The collection, testing and use of BLOOD AND BLOOD COMPONENTS in Europe

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The collection, testing and use of blood and blood components in Europe

2012 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 2012. In its present form, it follows a series of similar reports which have assessed such data starting in 1989.

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. 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 Blood Establishments (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, 17 th edition, 2013*). 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, 30 questionnaires were received in 2012, which implies a response rate of 65 %. The response rates for the 2010 and 2011 surveys were 72 % and 70 %, respectively.

The average number of donors in relation to the general population was 24 per 1 000 inhabitants. On average, 23 % of the donor base consisted of first-time donors.

The number of Whole Blood (WB) collections was on average 36 per 1 000 inhabitants, and the average use of Red Blood Cells (RBC) was 36 per 1 000

inhabitants. On average, 3.9 litres (L) of plasmapheresis plasma per 1 000 inhabitants was collected.

More than half (57%) of the reporting MS indicate that the use of blood was expressed as units (U) distributed by BE, the remaining 43 % of MS reported it as transfused units. The use of RBC varied considerably (range 0-99) with a median of 37 U per 1 000 inhabitants. Four reporting MS (14 %) used less than 20 U per 1 000 inhabitants, most likely reflecting an insufficient supply. On average the fresh frozen plasma (FFP)/RBC ratio was 0.39. In the respondent MS, on average 35 % of the total platelet volume was supplied by (random) single donor platelets by apheresis; in 9 countries (36 %), this volume amounted to more than 50 %.

The amount of plasma delivered for fractionation into medicinal products differed greatly among MS (range 0-50 L), with an average yield of 10 L of plasma for fractionation per 1 000 inhabitants. However, 8 % of the reporting MS delivered 20 L or more plasma per 1 000 inhabitants. In Europe, on average, 60 % of the plasma for fractionation was from recovered plasma.

In 44 % of the MS, all RBC components were leucocyte-depleted. Platelet concentrates were 100 % leucocyte-depleted in 58 % of MS and, in 38 % of the MS, all plasma for transfusion was leucocyte-depleted. In 50 % of the reporting MS, all FFP was safeguarded by either quarantine or pathogen inactivation methods.

All donations were tested for anti-HIV-1/2, HBsAg and anti-HCV in 28/29 reporting MS. All donations were tested for syphilis in 93 % of MS. Anti-HTLV-I/II testing was performed on all donations in 18 % of reporting MS, and only on first-time donors in 11 %. Anti-HBc testing was performed on all donations in 30 % of MS, and only on first-time donors in 19 %. Prevalences and incidences of infectious diseases varied greatly among MS, but highest incidence rates were found in the Baltic States (i.e., Estonia, Latvia and Lithuania) and in Southern countries. The median prevalence amongst first-time tested donors was 6.4, 93 and 65 per 100 000 donors for HIV-1/2, HBV and HCV, respectively. The median incidence amongst repeat donors was 0.9, 1.2 and 2.3 per 100 000 donor years for HIV-1/2, HBV and HCV, respectively.

Nucleic Acid Testing (NAT) for HIV was performed on each donation in 63 % of reporting MS. HBV NAT and HCV NAT was performed on each donation in 58 % and 63 % of MS, respectively.

Bacterial screening was reported in 67 % of reporting MS. Screening of 80 % or more of platelet concentrates was performed in 35 % of MS. The median rate reported for confirmed-positive cultured platelet concentrates was 0.08 %.

All MS reported having legally-binding national regulations for the collection, testing, processing, storage and distribution of blood and blood components. In 87 % of the reporting MS, a National Council or Expert Committee existed to advise the Ministry

of Health on transfusion-related policy issues. In 83 % of MS, a national blood policy on the quality and safety of blood and blood components was in place.

In 87 % 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 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 91 % of MS.

Ninety percent 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 12 serious adverse reactions per 100 000 distributed blood components was calculated. This estimate is based on data provided by 21 MS. Anaphylaxis, TACO (Transfusion Associated Circulatory Overload) and haemolysis 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. In brief, the EDQM circulated questionnaires to experts in MS in the form of a web-based application. The MS were requested to complete the questionnaire within a given timeframe with data collated during the year 2012. After the deadline, data tables were prepared and distributed for review by MS and corrected accordingly where necessary. Requests for additional information or clarifications from national experts were submitted by the authors where incomplete or incomprehensible data sets were returned. During the compilation of the data from the questionnaires, some of the data provided did not meet the necessary requirements and these have not been transcribed in the report, resulting in empty fields in some tables. The report was adopted by the CD-P-TS.

Trend analysis and incomplete data

Comparisons with results from the previous surveys and trend analyses are envisaged. The most recent report on trend analyses was published in 2015 and comprised questionnaire data from 2001 through to 2011 (http://www.edqm.eu/en/blood-transfusion-reports-70.html). Not all of the information requested in the questionnaire is included in the reported tables, but additional data are 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 it was not provided. The absence of a response (or data inconsistency) is represented by empty fields in the tables.

Remarks on the data collection process

It remains the responsibility of the individual MS to check that the data reported in the questionnaires 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 was significantly reduced. In addition, the Julius Centre can, on request, provide MS with a spreadsheet 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.

RESULTS

Response rate

Forty-six of the MS of the CoE were invited to send completed questionnaires. Replies were received from 30 MS by the deadline for submissions; a response rate of 65 %. The response rates were 2010 and 2011 surveys were 72 % and 70 %, 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 yet always be the case. Therefore, it is not certain whether this requirement was always met in generating the data for this survey. Definitions have been largely addressed by the *EC Council Recommendation of 29 June 1998 on the suitability of blood and plasma donors and the screening of donated blood in the European Community (98/463/EC)*.

The terms 'regular and repeat donors' are defined by *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. As some of these donors may also qualify as regular donors the total number of donors reported may be less than the sum of first time and regular and repeat donors. 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 disease 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 2012, 23 % (range 10-106 %) 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 figure of 106% of first time donors reported by a member state is most likely a data entry error.

The average number of donors in relation to the general population is 25 (range 3-44) per 1 000 inhabitants. This number may reflect the commitment of the population to donate blood in relation to demand. Differences exist but, in general terms, fewer than 10 donors per 1 000 inhabitants should really pose a problem with supply and around 30 donors per 1 000 inhabitants seems an achievable goal from the given data. Not all countries with a relatively high number of donors per 1 000 inhabitants deliver high numbers of 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: Tables 2.1 and 2.2

• 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 derived from human blood or plasma (see Table 4). The number of WB collections in the 30 MS reporting was, on average, 36 (range 4-59) per 1 000 inhabitants. Given the average use of RBC per 1 000 inhabitants (36 U, range 0-99 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 sometime perceived 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 27 MS that reported data on autologous donations, they only contributed on average to around 0.3 % (range 0-2.9 %, 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 collected by apheresis per 1 000 inhabitants reflects the volume of national plasmapheresis programmes. In the 28 reporting MS, on average 3.9 L (range 0-47 L, median 0.4 L) of plasma per 1 000 inhabitants was collected by plasmapheresis. The Czech Republic, Germany and the Netherlands are prominent as countries with considerably more extensive plasmapheresis programmes, with 10 L or more of plasmapheresis plasma per 1 000 inhabitants per annum.
Platelet apheresis may be aimed at Human Leucocyte Antigen (HLA) or Human Platelet Antigen (HPA) typed donations for refractory patients. 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 components is given in Table 3. In the 25 reporting MS, on average 35 % (range 0-86 %, median 31 %) 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 is primarily applied in Lithuania, Norway and Iceland with 7 %, 2% and 1% of all RBC collections respectively. Granulocyte apheresis donations are infrequent, as indications appear to be limited, with a maximum of 0.04% of all RBC collections in Sweden.

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 approximation of blood use estimates, and the heterogeneity of the given data may result in only minor deviations. Fifty-seven percent (16/28) of the respondent MS indicated that the use of blood was expressed as the units distributed by BE, whereas 12 MS (43 %) reported it as transfused units.

WB "must be considered as a source material and has no, or only a very restricted, role in transfusion therapy" (*Guide to the Preparation, Use and Quality Assurance of Blood and Blood Components, 17 th edition, 2013*). However, in countries with limited resources, transfusion therapy with WB may be needed when the infrastructure for blood component preparation is lacking. In 27 reporting MS, on average 2.9 % (range 0-51 %, median 0.006 %) of prescriptions of RBC transfusions by physicians were performed with WB. In Montenegro WB accounted for 26% of the total volume of RBC components used.

The use of RBC per 1 000 inhabitants varied considerably. In 30 reporting MS, it averaged 34 RBC components per 1 000 inhabitants (range 0-99, median 37 units). Rejman (2000) suggested in his report on the 1997 survey that 40-60 WB donations per 1 000 inhabitants would be needed for optimal supply; a figure largely driven by the need for RBC for transfusion. Apparently, the use of RBC has been greatly reduced in the last decade. 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 1 000 inhabitants could reflect the results of these programmes. In 4/30 (14 %) of the reporting MS, less than 20 RBC U per 1 000 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.* RBC use) in some countries increased the FFP/RBC ratio by decreasing the rate of RBC use. On average, the FFP/RBC ratio was 0.39 (range 0.02-1.6, median 0.25, so one in four).

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. In the 25 reporting MS, on average 35 % (range 0-86 %, median 31 %) of the adult therapeutic doses of platelets were produced by single donor platelets by apheresis. (Table 3). In 9 of 25 reporting countries (36 %), this volume amounted to more than 50 %.

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

Plasma for fractionation: Tables 4.1 and 4.2

The total amount of plasma delivered 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 10 L (range 0-50 L) per 1 000 inhabitants of plasma for fractionation into medicinal products. However, 2 of the 25 (8 %) reporting MS delivered 20 L or more plasma per 1 000 inhabitants.

In 10 reporting MS, a significant supply of plasma for fractionation was recovered plasma. On average, 60 % of the plasma for fractionation was from recovered plasma (range 0-100 %, median 65 %).

Reporting on the use of medicinal products derived from human plasma was limited. The 12 MS that reported Factor VIII (excluding Lithuania) use indicated an average use of 36 x 10^6 IU (range 0- 139, median 11). The average amount of polyvalent immunoglobulins used was 1 238 Kg (range 0-5 635 Kg, median 430 Kg) and the average amount of human albumin used was 5 514 Kg (range 0- 35 961 Kg, median 1 174 Kg). In the 8 MS that manufactured immunoglobulins, the average proportion of intravenous administration was 86 % (range 57-100 %, median 93 %).

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

In 12/27 (44 %) of reporting MS, 100 % leucocyte-depletion of RBC components was carried out. This was the case for platelet concentrates in 15/26 (58 %) reporting MS. Complete (100 %) leucocyte-depletion was applied to plasma for transfusion in 8/21 (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 12/24 (50 %) of the reporting MS, nearly all FFP (>=99 %) were safeguarded by either method; in 5/24 (21 %) MS using mainly quarantine (>95 %); in 5/22 (23 %) using mainly pathogen reduction technologies (>99 %); and in 2/24 (8 %) using a combination of the two methods.

Screening for infectious markers and serological test methods: Tables 6.1 and 6.2

In all reporting MS, all donations were tested for anti-HIV-1/2, HBsAg and anti-HCV, with the exception of France which tests 100% of its donations with HCVAg instead of anti-HCV. In 27/30 (93 %) 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 5/28 (18 %) of the reporting MS, and only on first-time donors in 3/28 (11 %) MS.

Testing for anti-HBc was performed on all donations in 8/27 (30 %) reporting MS, and only on first-time donors in 5/27 (19 %) 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, 26 of 27 (96 %) MS that were able to provide the absolute numbers of positive donors provided confirmed positive infections for HIV, HBV and HCV, syphilis and/or HTLV-I/II (see Table 7.1).

• First-time tested donors

The frequency of 'confirmed positive' donors among all first-time tested donors 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 83 for HIV-1/2, from 0 to 6 476 for HBV and 0 to 3 267 for HCV. Although considerable differences in the geographical distribution of these infections exist in Europe, it is questionable as to whether the extremely high frequencies in some countries reflect reliable data on actual 'confirmed positive donors' or, merely, represent repeat positive donors screened by Enzyme-Linked Immunosorbent Assay (ELISA) and, thereby, include many false positives. 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 6.4, 93 and 65 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. 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 agents varied greatly among MS. Previous reports showed Northwest-Southeast gradient in Europe, with HBV and HCV infections relatively infrequent in repeat donors in all North-Western countries. The 2012 data are in accordance with this gradient, although with no response from part of the mid-Eastern countries, a slightly different pattern. Highest incidence rates were found in the Baltic States (i.e., Estonia, Latvia and Lithuania), and with a lesser elevation the Southern countries (Greece, Italy, Spain, Montenegro and Croatia).

The incidence per 100 000 repeat tested donor years ranged from 0 to 39 for HIV-1/2, from 0 to 64 for HBV and 0 to 319 for HCV. The median incidence amongst repeat donors was 0.9, 1.2 and 2.3 per 100 000 donor years for HIV-1/2, HBV and HCV, respectively.

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

NAT testing for HIV was performed on each donation in 17/27 (63 %) of the reporting MS. NAT testing for HBV was performed on each donation in 15/26 (58 %) respondent MS. NAT testing for HCV was performed on each donation in 17/27 (63 %) of the MS. In most MS where the incidence rates were relatively high (see Table 7.2 for comparison), NAT on each donation appeared to be performed. This is in accordance with the fact that the effectiveness (or 'yield') of NAT testing is higher 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 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 ^{o}C, thus facilitating bacterial growth. Application of bacterial testing was reported by 20 MS (67 %). In 7/20 (35 %) reporting MS, bacterial culture was performed on 80 % or more of all platelets (concentrates recovered from both WB donations and apheresis platelets). Among the 12 MS that reported on the parameter, the average rate of confirmed positively-cultured platelet concentrates was 0.08 % (ranging from 0 to 0.28 %, median 0.03 %).

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 26/30 (87 %) of the reporting MS, a National Council or Expert Committee advised the Ministry of Health on transfusion-related issues. In 25/30 (83 %) of the MS, there was a national policy on the quality and safety of blood and blood components. Of these 25 MS, 22 (88 %) had implemented the national blood policy or were in the process of doing so.

Quality management: Tables 11.1 and 11.2

In 26/30 (87 %) of the reporting MS, a QS was established and maintained by BE. In the remaining four MS, the implementation of such a system was planned. In 27/30 (90 %) reporting MS, inspections were performed at least every 2 years. The vast majority of these inspections (25/27, 93 %) were (partly) carried out by the national authority.

In 16/25 (64 %) of the reporting MS, all donations were covered by GMP. Of the nine MS that reported that GMP was not (always) applied, six reported that 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, 22/25 (88 %) 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 13/27 (48 %) of the respondent MS. In ten 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 25/27 (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 10/23 (43 %) reporting MS. In nine MS, components were coded using another system. Overall, 21/23 reporting MS (91 %) reported that all components were coded using either ISBT or another system.

Haemovigilance: Tables 12.1 and 12.2

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 (TACO) or to recipient properties (allergy). In contrast to the *EC Directives 2002/98/EC* and *2005/61/EC*, haemovigilance data which may not be caused by blood component properties, such as TACO, are also reported here.

Of the reporting MS, 3/29 (10 %) indicated that they did not have a haemovigilance reporting system at a national level. In all of the MS that did have a reporting system, with the exception of Sweden, this system was associated with a national authority. Data on transfusion complications were provided by 21/30 MS (70 %). 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 components (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 12 serious adverse reactions per 100 000 distributed blood components seems a reasonable estimate. The median estimate is

5.4 per 100 000 components distributed. Anaphylaxis, TACO and haemolysis were the most frequently reported serious adverse reactions.

REFERENCES

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- Guideline on epidemiological data on blood transmissible infections, Committee for Medicinal Products for Human Use (CHMP), EMA/CHMP/BWP/548524/2008, April 2010.

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- Schreiber GB, Glynn SA, Busch MP, Sharma UK, Wright DJ, Kleinman SH. Retrovirus Epidemiology Donor Study. Incidence rates of viral infections among repeat donors: are frequent donors safer? Transfusion 2001;41:730-735.

- The Collection, Testing and Use of Blood and Blood Products in Europe in 2001, Council of Europe Publishing, Strasbourg, 2004.

TABLES

List of countries that participated in the survey

(30 out 46 MS)

Armenia, Belgium, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Moldova, Montenegro, Netherlands, Norway, Portugal, Russian Federation, Serbia, Slovakia, Spain, Sweden, Switzerland, and the United Kingdom.

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Country	Response questionnaires
Albania	
Andorra	
Armenia	1
Austria	
Azerbaijan	
Belgium	1
Bosnia / Herzegovina	
Bulgaria	
Croatia	1
Cyprus	
Czech Republic	1
Denmark	1
Estonia	1
Finland	1
France	1
FYR Macedonia	
Georgia	1
Germany	1
Greece	1
Hungary	1
Iceland	1
Ireland	1
Italy	1
Latvia	1
Liechtenstein	
Lithuania	1
Luxembourg	1
Malta	
Moldova	1
Montenegro	1
Netherlands	1
Norway	1
Poland	
Portugal	1
Romania	
Russian Federation	1
San Marino	
Serbia	1
Slovakia	1
Slovenia	
Spain	1
Sweden	1
Switzerland	1
Turkey	
Ukraine	
United Kingdom	1

Response	**30**
Response Rate	**65%**

Table 1

Survey 2012

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 1,000	donors per 1,000 inhabitants
Albania								
Andorra								
Armenia	3 998	9 720	106,4	5 805	3 915	9 137	3 000	3,0
Austria								
Azerbaijan								
Belgium	245 898	51 771	17,4	51 771	0	297 669	11 100	26,8
Bosnia / Herzegovina								
Bulgaria								
Croatia	92 517	12 023	11,5	12 023		104 540	4 285	24,4
Cyprus								
Czech Republic	255 000	49 200	18,1			272 200	10 520	25,9
Denmark	229 877	35 522	15,4	23 981	11 541	230 000	5 603	41,1
Estonia	28 359	7 510	20,9	7 510	0	35 869	1 323	27,1
Finland	144 226	15 759	9,9	15 759	0	159 985	5 427	29,5
France	1 372 810	356 170	20,6	356 170		1 728 980	65 543	26,4
FYR Macedonia								
Georgia	28 576	6 644	18,9			35 220	4 491	7,8
Germany	2 459 582	496 778	17,0	408 883	87 895	2 929 360	80 524	36,4
Greece	301 183	53 205	15,0	19 180	19 180	354 388	10 500	33,8
Hungary	234 901	44 785	16,0	44 785	0	279 686	9 634	29,0
Iceland	6 591	1 808	21,5	0	1 808	8 399	322	26,1
Ireland	76 272	10 758	12,2	10 758	1 326	88 356	4 610	19,2
Italy	1 443 770	384 710	22,1	238 393	153 248	1 739 712	59 394	29,3
Latvia	23 796	9 315	28,1	9 315	0	33 111	2 000	16,6
Liechtenstein								
Lithuania	32 962	22 922	41,0	22 922	0	55 884	2 988	18,7
Luxembourg	9 364	1 106	10,6	740	366	10 470	537	19,5
Malta								
Moldova	43 517	20 444	32,0	20 444		63 961	3 409	18,8
Montenegro	7 297	4 864	40,0	4 864		12 161	626	19,4
Netherlands	312 018	46 936	13,1	0	46 936	358 954	16 730	21,5
Norway	100 052	16 589	14,3		16 589	115 641	5 051	22,9
Poland								
Portugal	419 747	44 877	9,7	44 877	0	464 624	10 487	44,3
Romania								
Russian Federation	1 018 015	589 516	36,7			1 607 531	142 621	11,3
San Marino								
Serbia	208 975	40 266	100,0			249 241	7 199	34,6
Slovakia	91 557	29 985	24,7	23 286	1 216	121 542	5 411	22,5
Slovenia								
Spain	962 219	233 062	19,5			1 195 281	46 008	26,0
Sweden	388 462				43 055	431 517	9 556	45,2
Switzerland	199 388	26 188	11,6	26 188	0	225 576	7 997	28,2
Turkey								
Ukraine								
United Kingdom	1 180 357	195 781	14,3	187 504	5 531	1 373 392	63 700	21,6

Country	Comments
Czech Republic	Change of the interpretation of definitions (in CZ): earlier numbers of regular / repeat donors were counted according to 'CoE, Guide ...definition' not respecting whether donor was active in a given year. 'Number of regular plus repeated donors actice in a given year' is based on qualified estimation.
Denmark	The number of first time donors giving blood and the total number of donors are estimated. Bleeding of first time donors was permitted in Denmark from 1. January 2012.
Norway	We do not distinguish between regular and repeat donors.

Table 2.1
Survey 2012

Collection of whole blood, autologous blood and blood (apheresis) components

Country	whole blood collections				apheresis collections					
	whole blood units	whole blood per 1,000 inhabitants	autologous units	% autologous whole blood units	plasma apheresis (L)	plasma in L per 1,000 inhabitants	platelets apheresis (U)	RBC apheresis (U)	granulocytes apheresis (U)	multi-component apheresis (U)
Albania										
Andorra										
Armenia	13 020	4,3	0	0,0	94	0,03	32	0	0	0
Austria										
Azerbaijan										
Belgium	538 336	48,5	129	0,0	66 861	6,02	13 471	2 506	99	15 543
Bosnia / Herzegovina										
Bulgaria										
Croatia	179 304	41,8	438	0,2	553	0,13	2 646			2 528
Cyprus										
Czech Republic	430 700	40,9	12 800	2,9	494 500	47,01	16 900	1 400		
Denmark	298 083	53,2	0	0,0	1 852	0,33	2 518	0	6	0
Estonia	58 120	43,9	0	0,0	990	0,75	105	230	0	568
Finland	246 429	45,4	0	0,0	2 586	0,48	4 565	0	0	0
France	2 632 089	40,2	0	0,0	259 818	3,96	5 065	8	368	126 810
FYR Macedonia										
Georgia	32 390	7,2	0	0,0						
Germany	4 785 048	59,4	15 064	0,3	1 924 743	23,90	196 106	14 699	629	19 917
Greece	542 240	51,6	753	0,1	333	0,03	13 190	0		1 200
Hungary	425 637	44,2			0	0,00	3 050	626		0
Iceland	12 363	38,4			115	0,36	692	146	0	
Ireland	141 354	30,7	2	0,0	0	0,00	11 978	0	0	0
Italy	2 683 127	45,2	61 634	2,2	229 172	3,86	10 520	652	229	92 692
Latvia	53 180	26,6	0	0,0	0	0,00	2 073	0	0	
Liechtenstein										
Lithuania	79 367	26,6	149	0,2			1 049	5 952		2 221
Luxembourg	20 631	38,4	34	0,2	2 314	4,31	679	0	0	0
Malta										
Moldova	69 322	20,3	148	0,2	4 989	1,46				
Montenegro	15 706	25,1	0	0,0	0	0,00	0	0	0	0
Netherlands	506 556	30,3	45	0,0	170 177	10,17	4 825	0	35	0
Norway	198 584	39,3	7	0,0	2 815	0,56	5 100	3 260	0	1 394
Poland										
Portugal	392 910	37,5	805	0,2	0	0,00	4 568	346	0	0
Romania										
Russian Federation	2 208 184	15,5			352 035	2,47				
San Marino										
Serbia	230 224	32,0	33	0,0	280	0,04	1 967			
Slovakia	204 773	37,8	881	0,4	91	0,02	6 276	84	23	
Slovenia										
Spain	1 702 768	37,0	7 195	0,4	22 564	0,49	5 747	493	0	24 235
Sweden	460 779	48,2	37	0,0	30 103	3,15	7 735	1 546	169	100
Switzerland	339 520	42,5	1 365	0,4	595	0,07	10 991	425		7 802
Turkey										
Ukraine										
United Kingdom	2 263 885	35,5	2	0,0	101	0,00	138 399	0	22	0

Country	Comments
Belgium	Multicomponent donations are donations of platelets and plasma
Czech Republic	"WB donation total" incl. autologous donation
Germany	Data not available to voluntary non-remunerated donations (%).
Hungary	We have not got any information about the number of the plasmapheresis in the private sector.
Montenegro	Collection of Blood and Blood Components bz apheresis procedures are not present in MNE still.
Switzerland	The number given for plasma apheresis donations in liters is an estimate: the number of procedures is multiplicated with 360 ml (as units collected may vary between 120-600ml)

Table 2.2
Survey 2012

Profile of donations

Country	whole blood donations			red cell apheresis		plasmapheresis donations	platelet apheresis
	% voluntary, non-remunerated	% from replacement donors	% from autologous donors	% voluntary, non-remunerated	% from autologous donors	% voluntary, non-remunerated	% voluntary, non-remunerated
Albania							
Andorra							
Armenia	40	0	0,00	0		0	0
Austria							
Azerbaijan							
Belgium	100	0	0,02	100	0	100	100
Bosnia / Herzegovina							
Bulgaria							
Croatia	100		0,24			100	100
Cyprus							
Czech Republic	100	0	2,97		0		
Denmark	100	0	0,00	100		100	100
Estonia	100	0	0,00	100		100	100
Finland	100	0	0,00	0		100	100
France	100		0,00	100	0	100	100
FYR Macedonia							
Georgia	10	24	0,00				
Germany	100	0	0,31	100	14	100	100
Greece	49	51	0,14	0		63	63
Hungary	100			100			100
Iceland	100			100		100	100
Ireland	100	0	0,00				100
Italy	100	0	2,30	100	19	100	100
Latvia	100		0,00				0
Liechtenstein							
Lithuania	32		0,19	24			22
Luxembourg	100	0	0,16	0		100	100
Malta							
Moldova	46	37 435	0,21			25	
Montenegro	33	67	0,00	0			0
Netherlands	100	0	0,01			100	100
Norway	100	0	0,00	100	0	100	100
Poland							
Portugal	100	0	0,20	100	0		100
Romania							
Russian Federation	91						
San Marino							
Serbia	91	21 249	0,01			100	100
Slovakia	100	0	0,43	100	0	100	100
Slovenia							
Spain	100	0	0,42	100		100	100
Sweden	100	0	0,01	100	1	100	100
Switzerland	100	0	0,40	100		100	100
Turkey							
Ukraine							
United Kingdom	100	0	0,00	0		100	100

Country	Comments
Belgium	Multicomponent donations are donations of platelets and plasma
Czech Republic	"WB donation total" incl. autologous donation
Germany	Data not available to voluntary non-remunerated donations (%).
	Family / Replacement donations are not allowed.
Hungary	We have not got any information about the number of the plasmapheresis in the private sector.
Montenegro	Collection of Blood and Blood Components bz apheresis procedures are not present in MNE still.
Switzerland	The number given for plasma apheresis donations in liters is an estimate: the number of procedures is multiplicated with 360 ml (as units

Table 3
Survey 2012

Use of blood and blood components for transfusion

Country	Transfused or distributed	whole blood (U)	% whole blood of total RBCs	red blood cell concentrates (U)	r.b.c. (U) per 1,000 inhabitants	plasma for transfusion (U)	platelets total (U)	platelets recovered (U)	platelets apheresis (U)	% platelets by apheresis	cryoprecipitate (10^6 IU FVIII)
Albania											
Andorra											
Armenia	Trans.	0	0,0	11 294	3,8	11 087	2 159	2 127	32	1,5	710
Austria											
Azerbaijan											
Belgium	Trans.	0	0,0	491 774	44,3	89 053	68 668	33 064	35 604	51,8	0
Bosnia / Herzegovina											
Bulgaria											
Croatia	Distr.	321	0,2	177 061	41,3	91 593	21 969	19 169	2 800	12,7	1
Cyprus											
Czech Republic	Trans.	654	0,2	393 804	37,4	187 000	37 100	9 200	27 900	75,2	
Denmark	Trans.	0	0,0	277 960	49,6	60 692	33 631	32 001	1 630	4,8	1
Estonia	Trans.	46	0,1	55 162	41,7	25 993	6 985	5 712	1 273	18,2	873
Finland	Distr.	0	0,0	229 090	42,2	49 429	41 565	41 085	480	1,2	0
France	Distr.	0	0,0	2 517 097	38,4	387 976	300 683	154 955	145 728	48,5	0
FYR Macedonia											
Georgia	Trans.										
Germany	Distr.	3 550	0,1	4 633 911	57,5	1 571 068	589 179	226 457	362 722	61,6	0
Greece	Distr.	0	0,0	413 568	39,4	193 872	129 807	115 897	13 910	10,7	0
Hungary	Distr.	0	0,0	414 755	43,1	97 219	47 695	44 645	3 050	6,4	0
Iceland	Distr.	0	0,0	11 538	35,8	3 284	2 330	732	1 598	68,6	0
Ireland	Distr.	0	0,0	135 357	29,4	21 240	24 971	5 117	19 854	79,5	197
Italy	Trans.	1 469	0,1	2 564 093	43,2	432 884	219 785	146 334	73 451	33,4	2 950
Latvia	Distr.	0	0,0	51	0,0	35	7 681	7 677	4	0,1	7
Liechtenstein											
Lithuania	Trans.	0	0,0	87 402	29,3	31 156	19 002	8 586	10 416	54,8	
Luxembourg	Distr.	0	0,0	19 889	37,0	4 100	2 765	1 904	861	31,1	0
Malta											
Moldova	Distr.	160	0,4	39 100	11,5	63 041	8 399				13 160
Montenegro	Trans.	3 990	26,2	15 250	24,4	10 298	509	509	0	0,0	544
Netherlands	Distr.	363	0,1	453 623	27,1	67 807	57 720	52 418	5 302	9,2	0
Norway	Trans.	132	0,1	191 431	37,9	49 733	24 508	16 911	7 597	31,0	
Poland											
Portugal	Trans.	133	0,0	341 976	32,6	6 578	38 942				
Romania											
Russian Federation	Distr.	1 335	0,1	1 669 907	11,7	1 907 368	148 684				
San Marino											
Serbia											
Slovakia	Distr.	420	0,2	189 805	35,1	86 679	15 033	2 748	12 285	81,7	0
Slovenia											
Spain	Trans.	95	0,0	1 553 720	33,8	198 521	188 510	158 356	30 154	16,0	1 557
Sweden	Trans.			460 837	48,2	182 893	48 523	40 788	7 735	15,9	
Switzerland	Distr.			297 588	37,2	49 832	34 265	11 526	22 739	66,4	
Turkey											
Ukraine											
United Kingdom	Distr.	2	0,0	2 102 521	33,0	286 402	310 428	43 333	267 095	86,0	156 559

Country	Comments
Croatia	FVIII in Cryoprecipitate is calculated as total content of FVIII in all Cryo pools (3387 pools, 1 pool is prepared from 10 donors), expressed as value 0,1227x10*6 IU.
Czech Republic	Number of components issued for transfusion
Germany	Total number of whole blood units covers only autologous blood.
	Number of plasma units (plasma or FFP) for transfusion covers units quarantined FFP and lyophilised plasma, transfused SD-plasma reported by users and units autologous plasma (0.8% autologous of total).
	Cryoprecipitate not in use.
Ireland	Cryo: 9 pools of cryo and 152 single units issued. Most fibrinogen replacement in the country is with fibrinogen concentrate.
Norway	All plasma is Octaplas 200 ml
Serbia	data not available
United Kingdom	Figures given are for number of units of clinical cryoprecipitate

Table 4.1
Survey 2012

Plasma for fractionation into medicinal products

Country	plasma for fractionation (L)	plasma for fractionation per 1,000 inhabitants (L)	Plasma for fractionation into FVIII recovered from whole blood donations (litres)	% fractionation plasma recovered	plasma for transfusion per 1,000 inhabitants (U)	plasma for transfusion / total red blood cell ratio (U)
Albania						
Andorra						
Armenia	0	0,00	0		3,70	0,98
Austria						
Azerbaijan						
Belgium	192 336	17,33	121 776	63,31	8,02	0,18
Bosnia / Herzegovina						
Bulgaria						
Croatia	18 774	4,38			21,38	0,52
Cyprus						
Czech Republic	526 000	50,00	65 100	12,38	17,78	0,47
Denmark	59 378	10,60	59 378	100,00	10,83	0,22
Estonia	10 000	7,56			19,65	0,47
Finland	62 000	11,43			9,11	0,22
France	862 074	13,15	682 053	79,12	5,92	0,15
FYR Macedonia						
Georgia						
Germany	3 088 862	38,36	1 213 848	39,30	19,51	0,34
Greece					18,46	0,47
Hungary	97 219	10,09	97 219	100,00	10,09	0,23
Iceland	0	0,00			10,20	0,28
Ireland	0	0,00	0		4,61	0,16
Italy	772 593	13,01	509 016	65,88	7,29	0,17
Latvia					0,02	0,69
Liechtenstein						
Lithuania	0	0,00			10,43	0,36
Luxembourg	7 632	14,20	0	0,00	7,63	0,21
Malta						
Moldova	3 321	0,97			18,49	1,61
Montenegro					16,45	0,68
Netherlands	316 936	18,94	136 943	43,21	4,05	0,15
Norway	52 785	10,45			9,85	0,26
Poland						
Portugal					0,63	0,02
Romania						
Russian Federation	138 248	0,97			13,37	1,14
San Marino						
Serbia	5 627	0,78				
Slovakia	26 630	4,92	26 630	100,00	16,02	0,46
Slovenia						
Spain	368 528	8,01			4,31	0,13
Sweden	128 940	13,49			19,14	0,40
Switzerland	77 907	9,74			6,23	0,17
Turkey						
Ukraine						
United Kingdom	0	0,00	0		4,50	0,14

Country	Comments
Croatia	Plasma for fractionation is processed and freeze between 24 and 72 hours of donation. All plasma is delivered to Institute of Immunology to Institute of Immunology (Zagreb, Croatia). From that plasma Institute manufacture only albumin and immunoglobulines.
Estonia	Plasma was sold without the special indication
Finland	Plasma for fractionation = FFP24 sold/sent to Baxter
Germany	Data on the amount of plasma for fractionation of factor VIII are not collected separately. The number therefore indicates the amount of plasma delivered for manufacture of plasma derivatives except for plasma for manufacturing of specific immunoglobulines. Data not available to other component units.
Hungary	We have not got any information about the number of the plasmapheresis in the private sector.
Luxembourg	During 2012 We had a toll manufacturing agreement with Octapharma for the fabrication of Ig albumin and PPSB issued from our own plasma.
Norway	We sell the plasma. It is not known to us how it is used.
Switzerland	No Information about final products

Table 4.2
Survey 2012

Use of medicinal products derived from human plasma

Country	FVIII (excluding cryo and excluding recombinant) (10^6 IU)	Immunoglobulins (kg)			Human albumin (kg)
		Polyvalent (kg)	Intravenous (%)	Subcutaneous plus intramuscular (%)	
Albania					
Andorra					
Armenia	0	0			0
Austria					
Azerbaijan					
Belgium					
Bosnia / Herzegovina					
Bulgaria					
Croatia					
Cyprus					
Czech Republic	26	330	87	13	1 174
Denmark	31	530	57	43	1 509
Estonia	6	13	100	0	203
Finland					
France					
FYR Macedonia					
Georgia					
Germany	139	5 635	92	8	16 052
Greece					
Hungary					
Iceland	0	0			0
Ireland					
Italy	132	3 732	94	6	35 961
Latvia					
Liechtenstein					
Lithuania	7 381 000				
Luxembourg	0	8	100	0	210
Malta					
Moldova					795
Montenegro					
Netherlands	15	1 065	94	6	1 300
Norway					
Poland					
Portugal					
Romania					
Russian Federation					
San Marino					
Serbia					
Slovakia					
Slovenia					
Spain	76	2 582			11 902
Sweden	2	957	67	33	2 581
Switzerland					
Turkey					
Ukraine					
United Kingdom	0	0			0

Country	Comments
Croatia	In Croatia, there are no exact full data collected on national level about the use of medicinal products derived from human plasma.
Czech Republic	as "amount distributed" (amount actually used is not known)
Finland	Several suppliers in Finland
Luxembourg	PPSB: 134 000 UI
	We are not the onlyone provider for medical products in Luxembourg
Netherlands	These are estimated numbers
Serbia	data not available
Switzerland	No information
United Kingdom	No data. Supplied to hospitals directly from the manufacturer.

Table 5.1
Survey 2012

Special processing of blood components

Country	red blood cells		plasma for transfusion		platelets		
	leuco depleted %	irradiated %	leuco depleted %	irradiated %	leuco depleted %	irradiated %	path.inact. %
Albania							
Andorra							
Armenia	0	0	0	0	0	0	0
Austria							
Azerbaijan							
Belgium	100		100	0	100		42
Bosnia / Herzegovina							
Bulgaria							
Croatia	42				80		
Cyprus							
Czech Republic	25	5	0	1	90	60	0
Denmark	100	4	1	0	100	25	0
Estonia	7	4	0	0	56	24	6
Finland	100	4	100	0	100	44	0
France	100		100		100		8
FYR Macedonia							
Georgia							
Germany	100	5		0	100	39	0
Greece	37	20	45	15	75	42	0
Hungary	12	8	9		44		0
Iceland	25	13	9	1	100	71	19
Ireland	100	14	100		100	100	0
Italy	30	6	30	0	20	63	4
Latvia							
Liechtenstein							
Lithuania	28		10	0	100	0	20
Luxembourg	100	1	100	0	100	3	0
Malta							
Moldova							
Montenegro	5	1	0	0	0	0	0
Netherlands	100	5	100	0	100	35	0
Norway	100	7	0	0	100	30	11
Poland							
Portugal	100				77		
Romania							
Russian Federation	29		23		28	1	3
San Marino							
Serbia	43	1					
Slovakia	35	3			95	10	0
Slovenia							
Spain	97	6			100	52	
Sweden	88	4	97	4	100	56	18
Switzerland	100	2	100	0	100	0	100
Turkey							
Ukraine							
United Kingdom	100	9	100	0	100	56	0

Country	Comments
Croatia	In Croatia, there is no decision at natioanl level for universal pre-storage leucodepletion of blood components.
	Blood components are irradiated by gamma irradiation in some Hospitals, no data avaliable.
Finland	Also hospital irridate components.
	FFP8 sold/sent to Octpharma; Finnish hospitals use only Octaplas
Germany	Data on leukocyte depleted plasma for transfusion are not collected.
Ireland	99% of plasma used is SD-Plasma and most fibrinogen replacement is with fibrinogen concentrate.
Lithuania	Data for apheresis platelets
Montenegro	Leukocite depleted and irradiated RC and PLT are prepared in specific cases only.
Norway	All plasma is Octaplas 200 ml
United Kingdom	Methylene Blue treated plasma and cryopreciate is imported

Table 5.2
Survey 2012

Inactivation or quarantine of plasma

Country	fresh frozen plasma		cryoprecipitate reduced plasma		cyroprecipitate	
	quarantined %	virus inactivated %	quarantined %	virus inactivated %	quarantined %	virus inactivated %
Albania						
Andorra						
Armenia	62	0	0	0	100	0
Austria						
Azerbaijan						
Belgium	0	100	0	0	0	0
Bosnia / Herzegovina						
Bulgaria						
Croatia						
Cyprus						
Czech Republic	100	0	100	0	100	0
Denmark	0	0	1	0	0	0
Estonia	0	0	0	0	0	0
Finland	0	100	0	0	0	0
France	38	62				
FYR Macedonia						
Georgia						
Germany	100	0	0	0	0	0
Greece	22	8	0	0	0	0
Hungary						
Iceland	0	0	0	0	0	0
Ireland	0	99	0	0	0	0
Italy	8	12	0	0	0	
Latvia						
Liechtenstein						
Lithuania	57	0				
Luxembourg	0	100	0	0	0	0
Malta						
Moldova						
Montenegro	0	0	0	0	0	0
Netherlands	100	0				
Norway	0	100	0	0	0	0
Poland						
Portugal						
Romania						
Russian Federation	95	4				
San Marino						
Serbia	5					
Slovakia	54	0	0	0	0	0
Slovenia						
Spain	31	69	76	24	66	34
Sweden	0	3				
Switzerland	100					
Turkey						
Ukraine						
United Kingdom	0	3	0	0	0	5

Country	Comments
Finland	FFP8 sold/sent to Octpharma; Finnish hospitals use only Octaplas
Germany	Cryoprecipitate reduced plasma components and Cryoprecipitate: Not in use
Ireland	99% of plasma used is SD-Plasma and most fibrinogen replacement is with fibrinogen concentrate.
Norway	All plasma is Octaplas 200 ml
	Cryo used is a commercial product.
United Kingdom	Methylene Blue treated plasma and cryopreciate is imported

Table 6.1
Survey 2012

Donation testing strategy for infectious agents

Country	Type of test: anti-HIV 1+2	HIVAg	HBsAg	Anti-HBc	anti-HCV	HCVAg	anti-HTLV I/II	Syphilis	Malaria	Other
Albania										
Andorra										
Armenia	100	100	100	100	100	0	0	100	0	brucellosis: Testing every donation.
Austria										
Azerbaijan										
Belgium	100	0	100	First	100	0	0	100		
Bosnia / Herzegovina										
Bulgaria										
Croatia	100	100	100	0	100	100	0	100	0	
Cyprus										
Czech Republic	100	100	100	5	100	35	0	100	0	
Denmark	100	100	100	First	100	0	0	0		
Estonia	100	100	100	0	100	0	0	100	0	
Finland	100	100	100	0	100	0	0	100	0	
France	100	0	100	100	100	0	100	100		
FYR Macedonia										
Georgia	100	0	100	0	100	0	0	100	0	
Germany	100		100	100	100	0	0	100	0	
Greece	100	0	100		100		100	100		
Hungary	100	100	100	First	100	0	0	100	0	
Iceland	100	100	100	0	100	0	0	0		
Ireland	100	0	100	100	100	0	100	100	0	
Italy	100	64	100	0	100	0	0	100	0	
Latvia	100		100		100			100		
Liechtenstein										
Lithuania	100	90	100	20	100			100		
Luxembourg	100	100	100	First	100	0	First	100		anti-CMV IgG: Testing 1%.
Malta										
Moldova	100	100	100	100	100	0	0	100	0	
Montenegro	100	100	100		100		0	100	0	
Netherlands	100	0	100	100	100	0	100	100	0	Anti-Parvovirus B19 IgG: Testing 5%. Anti-CMV IgG: Testing 0%.
Norway	100		100	50	100	0	0	First	1	
Poland										
Portugal	100	100	100	100	100	0	First	100		
Romania										
Russian Federation	100	100	100	0	100	0	0	100	0	ALT: Testing every donation.
San Marino										
Serbia	100	100	100	0	100	100	0	100	0	
Slovakia	100	100	100	100	100	0	0	100	0	
Slovenia										
Spain	100	0	100	0	100	0	30	100	1	Chagas disease: Testing 5%.
Sweden	100	100	100	First	100	0	First	100	First	Chagas: Testing first donation only.
Switzerland	100	100	100	0	100	First	0	100		
Turkey										
Ukraine										
United Kingdom	100	100	100	1	100	0	100	100	2	Chagas' disease: Testing 1%. Anti-CMV: Testing 30%.

Country	Comments
Belgium	Malaria: In case of history of malaria or stay in endemic region; anti-CMV: very small % of red cells and platelets tested for some indications;
Czech Republic	Anti-HIV: HIV Ag+Ab combined test; HIV Ag: HIV Ag+Ab combined test; Anti-HBc: some BE´s screen first time donors; HCV Ag: some BE´s use HCV Ag+Ab comnined test;
Denmark	Anti-HBc: Anti-HBc screening of first time donors was implemented in Denmark during the first 3 months of 2012.; Anti-HTLV: Anti-HTLV I/II testing of first time donors in Denmark was stopped by the end of 2011.; Malaria: Only after stay in a malaria area in 1) persons with fever during/after stay in a malaria area and 2) persons born/raised in a malaria area;
Finland	Anti-HBc: Anti-HBc is a confirmatory assay for HBsAg or HBV-NAT positive; Malaria: Based on risk assessment (445 tests in 2012);
France	Malaria: If necessary (Individuals who have lived in a malaria area or with history of undiagnosed febrile illness, visitors to endemic areas...); Chagas disease: If necessary (Individuals who have lived in a Chagas area or with history of Chagas disease or visitors to endemic areas...); Other tests can be added according to specific therapeutic indications: The tests listed above are the minimum laboratory tests required by the French regulation for blood donation. Other tests can be added according to specific therapeutic indications: detection of anti-CMV antibodies; Parvo B19 and HAV NAT for source plasma for fractionation...;
Germany	HIV Ag: No data. Antigen-Tests and Antibody-Antigen-Combitests for HIV-1/2 are used by some of the blood establishments.; HBsAg: Persons, tested positive for anti-HBc, can further donate blood if a sensitive assay for HBV-Genom results negative and if anti-HBs antibody-titer stays above 100 IU/l.; Syphilis: Not required for donations of plasma for fractionation.;
Greece	Malaria: screening for malaria applied only in about 1% of donor blood in the affected area of Evrotas Lakonia; WNV-RNA: SCREENING OF DONOR BLOOD FOR WNV-RNA IS PERFORMED SEASONALLY IN EVERY DONATION OF THE AFFECTED AREA;
Iceland	Malaria: Only very few if travelling to malary area;
Ireland	anti-CMV: first time and previous CMV seronegative;
Italy	HIV Ag: combo test;
Lithuania	HIV Ag: not mandatory; Anti-HBc: not mandatory; HCV Ag: not mandatory; Anti-HTLV: not mandatory;
Luxembourg	HIV Ag: The serological test used for HIV Ab screening ensure the detection of antibodies and antigens HIV; Malaria: 10% Come back from endemic areas;
Montenegro	Anti-HBc: Anti-HBc test is performed in cases of HBsAg reactivity only.; HCV Ag: Limited number of tests and we used it for first time donation but not at total number of blood donors.;
Netherlands	Anti-HBc: All blood donations were tested for presence of anti-HBc; anti-HBs levels were determined for all anti-HBc repeatedly reactive donations; donations showing anti-HBs levels < 200 mIU/mL were not released for clinical or manufacturing use; Malaria: The Malaria Total Antibody EIA, supplied by Lab 21 Ltd, was performed for (re)entry purposes of blood donor candidates who recovered from malaria infection at least 3 years before; Anti-Parvovirus B19 IgG: Blood products from donors with detectable IgG antibodies to B19 in two separate blood samples, one taken at least six months after the other, were considered to be B19-virus safe; B19-virus safe cellular blood products were administered to selected groups of patients; Anti-CMV IgG: On demand testing;
Norway	HIV Ag: Is done 100 %, but not a requirement; Anti-HBc: First time donation and if more than 6 months since last donation.; Malaria: Selected donors;
Portugal	HIV Ag: HIVAg+Ab Combo; Anti-HTLV: Testing also travellers returning from endemic zones; Malaria: Testing travellers returning from endemic zones and residents;
Spain	Anti-HTLV: Selective testing in most of Blood Establishments; Malaria: Selective testing; Chagas disease: Selective testing;
Sweden	Malaria: Few donors for rare blood tested if they have had malaria; Chagas: Few donors who lived over 5 years in South America were tested;
Switzerland	Malaria: Donor at risk; Chagas: Donor at risk; CMV: Immuno-deficient patients and neonate;
United Kingdom	HIV Ag: Screened using HIV Ab/Ag combo assay for NHSBT, SNBTS and WBS.; Anti-HBc: Donors that have had body piercing between 4 and 12 months ago; or history of jaundice or hepatitis; or contact with a person with hepatitis B; or had a procedure involving flexible endoscopy 4-6 months ago.; Malaria: Testing for donors who have been resident for 6 months in a malarial area and it is 6 months since their return. Ever had malaria diagnosed and 3 years since anti-malarial therapy completed and symptoms resolved. Ever had a fever which may have been malaria whilst in a malaria area or 6 months since return from the area. Between 6 and 12 months since return from a malarial endemic area.; Chagas' disease: If at least 6 months following the date of last exposure (i.e stayed in rural South or Central America for >4 weeks, or received a transfusion there prior to 1980, or donor or their mother was born in South or Central America). Accept if validated test for T.cruzi antibody is negative.;

Table 6.2
Survey 2012

Use of simple rapid tests

Country	Type of test (% of donations)			
	anti-HIV 1+2	HBsAg	anti-HCV	Comments
Albania				
Andorra				
Armenia	0	0	0	
Austria				
Azerbaijan				
Belgium	0	0	0	
Bosnia / Herzegovina				
Bulgaria				
Croatia	0	0	0	
Cyprus				
Czech Republic	0	0	0	
Denmark	0	0	0	
Estonia	0	0	0	
Finland	0	0	0	
France	0	0	0	
FYR Macedonia				
Georgia	0	0	0	
Germany	0	0	0	
Greece				
Hungary	0	0	0	
Iceland	0	0	0	
Ireland	0	0	0	
Italy	0	0	0	
Latvia				
Liechtenstein				
Lithuania	0	0	0	
Luxembourg	0	0	0	
Malta				
Moldova	0		0	
Montenegro	0	0	0	
Netherlands	0	0	0	
Norway	0	0	0	
Poland				
Portugal	0	0	0	
Romania				
Russian Federation				
San Marino				
Serbia	0	0	0	
Slovakia	0	0	0	
Slovenia				
Spain	0	0	0	
Sweden	0	0	0	
Switzerland	0	0	0	
Turkey				
Ukraine				
United Kingdom	0	0	0	

Table 7.1
Survey 2012

Country	Proportion confirmatory testing (%)	Confirmed seropositive donors (absolute numbers)									
		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											
Armenia	None										
Austria											
Azerbaijan											
Belgium	All	2	8	54	6	12	6			32	7
Bosnia / Herzegovina											
Bulgaria											
Croatia	All	1	5	11	5	3	2			0	8
Cyprus											
Czech Republic	All	4	5	21	9	87	24			20	10
Denmark	All	0	0	4	0	4	0				
Estonia	All	5	1	7	5	25	7			11	6
Finland	All	1	0	0	1	10	4			0	1
France	All	7	19	262	3	129	11	15	2	285	133
FYR Macedonia											
Georgia	All										
Germany	All	32	82	481	30	299	59			221	124
Greece	All	25	14	607	171	117	84	3	1	73	49
Hungary	All	2	2	75	14	93	19			40	54
Iceland	All	0	0	0	0	0	0				
Ireland	All	1	0	2	0	3	2	0	0	3	3
Italy	All	63	72	684	51	314	33			509	157
Latvia		7	4								
Liechtenstein											
Lithuania	All	16	13	146	21	377	105			145	51
Luxembourg	All	0	0	3	0	2	0	1	0	3	0
Malta											
Moldova	All	17		1 324		668				1 005	
Montenegro	All	0	0	21	0	16	2			27	3
Netherlands	All	0	2	13	3	4	0	1	1	8	7
Norway	All	1	0	5	1	9	2	0	0	0	0
Poland											
Portugal	All	17	14	46	5	29	2			147	452
Romania											
Russian Federation	All										
San Marino											
Serbia	26			41		36				18	
Slovakia	All	2	0	22	2	17	8			22	10
Slovenia											
Spain	All	59	83	404	69	223	29	35	0	425	296
Sweden	All	0	0	14	1	11	3	1		1	1
Switzerland	All	1	1	21	5	19	3			14	9
Turkey											
Ukraine											
United Kingdom	All	8	7	65	6	64	5	9	1	54	22

Country	Comments
Czech Republic	Testing: confirmatory testing is centralized to National Reference Lab.
Finland	Outcomes: Syphilis testing: In 2012 implementation of TrpaAb test (instead of cardiolipin-test). 51 positive results for TrpaAb (2 first time tested and 49 repeat tested donors) of which only 1 case of acute syphilis infection. 50 cases of seropositivity for treated old infection or serological scar without any clinical disease or history of disease.
Germany	Outcomes: The number of confirmed seropositive HBV Tests includes 8 HBsAg negative first time and 7 repeat donors tested positive for anti-HBc and NAT.
Netherlands	Testing: Anti-HBs levels were determined for all anti-HBc repeatedly reactive donations; donations showing anti-HBs levels < 200 mIU/mL were not released for clinical or manufacturing use
Norway	Outcomes: HTLV not tested.
Russian Federation	Outcomes: Confirmatory testing in repeated reactive donors is performing, but the existing official form of reporting does not allow separating the requested data
Serbia	Outcomes: datas consider first time tested donors as well repeted donors. datas are recorded by "Blood transfusion Institute of Serbia"
Slovakia	Outcomes: We do not test HTLV
Sweden	Outcomes: First time tested, not allowed to donate
Switzerland	Outcomes: No Information about HTLV I/II

Table 7.2
Survey 2012

Country	Prevalence and incidence calculated per 100,000 donors					
	HIV 1 / 2		HBV		HCV	
	prevalence per 100,000 first time tested donors	incidence per 100,000 repeat donors	prevalence per 100,000 first time tested donors	incidence per 100,000 repeat donors	prevalence per 100,000 first time tested donors	incidence per 100,000 repeat donors
Albania						
Andorra						
Armenia						
Austria						
Azerbaijan						
Belgium	3,86	3,25	104,31	2,44	23,18	2,44
Bosnia / Herzegovina						
Bulgaria						
Croatia	8,32	5,40	91,49	5,40	24,95	2,16
Cyprus						
Czech Republic	8,13	1,96	42,68	3,53	176,83	9,41
Denmark	0,00	0,00	11,26	0,00	11,26	0,00
Estonia	66,58	3,53	93,21	17,63	332,89	24,68
Finland	6,35	0,00	0,00	0,69	63,46	2,77
France	1,97	1,38	73,56	0,22	36,22	0,80
FYR Macedonia						
Georgia						
Germany	6,44	3,33	96,82	1,22	60,19	2,40
Greece	46,99	4,65	1140,87	56,78	219,90	27,89
Hungary	4,47	0,85	167,47	5,96	207,66	8,09
Iceland	0,00	0,00	0,00	0,00	0,00	0,00
Ireland	9,30	0,00	18,59	0,00	27,89	2,62
Italy	16,38	4,99	177,80	3,53	81,62	2,29
Latvia	75,15	16,81				
Liechtenstein						
Lithuania	69,80	39,44	636,94	63,71	1644,71	318,55
Luxembourg	0,00	0,00	271,25	0,00	180,83	0,00
Malta						
Moldova	83,15		6476,23		3267,46	
Montenegro	0,00	0,00	431,74	0,00	328,95	27,41
Netherlands	0,00	0,64	27,70	0,96	8,52	0,00
Norway	6,03	0,00	30,14	1,00	54,25	2,00
Poland						
Portugal	37,88	3,34	102,50	1,19	64,62	0,48
Romania						
Russian Federation						
San Marino						
Serbia			101,82		89,41	
Slovakia	6,67	0,00	73,37	2,18	56,70	8,74
Slovenia						
Spain	25,32	8,63	173,34	7,17	95,68	3,01
Sweden		0,00		0,26		0,77
Switzerland	3,82	0,50	80,19	2,51	72,55	1,50
Turkey						
Ukraine						
United Kingdom	4,09	0,59	33,20	0,51	32,69	0,42

Table 8.1
Survey 2012

NAT testing

Country	HIV NAT		HBV NAT		HCV NAT		Other NAT tests (separated by ';')	
	which donations	Size Minipool	which donations	Size Minipool	which donations	Size Minipool	which donations	Size Minipool
Albania								
Andorra								
Armenia	None		None		None			
Austria								
Azerbaijan								
Belgium	All	6	All	6	All	6		
Bosnia / Herzegovina								
Bulgaria								
Croatia	None		None		None			
Cyprus								
Czech Republic								
Denmark	All	1	All	1	All	1		
Estonia	All	6	All	6	All	6		
Finland	All		All		All		All HAV; All ParvoB19	16; 16
France	All		All		All			
FYR Macedonia								
Georgia	None		None		None			
Germany	All	96			All	96		
Greece	All		All		All		All WNV-RNA	
Hungary	None		None		None			
Iceland	None		None		None			
Ireland	All	1	All	1	All	1		
Italy	All		All		All		All West Nile Virus testing	
Latvia								
Liechtenstein								
Lithuania	All	6	All	6	All	6		
Luxembourg	All	96	All	96	All	96	All PCR HAV; All PCR PARVOVIRUS B19	96; 96
Malta								
Moldova	All	10	None		All	10		
Montenegro	None		None		None			
Netherlands	All	6	All	6	All	6		
Norway	None		None		None			
Poland								
Portugal	All	5	All	5	All	5	All HBV+HCV+HIV - Triplex	5
Romania								
Russian Federation								
San Marino								
Serbia	None		None		None			
Slovakia	None		None		None			
Slovenia								
Spain	All	1	All	1	All	1		
Sweden	None		None		None			
Switzerland	All	6	All	6	All	6	First Parvo-B19; All HAV	480; 480
Turkey								
Ukraine								
United Kingdom	All	24	All	24	All	24	West Nile Virus	6

Country	Comments
Armenia	NAT testing hasn't been performed yet
Belgium	HIV: size of pools: 6 or 8 depending on BE; HBV: size of pools: 6 or 8 depending on BE; HCV: size of pools: 6 or 8 depending on BE;
Czech Republic	HIV-HBV-HCV NAT tested in only 1 BE (cca 5% of donations). No "NAT-only" pozitivity
Finland	HIV: ID-NAT test; HBV: ID-NAT test; HCV: ID-NAT test;
France	HIV: Size of minipools : ID-NAT in 11 regions and minipools of 8 in 5 regions.; HBV: Size of minipools : ID-NAT in 11 regions and minipools of 8 in 5 regions.; HCV: Size of minipools : ID-NAT in 11 regions and minipools of 8 in 5 regions.;
Germany	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.;
Greece	HIV: ID NAT only; HBV: ID NAT only; HCV: ID NAT only; WNV-RNA: WNV-RNA tested seasonally in all donation in the affected areas;
Italy	West Nile Virus testing: testing applied only in defined Summer periods;
Lithuania	HIV: ID or 6; HBV: ID or 6; HCV: ID or 6;
Netherlands	HIV: A multiplex real-time PCR test was used to simultaneously detect HIV-1 RNA, HIV-2 RNA, HCV RNA, and HBV DNA; HBV: A multiplex real-time PCR test was used to simultaneously detect HIV-1 RNA, HIV-2 RNA, HCV RNA, and HBV DNA; HCV: A multiplex real-time PCR test was used to simultaneously detect HIV-1 RNA, HIV-2 RNA, HCV RNA, and HBV DNA;
Russian Federation	NAT- test is not mandatory, but is performing by some blood establishments. Accurate data in frame of reporting is not available
Spain	HIV: Size of minipool: 1-8; HBV: Size of minipool: 1-8; HCV: Size of minipool: 1-8;
Switzerland	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; Parvo-B19: Size of minipools: max. 480; HAV: Size of minipools: max. 480;
United Kingdom	West Nile Virus: Travellers to at risk areas are tested;

Table 8.2

Survey 2012

Country	NAT only positive results					
	HIV 1		HBV		HCV	
	first time tested donor	repeat donor	first time tested donor	repeat donor	first time tested donor	repeat donor
Albania						
Andorra						
Armenia						
Austria						
Azerbaijan						
Belgium	0	0	0	0	0	1
Bosnia / Herzegovina						
Bulgaria						
Croatia						
Cyprus						
Czech Republic						
Denmark	0	0	1	0	0	0
Estonia	1	0	0	4	0	2
Finland	0	0	0	1	0	1
France	1	1	10	5	0	0
FYR Macedonia						
Georgia						
Germany	1	3	0	7	0	10
Greece	1	1	65	13	3	
Hungary						
Iceland						
Ireland	0	0	0	0	0	0
Italy	0	8	32	101	3	1
Latvia						
Liechtenstein						
Lithuania	0	0	4	4	8	16
Luxembourg	0	0	3	0	0	0
Malta						
Moldova	0	0			2	0
Montenegro						
Netherlands	0	0	0	3	0	0
Norway						
Poland						
Portugal						
Romania						
Russian Federation						
San Marino						
Serbia						
Slovakia						
Slovenia						
Spain	4		70		2	
Sweden						
Switzerland						
Turkey						
Ukraine						
United Kingdom	0	0	2	1	0	1

Table 9

Survey 2012

Bacterial screening

Country	Total platelets adult doses issued	% adult doses screened for bacteria								Total platelets % screened	Total platelets % confirmed positive
		Recovered platelets				Apheresis platelets					
		Total	using culture-based methods	rapid detection methods	both methods	Total	using culture-based methods	rapid detection methods	both methods		
Albania											
Andorra											
Armenia	2 159	0	0	0	0	0	0	0	0	1	0
Austria											
Azerbaijan											
Belgium	68 668	69	69	0	0	42	42	0	0	59	
Bosnia / Herzegovina											
Bulgaria											
Croatia	21 969	2,82	2,82			4,85	4,85			3,14	0,24
Cyprus											
Czech Republic	37 100	1	1	0	0	1	1	0	0	1	
Denmark	33 631	100	100	0	0	100	100	0	0	100	0,040
Estonia	6 985	100	100	0	0	100	100	0	0	100	0,20
Finland	41 565	8	8	0	0	9	9	0	0	8	0,030
France	300 683									0	
FYR Macedonia											
Georgia											
Germany	589 179										
Greece	129 807										
Hungary	47 695	32	4			32				6,1	0
Iceland	2 330									0	
Ireland	24 971	100	100	0	0	100	100	0	0	100	0,038
Italy	219 785	10	10							10	
Latvia	7 681										
Liechtenstein											
Lithuania	19 002									3	
Luxembourg	2 765	4	4	0	0	5,5	5,5	0	0	4,5	0
Malta											
Moldova	8 399										
Montenegro	509										
Netherlands	57 720	100	100	0	0	100	100	0	0	100	0,28
Norway	24 508	82	82	0	0	82	82	0	0	82	0
Poland											
Portugal	38 942	100	100	0		100	100	0		100	
Romania											
Russian Federation	148 684										
San Marino											
Serbia											
Slovakia	15 033	1	1			1	1			1	
Slovenia											
Spain	188 510										
Sweden	48 523									36,6	0,11
Switzerland	34 265										
Turkey											
Ukraine											
United Kingdom	310 428	100	100	0	0	99,08	100	0	0	99,21	0

Country	Comments
Czech Republic	results are not reported at national level
Finland	All outdated platelets screened using culture-based method
Germany	No data. Microbiological control as a statistic process control 0.4 x the square root of N of each processing line per month and per processing plant at the end of shelf life.
Italy	Number to be reported is 10% Percentage of screened units confirmed positive by further testing: not determined.
Luxembourg	All these controls concerned expired products.
Netherlands	All platelet products were cultured with the BacT/ALERT culturing system; products were released on a negative-to-date basis
Russian Federation	Confirmatory testing and screening for the presence of bacteria in platelet preparations is performing, but the existing official form of reporting does not allow separating the requested data.
Serbia	we dont test it
United Kingdom	0.02% confirmed positive

Table 10
Survey 2012

Country	Organisation, registration and labelling			
	National Council or Expert Committee	national blood policy		national regulations
		on quality and safety	implementing	
Albania				
Andorra				
Armenia	Yes	Yes	Yes	Yes
Austria				
Azerbaijan				
Belgium	Yes	Yes	Yes	Yes
Bosnia / Herzegovina				
Bulgaria				
Croatia	Yes	No		Yes
Cyprus				
Czech Republic	Yes	Yes	Yes	Yes
Denmark	Yes	Yes	Yes	Yes
Estonia	Yes	No	No	Yes
Finland	Yes	Yes	No	Yes
France	Yes	Yes	Yes	Yes
FYR Macedonia				
Georgia	No	Yes	Yes	Yes
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	Yes	Yes	No	Yes
Malta				
Moldova	Yes	Yes	Yes	Yes
Montenegro	Yes	Yes	Yes	Yes
Netherlands	Yes	Yes	Yes	Yes
Norway	Yes	Yes	Yes	Yes
Poland				
Portugal	Yes	Yes	Yes	Yes
Romania				
Russian Federation	Yes	Yes	Yes	Yes
San Marino				
Serbia	Yes	Yes	Yes	Yes
Slovakia	Yes	Yes	No	Yes
Slovenia				
Spain	Yes	Yes	Yes	Yes
Sweden	No	No		Yes
Switzerland	No	Yes	Yes	Yes
Turkey				
Ukraine				
United Kingdom	Yes	Yes	Yes	Yes

Country	Comments
Belgium	National blood plan on implementing national blood policy:requirements for quality and safety of blood components are laid down in the law on blood.
France	The French National Agency for Medicines and Health Products Safety (ANSM), national competent authority for blood and blood components, advises the Ministry of Health. Expert working groups are created with this agency.

Table 11.1

Survey 2012

Quality Management related issues

Country	QMS established and maintained	% donations covered by % GMP	% donations covered by % ISO 9000	% donations covered by % other	Other procedures	Inspections every second year	Description of "Other" organisation/body	System of educ. and training
Albania								
Andorra								
Armenia	Planned			100		No		Yes
Austria								
Azerbaijan								
Belgium	Yes	100	95			National+Other	When covered by ISO 9000 also inspection by ISO	Yes
Bosnia / Herzegovina								
Bulgaria								
Croatia	Yes	55	55			No		Yes
Cyprus								
Czech Republic	Yes	100	40			National		Yes
Denmark	Yes	100				National		Yes
Estonia	Yes	100	100			National		No
Finland	Yes	100	0	100	management system based on	National+Other	Internal audits and audits by plasma	Yes
France	Yes			100	National good practice guidelines for	National	National inspections of blood	Yes
FYR Macedonia								
Georgia	Planned					No		No
Germany	Yes	100				National+Other	Regional authorities in charge of GMP inspections.	Yes
Greece	Yes	80	25			National		
Hungary	Yes	100				National		Yes
Iceland	Yes		100			National		No
Ireland	Yes	100	0			National		Yes
Italy	Yes		40	100	national requirements	Other	regional health authorities + nationally qualified inspectors	Yes
Latvia	Yes					National		Yes
Liechtenstein								
Lithuania	Yes		100			National		Yes
Luxembourg	Yes	100	100	100	ISO 9001, ISO 15189	National		Yes
Malta								
Moldova	Yes					National		Yes
Montenegro	Planned					National		No
Netherlands	Yes	100	0	0		National		Yes
Norway	Yes	100	67			National		Yes
Poland								
Portugal	Yes	100	100			National		Yes
Romania								
Russian Federation	Yes					National+Other		Yes
San Marino								
Serbia	Planned	49	49			National		Yes
Slovakia	Yes	100				National+Other	fractionator	Yes
Slovenia								
Spain	Yes		100			Other	Inspections conducted by Regional authorities and acreditations by scientific societies	Yes
Sweden	Yes	100		100	ISO 17025 ISO 15189 SWEDAC	National	The National Board of Health and Welfare	Yes
Switzerland	Yes	100	60	0		National+Other	Additionally to having an establishment license issued	Yes
Turkey								
Ukraine								
United Kingdom	Yes	100	4	0	4 UK Blood Services each have their own National procedures ISO 9000 Wales only	National	Wales only BSI ISO series every 6 months	Yes

Table 11.2
Survey 2012

Quality Management related issues

Country	% donations labelled according to		% components coded according to		Comments
	ISBT 128	another system	ISBT 128	another system	
Albania					
Andorra					
Armenia		100			
Austria					
Azerbaijan					
Belgium	94	6	94	6	
Bosnia / Herzegovina					
Bulgaria					
Croatia		100		100	65% donation and components are labeled with Code 128; 40% with Codebar; In May 2011 Croatian Blood transfuzion Service started with implentation of IT system e-Delphyn on national level with Code 128 system for identification and labeling. Today, all Blood establishment (8/8) and 20/35 Hospital Blood Banks are using the same National IT system e-Delphyn. Implementation will be finished in 2015.
Cyprus					
Czech Republic		100		100	national system
Denmark	100		100		
Estonia	100		0		We have our own component codes
Finland	100	0	100	0	
France		100		100	Specific national coding system since 1994 for blood establishments, blood donors, blood donations, blood and blood components, ABO donors grouping. ANSM is in charge of this National coding system.
FYR Macedonia					
Georgia					
Germany					Any unique code, mostly used is Eurocode.
Greece		100			
Hungary	100				
Iceland	100		100		
Ireland	0	100	0	100	Codabar
Italy	0	100	0	100	national regulation UNI 10529
Latvia	100	100	100		
Liechtenstein					
Lithuania		100		100	local
Luxembourg	0	100	0	100	
Malta					
Moldova	100		100		
Montenegro		100			
Netherlands	100	0	100	0	
Norway	100	0	100	0	
Poland					
Portugal	100		100		
Romania					
Russian Federation					
San Marino					
Serbia	50		50		
Slovakia	70		0	100	ISBT donation number is used by minimaly 70 %, but probably it is more
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
Survey 2012

Country	Haemovigilance system Available / organisation	Description of 'Other' organisation/body
Albania		
Andorra		
Armenia	No	
Austria		
Azerbaijan		
Belgium	National	
Bosnia / Herzegovina		
Bulgaria		
Croatia	National+Other	Refferal Centre MoH: Croatian Institute of Transfusion Medicine
Cyprus		
Czech Republic	National	
Denmark	National+Other	State Serum Institut & Danish Society Clin. Immunology
Estonia	National	
Finland	National+Other	Finnish Red Cross Blood Service
France	National	
FYR Macedonia		
Georgia	No	
Germany	National	
Greece	National	National Coordinating Haemovigilance Centre (SKAE) of the Hellenic CDC of the Ministry of Health
Hungary	National	
Iceland	National	
Ireland	National	
Italy	National	
Latvia	National+Other	
Liechtenstein		
Lithuania	National	
Luxembourg	National	
Malta		
Moldova	National	
Montenegro	No	
Netherlands	National+Other	TRIP Foundation
Norway	National	
Poland		
Portugal	National	
Romania		
Russian Federation	National	
San Marino		
Serbia	National	
Slovakia	National	
Slovenia		
Spain	National	
Sweden	Other	Swedish Society of Transfusion Medicine
Switzerland	National	
Turkey		
Ukraine		
United Kingdom	National+Other	Serious Hazards of Transfusion (SHOT)

Country	Comments
Croatia	Haemovigilance system in CROATIA registers all reactions. In 2012 there were 354 reactions registered, out of them 23 SAR with imputability level 2 and 3, and all were reported to the CA.
France	ANSM
Netherlands	TRIP Foundation is the Dutch National Hemovigilance Office
United Kingdom	Medicines and Healthcare products Regulatory Agency (MHRA) [SABRE and SHOT]

Table 12.2
Survey 2012

Hemovigilance – number of serious adverse reactions

Country	total number components transfused: whole blood + RBC + FFP + Platelets	Imputability "likely, probable or certain" (level 2 or level 3)																Incidence high imputability serious adverse reactions per 100,000 components
		Hemolysis ABO	Hemolysis other allo antibody	Non immun. Hemol.	PT Purpura	Anaphylaxis	TRALI	GVHD	TA-HBV	TA-HCV	TA-HIV	TA-Other viral	TA-Bacterial	TA-Malaria	TA-Parasitic	TA-TACO	TA-Other serious	
Albania																		
Andorra																		
Armenia	24 540																	
Austria																		
Azerbaijan																		
Belgium	649 495	5	9			11	5						4			3	35	11,1
Bosnia / Herzegovina																		
Bulgaria																		
Croatia	290 623	1	5		1	10	2									3		7,6
Cyprus																		
Czech Republic	617 904	0	0	0	0	10	0	1	0	0	0	0	0	0	0	0	0	1,8
Denmark	372 283	0	3	0	0	1	0	0	0	0	0	0	0	0	0	3	0	1,9
Estonia	88 140	1	1															2,3
Finland	320 084	5	0	0	0	8	1	0	0	0	0	0	0	0	0	4	2	6,2
France	3 205 756	2	2	1		23	17						5	1		25	5	2,5
FYR Macedonia																		
Georgia																		
Germany	6 794 158	4	4	0	0	0	1	0	1	0	0	0	5	0	0	4	0	0,3
Greece	737 247	2	1	4		11	4					1	1			6	15	6,1
Hungary	559 669	3	1		5	2											11	3,9
Iceland	17 152																	
Ireland	181 568	0	9	0	0	33	1	0	0	0	0	0	0	0	0	11	21	41,3
Italy	3 216 762	7	12	2	1	21	3						0			26	897	30,1
Latvia	7 767																	
Liechtenstein																		
Lithuania	137 560	2			2													2,9
Luxembourg	26 754	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0,0
Malta																		
Moldova	110 540																	
Montenegro	26 057																	
Netherlands	579 150	0	0	0	1	2	2	0	0	0	0	0	0	0	0	0	1	1,0
Norway	265 672	2	1	0	0	9	1	0	0	0	0	0	0	0	0	5	0	6,8
Poland																		
Portugal	387 496	8				67	1	0	0	0	0	0	0	0	0	12	0	22,7
Romania																		
Russian Federation	3 725 959	3																0,1
San Marino																		
Serbia																		
Slovakia	291 517																	
Slovenia																		
Spain	1 940 751	3	2	1		56	18						3			31		5,9
Sweden	692 253																	
Switzerland	381 685	2	1		1	17	1		2							5	286	82,5
Turkey																		
Ukraine																		
United Kingdom	2 699 351	3	10	0	1	97	7	1	0	0	0	2	0	0	0	25		5,4
Total		53	61	8	12	378	64	2	3	0	0	3	18	1	0	163	1273	

Country	Comments
Croatia	There was 1 DSTR reaction registered with imputability level 3.
France	The French haemovigilance system requires the reporting as soon as possible any adverse reactions occurred in transfusion context in a recipient of blood and blood components regardless of the imputability to the transfusion. The imputability level cannot be confirmed until the end of the investigation. For this reason, the French haemovigilance database contains a lot of reporting of adverse reactions occurred in the context transfusion in patients with imputability level 0=excluded. The ISBT working party on haemovigilance recommends the following: Only possible=1, probable=2 and certain=3 imputability levels should be used for international comparisons. Also, the french competent authority on blood and blood components recommends to EDQM the suppression of the imputability levels NA and 0 in the blood questionnaire for the coming years. The confirmed serious adverse reactions (SAR) involved in this above French data are those concerning the severity levels 3 and 4 and all the imputability levels (NA, 0, 1, 2, and 3). In total, 199 SAR occurred in a context of transfusion patients were reported in France in 2012: 2 are with imputability level NA, 116 with imputability level 0 and 1 (58%), 55 SAR are with imputability level 2 = likely (28%) and 26 SAR with imputability level 3=certain (13%). In addition, 80% (20/25 reports) of the transfusion-associated bacterial infections reported are with imputability level 0=excluded. The 35 others SAR are: - 21 unclassifiable complications of transfusion or unspecified/unknowned SAR (20 with imputability level 0-1 and 1 with imputability level 2) - 1 metabolic complication of transfusion with imputability level 3 - 4 transfusion-associated dyspnea or other dyspnea (3 with imputability level 0-1 and 1 with imputability level 2) - 4 pulmonary embolism with imputability level 0 - 1 transfusion inefficacy with imputability level 3 - 4 hypotensive transfusion réactions (3 with imputability level 0-1 and 1 imputability 2 with imputability level 2)
Greece	8 TAD and 7 Severe NHFTR are included In other serious adverse reactions
Netherlands	Please note that the numbers are based on the initial report; in a number of cases it was concluded that the adverse reaction was not transfusion-related
Slovakia	Other reactions are pyretic reactions
Switzerland	All Transfusion associated infections with imputability level not available are cases with investigations pending;Of the 299 "other serious reactions" 279 are Allo-Antibodies detected without clinical sings or symptoms.
United Kingdom	Imputability level and severity not analysed by SHOT data

ENG

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