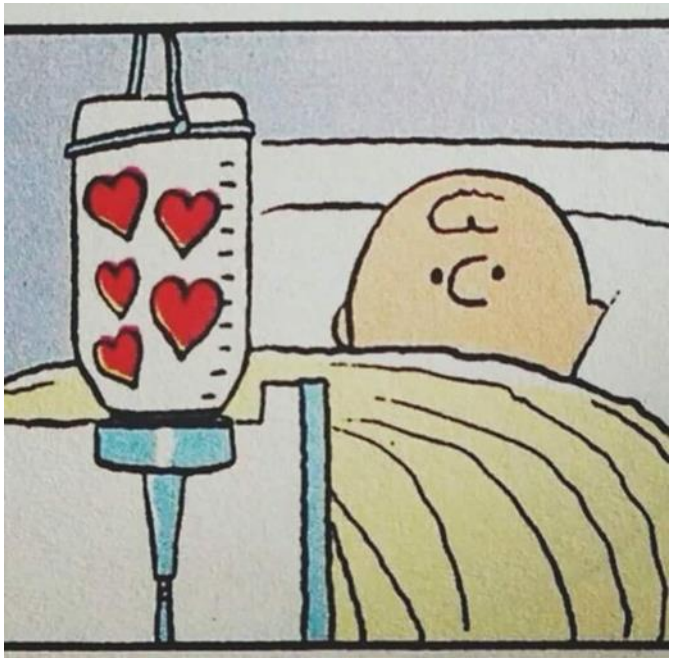
Adverse delayed reactions / patients

24 hours after transfusion

Delayed hemolytic	Rare transfusion reaction, most delayed hemolytic reaction are unnoticed, reaction of recipient`s antibodies to donor`s antigens	Lower Hb, positive DCT and ICT, clinical and laboratory signs of haemolysis
TA-GvHD	Rare transfusion reaction, donor lymphocytes engraft in recipient and mount attack on host tissue	Erythroderma, maculopapular rash, anorexia, nausea, vomiting, diarrhea, hepatitis, pancytopenia, fever
PTP	Rare transfusion reaction, recipient platelet antibodies destroy autologous platelets	Thrombocytopenic purpura, bleeding 8-10 day after transfusion
Transmission of viral infection	Rare transfusion reaction, transmission of HBV, HCV, HIV, CMV, ect.	/
Iron overload	Rare transfusion reaction, patients with multiple transfusions (more than 100)	High levels of iron, diabetes, cirrhosis, cariomyopathy
Immunomodulation	Immune response to foreign antigens on RBCs	/

ADVERSE REACTIONS 2016

Patients



NTR	Reports 2016	Reports 2017
TRALI	2	0
TACO	11	5
Allergic	52	34
Anaphylactic	5	0
NHFTR	60	38
Virus tr.	3	1
TAD	1	1
Other	1	2
Sumary	**135**	81

Recipients / transfused / adverse reactions / blood components

Year	RED BLOOD CELLS	PLATELETS	PLASMA
2014	0,94	1,34	1,13
2015	0,93	1,67	1,06
2016	1,07	0,90	1,13
2017	0,58	1,55	0,67

Adverse reactions by Imputability

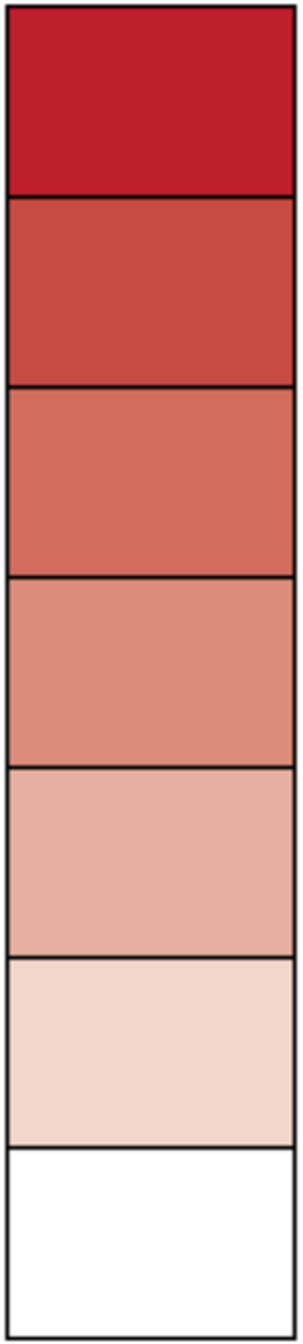
Imputability	NTR
3	14
2	25
1	42
0	5

PRIJAVA NEŽELENIH UČINKOV TRANSFUZIJE KRVI

9. Povezanost s transfuzijo:

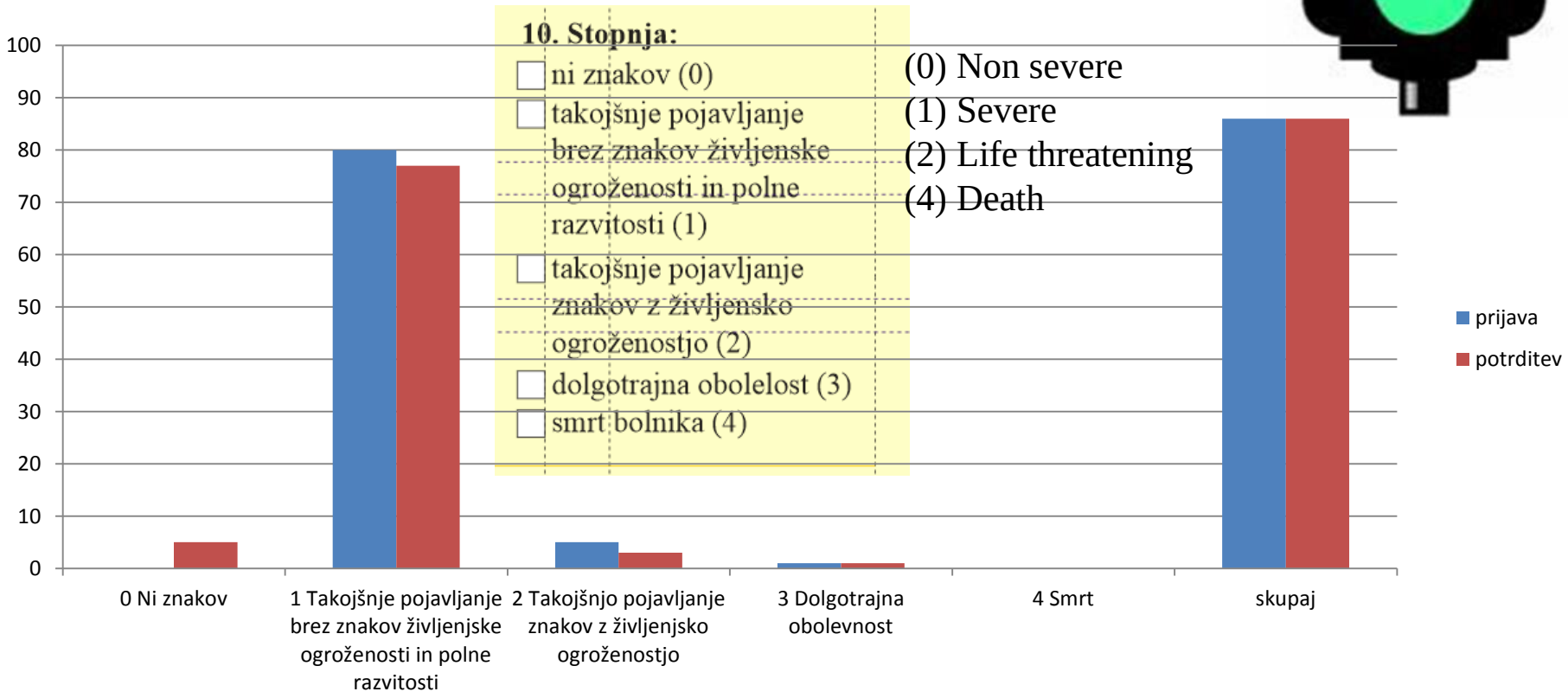
- ☐ povezava izključena (0)
- ☐ malo verjetna povezava (0)
- ☐ možna povezava (1)
- ☐ verjetna povezava (2)
- ☐ nedvomna povezava (3)

(1) Possible
(2) Probable
(3) Definite



Adverse reactions by Severty

PRIJAVA NEŽELENIH UČINKOV TRANSFUZIJE KRVI



Adverse reactions / hospitals 2014–2017

Hospital	1	2	3	4	5	6	7	8	9	10	11	12
2014	52	10	8	6	0	2	1	2	19	0	4	14
2015	54	8	13	4	4	5	7	0	15	0	1	8
2016	67	7	11	4	1	3	0	3	15	0	4	14
2017	40	6	6	1	1	1	1	3	14	1	6	6

Hospital	1	2	3	4	5	6	7	8	9	10	11	12
Št. reakcij na 1000 izdanih komponent	1,17	1,35	1,8	0,93	0,44	0,99	0	2	0,7	0	1,32	1,48

Adverse events

Adverse events

A.	Incorrect blood component transfused
B.	Transfused Blood Component does not meet the standards
C.	Wrong handling with blood component outside the transfusion
D.	Near miss
E.	Adverse events within collecting, processing, storage and distribution of blood products

[1] Summarised by SHOT classification 2015

Adverse events

A. Incorrect blood component transfused

- Transfused blood components was intended for different patient (match or miss match in blood group)
- Transfusion of wrong blood component (match or miss match in blood group)
- Miss match transfusion because of wrong blood in the tube (WBIT)
- Miss match transfusion because of laboratory mistake
- Miss match transfusion because of mistake with issuing blood component

Adverse events

B. Transfused Blood Component does not meet the standards
• Inadequate CMV status
• Blood component was not irradiated
• Inadequate antigen blood for patient with known antibodies
• Inadequate HLA platelets for patient with known anti-HLA antibodies
• Transfusion of too old blood component

Adverse events

C. Wrong handling with blood component outside the transfusion
• Interrupted cold chain
• Inadequate storage of blood component in hospital department
• Too long transfusion
• Wrong identification of patient before transfusion
• Use of wrong transfusion system
• Transfusion after 72 hours after issuing blood component
• Urgent transfusion of 0 RhD negative blood component when there was an adequate cross matched blood unit waiting in transfusion institution
• Application of drugs or incompatible fluids on the same blood line as transfusion

Adverse events

D. Near miss
• Inadequate ordering of the blood unit (administrative mistake)
• Wrong interpretation of bed-side test
• Wrong blood in the tube
• Laboratory mistake

DEL C
Obrazec za letno obveščanje o hudih neželenih dogodkih

Služba za hemovigilanco **ZAVOD RS ZA TRANSFUZIJSKO MEDICINO**

Obdobje poročanja	od 1. januarja do 31. decembra 2017

Skupno število enot predelane krvi in komponent krvi: **188.255**

Hud neželen dogodek, ki je vplival na kakovost in varnost komponente krvi zaradi nepravilnosti pri:	**Skupno število**	**Specifikacija***			
		Napaka izdelka	**Napaka v opremi**	**Človeška napaka**	**Drugo (navedite)**
zbiranju polne krvi	6				6 **(5,6,7,8,17,18)**
aferezi					
testiranju dajalcev	1		1 **(19)**		
predelavi					
skladiščenju					
razdeljevanju	1			1 **(12)**	
materialih					
drugo (navedite)	11		1 **(4)**	5 **(1,2,3,10,13)**	5 **(9,11,14,15,16)**

Near miss 2017

Near miss	No.
Pomanjkljiva naročilnica, vzorec, administrativna napaka	683
Napačno orientacijska določitev KS na oddelku	256
Napačna kri v epruveti	16
Napaka v laboratoriju	110
Izdaja napačne komponente/izvida	20
Oprema	11
Napaka v informacijskem sistemu	18
Total	**1.114**


Compoflex

Local reactions / blood donors:

Vessel damage		
	Common	Rare
	Haematoma	Deep venous thrombosis
	Arteria puncture	Arteriovenous fistula
	Delayed bleeding (leakage of blood from venipuncture site after the initial bleeding has stopped)	Compartment sydrome
		Pseudoaneurysm
Nerve injury	Injury or irritation of a nerve with a nidle	
	Nerve irritation (injury rare) because of haematoma	
	Nerve irritation (injury rare) because of local infection	
Inflammation	Thrombophlebitis	
	Cellulitis	
Allergic	Localised allergic reaction	

IHN, Standard for survellance of complications related to blood donation; Donor vigilance, december 2014

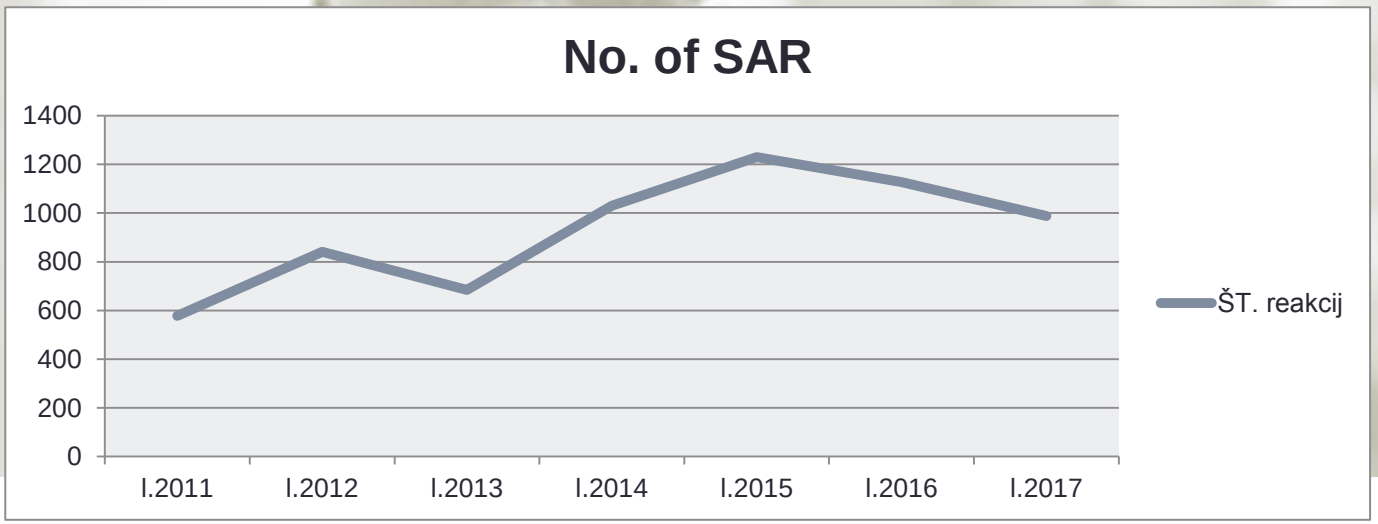
Generalized reactions / blood donors:

Vasovagal reaction	
	With or without loss of consciousness
	With or without other complications (convulsions, urinary or faecal incontinence)
	With or without injury
Complications related to apheresis	
	Citrate reaction
	Haemolysis
	Air embolism
Anaphylactic reaction	
Other complications	
	Acute cardiac symptoms
	Miocardial infarction
	Cardiac arrest
	TIA
	Cerebrovascular accident
	Death

IHN, Standard for survellance of complications related to blood donation; Donor vigilance, december 2014

No. of reaction / Blood donations in 2011-2017

Blood donors



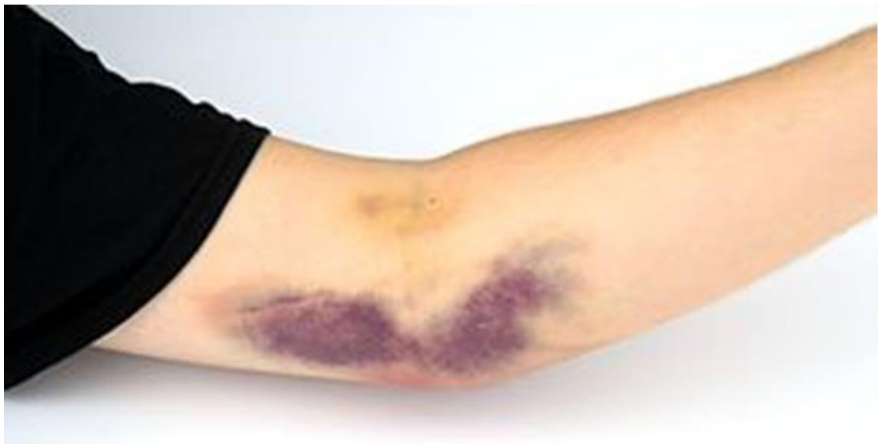
No. of reaction / Blood donations in 2011-2017

Blood donors

Leto	2011	2012	2013	2014	2015	2016	2017
No. of donation	100.944	96.062	93.636	88.700	88.200	90.450	89.316
No. of reactions	578	841	685	1030	1230	1127	988
R/1000 donations	**5,73**	**8,58**	**7,32**	**11,61**	**13,95**	**12,46**	**11,06**

Adverse reaction / Blood donors

Vessel damage	
Hematoma	70
Puncture of arteria	1
Nerve injury	5
Vasovagal reaction	758
Complications of apheresis	
Citrate reaction	89
Vasovagal reaction	23
Hematoma	42
total	**988**



Annual report of SAR / SAE

- 31 countries (28 EU member states, Ireland, Liechtenstein, Norway)
- 25 milion units issued
- 1349 SAR
- 25 deaths (not directly attributable to quality/safety of blood components but rather to clinical practise)
- 2338 SAE (due to human error, reporting rates vary considerably between countries).

SAR / blood components

No.		
811	⟹	Related to red blood cells
310	⟹	Related to platelets
170	⟹	Related to plasma
1	⟹	Related to whole blood
57	⟹	Related to more than one blood component

1349 SAR

- Anaphylaxis/ hypersensitivity: 453 cases
- Febrile non-haemolytic transfusion reaction (FNHTR): 357 cases
- Transfusion associated circulatory overload (TACO): 185 cases
- Immunological haemolysis: 172 cases, of which
  - 78 cases due to ABO incompatibility and
  - 78 cases due to other alloantibodies
  - 16 Delayed haemolytic transfusion reaction
- Transfusion associated dyspnoea (TAD): 53 cases
- Transfusion related acute lung injury (TRALI): 48 cases

1349 SAR

- Transfusion transmitted infections: 34 cases, of which
  - 17 bacterial infection, and
  - 17 viral infectionof which
    - 9 were hepatitis E,
    - 3 hepatitis C,
    - 2 HIV,
    - 2 hepatitis B,
    - and one Cytomegalovirus

- Hypotension: 11 cases
- Non-immunological haemolysis: 7 cases
- Posttransfusion purpura: 5 cases
- Hypertension: 4 cases
- Circulatory disorders (other than circulatory overload): 1 case
- Other: 19

Deaths / SAR

- 10 were associated to immunological haemolysis(5 due to ABO incompatibility associated to red blood cells transfusion)
- 8 were associated with TACO
- 5 were associated with TRALI
- 1 was associated with bacterial transmission,
- 1 was reported under the “other”

SAR

•**Whole blood collection:**	449	SAE (19.2 %)
•**Apheresis collection:**	43	SAE (1.8 %)
•**Testing of donations:**	149	SAE (6.4 %)
•**Processing:**	124	SAE (5.3 %)
•**Storage:**	276	SAE (11.8 %)
•**Distribution:**	328	SAE (14.0 %)
•**Materials:**	17	SAE (0.7 %)
•**Other activity steps**:	952	SAE (40,7 % of reported SAE)


Thank you
for your
attention