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FINAL REPORT

THE COLLECTION, TESTING AND USE OF BLOOD AND BLOOD PRODUCTS IN EUROPE IN 2003

Prepared by: Cees L. van der Poel, Mart P. Janssen

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Cees L. van der Poel[1,2], Mart P. Janssen[1]

1) Julius Center for Health Sciences and Primary Care, University Utrecht, Utrecht, The Netherlands
2) Sanquin Blood Supply Foundation, Amsterdam, The Netherlands

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

Alina Tatarenko

Health Division
Directorate General III - Social Cohesion
Department of Health
and of the Partial Agreement
in the Social and Public Health Field
Council of Europe
67075 Strasbourg Cedex France

Tel: + 33 (0) 3 88 41 2847
Fax: + 33 (0) 3 88 41 2726
e-mail: Alina.Tatarenko@coe.int

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SUMMARY 2003

This report considers data on the donors, collection, testing, use and quality aspects of blood and blood components in Member States of the Council of Europe. Data were supplied in response to a questionnaire requesting details on donors, collections, testing, distribution and quality aspects of blood and blood components for the year 2003. In its present form it follows a series of similar reports which have assessed the blood supply in the Member States in 1989, 1991, 1993, 1995, 1997 and 2001 and 2002.

As of 2001, a new questionnaire was designed by SP-R-GS experts and the SP-HM bureau, primarily aimed at obtaining data from blood establishments. As opposed to the 1997 survey (Rejman 2000), Member States of the European Community were included in the survey. Comparisons with results from previous surveys were not attempted. Not all the relevant information was obtained from each Member State. It is noted that the questionnaire may have generated initial difficulties in data retrieval, and as the process is intended to continue further annually, it is expected that the quality, response rate and publishing speed of the survey is to improve. A separate Qualitative Evaluation Report on the 2001 Questionnaire with recommendations for improvement of the process was performed and was reported to SP-HM in November 2003. It is anticipated that the 2004 questionnaire will be adapted taking into account this evaluation and the experience on 2001 - 2003 data.

In contrast to earlier reports the proportion of donations by voluntary non-remunerated donors was not assessed by the present questionnaire. However the EC has acknowledged its importance in its new Directive 2002/98/EC setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components.

In total 30 questionnaires were received, the response rate being 67 percent.

The average number of donors in relation to the general population is 27 per 1,000 inhabitants, and on average 21 percent of the donor base consists of first time donors.

The number of whole blood collections is on average 35 per 1,000 inhabitants, and the average use of red blood cells is 35 per 1,000 inhabitants. On average 4 litres of plasmapheresis plasma per 1,000 inhabitants are collected, and 6 Member States stand out with 7 - 30 litres of plasmapheresis plasma per 1,000 inhabitants.

The use of red blood cells varies considerably (range 1-71) but averages 35 total red blood cell products per 1,000 inhabitants. In 5 / 30 (17%) of the reporting Members States below 20 units per 1,000 inhabitants are used, probably reflecting insufficient supply. On average in the reporting Member States, 35 percent of the total platelet volume is supplied by (random) single

donor platelets by apheresis, in 8 countries this volume amounts to more than 50 percent.

The total amount of plasma delivered for fractionation into medicinal products differs greatly (range 0-30) among Member States, an average yield of 9 litres of plasma for fractionation per 1,000 inhabitants is found. However 6 / 30 (20%) of reporting Member States deliver 17 litres or more per 1,000 inhabitants. The use of plasma for transfusion would be competitive with the yield of (recovered) plasma fractionation. On average 10 units of plasma per 1,000 inhabitants are used for transfusion, or 0.44 units of plasma per unit of red blood cells. In 3 Member States a below-average use of plasma for transfusion is paired to an above-average yield of plasma for fractionation. However in 3 other Member States a high yield of plasma for fractionation is observed in the presence of an above-average of use of fresh plasma for transfusion.

In 36% of Member States, 100 percent leucodepletion of red blood cell products is carried out. Platelet concentrates are 100% leucodepleted in 50% of Member States. In 9 / 22 (41%) reporting Member States 100% of FFP is additionally safeguarded by either quarantine or pathogen reduction methods.

In all 30 reporting Member States, each donation is tested for anti-HIV-1/2, HBsAg and anti-HCV. In 26 / 30 (87%) reporting Member States, all donations are tested for Syphilis, in 2 countries new donors are tested for syphilis. Anti-HTLV-I/II testing is performed on all donations in 8 / 30 (27%) of reporting Member States, and on first time donors in 4 / 30 (13)%. Anti-HBc is tested for all donations in 2 / 30 (7%) of reporting Member States, and only on first time donors in another 4. Prevalence and incidence of infectious diseases vary greatly among Member States, and it may be noted that in Europe a North-South gradient exists for hepatitis B and C virus. The present data sets suggest that confirmatory testing is not available in all countries, and data may include false positive test results.

Nucleic Acid Testing (NAT) for HCV is performed on each donation in 15 (50%) of 30 Member States, whereas HIV NAT on each donation is performed in 10 (33%) and HBV NAT in 3 (10%).

In 22 / 30 (73%) of the reporting Member States a National Council or Expert Committee to advise the Ministry of Health on transfusion related policy issues exists. Labeling is partially performed according to ISBT-128 for the donation number in 5 countries and for 100% in 4. Labeling of the finished component code by ISBT-128 is (partially) implemented in 6 countries, and 4 countries have 100% ISBT-128 at the donation as well as the finished component level.

In 19 / 30 (63%) of the reporting Member States a Quality System is established and maintained in blood establishments, in 9 countries this is planned. In 16 / 30 (53%) of Member States 100 percent of the donations are covered by GMP. In 3 countries this is the case for ISO 9000. In 25 / 30 (83%) of the reporting Member States inspections are performed at least every 2 years, in 19 countries (also) by the national authority. In 22 / 30 (73%) of the

Member States a haemovigilance system is installed, in 14 countries organized by the national authority.

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Study methods

The questionnaire and methods in this survey were in principle the same as the one described for the 2001 survey. (www.coe.int/T/E/Social_Cohesion/Health/Activities/Blood_transfusion/Report%202001%20survey.asp). Briefly, the Council of Europe SP-HM Secretariat circulated the questionnaire to Member States requesting that the completed forms be returned to the Secretariat by August 2004. Completed questionnaires were received by the authors in August 2004. After meetings with SP-HM and CDSP, corrections and additions were provided by Member States until march 2005, after which the report was finalized.

In Members States and in blood establishments, data may be administered in different formats, and different definitions may be used. This may result in discrepancies in reporting the data in another format. Some data may not be available. It is anticipated that consistency, improvements and persistence in these CoE survey methods will eventually result in higher response rates among Member States, when the questionnaires are used yearly. In order to facilitate uniformity, definitions of the EC Directives and CoE Guidelines are used as far as possible (Council Recommendation 98/463/EC, Directive 2002/98/EC, Guide to Preparation 2002).

The data in the completed questionnaires were reviewed by the authors after submission by the Member States. Additional or explanatory questions to Member States or to National experts were posed by the authors in case of incomplete or incomprehensible data sets were returned. Non-response can also be attributed to lack of clarity or inconsistent questioning in the questionnaire, unfamiliarity with the query format, or adaptations that need to be made to computer data systems in blood establishments in order to allow retrieval of the exact data requested. During the process it became clear that some data did not fulfill definitions, these were deleted. A Qualitative Evaluation Report on the Questionnaire with recommendations for improvement of the process had previously been reported by the authors to SP-HM and discussed in November 2003. It is anticipated that as Member States become accustomed to the survey the ease, speed and quality of reporting and publishing will improve. A revision of the questionnaire is envisioned for the 2004 survey.

Trend analysis and incomplete data

Comparisons with results from the previous surveys or trend analysis was not attempted, rather each year is reported separately. Not all information, requested in the Questionnaire is included in the tables, but these provide detail where sufficient information is available to justify presentation.

Occasionally totals in the tables may not precisely match the contributing figures because of rounding. It has been assumed that information was not available when information was not provided. Non-availability of the data is represented by empty fields in the tables.

Remarks to the data

Remarks made by the Member States to the data are given in the footnotes of the tables.

Response

Member States (MS) (n= 45) of the Council of Europe (CoE) were invited to send completed questionnaires. Reply was received from 30 Member States, the response rate being 67 percent. For the 2001 and 2002 questionnaires, the response rate was 86 percent and 60 percent respectively.

Donors, first time donors and inhabitants: Table 1

The questionnaire requires data on donors “active during the year”, and therefore would include only those donors who actually donated during the reporting year. However the definition “donors active during the year” may represent a rather precise selection and query on a given donor database. Probably in many establishments or countries, the – often standard - query format on the donor database would need to be changed. This may not always be possible. Therefore the authors doubt whether this requirement was always met in generating the data for this survey. If such detail would be felt important in the future, the “inactive” number of donors e.g. 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 these definitions include for regular donors, all donors who’s last previous donation was less than 2 years ago, and for repeat donors, those donors who’s last previous donation was more than 2 years ago. The total of the two categories represent those donors, who are known to the system or establishment and in many countries form the basis of – the safety of - the blood supply. In 1 MS (Germany) repeat and regular donors were not registered separately. These data are needed for the calculation of the prevalence of infectious diseases among new donors and the incidence of infectious diseases among repeat and regular donors (see Table 7). For EC countries, the reporting of prevalence and incidence on these donor populations becomes mandatory in 2005 as of Directive 2002/98/EC.

The term in this survey “first time donors” includes all donors who actually are 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 later. They become known as “qualified donors” when their infectious disease tests at examination as applicant donor were negative. Including only “qualified donors” in the report will generate bias in reporting infectious disease markers (see 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 actually are tested for the first time or donate for the first time. It is assumed that all "first time donors" are actually tested, as is 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 diseases markers in the general population of the 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 turn-over rate in the donor base. It may however be influenced by recruitment programs. 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*.

Excluding the countries were first time donors and repeat plus regular donors are not reported separately, on average 21 percent (range 6-79) of the total donor base consists of "first time" donors. It is known that first time donors may have higher incidences of infectious diseases as compared to regular or repeat donors (Schreiber 2001).

The average number of donors in relation to the general population is 27 (range 2-67) 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 13 donors per 1,000 inhabitants (average minus SD) may pose a problem with supply and around 30 donors per 1,000 inhabitants seems an achievable goal from the given data. Not all countries with a relatively high number of donors per 1,000 inhabitants deliver as high a number of red blood cell units to the hospitals though (see Table 3), but in general these figures run parallel. As stated before, some caution as to the interpretation of the number of “active” donors seems justified, and bias may occur by "inactive" donors in the database, however maintaining "inactive" donors in the database 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 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 3). The number of whole blood collections is on average 35 (range 0.2-62) per 1,000 inhabitants. Given the average use of red blood cells of 35 per 1,000 inhabitants (see Table 3), the number of whole blood collections appears to either fit the demand of red blood cell products, or conversely the use in the hospitals is limited by supply.

Autologous donations are promoted in relation to safe blood transfusions by limiting exposure to allogeneic blood for patients and also in relation to enhancing the supply of blood. In general the factor of enhancing supply appears not to be important, in countries where autologous donations are given, they contribute on average 1 percent (range 0-6), of the whole blood donations. This is in conjunction with the literature. However it should be taken into account that surgery and anesthesiology techniques such as pre-operative hemodilution and intra-operative blood salvage are not included in the presented data. In this survey only the pre-operative autologous blood donations (PABD) are taken into account.

Plasmapheresis collections provide source plasma, including plasma with specific antibodies, for fractionation into medicinal products. In some countries plasma for transfusion is also collected by apheresis donations. The volume of plasma collection by apheresis per 1,000 inhabitants, reflects the volume of

the national plasmapheresis programs. The average amounts up to 4 litres (range 0-30) of plasmapheresis plasma per 1,000 inhabitants. Apparently Belgium, Germany, Latvia, Luxembourg Netherlands and Sweden stand out as countries with a more than average plasmapheresis volume of 7 to 30 litres plasmapheresis plasma per 1,000 inhabitants per annum. Germany experienced a significant increase for 2003 since 2002.

Platelet apheresis may include the traditional situation for specially HLA or HPA typed donations, as well as more recent developments replacing pooled whole blood derived platelets by platelet apheresis by random donors in order to minimize patient exposure to allogeneic donors. The latter data e.g.: the relative importance of platelet apheresis for the total supply of platelet products is given in Table 3. On average 35 percent (range 0-100) of the adult therapeutic doses of platelets are produced by apheresis. These extremes reflect different models: low access to HLA typed platelet donors, centres where plateletapheresis is only performed on typed donors, and centres striving towards 100% platelet supply by apheresis.

Red blood cell apheresis is a relatively new development and may be of particular interest for autologous programs, and for collections of rare types of red blood cell donors.

Granulocyte apheresis donations appear scattered in numbers, probably as the indications for this blood component are disputed.

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. Data on the use in hospitals are generally difficult to obtain in many Member States, however in some countries such as Denmark, blood banks are hospital based and the data are related to transfusions issued. As product loss in hospitals – for example by outdating - may be 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 limited deviations.

Whole blood “must be considered as a source material and has no, or only a very restricted, place in transfusion therapy” (Guide to preparation 2001). However in countries with limited resources, transfusion therapy with whole blood may be needed when the infrastructure for blood component preparation is lacking. On average 7 percent (range 0-51) of the RBC transfusions are performed with whole blood. In 5 / 30 (17%) 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 used.

The use of red blood cells in the Council of Europe Member States varies considerably per 1,000 inhabitants, but averages 35 total red blood cell products per 1,000 inhabitants (range 1-71). Rejman suggested in his report on the 1997 survey that 40 – 60 whole blood donations per 1,000 inhabitants would be needed for optimal supply, a figure largely driven by the need for red blood cells for transfusion (Rejman 2000). Red blood cells are mainly used in surgery, obstetrics, hematology and oncology care, and in some countries programs for “better use of blood” or “optimal use of blood” have recently been installed. Therefore a use of red blood cells of about 40 units per 1,000 inhabitants could reflect insufficient supply or rather more stringent use. In 5 / 30 (17%) of the reporting Members States below 20 units per 1,000 inhabitants are used, most likely reflecting insufficient supply. Also, the use may fit the demand, e.g.: the level of clinical care. A better benchmark may be achieved by including the number of hospital beds in a future survey in relation to the red blood cell use.

The use of plasma for transfusion (FFP) has been discouraged the last decennia, mainly because its clinical indications are limited and more plasma is needed for its primary use as source material for fractionation into medicinal products. However, with multiple coagulation disorders, including TTP, fresh frozen plasma 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 programs for "better use of blood" (e.g. red blood cells) the decline of red blood cell use may increase the FFP / RBC ratio. On average the FFP / RBC ratio is 44 percent (range 10-176%). As this is of interest with regard to the supply of plasma for fractionation into medicinal products, the data are presented in Table 4. On average 10 units of plasma for fractionation (source plasma + recovered plasma) per 1,000 inhabitants is used (range 0-21).

Platelets are in Europe generally recovered from 4-5 buffy-coats of whole blood donations. Recent discussions on blood safety – especially in relation to the unknown risk of vCJD – initiated programs to enhance the use of random single-donor platelets by apheresis. These programs may have been influential in some Member States where the use of *apheresis platelets* in relation to *recovered platelets* is relatively high. Seemingly the use of apheresis platelets may be stimulated, but it should be noted that some issues have not been solved. It is not known to what extent donors are willing to undergo apheresis for general platelet supply. Risks for the donors may increase as compared to whole blood donations. The amount of risk reduction for the recipients of platelets is discussed. In countries, where a large proportion of red blood cells are delivered as whole blood, platelets by apheresis may be the product of choice. In countries where apheresis platelets represent a minor volume, only the demand of HLA or HP typed products may have been the driving force. On average in the reporting Member States, 35 percent (range 0-100) of the adult therapeutic doses of platelets are produced by (random) single donor platelets by apheresis, in 8 countries this volume amounts to more than 50 percent.

Cryoprecipitate may still be used for fibrinogen, FVIII deficiency, Von Willebrand's disease, and complex coagulation disorders. This product was largely abandoned in most Member States but remains in 10. It is not clear whether application as a source of fibrinogen for fibrin sealant is included in these figures.

Blood components delivered for manufacture of medicinal products: Table 4

The total amount of plasma delivered for fractionation into medicinal products differs among Member States. This becomes more clear if the figure is related to the population size. In the reporting Member States an average yield of 9 (range 0-30) litres of plasma for fractionation into medicinal products per 1,000 inhabitants is found. However 6 / 30 (20%) of reporting Member States deliver 17 litres (average + SD) plasma or more per 1,000 inhabitants: Belgium, Denmark, Germany, Luxembourg, The Netherlands and Sweden. Especially Germany had a high yield as compared to the 2002 data. Apart from a query on the total yield of plasma for fractionation, the questionnaire encompasses two specified questions on plasma delivered for FVIII production *versus* other plasma. These specified questions are poorly understood by respondents, often the total yield of plasma is indicated as plasma for VIII. The effects of the differences between Member States in plasma yield as related to supply may be better understood when the use of FVIII, immunoglobulins and albumen per country is known.

It has been discussed, that the use of fresh frozen plasma for transfusion (FFP) would be competitive with the yield of plasma (recovered) from whole blood donations for manufacture of medicinal products e.g.: FVIII. On average in the reporting Member States 10 units of plasma (FFP) (range 0-20) per 1,000 inhabitants are used for transfusion, or 0.44 units of fresh frozen plasma per delivered unit of red blood cells. Apparently in Finland, Luxembourg and The Netherlands a below-average use of fresh frozen plasma for transfusion is paired to an above-average yield of plasma for manufacture of medicinal products. However in Denmark, Germany and Sweden a high yield of plasma for manufacture of medicinal products is observed together with an above-average use of plasma for transfusion.

Special processing of blood components: Tables 5.1 and 5.2

In 10 / 28 (36%) of reporting Member States, 100 percent leucodepletion of red blood cell products is carried out. This is the case for platelet concentrates in 13 / 26 (50%) reporting Member States. Hundred percent leucodepletion is applied for plasma for transfusion in 9 reporting Member 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 numbers may reflect the volume of high 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 cyroprecipitate (CP) may be additionally safeguarded against infectious diseases. One method is a quarantine step e.g.: the plasma is stored and only released if the donor is negative for infectious disease markers (IDM) on a next donation 4-6 months later. Another method is the application of “virus inactivation” or “pathogen reduction” by Solvent Detergent (SD) or Methylene Blue (MB) treatment. In 9 / 22 (41%) reporting Member States 100% of FFP is safeguarded by either method, in 4 Member States by 100% quarantine, in 3 by 100% pathogen reduction and in 2 by either method.

Screening for infectious agents, serological test methods: Table 6

In all 30 reporting Member States, all donations are tested for anti-HIV-1/2, HBsAg and anti-HCV. In 26 / 30 (87%) reporting Member States, all donations are tested for Syphilis. It is debated in the literature whether Syphilis testing is necessary, in Sweden and Norway only new donors are tested for syphilis, in Denmark and Iceland syphilis testing is not performed.

Testing for anti-HTLV-I/II is performed on all donations in 8 / 30 (27%) reporting Member States, and only on first time donors in 4 / 30 (13%) countries.

Testing for anti-HBc is performed on all donations in 2 / 30 (7%) reporting Member States, and only on first time donors in 4 countries. Testing for NAT is reported separately in Table 8. Testing for HCV NAT on all donations is performed in 15 / 30 (50%) of the countries, whereas HIV NAT on each donation is performed in 10 (33%) and HBV NAT in 3 (10%).

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. These donors are then notified and do not donate anymore. A most common flow-chart for confirmation conforms with EC Recommendation 98/463/EC.

In table 7.1 the absolute numbers are given of “confirmed positive” donors among all first time donors tested (see Table 1) and among all repeat and regular donors tested (see Table 1). Although the definition of confirmed positive donors is not always uniformly understood, 25 of 30 (83%) Member States were able to provide the absolute numbers of confirmed positive donors thus specified (see Table 7.1).

The number of “confirmed positive” donors among all first time donors tested (see 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 from. It should be noted that the general population may have different rates of infectious diseases

than blood donors. Even at 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 donors), and is given in Table 7.2. The prevalence per 100.000 first time tested donors, if calculated from the provided data sets, ranges from 0.00 to 632.99 (!) for HIV-1/2, from 7.22 to 30300 (!) for HBV and 0.00 to 56100 (!) for HCV. Although considerable differences in geographical spread of these infections in Europe may exist, it is doubted whether the very high frequencies of some countries reflect reliable data sets on indeed "confirmed positive donors" or merely refer to only screening test (ELISA) positive donors thus including many false positives (see definitions in the questionnaire). Unfortunately the geographical spread of these infections may coincide with low resources and lack of confirmatory testing.

The number of “confirmed positive” donors among all repeat and regular donors tested, yields the “incidence” of an infectious disease among repeat and regular donors. This incidence accounts for the frequency with which repeat and regular donors acquire a new infection. It is this frequency that relates to blood safety via the window period of infectious disease testing (Schreiber 1996). The incidence of infectious diseases among repeat and regular donors was calculated from Table 7.1 (number of confirmed positive donors) and Table 1 (number of donors), and is given in Table 7.2.

The prevalences and incidences of infectious diseases vary greatly among Member States, and in general it is 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. This may also but to a lesser extent be the case for HIV. The incidence per 100.000 repeat tested donor years, if calculated from the provided data sets, ranges from 0.00 to 195.82 (!) for HIV-1/2, from 0.00 to 6984.33 (!) for HBV and 0.00 to 4438.64 (!) for HCV. Although considerable differences in geographical spread of these infections in Europe may exist, it is doubted whether the very high frequencies of some countries reflect reliable data sets or merely refer to only screening test (ELISA) positive donors (including many false positives) as opposed to "confirmed positive donors" (see definitions in the questionnaire).

Nucleic Acid Testing (NAT): Tables 8.1 and 8.2

Nucleic Acid Testing (NAT) for HCV is performed on each donation in 15 / 30 (50%) reporting Member States. NAT for HIV is performed on each donation in 10 / 30 (33%) reporting Member States. NAT for HBV is performed on each donation in 3 (10%) Member States. NAT on plasma for fractionation is performed in 8, 5 and 3 Member States for HCV, HIV and HBV respectively. However, some Member States report that NAT on plasma for fractionation is performed by fractionators and that data are lacking, therefore these data may be incomplete.

The "yield" of NAT is defined as the finding of a NAT-positive donor, who is not found seropositive for that virus in serological screening on the same

donation. But is shown later to be confirmed positive by separate NAT (individual NAT) on the same sample or confirmed by later serology. The yield of NAT for HCV, HIV and HBV among first time tested donors and repeat donors is given in table 8.2.

Organisation, registration and labeling: Table 9

In 22 / 30 (73%) of the reporting Member States a National Council or Expert Committee to advise the Ministry of Health on transfusion related policy issues exists.

Labeling according to ISBT-128 for the donation number is partially performed in 5 countries, and 4 countries have 100% ISBT-128 code for the donation. Labeling of the finished component code is more complex, is in general behind developments of donation labeling, as it includes automation applications in the hospitals. ISBT-128 labeling of the issued component is partially implemented in 6 countries, and 3 countries have 100% ISBT-128 coding at the donation as well as the component level. Other systems of automated labeling exist, and these are summarized below table 9, for blood transfusion safety and traceability, automated donation and component labeling is important.

Quality management related issues: Table 10

In 19 / 30 (63%) of the reporting Member States a Quality System is established and maintained in blood establishments. In 9 (30%) countries this is planned.

In 16 / 30 (53%) of the reporting Member States 100 percent of the donations are covered by GMP. In 3 (10%) countries this is the case for ISO 9000. In 2 countries another QA system is used with 100 percent coverage of the donations. In 25 / 30 (83%) of the reporting Member States inspections are performed at least every 2 years, in 19 of which these inspections are (also) carried out by the national authority.

In 22 / 30 (73%) of the reporting Member States a haemovigilance system is installed, 14 / 30 (47%) haemovigilance systems are organized by the national authority.

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Table 1
2003

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	1.532	5.661	78,7	7.193	3.212	2,2	
Azerbaijan							
Albania							
Austria	505.080	45.552	8,3	550.632	8.174	67,4	
Belgium	230.048	39.005	14,5	269.053	10.000	26,9	
Bosnia / Herzegovina	32.992	8.034	19,6	41.026	3.900	10,5	
Bulgaria	116.747	31.294	21,1	148.041	7.973	18,6	
Croatia	79.335	18.334	18,8	97.669	4.437	22,0	
Cyprus							
Czech Republic	332.400	33.300	9,1	365.700	10.300	35,5	
Denmark	211.969	25.000	10,5	236.969	5.000	47,4	1)
Estonia							
Former Yug. Rep. Macedonia	19.852	8.057	28,9	27.909	2.202	12,7	
Finland	149.192	18.944	11,3	168.136	5.220	32,2	
France	1.195.109	345.219	22,4	1.540.328	60.186	25,6	
Georgia	7.000	1.000	12,5	8.000	5.000	1,6	
Germany	1.787.471	569.086	24,1	2.356.557	82.532	28,6	2)
Greece	301.005	58.180	16,2	359.185	10.500	34,2	
Hungary							
Iceland	7.374	2.441	24,9	9.815	291	33,7	
Ireland		25.405			3.917		
Italy	1.191.000	292.000	19,7	1.483.000	57.000	26,0	
Latvia	35.615	13.131	26,9	48.746	2.300	21,2	
Liechtenstein							
Lithuania							
Luxembourg	12.847	758	5,6	13.605	435	31,3	
Malta							
Moldovia							
Netherlands	474.488	35.091	6,9	509.579	16.193	31,5	
Norway	90.985	13.853	13,2	104.838	4.577	22,9	
Poland	238.137	180.663	43,1	418.800	38.500	10,9	
Portugal							
Romania	142.656	80.916	36,2	223.572	22.435	10,0	
Russian Federation							
San Marino							
Serbia and Montenegro	9.531	6.391	40,1	15.922	650	24,5	
Slovak Republic	112.719	26.435	19,0	139.154	5.300	26,3	
Slovenia	95.607	11.190	10,5	106.797	1.964	54,4	
Spain							
Sweden	261.481	39.996	13,3	301.477	8.973	33,6	
Switzerland	195.000	24.989	11,4	219.989	7.364	29,9	
Turkey							
Ukraine	768.102	293.297	27,6	1.061.399	47.442	22,4	
United Kingdom	1.431.944	297.491	17,2	1.729.435	58.785	29,4	

1) Denmark: only total number of donors available
2) Germany: data on repeat and regular donor by extrapolation

Table 2

2003

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

country	whole blood collections				apheresis collections					
	whole blood units	whole blood per 1,000 inhabitants	autologous units	% autologous whole blood units	plasma apheresis (L)	plasma in L per 1,000 inhabitants	platelets apheresis (U)	red blood cells apheresis (U)	granulocytes apheresis (U)	
Andorra										
Armenia	7.845	2,4	150	1,9	1.726	0,54		7.845		
Azerbaijan										
Albania										
Austria	505.080	61,8	13.400	2,6	0	0,00	22.907			
Belgium	503.228	50,3	1.720	0,3	92.532	9,25	21.283	0	10	
Bosnia / Herzegovina	36.492	9,4	6	0,0			450			
Bulgaria	148.226	18,6	185	0,1			271	0	0	
Croatia	160.800	36,2	1.179	0,7	297	0,07	1.400	0	0	
Cyprus										
Czech Republic	431.400	41,9	19.100	4,2	47.500	4,61	18.300	1.500	<200	
Denmark	906	0,2			429	0,09	1.416	0		
Estonia										
Former Yug. Rep. Macedonia	53.716	24,4	21	0,0	0	0,00	100	0	0	
Finland	297.292	57,0	0	0,0	1.620	0,31	759	0	0	
France	2.211.123	36,7	66.594	2,9	128.892	2,14	157.336	0	235	
Georgia	25.000	5,0			6.000	1,20	100			
Germany	4.633.338	56,1	188.036	3,9	2.500.259	30,29	231.538	11.910		1)
Greece	599.473	57,1	4.706	0,8	910	0,09	26.073	5.613	<25	
Hungary										
Iceland	14.668	50,4	2	0,0	0	0,00	252	0		
Ireland	145.799	37,2	9	0,0	0	0,00	8.684	0	0	
Italy	2.178.000	38,2	127.000	5,5	183.000	3,21	64.500			
Latvia	56.402	24,5	0	0,0	18.243	7,93	1.636	64		
Liechtenstein										
Lithuania										
Luxembourg	21.773	50,1	372	1,7	4.344	9,99	811	0	0	
Malta										
Moldovia										
Netherlands	671.534	41,5	501	0,1	150.181	9,27	4.309	736	237	
Norway	199.582	43,6	53	0,0	1.463	0,32	3.485	4.631	0	
Poland	880.575	22,9	2.952	0,3	35.349	0,92	20.898	58	148	
Portugal										
Romania	346.023	15,4	400	0,1	229	0,01	488		50	
Russian Federation										
San Marino										
Serbia and Montenegro	13.723	21,1	10	0,1						
Slovak Republic	157.407	29,7	2.767	1,7	386	0,07	4.024	0	0	
Slovenia	84.895	43,2	1.918	2,2	299	0,15	735	0	10	
Spain										
Sweden	481.078	53,6	483	0,1	108.673	12,11	8.260	921	71	
Switzerland	394.495	53,6	18.000	4,4	1.450	0,20	23.000	221	200	2)
Turkey										
Ukraine	838.465	17,7								
United Kingdom	2.753.086	46,8	938	0,0	1.230	0,02	112.872	1.900	164	

1) Germany: data on whole blood, plasmaphaeresis and red cell aphaeresis include autologous, platelet aphaeresis data based on number of concentrates

2) Switzerland: autologous units are estimate

Table 3
2003

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)*
Andorra								
Armenia	70	2,8	2.464	0,8	4.456	70	0	70
Azerbaijan								
Albania								
Austria	0	0,0	447.200	54,7	89.000	40.002	17.383	22.619
Belgium	0	0,0	478.401	47,8	92.279	38.000	27.333	10.667
Bosnia / Herzegovina	8.753	24,4	27.174	9,2	24.276	2.961	2.214	747
Bulgaria	4.954	3,7	129.167	16,8	86.669	17.210	16.939	271
Croatia	4.074	2,7	148.714	34,4	93.299	11.049	9.176	1.873
Cyprus								
Czech Republic	1.200	0,3	412.800	40,2	171.000	22.600	5.600	17.000
Denmark	151	0,0	354.034	70,8	60.766	94.755	91.267	3.488
Estonia								
Former Yug. Rep. Macedonia	53.716	51,2	51.298	47,7		1.681	1.581	100
Finland	26	0,0	270.962	51,9	43.060	31.700	31.030	670
France	0	0,0	1.952.304	32,4	265.332	199.931	24.700	175.231
Georgia	1.500	5,6	25.500	5,4	24.000	1.500	1.400	100
Germany	30.810	0,7	4.113.511	50,2	1.304.870	333.745	114.402	219.343
Greece	5.100	0,9	594.212	57,1	154.232	132.626	114.902	17.724
Hungary								
Iceland	0	0,0	14.128	48,5	4.388	985	599	386
Ireland			130.088		22.171	16.521	9.689	6.832
Italy	48.000	2,2	2.150.000	38,6	503.333	192.250	127.750	64.500
Latvia	0	0,0	49.738	21,6	47.971	4.130	917	3.213
Liechtenstein								
Lithuania								
Luxembourg	0	0,0	19.835	45,6	3.718	8.014	4.312	3.702
Malta								
Moldovia								
Netherlands	301	0,0	608.671	37,6	111.620	47.314	45.751	1.563
Norway	258	0,1	183.289	40,1	39.702	13.664	9.428	4.236
Poland	1.608	0,2	831.045	21,6	355.864	40.091	16.808	23.283
Portugal								
Romania	149.460	45,9	176.030	14,5	171.914	41.243	38.321	2.922
Russian Federation								
San Marino								
Serbia and Montenegro	4.467	32,6	9.256	21,1	9.256	1.028	1.028	0
Slovak Republic	23.742	12,1	172.698	37,1	19.256	8.477	4.474	4.003
Slovenia			78.075		32.671	21.737	20.605	1.132
Spain								
Sweden	169	0,0	445.474	49,7	120.954	32.531	19.122	13.409
Switzerland	5.255	1,7	308.965	42,7	81.261	23.000	2.500	20.500
Turkey								
Ukraine	2.117	9,5	20.203	0,5	22.438	5.917	5.917	0
United Kingdom	754	0,0	2.568.896	43,7	377.560	266.089	163.719	102.370

1) Italy: plasma for transfusion data given in Litres, here recalculated into Units of 300 mL

Table 4
2003

country	Plasma for fractionation into medicinal products				
	plasma for fractionation (L)	plasma for fractionation per 1,000 inhabitants (L)	plasma for transfusion per 1,000 inhabitants (U)	plasma for transfusion / total red blood cell ratio (U)	
Andorra					
Armenia	9.049	2,82	1,39	1,76	1)
Azerbaijan					
Albania					
Austria	59.721	7,31	10,89	0,20	2)
Belgium	207.444	20,74	9,23	0,19	
Bosnia / Herzegovina			6,22	0,68	
Bulgaria	10.833	1,36	10,87	0,65	
Croatia	17.575	3,96	21,03	0,61	
Cyprus					
Czech Republic	79.000	7,67	16,60	0,41	
Denmark	86.751	17,35	12,15	0,17	
Estonia					
Former Yug. Rep. Macedonia	4.784	2,17			
Finland	72.500	13,89	8,25	0,16	
France	576.272	9,57	4,41	0,14	
Georgia	1.000	0,20	4,80	0,89	
Germany	2.484.216	30,10	15,81	0,31	3)
Greece	19.557	1,86	14,69	0,26	
Hungary					
Iceland	0	0,00	15,08	0,31	
Ireland			5,66		
Italy	529.000	9,28	8,83	0,23	
Latvia	18.469	8,03	20,86	0,96	
Liechtenstein					
Lithuania					
Luxembourg	7.652	17,59	8,55	0,19	
Malta					
Moldovia					
Netherlands	310.449	19,17	6,89	0,18	
Norway	49.842	10,89	8,67	0,22	
Poland	134.796	3,50	9,24	0,43	
Portugal					
Romania			7,66	0,53	4)
Russian Federation					
San Marino					
Serbia and Montenegro			14,24	0,67	
Slovak Republic	16.484	3,11	3,63	0,10	
Slovenia	10.959	5,58	16,63		
Spain					
Sweden	198.167	22,08	13,48	0,27	
Switzerland	73.474	9,98	11,03	0,26	
Turkey					
Ukraine	84.844	1,79	0,47	1,01	
United Kingdom	0	0,00	6,42	0,15	

1) Armenia: 8820 Litres of anti-D plasma
2) Austria: plasma from industrial centres not included
3) Germany: hyper-immune plasma not included
4) Romania: no contract for fractionation sofar

Table 5.1
2003

country	Special processing of blood components						
	red blood cells		plasma for transfusion		platelets		
	leuco depleted %	irradiated %	leuco depleted %	irradiated %	leuco depleted %	irradiated %	
Andorra							
Armenia	0	0	0	0	0	0	
Azerbaijan							
Albania							
Austria	100	6	100	1	100	30	1)
Belgium	35	1	0	0	100	2	2)
Bosnia / Herzegovina	10	50			75	60	
Bulgaria	12	0	0	0	0	0	
Croatia	6				20		
Cyprus							
Czech Republic	8	10		5	25	40	3)
Denmark	16				93		4)
Estonia							
Former Yug. Rep. Macedonia	3	0	0	0	10	0	
Finland	100	2	100	0	100	22	5)
France	100	7	100	0	100	43	
Georgia	5						
Germany	100				100		
Greece	35	8	25	5		9	
Hungary							
Iceland	16	5	0	0	100	51	
Ireland	100		100		100		
Italy	20				70		
Latvia	65	1	73		100	10	
Liechtenstein							
Lithuania							
Luxembourg	100		100	0	100		
Malta							
Moldovia							
Netherlands	100	3	100		100	23	
Norway	100		100		100		6)
Poland	4	3	0	0	90	90	
Portugal							
Romania	3	1			3	1	
Russian Federation							
San Marino							
Serbia and Montenegro							
Slovak Republic	14	22	14	0	66	35	
Slovenia	18	3	14	0	36	6	
Spain							
Sweden	61	3		2	93	47	
Switzerland	100		100		100		7)
Turkey							
Ukraine	5						
United Kingdom	100	5	100	0	100	42	

1) Austria: alle whole blood units in-line filtered
2) Belgium: no data on irratiation in hospitals
3) Czech Republic: filtration additional 4% of red cells and 15% of platelets post storage
4) Denmark: minimal frequencies are given for leucodepletion
5) Finland: irradiation also by hospitals, no data
6) Norway: SD plasma only
7) Switzerland: irradiation in hospitals, no data

Table 5.2
2003

country	Inactivation or quarantine of plasma						
	fresh frozen plasma		cryoprecipitate reduced plasma		cyroprecipitate		
	quarantined %	virus inactivated %	quarantined %	virus inactivated %	quarantined %	virus inactivated %	
Andorra							
Armenia	0	0	0	0	0	0	
Azerbaijan							
Albania							
Austria							1)
Belgium	0	100					
Bosnia / Herzegovina							
Bulgaria	0	0	0	0	0	0	
Croatia							
Cyprus							
Czech Republic	100		100		100		2)
Denmark							
Estonia							
Former Yug. Rep. Macedonia	0	0	0	0	0	0	
Finland	1	0	0	0	0	0	3)
France	57	43					
Georgia							
Germany	100	0					4)
Greece	20	8					
Hungary							
Iceland							
Ireland	0		0		0		
Italy							
Latvia	65						
Liechtenstein							
Lithuania							
Luxembourg	0	100	0	0	0	0	
Malta							
Moldovia							
Netherlands	100						
Norway	0	100					5)
Poland	69	0	90	0	92	0	
Portugal							
Romania	100		100		100		
Russian Federation							
San Marino							
Serbia and Montenegro							
Slovak Republic	42	0	1	0	1	0	
Slovenia	0	0	0	0	0	0	
Spain							
Sweden	0	0		0		0	
Switzerland	80	20					
Turkey							
Ukraine	11						
United Kingdom	0	2	0	0	0	0	

1) Austria: in 1 centre 100% of FFP is quarantined, no data on use of SD plasma by industry
2) Czech Republic: Cryoprecipitate used for fibrinogen
3) Finland: pediatric plasma quarantined for 4 months, donor retested
4) Germany: quarantine required for all FFP, which is 88,2% of volume, 11,8% is SD plasma
5) Norway: SD plasma only

Table 6
2003

country	Screening for infectious agents, methods												
	anti-HIV 1+2		HBsAg		anti-HCV		anti-HTLV I/II		Syphilis		anti-HBc		
	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	1		1		1				1				1)
Azerbaijan													
Albania													
Austria	1		1		1				1				2)
Belgium	1		1		1				1			1	
Bosnia / Herzegovina	1		1		1				1				
Bulgaria	1		1		1				1				
Croatia	1		1		1		1		1				
Cyprus													
Czech Republic	1		1		1				1				
Denmark	1		1		1			1					3)
Estonia													
Former Yug. Rep. Macedonia	1		1		1				1				
Finland	1		1		1			1	1				4)
France	1		1		1		1		1		1		5)
Georgia	1		1		1				1				
Germany	1		1		1				1				6)
Greece	1		1		1		1		1				7)
Hungary													
Iceland	1		1		1								
Ireland	1		1		1		1		1		1		
Italy	1		1		1				1				
Latvia	1		1		1				1				
Liechtenstein													
Lithuania													
Luxembourg	1		1		1		1		1			1	
Malta													
Moldovia													
Netherlands	1		1		1		1		1				
Norway	1		1		1			1		1		1	8)
Poland	1		1		1				1				
Portugal													
Romania	1		1		1		1		1				
Russian Federation													
San Marino													
Serbia and Montenegro	1		1		1				1				
Slovak Republic	1		1		1				1				
Slovenia	1		1		1				1				
Spain													
Sweden	1		1		1			1		1		1	
Switzerland	1		1		1				1				9)
Turkey													
Ukraine	1		1		1				1				
United Kingdom	1		1		1		1		1				

1) Armenia: each donation tested for Brucellosis
2) Austria: each donation tested for Neopterin
3) Denmark: anti-HTLV-I also after return from endemic area's
4) Finland: anti-HTLV-I also in repeat donors every 3 years
5) France: anti-HBs if anti-HBc is positive for plasma
6) Germany: ALT mandatory until december 2003, anti-HBc in some institutes
7) Greece: anti-HBc when required
8) Norway: anti-HBc repeated when more than 1 year ago
9) Switzerland: donors with history of hepatitis, tested for anti-HBc and anti-HBs

Table 7.1
2003

country	Confirmed seropositive donors (absolute numbers)										
	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	26	3	32	107	106	68			12	49	
Azerbaijan											
Albania											
Austria											1)
Belgium	2	1	56	7	29	3					
Bosnia / Herzegovina	0	0	14	8	5	5			2	4	
Bulgaria	12	0	2928	11	431	4			753	8	
Croatia	2	4	55	19	20	13	0		5	9	
Cyprus											
Czech Republic											
Denmark	0	0	12	1	11	1					
Estonia											
Former Yug. Rep. Macedonia	51		205		139				0		
Finland	1	1	2	0	11	5	0	0	0	2	
France	20	10	427	11	283	22	49	7	118	47	
Georgia	3		303		561				108		
Germany	47	49	911	61	566	65			199	99	
Greece	22	10	1201	339	344	97	19	11	70	23	2)
Hungary											
Iceland	0	0	1	0	0	0					
Ireland	1	0	2	0	2	1	0	0	1	2	
Italy											3)
Latvia	11	4	148	23	285	155			19		
Liechtenstein											
Lithuania											
Luxembourg	0	0	2	0	0	0	0	0	0	0	
Malta											
Moldovia											
Netherlands	1	1	22	9	9	0	2	0	10	11	
Norway	0	0	1	2	9	1	0		2		
Poland	9	14	1218	27	1246	100			76	74	
Portugal											
Romania	18	11	2472	242	707	28	26	5	1151	931	
Russian Federation											
San Marino											
Serbia and Montenegro											
Slovak Republic	1	0	40	6	15	9			5	2	
Slovenia	0	0	19	1	10	0			2	5	
Spain											
Sweden	2	2	20	2	33	3	0				
Switzerland	3	2	43	5	30	6			15	14	
Turkey											
Ukraine											
United Kingdom	22	13	95	12	104	30	16	10	53	31	

1) Austria: no separate data on first time donors and repeat / regular donors
2) Greece: data based on estimate from 550484 tested units
3) Italy: confirmed data of 2003 not available yet

Table 7.2
2003

country	Prevelance and incidence calculated per 100,000 donors						
	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	
Andorra							
Armenia	459,28	195,82	565,27	6984,33	1872,46	4438,64	
Azerbaijan							
Albania							
Austria							1)
Belgium	5,13	0,43	143,57	3,04	74,35	1,30	
Bosnia / Herzegovina	0,00	0,00	174,26	24,25	62,24	15,16	
Bulgaria	38,35	0,00	9356,43	9,42	1377,26	3,43	
Croatia	10,91	5,04	299,99	23,95	109,09	16,39	
Cyprus							
Czech Republic							2)
Denmark	0,00	0,00	48,00	0,47	44,00	0,47	
Estonia							
Former Yug. Rep. Macedonia	632,99		2544,37		1725,21		
Finland	5,28	0,67	10,56	0,00	58,07	3,35	
France	5,79	0,84	123,69	0,92	81,98	1,84	
Georgia	300,00		30300,00		56100,00		
Germany	8,26	2,74	160,08	3,41	99,46	3,64	3)
Greece	37,81	3,32	2064,28	112,62	591,27	32,23	4)
Hungary							
Iceland	0,00	0,00	40,97	0,00	0,00	0,00	
Ireland	3,94		7,87		7,87		
Italy	13,01	3,27	265,41	3,61	197,26	3,36	5)
Latvia	83,77	11,23	1127,10	64,58	2170,44	435,21	
Liechtenstein							
Lithuania							
Luxembourg	0,00	0,00	263,85	0,00	0,00	0,00	
Malta							
Moldovia							
Netherlands	2,85	0,21	62,69	1,90	25,65	0,00	
Norway	0,00	0,00	7,22	2,20	64,97	1,10	
Poland	4,98	5,88	674,18	11,34	689,68	41,99	
Portugal							
Romania	22,25	7,71	3055,02	169,64	873,75	19,63	
Russian Federation							
San Marino							
Serbia and Montenegro							
Slovak Republic	3,78	0,00	151,31	5,32	56,74	7,98	
Slovenia	0,00	0,00	169,79	1,05	89,37	0,00	
Spain							
Sweden	5,00	0,76	50,01	0,76	82,51	1,15	
Switzerland	12,01	1,03	172,08	2,56	120,05	3,08	
Turkey							
Ukraine							
United Kingdom	7,40	0,91	31,93	0,84	34,96	2,10	

1) Austria: no separate data on first time donors and repeat / regular donors
2) Czech Republic: HCV data include indeterminates
3) Germany: data are based on extrapolation
4) Greece: data based on estimate from 550484 tested units
5) Italy: confirmed data of 2003 not available yet

Table 8.1
2003

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

1) Denmark: NAT by fractionator
2) Germany: HIV NAT and HBV NAT voluntary by 70% of institutes
3) Greece: HIV in SD NAT, HCV in MP NAT
4) Poland: HIV NAT and HCV NAT tested on 109,962 donations in 2 institutes, HBV NAT on 60,000 donations
5) Slovak Republic: NAT by fratcionator
6) Scotland and N-Ireland: also HIV NAT

Table 8.2
2003

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	0	1	1	0	2	
Belgium	0	0			1	0	
Bosnia / Herzegovina							
Bulgaria							
Croatia					0	0	
Cyprus							
Czech Republic							1)
Denmark		0		0		0	
Estonia							
Former Yug. Rep. Macedonia							
Finland					2	0	
France	0	0			0	0	
Georgia							
Germany	0	3	0	3	2	13	2)
Greece	0	0			1		3)
Hungary							
Iceland							
Ireland	0	0			0	0	
Italy					2	1	
Latvia							
Liechtenstein							
Lithuania							
Luxembourg	0	0	0	0	0	0	
Malta							
Moldovia							
Netherlands	0	0			0	0	
Norway					0	1	
Poland					2	5	
Portugal							
Romania							
Russian Federation							
San Marino							
Serbia and Montenegro							
Slovak Republic							
Slovenia					0	0	
Spain							
Sweden							4)
Switzerland	0	0			0	0	
Turkey							
Ukraine							
United Kingdom	0	0			1	1	

1) Czech Republic: NAT data from fractionator not available
2) Germany: one HCV NAT found by look-back (SD NAT pos / MP NAT neg)
3) Greece: NAT introduced during 2003
4) Sweden: NAT data from fractionators not available

Table 9
2003

country	Organisation, registration and labelling					
	National Council or Expert Committee	ID and labelling of donation number		ID and labelling of component code		
		% ISBT	% Other	% ISBT	% Other	
Andorra						
Armenia	no		100		0	1)
Azerbaijan						
Albania						
Austria	yes		100		100	2)
Belgium	yes	100	0	30		3)
Bosnia / Herzegovina	no		100		100	1)
Bulgaria	yes		100			3)
Croatia	yes		100		100	2)
Cyprus						
Czech Republic	yes		100		100	3)
Denmark	yes	44		16		4)
Estonia						
Former Yug. Rep. Macedonia	no		100		100	
Finland	no	100		100		
France	yes		100		100	2)
Georgia	yes		100		100	
Germany	yes					5)
Greece	yes		100		100	6)
Hungary						
Iceland	no	92		92		7)
Ireland	yes		100		100	2)
Italy	yes	80	20	80	20	
Latvia	yes					
Liechtenstein						
Lithuania						
Luxembourg	no		100		100	2)
Malta						
Moldovia						
Netherlands	yes	100		100		
Norway	yes	66	34	66	34	
Poland	yes		100		100	4)
Portugal						
Romania	yes		100		100	1)
Russian Federation						
San Marino						
Serbia and Montenegro	no		100			
Slovak Republic	yes		90		90	8)
Slovenia	yes	0	100	0	100	2)
Spain						
Sweden	yes	85	15	85	15	9)
Switzerland	no	100		100		
Turkey						
Ukraine	yes					
United Kingdom	yes	0	100	0	100	

1) Armenia, Bosnia / Herzegovina, Romania: eye readable key data on label
2) Austria, Croatia, France, Ireland, Luxembourg, Slovenia: Codabar
3) Belgium, Bulgaria, Czech Republic: national sytem
4) Denmark, Poland: local sytems
5) Germany: labelling compatible with unique identification
6) Greece: 70% computerized
7) Iceland: ISBT 128 in Reykjavik
8) Slovak Republic: compatible with CoE recommendations
9) Sweden: 15% on earlier national code

Table 10
2003

country	Quality Management related issues						
	QA system established and maintained	% donations covered by			Inspections each second year, by	Haemovigilance system operated by	
		% GMP	% ISO 9000	% other			
Andorra							
Armenia	planned	0	0		nat author	no	
Azerbaijan							
Albania							
Austria	yes	100	100		nat author	nat author	
Belgium	yes	100			nat author & plasma fract	planned	
Bosnia / Herzegovina	planned				no	no	
Bulgaria	planned	52			planned	nat author	
Croatia	yes	100	48		no	other org	1)
Cyprus							
Czech Republic	yes	100	20		nat author	nat author	
Denmark		100			nat author	other org	
Estonia							
Former Yug. Rep. Macedonia	planned				Tx specialist	no	
Finland	yes	100			nat author	other org	
France	yes & planned		100	100	nat author	nat author	2)
Georgia	planned				other org	no	
Germany	yes	100			nat author	nat author	
Greece	yes	70			nat author	other org	
Hungary							
Iceland	yes		92		other org	no	
Ireland	yes	100	33		nat author	nat author	
Italy	planned				no	nat author	
Latvia	yes			100	nat author	other org	3)
Liechtenstein							
Lithuania							
Luxembourg	yes	100	100		nat author	nat author & RC	4)
Malta							
Moldovia							
Netherlands	yes	100			nat author	other org & nat author	
Norway	yes	100	24		no	planned	
Poland	yes	100			other org	nat author	
Portugal							
Romania	planned				other org	no	5)
Russian Federation							
San Marino							
Serbia and Montenegro	no				local author	no	
Slovak Republic	planned	90	1,2		nat author	nat author	6)
Slovenia	yes	100			nat author & other org	other org	
Spain							
Sweden	yes	100	83		nat author & other org	nat author	7)
Switzerland	yes	100	65		nat author	nat author	
Turkey							
Ukraine					nat author	nat author	
United Kingdom	yes	100			nat author	other org	

1) Croatia: QMS in Institute of Transfusion Medicine EN ISO 9001-2000 about 48% of donations
2) France: QMS is EN ISO 9001-2000 and other national system
3) Latvia: national requirements for blood establishments
4) Luxembourg: QMS is EN ISO 9001-2000
5) Romania: SOP's in construction
6) Slovak Republic: QMS: vairous levels of ISO, 1 centre certified
7) Sweden: EN ISO/IEC 17025 or EN ISO 15189

APPENDIX

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

The 2003 Survey"

COUNTRY	
Information provided by	
Institution	
Address	
Tel. & fax.	
e-mail address	

Population in country, number	

SECTION A. Collection and use of blood and blood components

1. Donors active during the year

1.1	**Regular and repeat donors**, number	
1.2	**First time donors**, total number	
	First time donors, on first visit -	
1.2.1	- donating blood or components, number	
1.2.2	- giving blood samples for testing only, number	
1.3	**Autologous donors** (pre-deposit), number	

2. Collection of blood and blood components

2.1	**Whole blood**, number of donations	
2.1.1	- **autologous** (pre-deposit), number of donations	
2.2	**Red cells** (apheresis), number of adult therapeutic doses	
2.3	**Plasma** (apheresis), litres	
2.4	**Platelets** (apheresis), number of adult therapeutic doses *	
	* mean number of platelets in an adult therapeutic dose:	x 10^9
2.5	**Granulocytes** (apheresis), number of donations	

3. Use of blood and blood components for transfusion

Please, indicate if the figures given relate to blood and blood components
☐ transfused, or
☐ distributed to hospital blood banks

	Blood components	number of units
3.1	**Whole blood**	
3.2	**Red cells** (all types of red cells for transfusion, excl. autologous)	
3.2.1	**- autologous** (pre-deposit)	

3.3	**Plasma** (all types of plasma for transfusion)	
3.4	**Platelets** (adult therapeutic doses)	
3.4.1	– recovered from whole blood (adult therapeutic doses)	
3.4.2	– from platelet apheresis (adult therapeutic doses)	
3.5	**Cryoprecipitate**, FVIII IU*10^6	

4. Blood components delivered for manufacture of medicinal products

4.1	**Plasma for fractionation**, total, kg*	
4.1.1	– fresh frozen, for FVIII production, kg	
4.1.2	– other plasma, kg	
4.2	**Other components** (e.g. erythrocytes, buffy coat), units	

*kg = L x 1.026

5. Special processing of blood components

5.1	**Blood components leucocyte depleted** (<1x10^6/unit), **pre-storage, and irradiated blood components**	Percent leucocyte depleted	Percent irradiated
5.1.1.	Red cells	%	%
5.1.2	Plasma (for transfusion)	%	%
5.1.3	Platelets	%	%

5.2	**Plasma components** (for transfusion) **quarantined or virus inactivated**	***Percent of plasma components***	
		quarantined	virus inactivated
5.2.1.	**Fresh frozen plasma**	%	%
5.2.2	**Cryoprecipitate reduced plasma**	%	%
5.2.3	**Cryoprecipitate**	%	%

Please use the following space to provide any further information that you regard to be useful about the collection and use of blood and blood components.

SECTION B. Testing of blood and blood components

6. Screening for infectious agents, serological test methods

	Screening test performed	each donation	1st time donors	plasma for fract.	Comments
6.1	anti-HIV 1+2	☐	☐	☐	
6.2	HBsAg	☐	☐	☐	
6.3	anti-HCV	☐	☐	☐	
6.4	anti-HTLV I/II	☐	☐	☐	
6.5	Syphilis*	☐	☐	☐	
6.6	anti-HBc	☐	☐	☐	
6.7	anti-CMV	☐	☐	☐	
6.8	Others,	☐	☐	☐	
	please specify	☐	☐	☐	
		☐	☐	☐	
		☐	☐	☐	

*e.g. TPHA, RPR, VDRL, or other screening tests.

7. Confirmed seropositive test results

7	**Confirmed seropositive**[1]	HIV 1	HIV 2	HBV	HCV	HTLV I/II	Syphilis
7.1	First time tested donors[2], No.						
7.2	Repeat tested donors[3], number						

[1] Confirmed seropositive: Repeatedly reactive (= 2 times reactive) in a screening test and positive
in at least one supplementary test based on an other principle.

[2] First time tested donor: Person who is tested for the first time (with or without donation) without report of prior serological testing.

[3] Repeat tested donor: Donor who has been subjected to previous serological testing in a given
blood system.

8. Nucleic Acid Testing, NAT

8.1	**Screening for infectious agents, NAT**				
	Screening test performed	each donation	1st time donors	plasma for fract.	Comments
8.1.1	HIV NAT	☐	☐	☐	
8.1.2	HBV NAT	☐	☐	☐	
8.1.3	HCV NAT	☐	☐	☐	

8.2	Size of **mini-pool**(s)	HIV:	HBV:	HCV:

8.3	**NAT only positive[4] test results,** number	HIV	HBV	HCV
8.3.1	First time donors			
8.3.2	Regular and repeat donors			

8.4	**NAT only positive[4] donations**,	HIV	HBV	HCV
	detected by a ***look-back*** investigation			

[4] NAT only positive:
Positive in a NAT assay for a specific virus (HIV, HCV or HBV), not found seropositive for that
virus in serological screening, and shown to be true positive by separate PCR or later serology.

Please use the following space to provide any further information that you regard to be useful about the testing of blood and blood components.

SECTION C. General information

9. Organisation, registration and labelling

9.1	**National council or expert committee** to advise Ministry of Health on transfusion related issues	☐ Yes	☐ No

9.2	**System used for identification and labelling of donations and components**		
	Percent donations labelled according to	ISBT 128	Another system*
9.2.1	donation number	%	%
9.2.2	component code	%	%
	* please, specify		

10. Quality management related issues

10.1	**Quality system established and maintained in blood establishments**			☐ Yes ☐ Planned ☐ No
	Percent donations covered by	GMP	ISO 9000 series	Other *
		%	%	%
	* please, specify:			

10.2	Are **inspections** performed at least each second year? ☐ No ☐ Yes, by ☐ a national authority ☐ another qualified body or organisation
	Comments:
10.3	**Haemovigilance** – is there a haemovigilance reporting system on national level? ☐ No ☐ Yes, - operated by a national authority ☐ Yes, - operated by another organisation*
	*please, specify:
	Comments

Please use the following space to provide any further information that you regard to be useful about organisational and quality management related blood issues