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

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2011 report

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2011 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 (MSs) of the Council of Europe (CoE). Data were supplied by MSs in response to a questionnaire requesting detailed information on donors, collections, testing, distribution and quality aspects of blood and blood components for the year 2011. 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 2001-2010.

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

As in previous years, not all relevant data was obtained from each MS. In view of the difficulties in implementation data retrieval from automated blood banking systems, and collating data from many Blood Establishments (BEs) 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) acknowledged the importance of this data in *Directive 2002/98/EC*.

In MSs and in BEs, 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 the adoption of uniform data collection by BEs and MSs, thereby generating better data and higher response rates among MSs. 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, 17th 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, questionnaires from 32 MSs were completed with data from 2011, meaning a response rate of 70 %. The response rates for the 2009 and 2010 surveys were 63 % and 72 %, respectively.

The average number of donors in relation to the general population was 25 per 1000 inhabitants. On average, 24 % of the donor base consisted of first-time donors.

The number of Whole Blood (WB) collections was on average 37 per 1000 inhabitants, and the average use of Red Blood Cells (RBCs) was 37 per 1000 inhabitants. On average, 3.9 litres (L) of plasmapheresis plasma per 1000 inhabitants was collected.

The use of blood was expressed as units (U) distributed by BEs in 62 % of the reporting MSs; the remaining 38 % of MSs reported it as transfused units. The use of RBCs varied considerably (range 8-126 U, median 37 U) and averaged 37 total RBC U per 1000 inhabitants. Three reporting MSs (9 %) used less than 20 U per 1000 inhabitants, most likely reflecting an insufficient supply. In the respondent MSs, on average 33 % of the total platelet volume was supplied by (random) single donor platelets by apheresis; in 8 countries (27 %), this volume amounted to more than 50 %.

The amount of plasma delivered for fractionation into medicinal products differed greatly among MSs (range 0-49 L), with an average yield of 8.5 L of plasma for fractionation per 1000 inhabitants. However, 6 % of the reporting MSs delivered 20 L or more plasma per 1000 inhabitants. In Europe, on average, 55 % of the plasma for fractionation was from recovered plasma.

In 43 % of the MSs, all RBC products were leucocyte-depleted. Platelet concentrates were 100 % leucocyte-depleted in 53 % of MSs and, in 32 % of the MSs, all plasma for transfusion was leucocyte-depleted. In 43 % of the reporting MSs, 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 32 reporting MSs. All donations were tested for syphilis in 91 % of MSs. Anti-HTLV-I/II testing was performed on all donations in 26 % of reporting MSs, and only on first-time donors in 11 %. Anti-HBc testing was performed on all donations in 31 % of MSs, and only on first-time donors in 15 %. Prevalence and incidences of infectious diseases varied greatly among MSs, and it is noteworthy that a Northwest-Southeast gradient exists in Europe, with HBV and HCV infections relatively infrequent in repeat donors in all Northwestern countries. The median prevalence amongst first-time tested donors was 6.0, 96 and 78 per 100 000 donors for HIV-1/2, HBV and HCV, respectively. The median incidence amongst repeat donors was 1.0, 1.3 and 1.5 per 100 000 donor years for HIV-1/2, HBV and HCV, respectively.

Nucleic Acid Testing (NAT) for HIV was performed on each donation in 58 % of reporting MSs. HBV NAT and HCV NAT were performed on each donation in 56 % and 57 % of MSs, respectively.

Bacterial screening was performed in 69 % of reporting MSs. Screening of 80 % or more of platelet concentrates was performed in 27 % of MSs. The median rate reported for confirmed-positive cultured platelet concentrates was 0.03 %.

All MSs reported having legally binding national regulations for the collection, testing, processing, storage and distribution of blood and blood components. In 84 % of the reporting MSs, a National Council or Expert Committee existed to advise the Ministry of Health on transfusion-related policy issues. In 88 % of MSs, a national blood policy on the quality and safety of blood and blood components was in place.

In 94 % of MSs, a Quality System (QS) had been established and was maintained in BEs. Inspections were (partly) carried out by a national or other authority at least every 2 years in 97 % of the reporting MSs. All donations were covered either by International Society for Blood Transfusion (ISBT) procedures, Good Manufacturing Practices (GMPs) or other procedures in 86 % of the reporting MSs. Labelling of donations according to either ISBT-128 or other procedures was performed by 89 % of MSs for all donations. Labelling of all components by either ISBT or another system was done by 86 % of MSs.

Ninety-four per cent of all MSs 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 6.4 serious adverse reactions per 100 000 distributed blood components was calculated. This estimate is based on data provided by 26 MSs. Anaphylaxis, TACO and haemolysis appeared to be the most frequent serious adverse reactions.

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The EDQM/CoE and the authors express their sincere thanks to all colleagues and experts in MSs who collated data at a national level and provided it for inclusion in this report, and also to Prof Olof Akerblom for reviewing the initial versions of the questionnaire and Dr. Cees van der Poel for his continuous efforts and drive to improve the data collection process and reporting.

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List of abbreviations

Ag	Antigen
BEs	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
IDMs	Infectious Disease Markers
ISBT	International Society for Blood Transfusion
ISO	International Organization for Standardization
IU	International Unit
L	Litres
MSs	Member States of the Council of Europe
NAT	Nucleic Acid Amplification Techniques

PABD	Pre-operative Autologous Blood Donation
QS	Quality System
RBCs	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 questionnaire to experts in MSs in the form of a web-based application. The MSs were requested to complete the questionnaire within a given timeframe with data collated in 2011. After the deadline, data tables were prepared and distributed for review by MSs 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 some 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 last trend analyses were reported in February 2011 and comprised questionnaire data from 2001 through to 2008 (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

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, 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 MSs 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

The 47 MSs of the CoE were invited to complete the web-based questionnaires. Replies were received from 32 MSs by the deadline for submissions; a response rate of 70 %. The response rates were 72 % and 63 % for the 2008 and 2009 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 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 donation was less than 2 reporting years earlier) and for repeat donors (*i.e.* donors whose last 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 BEs and, in many countries, form the basis and guarantee of continuity of the blood supply. These data are needed to calculate 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 (IDMs) (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 are actually tested for the first time in the reporting year, either at the time of donation or if they donate at a later stage.

It should be taken into account that 'first-time donors' are already a selected population and, therefore, the prevalence of infectious diseases markers in the general population of a given MS may be different. The ratio of first-time donors to the total number of donors in general reflects the annual donor recruitment or, more generally, the turnover rate in the donor base. However, this figure may be influenced by recruitment programmes. The number of first-time donors, as compared to the total number of donors, becomes less meaningful in systems that only register donations and even less so only the (uniquely identifiable) donors are registered.

Excluding MSs where first-time donors and repeat plus regular donors were not reported separately, in 2011, 24 % (range 7-100 %) 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 25 (range 5-45) per 1000 inhabitants. This number may reflect the commitment of the population to donate blood in relation to demand. Differences exist but, arbitrarily, fewer 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 32 MSs reporting averaged 37 (range 9-61) per 1000 inhabitants. Given the average use of RBC per 1000 inhabitants (37 U, range 8-126 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 28 MSs that reported autologous donations, they only contributed on average to around 0.3 % (range 0-3.3 %, median 0.03 %) of the WB donations. This is consistent 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) was 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 28 reporting MSs, on average 3.9 L (range 0-45 L, median 0.4 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 30 reporting MSs, on average 33 % (range 0-83 %, median 29 %) 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 MSs 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 hospitals, but rather the number of blood components that have been distributed to hospitals by BEs (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 MSs although, in some countries, BEs 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 MSs, the use of blood was expressed as the units distributed by BEs, whereas 12 MSs 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, 17th 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 32 reporting MSs, on average 2.6 % (range 0-56 %, median 0.03 %) of RBC transfusions were performed with WB. In Greece, WB accounted for more than 1/2 (and, in Romania, 19 %) of the total volume of RBC products used.

The use of RBC per 1000 inhabitants varied considerably. In 32 reporting MSs, it averaged 37 total RBC products per 1000 inhabitants (range 8-126, median 37). 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 introduced 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 3/32 (9 %) of the reporting MSs, 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.* RBC use) in some countries increased the FFP/RBC ratio by decreasing the rate of RBC use. On average, the FFP/RBC ratio was 0.41 (range 0.02-1.68, median 0.25 (1:4)).

In Europe, platelets are generally recovered from 4-5 buffy-coats of WB donations. Discussions on blood safety in relation to variant Creutzfeldt-Jakob disease (vCJD) have inspired programmes to enhance the use of random single-donor platelets by apheresis in order to reduce donor exposure to recipients. These programmes may have been influential in some MSs 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 30 reporting MSs, on average 33 % (range 0-83 %, median 29 %) of the adult therapeutic doses of platelets were produced by single donor platelets by apheresis (Table 3). In 8 countries (27 %), 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 MSs.

Plasma for fractionation: Table 4

The total amount of plasma issued for fractionation into medicinal products differed among MSs. This variation was clearer when the figures were related to population size. In 31 of the reporting MSs, there was an average yield of 8.5 L (range 0-49 L) per 1000 inhabitants of plasma for fractionation into medicinal products. However, 2 of the 31 (6 %) reporting MSs delivered 20 L or more plasma per 1000 inhabitants.

In Europe, the main supply of plasma for fractionation was recovered plasma; in 12 reporting MSs, on average, 55 % of the plasma for fractionation was from recovered plasma (range 0-100 %, median 62 %).

Reporting on the use of medicinal products derived from human plasma was limited. The 16 MSs that reported Factor VIII use indicated an average use of 181 x 10^6 IU (range 0-2.478, median 6). The average amount of polyvalent immunoglobulins used was 841 Kg (range 0-4.528 Kg, median 9 Kg) and the average amount of human albumin used was 4.293 Kg (range 0-36.443 Kg, median 1.225 Kg). In the 9 MSs that produced immunoglobulins, the average proportion of intravenous administration was 86 % (range 63-100 %, median 93 %).

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

In 13/30 (43 %) of reporting MSs, 100 % leucocyte-depletion of RBC products was carried out. This was the case for platelet concentrates in 16/30 (53 %) reporting MSs. Complete (100 %) leucocyte-depletion was applied to plasma for transfusion in 8/25 (32 %) of the reporting MSs.

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 IDMs 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 12/28 (43 %) of the reporting MSs, nearly all FFP (>=98 %) was safeguarded by either method; in 6/27 (22 %) MSs using only quarantine; in 5/23 (22 %) using almost solely pathogen reduction; and in 1/28 (4 %) using a combination of the two methods.

Screening for infectious markers and serological test methods: Table 6

In all 32 reporting MSs, all donations were tested for anti-HIV-1/2, HBsAg and anti-HCV. In 29/32 (91 %) of these MSs, 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 7/27 (26 %) of the reporting MSs, and only on first-time donors in 3/27 (11 %) MSs.

Testing for anti-HBc was performed on all donations in 8/26 (31 %) reporting MSs, and only on first-time donors in 4/26 (15 %) MSs.

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 %) MSs that were able to provide the absolute numbers of confirmed positive donors provided these data for Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) and Hepatitis C Virus (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 97 for HIV-1/2, from 0 to 3.224 for HBV and 0 to 1.537 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 (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 among first-time tested donors was 6.0, 96 and 78 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 MSs. Overall, it is noteworthy that a Northwest-Southeast gradient exists in Europe, with HBV

and HCV infections relatively infrequent in all Northwestern countries. The highest incidence rates were found in the Eastern countries, and also in Lithuania, Estonia, Greece, Portugal and Montenegro.

The incidence per 100 000 repeat tested donor years ranged from 0 to 16 for HIV-1/2, from 0 to 65 for HBV and 0 to 151 for HCV. The median incidence among repeat donors was 1.0, 1.3 and 1.5 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 18/31 (58 %) reporting MSs. NAT testing for HBV was performed on each donation in 15/27 (56 %) respondent MSs. NAT testing for HCV was performed on each donation in 16/28 (57 %) MSs. Interestingly, NAT on each donation appeared to be performed more often in MSs 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 22 MSs (69 %). In 6/22 (27 %) reporting MSs, bacterial culture was performed on 80 % or more of all platelets (concentrates recovered from both WB donations and apheresis platelets). Among the 18 MSs that reported on the parameter, the average rate of confirmed positively-cultured platelet concentrates was 0.14 % (ranging from 0 to 1 %, median 0.03 %).

Organisation and registration: Table 10

All MSs reported that there were legally binding national regulations for the collection, testing, processing, storage and distribution of blood and blood components. In 27/32 (84 %) reporting MSs, a National Council or Expert Committee advised the Ministry of Health on transfusion-related issues. In 28/32 (88 %) MSs, there was a national policy on the quality and safety of blood and blood components. Of these 28 MSs, 23 (82 %) had implemented the national blood policy or were in the process of doing so.

Quality management: Table 11

In 30/32 (94 %) reporting MSs, a QS was established and maintained by BEs. In the remaining reporting MSs, the implementation of such a system was planned. In 30/31 (96 %) reporting MSs, inspections were performed at least every 2 years. The vast majority of these inspections (28/30, 93 %) were (partly) carried out by the national authority.

In 18/28 (64 %) reporting MSs, all donations were covered by GMPs. In the 10 MSs that reported that GMPs were not (always) applied, all donations were covered in six of these MSs either by ISO 9000 or other procedures. In four MSs, donations were fully covered by both GMP and International Organization for Standardization (ISO) procedures. In total, 24/28 (86 %) reporting MSs 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 12/28 (43 %) of the

respondent MSs. In 10 MSs, 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 25/28 (89 %) of the reporting MSs.

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 11/22 (50 %) reporting MSs. In 16 MSs, components were coded using another system. Overall, 24/28 reporting MSs (86 %) 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 *2005/61/EC*, haemovigilance data which may not be caused by blood component properties, such as TACO, are also reported here.

Of the reporting MSs, only 2/32 (6 %) indicated that they did not have a haemovigilance reporting system at a national level. In all of the 30 MSs that did have a reporting system, it was associated with a national authority. Data on transfusion complications were provided by 26/32 MSs (81 %). 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 6.4 serious adverse reactions per 100 000 distributed blood components seems a reasonable estimate. Anaphylaxis, TACO and haemolysis were the most frequently reported serious adverse reactions.

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TABLES

List of countries that participated in the 2011 survey (32 out of 47 MSs)

Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Moldova, Montenegro, Netherlands, Norway, Portugal, Romania, Russian Federation, 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								
Armenia								
Austria								
Azerbaijan								
Belgium	244 106	53 524	18.0	53 524	0	297 630	11 036	27.0
Bosnia / Herzegovina								
Bulgaria	109 140	33 961	23.7	33 961		143 101	7365	19.4
Croatia	97 368	8599	8.1	8599		105 967	4285	24.7
Cyprus								
Czech Republic	345 562	49 122	12.4	49 122	0	370 500	10 330	38.2
Denmark	224 173	25 647	10.3	0	25 647	249 820	5581	44.8
Estonia	28 844	3752	11.5	3752	0	32 596	1321	24.7
Finland	154 038	19 775	11.4	19 775	0	173 813	5401	32.2
France	1 375 926	365 593	21.0			1 741 519	65 350	26.6
FYR Macedonia								
Georgia	27 732	12 859	31.7	12 859	0	40 591	4000	10.1
Germany	2 523 769	542 542	17.7	450 576	91 966	3 066 311	81 844	37.5
Greece	314 382	57 000	15.3	257 292		371 382	10 500	35.4
Hungary	182 659	56 632	23.7	56 632	0	239 291	9986	24.0
Iceland	7798	1398	15.2	0	1398	9196	320	28.8
Ireland	78 029	12 900	14.2	11 686	1214	90 929	4588	19.8
Italy	1 417 036	394 911	21.8	297 321	150 761	1 811 947	60 626	29.9
Latvia	36 113	12 005	24.9	12 005	0	48 118	2073	23.2
Liechtenstein								
Lithuania	59 615	23 034	27.9			82 649	3000	27.5
Luxembourg	12 544	907	6.7	590	317	13 451	537	25.0
Malta	10 013	2300	18.7	2300	0	12 313	410	30.0
Moldova	44 532	20 555	31.6	20 555	0	65 087	3560	18.3
Montenegro	6759	4693	41.0	4693		11 452	626	18.3
Netherlands	305 019	35 166	10.3	0	35 166	340 185	16 693	20.4
Norway	100 881	17 940	15.1	0	17 940	118 821	4986	23.8
Poland								
Portugal	268 878	41 923	13.5	41 923	0	310 801	10 500	29.6
Romania		88 066	100.0	88 066		88 066	19 043	4.6
Russian Federation	1 099 547	569 228	34.1			1 668 775	141 073	11.8
San Marino								
Serbia	41 592	6845	100.0			48 437	7500	6.5
Slovakia	94 479	40 140	29.8	32 083	759	134 619	5405	24.9
Slovenia								
Spain	1 003 730	232 893	18.8			1 236 623	45 973	26.9
Sweden	405 407				45 546	405 407	9483	42.8

Table 1 (continued) – Donors, first time donors and inhabitants

Country	Regular and repeat donors	First time donors	% first time donors	First time donors donating	First time donors tested only	Total donors	Inhabitants x 1000	Donors per 1000 inhabitants
Switzerland	198 473	29 472	12.9	29 472	0	227 945	7955	28.7
Turkey								
Ukraine								
United Kingdom	1 266 684	216 083	14.6	205 432	4303	1 482 767	63 200	23.5

Country	Comments
Czech Republic	About 50 % of first time donors make another donation in the same year thus becoming regular donors. The total number of donors cannot be calculated by adding the figures reported in the two first columns.
France	The French blood service is composed of EFS with 17 blood centers and the French army transfusion service (CTSA) with 1 blood center. The data of both establishments are reported in the answers.
Lithuania	No data on first time donors and on first time donors donating.
Serbia	Data are only from south region of Serbia.
Slovakia	40 140 donors were registered as a new donor. 8507 of them were refused and from 759 of these refused donors blood a sample was taken and tested.

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

	Whole blood collections				Apheresis collections					
Country	**Whole blood (U)**	**WB per 1000 inhabitants**	**Autologous (U)**	**% autologous WB (U)**	**Plasma apheresis (L)**	**Plasma in L per 1000 inhabitants**	**Platelets apheresis (U)**	**RBC apheresis (U)**	**Granulocytes apheresis (U)**	**Multi-component apheresis (U)**
Albania										
Andorra										
Armenia										
Austria										
Azerbaijan										
Belgium	542 155	49.1	110	0.0	61 440	5.57	13 710	2441	45	15 013
Bosnia / Herzegovina										
Bulgaria	165 255	22.4			293	0.04	1069			
Croatia	177 680	41.5	905	0.5	71	0.02	2464			2464
Cyprus										
Czech Republic	416 822	40.4	14 219	3.3	459 300	44.46	17 300	2000	30	
Denmark	312 421	56.0	0	0.0	1717	0.31	1742	0	10	0
Estonia	57 027	43.2	0	0.0	723	0.55	430	205	0	340
Finland	263 408	48.8	0	0.0	2882	0.53	545	0	0	0
France	2 606 948	39.9	1830	0.1	468 201	7.16	5602	191	296	129 705
FYR Macedonia										
Georgia	36 904	9.2	50	0.1	0	0.00	120	0	0	0
Germany	4 949 841	60.5	24 301	0.5	1 870 069	22.85	191 743	15 691		31 373
Greece	564 925	53.8	891	0.2	515	0.05	22 631	49		1
Hungary	424 524	42.5	769	0.2			2893	732	165	0
Iceland	12 829	40.1	0	0.0	90	0.28	766	189	0	0
Ireland	142 633	31.1	9	0.0	0	0.00	11 391	0	0	0
Italy	2 744 603	45.3	65 022	2.3	218 609	3.61	10 992	0	163	85 394
Latvia	55 933	27.0	0	0.0			1779	0	0	
Liechtenstein										
Lithuania	77 353	25.8	480	0.6	528	0.18	3087	7506	0	
Luxembourg	20 387	38.0	66	0.3	1892	3.52	593	0	0	0

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

	Whole blood collections				Apheresis collections					
Country	**Whole blood (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	16 485	40.2	0	0.0	0	0.00	475	0	0	0
Moldova	71 442	20.1	29	0.0	3378	0.95	0	0	0	0
Montenegro	14 831	23.7								
Netherlands	538 338	32.2	56	0.0	211 697	12.68	4539	0	73	0
Norway	203 352	40.8	14	0.0	2552	0.51	4741	3577	0	2173
Poland										
Portugal	405 029	38.6					4930	930	0	
Romania	398 993	21.0	26	0.0	1	0.00	6232		0	
Russian Federation	2 212 398	15.7			382 263	2.71				
San Marino										
Serbia	234 092	31.2	8	0.0	650	0.09	2072	188		
Slovakia	201 404	37.3	864	0.4	33	0.01	6031	176	11	0
Slovenia										
Spain	1 735 316	37.7	9067	0.5	28 806	0.63	7529	870	0	24 174
Sweden	484 224	51.1	54	0.0	34 624	3.65	8929	1676	173	
Switzerland	348 784	43.8	1748	0.5	1551	0.19	17 760	1277	0	7747
Turkey										
Ukraine										
United Kingdom	2 352 835	37.2	3	0.0	122	0.00	173 767	0	29	0

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

Country	Comments
Belgium	Multicomponent donations are donations of platelets and plasma.
Georgia	The number 120 refers to manual platelet apheresis procedures.
Germany	Data not available to voluntary non-remunerated donations (%) and granulocytes apheresis donations. Family / Replacement donations are not allowed.
Greece	28 868 RBCs imported from Swiss Red Cross.
Lithuania	Number of multi-component apheresis donations not available, voluntary non-remunerated donations 29 % of all donations.
Montenegro	Collection of Blood and Blood components by apheresis procedures are not yet implemented.
Norway	Litres of apheresis plasma is estimated from numbers of procedures.
Romania	Few BEs perform multi-component apheresis procedures, but detailed figures are not centralised in the national annual report.
Serbia	Data are from National Blood Transfusion Institute, Belgrade.
Switzerland	The number given for plasma apheresis donations relates to the number of donations and not to litres.

Table 2.2 – Profile of donations

	Whole blood donations			Red cell apheresis		Plasmapheresis donations	Platelet apheresis
Country	**% volontary, non-remunerated**	**% from replacement donors**	**% from autologous donors**	**% voluntary, non-remunerated**	**% from autologous donors**	**% voluntary, non-remunerated**	**% voluntary, non-remunerated**
Albania							
Andorra							
Armenia							
Austria							
Azerbaijan							
Belgium	100	0	0.02	100	0	100	100
Bosnia / Herzegovina							
Bulgaria	18	78					
Croatia	100		0.51			100	100
Cyprus							
Czech Republic	100	0	3.41	33		25	33
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	0.07	100	0	100	100
FYR Macedonia							
Georgia	18	16	0.14	0			0
Germany		0	0.49		0		
Greece	49	51	0.16	90	0	49	70
Hungary	100		0.18	100	105		100
Iceland	100	0	0.00	100	0	100	100
Ireland	100	0	0.01	0			100
Italy	100	0	2.37	0		100	100
Latvia	100		0.00				0
Liechtenstein							
Lithuania	29	0	0.62	29	0	0	29
Luxembourg	100	0	0.32	0		100	100
Malta	100	0	0.00	0			100
Moldova	34	66	0.04	0		15	0
Montenegro	33	67					
Netherlands	100	0	0.01			100	100
Norway	100	0	0.01	100	0	100	100
Poland							
Portugal	100	0		100			100
Romania	100	0	0.01			100	100
Russian Federation	92						
San Marino							
Serbia	90	10	0.00	90		93	100
Slovakia	100	0	0.43	0	0	100	12
Slovenia							

Table 2.2 (continued) – Profile of donations

	Whole blood donations			Red cell apheresis		Plasmapheresis donations	Platelet apheresis
Country	**% volontary, non-remunerated**	**% from replacement donors**	**% from autologous donors**	**% voluntary, non-remunerated**	**% from autologous donors**	**% voluntary, non-remunerated**	**% voluntary, non-remunerated**
Spain	100	0	0.52	100		100	100
Sweden	100	0	0.01	100	1	100	100
Switzerland	100	0	0.50	100	13		100
Turkey							
Ukraine							
United Kingdom	100	0	0.00	0		100	100

Country	Comments
Georgia	No automated platelet apheresis procedures performed in Georgia.
Germany	Data not available to voluntary non-remunerated donations (%) and granulocytes apheresis donations. Family / Replacement donations are not allowed.
Greece	28 868 RBCs imported from Swiss Red Cross.
Lithuania	Voluntary non-remunerated donations 29 % of all donations.
Montenegro	Collection of Blood and Blood components by apheresis procedures are not present in MNE stil.
Serbia	Data are from National Blood Transfusion Institute, Belgrade.

Table 3 – Use of blood and blood components for transfusion

Country	Transfused or distributed	Whole blood (U)	% WB of total RBCs	Red blood cell concentrates (U)	RBC (U) per 1000 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											
Austria											
Azerbaijan											
Belgium	Trans.	0	0.0	493 396	44.7	87 182	69 342	35 789	33 553	48.4	0
Bosnia / Herzegovina											
Bulgaria	Distr.	403	0.3	156 115	21.2	84 930	5492	3923	1569	28.6	
Croatia	Distr.	547	0.3	175 108	40.9	82 597	16 257	13 351	2906	17.9	1
Cyprus											
Czech Republic	Trans.	404	0.1	389 100	37.7	187 388	34 057	8248	25 809	75.8	
Denmark	Trans.	0	0.0	294 449	52.8	66 345	34 557	33 677	880	2.5	
Estonia	Distr.	40	0.1	53 884	40.8	30 245	6285	4865	1420	22.6	687
Finland	Distr.	0	0.0	242 951	45.0	49 872	41 929	41 222	707	1.7	0
France	Distr.	0	0.0	2 449 452	37.5	379 922	292 646	142 281	150 365	51.4	0
FYR Macedonia											
Georgia	Distr.	63	0.2	31 864	8.0	33 365	5288	5168	120	2.3	68
Germany	Distr.	4041	0.1	4 679 554	57.2	1 193 057	520 326	190 973	329 353	63.3	0
Greece	Distr.	739 543	55.9	1 323 352	126.0	187 102	131	108	23	17.6	
Hungary	Trans.	0	0.0	422 976	42.4	98 027	37 692	34 023	3669	9.7	0
Iceland	Distr.	0	0.0	12 248	38.3	3607	2087	856	1231	59.0	0
Ireland	Distr.	0	0.0	138 103	30.1	23 323	24 779	5345	19 434	78.4	80
Italy	Trans.	2209	0.1	2 576 868	42.5	445 309	217 033	140 211	76 822	35.4	2705
Latvia	Distr.	0	0.0	55 361	26.7	50 060	6888	3434	3454	50.1	8517
Liechtenstein											
Lithuania	Trans.	0	0.0	87 305	29.1	34 833	18 562	9851	8711	46.9	
Luxembourg	Distr.	0	0.0	19 575	36.4	5265	2359	1667	692	29.3	0
Malta	Distr.	1	0.0	15 679	38.2	3986	1296	857	439	33.9	
Moldova	Trans.	39	0.1	37 350	10.5	62 764	8693	8693	0	0.0	14 356

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

Country	Transfused or distributed	Whole blood (U)	% WB of total RBCs	Red blood cell concentrates (U)	RBC (U) per 1000 inhabitants	Plasma for transfusion (U)	Platelets total (U)	Platelets recovered (U)	Platelets apheresis (U)	% platelets by apheresis	Cryoprecipitate (10^6 IU FVIII)
Montenegro	Trans.	420	2.9	14 586	23.3	8200	670				592
Netherlands	Distr.	597	0.1	530 875	31.8	86 932	64 002	59 202	4800	7.5	0
Norway	Trans.	111	0.1	194 373	39.0	48 671	22 386	16 099	6287	28.1	
Poland											
Portugal	Distr.	0	0.0	268 807	25.6	4958	28 048	25 052	2996	10.7	
Romania	Distr.	73 793	18.7	395 155	20.8	262 007	28 749	21 254	7495	26.1	19 465
Russian Federation	Distr.	2213	0.1	1 592 144	11.3	1 893 284	157 984				
San Marino											
Serbia	Trans.	11 658	5.0	233 015	31.1	129 575	68 333	66 333	2000	2.9	20 442
Slovakia	Distr.	502	0.3	183 132	33.9	83 462	24 912	13 477	11 435	45.9	4
Slovenia											
Spain	Trans.	176	0.0	1 576 350	34.3	210 414	191 840	163 508	28 332	14.8	1918
Sweden	Trans.	0	0.0	485 071	51.2	85 808	49 866	34 616	15 250	30.6	
Switzerland	Distr.	0	0.0	308 628	38.8	53 937	33 676	7569	26 107	77.5	0
Turkey											
Ukraine											
United Kingdom	Distr.	0	0.0	2 163 622	34.2	298 746	307 924	52 682	255 242	82.9	148 814

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

Country	Comments
Croatia	FVIII in Cryoprecipitate is calculated as total content of FVIII in all Cryo pools (298 pools, 1 pool is prepared from 10 donors), expressed as value $0.18x10^6$.
Denmark	Cryoprecipitate: 286 units (procured from 4 donors each). Total amount of FVIII is 298.584 IU.
Finland	Autologous pre-deposit units are collected only in cases where no compatible allogeneous blood is available. No data on the number of autologous pre-deposit blood units are available.
Georgia	1. No automated plateletpheresis procedures performed in Georgia. The number 120 refers to manual plateletpheresis procedures. 2. Data incomplete - Data from Batumi regional center (which has collected 2714 WB donations) is not available!
Greece	* These figures includes 28 868 units RBCs imported from Swiss Red Cross.
Ireland	Most fibrinogen replacement is with fibrinogen concentrate.
Italy	FFP units include 106.359 units of pathogen-inactivated plasma (Plasmasafe) produced by contract manufacturing.
Lithuania	Cryoprecipitate (FVIII IU x 10^6), Number of autologous red cell units (pre-deposit) na.
Malta	Re cryoprecipitate, 799 units were distributed but cannot convert to FVIII x 10^6.
Norway	All plasma transfusions are Octaplas 200 ml/unit.
Romania	The figure for Cryoprecipitate represents the number of units distributed.
United Kingdom	Figures given are for number of units of clinical cryoprecipitate.

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)
Albania					
Andorra					
Armenia					
Austria					
Azerbaijan					
Belgium	182 719	16.56	63.62	7.90	0.18
Bosnia / Herzegovina					
Bulgaria	15 394	2.09		11.53	0.54
Croatia	21 150	4.94		19.28	0.47
Cyprus					
Czech Republic	505 200	48.91	12.06	18.14	0.48
Denmark	66 061	11.84	99.91	11.89	0.23
Estonia	7607	5.76		22.90	0.56
Finland	72 897	13.50	86.94	9.23	0.21
France	872 193	13.35	71.23	5.81	0.16
FYR Macedonia					
Georgia	0	0.00		8.34	1.05
Germany	3 007 779	36.75	39.12	14.58	0.25
Greece	39	0.00		17.82	0.14
Hungary	84 503	8.46	100.00	9.82	0.23
Iceland	0	0.00		11.29	0.29
Ireland	0	0.00		5.08	0.17
Italy	750 865	12.39	61.08	7.35	0.17
Latvia	6320	3.05		24.15	0.90
Liechtenstein					
Lithuania	4880	1.63		11.61	0.40
Luxembourg	6531	12.16	0.00	9.80	0.27
Malta	0	0.00		9.72	0.25
Moldova	4087	1.15		17.63	1.68
Montenegro				13.10	0.56
Netherlands	332 161	19.90	44.26	5.21	0.16
Norway	55 210	11.07		9.76	0.25
Poland					
Portugal	0	0.00		0.47	0.02
Romania	0	0.00		13.76	0.66
Russian Federation	133 023	0.94		13.42	1.19
San Marino					
Serbia	5772	0.77		17.28	0.56
Slovakia	26 320	4.87	86.30	15.44	0.46
Slovenia					
Spain	366 578	7.97		4.58	0.13
Sweden	136 703	14.42		9.05	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)
Switzerland	85 910	10.80	0.00	6.78	0.17
Turkey					
Ukraine					
United Kingdom	0	0.00		4.73	0.14

Country	Comments
Croatia	All plasma is delivered to Institute of Immunology (Zagreb, Croatia). From that plasma Institute manufacture of only albumin and immunoglobulines.
Estonia	Plasma was sold without special indication.
Finland	9521 litres of plasma was used for production of Octaplas.
Italy	Plasma for specific Igs: produced for preparation of anti-HBV Igs.
Lithuania	Plasma was sold to manufacturers.
Moldova	Other plasma represents FFP and decryoprecipitate plasma.
Norway	All plasma sold to Baxter. How they use it is unknown to us.
Romania	No contract or plant for fractionation.
Serbia	Data are only from National Blood Transfusion Institute, Belgrade.
Sweden	Plasma from whole blood 102 079 L. Plasma from apheresis 34 624 L.

Table 4.2 – Use of medicinal products derived from human plasma

		Immunoglobulins (kg)			
Country	**FVIII (excluding cryo and excluding recombinant) (10^6 IU)**	**Polyvalent (kg)**	**Intravenous (%)**	**Subcutaneous plus intramuscular (%)**	**Human albumin (kg)**
Albania					
Andorra					
Armenia					
Austria					
Azerbaijan					
Belgium					
Bosnia / Herzegovina					
Bulgaria					
Croatia					
Cyprus					
Czech Republic	31	334	82	18	1295
Denmark		482	67	39	1383
Estonia	2	5	100	0	46
Finland	8	475	77	23	623
France					
FYR Macedonia					
Georgia	0	0			0
Germany	178	4528	93	7	14 608
Greece					
Hungary					
Iceland	0	0			0
Ireland					
Italy	92	3571	97	3	36 443
Latvia					
Liechtenstein					
Lithuania	8	9			
Luxembourg	1	1	100	0	173
Malta	0	0			0
Moldova					1225
Montenegro					
Netherlands	15	1000	95	5	1300
Norway					
Poland					
Portugal	0	0			0
Romania					
Russian Federation					
San Marino					
Serbia					
Slovakia					
Slovenia					
Spain	82	2864			11 729
Sweden	3	1025	63	37	2159

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

		Immunoglobulins (kg)			
Country	**FVIII (excluding cryo and excluding recombinant) (10^6 IU)**	**Polyvalent (kg)**	**Intravenous (%)**	**Subcutaneous plus intramuscular (%)**	**Human albumin (kg)**
Switzerland	2478	0			1994
Turkey					
Ukraine					
United Kingdom	0	0			0

Country	Comments
Bulgaria	Data not available.
Croatia	In Croatia, there is no exact full data, collected on national level, about the use of medicinal products derived from human plasma.
Denmark	Total amount of FVIII (excluding cryo and recombinant): Haemate 1.250.000 IU.
Finland	Plasma derived FVIII accounts for 24 % of total use of FVIII.
France	Data not available at EFS nor at a national scale.
Iceland	The Blood Bank does not have this information.
Ireland	Data not available.
Luxembourg	We are not the sole provider for hospitals regarding plasma derivated medicinal products.
Moldova	Ig intramuscular is expressed in dose, human albumin 10 % expressed in litres.
Netherlands	These are estimated numbers.
Romania	These products are not managed by BEs, but by hospitals, therefore data are not available.
United Kingdom	No data supplied to hospitals direct from the manufacturers.

Table 5.1 – Special processing of blood components

Country	Red blood cells		Plasma for transfusion		Platelets		
	% leucocyte depleted	% irradiated	% leucocyte depleted	% irradiated	% leucocyte depleted	% irradiated	% Path. inact.
Albania							
Andorra							
Armenia							
Austria							
Azerbaijan							
Belgium	100		100	0	100		45
Bosnia / Herzegovina							
Bulgaria	1		6		6		
Croatia	59				99		
Cyprus							
Czech Republic	32	5			85	50	
Denmark	100	4	1	0	100	6	0
Estonia	9	4	0	0	71	30	0
Finland	100	7	0	0	100	20	0
France	100	0	100	0	100	0	8
FYR Macedonia							
Georgia		0	0	0	0	0	0
Germany	100	4		0	100	40	0
Greece	40	21	48	15	76	30	0
Hungary	12	8	4	5	66	50	0
Iceland	25	13	5	2	100	88	0
Ireland	100	11	100		100	100	0
Italy	26	6	30	0	21		
Latvia	4	1	0	0	100	6	0
Liechtenstein							
Lithuania	30				50		3
Luxembourg	100	1	100	0	100	1	0
Malta	100	3	100	0	100	24	0
Moldova							
Montenegro							
Netherlands	100	5	100	0	100	34	0
Norway	100	7	0	0	100	34	18
Poland							
Portugal	100				100		
Romania	5		5	0	26		0
Russian Federation	23		18		29	1	2
San Marino							
Serbia	43				5		
Slovakia	33	4	0		45	8	0
Slovenia							
Spain	97	5	56		97	38	
Sweden	89	5	91	4	100	56	17
Switzerland	100	2	100	0	100	3	0

Table 5.1 (continued) – Special processing of blood components

Country	Red blood cells		Plasma for transfusion		Platelets		
	% leucocyte depleted	% irradiated	% leucocyte depleted	% irradiated	% leucocyte depleted	% irradiated	% Path. inact.
Turkey							
Ukraine							
United Kingdom	100	9	100	0	100	55	0

Country	Comments
Croatia	In Croatia, there is no decision at national level for universal pre-storage leucodepletion of blood components. Blood components are irradiated by gamma irradiation in some Hospitals, no data avaliable.
Finland	No regular FFP is used in Finland. The only fresh frozen plasma available is Octaplas.
Germany	Data on leukocyte depleted plasma for transfusion are not collected. Cryoprecipitate reduced plasma components and Cryoprecipitate: not in use.
Ireland	Most fibrinogen replacement is with fibrinogen concentrate.
Lithuania	Irradiated red cells, platelets, plasma (%).
Luxembourg	Our FFP is treated solvant detergent (toll manufacturing agreement with Octapharma).
Montenegro	Leukocyte depleted and irradiated blood components (RC and PLT) are prepared in specific cases only.
Norway	All plasma transfused are Octaplas 200 ml/unit.
Romania	Irradiation is performed either in BE of Bucharest or in few hospitals- HBBs, therefore total number of irradiated components is not available.
Serbia	Data are from National Blood Transfusion Institute, Belgrade.
Slovakia	We do not collect information about irradiation of plasma.

Table 5.2 – Inactivation or quarantine of plasma

Country	Fresh frozen plasma		Cryoprecipitate reduced plasma		Cryoprecipitate	
	% quarantined	% virus inactivated	% quarantined	% virus inactivated	% quarantined	% virus inactivated
Albania						
Andorra						
Armenia						
Austria						
Azerbaijan						
Belgium	0	100	0	0	0	0
Bosnia / Herzegovina						
Bulgaria	100					
Croatia						
Cyprus						
Czech Republic	100					
Denmark	0	0	1	0	0	0
Estonia	0	0	0	0	0	0
Finland	0	0	0	0	0	0
France	0	100	0	0	0	0
FYR Macedonia						
Georgia	0	0	0	0	0	0
Germany	99	1	0	0	0	0
Greece	25	10				
Hungary	0	0	0	0	0	0
Iceland	0	0	0	0	0	0
Ireland		99	0	0	0	0
Italy	8	9				
Latvia	62	0	0	0	100	0
Liechtenstein						
Lithuania	93					
Luxembourg	0	100	0	0	0	0
Malta	0	0	0	0	0	0
Moldova						
Montenegro						
Netherlands	100	0				
Norway	0	100	0	0	0	0
Poland						
Portugal	100					
Romania	50	0	50	0	50	0
Russian Federation	91	3				
San Marino						
Serbia	5					
Slovakia	54	0	0	0	0	0
Slovenia						
Spain	33	67	76	24	66	34
Sweden						
Switzerland	100	0	0	0	0	0

Table 5.2 (continued) – Inactivation or quarantine of plasma

Country	Fresh frozen plasma		Cryoprecipitate reduced plasma		Cryoprecipitate	
	% quarantined	% virus inactivated	% quarantined	% virus inactivated	% quarantined	% virus inactivated
Turkey						
Ukraine						
United Kingdom	0	3	0	0	0	4

Country	Comments
Croatia	In Croatia, there is no decision at national level for universal pre-storage leucodepletion of blood components. Blood components are irradiated by gamma irradiation in some Hospitals, no data avaliable.
Finland	No regular FFP is used in Finland. The only fresh frozen plasma available is Octaplas.
Germany	Data on leukocyte depleted plasma for transfusion are not collected. Cryoprecipitate reduced plasma components and Cryoprecipitate: not in use.
Ireland	Most fibrinogen replacement is with fibrinogen concentrate.
Lithuania	Irradiated red cells, platelets, plasma (%).
Luxembourg	Our FFP is treated solvant detergent (toll manufacturing agreement with Octapharma).
Montenegro	Leukocyte depleted and irradiated blood components (RC and PLT) are prepared in specific cases only.
Norway	All plasma transfused are Octaplas 200 ml/unit.
Romania	Irradiation is performed either in BE of Bucharest or in few hospitals- HBBs, therefore total number of irradiated components is not available.
Serbia	Data are from National Blood Transfusion Institute, Belgrade.
Slovakia	We do not collect information about irradiation of plasma.

Table 6.1 – Donation testing strategy for infectious agents

	Type of test									
Country	**Anti-HIV 1+2**	**HIVAg**	**HBsAg**	**Anti-HBc**	**Anti-HCV**	**HCVAg**	**Anti-HTLV I/II**	**Syphilis**	**Malaria**	**Other**
Albania										
Andorra										
Armenia										
Austria										
Azerbaijan										
Belgium	100	0	100	First	100	0	0	100		
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	30	0	100	0	
Denmark	100	66	100	0	100	0	First	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	0	100	100		WNV-RNA: testing 18 %.
Hungary	100	100	100	First	100	0	0	100	100	
Iceland	100	100	100	0	100	0	0	0	0	
Ireland	100	0	100	100	100	0	100	100	0	anti-CMV: testing 77 %.
Italy	100	93	100	0	100	0	0	100	0	
Latvia	100	0	100	0	100	0	0	100	0	
Liechtenstein										
Lithuania	100	0	100	0	100	0		100	0	
Luxembourg	100		100	First	100	0	First	100		
Malta	100	0	100	100	100	0	0	100	0	

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

	Type of test									
Country	**Anti-HIV 1+2**	**HIVAg**	**HBsAg**	**Anti-HBc**	**Anti-HCV**	**HCVAg**	**Anti-HTLV I/II**	**Syphilis**	**Malaria**	**Other**
Moldova	100	100	100	100	100	0	0	100	0	
Montenegro	100	100	100		100			100		
Netherlands	100	0	100	100	100	0	100	100	0	Anti-Parvovirus B19 IgG: testing 5 %. Anti-CMV IgG: testing 0 %.
Norway	100	0	100	50	100	0	0	First	2	
Poland										
Portugal	100	100	100	100	100	0	100	100	5	
Romania	100	100	100	0	100	100	100	100	0	ALT: testing every donation.
Russian Federation	100	100	100	0	100	0	0	100	0	ALT: testing every donation.
San Marino										
Serbia	100	100	100	0	100	0	0	100	0	
Slovakia	100	100	100	100	100	0	0	100	0	
Slovenia										
Spain	100	0	100	0	100	0	25	100	1	Chagas disease: testing 7 %.
Sweden	100	100	100	First	100	0	First	100	0	
Switzerland	100	0	100	0	100	0	0	100	0	Chagas screening test: testing 0 %. CMV: testing 0 %.
Turkey										
Ukraine										
United Kingdom	100	100	100	1	100	0	100	100	1	Chagas' disease: testing 1 %. Anti-CMV: testing 30 %.

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

Country	Comments
Belgium	Malaria: in case of history of malaria or stay in endemic region; anti-CMV: very small % of red cells and platelets for some immunodeficient patients.
Czech Republic	Anti-HIV: HIV Ab+Ag combined test; HIV Ag: HIV Ab+Ag combined test; anti-HBc: first time donors in some BE (not obligatory); HCV Ag: combined test HCV Ab+Ag in some BE (not obligatory); Syphilis: test for specific antibodies.
Denmark	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	Malaria: tested 0.15 %. Testing donors who 1) have lived in malaria endemic area before the age of 5 years, 2) have travelled to malaria endemic area AND had fever of unknown origin, 3) have had confirmed or suspected malaria.
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...).
Germany	HIV Ag: no data. Antibody-Antigen-Combitests for HIV-1/2 are used by some of the blood establishments; anti-HBc: persons, tested positive for anti-HBc, can further donate blood if a sensitive assay for HBV-Genom results negative and if anti-HBs antibody-titer stays above 100 IU/l.
Greece	Malaria: screening for malaria applied in less than 0.5 % of donor blood in a few affected areas (Evrotas-Lakonia and Marathon - Attiki); WNV-RNA: in affected areas during season.
Iceland	Malaria: only if travelling in Malary area.
Ireland	Anti-CMV: first time and previous CMV seronegative donations.
Italy	Anti-HIV: 93 % test Combo Ag/Ab; HIV Ag: test Combo Ag/Ab.
Luxembourg	HIV Ag: we use the test duo Abbott (it's not a real detection of AG P24); Malaria: when the donor comes back from an endemic area; CMV screening test: when we transfuse pregnant CMV- or New borns or ID.
Malta	No NAT available.
Montenegro	Anti-HBc: anti-HBc tests are done only in cases of HBsAg reactivity.
Netherlands	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-CMV IgG: on demand testing.
Norway	HIV Ag: most blood banks use a combined Ab/Ag test but this is not a requirement; anti-HBc: all new donors and all donors who donated more than 6 months ago; Malaria: selected cases only.
Romania	Anti-HIV: Combo tests are used; HIV Ag: as Combo tests performed for every donation; anti-HCV: Combo tests are used; HCV Ag: as Combo tests performed for every donation.
Spain	Anti-HTLV: 2 testing strategies: selective testing 75 % and uinversal testing 25 %; Malaria: selective testing; Chagas disease: selective testing.
Switzerland	Anti-HIV: ---; HBsAg: ---; Anti-HBc: ---; Anti-HCV: ---; HCV Ag: ---; Anti-HTLV: ---; Syphilis: ---; Malaria: in populations at risk. No information about percentage; Chagas screening test: in populations at risk. No information about percentage; CMV: immuno-deficient patients and neonates. Not mandatory; ---
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 person with hepatitis B: OR had a procedure involving flexible endoscopy 4-6 months ago.

Table 6.2 – Use of simple rapid tests

Country	Type of test (% of donations)			
	Anti-HIV 1+2	HBsAg	Anti-HCV	Comments
Albania				
Andorra				
Armenia				
Austria				
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				
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	0	0	0	
Liechtenstein				
Lithuania	0	0	0	
Luxembourg	0	0	0	
Malta	0	0	0	
Moldova	0	0	0	
Montenegro	0			
Netherlands	0	0	0	
Norway	0	0	0	
Poland				
Portugal	0	0	0	
Romania	0	0	0	
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	---Anti-HIV: ---; HBsAg: ---; Anti-HCV: ---
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											
Armenia											
Austria											
Azerbaijan											
Belgium	All	2	0	41	1	21	0			18	8
Bosnia / Herzegovina											
Bulgaria	All	1		1095		116				250	
Croatia	100	1	1	20	1	12	2			3	4
Cyprus											
Czech Republic	All	4	2	29	13	106	28			17	10
Denmark	All	0	1	4	3	4	0	0			
Estonia	All	2	1	10	2	36	6			8	10
Finland	All	0	0	0	1	5	4			0	0
France	All	16	20	257	7	124	16	19	2	248	110
FYR Macedonia											
Georgia	All										
Germany	All	40	62	631	21	336	37			223	107
Greece	All	31	20	783	203	685	175	3	2	72	47
Hungary	All	3	2	5	2	90	15			0	11
Iceland	All	0	0	1	0	0	2				
Ireland	All	0	0	5	0	1	0	0	1	4	1
Italy	All	60	69	663	36	372	32			469	112
Latvia		4	6								
Liechtenstein											
Lithuania	All	11	5	129	10	354	90			127	47
Luxembourg	All	0	0	0	0	2	0	0	0	2	0
Malta	All	0	0	4	1	1	0			0	1
Moldova	All	20									

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	All	1		7	1	8	0			3	2
Netherlands	All	1	0	12	5	7	0	3	0	10	5
Norway	All	0	0	5	0	6	0			6	0
Poland											
Portugal	All		44		76		29		419		689
Romania	All	37	11	2711	20	520	20	31	1	992	44
Russian Federation	All										
San Marino											
Serbia		2	0	56		42				28	
Slovakia	All	1	1	29	3	10	6	0	0	4	9
Slovenia											
Spain	All	61	87	391	28	230	22	22	0	409	435
Sweden	All	0	0	17	1	23	3	2		7	0
Switzerland	All	2	2	43	6	15	2	0	0	19	8
Turkey											
Ukraine											
United Kingdom	All	11	12	82	6	81	5	11	3	69	16

Country	Comments
Georgia	Testing: only donations tested repeatedly reactive for Anti-HIV 1+2.
Latvia	Testing: only HIV.
Luxembourg	Outcomes: regarding syphilis: each time it was a cured disease.
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.
Russian Federation	Outcomes: confirmatory testing in repeated reactive donors is performed, but the existing official form of reporting does not allow separating the requested data.
Serbia	Testing: RR samples are confirmed only in NBTI, Belgrade; Outcomes: date from 240 cell related to north region, 243 252 related to north and central region, and 245 is related to south.
Switzerland	Testing: ---; Outcomes: number of confirmed seropositive 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						
Azerbaijan						
Belgium	3.74	0.00	76.60	0.41	39.23	0.00
Bosnia / Herzegovina						
Bulgaria	2.94		3224.29		341.57	
Croatia	11.63	1.03	232.59	1.03	139.55	2.05
Cyprus						
Czech Republic	8.14	0.58	59.04	3.76	215.79	8.10
Denmark	0.00	0.45	15.60	1.34	15.60	0.00
Estonia	53.30	3.47	266.52	6.93	959.49	20.80
Finland	0.00	0.00	0.00	0.65	25.28	2.60
France	4.38	1.45	70.30	0.51	33.92	1.16
FYR Macedonia						
Georgia						
Germany	7.37	2.46	116.30	0.83	61.93	1.47
Greece	54.39	6.36	1373.68	64.57	1201.75	55.66
Hungary	5.30	1.09	8.83	1.09	158.92	8.21
Iceland	0.00	0.00	71.53	0.00	0.00	25.65
Ireland	0.00	0.00	38.76	0.00	7.75	0.00
Italy	15.19	4.87	167.89	2.54	94.20	2.26
Latvia	33.32	16.61				
Liechtenstein						
Lithuania	47.76	8.39	560.04	16.77	1536.86	150.97
Luxembourg	0.00	0.00	0.00	0.00	220.51	0.00
Malta	0.00	0.00	173.91	9.99	43.48	0.00
Moldova	97.30					
Montenegro	21.31		149.16	14.80	170.47	0.00
Netherlands	2.84	0.00	34.12	1.64	19.91	0.00
Norway	0.00	0.00	27.87	0.00	33.44	0.00
Poland						
Portugal		16.36		28.27		10.79
Romania	42.01		3078.37		590.47	
Russian Federation						
San Marino						
Serbia	29.22	0.00	818.12		613.59	
Slovakia	2.49	1.06	72.25	3.18	24.91	6.35
Slovenia						
Spain	26.19	8.67	167.89	2.79	98.76	2.19
Sweden		0.00		0.25		0.74

Table 7.2 (continued) – Prevelance and incidence calculated per 100 000 donors

Country	HIV 1 / 2		HBV		HCV	
	Prevelance per 100 000 first time tested donors	Incidence per 100 000 repeat donors	Prevelance per 100 000 first time tested donors	Incidence per 100 000 repeat donors	Prevelance per 100 000 first time tested donors	Incidence per 100 000 repeat donors
Switzerland	6.79	1.01	145.90	3.02	50.90	1.01
Turkey						
Ukraine						
United Kingdom	5.09	0.95	37.95	0.47	37.49	0.39

Table 8.1 – Nucleic Acid Amplification Techniques (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								
Austria								
Azerbaijan								
Belgium	All	6	All	6	All	6		
Bosnia / Herzegovina								
Bulgaria	None		None		None			
Croatia	None		None		None			
Cyprus								
Czech Republic	None		None		None			
Denmark	All	1	All	1	All	1		
Estonia	All	6	All	6	All	6		
Finland	All	1	All	1	All	1	All parvo-B19; All HAV	96; 96
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		All none	
Iceland	None		None		None			
Ireland	All	1	All	1	All	1		
Italy	All		All		All		All WNV NAT testing	
Latvia	All	24		24		24		
Liechtenstein								
Lithuania	All		All		All			
Luxembourg	All	96	All	96	All	96	All HAV; All Parvivirus B19; All	96; 96
Malta	None							
Moldova	All		None		All			
Montenegro	None							

Table 8.1 (continued) – Nucleic Acid Amplification Techniques (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
Netherlands	All	6	All	6	All	6		
Norway	None		None		None			
Poland								
Portugal	All		All		All			
Romania	None		None		None			
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		
Turkey								
Ukraine								
United Kingdom	All	24	All	24	All	24	WNV	6

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

Country	Comments
Belgium	HIV: size of minipools: 6 or 8 depending on BE; HBV: size of minipools: 6 or 8 depending on BE; HCV: size of minipools: 6 or 8 depending on BE.
Finland	parvo-B19; HAV.
France	HIV: size of minipools: ID-NAT in 9 regions and minipools of 8; HBV: size of minipools: ID-NAT in 9 regions and minipools of 8; HCV: size of minipools: ID-NAT in 9 regions and minipools of 8.
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 used only; HCV: ID-NAT used only; WNV-RNA: ID-NAT used only.
Hungary	None.
Italy	WNV NAT testing: testing applied only in defined Summer periods and in defined affected areas.
Latvia	HIV: only seronegatives samples are testing by NAT; HBV: only seronegatives samples are testing by NAT; HCV: only seronegatives samples are testing by NAT.
Luxembourg	HAV; Parvivirus B19.
Malta	HIV: no NAT testing available; no NAT available.
Netherlands	A multiplex real-time PCR test was used to simultaneously detect HIV-1 RNA, HIV-2 RNA, HCV RNA, and HBV DNA.
Norway	HIV: Done by Baxter on plasma for fractionation; HBV: done by Baxter on plasma for fractionation; HCV: done by Baxter on plasma for fractionation.
Russian Federation	NAT- test is not mandatory, but is performed by some blood establishments. Accurate data for reporting period is not available.
Spain	HIV: size of minipools: range 1-8; HBV: size of minipools: range 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; ---
United Kingdom	HBV: NHSBT - 4 of 5 HBV NAT only were occult infections, 1 of 5 (new donor) had an acute infection; West Nile Virus (WNV): NHSBT test performed on donors who have travelled to a WNV area.

Table 8.2 – NAT-only positive results

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						
Azerbaijan						
Belgium	0	1	0	1	0	1
Bosnia / Herzegovina						
Bulgaria						
Croatia						
Cyprus						
Czech Republic						
Denmark	0	0	2	2	0	0
Estonia	0	0	0	1	1	0
Finland	0	0	0	0	0	0
France	0	2	7	3	0	0
FYR Macedonia						
Georgia						
Germany	0	7	0	3	0	9
Greece	2	1	31	8	4	1
Hungary						
Iceland						
Ireland	0	0	0	0	0	0
Italy	0	2	26	98	3	1
Latvia	0	0	0	0	0	7
Liechtenstein						
Lithuania						
Luxembourg	0	0	0	0	0	0
Malta						
Moldova						
Montenegro						
Netherlands	0	0	1	2	0	0
Norway						
Poland						
Portugal						
Romania						
Russian Federation						
San Marino						
Serbia						
Slovakia						
Slovenia						
Spain	5		100		4	
Sweden						
Switzerland						
Turkey						
Ukraine						
United Kingdom	0	0	4	3	0	0

Table 9 – Bacterial screening

Country	Total platelets adult doses issued	% bacterial screened		Total platelets % screened	Total platelets % confirmed +ve
		Recovered	Apheresis		
Albania					
Andorra					
Armenia					
Austria					
Azerbaijan					
Belgium	69 342	61.42	48.75	55.29	
Bosnia / Herzegovina					
Bulgaria	5492			1	
Croatia	16 257	4.1	7.02	4.55	0.34
Cyprus					
Czech Republic	34 057	1	1	1	
Denmark	34 557	100	100	100	0.08
Estonia	6285	100	100	100	0.42
Finland	41 929	6.3	3.3	6.3	0.1884
France	292 646				
FYR Macedonia					
Georgia	5288	0	0	1	0
Germany	520 326				
Greece	131				
Hungary	37 692	5	18	7	0
Iceland	2087			0	
Ireland	24 779	100	100	100	0.022
Italy	217 033	10	10	10	1
Latvia	6888	99.5	32.5	66	0.13
Liechtenstein					
Lithuania	18 562	3	3	3	
Luxembourg	2359	9	4	10	0
Malta	1296	11.062	4.042	5.92	0
Moldova	8693	2		2	
Montenegro	670				
Netherlands	64 002	100	100	100	0.33944
Norway	22 386	76	76	76	
Poland					
Portugal	28 048	100	100	100	0.02
Romania	28 749		100		
Russian Federation	157 984				
San Marino					
Serbia	68 333	0.03	0.03	0.03	0.03
Slovakia	24 912	1	1	1	0
Slovenia					
Spain	191 840				
Sweden	49 866			44	0.03

Table 9 (continued) – Bacterial screening

Country	Total platelets adult doses issued	% bacterial screened		Total platelets % screened	Total platelets % confirmed +ve
		Recovered	Apheresis		
Switzerland	33 676	0	0	0	0
Turkey					
Ukraine					
United Kingdom	307 924	99.98	99.72	99.84	0

Country	Comments
Finland	Only outdated platelets are cultured in order to monitor the contamination rate of blood collection.
France	Bacterial screening not performed.
Georgia	The screening for the presence of bacteria in platelets is performed only at the JAMC blood bank which collected 2828 WB donations.
Germany	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).
Italy	Number to be reported is 10 %.
Moldova	Percentage of platelet adult doses screened for the presence of bacteria - 2.
Norway	Should be 76 %.
Romania	All BEs producing platelets perform bacteriologic control on regular basis; the % of tested units varies based on the production level. Detailed figures are not centralised.
Russian Federation	Confirmatory testing and screening for the presence of bacteria in platelet preparations is performed, but the existing official form of reporting does not allow separating the requested data.
United Kingdom	0.02 % confirmed positive.

Table 10 – Organisation, registration and labelling

Country	National Council or Expert Committee	National blood policy		National regulations
		on quality and safety	Implementing	
Albania				
Andorra				
Armenia				
Austria				
Azerbaijan				
Belgium	Yes	Yes		Yes
Bosnia / Herzegovina				
Bulgaria	Yes	Yes	Yes	Yes
Croatia	Yes	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				
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	No	Yes
Luxembourg	Yes	Yes	Yes	Yes
Malta	Yes	Yes	Yes	Yes
Moldova	Yes	Yes	Yes	Yes
Montenegro	Yes	Yes	Yes	Yes
Netherlands	Yes	Yes	Yes	Yes
Norway	Yes	Yes	Yes	Yes
Poland				
Portugal	Yes	Yes	Yes	Yes
Romania	Yes	Yes	Yes	Yes
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
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 – Quality management related issues

Country	QMS established and maintained	% donations covered by			Other procedures	Inspections every second year	Description of "Other" organisation/body	System of educ. and training
		GMP	ISO 9000	Other				
Albania								
Andorra								
Armenia								
Austria								
Azerbaijan								
Belgium	Yes	100	9 5			National+Other	If covered by 9000 series: also inspected by body of ISO	Yes
Bosnia / Herzegovina								
Bulgaria	Yes	100				National		Yes
Croatia	Yes	100	54			National	Refferal Center of MoH: Croatian Institute of Transfusion Medicine	Yes
Cyprus								
Czech Republic	Yes	100	40			National		Yes
Denmark	Yes	100				National		Yes
Estonia	Yes	100	100			National		Yes
Finland	Yes	100	0			National+Other	FINAS (Finnish National Accrediatation Service)	Yes
France	Yes			100	National good practice guidelines for transfusion (collection, processing, testing, quality control, storage, distribution, issue, transportation, quality management, haemovigilance, etc.)	National	National inspections of blood establishments by the ANSM, regional hospital blood banks inspections by the regional health agencies.	Yes
FYR Macedonia								
Georgia	Planned	0	0	0		No		No
Germany	Yes	100				National+Other	Regional authorities in charge of GMP inspections.	Yes
Greece	Yes	80	25			National		
Hungary	Yes	100				National+Other		Yes
Iceland	Yes		100			National+Other	British Standards Institution	No

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				
Ireland	Yes	100	0			National		Yes
Italy	Yes		40	100	National requirements issued on 16th December 2010 complying with European directives on blood and blood components and applicable GMPs	Other	Regional health authorities + nationally qualified inspectors	Yes
Latvia	Yes					National		Yes
Liechtenstein								
Lithuania	Yes		80			National		Yes
Luxembourg	Yes	100	100	100		National		Yes
Malta	Yes	0	0	100	EU Directives (in conjunction with EDQM Manual 16th edition)	National		Yes
Moldova	Yes					National		Yes
Montenegro	Planned					National		No
Netherlands	Yes	100	100	0		National+Other	Lloyd's Register (for ISO certification)	Yes
Norway	Yes	100	66			National		Yes
Poland								
Portugal	Yes	100	100			National		
Romania	Yes			100	Directive 2005/62/EC and regulation on quality requirements	National		Yes
Russian Federation	Yes							Yes
San Marino								
Serbia	Yes	25	55			National		
Slovakia	Yes	100				National		Yes
Slovenia								
Spain	Yes		100			Other	Inspections conducted by Regional authorities and acreditations by scientific societies	Yes
Sweden	Yes	100		100	91 % Swedac ISO/IEC 17025/ISO/IEC 15189, 100 % accreditation by Medical Products Agency	National	National Board of Health and Welfare, Medical Products Agency	Yes
Switzerland	Yes	100	60	0	---	National+Other		Yes
Turkey								

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				
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

Country	Comments
Estonia	Education and regular training is provided by blood centers locally for their own personnel, not on national level.
Italy	The new inspection system has been implemented and is expected to be fully operating by 31st December 2014.
Serbia	Data 345 is related to south region, 346 south and north, 347 is related to central region.
Slovakia	No information available concerning the number of blood establishments which are ISO certified.
Sweden	100 % National Board of Health and Welfare, 91 % Swedac ISO/IEC 17025/ISO/IEC 15189, 100 % accreditation by Medical Products Agency.

Table 11.2 – Quality management related issues

Country	% donations labelled according to		% component coded according to		Comments
	ISBT 128	another system	ISBT 128	another system	
Albania					
Andorra					
Armenia					
Austria					
Azerbaijan					
Belgium	93	7	93	7	
Bosnia / Herzegovina					
Bulgaria				100	
Croatia		60		60	Codabar
Cyprus					
Czech Republic		100		100	National labelling system (producer / donation No / product No / blood group etc. incl. barcode standard) since 1996
Denmark	100		100		
Estonia	100		0	100	Estonian Blood Service Infomation System; when we started with ISBT128 (1996) component codes didn't exist and we had to create our own 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	0		0		
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		

Table 11.2 (continued) – Quality management related issues

Country	% donations labelled according to		% component coded according to		Comments
	ISBT 128	another system	ISBT 128	another system	
Liechtenstein					
Lithuania		100		100	Local
Luxembourg	0	100	0	100	
Malta	0	100	0	100	Codabar
Moldova	100		100		
Montenegro		100			
Netherlands	100	0	100	0	
Norway	100		100		
Poland					
Portugal	100		100		
Romania		100		100	As most of BEs do not have an IT system to generate the final label, different printed labels are used to cover the labelling requirements, donation codes included
Russian Federation					
San Marino					
Serbia	10	75	10	45	e progesa system, Mac system in south region; data 360 and 361 is related to south region, 362 are related to north and central region, and 363 is related to central region
Slovakia	50	50	0	50	System developed inhouse, codification of blood components according system developed by our ministry of health and used also for facturation by assurance companies
Slovenia					
Spain	63	37	63	37	Codabar (76 %) Eurocode (18 %); Code 39 (6 %)
Sweden	100		100		
Switzerland	100	0	100	0	No information; ---
Turkey					
Ukraine					
United Kingdom	100	0	0	100	Codabar; donation numbers ISBT 128, product labels Codabar

Table 12.1 – Haemovigilance system

Country	Haemovigilance system	
	Available / organisation	Description of "Other" organisation/body
Albania		
Andorra		
Armenia		
Austria		
Azerbaijan		
Belgium	National	
Bosnia / Herzegovina		
Bulgaria	National	
Croatia	National+Other	By Refferal centre MoH: Croatian Institute of Transfusion Medicine
Cyprus		
Czech Republic	National	
Denmark	National+Other	State Serum Institute & 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	
Liechtenstein		
Lithuania	National	
Luxembourg	National	
Malta	National	
Moldova	National	
Montenegro	No	
Netherlands	National+Other	TRIP Foundation
Norway	National	
Poland		
Portugal	National	
Romania	National	
Russian Federation	National	
San Marino		

Table 12.1 (continued) – Haemovigilance system

Country	Haemovigilance system	
	Available / organisation	Description of "Other" organisation/body
Serbia	National	
Slovakia	National	
Slovenia		
Spain	National	
Sweden	National+Other	National Board of Health and Welfare, BIS/Swedish Association of Transfusion Medicine
Switzerland	National	No other bodies/organisations.
Turkey		
Ukraine		
United Kingdom	National+Other	Serious Hazards of Transfusion (SHOT)

Country	Comments
Croatia	Haemovigilance system in Croatia registers all reactions. In 2011 there were 314 reactions registered, out of them 20 SARE with imputability level 2 or 3, and they are reported to the Competent Authority.
France	ANSM.
Luxembourg	Hospitals and blood establishment must inform Ministry of Health for each SARE.
Netherlands	TRIP Foundation is the Dutch National Hemovigilance Office.
Norway	www.hemovigilans.no
United Kingdom	Medicines and Healthcare products Regulatory Agency MHRA (SABRE and SHOT).

Table 12.2 – Haemovigilance - number of serious adverse reactions

Country	Imputability "likely, probable or certain" (level 2 or level 3)																Incidence high imputability serious adverse reactions per 100 000 component
	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																	
Austria																	
Azerbaijan																	
Belgium	6	11			8	4						6			5	51	14.0
Bosnia / Herzegovina																	
Bulgaria																	
Croatia		10			5	1									4		7.3
Cyprus																	
Czech Republic	0	0	0	0	5	2	0	0	0	0	0	0	0	0	0	5	2.0
Denmark	0	4	0	0	2	1	0	0	0	0	0	0	0	0	3	0	2.5
Estonia		2	2			1		1									6.6
Finland	2	1	1	0	3	2	0	0	0	0	0	0	0	0	2	0	3.3
France	0	2	2	1	23	17	0	0	0	0	1	4	0	0	22	5	2.5
FYR Macedonia																	
Georgia																	
Germany	4	11	0	1	3	0	0	0	0	0	0	3	0	0	12	3	0.6
Greece	1	2	2		1	4						4			10	29	3.5
Hungary	3	1		2	3												1.6

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

Country	Imputability "likely, probable or certain" (level 2 or level 3)																Incidence high imputability serious adverse reactions per 100 000 component
	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	
Iceland					1												5.6
Ireland	0	3	0	0	47	0	0	0	0	0	0	0	0	0	13	13	40.8
Italy	4	3	3	2	416	3									16	11	14.1
Latvia					2												1.8
Liechtenstein																	
Lithuania					11	1										3	10.7
Luxembourg	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Malta	1														5		28.6
Moldova	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Montenegro																	
Netherlands	0	1	0	0	2	1	0	0	0	0	0	1	1	0	0	0	0.9
Norway	2	1	0	0	7	6	0		0	0	0	0	0	0	4	1	7.9
Poland																	
Portugal	7				78	2									14	486	194.5
Romania					1												0.1
Russian Federation																	
San Marino																	
Serbia	3				15							3			7	63	21.1

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

Country	Imputability "likely, probable or certain" (level 2 or level 3)																Incidence high imputability serious adverse reactions per 100 000 component
	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	
Slovakia																	
Slovenia																	
Spain	11	4			29	24	1								26		4.8
Sweden																	
Switzerland	1	1	0	1	20	2	0	0	0	0	0	0	0	0	6	146	44.7
Turkey																	
Ukraine																	
United Kingdom	2	28	4	2	0	1	0	0	0	0	0	0	0	0	31	0	2.5
Total	47	85	14	9	682	72	1	1	0	0	1	21	1	0	180	816	

Country	Comments
Greece	Other include 7 TAD, 10 Allergic, 10 NHFTR, 2 Unspecific.
Luxembourg	Regarding haemovigilance, we had, during 2011, any SARE.
Montenegro	In preparation.
Netherlands	Please note that the numbers correspond to the initial type of reaction; in a number of cases the final conclusion was that the reaction was not related to transfusion.
Norway	Other: serious hypotensive reaction.
Slovakia	Other serious adverse transfusion reaction: 345 fever; 58 nondefined.
United Kingdom	Imputability level and severity not analysed by SHOT data.

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