Department of Biological Standardisation
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Report on the collection, testing and use of blood and blood components in Europe in 2004

COUNCIL OF EUROPE
European Committee (Partial Agreement) on blood transfusion (CD-P-TS)

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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 of the Council of Europe (CoE). Data were supplied by member states in response to a questionnaire requesting details for the year 2004. In its present form, the report follows a series of similar reports that have assessed such data in 1989, 1991, 1993, 1995, 1997, 2001, 2002 and 2003.

A qualitative evaluation report of the earlier questionnaires that contained recommendations for improvement of the process was prepared and was published in November 2004. The 2004 format of the questionnaire was reviewed and improved upon by the authors and the Committee of Experts on Blood Transfusion (SP-GS).

All the relevant information was not obtained from the member states in 2004. Given the difficulties in data retrieval from automated blood banking systems, and collating data from the different blood establishments on a national level within the member states, the process is designed to improve through annual repetition. In fact it is noted in 2004 that the quality of the responses to the survey had improved and that respondents seemed to be more at ease with the filling in of the respective questionnaires. Furthermore, the critical review by the blood transfusion experts of the Council of Europe nework provided an important support.

In contrast to the 2001-2003 reports, the proportion of donations by voluntary non-remunerated and replacement donors is included in the questionnaire used for the present report. The European Commission (EC) has acknowledged the importance of this aspect in its Directive 2002/98/EC.

In addition, in 2004 two new items were included. Bacterial screening for platelet concentrates, previously performed on about 1% of the platelet concentrates for quality control purposes (*Guide to the preparation, use and quality assurance of blood components,* Council of Europe), was carried out in some countries for the screening of all platelets or all aphaeresis platelets. Bacterial contamination represents an important risk in the transfusion of platelets. Table 9 provides an insight into these data. The second new aspect is the addition of a paragraph and table 12 on haemovigilance data. As of 2006, haemovigilance reporting has become mandatory in the European Union (EU) member states (Directive 2005/61EC).

Data in the member states and in blood establishments may be provided in different formats and several definitions may be used. This could result in discrepancies when reporting the data in a different format. Some data may not be available at all. It is anticipated that consistency, improvement and persistence in the Council of Europe and the European Commission survey methods will result in better data reporting and higher response rates among member states, if the questionnaires are used annually. In order to facilitate uniformity, definitions of the EC Directives and CoE Guidelines are used insofar as possible (Council Recommendation 98/463/EC, Directive 2002/98/EC, *Guid*e, 2002 edition). Furthermore, the fact that EMEA uses the same definitions, especially for infectious disease epidemiology in donor populations (*Guideline on Epidemiological data on Blood Transmissible Infections for inclusion in the Guideline on the Scientific data requirements for a Plasma Master File*

EMEA/CPMP/BWP/3794/03) is a welcome factor. Uniformity of these definitions is of importance to the field and helps in circumventing unnecessary and costly repetitions in the collating of data.

In total, 33 questionnaires were received. The response rate was 73.3%. For the 2001, 2002 and 2003 surveys, the response rate was 86%, 60% and 64% respectively.

The average number of donors in relation to the general population is 25 per 1 000 inhabitants. On average, 23% of the donors are first-time donors.

The number of whole blood collections is, on average, 37 per 1 000 inhabitants and the average use of red blood cells is 37 per 1 000 inhabitants. On average four litres of plasmaphaeresis plasma per 1 000 inhabitants are collected and three member states stand out with 17- 45 litres of plasmaphaeresis plasma per 1 000 inhabitants.

The use of red blood cells varies considerably (range: 4-73) but averages 37 total red blood cell units per 1 000 inhabitants. In four (13%) of the reporting member states, an average below an arbitrary threshold of 20 units per 1 000 inhabitants is observed, most likely reflecting an insufficient supply. On average, in the reporting member states, 38% (35% in 2003) of the total platelet volume is supplied by (random) single donor platelets by aphaeresis; in nine countries (eight in 2003) this volume amounts to more than 50%.

The amount of plasma delivered for fractionation into medicinal products differs greatly (range 0-27) among the member states. An average yield of eight litres of plasma (nine in 2003) for fractionation per 1 000 inhabitants is found. However, six (21%) out of the 28 reporting member states deliver 15 litres or more per 1 000 inhabitants (20% in 2003). In Europe, on average 76% of the plasma for fractionation is from recovered plasma.

In 11 (34%) out of 32 member states, 100% leucodepletion of red blood cell products is carried out. Platelet concentrates are 100% leucodepleted in 14 (50%) out of 30 member states. In 12 (50%) of the 25 reporting member states, 100% of fresh frozen plasma (FFP) is additionally safeguarded either by quarantine or pathogen reduction methods.

In all 33 reporting member states, each donation is tested for anti-HIV-1/2, HBsAg and anti-HCV. In 28 (84%) of the states, all donations are tested for syphilis. Anti-HTLV-I/II testing is performed on all donations in seven (21%) of the reporting member states, and on first-time donors in four (12%). Anti-HBc is performed on all donations in five (15%) of the reporting states, and on first-time donors only in another five. The prevalence and incidence of infectious diseases vary greatly among member states, and a North-South gradient is noted for hepatitis B and C viruses. The present sets of data would suggest that confirmatory testing is not available or reported in all countries and that data may include false positive (screening) test results.

Nucleic Acid Testing (NAT) for HCV is performed on each donation in 17 (51%) of the 33 reporting states, whereas HIV NAT on each donation is performed in 11 (33%) and HBV NAT in four (12%). The NAT yield is given in Table 8.2.

Bacterial screening of platelet concentrates is a new set of data in this 2004 report. Data on haemovigilance have repeatedly shown the importance of bacterial safety of platelet concentrates. Data were provided by 18 member states and in two (11%) of the member states, 90-100% of the recovered platelet concentrates are bacterially screened. Aphaeresis platelet concentrates are 90-100% screened in three (17%) member states. The average rate of confirmed positively cultured platelet concentrates in 16 reporting member states was 0,25% (ranging from 0-1%), which is in line with what has been written. Some other member states reported to have a quality control (QC) programme in place for bacterial testing.

A National Council or Expert Committee to advise the Ministry of Health on transfusion-related policy issues has been set up in 28 (85%) of the 33 reporting member states (73% in 2003). Labelling according to ISBT-128 for the donation number is partially performed in seven countries and five (25%) countries have 100% ISBT-128 coding for the donations. ISBT-128 labelling of the components supplied is partially done in seven countries and four countries (20%) have 100% ISBT-128 coding at both the donation component levels.

In blood establishments of 28 (85%) of the reporting member states, a quality system has been established and maintained. In four (12%) countries the implementation of such a system is planned. In 17 (51%) of the reporting member states, 100% of the donations are covered by GMP. In three (9%) countries this is the case for ISO 9000. In 26 (78%) countries, inspections are performed at least every 2 years. In 21 of these countries such inspections are (partially) carried out by the national authority.

Haemovigilance reporting, that is to say reporting of serious adverse events, consists of a new set of data in the 2004 report. The format for data acquisition on haemovigilance in the 2004 Council of Europe questionnaire, in its original form, was developed by experts of the Council of Europe in co-operation with the European Commission, adapted and included in Directive 2005/61/EC. Reporting of serious adverse reactions as performed in haemovigilance programmes constitutes a high level of surveillance, as these reactions are not just unexpected untoward effects but well-known complications of blood transfusion. In this report only serious adverse reactions, which are probably or certainly ascribable to transfusion (imputability grade 2 to 3) and reactions such as Transfusion Associated Circulatory Overload (TACO) which are not caused by the blood component are reported (Table 12). When taking into account the possibility of under-reporting and the differences in national reporting systems, an average incidence is estimated at 1-20 serious adverse reactions per 100 000 distributed blood components. Hemolysis caused by other blood group incompatibilities than ABO, anaphylaxis, transfusion-related acute lung injury (TRALI) and TACO appears to stand out as the most frequent serious adverse reaction.

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STUDY METHODS

The methods used for this survey were, in principle, the same as those described for the 2001 survey. Nevertheless, a qualitative evaluation report on the questionnaire, with recommendations for improvement of the process, had previously been submitted by the authors to the Committee on Blood Transfusion and Immunohaematology (SP-HM) and discussed in November 2004. A revised version of the questionnaire containing additional questions was thereafter drafted for the 2004 survey. The Council of Europe Secretariat then circulated the questionnaire to the member states requesting that the completed forms be returned to the Secretariat by September 2005. The authors received the completed questionnaires up until October 2005. Following meetings with the SP-HM and the European Health Committee (CDSP), corrections and additions were suggested by member states and additional completed questionnaires were received up until August 2006.

The authors reviewed the data in the completed questionnaires that were submitted by the member states. Following this review and, in the case of incomplete or incomprehensible data, additional questions were asked and explanations requested. Non-response was attributed to lack of clarity or inconsistent questions, unfamiliarity with the query format, or adaptations that had to be made to computer data systems in blood establishments in order to allow retrieval of the exact data requested. During the evaluation process some of the data did not fulfil definitions and they were deleted. A preliminary report was prepared and submitted to the European Committee (Partial Agreement) on Blood Transfusion and this was finalised in October 2007.

Trend analysis and incomplete data

Comparison with the results of the previous surveys in the form of a trend analysis is foreseen. Not all information requested in the questionnaire is included in the tables but details where sufficient information is available to justify presentation are provided. Sometimes, totals in the tables may not precisely match the contributing figures because of rounding. It was assumed that information was not available when this was not provided. Empty fields in the tables represent non-availability of data.

Remarks to the data

Remarks added by the member states to the data are given in the footnotes of the tables.

RESULTS: TABLES AND COMMENTS

Response rate

All the member states (n=45) of the Council of Europe were invited to send in completed questionnaires. Replies were received on 1 September 2006 from 33 countries, the response rate being 73,3%. For the 2001, 2002 and 2003 surveys, the response rate was 86%, 60% and 64% respectively.

Donors, first- time donors and inhabitants - Table 1

The questionnaire requires data on donors "active during the year", and therefore should only include those donors who actually donated during the reporting year. However, the definition "donors active during the year" may require a precise query in a given donor database. Probably in many establishments or countries, the – often-standard - query format in the donor database would need to be changed. This may not always be possible in the short term. The authors therefore doubt that this query requirement was always met in generating the data for this survey. If such details were felt important for the future, the "inactive" number of donors (the number of donors in the databases who *did not* donate during the reporting year) would need to be reported as well. This definition problem however is 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 EC* (98/463/EC).

The terms "regular and repeat donors" are defined by the EC Council Recommendation (98/463/EC) and according to these definitions, regular donors are those donors whose last donation goes back to less than 2 years while for repeat donors the last donation would be more than 2 years. The total of the two categories represents those donors who are known to the system or establishment and in many countries form the basis of – the safety of - the blood supply. These data are needed for the calculation of the prevalence of infectious diseases among new donors and the incidence of infectious diseases among repeat and regular donors (Table 7). For EU member states, the reporting of the prevalence and incidence in these donor populations became mandatory in 2005 with Directive 2002/98/EC.

The term "first time donors" in this survey includes all donors who are actually tested for the first time or who donate for the first time. There are systems where "applicant donors" (98/463/EC) are only tested and come back for a first donation at a later stage. They are referred to as "qualified donors" only after the infectious disease tests done during the "applicant" donor examination prove negative. Including only "qualified donors" in the report will result in a bias in reporting infectious disease markers (Table 7). The term "new donors" in Council Recommendation 98/463/EC does not specify this and allows for 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 or donate for the first time. It is assumed that all "first-time donors" are actually tested, as is the practice in most countries.

It should be taken into account that “first-time donors” are already a selected population and therefore the prevalence of infectious disease markers in the general population of a given member state may be different. The number of first-time donors as compared to the total number of donors in general, reflects the annual donor recruitment or turnover rate in the donor base. It may however be influenced by recruitment programmes. The number of first-time donors as compared to the total number of donors becomes meaningless in systems that only register *donations* –and not so much the (*uniquely identifiable) donors*.

If the countries where first-time, repeat and regular donors, not reported separately, are excluded, 23% (range 6-65) of the total number of donors in the 33 reporting member states consists of "first-time" donors. It is known that in first-time donors the incidence of infectious diseases could be higher when compared to regular or repeat donors (Schreiber 2001).

The average number of donors in relation to the general population is 25 (range 2-53) per 1 000 inhabitants. This number may reflect the commitment of the population to donate blood in relation to the demand. Differences exist, but arbitrarily less than 10 donors per 1,000 inhabitants could pose a problem with the supply; from the given data, around 30 donors per 1,000 inhabitants would seem an achievable goal. Not all countries with a relatively high number of donors per 1,000 inhabitants deliver a high number of red blood cell units to the hospitals though (see Table 3), but in general these figures are correlated. As stated earlier, some caution as to the interpretation of the number of “active” donors seems justified; bias may occur by "inactive" donors in the database, but maintaining "inactive" donors may be a strategy to "re-activate" known donors.

Collection of whole blood, autologous blood and blood components - Table 2

Whole blood collections are the basis for blood supply in most countries, not only for the preparation of blood components but also for providing “recovered plasma” as source material for the manufacture of medicinal products (Table 3). The number of whole blood collections in 33 member states that responded is on average 37 (range 0.02-74) per 1 000 inhabitants. Given the average use of red blood cells of 37 per 1,000 inhabitants (Table 3), the number of whole blood collections appears either to meet the demand of red blood cell products or conversely the use in the hospitals is limited by supply.

Autologous donation has been promoted to ensure safe blood transfusions by limiting exposure to allogeneic blood for patients and to enhance the supply of blood. In general, enhancing supply does not appear to be important; in 27 countries where autologous donation is practised, it makes up for, on average, only 1% (range 0-5), of total blood donation and would confirm what has been written. However, it should be taken into account that surgery and anaesthesiology techniques such as pre-operative hemodilution and intra-operative blood salvage are not included in the data presented. In this survey only the pre-operative autologous blood donations (PABD) are taken into account.

Plasmaphaeresis collections provide source plasma, including plasma with specific antibodies for fractionation into medicinal products. In some countries, plasma for

transfusion (FFP) is also collected through aphaeresis donations. The volume of plasma collection by aphaeresis per 1 000 inhabitants, reflects the volume of the national plasmaphaeresis programmes. In 31 reporting member states on average 4 litres (range 0-45) of plasma per 1 000 inhabitants are collected by plasmaphaeresis. It appears that Germany, the Netherlands and Bulgaria stand out as above average with programmes of 17, 20 and 45 litres of plasmaphaeresis plasma per 1000 inhabitants per annum. Bulgaria apparently turns to remunerated donors (Table 1.1).

Platelet aphaeresis may be used as HLA or HPA typed donation for refractory patients, and to replace the provision of platelets from pooled whole blood donations by aphaeresis platelet in order to reduce donor exposure in patients. The relative importance of platelet aphaeresis for the total supply of platelet products is given in Table 3. In 32 member states that responded on average 38% (range 0-88) of the adult therapeutic doses of platelets are produced by aphaeresis. The extremes may reflect different models: little access to HLA typed platelet donors or countries striving for 100% platelet supply by aphaeresis.

Red blood cell aphaeresis is a relatively new development and may be of particular interest for autologous programmes and for the collection of rare types of red blood cells. It appears to be increasingly used for supply reasons.

Granulocyte aphaeresis donations are infrequent, as indications may be limited.

The relative contribution of voluntary non-remunerated donations to total supply is given in Table 1.1.

Use of blood and blood components for transfusion - Table 3

The term “the use of blood” may be somewhat misleading, as the reported data may not reflect the actual use of blood or blood components in the hospitals, but rather the number of blood components that have been delivered to hospitals by blood establishments. This depends on the source of the data and the national infrastructure. In many member states, data on the use in hospitals are generally difficult to obtain; however, in some countries such as Denmark, blood banks are hospital-based and the data are related to actual transfusions made. As product losses in hospitals – for example through outdating – are limited, the number of blood components delivered to hospitals may be viewed as a proxy to the use of blood and the heterogeneity of the given data may result in minor deviations.

Whole blood “must be considered as a source material and has no, or only a very restricted, place in transfusion therapy” (2001 *Guide*). However, in countries with limited resources such as Azerbaijan and Bosnia-Herzegovina, transfusion therapy with whole blood may be needed when the infrastructure for

blood component preparation is lacking. In 30 reporting countries, on average 5% (range 0-73) of the RBC transfusions are performed with whole blood. In three out of 30 (10%) of the reporting member states, the use of whole blood accounts for more than 10 percent of the total volume of red blood cell products.

The use of red blood cells per 1 000 inhabitants varies considerably. In 30 reporting member states it averages 37 total red blood cell products per 1 000 inhabitants (range 4-73). In his report on the 1997 survey, Rejman suggests that 40-60 whole blood donations per 1 000 inhabitants would be needed for optimal supply, a figure largely determined by the need for red blood cells for transfusion (Rejman 2000). Red blood cells 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 set up in order to reduce unnecessary donor exposure in patients. Therefore the use of red blood cells of between 30 and 40 RBC units per 1 000 inhabitants could reflect the results of these rationalisation programmes. In four (13%) out of the 30 reporting member states, under 20 units per 1000 inhabitants are used, most likely reflecting the insufficient supply of blood or limited hospital care. Including the number of hospital beds in a future survey and relating this to the red blood cell use may achieve a better benchmark.

Over the past decade the use of plasma for transfusion (FFP) has been discouraged mainly because its clinical indications are limited and more plasma is needed as source material for fractionation into medicinal products. However, in multiple coagulation disorders, including Thrombotic Thrombocytopenic Purpura (TTP), FFP transfusions are needed. In order to provide a benchmark, the use of plasma for transfusion can be related to the use of red blood cell transfusions (use of FFP/RBC ratio). It should be taken into account that in some countries owing to programmes for "better use of blood (and its components)", the decline of red blood cell use has increased the FFP/RBC ratio. On average, the FFP/RBC ratio is 0.39 (range 0.13–1.4).

In Europe, platelets are generally recovered from 4 to 5 buffy coats of whole blood donations. Discussions on blood safety in relation to variant Creutzfeldt-Jakob Disease (vCJD) later led to the setting up of programmes to enhance the use of random single-donor platelets by aphaeresis in order to reduce donor exposure in recipients. These programmes may have been influential in some member states where the use of aphaeresis platelets in relation to recovered platelets is relatively high. The extent to which donors are willing to undergo aphaeresis may be limited, as no supply ever reaches 100% aphaeresis platelets. On average, in 32 reporting member states, 38% (range 0-88) of the adult therapeutic doses of platelets are produced by (random) single donor platelets by aphaeresis (Table 3).

Cryoprecipitate may occasionally be used for fibrinogen, Von Willebrand’s disease and complex coagulation disorders. The use of this product has been abandoned in most member states.

Blood components delivered for manufacture of medicinal products - Table 4

The total amount of plasma used for fractionation into medicinal products differs from one country to another. This becomes more clear if the figure is related to the population size. In 28 reporting member states an average yield of 8 (range 0-27) litres of plasma per 1 000 inhabitants is used for fractionation into medicinal products. However, in six (21%) of these countries, the figure is 15 or more litres (average + Standard Deviation (SD)) of plasma per 1 000 inhabitants (Table 4).

In Europe, the main supply of plasma for fractionation is from recovered plasma and this is the case for an average of 76% of the plasma for fractionation (range 18-100%) (Table 4) in 18 reporting member states.

Apart from a query on the total yield of plasma for fractionation, the questionnaire encompasses two specific questions on plasma delivered for FVIII production *versus* plasma for fractionation. Respondents poorly understand these specific questions.

Special processing of blood components - Tables 5.1 and 5.2

In 11 out of 32 (34%) reporting member states, 100% leucodepletion of red blood cell products is carried out. This is the case for platelet concentrates in 14 out of 30 (50%) states. One hundred percent leucodepletion is practiced for plasma for transfusion in 10 states.

Irradiation of blood components is carried out in order to prevent Graft versus Host Disease (GvHD). As a rule this is relevant for blood components that may carry residual leukocytes and for a selected group of recipients only. The number of units may reflect the degree of extensive clinical care; however in many instances irradiation is carried out in hospitals, where it generally appears more difficult to obtain data.

Fresh frozen plasma for transfusion (FFP), cryosupernatant plasma (CSP) and cryoprecipitate (CP) may be additionally safeguarded against infectious diseases. One method is a quarantine step - for example, the plasma is stored and only released if the donor is negative for infectious disease markers (IDM) on a subsequent donation four to six months later. Another method is the application of “virus inactivation” or “pathogen reduction” by Solvent Detergent (SD) or Methylene Blue (MB) treatment. In 12 of the 25 (50%) states reporting, 100% of FFP is safeguarded by either one or the other of the methods, in four member states, 100% by the quarantine method and in three by 100% pathogen reduction.

Screening for infectious agents by serological test methods - Table 6

In all 33 reporting member states, all donations are tested for anti-HIV-1/2, HBsAg and anti-HCV. In 28 countries (84%) the donations are tested for syphilis. It is debated in literature whether syphilis testing is necessary. In Germany, Sweden and Norway only new donors are tested for syphilis whilst in Denmark and Iceland syphilis testing is not performed at all.

Testing for anti-HTLV-I/II is performed on all donations in seven (21%) of the reporting states and on first-time donors only in four (12%) of the 33 countries.

For anti-HBc, testing is done on all donations in five (15%) states and on first-time donors in five other countries. This is a slight increase as compared to 2003. Testing by NAT is reported separately in Table 8.

Confirmed seropositive test results - Tables 7.1 and 7.2

In general, donors who are found positive in blood screening for infectious disease markers need to be "confirmed" with another technique to diagnose infection, given the limited positive predictive value of serological screening tests. Confirmed positive donors are then notified and deferred from further donations. A most common flow-chart for confirmation is given in EC Recommendation 98/463/EC.

In Table 7.1, the absolute numbers are given of "confirmed positive" donors as reported for all first-time donors tested and for all repeat and regular donors (Table 1). Overall, 31 of 33 (93%) member states were able to provide the absolute numbers of confirmed positive donors as specified (Table 7.1).

The frequency of "confirmed positive" donors among all first-time donors tested (Table 1) yields the "prevalence" of an infectious disease marker (IDM) among first-time donors. This reflects the characteristics of the population where the first-time donors are recruited. It should be noted that the general population might have different rates of infectious diseases than blood donors. Even on their first visit, blood donors are a selected population. The "prevalence" of infectious diseases among first-time donors was calculated using Table 7.1 (number of confirmed positive donors) and Table 1 (number of first-time donors) and the ratio is given in Table 7.2. The prevalence per 100 000 first-time tested donors, if calculated from the provided data sets, ranges from 0 to 500 for HIV-1/2, from 0 to 21 000 for HBV and from 11 to 9 000 for HCV. Although considerable differences in geographical spread of these infections in Europe exist, it is doubted whether the extreme high frequencies of some countries reflect reliable data sets on indeed "confirmed positive donors" or merely refer to only screening test (ELISA) on repeat positive donors thus including many false positives. The geographical spread of the high prevalence areas may coincide with low resources and lack of confirmatory testing.

The frequency of "confirmed positive" donors among all repeat and regular donors tested yields the "incidence" of an infectious disease among repeat and regular donors (for example, donors who had been tested before and had been found negative were allowed to donate again). The "incidence" accounts for the frequency with which repeat and regular donors acquire a new infection. It is this frequency that directly relates to blood safety via the window period of infectious disease testing (Schreiber 1996, *Guideline on Epidemiological data* EMEA/CPMP/BWP/3794/03). The incidence of infectious diseases among repeat and regular donors was calculated using Table 7.1 (number of confirmed positive donors) and Table 1 (number of repeat and regular donors), and is given in Table 7.2. As with the prevalence data in first-time donors, the extreme high incidences may refer to only screening test (ELISA) on repeat positive donors instead of confirmed positive donors thus including many false

positives. The geographical spread of the high incidence areas coincides with high prevalence areas and may be linked to low resources and lack of confirmatory testing.

Notwithstanding the limitations of the data and the question as to whether or not all the screening tests of positive donors were submitted to confirmatory testing, the prevalence and incidence rates of infectious diseases vary greatly among member states. Overall, it is to be noted that in Europe a north-south gradient exists. Hepatitis B virus and hepatitis C virus infections are more common in the southern countries. The incidence per 100 000 tested repeat donors, if calculated from the provided data sets, ranges from 0 to 86 for HIV-1/2, from 0 to 596 for HBV and from 0 to 293 for HCV. Although considerable differences in geographical spread of these infections in Europe exist, it is doubted whether the very high frequencies of some countries reflect reliable data sets or merely refer to only the screening test (ELISA) of positive donors (including many false positives) as opposed to "confirmed positive donors".

Nucleic Acid Testing (NAT) - Tables 8.1 and 8.2

Nucleic Acid Testing (NAT) for HCV is performed on each donation in 17 of the 33 (51%) reporting member states. NAT for HIV is performed on each donation in 11 (33%) states. NAT for HBV is performed on each donation in four (12%) countries. Interestingly, NAT on each donation appears to be performed more often in member states where the incidence rates are relatively low (see Table 7.2 for comparison). As the effectiveness (or “yield”) of NAT testing relates to the incidence, an argument could be found in applying NAT testing preferably in high incidence areas. Unfortunately, these areas are the ones with limited resources.

The "yield" of NAT is defined as the finding of a NAT-positive donor who is not found seropositive for the virus in the serological screening on the same donation but is shown later to be confirmed positive by a separate NAT (individual NAT) on the same sample or confirmed by a further serology test. 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 was added in the 2004 report - bacterial screening of platelet concentrates. Haemovigilance data have repeatedly reported the importance of bacterial safety of platelet concentrates. This is due to the fact that the storage temperature of platelets is around 22^{o}C, thus allowing bacterial growth more easily. Data on bacterial testing were reported by 18 member states. In two of these (11%), 90-100% of platelet concentrates recovered from whole blood donations are bacterially screened; in 13 others this is performed on 3-50% of recovered platelet concentrates. Aphaeresis platelet concentrates are 90-100% screened for bacteria in three (17%) of the reporting member states.

Overall, more than 10% of platelet concentrates are bacterially screened in 11 out of 18 (61%) of the reporting states. This suggests that in these 11 states, blood establishments are gradually expanding their bacterial testing programme from a quality control (QC) level (testing of 1% of concentrates) to a higher level even though it may not be the case in all the establishments of the country. Among 16

reporting member states, the average rate of confirmed positively cultured platelet concentrates was 0.25% (ranging from 0-1%), which concurs with what has been written. The other member states reported to have QC programmes for bacterial testing in place.

Organisation, registration and labelling - Table 10

In 28 of the 33 (85%) reporting member states, a national council or expert committee to advise the Ministry of Health on transfusion related policy issues has been set up.

It is requested that the labelling of donations and of resulting components be one and the same so as to allow full traceability. Labelling according to ISBT-128 for the donation number is partially performed in seven countries and five countries (25%) have 100% ISBT-128 code for the donations. Labelling of the finished component is more complex and in general behind in terms of development in donation labelling as it includes implementation of automation applications in hospitals. ISBT-128 labelling of the issued component is partially implemented in seven countries and four countries (20%) have 100% ISBT-128 coding of the donation and of the component level. There are other systems of automated labelling and these are summarised in Table 10 and specified at the bottom of the table.

Quality management related issues - Table 11

In 28 out of the 33 reporting Member States (85%) a quality system is in place and maintained in blood establishments. In four countries (12%), the setting up of such a system is planned.

In 17 countries (51%), 100% of the donations are covered by GMP. In three others (9%) this is the case for ISO 9000. In five, a different quality system is used with 100% coverage of the donations. In 26 member states (78%) inspections are performed at least every 2 years, in 21 of which these inspections are (partially) carried out by the national authority.

In 27 states (81%) a haemovigilance system is in place and in 17 out of the 33 (51%), haemovigilance systems are organised by, or in co-operation with, the national authority.

Haemovigilance - Table 12

A new data set was added for the 2004 report - haemovigilance reporting – (for example, reporting of serious adverse events). The format for data acquisition on haemovigilance in the 2004 Council of Europe questionnaire, in its original form, was developed by experts of the Council of Europe in co-operation with the European Commission, adapted and included in Directive 2005/61/EC which came into force in August 2006. 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 in 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 to transfusion, even if most likely related to the transfusion, may be restricted to a given recipient. Therefore, in this report only serious adverse reactions that are probably or certainly (imputability grade 2 to 3) related to the transfusion of a blood component are presented. The term imputability includes not only the causal relationship to the product properties but also to the transfusion itself (TACO) or to the recipient's condition (for example, allergy).

In contrast to the EC Directives 2002/98/EC and 2005/61/EC, this surveillance also reports haemovigilance data which may not be caused by blood component properties, such as TACO.

Haemovigilance data submitted by 20 member states are presented in Table 12.

The incidence of serious adverse reactions with high imputability (level 2 to 3, that is, "likely" or "certain") in relation to the total number of blood products (whole blood + red blood cells + plasma + platelets) issued (or transfused) can be calculated. As this is the first year for such reporting, the data should be regarded with some restraint. Taking into account the possibility of under reporting and the differences in national reporting systems, an average incidence of 1-20 per 100 000 distributed blood components seems a reasonable estimate. Hemolysis due to blood group incompatibilities other than ABO blood types, anaphylaxis, TRALI and TACO appear to stand out as the most frequent serious adverse reactions.

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Table 1

2004

Donors, first time donors and inhabitants

country	regular and repeat donors	first time donors	% first time donors	total donors	inhabitants x 1,000	donors per 1,000 inhabitants
Andorra						
Armenia						
Azerbaijan	10 419	8 665	45,4	19 084	8 000	2,4
Albania						
Austria	265 615	93 717	26,1	359 332	8 090	44,4
Belgium	261 519	54 512	17,2	316 031	10 289	30,7
Bosnia / Herzegovina	37 305	12 525	25,1	49 830	3 843	13,0
Bulgaria	120 961	31 852	20,8	152 813	7 840	19,5
Croatia	75 848	15 583	17,0	91 431	4 437	20,6
Cyprus						
Czech Republic	349 300	29 300	7,7	378 600	10 300	36,8
Denmark	233 975	25 000	9,7	258 975	5 100	50,8
Estonia						
Former Yug. Rep. Macedonia						
Finland	142 660	16 858	54,2	159 518	5 220	30,6
France					62 371	
Georgia	7 000	1 000	12,5	8 000	5 000	1,6
Germany	2 301 703	518 636	18,4	2 820 339	82 501	34,2 1)
Greece	318 031	41 591	11,6	359 622	10 500	34,2
Hungary	311 050	66 472	17,6	377 522	10 142	37,2
Iceland	7 241	2 343	24,4	9 584	294	32,6
Ireland	98 722	17 630	15,2	116 352	3 917	29,7
Italy	122 400	223 000	64,6	345 400	57 000	6,1
Latvia	33 690	12 308	26,8	45 998	2 300	20,0
Liechtenstein						
Lithuania	24 578	15 155	38,1	39 733	3 500	11,4
Luxembourg	12 512	801	6,0	13 313	440	30,3
Malta		8 615			400	
Moldovia	40 646	14 972	26,9	55 618	3 386	16,4
Netherlands	468 540	34 004	6,8	502 544	16 292	30,8
Norway	93 431	14 744	13,6	108 175	4 606	23,5
Poland	241 693	182 488	43,0	424 181	38 600	11,0
Portugal						
Romania	140 300	81 184	36,7	221 484	21 800	10,2
Russian Federation	2 031 747	746 403	26,9	2 778 150	140 000	19,8
San Marino						
Serbia and Montenegro						
Slovak Republic	121 926	22 668	15,7	144 594	5 300	27,3
Slovenia	94 935	9 222	8,9	104 157	1 964	53,0
Spain	741 401	323 544	30,4	1 064 945	40 904	26,0
Sweden	244 770	32 935	11,9	277 705	9 009	30,8
Switzerland	215 600	26 559	11,0	242 159	7 360	32,9
Turkey						
Ukraine						
United Kingdom	1 346 587	288 122	17,6	1 634 709	58 800	27,8

1) Number of regular and repeat donors by extrapolation

Table 1.1
2004

Profile of donations

country	whole blood donations			red cell apheresis		plasmapheresis donations	platelet apheresis	
	% voluntary, non-remunerated	% from replacement donors	% from autologous donors	% voluntary, non-remunerated	% from autologous donors	% voluntary, non-remunerated	% voluntary, non-remunerated	
Andorra								
Armenia								
Azerbaijan			0,00					
Albania								
Austria	100	0	0,68	100	213		100	
Belgium	100	0	0,34	100	0	100	100	
Bosnia / Herzegovina	47	2	0,03		100		100	
Bulgaria	96	65	0,02			0	0	
Croatia	100	0	0,72			8	100	
Cyprus								
Czech Republic	99	0	4,13	32	0	82	32	
Denmark	100					100	100	
Estonia								
Former Yug. Rep. Macedonia								
Finland	100	0	0,00			100	100	
France	100	0	2,34	100	400	0	100	
Georgia	1	17	0,00			0	0	
Germany			0,10		21			
Greece	47	53	0,73	35	0	39	30	
Hungary	100					34	100	
Iceland	100	0	0,02	0			100	
Ireland	100		0,01	100			100	
Italy	100	3	5,33			100	100	1)
Latvia	98	0	0,00					
Liechtenstein								
Lithuania	11	3					9	
Luxembourg	100	0	1,73			100	100	
Malta	100			100	0		100	
Moldovia	97	3	0,26			61		
Netherlands	100	0	0,07			100	100	
Norway	100	0	0,02	100	0	100	100	
Poland	100		0,27			94	78	2)
Portugal								
Romania	100	0		0		100	100	
Russian Federation	84							
San Marino								
Serbia and Montenegro								
Slovak Republic	1	1	1,30			100	1	
Slovenia	100	0	2,34	0		100	100	
Spain	100		1,56	100	258	100	100	
Sweden	100	0	0,09	100	0	100	0	
Switzerland	100	0	4,24	100		2	100	
Turkey								
Ukraine								
United Kingdom	100	0	0,02	100	0	10	100	

1) 27000 platelet / plasma combined apheresis

2) Hyper-immune plasma from paid donors

Table 2

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

2004	whole blood collections				apheresis collections					
country	whole blood units	whole blood per 1,000 inhabitants	autologous units	% autologous whole blood units	plasma apheresis (L)	plasma in L per 1,000 inhabitants	platelets apheresis (U)	RBC apheresis (U)	granulocytes apheresis (U)	
Andorra										
Armenia										
Azerbaijan	20 874	2,6	0	0,0	1 014	0,13	176	7 480		
Albania										
Austria	495 994	61,3	3 390	0,7	80	0,01	15 887	3 209	69	
Belgium	503 228	48,9	1 698	0,3	94 323	9,17	31 075	2 745	13	
Bosnia / Herzegovina	37 396	9,7	10	0,0	0	0,00	500	10	6	
Bulgaria	152 839	19,5	26	0,0	356 150	45,43	349	0	0	
Croatia	156 705	35,3	1 131	0,7	4 218	0,95	1 491	0	0	
Cyprus										
Czech Republic	433 500	42,1	17 900	4,0	54 200	5,26	15 000	2 000	24	
Denmark	375 469	73,6			1 084	0,21	279		0	
Estonia										
Former Yug. Rep. Macedonia										
Finland	282 753	54,2	0	0,0	1 415	0,27	682	0	0	
France	2 113 676	33,9	49 374	2,3	139 822	2,24	167 321	2 384	181	
Georgia	29 000	5,8	0	0,0	5 000	1,00	100	0	0	
Germany	4 714 955	57,2	4 940	0,1	1 448 004	17,55	242 542	12 035		
Greece	617 462	58,8	4 502	0,7	1 102	0,10	23 197	4 880	<20	
Hungary	505 344	49,8			295	0,03	5 237		21	
Iceland	14 989	51,0	3	0,0	0	0,00	337	0	0	
Ireland	152 361	38,9	20	0,0			6 134	14		
Italy	2 270 000	39,8	121 000	5,1	186 000	3,26	63 000		396	1)
Latvia	54 609	23,7	0	0,0	10 533	4,58	1 526	0		
Liechtenstein										
Lithuania	84 233	24,1			0	0,00	637	7	0	
Luxembourg	21 017	47,8	363	1,7	2 923	6,64	990	0	0	
Malta	15 300	38,3					264	15 036		
Moldovia	60 155	17,8	157	0,3	991	0,29	0	0	0	
Netherlands	635 298	39,0	416	0,1	339 032	20,81	2 729			
Norway	201 229	43,7	33	0,0	2 376	0,52	4 307	4 782	0	
Poland	913 929	23,7	2 452	0,3	20 962	0,54	23 861	0	105	
Portugal										
Romania	364 215	16,7			182	0,01	553	0	0	
Russian Federation	2 774	0,0			295 396	2,11				
San Marino										
Serbia and Montenegro										
Slovak Republic	138 072	26,1	1 800	1,3	4	0,00	2 830	0	1	
Slovenia	84 962	43,3	1 986	2,3	272	0,14	869	0	3	
Spain	1 564 569	38,2	24 390	1,5	13 500	0,33	31 119	9 446	14	
Sweden	471 696	52,4	401	0,1	68 080	7,56	8 260	543	77	
Switzerland	377 288	51,3	16 000	4,1	4 600	0,63	14 000	910	0	2,3)
Turkey										
Ukraine										
United Kingdom	2 601 488	44,2	558	0,0	970	0,02	67 047	1 270	126	

1) 27000 platelet / plasma combined apheresis

2) 901 RBC collected in combined apheresis procedures

3) 19800 platelet concentrates collected with approx 14000 procedures

Table 3
2004

Use of blood and blood components for transfusion

country	whole blood (U)	% whole blood of total RBCs	red blood cell concentrates (U)	r.b.c. (U) per 1,000 inhabitants	plasma for transfusion (U)	platelets total (U)	platelets recovered (U)	platelets apheresis (U)	% platelets by apheresis	cryoprecipitate (10^6 IU FVIII)	
Andorra											
Armenia											
Azerbaijan	20 698	73,5	28 178	3,5	6 853	176	44	132	75,0	0	
Albania											
Austria	0	0,0	464 041	57,4	92 468	25 600	9 027	16 573	64,7	0	
Belgium	82	0,0	517 214	50,3	103 158	59 803	32 432	27 371	45,8	0	
Bosnia / Herzegovina	13 290	36,9	36 015	9,4	12 361	2 539	1 302	1 237	48,7		
Bulgaria	3 846	2,8	139 753	17,8	93 534	5 595	5 250	345	6,2	0	
Croatia	3 785	2,4	155 859	35,1	96 669	12 137	10 683	1 454	12,0	0	
Cyprus											
Czech Republic	1 200	0,4	327 700	31,8	179 600	24 400	5 200	19 200	78,7		
Denmark	150	0,0	371 694	72,9	57 050	32 484	31 784	700	2,2	0	
Estonia											
Former Yug. Rep. Macedonia											
Finland	695	0,3	254 996	48,8	39 855	32 224	31 662	562	1,7	0	1)
France	0	0,0	2 043 426	32,8	270 777	209 045	25 711	183 334	87,7	0	
Georgia	1 000	3,3	30 000	6,0	28 000	2 000	1 500	500	25,0	0	
Germany	11 824	0,3	4 490 776	54,4	1 374 986	373 538	141 421	232 117	62,1	0	
Greece	920	0,1	622 150	59,3	234 842	166 477	143 531	22 946	13,8	0	2)
Hungary	10	0,0	412 793	40,7	93 268	14 520	9 276	5 244	36,1	0	
Iceland	0	0,0	14 839	50,5	4 306	933	388	545	58,4	0	
Ireland	0	0,0	136 250	34,8	26 937	17 598	9 493	8 105	46,1	0	
Italy	25 000	1,1	2 361 000	41,4	546 000	123 000	61 000	62 000	50,4	3 900	3)
Latvia	0	0,0	50 488	22,0	47 942	3 819	830	2 989	78,3	1 900	
Liechtenstein											
Lithuania	12		80 990		27 420	14 664	13 420	1 244	8,5	1 639	
Luxembourg	0	0,0	20 212	45,9	4 063	2 125	1 204	921	43,3	0	
Malta	0	0,0	15 036	37,6	15 036	15 300	15 036	264	1,7	766	
Moldovia	37	0,2	21 357	6,3	29 297	293	293	0	0,0	2 142	
Netherlands	252	0,0	595 506	36,6	92 269	52 685	48 003	4 682	8,9	0	
Norway	154	0,1	191 431	41,6	39 706	16 007	8 318	7 689	48,0	0	4)
Poland	167	0,0	890 715	23,1	365 439	50 212	24 685	25 527	50,8	1	
Portugal											
Romania	140 896		354 576			59 267	58 727	540	0,9	18 246	
Russian Federation								221 376		29	
San Marino											
Serbia and Montenegro											
Slovak Republic	24 809	13,5	183 341	34,6	50 236	8 454	4 681	3 773	44,6	0	
Slovenia	0	0,0	79 616	40,5	32 988	25 680	24 286	1 394	5,4	0	
Spain	1 163	0,1	1 426 762	34,9	261 800	119 311	77 831	41 480	34,8	6 248	
Sweden	88	0,0	454 920	50,5	114 180	35 121	20 789	14 332	40,8	0	
Switzerland	4 850	1,6	310 629	42,2	66 309	18 509	2 408	16 101	87,0	0	
Turkey											
Ukraine											
United Kingdom	1 087	0,0	2 435 312	41,4	351 746	261 317	148 759	112 558	43,1	7	

1) reconstituted whole blood for pediatric use cc components dropped out f.i. invalid temperature during transort not include 2804 doses of Octaplas by pharmaceutic dept not included
2) 26200 RBC concentrates imported from Swis Red Cross. Extra Extra plasma stocked in 2004 for Olympic Games
3) Whole blood units are distributed for further preparation
4) Plasma for transfusion is SD plasma

Table 4

2004

Plasma for fractionation into medicinal products

country	plasma for fractionation (L)	plasma for fractionation per 1,000 inhabitants (L)	% fractionation plasma recovered	plasma for transfusion per 1,000 inhabitants (U)	plasma for transfusion / total red blood cell ratio (U)	
Andorra						
Armenia						
Azerbaijan	0	0,00		0,86	0,24	
Albania						
Austria	61 403	7,59	108,59	11,43	0,20	
Belgium	228 587	22,22	53,65	10,03	0,20	
Bosnia / Herzegovina	0	0,00		3,22	0,34	
Bulgaria	11 796	1,50	100,00	11,93	0,67	
Croatia	16 356	3,69	76,17	21,79	0,62	
Cyprus						
Czech Republic	78 100	7,58	55,70	17,44	0,55	
Denmark	82 434	16,16	99,00	11,19	0,15	
Estonia						
Former Yug. Rep. Macedonia						
Finland	44 782	8,58	100,00	7,64	0,16	
France	601 633	9,65	82,47	4,34	0,13	
Georgia	1 000	0,20	100,00	5,60	0,93	
Germany	2 232 294	27,06	43,17	16,67	0,31	
Greece	19 693	1,88	94,40	22,37	0,38	
Hungary				9,20	0,23	1)
Iceland	0	0,00		14,65	0,29	
Ireland	0	0,00		6,88	0,20	
Italy				9,58	0,23	
Latvia	14 577	6,34	34,86	20,84	0,95	
Liechtenstein						
Lithuania	19 861	5,67	100,00	7,83		
Luxembourg	6 767	15,38	72,22	9,23	0,20	
Malta				37,59	1,00	2)
Moldovia	5 571	1,65	74,04	8,65	1,37	
Netherlands	310 857	19,08	57,77	5,66	0,15	
Norway	49 036	10,65	76,80	8,62	0,21	3)
Poland	143 995	3,73	79,29	9,47	0,41	
Portugal						
Romania						
Russian Federation	183 012	1,31				
San Marino						
Serbia and Montenegro						
Slovak Republic	15 237	2,87	99,87	9,48	0,27	
Slovenia	10 500	5,35	97,41	16,80	0,41	
Spain	270 975	6,62		6,40	0,18	
Sweden	157 941	17,53	58,52	12,67	0,25	
Switzerland	92 362	12,55	26,36	9,01	0,21	
Turkey						
Ukraine						
United Kingdom				5,98	0,14	

1) Fractionation performed outside Hungary

2) Plasma not used for fractionation

3) 9000 litres of plasma used for manufacture of SD plasma

Table 5.1
2004

Special processing of blood components

country	red blood cells		plasma for transfusion		platelets		
	leuco depleted %	irradiated %	leuco depleted %	irradiated %	leuco depleted %	irradiated %	
Andorra							
Armenia							
Azerbaijan	7	0	0	0	0	0	
Albania							
Austria	100	7	100	4	100	35	
Belgium	45	1	100	0	100	3	1)
Bosnia / Herzegovina	20	2	20	5	60	20	
Bulgaria	6					1	
Croatia	6				29		
Cyprus							
Czech Republic	13	12	0		65	65	2)
Denmark	17				94		
Estonia							
Former Yug. Rep. Macedonia							
Finland	100	2	100	0	100	25	3)
France	100	7	100	0	100	43	
Georgia	5	0	0	0	0	0	
Germany	100	3			100	30	
Greece	35	10	23	8		12	4)
Hungary	6	1	0	3	34	35	
Iceland	16	4	0	2	100	57	
Ireland	100	7	100	0	100	93	5)
Italy	28	7	8	0	55	29	
Latvia	65	1	73		100	10	
Liechtenstein							
Lithuania	2	1	0	2	9	9	
Luxembourg	100	2	100	0	100	2	
Malta	100	1	100	0	100	1	
Moldovia							
Netherlands	100	2	100	0	100	26	
Norway	100	6		0	100	38	
Poland	9	4	0	0	36	37	
Portugal							
Romania	4	1	0	0	0	1	
Russian Federation							
San Marino							
Serbia and Montenegro							
Slovak Republic	14	25	14	0	66	35	
Slovenia	17	5	30	0	48	10	
Spain	92		74		90		
Sweden	64	3			85	40	
Switzerland	100		100		100		6)
Turkey							
Ukraine							
United Kingdom	100	6	100	0	100	44	

1) Most irradiation in hospitals, no data
2) RBC and platelets partiallly bedside filtration
3) Non leukodepleted RBC for kidney transplant protocol
4) Apheresis platelets 100% leukocyte depleted
5) 99% of plasma is SD treated
6) Irradiation in hospitals, no data

Table 5.2

2004

Inactivation or quarantine of plasma

country	fresh frozen plasma		cryoprecipitate reduced plasma		cyroprecipitate		
	quarantined %	virus inactivated %	quarantined %	virus inactivated %	quarantined %	virus inactivated %	
Andorra							
Armenia							
Azerbaijan	0	0	0	0	0	0	
Albania							
Austria							
Belgium	0	100					
Bosnia / Herzegovina	0	0	0	0	0	0	
Bulgaria							
Croatia							
Cyprus							
Czech Republic	100	0	100	0			
Denmark	0						
Estonia							
Former Yug. Rep. Macedonia							
Finland	1	0	0	0			1)
France	62	38					
Georgia	0	0	0	0	0	0	
Germany	89	11					2)
Greece							
Hungary	0	0	0	0	0	0	
Iceland	0	0	0	0	0	0	
Ireland	0	92	0	0	0	0	
Italy							
Latvia	65						
Liechtenstein							
Lithuania							3)
Luxembourg	0	100					
Malta	100	0	100	0	100	0	
Moldovia							
Netherlands	100	0					
Norway	0	100					
Poland	80	0	100	0	96	0	
Portugal							
Romania	100	0	100	0	100	0	
Russian Federation							
San Marino							
Serbia and Montenegro							
Slovak Republic	42	0	1	0	1	0	
Slovenia	5	0	0	0	0	0	
Spain	42	58					
Sweden	0	0					4)
Switzerland	85	15					
Turkey							
Ukraine							
United Kingdom	0	3	0	1	0	1	

1) Quarantined FFP for pediatric use

2) Data on plasma manufactured in Germany, SD plasma not included

3) Plasma quarantined since December 2004

4) Plasma for transfusion mostly recoverd from leukoreduced whole blood

Cryo reduced plasma only in some TPE settings

Table 6
2004

country	Screening for infectious agents, methods																	
	anti-HIV 1+2		HIVAg		HBsAg		Anti-HBc		anti-HCV		HCVAg		anti-HTLV I/II		Syphilis		Other tests	
	each donation	1st time donors	each donation	1st time donors	each donation	1st time donors	each donation	1st time donors	each donation	1st time donors	each donation	1st time donors	each donation	1st time donors	each donation	1st time donors	each donation	1st time donors
Andorra																		
Armenia																		
Azerbaijan	1				1				1						1			
Albania																		
Austria	1				1				1						1		neopterin, ALT	
Belgium	1				1			1	1		1				1			1)
Bosnia / Herzegovina	1		1		1				1						1			
Bulgaria	1		1		1				1						1			
Croatia	1				1				1						1			
Cyprus																		
Czech Republic	1		1		1				1						1			2)
Denmark	1				1				1					1				
Estonia																		
Former Yug. Rep. Macedonia																		
Finland	1				1				1					1	1			3)
France	1				1		1		1				1		1			4)
Georgia	1				1				1						1			
Germany	1				1				1							1		5)
Greece	1				1				1				1		1			
Hungary	1				1			1	1						1			
Iceland	1		1		1				1									6)
Ireland	1				1		1		1				1		1			
Italy	1				1				1						1		1	7)
Latvia	1				1				1						1			8)
Liechtenstein																		
Lithuania	1				1				1						1			
Luxembourg	1		1		1			1	1				1		1		1	9)
Malta	1				1		1		1						1		1	10)
Moldovia	1		1		1		1		1		1				1			11)
Netherlands	1				1				1				1		1			
Norway	1				1			1	1					1		1		12)
Poland	1				1				1						1			13)
Portugal																		
Romania	1		1		1				1				1		1			14)
Russian Federation	1		1		1				1						1			15)
San Marino																		
Serbia and Montenegro																		
Slovak Republic	1				1				1						1			
Slovenia	1				1				1						1			
Spain	1				1				1						1			
Sweden	1				1			1	1					1		1		16)
Switzerland	1				1		1		1						1		1	17)
Turkey																		
Ukraine																		
United Kingdom	1		1		1				1				1		1			

1) HIV Ag on 0,5% of donations anti-HBc on 5,8% of donations anti-HTLV on 0,5% of donations
2) Combined HIV Ab and Ag test
3) Repeat donors re-screened every 3 years
4) Anti-malaria conform 2004/33/EC, a-CMV individually
5) Syphilis not required for plasma for fractionation
6) + 11) + 14) HIV Ab / Ag combitest
7) + 10) + 15) ALT on each donation
8) CMV IgM on apheresis platelets and pediatric components
9) HIV Ab / Ag combitest Full blood count on each donation

Table 7.1
2004

Confirmed seropositive donors (absolute numbers)

country	HIV 1 /2		HBV		HCV		HTLV-I/II		syphilis		
	first time donor	repeat donor	first time donor	repeat donor	first time donor	repeat donor	first time donor	repeat donor	first time donor	repeat donor	
Andorra											
Armenia											
Azerbaijan	9	9	191	3	369	5				8	
Albania											
Austria	2	4	76	11	51	16			34	19	
Belgium	1	2	70	8	27	4			11	6	
Bosnia / Herzegovina	0	0	27	17	11	4			5	1	1)
Bulgaria	6	0	2783	8	656	4			785	2	
Croatia	1	3	27	7	7	26			2	16	
Cyprus											
Czech Republic	1	1	24	52	30	35			17	70	2)
Denmark	1	2	9	1	8	1	0	0			
Estonia											
Former Yug. Rep. Macedonia											
Finland	0	0	4	0	5	5	0	0	1	0	
France	15	20	408	4	221	28	43	4	144	42	
Georgia	5	3	210	41	90	6			120	3	
Germany	25	52	812	35	443	75			188	117	
Greece	48	15	1291	364	361	133	1	1	37	8	
Hungary	1	2		9		255				123	
Iceland	0	0	0	0	1	0					
Ireland	1	0	2	1	5	1	0	0	1	4	
Italy	36	33	1049	43	661	53			328	244	
Latvia	7	1									
Liechtenstein											
Lithuania	2	0	284	16	309	72			136	65	
Luxembourg	1	0	2	0	1	0	0	0	0	0	
Malta	0	0	12	0	3	0			0	0	
Moldovia											
Netherlands	0	4	23	6	12	3	2	1	19	17	
Norway	0	0	3	1	5	0	1	0	0	3	
Poland	15	2	1189	43	1199	170			110	76	
Portugal											
Romania	22	6	3563	224	1038	179	38	2	1454	590	
Russian Federation											
San Marino											
Serbia and Montenegro											
Slovak Republic	0	0	40	2	25	5			10	0	
Slovenia	0	2	19	1	1	0			1	5	
Spain	93	36	592	37	487	28			271	78	
Sweden	1	2	12	2	22	0	2				
Switzerland	0	5	42	4	17	2			17	20	3)
Turkey											
Ukraine											
United Kingdom	13	12	97	13	101	24	12	3	51	47	

1) Syphilis testing THPA+, not confirmed
2) HCV results include indeterminate confirmation
3) Syphilis data in repeat donors no seroconversions but more sensitive new tests

Table 7.2
2004

Prevalence and incidence calculated per 100,000 donors

country	HIV 1 / 2 prevalence per 100,000 first time tested donors	HIV 1 / 2 incidence per 100,000 repeat donors	HBV prevalence per 100,000 first time tested donors	HBV incidence per 100,000 repeat donors	HCV prevalence per 100,000 first time tested donors	HCV incidence per 100,000 repeat donors	
Andorra							
Armenia							
Azerbaijan	103,87	86,38	2204,27	28,79	4258,51	47,99	
Albania							
Austria	2,13	1,51	81,10	4,14	54,42	6,02	
Belgium	1,83	0,76	128,41	3,06	49,53	1,53	
Bosnia / Herzegovina	0,00	0,00	215,57	45,57	87,82	10,72	1)
Bulgaria	18,84	0,00	8737,28	6,61	2059,53	3,31	
Croatia	6,42	3,96	173,27	9,23	44,92	34,28	
Cyprus							
Czech Republic	3,41	0,29	81,91	14,89	102,39	10,02	2)
Denmark	4,00	0,85	36,00	0,43	32,00	0,43	
Estonia							
Former Yug. Rep. Macedonia							
Finland	0,00	0,00	23,73	0,00	29,66	3,51	
France							
Georgia	500,00	42,86	21000,00	585,71	9000,00	85,71	
Germany	4,82	2,26	156,56	1,52	85,42	3,26	3)
Greece	115,41	4,72	3104,04	114,45	867,98	41,82	
Hungary	1,50	0,64		2,89		81,98	
Iceland	0,00	0,00	0,00	0,00	42,68	0,00	
Ireland	5,67	0,00	11,34	1,01	28,36	1,01	
Italy	16,14	26,96	470,40	35,13	296,41	43,30	
Latvia	56,87	2,97					
Liechtenstein							
Lithuania	13,20	0,00	1873,97	65,10	2038,93	292,94	
Luxembourg	124,84	0,00	249,69	0,00	124,84	0,00	
Malta	0,00		139,29		34,82		
Moldovia							
Netherlands	0,00	0,85	67,64	1,28	35,29	0,64	
Norway	0,00	0,00	20,35	1,07	33,91	0,00	
Poland	8,22	0,83	651,55	17,79	657,03	70,34	
Portugal							
Romania	27,10	4,28	4388,80	159,66	1278,58	127,58	
Russian Federation							
San Marino							
Serbia and Montenegro							
Slovak Republic	0,00	0,00	176,46	1,64	110,29	4,10	
Slovenia	0,00	2,11	206,03	1,05	10,84	0,00	
Spain	28,74	4,86	182,97	4,99	150,52	3,78	
Sweden	3,04	0,82	36,44	0,82	66,80	0,00	
Switzerland	0,00	2,32	158,14	1,86	64,01	0,93	4)
Turkey							
Ukraine							
United Kingdom	4,51	0,89	33,67	0,97	35,05	1,78	

1) Syphilis testing THPA+, not confirmed
2) HCV results includes indeterminate confirmation
3) Number of regular and repeat donors by extrapolation
4) Syphilis data in repeat donors no seroconversions but more sensitive new tests

Table 8.1
2004

country	NAT testing									
	HIV NAT			HBV NAT			HCV NAT			
	each donation	first time donors	Size Minipool	each donation	first time donors	Size Minipool	each donation	first time donors	Size Minipool	
Andorra										
Armenia										
Azerbaijan										
Albania										
Austria	1		96	1		96	1		96	
Belgium	1		8				1		8	1)
Bosnia / Herzegovina										
Bulgaria										
Croatia										
Cyprus										
Czech Republic										
Denmark										
Estonia										
Former Yug. Rep. Macedonia										
Finland							1		96	
France	1		8 to 24				1		8 to 24	2)
Georgia										
Germany	1		< 96			< 96	1		< 96	3)
Greece									25	4)
Hungary										
Iceland										
Ireland	1		8				1		8	
Italy							1		10 to 24	5)
Latvia										
Liechtenstein										
Lithuania	1			1			1			6)
Luxembourg	1		96	1		96	1		96	
Malta										
Moldovia										
Netherlands	1		48				1		48	
Norway							1		24	
Poland							1		48	7)
Portugal										
Romania										
Russian Federation										
San Marino										
Serbia and Montenegro										
Slovak Republic	1			1			1			
Slovenia							1		24	
Spain	1		1-24				1		1-24	
Sweden									96	
Switzerland	1		16 to 48				1		16 to 48	
Turkey										
Ukraine										
United Kingdom							1		48	

1) 6% of donations other pool size
2) NAT for HBV, HIV and HCV on individual donations in Carribean
3) HIV NAT since april 2004 HBV NAT voluntary on >75% donations HCV NAT on each donation not required for plasma for fractionation
4) HCV NAT in plasma from 82,712 units, additional 7 centres test SD NAT for HIV and HCV
5) HIV and HBV NAT locally
6) HIV, HBV, HCV NAT since December 2004

Table 8.2
2004

country	NAT only positive results					
	HIV 1		HBV		HCV	
	first time tested donor	repeat donor	first time tested donor	repeat donor	first time tested donor	repeat donor
Andorra						
Armenia						
Azerbaijan						
Albania						
Austria	0	1	2	1	1	0
Belgium	0	0			0	2
Bosnia / Herzegovina						
Bulgaria						
Croatia						
Cyprus						
Czech Republic						
Denmark						
Estonia						
Former Yug. Rep. Macedonia						
Finland					0	0
France	0	0	0	0	0	1
Georgia						
Germany	0	3	0	0	0	9
Greece					0	0
Hungary						
Iceland						
Ireland	0	0			0	0
Italy						
Latvia						
Liechtenstein						
Lithuania	0	0	0	0	1	0
Luxembourg	0	0	0	0	0	0
Malta						
Moldovia						
Netherlands	0	0			0	0
Norway					0	0
Poland					3	8
Portugal						
Romania						
Russian Federation						
San Marino						
Serbia and Montenegro						
Slovak Republic						
Slovenia						0
Spain	2				2	
Sweden					0	0
Switzerland	0	0			0	0
Turkey						
Ukraine						
United Kingdom	0	2			4	0

Table 9

2004

country	Bacterial screening					
	total platelets adult doses issued	% bacterial screened recovered	% bacterial screened apheresis	total platelets % screened	total platelets % confirmed pos	
Andorra						
Armenia						
Azerbaijan	176					
Albania						
Austria	25600	36,77	52,55	22,3	0,27	
Belgium	59803	99,7	82,9	89,8	0,4	1)
Bosnia / Herzegovina	2539	8	10	20		2)
Bulgaria	5595	10		10	0	
Croatia	12137	2,7	7,7	3,6	0,35	3)
Cyprus						
Czech Republic	24400			0,4		4)
Denmark	32484				0,2	
Estonia						
Former Yug. Rep. Macedonia						
Finland	32224	0	0	0		
France	209045	0	0	0	0	
Georgia	2000			5	0	
Germany	373538					5)
Greece	166477					6)
Hungary	14520	31	29	28	1	7)
Iceland	933			0		
Ireland	17598	8,4	12,4	10,2	0,1	8)
Italy	123000	3	5	3	0	9)
Latvia	3819	48,4	89,1	75,8		
Liechtenstein						
Lithuania	14664	0,4		0,4		
Luxembourg	2125					10)
Malta	15300	10	9	10	0,84	
Moldovia	293			0		
Netherlands	52685	100	100	100	0,7	11)
Norway	16007					12)
Poland	50212	0	0	0	0	
Portugal						
Romania	59267	50	100	50		
Russian Federation						
San Marino						
Serbia and Montenegro						
Slovak Republic	8454	14	1	7,5	0	
Slovenia	25680					
Spain	119311					
Sweden	35121			26	0,09	
Switzerland	18509					13)
Turkey						
Ukraine						
United Kingdom	261317	5,1	6,8	5,8	0,07	

1) 13% of apheresis platelets and 7 % of all platelets pathogen inactivation, no screen
2) Bacterial screening only in one Canton
3) Bacterial screening of platelets only in one intsitute
4) 5) 10) 13) Bacterial testing at QC
6) Bacterial screening by some centres
7) Average percentages given
8) Bact screening started nov / dec 2004 and 100% since april 2005
9) Data shown are average over a wide distribution on 70% of centres
11) In 2004 after introduction of diversion bag frequency changed from 1,07% to 0,43%

Table 10
2004

Organisation, registration and labelling

country	National Council or Expert Committee	ID and labelling of donation number		ID and labelling of component code		
		% ISBT	% Other	% ISBT	% Other	
Andorra						
Armenia						
Azerbaijan	yes					
Albania						
Austria	yes	30	70	30	70	
Belgium	yes	94,2	5,8	30,4	69,6	1)
Bosnia / Herzegovina	no					2)
Bulgaria	yes		100			3)
Croatia	yes		100		80	4)
Cyprus						
Czech Republic	yes	0	100	0	100	5)
Denmark	yes	44	56	16	84	
Estonia						
Former Yug. Rep. Macedonia						
Finland	no	100	0	100	0	
France	yes	0	100	0	100	6)
Georgia	yes		100		100	
Germany	yes					
Greece	yes		100		100	7)
Hungary	yes	0	100	0	100	8)
Iceland	yes	92		92		9)
Ireland	yes	0	100	0	100	10)
Italy	yes		94		81	11)
Latvia	yes					
Liechtenstein						
Lithuania	yes		100			12)
Luxembourg	no	0	100	0	100	13)
Malta	no	100	0	100	0	
Moldovia	yes	0	100	0	100	
Netherlands	yes	100	0	100	0	
Norway	yes	70	30	70	30	14)
Poland	yes	0	100	0	100	15)
Portugal						
Romania	yes	0	100	0	100	16)
Russian Federation	yes					
San Marino						
Serbia and Montenegro						
Slovak Republic	yes		90		90	17)
Slovenia	yes		100		100	18)
Spain	yes	17	83	17	83	
Sweden	yes	85	15	85	15	19)
Switzerland	no	100	0	100	0	
Turkey						
Ukraine						
United Kingdom	yes	100	0	0	100	

1) Component codes are country specific
2) Expert committee needed No unified system used, some use ISBT 128
3) 5) 16) 19) National labelling system
4) 8) 10) 13) 18) Codabar
6) MONARCH for labelling
8) 70% of centres computerized, national scheme under development
9) One blood bank 100% ISBT-128, other centre no computer system for labeling
11) UNI = Unified Italian Codes
12) Local labelling system

Table 11

2004

Quality Management related issues

country	QA system established and maintained	% donations covered by			Inspections each second year, by	Haemovigilance system operated by	
		% GMP	% ISO 9000	% other			
Andorra							
Armenia							
Azerbaijan		0	0	0	nat author	nat author	
Albania							
Austria	yes	100	100		natl author & other org	natl author	
Belgium	yes	64,2	36		other body	planned	1)
Bosnia / Herzegovina	planned				no	no	
Bulgaria	yes	54			no	yes	
Croatia	yes	100	48		no	other org	2)
Cyprus							
Czech Republic	yes	100	40		natl author	natl author	
Denmark		100			natl author	other org	
Estonia							
Former Yug. Rep. Macedonia							
Finland	yes	100		100	natl auth	Finnish Red Cross	3)
France	yes	100	100		yes	natl auth	
Georgia	planned				natl auth	no	
Germany	yes	100			natl auth	natl auth	
Greece	yes	70	5		other org	natl auth	4)
Hungary	yes	100			natl auth	natl auth	
Iceland	yes		92		other org	no	5)
Ireland	yes	100	26		natl auth	natl auth	
Italy	planned				no	natl auth	6)
Latvia	yes			100	natl auth	no	
Liechtenstein							
Lithuania	planned				natl auth		7)
Luxembourg	yes	100	100		natl auth	natl auth	
Malta	yes	0	0	100	no	yes	8)
Moldovia	yes			100	natl auth	natl auth	
Netherlands	yes	100			natl auth	other org	
Norway	yes	100	24	2,6	no	other org	
Poland	yes	100	5		natl auth	natl auth	
Portugal							
Romania	no				no	no	
Russian Federation	yes	0	0	100	natl auth	natl auth	
San Marino							
Serbia and Montenegro							
Slovak Republic	yes	90	1,2		natl auth	natl auth	
Slovenia	yes	100	50		natl auth	other org	
Spain	yes		92		other	natl auth	
Sweden	yes	100		83	natl auth & other org	natl auth & other org	9)
Switzerland	yes	100	65	70	natl auth	natl auth	10)
Turkey							
Ukraine							
United Kingdom	yes	100			natl auth	SHOT system	

1) Inspections and hemovigilance system by national authority planned
2) One institute collecting 48% of donations is ISO certified
3) All donations also covered by ISO 17025
4) Inspections by National Body of Inspectors
5) Inspections by British Standard Institutions
6) Former regulations require inspections every 5 years, will change by 2002/98/EC
7) GMP and ISO launched in 2005

Table 12
2004

Hemovigilance

country	total number components transfused: whole blood + RBC + FFP + Platelets	Imputability "likely, probable or certain" (level 2 or level 3)															Incidence high imputability serious adverse reactions per 100,000 components
		hemolysis ABO	hemolysis other	PTP	Anaphylaxis	TRALI	GVHD	TA-HBV	TA-HCV	TA-HIV	TA-Other viral	TA-Bacterial	TA-Malaria	TA-Parasitic	TA-TACO	TA-Other serious	
Andorra																	
Armenia																	
Azerbaijan	35 207																
Albania																	
Austria	582 109	0	0	0		0	0	0	1	0		0	0	0	0	1	0,3
Belgium	680 175																
Bosnia / Herzegovina	50 915																
Bulgaria	238 882		0		4												1,7
Croatia	264 665	3	16		15	2				1		4			3		16,6
Cyprus																	
Czech Republic	531 700							0	0	0							
Denmark	461 228																
Estonia																	
Former Yug. Rep. Macedonia																	
Finland	327 075							2									0,6
France	2 523 248	5	6	0	31	13	0	0	0	0	0	4	0	0	48	18	5,0
Georgia	60 000																
Germany	6 239 300		8	1	4	14	0	4	0	0	0	5				0	0,6
Greece	1 023 469																
Hungary	520 581	4	0														0,8
Iceland	20 078																
Ireland	180 785	1	3					0		0					15	23(?)	10,5
Italy	3 030 000																
Latvia	102 249																
Liechtenstein																	
Lithuania	123 074																
Luxembourg	26 400	1															3,8
Malta	45 372	1			12											0	28,7
Moldovia	50 947																
Netherlands	740 460	2	10	0	18	4	0	0	0	0	0	1	0	0	2	17	7,3
Norway	247 144	3	2	0	0	1	0	0	0	0	0	0	0	0	1	0	2,8
Poland	1 306 366	7	10	0	1	15	0	0	0	0	0	13	0	0	0	0	3,5
Portugal																	
Romania	413 843																
Russian Federation																	
San Marino																	
Serbia and Montenegro																	
Slovak Republic	242 031	6	6	3	55	2											29,7
Slovenia	138 284				8										1	6	10,8
Spain	1 807 873																
Sweden	604 221	2	6	0	23	3	0	0	0	0	0	2	0	0			6,0
Switzerland	395 447	1	2	0	13	3									3	1	5,8
Turkey																	
Ukraine																	
United Kingdom	3 048 375	1	0	0	1	13	0	0	0	0	1	0	0	0	2		0,6

1) Hemovig reporting restricted to HIV, HBV and HCV
2) Immunological incompatibility without hemolysis, FNHR, RBC immunisation, Iron overload
3) 39 NHFTR reported
4) Also 3 syphilis transmission cases reported
5) Hemovigilance to be further elaborated
6) Serious Adverse Reaction due to Potassium level