DONOR SAFETY IN HAEMAPHERESIS: IMPLEMENTATION OF THE IHN-STANDARD 2014 INTO THE ONLINE SYSTEM FOR ASSESSMENT AND EVALUATION OF DONOR AND APHERESIS COMPLICATIONS

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for the DGTI Haemapheresis Vigilance Working Party

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On-line Assessment of Complications in Haemaphereses

- The Haemapheresis Vigilance Working Party of the German Society for Transfusion Medicine and Immunohaematology (DGTI) and Aix Scientifics®
- Internet-based system for assesment and evaluation of complications in haemaphereses:
  https://www.haemapheresisvigilance.eu
- All complications: donor-, procedure-, staff-related complications as well as technical events
- Jan 23, 2012 – Dec 31, 2015 assessment of 17.093 AE out of approx. 345.000 haemaphereses from 20 apheresis centres in Germany (15), Austria (1) and Switzerland (4)

On-line haemapheresis vigilance system: Overview

- Web-based system, currently available in German and English
  - Login-Page: centre-specific access and user-identification
  - Data Assessment – Pages (2 HTML-pages)
    - Data for donor and procedure variables (1 page)
    - Complication data (1 page)
  - Administration & data evaluation (3 HTML-pages)
    - Creating defaults for apheresis procedures (► facilitates data assessment)
    - Centre-specific evaluation and comparison to the benchmark of all other participating centres
      - Evaluation according to IHN standard Dec, 2014

Implementation IHN – Standards 2014

Standard for Surveillance of
Complications Related to Blood Donation

Working Group on Complications Related to Blood Donation

International Society of Blood Transfusion
Working Party on Haemovigilance

European Haemovigilance Network

2008

International Society of Blood Transfusion

International Haemovigilance Network

Advancing Transfusion and Cellular Therapies Worldwide

Standard for Surveillance of
Complications Related to Blood Donation

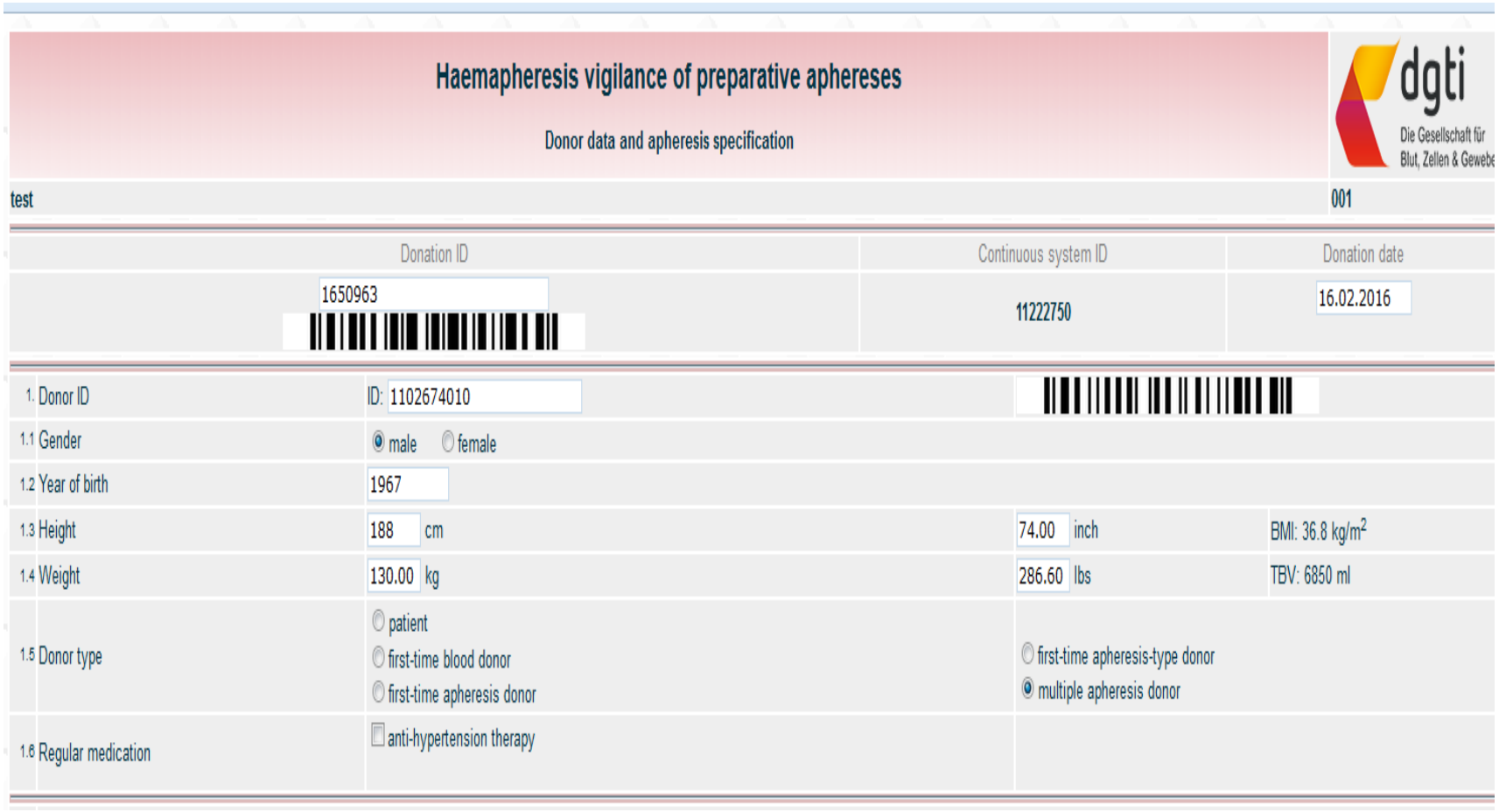
Working Group on Donor Vigilance
of the
International Society of Blood Transfusion
Working Party on Haemovigilance

in collaboration with

The International Haemovigilance Network
The AABB Donor Haemovigilance Working Group

December 11, 2014

On-line haemapheresis vigilance system: Donor data



Haemapheresis vigilance of preparative aphereses

Donor data and apheresis specification

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test 001

Donation ID	Continuous system ID	Donation date
1650963	11222750	16.02.2016

1. Donor ID	ID: 1102674010			
1.1 Gender	male / female			
1.2 Year of birth	1967			
1.3 Height	188 cm		74.00 inch	BMI: 36.8 kg/m²
1.4 Weight	130.00 kg		286.60 lbs	TBV: 6850 ml
1.5 Donor type	patient / first-time blood donor / first-time apheresis donor		first-time apheresis-type donor / multiple apheresis donor	
1.6 Regular medication	anti-hypertension therapy			

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On-line haemapheresis vigilance system: Apheresis data I

https://www.aix-scientifics.com/cgi-local/dgti/2/bin/dgti2.pl?160229_75495_0002

1.1	Gender	◉ male ○ female			
1.2	Year of birth	1967			
1.3	Height	188 cm		74.00 inch	BMI: 36.8 kg/m²
1.4	Weight	130.00 kg		286.60 lbs	TBV: 6850 ml
1.5	Donor type	○ patient ○ first-time blood donor ○ first-time apheresis donor		○ first-time apheresis-type donor ◉ multiple apheresis donor	
1.6	Regular medication	☐ anti-hypertension therapy			

2. Specification of planned procedure

○ PLS | ◉ PLT | ○ SC | ○ PMN | ○ RBC | ○ MNC

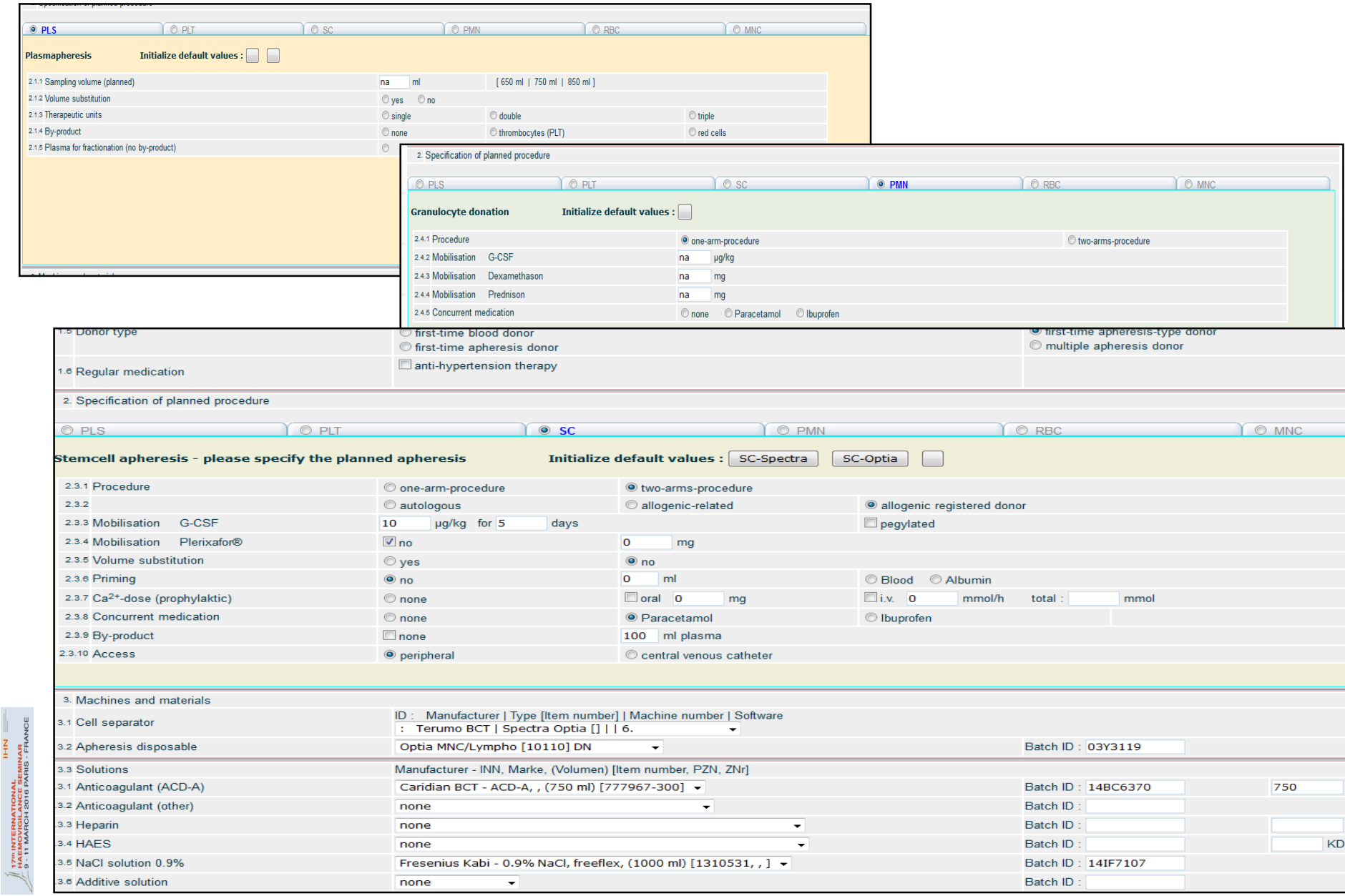
Platelet apheresis **Initialize default values :** ☐ ☐ ☐

2.2.1	Procedure	◉ one-arm-procedure	○ two-arms-procedure	
2.2.2	Therapeutic units	○ single	◉ double	○ triple
2.2.3	Plasma-reduced	○ yes	◉ no	
2.2.4	Volume substitution	○ yes	◉ no	
2.2.5	Ca^{2+}-dose (prophylaktic)	◉ none	○ oral 500 mg	○ oral 1.000 mg
2.2.6	By-product	◉ none	○ plasma ○ plasma + red cells	○ red cells

3. Machines and materials

3.1	Cell separator	ID : Manufacturer | Type [Item number] | Machine number | Software : Terumo BCT | Trima Accel [81000] | | 5.1			
3.2	Apheresis disposable	Einphasen LRS PLT-PLS-Set [80300] SN		Batch ID : 10Y1116	
3.3	Solutions	Manufacturer - INN, Marke, (Volumen) [Item number, PZN, ZNr]			
3.3.1	Anticoagulant (ACD-A)	Caridian BCT - ACD-A, , (750 ml) [777967-300]		Batch ID : 15BC6033	750 ml
3.3.2	Anticoagulant (other)	none		Batch ID :	
3.3.3	Heparin	none		Batch ID :	IE/apheresis
3.3.4	HAES	none		Batch ID :	KD
3.3.5	NaCl solution 0.9%	none		Batch ID :	
3.3.6	Additive solution	none		Batch ID :	

On-line haemapheresis vigilance system: Apheresis data II



Haemapheresis vigilance system: Complication data I

Haemapheresis vigilance of preparative aphereses

Complication data

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test

001

Donation ID	Continuous system ID	Donation date
1650963	11222750	16.02.2016

Donor ID — ID: 1102674010

4.1 Course of apheresis

- ○ Event without termination
- ○ Termination, but all planned products are obtained
- ○ Termination, but all planned products are obtained, no reinfusion
- ○ Termination, planned products are only obtained partly
- ◉ Termination, planned products are only obtained partly, no reinfusion
- ○ Termination, no useful products

4.2 Obtained

- na ml of planned ml
- na 10^9 Cells of planned 10^9 Cells
- ☐ Plasma for fractionation (no by-product)

4.3 Therapeutic units for human use

- ☐ 1 ☐ 2 ☐ 3 PLS-bags
- ☑ 1 ☐ 2 ☐ 3 thrombocytes (PLT)
- ☐ 1 ☐ 2 red cells
- ☐ stem cells ☐ granulocytes (PMN)
- ☐ lymphocytes ☐ monocytes

5. Time point of the event

- ○ before the apheresis
- ○ first ○ second ◉ third=last part of apheresis
- ○ after the end of apheresis ○ after leaving the institute

6. Specification of the event

☑ Puncture ☐ Anticoagulation ☐ Circulation ☐ Donor ☐ Technics ☐ Other AE

Haemapheresis vigilance system: Complication data II

5.	Time point of the event	○ before the apheresis ○ first ○ second ◉ third=last part of apheresis ○ after the end of apheresis ○ after leaving the institute

6. Specification of the event

☑ Puncture | ☐ Anticoagulation | ☐ Circulation | ☐ Donor | ☐ Technics | ☐ Other AE

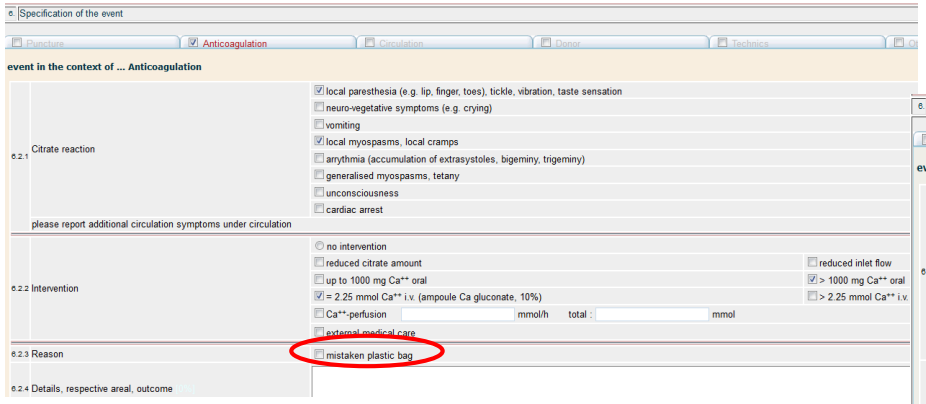
event in the context of ... Puncture

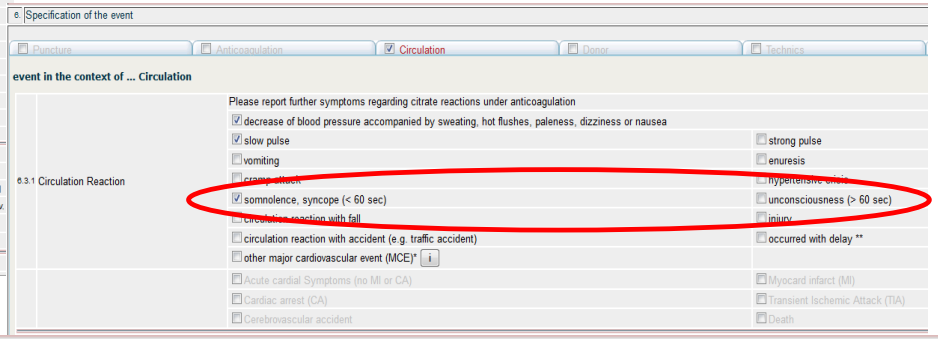
☑ venous puncture ☐ arterial puncture ☐ neural puncture ☐ paravenous puncture

6.1.1	Worse blood flow	☐ leading to medical intervention or termination				
6.1.2	Pain at the location of puncture	◉ no	acute pain	○ for < 20 min	○ > 20 min	
			○ for < 14 days	○ > 14 days	○ > 12 months	
		☐ tendon injury	☐ local infection	☐ local inflammation	☐ thrombophlebitis	☐ occurred with delay **
6.1.3	Paravasat / Haematoma i	○ no	○ < 20 mm	◉ > 20 mm	○ > 50 mm	○ > 100 mm
		☐ painful arm / movement limitation i		☐ Compartment syndrome i		☐ occurred with delay **
		☐ Deep Venous Thrombosis (DVT) i	☐ Arteriovenous fistula i	☐ Brachial artery pseudoaneurysma i		
6.1.4	ZVK-complication	☐				
6.1.5	Local paresthesia i	◉ no	○ for < 14 days	○ > 14 days	○ > 12 months	☐ occurred with delay **
6.1.6	Local sensitive paresis i	◉ no	○ for < 14 days	○ > 14 days	○ > 12 months	☐ occurred with delay **
6.1.7	Local motor paresis i	◉ no	○ for < 14 days	○ > 14 days	○ > 12 months	☐ occurred with delay **

6.1.8	Intervention	○ no intervention	☐ new positioning of needle
		☑ change of machine setting	☐ re-puncture
		☐ change of disposable	☐ external medical care
6.1.9	Details, respective areal, outcome	nach 47 Minuten Vene para. Spender mit Heparin ausgestattet. Kein Plasma gesammelt wegen HKT 50. Einfachkonzentrat erhalten mit Ertrag 3,8	

Haemapheresis vigilance system: Complication data III





6. Specification of the event

Puncture | Anticoagulation | Circulation | Donor | Technics

Technical events, which lead to a discontinuation

6.5.1 Unexpected low yield	☐	6.5.10 Priming failure of the set	☐
6.5.2 Platelet aggregation	☐	6.5.11 Display defect	☐
6.5.3 Haemolysis	☐	6.5.12 Sensor/valve defect	☐
6.5.4 Red cell overflow	☐	6.5.13 Pump	☐
6.5.5 Leukocyte contamination	☐	6.5.14 Centrifuge	☐
6.5.6 Welding failure of disposable	☐	6.5.15 Power supply (Power supply defect)	☐
6.5.7 Disposable leckage	☑	6.5.16 Software crash	☐
6.5.8 Sticky disposable	☐	6.5.17 Software error	☐
6.5.9 Disposable kinking	☐		

6.5.18 Disposable/maschine-related event ◉ Operator error ○ other reason ○ (please specify) i

6.5.19 Intervention: ☐ no intervention; ☑ change of disposable; ☐ change of apheresis machine; ☑ disposable returned to producer

6.5.20 Alarm message of the device, details, outcome

On-line haemapheresis vigilance system: Data evaluation

PD Dr. med. Hans-Gert Heuft 001

Basic Data
for the year 2015

	präparative Plasma-Apheresen	präparative Thrombozyt-Apheresen	präparative Stammzell-Apheresen	präparative Granulozyt-Apheresen	präparative Erythrozyt-Apheresen	präparative Mononuclear-Apheresen	Vollblutspende
	PLS	PLT	SC	PMN	EK	MNC	Blut
Jan		528	16	8		3	
Feb		473	20	8		4	
Mar		539	24	11		9	
Apr		521	33	11		13	
Mai		453	22	11		4	
Jun		531	32	7		9	
Jul		515	15	8		7	
Aug		447	25	5		5	
Sep		490	23	7		4	
Okt		518	17	1		4	
Nov		479	25	3		4	
Dez		496	27	1		4	

	PLS	PLT	SC	PMN	EK	MNC	Blut
I. Quartal	0	1540	60	27	0	16	0
II. Quartal	0	1505	87	29	0	26	0
III.Quartal	0	1452	63	20	0	16	0
IV. Quartal	0	1493	69	5	0	12	0
total	0	5990	279	81	0	70	0

On-line haemapheresis vigilance system:

Data evaluation (automated; procedure-specific, here: plateletpheresis, Hannover 2014)

Adverse events during preparative Platelet Aphereses (PLT)
percentage from aphereses of this type 6246 donations of this type in your centre in full year 2014
Compare: Benchmark Data of othere study centres in brackets (....)
based on 13219 preparative Platelet Aphereses in 4 other centres

			mild	moderate	all severe	severe > 1 y	total
A	**Complications mainly with local symptoms**	**[i]**					
A 1.	**Complications mainly characterized by the occurrence of blood outside the vessels.**						
A 1.1	Haematoma	[i]	1.2 % (0.6 %)	0.6 % (0.1 %)	0 % (0 %)	0 % (0 %)	1.9 % (0.7 %)
A 1.2	Arterial puncture	[i]	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)
A 1.3	Delayed bleeding	[i]	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)
A 2.	**Complications mainly characterized by pain**						
A 2.1	Nerve irritation	[i]	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)
A 2.2	painful arm / movement limitation	[i]	0.1 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)	0.1 % (0 %)
A 3.	**Other complications with local symptoms**						
A 3.1	Thrombophlebitis	[i]	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)
A 3.2	Allergy (local)	[i]	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)
A 4.	**further major vessel injuries**						
A 4.1	Deep Venous Thrombosis (DVT)	[i]	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)
A 4.2	Arteriovenous fistula	[i]	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)
A 4.3	Compartment syndrome	[i]	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)
A 4.4	Brachial artery pseudoaneurysma	[i]	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)
A total	**Total number local symptoms**		1.3 % (0.92 %)	0.66 % (0.14 %)	0.03 % (0 %)	0 % (0 %)	1.99 % (1.05 %)
B	**Complications mainly with generalized symptoms.**	**[i]**					
B.1	Immediate Vasovagal reaction	[i]	0.4 % (0.4 %)	0.1 % (0 %)	0 % (0 %)	0 % (0 %)	0.6 % (0.4 %)
B.2	Immediate Vasovagal Reaction with injury	[i]	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)
B.3	Delayed Vasovagal Reaction	[i]	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)
B.4	Delayed Vasovagal Reaction with injury	[i]	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)
B.a	-- thereof with < 60 sec unconsciousness	[i]	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)
B.b	-- thereof with > 60 sec unconsciousness	[i]	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)
B total	**Total number of Vasovagal Reactions**		0.43 % (0.36 %)	0.11 % (0.02 %)	0.02 % (0 %)	0 % (0 %)	0.56 % (0.37 %)
C	**Further Complications**						
C.1	Citrate reaction		0.1 % (1.3 %)	0.1 % (0 %)	0 % (0 %)	0 % (0 %)	0.2 % (1.3 %)
C.2	Haemolysis		0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)
C.3	Generalised allergic reaction		0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)
C.4	Air embolism	[i]	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)
D	**Allergic reactions**						
D 1	Local allergic reactions	[i]	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)
D.2	Generalised allergic reaction	[i]	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)
E	**Major cardiovascular event (MCE)**	**[i]**					
E.1	Acute cardiac symptoms (other than MI or CA)		0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)
E.2	Myocard infarct (MI)		0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0.1 %)
E.3	Cardiac arrest (CA)		0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)
E.4	Transient Ischemic Attack (TIA)		0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)
E.5	Cerebrovascular accident		0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)
E.6	Death		0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)
F	**Other complications related to blood donation**						
F	Other complications related to blood donation		0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)	0 % (0 %)

On-line haemapheresis vigilance system:

Data aquisition: Jan, 2012 – Dec, 2015

Centre	Frequency	Percent	Completed Frequency	Completed Percent
	1	0.01	0	0
	7	0.04	4	0.03
	7	0.04	0	0
	48	0.29	48	0.41
	125	0.75	1	0.01
	132	0.79	132	1.12
	197	1.18	156	1.33
	201	1.20	201	1.71
	214	1.28	210	1.79
	303	1.81	220	1.87
	417	2.49	368	3.14
	703	4.20	1	0.01
	1108	6.62	0	0
MH Hannover	1158	6.92	1149	9.79
	1199	7.16	1035	8.82
	1478	8.83	6	0.05
	1701	10.16	1691	14.41
	2232	13.33	1761	15.01
	2624	15.67	2605	22.20
	2888	17.25	2148	18.30
Total	**16.744**	**100**	**11.736**	**100**

On-line haemapheresis vigilance system:

Data aquisition: Jan, 2012 – Dec, 2015; PRELIMINARY Results

Apheresis procedure	Frequency	Percent
PLS	10535	63.03
PLT	5769	34.52
Stem cells	363	2.17
PMN	1	0.01
Ery	10	0.06
MNC	36	0.22
Total*	16714	100 %

*Missing, n=30

On-line haemapheresis vigilance system:

Data aquisition: Jan, 2012 – Dec, 2015; PRELIMINARY Results

	Frequency, n	Frequency, %
Blood access injuries	9372	54.5
Anticoagulation	1894	11.0
Circulation	1955	11.4
Donor events	2527	14.7
Technical events	1427	8.3
Other events	17	0.1
Total*	17192	100
Double events*	849	4.9

*Combined AE, such as „anticoagulation plus circulation“ or „blood access injuries plus donor compliance“

On-line haemapheresis vigilance system:

Data aquisition: Jan, 2012 – Dec, 2015; PRELIMINARY Results

Adverse events - Grading	Frequency, completed AE	Percent
Minor	10597	90.30
Moderate	962	8.20
Severe	177	1.5
Total	11736	100

Conclusions

- DGTI online haemapheresis vigilance system
  - Comprehensive
    - all conceivable apheresis procedures
    - all apheresis maschines
    - including donor compliance, technical failures
  - Automated grading of the events
  - Automated evaluation of centre data, including benchmark

  - Easy-to-use and fast

  and

  - Not expensive (non-profit system, developed for a scientific society)

Haemapheresis vigilance working party

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Thank you for your attention!

Hans-Gert Heuft, AG Hämapheresevigilanz (AGHV), Stand 03/2016

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