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EUROPEAN COMMITTEE (PARTIAL AGREEMENT) ON BLOOD TRANSFUSION

The collection, testing and use of blood and blood products in Europe in 2004

Draft report

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DRAFT REPORT

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European Committee (Partial Agreement) on Blood Transfusion

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SUMMARY

This report provides data on the donors, collection, testing, use and quality aspects of blood and blood components in Member States of the Council of Europe. Data were supplied by Member States in response to a questionnaire requesting details on donors, collections, testing, distribution and quality aspects of blood and blood components for the year 2004. In its present form it follows a series of similar reports which have assessed such data in 1989, 1991, 1993, 1995, 1997, 2001, 2002 and 2003.

A Qualitative Evaluation Report on the questionnaire with recommendations for improvement of the process was performed earlier and was reported in November 2004, including the experience with the reporting of the data over the 3 previous years. As of the 2004 format, the questionnaire was reviewed and re-designed by the authors, SP-GS experts and the SP-HM bureau.

Also in 2004 not all relevant information was obtained from each Member State. As difficulties in implementation of data retrieval from automated blood banking systems, and collating data from many blood establishments on a national level within the Member States, the process is designed to improve by repetition annually. In fact it is noted in 2004 that the quality of the responses to the survey has improved and that respondents seem to be more at ease in filling in the questionnaires. In addition the network of CoE blood transfusion experts provides a important support by critical review.

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

In addition, in 2004 two other new items have been included. Bacterial screening for platelet concentrates earlier performed on about 1% of the platelet concentrates for quality control purposes (Guide to the preparation, use and quality assurance of blood components, CoE), became implemented during 2004 in some countries for screening of all platelets or all apheresis platelets. Bacterial contamination is an important risk of transfusion of platelets. Table 9 provides insight into these data. Also a paragraph and table 12 is added on hemovigilance data. As of 2006 hemovigilance reporting becomes mandatory in EC Member States (2005/61EC).

In Members States and in blood establishments, data may be administered in different formats, and different definitions may have been operational. This could 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 together with the European Commission will result in better data and higher response rates among Member States, when the questionnaires are used annually. 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). In addition it is welcomed that EMEA employs the same definitions, especially on infectious disease epidemiology in

donor populations (Guideline on Epidemiological data on Blood Transmissible Infections for inclusion in the Guideline on the Scientific data requirements for a Plasma Master File EMEA/CPMP/BWP/3794/03). Uniformity of such definitions is of importance to the field, and circumvents unnecessary and costly repetitions in collating the data.

In total 33 questionnaires were received, the response rate as of September 2006 being 73.3 percent. For the 2001, 2002 and 2003 surveys, the response rate was 86 percent, 60 percent and 64 respectively.

The average number of donors in relation to the general population is 25 per 1,000 inhabitants. On average 23 percent of the donor base consists of first time donors.

The number of whole blood collections is on average 37 per 1,000 inhabitants, and the average use of red blood cells is 37 per 1,000 inhabitants. On average 4 litres of plasmapheresis plasma per 1,000 inhabitants are collected, and 3 Member States stand out with 17 - 45 litres of plasmapheresis plasma per 1,000 inhabitants.

The use of red blood cells varies considerably (range 4 - 73) but averages 37 total red blood cell units per 1,000 inhabitants. In 4 (13%) of the reporting Members States below an arbitrary threshold of 20 units per 1,000 inhabitants are used, most likely reflecting an insufficient supply. On average in the reporting Member States, 38 percent (35 in 2003) of the total platelet volume is supplied by (random) single donor platelets by apheresis, in 9 countries (8 in 2003) this volume amounts to more than 50 percent.

The amount of plasma delivered for fractionation into medicinal products differs greatly (range 0-27) among Member States, an average yield of 8 litres of plasma (9 in 2003) for fractionation per 1,000 inhabitants is found. However 6 / 28 (21%) of reporting Member States deliver 15 litres or more per 1,000 inhabitants (20% in 2003). In Europe on average 76 % of the plasma for fractionation is from recovered plasma.

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

In all 33 reporting Member States, each donation is tested for anti-HIV-1/2, HBsAg and anti-HCV. In 28 / 33 (84%) reporting Member States, all donations are tested for Syphilis. Anti-HTLV-I/II testing is performed on all donations in 7 / 33 (21%) of reporting Member States, and on first time donors in 4 / 33 (12%). Anti-HBc is performed on all donations in 5 / 33 (15%) of reporting Member States, and only on first time donors in another 5. Prevalence and incidence of infectious diseases vary greatly among Member States, and it is 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 or reported in all countries, and data may include false positive (screening) test results.

Nucleic Acid Testing (NAT) for HCV is performed on each donation in 17 (51%) of 33 reporting Member States, whereas HIV NAT on each donation is performed in 11 (33%) and HBV NAT in 4 (12%). The NAT yield is given in Table 8.2.

Bacterial screening of platelet concentrates is a new data set added in this 2004 report. Hemovigilance data have repeatedly reported the importance of bacterial safety of platelet concentrates. Data were reported by 18 Member States. In 2 / 18 (11%) Member States 90-100 % of the recovered platelet concentrates are bacterially screened. Apheresis platelet concentrates are 90-100% screened in 3 (17%) of Member States. Among 16 reporting Member States, the average rate of confirmed positively cultured platelet concentrates was 0,25%, (ranging from 0-1 %) which is in line with the literature. Other Member States reported to have QC programme of bacterial testing in place.

In 28 / 33 (85%) of the reporting Member States (73% in 2003) a National Council or Expert Committee to advise the Ministry of Health on transfusion related policy issues exists. Labelling according to ISBT-128 for the donation number is partially performed in 7 countries, and 5 (25%) countries have 100% ISBT-128 code for the donations. ISBT-128 labelling of the issued component is partially implemented in 7 countries, and 4 countries (20%) have 100% ISBT-128 coding at the donation as well as the component level.

In 28 / 33 (85%) of the reporting Member States a Quality System is established and maintained in blood establishments. In 4 (12%) countries the implementation of such a system is planned. In 17 / 33 (51%) of the reporting Member States 100 percent of the donations are covered by GMP. In 3 (9%) countries this is the case for ISO 9000. In 26 / 33 (78%) of the reporting Member States inspections are performed at least every 2 years, in 21 of which these inspections are (partially) carried out by the national authority.

Hemovigilance reporting e.g. reporting of serious adverse events is a new data set in the 2004 report. The format for data acquisition on hemovigilance in the 2004 CoE questionnaire in its basic form was developed in collaboration of Council of Europe, experts and European Commission and adapted into Directive 2005/61/EC. Reporting of serious adverse reactions as performed in hemovigilance programmes is a high level of surveillance, as these reactions are not unexpected untoward effects but well known complications of blood transfusion. In this report only those serious adverse reactions are presented which are probably of certainly (imputability grade 2 to 3) ascribable to the transfusion of, and data which are not caused by the product itself, such as TACO (transfusion associated circulatory overload) are reported (Table 12). Taking the possibility of underreporting and the differences in national reporting systems into account, an average incidence is estimated of 1 - 20 serious adverse reactions per 100,000 distributed blood components. Hemolysis due to other blood group incompatibilities than ABO, anaphylaxis, TRALI and TACO appear to stand out as the most frequent serious adverse reactions.

Acknowledgements

The Council of Europe and the authors are grateful to all colleagues in Member States who collated data for inclusion in this report, and especially to Prof. Olof Akerblom for reviewing the questionnaire.

STUDY METHODS

The methods in this survey were in principle the same as the one described for the 2001 survey. Briefly, the Council of Europe Secretariat circulated the questionnaire to Member States requesting that the completed forms be returned to the Secretariat by September 15th 2005. Completed questionnaires were received by the authors received until October 2005. After meetings with SP-HM and CDSP, corrections and additions were provided by Member States, and additional completed questionnaires were received until august 2006, after which the report was worked out and finalized.

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. At evaluation 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 2004. A revision of the questionnaire with new additional questioning was thereafter implemented for the 2004 survey.

Trend analysis and incomplete data

Comparisons with results from the previous surveys or trend analysis is envisioned. 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 was 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 added by the Member States to the data are given in the footnotes of the tables.

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The Council of Europe and the authors are grateful to all colleagues who provided data for inclusion in this report, and especially to prof. Olof Akerblom for elaborating on the questionnaire.

RESULTS

Response rate

Member States (n= 45) of the Council of Europe (CoE) were invited to send completed questionnaires. Reply was received as of Spetember 1st, 2006 from 33 Member States, the response rate being 73,3 %. For the 2001, 2002 and 2003 surveys, the response rate was 86 percent, 60 percent and 64 respectively.

Donors, first time donors and inhabitants: Table 1

The questionnaire requires data on donors "active during the year", and therefore should include only those donors who actually donated during the reporting year. However the definition "donors active during the year" may require a precise 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 on the short term. 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. 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 became 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, in 33 Member States reporting, 23 percent (range 6-65) 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 25 (range 2-53) per 1,000 inhabitants. This number may reflect the commitment of the population to donate blood in relation to the demand. Differences exist, but arbitrarily less than 10 donors per 1,000 inhabitants could pose a problem with 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 are related. 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 in 33 Member States reporting, is on average 37 (range 0.02-74) per 1,000 inhabitants. Given the average use of red blood cells of 37 per 1,000 inhabitants (see Table 3), the number of whole blood collections either appears to fit the demand of red blood cell products, or determines the use in the hospitals by limiting supply.

Autologous donations have been 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 27 countries where autologous donations are given, they contribute on average 1 percent (range 0-5), to the whole blood donations. This is in conjunction with the literature. However it should be taken into account that surgery and anaesthesiology techniques such as pre-operative hemodilution and intra-operative blood salvage are not included in the 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 (FFP) 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. In 31 reporting Member States on average 4 litres (range 0-45) of plasma per 1,000 inhabitants is collected by plasmapheresis. Apparently Germany, The Netherlands and Bulgaria stand out as countries with a more than average plasmapheresis programmes of 17, 20 and 45 litres of plasmapheresis plasma per 1,000 inhabitants per annum, where Bulgaria is apparently employing remunerated donors (see Table 1.1).

Platelet apheresis may be aimed at HLA or HPA typed donations for refractory patients, as well as to replace the provision of platelets from pooled whole blood donations by apheresis platelet in order to reduce ponor exposure in patients. The relative importance of platelet apheresis for the total supply of platelet products is given in Table 3. In 32 reporting Member States on average 38 percent (range 0-88) of the adult therapeutic doses of platelets are produced by apheresis. The extremes may reflect different models: low access to HLA typed platelet donors or Member States 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. It appears to be increasingly used fro supply reasons.

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

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

Use of blood and blood components for transfusion: Table 3

The term “the use of blood” may be somewhat misleading as the reported data may not reflect the actual use of blood or blood components in the hospitals, but rather the number of blood components that have been delivered to hospitals by blood establishments. This depends on the source of the data and the national infrastructure. 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 actual transfusions issued. As product losses in hospitals – for example by outdating – is limited, the number of blood components delivered to hospitals may be viewed as a proxy to the use of blood, and the heterogeneity of the given data may result in minor deviations.

Whole blood “must be considered as a source material and has no, or only a very restricted, place in transfusion therapy” (Guide to preparation 2001). However in countries with limited resources such as Azerbaijan and Bosnia-Herzegovina, transfusion therapy with whole blood may be needed when the infrastructure for blood component preparation is lacking. In 30 reporting countries, on average 5 percent (range 0-73) of the RBC transfusions are performed with whole blood. In 3 / 30 (10%) of the reporting Member States the use of whole blood accounts for more than 10 percent of the total volume of red blood cell products used.

The use of red blood cells per 1,000 inhabitants varies considerably. In 30 reporting Member States it averages 37 total red blood cell products per 1,000 inhabitants (range 4-73). 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, haematology and oncology care, and in some countries programs for “better use of blood” or for “optimal use of blood” have recently been installed. This in order to reduce unnecessary donor exposure to patients. Therefore the use of red blood cells between 30 and 40 RBC units per 1,000 inhabitants could reflect the results of programmes for more stringent use. In 4 / 30 (13%) of the reporting Member States below 20 units per 1,000 inhabitants are used, most likely reflecting insufficient supply of blood or limited hospital care. A better benchmark may be achieved by including the number of hospital beds in a future survey, and relate this 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 was needed for 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 programmes for "better use of blood" (e.g. red blood cells) the decline of red blood cell use increased the FFP / RBC ratio. On average the FFP / RBC ratio is 0.39 (range 0.13 – 1.4).

Platelets are in Europe generally recovered from 4-5 buffy-coats of whole blood donations. Discussions on blood safety in relation to vCJD initiated programs to enhance the use of random single-donor platelets by apheresis in order to reduce donor exposure to recipients. These programs may have been influential in some Member States where the use of apheresis platelets in relation to recovered platelets is relatively high. The extent to which donors are willing to undergo apheresis may have been limited, as no supply reaches 100% apheresis platelets. On average in 32 reporting Member States, 38 percent (range 0-88) of the adult therapeutic doses of platelets are produced by (random) single donor platelets by apheresis (Table 3).

Cryoprecipitate may incidentally be used for fibrinogen, Von Willebrand’s disease, and complex coagulation disorders. This product is largely abandoned in most Member States.

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 28 reporting Member States an average yield of 8 (range 0-27) litres per 1,000 inhabitants is found of plasma for fractionation into medicinal products. However 6 / 28 (21%) of reporting Member States deliver 15 or more litres (average + SD) plasma per 1,000 inhabitants (Table 4).

In Europe the main supply of plasma for fractionation is by recovered plasma, in 18 reporting Member States on average 76 % of the plasma for fractionation is from recovered plasma (range 18-100%) (Table 4).

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 for fractionation. These specified questions are poorly understood by respondents.

Special processing of blood components: Tables 5.1 and 5.2

In 11 / 32 (34%) of reporting Member States, 100 percent leucodepletion of red blood cell products is carried out. This is the case for platelet concentrates in 14 / 30 (50%) reporting Member States. Hundred percent leucodepletion is applied for plasma for transfusion in 10 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 12 / 25 (50%) reporting Member States 100% of FFP is safeguarded by either method, in 4 Member States for 100% by quarantine, and in 3 by 100% pathogen reduction.

Screening for infectious agents, serological test methods: Table 6

In all 33 reporting Member States, all donations are tested for anti-HIV-1/2, HBsAg and anti-HCV. In 28 / 33 (84%) reporting Member States, all donations are tested for Syphilis. It is debated in the literature whether Syphilis testing is necessary, in Germany, 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 7 / 33 (21%) reporting Member States, and only on first time donors in 4 / 33 (12%) countries.

Testing for anti-HBc is performed on all donations in 5 / 33 (15%) reporting Member States, and only on first time donors in 5 other countries. This is a slight increase as compared to 2003. 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, given the limited positive predictive value of serological screening tests. Confirmed positive donors are then notified and deferred from further donations. A most common flow-chart for confirmation is given in EC Recommendation 98/463/EC.

In table 7.1 the absolute numbers are given of "confirmed positive" donors as reported among all first time donors tested (see Table 1) respectively among all repeat and regular donors tested (see Table 1). Overall 31 of 33 (93%) Member States were able to provide the absolute numbers of confirmed positive donors thus specified (see Table 7.1).

The frequency 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 first time donors), and the ration is given in Table 7.2. The prevalence per 100.000 first time tested donors, if calculated from the provided data sets, ranges from 0 to 500 (!) for HIV-1/2, from 0 to 21000 (!) for HBV and 11 to 9000 (!) for HCV. Although considerable differences in geographical spread of these infections in Europe exist, it is doubted whether the extreme high frequencies of some countries reflect reliable data sets on indeed "confirmed positive donors" or merely refer to only screening test (ELISA) repeat positive donors thus including many false positives (see definitions in the questionnaire). The geographical spread of the high prevalence area's may coincide with low resources and lack of confirmatory testing.

The frequency of "confirmed positive" donors among all repeat and regular donors tested, yields the "incidence" of an infectious disease among repeat and regular donors (e.g. the donors who had been tested before, were previously found negative and were allowed to donate again). The "incidence" accounts for the frequency with which repeat and regular donors acquire a new infection. It is this frequency that directly relates to blood safety via the window period of infectious disease testing (Schreiber 1996, Guideline on Epidemiological data EMEA/CPMP/BWP/3794/03). The incidence of infectious diseases among repeat and regular donors was calculated from Table 7.1 (number of confirmed positive donors) and Table 1 (number of repeat and regular donors), and is given in Table 7.2. As with the prevalence data in first time donors, the extreme high incidences may refer to only screening test (ELISA) repeat positive donors instead of confirmed positive donors thus including many false positives (see definitions in the questionnaire). The geographical spread of the high incidence area's coincides with high prevalence area's and maybe linked to low resources and lack of confirmatory testing.

Notwithstanding the limitations of the data and the question whether all screening test positive donors were submitted to confirmatory testing, the prevalence and incidence rates of infectious diseases vary greatly among Member States. Overall it is

to be noted that in Europe a North-South gradient exists. Hepatitis B virus and hepatitis C virus infections are more common in the Southern countries. The incidence per 100.000 repeat tested donor years, if calculated from the provided data sets, ranges from 0 to 86 (!) for HIV-1/2, from 0 to 596 (!) for HBV and 0 to 293 (!) for HCV. Although considerable differences in geographical spread of these infections in Europe exist, it is doubted whether the very high frequencies of some countries reflect reliable data sets or merely refer to only 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 17 / 33 (51%) reporting Member States. NAT for HIV is performed on each donation in 11 / 33 (33%) reporting Member States. NAT for HBV is performed on each donation in 4 (12%) Member States. Interestingly, NAT on each donation appears to be performed more often in Member States where the incidence rates are relatively low (see Table 7.2 for comparison). As the effectiveness (or "yield") of NAT testing relates to the incidence, an argument could be found in applying NAT testing preferably in high incidence area's. Unfortunately these area's appear to coincide with limited resources.

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 among repeat donors is given in table 8.2.

Bacterial screening: Table 9

A new data set was added in the 2004 report: Bacterial screening of platelet concentrates. Hemovigilance data have repeatedly reported the importance of bacterial safety of platelet concentrates. This is due to the fact that the storage temperature of platelets is around 22^{o}C, thus allowing bacterial growth more easily. Data on bacterial testing were reported by 18 Member States. In 2 / 18 (11%) Member States 90 - 100 % of platelet concentrates recovered from whole blood donations are bacterially screened, and in 13 Member States this is performed on 3 - 50 % of recovered platelet concentrates. Apheresis platelet concentrates are 90 - 100% screened for bacteria in 3 (17%) of reporting Member States.

Overall, more than 10% of platelet concentrates are bacterially screened in 11 / 18 (61%) reporting Member States. This suggests that in these 11 Member States, blood establishments are gradually expanding their bacterial testing programme from a QC level (testing of 1% of concentrates) to a higher level, be it not in all establishments of the country. Among 16 reporting Member States, the average rate of confirmed positively cultured platelet concentrates was 0,25%, (ranging from 0-1 %) which is congruent with the literature. Other Member States reported to have QC programme of bacterial testing in place.

Organisation, registration and labelling: Table 10

In 28 / 33 (85%) of the reporting Member States a National Council or Expert Committee to advise the Ministry of Health on transfusion related policy issues exists.

It is requested that the labelling of donations and issued components is unique as to allow full traceability. Labelling according to ISBT-128 for the donation number is partially performed in 7 countries, and 5 (25%) countries have 100% ISBT-128 code for the donations. Labelling of the finished component code is more complex, is in general behind in developments of donation labelling, as it includes implementation of automation applications in hospitals. ISBT-128 labelling of the issued component is partially implemented in 7 countries, and 4 countries (20%) have 100% ISBT-128 coding at the donation as well as the component level. Other systems of automated labelling exist, and these are summarized in Table 9, and specified below the table.

Quality management related issues: Table 11

In 28 / 33 (85%) of the reporting Member States a Quality System is established and maintained in blood establishments. In 4 (12%) countries the implementation of such a system is planned.

In 17 / 33 (51%) of the reporting Member States 100 percent of the donations are covered by GMP. In 3 (9%) countries this is the case for ISO 9000. In 5 countries another quality system is used with 100 percent coverage of the donations. In 26 / 33 (78%) of the reporting Member States inspections are performed at least every 2 years, in 21 of which these inspections are (partially) carried out by the national authority.

In 27 / 33 (81%) of the reporting Member States a hemovigilance system is installed, 17 / 33 (51%) hemovigilance systems are organized by or in collaboration with the national authority.

Hemovigilance: Table 12

A new data set was added for the 2004 report: hemovigilance reporting e.g. reporting of serious adverse events. The format for data acquisition on hemovigilance in the 2004 questionnaire in its basic form was developed by Council of Europe experts, submitted to the European Commission and adapted after slight modifications by the European Commission into Directive 2005/61/EC, coming into force in august 2006. Reporting of serious adverse reactions as performed in hemovigilance programmes can be considered as a high level of surveillance, as most of these serious reactions are not unexpected untoward effects but well known complications of blood transfusion from the medical literature and commonly indicated in the “information leaflets” for physicians and patients. Most recipients of blood transfusions are very ill and have underlying pathology or medications that greatly influence the signs and symptoms of a possible transfusion reaction. A serious adverse reactions on transfusion, even if most likely related to the transfusion, may be restricted to the given recipient. Therefore, in this report only those serious adverse reactions are presented which are probably of certainly (imputability grade 2 to 3) related to the

transfusion of the blood component. The term imputability includes the causal relationship to the product properties, but also to the transfusion itself (TACO) or recipient properties (Allergy).

In contrast to the EC Directives 2002/98/EC and 2005/61/EC, in this surveillance, also hemovigilance data which may not be caused by blood component properties, such as TACO (transfusion associated circulatory overload) are reported. Hemovigilance data submitted by 20 Member States, are presented in Table 12.

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

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Table 1
2004

Donors, first time donors and inhabitants

country	regular and repeat donors	first time donors	% first time donors	total donors	inhabitants x 1,000	donors per 1,000 inhabitants	
Andorra							
Armenia							
Azerbaijan	10.419	8.665	45,4	19.084	8.000	2,4	
Albania							
Austria	265.615	93.717	26,1	359.332	8.090	44,4	
Belgium	261.519	54.512	17,2	316.031	10.289	30,7	
Bosnia / Herzegovina	37.305	12.525	25,1	49.830	3.843	13,0	
Bulgaria	120.961	31.852	20,8	152.813	7.840	19,5	
Croatia	75.848	15.583	17,0	91.431	4.437	20,6	
Cyprus							
Czech Republic	349.300	29.300	7,7	378.600	10.300	36,8	
Denmark	233.975	25.000	9,7	258.975	5.100	50,8	
Estonia							
Former Yug. Rep. Macedonia							
Finland	14.266	16.858	54,2	31.124	5.220	6,0	
France					62.371		
Georgia	7.000	1.000	12,5	8.000	5.000	1,6	
Germany	2.301.703	518.636	18,4	2.820.339	82.501	34,2	1)
Greece	318.031	41.591	11,6	359.622	10.500	34,2	
Hungary	311.050	66.472	17,6	377.522	10.142	37,2	
Iceland	7.241	2.343	24,4	9.584	294	32,6	
Ireland	98.722	17.630	15,2	116.352	3.917	29,7	
Italy	122.400	223.000	64,6	345.400	57.000	6,1	
Latvia	33.690	12.308	26,8	45.998	2.300	20,0	
Liechtenstein							
Lithuania	24.578	15.155	38,1	39.733	3.500	11,4	
Luxembourg	12.512	801	6,0	13.313	440	30,3	
Malta		8.615			400		
Moldovia	40.646	14.972	26,9	55.618	3.386	16,4	
Netherlands	468.540	34.004	6,8	502.544	16.292	30,8	
Norway	93.431	14.744	13,6	108.175	4.606	23,5	
Poland	241.693	182.488	43,0	424.181	38.600	11,0	
Portugal							
Romania	140.300	81.184	36,7	221.484	21.800	10,2	
Russian Federation	2.031.747	746.403	26,9	2.778.150	140.000	19,8	
San Marino							
Serbia and Montenegro							
Slovak Republic	121.926	22.668	15,7	144.594	5.300	27,3	
Slovenia	94.935	9.222	8,9	104.157	1.964	53,0	
Spain	741.401	323.544	30,4	1.064.945	40.904	26,0	
Sweden	244.770	32.935	11,9	277.705	9.009	30,8	
Switzerland	215.600	26.559	11,0	242.159	7.360	32,9	
Turkey							
Ukraine							
United Kingdom	1.346.587	288.122	17,6	1.634.709	58.800	27,8	

1) Number of regular and repeat donors by extrapolation

Table 1.1
2004

Profile of donations

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

1) 27000 platelet / plasma combined apheresis
2) Hyper-immune plasma from paid donors

Table 2

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

2004	whole blood collections				apheresis collections					
country	whole blood units	whole blood per 1,000 inhabitants	autologous units	% autologous whole blood units	plasma apheresis (L)	plasma in L per 1,000 inhabitants	platelets apheresis (U)	RBC apheresis (U)	granulocytes apheresis (U)	
Andorra										
Armenia										
Azerbaijan	20.874	2,6	0	0,0	1.014	0,13	176	7.480		
Albania										
Austria	495.994	61,3	3.390	0,7	80	0,01	15.887	3.209	69	
Belgium	503.228	48,9	1.698	0,3	94.323	9,17	31.075	2.745	13	
Bosnia / Herzegovina	37.396	9,7	10	0,0	0	0,00	500	10	6	
Bulgaria	152.839	19,5	26	0,0	356.150	45,43	349	0	0	
Croatia	156.705	35,3	1.131	0,7	4.218	0,95	1.491	0	0	
Cyprus										
Czech Republic	433.500	42,1	17.900	4,0	54.200	5,26	15.000	2.000	24	
Denmark	375.469	73,6			1.084	0,21	279		0	
Estonia										
Former Yug. Rep. Macedoni										
Finland	282.753	54,2	0	0,0	1.415	0,27	682	0	0	
France	2.113.676	33,9	49.374	2,3	139.822	2,24	167.321	2.384	181	
Georgia	29.000	5,8	0	0,0	5.000	1,00	100	0	0	
Germany	4.714.955	57,2	4.940	0,1	1.448.004	17,55	242.542	12.035		
Greece	617.462	58,8	4.502	0,7	1.102	0,10	23.197	4.880	<20	
Hungary	505.344	49,8			295	0,03	5.237		21	
Iceland	14.989	51,0	3	0,0	0	0,00	337	0	0	
Ireland	152.361	38,9	20	0,0			6.134	14		
Italy	2.270.000	39,8	121.000	5,1	186.000	3,26	63.000		396	1)
Latvia	54.609	23,7	0	0,0	10.533	4,58	1.526	0		
Liechtenstein										
Lithuania	84.233	24,1			0	0,00	637	7	0	
Luxembourg	21.017	47,8	363	1,7	2.923	6,64	990	0	0	
Malta	15.300	38,3					264	15.036		
Moldovia	60.155	17,8	157	0,3	991	0,29	0	0	0	
Netherlands	635.298	39,0	416	0,1	339.032	20,81	2.729			
Norway	201.229	43,7	33	0,0	2.376	0,52	4.307	4.782	0	
Poland	913.929	23,7	2.452	0,3	20.962	0,54	23.861	0	105	
Portugal										
Romania	364.215	16,7			182	0,01	553	0	0	
Russian Federation	2.774	0,0			295.396	2,11				
San Marino										
Serbia and Montenegro										
Slovak Republic	138.072	26,1	1.800	1,3	4	0,00	2.830	0	1	
Slovenia	84.962	43,3	1.986	2,3	272	0,14	869	0	3	
Spain	1.564.569	38,2	24.390	1,5	13.500	0,33	31.119	9.446	14	
Sweden	471.696	52,4	401	0,1	68.080	7,56	8.260	543	77	
Switzerland	377.288	51,3	16.000	4,1	4.600	0,63	14.000	910	0	2,3)
Turkey										
Ukraine										
United Kingdom	2.601.488	44,2	558	0,0	970	0,02	67.047	1.270	126	

1) 27000 platelet / plasma combined apheresis

2) 901 RBC collected in combined apheresis procedures

3) 19800 platelet concentrates collected with approx 14000 procedures

Table 3
2004

Use of blood and blood components for transfusion

country	whole blood (U)	% whole blood of total RBCs	red blood cell concentrates (U)	r.b.c. (U) per 1,000 inhabitants	plasma for transfusion (U)	platelets total (U)	platelets recovered (U)	platelets apheresis (U)	% platelets by apheresis	cryoprecipitate (10^6 IU FVIII)	
Andorra											
Armenia											
Azerbaijan	20.698	73,5	28.178	3,5	6.853	176	44	132	75,0	0	
Albania											
Austria	0	0,0	464.041	57,4	92.468	25.600	9.027	16.573	64,7	0	
Belgium	82	0,0	517.214	50,3	103.158	59.803	32.432	27.371	45,8	0	
Bosnia / Herzegovina	13.290	36,9	36.015	9,4	12.361	2.539	1.302	1.237	48,7		
Bulgaria	3.846	2,8	139.753	17,8	93.534	5.595	5.250	345	6,2	0	
Croatia	3.785	2,4	155.859	35,1	96.669	12.137	10.683	1.454	12,0	0	
Cyprus											
Czech Republic	1.200	0,4	327.700	31,8	179.600	24.400	5.200	19.200	78,7		
Denmark	150	0,0	371.694	72,9	57.050	32.484	31.784	700	2,2	0	
Estonia											
Former Yug. Rep. Macedonia											
Finland	695	0,3	254.996	48,8	39.855	32.224	31.662	562	1,7	0	1)
France	0	0,0	2.043.426	32,8	270.777	209.045	25.711	183.334	87,7	0	
Georgia	1.000	3,3	30.000	6,0	28.000	2.000	1.500	500	25,0	0	
Germany	11.824	0,3	4.490.776	54,4	1.374.986	373.538	141.421	232.117	62,1	0	
Greece	920	0,1	622.150	59,3	234.842	166.477	143.531	22.946	13,8	0	2)
Hungary	10	0,0	412.793	40,7	93.268	14.520	9.276	5.244	36,1	0	
Iceland	0	0,0	14.839	50,5	4.306	933	388	545	58,4	0	
Ireland	0	0,0	136.250	34,8	26.937	17.598	9.493	8.105	46,1	0	
Italy	25.000	1,1	2.361.000	41,4	546.000	123.000	61.000	62.000	50,4	3.900	3)
Latvia	0	0,0	50.488	22,0	47.942	3.819	830	2.989	78,3	1.900	
Liechtenstein											
Lithuania	12		80.990		27.420	14.664	13.420	1.244	8,5	1.639	
Luxembourg	0	0,0	20.212	45,9	4.063	2.125	1.204	921	43,3	0	
Malta	0	0,0	15.036	37,6	15.036	15.300	15.036	264	1,7	766	
Moldovia	37	0,2	21.357	6,3	29.297	293	293	0	0,0	2.142	
Netherlands	252	0,0	595.506	36,6	92.269	52.685	48.003	4.682	8,9	0	
Norway	154	0,1	191.431	41,6	39.706	16.007	8.318	7.689	48,0	0	4)
Poland	167	0,0	890.715	23,1	365.439	50.212	24.685	25.527	50,8	1	
Portugal											
Romania	140.896		354.576			59.267	58.727	540	0,9	18.246	
Russian Federation								221.376		29	
San Marino											
Serbia and Montenegro											
Slovak Republic	24.809	13,5	183.341	34,6	50.236	8.454	4.681	3.773	44,6	0	
Slovenia	0	0,0	79.616	40,5	32.988	25.680	24.286	1.394	5,4	0	
Spain	1.163	0,1	1.426.762	34,9	261.800	119.311	77.831	41.480	34,8	6.248	
Sweden	88	0,0	454.920	50,5	114.180	35.121	20.789	14.332	40,8	0	
Switzerland	4.850	1,6	310.629	42,2	66.309	18.509	2.408	16.101	87,0	0	
Turkey											
Ukraine											
United Kingdom	1.087	0,0	2.435.312	41,4	351.746	261.317	148.759	112.558	43,1	7	

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

Table 4
2004

Plasma for fractionation into medicinal products

country	plasma for fractionation (L)	plasma for fractionation per 1,000 inhabitants (L)	% fractionation plasma recovered	plasma for transfusion per 1,000 inhabitants (U)	plasma for transfusion / total red blood cell ratio (U)	
Andorra						
Armenia						
Azerbaijan	0	0,00		0,86	0,24	
Albania						
Austria	61.403	7,59	108,59	11,43	0,20	
Belgium	228.587	22,22	18,92	10,03	0,20	
Bosnia / Herzegovina	0	0,00		3,22	0,34	
Bulgaria	11.796	1,50	100,00	11,93	0,67	
Croatia	16.356	3,69	76,17	21,79	0,62	
Cyprus						
Czech Republic	78.100	7,58	55,70	17,44	0,55	
Denmark	82.434	16,16	99,00	11,19	0,15	
Estonia						
Former Yug. Rep. Macedonia						
Finland	44.782	8,58	100,00	7,64	0,16	
France	601.633	9,65	82,47	4,34	0,13	
Georgia	1.000	0,20	100,00	5,60	0,93	
Germany	2.232.294	27,06	43,17	16,67	0,31	
Greece	19.693	1,88	94,40	22,37	0,38	
Hungary				9,20	0,23	1)
Iceland	0	0,00		14,65	0,29	
Ireland	0	0,00		6,88	0,20	
Italy				9,58	0,23	
Latvia	14.577	6,34	34,86	20,84	0,95	
Liechtenstein						
Lithuania	19.861	5,67	100,00	7,83		
Luxembourg	6.767	15,38	72,22	9,23	0,20	
Malta				37,59	1,00	2)
Moldovia	5.571	1,65	74,04	8,65	1,37	
Netherlands	310.857	19,08	57,77	5,66	0,15	
Norway	49.036	10,65	76,80	8,62	0,21	3)
Poland	143.995	3,73	79,29	9,47	0,41	
Portugal						
Romania						
Russian Federation	183.012	1,31				
San Marino						
Serbia and Montenegro						
Slovak Republic	15.237	2,87	99,87	9,48	0,27	
Slovenia	10.500	5,35	97,41	16,80	0,41	
Spain	270.975	6,62		6,40	0,18	
Sweden	157.941	17,53	58,52	12,67	0,25	
Switzerland	92.362	12,55	26,36	9,01	0,21	
Turkey						
Ukraine						
United Kingdom				5,98	0,14	

1) Fractionation performed outside Hungary
2) Plasma not used for fractionation
3) 9000 litres of plasma used for manufacture of SD plasma

Table 5.1
2004

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

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

Table 5.2
2004

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

1) Quarantined FFP for pediatric use
2) Data on plasma manufactured in Germany, SD plasma not included
3) Plasma quarantined since December 2004
4) Plasma for transfusion mostly recoverd from leukoreduced whole blood Cryo reduced plasma only in some TPE settings

Table 6
2004

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

1) HIV Ag on 0,5% of donations anti-HBc on 5,8% of donations anti-HTLV on 0,5% of donations
2) Combined HIV Ab and Ag test
3) Repeat donors re-screened every 3 years
4) Anti-malaria conform 2004/33/EC, a-CMV individually
5) Syphilis not required for plasma for fractionation
6) + 11) + 14) HIV Ab / Ag combitest
7) + 10) + 15) ALT on each donation
8) CMV IgM on apheresis platelets and pediatric components
9) HIV Ab / Ag combitest Full blood count on each donation
12) Most blood banks use HIV Ab / Ag combitest Anti-HBc also if last donation > 12 months ago
13) Partial CMV testing in 1 of 21 centres
16) Anti-HBc in repeat donors after a risk moment
17) 20% of donations tested for a-HBc ALT on all donations

Table 7.1
2004

Confirmed seropositive donors (absolute numbers)

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

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

Table 7.2

Prevelance and incidence calculated per 100,000 donors

2004	HIV 1 / 2		HBV		HCV		
country	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							
Azerbaijan	103,87	86,38	2204,27	28,79	4258,51	47,99	
Albania							
Austria	2,13	1,51	81,10	4,14	54,42	6,02	
Belgium	1,83	0,76	128,41	3,06	49,53	1,53	
Bosnia / Herzegovina	0,00	0,00	215,57	45,57	87,82	10,72	1)
Bulgaria	18,84	0,00	8737,28	6,61	2059,53	3,31	
Croatia	6,42	3,96	173,27	9,23	44,92	34,28	
Cyprus							
Czech Republic	3,41	0,29	81,91	14,89	102,39	10,02	2)
Denmark	4,00	0,85	36,00	0,43	32,00	0,43	
Estonia							
Former Yug. Rep. Macedonia							
Finland	0,00	0,00	23,73	0,00	29,66	35,05	
France							
Georgia	500,00	42,86	21000,00	585,71	9000,00	85,71	
Germany	4,82	2,26	156,56	1,52	85,42	3,26	3)
Greece	115,41	4,72	3104,04	114,45	867,98	41,82	
Hungary	1,50	0,64		2,89		81,98	
Iceland	0,00	0,00	0,00	0,00	42,68	0,00	
Ireland	5,67	0,00	11,34	1,01	28,36	1,01	
Italy	16,14	26,96	470,40	35,13	296,41	43,30	
Latvia	56,87	2,97					
Liechtenstein							
Lithuania	13,20	0,00	1873,97	65,10	2038,93	292,94	
Luxembourg	124,84	0,00	249,69	0,00	124,84	0,00	
Malta	0,00		139,29		34,82		
Moldovia							
Netherlands	0,00	0,85	67,64	1,28	35,29	0,64	
Norway	0,00	0,00	20,35	1,07	33,91	0,00	
Poland	8,22	0,83	651,55	17,79	657,03	70,34	
Portugal							
Romania	27,10	4,28	4388,80	159,66	1278,58	127,58	
Russian Federation							
San Marino							
Serbia and Montenegro							
Slovak Republic	0,00	0,00	176,46	1,64	110,29	4,10	
Slovenia	0,00	2,11	206,03	1,05	10,84	0,00	
Spain	28,74	4,86	182,97	4,99	150,52	3,78	
Sweden	3,04	0,82	36,44	0,82	66,80	0,00	
Switzerland	0,00	2,32	158,14	1,86	64,01	0,93	4)
Turkey							
Ukraine							
United Kingdom	4,51	0,89	33,67	0,97	35,05	1,78	

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

Table 8.1
2004

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

1) 6% of donations other pool size
2) NAT for HBV, HIV and HCV on individual donations in Carribean
3) HIV NAT since april 2004 HBV NAT voluntary on >75% donations HCV NAT on each donation not required for plasma for fractionation
4) HCV NAT in plasma from 82,712 units, additional 7 centres test SD NAT for HIV and HCV
5) HIV and HBV NAT locally
6) HIV, HBV, HCV NAT since December 2004
7) In 3 of 21 centres single donation NAT for HIV and HCV

Table 8.2
2004

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

Table 9

2004

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

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

Table 10
2004

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

1) Component codes are country specific
2) Expert committee needed — No unified system used, some use ISBT 128
3) 5) 16) 19) National labelling system
4) 8) 10) 13) 18) Codabar
6) MONARCH for labelling
8) 70% of centres computerized, national scheme under development
9) One blood bank 100% ISBT-128, other centre no computer system for labeling
11) UNI = Unified Italian Codes
12) Local labelling system
14) 100% ISBT 128 to be installed in 2005
15) Polish local labelling system
16) National coding system with unique donation number
!7) Labelling according to CoE recommendations
19) Other system is earlier national system

Table 11

2004

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

1) Inspections and hemovigilance system by national authority planned
2) One institute collecting 48% of donations is ISO certified
3) All donations also covered by ISO 17025
4) Inspections by National Body of Inspectors
5) Inspections by British Standard Institutions
6) Former regulations require inspections every 5 years, will change by 2002/98/EC
7) GMP and ISO launched in 2005
8) National authority being established
9) EN ISO /IEC 17025 or EN ISO 15189
10) Some centres next to ISO 9001:2000 also ISO 17025

Table 12
2004

Hemovigilance

country	total number components transfused: whole blood + RBC + FFP + Platelets	Imputability "likely, probable or certain" (level 2 or level 3)															Incidence high imputability serious adverse reactions per 100,000 components	
		hemolysis ABO	hemolysis other	PTP	Anaphylaxis	TRALI	GVHD	TA-HBV	TA-HCV	TA-HIV	TA-Other viral	TA-Bacterial	TA-Malaria	TA-Parasitic	TA-TACO	TA-Other serious		
Andorra																		
Armenia																		
Azerbaijan	35.207																	
Albania																		
Austria	582.109	0	0	0		0	0	0	1	0		0	0	0	0	1	0,3	
Belgium	680.175																	
Bosnia / Herzegovina	50.915																	
Bulgaria	238.882		0		4												1,7	
Croatia	264.665	3	16		15	2				1		4			3		16,6	
Cyprus																		
Czech Republic	531.700							0	0	0								1)
Denmark	461.228																	
Estonia																		
Former Yug. Rep. Macedonia																		
Finland	327.075							2									0,6	
France	2.523.248	5	6	0	31	13	0	0	0	0	0	4	0	0	48	18	5,0	2)
Georgia	60.000																	
Germany	6.239.300		8	1	4	14	0	4	0	0	0	5				0	0,6	
Greece	1.023.469																	
Hungary	520.581	4	0														0,8	3)
Iceland	20.078																	
Ireland	180.785	1	3					0		0					15	23(?)	10,5	
Italy	3.030.000																	
Latvia	102.249																	
Liechtenstein																		
Lithuania	123.074																	
Luxembourg	26.400	1															3,8	
Malta	45.372	1			12											0	28,7	
Moldovia	50.947																	
Netherlands	740.460	2	10	0	18	4	0	0	0	0	0	1	0	0	2	17	7,3	
Norway	247.144	3	2	0	0	1	0	0	0	0	0	0	0	0	1	0	2,8	
Poland	1.306.366	7	10	0	1	15	0	0	0	0	0	13	0	0	0	0	3,5	
Portugal																		
Romania	413.843																	
Russian Federation																		4)
San Marino																		
Serbia and Montenegro																		
Slovak Republic	242.031	6	6	3	55	2											29,7	
Slovenia	138.284				8										1	6	10,8	5)
Spain	1.807.873																	
Sweden	604.221	2	6	0	23	3	0	0	0	0	0	2	0	0			6,0	
Switzerland	395.447	1	2	0	13	3									3	1	5,8	6)
Turkey																		
Ukraine																		
United Kingdom	3.048.375	1	0	0	1	13	0	0	0	0	1	0	0	0	2		0,6	

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

APPENDIX

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

The 2004 Survey"

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

Strasbourg, 30 May 2005 SP-HM (2005) 2

SP-HM/docs/quest04

QUESTIONNAIRE ON THE COLLECTION, TESTING AND USE OF BLOOD AND BLOOD COMPONENTS IN EUROPE

THE 2004 SURVEY

This questionnaire consists of three sections: A. Collection and use of blood and blood components, B. Testing of blood and blood components, and C. General information. At the end of each section, please provide any additional information and comments that you think may be useful for the interpretation of the data and for the future improvement of the questionnaire. When information or data on specific terms is not available, please indicate "n.a." (=data not yet available). This questionnaire has been elaborated by Dr. Olof Akerblom and Dr. C.L. van der Poel. Any questions you might have when filling out the questionnaire should be directly addressed to Dr C.L. van der Poel, c.vanderpoel@sanquin.nl

Directive 2002/98/EC, Annex II, requests Member States of the European Union to report annually on the blood establishment's activity. This request includes figures also asked for in this questionnaire (No. 1.1 + 1.2.1, 2.1-5, 3.1-5, 4.1-2, 7.1 + 8.3.1, 7.2 + 8.3.2, and 12.2).

The questionnaire is to be completed and returned by 15 September 2005 to Dr C.L. van der Poel, c.vanderpoel@sanquin.nl, copy to the Secretariat, Health Division, Council of Europe, F-67075 Strasbourg Cedex, Fax: + 33 388 41 2726; e-mail: sophie-marie.leguilloux@coe.int

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

The 2004 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	
1.2.1	- on first visit donating blood or blood components, number	
1.2.2	- on first visit giving blood samples for testing only, number	

* Definition – see Council Recommendation 98/463/EC.

2. Collection of blood and blood components

2.1	**Whole blood**, number of donations (*excl*. autologous)	
2.1.1	**-** voluntary non-remunerated, per cent of donations	%
2.1.2	- replacement donations, number	
2.1.3	**-** autologous donations**,** pre-deposit, number	
2.2	**Red cells apheresis**, number of donations (procedures)	
2.2.1	**-** voluntary non-remunerated, per cent of donations	%
2.2.2	**-** autologous donations, pre-deposit, number	
2.3	**Plasma apheresis**, litres	
2.3.1	- collected from voluntary non-remunerated, litres	
2.4	**Platelets apheresis**, number of donations (procedures)	
2.4.1	**-** voluntary non-remunerated, per cent of donations	%
2.5	**Granulocytes apheresis**, number of donations (procedures)	

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

3. Use of blood and blood components intended for transfusion

Please, indicate if the figures given relate to blood and blood components ☐ distributed to hospital blood banks, *or* ☐ transfused		
3.1	**Whole blood,** units[1]	
3.2	**Red cells** (red cells for transfusion, *excl*. autol.), units[2]	
3.2.1	**- red cells autologous,** pre-deposit, units	
3.3	**Plasma** (plasma or FFP for transfusion), units[2]	
3.4	**Platelets** (adult therapeutic doses[3]), total number	
3.4.1	– recovered from whole blood (adult therapeutic doses[3])	
3.4.2	– collected by platelet apheresis (adult therapeutic doses[3])	
3.5	**Cryoprecipitat**e, FVIII IU x 10^6	

[1] A unit of whole blood consists of approximately 450 or 500 ml of blood, collected in a suitable amount of anticoagulant solution.

[2] A unit of red cells or plasma is red cells or plasma recovered from one unit of whole blood, or a comparable unit of red cells or plasma collected by apheresis.

[3] An adult therapeutic dose usually consists of 200 – 450 x 10^9 platelets.

4. Blood components delivered for the manufacture of medicinal products

4.1	**Plasma for fractionation**, total, **litres**[1]	
4.1.1	– human plasma for fractionation into FVIII, litres	
4.1.1.	- recovered from whole blood donations, litres	
4.1.1.	- from plasmapheresis (source plasma), litres	
4.1.2	– for preparation of specific immunoglobulines[2], litres	
4.1.3	– other plasma, litres	

4.2	**Other components** (e.g. erythrocytes, buffy coat), units	

[1] litres = kg x 0.975 [2] e.g. anti-D, anti-HBs, anti-Zoster, etc.

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

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 special processing of blood components.

Please use the following space to provide any further information that you regard to be useful about the issues addressed in Section A (Tables 1 –5).

SECTION B. Testing of blood and blood components

6. Screening for infectious agents, serological test methods

Screening tests required *only* by plasma fractionators should *not* be reported below.

	Screening test performed	**only 1st time donor**	**every donation**	Comments
6.1	anti-HIV 1+2	☐	☐	
6.1.1	HIV-Ag	☐	☐	
6.2	HBsAg	☐	☐	
6.2.1	anti-HBc	☐	☐	
6.3	anti-HCV	☐	☐	
6.3.1	HCV-Ag	☐	☐	
6.4	anti-HTLV I/II	☐	☐	
6.5	Syphilis*	☐	☐	
6.6	Others,	☐	☐	
	please specify	☐	☐	

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

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

7. Confirmed seropositive test results

7	**Confirmed seropositive**[1]	HIV 1/2	HBsAg	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 ***plus*** positive
in at least one supplementary test based on another principle.

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

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

8. Nucleic Acid Testing, NAT

The testing performed by plasma fractionators should *not* be reported below.

8.1	**Screening for infectious agents, NAT (minipools)**			
	Screening test performed	**only 1st time donor**	**every donation**	Comments
8.1.1	HIV NAT	☐	☐	
8.1.2	HBV NAT	☐	☐	
8.1.3	HCV NAT	☐	☐	
8.1.4	other NAT	☐	☐	please specify:

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			

[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 ***plus*** 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 by NAT.

9. Screening for the presence of bacteria in platelet preparations

9.1	**% of platelet adult doses screened for the presence of bacteria**	%
9.1.1	- recovered platelet pools (adult doses)	%
9.1.2	- apheresis platelets (adult doses)	%
9.2	**% of screened units confirmed positive by further testing**	%
Comments		

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

10. Organisation, registration and labelling

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

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

11. Quality management related issues

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

11.2	Are **inspections** performed at least each second year? ☐ No ☐ Yes, by ☐ a national authority ☐ another qualified body or organisation
	Comments:

12. Haemovigilance

12.1	Is there a **haemovigilance reporting system** on national level? ☐ No ☐ Yes, - operated by a national authority ☐ Yes, - operated by another organisation* - if "Yes", please give haemovigilance data, if available, in Table 12.2
	*please, specify:
	Comments

12.2 Haemovigilance data Serious adverse reactions* observed in recipients of blood or blood components:		Serious adverse reactions* reported - total number	- with imputability level* NA	0 - 1	2	3
Immunological haemolysis due to	ABO incompatibility					
	other allo-antibody					
Non-immunological haemolysis						
Post-Transfusion Purpura						
Anaphylaxis / hypersensitivity						

Transfusion Related Acute Lung Injury						
Graft Versus Host Disease						
Transfusion-associated viral infection	HBV					
	HCV					
	HIV-1/2					
	Other					
Transfusion-associated bacterial infection						
Transfusion-associated parasitical infection	Malaria					
	Other					
Circulatory overload						
Other serious reactions						

* When completing this table, please use the definitions of serious adverse reaction and imputability presented on the next page.

12.3 Definitions to be used in this section:

12.3.1 ***Serious adverse reaction*** – an unintended response in a patient associated with the transfusion of blood or blood components that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity.

12.3.2 ***Imputability*** - the likelihood that a serious adverse reaction in a recipient can be attributed to the blood or blood component transfused.

Imputability scale to assess serious adverse reactions:

Imputability scale		Explanation
NA	Not assessable	When there is insufficient data for imputability assessment.
0	Excluded	When there is conclusive evidence beyond reasonable doubts for attributing the adverse reaction to alternative causes.
0	Unlikely	When the evidence is clearly in favour of attributing the adverse reaction to causes other than the blood or blood components.
1	Possible	When the evidence is indeterminate for attributing adverse reaction either to the blood or blood component or to alternative causes.
2	Likely, Probable	When the evidence is clearly in favour of attributing the adverse reaction to the blood or blood component..
3	Certain	When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to the blood or blood component.

Please use the following space to provide any further information that you regard to be useful about organisational and quality management related blood issues as well as haemovigilance and the collection and reporting of haemovigilance data