2006 Report

The Collection, Testing and Use of Blood and Blood Components in Europe

European Committee (Partial Agreement) on Blood Transfusion (CD-P-TS)

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2006 Report

C.L. van der Poel, MD, PhD[1], M.P. Janssen, PhD[1] and M.-E. Behr-Gross, PhD[2]

1. Julius Center for Health Sciences and Primary Care, University Utrecht, Utrecht, The Netherlands
2. European Directorate for the Quality of Medicines and HealthCare, Council of Europe, Strasbourg, France

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For further information concerning the work of the Council of Europe / EDQM in the area of blood transfusion please contact:

Dr Marie-Emmanuelle Behr-Gross
Department of Biological Standardisation, OMCL Network & HealthCare
European Directorate for the Quality of Medicines and HealthCare (EDQM)
Council of Europe
7 allée Kastner, CS 30026
F - 67081 STRASBOURG
FRANCE
tel: +33 (0)3 90 21 41 08
fax: +33 (0)3 88 41 27 71
E-mail: marie-emmanuelle.behr-gross@edqm.eu

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SUMMARY

This report provides data on the donors, collection, testing, use and quality aspects of blood and blood components in Member States (MS) of the Council of Europe (CoE). Data were supplied by MS in response to a questionnaire requesting detailed information on donors, collections, testing, distribution and quality aspects of blood and blood components for the year 2006. In its present form it follows a series of similar reports which have assessed such data in 1989, 1991, 1993, 1995, 1997, and in its present revised form in 2001, 2002, 2003, 2004 and 2005.

A qualitative evaluation report on the questionnaire with recommendations for improvement of the process was previously performed and was reported in November 2004, including experience with reporting of data from the 3 previous years. As of 2004, the format of the questionnaire was reviewed and re-designed by the authors and the CoE experts belonging to the Committee of Experts on Quality Assurance in Blood Transfusion Services (SP-GS) and the Committee of Experts on Blood Transfusion (SP-HM) bureau.

Also, for the 2006 as for fomer years, not all relevant data was obtained from each MS. Due to difficulties in implementation of data retrieval from automated blood banking systems, and collating data from many Blood Establishments (BE) on a national level within the MS, the process is designed so that annual repetition will lead to improvements.

In contrast to surveys for the year 2003 and earlier, the proportion of donations by voluntary non-remunerated and replacement donors was requested as of the 2004 questionnaire. The European Commission (EC) has acknowledged its importance in its *Directive 2002/98/EC*.

In MS and in BE, data may be administered in different formats, and different definitions may have been operational. This could result in discrepancies in reporting the data in another format. Some data may not be available. It is anticipated that consistency and persistence with these CoE survey methods, together with the EC will result in adaptation of the BE and MS towards uniform data collecting, thereby generating better data and higher response rates among MS, when the questionnaires are used annually. In order to facilitate uniformity, definitions of the EC Directives and CoE Guidelines are used as far as possible (*Council Recommendation 98/463/EC, Directive 2002/98/EC, Guide to the Preparation, use and Quality Assurance, 9th edition, 2002*). In addition, it is to be welcomed that the European Medicines Agency (EMA) employs the same definitions, especially on infectious disease epidemiology in donor populations (*Guideline on Epidemiological data on Blood Transmissible Infections* for inclusion in the *Guideline on the Scientific data requirements for a Plasma Master File EMEA/CPMP/BWP/3794/03*). Uniformity of such definitions is of importance to the field, and circumvents unnecessary and costly repetitions in collating the data.

In total 37 questionnaires were received in 2006; the response rate, at 80%, was somewhat higher than before. For the 2001, 2002, 2003, 2004 and 2005 surveys, the response rates were 84%, 60%, 67%, 73% and 72%, respectively.

The average number of donors in relation to the general population is 29 (range 2-90) per 1,000 inhabitants. On average 23 % of the donor base consists of first time donors.

The number of Whole Blood (WB) collections is on average 36 per 1,000 inhabitants, the average use of Red Blood Cells (RBC) is 37 per 1,000 inhabitants. On average 2.5 Litres (L) of plasmapheresis plasma per 1,000 inhabitants are collected.

The use of RBC varies considerably (range 3 - 67) and averages 37 total RBC Units (U) per 1,000 inhabitants. In 3 of the reporting MS less than 20 U per 1,000 inhabitants are used, most likely reflecting an insufficient supply. On average in the reporting MS, 32% of the total platelet volume

is supplied by (random) single donor platelets by apheresis, in 8 countries this volume amounts to more than 50%.

The amount of plasma delivered for fractionation into medicinal products differs greatly (range 0-26) among MS, an average yield of 7.2 L of plasma for fractionation per 1,000 inhabitants is found. However 6 / 31 (19%) of reporting MS deliver 15 L or more per 1,000 inhabitants. In Europe on average 70% of the plasma for fractionation is from recovered plasma.

In 12 / 33 (36%) MS, 100% leucocyte depletion of RBC products is carried out. Platelet concentrates are 100% leucocyte depleted in 17 / 33 (53%) of MS. In 13 / 25 (52%) reporting MS (nearly) 100% of Fresh Frozen Plasma (FFP) is additionally safeguarded by either quarantine or pathogen reduction methods.

In 35 / 37 (95%) reporting MS, each donation is tested for anti-HIV-1/2, HBsAg and anti-HCV. In 31 (84%) reporting MS, all donations are tested for syphilis. Anti-HTLV-I/II testing is performed on all donations in 8 (22%) of reporting MS, and on first time donors in 4 (11%). Anti-HBc is performed on all donations in 6 (16%) MS, and only on first time donors in another 4 (11%). Prevalence and incidence of infectious diseases vary greatly among MS, and it is noted that in Europe a North-South gradient exists for hepatitis B (HBV) and C virus (HCV).

Nucleic Acid Amplification Techniques (NAT) testing for HCV is performed on each donation in 18 / 37 (49%) reporting MS, whereas HIV NAT on each donation is performed in 14 / 37 (38%) and HBV NAT in 6 (16%) MS. The yield of “NAT-only” positive donations, if performed and reported is given in Table 8.2.

Bacterial screening is performed on about 80% or more of the platelet concentrates in 6 (16%) MS. Haemovigilance data have repeatedly demonstrated the importance of bacterial safety of platelet concentrates. Among 13 reporting MS, the average rate of confirmed positively cultured platelet concentrates was 0.13%, (ranging from 0-0.50%). Other MS reported having Quality Control (QC) programmes of bacterial testing in place.

In 23 / 37 (62%) of the reporting MS a National Council or Expert Committee to advise the Ministry of Health on transfusion related policy issues exists.

In 27 / 37 (73%) of the reporting MS, a Quality System (QS) is established and maintained in BE. In 8 (22%) countries the implementation of such a system is planned. In 19 / 37 (51%) of the reporting MS, 100 % of the donations are covered by Good Manufacturing Practice (GMP). In 4 (11%) countries this is the case for ISO 9000. In 25 / 37 (68%) of the reporting MS, inspections are performed at least every 2 years.

Labelling according to International Society for Blood Transfusion (ISBT)-128 for the donation number is performed in 15 countries, and 6 countries have 100% ISBT-128 code implementation for the donations. ISBT-128 labelling of components is implemented in 13 countries, of which 5 countries have 100% ISBT-128 coding at the component level.

Haemovigilance reporting in this survey started as of the year 2004. The format for data acquisition on haemovigilance for the 2004 CoE questionnaire in its basic form was developed in collaboration with the CoE, experts and EC and adapted into *Directive 2005/61/EC*. In this report only those serious adverse reactions are presented that are probably of certainly (imputability grade 2 to 3) ascribable to the transfusion of, and data which are not caused by the product itself, such as TACO (Transfusion Associated Circulatory Overload) are reported. Taking the possibility of underreporting and the differences in national reporting systems into account, an overall incidence is estimated at about 8 serious adverse reactions per 100,000 distributed blood components, where the higher incidences may reflect better reporting rather than lower quality. Haemolysis, anaphylaxis, Transfusion Related Acute Lung Injury (TRALI) and TACO appear to stand out as the more frequent serious adverse reactions.

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LIST OF ABBREVIATIONS

Ag	Antigen
ALT	Alteplase testing
BE	Blood Establishments
CD-P-TS	European Committee (Partial Agreement) on Blood Transfusion
CI	Confidence Intervals
CP	Cryoprecipitate
CSP	Cryosupernatant Plasma
CMV	Cytomegalovirus
CoE	Council of Europe
EC	European Commission
EDQM	European Directorate for the Quality of Medicines and HealthCare
ELISA	Enzyme-Linked Immunosorbent Assay
EMA	European Medicines Agency
EU	European Union
FFP	Fresh Frozen Plasma
FTA	Fluorescent Treponemal Antibody
FVIII	Factor VIII
GMP	Good Manufacturing Practice
GTS	Ad hoc working group on the guide to the preparation, use and quality assurance of blood components
GVHD	Graft-Versus Host Disease
HBc	Hepatitis B core antigen
HBsAg	Hepatitis B surface Antigen
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HLA	Human Leucocyte Antigen
HPA	Human Platelet Antigen
HTLV	Human T cell Lymphotropic Virus
IDM	Infectious Disease Markers
ISBT	International Society for Blood Transfusion
IU	International Unit
L	Litres
MB	Methylene Blue

MS	Member States of the Council of Europe
NAT	Nucleic Acid Amplification Techniques
PABD	Pre-operative Autologus Blood Donation
Ph. Eur.	European Pharmacopoeia
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
QS	Quality System
RBC	Red Blood Cells
SD	Solvent Detergent
SP-GS	Committee of Experts on Quality Assurance in Blood Transfusion Services
SP-HM	Committee of Experts on Blood Transfusion
TA	Transfusion Associated
TACO	Transfusion Associated Circulatory Overload
TRALI	Transfusion Related Acute Lung Injury
TTP	Thrombotic Thrombocytopenic Purpura
U	Unit
vCJD	Variant Creutzfeld Jacob Disease
WB	Whole Blood
WHO	World Health Organisation

STUDY METHODS

The methods in this survey were, in principle, the same as in the previous surveys. Briefly, the European Directorate for the Quality of Medicines and Healthcare (EDQM) Secretariat circulated the questionnaire to Member States (MS) Experts requesting that the completed forms be returned to the Secretariat. Completed questionnaires and comments were received until November 2008. After meetings with GTS (Ad hoc working group on the guide to the preparation, use and quality assurance of blood components) and CD-P-TS (European Committee (Partial Agreement) on Blood Transfusion) in September and October 2009, corrections and additions were provided by MS Experts, and additional completed questionnaires were received until November 1st 2009, after which the report finalised and adopted by the CD-P-TS.

The data in the completed questionnaires were reviewed by the authors after submission by the MS. Request for additional information or clarification from national experts were posed by the authors where incomplete or incomprehensible data sets were returned. During questionnaire evaluation, some data provided did not fulfil requirements and these have not been presented here, resulting in some empty fields. A qualitative evaluation report on the questionnaire with recommendations for improvement of the process had previously been reported by the authors to SP-HM (Committee of Experts on Blood Transfusion) and discussed in November 2004. A revision of the questionnaire with new additional questioning was thereafter implemented for the 2004 and later surveys.

Trend analysis and incomplete data

Comparisons with results from the previous surveys and trend analyses are foreseen. Initial trend analyses were reported, in draft, in December 2007 and comprised questionnaire data from 2001 through to 2005. Not all information requested in the questionnaire is included in the tables reported, but these provide detail where sufficient information is available to justify presentation. Occasionally totals in the tables may not precisely match the contributing figures because of rounding. It was assumed that information was not available when information was not provided. The absence of a response (or data inconsistency) is represented by empty fields in the tables.

Remarks to the data

It remains the responsibility of the MS that the data reported in the questionnaires has been checked against the tables provided in the draft versions of this report.

With the launch of the web-posted questionnaire, which was set-up for collecting the data for 2007 and later surveys, the risk of errors may be reduced.

RESULTS

Response rate

The 46 MS of the Council of Europe (CoE) were invited to send completed questionnaires. Replies were received at the deadline for correction submissions in October 2009 from 37 MS; a response rate of 80%. For the 2004 and 2005 surveys the response rates were 73% and 72% respectively, which means there is an increase in MS response rate. It is possible that the longer period between the beginning and end of data collecting allowed more MS to report. However, it was also reported to the authors that changing blood supply systems and mergers of Blood Establishments (BE) hindered the process of data collection.

Donors, first time donors and inhabitants: Table 1

The questionnaire requires data on donors 'active during the year', and therefore should include only those donors who actually donated during the reporting year. However the definition 'donors active during the year' may require a precise query on a given donor database. In many establishments or countries, the query format on the donor database would need to be compliant. This may not always be possible. Therefore it is not certain whether this requirement was always met in generating the data for this survey. If this detail is deemed necessary in future, the 'inactive' number of donors (i.e. the number of donors in the databases that did not donate during the reporting year) would also need to be reported. This problem of definition has been largely addressed by the *European Commission (EC) Council Recommendation of 29 June 1998 on the suitability of blood and plasma donors and the screening of donated blood in the EC (98/463/EC)*.

The terms 'regular and repeat donors' are defined by the *EC Council Recommendation (98/463/EC)* and these definitions apply to regular donors (i.e. donors whose last previous donation was less than 2 years earlier) and for repeat donors (i.e. donors whose last previous donation was more than 2 years earlier). The total of the two categories represents those donors, who are known to the system or establishment and in many countries form the basis and guarantee of continuity of the blood supply. These data are needed for the calculation of the prevalence of infectious diseases among new donors and the incidence of infectious diseases among repeat and regular donors (see Table 7). For EU countries, the reporting of prevalence and incidence on these donor populations became mandatory in 2005 as of *Directive 2002/98/EC*.

In this survey, the term 'first time donors' includes all donors who are actually tested for the first time or who donate for the first time. There are systems where 'applicant donors' (*98/463/EC*) are only tested, and come back for a first donation later. They become known as 'qualified donors' when their applicant donor infectious disease tests are returned negative. Including only 'qualified donors' in the report will generate bias in reporting Infectious Disease Markers (IDM) (see Table 7). The term 'new donors' in *Council Recommendation 98/463/EC* does not specify this and allows for the exclusion of 'non-qualified donors'. Therefore in this survey the term 'first time tested donors' is used to include all donors who actually are tested for the first time, either at the time of donation or through pre-donation screening.

It should be taken into account that 'first time donors' are already a selected population and therefore the prevalence of infectious diseases markers in the general population of a given MS may be different. The ratio of first time donors to the total number of donors in general reflects the annual donor recruitment or, more generally, the turn-over rate in the donor base. This figure may however be influenced by recruitment programs. The number of first time donors, as

compared to the total number of donors, becomes less meaningful in systems that only register donations and less so, the (uniquely identifiable) donors.

Excluding MS where first time donors and repeat plus regular donors were not reported separately, 23% (range 7-83) of the total donor base consists of 'first time' donors. It is known that first time donors may have higher incidences of infectious diseases as compared to regular or repeat donors (Schreiber *et al.*, 2001).

The average number of donors in relation to the general population is 29 (range 2-90) per 1,000 inhabitants. This number may reflect the commitment of the population to donate blood in relation to the demand. Differences exist but, arbitrarily, less than 10 donors per 1,000 inhabitants should pose a problem with supply and around 30 donors per 1,000 inhabitants seems an achievable goal from the given data. Not all countries with a relatively high number of donors per 1,000 inhabitants deliver high numbers of Red Blood Cell (RBC) Units (U) to the hospitals (see Table 3), but in general these figures are related. As stated before, some caution as to the interpretation of the number of 'active' donors seems justified, and bias may occur by 'inactive' donors in the database. However, maintaining 'inactive' donors in the database may be a strategy to 're-activate' known donors.

Profile of donations: Table 1.1

The relative contribution of voluntary non-remunerated donations to the supply is given in Table 1.1.

Collection of Whole Blood, autologous blood and blood components: Table 2

- **Whole blood**

Whole Blood (WB) collections are the basis of the blood supply in most countries, not only for the preparation of blood components, but also for the delivery of 'recovered plasma' as source material for the manufacture of medicinal products (see Table 3). The number of WB collections in 37 MS reporting, is on average 36 (range 3-71) per 1,000 inhabitants. Given the average use of RBC per 1,000 inhabitants (see Table 3), the number of WB donations collected appears to either conform to the demand for RBC components or determines their use in hospitals by limiting supply.

- **Autologous blood**

Autologous donations have been promoted in relation to safe blood transfusions by limiting exposure to allogeneic blood for patients and also with the purpose of enhancing the supply of blood. In general the factor of enhancing supply appears not to be significant: in 29 countries where autologous donations are given, they contribute on average around 0.7% (range 0-4%) to the WB donations. This is in agreement with the literature and previous reporting. However it should be taken into account that surgery and anaesthesiology techniques, such as pre-operative hemodilution and intra-operative blood salvage, are not included in the presented data. In this survey only Pre-operative Autologous Blood Donations (PABD) are taken into account.

- **Blood components (Apheresis)**

Plasmapheresis collections provide source plasma, including plasma with specific antibodies, for fractionation into medicinal products. In some countries plasma for transfusion referred

to as Fresh Frozen Plasma (FFP) is also collected by apheresis donations. The volume of plasma collection by apheresis per 1,000 inhabitants reflects the volume of the national plasmapheresis programs. In 30 reporting MS, on average 2.5 litres (L) (range 0-14) of plasma per 1,000 inhabitants is collected by plasmapheresis. Apparently Austria, Bulgaria, Germany and The Netherlands stand out as countries with a considerably more extensive plasmapheresis programmes, with about 10 L or more of plasmapheresis plasma per 1,000 inhabitants per annum.

Platelet apheresis may be aimed at Human Leucocyte Antigen (HLA) or Human Platelet Antigen (HPA) typed donations for refractory patients, as well as to replace the provision of platelets from pooled WB donations by apheresis platelets in order to reduce donor exposure in patients. The relative importance of platelet apheresis for the total supply of platelet products is given in Table 3. In 34 reporting MS, on average 32% (range 0-82) of the adult therapeutic doses of platelets are produced by apheresis. The extremes may reflect different models: low access to HLA typed platelet donors or MS striving towards 100% platelet supply by apheresis.

RBC apheresis is a relatively new development and may be of particular interest for autologous programs, and for collections of rare types of RBC donors. It appears to be increasingly used for supply reasons.

Granulocyte apheresis donations are infrequent, as indications appear to be limited.

Use of blood and blood components for transfusion: Table 3

The term 'the use of blood' may be somewhat misleading as the reported data may not reflect the actual use of blood or blood components in the hospitals, but rather the number of blood components that have been delivered to hospitals by BE. This depends on the source of the data and the national infrastructure. Data on the use in hospitals are generally difficult to obtain in many MS, however in some countries such as Denmark, blood banks are hospital based and the data are related to actual transfusions issued. As component losses in hospitals are limited, the number of blood components delivered to hospitals represents an acceptable proxy to the blood use estimate, and the heterogeneity of the given data may result in only minor deviations.

WB 'must be considered as a source material and has no, or only a very restricted, place in transfusion therapy' (*Guide to the Preparation, Use and Quality Assurance of Blood and Blood Components, 8th edition, 2001*). However in countries with limited resources transfusion therapy with WB may be needed when the infrastructure for blood component preparation is lacking. In 26 reporting countries, on average 1.8% (range 0-34) of the RBC transfusions are performed with WB. In Romania the use of WB accounts for more than one third of the total volume of RBC products used.

The use of RBC per 1,000 inhabitants varies considerably. In 26 reporting MS it averages 37 total RBC products per 1,000 inhabitants (range 3-67). Rejman (2000) suggested in his report on the 1997 survey that 40 – 60 WB donations per 1,000 inhabitants would be needed for optimal supply, a figure largely driven by the need for RBC for transfusion. Apparently the use of RBC has been greatly reduced in the last decade. RBC's are mainly used in surgery, obstetrics, haematology and oncology care, and in some countries programs for 'better use of blood' or for 'optimal use of blood' have recently been installed in order to reduce unnecessary donor exposure to patients. Therefore the use of 30 to 40 RBC U per 1,000 inhabitants could reflect the results of these programmes. In 3 / 26 (12%) of the reporting MS, less than 20 units per 1,000 inhabitants are used, most likely reflecting insufficient supply of blood or limited hospital care. A better benchmark may be achieved by including the number of hospital beds in a future survey, and to relate this figure to RBC use.

The use of plasma for transfusion has been discouraged over the last decade, mainly because its clinical indications are limited and more plasma was needed for as source material for fractionation into medicinal products. However, with multiple coagulation disorders, including Thrombotic Thrombocytopenic Purpura (TTP), FFP transfusions are needed. In order to provide a benchmark, the use of plasma for transfusion can be related to the use of RBC transfusions (use of FFP/RBC ratio). It should be taken into account that, in the programmes for 'better use of blood' (e.g. RBC) in some countries, the decline of RBC use increased the FFP/RBC ratio. On average the FFP/RBC ratio is 0.36 (range 0.10 – 1.2, Table 4).

In Europe, platelets are generally recovered from 4-5 buffy-coats of WB donations. Discussions on blood safety in relation to Variant Creutzfeld Jacob Disease (vCJD) have inspired programmes to enhance the use of random single-donor platelets by apheresis in order to reduce donor exposure to recipients. These programmes may have been influential in some MS where the use of apheresis platelets in relation to recovered platelets is relatively high. The extent to which donors are willing to undergo apheresis may be limited, as no supply reaches 100% apheresis platelets. On average, in 29 reporting MS, 32% (range 0-92%) of the adult therapeutic doses of platelets are produced by (random) single donor platelets by apheresis (Table 3). In 8 countries this volume amounts to more than 50%.

Cryoprecipitate may incidentally be used for fibrinogen, Von Willebrand's disease, and complex coagulation disorders. This product has largely been abandoned by most MS.

Plasma for fractionation: Table 4

The total amount of plasma issued for fractionation into medicinal products differs among MS. This becomes clearer if the figure is related to the population size. In 31 reporting MS, an average yield of 7.2 L (range 0-26 L) per 1,000 inhabitants is found of plasma for fractionation into medicinal products. However, 6 of 31 (19%) reporting MS deliver 15 L or more plasma per 1,000 inhabitants.

In Europe, the main supply of plasma for fractionation is recovered plasma; in 18 reporting MS, on average 70% of the plasma for fractionation is from recovered plasma (range 0-100%).

Apart from a query on the total yield of plasma for fractionation, the questionnaire encompasses two specific questions on plasma delivered for factor VIII (FVIII) production versus other plasma for fractionation. These specific questions are poorly understood by respondents.

Special processing of blood components and pathogen reduction or quarantine of plasma: Tables 5.1 and 5.2

In 12 / 33 (36%) of reporting MS, 100% leucocyte depletion of RBC products is carried out. This is the case for platelet concentrates in 17 / 33 (53%) reporting MS. Hundred percent leucocyte depletion is applied for plasma for transfusion in 9 / 19 (47%) of the reporting MS.

Irradiation of blood components is carried out in order to prevent Graft versus Host Disease (GVHD) (as a rule, this is relevant for blood components that may carry residual leucocytes), and for a selected group of recipients only. The numbers may reflect the volume of high clinical care; although, in many instances, irradiation is carried out in hospitals where it generally appears more difficult to obtain data.

FFP for transfusion, cryosupernatant plasma (CSP) and cryoprecipitate (CP) may be additionally safeguarded against infectious diseases. One method is a quarantine step where the plasma is stored and only released if the donor is negative for IDM on a subsequent donation 4-6 months later. Another method is the application of 'virus inactivation' or 'pathogen reduction' by Solvent

Detergent (SD) or Methylene Blue (MB) treatment. In 13 / 25 (52%) reporting MS, nearly all FFP is safeguarded by either method, in 4 MS for 99% or more by quarantine, in 3 by 100% pathogen reduction, and in 6 by a combination of both.

Screening for infectious agents, serological test methods: Table 6

In 35 out of the 37 reporting MS (95%) all donations are tested for anti-HIV-1/2, HBsAg and anti-HCV. The two remaining countries (Iceland and Montenegro) test first time donors. In 31 (84%) of these MS, all donations are tested for syphilis. Only Montenegro, Sweden, Turkey and Norway test first time donors for syphilis. It is debated in the literature whether syphilis testing is necessary.

Testing for anti-HTLV-I/II is performed on all donations in 8 (22%) reporting MS, and only on first time donors in 4 (11%) countries.

Testing for anti-HBc is performed on all donations in 6 (16%) reporting MS, and only on first time donors in 4 (11%) MS.

Confirmed seropositive donors and prevalence and incidence of infectious diseases: Tables 7.1 and 7.2

Given the limited positive predictive value of serological screening tests, donors who are found positive in blood screening for IDM generally need to be 'confirmed' with another technique aimed at diagnosing infection. Confirmed positive donors are then notified and deferred from further donations. A typical flow-chart for confirmation is given in *EC Recommendation 98/463/EC*.

In Table 7.1, the absolute numbers of 'confirmed positive' donors reported among all first time donors tested (see Table 1) and among all repeat donors tested (see Table 1) are given. Overall 32 of 37 (86%) MS were able to provide the absolute numbers of confirmed positive donors for HIV, HBV and HCV (see Table 7.1).

- **First time donors**

The frequency of 'confirmed positive' donors among all first time donors tested (see Table 1), yields the 'prevalence' of an IDM among first time donors. This reflects the characteristics of the population from which first time donors are recruited. It should be noted that the general population may have different rates of infectious diseases than blood donors. Even at their first visit, blood donors are a selected population. The 'prevalence' of infectious diseases among first time donors was calculated from Table 7.1 (number of confirmed positive donors) and Table 1 (number of first time donors), and the ratio is given in Table 7.2.

The prevalence per 100,000 first time tested donors, as calculated from the provided data sets, ranges from 0 to 97 for HIV-1/2, from 0 to 3,666 for HBV and 0 to 978 for HCV. Although considerable differences in geographical distribution of these infections in Europe exist, it is questionable whether the extremely high frequencies in some countries reflect reliable data sets on actual 'confirmed positive donors' or, merely, refer only to repeat positive donors screened by Enzyme-Linked Immunosorbent Assay (ELISA) and, thereby, including many false positives (see definitions in the questionnaire in appendix). The geographical distribution of the high prevalence areas may coincide with low resources and lack of confirmatory testing.

- **Repeat and regular donors**

The frequency of 'confirmed positive' donors among all repeat and regular donors tested yields the 'incidence' of an infectious disease among repeat and regular donors (i.e. those donors who had previously been tested, were found to be negative, and were allowed to donate again). This 'incidence' accounts for the frequency with which repeat and regular donors acquire a new infection. It is this frequency that directly relates to blood safety via the window period of infectious disease testing (Schreiber *et al.,* 1996, *Guideline on Epidemiological data EMEA/ CPMP/BWP/3794/03*). The incidence of infectious diseases among repeat and regular donors was calculated from Table 7.1 (number of confirmed positive donors) and Table 1 (number of repeat and regular donors), and is given in Table 7.2. As with the prevalence data in first time donors, the extremely high incidences may refer only to repeat positive donors of ELISA screening instead of confirmed positive donors and, thereby, include many false positives (see definitions in the questionnaire).
The geographical distribution of the high incidence areas coincides with high prevalence areas and may be linked to low resources and lack of confirmatory testing.

Notwithstanding the limitations of the data and the question as to whether all positive screening test donors were submitted to confirmatory testing, the prevalence and incidence rates of infectious diseases vary greatly among MS. Overall it is to be noted that, in Europe, a North-South gradient exists: HBV and HCV infections are more common in the southern countries.

The incidence per 100,000 repeat tested donor years, if calculated from the provided data sets, ranges from 0 to 12 for HIV-1/2, from 0 to 251 for HBV and 0 to 121 for HCV. Although considerable differences in geographical distribution of these infections in Europe exist, it is doubtful whether the very high frequencies of some countries reflect reliable data sets or, merely, refer only to ELISA screening positive donors (including many false positives), as opposed to 'confirmed positive donors' (see definitions in the questionnaire).

Nucleic Acid Amplification Techniques (NAT) testing and NAT-only confirmed positive donors: Tables 8.1 and 8.2

NAT testing for HCV is performed on each donation in 18 / 37 (49%) reporting MS. NAT testing for HIV is performed on each donation in 14 / 37 (38%) reporting MS. NAT testing for HBV is performed on each donation in 6 (16%) MS. Interestingly, NAT on each donation appears to be performed more often in MS where the incidence rates are relatively low (see Table 7.2 for comparison). As the effectiveness (or 'yield") of NAT testing relates to the incidence, an argument could be made for preferentially applying NAT testing in high incidence areas. Unfortunately these areas appear to coincide with limited resources.

The 'yield' of NAT is defined as the identification of a NAT-positive donor, who is not found seropositive for that virus in serological screening on the same donation but is shown later to be a confirmed positive through detection from an additional NAT test on the same sample or by serology. The yield of NAT for HCV, HIV and HBV among first time tested donors and among repeat donors is given in Table 8.2.

Bacterial screening: Table 9

A new data set for bacterial screening of platelet concentrates was added in the 2004 report. Haemovigilance data have repeatedly shown the importance of bacterial safety of platelet concentrates. This is due to the fact that the storage temperature of platelets is around 22°C, thus allowing bacterial growth more easily. Data on bacterial testing were reported by 17 MS. In

6 (16%) MS, culture is performed on over 80% of all platelets (concentrates recovered both from WB donations and apheresis platelets).

Among the 13 reporting MS, the average rate of confirmed positively cultured platelet concentrates was 0.13% (ranging from 0 – 0.50%), which is congruent with the literature. Other MS reported having Quality Control (QC) programmes of bacterial testing in place.

Organisation and registration: Table 10

35 of 37 MS (95%) report that there are legally binding national regulations for the collection, testing, processing, storage and distribution of blood and blood components. In 23 / 37 (62%) of the reporting MS a National Council or Expert Committee advises the Ministry of Health on transfusion related issues. In 26 / 35 (74%) MS there is a national blood policy on the quality and safety of blood and blood components. Of these 27 MS, 20 (77%) have implemented the national blood policy or are in the process of doing so.

Quality management: Tables 11a, 11b and 11c

In 27 / 37 (73%) of the reporting MS, a Quality System (QS) is established and maintained by BE. In 8 (22%) countries the implementation of such a system is planned. Only in one MS has QS not been established and maintained by BE.

In 19 / 37 (51%) of the reporting MS, 100% of the donations are covered by GMP. In 4 countries (11%) this is the case for ISO 9000. In 4 countries another QS is used that coverages a large proportion of donations (over 80%). In 25 / 37 (68%) of the reporting MS, inspections are performed at least every 2 years, the large majority of these inspections are (partially) carried out by the national authority.

It is requested that the labelling of donations and issued components is unique so as to allow complete traceability. Labelling according to ISBT-128 for the donation number is partially performed in 15 countries, and 6 countries have 100% ISBT-128 code for the donations. In 24 countries coding by another system is reported, of which 16 countries indicate (almost) 100% coverage. Labelling of the finished component code is more complex, and generally lags behind developments in donation labelling, as it includes implementation of automation applications in hospitals. ISBT-128 labelling of the issued component is partially implemented in 13 countries, of which 5 indicate 100% ISBT-128 coding at the donation as well as the component level. Other component codes are used by 18 countries, of which 11 countries indicate 100% coverage.

In 26 / 37 (70%) of the reporting MS a haemovigilance system has been installed.

Haemovigilance: Table 12

Since 2004 this survey contains data on haemovigilance i.e. the reporting of serious adverse reactions. The format for data acquisition on haemovigilance in the 2004 questionnaire in its basic form was developed by CoE experts, submitted to the EC and adapted after slight modifications by the EC into *Directive 2005/61/EC*. Reporting of serious adverse reactions as performed in haemovigilance programmes can be considered as a high level of surveillance, as most of these serious reactions are not unexpected untoward effects but well known complications of blood transfusion from the medical literature and commonly indicated in the 'information leaflets' for physicians and patients. Most recipients of blood transfusions are very ill and have underlying pathology or medications that greatly influence the signs and symptoms of a possible transfusion reaction. A serious adverse reaction during or immediatly after transfusion, even if most likely related to the transfusion, may be restricted to the given recipient. Therefore, in this report only those serious adverse reactions are presented which are probably or certainly

(imputability grade 2 to 3, i.e. likely or certain) related to the transfusion of the blood component. The term imputability includes the causal relationship to the component properties, but also to the transfusion itself (Transfusion Associated Circulatory Overload (TACO)) or recipient properties (allergy).

In contrast to the *EC Directives 2002/98/EC* and *2005/61/EC*, haemovigilance data which may not be caused by blood component properties, such as TACO are also reported here. Haemovigilance data submitted by 23 MS, are presented in Table 12.

The incidence of serious adverse reactions with high imputability (level 2 to 3) can be calculated relative to the total number of blood components (WB + RBC + plasma + platelets) issued. Taking into account the possibility of under-reporting and the differences in national reporting systems, the incidence of 8 serious adverse reactions per 100,000 distributed blood components seems a reasonable estimate. Haemolysis, anaphylaxis, TRALI and TACO appear to stand out as the most frequent serious adverse reactions.

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TABLES

List of countries having participated in the survey
(37 out 46 MS)

Armenia, Austria, Belgium, Bosnia / Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Former Yug. Rep. Macedonia, Finland, France, Georgia, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey.

Table 1 - *Donors, first time donors and inhabitants*

Country	regular and repeat donors#	first time donors#	% first time donors#	total donors#	inhabitants x 1,000	donors per 1,000 inhabitants
Armenia	1,252	6,286	83.4	7,538	3,200	2.4
Austria	290,944	58,974	16.9	349,918	8,282	42.3
Belgium	253,424	51,526	16.9	304,950	10,500	29.0
Bosnia / Herzegovina	14,007	16,128	53.5	30,135	2,100	14.4
Bulgaria	115,160	31,637	21.6	146,797	7,719	19.0
Croatia	78,189	13,199	14.4	91,388	4,437	20.6
Cyprus	48,119	21,364	30.7	69,483	770	90.2
Czech Republic	296,200	22,900	7.2	319,100	10,300	31.0
Denmark	196,379	19,000	8.8	215,379	5,200	41.4
Estonia	25,035	7,219	22.4	32,254	1,345	24.0
Former Yug. Rep. Macedonia	5,200	3,060	37.0	8,260	2,034	4.1
Finland	145,562	18,108	11.1	163,670	5,256	31.1
France	1,527,209	1,164,034	43.3	2,691,243	63,195	42.6
Georgia	32,394	3,441	9.6	35,835	4,400	8.1
Germany	2,334,710	511,705	18.0	2,846,415	82,315	34.6
Greece	285,330	58,200	16.9	343,530	10,500	32.7
Hungary	300,000	55,811	15.7	355,811	10,077	35.3
Iceland	8,031	2,515	23.8	10,546	305	34.6
Ireland	94,970	23,620	19.9	118,590	4,240	28.0
Italy	1,310,625	228,829	14.9	1,539,454	59,000	26.1
Latvia	36,095	14,913	29.2	51,008	2,300	22.2
Lithuania	28,992	21,684	42.8	50,676	3,403	14.9
Luxembourg	13,421	1,146	7.9	14,567	440	33.1
Malta	7,725				401	
Montenegro	10,059	7,176	41.6	17,235	624	27.6
Netherlands	385,930	32,028	7.7	417,958	16,357	25.6
Norway	94,170	14,939	13.7	109,109	4,681	23.3
Poland	584,489	241,704	29.3	826,193	38,125	21.7
Portugal	263,501	41,288	13.5	304,789	10,700	28.5
Romania	226,361	83,110	26.9	309,471	21,000	14.7
Serbia		40,548	100.0		7,500	
Slovak Republic	100,204	27,835	21.7	128,039	5,393	23.7
Slovenia	96,367	11,870	11.0	108,237	2,000	54.1
Spain	818,031	297,985	26.7	1,116,016	43,929	25.4
Sweden	380,767	34,259	8.3	415,026	9,113	45.5
Switzerland	219,392	21,298	8.8	240,690	7,360	32.7
Turkey					75,000	

 # expressed as absolute numbers

Table 1.1 - *Profile of donations*

Country	WB donations			RBC apheresis		plasmapheresis donations	platelet apheresis
	% voluntary, non-remunerated	% from replacement donors	% from autologous donors	% voluntary, non-remunerated	% from autologous donors	% voluntary, non-remunerated	% voluntary, non-remunerated
Armenia	5	1	0.22	0			0
Austria	100	0	0.67	100	206	100	100
Belgium	100	0	0.14	100	0		100
Bosnia / Herzegovina	79	0					100
Bulgaria	25	0	0.13			0	0
Croatia	100		0.71			100	100
Cyprus	100						100
Czech Republic	100		4.02			92	34
Denmark	100		0.00			100	100
Estonia	100						89
Former Yug. Rep. Macedonia	94	0	0.40				17
Finland	100	0	0.00			100	100
France	100	0	0.80	100	0	100	100
Georgia	2	0					
Germany			1.75		19		
Greece	49	0	0.86	52		44	48
Hungary	100		0.25	100			100
Iceland	100		0.09	100		100	100
Ireland	100		0.00	100			100
Italy	100		4.51	100		100	100
Latvia	98	0	0.01	0		2	0
Lithuania	22	0					29
Luxembourg	100	0	0.87			100	100
Malta	100	0	0.00	100	0		100
Montenegro	20	1					
Netherlands	100	0	0.04	100	0	100	100
Norway	100		0.01	100		100	100
Poland	94	0	0.25	99	0	85	78
Portugal	100		0.62	100	0	233	100
Romania	100	0				100	100
Serbia	84	0	0.14				100
Slovak Republic	100	0	0.55	100	0		100
Slovenia	100	0	2.15	0		100	100
Spain	100		1.19	100		100	100
Sweden	100	0	0.04	100	2	100	0
Switzerland	100	0	1.33	100	13	100	100
Turkey	44	0					

Table 2 - *Collection of whole blood, autologous blood and blood components*

Country	WB collections				apheresis collections				
	WB (U)	WB per 1,000 inhabitants	autologous (U)	% autologous WB (U)	plasma apheresis (L)	plasma in L per 1,000 inhabitants	platelets apheresis (U)	RBC apheresis (U)	granulocytes apheresis (U)
Armenia	10,396	3.2	23	0.2	21	0.01	0	0	0
Austria	466,119	56.3	3,119	0.7	106,525	12.86	19,299	3,103	125
Belgium	547,515	52.1	787	0.1	62,191 donations		14,208	2,859	65
Bosnia / Herzegovina	39,875	19.0					332		
Bulgaria	148,993	19.3	188	0.1	76,950	9.97	410	0	0
Croatia	155,350	35.0	1,100	0.7	408	0.09	1,824		
Cyprus	48,119	62.5					270		
Czech Republic	405,800	39.4	16,300	3.9	50,700	4.92	15,300		few
Denmark	367,665	70.7	0	0.0	100	0.02	679	0	0
Estonia	53,795	40.0			0	0.00	906	0	0
Former Yug. Rep. Macedonia	17,427	8.6	70	0.4			31		
Finland	273,539	52.0	0	0.0	2,387	0.45	703	0	0
France	2,196,200	34.8	17,486	0.8	198,482	3.14	168,728	887	378
Georgia	32,394	7.4			910	0.21			
Germany	4,762,916	57.9	83,218	1.7	1,162,400	14.12	158,487	21,274	
Greece	603,312	57.5	5,200	0.9	650	0.06	29,320	1,960	
Hungary	421,394	41.8	1,033	0.2	0	0.00	4,562	12	73
Iceland	15,092	49.5	14	0.1	17	0.06	314	125	
Ireland	151,733	35.8	5	0.0	0	0.00	5,894	0	
Italy	2,404,267	40.8	108,487	4.3	208,409	3.53	64,537	27,770	1,153
Latvia	51,751	22.5	7	0.0	1,173	0.51	1,695		0
Lithuania	92,583	27.2					836		
Luxembourg	22,020	50.0	192	0.9	3,043	6.92	941	0	0
Malta	14,413	35.9	0	0.0	0	0.00	393	6	0
Montenegro	14,536	23.3							
Netherlands	578,145	35.3	216	0.0	168,199	10.28	3,842	70	473
Norway	200,972	42.9	25	0.0	3,467	0.74	4,040	4,144	0
Poland	957,041	25.1	2,387	0.2	9,206	0.24	18,843	285	115
Portugal	369,559	34.5	2,273	0.6	43	0.00	3,120	593	7
Romania	326,032	15.5			186	0.01	1,534		
Serbia	220,595	29.4	308	0.1	1,129	0.15	1,143		
Slovak Republic	170,207	31.6	944	0.6	0	0.00	4,180	28	15
Slovenia	83,760	41.9	1,798	2.1	552	0.28	1,244	0	1
Spain	1,587,885	36.1	18,908	1.2	16,984	0.39	13,488	878	72
Sweden	475,562	52.2	176	0.0	64,455	7.07	8,647	452	48
Switzerland	341,921	46.5	4,551	1.3	1,780	0.24	6,829	1,212	0
Turkey	528,849	7.1					64,512		

Table 3 - *Use of blood and blood components for transfusion*

Country	WB (U)	% WB of total RBCs	RBC concentrates (U)	RBC (U) per 1,000 inhabitants	plasma for transfusion (U)	platelets total (U)	platelets recovered (U)	platelets apheresis (U)	% platelets apheresis	CP (10^6 IU FVIII)
Armenia	12	0.1	9,547	3.0	9,393	273	273	0	0.0	0
Austria	0	0.0	435,912	52.6	61,903	36,263	10,445	25,818	71.2	
Belgium	0	0.0	508,686	48.4	89,218	64,067	36,127	27,940	43.6	0
Bosnia / Herzegovina	39,875		53,741		4,451	3,547	2,883	664	18.7	
Bulgaria	1,317		156,708		78,328	5,173	4,795	378	7.3	0
Croatia	2,205		146,589		80,900	13,741	11,917	1,824	13.3	0
Cyprus	48,119		96,238		35,000	19,000	18,730	270	1.4	0
Czech Republic	400	0.1	357,200	34.7	196,900	23,500	5,200	18,300	77.9	0
Denmark	0	0.0	348,231	67.0	65,792	29,800	27,464	2,336	7.8	0
Estonia	3		52,772		35,210	5,581	3,944	1,637	29.3	32,340
Former Yug. Rep. Macedonia	641	3.3	19,352	9.5	23,386	4,253	4,222	31	0.7	1,500,000
Finland	747	0.3	249,635	47.5	46,194	37,149	36,412	737	2.0	0
France	0	0.0	2,091,734	33.1	292,101	231,853	42,652	189,201	81.6	0
Georgia										
Germany	17,025	0.4	4,505,582	54.7	1,249,649	420,204	171,169	249,035	59.3	0
Greece	767	0.1	603,052	57.4	334,595	158,338	129,018	29,320	18.5	
Hungary	6	0.0	402,270	39.9	88,238	18,839	14,277	4,562	24.2	0
Iceland	0		14,934		5,333	1,039	509	530	51.0	0
Ireland	4	0.0	138,540	32.7	27,275	20,355	12,010	8,345	41.0	1,984
Italy	19,322	0.8	2,492,498	42.2	493,098					7,954
Latvia	5	0.0	46,498	20.2	46,562	4,800	1,567	3,233	67.4	3,025
Lithuania	5		88,749		35,728	6,283	4,651	1,632	26.0	780
Luxembourg	0	0.0	20,632	46.9	4,000	2,244	1,243	1,001	44.6	0
Malta	0	0.0	12,650	31.5	3,239	769	365	404	52.5	0
Montenegro	0		6,739		5,539	2,400				
Netherlands	0	0.0	556,725	34.0	92,380	56,376	51,896	4,480	7.9	0
Norway	57	0.0	194,955	41.6	45,005	18,057	12,459	5,598	31.0	49,500
Poland	210	0.0	905,375	23.7	358,612	67,237	39,011	28,227	42.0	8,398
Portugal	71	0.0	281,318	26.3	28,309	25,380	22,476	2,904	11.4	
Romania	111,864	34.3	325,789	15.5	202,072	67,584	66,037	1,547	2.3	17,537
Serbia	11,000		11,308		108,350	14,263	13,120	1,143	8.0	1,700,000
Slovak Republic	7,225	4.8	149,526	27.7	56,372	21,311	13,357	7,954	37.3	0
Slovenia	0	0.0	76,277	38.1	30,264	28,117	25,987	2,130	7.6	0
Spain	221	0.0	1,489,138	33.9	248,052	113,460	72,607	40,853	36.0	3,515
Sweden	0	0.0	463,705	50.9	116,481	35,165	21,222	13,943	39.7	0
Switzerland	4,219	1.4	308,120	41.9	74,577	21,885	1,853	20,032	91.5	0
Turkey	381,512		1,095,413		658,187	208,984	147,183	61,801	29.6	1,952

Table 4 - *Plasma for fractionation*

Country	plasma for fractionation (L)	plasma for fractionation per 1,000 inhabitants (L)	% fractionation plasma recovered	FFP per 1,000 inhabitants (U)	FFP / total RBC ratio (U/U)
Armenia	14	0.00	0.00	2.94	0.98
Austria	106,525	12.86		7.47	0.14
Belgium	179,553	17.10	64.92	8.50	0.18
Bosnia / Herzegovina	4,562	2.17	78.54	2.12	
Bulgaria	14,905	1.93		10.15	
Croatia	21,545	4.86		18.23	
Cyprus	0	0.00		45.45	
Czech Republic	82,900	8.05	55.49	19.12	0.55
Denmark	80,964	15.57	100	12.65	0.19
Estonia				26.18	
Former Yug. Rep. Macedonia				11.50	1.21
Finland	71,322	13.57	97.96	8.79	0.19
France	646,679	10.23	78.69	4.62	0.14
Georgia					
Germany	2,160,499	26.25	50.24	15.18	0.28
Greece	16,992	1.62		31.87	0.55
Hungary				8.76	0.22
Iceland	0	0.00		17.49	
Ireland	0	0.00		6.43	0.20
Italy	597,348	10.12	64.07	8.36	0.20
Latvia	400	0.17		20.24	1.00
Lithuania	11,027	3.24	100	10.50	
Luxembourg	7,144	16.24	72.26	9.09	0.19
Malta	0	0.00		8.08	0.26
Montenegro				8.87	
Netherlands	308,122	18.84	52.24	5.65	0.17
Norway	53,088	11.34		9.61	0.23
Poland	175,457	4.60	95.26	9.41	0.40
Portugal	0	0.00		2.65	0.10
Romania				9.62	0.62
Serbia	9,017	1.20	87.48	14.45	
Slovak Republic	28,256	5.24	100	10.45	0.38
Slovenia	10,763	5.38	94.87	15.13	0.40
Spain	302,105	6.88		5.65	0.17
Sweden	151,931	16.67	59.76	12.78	0.25
Switzerland	70,048	9.52	0.00	10.13	0.24
Turkey	0	0.00		8.78	

Table 5.1 - *Special processing of blood components*

Country	RBC		FFP		platelets	
	% leuco depleted	% irradiated	% leuco depleted	% irradiated	% leuco depleted	% irradiated
Armenia	0	0	0	0	0	0
Austria	100	7	100		100	36
Belgium	100		100		100	
Bosnia / Herzegovina	4					38
Bulgaria	6	1			7	1
Croatia	11				68	
Cyprus	80		50		100	
Czech Republic	11	5	0	2	60	40
Denmark	16	5	0	0	100	13
Estonia	5	2			14	9
Former Yug. Rep. Macedonia	3	0			1	
Finland	100	3	100	0	100	32
France	100	8	100	0	100	40
Georgia						
Germany	100	3		0	100	33
Greece	35	13	32	6	48	12
Hungary	8	4	2	28	58	10
Iceland	20	6	1	2	100	60
Ireland	100	3			100	80
Italy						
Latvia	11	1			100	29
Lithuania	9				26	
Luxembourg	100	1--2	100	0	100	1-2
Malta	100	1	100	0	100	1
Montenegro						
Netherlands	100	10	100	0	100	25
Norway	100	6			100	30
Poland	6	4	0	0	13	5
Portugal	100	13	100	0	100	100
Romania	7	2		1	1	1
Serbia	1	0	1		4	2
Slovak Republic	5	1			22	10
Slovenia	23	15			42	25
Spain	93				96	
Sweden	74	4	91	2	100	56
Switzerland	100		100		100	
Turkey						

Table 5.2 - *Pathogen reduction or quarantine of plasma*

Country	FFP		CP reduced plasma		CP	
	% quarantined	% virus inactivated	% quarantined	% virus inactivated	% quarantined	% virus inactivated
Armenia	0	0	0	0	0	0
Austria	38	63				
Belgium		100				
Bosnia / Herzegovina						
Bulgaria	0					
Croatia						
Cyprus		0		0		0
Czech Republic	100		100			
Denmark						
Estonia						
Former Yug. Rep. Macedonia						
Finland	2	18	0	0	0	0
France	55	45				
Georgia						
Germany	92	8	0	0	0	0
Greece	16	9				
Hungary	0	0	0	0	0	0
Iceland	0	0	0	0	0	0
Ireland		100	0	0	0	0
Italy						
Latvia	65					
Lithuania						
Luxembourg	0	100				
Malta	0	0	0	0	0	0
Montenegro						
Netherlands	100	0				
Norway						
Poland	99	0	100	0	100	0
Portugal	30	70			100	0
Romania	100		100		100	
Serbia						
Slovak Republic	30	0				
Slovenia	15	0	0	0	0	0
Spain	36	64				
Sweden	0	0				
Switzerland	85	15				
Turkey						

Table 6 - *Screening for infectious agents, serological test methods*#

Country	anti-HIV 1+2		HIVAg		HBsAg		Anti-HBc		anti-HCV		HCVAg		anti-HTLV I/II		syphilis		other tests	
	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B
Armenia	100				100	23			100						100		100	
Austria	100		17		100		17		100						100		100	
Belgium	100				100			100	100						100			
Bosnia / Herzegovina	100		100		100				100		100		100		100			
Bulgaria	100		100		100				100						100			
Croatia	100		100		100				100		80				100			
Cyprus	100		100		100				100						100			
Czech Republic	100		100		100				100		30				100		1	
Denmark	100		50		100				100					100				
Estonia	100		100		100				100		100				100			
Former Yug. Rep. Macedonia	100		100		100				100						100			
Finland	100				100				100		100			28	100			
France	100				100		100		100				100		100		40	
Georgia	100				100				100						100		100	
Germany	100				100		100		100						100			
Greece	100				100				100				100		100			
Hungary	100				100				100						100			
Iceland		100		100		100				100								
Ireland	100				100		100		100				100		100		75	
Italy	100				100				100						100		100	

 # expressed in per cent of total donation number **A = each donation** **B = first time donors**

Table 6 *(continued) - Screening for infectious agents, serological test methods*[#]

Country	anti-HIV 1+2		HIVAg		HBsAg		Anti-HBc		anti-HCV		HCVAg		anti-HTLV I/II		syphilis		other tests	
	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B
Latvia	100				100		100		100						100			
Lithuania	100				100				100						100			
Luxembourg	100	100	100	100	100	100		100	100	100			100	100	100	100	100	100
Malta	100				100		100		100						100		ALT	
Montenegro		100		100		100				100						100		
Netherlands	100				100				100				100		100			
Norway	100				100			100	100					100		100		
Poland	100	100	100	100	100	100			100	100				1.5	100	100		0.07
Portugal	100				100		100		100				100		100		ALT	
Romania	100		100		100				100				100		100			
Serbia	100		100		100				100						100			
Slovak Republic	100		100		100				100						100		100	
Slovenia	100		100		100		5		100						100			
Spain	100				100				100						100		0.011	
Sweden	100				100			100	100					100		100		
Switzerland	100				100				100						100		ALT	
Turkey	100				100				100							100		

 # expressed in per cent of total donation number **A = each donation** **B = first time donors**

Table 7.1 - *Confirmed seropositive donors*#

Country	HIV 1 / 2		HBV		HCV		HTLV-I/II		syphilis	
	1st time donors	repeat donor	1st time donors	repeat donor	1st time donors	repeat donor	1st time donors	repeat donor	1st time donors	repeat donor
Armenia	0									
Austria	4	5	47	13	30	20			18	20
Belgium	2	2	44	5	17	3			7	11
Bosnia / Herzegovina	0	0	18	0	5	0			2	0
Bulgaria	7		580	289	137	68			182	91
Croatia	0	1	26	34	13	16			7	14
Cyprus	2	0	18	6	4	0			6	7
Czech Republic	1	1	9	7	29	13			4	2
Denmark	0	3	6	0	5	1	0			
Estonia	7	3	20	7	48	11			2	2
Former Yug. Rep. Macedonia										
Finland	1	1	5	0	7	2	0	0	0	1
France	14	20	327	6	188	17	10	5	240	100
Georgia										
Germany	29	46	760	39	385	57			172	96
Greece	14	24	1139	285	185	44	3	2	52	23
Hungary	0	0	4	1	167	2			85	2
Iceland	0	0	0	1	0	0				
Ireland	1	0	3	1	2	0	0	0	1	2
Italy										
Latvia	6	4								
Lithuania	1		132	5	212	35			62	13
Luxembourg	0	0	0	0	0	0	0	0	0	0
Malta	0	0	1	0	2	0			0	0
Montenegro			53	1	42				24	1
Netherlands	1	4	21	5	5	5	0	0	13	10
Norway	0	1	4	2	5	2	0	0	4	0
Poland	213	12	1145	14	437	18	13	1	140	83
Portugal	17	13	39	10	68	27	1	2	167	109
Romania	16	8	3047	70	732	27	30	2	1074	78
Serbia										
Slovak Republic	0	0	39	10	14	11			2	12
Slovenia	0	0	12	3	4	2			1	6
Spain	58	50	465	37	410	24				
Sweden	1	1	17	1	20	3	2			
Switzerland	3	3	35	2	13	2			15	11
Turkey										

 # expressed as absolute number

Table 7.2 - *Prevelance and incidence of infectious diseases*

Country	HIV 1 / 2		HBV		HCV	
	prevelance per 100,000 first time tested donors	incidence per 100,000 repeat donors	prevelance per 100,000 first time tested donors	incidence per 100,000 repeat donors	prevelance per 100,000 first time tested donors	incidence per 100,000 repeat donors
Armenia	0.00					
Austria	6.78	1.72	79.70	4.47	50.87	6.87
Belgium	3.88	0.79	85.39	1.97	32.99	1.18
Bosnia / Herzegovina	0.00	0.00	111.61	0.00	31.00	0.00
Bulgaria	22.13		1833.30	250.96	433.04	59.05
Croatia	0.00	1.28	196.98	43.48	98.49	20.46
Cyprus	9.36	0.00	84.25	12.47	18.72	0.00
Czech Republic	4.37	0.34	39.30	2.36	126.64	4.39
Denmark	0.00	1.53	31.58	0.00	26.32	0.51
Estonia	96.97	11.98	277.05	27.96	664.91	43.94
Former Yug. Rep. Macedonia						
Finland	5.52	0.69	27.61	0.00	38.66	1.37
France	1.20	1.31	28.09	0.39	16.15	1.11
Georgia						
Germany	5.67	1.97	148.52	1.67	75.24	2.44
Greece	24.05	8.41	1957.04	99.88	317.87	15.42
Hungary	0.00	0.00	7.17	0.33	299.22	0.67
Iceland	0.00	0.00	0.00	12.45	0.00	0.00
Ireland	4.23	0.00	12.70	1.05	8.47	0.00
Italy						
Latvia	40.23	11.08				
Lithuania	4.61		608.74	17.25	977.68	120.72
Luxembourg	0.00	0.00	0.00	0.00	0.00	0.00
Malta		0.00		0.00		0.00
Montenegro			738.57	9.94	585.28	
Netherlands	3.12	1.04	65.57	1.30	15.61	1.30
Norway	0.00	1.06	26.78	2.12	33.47	2.12
Poland	88.12	2.05	473.72	2.40	180.80	3.08
Portugal	41.17	4.93	94.46	3.80	164.70	10.25
Romania	19.25	3.53	3666.23	30.92	880.76	11.93
Serbia						
Slovak Republic	0.00	0.00	140.11	9.98	50.30	10.98
Slovenia	0.00	0.00	101.10	3.11	33.70	2.08
Spain	19.46	6.11	156.05	4.52	137.59	2.93
Sweden	2.92	0.26	49.62	0.26	58.38	0.79
Switzerland	14.09	1.37	164.33	0.91	61.04	0.91
Turkey						

Table 8.1 - *Nucleic Acid Amplification (NAT) testing*

Country	HIV NAT			HBV NAT			HCV NAT		
	each donation#	first time donors	size minipool	each donation#	first time donors	size minipool	each donation#	first time donors	size minipool
Armenia									
Austria	Y		40-96	Y		40-96	Y		40-96
Belgium	Y		8				Y		8
Bosnia / Herzegovina									
Bulgaria									
Croatia									
Cyprus									
Czech Republic									
Denmark									
Estonia	Y		12				Y		12
Former Yug. Rep. Macedonia									
Finland							Y		96
France	Y		8 or 24	Y			Y		8 or 24
Georgia									
Germany	Y		max 96	N		max 96	Y		max 96
Greece	Y		24				Y		24
Hungary	N			N			N		
Iceland									
Ireland	Y		8				Y		8
Italy							Y		2 to 24
Latvia									
Lithuania	Y			Y			Y		
Luxembourg	Y		96	Y		96	Y		96
Malta									
Montenegro									
Netherlands	Y		48				Y		48
Norway							Y		24
Poland	Y		1-24	Y		1--24	Y		1-24
Portugal	Y			Y			Y		
Romania									
Serbia									
Slovak Republic	N		1	N		1	N		1
Slovenia							Y		24
Spain	Y		1-48				Y		1-48
Sweden									
Switzerland	Y	N	8-24	N	N		Y	N	8-24
Turkey	N	N		N	N		N	N	

 # Y = Performed N = Not performed

Table 8.2 - *NAT only positive results*#

Country	HIV 1		HBV		HCV	
	first time tested donor	repeat donor	first time tested donor	repeat donor	first time tested donor	repeat donor
Armenia						
Austria	0	0	0	0	0	0
Belgium	0	0			0	0
Bosnia / Herzegovina						
Bulgaria						
Croatia						
Cyprus						
Czech Republic						
Denmark						
Estonia					9	3
Former Yug. Rep. Macedonia						
Finland					0	1
France	1	2	1	0	1	0
Georgia						
Germany	3	2	1	3	0	5
Greece					2	
Hungary						
Iceland						
Ireland	0	0	0	0	0	0
Italy						
Latvia						
Lithuania			2	8	9	7
Luxembourg	0	0	0	0	0	0
Malta						
Montenegro						
Netherlands	0	0			0	0
Norway						
Poland	1	1	2	4	3	7
Portugal	13	0	5	0	14	0
Romania						
Serbia						
Slovak Republic						
Slovenia					0	0
Spain	4				2	
Sweden						
Switzerland	0	0			0	0
Turkey						

 # expressed as absolute number

Table 9 - *Bacterial screening*

Country	total platelets issued (adult therapeutic doses)	% platelets bacterial screened			% total platelets U confirmed positive
		recovered	apheresis	total	
Armenia	273				
Austria	36,263				
Belgium	64,067	100	79.7		0.05
Bosnia / Herzegovina	3,547				
Bulgaria	5,173	0.4			
Croatia	13,741	7.47	8.78		0.13
Cyprus	19,000				
Czech Republic	23,500				
Denmark	29,800			75	0.2
Estonia	5,581	100	100	100	
Former Yug. Rep. Macedonia	4,253				
Finland	37,149				
France	231,853	0	0	0	0
Georgia					
Germany	420,204	0	0	0	
Greece	158,338	2	2	0	
Hungary	18,839	6.7	10.6	0	0.04
Iceland	1,039				
Ireland	20,355	100	100	100	0.08
Italy					
Latvia	4,800	100	100	100	0.03
Lithuania	6,283	2.3	0.7	3	
Luxembourg	2,244				
Malta	769	23	10	16	0.5
Montenegro	2,400			0	
Netherlands	56,376	100	100	100	0.35
Norway	18,057	80	80	80	
Poland	67,237	0.6	0.1	0.7	0.2
Portugal	25,380				
Romania	67,584	50	100	0	
Serbia	14,263	0.5	1	0.52	
Slovak Republic	21,311	3	3	3	0
Slovenia	28,117	12	10	11	0.1
Spain	113,460				
Sweden	35,165			32	0.001
Switzerland	21,885			0	
Turkey	208,984				

Table 10 - *Organisation and registration*#

Country	National Council or Expert Committee	National blood policy		National regulations
		on quality and safety	implementing	
Armenia	N	N		Y
Austria	Y	Y	Y	Y
Belgium	Y	Y		Y
Bosnia / Herzegovina	Y	Y	Y	Y
Bulgaria	N	Y	Y	Y
Croatia	Y	N		Y
Cyprus	N			Y
Czech Republic	Y	Y	Y	Y
Denmark	Y	Y	Y	Y
Estonia	N	N	N	Y
Former Yug. Rep. Macedonia	N	N		
Finland	N	Y	Y	Y
France	Y	Y	N	Y
Georgia	Y	N		Y
Germany	Y	Y	N	Y
Greece	Y	Y	Y	Y
Hungary	Y	Y	Y	Y
Iceland	N	N	N	Y
Ireland	N	N	N	Y
Italy	Y	Y	Y	Y
Latvia	Y	Y	Y	Y
Lithuania	N	Y	Y	Y
Luxembourg	N	N	N	Y
Malta	Y	Y	Y	Y
Montenegro	Y			
Netherlands	Y	Y	Y	Y
Norway	Y	Y	N	Y
Poland	N	Y	Y	Y
Portugal	N	Y	Y	Y
Romania	Y	Y	Y	Y
Serbia	Y	Y	Y	Y
Slovak Republic	Y	Y		Y
Slovenia	Y	Y		Y
Spain	Y	Y	Y	Y
Sweden	N	Y	Y	Y
Switzerland	N	Y	Y	Y
Turkey	Y	N		Y

 # Y = Performed N = Not performed

Table 11a - *Quality Management*#

Country	QMS established and maintained	% donations covered by			inspections each second year	system of education and training	% donations labelled according to		% component code according to		haemovigilance system operated
		% GMP	% ISO 9000	% other			ISBT 128	another system	ISBT 128	another system	
Armenia	N				N	N	100				N
Austria	Y	100	100		Y	Y		100		100	Y
Belgium	Y	66.4	34.7		Y	Y	92.6	7.4	93.3	6.7	Y
Bosnia / Herzegovina	Y			100	N	N		100		100	
Bulgaria	Y	100			Y	Y		100			Y
Croatia	Y	100	48			Y		100			
Cyprus	Planned				N	N					N
Czech Republic	Y	100	40		Y	Y		100		100	Y
Denmark	Y	100			N	Y	100		100		Y
Estonia	Y	100			Y	Y	100		100		Y
Former Yug. Rep. Macedonia	Planned				N	Y					N
Finland	Y	100			Y	Y	100		100		Y
France	Y		100		Y	Y		100		100	Y
Georgia	Planned				N	N					N
Germany	Y	100			Y	Y		100		100	Y
Greece	Y	70	7		Y	Y	0.1	99.9			Y
Hungary		100			Y	Y					Y
Iceland	Y		90		Y	N	93		93		N
Ireland	Y	100	Planned		Y	Y		100		100	Y
Italy	Planned				N	Y		95		82	Y

 # Y = Established and maintained N = Not established

Table 11a *(continued) - Quality Management*[#]

Country	QMS established and maintained	% donations covered by			inspections each second year	system of education and training	% donations labelled according to		% component code according to		haemovigilance system operated
		% GMP	% ISO 9000	% other			ISBT 128	another system	ISBT 128	another system	
Latvia	Y		30		Y	Y					Y
Lithuania	Y	60			Y	Y		100			Y
Luxembourg	Y	100	100		Y	Y		100		100	Y
Malta	Y			100	Y	Y		100		100	Y
Montenegro	Planned					N		100			N
Netherlands	Y	100	25		Y	Y	100	0	100	0	Y
Norway	Y	100	41		N	Y	90		90		
Poland	Y	100	56.3		Y	Y		100		100	Y
Portugal	Y	100	90		Y	Y	80	20	80	20	N
Romania	Planned				N	Y		100			Y
Serbia	Planned	13	13		Y	Y	7.33	92.67	5.6	94.4	Y
Slovak Republic	Y	100			Y	Y	40	60	0	100	Y
Slovenia	Y	100	70		Y	Y		100		100	Y
Spain	Y		100		Y	Y	44	56	44	56	Y
Sweden	Y	100		83	Y	Y	89	11	89	11	Y
Switzerland	Y	100	65	90	Y	Y	100		100		Y
Turkey	Planned					Y					N

 # Y = Established and maintained N = Not established

Table 11b - *Quality Management*#

Country	QMS established and maintained	% donations covered by			comment	inspections each second year	inspections performed by	system of education and training
		% GMP	% ISO 9000	% other				
Armenia	N					N		N
Austria	Y	100	100			Y	Pharmazeutische Industrie (Plasmaabnehmer): once per year	Y
Belgium	Y	66.4	34.7			Y	By independent plasma fractionation department; if covered by 9000 series: also inspected by body for ISO certification.	Y
Bosnia / Herzegovina	Y			100		N		N
Bulgaria	Y	100				Y	National Drug Agency	Y
Croatia	Y	100	48					Y
Cyprus	N				Implementation of QMS planned	N		N
Czech Republic	Y	100	40			Y	State Institute for Drug Control	Y
Denmark	Y	100				N		Y
Estonia	Y	100			GMP donation are covered partly by ISO 9000 also but there is no exact data on the actual coverage.	Y	National Authority	Y
Former Yug. Rep. Macedonia	N				Implementation of QMS planned	N		Y
Finland	Y	100				Y	Finnish National Accreditation Service	Y
France	Y		100			Y	AFSSaPS (Regulatory Authority)	Y
Georgia	N				Implementation of QMS planned	N		N
Germany	Y	100				Y		Y
Greece	Y	70	7			Y	National Authority and the Coordinating Haemovigilance Centre (SKAE) of the Hellenic Center of Diseases Control and Prevention (KEELPNO)	Y
Hungary		100				Y		Y
Iceland	Y		90			Y	BSI (British Standards Institution)	N
Ireland	Y	100	Planned			Y	Irish medicines Board inspects IBTS twice a year	Y
Italy	N				Implementation of QMS planned	N		Y
Latvia	Y		30			Y	National Authority	Y

 # Y = Established and maintained N = Not established

Table 11b *(continued) - Quality Management*[#]

Country	QMS established and maintained	% donations covered by			comment	inspections each second year	inspections performed by	system of education and training
		% GMP	% ISO 9000	% other				
Lithuania	Y	60				Y	National Authority	Y
Luxembourg	Y	100	100		QMS is certified ISO9001:200 by TÜV Süddeutschland	Y	National Authority, every 6 months in the blood establishment	Y
Malta	Y			100		Y	National Authority	Y
Montenegro	N				Implementation of QMS planned			N
Netherlands	Y	100	25			Y		Y
Norway	Y	100	41			N	Not all blood banks are inspected every second year, but many are.	Y
Poland	Y	100	56.3			Y	National Authority	Y
Portugal	Y	100	90			Y	National Authority+ ISO	Y
Romania	N				Each blood component unit is labelled according to the legislation in force. Implementation of QMS planned	N		Y
Serbia	N	13	13		Implementation of QMS planned	Y	In one regional center there is GMP and ISO 9000 and inspection is perfomed by the qualified body, while in the remaining centres inspection is performed by the national authority.	Y
Slovak Republic	Y	100			Local SOPs and instructions: 100% only for National Blood Transfusion Service	Y	National Authority, Baxter, Biotest, Octapharma, Grifols	Y
Slovenia	Y	100	70			Y	National Authority and organisations accredited to perform the ISO 9001:2000 certification procedures	Y
Spain	Y		100			Y	Autonomous Local Authorities perform inspection, and usually is limited to a first inspection before a centre opens. 7 Autonomous Communities have started regular inspection programmes (= 2005)	Y
Sweden	Y	100		83	EN ISO/IEC 17140 or EN ISO 15189. 57 % of the BE have a specific technical accreditation for transfusion medicine, the others for the overall laboratory services.	Y	The Swedish National Board of Accreditation and Conformity Assessment (voluntary)	Y
Switzerland	Y	100	65	90		Y	National Authority	Y
Turkey	Planned							Y

**Y = Established and maintained** **N = Not established**

Table 11c - *Quality Management*[#]

Country	% donations labelled		% components coded according to		comments	haemovigilance system	
	ISBT 128	another system	ISBT 128	another system		available	operated by
Armenia	100					N	
Austria		100		100	Austria has its own system for the identification of donor type, product type, test results, product losses and product delivery given to hospitals.	Y	Up to 2007: Österreichisches Bundesinstitut für Gesundheitswesen (ÖBIG); Ab 2008: Gesundheit Österreich GmbH (GÖG); Overall management: Bundesministerium für Gesundheit, Familie und Jugend
Belgium	92.6	7.4	93.3	6.7	System developed in-house with codabar 39 or code 128** or ISBT 128-like	Y	National Authority
Bosnia / Herzegovina		100		100	Use of local system, but currently in the process of implementation of ISBT 128 code.		
Bulgaria		100			Unified national labelling system	Y	National Drug Agency
Croatia		100			Codabar		
Cyprus						N	
Czech Republic		100		100	National system in use since 1995 (ISBT compatible in major items)	Y	Obligatory national system covers serious adverse events / reactions related to the quality of product and donor epidemiology
Denmark	100		100			Y	
Estonia	100		100			Y	National Authority
Former Yug. Rep. Macedonia						N	
Finland	100		100			Y	The national Agency for Medicines inspects the haemovigilance system and results are reported to the agency according to EU directives and national law and decree
France		100		100	MONARCH	Y	National Authority (AFSSAPS)
Georgia						N	
Germany		100		100		Y	
Greece	0.1	99.9			Blood Med - Altec 55%, Blood - Pleroforiki 44.9%	Y	The National Coordinating Haemovigilance Centre (SKAE) of the Hellenic Center of Diseases Control and Prevention (KEELPNO). The submission of data by blood services is not mandatory.
Hungary						Y	
Iceland	93		93			N	The Blood Bank collects data on haemovigilance

**Y = Yes** **N = No**

Table 11c *(continued) - Quality Management*[#]

Country	% donations labelled		component code		comments	haemovigilance system	
	ISBT 128	another system	ISBT 128	another system		available	operated by
Ireland		100		100		Y	National Haemovigilance Office is located at the National Blood Centre, IBTS
Italy		95		82	UNI (Unified Italian Codes)	Y	
Latvia						Y	National Authority
Lithuania		100				Y	National Authority
Luxembourg		100		100	CODABAR	Y	Collaboration CNA-Red Cross BE
Malta		100		100	CODABAR	Y	
Montenegro		100				N	Adverse reactions are not regularly reported in Montenegro. Only a few cases in BTC CC in Podgorica have been reported.
Netherlands	100	0	100	0		Y	TRIP (Transfusion Reactions in Patients) Dutch National Hemovigilance Office, run by a foundation created by representatives of professional societies
Norway	90		90				Norwegian association for immunology and transfusion medicine.
Poland		100		100	Donation number: Polish, national standard. Component code: 4 different national codes (software dependent)	Y	National Authority
Portugal	80	20	80	20		N	
Romania		100			National system	Y	National Authority
Serbia	7.33	92.67	5.6	94.4	In one regional center there is labelling of the donations and components according ISBT 128	Y	National Authority
Slovak Republic	40	60	0	100		Y	Haemovigilance reporting system is operated by National Drug Agency
Slovenia		100		100	CODABAR SYSTEM	Y	Blood Transfusion Centre of Slovenia (collecting data & reporting to the national authority)
Spain	44	56	44	56	CODABAR SYSTEM	Y	National Authority
Sweden	89	11	89	11	Previously used a national coding system	Y	National authority and the Swedish Society for Transfusion Medicine.
Switzerland	100		100			Y	
Turkey						N	

**Y = Yes** **N = No**

Table 12 - *Hemovigilance*

Country	total number components transfused: WB + RBC + FFP + Platelets	Absolute number of serious adverse reactions with likely, probable or certain imputability (level 2 or level 3)																incidence high imputability serious adverse reactions per 100,000 components (U)
		Hemolysis ABO	Hemolysis other allo-antibody	Non immun. Hemol.	PT Purpura	Anaphy-laxis	TRALI	GVHD	TA-HBV	TA-HCV	TA-HIV	TA-Other viral	TA-Bacterial	TA-Malaria	TA-Parasitic	TA-TACO	TA-Other serious	
Armenia	19,213																	
Austria	534,078																	
Belgium	661,971	10	9	1		10	1		1				4			2	14	7.9
Bosnia / Herzegovina	61,739																	
Bulgaria	240,209		2															0.8
Croatia	241,230	2	11			10	1		1							7		13.3
Cyprus	150,238																	
Czech Republic	577,600		1			24	4						1					5.2
Denmark	443,823																	
Estonia	93,563																	
Former Yug. Rep. Macedonia	46,991																	
Finland	332,978	4	3	1		1												2.7
France	2,615,688	1	5			27	18					1	4			69	9	5.1
Georgia																		
Germany	6,175,435	4	13			4	7		4				7					0.6
Greece	1,095,985	6	6			30	5				2		2				5	5.1
Hungary	509,347	8																1.6
Iceland	21,306					2												9.4
Ireland	186,170		5			25	1									23	22	40.8

Table 12 *(continued) - Hemovigilance*

Country	total number components transfused: WB + RBC + FFP + Platelets	Absolute number of serious adverse reactions with likely, probable or certain imputability (level 2 or level 3)																incidence high imputability serious adverse reactions per 100,000 components (U)
		Hemolysis ABO	Hemolysis other allo-antibody	Non immun. Hemol.	PT Purpura	Anaphy-laxis	TRALI	GVHD	TA-HBV	TA-HCV	TA-HIV	TA-Other viral	TA-Bacterial	TA-Malaria	TA-Parasitic	TA-TACO	TA-Other serious	
Italy	2,985,596	21	1			552	7						2			18	1	20.2
Latvia	97,860																	
Lithuania	130,760					1												0.8
Luxembourg	26,876																	
Malta	16,658	1				1										1		18.0
Montenegro	14,678																	
Netherlands	705,481		11			17	11		2							15	14	9.9
Norway	258,017	1				1										3	4	3.5
Poland	1,331,223																	
Portugal	335,007																	
Romania	595,445	1																0.2
Serbia	133,921																	
Slovak Republic	227,208					13										4	9	11.4
Slovenia	134,658					1							1			6	1	6.7
Spain	1,850,650	1	7			26							3			13		2.7
Sweden	615,351																	
Switzerland	404,582	2				11	9		1							3	3	7.2
Turkey	1,962,584																	
TOTAL		62	74	2	0	756	64	0	9	0	2	1	24	0	0	164	82	

APPENDIX

Questionnaire on the collection, testing and use of blood and blood components in Europe
The 2006 Survey

REPORTING FROM COUNCIL OF EUROPE MEMBER STATES ON HE 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.

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 for infectious diseases (tables 7 + 8) are congruent with those requested by the 'Guideline on epidemiological data on blood transmissible infections' by the EMA (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 World Health Organisation (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-emanuelle.behr-gross@edqm.eu with a copy to Dr C.L. van der Poel, c.l.vanderpoel@umcutrecht.nl.

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

Population in country, number	

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 years in 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 (procedures)	

[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 ☐ distributed to hospital blood banks, *or* ☐ transfused		
3.1	Whole blood, **units[1], total number**	
3.2	**Red cells** (red cells for transfusion, *excl*. 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 10^9 platelets.

Comments to the data given in Table 3

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.	- recovered from whole blood donations, litres	
4.1.1.	- 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** (<1x10^6/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**	**Percent of plasma components**	
		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 1st time donation**	**Every donation**	(if not all donations tested:) **% donations tested**	**Comments**
6.1.1	anti-HIV 1+2	☐	☐		
6.1.1.1	HIV-Ag	☐	☐		
6.1.2	HBsAg	☐	☐		
6.1.2.1	anti-HBc	☐	☐		
6.1.3	anti-HCV	☐	☐		
6.1.3.1	HCV-Ag	☐	☐		
6.1.4	anti-HTLV I/II	☐	☐		
6.1.5	Syphilis[1]	☐	☐		
6.1.6	Malaria	☐	☐		
6.1.7	Others[2]	☐	☐		
		☐	☐		
		☐	☐		
		☐	☐		

[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 *ONLY*?				
	Screening test	**Yes,** all donations	**Yes,** % of donations	**No**	**Comments**
6.2.1	anti-HIV 1+2	☐	☐ %	☐	
6.2.2	HBsAg	☐	☐ %	☐	
8.2.3	anti-HCV	☐	☐ %	☐	

Comments to the data given in Table 6.2

7. Confirmatory testing

7.1	**Are repeatedly reactive screening test results subjected to confirmatory testing?** ☐ Yes, always ☐ Yes, approximately _____ % of them ☐ No

7.2 Confirmed seropositive test results

7.2	**Confirmed seropositive**[1]	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 1st time donor**	**every donation**	Comments
8.1.1	HIV NAT	☐	☐	
8.1.2	HBV NAT	☐	☐	
8.1.3	HCV NAT	☐	☐	
8.1.4	other NAT	☐	☐	please specify:

8.2	Size of **mini-pool**(s)	HIV:	HBV:	HCV:

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	☐ Yes	☐ No

10.2	**National Blood Policy**		
10.2.1	- is there a national blood policy on the quality and safety of blood and blood components?	☐ Yes	☐ No
	If yes,		
10.2.2	- is there a national blood plan on implementing the national blood policy?	☐ Yes	☐ No

10.3	**National Regulations** - are there national regulations, legally binding, for the collection, testing, processing, storage and distribution of blood and blood components?	☐ Yes	☐ No

Comments to the information given in Table 10

11. Quality management related issues

11.1	**Quality system established and maintained in blood establishments**		☐ Yes ☐ Planned ☐ No		
	Percent of donations covered by	GMP	ISO 9000 series	Local SOPs and instructions	Other *
		%	%	%	%
	* please, specify:				

11.2	Are **inspections** performed at least each second year? ☐ No ☐ Yes, by ☐ a national authority ☐ 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? ☐ Yes ☐ No

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

Comments to the information given in Table 11

12. Haemovigilance

12.1	Is there a **haemovigilance reporting system** on national level? ☐ No ☐ Yes, - operated by a national authority ☐ Yes, - operated by another organisation* - if "Yes", please give haemovigilance data, if available, in Table 12.2
	*please, specify:

12.2 Haemovigilance data Serious adverse reactions* observed in recipients of blood or blood components:		Serious adverse reactions* reported				
		- total	- with imputability level*			
		number	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

For further information concerning the work of the Council of Europe / EDQM in the area of blood transfusion please contact:

Dr Marie-Emmanuelle Behr-Gross
Department of Biological Standardisation,
OMCL Network & HealthCare
EDQM, Council of Europe
7 allée Kastner
CS 30026
F-67081 STRASBOURG
FRANCE
Tel: +33 (0)3 90 21 41 08
Fax: +33 (0)3 88 41 27 71
E-mail: marie-emmanuelle.behr-gross@edqm.eu

European Directorate for the Quality of Medicines & HealthCare (EDQM)
Council of Europe
7 allée Kastner
CS 30026
F-67081 STRASBOURG
FRANCE
Website: www.edqm.eu
For ordering: www.edqm.eu/store
FAQs & EDQM HelpDesk: www.edqm.eu/hd

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