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

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2009 report

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2009 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 2006. In its present form it follows a series of similar reports that have assessed such data in 1989, 1991, 1993, 1995, 1997, and annually in its present revised form from 2001 to 2008.

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

Also, 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 collating data from many Blood Establishments (BE) on a national level within the MS, the process is designed so that annual repetition will lead to improvements.

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

In MS and BE, data may be administered in different formats and different definitions may be used. This could result in discrepancies or errors if the data is then reported in another format. In addition, some data may not be available. It is anticipated that consistency and persistence with these CoE survey methods, together with the support of the EC, will result in adoption of uniform data collection by BE and MS, thereby generating better data and higher response rates among MS. In order to facilitate uniformity, definitions of the EC directives and CoE guidelines are used as far as possible (*EC Council Recommendation 98/463/EC, Directive 2002/98/EC, Guide to the preparation, use and quality assurance of blood components, 9th edition, 2002*). In addition, it is to be welcomed that the European Medicines Agency 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, 29 questionnaires were received in 2009. Thus, the response rate of 63 % was lower than that of the 2007 (76 %) and 2008 (72 %) surveys.

The average number of donors in relation to the general population was 30 per 1,000 inhabitants. On average 19 % of the donor base consisted of first-time donors.

The number of Whole Blood (WB) collections was on average 41 per 1,000 inhabitants, and the average use of Red Blood Cells (RBC) was 39 per 1000 inhabitants. On average, 3.7 litres (L) of plasmapheresis plasma per 1,000 inhabitants was collected.

The use of blood was expressed as units (U) distributed by BE in 69 % of the reporting MS; the remaining 31 % of MS reported it as transfused units. The use of RBC varied considerably (range 13-60 U, median 40 U) and averaged 39 total RBC U per 1000 inhabitants. Two MS (8 %) used less than 20 U per 1000 inhabitants, most likely reflecting an insufficient supply. In the respondent MS, on average 39 % of the total platelet volume was supplied by (random) single donor platelets by apheresis; in nine countries (35 %), this volume amounted to more than 50 %.

The amount of plasma delivered for fractionation into medicinal products differed greatly among MS (range 0-41 L), with an average yield of 9.8 L of plasma for fractionation per 1000 inhabitants. However 15 % of the reporting MS delivered 15 L or more plasma per 1000 inhabitants. In Europe, on average, 55 % of the plasma for fractionation was from recovered plasma.

In 46 % of the MS, all RBC products were leucocyte-depleted. Platelet concentrates were 100 % leucocyte-depleted in 58 % of MS and, in 45 % of the MS, all plasma for transfusion was leucocyte-depleted. In 38 % of the reporting MS, all Fresh Frozen Plasma (FFP) was safeguarded by either quarantine or viral inactivation methods.

In 96 % of the reporting MS, all donations were tested for anti-HIV-1/2, HBsAg and anti-HCV. All donations were tested for syphilis in 89 % of respondent MS. Anti-HTLV-I/II testing was performed on all donations in 23 % of reporting MS and on first-time donors in 8 % of cases. Anti-HBc testing was performed on all donations in 19 % MS and only on first-time donors in 15 %. Prevalence and incidences of infectious diseases varied greatly among MS and it is noteworthy that a North-South gradient exists in Europe for the prevalence of the Hepatitis B and C viruses. The median prevalence amongst first-time tested donors was 5.5, 79 and 50 per 100 000 donors for HIV-1/2, HBV and HCV, respectively. The median incidence amongst repeat donors was 1.1, 0.9 and 1.3 per 100 000 donor years for HIV-1/2, HBV and HCV, respectively.

Nucleic Acid Testing (NAT) for HIV was performed on each donation in 58 % of reporting MS. HBV NAT and HCV NAT on each donation was performed in 46 % and 56 % of MS, respectively.

Bacterial screening was performed in 72 % of reporting MS. Screening of 80 % or more of platelet concentrates was performed in 24 % of MS.

All MS reported having legally-binding national regulations for the collection, testing, processing, storage and distribution of blood and blood components. In 82 % of the reporting MS, a National Council or Expert Committee existed to advise the Ministry of Health on transfusion-related policy issues. In 89 % of MS, a national policy on the quality and safety of blood and blood components was in place.

In 96 % of MS, a Quality System (QS) had been established and was maintained in BE. Inspections were (partly) carried out by the national authority at least every 2 years in all of the 27 reporting MS. All donations were covered by International Society for Blood Transfusion (ISBT), Good Manufacturing Practice (GMP) or other procedures in 92 % of the reporting MS. Labelling of donations according to either ISBT-128 or other procedures was performed by 89 % of MS for all donations. Labelling of all components by either ISBT or another system was done by 85 % of MS.

Ninety-six per cent of all MS indicated that a national haemovigilance reporting system was present. Taking the possibility of under-reporting and differences in national reporting systems into account, an overall incidence rate of 8.9 serious adverse reactions per 100 000 distributed blood components was calculated. This estimate is based on data provided by 19 MS. Anaphylaxis, haemolysis and TACO appeared to be the most frequent serious adverse reactions.

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List of abbreviations

Ag	Antigen
BE	Blood Establishments
CD-P-TS	European Committee (Partial Agreement) on Blood Transfusion
CoE	Council of Europe
CP	Cryoprecipitate
CSP	Cryosupernatant Plasma
EC	European Commission
EDQM	European Directorate for the Quality of Medicines and HealthCare
ELISA	Enzyme-Linked Immunosorbent Assay
EU	European Union
FFP	Fresh Frozen Plasma
FVIII	Factor VIII
GMP	Good Manufacturing Practice
GTS	*Ad hoc* working group on the guide to the preparation, use and quality assurance of blood components
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
ISO	International Organization for Standardization
IU	International Unit
L	Litres
MS	Member States of the Council of Europe
NAT	Nucleic Acid Amplification Techniques

PABD	Pre-operative Autologous Blood Donation
QS	Quality System
RBC	Red Blood Cells
SP-GS	Committee of Experts on Quality Assurance in Blood Transfusion Services
SP-HM	Committee of Experts on Blood Transfusion
TACO	Transfusion Associated Circulatory Overload
TTP	Thrombotic Thrombocytopenic Purpura
U	Unit
vCJD	Variant Creutzfeldt-Jakob disease
WB	Whole Blood

STUDY METHODS

The methods applied in this survey were, in principle, the same as those used in the previous surveys. Briefly, the Secretariat of the European Directorate for the Quality of Medicines and Healthcare (EDQM) circulated the questionnaire to experts in MS, requesting that the completed forms be returned to the Secretariat. Completed questionnaires and comments were received until December 2010. After meetings with GTS (*Ad hoc* working group on the guide to the preparation, use and quality assurance of blood components) and CD-P-TS (European Committee (Partial Agreement) on Blood Transfusion) in March 2011, corrections and additions were provided by experts from MS, after which the report was finalised and adopted by the CD-P-TS.

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

Trend analysis and incomplete data

Comparisons with results from the previous surveys and trend analyses are envisaged. Initial trend analyses were reported, in draft format, in December 2007 and comprised data from 2001 through to 2005. Not all of the information requested in the questionnaire is included in the reported tables, but additional data is mentioned where justified. Occasionally, the end of row/column totals in the tables may not precisely match the sum of the contributing figures because of rounding. It was assumed that information was not available when information was not provided. The absence of a response (or data inconsistency) is represented by empty fields in the tables.

Remarks on the data

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

With the launch of the web-based questionnaire, which was established for collecting the data for the 2007 and subsequent surveys, the risk of errors may be reduced. In addition, the Julius Centre can, on request, provided MS with a spread sheet tool to pre-collate the requested data from more than one BE if needed so that the final data to be submitted can be combined using an automated procedure.

As the Austrian Red Cross collects blood in Liechtenstein and tests and processes it in their centre in Feldkirch (Austria), the blood transfusion data of Liechtenstein is included in the data provided by Austria.

RESULTS

Response rate

The 46 MS of the CoE were invited to send completed questionnaires. Replies were received from 29 MS by the deadline for submissions (July 2011); a response rate of 63 %. The response rates were 76 % and 72 % for the 2007 and 2008 surveys, respectively, which means there has been a decrease in the MS response rate. It is possible that a longer period between the beginning and end of data collection would enable more MS to submit reports. However, it is envisioned that with increasing familiarisation with the CoE surveys in MS, a shorter revision and reporting cycle should be possible.

Donors, first-time donors and inhabitants: Table 1

The questionnaire requires data on donors 'active during the year', and must include only those donors who actually donated during the reporting year. In many establishments or countries, the query format on the donor database would thus need to be compliant. This may not yet always be the case. 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 *EC Council Recommendation of 29 June 1998 on the suitability of blood and plasma donors and the screening of donated blood in the European Community (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 combined total of the two categories represents those donors who are known to the system or BE 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 European Union (EU) countries, the reporting of prevalence and incidence on these donor populations became mandatory in 2005 under *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 became known as 'qualified donors' when their applicant donor infectious disease tests are returned as negative. Only including 'qualified donors' in the report would generate a bias in reporting Infectious Disease Markers (IDM) (see Table 7). The term 'new donors' in *EC 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 in the reporting year, either at the time of donation or if they donate at a later stage.

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 turnover rate in the donor base. However, this figure may be influenced by recruitment programmes. The number of first-time donors, as compared to the total number of donors, becomes less meaningful in systems that only register donations and, even less so, only the (uniquely identifiable) donors.

Excluding MS where first-time donors and repeat plus regular donors were not reported separately, 19 % (range 10-40 %) of the total donor base consisted of 'first-time' donors. It is known that first-time donors may have higher incidences of infectious diseases compared to regular or repeat donors (Schreiber *et al.*, 2001).

The average number of donors in relation to the general population was 30 (range 15-62) per 1000 inhabitants. This number may reflect the commitment of the population to donate blood in relation to demand. Differences exist but, arbitrarily, less than 10 donors per 1000 inhabitants should really 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 RBC units to hospitals (see Table 3) but, in general, these figures are related. As stated before, some caution should be exercised in the interpretation of the number of 'active' donors, and 'inactive' donors may bias the database. However, maintaining 'inactive' donors in the database may be used as a strategy to 'reactivate' known donors.

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 a source material for the manufacture of medicinal products (see Table 4). The number of WB collections in the 28 respondent MS was, on average, 41 (range 18-67) per 1000 inhabitants. Given the average use of RBC per 1000 inhabitants (39 U, range 13-60 U, 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 the supply.

- Autologous blood

Autologous donations are promoted as safe blood transfusions because they limit patient exposure to allogeneic blood and also with a view to enhancing the blood supply. In general, enhancement of the blood supply does not appear to be significant: in the 27 MS where autologous donations are given, they only contributed on average to around 0.5 % (range 0-3.7 %, median 0.03 %) of 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 haemodilution and intra-operative blood salvage, are not included in the data presented here. In this survey, only Pre-operative Autologous Blood Donations (PABD) were 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 FFP) is also collected by apheresis donations. The volume of plasma collection by apheresis per 1000 inhabitants reflects the volume of national plasmapheresis programmes. In the 26 reporting MS, on average 3.7 L (range 0-38 L, median 0.2 L) of plasma per 1000 inhabitants was collected by plasmapheresis. The Czech Republic, Germany and the Netherlands are prominent as countries with considerably more extensive plasmapheresis programmes, with 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. It may also be used to replace the provision of platelets from pooled WB donations 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 26 reporting MS, on average 39 % (range 0-90 %, median 35 %) of the adult therapeutic doses of platelets were produced by apheresis. The vast range may reflect different blood management models, such as low access to HLA-typed platelet donors or MS striving towards 100 % platelet supply by apheresis.

RBC apheresis is a relatively new development and may be of particular interest for autologous programs and for collections of rare RBC blood types. 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 distributed to hospitals by BE (see *Directive 2002/98/EC* for a definition). This depends on the source of the data and the national infrastructure. Data on actual use in hospitals is generally quite difficult to obtain in many MS; although, in some countries, BE are hospital-based and the data provided can be related to actual transfusions issued. As component losses in hospitals are limited, the number of blood components delivered to hospitals represents an acceptable proxy of blood use estimates, and the heterogeneity of the given data may result in only minor deviations. For 18/26 (69 %) of the respondent MS, the use of blood was expressed as the units distributed by BE, whereas 8 MS reported it as transfused units.

WB "must be considered as a source material and has no, or only a very restricted, place in transfusion therapy" (*Guide to the Preparation, Use and Quality Assurance of Blood and Blood Components, 8th edition, 2001*). However, in countries with limited resources, transfusion therapy with WB may be needed when the infrastructure for blood component preparation is lacking. In 25 respondent MS, on average 1.2 % (range 0-27, median 0.00) of transfusions were performed with WB. In Romania, WB accounted for almost 1/3 of the total volume of RBC products used.

The use of RBC per 1000 inhabitants varied considerably. In 25 reporting MS, it averaged 39 total RBC products per 1000 inhabitants (range 13-60, median 40). 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. RBCs 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 installed 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 2/25 (8 %) of the reporting MS, less than 20 U blood per 1000 inhabitants were used, which most likely reflects an insufficient blood supply or limited hospital care. A better benchmark may be achieved by including the number of hospital beds in a future survey and linking this figure to RBC use. The use of plasma for transfusion has been discouraged over the last decade, mainly because its clinical indications are limited and there is a greater need for plasma as a source material for fractionation into medicinal products. However, FFP transfusions are needed for multiple coagulation disorders, including Thrombotic Thrombocytopenic Purpura (TTP). 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 programmes for 'better use of blood' (e.g. RBC use) in some countries increased the FFP/RBC ratio by reducing the rate of RBC use. On average, the FFP/RBC ratio among respondent MS was 0.34 (range 0.003-1.2, median 0.25).

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 the 26 reporting MS, 39 % (range 0-90 %, median 35 %) of the adult therapeutic doses of platelets were produced by (random) single donor platelets by apheresis (Table 3). In nine countries (35 %), this volume amounted to more than 50 %.

Cryoprecipitate may incidentally be used for fibrinogen, Von Willebrand's disease and complex coagulation disorders, though 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 differed among MS. This variation was clearer when the figures were related to population size. In 26 reporting MS, there was an average yield of 9.8 L (range 0-41 L) per 1000 inhabitants of plasma for fractionation into medicinal products. However, 4 of the 26 (15 %) reporting MS delivered 15 L or more plasma per 1000 inhabitants.

In Europe, the main supply of plasma for fractionation was recovered plasma; in 13 reporting MS, on average 54 % of the plasma for fractionation was from recovered plasma (range 0-100 %, median 65 %).

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

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

In 12/26 (46 %) of reporting MS, 100 % leucocyte depletion of RBC products was carried out. This was the case for platelet concentrates in 15/26 (58 %) of the respondent MS. Complete (100 %) leucocyte depletion was applied to plasma for transfusion in 10/22 (45 %) of the reporting MS.

Irradiation of blood components is carried out in order to prevent Graft Versus Host Disease (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 extent 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 or Methylene Blue treatment. In 9/24 (38 %) reporting MS, nearly all FFP (> 98 %) was safeguarded by either method; in 3/23 (13 %) MS using only quarantine, in 5/22 (23 %) MS using almost only pathogen reduction (one MS reported 98 % or more), and in 1/24 (4 %) MS using a combination of the two methods.

Screening for infectious markers & serological test methods: Table 6

In 27 out of 28 reporting MS (96 %), all donations were tested for anti-HIV-1/2, HBsAg and anti-HCV. In 25 (89 %) of respondent MS, all donations were tested for syphilis. Only in Norway were first-time donors tested for syphilis. It has been debated in the literature as to whether syphilis testing is necessary.

Testing for anti-HTLV-I/II was performed on all donations in 6/26 (23 %) reporting MS and only on first-time donors in 2/26 (8 %) MS.

Testing for anti-HBc was performed on all donations in 5/26 (19 %) reporting MS and only on first-time donors in 4/26 (15 %) MS.

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

Given the limited positive predictive value of serological screening tests, donors who are found to be positive for IDM blood screening tests 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 Council Recommendation 98/463/EC*.

In Table 7.1, the absolute numbers of 'confirmed positive' donors reported among all first-time tested donors (see Table 1) and among all repeat donors tested (see Table 1) are given. Overall, 25 of 27 (93 %) MS were able to provide the absolute numbers of confirmed positive donors for Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV) (see Table 7.1).

- First-time tested donors

The frequency of 'confirmed positive' donors among all first-time tested donors (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 the time of their first visit, blood donors are a selected population. The 'prevalence' of infectious diseases among first-time donors was calculated from the data in 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 of infectious diseases per 100 000 first-time tested donors ranged from 0 to 178 for HIV-1/2, from 0 to 1,964 for HBV and from 0 to 659 for HCV. Although considerable differences in the geographical distribution of these infections exist in Europe, it is questionable as to whether the extremely high frequencies in some countries reflect reliable data on actual 'confirmed positive donors' or, merely, represent repeat positive donors screened by Enzyme-Linked Immunosorbent Assay (ELISA) and, thereby, includes many false positives (see the definitions in the questionnaire in the Appendix). The geographical distribution of the high prevalence areas may coincide with low resources and a lack of confirmatory testing. Median prevalence estimates might be a more appropriate and robust reference for European prevalence of infectious diseases amongst first-time donors. The median prevalence amongst first-time tested donors was 5.5, 79 and 50 per 100 000 donors for HIV-1/2, HBV and HCV, respectively.

- Repeat tested donors

The frequency of 'confirmed positive' donors (*i.e.* donors found to be positive for infectious diseases with confirmatory testing) among all repeat plus regular donors tested yields the 'incidence' of an infectious disease among all 'repeat tested donors' (*i.e.* all donors who on a previous occasion have tested negative for an infectious disease). This 'incidence' accounts for the frequency with which repeat plus 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 plus regular donors was calculated from the data in Table 7.1 (number of confirmed positive donors) and Table 1 (number of repeat plus regular donors), and is presented in Table 7.2. As with the data on prevalence in first-time tested donors, it cannot be completely excluded that extremely high incidence rates may refer only to repeat positive donors of ELISA screening instead of confirmed positive donors and, thereby, include many false positives (see the definitions in the questionnaire in the Appendix). The geographical distribution of the high incidence areas coincides with high prevalence areas and may be linked to low resources and a 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 varied greatly among MS. Overall, it is noteworthy that a North-South gradient exists in Europe, with HBV and HCV infections more common in southern countries.

The incidence per 100 000 repeat tested donor years ranged from 0 to 29 for HIV-1/2, from 0 to 164 for HBV and from 0 to 87 for HCV. The median incidence amongst repeat donors was 1.1, 0.9 and 1.3 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 was performed on each donation in 15/26 (58 %) reporting MS. NAT testing for HBV was performed on each donation in 11/24 (46 %) of the respondent MS. NAT testing for HCV was performed on each donation in 14/25 (56 %) MS. Interestingly, NAT on each donation appeared 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.

The 'yield' of NAT is defined as the identification of a NAT-positive donor, who is not found to be sero-positive for that virus in serological screening on the same donation, but is later shown 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 dataset for bacterial screening of platelet concentrates has been added since 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 facilitating bacterial growth. Application of bacterial testing was reported by 21 MS (72 %). In 5/21 (24 %) reporting MS, bacterial culture was performed on 80 % or more of all platelets (concentrates recovered both from WB donations and apheresis platelets). Among the 13 MS that reported on the parameter, the average rate of confirmed positively-cultured platelet concentrates was 11 % (ranging from 0 to 98 %, median value: 0 %).

Organisation and registration: Table 10

All MS reported that there were legally-binding national regulations for the collection, testing, processing, storage and distribution of blood and blood components. In 23/28 (82 %) of the reporting MS, a National Council or Expert Committee advised the Ministry of Health on transfusion-related issues. In 25/28 (89 %) MS, there was a national policy on the quality and safety of blood and blood components. Of these 25 MS, 21 (84 %) had implemented the national blood policy or were in the process of doing so.

Quality management: Table 11

In 26/27 (96 %) of the reporting MS, a QS was established and maintained by BE; implementation of such a system was planned in the remaining respondent MS. All 27 reporting MS indicated that inspections were performed at least every 2 years. Almost all of these inspections (26/27, 96 %) were (partly) carried out by the national authority.

In 19/21 (90 %) of the reporting MS, all donations were covered by GMP. In the two MS that reported that GMP were not applied, donations were covered either by ISO 9000 or other procedures. In five MS, donations were fully covered by both GMP and International Organization for Standardization (ISO) procedures. In Italy, ISO only covered 40 % of all donations, but all donations were covered by other regulations. In Malta, all donations were covered by other regulations (EU directives and EDQM manual). Greece reported a mixture (93 %) of GMP and ISO coverage. In total, 23/25 (92 %) reporting MS covered 100 % of donations by either of these procedures.

It is requested that labelling of donations and issued components is unique so as to allow full traceability. Labelling according to ISBT-128 for 100 % of the donation numbers was performed in 13/21 (62 %) MS. In 10 MS, all donations were coded under another system, but a mix of ISBT and other systems also occurred. Overall, labelling of all donations (either to ISBT standards or those of another system) was performed by 24/27 of the reporting MS (89 %).

Labelling of the finished component code is more complex and, in general, lags behind in development as it includes implementation of software applications in hospitals. ISBT-128 labelling of all issued components was performed in 9/19 (47 %) reporting MS. Overall, 22/26 reporting MS (85 %) reported that all components were coded either by the ISBT or another system.

Haemovigilance: Table 12

Since 2004, this survey has contained 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 procedures 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 immediately after transfusion, even if it is most likely related to the transfusion procedure, 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 to 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.

Of the MS that reported having a national haemovigilance system (27/28, 96 % MS), 21 (76 %) provided actual haemovigilance data. The incidence of serious adverse reactions with high imputability (level 2 to 3, *i.e.* likely or certain) can be calculated relative to the total number of blood products (whole blood + red blood cells + plasma + platelets) issued (or transfused). Taking the possibility of under-reporting and the differences in national reporting systems into account, an average incidence of 8.9 serious adverse reactions per 100 000 distributed blood components seemed a reasonable estimate. Anaphylaxis, haemolysis and TACO were the most frequently reported serious adverse reactions.

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TABLES

List of countries that participated in the 2009 survey (29 out of 46 MSs)

Austria, Belgium, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lichtenstein, Luxembourg, Malta, Moldova, Montenegro, the Netherlands, Norway, 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	
Albania									
Andorra									
Armenia									
Austria	314 493	50 295	13.8	49 151	1144	364 788	8365	43.6	1)
Azerbaijan									
Belgium	311 836	63 992	17.0	63 992		375 828	10 789	34.8	
Bosnia/ Herzegovina									
Bulgaria									
Croatia	89 985	14 172	13.6	14 172		104 157	4437	23.5	
Cyprus									
Czech Republic	353 000	61 500	14.8	61 500		414 500	10 330	40.1	
Denmark	237 922	31 471	11.7	0	31 471	269 393	5535	48.7	
Estonia	14 732	5041	25.5	5 041	0	19 773	1340	14.8	2)
Finland	148 201	20 442	12.1	20 442	0	168 643	5351	31.5	
France	1 265 925	423 570	25.1			1 689 495	64 667	26.1	
FYR Macedonia									
Georgia									
Germany	2 498 893	644 329	20.5	535 352	108 977	3 143 222	81 850	38.4	
Greece	391 558	80 199	17.0			471 757	10 500	44.9	3)
Hungary	219 729	56 236	20.4	56 236		275 965	10 014	27.6	
Iceland	7516	1545	17.1	0	1 545	9061	319	28.4	
Ireland	84 029	13 633	14.0	12 081	2068	97 662	4459	21.9	
Italy	1 329 591	360 835	21.3	264 635	96 200	1 690 426	60 000	28.2	4)
Latvia	38 986	15 547	28.5	15 547		54 533	2248	24.3	
Liechtenstein							35		5)
Lithuania									
Luxembourg	9 205	1 162	11.2	40	1 122	10 367	494	21.0	6)
Malta	5760	2801	32.7	2801	0	8561	405	21.1	
Moldova	45 997	24 181	34.5	24 181		70 178	3568	19.7	
Montenegro	10 360	6944	40.1	4952		17 304	626	27.6	7)
Netherlands	328 866	37 941	10.3	0	37 941	366 807	16 580	22.1	
Norway	93 063	14 136	13.2	0	14 136	107 199	4858	22.1	
Poland									
Portugal									
Romania	434 405	117 481	21.3	117 475	6	551 886	21 500	25.7	8)
Russian Federation									
San Marino									
Serbia		50 358	100.0				7582		
Slovakia	98 583	35 733	26.6	28 264	4999	134 316	5200	25.8	
Slovenia	110 808	12 677	10.3	12 677		123 485	2000	61.7	
Spain									
Sweden	247 481	49 071	16.5		49 071	296 552	9341	31.7	

Table 1 (continued) – 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
Switzerland	229 937	30 440	11.7	30 440	0	260 377	7702	33.8
Turkey								
Ukraine								
United Kingdom	1 167 403	269 744	18.8	250 215	4 028	1 437 147	61 285	23.5

1) Regular donors: data not available.
2) There is no practise in the blood establishments of giving blood samples for testing only purposes.
3) Only in few centers, donors on first visit give blood sample for testing.
4) Only regular donors, first time donors someone has never donated either blood or plasma and someone who has donated before but not within the last two years in the same blood.
5) Donation campaigns are ONLY done by the Austrian Red cross.
6) It was the first time, during 2009, we accepted donations for the first time.
7) First time registered donors were 6944 from which 4952 gave blood in their first visit.
8) Number of regular and repeat donors is an estimation, given the lack of IT system.

Table 2.1 – Collection of whole blood, autologous blood and blood (apheresis) components

Country	WB collections				Apheresis collections						
	WB (U)	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)	
Albania											
Andorra											
Armenia											
Austria	472 206	56.4	6 435	1.3	0	0.00	22 229	1 488	157		1)
Azerbaijan											
Belgium	555 378	51.5	188	0.0	56 256	5.21	1 886	2 327	88	25 079	2)
Bosnia/ Herzegovina											
Bulgaria											
Croatia	175 173	39.5	891	0.5	411	0.09	1 895			1 895	3)
Cyprus											
Czech Republic	432 300	41.8	16 659	3.7	396 200	38.35	17 800	750	77		4)
Denmark	372 061	67.2	0	0.0	178	0.03	340	0	4	0	
Estonia	29 901	22.3	0	0.0	241	0.18	525	0	0	7	5)
Finland	267 417	50.0	0	0.0	2804	0.52	834	0	0	0	
France	2 478 814	38.3	3852	0.2	239 715	3.71	12 042	1 814	245	160 569	6)
FYR Macedonia											
Georgia											
Germany	4 908 796	60.0	45 461	0.9	1 755 624	21.45	173 888	12 013	526	25 483	7)
Greece	631 823	60.2	1 501	0.2	759	0.07	21 423	802		1 903	
Hungary	422 153	42.2	429	0.1			3 224	360			8)
Iceland	13 642	42.7	0	0.0	80	0.25	716	219	0	0	
Ireland	158 229	35.5	0	0.0	0	0.00	10 096	0	0	0	9)
Italy	2 598 305	43.3	79 406	3.0	235 178	3.92	21 174	31 850	361	84 900	10)
Latvia	58 523	26.0	2	0.0			1 848	0			
Liechtenstein											11)
Lithuania											
Luxembourg	22 105	44.8	79	0.4	2 426	4.92	902	0	0	0	
Malta	14 622	36.1	5	0.0	0	0.00	351	0	0	0	12)
Moldova	76 209	21.4	45	0.1	2 655	0.74					
Montenegro	15 312	24.5			0	0.00	0	0	0		13)
Netherlands	575 050	34.7	70	0.0	208 982	12.60	5 635	0	0	0	

Table 2.1 (continued) – Collection of whole blood, autologous blood and blood (apheresis components)

Country	WB collections				Apheresis collections						
	WB (U)	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)	
Norway	202 525	41.7	23	0.0	1 316	0.27	4 707	5 788	0	1 766	14)
Poland											
Portugal											
Romania	390 501	18.2	4	0.0	1 077	0.05	4 676	0			
Russian Federation											
San Marino											
Serbia	248 516	32.8	47	0.0	684	0.09	1 510				
Slovakia	193 964	37.3	1 029	0.5	56	0.01	5 119	204	19	56	15)
Slovenia	95 390	47.7	2 272	2.3	371	0.19	1 375		27	0	
Spain											
Sweden	501 287	53.7	110	0.0	40 998	4.39	8 515	1 296	254		
Switzerland	357 968	46.5	2 961	0.8	1 157	0.15	9 244	2 284		7 805	
Serbia											
Ukraine											
United Kingdom	2 376 670	38.8	0	0.0	182	0.00	119 584	0	57	0	16)

1) Multi-component-apheresis: data not available. Plasma Collection, Industriepl.,L.: 102690 98118 Industry. Quarantänepl.,L.: 3480 3164 (Hospital). MB-Pl.,L.: 973 938 (Hospital; Autologous red cell units, Apheresis: 4868, Concentrates: 2234, Total: 7102.
2) Multi-component donations: donations of platelets and plasma number of red cells includes 3929 small units for babies.
3) Multi-component = platelet + plasma Cryoprecipitate = 0.029.
4) Multicomponent apheresis is performed rarely (usually platelets + plasma), exact figures are not available cryoprecipitate is not in routine use.
5) 7 procedures for multi-component apheresis. Red cells and platelets were collected Issued 443 red cell doses for prenatal, neonatal and infant use.
6) Plasma apheresis donations: 399 526 simple plasma 100 % non remunerated donations. Mean volume per donation: 0.6 l.
7) Data on the number of voluntary non-remunerated donations (%) are not available. Replacement donations not allowed. Total number of whole blood units covers only autologous blood. Number of plasma units (plasma or FFP) for transfusion covers units quarantined FFP and lyophilised plasma and units autologous plasma (2.8 % autologous of total). Cryoprecipitate not in use.
8) In the Hungarian National Blood Transfusion Service collect whole blood and apheresis products from 100 % voluntary non-renumerated donors.
9) Note 98 % of plasma for transfusion is SD Octaplas.
10) Autologous units transfused: red cells: 6551, whole blood: 49 013, total: 55 564.
11) The numbers can be only provided by the Austrian Red Cross, section Vorarlberg.
12) Cryo Units: 650, Cryo (FVIII x 10^6): 0.0455 (Form does not accept this number).
13) Collection of blood and blood components by apheresis procedures are not done in Montenegro yet. Platelets and Cryoprecipitate data are refering only to the units transfused in the Clinical Center of MN - Podgorica, because only this Center prepares and uses these kinds of blood components.
14) All FFP is Octaplas 200 ml.
15) Plasma apheresis donation is only multicomponent donation together with platelets.
16) Single cryo units some of which are supplied as pools of 5 for adults.

Table 2.2 – Profile of donations

Country	Whole blood donations			Red cell 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	
Albania								
Andorra								
Armenia								
Austria	100	0	1.36	100	135		90	1)
Azerbaijan								
Belgium	100	0	0.03	100	0	100	100	2)
Bosnia/ Herzegovina								
Bulgaria								
Croatia	100		0.51			100	100	3)
Cyprus								
Czech Republic	100	0	3.85	34		23	34	4)
Denmark	100	0	0.00	0		100	100	
Estonia	100	0	0.00	0		100	100	5)
Finland	100	0	0.00	0		100	100	
France	100	0	0.16	100		100	100	6)
FYR Macedonia								
Georgia								
Germany		0	0.93		24			7)
Greece	49	50	0.24	62	1	16	93	
Hungary	100		0.10	100	119		100	8)
Iceland	100	0	0.00	100	0	100	100	
Ireland	100	0	0.00	0			100	
Italy	100	0	3.06	100	1	100	100	
Latvia	100		0.00				0	
Liechtenstein								9)
Lithuania								
Luxembourg	100	0	0.36	0		100	100	
Malta	100	0	0.03				100	
Moldova	23	77	0.06					
Montenegro	26	74						10)
Netherlands	100	0	0.01	0		100	100	
Norway	100	0	0.01	100	0	100	100	
Poland								
Portugal								
Romania	100		0.00			9	100	
Russian Federation								
San Marino								

Table 2.2 (continued) – Profile of donations

Country	Whole blood donations			Red cell 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	
Serbia	100	82	0.02	100			100	
Slovakia	100	0	0.53	100	0	179	88	11)
Slovenia	100	0	2.38				100	
Spain								
Sweden	100	0	0.02	100		100	100	
Switzerland	100	0	0.83	100	9	100	100	
Turkey								
Ukraine								
United Kingdom	100	0	0.00	0		100	100	

1) Multi-component-apheresis: data not available. Plasma Collection. °Industriepl.,L.: 102690 98118 (Industry). °Quarantänepl.,L.: 3480 3164 (Hospital). °MB-Pl.,L.: 973 938 (Hospital).
2) Multi-component donations: donations of platelets and plasma.
3) Multi-component = platelet + plasma.
4) Multicomponent apheresis is performed rarely (usually platelets + plasma), exact figures are not available.
5) 7 procedures for multi-component apheresis. Red cells and platelets were collected.
6) Plasma apheresis donations: 399 526 simple plasma 100 % non remunerated donations. Mean volume per donation: 0.6 l.
7) Data on the number of voluntary non-remunerated donations (%) are not available. Replacement donations not allowed.
8) The Hungarian National Blood Transfusion Service collect whole blood and apheresis products from 100 % voluntary non-renumerated donors.
9) The numbers can be only provided by the Austrian Red Cross, section Vorarlberg.
10) Collection of blood and blood components by apheresis procedures are not done in Montenegro yet.
11) Plasma apheresis donation is only multicomponent donation together with platelets.

Table 3 – Use of blood and blood components for transfusion

Country	Transfused or distributed	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)	
Albania												
Andorra												
Armenia												
Austria	Distr.	301	0.1	425 537	50.9	74 420	37 245	8 836	28 409	76.3	0	1)
Azerbaijan												
Belgium	Distr.	0	0.0	522 475	48.4	87 242	68 910	41 100	27 810	40.4	0	2)
Bosnia/ Herzegovina												
Bulgaria												
Croatia	Distr.	451	0.3	173 351	39.1	69 757	13 316	11 275	2 041	15.3	0	3)
Cyprus												
Czech Republic	Trans.	256	0.1	408 856	39.6	199 752	32 225	5 796	26 429	82.0		4)
Denmark	Trans.	0	0.0	330 781	59.8	69 753	32 642	31 240	1 402	4.3	247	
Estonia	Distr.	6	0.0	28 124	21.0	7 098	2 994	2 038	956	31.9	414	5)
Finland		543	0.2	251 742	47.0	50 412	39 929	39 050	879	2.2	0	
France	Distr.			2 332 640		334 761	261 406	94 982	166 424	63.7	0	6)
FYR Macedonia												
Georgia												
Germany	Distr.	7 362	0.2	4 727 995	57.8	1 226 692	466 793	178 234	288 559	61.8		7)
Greece	Distr.	93	0.0	582 786	55.5	220 579	132 680	115 832	16 848	12.7		
Hungary	Distr.	0	0.0	361 151	36.1	93 987	14 259	11 191	3 068	21.5		8)
Iceland	Distr.	0	0.0	13 603	42.6	4 464	1 984	762	1 222	61.6	0	
Ireland	Distr.	0	0.0	146 585	32.9	479	26 329	9 155	17 174	65.2	1 460	9)
Italy	Trans.	4 140	0.2	2 496 132	41.6	513 540	205 215	128 595	76 620	37.3	1 661	10)
Latvia	Distr.	0	0.0	53 251	23.7	38 273	6 208	2 774	3 434	55.3	4 884	
Liechtenstein												11)
Lithuania												
Luxembourg	Distr.	0	0.0	20 272	41.1	4 410	2 315	1 386	929	40.1	0	
Malta	Distr.	0	0.0	14 164	35.0	7 303	1 090	780	310	28.4		12)
Moldova	Distr.	0	0.0	47 925	13.4	58 264	8 574	8 574	0	0.0	13 403	
Montenegro	Trans.	542		12 930		8 769	751				383	13)
Netherlands	Distr.	0	0.0	564 290	34.0	90 390	53 929	49 354	4 575	8.5	0	

Table 3 (continued) – Use of blood and blood components for transfusion

Country	Transfused or distributed	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)	
Norway	Trans.	75	0.0	194 732	40.1	45 415	20 464	13 590	6 874	33.6	13 590	14)
Poland												
Portugal												
Romania	Distr.	102 024	27.3	373 487	17.4	252 216	24 776	19 525	5 251	21.2	17 820	
Russian Federation												
San Marino												
Serbia		248 216		462 542		168 224			1 510		18 028	
Slovakia	Trans.	941	0.5	179 044	34.4	78 988	27 832	17 826	10 006	36.0	0	15)
Slovenia	Distr.	0	0.0	87 005	43.5	31 293	9 405	7 184	2 221	23.6	0	
Spain												
Sweden	Trans.	0	0.0	495 011	53.0	104 920	43 256	28 414	14 842	34.3		
Switzerland	Trans.	2 109	0.7	314 077	40.8	70 353	29 654	2 831	26 823	90.5	0	16)
Turkey												
Ukraine												
United Kingdom	Distr.	1	0.0	2 216 456	36.2	315 357	278 860	73 009	205 851	73.8	122 458	17)

1) Multi-component-apheresis: data not available. Plasma Collection °Industriepl.,L.: 102690 98118 (Industry); °Quarantänepl.,L.: 3480 3164 (Hospital) °MB-Pl.,L.: 973 938 (Hospital; Autologous red cell units: -Apheresis:4868, -Concentrates:2234, -Total: 7102.
2) Multi-component donations: donations of platelets and plasma; number of red cells includes 3929 small units for babies.
3) Multi-component = platelet + plasma; Cryoprecipitate = 0.029.
4) Multicomponent apheresis is performed rarely (usually platelets + plasma), exact figures are not available; cryoprecipitate is not in routine use.
5) 7 procedures for multi-component apheresis. Red cells and platelets were collected; Issued 443 red cell doses for prenatal, neonatal and infant use.
6) Plasma apheresis donations: 399 526 simple plasma 100 % non remunerated donations. Mean volume per donation: 0.6 l.
7) Data on the number of voluntary non-remunerated donations (%) are not available. Replacement donations not allowed. Total number of whole blood units covers only autologous blood. Number of plasma units (plasma or FFP) for transfusion covers units quarantined FFP and lyophilised plasma and units autologous plasma (2.8 % autologous of total). Cryoprecipitate not in use.
8) The Hungarian National Blood Transfusion Service collect whole blood and apheresis products from 100 % voluntary non-renumerated donors.
9) Note 98 % of plasma for transfusion is SD Octaplas.
10) Autologous units transfused: red cells; 6551, whole blood: 49 013, total: 55 564.
11) The numbers can be only provided by the Austrian Red Cross, section Vorarlberg.
12) Cryo Units: 650, Cryo (FVIII x 10^6): 0.0455 (Form does not accept this number).
13) Collection of blood and blood components by apheresis procedures are not done in Montenegro yet; Platelets and Cryoprecipitate data are refering only to the units transfused in the Clinical Center of MN - Podgorica, because only this Center prepares and uses these kinds of blood components.
14) All FFP is Octaplas 200 mL.
15) Plasma apheresis donation is only multicomponent donation together with platelets.
16) Total number of WB units. Exclusively autologous.
17) Single cryo units some of which are supplied as pools of 5 for adults.

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)	
Albania						
Andorra						
Armenia						
Austria	98 118	11.73	0.00	8.90	0.17	
Azerbaijan						
Belgium	178 629	16.56	68.51	8.09	0.17	
Bosnia/Herzegovina						
Bulgaria						
Croatia	20 672	4.66		15.72	0.40	
Cyprus						
Czech Republic	423 343	40.98	12.57	19.34	0.49	1)
Denmark	71 900	12.99		12.60	0.21	2)
Estonia	6 839	5.10	0.00	5.30	0.25	
Finland	60 582	11.32	100.00	9.42	0.20	3)
France	827 740	12.80	77.37	5.18		
FYR Macedonia						
Georgia						
Germany	2 932 794	35.83	41.17	14.99	0.26	
Greece	24 207	2.31		21.01	0.38	
Hungary	74 228	7.41		9.39	0.26	4)
Iceland	0	0.00		13.98	0.33	
Ireland	0	0.00		0.11	0.00	
Italy	686 999	11.45	65.10	8.56	0.21	
Latvia	823	0.37		17.02	0.72	
Liechtenstein						5)
Lithuania						
Luxembourg	7 340	14.87	77.62	8.94	0.22	6)
Malta	0	0.00		18.03	0.52	
Moldova	4 828	1.35	5.55	16.33	1.22	7)
Montenegro				14.00		8)
Netherlands	334 420	20.17	46.93	5.45	0.16	
Norway	53 552	11.02		9.35	0.23	9)
Poland						
Portugal						
Romania	0	0.00		11.73	0.68	10)
Russian Federation						
San Marino						
Serbia				22.19		
Slovakia	23 847	4.59	100.00	15.19	0.44	
Slovenia	14 106	7.05	97.37	15.65	0.36	
Spain						
Sweden	115 186	12.33	64.65	11.23	0.21	
Switzerland	77 378	10.05		9.13	0.22	

Table 4 (continued) – 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)
Turkey					
Ukraine					
United Kingdom	0	0.00		5.15	0.14

1) Eg. plasma produced in 2009 and prepared for delivery (e.g. plasma produced in 2009 but sent in 2010 is included, plasma produced in 2008 but sent in 2009 is not included).
2) In our contract with CSL the amount of plasma for FVIII or other components has not been stated. However we only deliver plasma, recovered from whole blood for fractionation.
3) 13 196 litres of FFP were used for production of virus inactivated plasma for clinical use (Octaplas). 4320 units of outdated red cells were used for production of a medicinal product.
4) This is kg.
5) See Austrian Red Cross.
6) Other plasma : from thrombapheresis.
7) 268 L is 12 000 units of cryoprecipitate, other plasma represents 12 000 units decryoprecipitate plasma.
8) As mentioned above, collection and preparing of all blood components have been done from whole blood and none of the components have not been delivered for the manufacturing of medicinal products.
9) Plasma for fractionation. We do not know what they (Baxter) do produce.
10) No fractionation plant or 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. %	
Albania								
Andorra								
Armenia								
Austria	100	12	100	0	100	70	0	1)
Azerbaijan								
Belgium	100		100	0	100		31	
Bosnia/ Herzegovina								
Bulgaria								
Croatia	17		1		89			
Cyprus								
Czech Republic	29	7	0	3	80	20	0	2)
Denmark	65	2	0	1	97	29	0	
Estonia	6	4	0	0	43	23	0	3)
Finland	100	3	0	0	100	33	0	4)
France	100		100		100			
FYR Macedonia								
Georgia								
Germany	100	4		0	100	34	0	5)
Greece	37	18	40	12	75	24		
Hungary	10	3		3	34	12	0	
Iceland	21	10	5	2	100	85	0	
Ireland	100	13	100	0	100	100	0	6)
Italy	16	5	36	0	57	23	1	7)
Latvia	15	2	0	0	57	28	0	
Liechtenstein								
Lithuania								
Luxembourg	100	0	100	0	100	4	0	
Malta	100	5	100	0	100	10	0	
Moldova								
Montenegro								8)
Netherlands	100	4	100	0	100	42	0	
Norway	100	8	100	0	100	33	21	9)
Poland								
Portugal								
Romania	5		5		2		0	10)
Russian Federation								
San Marino								
Serbia	53	2			8	1		
Slovakia	20	1			41	1	0	
Slovenia	78	3	48	0	100	18	53	11)
Spain								
Sweden	87	4	93	3	100	50	10	12)

Table 5.1 (continued) – Special processing of blood components

Country	RBC		Plasma for transfusion		Platelets			
	% leucocyte depleted	% irradiated	% leucocyte depleted	% irradiated	% leucocyte depleted	% irradiated	Path.inact. %	
Switzerland	100		100		100			
Turkey								
Ukraine								
United Kingdom	100	8	100	0	100	54	0	13)

1) Cryoprecipitate: not produced by blood establishments.
2) Cryoprecipitate is not in a routine use.
3) Number of irradiated red cells is rounded to 4 (3.6 % as original data).
4) Hospitals also irradiate blood components. All plasma for transfusion is Octaplas.
5) Data on leukocyte depleted plasma for transfusion are not collected. Cryoprecipitate reduced plasma components and Cryoprecipitate: not in use.
6) A very small percentage of cryo for neonates is quarantined 0.01 %.
7) Platelets leucoreduced prestorage/platelets Aferesis*100.
8) Leukocite depleted and irradiated blood components (RC and PLT) are prepared in specific cases only.
9) Only Octaplas used.
10) Around 50-70 % of FFP is quarantined; data not available, accurate data unavailable.
11) Pathogen reducion of PLP started in July 2009.
12) All irradiated components are previously lecukocyte depleted.
13) FFP and cryo is imported & Methylene Blue treated for children under 16.

Table 5.2 – Inactivation or quarantine of plasma

Country	FFP		CP reduced plasma		Cryoprecipitate		
	% quarantined	% virus inactivated	% quarantined	% virus inactivated	% quarantined	% virus inactivated	
Albania							
Andorra							
Armenia							
Austria	19	6	0	0	0	0	1)
Azerbaijan							
Belgium	0	100	0	0	0	0	
Bosnia/Herzegovina							
Bulgaria							
Croatia							
Cyprus							
Czech Republic	100	0					2)
Denmark	0	0	0	0	0	0	
Estonia	0	0	0	0	0	0	3)
Finland	0	100	0	0	0	0	4)
France	35	100	35	0	0	0	
FYR Macedonia							
Georgia							
Germany	100	0	0	0	0	0	5)
Greece	21						
Hungary	0						
Iceland	0	0					
Ireland	0	98	0	0	0	0	6)
Italy	15	12	0	0	0	0	7)
Latvia	59	0			100	0	
Liechtenstein							
Lithuania							
Luxembourg	0	100	0	0	0	0	
Malta	30	0	0	0	50	0	
Moldova							
Montenegro							8)
Netherlands	100	0	0	0	0	0	
Norway	0	0	0	0	0	0	9)
Poland							
Portugal							
Romania		0		0		0	10)
Russian Federation							
San Marino							
Serbia							
Slovakia	46	0	0	0	0	0	
Slovenia	0	0	0	0	0	0	11)
Spain							
Sweden	0	1					12)
Switzerland	92	8					
Turkey							

Table 5.2 (continued) – Inactivation or quarantine of plasma

Country	FFP		CP reduced plasma		Cryoprecipitate		
	% quarantined	% virus inactivated	% quarantined	% virus inactivated	% quarantined	% virus inactivated	
Ukraine							
United Kingdom	0	4	0	0	0	4	13)

1) Cryoprecipitate: not produced by blood establishments.
2) Cryoprecipitate is not in a routine use.
3) Number of irradiated red cells is rounded to 4 (3.6 % as original data).
4) Hospitals also irradiate blood components. All plasma for transfusion is Octaplas.
5) Data on leukocyte depleted plasma for transfusion are not collected. Cryoprecipitate reduced plasma components and Cryoprecipitate: not in use.
6) A very small percentage of cryo for neonates is quarantined 0.01 %.
7) Platelets leucoreduced prestorage/platelets Aferesis*100.
8) Leukocyte depleted and irradiated blood components (RC and PLT) are prepared in specific cases only.
9) Only Octaplas used.
10) Around 50-70 % of FFP is quarantined; data not available. Accurate data unavailable.
11) Pathogen reduction of PLP started in July 2009.
12) All irradiated components are previously lecukocyte depleted.
13) FFP and cryo is imported & Methylene Blue treated for children under 16.

Table 6.1 – 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	
Albania											
Andorra											
Armenia											
Austria	100	100	100	21	100	0	0	100	0	Neopterin-Screening-Elisa-Test (Brahms, IBL): Testing every donation. ALT (Abbott, Rochè, Dade/Siemens): Testing 29 %. Anti-CMV (IgG, IgM), Abbott, Dade/Siemens: Testing 34 %.	
Azerbaijan											
Belgium	100	0	100	First	100	0	0	100			1)
Bosnia/Herzegovina											
Bulgaria											
Croatia	100	100	100	0	100	100	0	100	0		2)
Cyprus											
Czech Republic	100	100	100	0	100	20	0	100	0		3)
Denmark	100	100	100	0	100	0		0			4)
Estonia	0	0	100	0	100	0	0	100	0	HIV 1/2 Ag/Ab: Testing every donation.	
Finland	100	100	100	0	100	0	0	100			5)
France	100	0	100	100	100	0	100	100			6)
FYR Macedonia											
Georgia											
Germany	100		100	100	100	0	0	100	0		7)
Greece	100		100		100		100	100			8)
Hungary	100	0	100	First	100	0	0	100	0		
Iceland	100	100	100	0	100	0	0	0			9)
Ireland	100	0	100	100	100	0	100	100	0		10)
Italy	100	0	100	0	100	0	0	100	0		
Latvia	100	0	100	0	100	0	0	100	0		
Liechtenstein											
Lithuania											
Luxembourg	100	100	100	First	100	0	First	100	2	Anti CMV screening test: Testing 0 %.	11)
Malta	100	100	100	100	100	100	0	100	0		

Table 6.1 (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	
Moldova	100	100	100	0	100	0	0	100	0		
Montenegro	100	100	100		100	0	0	100	0		12)
Netherlands	100	0	100	0	100	0	100	100	0	Anti-Parvo: Testing 0 %.	
Norway	100	100	100	10	100	0	0	First		Testing 1%.	13)
Poland											
Portugal											
Romania	100	100	100	0	100	100	100	100	0	ALT: Testing every donation.	14)
Russian Federation											
San Marino											
Serbia	100		100	0	100	0		100	0		
Slovakia	100	100	100	100	100	0	0	100	0		
Slovenia	100	100	100	0	100	0	0	100	0		
Spain											
Sweden	100		100	First	100	0	First	100	0		15)
Switzerland	100	50	100	0	100	0	0	100	1	CMV: Testing first donation only.	16)
Turkey											
Ukraine											
United Kingdom	100	100	100	1	100	0	100	100	1	Chagas' disease: Testing 1 %. Anti-CMV: Testing 30 %.	17)

1) Anti-HBc: and if indicated; Malaria: in case of history of malaria; ant-CMV: very small % of red cells and PLT for patients with allogeneic stem cell transplantation (both donor and recipient CMV seronegative), intra uterine transfusion and neonates weighing less than 1500 g.
2) Anti-HIV: At/Ab combo test; HIV Ag: At/Ab combo test; Anti-HCV: At/Ab combo test; HCV Ag: At/Ab combo test.
3) Anti-HIV: HIV Ab + Ag combined test is used; HIV Ag: HIV Ab + Ag combined test is used; Anti-HCV: 20 % donations are tested using HCV Ab+Ag combined test; HCV Ag: 20 % donations are tested using HCV Ab+Ag combined test; Syphilis: specific antibody.
4) Anti-HTLV: First time donors and donors traveling to endemic areas; Malaria: Donors traveling to endemic areas.
5) Malaria: Only donors who have visited or resided in endemic areas are tested, 0.1 % of donations.
6) Malaria: Only if donor has been travelling or living in exposed areas. Chagas disease: Only if donor has been travelling or living in exposed areas.
7) HIV Ag: No data. Antibody-Antigen-Combitests for HIV-1/2 are used by some of the blood establishments; Anti-HBc: Persons, tested positive for anti-HBc, can further donate blood if a sensitive assay for HBV-Genom results negative and if anti-HBs antibody-titer stays above 100 IU/l.
8) Anti-HIV: Data on 582 808 donations; HIV Ag: When required; HBsAg: Data on 582 808 donations; Anti-HBc: When required; Anti-HCV: Data on 582 808 donations; HCV Ag: When required; Anti-HTLV: Data on 582 808 donations; Syphilis: Data on 582 808 donations; Malaria: When required.
9) Malaria: Only if travelling in malary area, few tests/year.
10) Anti-CMV: First time donors and previous CMV seronegative donors.
11) HIV Ag. It is a serological test with detection of Ag P24; Malaria: After a travel in an area with malaria; Anti CMV screening test: Only since December for new born and immunodepletion.
12) Anti-HBc: Anti-HBc tests are done only in cases of HBsAg positive results.
13) HIV Ag: HIV combo used. Ag testing is not a requirement; Anti-HBc: First time donors and if more than 6 months since the previous donation. % above is an estimate.
14) Anti-HIV: AgAb HIV 1+2 Combo for screening; HIV Ag: AgAb HIV 1+2 Combo for screening; Anti-HCV: AgAb HCV Combo for screening; HCV Ag: AgAb HCV Combo for screening.
15) HIV Ag: A combined ag-ab test is implemented, but coverage not yet known.
16) Malaria: after stay longer than 6 months in countries at risk; CMV: for immunodeficient patients and neonates.
17) HIV Ag: Screened using HIV-Ab/Ag Combo assay; Malaria: If at least 6 months has passed since the date of the last potential exposure to malaria, or the date of recovery from symptoms that may have been caused by malaria, a validated test for malaria antibody is negative, accept.

Table 6.2 – Use of simple rapid tests

Country	Type of test (% of donations)			
	Anti-HIV 1+2	HBsAg	Anti-HCV	Comments
Albania				
Andorra				
Armenia				
Austria	0	0	0	
Azerbaijan				
Belgium	0	0	0	
Bosnia/Herzegovina				
Bulgaria				
Croatia	0	0	0	
Cyprus				
Czech Republic	0	0	0	
Denmark	0	0	0	
Estonia	0	0	0	
Finland	0	0	0	
France	0	0	0	
FYR Macedonia				
Georgia				
Germany	0	0	0	
Greece	0	0	0	
Hungary	0	0		
Iceland	0	0	0	
Ireland	0	0	0	
Italy	0	0	0	
Latvia	0	0	0	
Liechtenstein				
Lithuania				
Luxembourg	0	0	0	
Malta	0	0	0	
Moldova	0	0	0	
Montenegro	0	0	0	Rapid tests are not in use in Blood Transfusion practice in Montenegro.
Netherlands	0	0	0	
Norway	0	0	0	
Poland				
Portugal				
Romania	0	0	0	
Russian Federation				
San Marino				
Serbia	0	0	0	
Slovakia	0	0	0	
Slovenia	0	0	0	
Spain				
Sweden	0	0	0	
Switzerland	0	0	0	
Turkey				
Ukraine				
United Kingdom	0	0	0	

Table 7.1 – Confirmed seropositive donors (absolute numbers)

Country	Proportion confirmatory testing		HIV 1 / 2		HBV		HCV		HTLV-I/II		Syphilis		
	%	Comments	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	
Albania													
Andorra													
Armenia													
Austria	100		4	5	49	9	17	12			28	32	
Azerbaijan													
Belgium	100		1	2	52	3	24	1			14	22	
Bosnia/Herzegovina													
Bulgaria													
Croatia	100		0	1	20	7	8	4			5	15	
Cyprus													
Czech Republic	100	All confirmatory testing is done in central National Reference Lab.	4	2	36	9	126	14			32	19	1)
Denmark	100			1	18		6	1	1				
Estonia	100		5	1	5	0	29	2	0	0	9	15	2)
Finland	100		0	1	2	0	5	2			0	3	
France	100		11	22	322	5	181	13	35	0	249	79	3)
FYR Macedonia													
Georgia													
Germany	100		42	51	805	15	499	55			202	97	
Greece	100	Percentage of RR donations tested is 0.5 %	24	19	1 006	301	201	64	4	1	85	44	
Hungary	100	1.42 % of the screened repeatedly reactive test is positive after the confirmatory process.	2	5	26	10	112	9			10	57	4)
Iceland	100		0	0	1	0	0	0					
Ireland	100		2	0	4	1	1	1	0	0	6	5	
Italy	100		57	54	867	48	408	44			384	176	
Latvia		Only HIV-1/2	9	9									
Liechtenstein													
Lithuania													
Luxembourg	100		0	1	0	0	1	0	0	0	0	0	

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

Country	Proportion confirmatory testing		HIV 1 / 2		HBV		HCV		HTLV-I/II		Syphilis		
	%	Comments	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	
Malta	100		0	0	5	0	0	1			1	0	
Moldova	100		43	0	0	0	0	0			0	0	
Montenegro	65		2	3	7	17	6	9					5)
Netherlands	100		0	2	21	3	10	0	2	0	8	8	
Norway	100		1	1	2	1	5	0			1	1	
Poland													
Portugal													
Romania		"100 % for HIV, HCV, HTLV, 57 % FOR HBV 36 % for Syphilis"	33	7	2 307	0	774	15	42	1	592	0	
Russian Federation													
San Marino													
Serbia	51												
Slovakia	100		0	0	48	8	29	7			13	13	
Slovenia	100		0	0	11	1	2	0			9	5	
Spain													
Sweden	100		1	1	21	0	29	1	1		5	5	
Switzerland	100		2	2	39	2	21	1	0	0	29	8	
Turkey													
Ukraine													
United Kingdom	100		12	14	97	8	80	7	22	1	70	25	6)

1) Total number of donations has incresed by 80 % comparing to 2009!
2) "Repeat tested donors" represents data for repeat and regular donors.
3) 35 confirmed seropositive HTLV I/II tests : 20 in Continental France and 15 in overseas territories (Martinique and Guadeloupe).
4) PCR test is used by the confirmatory laboratory.
5) Diagnostics of Syphilis has been done by ELISA test and confirmatory tests are not done.
6) There were 6 co-infected donors: 2 HBsAg(carrier)/ T.pallidum; 1 HBsAg(carrier)/ HTLV; 1 HCV/HTLV: 1 HCV/T.pallidum; 1 T.Pallidum/HTLV, all in first time tested donors except the HCV/T. Pallidum case.

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	
Albania							
Andorra							
Armenia							
Austria	7.95	1.59	97.43	2.86	33.80	3.82	1)
Azerbaijan							
Belgium	1.56	0.64	81.26	0.96	37.50	0.32	
Bosnia/Herzegovina							
Bulgaria							
Croatia	0.00	1.11	141.12	7.78	56.45	4.45	
Cyprus							
Czech Republic	6.50	0.57	58.54	2.55	204.88	3.97	2)
Denmark		0.42	57.20		19.07	0.42	
Estonia	99.19	6.79	99.19	0.00	575.28	13.58	3)
Finland	0.00	0.67	9.78	0.00	24.46	1.35	
France	2.60	1.74	76.02	0.39	42.73	1.03	4)
FYR Macedonia							
Georgia							
Germany	6.52	2.04	124.94	0.60	77.44	2.20	
Greece	29.93	4.85	1254.38	76.87	250.63	16.34	5)
Hungary	3.56	2.28	46.23	4.55	199.16	4.10	6)
Iceland	0.00	0.00	64.72	0.00	0.00	0.00	
Ireland	14.67	0.00	29.34	1.19	7.34	1.19	
Italy	15.80	4.06	240.28	3.61	113.07	3.31	7)
Latvia	57.89	23.09					
Liechtenstein							8)
Lithuania							
Luxembourg	0.00	10.86	0.00	0.00	86.06	0.00	9)
Malta	0.00	0.00	178.51	0.00	0.00	17.36	
Moldova	177.83	0.00	0.00	0.00	0.00	0.00	
Montenegro	28.80	28.96	100.81	164.09	86.41	86.87	10)
Netherlands	0.00	0.61	55.35	0.91	26.36	0.00	
Norway	7.07	1.07	14.15	1.07	35.37	0.00	
Poland							
Portugal							
Romania	28.09	1.61	1963.72	0.00	658.83	3.45	11)
Russian Federation							
San Marino							
Serbia							
Slovakia	0.00	0.00	134.33	8.11	81.16	7.10	
Slovenia	0.00	0.00	86.77	0.90	15.78	0.00	
Spain							
Sweden	2.04	0.40	42.80	0.00	59.10	0.40	

Table 7.2 (continued) – 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	
Switzerland	6.57	0.87	128.12	0.87	68.99	0.43	
Turkey							
Ukraine							
United Kingdom	4.45	1.20	35.96	0.69	29.66	0.60	12)

1) Regular Donors: data not available.
2) Total number of donations has increased by 80 % comparing to 2009!
3) "Repeat tested donors" represents data for repeat and regular donors; there is no practise in the blood establishments of giving blood samples for testing only purposes.
4) 35 confirmed seropositive HTLV I/II tests : 20 in Continental France and 15 in overseas territories (Martinique and Guadeloupe).
5) Only in few centers, donors on first visit give blood sample for testing.
6) PCR test is used by the confirmatory laboratory.
7) Only regular donors; first time donors someone has never donated either blood or plasma and someone who has donated before but not within the last two years in the same blood establishment.
8) Donation campaigns are ONLY done by the Austrian Red Cross.
9) It was the first time, during 2009, we accepted donation on first time.
10) Diagnostics of Syphilis has been done by ELISA test and confirmatory tests are not done; first time registered donors were 6944 from which 4952 gave blood in their first visit.
11) Number of regular and repeat donors is an estimation, given the lack of IT system. Last category is very rare, not a usual procedure.
12) There were 6 co-infected donors: 2 HBsAg(carrier)/ T.pallidum; 1 HBsAg(carrier)/ HTLV; 1 HCV/HTLV: 1 HCV/T.pallidum; 1 T.pallidum/HTLV, all in first time tested donors except the HCV/T. pallidum case.

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	
Albania									
Andorra									
Armenia									
Austria	All	96	All	96	All	96	All HAV: Frankfurt (D), Wiesenheid (D), Linz (A); All PV B19: Frankfurt (D), Wiesenheid (D), Linz (A)	96; 96	1)
Azerbaijan									
Belgium	All	8			All	8			
Bosnia/Herzegovina									
Bulgaria									
Croatia	None		None		None				2)
Cyprus									
Czech Republic	None		None		None		First		3)
Denmark	All	1	All	1	All	1			4)
Estonia	All	12	None	0	All	12			5)
Finland	All	1	All	1		1	All HAV; All Parvovirus B19	96; 96	6)
France	All		None		All				7)
FYR Macedonia									
Georgia									
Germany	All	96			All	96			8)
Greece	All	1	All	1	All	1			9)
Hungary	None		None		None				10)
Iceland	None		None		None				
Ireland	All	1	All	1	All	1			11)
Italy	All	6	All	6	All	6			12)
Latvia			None		None				
Liechtenstein									
Lithuania									
Luxembourg	All	100	All	100	All	100	First Parvo B 19	100	13)
Malta	None		None		None				
Moldova	None		None		None				
Montenegro	None								14)

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	
Netherlands	All	6	All	6	All	6			15)
Norway	None		None		None				
Poland									
Portugal									
Romania	None		None		None				
Russian Federation									
San Marino									
Serbia									
Slovakia	None		None		None				
Slovenia	All		All		All				
Spain									
Sweden	None		None		None				16)
Switzerland	All	1	All	1	All	1			17)
Turkey									
Ukraine									
United Kingdom	All		All	24	All				18)

1) HIV: pool size 3-24-30-96; HBV: pool size-Variation:3-24-40-96; HCV: pool size-Variation:3-24-40.96; HAV: Frankfurt (D), Wiesenheid (D), Linz (A); PV B19: Frankfurt (D), Wiesenheid (D), Linz (A).
2) NAT screening of blood donors is not mandatory in Croatia yet. According to Ministry of Health it will be introduced in 2011.
3) HIV: NAT testing is done only in plasma for processing by fractionator and results are back reported; HBV: NAT testing is done only in plasma for processing by fractionator and results are back reported; HCV: NAT testing is done only in plasma for processing by fractionator and results are back reported; "other NAT in first time donors" pressed by chance but there is no way how to correct it.
4) HIV: Different strategy in the country for testing first time donors; HBV: Different strategy in the country for testing first time donors; HCV: Different strategy in the country for testing first time donors.
5) HBV: Planned in 2011.
6) Other: HAV; Parvovirus B19: in total 29 positives.
7) HIV: Size of pools: 24 and 8. 2 screening techniques used; HBV: HBV NAT testing only in overseas and Army blood services. In all countries from 2010 in IDT; HCV: Size of pools: 24 and 8. 2 screening techniques used.
8) HIV: Pool size for NAT tests 10 to 96; HBV: No Data. HBV 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.
9) HIV: Data on 582 808 donations; HBV: Data on 582 808 donations; HCV: Data on 582 808 donations.
10) NAT test are used for confirmatory process.
11) HIV: HIV/HCV NAT in minipool of 8 until April then ID NAT for HCV/HIV/HBV; HBV: HBV NAT implemented from April 2009; HCV: MP-8 NAT until April 2009 then ID NAT.
12) HIV: performed by law since June 2008; HBV: performed by law since June 2008.
13) Other: Parvo B 19.
14) NAT testing is not performed in BTS in Montenegro, yet.
15) HBV: In the Netherlands, HBV NAT was introduced in November 2008. During 2009, almost all HBV NAT only positive donors were repeat donors who suffered previously undiagnosed occult hepatitis B infection.
16) NAT-testing is performed by plasma buyers and any verified positive results reported back.
17) HIV: size of minipools ranges from 1 to 48; HBV: size of minipools ranges from 1 to 24; HCV: size of minipools ranges from 1 to 48.
18) HIV: Minipools: England – 24; Wales – 24; Northern Ireland – 96; Scotland – Max 95; HBV: HBV NAT in England and Wales only with minipools of 24. England - Triplex NAT screening was implemented in NHSBT during 2009. Beginning in April 2009 and completed in December 2009. Prior to this duplex HCV/HIV NAT was performed on pools of 48. HCV: Minipools: England – 24; Wales – 24; Northern Ireland – 96; Scotland – Max 95.

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
Albania						
Andorra						
Armenia						
Austria	0	0	0	0	0	0
Azerbaijan						
Belgium	0	1		1	1	1
Bosnia/Herzegovina						
Bulgaria						
Croatia						
Cyprus						
Czech Republic						
Denmark			1	1		1
Estonia	6	0	0	0	20	1
Finland	0	0	0	1	0	2
France	0	3	0	0	0	1
FYR Macedonia						
Georgia						
Germany	1	3	0	3	0	11
Greece	0	0	69	21	1	1
Hungary						
Iceland						
Ireland	0	0	0	2	0	0
Italy		3	18	85	3	2
Latvia						
Liechtenstein						
Lithuania						
Luxembourg	0	1	0	0	1	0
Malta						
Moldova						
Montenegro						
Netherlands	0	0	0	10	0	0
Norway						
Poland						
Portugal						
Romania						
Russian Federation						
San Marino						
Serbia						
Slovakia						
Slovenia	0	0	0	1	0	0
Spain						
Sweden						
Switzerland	0	0				
Turkey						
Ukraine						
United Kingdom	0	0	0	4	0	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			
Albania						
Andorra						
Armenia						
Austria	37 245	36	28	64	0	1)
Azerbaijan						
Belgium	68 910	80	52	69		2)
Bosnia/Herzegovina						
Bulgaria						
Croatia	13 316	5	7	5	0	3)
Cyprus						
Czech Republic	32 225	1	1	1		4)
Denmark	32 642	89	89	89	0	5)
Estonia	2 994	100	100	100	21	6)
Finland	39 929	0	0	0	0	7)
France	261 406					
FYR Macedonia						
Georgia						
Germany	466 793					8)
Greece	132 680	12	9	8	11	
Hungary	14 259	14	100	34	43	9)
Iceland	1 984			0		
Ireland	26 329	100	100	100	5	10)
Italy	205 215	9	12	10	98	
Latvia	6 208	99	67		0	
Liechtenstein						
Lithuania						
Luxembourg	2 315	2	2	2	0	
Malta	1 090	8	15	10	0	
Moldova	8 574					
Montenegro	751					11)
Netherlands	53 929	100	100	100		
Norway	20 464			94	0	12)
Poland						
Portugal						
Romania	24 776					13)
Russian Federation						
San Marino						
Serbia			3	1		
Slovakia	27 832			7	0	
Slovenia	9 405					
Spain						
Sweden	43 256			33	0	14)

Table 9 (continued) – Bacterial screening

Country	Total platelets issued (adult therapeutic doses)	% bacterial screened		% of platelet adult doses screened	% of screened units confirmed positive	
		Recovered	Apheresis			
Switzerland	29 654	0	0	0	0	15)
Turkey						
Ukraine						
United Kingdom	278 860	21	13	15	1	16)

1) All PCs: 100 % (aerobic), outcome 0.09 % positive (confirmed by repetition) - 100 % (anaerobic).
2) Platelet concentrates are pathogen inactivated or screened for the presence of bacteria.
3) Presented data on bacteria screening are only for screeneng made in Croatian Institute of Transfusion Medicine in Zagreb, responsible for 51 % of all donations in Croatia. Confirmed positive by further testing = 0.18 %.
4) Bacterial screening is done only as a "statistical process control", data on positivity / negativity are not available at a national level.
5) Aproximately 0.1 % of the screened units were confirmed positive.
6) Percentage of screened units confirmed by further testing - 0.21 %.
7) No in-process screening for bacteria. All outdated platelet components are screened for bacteria.
8) Sterility testing as a statistic process control 0.4 x the square root of n of each blood component per month and per processing plant at the end of shelf life ("n" is the number of units produced for each blood component).
9) Ad. last row 0.43 %.
10) 0.05 % of screened units confirmed positive.
11) Screening for presence of bacterial contamination of units of PLT has been done occasionally.
12) 46 concentrates confirmed positive.
13) Control is done on BactAlert or Hemoline system. Data unavailable.
14) 0.1 % units were verified positive for bacteria.
15) Only QC on outdated units.
16) 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		
Albania					
Andorra					
Armenia					
Austria	Yes	Yes	Yes	Yes	
Azerbaijan					
Belgium	Yes	Yes		Yes	
Bosnia/Herzegovina					
Bulgaria					
Croatia	Yes	No	No	Yes	
Cyprus					
Czech Republic	Yes	Yes	Yes	Yes	
Denmark	Yes	Yes	Yes	Yes	
Estonia	No	Yes	No	Yes	
Finland	No	Yes	Yes	Yes	
France	Yes	Yes	No	Yes	
FYR Macedonia					
Georgia					
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	
Liechtenstein					
Lithuania					
Luxembourg	Yes	Yes	Yes	Yes	
Malta	Yes	Yes	Yes	Yes	
Moldova	Yes	Yes	Yes	Yes	
Montenegro	Yes	Yes	Yes	Yes	
Netherlands	Yes	Yes	Yes	Yes	
Norway	Yes	Yes	Yes	Yes	
Poland					
Portugal					
Romania	Yes	Yes	Yes	Yes	
Russian Federation					
San Marino					
Serbia	Yes	Yes	Yes	Yes	
Slovakia	Yes	Yes	Yes	Yes	
Slovenia	Yes	Yes		Yes	
Spain					
Sweden	Yes	Yes	Yes	Yes	1)
Switzerland	No	Yes	Yes	Yes	
Turkey					
Ukraine					
United Kingdom	Yes	Yes	Yes	Yes	

1) The Swedish Blood Alliance and the Swedish Society of Transfusion Medicine participate in the open consulation process concerning regulations.

Table 11.1 – 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				
Albania								
Andorra								
Armenia								
Austria	Yes	100	100		Blood safety regulation, Blood donor directive, Guidelines for blood group serology, Directives on human blood derives and medicinal products.	National	AGES PharmMed (Nationale Einrichtung)	
Azerbaijan								
Belgium	Yes	100	95			National+Other	If covered by 9000 series: also inspected by body for ISO certification	Yes
Bosnia/Herzegovina								
Bulgaria								
Croatia	Yes	100	51			National		Yes
Cyprus								
Czech Republic	Yes	100	50			National		Yes
Denmark	Yes	100		15	ISO 15189	National		Yes
Estonia	Yes	100	100	0		National		
Finland	Yes	100	0			National		Yes
France	Yes		100			National	AFSSAPS	Yes
FYR Macedonia								
Georgia								
Germany	Yes	100				National		Yes
Greece	Yes	79	14			Other	EKEVYL, ELOT for some centers only	Yes
Hungary	Yes	100				National		Yes
Iceland	Yes		100			National+Other		No
Ireland	Yes	100	0			National		Yes
Italy	Yes	0	40	100	Regional Authorisation and Accreditation			
Latvia	Yes					National		Yes
Liechtenstein								
Lithuania								

Table 11.1 (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				
Luxembourg	Yes	100	100	100	AFSSAPS (FFP sd Bordeaux) Octapharma (derivated components)	National+Other	AFSSAPS, Octapharma	Yes
Malta	Yes			100	CoE Guide, National legislation based on EU Directives	National		Yes
Moldova		100	100			National		Yes
Montenegro	Planned					National		No
Netherlands	Yes	100	100			National		Yes
Norway	Yes	100	42			National		Yes
Poland								
Portugal								
Romania	Yes					National		No
Russian Federation								
San Marino								
Serbia	Yes		40			National		Yes
Slovakia	Yes	100	0			National+Other	National drug agency, Fractionator	Yes
Slovenia	Yes	100				National+Other	Organisations accredited to perform the ISO 9001:2000 certification procedures	Yes
Spain								
Sweden	Yes	100	0	72	ISO/IEC 17025 or ISO/IEC 15189	National+Other	SWEDAC	Yes
Switzerland	Yes	100	65	0		National+Other	Hospital blood banks are inspected by cantonal authorities	Yes
Turkey								
Ukraine								
United Kingdom	Yes	100	4	0	4 UK Blood Services each have their own "National" procedures - ISO 9000 Wales only	National+Other	Wales only - BSI ISO series every 6 months	Yes

Table 11.2 – Quality management related issues

Country	% donations labelled according to		Component code		Comments
	ISBT 128	another system	ISBT 128	another system	
Albania					
Andorra					
Armenia					
Austria	100			100	Different systems
Azerbaijan					
Belgium	93	7	93	7	System developed in-house, with codabar 39 or code 128, ISBT or ISBT 128-like
Bosnia/Herzegovina					
Bulgaria					
Croatia		60		60	Codabar
Cyprus					
Czech Republic		100		100	National labelling system using code 128 and standardised format for producer / donation number / component code
Denmark	100		100		
Estonia	100	0	100	0	
Finland	100	0	100	0	
France		100		100	Monarch Barcode
FYR Macedonia					
Georgia					
Germany					Any unique code, Eurocode mostly used
Greece		85		85	Percentage donations labelled according to ISBT 128 (% donation number): Planned Percentage components labelled according to another system (% component codes): Blood Med and Blood Pliroforiki
Hungary	100			100	Codabar
Iceland	100		100		
Ireland	0	100	0	100	Codabar
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 directive
Latvia	100		100		

Table 11.2 (continued) – Quality management related issues

Country	% donations labelled according to		Component code		Comments
	ISBT 128	another system	ISBT 128	another system	
Liechtenstein					
Lithuania					
Luxembourg	0	100		100	Local system; ISBT 128 is too expensive
Malta	0	100	0	100	Codabar
Moldova	100		100		
Montenegro		100			
Netherlands	100	0	100	0	
Norway	100		100		
Poland					
Portugal					
Romania	0	100	0	100	
Russian Federation					
San Marino					
Serbia	13		13		
Slovakia	75	25	0		
Slovenia		100		100	Codabar system
Spain					
Sweden	100	0	100		
Switzerland	100	0	100	0	
Turkey					
Ukraine					
United Kingdom	100	0	0	100	Codabar; Donation numbers ISBT 128, Product labels Codabar

Table 12.1 – Haemovigilance system

Country	Description of "Other" organisation/body	
	Available / organisation	Description of "Other" organisation/body
Albania		
Andorra		
Armenia		
Austria	National	AGES PharmMed (National Institution)
Azerbaijan		
Belgium	National	
Bosnia/Herzegovina		
Bulgaria		
Croatia	National+Other	Croatian Institute of Transfusion Medicine
Cyprus		
Czech Republic	National	
Denmark	National+Other	Danish Society of Clinical Immunology
Estonia	National	
Finland	National+Other	Finnish Red Cross Blood Service
France	National+Other	Hospitals, EFS and Competent Authority (AFSSAPS)
FYR Macedonia		
Georgia		
Germany	National	
Greece	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	National	
Iceland	National	
Ireland	National	
Italy	National	
Latvia	National	
Liechtenstein		
Lithuania		
Luxembourg	National+Other	Hospitals and CTS
Malta	National	
Moldova	National	
Montenegro	No	
Netherlands	Other	TRIP
Norway	National	
Poland		
Portugal		
Romania	National	
Russian Federation		
San Marino		
Serbia	Other	
Slovakia	National	National Drug Agency
Slovenia	National+Other	Service for Haemovigilance at the Blood Transfusion Centre of Slovenia
Spain		

Table 12.1 (continued) – Haemovigilance system

Country	Description of "Other" organisation/body	
	Available / organisation	Description of "Other" organisation/body
Sweden	National+Other	Swedish Society for Transfusion Medicine
Switzerland	National	
Turkey		
Ukraine		
United Kingdom	National+Other	MHRA (SABRE) & SHOT

Table 12.2 – Haemovigilance - number of serious adverse reactions

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		
Albania																			
Andorra																			
Armenia																			
Austria	537 202																		1)
Azerbaijan																			
Belgium	678 627	5	9	3		6	2						2			2	34	9.3	
Bosnia/ Herzegovina																			
Bulgaria																			
Croatia	256 424		13	1		2	4									2		8.6	
Cyprus																			
Czech Republic	640 833	2	0	0	0	9	6	0	1	0	0	0	0	0	0	0	9	4.2	2)
Denmark	433 176		3			2	1						1					1.6	
Estonia	38 216																		
Finland	342 083	1	3	0	1	2	0	0	0	0	0	2	2	0	0	1	1	3.8	3)
France	2 928 807	4	7		1	60	23						6			87		6.4	4)
FYR Macedonia																			
Georgia																			

Table 12.2 (continued) – Haemovigilance - number of serious adverse reactions

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		
Germany	6 421 480	8	4			8	4						2					0.4	
Greece	936 045	7	7			14											8	3.8	5)
Hungary	469 397	2	3			11	2			1							25	9.4	
Iceland	20 051																		
Ireland	173 393	0	13	0	0	22	0	0	0	0	0	0	0	0	0	15	14	36.9	
Italy	3 214 887	13	7	1	0	243	4	0					1			14	9	9.1	
Latvia	97 732					3										1		4.1	
Liechtenstein																			
Lithuania																			
Luxembourg	26 997	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0	6)
Malta	22 557		2			1	1											17.7	
Moldova	114 763					39												34.0	
Montenegro	22 450																		7)
Netherlands	708 609	0	1	0	0	3	4	0	1	0	0	0	0	0	0	0	4	1.8	8)
Norway	260 611	4	3			15	2					2						10.0	9)
Poland																			
Portugal																			
Romania	650 479																		

Table 12.2 (continued) – Haemovigilance - number of serious adverse reactions

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		
Russian Federation																			
San Marino																			
Serbia	630 766																		
Slovakia	285 864	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0	10)
Slovenia	127 703					7	1									3	2	10.2	
Spain																			
Sweden	643 187																		11)
Switzerland	414 084	2	0	0	0	18	0	0	0	0	0	0	4	0	0	6	4	8.2	12)
Turkey																			
Ukraine																			
United Kingdom	2 810 673	3	25	2	0	76	6	0	0	0	0	0	2	0	0	18	48	6.4	
Total		51	100	7	2	541	60	0	2	1	0	4	20	0	0	149	158		

1) Febrile transfusion reactions: 126; Allergic transfusion reactions: 160; other reactions: 14.
2) Only severe adverse events and severe adverse reactions are reported here (figures from obligatory national system).
3) Other transfusion-associated viral infection: parvovirus B19.
4) Only serious adverse reactions with a certain imputability are reported. Other serious adverse reactions: 1 post-transfusion purpura, 1 gas embolism, 14 unknown.
5) Data on 819 914 blood products.
6) During 2009, we had only 16 not serious adverse reaction reported.
7) Implementation of haemovigilance system has been planned together with the new organisation of Blood Transfusion Service in MN at the National level.
8) Other transfusion related viral infection is HTLV.
9) Other viral infection is Parvovirus B19 in one donor transmitted to two patients.
10) 256 of other serious reactions are febrile reactions.
11) A TT-HAV- infection occurred.
12) Further information concerning national haemovigilance is provided at: http://www.swissmedic.ch/marktueberwachung/00159/00160/00437/index.html?lang=en.

APPENDIX

Questionnaire on the collection, testing and use of blood and blood components in Europe, the 2009 Survey

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

THE 2009 SURVEY

This questionnaire consists of three sections:

A. Collection and use of blood and blood components,

B. Testing of blood and blood components, and

C. General information.

At the end of each section, please provide any additional information and comments that you think may be useful for the interpretation of the data. When information or data on specific terms is not available, please leave an empty field. This questionnaire is copyright of Dr. C.L. van der Poel, Julius Centre of the University Utrecht, under auspicies of the TS-GPUQA working group of the EDQM Blood Transfusion Committee (CD-P-TS). Earlier versions were developed together with Dr. Olof Akerblom.

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

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

The questionnaire is to be completed by November 1, 2009.

The questionnaire is to be completed by November 1, 2009.

RESPONDENT INFORMATION	
Name respondent *	
Institution *	
Address *	
Email address *	
Telephone (including country code) *	

* = input required

COUNTRY OF REFERENCE	
Country name *	<Please specify>
If non-CoE member state, please specify country name	
Population size *	
Number of hospital beds?	

SECTION A: Collection and use of blood and blood components

DONORS ACTIVE DURING THE YEAR	
Regular plus repeat donors	
First time donors (total)	
First time donors, on first visit donating blood or blood components	
First time donors, on first visit giving blood samples for testing only	
Additional comments or remarks	

COLLECTION OF BLOOD AND BLOOD COMPONENTS	
Whole blood donations	
Total number of whole blood donations	
Voluntary non-remunerated donations (%)	
Replacement donations (%)	
Number of autologous whole blood donations	
Red cells apheresis donations	
Total number of red cells apheresis donations (procedures)	
Percentage voluntary non-remunerated donations (%)	
Number of autologous donations	
Plasma apheresis donations	
Plasma apheresis (in liters)	
Liters collected from voluntary non-remunerated donors	
Platelets apheresis donations	
Total number of platelets apheresis donations (procedures)	
Percentage voluntary non-remunerated donations (%)	
Other forms of apheresis donations	
Number of granulocytes apheresis donations (procedures)	
Number of multi-component apheresis donations	
Additional comments or remarks	

USE OF BLOOD AND BLOOD COMPONENTS INTENDED FOR TRANSFUSION

Please, indicate what the data below relate to

- ○ Blood and blood components distributed to hospital blood banks
- ○ Blood and blood components transfused

Total number of whole blood units	
Number of red cell units (red cells for transfusion, excl. autol.)	
Number of autologous red cell units (pre-deposit)	
Number of plasma units (plasma or FFP) for transfusion	
Total number of platelets (adult therapeutic doses)	
Platelets recovered from whole blood (adult therapeutic doses)	
Platelets collected by platelet apheresis (adult therapeutic doses)	
Cryoprecipitate (FVIII IU x 10^6)	

Additional comments or remarks

BLOOD COMPONENTS DELIVERED FOR THE MANUFACTURE OF MEDICINAL PRODUCTS

Total plasma for fractionation (liters)	
Plasma for fractionation into FVIII (litres)	
Plasma for fractionation into FVIII, recovered from whole blood donations (litres)	
Plasma for fractionation into FVIII, from plasmapheresis (litres source plasma)	
Plasma for preparation of specific immunoglobulines (liters)	
Other plasma (litres)	
Other component units (e.g. erythrocytes, buffy coats)	

Additional comments or remarks

SPECIAL PROCESSING OF BLOOD COMPONENTS

Red cell components (for transfusion) further processing

Leukocyte depleted red cells (%)	
Irradiated red cells (%)	

Platelet components (for transfusion) further processing

Leukocyte depleted platelets (%)	
Irradiated platelets (%)	
Pathogen reduced (virus inactivated) platelets (%)	

Plasma components (for transfusion) further processing

Leukocyte depleted plasma for transfusion (%)	
Irradiated plasma for transfusion (%)	
Plasma for transfusion quarantined (%)	
Plasma for transfusion virus inactivated (%)	

Cryoprecipitate reduced plasma components quarantined (%)

Cryoprecipitate reduced plasma components virus inactivated (%)

Cryoprecipitate quarantined (%)

Cryoprecipitate virus inactivated (%)

Additional comments or remarks

SECTION B: Testing of blood and blood components

SCREENING FOR INFECTIOUS AGENTS, SEROLOGICAL TEST METHODS

Anti-HIV 1+2 screening test

Testing strategy

- ○ Every donation
- ○ Only first time donation
- ○ No testing
- ○ Other testing strategy*

***If other testing strategy: Percentage of donations tested (%)**

Comments

HIV-Ag screening test

Testing strategy

- ○ Every donation
- ○ Only first time donation
- ○ No testing
- ○ Other testing strategy*

***If other testing strategy: Percentage of donations tested (%)**

Comments

HBsAg screening test

Testing strategy

- ○ Every donation
- ○ Only first time donation
- ○ No testing
- ○ Other testing strategy*

***If other testing strategy: Percentage of donations tested (%)**

Comments

Anti-HBc screening test

Testing strategy

- ○ Every donation
- ○ Only first time donation
- ○ No testing
- ○ Other testing strategy*

***If other testing strategy: Percentage of donations tested (%)**

Comments

Anti-HCV screening test

Testing strategy

- ○ Every donation
- ○ Only first time donation
- ○ No testing
- ○ Other testing strategy*

***If other testing strategy: Percentage of donations tested (%)**

Comments

HCV-Ag screening test

Testing strategy

- Every donation
- Only first time donation
- No testing
- Other testing strategy*

***If other testing strategy: Percentage of donations tested (%)**

Comments

Anti-HTLV I/II screening test

Testing strategy

- Every donation
- Only first time donation
- No testing
- Other testing strategy*

***If other testing strategy: Percentage of donations tested (%)**

Comments

Syphilis screening test

Testing strategy

- Every donation
- Only first time donation
- No testing
- Other testing strategy*

***If other testing strategy: Percentage of donations tested (%)**

Comments

Malaria screening test

Testing strategy

- Every donation
- Only first time donation
- No testing
- Other testing strategy*

***If other testing strategy: Percentage of donations tested (%)**

Comments

Other screening test

Name of screening test

Testing strategy

- Every donation
- Only first time donation
- Other testing strategy*

***If other testing strategy: Percentage of donations tested (%)**

Comments

Other screening test

Name of screening test

Testing strategy

- Every donation
- Only first time donation
- Other testing strategy*

***If other testing strategy: Percentage of donations tested (%)**

Comments

Other screening test

Name of screening test

Testing strategy

- ○ Every donation
- ○ Only first time donation
- ○ Other testing strategy*

***If other testing strategy: Percentage of donations tested (%)**

Comments

Other screening test

Name of screening test

Testing strategy

- ○ Every donation
- ○ Only first time donation
- ○ Other testing strategy*

***If other testing strategy: Percentage of donations tested (%)**

Comments

Additional comments or remarks

THE USE OF SIMPLE RAPID TESTS

Anti-HIV 1+2 screening test

Simple rapid tests

- ○ No
- ○ Yes, all donations
- ○ Yes, percentage of donations tested*

***Percentage of donations tested (%)**

Comments

HBsAg screening test

Simple rapid tests

- ○ No
- ○ Yes, all donations
- ○ Yes, percentage of donations tested*

***Percentage of donations tested (%)**

Comments

Anti-HCV screening test

Simple rapid tests

- ○ No
- ○ Yes, all donations
- ○ Yes, percentage of donations tested*

***Percentage of donations tested (%)**

Comments

Additional comments or remarks

CONFIRMATORY TESTING

Are repeatedly reactive screening test results subjected to confirmatory testing?

- ○ Yes, all screening test repeatedly reactive donations are subject to confirmatory testing
- ○ No, as a rule not subjected to confirmatory testing
- ○ Yes, percentage of repeatedly reactive donations tested with confirmatory assays*

***Percentage of RR donations tested (%)**

Comments

Confirmed seropositive HIV-1/2 tests

Number of first time tested donors

Number of repeat tested donors

Confirmed seropositive HBsAg tests

Number of first time tested donors

Number of repeat tested donors

Confirmed seropositive HCV tests

Number of first time tested donors

Number of repeat tested donors

Confirmed seropositive HTLV I/II tests

Number of first time tested donors

Number of repeat tested donors

Confirmed seropositive Syphilis tests

Number of first time tested donors

Number of repeat tested donors

Additional comments or remarks

NUCLEIC ACID TESTING (NAT)

HIV NAT test

Which donations are NAT tested?

- ○ All donations
- ○ First time donations only
- ○ None

Size of minipools

Number of *NAT only* positive first time donors

Number of *NAT only* positive regular plus repeat donors

Comments

HBV NAT test

Which donations are NAT tested?

- ○ All donations
- ○ First time donations only
- ○ None

Size of minipools

Number of *NAT only* positive first time donors

Number of *NAT only* positive regular plus repeat donors

Comments

HCV NAT test

Which donations are NAT tested?

- ○ All donations
- ○ First time donations only
- ○ None

Size of minipools

Number of *NAT only* positive first time donors

Number of *NAT only* positive regular plus repeat donors

Comments

Other NAT test

Specify NAT test name

Which donations are NAT tested?

- All donations
- First time donations only

Size of minipools

Number of *NAT only* positive first time donors

Number of *NAT only* positive regular plus repeat donors

Comments

Other NAT test

Specify NAT test name

Which donations are NAT tested?

- All donations
- First time donations only

Size of minipools

Number of *NAT only* positive first time donors

Number of *NAT only* positive regular plus repeat donors

Comments

Other NAT test

Specify NAT test name

Which donations are NAT tested?

- All donations
- First time donations only

Size of minipools

Number of *NAT only* positive first time donors

Number of *NAT only* positive regular plus repeat donors

Comments

Additional comments or remarks

SCREENING FOR THE PRESENCE OF BACTERIA IN PLATELET PREPARATIONS

Percentage of platelet adult doses screened for the presence of bacteria (%)

Percentage of recovered platelet doses screened for the presence of bacteria (%)

Percentage of apheresis platelet doses screened for the presence of bacteria (%)

Percentage of screened units confirmed positive by further testing (%)

Additional comments or remarks

SECTION C:

General Information

NATIONAL COORDINATION

National council or expert committee to advise Ministry of Health on transfusion related issues?
- ○ Yes
- ○ No

Is there a national blood policy on the quality and safety of blood and blood components?
- ○ Yes
- ○ No

If yes, is there a national blood plan on implementing the national blood policy?
- ○ Yes
- ○ No

Are there national regulations, legally binding, for the collection, testing, processing, storage and distribution of blood and blood components?
- ○ Yes
- ○ No

Additional comments or remarks

QUALITY MANAGEMENT RELATED ISSUES

Quality system established and maintained in blood establishments?
- ○ Yes
- ○ Planned
- ○ No

Percentage of donations covered by GMP (%)

Percentage of donations covered by ISO 9000 series (%)

Percentage of donations covered by local SOP's and instruction (%)

Percentage of donations covered by other* procedures (%)

***Please specify such other procedures**

Are inspections performed at least each second year?
- ○ No
- ○ Yes, by a national authority
- ○ Yes, another qualified body or organisation*
- ○ Yes, both national authority and other body or organisation*

***Please specify such other body/organisation**

Is there a system of education and regular training of staff in blood transfusion medicine?
- ○ Yes
- ○ No

System used for identification and labelling of donations and components

Percentage donations labelled according to ISBT128 (% donation numbers)

Percentage components labelled according to ISBT128 (% component codes)

Percentage donations labelled according to another system* (% donation numbers)

Percentage components labelled according to another system* (% component codes)

***If information provided, please specify such system**

Additional comments or remarks

HAEMOVIGILANCE REPORTING

Is there a haemovigilance reporting system on national level?

- ○ No
- ○ Yes, by a national authority
- ○ Yes, another qualified body or organisation*
- ○ Yes, both national authority and other body or organisation*

***Please specify such other body/organisation**

Additional comments or remarks

SERIOUS ADVERSE REACTIONS REPORTED

Immunological haemolysis due to ABO incompatibility	
Number with imputability level not available	
Number with imputability level 0 or 1 (excluded, unlikely or possibly)	
Number with imputability level 2 (likely or probable)	
Number with imputability level 3 (certain)	
Total number of serious adverse reactions reported	0
Immunological haemolysis due to other allo-antibody	
Number with imputability level not available	
Number with imputability level 0 or 1 (excluded, unlikely or possibly)	
Number with imputability level 2 (likely or probable)	
Number with imputability level 3 (certain)	
Total number of serious adverse reactions reported	0
Non-immunological haemolysis	
Number with imputability level not available	
Number with imputability level 0 or 1 (excluded, unlikely or possibly)	
Number with imputability level 2 (likely or probable)	
Number with imputability level 3 (certain)	
Total number of serious adverse reactions reported	0
Post-Transfusion Purpura	
Number with imputability level not available	
Number with imputability level 0 or 1 (excluded, unlikely or possibly)	
Number with imputability level 2 (likely or probable)	
Number with imputability level 3 (certain)	
Total number of serious adverse reactions reported	0

SERIOUS ADVERSE REACTIONS REPORTED (continued)

Anaphylaxis / hypersensitivity	
Number with imputability level not available	
Number with imputability level 0 or 1 (excluded, unlikely or possibly)	
Number with imputability level 2 (likely or probable)	
Number with imputability level 3 (certain)	
Total number of serious adverse reactions reported	0

Transfusion Related Acute Lung Injury

Number with imputability level not available	
Number with imputability level 0 or 1 (excluded, unlikely or possibly)	
Number with imputability level 2 (likely or probable)	
Number with imputability level 3 (certain)	
Total number of serious adverse reactions reported	0

Graft Versus Host Disease

Number with imputability level not available	
Number with imputability level 0 or 1 (excluded, unlikely or possibly)	
Number with imputability level 2 (likely or probable)	
Number with imputability level 3 (certain)	
Total number of serious adverse reactions reported	0

Transfusion-associated HBV infection

Number with imputability level not available	
Number with imputability level 0 or 1 (excluded, unlikely or possibly)	
Number with imputability level 2 (likely or probable)	
Number with imputability level 3 (certain)	
Total number of serious adverse reactions reported	0

SERIOUS ADVERSE REACTIONS REPORTED (continued)

Transfusion-associated HCV infection

Number with imputability level not available	
Number with imputability level 0 or 1 (excluded, unlikely or possibly)	
Number with imputability level 2 (likely or probable)	
Number with imputability level 3 (certain)	
Total number of serious adverse reactions reported	0

Transfusion-associated HIV-1/2 infection

Number with imputability level not available	
Number with imputability level 0 or 1 (excluded, unlikely or possibly)	
Number with imputability level 2 (likely or probable)	
Number with imputability level 3 (certain)	
Total number of serious adverse reactions reported	0

Other transfusion-associated viral infection

Number with imputability level not available	
Number with imputability level 0 or 1 (excluded, unlikely or possibly)	
Number with imputability level 2 (likely or probable)	
Number with imputability level 3 (certain)	
Total number of serious adverse reactions reported	0

Transfusion-associated bacterial infection

Number with imputability level not available	
Number with imputability level 0 or 1 (excluded, unlikely or possibly)	
Number with imputability level 2 (likely or probable)	
Number with imputability level 3 (certain)	
Total number of serious adverse reactions reported	0

SERIOUS ADVERSE REACTIONS REPORTED (continued)

Transfusion-associated malaria infection

Number with imputability level not available	
Number with imputability level 0 or 1 (excluded, unlikely or possibly)	
Number with imputability level 2 (likely or probable)	
Number with imputability level 3 (certain)	
Total number of serious adverse reactions reported	0

Other transfusion-associated parasitical infection

Number with imputability level not available	
Number with imputability level 0 or 1 (excluded, unlikely or possibly)	
Number with imputability level 2 (likely or probable)	
Number with imputability level 3 (certain)	
Total number of serious adverse reactions reported	0

Circulatory overload

Number with imputability level not available	
Number with imputability level 0 or 1 (excluded, unlikely or possibly)	
Number with imputability level 2 (likely or probable)	
Number with imputability level 3 (certain)	
Total number of serious adverse reactions reported	0

Other serious reactions

Number with imputability level not available	
Number with imputability level 0 or 1 (excluded, unlikely or possibly)	
Number with imputability level 2 (likely or probable)	
Number with imputability level 3 (certain)	
Total number of serious adverse reactions reported	0

Additional comments or remarks

* = Input is required

This form was created at www.formdesk.com

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

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