2008 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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2008 Report

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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 2008. In its present form it follows a series of similar reports that have assessed such data in 1989, 1991, 1993, 1995, 1997 and, in its present revised form, as of the 2001 survey.

A Qualitative Evaluation Report on the questionnaire with recommendations for improvement of the process was performed and was reported in November 2004, including experience with data presentation from the 3 previous years. The format of the questionnaire was reviewed and re-designed by the authors and the CoE experts of the Committee of Experts on Quality Assurance in Blood Transfusion Services (SP-GS) and the Committee of Experts on Blood Transfusion (SP-HM) bureau in 2004.

Also, in 2008 as for former years, not all relevant data was obtained from each MS. Due to difficulties in implementation of data retrieval from automated blood banking systems, and the collation of 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 years 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 of this information 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 if data is reported in different formats. In addition, some data may not be available from all respondents. It is anticipated that consistency and persistence with these CoE survey methods, in collaboration with the EC, will result in adaptation of the BE and MS towards uniform data collecting, and thereby the generation of 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 of Blood and Blood Components, 9th edition, 2003*). 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 data.

In total, 33 questionnaires were received in 2008; the response rate (72%) is lower than previous years, despite the fact that an easier (web-based) system for data entry has been established. For the 2001 to 2007 surveys the response rates were 84%, 60%, 67%, 73%, 72%, 80% and 76%, respectively.

The average number of donors in relation to the general population is 29 (range 9-63) per 1000 inhabitants. On average 19% of the donor base consists of first time donors.

The number of whole blood (WB) collections is, on average, 39 per 1000 inhabitants, the average use of red blood cells (RBC) is 41 per 1000 inhabitants.

On average 2.6 litres (L) of plasmapheresis plasma per 1000 inhabitants are collected.

Blood use is either expressed in units issued by the BE (77% of the reporting MS), or reported as transfused units (23% of the reporting MS). The use of RBC varies considerably (range 9 - 60) and averages 41 total RBC Units (U) per 1000 inhabitants. In three of the reporting MS, less than 20 U per 1000 inhabitants are used, most likely reflecting an insufficient supply. In the reporting MS, on average 38% of the total platelet volume is supplied by (random) single donor platelets by apheresis; in 10 countries this volume amounts to more than 50%.

The amount of plasma delivered for fractionation into medicinal products differs greatly (range 0-31) among MS; an average yield of 8.2 L of plasma for fractionation per 1000 inhabitants is found. However, 17% of reporting MS deliver 15 L or more per 1000 inhabitants. In Europe, on average, 51% of the plasma for fractionation is from recovered plasma.

In 45% of the MS, 100% leucocyte depletion of RBC is carried out. Platelet concentrates and Fresh Frozen Plasma (FFP) are 100% leucocyte depleted in 55% and 33% of reporting MS, respectively. In 38% of the reporting MS all FFP is additionally safeguarded by either quarantine or pathogen reduction methods.

In all reporting MS, each donation is tested for anti-HIV-1/2, HBsAg and anti-HCV. In 91% of the reporting MS, all donations are tested for syphilis. Anti-HTLV-I/II testing is performed on all donations in 20% of reporting MS, and on first time donors in 7%. Anti-HBc is performed on all donations in 21% of the MS, and only on first time donors in another 14%. Prevalence and incidence of infectious diseases vary greatly among MS, and it is noted that in Europe a North-South gradient exists for the frequencies of hepatitis B (HBV) and C virus (HCV). The median prevalence amongst 'first time tested donors' is 6.9, 115 and 63 per 100 000 donors for HIV-1/2, HBV and HCV respectively. The median incidence amongst 'repeat donors' is 0.6, 1.7 and 2.0 per 100 000 donor years for HIV-1/2, HBV and HCV respectively.

Nucleic Acid Amplification Techniques (NAT) testing for HCV is performed on each donation in 57% of reporting MS, whereas HIV NAT and HBV NAT is performed on each donation in 59% and 36% of the MS, respectively.

Bacterial screening on platelet concentrates is performed in 73% of the MS. Screening of 80% or more of the platelet concentrates is performed in 21% of the MS. Haemovigilance data have repeatedly demonstrated the importance of bacterial safety for platelet concentrates.

All MS report that legally-binding national regulations for the collection, testing, processing, storage and distribution of blood and blood components are in place. In 76% of the reporting MS a National Council or Expert Committee to advise the Ministry of Health on transfusion-related policy issues exists. In 80% of the MS, a national blood policy on the quality and safety of blood and blood components is in place.

In 91 % of the reporting MS, a Quality System (QS) is established and maintained in BE. All donations are covered by ISBT, GMP or other procedures in 83% (25/30) of reporting MS. All donations are covered by Good Manufacturing Practices (GMP) in 20/24 MS reporting to have GMP. In 94% of the reporting MS, inspections are performed by the national authority at least every 2 years.

Labelling according to International Society for Blood Transfusion (ISBT)-128 or other procedures for donation tracking is performed by 87% of reporting MS. Labelling of all components by either ISBT 128 or another system is done by 86% of reporting MS.

Haemovigilance reporting in this survey began in 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 or certainly (imputability grade 2 to 3) ascribable to transfusion of blood products, and data on some conditions that are not caused by these products themselves, such as TACO (Transfusion Associated Circulatory Overload), are

also reported. A national haemovigilance reporting system is present in 88% of the MS. Taking into account the possibility of under-reporting and the differences in national reporting systems, an overall incidence of approximately 6.9 serious adverse reactions per 100 000 distributed blood components is estimated. This estimate is based on data provided by 23 MS. Haemolysis, anaphylaxis, Transfusion Related Acute Lung Injury (TRALI) and TACO and transfusion associated HCV infections appear to be the most 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
FYR Macedonia	The former Yugoslav Republic of Macedonia
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 Autologous 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 Creutzfeldt-Jakob disease
WB	Whole Blood
WHO	World Health Organisation

STUDY METHODS

The methods in this survey are, in principle, the same as those used in previous surveys, with the following modifications. As of the 2007 survey, a dedicated web-based application was developed for performing data collection. Each MS nominated an expert who was granted access to the website and could complete, repeatedly edit and, thereafter, finalise an on-line electronic datasheet for its respective MS. Data collection was completed on 1 November 2010. This report was presented in a draft form to the European Committee (Partial Agreement) on Blood Transfusion (CD-P-TS) in November 2010 for review and approval by MS representatives.

Trend analysis

Comparisons with results from the previous surveys and trend analyses are foreseen. Initial trend analyses have been published (van der Poel *et al,* 2011) 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 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 by transcription of the data by the authors has been eliminated.

RESULTS

Response rate

The 46 MS of the Council of Europe (CoE) were invited to participate in the 2008 survey. Replies were received at the deadline for submission on 1 November 2010 from 33 MS; a response rate of 72%. For the 2001 to 2007 surveys, the response rates were 84%, 60%, 67%, 73%, 72%, 80% and 76%, respectively. It is possible that the longer period between the beginning and end of data collecting allowed more MS to report. 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. Definitions have 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 reporting years earlier) and for repeat donors (i.e. donors whose last previous donation was more than 2 reporting 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 tested donors' includes all donors who are actually tested for the first time in the reporting year. ´First time donors´ includes all donors who donated for the first time in the reporting year. 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 themselves.

Excluding the 13 MS where first time donors and repeat plus regular donors were not reported separately, 19 % (range 7-53) 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) and that higher incidence translates into an enhanced risk of donations being released with undetected viraemia.

The average number of donors in relation to the general population is 29 (range 9-63) per 1000 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 1000 inhabitants should pose a problem with supply and around 30 donors per 1000 inhabitants seems an achievable goal from the given data. Not all countries with a relatively high number of donors per 1000 inhabitants deliver high numbers of red blood cell (RBC) Units (U) to 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 28 reporting MS, is on average 39 (range 9-64) per 1000 inhabitants. Given the average use of RBC of 41 (range 9-60) per 1000 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. It is noteworthy that the average use of RBC is slightly higher than the average of WB collections. This is due to the fact that a number of countries with a relatively low number of collections did not provide data on RBC use. For countries that provided numbers for both collection and RBC use, the latter is on average 4% lower than the number of units collected per 1000 inhabitants.

- **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 0.5% (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 1000 inhabitants reflects the volume of the national plasmapheresis programs. In 31 reporting MS, on average 2.6 litres (L) (range 0-20L) of plasma per 1000 inhabitants is collected by plasmapheresis. Apparently, the Czech Republic, Germany and The Netherlands stand out as countries with considerably more extensive plasmapheresis programmes, with about 10 L or more of plasmapheresis plasma per 1000 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 24 reporting MS, on average 38 % (range 0-93%) 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 programmes, 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, for example by exceeding expiry dates, 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.

In 24 / 31 (77%) reporting MS, the use of blood is expressed as the units distributed by the blood establishments, in 7 it is reported as transfused units, and 2 MS have not reported this information.

WB must be considered as a source material and has no, or only a very restricted, use 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 22 reporting countries, on average 2.2% (range 0-50%) of the RBC transfusions are performed with WB. In the Former Yugoslavian Republic of Macedonia, the use of WB accounts for more than half of the total volume of RBC products used.

The use of RBC per 1000 inhabitants varies considerably. In 22 reporting MS it averages 41 total RBC products per 1000 inhabitants (range 9-60). Rejman (2000) suggested in his report on the 1997 survey that 40 – 60 WB donations per 1000 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 programmes for 'better use of blood' or for 'optimal use of blood' have recently been established in order to reduce unnecessary donor exposure to patients. Therefore, the use of 30 to 40 RBC U per 1000 inhabitants could reflect the results of

these programmes. In 3 / 24 (13%) of the reporting MS, less than 20 units per 1000 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 (FFP) has been discouraged over the last decade, mainly because its clinical indications are limited and more plasma was needed 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 0.34 (range 0.005-1, Table 4).

In Europe, platelets are generally recovered from 4-5 buffy-coats of WB donations. Discussions on blood safety in relation to Variant Creutzfeldt-Jakob 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, 38% (range 0-93%) of the adult therapeutic doses of platelets are produced by (random) single donor platelets by apheresis (Table 3). In 10 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 25 reporting MS, an average yield of 8.2 L (range 0-31 L) per 1000 inhabitants is found of plasma for fractionation into medicinal products. However, 5 / 30 (17%) of reporting MS deliver 15 L or more plasma per 1000 inhabitants.

In Europe, the main supply of plasma for fractionation is recovered plasma; in 17 reporting MS, on average 51% 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 13 / 29 (45%) of reporting MS, 100% leucocyte depletion of RBC products is carried out. This is the case for platelet concentrates in 16 / 29 (55%) reporting MS (1 country applies it to 99% of platelets). Hundred percent leucocyte depletion is applied for plasma for transfusion in 9 / 27 (33%) 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 10 / 24 (42%) reporting MS, nearly all FFP is safeguarded by either method, in 2 / 27 (7%) MS for 100% by quarantine, in 6 / 28 (21%) by 100% pathogen reduction (one of these MS reported for only 98% or more of FFP), and in 3 / 29 (10%) MS by a combination of both. In 38% of the reporting MS, all FFP plasma is safeguarded by one of these measures.

Screening for infectious agents, serological test methods: Table 6

In all 33 reporting MS, all donations are tested for anti-HIV-1/2, HBsAg and anti-HCV. In 30 / 33 (91%) of these MS, all donations are tested for syphilis. It is debated in the literature whether systematic syphilis testing is necessary.

Testing for anti-HTLV-I/II is performed on all donations in 6 / 30 (20%) reporting MS, and only on first time donors in 2 (7%) MS.

Testing for anti-HBc is performed on all donations in 6 (21%) reporting MS, and only on first time donors in 4 (14%) MS.

Confirmed seropositive donors, 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 28 of 33 (85%) 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 (excluding the entry from FYR Macedonia, which is erroneous), ranges from 0 to 747 for HIV-1/2, from 0 to 31,919 for HBV and 0 to 57,895 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 (Georgia and Bulgaria) 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. Median estimates might, therefore, be more appropriate values as a reference for European prevalence amongst first time donors. The median prevalence amongst first time tested donors is 6.9, 115 and 63 per 100 000 donors for HIV-1/2, HBV and HCV respectively.

- **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 southern countries.

The incidence per 100 000 repeat tested donor years, if calculated from the provided data sets, ranges from 0 to 75 for HIV-1/2, from 0 to 1,003 for HBV and 0 to 225 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 (FYR Macedonia) 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). Again, the median incidence amongst repeat donors is 0.6, 1.7 and 2.0 per 100 000 donor years for HIV-1/2, HBV and HCV, respectively.

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

NAT testing for HIV is performed on each donation in 17 / 29 (59%) reporting MS. NAT testing for HBV is performed on each donation in 10 / 28 (36%) reporting MS. NAT for HCV is performed on each donation in 16 / 28 (57%) of the reporting 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 24 / 33 (73 %) MS. In 5 / 24 (21%) MS, culture is performed on over 80% of all platelets (concentrates recovered both from WB donations and apheresis platelets).

Organisation and registration: Table 10

All 33 MS report that there are legally-binding national regulations for the collection, testing, processing, storage and distribution of blood and blood components. In 25 / 33 (76%) of the reporting MS a National Council or Expert Committee advises the Ministry of Health on transfusion related issues. In 24 / 30 (80%) MS, a national blood policy on the quality and safety of blood and blood components is being implemented.

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

In 29 / 32 (91%) of the reporting MS, a Quality System (QS) is established and maintained by BE. In 20 / 24 (83%) of the reporting MS, 100% of the donations are covered by GMP. In 3 countries that have no GMP, 100% of donations are covered by ISO 9000. Four countries have both 100% GMP and 100% ISO. In Italy, ISO only covers 40% of all donations, but 100% of donations are covered by other regulations. In Malta, all donations are covered by other regulations (EU directive and the EDQM manual). In total 25 / 30 reporting countries (83%) have procedures covering 100% of donations.

In 29 / 33 (94%) of the reporting MS inspections are performed at least every 2 years; the large majority of these inspections (9 / 29, 69%) 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 100% of the donation number is partially performed in 10 / 20 (50%) MS. However, labelling of all donations to either ISBT standards or another system is performed by 27 / 31 of reporting countries (87%).

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 all issued component is performed in 6 / 18 (33%) reporting countries. However, 24 / 28 countries (86%) report that all components are coded by either ISBT or another system.

A national haemovigilance reporting system has been established in 29 / 33 (88%) MS.

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.

Of the Member States that reported having a national haemovigilance system, 23 / 29 (79%) provided actual haemovigilance data. 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 6.9 serious adverse reactions per 100 000 distributed blood components seems a reasonable estimate. Haemolysis, anaphylaxis, TRALI and TACO and transfusion associated HCV infections appear to be the most frequent serious adverse reactions.

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TABLES

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

Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, FYR Macedonia, Finland, France, Georgia, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Romania, Serbia, Slovak Republic, Slovenia, Sweden, Switzerland, United Kingdom

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

Country	regular and repeat donors	first time donors	% first time donors	First time donors donating	First time donors tested only	total donors	inhabitants x 1000	donors per 1000 inhabitants	
Austria	286 114	52 844	15.6	49 035	3 809	338 958	8 337	40.7	1)
Belgium	247 263	52 242	17.4	52 242	0	299 505	10 500	28.5	
Bulgaria	114 974	30 900	21.2	30 900		145 874	7 640	19.1	
Croatia	84 509	14 457	14.6	14 457	0	98 966	4 437	22.3	
Cyprus	44 012	4 532	9.3	4 025	0	48 544	766	63.3	2)
Czech Republic	313 553	49 644	13.7	49 644	0	363 197	10 300	35.3	
Denmark	229 536	26 054	10.2	0	26 054	255 590	5 511	46.4	
Estonia	24 839	9 224	27.1	9 224	0	34 063	1 341	25.4	
FYR Macedonia	20 037	3 789	15.9	3 789	0	23 826	2 047	11.6	
Finland	140 715	22 572	13.8	22 572	0	163 287	5 347	30.5	
France	1 093 021	412 728	27.4			1 505 749	63 960	23.5	
Georgia	34 947	2 945	7.8	2 533	412	37 892	4 400	8.6	
Germany	2 376 193	569 990	19.3	471 409	98 581	2 946 183	82 002	35.9	
Greece	342 544	70 604	17.1			413 148	10 500	39.3	3)
Hungary	224 273	45 703	16.9	45 703		269 976	10 040	26.9	
Iceland	7 681	1 701	18.1	0	1 701	9 382	315	29.7	
Ireland	82 433	14 558	15.0	13 001	1 557	96 991	4 451	21.8	
Italy	1 326 000	293 000	18.1			1 619 000	60 000	27.0	
Latvia	39 323	15 547	28.3	15 547		54 870	2 300	23.9	
Lithuania	28 291	31 415	52.6	31 415		59 706	3 366	17.7	
Luxembourg	13 146	1 023	7.2	0	1 023	14 169	475	29.8	
Malta	12 184	2 946	19.5	2 946	0	15 130	400	37.8	4)
Montenegro	6 247	5 952	48.8	4 806		12 199	620	19.7	5)
Netherlands	366 070	28 517	7.2		28 517	394 587	16 500	23.9	
Norway	93 326	13 916	13.0	0	13 916	107 242	4 799	22.3	
Poland	625 950	271 737	30.3	271 737		897 687	38 136	23.5	
Romania		113 773		113 773			21 500		6)
Serbia		46 458	100.0				7 480		
Slovak Republic	74 188	33 323	31.0			107 511	5 417	19.8	7)
Slovenia	104 174	10 589	9.2	10 589	0	114 763	2 000	57.4	
Sweden	246 271	44 425	15.3		44 425	290 696	9 256	31.4	
Switzerland	223 248	30 705	12.1	30 705	0	253 953	7 702	33.0	
United Kingdom	1 355 328	250 281	15.6	246 113	0	1 605 609	61 113	26.3	

1) Regular donors: data not available
2) First time donors are testing few days before donation and if the results allow then they proceed for donation. For the donors at the mobile unit this case is not implemented
3) Only in a few centers do donors give blood samples for testing on their first visit
4) Acute Beds = 1102
5) 5 952 first-time donors were registered, of which 4806 gave blood in their first visit
6) Total estimated number of donors = 209 287
7) New donors are not tested if they are refused for donation

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	
Austria	100	0	0.71	100	143		91	
Belgium	100	0	0.06	100	0	100	100	1)
Bulgaria	20	78	0.05	0			0	
Croatia	100	0	0.54			100	100	2)
Cyprus	100	0	0.00	98			100	3)
Czech Republic	100	0	4.19	34		39	34	
Denmark	100	0	0.00			100	100	
Estonia	100	0	0.01	0			100	
FYR Macedonia	100	2	0.00	0			100	
Finland	100	0	0.00	0		4	100	
France	100		0.24	100			100	4)
Georgia	3	8	0.00					
Germany		0	1.21		25			5)
Greece	49	51	0.41	60	0	8	65	
Hungary	100						12	
Iceland	100	0	0.00	0	0	100	100	
Ireland	100	0	0.00				100	
Italy	100	0	3.76	100		100	100	
Latvia	98		0.00				0	
Lithuania	33	7						
Luxembourg	100	0	0.55	0		100	100	
Malta	100	0	0.00				100	
Montenegro	28	72		0			0	6)
Netherlands	100	0	0.02	100		100	100	
Norway	100	0	0.01	100	0	100	100	
Poland	90	10	0.00	100	0	0	100	
Romania	100			0		100	100	
Serbia	100	15	0.02	100	49	85	100	
Slovak Republic	100	0	0.27	100	0	100	100	
Slovenia	100	0	1.65	0		46	100	
Sweden	100	0	0.02	100	1	100	100	
Switzerland	100	0	0.92	100	11	100	100	
United Kingdom	100	0	0.00	100	0	100	100	7)

1) Multi-component apheresis procedures = platelet + plasma
2) Multi-component apheresis donations = platelets + plasma
3) Single donor platelets are collected using a Haemonetics cell separator [MCS+]
4) Plasma apheresis donations: 312 419 simple plasma 100% non-remunerated donations.
   Mean volume per donation: 0.6 L
5) Data not available for voluntary non-remunerated donations (%) and number of granulocyte apheresis donations (procedures).
   Replacement donations not allowed
6) Collection of blood and blood components by apheresis procedures are not yet done in Montenegro.
   All units of blood are collected as whole blood and separated into blood components
7) 211 multi-component procedures are also counted as red cell and platelet procedures

Table 2 – *Collection of whole blood, autologous blood and blood (apheresis) components*

	WB collections					apheresis collections						
Country	**WB (U)**	**Transfused or distributed**	**WB per 1000 inhabitants**	**autologous (U)**	**% autologous WB (U)**	**plasma apheresis (L)**	**plasma in L per 1000 inhabitants**	**platelets apheresis (U)**	**RBC apheresis (U)**	**granulocytes apheresis (U)**	**multi-component apheresis (U)**	
Austria	484 955	Distr.	58.2	3 466	0.7	0	0.00	20 844	2 062	63		1)
Belgium	548 601	Distr.	52.2	305	0.1	47 032	4.48	4 522	4 522	21	22 452	2)
Bulgaria	154 083	Distr.	20.2	74	0.0	312	0.04	453	0	0	0	3)
Croatia	166 347	Distr.	37.5	905	0.5	409	0.09	1 839	0		1 839	4)
Cyprus	49 294	Distr.	64.3	0	0.0	0	0.00	0	0	0	0	
Czech Republic	410 594	Trans.	39.9	17 197	4.0	206 776	20.08	18 074	2 500			
Denmark	353 611	Trans.	64.2	0	0.0	252	0.05	426	0	5	0	5)
Estonia	54 020	Trans.	40.3	3	0.0	0	0.00	823	0	0	0	
FYR Macedonia	20 037	Distr.	9.8	0	0.0	0	0.00	90	0			6)
Finland	272 499	Distr.	51.0	0	0.0	2 608	0.49	866	0	0	0	7)
France	2 367 443	Distr.	37.0	5 593	0.2	187 451	2.93	16 900	1 623	224	159 599	
Georgia	37 892	Distr.	8.6	0	0.0	0	0.00	0	0	0	0	
Germany	4 869 322	Distr.	59.4	58 782	1.2	1 593 554	19.43	171 690	14 136		17 305	8)
Greece	634 411		60.4	2 605	0.4	754	0.07	18 479	1 540		2 159	
Hungary	417 976	Distr.	41.6			68 000	6.77	49 109	96	96	0	
Iceland	14 931	Distr.	47.3	0	0.0	46	0.15	665	194	0	0	
Ireland	155 079	Distr.	34.8	0	0.0	0	0.00		0	0	0	9)
Italy	2 526 000	Trans.	42.1	95 000	3.6	213 000	3.55	80 000	35 000			
Latvia	58 523	Distr.	25.4	2	0.0			1 848	0	0		
Lithuania	94 992	Distr.	28.2					2 850				
Luxembourg	20 942	Distr.	44.1	115	0.5	1 570	3.31	1 377	0	0	0	
Malta	14 810	Distr.	37.0	0	0.0	0	0.00	320	0	0	0	10)
Montenegro	14 177	Trans.	22.9			0	0.00	0	0	0	0	11)
Netherlands	569 753	Distr.	34.5	110	0.0	188 977	11.45	5 220	0			
Norway	201 723	Trans.	42.0	19	0.0	3 460	0.72	4 077	4 492	0	1 364	12)

Table 2 (continued) – *Collection of whole blood, autologous blood and blood (apheresis) components*

	WB collections					apheresis collections						
Country	**WB (U)**	**Transfused or distributed**	**WB per 1000 inhabitants**	**autologous (U)**	**% autologous WB (U)**	**plasma apheresis (L)**	**plasma in L per 1000 inhabitants**	**platelets apheresis (U)**	**RBC apheresis (U)**	**granulocytes apheresis (U)**	**multi-component apheresis (U)**	
Poland	1 006 056	Distr.	26.4	0	0.0	70 486	1.85	25 076	180	147	5	
Romania	351 381	Distr.	16.3			46	0.00	3 993	0			
Serbia	244 516		32.7	42	0.0	805	0.11	1 420	72			
Slovak Republic	184 236	Distr.	34.0	504	0.3	19	0.00	4 090	257	22	0	
Slovenia	91 279	Distr.	45.6	1 502	1.6	219	0.11	1 474	0	26	0	
Sweden	497 158	Trans.	53.7	97	0.0	42 837	4.63	7 691	1 104	170		13)
Switzerland	354 169	Distr.	46.0	3 242	0.9	1 298	0.17	9 538	1 492	0	7 639	14)
United Kingdom	2 371 141	Distr.	38.8	2	0.0	261	0.00	93 239	258	42	211	15)

1) Multi-component apheresis: data not available. Plasma Collection: Industriepl.,fil.,L: 112112 109151. Quarantänepl.,fil.,L: 5797
2) Multi-component apheresis procedures are platelet + plasma procedures. Red cell unit includes 3,975 red cell units for pediatric use
3) The number of blood components distributed to the hospital blood banks includes the units available at 01.01.2008 in the BTC and units collected during 2008
4) Multi-component apheresis donations = platelets + plasma; FVIII IU x 10^6 = 0.029
5) Whole blood has not been routinely transfused since 1985
6) Stem cell by apheresis; total 41 procedures
7) Whole blood units are reconstituted red cells in FFP
8) Data not available for voluntary non-remunerated donations (%) and number of granulocyte apheresis donations (procedures). Replacement donations not allowed
9) In addition, 1,015 whole blood, plasma-reduced RBC units were distributed to hospitals for large volume neonatal use and 1,378 Pedipacks for infant small volume RBC transfusion
10) Cryo Units = 1,066. Cryo (FVIII x 10^6): 0.074620
11) Collection of blood and blood components by apheresis procedures are not yet done in Montenegro. All units of blood are collected as whole blood and separated into blood components. Platelets, plasma and cryoprecipitate data refer only to the units transfused in the Clinical Center of Montenegro - Podgorica. PLT and CP are prepared in BTC in Podgorica only
12) All FFP was Octaplas 200 ml
13) Multi-component apheresis procedures have not yet been reported
14) Total number of WB units: exclusively autologous
15) 211 multi-component procedures are also counted as red cell and platelet procedures. Figures are for single cryoprecipitate units

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

Country	WB (U)	% WB of total RBCs	RBC concentrates (U)	RBC (U) per 1000 inhabitants	plasma for transfusion (U)	platelets total (U)	platelets recovered (U)	platelets apheresis (U)	% platelets apheresis	CP (10^6 IU FVIII)	
Austria	0	0.0	440 792	52.9	79 112	36 300	7 572	28 728	79.1	0	
Belgium	0	0.0	518 479	49.4	91 777	65 030	40 049	24 981	38.4	0	1)
Bulgaria	775	0.5	149 033	19.5	61 800	4 029	3 178	851	21.1		2)
Croatia	519	0.3	160 037	36.1	71 957	11 816	9 448	2 368	20.0	0	3)
Cyprus	0	0.0	44 283	57.8	15 735	11 479	11 167	312	2.7	0	
Czech Republic	276	0.1	378 287	36.7	192 905	30 349	5 014	25 335	83.5		
Denmark	0	0.0	330 588	60.0	67 793	34 465	32 763	1 702	4.9	147	4)
Estonia	12	0.0	50 340	37.5	31 712	5 899	4 425	1 474	25.0	441	
FYR Macedonia	20 037	50.1	39 965	19.5	18 306	12 700	12 400	300	2.4	599	5)
Finland	630	0.2	253 339	47.4	52 917	37 455	36 785	670	1.8	0	6)
France			2 270 823		327 105	252 887	77 168	175 719	69.5	0	
Georgia	64	0.2	37 892	8.6	37 828	4 478	4 478	0	0.0	284	
Germany	11 457	0.2	4 698 533	57.3	1 332 564	472 346	184 493	287 853	60.9		
Greece	186	0.0	625 325	59.6	263 597	135 933	118 874	17 059	12.5		
Hungary	0		371 905		94 676	22 931	18 020	4 911	21.4	0	
Iceland	0	0.0	14 563	46.2	5 599	2 195	931	1 264	57.6	0	
Ireland	0	0.0	141 364	31.8	655	24 739	10 895	13 844	56.0	2 609	7)
Italy			2 464 000		506 000						
Latvia			58 625		38 273	6 208	2 774	3 434	55.3	4 884	
Lithuania	28		90 232		33 781	15 732	8 655	7 077	45.0	880	
Luxembourg	0	0.0	21 004	44.2	5 100	3 692	2 315	1 377	37.3	0	
Malta	0	0.0	14 485	36.2	6 274	1 169	849	320	27.4		8)
Montenegro	1 515		11 579		8 314			0		262	9)
Netherlands	0	0.0	563 696	34.2	96 622	50 784					
Norway	55	0.0	199 787	41.6	47 690	19 553	13 492	6 061	31.0		10)
Poland			845 538		316 782	134 505	91 504	43 001	32.0	7 192	
Romania	85 498		319 093		227 773	20 292	16 299	3 993	19.7	17 070	
Serbia	244 516		454 892		165 554			1 420		16 368	
Slovak Republic	1 335	1.0	134 726	24.9	75 895	12 816	4 558	8 258	64.4	1	
Slovenia	0	0.0	82 730	41.4	29 510	8 056	5 316	2 740	34.0	0	
Sweden	0	0.0	482 987	52.2	105 197	38 941	25 345	13 596	34.9	0	
Switzerland	2 543	0.8	316 561	41.1	65 823	27 669	2 043	25 626	92.6	0	11)
United Kingdom	729	0.0	2 218 146	36.3	294 223	266 577	95 752	170 825	64.1	123 814	12)

1) Red cell units include 3975 red cell units for pediatric use
2) The number of blood components distributed to the hospital blood banks includes the units available at 01.01.2008 in the BTC and units collected during 2008
3) FVIII IU x 10^6 = 0.029
4) Whole blood has not been routinely transfused since 1985
5) Stem cell by apheresis; total 41 procedures
6) Whole blood units are reconstituted red cells in FFP
7) In addition, 1015 whole blood, plasma reduced RBC units were distributed to hospitals for large volume neonatal use and 1378 Pedipacks for infant small volume RBC transfusion
8) Cryo Units = 1066. Cryo (FVIII x 10^6): 0.074620
9) Platelets, plasma and cryoprecipitate data refer only to the units transfused in the Clinical Center of Montenegro - Podgorica. PLT and CP are prepared in BTC in Podgorica only
10) All FFP was Octaplas 200 ml
11) Total number of WB units: exclusively autologous
12) 211 multi-component procedures are also counted as red cell and platelet procedures. Figures are for single cryoprecipitate units

Table 4 – *Plasma for fractionation into medicinal products*

Country	plasma for fractionation (L)	plasma for fractionation per 1000 inhabitants (L)	% fractionation plasma recovered	plasma for transfusion per 1000 inhabitants (U)	plasma for transfusion total RBC ratio (U/U)	
Austria	109 151	13.09	0.00	9.49	0.18	1)
Belgium	163 089	15.53	71.16	8.74	0.18	
Bulgaria	11 736	1.54	0.00	8.09	0.41	
Croatia	18 910	4.26		16.22	0.45	
Cyprus	0	0.00		20.53	0.36	2)
Czech Republic	247 330	24.01	21.57	18.73	0.51	
Denmark	73 440	13.32		12.30	0.21	3)
Estonia	4 758	3.55	0.00	23.65	0.63	4)
FYR Macedonia	0	0.00		8.94	0.46	
Finland	68 800	12.87	100.00	9.90	0.21	5)
France	769 931	12.04	20.51	5.11		
Georgia	0	0.00		8.60	1.00	
Germany	2 526 637	30.81	40.13	16.25	0.28	
Greece	15 402	1.47		25.10	0.42	
Hungary				9.43		6)
Iceland	0	0.00		17.75	0.38	
Ireland	0	0.00		0.15	0.00	
Italy	648 000	10.80	65.43	8.43		
Latvia	823	0.36		16.64		
Lithuania	72 715	21.60		10.03		7)
Luxembourg	7 600	16.00	76.49	10.74	0.24	8)
Malta	0	0.00		15.69	0.43	9)
Montenegro				13.41		10)
Netherlands	225 557	13.67	69.87	5.86	0.17	
Norway	54 214	11.30	67.82	9.94	0.24	11)
Poland	46 582	1.22	88.64	8.31		
Romania	0	0.00		10.59		12)
Serbia				22.13		
Slovak Republic	46 345	8.56	84.08	14.01	0.56	
Slovenia	14 096	7.05	98.45	14.76	0.36	
Sweden	113 419	12.25	62.23	11.36	0.22	
Switzerland	90 119	11.70	0.00	8.55	0.21	
United Kingdom	0	0.00		4.81	0.13	

1) Red cell apheresis (autologous) = 2943. Concentrates = 5886
2) The plasma collected is not further fractionated to products
3) The amount of plasma for FVIII or other components has not been stated. However, only plasma recovered from whole blood for fractionation is delivered
4) Only plasma is supplied to fractionators
5) Other plasma is used for production of pooled, virus-inactivated fresh frozen plasma (Octaplas)
6) HNBT Service has no information on the data collection of private plasmapheresis processes
7) Plasma for fractionation in units only (72 715 units)
8) Octapharma carries out fractionation for Luxembourg: albumin, gammaglobulins, Factor VIII, PPSB
9) No components were delivered for manufacture of medicinal products
10) Collection of plasma by apheresis procedures is not yet done in Montenegro
11) Total plasma includes plasma for Octaplas production
12) No contract for fractionation

Table 5.1 – *Special processing of blood components*

Country	RBC		plasma for transfusion		platelets			
	% leucocyte depleted	% irradiated	% leucocyte depleted	% irradiated	% leucocyte depleted	% irradiated	path.inact. %	
Austria	100	9	100	0	100	49	0	1)
Belgium	100		100	0	100		13	
Bulgaria	6	1	1	1	27	1		
Croatia	18	77	1					
Cyprus	100	0	0	0	0	0	0	
Czech Republic	21	6	0	1	73	29	0	
Denmark	31	2	0	1	99	29	0	
Estonia	5	3	0	0	44	21	0	
FYR Macedonia	5	0	0	0	1	0	0	
Finland	100	3	0	0	100	35	0	2)
France	100		100		100			
Georgia	0	0	0	0	0	0	0	
Germany	100	4		0	100	34	0	3)
Greece	35	16	38	11	70	19		
Hungary	11	5	16	2	71	12	0	
Iceland	22	10	3	2	100	68	17	4)
Ireland	100	24	100	0	100	100	0	5)
Italy								
Latvia	15	2	0	0	100	28	0	
Lithuania	9				40			
Luxembourg	100	1	100	0	100	2	0	
Malta	100	26	100	0	100	0	0	
Montenegro								6)
Netherlands	100		100		100		0	
Norway	100	7	0	0	100	34	16	7)
Poland			0	0				
Romania				0	20		0	
Serbia	50	2			7	1		
Slovak Republic	13		8		62		0	8)
Slovenia	45	5	0	0	74	36	0	
Sweden	83	4	94	2	100	56	4	
Switzerland	100		100		100			9)
Turkey								
Ukraine								
United Kingdom	100	8	100	0	100	54	0	10)

1) Cryoprecipitate: no production in the BE
2) Plasma for transfusion is virus-inactivated: pooled, virus-inactivated fresh frozen plasma (Octaplas)
3) Data on leucocyte-depleted plasma for transfusion are not collected. Cryoprecipitate-reduced plasma components and cryoprecipitate: not in use
4) Virus-inactivated platelets: 3-month project
5) 98% of plasma for transfusion was Solvent Detergent treated, Octaplas. The small amount of FFP used was leucocyte-depleted
6) Leucocyte-depleted and irradiated blood components (RC and PLT) are prepared in specific cases only
7) Plasma inactivated = Octaplas
8) Blood components are irradiated by blood banks. No data
9) Virus-inactivated : SD plasma
10) Scotland - Cryoprecipitate for use in neonates and children under 16 is imported from North America. It is treated with Methylene Blue and supplied as individual donations (i.e. not pooled) – approx. 800 units per year

Table 5.2 – *Inactivation or quarantine of plasma*

Country	FFP		CP reduced plasma		cyroprecipitate		
	% quarantined	% virus inactivated	% quarantined	% virus inactivated	% quarantined	% virus inactivated	
Austria	26	74	0	0	0	0	1)
Belgium	0	100	0	0	0	0	
Bulgaria	0	0	0	0	0		
Croatia							
Cyprus	0	0	0	0	0	0	
Czech Republic	100	0	100				
Denmark	0	0	0	0	0	0	
Estonia	0	0	0	0	0	0	
FYR Macedonia	0	0	0	0	0	0	
Finland	0	100	0	0	0	0	2)
France	35	100					
Georgia	19	0	0	0	0	0	
Germany	94	6	0	0	0	0	3)
Greece	15	11					
Hungary	0	0	0	0	0	0	
Iceland	0	0	0	0	0	0	4)
Ireland		98	0	0	0	0	5)
Italy							
Latvia	59	0			100	0	
Lithuania	60						
Luxembourg	0	100	0	0	0	0	
Malta	50	0	0	0	0	0	
Montenegro							6)
Netherlands	100	0	0	0	0	0	
Norway	0	100	0	0	0	0	7)
Poland		0				0	
Romania	50	0	50	0		0	
Serbia							
Slovak Republic	49	0	0	0	0	0	8)
Slovenia	0	0	0	0	0	0	
Sweden	0	1	0	0	0	0	
Switzerland	85	15					9)
United Kingdom	0	4	0	0	0	1	10)

1) Cryoprecipitate: no production in the BE
2) Plasma for transfusion virus-inactivated: pooled, virus-inactivated fresh frozen plasma (Octaplas)
3) Data on leucocyte-depleted plasma for transfusion are not collected. Cryoprecipitate-reduced plasma components and cryoprecipitate: not in use
4) Virus inactivated platelets: 3-month project
5) 98% of plasma for transfusion was Solvent Detergent treated, Octaplas. The small amount of FFP used was leucocyte-depleted
6) Leucocyte-depleted and irradiated blood components (RC and PLT) are prepared in specific cases only
7) Plasma inactivated = Octaplas
8) Blood components are irradiated by blood banks: no data
9) Virus-inactivated : SD plasma
10) Scotland - Cryoprecipitate for use in neonates and children under 16 is imported from North America. It is treated with Methylene Blue and supplied as individual donations (i.e. not pooled) – approx. 800 units per year

Table 6 – *Donation testing strategy for infectious agents*

Country	anti-HIV 1+2	HIVAg	HBsAg	Anti-HBc	anti-HCV	HCVAg	anti-HTLV I/II	Syphilis	Malaria	Other	
Austria	100	100	100	21	100	0	0	100	0	Neopterin-Screening-Elisa-Test (Brahms, IBL): Testing every donation. ALT (Abbott, Roche, Dade/Siemnes): Testing 29%. anti-CMV (IgG,IgM), Abbott,Dade/Siemens: Testing 34%.	1)
Belgium	100	0	100	First	100	0	0	100			2)
Bulgaria	100	100	100	0	100	100	0	100	0		
Croatia	100	100	100	0	100	100	0	100	0		3)
Cyprus	100	0	100	0	100	0	0	100	0		4)
Czech Republic	100	100	100	0	100	35	0	100	0		5)
Denmark	100	100	100	0	100	0		0			6)
Estonia	100	100	100	0	100	0	0	100	0		
FYR Macedonia	100	100	100	100	100	100	0	100	0		7)
Finland	100	100	100	0	100	0	23	100	0		8)
France	100	0	100	100	100	0	100	100			9)
Georgia	100	0	100	0	100	0	0	100	0		
Germany	100		100	100	100	0	0	100	0		10)
Greece	100		100		100		100	100			11)
Hungary	100	0	100	First	100	0		100	0		
Iceland	100	100	100	0	100	0	0	0			12)
Ireland	100	0	100	100	100	0	100	100	0		
Italy	100	0	100	0	100	0	0	100	0		13)
Latvia	100	0	100	0	100	0	0	100	0		
Lithuania	100		100		100			100			
Luxembourg	100	100	100	First	100	0	First	100	1		14)
Malta	100	100	100	100	100	100	0	100	0	CMV Ab: Testing 10%.	
Montenegro	100	100	100	0	100	0	0	100	0		15)
Netherlands	100	0	100	0	100	0	100	100			16)
Norway	100	100	100		100	0	0	First	1		17)
Poland	100	0	100	0	100	0	0	100	0		

Table 6 (continued) – *Donation testing strategy for infectious agents*

Country	anti-HIV 1+2	HIVAg	HBsAg	Anti-HBc	anti-HCV	HCVAg	anti-HTLV I/II	Syphilis	Malaria	Other	
Romania	100	100	100		100	100	100	100	0	ALT: Testing every donation.	18)
Serbia	100	0	100	0	100	0	0	100	0		
Slovak Republic	100	100	100	100	100	0	0	100	0		
Slovenia	100	100	100	0	100	0	0	100	0		19)
Sweden	100	0	100	First	100	0	First	100	0		20)
Switzerland	100	50	100	0	100	0	0	100	1	ALT : Testing every donation. CMV : Testing 2%.	21)
United Kingdom	100	100	100	1	100	0	100	100	1	Chagas' disease: Testing 1%. Anti-CMV: Testing 30%.	22)

1) Anti-HBc: about 90,000 donations tested annually
2) Malaria: on demand
3) Anti-HIV: HIV Ag/Ab combo. HIV Ag: HIV Ag/Ab combo. Anti-HCV: HCV Ag/Ab combo. HCV Ag: HCV Ag/Ab combo
4) (1) Anti-HIV+2, HBsAg and anti-HCV are performed with an ELISA method. (2) Syphilis testing uses a haemagglutination technique
5) Anti-HIV: HIV Ag/Ab combined test in use. HIV Ag: HIV Ag/Ab combined test in use. HCV Ag: combined Ag/Ab test is used in about 35% of donations
6) Anti-HTLV: first-time donors and donors having travelled to endemic areas. Malaria: donors having travelled to endemic areas
7) HIV Ag/Att in 100% of donations
8) Anti-HIV: anti-HIV/p24 antigen combitest. Anti-HTLV: anti-HTLV testing was terminated in August 2008. Malaria: donors having visited or born in malaria areas are tested
9) Malaria: only if donor has travelled to or lived in endemic areas. Chagas disease: only if donor has travelled to or lived in endemic areas
10) HIV Ag: no data. Antibody-Antigen-Combitests for HIV-1+2 are used by some blood establishments. Anti-HBc: donors that test positive for anti-HBc can donate blood if a sensitive assay for HBV genome is negative and if anti-HBs antibody-titer stays above 100 IU/l. Syphilis: not required for donations of plasma for fractionation
11) Anti-HIV: data on 568 210 donations. HIV Ag: when required. HBsAg: data on 568 210 donations. Anti-HBc: when required. Anti-HCV: data on 568 210 donations. HCV Ag: when required. Anti-HTLV: data on 568 210 donations. Syphilis: data on 568 210 donations. Malaria: when required
12) Malaria: only if having travelled in malaria area (few tests/year)
13) A significant proportion of Blood Services (not yet defined) perform HIVAg/Ab combo tests
14) HIV Ag: serologic test with P24 detection. Malaria: after having travelled in malaria area
15) Screening of collected units of blood is done by ELISA tests from different manufacturers
16) Malaria: only donors with a history of malaria are tested
17) HIV Ag: not a requirement, but always done. Anti-HBc: all new donors and all donors when more than 6 months has elapsed since previous donation. Malaria: no requirement – optional for blood banks that want to reduce quarantine time
18) Anti-HIV: 100% testing with Ag/Ab anti HIV (Combo test) reagent. HIV Ag: 100% testing with Ag/Ab anti HIV (Combo test) reagent. Anti-HCV: 100% testing with Ag/Ab anti HCV reagent. HCV Ag: 100% testing with Ag/Ab anti HCV reagent
19) HIV Ag: use of combo test anti-HIV
20) HIV Ag: combined antibody-antigen tests are available and will be a requirement. HCV Ag: combined antibody-antigen tests will be a requirement when available. Syphilis: every unit is tested for fractionators, the legal requirement is currently only for new donors
21) Malaria: after staying > 6 months in countries at risk. CMV: immuno-deficient patients and neonates
22) HIV Ag: screened using HIV-Ag/Ab Combo assay. Chagas' disease: donor acceptable if at least 6 months following the date of last exposure, a validated test for *T. cruzi* antibody is negative

Table 7.1 – *Confirmed seropositive donors (absolute numbers)*

Country	HIV 1 / 2		HBV		HCV		HTLV-I/II		syphilis		
	first time donors	repeat donors	first time donors	repeat donors	first time donors	repeat donors	first time donors	repeat donors	first time donors	repeat donors	
Austria	1	8	61	5	34	24			16	32	
Belgium	4	1	40	3	22	5			11	17	
Bulgaria			1900	66	160	9	0		600	12	
Croatia	1	4	27	11	8	3			6	6	
Cyprus	1	0	20	8	10	5	0	0	13	12	
Czech Republic	1	1	27	5	63	13			9	10	
Denmark	2	1	10	0	3	0	1	0			
Estonia	3	2	15	4	65	6			19	34	
FYR Macedonia	20037	15	20037	201	20037	45	0	0	20037	8	
Finland	1	1	3	2	14	3	0	0	0	3	
France											
Georgia	22		940		1705				380		1)
Germany	39	61	779	34	408	53			177	106	2)
Greece	25	20	980	293	281	89	3	1	102	52	3)
Hungary	5	3	155	198	144	56			46	43	4)
Iceland	0	0	1	0	0	0					
Ireland	1	0	4	2	3	0	0	0	5	2	
Italy	56	48	844	101	404	25	0	0	221	107	5)
Latvia	9	9									
Lithuania	13		96		178				42		6)
Luxembourg	0	0	0	0	0	0	0	0	2	0	
Malta	0	0	5	0	0	0			0	0	7)
Montenegro	1	0	31	2							8)
Netherlands	2	1	16	4	4	0	0	1	11	8	
Norway	0	0	5	1	13	1			2	2	
Poland											
Romania											
Serbia											
Slovak Republic	2	2	34	9	20	9			4	3	
Slovenia	0	0	10	0	4	0	0	0	3	3	
Sweden	0	2	11	1	19	0	1		8	9	9)
Switzerland	3	1	39	8	24	0			21	5	
United Kingdom	15	13	87	1	76	7	13	1	66	36	10)

1) Figures show total number of confirmed cases. There are no separate statistics for repeat or first-time donors
2) Donations not tested for HTLV I/II
3) Data on 70 604 first-time donors and on 342 544 repeat donors
4) Previous data on HBsAg + a-HBc positive samples was incorrect, hence the increase in confirmed seropositive results
5) Coverage 92.3% of donations
6) Total of confirmed seropositive tests is presented (first and repeat tested donors)
7) No testing for HTLV I/II
8) Confirmatory testing on HCV and syphilis was not done in 2008 because of the lack of tests
9) HTLV I/II tests are not performed on repeat tested donors. Data are collected on syphilis for the first year
10) Northern Ireland - repeat tested donors subjected to new syphilis screening test since last donation and in all cases of past syphilis treatment

Table 7.2 – *Prevelance and incidence calculated per 100 000 donors*

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	
Austria	1.89	2.80	115.43	1.75	64.34	8.39	1)
Belgium	7.66	0.40	76.57	1.21	42.11	2.02	
Bulgaria			6148.87	57.40	517.80	7.83	
Croatia	6.92	4.73	186.76	13.02	55.34	3.55	
Cyprus	22.07	0.00	441.31	18.18	220.65	11.36	2)
Czech Republic	2.01	0.32	54.39	1.59	126.90	4.15	
Denmark	7.68	0.44	38.38	0.00	11.51	0.00	
Estonia	32.52	8.05	162.62	16.10	704.68	24.16	
FYR Macedonia	528820.27	74.86	528820.27	1003.14	528820.27	224.58	
Finland	4.43	0.71	13.29	1.42	62.02	2.13	
France							
Georgia	747.03		31918.51		57894.74		3)
Germany	6.84	2.57	136.67	1.43	71.58	2.23	
Greece	35.41	5.84	1388.02	85.54	397.99	25.98	4)
Hungary	10.94	1.34	339.15	88.29	315.08	24.97	5)
Iceland	0.00	0.00	58.79	0.00	0.00	0.00	
Ireland	6.87	0.00	27.48	2.43	20.61	0.00	
Italy	19.11	3.62	288.05	7.62	137.88	1.89	6)
Latvia	57.89	22.89					
Lithuania	41.38		305.59		566.61		7)
Luxembourg	0.00	0.00	0.00	0.00	0.00	0.00	
Malta	0.00	0.00	169.72	0.00	0.00	0.00	8)
Montenegro	16.80	0.00	520.83	32.02			9)
Netherlands	7.01	0.27	56.11	1.09	14.03	0.00	
Norway	0.00	0.00	35.93	1.07	93.42	1.07	
Poland							
Romania							10)
Serbia							
Slovak Republic	6.00	2.70	102.03	12.13	60.02	12.13	11)
Slovenia	0.00	0.00	94.44	0.00	37.78	0.00	
Sweden	0.00	0.81	24.76	0.41	42.77	0.00	
Switzerland	9.77	0.45	127.02	3.58	78.16	0.00	
United Kingdom	5.99	0.96	34.76	0.07	30.37	0.52	

1) Regular Donors: data not available
2) First time donors are tested a few days before donation and, if the results allow, then they proceed for donation. For donors at the mobile unit, this is not implemented
3) Figures show total number of confirmed cases. There are no separate statistics for repeat or first time donors
4) Data on 70 604 first time donors and on 342 544 repeat donors. Only in a few centers do donors give blood samples for testing on their first visit
5) Previous data on HBsAg + a-HBc positive samples was incorrect, hence the increase in confirmed seropositive results
6) Coverage 92.3% of donations
7) Total of confirmed seropositive tests is presented (first and repeat tested donors)
8) Acute Beds = 1102
9) Confirmatory testing on HCV and syphilis was not done in 2008 because of the lack of tests. 5952 first-time donors were registered, of which 4806 gave blood on their first visit
10) Total estimated number of donors = 209 287
11) New donors are not tested if they are refused for donation

Table 8.1 – *Nucleic Acid Amplification Techniques (NAT) testing*

Country	HIV NAT		HBV NAT		HCV NAT		Other NAT tests (separated by ';')		
	Donations tested	Size Minipool	Donations tested	Size Minipool	Donations tested	Size Minipool	Donations tested	Size Minipool	
Austria	All	96	All	96	All	96	All HAV:Frankfurt, Wiesemheid, Linz; All PB19:Frankfurt,Wiesenheid, Linz	96; 96	1)
Belgium	All	8	None		All	8			
Bulgaria	None		None		None				
Croatia	None		None		None				
Cyprus	None		None		None				2)
Czech Republic	None		None		None				3)
Denmark	None		None		None				4)
Estonia	All	12	None		All	12			
FYR Macedonia	None		None		None				
Finland	All	1	All	1	All	1	All HAV RNA; All Parvovirus B 19	96; 96	5)
France	All		None		All				6)
Georgia	None		None		None				
Germany	All	96			All	96			7)
Greece	All	1	All	1	All	1			8)
Hungary									9)
Iceland	None		None		None				
Ireland	All	8	None		All	8			10)
Italy	All		All		All				
Latvia	All	24	All	24	All	24			
Lithuania	All	6	All	6	All	6			11)
Luxembourg	All	50	All	50		50	All PARVOVIRUS B19	50	12)
Malta	None		None		None				13)
Montenegro									14)
Netherlands	All	48	None		All	48			
Norway									15)
Poland	All		All		All				

Table 8.1 (continued) – *Nucleic Acid Amplification Techniques (NAT) testing*

Country	HIV NAT		HBV NAT		HCV NAT		Other NAT tests (separated by ';')		
	Donations tested	Size Minipool	Donations tested	Size Minipool	Donations tested	Size Minipool	Donations tested	Size Minipool	
Portugal									
Romania	None		None		None				
Serbia									
Slovak Republic	None		None		None				
Slovenia	All		All		All				
Sweden	None		None		None				16)
Switzerland	All	8	All	1	All	8			17)
United Kingdom	All		None		All				18)

1) HIV: pool size = 3-30-24-96. HBV: pool size = 3-24-40-96. HCV: pool size = 3-24-40-96. HAV: Frankfurt, Wiesemheid, Linz. PB19: Frankfurt, Wiesenheid, Linz
2) NAT has not yet been introduced in the Blood Center
3) HIV: results of NAT testing of plasma sent to fractionating company are reported back. HBV: results of NAT testing of plasma sent to fractionating company are reported back. HCV: results of NAT testing done on plasma by fractionating company are reported back
4) HIV: ID NAT was implemented 01 Jan. 2009. HBV: ID NAT was implemented 01 Jan. 2009. HCV: ID NAT was implemented 01 Jan. 2009
5) HAV: RNA. Parvovirus B 19: cut off = 10^4 IU/ml
6) HIV: pool size = 24 and 8 (2 different techniques used). HCV: pool size = 24 and 8 (2 different techniques used)
7) HIV: pool size for NAT tests = 10 to 96. HBV: no data - NAT test performed by blood donation service on a voluntary basis for approximately 75% of all donations. HCV: pool size for NAT tests = 10 to 96
8) HIV: data on 568 210 donations. HBV: data on 568 210 donations. HCV: data on 568 210 donations
9) NAT tests are used by the confirmation process
10) HIV: Procleix HCV/HIV-1 duplex assay. HCV: Procleix HCV/HIV-1 duplex assay
11) 60 % individual NAT testing, 40 % minipools (size 6)
12) Parvovirus B19
13) Data not available
14) NAT testing is not yet performed in Montenegro
15) HIV: by fractionator. HBV: by fractionator. HCV: by fractionator. HAV: fractionator. Parvo B19: by fractionator
16) Samples from all plasma units are tested by the factionators and any verified positive results are reported to the blood establishments
17) HIV: size of minipools ranges from 1- 24. HBV: NAT testing individually (Tigris) and 6 pools (Roche Cobas S201); 3 were anti-Hbc pos. HCV: size of minipools ranges from 1-24
18) HIV: size of minipools = 48 (NHSBT England & Wales), 96 (Northern Ireland), maximum 95 (SNBTS). HCV: size of minipools = 48 (NHSBT England & Wales), 96 (Northern Ireland), maximum 95 (SNBTS)

Table 8.2 – *NAT-only positive donors*

Country	HIV 1		HBV		HCV	
	first time tested donors	repeat donors	first time tested donors	repeat donors	first time tested donors	repeat donors
Austria	0	0	0	0	0	0
Belgium	0	1			0	0
Bulgaria						
Croatia						
Cyprus						
Czech Republic						
Denmark						
Estonia	0	0			0	2
FYR Macedonia						
Finland	0	1	0	1	0	0
France						
Georgia						
Germany	0	3	0	2	2	5
Greece	0	0	40	12	0	0
Hungary						
Iceland						
Ireland	0	0			0	0
Italy	0	2	20	64	3	2
Latvia					2	
Lithuania						
Luxembourg	0	0	0	0	0	0
Malta						
Montenegro						
Netherlands	0	0			0	0
Norway						
Poland						
Portugal						
Romania						
Serbia						
Slovak Republic						
Slovenia	0	8	0	7	0	1
Sweden						
Switzerland	0	0	0	5	0	0
United Kingdom	1	0			1	0

Table 9 – *Bacterial screening*

Country	total platelets issued (adult therapeutic doses)	% bacterial screened		% of platelet adult doses screened	% of screened units confirmed positive	
		recovered	apheresis			
Austria	36 300	27	27	54	54	1)
Belgium	65 030	96	65	86	0	2)
Bulgaria	4 029	3	0	3	0	
Croatia	11 816	4	5	4	1	
Cyprus	11 479	0	0	0	0	
Czech Republic	30 349					3)
Denmark	34 465			89	0	
Estonia	5 899	100	100	100	1	
FYR Macedonia	12 700	1	0	1	3	
Finland	37 455	0	0	0	0	4)
France	252 887					
Georgia	4 478	100	0	2	0	
Germany	472 346					5)
Greece	135 933	10	8	6	12	
Hungary	22 931	17	20	23	0	
Iceland	2 195	0	0	0		6)
Ireland	24 739	100	100	100	0	
Italy						
Latvia	6 208					
Lithuania	15 732			3		
Luxembourg	3 692	0	2	2	0	
Malta	1 169	20	20	20	0	
Montenegro						7)
Netherlands	50 784	100	100	100	100	
Norway	19 553			76	0	
Poland	134 505					
Romania	20 292					8)
Serbia			3	1		
Slovak Republic	12 816					9)
Slovenia	8 056	3	2	3	0	
Sweden	38 941			36	0	
Switzerland	27 669			0		10)
United Kingdom	266 577	17	16	15	1	11)

1) Screening and positive culture: all granulocytes = 0.12% (n=29); apheresis granulocytes = 0.059% (n=14); pooled granulocytes = 0.064% (n=15)
2) Remainder = pathogen-inactivated
3) Bacterial screening is done only as a "statistical" quality control in about 1% of products
4) No in-process screening for bacteria. All out-dated platelet components are cultured for bacteria
5) Sterility testing as a statistical process control 0.4 x SQR(n) at the end of shelf life
6) No screening of bacteria
7) Screening for presence of bacteria in PLT preparations is done occasionally
8) Screening performed on BactAlert/Hemoline (data not available)
9) Bacterial screening only as quality control in accordance with recommendation N°R15, not as routine practice to prolong shelf life
10) Only QC on outdated units
11) NHSBT (England) - no routine bacterial screening performed

Table 10 – *Organisation, registration and labelling*

Country	National Council or Expert Committee	national blood policy		national regulations	
		on quality and safety	implementing		
Austria	Yes	Yes	Yes	Yes	
Belgium	Yes	Yes	Yes	Yes	
Bulgaria	No	Yes	Yes	Yes	
Croatia	Yes	No	No	Yes	1)
Cyprus	No	No		Yes	2)
Czech Republic	Yes	Yes	Yes	Yes	
Denmark	Yes	Yes	Yes	Yes	
Estonia	No	No	No	Yes	
FYR Macedonia	Yes	Yes	Yes	Yes	
Finland	No	Yes	Yes	Yes	
France	Yes	Yes	No	Yes	
Georgia	Yes	No	No	Yes	
Germany	Yes	Yes	Yes	Yes	
Greece	Yes	Yes	Yes	Yes	
Hungary	Yes	Yes	Yes	Yes	
Iceland	No	No	No	Yes	
Ireland	No	No	No	Yes	
Italy	Yes	Yes	Yes	Yes	
Latvia	Yes	Yes	Yes	Yes	
Lithuania	Yes	Yes	Yes	Yes	
Luxembourg	Yes	Yes	Yes	Yes	
Malta	No	Yes	Yes	Yes	
Montenegro	Yes	Yes	Yes	Yes	
Netherlands	Yes	Yes	Yes	Yes	
Norway	Yes	Yes	Yes	Yes	
Poland	Yes	Yes		Yes	
Romania	Yes	Yes	Yes	Yes	
Serbia	Yes	Yes	Yes	Yes	
Slovak Republic	Yes	Yes	Yes	Yes	
Slovenia	Yes	Yes		Yes	
Spain					
Sweden	Yes	Yes	Yes	Yes	3)
Switzerland	No	Yes	Yes	Yes	
United Kingdom	Yes	Yes	Yes	Yes	4)

1) Currently, the National Blood Policy is in the process of adoption by the Ministry of Health and Social Welfare
2) Directives have been transposed into law. Most of the articles are empirically followed and implemented by personnel. No national regulations have been officially regulated by the Ministry of Health
3) The Swedish Blood Alliance and the Swedish Society for Transfusion Medicine participate in the consultation procedures for new regulations
4) Guidelines for the Blood Transfusion Services in the UK (7th Edition)

Table 11a – *Quality management related issues*

Country	QMS established and maintained	% donations covered by			Other procedures	Inspections every second year	Description of Other organisation/body	System of educ. and training
		GMP	ISO 9000	Other				
Austria	Yes	100	100		Blutsicherheitsgesetz,Blutspenderverordnung,Richtlinien für Blutgruppenserologie u.Transfusionsmedizin,Verordnung:Arzneimittel aus menschlichem Blut	National	AGES PharmMed (Nationale Einrichtung)	Yes
Belgium	Yes	100	35			National+Other	national authority and fractionator	Yes
Bulgaria	Yes	100				National		Yes
Croatia	Yes	100	50			National	Inspection is performed only in CITM, but each 5 years.	Yes
Cyprus	Planned	0	0	0	0	No		No
Czech Republic	Yes	100	40			National		Yes
Denmark	Yes	100		15	ISO15189	National		
Estonia	Yes	100	100			National		No
FYR Macedonia	Yes					National		Yes
Finland	Yes	100	0			National	National Agency for Medicines	Yes
France	Yes		100			National	AFSSAPS	Yes
Georgia	Planned		0			National		No
Germany	Yes	100				National		Yes
Greece	Yes	75	12			Other	EKEVYL, ELOT for some centers only	Yes
Hungary	Yes	100				National+Other	Plasma fractionation factory	Yes
Iceland	Yes		100			National+Other		No
Ireland	Yes	100	0			National		Yes
Italy	Yes	0	40	100	Regional authorisation and accreditation	No		Yes
Latvia	Yes		100			National		Yes
Lithuania		60				National		Yes
Luxembourg	Yes	100	100	100	EFS BORDEAUX for FFP	National+Other	EFS BORDEAUX	Yes
Malta	Yes			100	EU Directive 2002/98/EC / EDQM Manual	National		Yes
Montenegro	Planned					National		No
Netherlands	Yes	100	100			National		Yes

Table 11a (continued) – *Quality management related issues*

Country	QMS established and maintained	% donations covered by			Other procedures	Inspections every second year	Description of Other organisation/body	System of educ. and training
		GMP	ISO 9000	Other				
Norway	Yes	100	42			National		No
Poland	Yes	100				National		No
Romania	Yes					National		
Serbia	Yes		3			Other		Yes
Slovak Republic	Yes	100	0			National+Other	fractionator	Yes
Slovenia	Yes	100				National+Other	organisations aaccredited to perform the ISO 9001:2000 certification proces	Yes
Sweden	Yes	100	0	64	ISO/IEC 17025 or ISO/IEC 15189	National+Other	ISO/IEC 17025 or ISO/IEC 15189	Yes
Switzerland	Yes	100	65	90	All RBTS comply also with ISO 17025	National+Other	METAS : national accreditation body	Yes
United Kingdom	Yes	100	4	0	4 UK Blood Services each have its own National; procedures – ISO 9000 Wales only.	National+Other	Wales only – BSI ISO series every 6 months	Yes

Table 11b - *Quality management related issues*

Country	"% donations labelled according to		component code		Comments	Haemovigilance system	
	ISBT 128	another system	ISBT 128	another system		Available / organisation	Description of Other organisation/body
Andorra							
Armenia							
Azerbaijan							
Albania							
Austria	100			100	Verschiedene Systeme	National	AGES PharmMed (Nationale Einrichtung)
Belgium	93	7	93	7		National	
Bulgaria		100		100		National	
Croatia		90		50	Codabare	National+Other	Croatian Institute of Transfusion Medicine (CITM)
Cyprus	0	0	0	0		No	
Czech Republic		100		100	national labelling system using code 128 and standardised producer / donation / component number	National	
Denmark	100		100			National+Other	Danish Society for Clinical Immunology
Estonia	100	0	0	100	Local component coding is implemented	National	
FYR Macedonia		100		100	PROGESA Softver	No	
Finland	100	0	100	0		Other	Finnish Red Cross Blood Service
France		100		100	Monarch Barcode	National+Other	Hospitals, EFS and competent authority (AFSSAPS)
Georgia		100				No	
Germany					Any unique code, mostly used is Eurocode.	National	
Greece		85		85	"Percentage donations labelled according to ISBT 128 (% donation numbers): Planned. Percentage components labelled according to another system (% component codes): Blood Med and Blood-Pliroforiki"	Other	National Coordinating Haemovigilance Centre (SKAE) of the Hellenic Centre of Diseases Control and Prevention (KEELPNO) of the Ministry of Health and Social Solidarity
Hungary	100	0		100	codabar	National	
Iceland	100	0	100	0		National	

Table 11b (continued) - *Quality management related issues*

Country	"% donations labelled according to		component code		Comments	Haemovigilance system	
	ISBT 128	another system	ISBT 128	another system		Available / organisation	Description of Other organisation/body
Ireland	0	100	0	100	CODABAR modulus 11	National	
Italy	0	100	0	100	National regulation (UNI 10529); A new regional and national inspection system will be implemented starting from 2010 in compliance with EU directives	National	
Latvia	100		100			National	
Lithuania		100		100		National	
Luxembourg	0	100	0	100	LOCAL SYSTEM; ISBT 128 IS TOO EXPENSIVE	Other	CTS and HOSPITALS
Malta	0	100	0	100	Codabar	National	
Montenegro		100				No	
Netherlands	100	0	100	0		National+Other	TRIP
Norway	98	2	98	2		National	
Poland						Other	Institute of Haematology and Blood Transfusion
Portugal							
Romania		100				National	
Serbia	13		13			Other	
Slovak Republic	0	100	0	100		National	
Slovenia		100		100	codabar system	National+Other	Blood Transfusion Centre of Ljubljana
Sweden	84	16	85	15	previous national Blood-Id system still applied by 2 Blood esttblishments	National+Other	The Swedish Society for Transfusion Medicine
Switzerland	100		100			National	
Ukraine							
United Kingdom	100	0	0	100	Codabar; Donation numbers ISBT 128, Product labels Codabar	National+Other	MHRA (SABRE) & SHOT

Table 12 - *Haemovigilance*

Country	total number components transfused: WB + RBC + FFP + Platelets (U)	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 component U	
		haemolysis ABO	haemolysis other allo antibody	Non immun. Hemol.	PTP	Anaphylaxis	TRALI	GVHD	HBV	HCV	HIV	Other viral	Bacterial	Malaria	Parasitic	TACO	Other serious		
Austria	556 204																		1)
Belgium	675 286	4	4	1		10	3						4			4	7	5.5	
Bulgaria	214 862																		
Croatia	243 810																		2)
Cyprus	71 497	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0	3)
Czech Republic	601 541	2	1	0	0	7	2	0	0	0	0	0	0	0	0	0	0	2.0	
Denmark	432 846	1	1										1					0.7	
Estonia	87 951	0	1	2		1												4.5	
FYR Macedonia	70 971																		
Finland	343 711	2	1	1	0	3	0	0	0	0	0	0	0	0	0	0	0	2.0	
France	2 850 815	3	7			47	26		56	207	39		5			107		17.4	4)
Georgia	80 198																		
Germany	6 503 443	5	6	1	1	12	15		1				6					0.7	
Greece	1 024 855	8	9			20	4						2			11	4	5.7	5)

Table 12 (continued) - *Haemovigilance*

Country	total number components transfused: WB + RBC + FFP + Platelets (U)	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 component U	
		haemolysis ABO	haemolysis other allo antibody	Non immun. Hemol.	PTP	Anaphylaxis	TRALI	GVHD	HBV	HCV	HIV	Other viral	Bacterial	Malaria	Parasitic	TACO	Other serious		
Hungary	489 512	2	2	1	0	0	6	0	0	0	0	0	0	0	0	0	0	2.2	
Iceland	22 357					1											1	8.9	
Ireland	166 758	0	4	0	0	34	0	0	0	0	0	0	0	0	0	27	24	53.4	
Italy	2 970 000																		
Latvia	103 106					4										1		4.8	
Lithuania	139 745					2												1.4	
Luxembourg	29 796	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0	6)
Malta	21 928	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	9.1	
Montenegro	19 893																		7)
Netherlands	711 102	7	4			32	17		1							16		10.8	
Norway	267 030	1	2			2						1	1			7		5.2	
Poland	1 296 825																		
Romania	567 158																		
Serbia	620 446																		

Table 12 (continued) - *Haemovigilance*

Country	total number components transfused: WB + RBC + FFP + Platelets (U)	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 component U	
		haemolysis ABO	haemolysis other allo antibody	Non immun. Hemol.	PTP	Anaphylaxis	TRALI	GVHD	HBV	HCV	HIV	Other viral	Bacterial	Malaria	Parasitic	TACO	Other serious		
Slovak Republic	223 437	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.4	8)
Slovenia	120 296	0	0	0	0	4	0	0	0	0	0	0	0	0	0	3	0	5.8	
Sweden	627 125	4	2			13	4						3			3		4.6	
Switzerland	410 053		2			20	2						1			2	4	7.6	
United Kingdom	2 778 946	4	30	0	1	68	10						6				58	6.4	
Total		44	78	6	2	280	89	0	58	207	39	1	29	0	0	181	98		

1) Febrile transfusion reactions = 169. Allergic transfusion reactions = 215
2) Haemovigilance reporting system covers all reactions, not only serious ones. Therefore, data on all reactions presented here
3) Data collected for adverse reactions submitted to EU Regulatory Committee, but not available here
4) Only serious adverse reactions with a certain imputability are reported. Other serious adverse reactions: 1 FNHR, 1 epileptic seizure, 15 unknown
5) Data on 844 885 issued blood components
6) Only 16 non-serious adverse reactions reported in 2008 with imputability level 1 (7) and level II (9)
7) Haemovigilance systems on the national, regional and local levels are being prepared
8) All allergic reactions presented with dermatological symptoms - purpura (not anaphylaxis). Other serious reactions are febrile reactions

APPENDIX

Questionnaire on the collection, testing and use of blood and blood components in Europe
The 2008 survey

Strasbourg, 31 March 2006

QUESTIONNAIRE ON THE COLLECTION, TESTING AND USE OF BLOOD AND BLOOD COMPONENTS IN EUROPE

THE 2008 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 and for the future improvement of the questionnaire. When information or data on specific terms is not available, please indicate "n.a." (=data not yet available).

This questionnaire has been elaborated by and is copyright of Dr Olof Akerblom and Dr C.L. van der Poel. Revisions and additions have been made to comply with a World Health Organisation (WHO) questionnaire on selected indicators. Any questions you might have when filling out the questionnaire should be directly addressed to Dr C.L. van der Poel, c.vanderpoel@sanquin.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 figures also asked for in this questionnaire (No. 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).

The questionnaire is to be completed and returned by 15 September 2006 to Dr C.L. van der Poel, c.vanderpoel@sanquin.nl, copy to the Secretariat, Health Division, Council of Europe, F-67075 Strasbourg Cedex, Fax: + 33 388 41 2726; e-mail: sophie-marie.leguilloux@coe.int

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

Comments to the data given in Table 1

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 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	**Cryoprecipitat**e, 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

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