SUPPLY PROJECT

"Strengthening voluntary non-remunerated plasma collection capacity in Europe"

REPORT ON THE RESULTS OF THE: WP 5.2

"SUPPORT TOOL ON STANDARDIZED DONOR VIGILANCE DATA"

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1. Introduction:

The improvement of donor safety in mechanical plasma donation is an essential point of this project. Systems for recording adverse events in plasma donation are established in many EU member states. In order to make the data from different countries comparable, a uniform recording and evaluation tool should be established in Europe. However, the exclusive recording of side effects does not allow any statements to be made about possible existing risk factors. Through additional monitoring of data on the donors, the donation process and the devices used, it may be possible to identify and reduce further risk factors. Since in some EU member states different organisations carry out mechanical plasma donation and information between these organisations is not yet possible for reasons of data protection, a reporting system should currently be established that takes these restrictions into account and still allows the most comprehensive possible assessment of the risks involved in plasma donation. These restrictions should be taken into account and still allow a comprehensive assessment of the risks associated with plasma donation. The support tool we designed is the first approach to lay the foundations for the further development and design of an EU-wide collection of data, risks and side effects. In a further step, a query of the individual organisations coordinated down to the last detail, should take place in another project for an optimal collection and evaluation of the data.

2. Preconditions for the development of a tool for the analysis of data on possible risks and adverse events in plasma donation

In order to set up a tool for recording and evaluating adverse events and possible medium-term or long-term health risks, a standardised, uniform data collection is required as a first step.

For the development of this tool, various problem areas must be defined:

- The immediate recording of side effects in the plasma donation facility according to uniform criteria.

- The evaluation of the recorded side effects and the entry into the organisation's database according to standardised specifications.

- A combination of the registered side effects with further, additional information on the plasma donation involved

- The provision of information from each donor centre of a blood transfusion service on plasma donations, plasma donors, equipment used, and information on established safety concepts to reduce known risks.

- The consolidation of data from the individual facilities in the nationally active blood transfusion service and plausibility checks

3. Components of the Support Tool

3.1. Data from the facilities on important donation/donor information

In order to compare different organisations, it is necessary to collect basic information on each facility where plasma donation is performed.

To better understand the individual data requested, we have filled the data fields with real data from our blood donation service from 2022.

plasma donation facility	all			Observation period	Calendar year 2022
Name of the Organization	Nord-Ost			or date from	to

General Donation Information			
Whole blood donations yes/no	y		
Plasma donations Yes/No	y		
PLT - Apheresis Yes/No	y	PLT + Plasma Yes/No	y
RBC-Apheresis Yes/No	n	RBC + Plasma Yes/No	n

Number of PLT-Apheresis	8229
Number of RBC-Apheresis	0

Plasma donations/donors	female	male
total number of Plasma donations	47674	63127
total Number of activ Plasma donors	4255	4483
thereof first time donors	1150	953
thereof repeat donors	3104	3531

Number of plasma donations allowed per year	60
Minimum interval between 2 donations in days	3
uniform plasma target volume Y/N	n

plasma target volume depends on	bodyweight	target vol. ml
parameter 1 please describe	<61 kg	650
bodyweight	61-70 kg	750
	>70 kg	850
parameter 2 please describe		

If PLT apheresis with plasma	
plasma target volume in ml (mean value)	400-550

a) For the characterisation of the facility, we have limited ourselves to basic information. Further information can be added in the further design of the tool.

b) As an observation period, especially for the evaluation of registered adverse events, the calendar year is well-suited as a standard. A selection by date allows the analysis of data over a longer (or even shorter) period.

c) The information on all donation types performed in the facility during the observation period gives, at least to a limited extent, information on possible additional red cell and plasma losses in the facility.

d) Especially for the evaluation of adverse events in plasma donation, we consider the distinction between first-time donors and multiple donors useful.

e) Some organisations have different plasma donation volumes linked to certain parameters. In order to be able to evaluate these donation conditions, we have included the possibility of displaying these systems in the tool.

f) The evaluation of occurring adverse events in combination with age, gender or donation experience can best be carried out across organisations if the entire donor population is also grouped according to corresponding criteria. We have made initial groupings in this tool as a draft, as a suggestion. Of course, other groupings can be made subsequently, in consultation with all organisations.

General Donor information plasma donation

Age of the donors	number of donors		number of donations	
	male	female	male	female
Age group 1 (<25y)	848	1173	7608	8176
Age group 2 (25-44y)	1956	1569	25613	17360
Age group 3 (45-64)	1444	1343	25262	19261
Age group 4 (>64)	236	169	9129	7130
total	4484	4254	67612	51927

Age of first time donors	number of donors	
	male	female
Age group 1 (<25y)	394	518
Age group 2 (25-44y)	411	402
Age group 3 (45-64)	148	230
Age group 4 (>64)		
total	953	1150

Number of donations in the period	number of donors		Number of donations from this group in the period	
	male	female	male	female
1-5	1670	1908	4182	4828
6-11	873	846	7123	6962
12-27	1152	1038	21218	18548
28-52	720	445	26876	16294
more than 52	68	18	3764	1006

Interval between two donations in days	number of donors		
	total	male	female
2-4	29		
2-5	1069		
2-6	1096		
2-7	1521		
2-8	380		

The categorisation of donors according to the average donation interval between two plasma donations allows a more precise assessment of individual risks. For this analysis, however, the date of the first and last plasma donation in the year must also be included in the analysis in the individual organisations. In our tests, we only included donors who had at least two IgG determinations in the observed period. Another criterion could also be a minimum number of plasma donations; the only important thing is the reduction of included data that cannot be interpreted.

3.2. Uniform criteria for documenting a plasma donation

The process of each individual plasma donation needs to be documented in the IT system according to uniform criteria.

The requirements for the production of source plasma already include these documentation steps, for the comparison of properly performed plasma donations, aborted procedures and procedures with donor side effects, at least basic information must be available.

Each record of a plasma donation should contain at least the following information in the different organisations:

- Donation number
- Donor number
- Date of plasma donation
- Type of donation
- Age at time of plasma donation
- Gender of donor
- Body weight of the donor
- Height
- Haemoglobin level before or at the time of plasma donation
- Haematocrit
- Platelets (if measured)
- Leukocytes (if measured)
- Total protein (if measured)
- IgG (if measured)
- Type of device used
- Anticoagulant used
- Target volume of plasma
- Actual volume collected
- Anticoagulant used
- Start and end of donation or duration of plasma donation
- Procedure successfully completed Y/N

3.3. Device types and device settings used

For the combination of occurring side effects with data on the equipment or process parameters used, we have limited ourselves to basic information.

General Devices and Donation Information

Manufacturer / Device type	Software Revision used	Designation of the set used
Haemonetics PCS 2 (1)	H.1	625 HS/SC 630/ 620
Fresenius AURORA	2.0	6R2278
Fresenius A 200		6R2278

Main configuration Device type 1 Haemonetics PCS2		used anticoagulant
Standard withdrawal speed	100	Sodium citrate
Standard return speed	120	
AC/Whole blood ratio	1:16	

Main configuration Device type 2 Fresenius A200		used anticoagulant
Standard withdrawal speed	100	Sodium citrate
Standard return speed	120	
AC/Whole blood ratio	1:16	

Main configuration Device type 3 Fresenius AURORA 2.0		used anticoagulant
Standard withdrawal speed	100	Sodium citrate
Standard return speed	120	
AC/Whole blood ratio	1:16	

Information on plasma donation procedures

Manufacturer / Device type	number of successful procedures	Termination of the donation because of:					
		Donor/Flow problems	Haemolysis/ RBC overflow	Device error	Set defects	other	Total error
Fresenius A200	32473	600	646	125	68	116	1555
Fesenius AURORA	35678	878	35	90	43	289	1335
Haemonetics	37321	560	422	49	29	306	1366

The devices and device software used, already allow a good differentiation of the separation conditions.

The flow rates and the solutions used could provide even more detailed information. From our own experience, however, the flow rates, in particular, are already individually adapted by the operators to the constitution of the donors. In addition, the flow rates of all units are managed via the donor pressure monitor. If there are differences in the side effects, these are more likely to be due to different extracorporeal volumes or differently efficient regulation of the flow rates by the devices.

For the performance of the individual unit type, a differentiation between completed separations and separations that were completed incorrectly is an important statement. In our tool, we have differentiated the errors that occurred most frequently. This differentiation can be further refined in the further development of this evaluation. In the evaluation of the side effects that occurred, no haemolyses occurred in the donor. The evaluation of aborted separations, however, clearly shows a high number of procedures that lead to a transfer of RBC into the plasma due to kinks in the tubes or errors in the sensors.

3.4. Information on preventive measures taken by organisations to reduce health risks

The evaluation of possible health risks with regard to individual parameters such as IgG, TP or haemoglobin, can only be assessed in its statement if the procedures established by the different organisations for risk minimisation are known in detail. Different statements on the number of deviations that have occurred as well as on individual risks for the plasma donors can thus be better evaluated and subsequently generally valid recommendations can be developed.

Information on donor protection measures	
Parameter (please add)	Measures (please describe)
IgG	The IgG value is determined before the first donation. The interval between two IgG determinations is automatically set to 3 donations for first-time donors. An additional tool allows the doctors to see the values of the last IgG determination. Values below 6.8g/L are marked. Via the tool, the doctors can call up all IgG values of the last 365 days. Donation intervals are corrected on the basis of the history. If the IgG values remain constant, the interval between 2 IgG determinations is increased to 5 donations. If IgG levels fall, the interval between donors is extended
TP	see IgG
hemoglobin	In the case of donors who have a Hb value below the limit value on the occasion of a plasma donation, an individual donation pause is determined by the doctor. Before the next plasma donation, the Hb value must be above the limit values.

In grouping the donors, we have adopted the classification from the analysis report of working group 5.1. Feedback from the institutions surveyed suggests that this subdivision of plasma donors according to the donation frequency of a year is not a problem for most institutions.

We have implemented different questions for the evaluation. For sites with different collection quantities, it can be investigated whether different collection quantities have an influence on the IgG content in plasma donors. In addition, the number of individually performed plasma donations in one year and the gender of the donors were taken into account.

General information on IgG, total protein

donation frequenzy	IgG mean Values depending on the target volume g/L		
Number of donations in the period	target volume 1*	target volume 2*	target volume 3*
1-5 donations	10,02	10,04	10,08
6-11 donations	9,34	9,33	9,38
12-27 donations	8,90	8,81	8,91
28-52 donations	8,54	8,54	8,81
more than 52 donations	8,38	8,54	8,81

* Mean value of the individual donation volumes
<676 ml
676-775 ml
>775 ml

donation frequenzy	Men - Mean values of the group				Women - Mean values of the group			
Number of donations in the period	Number of donors*	IgG	TP	HB	Number of donors*	IgG	TP	HB
1-5 donations	847	9,97	73,43	14,75	1038	10,09	72,92	13,30
6-11 donations	873	9,27	71,83	14,67	846	9,56	71,53	13,08
12-27 donations	1152	8,85	70,80	14,59	1038	8,92	69,99	12,95
28-52 donations	720	8,67	69,94	14,41	445	8,74	69,25	12,85
more than 52 donations	68	8,47	70,05	13,37	18	8,23	69,86	12,81

* with at least one IgG/TP determination

	IgG g/L	TP g/L	Hb g/dl
lower limit value male	6,0	60,0	13,5
upper limit value female	17,0	84,0	18,5
lower limit value male	6,0	60,0	12,0
upper limit value female	17,0	84,0	16,5

We have created an additional possibility to evaluate the effects of plasma donations by asking for measurement results on the occasion of a plasma donation that are outside the limits. These values were coupled with the donor frequency and set in relation to the total number of donations in the respective group.

Number of values out of specification (IgG,TP,Hb)						
donation frequenzy	Number of measurements below the limit			Number of measurements above the limit		
Number of donations in the period	IgG	TP	Hb	IgG	TP	Hb
1-5	57	5	570	18	17	6
6-11	73	15	507	58	9	5
12-27	185	50	1083	160	12	17
28-52	78	54	781	290	10	13
more than 52	4	16	71	53	1	0

Interval between two donations in days	number of donors	Mean value IgG g/l	Median IgG g/l
2-4	29	9,097	8,655
5-9	1069	8,753	8,74
10-14	1096	8,85	8,655
15-30	1521	9,182	9,045
>30	380	9,424	9,265

We have created an additional possibility to evaluate the effects of plasma donations by asking for measurement results on the occasion of a plasma donation that are outside the limits. The number of values that lie outside the range shows both the possible effects of plasma donations, but also the results of preventive measures to improve donor safety.

3.5. Recording and definition of occurring adverse reactions

For a safe and meaningful donor vigilance system, all adverse events that occur must be registered. The first documentation must take place promptly in the donation facility and must be precisely defined within the framework of an SOP. The complete registration of side effects takes place in several individual steps.

1. After the medical care has been given, the type of adverse reaction, the time of occurrence, any medication administered and the corresponding donation identification number are recorded by the operator/physician present. This is either done on a form or is already recorded in the database at this time.

2. Any adverse reactions that occur, are checked by a person qualified for this activity. After a telephone call back to the donor concerned, the severity of the adverse reaction is also assessed and recorded in the IT system.

3. In the IT system, all data on the donation, the donor and the recorded side effect are linked together. For a targeted evaluation of the occurring adverse reactions, the following information must be contained in each data record.

4. For a comprehensive assessment of side effects that occur, we have defined parameters that describe these side effects in brief form (a). Additional data from the donor and donation database we defined in a further step (b and c).

a) Short description of the adverse reaction:

a) Adverse Reaction
Donation ID
Donor ID
internal code
Typ of advers reaction
Time of occurence
medicine used?
OMR/EMR
Degree of severity

b) Donor information:

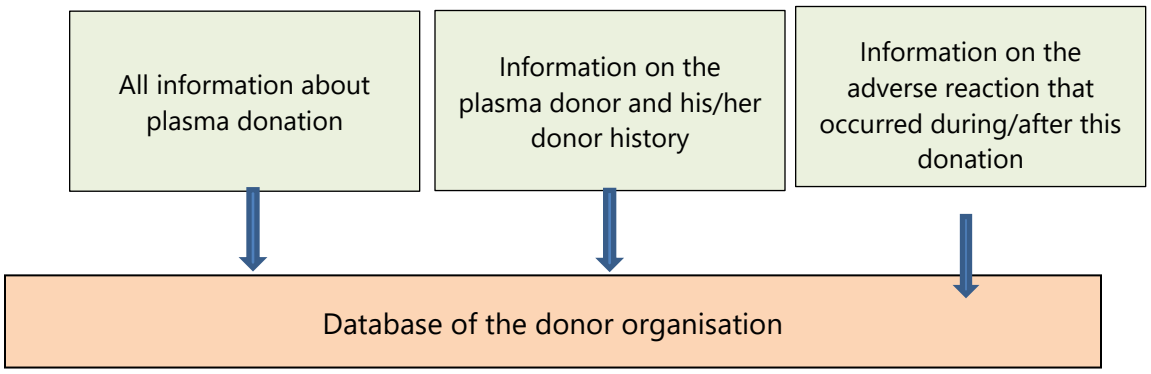
b) donor information
age
sex
Donation type
First time donor?
No plasma donation in the op
total number of plasma donations
body weight
body height

c) Donation information:

c) donation information
target volume plasma in ml
collected volume in ml
anticoagulant used in ml

These data on side effects , donor and donation, are basic parameters. In designing this tool, we wanted to create a basis that would enable as many institutions as possible to record and collect data in a uniform manner across countries. In further expansion stages, additional parameters can be integrated. If side effects occur, much more information is of course documented. From my own experience, however, it is not possible in routine to enter all this information into the database. The acceptance and participation of all employees in working on their own donor vigilance system increases if only absolutely necessary information has to be recorded again.

The documentation of donor adverse events can of course also be done in an external system, but the assignment of the occurred event to donor and donation in the own database offers many advantages.



3.6 Data transfer from the individual organisations to a central unit

We have deliberately used an MS Excel application for our tool that is accessible to every user. It offers several possible options.

- If the participating blood transfusion services are able to enter the registered adverse events into their own IT system, it should be possible to fill in the complete spreadsheet "Data Input". The user automatically receives his own evaluation of his donor vigilance on the "Results" page. The Excel file can be sent, protected, to a central registry. It is also possible to send the form for recording all the required data as a web-based form and to have it filled out and returned by the participant.

- If it is not possible to integrate the data records on the registered adverse reactions in one's own IT system and to link them to all donation/donor data, the adverse reactions can also be recorded in full in a separate file in accordance with the recommendations. This file must be sent to a central office together with the data entry form.

3.7 Uniform definition of adverse reactions

In the first step, we conducted a literature research* on definitions of occurring adverse reactions and for the definition of degrees of severity. In addition, we used our practical experience from the donor vigilance tool of our blood transfusion service.

The basis for the classification of the individual categories is the ISBT nomenclature (IHN, AABB), but for practical reasons, we have not adopted the subdivision into groups A-F listed there. We have also included in the development of our proposal publications that allow classification into different degrees of severity for the individual side effects*.

We have made a subdivision into puncture-related adverse reactions (VR) and "systemic" side effects (SR). This classification is simple for the medical staff and still allows the recording of all occurring side effects during apheresis and whole blood donation.

The recording of side effects should take place promptly, but should also enable further processing of the event at a later point in time. In our donor vigilance system, we also allow the recording of several side effects for one donation. This measure also allows for a good assessment of severity, as subsequently recorded more severe side effects automatically set the grade higher.

In the case of puncture-related side effects, we also record events that are not yet classified as side effects. However, relevant side effects can also result from these errors during the puncture, hours later. We have not included these events in our current tool, but information about them is helpful for better monitoring of donors and plasma donation.

The side effects were classified into the following categories:

Side effects, as a consequence of venipuncture (VR)

Haematoma	VR 01
Delayed bleeding	VR 02
Infiltration	VR 03
Nerve injury	VR 04
Other - Painful arm	VR 05
Nerve injury after haematoma	VR 06
Arterial puncture	VR 07
Tendon injury	VR 08
Local allergic reaction	VR 09
Cellulitis	VR 10
Thrombophlebitis	VR 11
Brachial artery pseudoaneurysm	VR 12
Arterionevous fistula	VR 13
Compartment syndrome	VR 14
Deep venous thrombosis	VR 15

"Systemic" side effects as a consequence of plasma donation (SR)

Mild vasovagale reaction without LOC/ without medical intervention	SR 01
Mild vasovagale reaction without LOC + medication	SR 02
Mild vasovagale reaction with LOC < 60 sec./ medication	SR 03
Vasovagale reaction with LOC > 60 sec	SR 04
Hypertension	SR 05
Citrate reaction	SR 06
Sickness	SR 07
Arrhytmia	SR 08
Convulsive seizure	SR 09
Injury in donors with a vasovagale reaction	SR 10
Injury/accidents related to plasma donation	SR 11
Angina pectoris	SR 12
Myocardial infarction	SR 13
Cerebrovascular accident/ Transient Ischemic Attack	SR 14
Mild generalized allergic reaction	SR 15
Anaphylactic reaction	SR 16
Haemolysis	SR 17
Air embolism	SR 18
Death	SR 19

3.8 Severity Grading

Based on our experience and the results of our literature research, we have decided on the following table. A detailed description and definition of side effects and their classification according to severity was not part of our task. However, for the development of a tool to analyse data from several organisations, we at least had to make a determination.

Grade of severity 1	No Outside Medical Care (OMC) - short duration (≤ 2 weeks) - Resolved with no or minimal intervention
Grade of severity 2	Outside medical care (OMC) no hospitalisation or Duration > 2 weeks ≤ 6 month or Limitation on ADL für ≤ 2 weeks
Grade of severity 3	Not life threatening AND any of the following: - Hospitalisation - or duration > 6 monzh - or limitations on ADL > 2 weeks - or require surgery - or other serious complication (SR 12-14)
Grade of severity 4	Immediate intervention requiered to prevent death

As severity 5 (death) is extremely rare, we have included it in the individual adverse reactions.

*

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2) Goldman M, Land K, Robillard P, et al Development of standard definitions for surveillance of complications related to blood donation. Vox Sang 2016;110;185-8

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6) Ulrich Diekamp, Johannes Gneißl, Angela Rabe, Stephan T Kießig " Donor Hemovigilance with Blood Donation"

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10) Ritter S, Hamouda O, Offergeld R. Demography and donation frequencies of blood and plasma donor populations in Germany. Update 2010 and 5-year comparison. Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz. 2012;55:914-922.

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13) B.H. Newman "Donor reactions and injuries from whole blood donation" Transfus Med Rev (1997)

14) E M Wood, A L Ang, A Bisht, P H Bolton-Maggs, A G Bokhorst, O Flesland, K Land, J C Wiersum-Osselton, M R Schipperus, P Tiberghien, B I Whitaker "International haemovigilance: what have we learned and what do we need to do next?" Transfus Med. 2019 Aug;29(4):221-230

15) Kevin J. Land, Mary Townsend, Mindy Goldman, Barbee I. Whitaker, Gabriela E. Perez, Jo C. Wiersum-Osselton "International validation of harmonized definitions for complications of blood donations" Transfusion 2018; 58;2589-2595

4 Automatic calculation of relative donor risks in the Excel tool

4.1 Data transfer without calculation from the table

The Excel table "Results" automatically takes over all the information entered on the page "Record data standard". In the upper part, the following data blocks are taken over 1:1 :

- General Information
- General Devices and Donation Information
- Information on plasma donation procedures
- General Donor information plasma donation
- Information on donor protection measures

4.2 General information on IgG, total protein

The IgG mean values of the donor groups as a function of donation frequency and target volume during plasma donation are adopted in the original. This is also done when evaluating the dependence of IgG values on donation frequency and donor gender. At the same time, diagrams are automatically created that allow a good graphical overview of the dependencies of the IgG levels. Die absolute Anzahl von Messergebnissen in Abhängigkeit von der Spendefrequenz,bei denen IgG, TP oder der Hämoglobinwert über- oder unterschritten wurde, wird automatisch für jede Gruppe, in ein relatives Risiko (%) umgerechnet. The corresponding diagram is created automatically.

4.3 Relative frequency of occurrence of adverse events

For the assessment of the risk of occurring side effects, we have stored a few standard evaluations with formulas in our tool for the beginning. We have selected the following categories:

a) The risk for first-time donors, subdivided according to gender and age groups.

b) The risk for multiple donors in relation to the number of plasma donations, grouped by age group and gender.

c) The risk for multiple donors in relation to the number of donors, grouped by age groups and gender.

d) The risk for multiple donors who donate plasma on a specific type of device.

Of course, other automatic evaluations can also be generated, depending on the question. It only has to be noted that information on total donations must be available in the data entry spreadsheet.

5 Summary

The self-sufficiency of EU countries with source plasma is an important point to minimise dependencies on other countries for the production of medicines. The implementation of machine plasma donations, must guarantee a high safety standard for all plasma donors. All organisations also register adverse reactions that occur at the present time. However, for a comprehensive analysis of these risks that occur during or after a donation, it makes sense to bring together the data of all organisations involved in a central database. Since the legal regulations on data protection in the countries of the organisations participating in this project do not allow an exchange of all data, we have created a preliminary tool, which should facilitate the first step on the way to a central register.

For the collection and evaluation of data from different organisations, it is necessary to collect the required data in a defined, uniform way. This uniform procedure applies to data collected during each individual plasma donation as well as to data that provide basic insights into a donor's donation history.

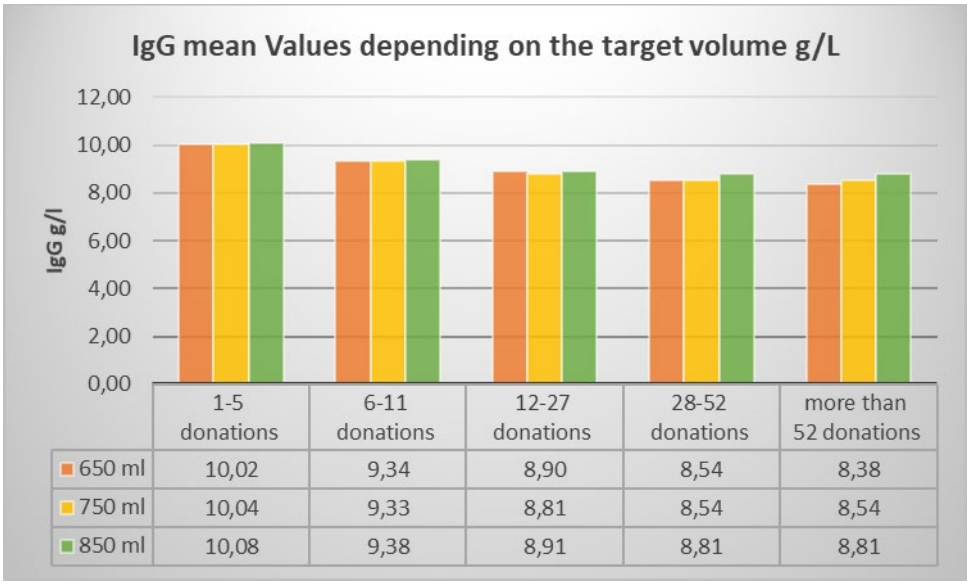
We have grouped the donors or donations according to age, gender or the number of donations made in the same way as in the WP 5.1 survey. Of course, it is relatively easy to carry out other groupings. However, it is important that all participating organisations work with the same classification.

MS-Excel was deliberately chosen as the basis for this first step. It is available everywhere and it is relatively easy to import and export data. Intended changes or additional questions can be easily incorporated. Excel spreadsheets can be made available relatively easily, either as a website or as an application. On this basis, it is possible to collect, sort and subsequently evaluate all incoming data. The evaluation required for the summary evaluation can only be created when the equipment and consumables used are available from all participants. However, adapting this small part of the tool is not a big problem.

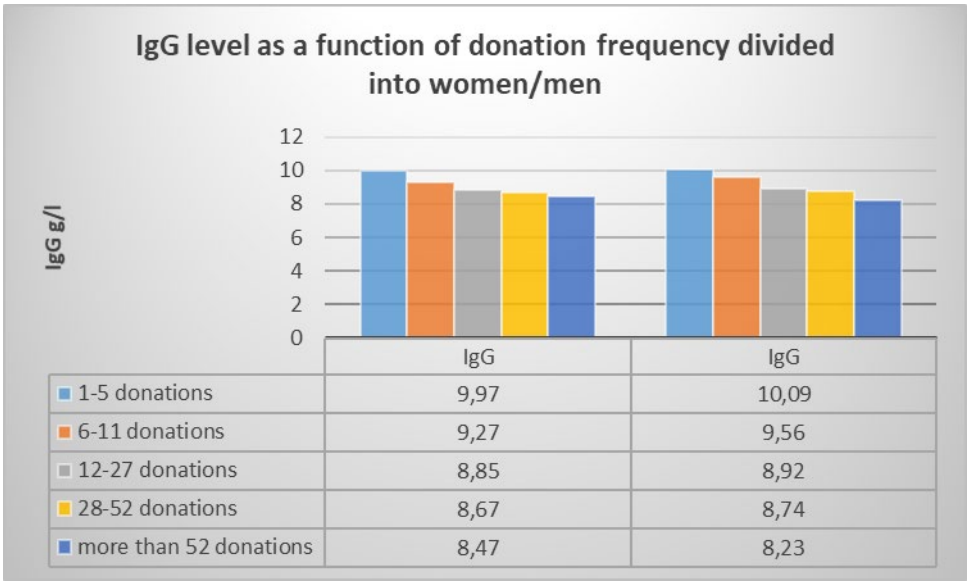
6 Results of a calculation of real data of the DRK Blutspendedienst Nord-Ost from the year 2022 (Data from 110801 plasma donations). (Attachment)

On the Excel spreadsheet "Results", each cell has been programmed with a calculating formula. In order to check the correct programming and at the same time to gain an idea of the significance of the analyses, the input page of the Excel tool was filled with real data from the Nord-Ost Blood Donation Service from the year 2022.

6.1 IgG, TP and haemoglobin

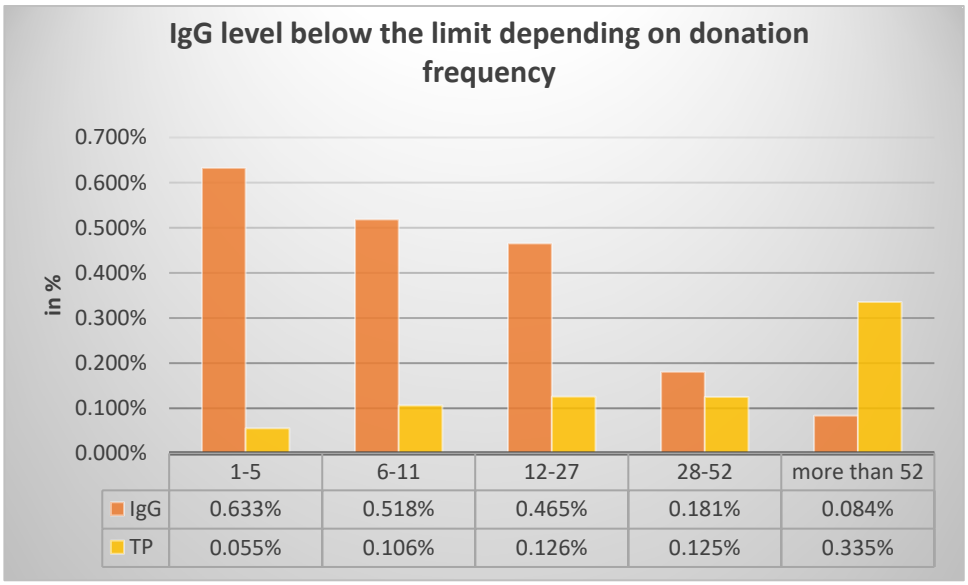


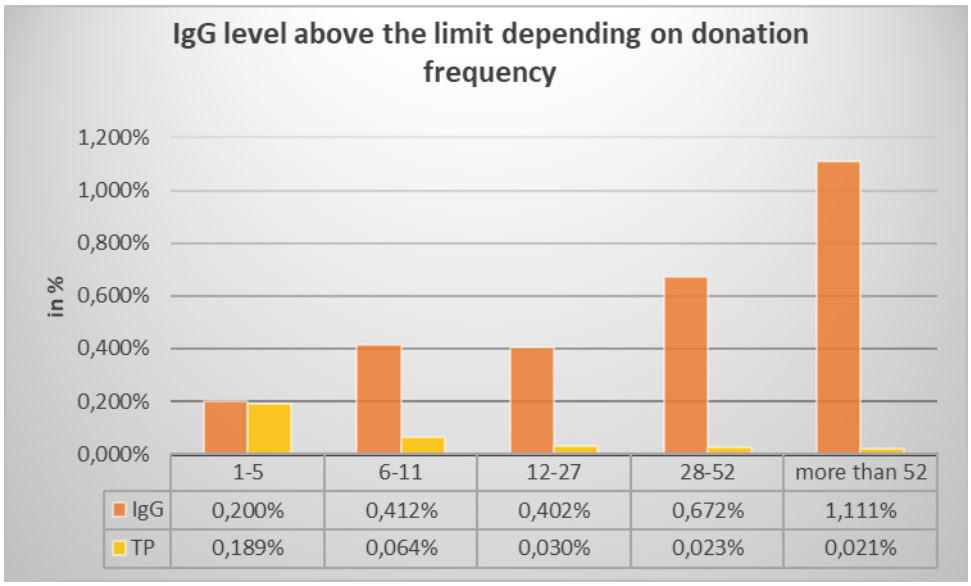
	1-5 donations	6-11 donations	12-27 donations	28-52 donations	more than 52 donations
650 ml	10,02	9,34	8,90	8,54	8,38
750 ml	10,04	9,33	8,81	8,54	8,54
850 ml	10,08	9,38	8,91	8,81	8,81



	IgG	IgG
1-5 donations	9,97	10,09
6-11 donations	9,27	9,56
12-27 donations	8,85	8,92
28-52 donations	8,67	8,74
more than 52 donations	8,47	8,23

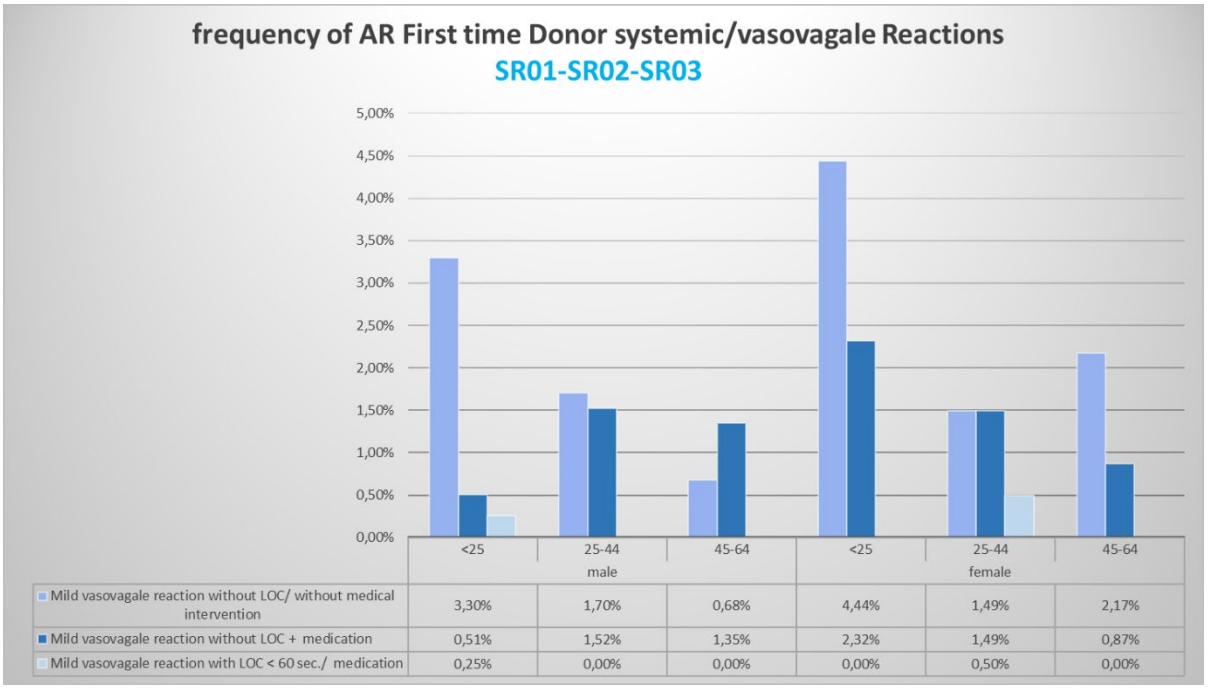
values out of specification (IgG,TP,Hb) in % of donations						
donation frequenzy	Number of measurements below the limit			Number of measurements above the limit		
Number of donations in the period	IgG	TP	Hb	IgG	TP	Hb
1-5	0,633%	0,055%	6,326%	0,200%	0,189%	0,067%
6-11	0,518%	0,106%	3,600%	0,412%	0,064%	0,035%
12-27	0,465%	0,126%	2,723%	0,402%	0,030%	0,043%
28-52	0,181%	0,125%	1,809%	0,672%	0,023%	0,030%
more than 52	0,084%	0,335%	1,488%	1,111%	0,021%	0,000%

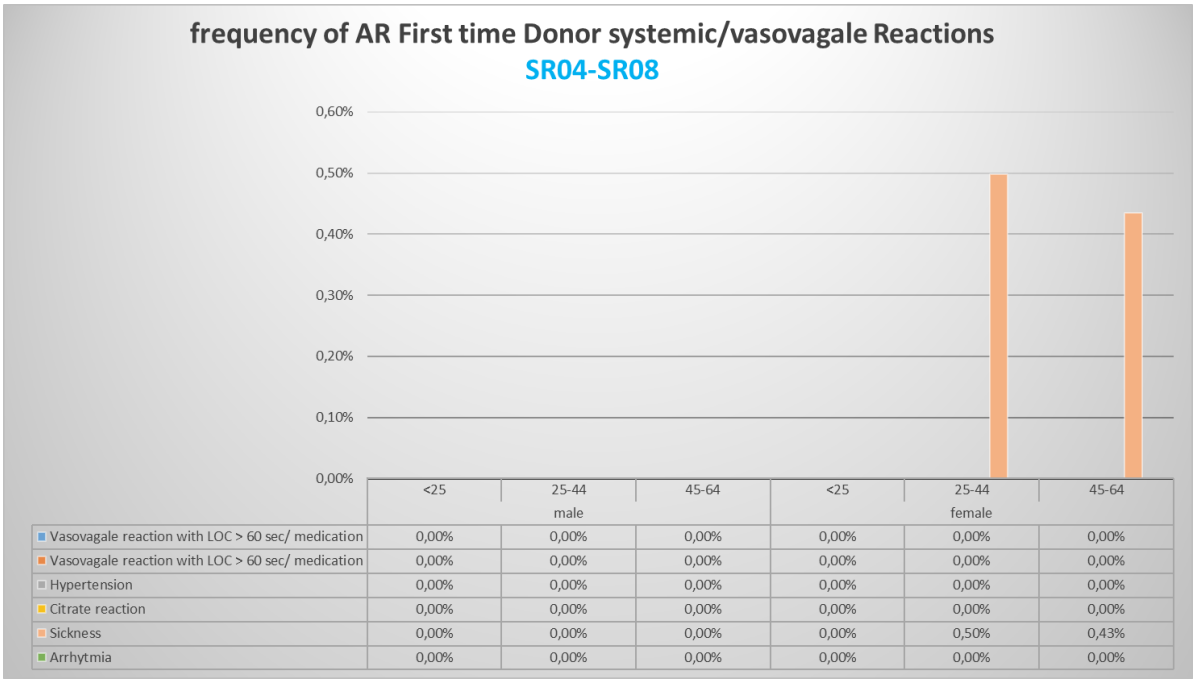

IgG level below the limit depending on donation frequency
0.700%
0.600%
0.500%
0.400%
0.300%
0.200%
0.100%
0.000%
in %
1-5
6-11
12-27
28-52
more than 52
IgG
0.633%
0.518%
0.465%
0.181%
0.084%
TP
0.055%
0.106%
0.126%
0.125%
0.335%


IgG level above the limit depending on donation frequency
1,200%
1,000%
0,800%
0,600%
0,400%
0,200%
0,000%
in %
1-5
6-11
12-27
28-52
more than 52
IgG
0,200%
0,412%
0,402%
0,672%
1,111%
TP
0,189%
0,064%
0,030%
0,023%
0,021%

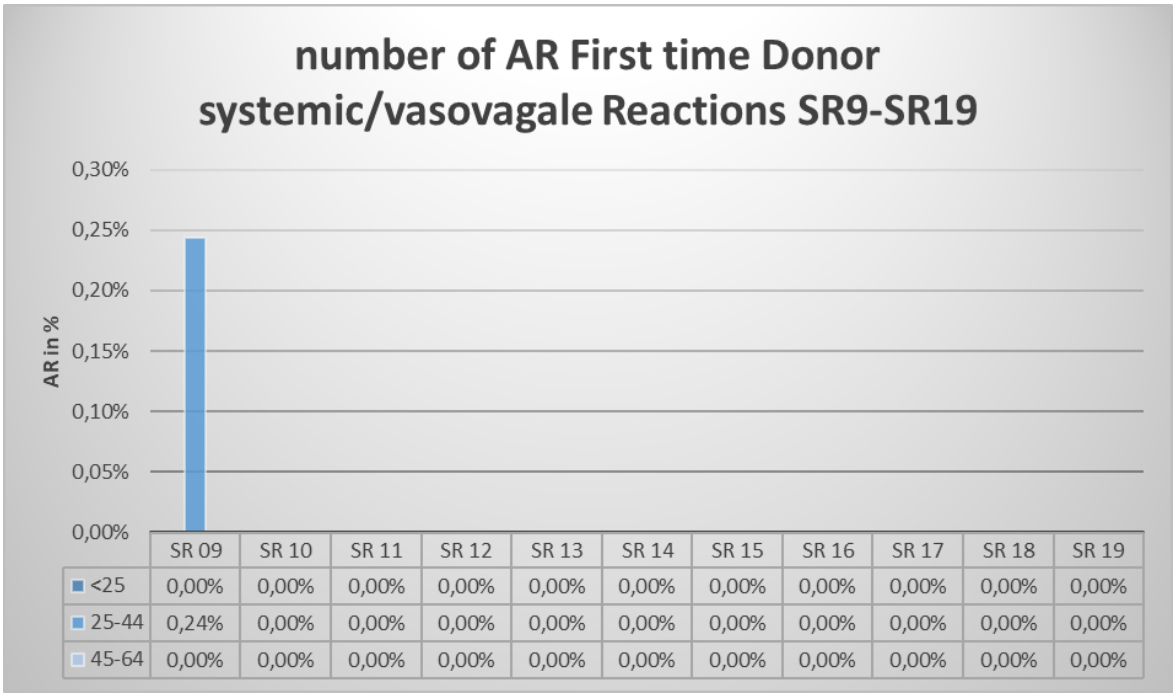
6.2 Risk for the occurrence of side effects in first-time plasma donors

frequency of AR First time Donor systemic/vasovagale Reactions								Number of severity grades			
adverse reaction		gender	<25	25-44	45-64	>64	total	1	2	3	4
Mild vasovagale reaction without LOC/ without medical intervention	SR 01	male	3,30%	1,70%	0,68%		2,20%	21	0	0	0
		femal	4,44%	1,49%	2,17%		2,96%	34	0	0	0
Mild vasovagale reaction without LOC + medication	SR 02	male	0,51%	1,52%	1,35%		1,05%	10	0	0	0
		femal	2,32%	1,49%	0,87%		1,74%	20	0	0	0
Mild vasovagale reaction with LOC < 60 sec./ medication	SR 03	male	0,25%	0,00%	0,00%		0,10%	0	1	0	0
		femal	0,00%	0,50%	0,00%		0,17%	0	2	0	0
Vasovagale reaction with LOC > 60 sec/ medication	SR 04	male	0,00%	0,00%	0,00%		0,00%	0	0	0	0
		femal	0,00%	0,00%	0,00%		0,00%	0	0	0	0
Hypertension	SR 05	male	0,00%	0,00%	0,00%		0,00%	0	0	0	0
		femal	0,00%	0,00%	0,00%		0,00%	0	0	0	0
Citrate reaction	SR 06	male	0,00%	0,00%	0,00%		0,00%	0	0	0	0
		femal	0,00%	0,00%	0,00%		0,00%	0	0	0	0
Sickness	SR 07	male	0,00%	0,00%	0,00%		0,00%	0	0	0	0
		femal	0,00%	0,50%	0,43%		0,26%	0	0	0	0
Arrhytmia	SR 08	male	0,00%	0,00%	0,00%		0,00%	0	0	0	0
		femal	0,00%	0,00%	0,00%		0,00%	0	0	0	0

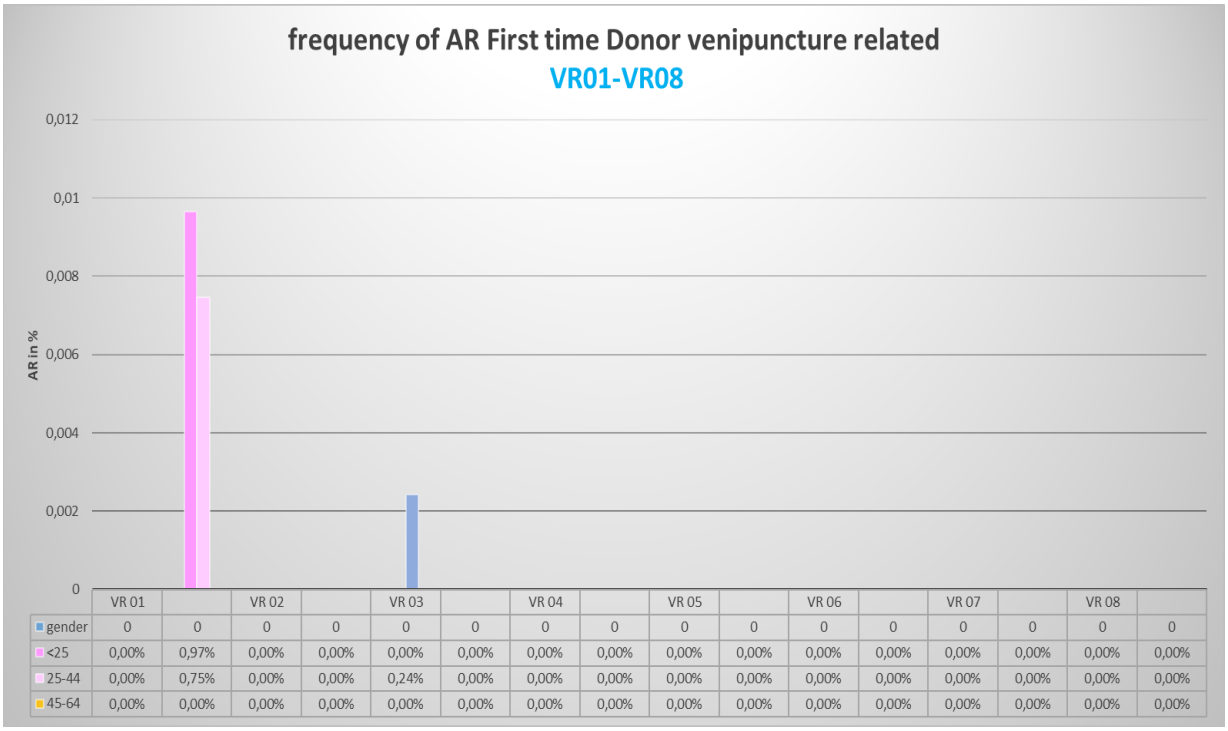




number od AR First time Donor systemic/vasovagale Reactions								Number of severity grades			
adverse reaction		gender	<25	25-44	45-64	>64	total	1	2	3	4
Convulsive seizure	SR 09	male	0,00%	0,24%	0,00%		0,10%	0	1	0	0
		femal	0,00%	0,00%	0,00%		0,00%	0	0	0	0
Injury in donors with a vasovagale reaction	SR 10	male	0,00%	0,00%	0,00%		0,00%	0	0	0	0
		femal	0,00%	0,00%	0,00%		0,00%	0	0	0	0
Injury/accidents related to plasma donation	SR 11	male	0,00%	0,00%	0,00%		0,00%	0	0	0	0
		femal	0,00%	0,00%	0,00%		0,00%	0	0	0	0
Angina pectoris	SR 12	male	0,00%	0,00%	0,00%		0,00%	0	0	0	0
		femal	0,00%	0,00%	0,00%		0,00%	0	0	0	0
Myocardial infarction	SR 13	male	0,00%	0,00%	0,00%		0,00%	0	0	0	0
		femal	0,00%	0,00%	0,00%		0,00%	0	0	0	0
Cerebrovascular accident/ Transient Ischemic Attack	SR 14	male	0,00%	0,00%	0,00%		0,00%	0	0	0	0
		femal	0,00%	0,00%	0,00%		0,00%	0	0	0	0
Mild generalized allergic reaction	SR 15	male	0,00%	0,00%	0,00%		0,00%	0	0	0	0
		femal	0,00%	0,00%	0,00%		0,00%	0	0	0	0
Anaphylactic reaction	SR 16	male	0,00%	0,00%	0,00%		0,00%	0	0	0	0
		femal	0,00%	0,00%	0,00%		0,00%	0	0	0	0
Haemolysis	SR 17	male	0,00%	0,00%	0,00%		0,00%	0	0	0	0
		femal	0,00%	0,00%	0,00%		0,00%	0	0	0	0
Air embolism	SR 18	male	0,00%	0,00%	0,00%		0,00%	0	0	0	0
		femal	0,00%	0,00%	0,00%		0,00%	0	0	0	0
Death	SR 19	male	0,00%	0,00%	0,00%		0,00%	0	0	0	0
		femal	0,00%	0,00%	0,00%		0,00%	0	0	0	0



frequency od AR First time Donor venipuncture related								Number of severity grades			
adverse reaction		gender	<25	25-44	45-64	>64	total	1	2	3	4
Haematoma	VR 01	male	0,00%	0,00%	0,00%		0,00%	0	0	0	0
		femal	0,97%	0,75%	0,00%		0,70%	8	0	0	0
Delayed bleeding	VR 02	male	0,00%	0,00%	0,00%		0,00%	0	0	0	0
		femal	0,00%	0,00%	0,00%		0,00%	0	0	0	0
Infiltration	VR 03	male	0,00%	0,24%	0,00%		0,10%	1	0	0	0
		femal	0,00%	0,00%	0,00%		0,00%	0	0	0	0
Nerve injury	VR 04	male	0,00%	0,00%	0,00%		0,00%	0	0	0	0
		femal	0,00%	0,00%	0,00%		0,00%	0	0	0	0
Other - Painful arm	VR 05	male	0,00%	0,00%	0,00%		0,00%	0	0	0	0
		femal	0,00%	0,00%	0,00%		0,00%	0	0	0	0
Nerve injury after haematoma	VR 06	male	0,00%	0,00%	0,00%		0,00%	0	0	0	0
		femal	0,00%	0,00%	0,00%		0,00%	0	0	0	0
Arterial puncture	VR 07	male	0,00%	0,00%	0,00%		0,00%	0	0	0	0
		femal	0,00%	0,00%	0,00%		0,00%	0	0	0	0
Tendon injury	VR 08	male	0,00%	0,00%	0,00%		0,00%	0	0	0	0
		femal	0,00%	0,00%	0,00%		0,00%	0	0	0	0

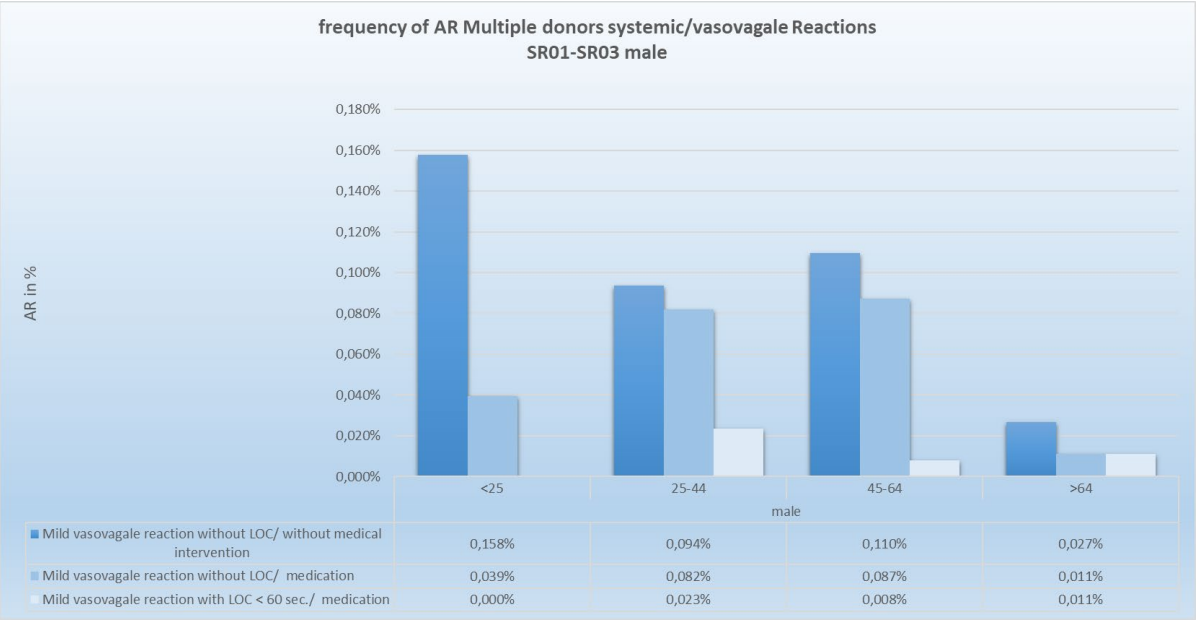


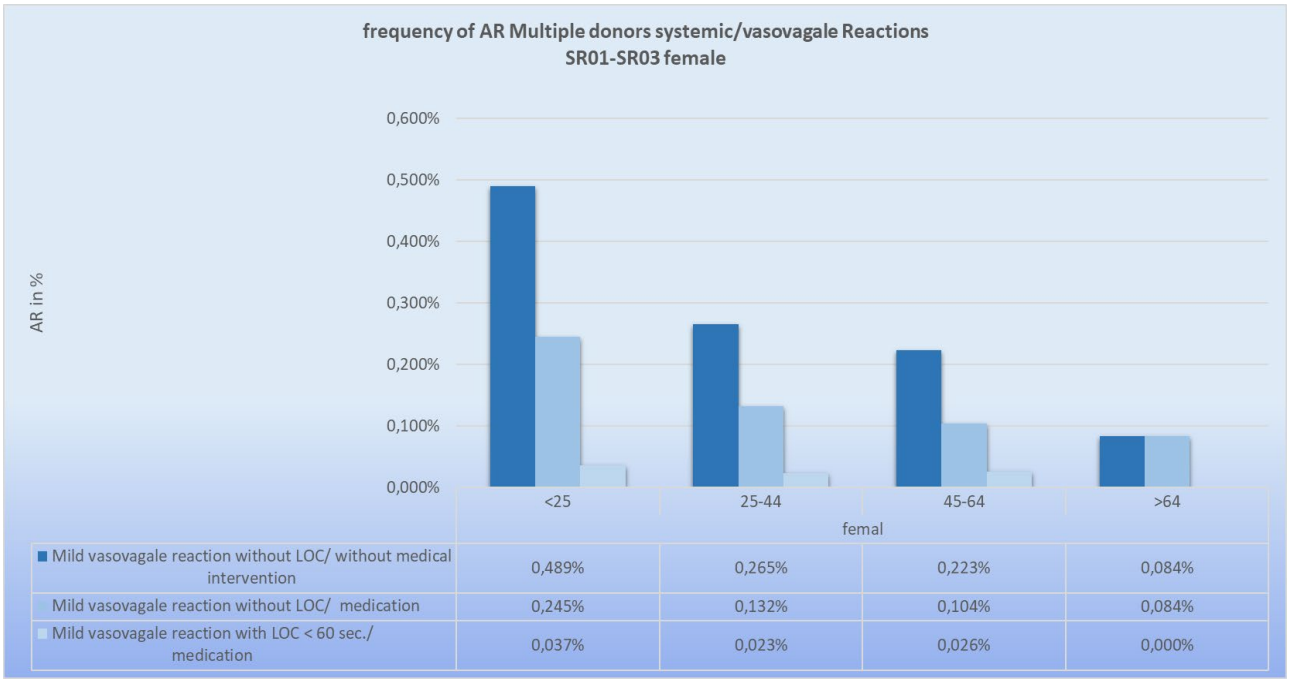
	VR 01		VR 02		VR 03		VR 04		VR 05		VR 06		VR 07		VR 08	
gender	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
<25	0,00%	0,97%	0,00%	0,00%	0,00%	0,00%	0,00%	0,00%	0,00%	0,00%	0,00%	0,00%	0,00%	0,00%	0,00%	0,00%
25-44	0,00%	0,75%	0,00%	0,00%	0,24%	0,00%	0,00%	0,00%	0,00%	0,00%	0,00%	0,00%	0,00%	0,00%	0,00%	0,00%
45-64	0,00%	0,00%	0,00%	0,00%	0,00%	0,00%	0,00%	0,00%	0,00%	0,00%	0,00%	0,00%	0,00%	0,00%	0,00%	0,00%

number od AR First time Donor venipuncture related								Number of severity grades			
adverse reaction		gender	<25	25-44	45-64	>64	total	1	2	3	4
Local allergic reaction	VR 09	male	0,00%	0,00%	0,00%		0,00%	0	0	0	0
		femal	0,00%	0,00%	0,00%		0,00%	0	0	0	0
Cellulitis	VR 10	male	0,00%	0,00%	0,00%		0,00%	0	0	0	0
		femal	0,00%	0,00%	0,00%		0,00%	0	0	0	0
Thrombophlebitis	VR 11	male	0,00%	0,00%	0,00%		0,00%	0	0	0	0
		femal	0,00%	0,00%	0,00%		0,00%	0	0	0	0
Brachial artery pseudoaneurysm	VR 12	male	0,00%	0,00%	0,00%		0,00%	0	0	0	0
		femal	0,00%	0,00%	0,00%		0,00%	0	0	0	0
Arterionevous fistula	VR 13	male	0,00%	0,00%	0,00%		0,00%	0	0	0	0
		femal	0,00%	0,00%	0,00%		0,00%	0	0	0	0
Compartment syndrome	VR 14	male	0,00%	0,00%	0,00%		0,00%	0	0	0	0
		femal	0,00%	0,00%	0,00%		0,00%	0	0	0	0
Deep venous thrombosis	VR 15	male	0,00%	0,00%	0,00%		0,00%	0	0	0	0
		femal	0,00%	0,00%	0,00%		0,00%	0	0	0	0

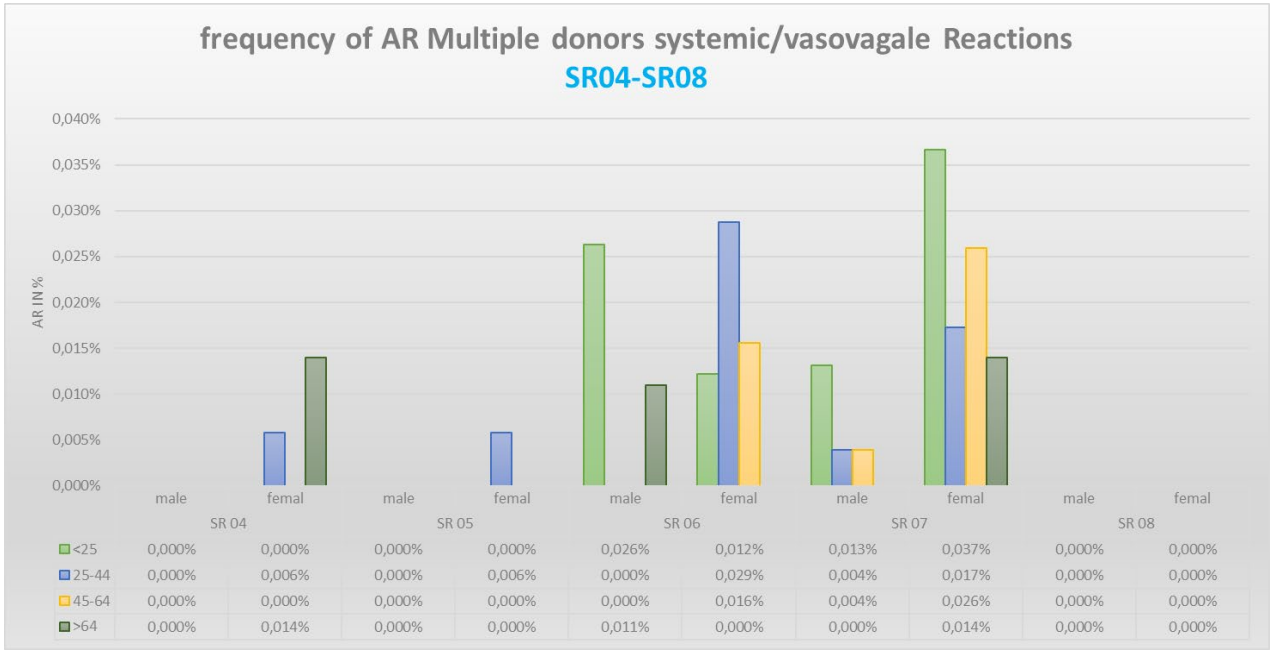
6.3 Relative frequency of occurrence of side effects in multiple donors in relation to plasma donation

frequency of AR Multiple donors systemic/vasovagale Reactions in relations to the **donations**								Number of severity grades			
adverse reaction		gender	<25	25-44	45-64	>64	total	1	2	3	4
Mild vasovagale reaction without LOC/ without medical intervention	SR 01	male	0,158%	0,094%	0,110%	0,027%	0,070%	47	0	0	0
		femal	0,489%	0,265%	0,223%	0,084%	0,260%	135	0	0	0
Mild vasovagale reaction without LOC/ medication	SR 02	male	0,039%	0,082%	0,087%	0,011%	0,070%	47	0	0	0
		femal	0,245%	0,132%	0,104%	0,084%	0,133%	69	0	0	0
Mild vasovagale reaction with LOC < 60 sec./ medication	SR 03	male	0,000%	0,023%	0,008%	0,011%	0,013%	9	0	0	0
		femal	0,037%	0,023%	0,026%	0,000%	0,023%	11	1	0	0
Vasovagale reaction with LOC > 60 sec	SR 04	male	0,000%	0,000%	0,000%	0,000%	0,000%	0	0	0	0
		femal	0,000%	0,006%	0,000%	0,014%	0,002%	0	1	0	0
Hypertension	SR 05	male	0,000%	0,000%	0,000%	0,000%	0,000%	0	0	0	0
		femal	0,000%	0,006%	0,000%	0,000%	0,002%	0	1	0	0
Citrate reaction	SR 06	male	0,026%	0,000%	0,000%	0,011%	0,004%	3	0	0	0
		femal	0,012%	0,029%	0,016%	0,000%	0,012%	6	0	0	0
Sickness	SR 07	male	0,013%	0,004%	0,004%	0,000%	0,004%	3	0	0	0
		femal	0,037%	0,017%	0,026%	0,014%	0,023%	12	0	0	0
Arrhytmia	SR 08	male	0,000%	0,000%	0,000%	0,000%	0,000%	0	0	0	0
		femal	0,000%	0,000%	0,000%	0,000%	0,000%	0	0	0	0



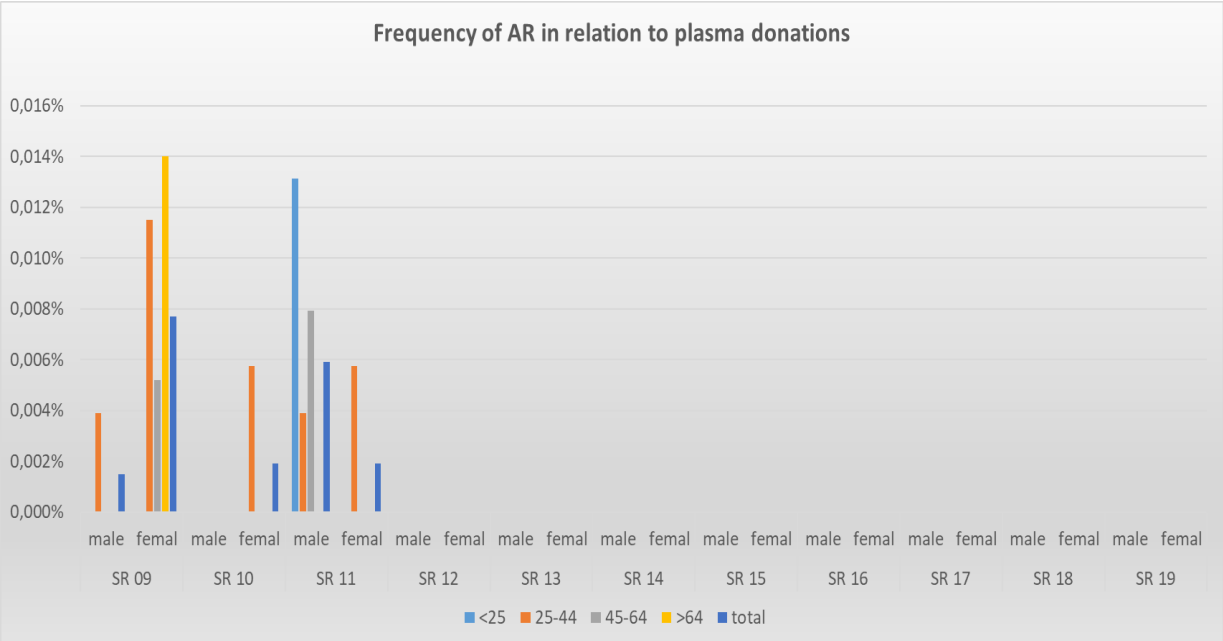


	<25	25-44	45-64	>64
Mild vasovagale reaction without LOC/ without medical intervention	0,489%	0,265%	0,223%	0,084%
Mild vasovagale reaction without LOC/ medication	0,245%	0,132%	0,104%	0,084%
Mild vasovagale reaction with LOC < 60 sec./ medication	0,037%	0,023%	0,026%	0,000%

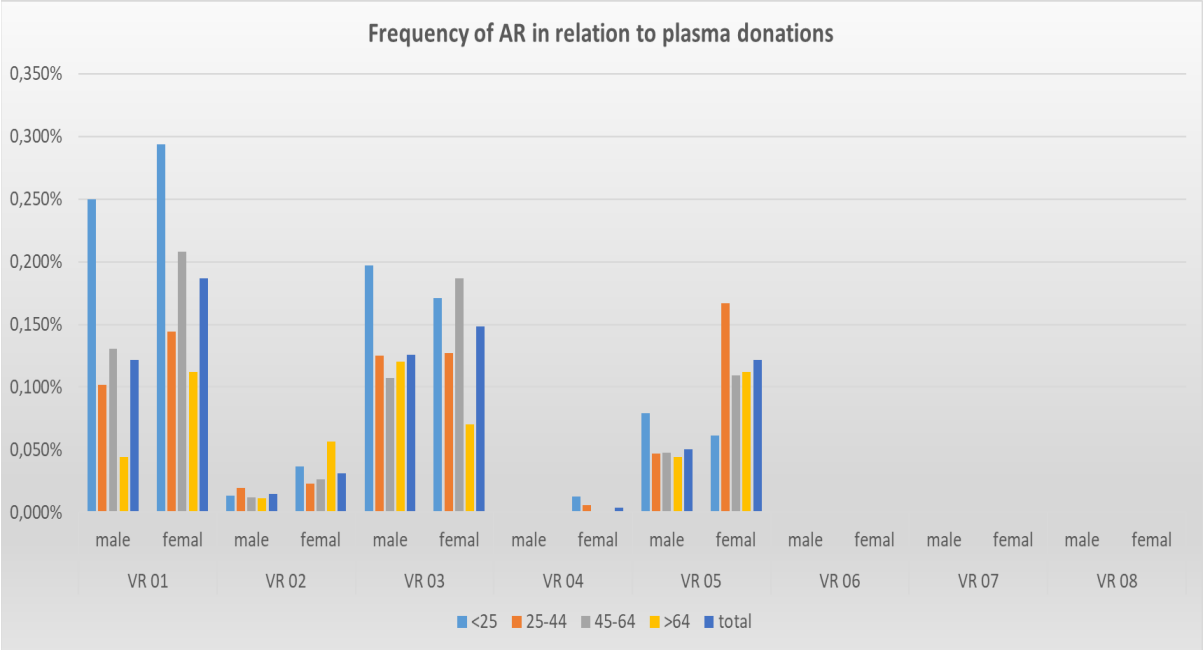


	SR 04		SR 05		SR 06		SR 07		SR 08	
	male	femal	male	femal	male	femal	male	femal	male	femal
<25	0,000%	0,000%	0,000%	0,000%	0,026%	0,012%	0,013%	0,037%	0,000%	0,000%
25-44	0,000%	0,006%	0,000%	0,006%	0,000%	0,029%	0,004%	0,017%	0,000%	0,000%
45-64	0,000%	0,000%	0,000%	0,000%	0,000%	0,016%	0,004%	0,026%	0,000%	0,000%
>64	0,000%	0,014%	0,000%	0,000%	0,011%	0,000%	0,000%	0,014%	0,000%	0,000%

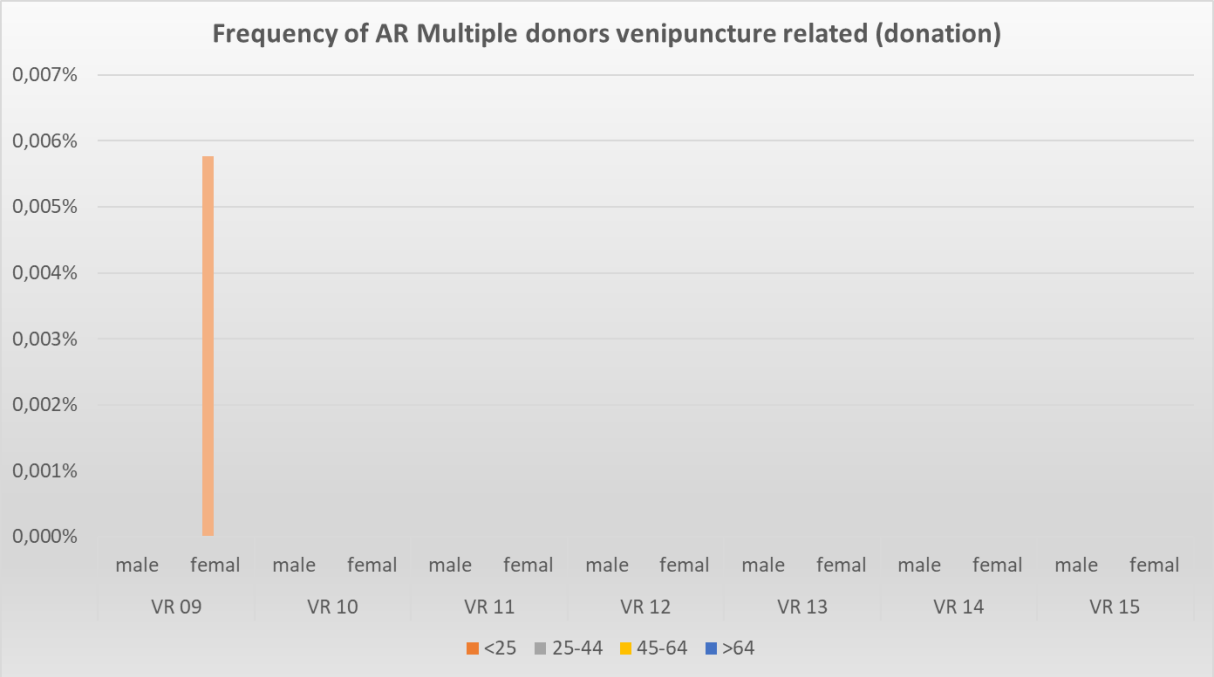
frequency of AR Multiple donors systemic/vasovagale Reactions in relation to the donations								Number of severity grades			
adverse reaction		gender	<25	25-44	45-64	>64	total	1	2	3	4
Convulsive seizure	SR 09	male	0,000%	0,004%	0,000%	0,000%	0,001%	1	0	0	0
		femal	0,000%	0,012%	0,005%	0,014%	0,008%	4	0	0	0
Injury in donors with a vasovagale reaction	SR 10	male	0,000%	0,000%	0,000%	0,000%	0,000%	0	0	0	0
		femal	0,000%	0,006%	0,000%	0,000%	0,002%	0	1	0	0
Injury/accidents related to plasma donation	SR 11	male	0,013%	0,004%	0,008%	0,000%	0,006%	1	3	0	0
		femal	0,000%	0,006%	0,000%	0,000%	0,002%	0	1	0	0
Angina pectoris	SR 12	male	0,000%	0,000%	0,000%	0,000%	0,000%	0	0	0	0
		femal	0,000%	0,000%	0,000%	0,000%	0,000%	0	0	0	0
Myocardial infarction	SR 13	male	0,000%	0,000%	0,000%	0,000%	0,000%	0	0	0	0
		femal	0,000%	0,000%	0,000%	0,000%	0,000%	0	0	0	0
Cerebrovascular accident/ Transient Ischemic Attack	SR 14	male	0,000%	0,000%	0,000%	0,000%	0,000%	0	0	0	0
		femal	0,000%	0,000%	0,000%	0,000%	0,000%	0	0	0	0
Mild generalized allergic reaction	SR 15	male	0,000%	0,000%	0,000%	0,000%	0,000%	0	0	0	0
		femal	0,000%	0,000%	0,000%	0,000%	0,000%	0	0	0	0
Anaphylactic reaction	SR 16	male	0,000%	0,000%	0,000%	0,000%	0,000%	0	0	0	0
		femal	0,000%	0,000%	0,000%	0,000%	0,000%	0	0	0	0
Haemolysis	SR 17	male	0,000%	0,000%	0,000%	0,000%	0,000%	0	0	0	0
		femal	0,000%	0,000%	0,000%	0,000%	0,000%	0	0	0	0
Air embolism	SR 18	male	0,000%	0,000%	0,000%	0,000%	0,000%	0	0	0	0
		femal	0,000%	0,000%	0,000%	0,000%	0,000%	0	0	0	0
Death	SR 19	male	0,000%	0,000%	0,000%	0,000%	0,000%	0	0	0	0
		femal	0,000%	0,000%	0,000%	0,000%	0,000%	0	0	0	0



frequency of AR Multiple donors venipuncture related (donations)								Number of severity grades			
adverse reaction		gender	<25	25-44	45-64	>64	total	1	2	3	4
Haematoma	VR 01	male	0,250%	0,102%	0,131%	0,044%	0,121%	80	2	0	0
		femal	0,294%	0,144%	0,208%	0,112%	0,187%	96	1	0	0
Delayed bleeding	VR 02	male	0,013%	0,020%	0,012%	0,011%	0,015%	9	1	0	0
		femal	0,037%	0,023%	0,026%	0,056%	0,031%	15	1	0	0
Infiltration	VR 03	male	0,197%	0,125%	0,107%	0,120%	0,126%	85	0	0	0
		femal	0,171%	0,127%	0,187%	0,070%	0,148%	77	0	0	0
Nerve injury	VR 04	male	0,000%	0,000%	0,000%	0,000%	0,000%	0	0	0	0
		femal	0,012%	0,006%	0,000%	0,000%	0,004%	0	2	0	0
Other - Painful arm	VR 05	male	0,079%	0,047%	0,048%	0,044%	0,050%	33	1	0	0
		femal	0,061%	0,167%	0,109%	0,112%	0,121%	61	2	0	0
Nerve injury after haematoma	VR 06	male	0,000%	0,000%	0,000%	0,000%	0,000%	0	0	0	0
		femal	0,000%	0,000%	0,000%	0,000%	0,000%	0	0	0	0
Arterial puncture	VR 07	male	0,000%	0,000%	0,000%	0,000%	0,000%	0	0	0	0
		femal	0,000%	0,000%	0,000%	0,000%	0,000%	0	0	0	0
Tendon injury	VR 08	male	0,000%	0,000%	0,000%	0,000%	0,000%	0	0	0	0
		femal	0,000%	0,000%	0,000%	0,000%	0,000%	0	0	0	0

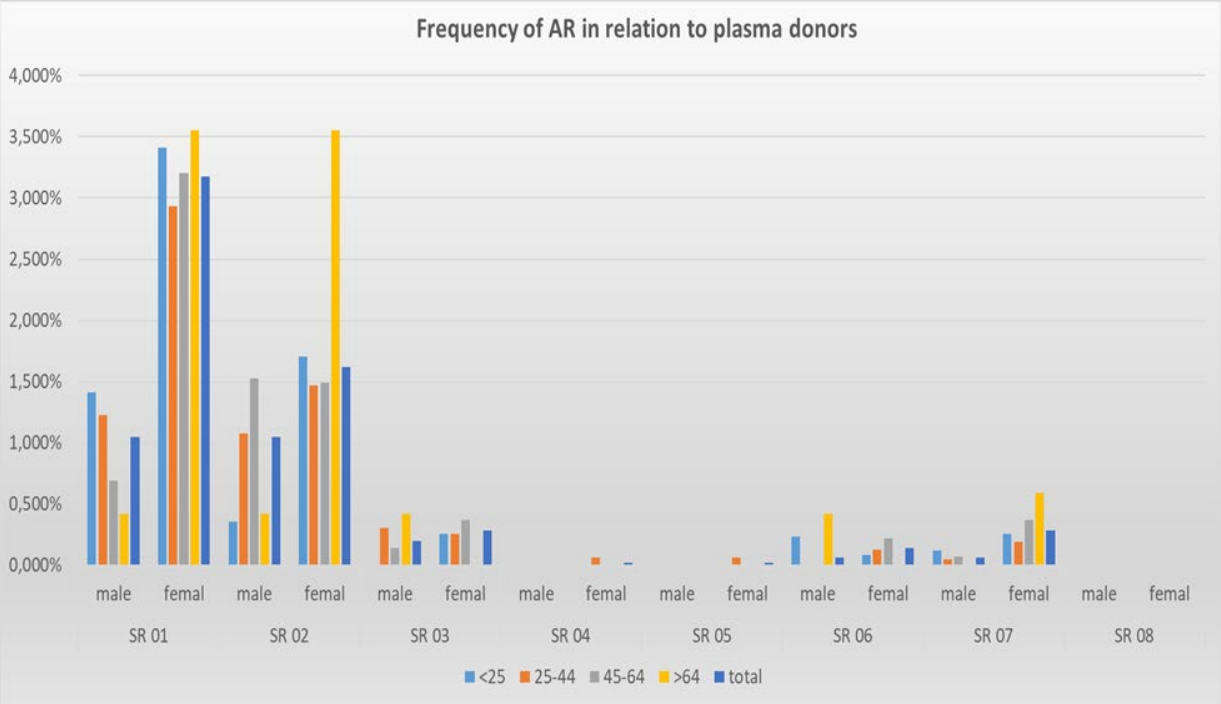


number od AR Multiple donors venipuncture related (donation)								Number of severity grades			
adverse reaction		gender	<25	25-44	45-64	>64	total	1	2	3	4
Local allergic reaction	VR 09	male	0,000%	0,000%	0,000%	0,000%	0,000%	0	0	0	0
		femal	0,000%	0,006%	0,000%	0,000%	0,002%	1	0	0	0
Cellulitis	VR 10	male	0,000%	0,000%	0,000%	0,000%	0,000%	0	0	0	0
		femal	0,000%	0,000%	0,000%	0,000%	0,000%	0	0	0	0
Thrombophlebitis	VR 11	male	0,000%	0,000%	0,000%	0,000%	0,000%	0	0	0	0
		femal	0,000%	0,000%	0,000%	0,000%	0,000%	0	0	0	0
Brachial artery pseudoaneurysm	VR 12	male	0,000%	0,000%	0,000%	0,000%	0,000%	0	0	0	0
		femal	0,000%	0,000%	0,000%	0,000%	0,000%	0	0	0	0
Arterionevous fistula	VR 13	male	0,000%	0,000%	0,000%	0,000%	0,000%	0	0	0	0
		femal	0,000%	0,000%	0,000%	0,000%	0,000%	0	0	0	0
Compartment syndrome	VR 14	male	0,000%	0,000%	0,000%	0,000%	0,000%	0	0	0	0
		femal	0,000%	0,000%	0,000%	0,000%	0,000%	0	0	0	0
Deep venous thrombosis	VR 15	male	0,000%	0,000%	0,000%	0,000%	0,000%	0	0	0	0
		femal	0,000%	0,000%	0,000%	0,000%	0,000%	0	0	0	0

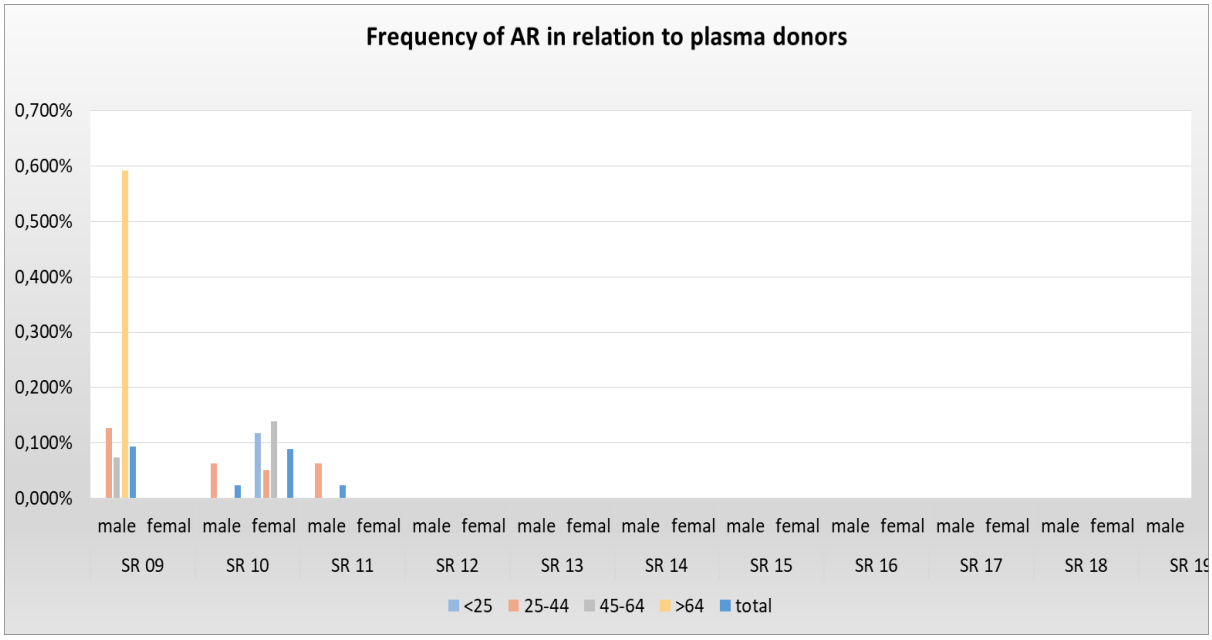


6.4 Relative frequency of occurrence of side effects in multiple donors in relation to the individual donor

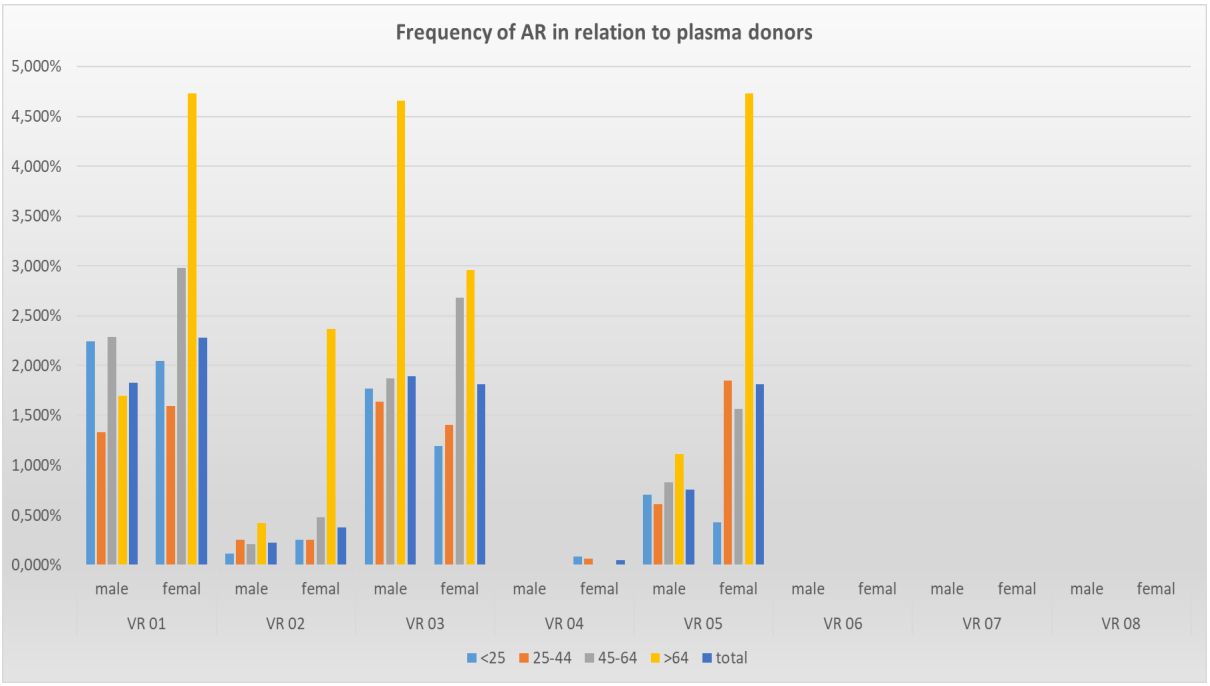
frequency of AR Multiple donors systemic/vasovagale Reactions in relations to the **donors**								Number of severity grades			
adverse reaction		gender	<25	25-44	45-64	>64	total	1	2	3	4
Mild vasovagale reaction without LOC/ without medical intervention	SR 01	male	1,415%	1,227%	0,693%	0,424%	1,048%				
		femal	3,410%	2,932%	3,202%	3,550%	3,173%				
Mild vasovagale reaction without LOC/ medication	SR 02	male	0,354%	1,074%	1,524%	0,424%	1,048%				
		femal	1,705%	1,466%	1,489%	3,550%	1,622%				
Mild vasovagale reaction with LOC < 60 sec./ medication	SR 03	male	0,000%	0,307%	0,139%	0,424%	0,201%				
		femal	0,256%	0,255%	0,372%	0,000%	0,282%				
Vasovagale reaction with LOC > 60 sec	SR 04	male	0,000%	0,000%	0,000%	0,000%	0,000%				
		femal	0,000%	0,064%	0,000%	0,000%	0,024%				
Hypertension	SR 05	male	0,000%	0,000%	0,000%	0,000%	0,000%				
		femal	0,000%	0,064%	0,000%	0,000%	0,024%				
Citrate reaction	SR 06	male	0,236%	0,000%	0,000%	0,424%	0,067%				
		femal	0,085%	0,127%	0,223%	0,000%	0,141%				
Sickness	SR 07	male	0,118%	0,051%	0,069%	0,000%	0,067%				
		femal	0,256%	0,191%	0,372%	0,592%	0,282%				
Arrhytmia	SR 08	male	0,000%	0,000%	0,000%	0,000%	0,000%				
		femal	0,000%	0,000%	0,000%	0,000%	0,000%				



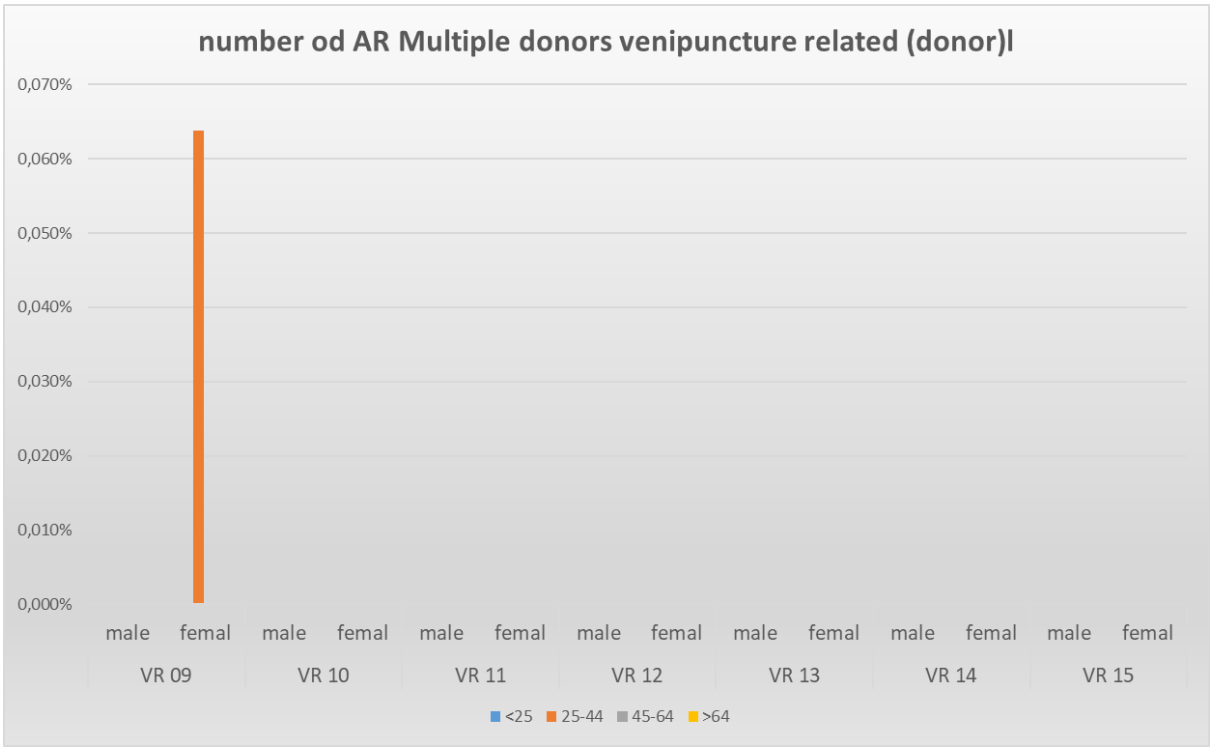
frequency of AR Multiple donors systemic/vasovagale Reactions in relation to the donors								Number of severity grades			
adverse reaction		gender	<25	25-44	45-64	>64	total	1	2	3	4
Convulsive seizure	SR 09	male	0,000%	0,051%	0,000%	0,000%	0,022%				
		femal	0,000%	0,127%	0,074%	0,592%	0,094%				
Injury in donors with a vasovagale reaction	SR 10	male	0,000%	0,000%	0,000%	0,000%	0,000%				
		femal	0,000%	0,064%	0,000%	0,000%	0,024%				
Injury/accidents related to plasma donation	SR 11	male	0,118%	0,051%	0,139%	0,000%	0,089%				
		femal	0,000%	0,064%	0,000%	0,000%	0,024%				
Angina pectoris	SR 12	male	0,000%	0,000%	0,000%	0,000%	0,000%				
		femal	0,000%	0,000%	0,000%	0,000%	0,000%				
Myocardial infarction	SR 13	male	0,000%	0,000%	0,000%	0,000%	0,000%				
		femal	0,000%	0,000%	0,000%	0,000%	0,000%				
Cerebrovascular accident/ Transient Ischemic Attack	SR 14	male	0,000%	0,000%	0,000%	0,000%	0,000%				
		femal	0,000%	0,000%	0,000%	0,000%	0,000%				
Mild generalized allergic reaction	SR 15	male	0,000%	0,000%	0,000%	0,000%	0,000%				
		femal	0,000%	0,000%	0,000%	0,000%	0,000%				
Anaphylactic reaction	SR 16	male	0,000%	0,000%	0,000%	0,000%	0,000%				
		femal	0,000%	0,000%	0,000%	0,000%	0,000%				
Haemolysis	SR 17	male	0,000%	0,000%	0,000%	0,000%	0,000%				
		femal	0,000%	0,000%	0,000%	0,000%	0,000%				
Air embolism	SR 18	male	0,000%	0,000%	0,000%	0,000%	0,000%				
		femal	0,000%	0,000%	0,000%	0,000%	0,000%				
Death	SR 19	male	0,000%	0,000%	0,000%	0,000%	0,000%				
		femal	0,000%	0,000%	0,000%	0,000%	0,000%				



number of AR Multiple donors venipuncture related (donors)								Number of severity grades			
adverse reaction		gender	<25	25-44	45-64	>64	total	1	2	3	4
Haematoma	VR 01	male	2,241%	1,329%	2,285%	1,695%	1,829%				
		femal	2,046%	1,593%	2,978%	4,734%	2,280%				
Delayed bleeding	VR 02	male	0,118%	0,256%	0,208%	0,424%	0,223%				
		femal	0,256%	0,255%	0,482%	2,367%	0,376%				
Infiltration	VR 03	male	1,769%	1,636%	1,870%	4,661%	1,896%				
		femal	1,194%	1,402%	2,681%	2,959%	1,810%				
Nerve injury	VR 04	male	0,000%	0,000%	0,000%	0,000%	0,000%				
		femal	0,085%	0,064%	0,000%	0,000%	0,047%				
Other - Painful arm	VR 05	male	0,708%	0,613%	0,831%	1,111%	0,758%				
		femal	0,426%	1,848%	1,564%	4,734%	1,810%				
Nerve injury after haematoma	VR 06	male	0,000%	0,000%	0,000%	0,000%	0,000%				
		femal	0,000%	0,000%	0,000%	0,000%	0,000%				
Arterial puncture	VR 07	male	0,000%	0,000%	0,000%	0,000%	0,000%				
		femal	0,000%	0,000%	0,000%	0,000%	0,000%				
Tendon injury	VR 08	male	0,000%	0,000%	0,000%	0,000%	0,000%				
		femal	0,000%	0,000%	0,000%	0,000%	0,000%				



number od AR Multiple donors venipuncture related (donor)								Number of severity grades			
adverse reaction		gender	<25	25-44	45-64	>64	total	1	2	3	4
Local allergic reaction	VR 09	male	0,000%	0,000%	0,000%	0,000%	0,000%				
		femal	0,000%	0,064%	0,000%	0,000%	0,024%				
Cellulitis	VR 10	male	0,000%	0,000%	0,000%	0,000%	0,000%				
		femal	0,000%	0,000%	0,000%	0,000%	0,000%				
Thrombophlebitis	VR 11	male	0,000%	0,000%	0,000%	0,000%	0,000%				
		femal	0,000%	0,000%	0,000%	0,000%	0,000%				
Brachial artery pseudoaneurysm	VR 12	male	0,000%	0,000%	0,000%	0,000%	0,000%				
		femal	0,000%	0,000%	0,000%	0,000%	0,000%				
Arterionevous fistula	VR 13	male	0,000%	0,000%	0,000%	0,000%	0,000%				
		femal	0,000%	0,000%	0,000%	0,000%	0,000%				
Compartment syndrome	VR 14	male	0,000%	0,000%	0,000%	0,000%	0,000%				
		femal	0,000%	0,000%	0,000%	0,000%	0,000%				
Deep venous thrombosis	VR 15	male	0,000%	0,000%	0,000%	0,000%	0,000%				
		femal	0,000%	0,000%	0,000%	0,000%	0,000%				



6.5 Donors with multiple recorded adverse events systemic (SR) or puncture-related (VR)

Plasma donors with multiple AEs in the reporting period				
	only SR	only VR	SR and VR	total
Number of donors with 2 adverse events	124	62	36	222
Number of donors with 3 adverse events	13	7	6	26
Number of donors with 4 adverse events	0	1	3	4
Number of donors with 5 adverse events	0	1	1	2
Number of donors with 6 adverse events	0	0	0	0
Number of donors with more than 6 adverse events	0	0	0	0

6.6 Relative frequency with different types of equipment in use

frequency of AR all donors systemic/vasovagale Reactions and Type of the used Equipment					
adverse reaction		gender	Fresenius A 200	Fresenius AURORA	PCS 2
Mild vasovagale reaction without LOC/ without medical intervention	SR 01	male	0,092%	0,116%	0,251%
		femal	0,145%	0,499%	0,705%
Mild vasovagale reaction without LOC + medication	SR 02	male	0,068%	0,077%	0,133%
		femal	0,072%	0,148%	0,356%
Mild vasovagale reaction with LOC < 60 sec./ medication	SR 03	male	0,005%	0,014%	0,030%
		femal	0,006%	0,043%	0,040%
Vasovagale reaction with LOC > 60 sec	SR 04	male	0,000%	0,000%	0,000%
		femal	0,000%	0,000%	0,007%
Hypertension	SR 05	male	0,000%	0,000%	0,000%
		femal	0,000%	0,000%	0,007%
Citrate reaction	SR 06	male	0,010%	0,000%	0,005%
		femal	0,024%	0,000%	0,013%
Sickness	SR 07	male	0,005%	0,005%	0,005%
		femal	0,006%	0,086%	0,013%
Arrhytmia	SR 08	male	0,000%	0,000%	0,000%
		femal	0,000%	0,000%	0,000%

number of AR all donors systemic/vasovagale Reactions and Type of the used Equipment					
adverse reaction		gender	Fresenius A 200	Fresenius AURORA	Haemonetics PCS 2
Convulsive seizure	SR 09	male	0,000%	0,005%	0,005%
		femal	0,000%	0,025%	0,000%
Injury in donors with a vasovagale reaction	SR 10	male	0,000%	0,000%	0,000%
		femal	0,006%	0,000%	0,000%
Injury/accidents related to plasma donation	SR 11	male	0,000%	0,000%	0,000%
		femal	0,000%	0,000%	0,000%
Angina pectoris	SR 12	male	0,000%	0,000%	0,000%
		femal	0,000%	0,000%	0,000%
Myocardial infarction	SR 13	male	0,000%	0,000%	0,000%
		femal	0,000%	0,000%	0,000%
Cerebrovascular accident/ Transient Ischemic Attack	SR 14	male	0,000%	0,000%	0,000%
		femal	0,000%	0,000%	0,000%
Mild generalized allergic reaction	SR 15	male	0,000%	0,000%	0,000%
		femal	0,000%	0,000%	0,000%
Anaphylactic reaction	SR 16	male	0,000%	0,000%	0,000%
		femal	0,000%	0,000%	0,000%
Haemolysis	SR 17	male	0,000%	0,010%	0,000%
		femal	0,000%	0,031%	0,000%
Air embolism	SR 18	male	0,000%	0,000%	0,000%
		femal	0,000%	0,000%	0,000%
Death	SR 19	male	0,000%	0,000%	0,000%
		femal	0,000%	0,000%	0,000%

frequency of AR all donors venipuncture related Reactions and Type of the used Equipment					
adverse reaction		gender	Fresenius A 200	Fresenius AURORA	Haemonetics PCS 2
Haematoma	VR 01	male	0,266%	0,077%	0,054%
		femal	0,458%	0,105%	0,081%
Delayed bleeding	VR 02	male	0,010%	0,034%	0,005%
		femal	0,018%	0,080%	0,000%
Infiltration	VR 03	male	0,131%	0,255%	0,030%
		femal	0,109%	0,357%	0,007%
Nerve injury	VR 04	male	0,000%	0,000%	0,000%
		femal	0,000%	0,012%	0,000%
Other - Painful arm	VR 05	male	0,044%	0,101%	0,020%
		femal	0,048%	0,296%	0,020%
Nerve injury after haematoma	VR 06	male	0,000%	0,000%	0,000%
		femal	0,000%	0,000%	0,000%
Arterial puncture	VR 07	male	0,000%	0,000%	0,000%
		femal	0,000%	0,000%	0,000%
Tendon injury	VR 08	male	0,000%	0,000%	0,000%
		femal	0,000%	0,000%	0,000%

frequency of AR all donors venipuncture related Reactions and Type of the used Equipment					
adverse reaction		gender	Fresenius A 200	Fresenius AURORA	Haemonetics PCS 2
Local allergic reaction	VR 09	male	0,000%	0,000%	0,000%
		femal	0,000%	0,000%	0,007%
Cellulitis	VR 10	male	0,000%	0,000%	0,000%
		femal	0,000%	0,000%	0,000%
Thrombophlebitis	VR 11	male	0,000%	0,000%	0,000%
		femal	0,000%	0,000%	0,000%
Brachial artery pseudoaneurysm	VR 12	male	0,000%	0,000%	0,000%
		femal	0,000%	0,000%	0,000%
Arterionevous fistula	VR 13	male	0,000%	0,000%	0,000%
		femal	0,000%	0,000%	0,000%
Compartment syndrome	VR 14	male	0,000%	0,000%	0,000%
		femal	0,000%	0,000%	0,000%
Deep venous thrombosis	VR 15	male	0,000%	0,000%	0,000%
		femal	0,000%	0,000%	0,000%