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REPORT

THE COLLECTION, TESTING AND USE OF BLOOD AND BLOOD PRODUCTS IN EUROPE IN 2001

Prepared by: A.R. Maillé, L. Bonneux, C.L. van der Poel

The collection, testing and use of blood and blood products in Europe in 2001

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A.R. Maillé[1], L. Bonneux[1], C.L. van der Poel[2]

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

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 2001. 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, and 1997.

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 therefore not attempted. Not all the relevant information was obtained from each Member State, as the average response rate was 86%. It is noted that the new format may have generated initial difficulties in data retrieval, and as the process will continue for the year 2002 and further, 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 has been 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 37 / 43 questionnaires were received, the response being 86 percent.

The average number of donors in relation to the general population is 20 per 1,000 inhabitants, and on average 25.5 percent of the donor base consists of first time donors.

The number of whole blood collections is on average 35.7 per 1,000 inhabitants, and the average use of red blood cells is 34.4 per 1,000 inhabitants. On average up to 2,6 liters of plasmapheresis plasma per 1,000 inhabitants are collected, and 4 Member States stand out with between 7.6 and 13.8 liters of plasmapheresis plasma per 1,000 inhabitants.

The use of red blood cells varies considerably but averages 31.9 total red blood cell products per 1,000 inhabitants. In 9 / 37 (24%) of the reporting Members States below 20 units per 1,000 inhabitants are collected, probably reflecting insufficient supply. On average in 29 reporting Member States, 32 percent of the total platelet volume is supplied by (random) single donor

platelets by apheresis, in 10 countries this volume amounts to more than 50 percent.

The total amount of plasma delivered for fractionation into medicinal products differs greatly among Member States, an average yield of 7.4 liters of plasma for fractionation per 1,000 inhabitants is found. However 8 / 37 (21%) of reporting Member States deliver in the range of 12 – 23 liters per 1,000 inhabitants. Of these 8 countries, 3 countries collect considerably more plasma by apheresis than the average of 2.6 liters of plasmapheresis plasma per 1,000 inhabitants. The use of plasma for transfusion would be competitive with the yield of (recovered) plasma fractionation. On average 10.4 units of plasma per 1,000 inhabitants are used for transfusion, or 0.4 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. In 2 other Member States a high yield of plasma for fractionation is observed in the presence of an above-average of use of plasma for transfusion.

In 19% of Member States, 100 percent leucodepletion of red blood cell products is carried out. Platelet concentrates are 100% leucodepleted in 32% of Member States. In 30% of Member States 100% of FFP is additionally safeguarded by either quarantine or pathogen reduction methods.

In all reporting Member States, all donations are tested for anti-HIV-1/2 and HBsAg. In all but one of 37 reporting Member States, all donations are also tested for anti-HCV. In all but the Scandinavian countries, all donations are tested for Syphilis. Anti-HTLV-I/II testing is performed on all donations in 22% of Member States, and on first time donors in 11%. Anti-HBc is tested for all donations in 5 / 37 (14%) of reporting Member States, and only on first time donors in another 5 (14%). 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. Nucleic Acid Testing (NAT) for HCV is performed on each donation in 32% of Member States. In addition, 19% reporting Member States perform HCV-NAT on plasma for fractionation. NAT for HIV is performed on each donation in 8 / 37 (22%) reporting Member States. In addition, 5 / 37 (14%) Member States perform HIV-NAT on plasma for fractionation. NAT for HBV is performed on each donation in 2 Member States. The occurrence of a NAT-positive donor, not found seropositive for that virus in serological screening, is a rare event.

In 70% of the reporting Member States a National Council or Expert Committee to advise the Ministry of Health on transfusion related issues exists. Labeling is performed according to ISBT-128 for the donation number in 9 countries, whereas 11 indicate to be further working on implementation. Labeling of the finished component code by ISBT-128 is (partially) implemented in 8 countries. Only 3 countries have 100% ISBT-128 at the donor as well as the finished component level.

In 57% of the reporting Member States a Quality System is established and maintained in blood establishments. In 49% of Member States 100 percent of the donations are covered by GMP. In 2 countries this is the case for ISO

9000 respectively for 92 and 100% of the donations. In 76% of the reporting Member States inspections are performed at least every 2 years, in 24 countries by the national authority. In 62% of the Member States a haemovigilance system is installed, in 16 countries organized by the national authority.

Acknowledgements

The Council of Europe SP-HM Secretariat and the authors are grateful to all colleagues who provided data for inclusion in this report.

Study methods

The questionnaire used in this survey was newly designed by transfusion experts of member states after discussions in SP-HM and SP-R-GS in 2001 and 2002, following the publication of the Rejman report in 2000 on 1997 data, and when it was felt that EC member states would need to be included in the reporting. The new questionnaire on 2001 is attached in the Appendix. The Council of Europe SP-HM Secretariat circulated the 2001 questionnaire to Member States requesting that the completed forms be returned to the Secretariat by September 2002. The completed questionnaires were received by the authors in March 2003. After meetings with SP-HM and CDSP, corrections and additions were provided by 7 Member States until March 2004.

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 at all. It is therefore 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 2001).

As opposed to previous survey methods (Rejman 2000), the present questionnaire was not elaborated upon by the authors after submission by the Member States. No additional or explanatory questions to Member States or to National experts were posed when incomplete data sets were returned or in case of no reply. It was rather felt that non-response could have been attributed to unclarity 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 of reviewing the returned data sets, the 2001 questionnaire was evaluated for response rate, clarity and consistency. A separate Qualitative Evaluation Report on the 2001 Questionnaire with recommendations for improvement of the process has been reported by the authors to SP-HM and discussed in November 2003. Thereafter, corrections and additions from 7 Member States were received until March 2004. It is anticipated that as we become accustomed to the survey the ease, speed and quality of reporting and publishing will improve. It is expected that the surveys of 2002 and 2003 can be published sooner, after which a revision of the questionnaire is envisioned for the 2004 survey.

Comparisons with results from previous surveys was not attempted, as the last report on 1997 data by Rejman in 2000 was quite differently designed and did not include EC member states. 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 the information was not available when some information was not provided. Non-availability of the data is represented by empty fields in the tables. Unclarity of data or explanations given by the Member States in the questionnaires is represented by footnotes in the tables. In addition some specific remarks by the authors are given in *italics* in the footnotes of the tables.

Member States of the Council of Europe (n=43) were invited to send completed questionnaires. No reply was received from Andorra, Federal Republic of Yugoslavia, Liechtenstein, Malta, Russian Federation, and Ukraine. In total 37 questionnaires were received, the response rate thus being 86 percent. For the United Kingdom, only the data on England and Wales are included. Portuguese data represent 3 blood centers (about 50% of the national volume). Georgia data represent 4 blood centers.

In addition, questionnaires were sent to Australia, USA, New Zealand, Canada, Mexico, Japan and Israel with observers or representatives at the SP-R-GS or SP-HM meetings (n=7). However, since only 1 of 7 observer states returned a completed questionnaire, in the view of the authors, the response of this part of the study is too low to justify inclusion in this report.

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” would 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. Probably not in all systems regular and repeat donors are registered separately. In 3 reporting Member States (Austria, Cyprus and Turkey) new donors and applicant donors were not registered or not reported *separately from* repeat and regular donors. In Germany only new donors were reported. These limitations hamper 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), terms for which separate reporting of both donor populations is necessary. 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 would 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 donorbase. It may be influenced by extraordinary 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 25.5 percent of the total donor base consists of "first time" donors. It is known that repeat and regular donors may have lower incidences of infectious diseases (Schreiber 2001).

The average number of donors in relation to the general population is 25 per 1,000 inhabitants. This number may reflect the commitment of the population to donate blood in relation to the demand. Differences exist, but less than 20 donors per 1,000 inhabitants 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, such as Croatia, 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.

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 35.7 per 1,000 inhabitants. Given the average use of red blood cells of 34.4 per 1,000 inhabitants, and taking product loss into account, 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 to less than 5 percent of the 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 the present 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 number

of plasmapheresis collections per 1,000 inhabitants, reflects the magnitude of the national plasmapheresis programs. The average amounts up to 2,6 plasmapheresis plasma in liters per 1,000 inhabitants. Apparently Belgium, Germany, Luxembourg and Sweden stand out as countries with plasmapheresis programs with 7.6 to 13.8 liters plasmapheresis plasma per 1,000 inhabitants.

Plateletapheresis 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 plateletapheresis by random donors in order to minimize patient exposure to allogeneic donors. The latter data e.g.: the relative importance of plateletapheresis for the total supply of platelet products is given in Table 3.

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 limited.

Use of blood and blood components for transfusion: Table 3

The term “the use of blood” may be somewhat misleading as the reported data may not reflect the actual use of blood or blood components in the hospitals, but rather the number of blood components that have been delivered to hospitals by blood establishments. 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. 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.

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. In 6 / 37 (16%) 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 31.9 total red blood cell products per 1,000 inhabitants. 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 it may be questioned whether a use of red blood cells of about 40 units per 1,000 inhabitants would reflect insufficient supply or rather more stringent use. In 9 / 37 (24%) of the reporting Members States below 20 units per 1,000 inhabitants are collected, probably reflecting insufficient supply. Conversely, the supply 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 the 2004 survey in relation to the red blood cell use.

The use of plasma for transfusion 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). As this is of interest with regard to the supply of plasma for fractionation into medicinal products, the data are presented in Table 4.

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 29 reporting Member States, 32 percent of the total platelet volume is supplied by (random) single donor platelets by apheresis, in 10 countries this volume amounts to more than 50 percent.

Cryoprecipitate may still be used for correction of FVIII deficiency states, Von Willebrand's disease, fibrinogen defects and complex coagulation disorders. This practice has largely been abandoned in most Member States and only remains in Estonia, Latvia, Romania and the United Kingdom (Rejman 2000).

Blood components delivered for manufacture of medicinal products: Table 4

The total amount of plasma delivered for fractionation into medicinal products differs greatly 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 7.4 liters fresh plasma for fractionation into medicinal products per 1,000 inhabitants is found. However 8 / 37 (21%) of reporting Member States deliver in the range of 12 – 23 liters per 1,000 inhabitants: Belgium, Denmark, Finland, Germany, Luxembourg, The Netherlands, Sweden and Switzerland. Of these, Germany, Luxembourg, and Sweden collect considerably more plasma by apheresis per 1,000 inhabitants (see Table 2). 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 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 10.4 units of plasma per 1,000 inhabitants are used for transfusion, or 0.4 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 Germany and Sweden a high yield of plasma for manufacture of medicinal products is observed paired to an above-average of use of plasma for transfusion.

Other components to be used for manufacture into medicinal products are rare, only Finland delivers red blood cells for such purposes.

Special processing of blood components: Tables 5.1 and 5.2

In 7 / 37 (19%) of reporting Member States, 100 percent leucodepletion of red blood cell products is carried out. This is also the case for platelet concentrates in 12 / 37 (32%) Member States. Hundred percent (100 %) leucodepletion is applied for plasma for transfusion in only 4 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.

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 11 / 37 (30%) Member States 100% of FFP is

safeguarded by either method. For CSP and CP this appears to be the case only in one country.

Screening for infectious agents, serological test methods: Table 6

In all 37 reporting Member States, all donations are tested for anti-HIV-1/2 and HBsAg. In all *but one* of 37 reporting Member States, all donations are also tested for anti-HCV. In all *but 4* reporting Member States, e.g.: the Scandinavian countries, all donations are tested for Syphilis. It is debated in the literature whether Syphilis testing is necessary.

Testing for anti-HTLV-I/II is performed on all donations in 8 / 37 (22%) reporting Member States, and only on first time donors in 4 / 37 (11%) countries.

Testing for anti-HBc is performed on all donations in 5 / 37 (14%) reporting Member States, and only on first time donors in 5 countries. Testing for 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. 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, 26 of 37 (70%) of the 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 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 may 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.

Nucleic Acid Testing (NAT): Tables 8.1 and 8.3

Nucleic Acid Testing (NAT) for HCV is performed on each donation in 12 / 37 (32%) reporting Member States. In addition, 7 (19%) reporting Member States perform HCV-NAT on plasma for fractionation. NAT for HIV is performed on each donation in 8 / 37 (22%) reporting Member States. In addition, 5 / 37 (14%) reporting Member States perform HIV-NAT on plasma for fractionation. NAT for HBV is performed on each donation in 2 Member States. In addition, 1 reporting Member State performs HBV-NAT on plasma for fractionation.

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 8.3.

Organisation, registration and labeling: Table 9

In 26 / 37 (70%) 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 9 countries, 4 countries have 100% ISBT-128 code for the donation, whereas 11 indicate to be further working on implementation of ISBT-128 coding. Labeling of the finished component code is more complex, as it includes automation applications in the hospitals. It is partially implemented in 8 countries. Only 3 countries have 100% ISBT-128 coding at the donation as well as the component level.

Quality management related issues: Table 10

In 21 / 37 (57%) of the reporting Member States a Quality System is established and maintained in blood establishments. In 10 countries this is planned.

In 18 / 37 (49%) of the reporting Member States 100 percent of the donations are covered by GMP. In 2 countries this is the case for ISO 9000 respectively for more than 90 % of the donations. In 2 countries another QA system is used with 100 percent coverage of the donations. In 28 / 37 (76%) of the reporting Member States inspections are performed at least every 2 years, in 24 of which inspections are carried out by the national authority.

In 23 / 37 (62%) of the reporting Member States a hemovigilance system is installed, 16 (68%) of these hemovigilance systems are organized by the national authority.

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Table 1

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	1594	7660	82,8	9254	3500	2,6	
Azerbaijan	13155	8213	38,4	21368	8141	2,6	
Albania	1244	3730	75,0	4974			
Austria		48000		48000	8200	5,9	
Belgium	232099	44424	16,1	276523	10000	27,7	
Bosnia / Herzegovina							
Bulgaria	110006	35122	24,2	145128	7974	18,2	
Croatia	171890	22577	11,6	194467	4400	44,2	
Cyprus	19646			19646	600	32,7	
Czech Republic	324000	36100	10,0	360100	10300	35,0	
Denmark	235944	25000	9,6	260944	5300	49,2	1)
Estonia	20295	8937	30,6	29232	1361	21,5	
Fed Rep Yugoslavia							
Finland	165918	22447	11,9	188365	5300	35,5	
France	1140000	382000	25,1	1522000	61000	25,0	
Georgia	6476	11070	63,1	17546	4400	4,0	
Germany		547436			82260		2)
Greece	278355	108249	28,0	386604	10900	35,5	3)
Hungary	329945	55424	14,4	385369	10043	38,4	
Iceland	7148	1762	19,8	8910	287	31,1	
Ireland	85294	39224	31,5	124518	4000	31,1	
Italy	1117000	193000	14,7	1310000	58000	22,6	
Latvia	37183	11796	24,1	48979	2300	21,3	
Liechtenstein							
Lithuania	20806	10739	34,0	31545	3500	9,0	
Luxembourg	11133	1256	10,1	12389	435	28,5	
Malta							
Moldovia	28160	8438	23,1	36598	3627	10,1	
Netherlands	566000	58000	9,3	624000	16000	39,0	
Norway	86324	10676	11,0	97000	4500	21,6	
Poland	249457	161639	39,3	411096	39000	10,5	
Portugal	78051	32112	29,1	110163	10356	10,6	
Romania	120897	45760	27,5	166657	22000	7,6	
Russian Federation							
Slovak Republic	111260	37286	25,1	148546	5370	27,7	
Slovenia	90221	10221	10,2	100442	2000	50,2	
Spain	636945	267559	29,6	904504	40123	22,5	
Sweden	274481	34057	11,0	308538	8900	34,7	4) 5)
Switzerland	240000	31577	11,6	271577	7000	38,8	
Turkey		1045852		1045852	67000	15,6	
Ukraine							
United Kingdom	1625000	261000	13,8	1886000	47726	39,5	

1) Denmark: No official figures, rule of thumb is 10%. At first visit only samples for testing will be done.

3) Germany: the number of first time donors are provided, it was not possible to provide the number of repeat and regular donors.

3) Greece: no exact data on donors due to lack of donordatabases. Figures are estimated based on various local studies.

4) Sweden: first time donors donating blood components: less than 1000.

5) Sweden: first time donors donating only samples more than 33000.

Table 2

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	9876	2,8	38	0,4	78	0,02				
Azerbaijan	13206	1,6			21	0,00	35			
Albania	14158		182	1,3						
Austria	513839	62,7	10000	1,9			20000	2000	300	
Belgium	528207	52,8	3991	0,8	97917	9,79	18624	0	0	1)
Bosnia / Herzegovina										
Bulgaria	145128	18,2	288	0,2	192	0,02	108			
Croatia	152274	34,6	1021	0,7	7000	1,59	844			
Cyprus	19646	32,7					423		53	
Czech Republic	410300	39,8	18300	4,5	31100	3,02	15600	3500	100	
Denmark	356783	67,3	0	0,0	910	0,17	1427	0	0	2)
Estonia	49979	36,7	12	0,0	29	0,02	279			
Fed Rep Yugoslavia										
Finland	318912	60,2	0	0,0	1565	0,30	836	0	0	
France	2137099	35,0	88700	4,2	75670	1,24	154627	0	100	
Georgia	15406	3,5	0	0,0	230	0,05		0		
Germany	4529545	55,1	219425	4,8	815990	9,92	224826	16832		
Greece	590536	54,2	2798	0,5	2300	0,21	16657	3240		
Hungary	429724	42,8			1928	0,19	52456	0	0	
Iceland	13807	48,2	0	0,0	0	0,00	416	0	0	
Ireland	142752	35,7	98	0,1	0	0,00	5757	26	22	
Italy	2066000	35,6	140000	6,8	173000	2,98	61000			
Latvia	57486	25,0			1593	0,69	1373			
Liechtenstein										
Lithuania	74301	21,2			2507	0,72	321			
Luxembourg	21195	48,7	684	3,2	3303	7,59	661	0	0	
Malta										
Moldovia	40023	11,0	38	0,1	438	0,12				
Netherlands	705500	44,1	871	0,1	77200	4,83	2374			
Norway	190757	42,4	0	0,0	1704	0,38	4169	186286	0	3)
Poland	827953	21,2	6332	0,8	62132	1,59	18824	0	72	
Portugal	119878	11,6	165	0,1			538			
Romania	352000	16,0	360	0,1	185	0,01	450		213	
Russian Federation										
Slovak Republic	180204	33,6	1716	1,0	1424	0,27	4856	0	12	
Slovenia	89065	44,5	2253	2,5	970	0,49	543	0	0	
Spain	1458172	36,3	22698	1,6	13816	0,34	48561	5040	0	
Sweden	454036	51,0	867	0,2	123365	13,86	12213	703		
Switzerland	415345	59,3	20000	4,8	11100	1,59	20000	68	200	
Turkey	839276	12,5								
Ukraine										
United Kingdom	2380000	49,9	1200	0,1	1400	0,03	101700	850	275	

1) Belgium: the number of platelet apheresis procedures differs from adult - single donor - therapeutic doses

2) Denmark: platelets is number of drawings

3) *Authors*: Norway: the number of RBC apheresis is questioned

Table 3

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	62	0,9	6696	1,9	7608					10
Azerbaijan	16000	76,1	5012	2,6	6150	35		35	100,0	
Albania	2836	20,6	10920		10920	270				2765
Austria	0	0,0	400000	48,8	70000	20000	4000	16000	80,0	
Belgium	4	0,0	490476	49,0	88800	37000	27482	9518	25,7	0
Bosnia / Herzegovina										
Bulgaria	7266	5,7	119345	15,9	75259	10969	10861	108	1,0	
Croatia	7686	5,1	144457	34,6	143453	57410	57410	844	1,5	1172
Cyprus	26127	59,2	18000	73,5	6438	8377				
Czech Republic	1100	0,3	412700	40,2	168200	21700	6100	15600	71,9	1000
Denmark	181	0,1	330180	62,3		21968	20978	990	4,5	
Estonia	63	0,1	50548	37,2	29130	2701	2301	400	14,8	21800
Fed Rep Yugoslavia										
Finland	395	0,1	283849	53,6	37148	35335	34575	760	2,2	0
France	0	0,0	2013970	33,0	256954	198702	25429	173273	87,2	0
Georgia										
Germany	19281	0,6	3355155	41,0	4237363	268695	87373	181322	67,5	
Greece	25800	4,3	567534	54,4	169900	127178	114546	12632	9,9	
Hungary	68	0,0	374097	37,3	89757	123665	9640			0
Iceland	0	0,0	13805	48,2	2923	919	605	314	34,2	139
Ireland	494	0,4	120027	30,1	24600	14010	9043	4967	35,5	1840
Italy	41500	1,9	2160000	38,0	147000	479000	645000	61000	12,7	2000
Latvia	56	0,1	57059	24,8	55230	2433	1060	1373	56,4	7268
Liechtenstein										
Lithuania	115	0,2	64214	18,4	34320	20352	20331	321	1,6	1017
Luxembourg	0	0,0	20121	46,3	3322	1805	1256	549	30,4	0
Malta										
Moldovia	1110	5,5	18999	5,5	17686	1106	1106			1903
Netherlands	5	0,0	603417	37,7	99500	150187	148238	1949	1,3	
Norway	164	0,1	175674	39,1	30946	15437	11000	4500	29,2	0
Poland	9187	1,5	615930	16,0	284651	36562	17772	18790	51,4	
Portugal	41	0,0	123812	12,0	4455	74265	73768	497	0,7	506
Romania	179655	53,1	158733	15,4	147841	34535	34085	450	1,3	13482
Russian Federation										
Slovak Republic	19224	11,1	154582	32,4	90525	7306	3250	4056	55,5	0
Slovenia	2300	2,6	85000	43,7	27000	28000	27000	7000	25,0	0
Spain	5155	0,4	1260000	31,5	184893	542239				7144
Sweden	745	0,2	435336	49,0	132674	31352	19139	12213	39,0	
Switzerland	6401	2,3	266486	39,0	71505	17000	1926	14184	83,4	
Turkey	671941	80,3	164505	12,5	300000	39000	12000	27000	69,2	
Ukraine										
United Kingdom	2700	0,1	2203500	46,2	329000	215000	128300	86700	40,3	72000

1) *Authors:* Georgia: data submitted from 4 centres, not allowing interpretation of totals

2) *Authors:* Germany: plasma for transfusion given in Litres, units were asked, her represented arbitrarily by dividing / 0,300 (see also Table 4)

3) *Authors*: Spain: plasma for transfusion given in Litres, units were asked, her represented arbitrarily by dividing / 0,300 (see also Table 4)

Table 4

Plasma for fractionation into medicinal products

country	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	7	0,00	2,17	1,13	
Azerbaijan	0	0,00	0,76	0,29	
Albania	0			0,79	
Austria			8,54	0,18	
Belgium	235390	23,54	8,88	0,18	
Bosnia / Herzegovina					
Bulgaria	10526	1,32	9,44	0,59	1)
Croatia	9436	2,14	32,60	0,94	
Cyprus	0	0,00	10,73	0,15	
Czech Republic	63500	6,17	16,33	0,41	
Denmark	83907	15,83	0,00		
Estonia	7200	5,29	21,40	0,58	
Fed Rep Yugoslavia					
Finland	76450	14,42	7,01	0,13	2)
France	480366	7,87	4,21	0,13	
Georgia	651	0,15	0,00		
Germany	1679183	20,41	51,51	1,26	3)
Greece	29367	2,69	15,59	0,29	
Hungary	60753	6,05	8,94	0,24	
Iceland			10,20	0,21	
Ireland	2438	0,61	6,15	0,20	
Italy	461000	7,95	2,53	0,07	
Latvia	17574	7,64	24,01	0,97	
Liechtenstein					
Lithuania	11298	3,23	9,81	0,53	
Luxembourg	8332	19,15	7,64	0,17	
Malta					
Moldovia	3375	0,93	4,88	0,88	
Netherlands	266670	16,67	6,22	0,16	
Norway	41160	9,15	6,88	0,18	
Poland	171568	4,40	7,30	0,46	
Portugal	0	0,00	0,43	0,04	
Romania	2026	0,09	6,72	0,44	4)
Russian Federation					
Slovak Republic	11849	2,21	16,86	0,52	
Slovenia	13000	6,50	13,50	0,31	
Spain	223064	5,56	4,61	0,15	5)
Sweden	205061	23,04	14,91	0,30	
Switzerland	85578	12,23	10,22	0,26	
Turkey			4,48	0,36	
Ukraine					
United Kingdom	0	0,00	6,89	0,15	

1) Bulgaria: data may not be accurate.

2) Finland: red cells

3) *Authors:* Germany: plasma for transfusion given in Litres, units were asked, her represented arbitrarily by dividing / 0,300 (Table 3)

4) Romania: the volume of plasma for fractionation was not sufficient, in the absence of a contract it was not delivered.

5) *Authors*: Spain: plasma for transfusion given in Litres, units were asked, her represented arbitrarily by dividing / 0,300 (Table 3)

Table 5.1

Special processing of blood components

country	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	0	0	0	0	0	0
Albania	17	0	8	0	2	0
Austria	100	10	50	1	100	30
Belgium	24	1	0	0	100	1
Bosnia / Herzegovina						
Bulgaria	3	0	0	0	0	0
Croatia	2				2	
Cyprus	0	0	0	0	0	0
Czech Republic	8				30	
Denmark	14		0		83	
Estonia	3	0	0	0	22	2
Fed Rep Yugoslavia						
Finland	14	20	0	0	100	23
France	100	5	100		100	40
Georgia	2	0	0	0	0	0
Germany	83				91	
Greece	30		22			1)
Hungary	5	1	0	1		5
Iceland	5	1	0	0	100	24
Ireland	100	10	75	0	100	63
Italy	30					
Latvia	59	2	0	0	100	0
Liechtenstein						
Lithuania	0	1	0	1	3	3
Luxembourg	0	100	0	0	0	0
Malta						
Moldovia						
Netherlands	27		50		100	
Norway	100		0	0	100	
Poland	3	4	0	0	71	90
Portugal	100				100	
Romania	15	0			5	
Russian Federation						
Slovak Republic	0	1	0	0	0	35
Slovenia	20	1	40		30	
Spain	18		20		30	
Sweden	43	2			95	95
Switzerland	100		100		100	
Turkey	0	0	0	0	0	0
Ukraine						
United Kingdom	100	4	100	0	100	29

1) Greece: leuco depleted: a range of 30 - 100 was presented, dependent on various blood centers

Table 5.2

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							
Albania							
Austria	50	50			0	0	
Belgium	0	100	0	0	0	0	1)
Bosnia / Herzegovina							
Bulgaria							
Croatia							
Cyprus							
Czech Republic	100	5	100	0	100	0	
Denmark	0	0	0	0	0	0	
Estonia	0	0	0	0	0	0	
Fed Rep Yugoslavia							
Finland	3	0	0	0			
France	49	51	0	0	0	0	
Georgia	0	0	0	0	0	0	
Germany	95	5					
Greece		5					2)
Hungary	0	0	0	0	0	0	
Iceland							
Ireland	0	0	0	0	0	0	
Italy							
Latvia	0	0					
Liechtenstein							
Lithuania							
Luxembourg	0	100	0	0	0	0	
Malta							
Moldovia							
Netherlands	75	25					
Norway	5	95					
Poland	66	0	0	0	0	0	3)
Portugal	11		0		0		
Romania	100		100		100		
Russian Federation							
Slovak Republic	32	0	0	0	0	0	
Slovenia							
Spain	48	52					
Sweden	0	0	0	0			
Switzerland	80	20					
Turkey							
Ukraine							
United Kingdom	0	0	0	0	0	0	

1) Belgium: SD plasma, with exception of autologous plasma; irradiation often performed in hospitals, no data on this

2) Greece: Quarantine plasma is performed in practice, no national regulation at this issue

3) Poland: mean percentage of quarantined plasma is reduced because in 2 out of 8 centres this percentage is very low (9 and 12 %)

Table 6

Screening for infectious agents, methods

country	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		1)
Azerbaijan	1		1		1				1				
Albania	1	1	1	1	1	1			1	1			2) 3)
Austria	1		1		1				1				4)
Belgium	1		1		1				1			1	
Bosnia / Herzegovina													
Bulgaria	1		1		1				1				
Croatia	1		1		1				1				
Cyprus	1	1	1	1	1	1			1	1			
Czech Republic	1	1	1	1	1	1			1	1			
Denmark	1	1	1	1	1	1		1					5)
Estonia	1		1		1				1				
Fed Rep Yugoslavia													
Finland	1		1		1			1	1				6)
France	1		1		1		1		1		1		3) 7)
Georgia	1	1	1	1		1			1	1			8)
Germany	1	1	1	1	1	1			1	1			3) 9)
Greece	1		1		1		1		1		1		3) 10)
Hungary	1		1		1				1			1	
Iceland	1	1	1	1	1	1							
Ireland	1		1		1		1		1		1		3)
Italy	1		1		1				1				11)
Latvia	1		1		1				1				3)
Liechtenstein													
Lithuania	1		1		1				1				
Luxembourg	1		1		1		1		1			1	12)
Malta													
Moldovia	1		1		1				1				13)
Netherlands	1	1	1	1	1	1	1	1	1	1			14)
Norway	1	1	1	1	1	1		1		1		1	15)
Poland	1		1		1				1				3) 16)
Portugal	1		1		1		1		1		1		13)
Romania	1		1		1		1		1			1	
Russian Federation													
Slovak Republic	1		1		1				1				3) 13)
Slovenia	1		1		1				1				3)
Spain	1		1		1				1				
Sweden	1	1	1	1	1	1		1		1		1	13)
Switzerland	1	1	1	1	1	1			1	1			2) 3)
Turkey	1		1		1				1				17)
Ukraine													
United Kingdom	1		1		1		1		1				3) 18)

Notes by the authors: Countries in italics were not reporting any donations

1) Armenia: anti-HBc: not in all organisations; each donor: Brucelosis
2) Albania: each donor and first time donor: ALT
3) anti-CMV for selected patients
4) Austria: each donation: B19 selected; Neopterin; ALAT
5) Denmark: anti-HTLV I/II: first time donors and donors travelled in malaria area
6) Finland: anti-HTLV I/II: first time donors, regulary donors every 3 years
7) France: each donation and plasma for fract.: ALT
8) Georgia: Syphilis: RPR
9) each donation, first time donation, plasma for fract.: ALT
10) Greece: anti-HBC: when required
11) Italy: each donation: ALAT
12) Luxembourg: each donation: ALT, AST, Gamma-gt, 18 parameter blood control
13) each donation: ALT
14) Netherlands: Syphilis: cross-reactions with Borrelia are found
16) Poland: HCV-Ag in part of the donations
18) United Kingdom: anti-HTLV I/II: started september 2002

Table 7.1 **Confirmed seropositive donors (absolute numbers)**

country	HIV 1		HIV 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	first time donor	repeat donor	
Andorra													
Armenia	2				134	14	224	19			18		
Azerbaijan	34	8	1	2	152	124	242	162			106	78	
Albania	2				269	86	19	17				5	
Austria		928		928		684		900				932	1)
Belgium	0	0	0	0	63	3	31	9					
Bosnia / Herzegovina													
Bulgaria	3	2	0	0									
Croatia	1				45	42	22	23			6	17	
Cyprus	0	0	0	0	10	26	2						
Czech Republic	0	0	0	0	34	50	102	165			21	57	2)
Denmark	0	1	0	0	13	5	11	2	0				
Estonia	10	1			52	1	168	3			23	2	
Fed Rep Yugoslavia													
Finland	0	0	0	0	10	0	12	3	1	0	1	7	
France	26	19	0	0	434	10	322	43	39	6	132	52	
Georgia	22				117	73	297	235			47	45	
Germany	25	28			851	74	507	83			178	80	
Greece	18	9	0	0	1830	487	356	101	1	1	294	77	
Hungary	2	0	0	0	551	20	489	13	0	0	0	0	
Iceland	0	0	0	0	0	1	2	0					
Ireland	0	1	0	0	3	2	4	4	1	0	3	2	
Italy													3)
Latvia	8				185		538						
Liechtenstein													
Lithuania	1				382		565				228		4)
Luxembourg	0	1	0	0	1	0	2	0	0	0	1	0	
Malta													
Moldovia	5	0	5	0	1944	0	1299	0			755	0	
Netherlands	0	3	0	0	23	7	5	1	3	1	13	8	5)
Norway													6)
Poland	21	4	0	0	1133	60	1337	223			83	91	
Portugal	11	3	0	0	84	5	67	0	3	0	4	20	
Romania	26	7	1	0	1704	170	850	54	56	8			7)
Russian Federation													
Slovak Republic	2	0		0	80	6	81	1			9	6	8)
Slovenia													9)
Spain	52	24			524	29	529	97			167	44	
Sweden	1	0	0	0	20	3	41	1	2				10)
Switzerland	1	6	0	0	34	7	22	1			7	2	
Turkey													4) 11)
Ukraine													
United Kingdom	9	2			62	5	127	8			36	17	8)

1) A*uthors:* Austria: numbers appear too high for confirmed positive donors, probably unconfirmed screening test results were given
2) Czech Republic: includes also indeterminate repeatedly reactive samples
3) *Authors* : Italy: frequencies, probably per 100,000 donations were given, instead of absolute numbers
4) Lithuania, Turkey: no distinction between first time and repeat donors were made
5) Netherlands: syphilis can not be diagnosed on FTA-Abs, cross-reactions with Borrelia are found
6) Norway: only data from Blood Bank Oslo, with 25% of activity in the country available
7) Romania: no supplemental testing for syphilis
8) Slovak Republic, United Kingdom: HIV1 and HIV2 combined
9) Slovenia: provided percentages instead of absolute numbers
10) Sweden: HCV confirmed by NAT by the plasma fractionator.
11) *Authors* : Turkey: extremely high numbers, appearing to be the number of donations tested, rather than number of confirmed positive donations

Table 7.2

Prevelance and incidence calculated per 100,000 donors

country	HIV 1		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	26,11		1749,35	878,29	2924,28	1191,97	
Azerbaijan	413,98	60,81	1850,72	942,61	2946,55	1231,47	
Albania	53,62		7211,80	6913,18	509,38	1366,56	
Austria							1)
Belgium	0,00	0,00	141,82	1,29	69,78	3,88	
Bosnia / Herzegovina							
Bulgaria	8,54	1,82					
Croatia	4,43		199,32	24,43	97,44	13,38	
Cyprus							1)
Czech Republic	0,00	0,00	94,18	15,43	282,55	50,93	
Denmark	0,00	0,42	52,00	2,12	44,00	0,85	
Estonia	111,89	4,93	581,85	4,93	1879,83	14,78	
Fed Rep Yugoslavia							
Finland	0,00	0,00	44,55	0,00	53,46	1,81	
France	6,81	1,67	113,61	0,88	84,29	3,77	
Georgia	198,74		1056,91	1127,24	2682,93	3628,78	
Germany	4,57		155,45		92,61		2)
Greece	16,63	3,23	1690,55	174,96	328,87	36,28	
Hungary	3,61	0,00	994,15	6,06	882,29	3,94	
Iceland	0,00	0,00	0,00	13,99	113,51	0,00	
Ireland	0,00	1,17	7,65	2,34	10,20	4,69	
Italy							
Latvia	67,82		1568,33	0,00	4560,87		
Liechtenstein							
Lithuania	9,31		3557,13	0,00	5261,20		
Luxembourg	0,00	8,98	79,62	0,00	159,24	0,00	
Malta							
Moldovia	59,26	0,00	23038,63	0,00	15394,64	0,00	3)
Netherlands	0,00	0,53	39,66	1,24	8,62	0,18	
Norway							
Poland	12,99	1,60	700,94	24,05	827,15	89,39	
Portugal	34,26	3,84	261,58	6,41	208,64	0,00	
Romania	56,82	5,79	3723,78	140,62	1857,52	44,67	
Russian Federation							
Slovak Republic	5,36	0,00	214,56	5,39	217,24	0,90	
Slovenia							
Spain	19,43	3,77	195,84	4,55	197,71	15,23	
Sweden	2,94	0,00	58,73	1,09	120,39	0,36	
Switzerland	3,17	2,50	107,67	2,92	69,67	0,42	
Turkey							1)
Ukraine							
United Kingdom	3,45	0,12	23,75	0,31	48,66	0,49	

1) *Authors* : no caluclations were performed in case of uncertainty of data on infectious disease markers, or lack of data on repeat versus first time tested donors

2) Germany: no data on repeat donors, prevalence in first time tested donors given

3) *Authors* : Moldovia: numbers appear too high? Numbers may include screening test only results

Table 8.1

NAT testing

country	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										
Azerbaijan										
Albania										
Austria	1			1			1			
Belgium										
Bosnia / Herzegovina										
Bulgaria										
Croatia										
Cyprus										
Czech Republic			1			1			1	
Denmark										
Estonia	1								1	1) 2)
Fed Rep Yugoslavia										
Finland							1			
France	1		1				1		1	3)
Georgia										
Germany							1	1		
Greece									1	
Hungary										
Iceland										
Ireland	1						1			
Italy										4)
Latvia										
Liechtenstein										
Lithuania										
Luxembourg	1			1			1			
Malta										
Moldovia										
Netherlands	1	1	1				1	1	1	
Norway							1	1	1	
Poland									1	
Portugal	1						1			
Romania										5)
Russian Federation										
Slovak Republic			1						1	
Slovenia										
Spain							1			
Sweden			1						1	
Switzerland	1						1			
Turkey										
Ukraine										
United Kingdom							1			

1) Estonia: HIV NAT 20% of donations

2) Estonia: HCV NAT 80% of donations

3) France: HIV NAT=HIV1 NAT

4) Italy: HCV-NAT is mandatory since June 28, 2001

5) Romania: NAT screening not possible due to high costs

Table 8.3

NAT only positive results

country	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							
Belgium							
Bosnia / Herzegovina							
Bulgaria							
Croatia							
Cyprus							
Czech Republic							
Denmark							
Estonia					2	2	
Fed Rep Yugoslavia							
Finland					1	1	
France	0	1	0	0	1	1	
Georgia							
Germany	0	1	0	1	0	1	1)
Greece					0	0	
Hungary							
Iceland							
Ireland	0	0			0	0	
Italy							
Latvia							
Liechtenstein							
Lithuania							
Luxembourg	0	0	0	0	0	0	
Malta							
Moldovia							
Netherlands	0	0			0	0	
Norway					0	1	
Poland					2	4	
Portugal							
Romania							
Russian Federation							
Slovak Republic							
Slovenia							
Spain						1	2)
Sweden		0				1	3)
Switzerland	0	1			0	1	
Turkey							
Ukraine							
United Kingdom					1		

1) Germany: repeat donors: blood services may test anti-HBc and HBV-NAT and HIV-NAT on a voluntary basis

2) *Authors* : Spain: 131 "HCV NAT only" were given in first time donors, the high number may include serologically positives

3) Sweden: HCV regular donor: was detected by NAT by the plasma fractionator, later the donor became seropositive

Table 9

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	**1**		100			1)
Azerbaijan	**0**					
Albania	**1**		manual			
Austria	**0**					2)
Belgium	**1**	50,6		10		
Bosnia / Herzegovina						
Bulgaria	**1**		100			3)
Croatia	**1**		50		50	4)
Cyprus	**0**					
Czech Republic	**0**		100		100	5)
Denmark	**1**	30		10		6)
Estonia	**0**	93,2	6,8	93,2	6,8	7)
Fed Rep Yugoslavia						
Finland	**0**	100		100		
France	**1**	0	100	0	100	8)
Georgia	**1**					9)
Germany	**1**					10)
Greece	**1**		100			11)
Hungary	**1**	0	100	0	100	12)
Iceland	**0**		100		100	13)
Ireland	**0**		100		100	14)
Italy	**1**					
Latvia	**1**	100	0	0	0	
Liechtenstein						
Lithuania	**1**		100			
Luxembourg	**0**		100		100	15)
Malta						
Moldovia	**1**	64	n.a.	64	n.a.	
Netherlands	**1**	100		100		
Norway	**1**	40	60	40	60	16)
Poland	**1**		100		100	17)
Portugal	**1**		100		100	18)
Romania	**1**		100		100	19)
Russian Federation						
Slovak Republic	**1**	50				
Slovenia	**1**		100		100	20)
Spain	**1**	10	75	10	75	
Sweden	**1**	25	75	25	75	21)
Switzerland	**0**		100		100	22)
Turkey	**1**	2	98	2	98	
Ukraine						
United Kingdom	**1**	100		100		

1) Armenia: no national council or expert committee, this function realized by the Center of Haematology
2) Austria: ISBT is in preparation, up till now labelling is according to the national guidelines
3) Bulgaria: eye-readable labels for the country
4) Croatia: in home computer labelling system
5) Czech Republc: National system compatible with ISBT, donation number'' substituted by 'unique ID number'
6) Danmark: ISBT 128 implementation in progress, figures are end of 2001
7) Estonia: 'Other' refers to a local system
8) France: CODABAR Monarch, unique donation number with 10 characters and modulo 11 check-digit, National blood component code
9) Georgia: 1 of 4 responding centers reports 100% use of ISBT 128 for donation number and component code
10) Germany: labelling systems vary, mainly Eurocode and ISBT 128, including donation number and component code. Percentage cannot be specified
11) Greece: national uniform system. Adaptation to ISBT 128 in progress.
12) Hungary: ISBT Codabar
13) Iceland: Databyraan (Sweden) in Reykjavik (92% of collections), Akureyris (8%) not computerised and separate institute.
14) Ireland: Codabar is used
15) Luxembourg: YYYY-NNNNN barcoded
16) Norway: Manual systems in use in 3 of 56 centres. 2 of 4 IT systems compatible with ISBT 128.
17) Poland: expert committee under organisation; ID and labelling local system
18) Portugal: code bar similar to ISBT 128
19) Romania: no bar-code labelling yet
20) Slovenia: Codabar
21) Sweden: the transition to ISBT 128
22) Switzerland: Codabar use, move to ISBT 128 planned

Table 10

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	planned				other organization	national authority	
Azerbaijan					no	no	
Albania	yes				inter audit	no	
Austria	yes & planned	100	70		national authority	national authority	
Belgium	yes	100			national authority & other org	no	
Bosnia / Herzegovina							
Bulgaria	planned	52			national and regional BTC	national authority	1)
Croatia		50	50		no	no	
Cyprus	no				no	no	
Czech Republic	yes	100	10		national authority	national authority	
Denmark	yes	100			national authority	other organisation	2)
Estonia	no	100			national authority & other org	national authority	3)
Fed Rep Yugoslavia							
Finland	yes	100			national authority	other organisation	4)
France	yes			100	national authority	national authority	
Georgia	planned				other organisation	no	5)
Germany	yes	100			national authority	national authority	
Greece	yes				national authority	other organisation	6)
Hungary	yes	100			national authority	other organisation	7)
Iceland	yes	92	92		other organisation	no	8)
Ireland	yes	100	30		national authority	national authority	
Italy					no		9)
Latvia	planned				national authority	national authority	
Liechtenstein							
Lithuania	yes			100	national authority	no	
Luxembourg	yes	100	100		national authority	national authority	
Malta							
Moldovia	yes		64		national authority	national authority	
Netherlands	yes	100			national authority	nother organisation	10)
Norway	yes	100	4		national authority & other org	no	11)
Poland	yes	100			national authority	national authority	
Portugal	yes & planned				national authority	national authority	12)
Romania	planned	100			no	no	13)
Russian Federation							
Slovak Republic	yes & planned	60			no	other organisation	14)
Slovenia	yes & planned	100			no	no	
Spain	yes		75				
Sweden	yes	100		some	national authority	national authority	15)
Switzerland	yes	100	30		national authority	national authority	
Turkey	planned				national authority	national authority	
Ukraine							
United Kingdom	yes	100			national authority	other organisation	

1) Bulgaria: inspections planned by National Expert Committee in 2003

2) Denmark: Danish Society for Clinical Immunology

3) Estonia: Inspections also by State Agency of Medicins

4) Finland: unofficial system operated by the Finnish Red Cross BTS

5) Georgia: Ministry of Health

6) Greece: National Coordinating Haemovigiliance Centre, under Hellenic Centre for Infectious Diseases Control

7) Hungary: special office of Headquarter of HNBTS analyses the data

8) Iceland: Reykjavik Centre ISO 9002 certified since 2000, the Akureyri Centre no quality system; British Standars Institute covers ISO-audits.

9) Italy: only at a local level, planned to be implemented at national level in 2003

10) Netherlands: Foundation for registration of Transfusion Reactions in Patients (TRIP) expected to become operational in 2002

11) Norway: inspections 1 / yr specialist transfusion medicine. Inspection by National Medicine Agency for renewal GMP certificate (every 3 to 4 years)

12) Portygal: accreditation of Portugese Blood Institute; inspections every 4-5 yrs; Haemovigilance system voluntary

13) Romania: hemovigilance on regional level.

14) Slovac Republic: partially operated by the Institute of Health Statistics

15) Sweden: ISO/IEC 17025 on donations: 5%, on testing and processing: 75%;haemovigilance: reported to a national authority.

APPENDIX

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

The 2001 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, incl. autologous)	
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, litres	
4.1.1	– fresh frozen, for FVIII production, litres	
4.1.2	– other plasma, litres	
4.2	**Other components** (e.g. erythrocytes, buffy coat), units	

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. 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