

**Reporting from Council of Europe member states on the collection, testing and use of
blood and blood components in Europe
The 2006 Survey**

This questionnaire consists of three sections:

A. Collection and use of blood and blood components,

B. Testing of blood and blood components, and

C. General information.

At the end of each section, please provide any additional information and comments that you think may be useful for the interpretation of the data. When information or data on specific terms is not available, please leave an empty field.

This questionnaire is copyright of Dr. C.L. van der Poel, Julius Centre of the University Utrecht, under auspices of the TS-GPUQA working group of the EDQM Blood Transfusion Committee (CD-P-TS). Earlier versions were developed together with Dr. Olof Akerblom.

Any questions you might have when filling out the questionnaire should be directly addressed to Dr. C.L. van der Poel, c.l.vanderpoel@umcutrecht.nl

Directive 2002/98/EC, Annex II, requests Member States of the European Union to report annually on the blood establishment's activity. This request includes data with similar definitions also asked for in this questionnaire (questions 1.1 + 1.2.1, 2.1-5, 3.1-5, 4.1-2, 7.1 + 8.3.1, 7.2 + 8.3.2, and 12.2). Definitions and data requested on confirmatory testing and NAT testing of for infectious diseases (tables 7 + 8) are congruent with those requested by the "Guideline on epidemiological data on blood transmissible infections" by the EMEA (EMEA/CPMP/BWP/3794/03). Definitions and data requested on haemovigilance (table 12) are congruent with those requested by Directive 2005/61/EC. A process has started to harmonise with WHO questionnaires. As a first action, as of the 2005 questionnaire, revisions and additions were made to adapt a WHO draft questionnaire on selected indicators.

The questionnaire is to be completed and returned by 14 September 2007 to Dr. M-E. Behr-Gross, EDQM, 7 allée Kastner, F-67081 Strasbourg, France. Fax: + 33 388 41 2771; e-mail: marie-emmanuelle.behr-gross@edqm.eu with a copy to Dr. C.L. van der Poel, c.l.vanderpoel@umcutrecht.nl.

Questionnaire on the collection, testing and use of blood and blood components in Europe

The 2006 Survey

COUNTRY	
Information provided by	
Institution	
Address	
Tel. & fax.	
e-mail address	

Population in country, number	
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SECTION A Collection and use of blood and blood components

1. Donors active during the year

1.1	Regular and repeat donors,* number	
1.2	First time donors,* total number	
1.2.1	- on first visit donating blood or blood components, number	
1.2.2	- on first visit giving blood samples for testing only, number	

* Definition according to the Council Recommendation 98/463/EC and Council of Europe Guide to the preparation, use and quality assurance of blood components, Appendix 1.

First time donor Someone who has never donated either blood or plasma

Repeat donor Someone who has donated before but not within the last two years in the same blood establishment

Regular donor Someone who donated blood or plasma within the last two year sin the same blood establishment

2. Collection of blood and blood components

2.1	Whole blood, total number of donations	
2.1.1	- voluntary non-remunerated, per cent of donations	%
2.1.2	- replacement donations, ¹ per cent of donations	%
2.1.3	- autologous donations, pre-deposit, number	
2.2	Red cells apheresis, total number of donations (procedures)	
2.2.1	- voluntary non-remunerated, per cent of donations	%
2.2.2	- autologous donations, pre-deposit, number	
2.3	Plasma apheresis, total in litres	
2.3.1	- collected from voluntary non-remunerated, litres	
2.4	Platelets apheresis, total number of donations (procedures)	
2.4.1	- voluntary non-remunerated, per cent of donations	%
2.5	Granulocytes apheresis, number of donations (procedures)	
2.6	Multi-component apheresis,² number of donations	

¹ Replacement donations Donations collected from donors recruited by patients to enable them to undergo therapy, which requires blood transfusion

² Multi-component apheresis means the collection in one session of two or more different types of blood components, *i.e.* erythrocytes + plasma, platelets + plasma, etc.

Comments to the data given in Table 1 and in Table 2

3. Use of blood and blood components intended for transfusion

Please, indicate if the figures given relate to blood and blood components <input type="checkbox"/> distributed to hospital blood banks, <i>or</i> <input type="checkbox"/> transfused		
3.1	Whole blood , units ¹ , total number	
3.2	Red cells (red cells for transfusion, <i>excl.</i> autol.), units ²	
3.2.1	- red cells autologous , pre-deposit, units	
3.3	Plasma (plasma or FFP for transfusion), units ²	
3.4	Platelets (adult therapeutic doses ³), total number	
3.4.1	– recovered from whole blood (adult therapeutic doses ³)	
3.4.2	– collected by platelet apheresis (adult therapeutic doses ³)	
3.5	Cryoprecipitate , FVIII IU x 10 ⁶	

¹ A unit of whole blood consists of approximately 450 or 500 ml of blood, collected in a suitable amount of anticoagulant solution.

² A unit of red cells or plasma is red cells or plasma recovered from one unit of whole blood or a comparable volume of red cells or plasma collected by apheresis.

³ An adult therapeutic dose usually consists of 200 – 450 x 10⁹ platelets.

Comments to the data given in Table 3

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4. Blood components delivered for the manufacture of medicinal products

4.1	Plasma for fractionation , total, litres ¹	
4.1.1	– human plasma for fractionation into FVIII, litres	
4.1.1.1	- recovered from whole blood donations, litres	
4.1.1.2	- from plasmapheresis (source plasma), litres	
4.1.2	– for preparation of specific immunoglobulines ² , litres	
4.1.3	– other plasma, litres	
4.2	Other components (e.g. erythrocytes, buffy coat), units	

¹ litres = kg x 0.975

² e.g. anti-D, anti-HBs, anti-Zoster, etc.

Comments to the data given in Table 4

5. Special processing of blood components

5.1	Blood components leucocyte depleted (<math>1 \times 10^6</math>/unit), pre-storage, and irradiated blood components	Percent leucocyte depleted	Percent irradiated
5.1.1.	Red cells	%	%
5.1.2	Plasma (for transfusion)	%	%
5.1.3	Platelets	%	%

5.2	Plasma components (for transfusion) quarantined or virus inactivated	<i>Percent of plasma components</i>	
		quarantined	virus inactivated
5.2.1.	Plasma	%	%
5.2.2	Cryoprecipitate reduced plasma	%	%
5.2.3	Cryoprecipitate	%	%

Comments to the data given in Table 5

SECTION B Testing of blood and blood components

6. Screening for infectious agents, serological test methods

Screening tests required *only* by plasma fractionators should *not* be reported below.

6.1	Screening test performed	only 1 st time donation	Every donation	(if not all donations tested:) % donations tested	Comments
6.1.1	anti-HIV 1+2	<input type="checkbox"/>	<input type="checkbox"/>		
6.1.1.1	HIV-Ag	<input type="checkbox"/>	<input type="checkbox"/>		
6.1.2	HBsAg	<input type="checkbox"/>	<input type="checkbox"/>		
6.1.2.1	anti-HBc	<input type="checkbox"/>	<input type="checkbox"/>		
6.1.3	anti-HCV	<input type="checkbox"/>	<input type="checkbox"/>		
6.1.3.1	HCV-Ag	<input type="checkbox"/>	<input type="checkbox"/>		
6.1.4	anti-HTLV I/II	<input type="checkbox"/>	<input type="checkbox"/>		
6.1.5	Syphilis ¹	<input type="checkbox"/>	<input type="checkbox"/>		
6.1.6	Malaria	<input type="checkbox"/>	<input type="checkbox"/>		
6.1.7	Others ²	<input type="checkbox"/>	<input type="checkbox"/>		
		<input type="checkbox"/>	<input type="checkbox"/>		
		<input type="checkbox"/>	<input type="checkbox"/>		
		<input type="checkbox"/>	<input type="checkbox"/>		

¹ e.g. TPHA, RPR, VDRL, or other screening tests.

² Please specify, e.g. Chagas' disease, brucellosis, WNV, anti-CMV

Comments to the data given in Table 6.1

6.2	The use of simple rapid tests				
	Are any of these screening test performed using a rapid test technique <i>ONLY</i> ?				
	Screening test	Yes, all donations	Yes, % of donations	No	Comments
6.2.1	anti-HIV 1+2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6.2.2	HBsAg	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
8.2.3	anti-HCV	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Comments to the data given in Table 6.2

7. Confirmatory testing

7.1	Are repeatedly reactive screening test results subjected to confirmatory testing? <input type="checkbox"/> Yes, always <input type="checkbox"/> Yes, approximately _____ % of them <input type="checkbox"/> No
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7.2 Confirmed seropositive test results

7.2	Confirmed seropositive¹	HIV 1/2	HBsAg	HCV	HTLV I/II	Syphilis
7.2.1	First time tested donors ² , number					
7.2.2	Repeat tested donors ³ , number					

¹ Confirmed seropositive: Repeatedly reactive (≥ 2 times reactive) in a screening test *plus* positive in at least one supplementary test based on another principle.

² First time tested donor: Person who is tested for the first time (with or without donation) without report of prior serological testing in the blood establishment.

³ Repeat tested donor: Donor who has been subjected to previous serological testing in a given blood establishment.

Comments to the data given in Table 7

8. Nucleic Acid Testing, NAT

The testing performed by plasma fractionators should *not* be reported below.

8.1 Screening for infectious agents, NAT (minipools)				
	Screening test performed	only 1 st time donor	every donation	Comments
8.1.1	HIV NAT	<input type="checkbox"/>	<input type="checkbox"/>	
8.1.2	HBV NAT	<input type="checkbox"/>	<input type="checkbox"/>	
8.1.3	HCV NAT	<input type="checkbox"/>	<input type="checkbox"/>	
8.1.4	other NAT	<input type="checkbox"/>	<input type="checkbox"/>	please specify:

8.2	Size of mini-pool(s)	HIV:	HBV:	HCV:
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8.3	NAT only positive ⁴ test results, number	HIV	HBV	HCV
8.3.1	First time donors			
8.3.2	Regular plus repeat donors			

⁴ NAT only positive:

Positive in a NAT assays for a specific virus (HIV, HCV or HBV), not found seropositive for that virus in serological screening *plus* shown to be true positive by separate PCR or later serology.

Comments to the data given in Table 8

9. Screening for the presence of bacteria in platelet preparations

9.1	% of platelet adult doses screened for the presence of bacteria	%
9.1.1	- recovered platelet pools (adult doses)	%
9.1.2	- apheresis platelets (adult doses)	%
9.2	% of screened units confirmed positive by further testing	%

Comments to the data given in Table 9

SECTION C General Information

10. National co-ordination

10.1	National council or expert committee to advise Ministry of Health on transfusion related issues	<input type="checkbox"/> Yes	<input type="checkbox"/> No
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10.2	National Blood Policy		
10.2.1	- is there a national blood policy on the quality and safety of blood and blood components? If yes,	<input type="checkbox"/> Yes	<input type="checkbox"/> No
10.2.2	- is there a national blood plan on implementing the national blood policy?	<input type="checkbox"/> Yes	<input type="checkbox"/> No

10.3	National Regulations - are there national regulations, legally binding, for the collection, testing, processing, storage and distribution of blood and blood components?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
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Comments to the information given in Table 10

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Quality management related issues

11.1	Quality system established and maintained in blood establishments		<input type="checkbox"/> Yes <input type="checkbox"/> Planned <input type="checkbox"/> No		
	Percent of donations covered by	GMP	ISO 9000 series	Local SOP:s and instructions	Other *
		%	%	%	%
	* please, specify:				

11.2	Are inspections performed at least each second year?
	<input type="checkbox"/> No <input type="checkbox"/> Yes, by <input type="checkbox"/> a national authority <input type="checkbox"/> another qualified body or organisation*
	* please, specify:

11.3	Education and training
	- is there a system of education and regular training of staff in blood transfusion medicine? <input type="checkbox"/> Yes <input type="checkbox"/> No

11.4	System used for identification and labelling of donations and components		
	Percent donations labelled according to	ISBT 128	Another system*
<u>11.4.1</u>	donation number	%	%
<u>11.4.2</u>	component code	%	%
	* please, specify		

Comments to the information given in Table 11

12. Haemovigilance

12.1	<p>Is there a haemovigilance reporting system on national level?</p> <p><input type="checkbox"/> No <input type="checkbox"/> Yes, - operated by a national authority</p> <p><input type="checkbox"/> Yes, - operated by another organisation*</p> <p>- if “Yes”, please give haemovigilance data, if available, in Table 12.2</p>
	<p>*please, specify:</p> <hr/>

12.2 Haemovigilance data Serious adverse reactions* observed in recipients of blood or blood components:	Serious adverse reactions* reported					
	- total number	- with imputability level*	NA	0 - 1	2	3
Immunological haemolysis due to						
ABO incompatibility						
other allo-antibody						
Non-immunological haemolysis						
Post-Transfusion Purpura						
Anaphylaxis / hypersensitivity						
Transfusion Related Acute Lung Injury						
Graft Versus Host Disease						
Transfusion-associated viral infection	HBV					
	HCV					
	HIV-1/2					
	Other					

Transfusion-associated bacterial infection					
Transfusion-associated parasitical infection	Malaria				
	Other				
Circulatory overload					
Other serious reactions					

* When completing this table, please use the definitions of serious adverse reaction and imputability presented on the next page.

12.3 Definitions to be used in this section:

12.3.1 **Serious adverse reaction** – an unintended response in a patient associated with the transfusion of blood or blood components that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity.

12.3.2 **Imputability** - the likelihood that a serious adverse reaction in a recipient can be attributed to the blood or blood component transfused.

Imputability scale to assess serious adverse reactions:

Imputability scale		Explanation
NA	Not assessable	When there is insufficient data for imputability assessment.
0	Excluded	When there is conclusive evidence beyond reasonable doubts for attributing the adverse reaction to alternative causes.
0	Unlikely	When the evidence is clearly in favour of attributing the adverse reaction to causes other than the blood or blood components.
1	Possible	When the evidence is indeterminate for attributing adverse reaction either to the blood or blood component or to alternative causes.
2	Likely, Probable	When the evidence is clearly in favour of attributing the adverse reaction to the blood or blood component.
3	Certain	When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to the blood or blood component.

Comments to the information given in Table 12