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

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2010 report

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2010 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 2010. In its present form it follows a series of similar reports which have assessed such data in 1989, 1991, 1993, 1995, 1997, and annually in its present revised form in 2001-2009.

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 was requested as of 2004. The European Commission (EC) has acknowledged the importance of this data in *Directive 2002/98/EC*.

In MS and in 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. 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 (*EMA Guideline on Epidemiological data on Blood Transmissible Infections* and the *EMA Guideline on the Scientific data requirements for a Plasma Master File*). Uniformity of such definitions is of importance to the field, and circumvents unnecessary and costly repetitions in collating data.

In total, 33 questionnaires were received in 2010. Thus, the response rate of 72 % was 9 % higher than in the previous year. The (final) response rates for the 2008 and 2009 surveys were 72 % and 63 %, respectively.

The average number of donors in relation to the general population was 27 per 1,000 inhabitants. On average, 24 % of the donor base consisted of first-time donors.

The number of Whole Blood (WB) collections was on average 38 per 1000 inhabitants, and the average use of Red Blood Cells (RBC) was 36 per 1000 inhabitants. On average, 3.7 litres (L) of plasmapheresis plasma per 1000 inhabitants was collected.

The use of blood was expressed as units (U) distributed by BE in 63 % of the reporting MS; the remaining 37 % of MS reported it as transfused units. The use of RBC varied considerably (range 3-84 U, median 35 U) and averaged 36 total RBC U per 1000 inhabitants. Three reporting MS (9 %) used less than 20 U per 1000 inhabitants, most likely reflecting an insufficient supply. In the respondent MS, on average 37 % of the total platelet volume was supplied by (random) single donor platelets by apheresis; in 11 countries (34 %), this volume amounted to more than 50 %.

The amount of plasma delivered for fractionation into medicinal products differed greatly among MS (range 0-52 L), with an average yield of 8.5 L of plasma for fractionation per 1000 inhabitants. However, 10 % of the reporting MS delivered 20 L or more plasma per 1000 inhabitants. In Europe, on average, 46 % of the plasma for fractionation was from recovered plasma.

In 38 % of the MS, all RBC products were leucocyte-depleted. Platelet concentrates were 100 % leucocyte-depleted in 56 % of MS and, in 38 % of the MS, all plasma for transfusion was leucocyte-depleted. In 45 % of the reporting MS, all Fresh Frozen Plasma (FFP) was safeguarded by either quarantine or viral inactivation methods.

All donations were tested for anti-HIV-1/2, HBsAg and anti-HCV in all 33 reporting MS. All donations were tested for syphilis in 91 % of MS. Anti-HTLV-I/II testing was performed on all donations in 21 % of reporting MS, and on first-time donors in 6 %. Anti-HBc testing was performed on all donations in 22 % of MS, and only on first-time donors in 9 %. 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 5.0, 86 and 61 per 100 000 donors for HIV-1/2, HBV and HCV, respectively. The median incidence amongst repeat donors was 1.0, 2.1 and 2.8 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 52 % of reporting MS. HBV NAT and HCV NAT was performed on each donation in 48 % and 60 % of MS, respectively.

Bacterial screening was performed in 64 % of reporting MS. Screening of 80 % or more of platelet concentrates was performed in 33 % of MS. The median rate reported for confirmed-positive cultured platelet concentrates was 0.05 %.

All MS reported having legally-binding national regulations for the collection, testing, processing, storage and distribution of blood and blood components. In 88 % of the reporting MS, a National Council or Expert Committee existed to advise the Ministry of Health on transfusion-related policy issues. In 88 % of MS, a national blood policy on the quality and safety of blood and blood components was in place.

In 91 % of MS, a Quality System (QS) had been established and was maintained in BE. Inspections were (partly) carried out by a national or other authority at least every 2 years in 97 % of the reporting MS. All donations were covered either by International Society for Blood Transfusion (ISBT), Good Manufacturing Practice (GMP) or other procedures in 90 % of the reporting MS. Labelling of donations according to either ISBT-128 or other procedures was performed by 93 % of MS for all donations. Labelling of all components by either ISBT or another system was done by 88 % of MS.

Ninety-one 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 6.7 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 May 2012. Data tables were distributed for review among MS and corrections and additions were provided by MS experts, after which the report was finalised and adopted by the CD-P-TS.

The data in the completed questionnaires was 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 February 2011 and comprised questionnaire data from 2001 through to 2005. In addition, an update of this report, including the years 2006-2008, has been finalised. 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 2007 and subsequent surveys, the risk of errors may be reduced. In addition, the Julius Centre can, on request, provide 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. The very few adverse transfusion reactions that occur in Liechtenstein are reported to Swissmedic (Switzerland) and to the European Commission.

RESULTS

Response rate

The 46 MS of the CoE were invited to send completed questionnaires. Replies were received from 33 MS by the deadline for submissions (May 2012); a response rate of 72 %. The response rates were 72 % and 63 % for the 2007 and 2008 surveys, respectively, which indicates that there is a stable MS response rate.

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 y*et alw*ays 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 *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 are 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 turn-over 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, in 2010, 24 % (range 11-100 %) 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 is 27 (range 2-51) 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 interpreting 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 're-activate' 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 source material for the manufacture of medicinal products (see Table 4). The number of WB collections in the 33 MS reporting was, on average, 38 % (range 0-101) per 1000 inhabitants. Given the average use of RBC per 1000 inhabitants (36 U, range 2.90-84 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 exposure to allogeneic blood for patients 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 30 MS that reported autologous donations, they only contributed on average to around 0.3 % (range 0-3.4 %, median 0.02 %) of the WB donations. This is in agreement with the literature and previous reporting. However, it should be taken into account that surgery and anaesthesiology techniques, such as pre-operative 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 30 reporting MS, on average 3.7 L (range 0-50 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 13 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 by apheresis platelets in order to reduce donor exposure in patients. The relative importance of platelet apheresis for the total supply of platelet products is given in Table 3. In the 32 reporting MS, on average 37 % (range 0-85 %, median 32 %) 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 programmes and for collections of RBC of rare 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 20/32 (63 %) of the respondent MS, the use of blood was expressed as the units distributed by BE, whereas 12 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 33 reporting MS, on average 2.9 % (range 0-50 %, median 0.04 %) of transfusions were performed with WB. In Romania, WB accounted for almost 1/3 (and, in Hungary, a half) of the total volume of RBC products used.

The use of RBC per 1000 inhabitants varied considerably. In 33 reporting MS, it averaged 36 total RBC products per 1000 inhabitants (range 3-84, median 35). 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 3/33 (9 %) of the reporting MS, less than 20 RBC U 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 the FFP/RBC ratio). It should be taken into account that programmes for 'better use of blood' (*e.g.* RRBC use) in some countries increased the FFP/RBC ratio by decreasing the rate of RBC use. On average, the FFP/RBC ratio was 0.45 (range 0.033-2.0, median 0.32).

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 32 reporting MS, 37 % (range 0-85 %, median 32 %) of the adult therapeutic doses of platelets were produced by (random) single donor platelets by apheresis (Table 3). In 11 countries (34 %), 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 31 of the reporting MS, there was an average yield of 8.5 L (range 0-52 L) per 1000 inhabitants of plasma for fractionation into medicinal products. However, 3 of the 31 (10 %) reporting MS delivered 20 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, 46 % of the plasma for fractionation was from recovered plasma (range 0-100 %, median 44 %).

Reporting on the use of medicinal products derived from human plasma was limited. The 11 MS that reported Factor VIII use indicated an average use of 30 x 10^6 IU (range 0-161, median 6). The average amount of polyvalent immunoglobulins used was 1287 Kg (range 0-6460 Kg, median 287 Kg) and the average amount of human albumen used was 4839 Kg (range 0-34 740 Kg, median 553 Kg). In the 8 MS that produced immunoglobulins, the average proportion of intravenous administration was 74 % (range 0-100 %, median 92 %).

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

In 12/32 (38 %) of reporting MS, 100 % leucocyte-depletion of RBC products was carried out. This was the case for platelet concentrates in 18/32 (56 %) reporting MS. Complete (100 %) leucocyte-depletion was applied to plasma for transfusion in 9/24 (38 %) 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 14/31 (45 %) of the reporting MS, nearly all FFP (> 98 %) was safeguarded by either method; in 7/29 (24 %) MS using only quarantine; in 5/27 (19 %) using almost solely pathogen reduction (one MS reported 98 % or more); and in 2/31 (6 %) using a combination of the two methods.

Screening for infectious markers & serological test methods: Table 6

In all 33 reporting MS, all donations were tested for anti-HIV-1/2, HBsAg and anti-HCV. In 30/33 (91 %) of these MS, all donations were tested for syphilis. In Norway, only first-time donors were tested for syphilis, whereas donors in Denmark and Iceland were not tested for syphilis. It is still debated in the literature whether syphilis testing is necessary.

Testing for anti-HTLV-I/II was performed on all donations in 7/33 (21 %) of the reporting MS, and only on first-time donors in 2/33 (6 %) MS.

Testing for anti-HBc was performed on all donations in 7/32 (22 %) reporting MS, and only on first-time donors in 3/32 (9 %) 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 tested donors (see Table 1) are given. Overall, 29 of 32 (91 %) MS that were able to provide the absolute numbers of confirmed positive donors provided this data 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 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 147 for HIV-1/2, from 0 to 3390 for HBV and 0 to 1939 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, represents repeat positive donors screened by Enzyme-Linked Immunosorbent Assay (ELISA) and, thereby, includes many false positives (see 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 5.0, 86 and 61 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 had 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 for 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 125 for HIV-1/2, from 0 to 403 for HBV and 0 to 253 for HCV. The median incidence amongst repeat donors was 1.0, 2.1 and 2.8 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 14/27 (52 %) of the reporting MS. NAT testing for HBV was performed on each donation in 13/24 (48 %) respondent MS. NAT testing for HCV was performed on each donation in 18/30 (60 %) of the MS. Interestingly, NAT on each donation appeared to be performed more often in MS where the incidence rates were relatively low (see Table 7.2 for comparison). As the effectiveness (or 'yield') of NAT testing relates to the incidence of the disease, 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 data set 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 (64 %). In 7/21 (33 %) reporting MS, bacterial culture was performed on 80 % or more of all platelets (concentrates recovered from both WB donations and apheresis platelets). Among the 19 MS that reported on the parameter, the average rate of confirmed positively-cultured platelet concentrates was 0.7 % (ranging from 0 to 10 %, median 0.05 %).

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 29/33 (88 %) of the reporting MS, a National Council or Expert Committee advised the Ministry of Health on transfusion-related issues. In 29/33 (88 %) of the MS, there was a national policy on the quality and safety of blood and blood components. Of these 29 MS, 25 (86 %) had implemented the national blood policy or were in the process of doing so.

Quality management: Table 11

In 30/33 (91 %) of the reporting MS, a QS was established and maintained by BE. In the remaining reporting MS, the implementation of such a system was planned. In 31/32 (97 %) reporting MS, inspections were performed at least every 2 years. The vast majority of these inspections (28/31, 90 %) were (partly) carried out by the national authority.

In 19/21 (90 %) of the reporting MS, all donations were covered by GMP. In the 7 MS that reported that GMP were not applied, all donations were covered either by ISO 9000 or other procedures. In three MS, donations were fully covered by both GMP and International Organization for Standardization (ISO) procedures. In total, 26/29 (90 %) 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 by 14/20 (70 %) of the respondent MS. In 11 MS, all donations were coded under another system, but a combination of ISBT and other systems also occurred. Overall, labelling of all donations (either to ISBT standards or those of another system) was performed by 27/29 (93 %) of the reporting MS.

Labelling of the finished component code is more complex and, in general, lags behind in development as it includes implementation of automated applications in hospitals. ISBT-128 labelling of all issued components was performed by 9/17 (53 %) reporting MS. In 12 MS, components were coded using another system. Overall, 23/26 reporting MS (88 %) reported that all components were coded using either ISBT or another system.

Haemovigilance: Table 12

Since 2004, this survey has presented 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 that 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 2*005/61/EC*, haemovigilance data which may not be caused by blood component properties, such as TACO, are also reported here.

Of the reporting MS, only 3/33 (9 %) indicated that they did not have a haemovigilance reporting system at a national level. Of the 30 MS that did have a reporting system, 28 (93 %) it was associated with a national authority. Data on transfusion complications were provided by 26/33 MS (79 %). 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 6.7 serious adverse reactions per 100 000 distributed blood components seems 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 2010 survey (33 out of 46 MSs)

Andorra, Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, FYR Macedonia, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Malta, Moldova, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Spain, 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	4060	6401	61.2	5914	487	10 461	3246	3.2	
Armenia									
Austria	287 995	46 603	13.9	45 571	1032	334 598	8388	39.9	1)
Azerbaijan									
Belgium	304 642	61 171	16.7	61 171	0	365 813	10 840	33.7	
Bosnia / Herzegovina									
Bulgaria	84 006	35 104	29.5	35 104	0	119 110	7365	16.2	
Croatia	92 642	11 684	11.2	11 684		104 326	4418	23.6	
Cyprus									
Czech Republic	321 006	55 170	14.7	55 170	2870	376 176	10 330	36.4	
Denmark	227 949	27 282	10.7	0	27 282	255 231	5560	45.9	
Estonia	36 136	8669	19.3	8669	0	44 805	1340	33.4	
Finland	135 175	19 427	12.6	19 427	0	154 602	5399	28.6	
France	1 766 435	359 351	16.9			2 125 786	65 027	32.7	2)
FYR Macedonia		4685	100.0	4685		4685	2053	2.3	3)
Georgia									
Germany	2 514 042	559 995	18.2	469 467	90 528	3 074 037	81 752	37.6	
Greece	457 814	75 201	14.1			533 015	10 500	50.8	
Hungary	271 581	51 154	15.9	51 154	0	322 735	9986	32.3	
Iceland	7161	1625	18.5	0	1625	8786	318	27.7	
Ireland	81 550	15 187	15.7	13 744	1443	96 737	4581	21.1	
Italy	1 344 113	378 390	22.0	281 153	97 237	1 722 503	60 341	28.5	4)
Latvia	36 946	13 415	26.6	13 415	0	50 361	2000	25.2	
Liechtenstein									
Lithuania	50 124	22 539	31.0	22 539	0	72 663	3287	22.1	
Luxembourg									
Malta	10 584	1755	14.2	1755	0	12 339	418	29.5	
Moldova	41 656	19 675	32.1	19 675		61 331	3560	17.2	
Montenegro	6455	6536	50.3	4555	0	12 991	620	20.9	5)
Netherlands	314 786	37 297	10.6	0	37 297	352 083	16 656	21.1	
Norway	97 642	23 652	19.5	0	23 652	121 294	4920	24.7	
Poland	431 251	272 310	38.7	221 399		703 561	38 200	18.4	6)
Portugal	261 446	32 125	10.9	32 125		293 571	10 556	27.8	
Romania	378 883	101 267	21.1	101 267	0	480 150	19 000	25.3	
Russian Federation									
San Marino									
Serbia	159 000	44 472	100.0	44 472		203 472	7321	27.8	
Slovakia	84 114	36 205	30.1	28 824	1092	120 319	5430	22.2	
Slovenia									
Spain	889 160	243 880	21.5			1 133 040	45 924	24.7	

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
Sweden	245 289				45 741	245 289	9416	26.1
Switzerland	207 021	26 292	11.3	26 292	0	233 313	7870	29.6
Turkey								
Ukraine								
United Kingdom	1 348 990	217 473	13.9	210 702	5271	1 566 463	62 300	25.1

1) Regular donors: data not available.
2) The French Blood system is composed of EFS with 17 blood centers and the French Army Transfusion Service (CTSA) with one blood center.
   Data from both establishments are reported.
3) There is only data about the number of donations, not the exact number of blood donors.
4) In Italy, a regular donor is one who donates at least once within the last 24 months. Donors who donate less frequently are considered first-time donors even if they have donated previously.
5) In 2010, 6536 first time donors were registered, of which 4555 gave blood on their first visit.
6) In Poland, there are 23 blood establishments. The National Blood Center receives data from 22, because one of the establishment is under the responsibility of the Ministry of the Interior and has no obligation to transfer data to the Ministry of Health.

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	11 612	3.6	1	0.0	25	0.01	10	0	0	0	
Armenia											
Austria	474 109	56.5	2241	0.5	0	0.00	26 958	1112	348		
Azerbaijan											
Belgium	549 266	50.7	151	0.0	56 402	5.20	12 133	2185	22	15 314	1)
Bosnia / Herzegovina											
Bulgaria	161 727	22.0	110	0.1	350	0.05	1124	0	0	0	
Croatia	175 014	39.6					2341			2341	
Cyprus											
Czech Republic	440 700	42.7	15 500	3.4	512 764	49.64	18 003	2112			2)
Denmark	337 000	60.6	0	0.0	420	0.08	1329	0	0	0	
Estonia	58 729	43.8	0	0.0	426	0.32	658	111	0	0	
Finland	265 592	49.2	0	0.0	2777	0.51	693	0	0	0	
France	2 483 577	38.2	2452	0.1	308 802	4.75	8388	31 783	297	145 038	
FYR Macedonia	23 647	11.5	1	0.0			48				
Georgia											
Germany	4 940 257	60.4	34 418	0.7	1 925 712	23.56	176 626	13 665		33 301	
Greece	613 275	58.4	1231	0.2	603	0.06	23 896	50		1986	
Hungary	418 794	41.9	555	0.1	0	0.00	3385	771	93	0	
Iceland	13 915	43.8	0	0.0	135	0.43	659	184	0	0	
Ireland	151 894	33.2	3	0.0	0	0.00	11 197	0	0	0	
Italy	2 694 871	44.7	79 049	2.8	211 813	3.51	11 953	817	128	84 765	
Latvia	55 702	27.9	2	0.0	105	0.05	1688	0	0		
Liechtenstein											
Lithuania	68 324	20.8			7487	2.28	3060	5872	0		3)
Luxembourg											

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)	
Malta	14 548	34.8	2	0.0	0	0.00	548	0	0	0	
Moldova	66 790	18.8	37	0.1	3279	0.92	0	0	0	0	
Montenegro	15 325	24.7	0	0.0	0	0.00	0	0	0	0	4)
Netherlands	542 160	32.6	61	0.0	221 228	13.28	4116	4	69	0	
Norway	495 004	100.6	0	0.0	2757	0.56	4786	3888	0	1357	5)
Poland	1 122 650	29.4	1983	0.2	30 145	0.79	29 265	80	161		6)
Portugal	414 268	39.2					4385	902	19		
Romania	400 285	21.1	0	0.0	22	0.00	5593		0	43	
Russian Federation											
San Marino											
Serbia	2061	0.3	8	0.4	661	0.09	2441				
Slovakia	205 246	37.8	970	0.5	65	0.01	5997	226	14		7)
Slovenia											
Spain	1 740 091	37.9	10 652	0.6	16 805	0.37	7551	1119	0	26 280	
Sweden	493 438	52.4	98	0.0	32 058	3.40	8287	1778	184		
Switzerland	354 254	45.0	2202	0.6	1328	0.17	16 561	870	0	7445	
Turkey											
Ukraine											
United Kingdom	2 305 482	37.0	2	0.0	148	0.00	128 837	0	54	0	

1) Almost all multi-component donations are platelets plus plasma.
2) Autologous whole blood included in value for "total whole blood". Few cases of granulocyte apheresis - exact number not available. Few cases of multi-component apheresis - exact number not available.
3) Number of multi-component apheresis donations not available.
4) Apheresis procedures are not yet done in Montenegro.
5) Litres of apheresis plasma is estimated from number of procedures.
6) Data excludes incomplete donations.
7) Data on number of multi-component apheresis donations are not collected, but the number is very small and restricted to combination platelet/plasma apheresis.

Table 2.2 – Profile of donations

Country	Whole blood donations			Red cell apheresis		Plasmapheresis donations	Platelet apheresis	
	% volontary, non-remunerated	% from replacement donors	% from autologous donors	% voluntary, non-remunerated	% from autologous donors	% voluntary, non-remunerated	% voluntary, non-remunerated	
Albania								
Andorra	6	42	0.01	0		0	0	
Armenia								
Austria	100	0	0.47	100	131		100	
Azerbaijan								
Belgium	100	0	0.03	100	0	100	100	
Bosnia / Herzegovina								
Bulgaria	22	78	0.07	0		0	0	
Croatia	100						100	
Cyprus								
Czech Republic	100	0	3.52	100	0	20	34	
Denmark	100	0	0.00	100		100	100	
Estonia	100	0	0.00	100	0	100	100	
Finland	100	0	0.00	0		100	100	
France	100	0	0.10	100		0	100	
FYR Macedonia	23 039	508	0.00	99			20	
Georgia								
Germany		0	0.70		17			1)
Greece	49	50	0.20	95		16	72	
Hungary	100		0.13	100			100	
Iceland	100	0	0.00	100	0	100	100	
Ireland	100	0	0.00				100	
Italy	100	0	2.93	100	30	100	100	
Latvia	100		0.00	0			0	
Liechtenstein								
Lithuania	37	0		48		0	48	2)
Luxembourg								
Malta	100	0	0.01				100	
Moldova	30	70	0.06	0		92	0	
Montenegro	29	71	0.00	0			0	3)
Netherlands	100	0	0.01	100	0	100	100	
Norway	100	0	0.00	100	0	100	100	
Poland	99	8	0.18	100		91	86	4)
Portugal	100	0		100			100	
Romania	100		0.00			100	100	
Russian Federation								
San Marino								
Serbia	93	7	0.39			100	100	

Table 2.2 (continued) – Profile of donations

Country	Whole blood donations			Red cell apheresis		Plasmapheresis donations	Platelet apheresis
	% volontary, non-remunerated	% from replacement donors	% from autologous donors	% voluntary, non-remunerated	% from autologous donors	% voluntary, non-remunerated	% voluntary, non-remunerated
Slovakia	100	0	0.47	100	0	100	89
Slovenia							
Spain	100		0.61	100		100	100
Sweden	100	0	0.02	100		100	100
Switzerland	100	0	0.62	100	21	100	100
Turkey							
Ukraine							
United Kingdom	100	0	0.00	0		100	100

1) Data not available for voluntary non-remunerated donations (%). Family/replacement donations are not allowed.
2) Number of autologous donations not available.
3) Apheresis procedures are not yet done in Montenegro.
4) Data excludes incomplete donations.

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	Trans.	0	0.0	9456	2.9	18 983	7.02×10^2	6.92×10^2	1.00×10^1	1.4	579	
Armenia												
Austria	Distr.	0	0.0	404 297	48.2	61 355	34 649	10 752	23 897	69.0	0	
Azerbaijan												
Belgium	Distr.	0	0.0	516 035	47.6	92 761	69 328	36 201	33 127	47.8	0	
Bosnia / Herzegovina												
Bulgaria	Distr.	1654	0.9	183 120	24.9	93 666	6606	4531	2075	31.4	0	
Croatia	Distr.	458	0.3	172 510	39.0	79 721	15 674	13 297	2377	15.2	31	
Cyprus												
Czech Republic	Trans.	393	0.1	389 521	37.7	201 220	31 866	4729	27 137	85.2	0	1)
Denmark	Trans.	0	0.0	316 733	57.0	66 110	33 907	33 319	588	1.7	232	
Estonia	Trans.	19	0.0	51 586	38.5	27 196	6086	4466	1620	26.6	455	
Finland	Distr.	314	0.1	249 922	46.3	53 512	43 023	42 150	873	2.0	0	2)
France	Distr.	0	0.0	2 378 241	36.6	382 449	278 097	107 772	170 325	61.2	0	
FYR Macedonia	Distr.	2000	8.3	24 001	11.7	40 000	15 647	15 599	48	0.3	5135	
Georgia												
Germany	Distr.	5657	0.1	4 694 567	57.4	1 216 153	496 281	187 247	309 034	62.3		
Greece	Distr.	49	0.0	615 692	58.6	201 909	133 375	110 311	23 064	17.3	0	3)
Hungary	Distr.	418 794	49.8	840 338	84.2	95 960	26 298	22 613	3685	14.0	0	
Iceland	Distr.	0	0.0	12 438	39.2	3974	1670	589	1081	64.7	0	
Ireland	Distr.	0	0.0	140 037	30.6	23 612	24 431	5562	18 869	77.2	126	4)
Italy	Trans.	3025	0.1	2 522 355	41.8	395 602	205 791	130 571	75 220	36.6	2110	
Latvia	Distr.	0	0.0	52 017	26.0	36 758	6131	2913	3218	52.5	7462	
Liechtenstein												
Lithuania	Trans.	25	0.0	79 012	24.0	29 682	11 020	2305	8715	79.1	810	5)
Luxembourg												
Malta	Distr.	0	0.0	14 051	33.6	6161	1609	1080	529	32.9		6)
Moldova	Trans.	9	0.0	36 863	10.4	58 739	9083	9083	0	0.0	12 996	
Montenegro	Trans.	542	3.9	13 724	22.1	9404			0		500	

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)	
Netherlands	Distr.	619	0.1	548 793	32.9	81 742	56 165	53 073	3092	5.5	0	
Norway	Trans.	85	0.0	196 987	40.0	45 065	22 985	16 089	6896	30.0		7)
Poland	Distr.	628	0.1	1 089 655	28.5	384 442	107 768	72 388	35 380	32.8	10 284	
Portugal	Trans.	116	0.0	336 421	31.9	10 990	66 428	62 255	4173	6.3		
Romania	Distr.	109 597	27.6	396 490	20.9	249 245	22 664	15 864	6800	30.0	16 506	8)
Russian Federation												
San Marino												
Serbia		5249	2.3	229 628	31.4	143 538	119 678	117 237	2441	2.0	17 368	
Slovakia	Distr.	957	0.5	186 978	34.4	87 690	16 023	4 000	12 023	75.0	3	9)
Slovenia												
Spain	Trans.	140	0.0	1 618 419	35.2	200 583	192 332	159 881	32 451	16.9	2632	
Sweden	Trans.	0	0.0	488 373	51.9	89 064	42 817	28 701	14 116	33.0		
Switzerland	Distr.	2111	0.7	311 912	39.6	61 830	31 776	4731	27 045	85.1	0	10)
Turkey												
Ukraine												
United Kingdom	Distr.	16	0.0	2 182 950	35.0	303 377	287 027	61 326	225 701	78.6	136 404	11)

1) Number of blood components issued by hospital blood banks to clinical departments are given (but not those returned as "not-transfused").
2) Only Octaplas (200 ml per unit) is used in Finland.
3) Number of red cell units: This number includes 32 000 RBC units imported from Swiss Red Cross.
4) 126 individual packs of cryoprecipiate issued, comprising 81 single units and 9 pools of 5. Most firinogen replacement is with fibrinogen concentrate. Note: 317 units of FFP issued and 23 295 units of SD-plasma.
5) Number of autologous red cell units not available.
6) Cryoprecipitate - 0.03 x 10^6 IU (FVIII).
7) All plasma transfusions are Octaplas 200 ml/unit.
8) Number of adult doses estimated as 5 recovered units/1 dose. Cryoprecipitate = number of units distributed.
9) The 917 autologous pre-deposit red cell units is a sum of 694 autologous red cell units and 223 autologous whole blood units.
10) Total numer of WB units, exclusively autologous.
11) Single cryoprecipitate units, some of which are supplied as pools of 5 for adults.

Table 4.1 – 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	7	0.00	0.00	5.85	2.01	
Armenia						
Austria	104 430	12.45	0.00	7.31	0.15	
Azerbaijan						
Belgium	175 146	16.16	65.01	8.56	0.18	
Bosnia / Herzegovina						
Bulgaria	16 131	2.19	0.00	12.72	0.51	
Croatia	20 312	4.60		18.05	0.46	1)
Cyprus						
Czech Republic	541 072	52.38	10.09	19.48	0.52	2)
Denmark	67 372	12.12	99.86	11.89	0.21	
Estonia	7048	5.26		20.29	0.53	3)
Finland	78 742	14.58	90.80	9.91	0.21	4)
France	854 676	13.14	74.84	5.88	0.16	
FYR Macedonia	0	0.00		19.49	1.67	
Georgia						
Germany	2 886 080	35.30	36.50	14.88	0.26	
Greece	26 509	2.52		19.23	0.33	
Hungary	84 208	8.43		9.61	0.11	5)
Iceland	0	0.00		12.51	0.32	
Ireland	0	0.00		5.15	0.17	
Italy	726 508	12.04	65.00	6.56	0.16	
Latvia	3217	1.61		18.38	0.71	
Liechtenstein						
Lithuania	8154	2.48		9.03	0.38	
Luxembourg						
Malta	0	0.00		14.75	0.44	
Moldova	4215	1.18	6.12	16.50	1.59	6)
Montenegro	0	0.00		15.16	0.69	
Netherlands	338 800	20.34	43.68	4.91	0.15	
Norway	53 998	10.97		9.16	0.23	7)
Poland				10.06	0.35	8)
Portugal				1.04	0.03	
Romania	0	0.00		13.12	0.63	9)
Russian Federation						
San Marino						
Serbia	1779	0.24	0.00	19.61	0.63	
Slovakia	26 847	4.94	100.00	16.15	0.47	
Slovenia						
Spain	380 560	8.29		4.37	0.12	
Sweden	107 507	11.42		9.46	0.18	

Table 4.1 (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)	
Switzerland	82 146	10.44		7.86	0.20	10)
Turkey						
Ukraine						
United Kingdom	0	0.00		4.87	0.14	

1) The Institute of Immunology in Zagreb, Croatia is an independent center for plasma fractionation. Only albumin and immunoglobulin are produced from plasma collected by the Transfusion Service and delivered there; they do not produce FVIII.
2) Plasma from commercial plasma centers is included.
3) Plasma is just sold, wthout indication on the medicinal product.
4) 7241 litres are used for production of Octaplas for the Finnish market.
5) In Hungary, plasma fractionation is done by HumanBioplazma Ltd, (this company belongs to the Kedrion Group).
6) 258 L is 12 888 of cryoprecipitate, other plasma represents decryoprecipitate plasma.
7) All plasma for fractionation is sold to Baxter. How they use it is unknown to us.
8) Plasma was not delivered for fractionation in 2010.
9) No contract for fractionation.
10) No information about final products.

Table 4.2 – Use of medicinal products derived from human plasma

Country		Immunoglobulins (kg)ds				
	FVIII (excluding cryo and excluding recombinant) (10^6 IU)	Polyvalent (kg)	Intravenous (%)	Subcutaneous plus intramuscular (%)	Human albumin (kg)	
Albania						
Andorra	0	0			0	
Armenia						
Austria						
Azerbaijan						
Belgium						
Bosnia / Herzegovina						
Bulgaria						1)
Croatia						2)
Cyprus						
Czech Republic	36	287	89	11	1145	3)
Denmark						
Estonia	3	11	100	0	135	
Finland	6	501	81	19	553	
France						4)
FYR Macedonia	0	0			0	
Georgia						
Germany	161	2739	95	5	13 345	
Greece						
Hungary						
Iceland						
Ireland						
Italy	88	3269	98	2	34 740	
Latvia						
Liechtenstein						
Lithuania	8	6460	100			5)
Luxembourg						
Malta						
Moldova		880	0	100	1049	
Montenegro						6)
Netherlands						
Norway						
Poland						7)
Portugal						
Romania						8)
Russian Federation						
San Marino						
Serbia		15	33	67	276	

Table 4.2 (continued) – Use of medicinal products derived from human plasma

Country	FVIII (excluding cryo and excluding recombinant) (10^6 IU)	Polyvalent (kg)	Intravenous (%)	Subcutaneous plus intramuscular (%)	Human albumin (kg)	
Slovakia	30					9)
Slovenia						
Spain						
Sweden	3				1985	
Switzerland						10)
Turkey						
Ukraine						
United Kingdom	0	0			0	11)

1) No data.
2) In Croatia, there is no exact full data collection on a national level for use of medicinal products derived from human plasma.
3) Products are distributed to hospitals/pharmacies.
4) Data not available at a national scale nor at EFS.
5) Human albumin data not available. FVIII includes recombinant.
6) Data is not available because stocking of these products is not the responsibility of the BS.
7) No data available.
8) Data not available. These products are distributed via hospital pharmacies; BEs are not involved.
9) No information concerning immunglobulin use in Slovakia.
10) No information.
11) No data - supplied to hospitals directly by the manufactuers.

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	37	0	0	0	0	0	0	
Armenia								
Austria	100	14	100	0	100	51	0	
Azerbaijan								
Belgium	100		100	0	100			1)
Bosnia / Herzegovina								
Bulgaria	8	0	5	0	5	0	0	
Croatia	20				80			2)
Cyprus								
Czech Republic	29	6	0	0	85	4	0	
Denmark	91	4	1	0	100	6	0	
Estonia	7	4	0	0	48	24	0	
Finland	100	3	100	0	100	35	0	3)
France	100		100	0	100		8	
FYR Macedonia	0	0	0	0	128	0	0	
Georgia								
Germany	100	5		0	100	36	0	4)
Greece	38	20	55	16	78	28	0	
Hungary	13	7	5	86	71	50	0	
Iceland	23	11	8	2	100	89	0	
Ireland	100	8	100		100	100	0	
Italy	24	5	28	0	23	27	2	
Latvia	14	2			100	29	0	
Liechtenstein								
Lithuania	21	7	0	0	70	70	2	
Luxembourg								
Malta	100	5	100	0	100	6	0	
Moldova	0	0	0	0	0	0	0	
Montenegro								5)
Netherlands	100	4	100	0	100	34	0	
Norway	100	8	0	0	100	30	14	6)
Poland	13	5			96		8	
Portugal	100				100			
Romania	6				8	0	0	
Russian Federation								
San Marino								
Serbia	48				1		3	
Slovakia	24	3			69	4	0	7)
Slovenia								
Spain	97	4	56		100	40		
Sweden	84	4	94	4	100	53	9	
Switzerland	100	4	100	0	100	25	0	

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. %
Turkey							
Ukraine							
United Kingdom	100	9	100	0	100	56	0

1) Irradiation of blood components: only a small number is irradiated in the blood establishments. We do not have an idea of the number of irradiated blood components.
2) In Croatia, there has been no decision at a national level for universal pre-storage leuco-depletion of blood components. Irradiated blood components are used for certain patients, but there is no exact data.
3) Hospitals also irradiate red cell and platelet components.
4) Data on leukocyte-depleted plasma for transfusion is not collected.
5) Leucocyte-deplated and irradiated blood components (RC, PLT) are only prepared in specific cases.
6) All plasma transfusions are Octaplas 200 mL/unit.
7) Data on leucocyte-depleted and irradiated plasma is not collected.

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	0	0	0	0	0	0	
Armenia							
Austria	22	78	0	0	0	0	1)
Azerbaijan							
Belgium	0	100	0	0	0	0	
Bosnia / Herzegovina							
Bulgaria	100	0	0	0	0	0	
Croatia							
Cyprus							
Czech Republic	100						
Denmark	0	0	0	0	0	0	
Estonia	0	0	0	0	0	0	
Finland	0	100	0	0	0	0	
France	0	100	0	0	0	0	
FYR Macedonia	0	0	0	0	0	0	
Georgia							
Germany	100	0	0	0	0	0	2)
Greece	22	15					
Hungary	0	0	0	0	0	0	
Iceland	0	0					
Ireland		98	0	0	0	0	
Italy	5	29	0	0	0	0	
Latvia	69				100		
Liechtenstein							
Lithuania	100	0	0	0	100	0	
Luxembourg							
Malta	20	0	0	0	50	0	
Moldova	0	0	0	0	0	0	
Montenegro							
Netherlands	100	0					
Norway	0	100	0	0	0	0	3)
Poland	88	6			98		
Portugal	100				100		
Romania		0		0		0	
Russian Federation							
San Marino							
Serbia	75						
Slovakia	53	0	0	0	0	0	
Slovenia							
Spain	36	64	50	50	46	54	
Sweden	0	2					
Switzerland	100	9	0	0	0	0	

Table 5.2 (continued) – Inactivation or quarantine of plasma

Country	FFP		CP reduced plasma		Cryoprecipitate	
	% quarantined	% virus inactivated	% quarantined	% virus inactivated	% quarantined	% virus inactivated
Turkey						
Ukraine						
United Kingdom	0	3	0	0	0	4

1) Cryoprecipitate: not produced by the blood establishments.
2) Cryoprecipitate-reduced plasma components and cryoprecipitate are not used.
3) All plasma transfusions are Octaplas 200 mL/unit.

Table 6.1 – Donation testing strategy for infectious agents

Country	Anti-HIV 1+2	HIVAg	HBsAg	Anti-HB	Anti-HCV	HCVAg	Anti-HTLV I/II	Syphilis	Malaria	Other	
Albania											
Andorra	100	100	100	100	100	0	0	100	0	Brucellosis: every donation tested.	
Armenia											
Austria	100	100	100	27	100	0	0	100	0	Neopterin-Screening Test, Brahms: every donation tested. ALT: Testing 14 %.	1)
Azerbaijan											
Belgium	100	0	100	First	100	0	0	100			2)
Bosnia / Herzegovina											
Bulgaria	100	100	100	0	100	100	0	100	0		
Croatia	100	100	100	0	100	100	0	100	0		
Cyprus											
Czech Republic	100	100	100	2	100	35	0	100	0		3)
Denmark	100	0	100	0	100	0	First	0			4)
Estonia	100	100	100	0	100	0	0	100	0		
Finland	100	100	100	0	100	0	0	100	0		5)
France	100	0	100	100	100	0	100	100			6)
FYR Macedonia	100	0	100	0	100	100	0	100	0		
Georgia											
Germany	100		100	100	100	0	0	100	0		7)
Greece	100	0	100		100	0	100	100			8)
Hungary	100	0	100	First	100	0	0	100			
Iceland	100	100	100	0	100	0	0	0			9)
Ireland	100	0	100	100	100	0	100	100			10)
Italy	100	0	100	0	100	0	0	100	0		
Latvia	100	100	100	0	100	0	0	100	0		
Liechtenstein											
Lithuania	100	0	100	0	100	0	0	100	0		
Luxembourg											
Malta	100	100	100	100	100	0	0	100	0	CMV: Testing 12 %.	
Moldova	100	100	100	0	100	0	0	100	0		
Montenegro	100	100	100	0	100	0	0	100	0		

Table 6.1 (continued) – Donation testing strategy for infectious agents

Country	Anti-HIV 1+2	HIVAg	HBsAg	Anti-HB	Anti-HCV	HCVAg	Anti-HTLV I/II	Syphilis	Malaria	Other	
Netherlands	100	0	100	0	100	0	100	100	0	Anti-Parvovirus B19 IgG: Testing 5 %. Anti-CMV IgG: Testing 0 %.	11)
Norway	100	0	100	50	100	0	0	First	1		12)
Poland	100	0	100	0	100	0	0	100	0		13)
Portugal	100		100	100	100		100	100		ALT: Testing every donation.	
Romania	100	0	100	0	100	0	100	100	0	ALT: Testing every donation.	14)
Russian Federation											
San Marino											
Serbia	100	0	100	0	100	0	0	100	0		
Slovakia	100	100	100	100	100	0	0	100	0	ALT: Testing every donation.	15)
Slovenia											
Spain	100	0	100	0	100	0	22	100	1	Chagas disease: Testing 3 %.	16)
Sweden	100	100	100	First	100		First	100	0		17)
Switzerland	100		100	0	100	0	0	100			18)
Turkey											
Ukraine											
United Kingdom	100	100	100	1	100	0	100	100	1	Chagas' disease: Testing 1 %. Anti-CMV: Testing 30 %.	19)

1) Anti-CMV (IgM,IgG) Abbott, Siemens: 50 % of the blood establishments, if required.
2) Malaria: in case of history of malaria; anti-CMV: very small % of red cells and PLT for patients with allogeneic HSC transplantation or lung transplantation.
3) Anti-HIV: HIV Ab+Ag combined test is used; HIV Ag: HIV Ab+Ag combined test is used; Anti-HBc: some BEs test "never before tested donors"; HCV Ag: some BEs use combined Ag+Ab test.
4) Anti-HTLV: also donors not bled for >5 years; Malaria: donors born or raised in a malaria area. Other donors only if clinically suspected after travel to a malaria area.
5) Malaria: according to the EU Directive, approx. 0.1 % of donations.
6) Malaria: only if donor has been travelling to or living in endemic areas; Chagas disease: only if donor has been travelling to or living in endemic 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 donate blood if a sensitive assay for HBV-Genom results negative and if anti-HBs antibody-titer stays above 100 IU/l; Syphilis: not required for donations of plasma for fractionation.
8) Anti-HBc: when required; Malaria: when required.
9) Malaria: only if travelled in malaria area, *i.e.* few tests/year.
10) Anti-CMV: first-time donors and previously CMV sero-negative.
11) Malaria: the Malaria Total Antibody EIA, supplied by Lab 21 Ltd., was performed for (re)entry of blood donors who recovered from malaria infection at least 3 years before.
12) Anti-HBc: all new donors and all donors whose previous donation was more than 6 months previously; Malaria: some blood banks use a test to reduce quarantine time after visits to malaria endemic areas.
13) HIV Ag: detection of p24 antigen is recommended but not obligatory; HCV Ag: detection of core antigen is recommended but not obligatory.
14) Anti-HIV: Ag-Ab (Combo test) are currently in use; Anti-HCV: Ag-Ab (Combo test) are currently in use.
15) Anti-HBc: if positive, donor is definitively refused.
16) Malaria: selective testing on first-time donors; Chagas disease: selective testing on first-time donors.
17) HIV Ag: combined antibody-antigen test required since 2010.
18) HIV Ag: no information about percentage. Not mandatory; Malaria: in populations at risk. No information about percentage. Not mandatory; Chagas screening test: in populations at risk. No information about percentage. Not mandatory.
19) HIV Ag: screened using HIV-Ab/Ag combo assay - this does not include Northern Ireland Blood Transfusion Service; Anti-HBc: donors that have had a body-piercing between 4 and 12 months previously OR a history of jaundice or hepatitis OR contact with a person with hepatitis B OR had a procedure involving flexible endoscopy 4-6 months previously.

Table 6.2 – Use of simple rapid tests

Country	Type of test (% of donations)		
	Anti-HIV 1+2	HBsAg	Anti-HCV
Albania			
Andorra	0	0	0
Armenia			
Austria	0	0	0
Azerbaijan			
Belgium	0	0	0
Bosnia / Herzegovina			
Bulgaria	0	0	0
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	0	0	0
Georgia			
Germany	0	0	0
Greece	0	0	0
Hungary	0	0	0
Iceland	0	0	0
Ireland	0	0	0
Italy	0	0	0
Latvia			
Liechtenstein			
Lithuania	0	0	0
Luxembourg			
Malta	0	0	0
Moldova	0	0	0
Montenegro	0	0	0
Netherlands	0	0	0
Norway	0	0	0
Poland	0	0	0
Portugal	0	0	0
Romania	0	0	0
Russian Federation			
San Marino			
Serbia	0	0	0
Slovakia	0	0	0
Slovenia			
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		
		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	0											1)
Armenia												
Austria	100	2	4	46	6	18	5			15	23	
Azerbaijan												
Belgium	100	2	1	51	2	29	2			15	9	
Bosnia / Herzegovina												
Bulgaria	100	8		1190		309				331		
Croatia	100	0	0	10	5	8	4			2	5	
Cyprus												
Czech Republic	100	5	5	37	8	79	19			32	21	2)
Denmark	100	0	2	8	5	1	2	1	0			
Estonia	100	5	3	12	2	61	11			13	7	
Finland	100	0	3	2	2	2	4			0	3	
France	100	18	18	219	8	102	14	20	6	224	99	
FYR Macedonia	100		15		109		54				30	
Georgia												
Germany	100	29	53	651	21	385	54			236	98	
Greece	100	38	20	900	339	220	86	3	1	29	13	
Hungary	100	2	0	1	2	114	45	0	0	28	16	
Iceland	100	0	0	0	0	0	1					
Ireland	100	0	0	4	0	3	1	0	0	4	2	
Italy	100	49	55	741	132	417	37			455	178	3)
Latvia	100	7	4									
Liechtenstein												
Lithuania	100	8	16	174	14	437	74	0	0	117	37	
Luxembourg												
Malta	100	0	0	8	0	0	0			0	0	
Moldova	100	29										4)

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

Country	Proportion confirmatory testing (%)	HIV 1 / 2		HBV		HCV		HTLV-I/II		Syphilis		
		First time donors	Repeat donors	First time donors	Repeat donors	First time donors	Repeat donors	First time donors	Repeat donors	First time donors	Repeat donors	
Montenegro	65	4	0	16	26							5)
Netherlands	100	0	1	16	0	6	0	2	1	11	4	
Norway	100	0	0	10	0	11	0			2	0	6)
Poland	100	397	540	1225	132	2021	1090			404	347	
Portugal	100		47		87		58					7)
Romania		40	12	1866	10	628	10	30	0	385	16	8)
Russian Federation												
San Marino												
Serbia	28	2	0	35	9	29	16			22	50	
Slovakia	100	1	0	23	1	16	6			8	14	
Slovenia												
Spain	100	63	94	440	32	265	25	18		497	382	
Sweden	100	0	1	13	1	18	1	2		3	6	
Switzerland	100	0	4	36	8	15	5			8	4	9)
Turkey												
Ukraine												
United Kingdom	100	12	6	87	5	71	9	18	4	46	29	

1) Confirmatory tests are done outside of blood establishments, for example at the Armenian National AIDS Center, etc. Information concerning the confirmed sero-positive tests are available from the establishments doing confirmatory testing.
2) All confirmatory tests are done by the Central National Ref. Lab. (includes commercial plasma collecting centers).
3) All confirmed screening tests include serological and NAT-positive only. In Italy, NAT is used as a screening test.
4) Other specialised institutions in the country are responsible for confirmatory testing. Institutions responsible for confirmatory testing have not submitted the final statistics for the year 2010 for HBsAg, anti HCV or syphilis.
5) All repeatedly reactive screening tests of blood units collected in BTC CC of MNE are send for confirmatory testing and that is about 65 % of the total number of collected units in Montenegro. Confirmatory testing on HCV and Siphilis was not done in 2010.
6) HTLV test not performed.
7) Both first-time and repeat tested donors.
8) 100 % for HIV, HCV, HTLV; 56 % for HBV; 27 % for syphilis.
9) Number of confirmed sero-positive HTLV I/II tests is not available.

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	4.29	1.39	98.71	2.08	38.62	1.74
Azerbaijan						
Belgium	3.27	0.33	83.37	0.66	47.41	0.66
Bosnia / Herzegovina						
Bulgaria	22.79		3389.93		880.24	
Croatia	0.00	0.00	85.59	5.40	68.47	4.32
Cyprus						
Czech Republic	9.06	1.56	67.07	2.49	143.19	5.92
Denmark	0.00	0.88	29.32	2.19	3.67	0.88
Estonia	57.68	8.30	138.42	5.53	703.66	30.44
Finland	0.00	2.22	10.29	1.48	10.29	2.96
France	5.01	1.02	60.94	0.45	28.38	0.79
FYR Macedonia						
Georgia						
Germany	5.18	2.11	116.25	0.84	68.75	2.15
Greece	50.53	4.37	1196.79	74.05	292.55	18.78
Hungary	3.91	0.00	1.95	0.74	222.86	16.57
Iceland	0.00	0.00	0.00	0.00	0.00	13.96
Ireland	0.00	0.00	26.34	0.00	19.75	1.23
Italy	12.95	4.09	195.83	9.82	110.20	2.75
Latvia	52.18	10.83				
Liechtenstein						
Lithuania	35.49	31.92	772.00	27.93	1938.86	147.63
Luxembourg						
Malta	0.00	0.00	455.84	0.00	0.00	0.00
Moldova	147.40					
Montenegro	61.20	0.00	244.80	402.79		
Netherlands	0.00	0.32	42.90	0.00	16.09	0.00
Norway	0.00	0.00	42.28	0.00	46.51	0.00
Poland	145.79	125.22	449.85	30.61	742.17	252.75
Portugal		17.98		33.28		22.18
Romania	39.50	3.17	1842.65	2.64	620.14	2.64
Russian Federation						
San Marino						
Serbia	4.50	0.00	78.70	5.66	65.21	10.06
Slovakia	2.76	0.00	63.53	1.19	44.19	7.13
Slovenia						
Spain	25.83	10.57	180.42	3.60	108.66	2.81
Sweden		0.41		0.41		0.41

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	0.00	1.93	136.92	3.86	57.05	2.42
Turkey						
Ukraine						
United Kingdom	5.52	0.44	40.00	0.37	32.65	0.67

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	None		None		None				
Armenia									
Austria	All	96	All	96	All	96	All HAV: Frankfurt, Wiesenheid, Linz; All PV B19: Frankfurt, Wiesenheid, Linz	96; 96	1)
Azerbaijan									
Belgium	All	6	All	6	All	6			2)
Bosnia / Herzegovina									
Bulgaria	None		None		None				
Croatia	None		None		None				
Cyprus									
Czech Republic									3)
Denmark	All	1	All	1	All	1			4)
Estonia	All	6	None	6	All	6			
Finland	All	1	All	1	All	1	All HAV NAT; All Parvo B19 NAT	96; 96	5)
France	All				All				6)
FYR Macedonia	None		None		None				
Georgia									
Germany	All	96			All	96			7)
Greece	All	1	All	1	All	1	All WNV-NAT	1	8)
Hungary	None		None		None				
Iceland	None		None		None				
Ireland	All	1	All	1	All	1			
Italy	All		All		All				9)
Latvia	All	24		24		24			
Liechtenstein									
Lithuania	All	6	All	6	All	6			10)
Luxembourg									
Malta	None		None		None				
Moldova	All				All				
Montenegro									11)

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	All Coxiella burnetii DNA	1	12)
Norway	None		None		None				13)
Poland	All		All		All				14)
Portugal	All	6	All	6	All	6			15)
Romania	None		None		None				
Russian Federation									
San Marino									
Serbia	None		None		None				
Slovakia	None		None		None				
Slovenia									
Spain	All	1	All	1	All	1		1	16)
Sweden	None		None		None				
Switzerland	All	1	All	1	All	1	All ; All ; All		17)
Turkey									
Ukraine									
United Kingdom	All	24	All	24	All	24			

1) HIV: Pool: 3-30-24-96; HBV: Pool: 3-30-24-96; HCV: Pool: 3-30-24-96; HAV: Frankfurt, Wiesenheid, Linz: Pool: 3-30-24-96; PV B19: Frankfurt, Wiesenheid, Linz: Pool: 3-30-24-96.
2) HIV: Size of minipools = 6 or 8 depending on blood establishment; HBV: Size of minipools = 6 or 8 depending on blood establishment; HCV: Size of minipools = 6 or 8 depending on blood establishment.
3) HIV: only plasma for fractionation; HBV: only plasma for fractionation; HCV: only plasma for fractionation.
4) HIV: single donation test; HBV: single donation test; HCV: single donation test.
5) HAV NAT; Parvo B19 NAT.
6) HIV: Size of pools = 8 and 24 (2 screening techiques used); HCV: Size of pools = 8 and 24 (2 screening techiques used). Total testing results: total HIV = 39; total HBV = 234; total HCV = 117; total HTLV = 26; total Syphilis = 323.
7) 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.
8) HIV: data on 609 735 tested whole blood and apheresis units; HBV: data on 609 735 tested whole blood and apheresis units; HCV: data on 609 735 tested whole blood and apheresis units; WNV-NAT: testing performed on 27 100 blood units from the affected areas from 11th August 2010 to 1st November 2010.
9) HIV: 61 % ID testing, 39 % minipool testing; Size of minipools: 6-24; HBV: 61 % ID testing, 39 % minipool testing; Size of minipools: 6-24; HCV: 61 % ID testing, 39 % minipool testing; Size of minipools: 6-24; Data included in section "confirmatory testing".
10) HIV: ID NAT testing ~60 % donations; HBV: ID NAT testing ~60 % donations; HCV: ID NAT testing ~60 % donations.
11) NAT testing is not in use in Montenegro.
12) *Coxiella burnetii* DNA: as of 15 March 2010 until 01 November 2010, all donations by blood donors living in areas at high risk for Q-fever were individually tested.
13) HIV: done by fractionator. None found positive; HBV: done by fractionator. None found positive; HCV: done by fractionator. One found positive.
14) HIV: Size of minipools: 6 - when using real time PCR (Cobas MPX Roche) or single donation when using TMA method (Procleix Ultrio test Novartis). HBV: Size of minipools: 6 - when using real time PCR (Cobas MPX Roche) or single donation when using TMA method (Procleix Ultrio test Novartis). HCV: Size of minipools: 6 - when using real time PCR (Cobas MPX Roche) or single donation when using TMA method (Procleix Ultrio test Novartis). DNA parvovirus B19: Size of minipools: single donation, then 96-test was performed only in one blood establishment that delivered plasma for fractionation into immunoglobulin anti-D and anti-HbS.
15) HIV: both first-time and repeat tested donors; HBV: both first-time and repeat tested donors; HCV: both first-time and repeat tested donors.
16) HIV: Size of minipools: range 1-8; HBV: Size of minipools: range 1-8; HCV: Size of minipools: range 1-8; WNV: no. donations tested: 10 512.
17) HIV: Size of minipools ranges from 1 to 6; HBV: Size of minipools ranges from 1 to 6; HCV: Size of minipools ranges from 1 to 6.

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	0	0	1	0
Bosnia / Herzegovina						
Bulgaria						
Croatia						
Cyprus						
Czech Republic						
Denmark	0	0	0	4	0	0
Estonia	0	0	1	0	2	0
Finland	0	0	0	1	0	0
France	0	3	1	1	0	1
FYR Macedonia						
Georgia						
Germany	0	1	0	4	0	7
Greece	1	0	42	12	2	1
Hungary						
Iceland						
Ireland	0	0	0	0	0	0
Italy	0	0	21	95	7	2
Latvia	0	1	0	0	3	1
Liechtenstein						
Lithuania						
Luxembourg						
Malta						
Moldova						
Montenegro						
Netherlands	0	0	2	2	0	0
Norway						
Poland	21	22	446	21	520	10
Portugal		47		87		58
Romania						
Russian Federation						
San Marino						
Serbia						
Slovakia						
Slovenia						
Spain	4		72		1	
Sweden						
Switzerland	0	4	5	1	0	0
Turkey						
Ukraine						
United Kingdom	0	0	0	0	0	1

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	702					
Armenia						
Austria	34 649					1)
Azerbaijan						
Belgium	69 328			56		2)
Bosnia / Herzegovina						
Bulgaria	6606	1				
Croatia	15 674			29	0.30	3)
Cyprus						
Czech Republic	31 866	1	1	1	0.00	4)
Denmark	33 907	100	100	100	0.08	
Estonia	6086	100	100	100	0.29	
Finland	43 023	0	0	0	0.00	5)
France	278 097					6)
FYR Macedonia	15 647	100	0		0.00	
Georgia						
Germany	496 281					7)
Greece	133 375	14	10	9	10.00	
Hungary	26 298	3	2	5	0.05	
Iceland	1670	0	0	0	0.00	
Ireland	24 431	100	100	100	0.05	
Italy	205 791	10	10	10	1.00	8)
Latvia	6131	100		90	0.03	
Liechtenstein						
Lithuania	11 020	3	4			
Luxembourg						
Malta	1609	10	10	10	0.00	
Moldova	9083					
Montenegro						9)
Netherlands	56 165	100	100	100	0.53	
Norway	22 985	81	81	81		10)
Poland	107 768					11)
Portugal	66 428		100	100		
Romania	22 664					12)
Russian Federation						
San Marino						
Serbia	119 678	0	0	2	0.00	
Slovakia	16 023	1	1	1	0.00	
Slovenia						
Spain	192 332					
Sweden	42 817			36	0.11	

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	31 776	0	0	0	0.00
Turkey					
Ukraine					
United Kingdom	287 027	18	14	15	1.00

1) Al PCs: 66 % (aerobic); 62 % (anaerobic). Pool-PCs: 100 % (aerobic); 100 % (anaerobic). Apheresis-PCs: 50 % (aerobic); 44 % (anaerobic). Screening-result: positive culture (100 %).
2) Platelet concentrates are pathogen-inactivated or screened for the presence of bacteria.
3) It is planned to introduce triple NAT testing in Croatia in 2012.
4) Statistical process control.
5) No in-process bacterial testing. Approx. 5 % of out-dated platelets are cultured for bacteria in order to assess the contamination rate of platelet components.
6) No bacterial screening in France.
7) 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).
8) Percentages are 10 %.
9) Screening for the presence of bacteria PLT preparations is occasionaly done.
10) Should be 81 %.
11) We did not perform routine tests that screen for the presence of the bacteria in platelets, which are prepared in closed systems. Platelets are tested only when they are stored for longer than 5 days.
12) Total number of blood component units screened is 27 504. Data not available on each component number. Data on screening results not centralised.

Table 10 – Organisation, registration and labelling

Country	National Council or Expert Committee	National blood policy		National regulations	
		on quality and safety	Implementing		
Albania					
Andorra	No	Yes	Yes	Yes	
Armenia					
Austria	Yes	Yes	Yes	Yes	
Azerbaijan					
Belgium	Yes	Yes		Yes	
Bosnia / Herzegovina					
Bulgaria	Yes	Yes	Yes	Yes	
Croatia	Yes	No	No	Yes	
Cyprus					
Czech Republic	Yes	Yes	Yes	Yes	
Denmark	Yes	Yes	Yes	Yes	
Estonia	Yes	Yes	No	Yes	
Finland	No	Yes	Yes	Yes	
France	Yes	Yes	No	Yes	
FYR Macedonia	Yes	No		Yes	1)
Georgia					
Germany	Yes	Yes	Yes	Yes	
Greece	Yes	Yes	Yes	Yes	
Hungary	Yes	Yes	Yes	Yes	
Iceland	Yes	No	No	Yes	
Ireland	No	No	No	Yes	
Italy	Yes	Yes	Yes	Yes	
Latvia	Yes	Yes	Yes	Yes	
Liechtenstein					
Lithuania	Yes	Yes	Yes	Yes	
Luxembourg					
Malta	Yes	Yes	Yes	Yes	
Moldova	Yes	Yes	Yes	Yes	
Montenegro	Yes	Yes	Yes	Yes	2)
Netherlands	Yes	Yes	Yes	Yes	3)
Norway	Yes	Yes	Yes	Yes	
Poland	Yes	Yes	Yes	Yes	
Portugal	Yes	Yes	Yes	Yes	
Romania	Yes	Yes	Yes	Yes	
Russian Federation					
San Marino					
Serbia	Yes	Yes	Yes	Yes	
Slovakia	Yes	Yes	Yes	Yes	
Slovenia					
Spain	Yes	Yes	Yes	Yes	
Sweden	Yes	Yes	No	Yes	
Switzerland	No	Yes	Yes	Yes	
Turkey					
Ukraine					
United Kingdom	Yes	Yes	Yes	Yes	

1) Harmonised with EU Directives.
2) All these documents are the subject of revision and harmonisation with EU Directives during IPA 2010 implementation.
3) By law, there is only one blood establishment (Sanquin) allowed in the Netherlands.

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	Planned					National		Yes	
Armenia									
Austria	Yes	100	100			National	AGES PharmMed (National establishment)	Yes	
Azerbaijan									
Belgium	Yes	100	95			National+Other	If covered by 9000 series: also inspected by body for ISO	Yes	
Bosnia / Herzegovina									
Bulgaria	Yes	100				National		Yes	
Croatia	Yes	100	55			National		Yes	
Cyprus									
Czech Republic	Yes	100				National		Yes	1)
Denmark	Yes			100	Denmark is running GP (Good Practice according to the EU Blood Directives)	National		Yes	
Estonia	Yes	100				National		Yes	2)
Finland	Yes	100	0			National	Finnish Medicines Agency	Yes	
France	Yes		100			National	AFSSAPS	Yes	
FYR Macedonia	Planned	100	0	0		No		Yes	
Georgia									
Germany	Yes	100				National+Other	Regional authorities in charge of GMP inspections.	Yes	
Greece	Yes	83	19			National	EKEVYL, ELOT for some centers only		3)
Hungary	Yes	100							
Iceland	Yes		100			National+Other	British Standards Institution	No	
Ireland	Yes	100	0			National		Yes	
Italy	Yes		40	100	National requirements issued on 16th December 2010 to comply with European directives on blood and blood components and applicable GMPs	Other	Regional health authorities + nationally qualified inspectors	Yes	4)
Latvia	Yes					National		Yes	
Liechtenstein									

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				
Lithuania	Yes		80			National		Yes
Luxembourg								
Malta	Yes			100	EU Blood Directives	National		Yes
Moldova	Yes			100		National		Yes
Montenegro	Planned					National		No
Netherlands	Yes	100	100	0		National+Other	Lloyd's (ISO 9001 certification)	Yes
Norway	Yes	100	66			National		Yes
Poland	Yes	100	73	27	Other quality assurance systems	National		Yes
Portugal	Yes	100	100			National		Yes
Romania	Yes					National		Yes 5)
Russian Federation								
San Marino								
Serbia	Yes	50	70	70		Other		Yes
Slovakia	Yes	100	0			National+Other	Plasma fractionation company	Yes
Slovenia								
Spain	Yes		100			Other	Inspections conducted by regional authorities and accreditations by scientific societies	Yes
Sweden	Yes	100		72	ISO/IEC 17025 or IISO/IEC 15189	National+Other	SWEDAC	Yes
Switzerland	Yes	100	60	0		National+Other	Hospital Blood Banks are inspected by cantonal authorities.	Yes
Turkey								
Ukraine								
United Kingdom	Yes	100	4	0	The 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

1) Several BEs are ISO certified, but the exact number is not available.
2) Only on a local level.
3) ISO is accrediated by EKEVYL and ELOT.
4) The new blood inspection system has been implemented and is expected to be fully operational by 31st December 2014.
5) Regulation in place. Training ensured at a local level.

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					Blood components are labelled according to the form of Ministry of Health, Republic of Armenia
Armenia					
Austria	100			100	Different systems
Azerbaijan					
Belgium	93	7	93	7	Another system: system developed in-house using Codabar 39 or code 128
Bosnia / Herzegovina					
Bulgaria		100		100	National system
Croatia		90		90	Codabar
Cyprus					
Czech Republic		100		100	National labelling system using code 128 and specifying "producer code/donation number/ product number/product code/blood group/expiration date, *etc.*
Denmark	100		100		
Estonia	100		0		
Finland	100	0	100	0	
France		100		100	Monarch Barcode
FYR Macedonia					
Georgia					
Germany					Any unique code, Eurocode mostly used.
Greece		100			National labelling system
Hungary	100			100	
Iceland	100		100		
Ireland	0	100	0	100	Codabar
Italy	0	100	0	100	National regulation UNI 10529
Latvia	100				
Liechtenstein					
Lithuania		100		100	Local
Luxembourg					

Table 11.2 (continued) – Quality management related issues

Country	% donations labelled according to		Component code		Comments
	ISBT 128	another system	ISBT 128	another system	
Malta		100		100	Codabar
Moldova	100		100		
Montenegro		100			The introduction of labelling, recommended by the EU Directives, will also be the subject of IPA 2010.
Netherlands	100	0	100	0	Not applicable
Norway	100		100		
Poland					ISBT128 system was introduced in 2010, so we can estimate that 70 % of donations and components have been labelled according to ISBT128 at the end of 2010.
Portugal	100		100		
Romania		100		100	Separate labels used for ABO/D, BC name, donation code, validation, diff. qualification.
Russian Federation					
San Marino					
Serbia	20		20		
Slovakia	0	100	0	100	"National transfusion service use "number of donation" which is compatible with ISBT. Three IT systems are used in Slovakia"
Slovenia					
Spain	63	37	63	37	CODABAR (76 %), EUROCODE (18 %), CODE 39 (6 %)
Sweden	100		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	No		
Armenia			
Austria	National	AGES PharmMed (national establishment)	
Azerbaijan			
Belgium	National		
Bosnia / Herzegovina			
Bulgaria	National		
Croatia	National+Other	Croatian Institute of Transfusion Medicine	1)
Cyprus			
Czech Republic	National		2)
Denmark	National+Other	National authority: State Serum Institute. Other qualified organisation: Danish Society for Clinical Immunology conducting the "DART" reporting system	
Estonia	National		
Finland	National+Other	Finnish Red Cross Blood Service	
France	National+Other	Afssaps, EFS and hospitals	
FYR Macedonia	No		
Georgia			
Germany	National		
Greece	Other	National Co-ordinating 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	National		
Luxembourg			
Malta	National		
Moldova	National		

Table 12.1 (continued) – Haemovigilance system

Country	Description of "Other" organisation/body		
	Available / organisation	Description of "Other" organisation/body	
Montenegro	No		
Netherlands	Other	TRIP, which reports to the Competent Authority	3)
Norway	National		4)
Poland	National		
Portugal	National	Instituto Portugues do Sangue	
Romania	National		
Russian Federation			
San Marino			
Serbia	National		5)
Slovakia	National		6)
Slovenia			
Spain	National		
Sweden	National+Other	Swedish Society for Transfusion Medicine	
Switzerland	National		7)
Turkey			
Ukraine			
United Kingdom	National+Other	Serious Hazards of Transfusion (SHOT)	8)

1) Haemovigilance system in Croatia registers all reactions. In 2010, there were 375 reactions registered, of which 31 were SAREs with imputability level 2 and 3, and these were reported to THECA.
2) Severe adverse events and reaction are reported to the national authority, non-severe adverse events and reactions are reported to the professional body.
3) Hospitals report transfusion related incidents to TRIP and, if it is likely to be caused by the product, also to Sanquin. So errors in the hospital are not necessarily included in the reported figures.
4) www.hemovigilans.no
5) We try to implement it at national level according to the law.
6) National Institute for Drug Control.
7) Annual Reports are available at: http://www.swissmedic.ch/marktueberwachung/00159/00160/00437/index.html?lang=de
8) Medicines and Healthcare products Regulatory Agency MHRA (SABRE and 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	29 141	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0	
Armenia																			
Austria	500 301	2	1			3												1.2	
Azerbaijan																			
Belgium	678 124	8	8	1	0	8	3	0	0	0	0	0	5	0	0	5	59	14.3	
Bosnia / Herzegovina																			
Bulgaria	283 392																		
Croatia	267 905	1	15		1	7			2							3		10.8	1)
Cyprus																			
Czech Republic	622 607	1	0	0	0	7	5	0	1	0	0	0	0	0	0		0	2.2	
Denmark	416 750	1	2	0	0	0	1	0	0	0	0	0	1	0	0	3	0	1.9	
Estonia	84 868																		2)
Finland	346 457	3	2	0	0	6	0	0	0	0	0	0	0	0	0	1	2	4.0	3)
France	3 038 787	4	8	3	3	32	14	0	0	0	0	0	1	0	0	39	6	3.6	4)
FYR Macedonia	79 648																		
Georgia																			
Germany	6 407 001	4	13	0	1	4	0	0	1	0	1	0	2	0	0	8	3	0.6	
Greece	950 976	5		1		12	2						1			5	13	4.1	
Hungary	962 596	2			40	4											1	4.9	

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		
Iceland	18 082					2												11.1	
Ireland	188 080	1	13	0	0	42	0	0	0	0	0	0	0	0	0	14	16	45.7	
Italy	3 123 748	5	23	3	3	306	10						3			14	33	12.8	
Latvia	94 906					4										1		5.3	
Liechtenstein																			
Lithuania	119 714	0	0	0	0	10												8.4	
Luxembourg																			
Malta	21 821		1													5		27.5	
Moldova	104 685	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0	
Montenegro	23 128																		5)
Netherlands	686 700	0	0	0	0	1	2	0	0	0	0	0	2	0	0	0	2	1.0	
Norway	265 037	2	7	1	0	5	1	0	0	1	0	0	1	0	0	6	2	9.8	6)
Poland	1 581 865	12	22			187	4									9	13	15.6	
Portugal	413 839	2				1										2		1.2	
Romania	668 399																		
Russian Federation																			
San Marino																			
Serbia	492 844	3		1		15							3			9	355	78.3	7)

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		
Slovakia	290 691																		
Slovenia																			
Spain	2 011 334	10	6			41	21									16		4.7	8)
Sweden	620 254																		
Switzerland	405 518	1	0	0	0	18	1	0	0	0	0	0	1	0	0	7	2	7.4	
Turkey																			
Ukraine																			
United Kingdom	2 773 354	1	30	0	2	139	9	0	0	0	0	0	0	0	0	20	22	8.0	
Total		68	151	10	50	854	73	0	4	1	1	0	20	0	0	167	529		

1) 2 TAD - imputability level 3.
2) No serious adverse reactions reported to local authority in 2010.
3) Adverse reactions include those related to Octaplas transfusion. Anaphylaxis/hypersensitivity reactions include serious allergic reactions.
4) New regulations were published in August 2010 with new reporting modalities and levels, in order to comply with ISBT-EHN standards.
5) Implementation of a haemovigilance system is planned for IPA 2010.
6) Others are: TAD 1 - Hypotensive reaction 1 - UCT 5.
7) Data collected at national level.
8) Only serious adverse reactions with imputability level 2 or 3 are reported in this form.

APPENDIX

Questionnaire on the collection, testing and use of blood and blood components in Europe, the 2010 Survey

-

COUNCIL OF EUROPE
EUROPEAN COMMITTEE (PARTIAL AGREEMENT) ON BLOOD TRANSFUSION

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

THE 2010 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 and Dr. M.P. Janssen, Julius Centre of the University Utrecht, under auspicies of the EDQM Blood Transfusion Committee (CD-P-TS).

Any questions you might have when filling out the questionnaire should be directly addressed to Dr. M.P. Janssen (m.p.janssen@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 December 31, 2011.

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 (%)	
Family / 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	
Platelet apheresis donations	
Total number of platelet apheresis donations (procedures)	
Percentage voluntary non-remunerated donations (%)	
Other forms of apheresis donations	
Number of granulocyte apheresis donations (procedures)	
Number of multi-component apheresis donations (procedures)	
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 by blood establishments to hospitals and institutions ○ 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	

USE OF MEDICINAL PRODUCTS DERIVED FROM HUMAN PLASMA

FVIII (excluding cryo and excluding recombinant) (10^6 IU)	
Immunoglobulins, polyvalent (kg)	
Intravenous (kg)	
Subcutaneous plus intramuscular (kg)	
Human albumen (kg)	
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 platelets (%)	
Plasma components (for transfusion) further processing	
Leukocyte depleted plasma for transfusion (%)	
Irradiated plasma for transfusion (%)	
Plasma for transfusion quarantined (%)	
Plasma for transfusion pathogen reduced (%)	
Cryoprecipitate reduced plasma components quarantined (%)	
Cryoprecipitate reduced plasma components pathogen reduced (%)	

Cryoprecipitate quarantined (%)	
Cryoprecipitate pathogen reduced (%)	
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
Additional comments or remarks	

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

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

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