2007 Report

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

European Committee (Partial Agreement) on Blood Transfusion (CD-P-TS)

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2007 Report

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CONTENTS

Summary 4

Acknowledgements 6

List of abbreviations 7

Study methods 9

Results: Comments 10

References 18

Results: Tables 19

Table 1 - Donors, first time donors and inhabitants 20

Table 1.1 - Profile of donations 21

Table 2 - Collection of whole blood, autologous blood and blood (apheresis) components 22

Table 3 - Use of blood and blood components for transfusion 24

Table 4 - Plasma for fractionation into medicinal products 25

Table 5.1 - Special processing of blood components 26

Table 5.2 - Inactivation or quarantine of plasma 27

Table 6 - Donation testing strategy for infectious agents 28

Table 7.1 - Confirmed seropositive donors (absolute members) 30

Table 7.2 - Prevalence and incidence calculated per 100.000 donors 31

Table 8.1 - NAT testing 32

Table 8.2 - NAT-only positive results 34

Table 9 - Bacterial screening 35

Table 10 - Organisation, registration and labelling 36

Table 11a, b - Quality management related issues 37,38

Table 12 - Haemovigilance 39

Appendix 41

Questionnaire on the collection, testing and use of blood and blood components in Europe, the 2007 Survey

SUMMARY

This report provides data on the donors, collection, testing, use and quality aspects of blood and blood components in Member States (MS) of the Council of Europe (CoE). Data were supplied by MS in response to a questionnaire requesting detailed information on donors, collections, testing, distribution and quality aspects of blood and blood components for the year 2007. In its present form it follows a series of similar reports that have assessed such data in 1989, 1991, 1993, 1995, 1997 and, in its present revised form, in 2001, 2002, 2003, 2004, 2005 and 2006.

A Qualitative Evaluation Report on the questionnaire with recommendations for improvement of the process was previously performed and was reported in November 2004, including experience with reporting of data from the 3 previous years. The format of the questionnaire was reviewed and re-designed by the authors and the CoE experts of the Committee of Experts on Quality Assurance in Blood Transfusion Services (SP-GS) and the Committee of Experts on Blood Transfusion (SP-HM) bureau in 2004.

Also, in 2007, as for former years, not all relevant data was obtained from each MS. Due to difficulties in implementation of data retrieval from automated blood banking systems, and the collation of data from many blood establishments (BE) on a national level within MS, the process is designed so that annual repetition will lead to improvements.

In contrast to surveys for the years 2003 and earlier, the proportion of donations by voluntary non-remunerated and replacement donors was requested as of the 2004 questionnaire. The European Commission (EC) has acknowledged the importance of this information in its *Directive 2002/98/EC*.

In MS and in BE, data may be administered in different formats, and different definitions may have been operational. This could result in discrepancies if data is reported in different formats. In addition, some data may not be available from all respondents. It is anticipated that consistency and persistence with these CoE survey methods, in collaboration with the EC, will result in adaptation of the BE and MS towards uniform data collecting, and thereby the generation of better data and higher response rates among MS 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 the Preparation, Use and Quality Assurance of Blood & Blood Components, 9th edition, 2003*). In addition, it is to be welcomed that the European Medicines Agency (EMA) 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 data.

In total, 35 questionnaires were received in 2007; a response rate of 76%. For the 2001, 2002, 2003, 2004, 2005 and 2006 surveys, the response rates were 84%, 60%, 67%, 73%, 72% and 80% respectively.

The average number of donors in relation to the general population is 29 (range 3-63) per 1,000 inhabitants. On average, 21% of the donor base consists of first time donors.

The number of whole blood (WB) collections is on average 38 per 1,000 inhabitants, the average use of red blood cells (RBC) is 40 per 1,000 inhabitants. On average 1.8 litres (L) of plasmapheresis plasma per 1,000 inhabitants are collected.

The use of RBC varies considerably (range 8-64) and averages 40 total RBC Units (U) per 1,000 inhabitants. In 7% of the reporting MS, less than 20 U per 1,000 inhabitants are used, most likely reflecting an insufficient supply. In the reporting MS, on average 37% of the total platelet volume is supplied by (random) single donor platelets by apheresis; in 9 countries this volume amounts to more than 50%.

The amount of plasma delivered for fractionation into medicinal products differs greatly (range 0-27) among MS; yielding, on average, 7.0 L of plasma for fractionation per 1,000 inhabitants. However 17% of reporting MS deliver 15 L or more per 1,000 inhabitants. In Europe, on average 57% of the plasma for fractionation is from recovered plasma.

In 41% of the reporting MS, all RBC products are leucocyte depleted. Platelet concentrates are 100% leucocyte depleted in 52% of reporting MS, as is plasma for transfusion in 39% MS. In 44% of reporting MS, nearly all FFP is additionally safeguarded by either quarantine or pathogen reduction methods.

In 97% of the reporting MS, each donation is tested for anti-HIV-1/2, HBsAg and anti-HCV. In 88% of reporting MS, all donations are tested for syphilis. Anti-HTLV-I/II testing is performed on all donations in 20% of reporting MS, and on first time donors only in 7% of reporting MS. Anti-HBc is performed on all donations in 16%, and only on first time donors in 13%, of reporting MS. Prevalence and incidence of infectious diseases in donors vary greatly among MS, and it is noted that in Europe a North-South gradient exists for hepatitis B (HBV) and C virus (HCV). The median prevalence amongst first time tested donors is 8.2, 107 and 69 per 100,000 donors for HIV-1/2, HBV and HCV, respectively. The median incidence amongst repeat donors is 0.9, 1.1 and 1.7 per 100,000 donor years for HIV-1/2, HBV and HCV, respectively.

Nucleic Acid Amplification Techniques (NAT) testing for HCV is performed on each donation in 53% reporting MS, whereas HIV NAT and HBV NAT is performed on each donation in 48% and 29% of reporting MS, respectively.

Bacterial screening is performed on about 80% or more of the platelet concentrates in five (20%) MS. Haemovigilance data have repeatedly demonstrated the importance of bacterial safety for platelet concentrates.

Of 33 MS, 97% have legally-binding national regulations. In 70% of the reporting MS, a National Council or Expert Committee to advise the Ministry of Health on transfusion-related policy issues exists. In 76% of reporting Member States, there is a national blood policy on the quality and safety of blood and blood components in place.

In 82% of the reporting MS, a Quality System (QS) is established and maintained in BE blood establishments. Inspections are (partly) carried out by the national authority at least every 2 years in 84% of the reporting MS. All donations are covered by ISBT, GMP or other procedures in 85% (22/26) of reporting MS. When only GMP procedures are considered, coverage is 83% (20/24) of MS.

Haemovigilance reporting in this survey began in 2004. The format for data acquisition on haemovigilance for the 2004 CoE questionnaire, in its basic form, was developed in collaboration with the CoE, experts and EC and adapted into *Directive 2005/61/EC*. In this report, only those serious adverse reactions are presented that are probably or certainly (imputability grade 2 to 3) ascribable to transfusion of blood components, and data on some conditions that are not caused by these products themselves, such as TACO (Transfusion Associated Circulatory Overload), are also reported. There is a national haemovigilance reporting system in 88% of the reporting MS. Taking into account the possibility of under-reporting and the differences in national reporting systems, an overall incidence of approximately 7.4 serious adverse reactions per 100,000 distributed blood components is estimated, based on data provided by 23 MS. Higher incidences may reflect better reporting rather than lower quality. Haemolysis, anaphylaxis, Transfusion

Related Acute Lung Injury (TRALI) and TACO appear to be the most frequent serious adverse reactions.

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LIST OF ABBREVIATIONS

Ag	Antigen
ALT	Alteplase testing
BE	Blood Establishments
CD-P-TS	European Committee (Partial Agreement) on Blood Transfusion
CI	Confidence Intervals
CP	Cryoprecipitate
CSP	Cryosupernatant Plasma
CMV	Cytomegalovirus
CoE	Council of Europe
EC	European Commission
EDQM	European Directorate for the Quality of Medicines and HealthCare
ELISA	Enzyme-Linked Immunosorbent Assay
EMA	European Medicines Agency
EU	European Union
FFP	Fresh Frozen Plasma
FTA	Fluorescent Treponemal Antibody
FVIII	Factor VIII
GMP	Good Manufacturing Practice
GTS	Ad hoc working group on the guide to the preparation, use and quality assurance of blood components
GVHD	Graft-Versus Host Disease
HBc	Hepatitis B core antigen
HBsAg	Hepatitis B surface Antigen
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HLA	Human Leucocyte Antigen
HPA	Human Platelet Antigen
HTLV	Human T cell Lymphotropic Virus
IDM	Infectious Disease Markers
ISBT	International Society for Blood Transfusion
IU	International Unit
L	Litres
MB	Methylene Blue

MS	Member States of the Council of Europe
NAT	Nucleic Acid Amplification Techniques
PABD	Pre-operative Autologous Blood Donation
Ph. Eur.	European Pharmacopoeia
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
QS	Quality System
RBC	Red Blood Cells
SD	Solvent Detergent
SP-GS	Committee of Experts on Quality Assurance in Blood Transfusion Services
SP-HM	Committee of Experts on Blood Transfusion
TA	Transfusion Associated
TACO	Transfusion Associated Circulatory Overload
TRALI	Transfusion Related Acute Lung Injury
TTP	Thrombotic Thrombocytopenic Purpura
U	Unit
vCJD	Variant Creutzfeldt-Jakob disease
WB	Whole Blood
WHO	World Health Organisation

STUDY METHODS

The methods employed in this survey are, in principle, the same as those used in previous surveys (see 2001-2005 survey report), with the following modifications. For the 2007 survey, a dedicated web-based application was developed for performing data collection. Each MS nominated an expert who was granted access to the website and could complete, repeatedly edit and, thereafter, finalise an on-line electronic datasheet for its respective MS. Data collection was completed on 1 November 2009. This report was presented in a draft form to the European Committee (Partial Agreement) on Blood Transfusion (CD-P-TS) in November 2010 for review and approval by MS representatives.

In contrast to the reports from 2001-2006, data completed by the experts of the MS in the web-based application were not further reviewed or modified by the authors for this, the 2007, survey. Inherent to the automated method for data collection, as of 2007, and the experience built up over the years with the experts of the MS, the correctness of the data remains the responsibility of the MS. The tables for this report were generated automatically from the original data forms.

Trend analysis

Comparisons with results from the previous surveys and trend analyses are foreseen. Initial trend analyses have been published (van der Poel *et al*., 2011) and comprised questionnaire data from 2001 through to 2005. Not all information requested in the Questionnaire is included in the tables reported, 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. The absence of a response is represented by empty fields in the tables.

Remarks to the data

It remains the responsibility of the MS that the data reported in the questionnaires has been checked against the tables provided in the draft versions of this report.

With the launch of the web-posted questionnaire, which was set-up for collecting the data for 2007 and later surveys, the risk of errors by transcription of the data by the authors has been eliminated.

RESULTS

Response rate

The 46 MS of the Council of Europe (CoE) were invited to participate in the 2007 survey. Replies were received at the deadline for correction of submissions on December 31st 2010 from 35 MS; a response rate of 76%. For the 2001, 2002, 2003, 2004, 2005 and 2006 surveys, the response rates were 84, 60, 67, 73, 72 and 80%, respectively. It is possible that the longer period between the beginning and end of data collecting allowed more MS to report. However, it was also reported to the authors that changing blood supply systems and mergers of blood establishments (BE) hindered the process of data collection.

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. In many establishments or countries, the query format on the donor database would need to be compliant. This may not always be possible. Therefore, it is not certain whether this requirement was always met in generating the data for this survey. Definitions have been largely addressed by the *European Commission (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 apply to regular donors (i.e. donors whose last previous donation was less than 2 reporting years earlier) and for repeat donors (i.e. donors whose last previous donation was more than 2 reporting years earlier). The total of the two categories represents those donors, who are known to the system or establishment and in many countries form the basis and guarantee of continuity 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 EU countries, the reporting of prevalence and incidence on these donor populations became mandatory in 2005 as of *Directive 2002/98/EC*.

In this survey, the term 'first time tested donors' includes all donors who are actually tested for the first time in the reporting year. The term ´first time donors´ includes all donors who donated for the first time in the reporting year. There are systems where 'applicant donors' (*98/463/ EC*) are only tested, and come back for a first donation later. They become known as 'qualified donors' when their applicant donor infectious disease tests are returned negative. Including only 'qualified donors' in the report will generate bias in reporting Infectious Disease Markers (IDM) (see Table 7). The term 'new donors' in *Council Recommendation 98/463/EC* does not specify this and allows for the exclusion of 'non-qualified donors'. Therefore in this survey the term 'first time tested donors' is used to include all donors who actually are tested for the first time, either at the time of donation or through pre-donation screening.

Excluding MS where first time donors and repeat plus regular donors were not reported separately, 21 % (range 7-72) of the total donor base consists of 'first time' donors in 33 reporting MS. It is known that first time donors may have higher incidences of infectious diseases as compared to regular or repeat donors (Schreiber *et al*., 2001), and that higher incidence translates into an enhanced risk of donations being release with undetected viraemia.

The average number of donors in relation to the general population is 29 (range 3-63) 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 should 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 high numbers of red blood cell (RBC) Units (U) to the hospitals (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.

Profile of donations: Table 1.1

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

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

- **Whole blood**

Whole Blood (WB) collections are the basis of the blood supply in most countries, not only for the preparation of blood components, but also for the delivery of 'recovered plasma' as source material for the manufacture of medicinal products (see Table 3). The number of WB collections in 34 MS reporting is, on average, 38 (range 2-67) per 1,000 inhabitants. Given the average use of RBC per 1,000 inhabitants (see Table 3), the number of WB donations collected appears to either conform to the demand for RBC components or determines their use in hospitals by limiting supply.

- **Autologous blood**

Autologous donations have been promoted in relation to safe blood transfusions by limiting exposure to allogeneic blood for patients and also with the purpose of enhancing the supply of blood. In general the factor of enhancing supply appears not to be significant: in 31 countries where autologous donations are given, they contribute on average around 0.6% (range 0 4%) to the WB donations. This is in agreement with the literature and previous reporting. 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 pre-operative autologous blood donations (PABD) are taken into account.

- **Blood components (Apheresis)**

Plasmapheresis collections provide source plasma, including plasma with specific antibodies, for fractionation into medicinal products. In some countries plasma for transfusion referred to as Fresh Frozen Plasma (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 32 reporting MS, on average 1.8 L (range 0-17) of plasma per 1,000 inhabitants is collected by plasmapheresis. Apparently, Germany and The Netherlands stand out as countries with considerably more extensive plasmapheresis programmes, with about 10 L or more of plasmapheresis plasma collected per 1,000 inhabitants per annum.

Platelet apheresis may be aimed at Human Leucocyte Antigen (HLA) or Human Platelet Antigen (HPA) typed donations for refractory patients, as well as to replace the provision of platelets from pooled WB donations by apheresis platelets in order to reduce donor exposure in patients. The relative importance of platelet apheresis for the total supply of platelet products is given in Table 3. In 28 reporting MS, on average 37 % (range 2-93) 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 MS striving towards 100% platelet supply by apheresis.

RBC apheresis is a relatively new development and may be of particular interest for autologous programmes, and for collections of rare types of RBC donors. It appears to be increasingly used for supply reasons.

Granulocyte apheresis donations are infrequent, as indications appear to be limited.

Use of blood and blood components for transfusion: Table 3

The term 'the use of blood' may be somewhat misleading as the reported data may not reflect the actual use of blood or blood components in the hospitals, but rather the number of blood components that have been delivered to hospitals by BE. 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 MS, however in some countries such as Denmark, blood banks are hospital based and the data are related to actual transfusions issued. As component losses in hospitals are limited, for example by exceeding expiry dates, the number of blood components delivered to hospitals represents an acceptable proxy to the blood use estimate, and the heterogeneity of the given data may result in only minor deviations.

In 20 / 31 (65%) reporting MS, the use of blood is expressed as the units distributed by the BE, in 11 (35%) it is reported as transfused U, and 4 MS have not reported this information.

WB must be considered as a source material and has no, or only a very restricted, use in transfusion therapy (*Guide to the Preparation, Use and Quality Assurance of Blood and Blood Components, 8th edition 2001*). However, in countries with limited resources transfusion therapy with WB may be needed when the infrastructure for blood component preparation is lacking. In 27 reporting countries, on average 1% (range 0-21) of the RBC transfusions are performed with WB. In Montenegro, the use of WB accounts for more than one fifth of the total volume of RBC products used.

The use of RBC per 1,000 inhabitants varies considerably. In 27 reporting MS it averages 40 total RBC products per 1,000 inhabitants (range 8-64). Rejman (2000) suggested in his report on the 1997 survey that 40 – 60 WB donations per 1,000 inhabitants would be needed for optimal supply, a figure largely driven by the need for RBC for transfusion. Apparently the use of RBC has been greatly reduced in the last decade. RBC's are mainly used in surgery, obstetrics, haematology and oncology care, and in some countries programmes for 'better use of blood' or for 'optimal use of blood' have recently been established in order to reduce unnecessary donor exposure to patients. Therefore, the use of 30 to 40 RBC U per 1,000 inhabitants could reflect the results of these programmes. In 2 / 27 (7%) of the reporting MS, less than 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 to relate this figure to RBC use.

The use of plasma for transfusion has been discouraged over the last decade, mainly because its clinical indications are limited and more plasma was needed as source material for fractionation into medicinal products. However, with multiple coagulation disorders, including Thrombotic Thrombocytopenic Purpura (TTP), FFP transfusions are needed. In order to provide a benchmark, the use of plasma for transfusion can be related to the use of RBC transfusions (use of FFP/RBC

ratio). It should be taken into account that, in the programmes for 'better use of blood' (e.g. RBC) in some countries, the decline of RBC use increased the FFP/RBC ratio. On average the FFP/RBC ratio is 0.31 (range 0 – 0.6, Table 4).

In Europe, platelets are generally recovered from 4-6 buffy-coats of WB donations. Discussions on blood safety in relation to Variant Creutzfeldt-Jakob disease (vCJD) have inspired programmes to enhance the use of random single-donor platelets by apheresis in order to reduce donor exposure to recipients. These programmes may have been influential in some MS where the use of apheresis platelets in relation to recovered platelets is relatively high. The extent to which donors are willing to undergo apheresis may be limited, as no supply reaches 100% apheresis platelets. On average, in 30 reporting MS, 37% (range 2-93%) of the adult therapeutic doses of platelets are produced by (random) single donor platelets by apheresis (Table 3). In 9 countries (30%) this volume amounts to more than 50%.

Cryoprecipitate may incidentally be used for fibrinogen, Von Willebrand's disease, and complex coagulation disorders. This product has largely been abandoned by most MS.

Plasma for fractionation: Table 4

The total amount of plasma issued for fractionation into medicinal products differs among MS. This becomes clearer if the figure is related to the population size. In 30 reporting MS, an average yield of 7L (range 0-27 L) per 1,000 inhabitants is found of plasma for fractionation into medicinal products. However, 5 of 30 (17%) reporting MS deliver 15 L or more plasma per 1,000 inhabitants (average + SD).

In Europe, the main supply of plasma for fractionation is recovered plasma; in 18 reporting MS, on average 57% of the plasma for fractionation is from recovered plasma (range 0-100%).

Apart from a query on the total yield of plasma for fractionation, the questionnaire encompasses two specific questions on plasma delivered for factor VIII (FVIII) production versus other plasma for fractionation. These specific questions are poorly understood by respondents.

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

In 12 / 29 (41%) of reporting MS, 100% leucocyte depletion of RBC products is carried out. This is the case for platelet concentrates in 15 / 29 (52%) reporting MS. Hundred percent leucocyte depletion is applied for plasma for transfusion in 9 / 23 (39%) of the reporting MS.

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 leucocytes), and for a selected group of recipients only. The numbers may reflect the volume of high clinical care; although, in many instances, irradiation is carried out in hospitals where it generally appears more difficult to obtain data.

FFP for transfusion, cryosupernatant plasma (CSP) and cryoprecipitate (CP) may be additionally safeguarded against infectious diseases. One method is a quarantine step where the plasma is stored and only released if the donor is negative for IDM on a subsequent 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 / 27 (44%) reporting MS, nearly all FFP is safeguarded by either method, in 3 MS for 100% by quarantine, in 4 MS by (nearly) 100% pathogen reduction, and in 5 MS by a combination of both.

Screening for infectious agents, serological test methods: Table 6

In 33 out of the 34 MS (97%) that reported information on screening strategies, all donations are tested for anti-HIV-1/2, HBsAg and anti-HCV. In 30 / 34 (88%) of these MS, all donations are tested for syphilis. It is debated in the literature whether systematic syphilis testing is necessary.

Testing for anti-HTLV-I/II is performed on all donations in 6 / 30 (20%) reporting MS, and only on first time donors in 2 / 30 (7%) countries.

Testing for anti-HBc is performed on all donations in 5 / 32 (16%) reporting MS, and only on first time donors in 4 / 32 (13%) MS.

Confirmed seropositive donors and prevalence and incidence of infectious diseases: Tables 7.1 and 7.2

Given the limited positive predictive value of serological screening tests, donors who are found positive in blood screening for IDM generally need to be 'confirmed' with another technique aimed at diagnosing infection. Confirmed positive donors are then notified and deferred from further donations. A typical flow-chart for confirmation is given in *EC Recommendation 98/463/EC*.

In Table 7.1, the absolute numbers of 'confirmed positive' donors reported among all first time donors tested (see Table 1) and among all repeat donors tested (see Table 1) are given. Overall 29 of 35 (83%) reporting MS were able to provide the absolute numbers of confirmed positive donors for HIV, HBV and HCV (see Table 7.1).

- **First time donors**

The frequency of 'confirmed positive' donors among all first time donors tested (see Table 1), yields the 'prevalence' of an IDM among first time donors. This reflects the characteristics of the population from which first time donors are recruited. It should be noted that the general population may have different rates of infectious diseases than blood donors. Even at their first visit, blood donors are a selected population. The 'prevalence' of infectious diseases among first time donors was calculated from Table 7.1 (number of confirmed positive donors) and Table 1 (number of first time donors), and the ratio is given in Table 7.2.

The prevalence per 100,000 first time tested donors, as calculated from the provided data sets, ranges from 0 to 113 for HIV-1/2, from 0 to 12,608 for HBV and 0 to 5,514 for HCV. The median prevalence amongst first time tested donors is 8.2, 107 and 69 per 100,000 donors for HIV-1/2, HBV and HCV respectively.

Although considerable differences in geographical distribution of these infections in Europe exist, it is questionable whether the extremely high frequencies in some countries reflect reliable data sets on actual 'confirmed positive donors' or, merely, refer only to repeat positive donors screened by Enzyme-Linked Immunosorbent Assay (ELISA) and, thereby, including many false positives (see definitions in the questionnaire in appendix). The geographical distribution of the high prevalence areas may coincide with low resources and lack of confirmatory testing.

- **Repeat and regular donors**

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 (i.e. those donors who had previously been tested, were found to be negative, and were allowed to donate again). This '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 *et al*., 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 extremely high incidences may refer only to repeat positive donors of ELISA screening instead of confirmed positive donors and, thereby, include many false positives (see definitions in the questionnaire). The geographical distribution of the high incidence areas coincides with high prevalence areas and may be linked to low resources and lack of confirmatory testing.

Notwithstanding the limitations of the data and the question as to whether all positive screening test donors were submitted to confirmatory testing, the prevalence and incidence rates of infectious diseases vary greatly among MS. Overall it is to be noted that, in Europe, a North-South gradient exists: HBV and HCV infections are more common in southern countries.

The incidence per 100,000 repeat tested donor years, if calculated from the provided data sets, ranges from 0 to 9 for HIV-1/2, from 0 to 417 for HBV and 0 to 128 for HCV. Although considerable differences in geographical distribution of these infections in Europe exist, it is doubtful whether the very high frequencies of some countries reflect reliable data sets or, merely, refer only to ELISA screening positive donors (including many false positives), as opposed to 'confirmed positive donors' (see definitions in the questionnaire).

Nucleic Acid Amplification Techniques (NAT) testing and NAT-only confirmed positive donors: Tables 8.1 and 8.2

NAT testing for HCV is performed on each donation in 16 / 30 (53%) reporting MS. NAT testing for HIV is performed on each donation in 16 / 33 (48%) reporting MS. NAT for HBV is performed on each donation in 9 / 31 (29%) MS. Interestingly, NAT on each donation appears to be performed more often in MS 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 made for preferentially applying NAT testing in high incidence areas. Unfortunately these areas appear to coincide with limited resources.

The 'yield' of NAT is defined as the identification 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 a confirmed positive through detection from an additional NAT test on the same sample or by serology. The yield of NAT for HCV, HIV and HBV among first time tested donors and among repeat donors is given in Table 8.2.

Bacterial screening: Table 9

A new data set for Bacterial screening of platelet concentrates was added in the 2004 report. Haemovigilance data have repeatedly shown the importance of bacterial safety of platelet concentrates. This is due to the fact that the storage temperature of platelets is around 22OC, thus allowing bacterial growth more easily. Data on bacterial testing were reported by 18 / 35 (51%)

MS. In 5 / 25 (20%) MS performing bacterial screening, culture is performed on over 80% of all platelets (concentrates recovered both from WB donations and apheresis platelets).

Organisation and registration: Table 10

32 of 33 MS (97%) report that there are legally binding national regulations for the collection, testing, processing, storage and distribution of blood and blood components. In 23 / 33 (70%) of the reporting MS a National Council or Expert Committee advises the Ministry of Health on transfusion related issues. Of these 29 MS, 22 (76%) have implemented the national blood policy or are in the process of doing so.

Quality management: Tables 11a, 11b and 11c

In 27 / 33 (82%) of the reporting MS, a Quality System (QS) is established and maintained by BE. In 5 countries the implementation of such a system is planned.

In 20 / 24 (83%) of the reporting MS, 100% of the donations are covered by GMP. In two countries which have no GMP in place, 100% donations of the donations are covered by ISO 9000. In 27 / 32 (84%) of the reporting MS, inspections are performed at least every 2 years, and the large majority of these inspections (78%) are (partially) carried out by the national authority.

It is requested that the labelling of donations and issued components is unique so as to allow complete traceability. Labelling according to ISBT-128 for the donation number is performed in 8 out of 22 (36%) reporting countries for all units. However, labelling to either ISBT standards or another system is performed for over 95% of donations by 27 / 30 of reporting countries (90%).

Labelling of the finished component code is more complex, and generally lags behind developments in donation labelling, as it includes implementation of automation applications in hospitals. ISBT-128 labelling of the issued component is performed for all units in 5 countries. However, 23 / 28 countries (82%) report that over 95% of components are coded by either ISBT or another system.

A national haemovigilance system has been established in 29 / 33 (88%) of the reporting MS.

Haemovigilance: Table 12

Since 2004 this survey contains data on haemovigilance i.e. the reporting of serious adverse reactions. The format for data acquisition on haemovigilance in the 2004 questionnaire in its basic form was developed by CoE experts, submitted to the EC and adapted after slight modifications by the EC into *Directive 2005/61/EC*. Reporting of serious adverse reactions, as performed in haemovigilance programmes, can be considered as a high level of surveillance, as most of these serious reactions are not unexpected untoward effects but well known complications of blood transfusion from the medical literature and commonly indicated in the 'information leaflets' for physicians and patients. Most recipients of blood transfusions are very ill and have underlying pathology or medications that greatly influence the signs and symptoms of a possible transfusion reaction. A serious adverse reaction during or immediatly after 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 or certainly (imputability grade 2 to 3, i.e. likely or certain) related to the transfusion of the blood component. The term imputability includes the causal relationship to the component properties, but also to the transfusion itself (Transfusion Associated Circulatory Overload (TACO)) or recipient properties (allergy).

In contrast to the *EC Directives 2002/98/EC* and *2005/61/EC*, haemovigilance data which may not be caused by blood component properties, such as TACO, are also reported here. Haemovigilance data submitted by 23 MS are presented in Table 12.

Of the MS that reported having a national haemovigilance system, 23 / 29 (79%) provided actual haemovigilance data. The incidence of serious adverse reactions with high imputability (level 2 to 3) can be calculated relative to the total number of blood components (WB + RBC + plasma + platelets) issued. Taking into account the possibility of under-reporting and the differences in national reporting systems, the incidence of 7.4 serious adverse reactions per 100,000 distributed blood components seems a reasonable estimate. Haemolysis, anaphylaxis, TRALI and TACO appear to be the most frequent serious adverse reactions.

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TABLES

List of countries having participated in the survey
(35 out 46 MS)

Armenia, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Luxembourg, Malta, Moldova, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, United Kingdom

Table 1 – *Donors, first time donors and inhabitants*

Country	regular and repeat donors	first time donors	% first time donors	First time donors donating	First time donors tested only	total donors	inhabitants x 1,000	donors per 1,000 inhabitants	
Armenia	2 867	7 451	72.2	6 514	957	10 318	3 000	3.4	1)
Austria	441 258	53 935	10.9	49 386	4 549	495 193	8 309	59.6	2)
Belgium	288 970	49 589	14.6	49 589	0	338 559	10 500	32.2	
Bulgaria	79 554	32 547	29.0			112 101	7 640	14.7	
Croatia	80 323	13 809	14.7	13 809	0	94 132	4 437	21.2	
Cyprus	42 663	5 857	12.1	5 000	0	48 520	766	63.3	3)
Czech Republic	260 017	26 304	9.2	26 304	0	286 321	10 330	27.7	
Denmark	228 726	34 647	13.2	0	34 647	263 373	5 461	48.2	
Estonia	24 814	9 237	27.1	9 237	0	34 051	1 341	25.4	
Finland	161 562	17 963	10.0	17 963	0	179 525	5 303	33.9	
France	1 233 084	384 394	23.8			1 617 478	63 753	25.4	4)
Georgia	19 493	5 931	23.3	5 216	715	25 424	4 433	5.7	5)
Germany	2 430 281	548 607	18.4	452 119	96 488	2 978 888	82 218	36.2	
Greece	337 459	69 556	17.1			407 015	10 500	38.8	6)
Hungary	300 000	54 995	15.5	54 995	0	354 995	10 066	35.3	
Iceland	10 272	1 688	14.1	0	1 688	11 960	308	38.9	
Ireland	84 673	13 104	13.4	11 790	1 314	97 777	4 200	23.3	
Italy	1 290 000	280 000	17.8			1 570 000	59 000	26.6	
Latvia	38 348	17 009	30.7	17 009	0	55 357	2 200	25.2	
Luxembourg	12 375	1 017	7.6	0	1 017	13 392	450	29.8	
Malta	9 856	4 716	32.4	2 091		14 572	412	35.4	7)
Moldova	44 639	22 090	33.1	22 090	22 090	66 729	3 600	18.5	
Montenegro	6 120	4 200	40.7	4 200		10 320	624	16.5	
Netherlands	375 621	27 201	6.8	0	27 201	402 822	16 439	24.5	
Norway	93 303	12 191	11.6		12 191	105 494	4 737	22.3	8)
Poland	355 241	261 733	42.4	245 076	16 633	616 974	38 115	16.2	
Portugal							10 000		
Romania							21 500		9)
Serbia	102 514	44 072	100.0	44 072		146 586	7 560	19.4	
Slovakia	109 928	34 064	23.7			143 992	5 393	26.7	10)
Slovenia	97 055	10 271	9.6	10 271		107 326	2 000	53.7	
Spain	847 985	270 033	24.2			1 118 018	44 733	25.0	
Sweden	238 466	43 504	15.4	500	43 004	281 970	9 176	30.7	11)
Switzerland	214 986	26 077	10.8	26 077	0	241 063	7 594	31.7	
United Kingdom	1 193 094	245 517	17.1	237 448	0	1 438 611	60 975	23.6	

1) Donors passed blood testing but blood not donated had positive results for infection or other reason against donation
2) Repeat donors: data not available
3) First time donor selection policy is currently impossible to adopt due to efforts to maintain levels of blood availability
4) A 6% increase on 2006
5) Information based on statistics from 5 main blood centers, where 24,585 donations of whole blood were collected. Information from remaining blood centers not available
6) Donors on first visit give blood samples only for testing in only a few centres
7) First time donors (total) includes all new donors, including those deferred
8) Regular and repeat donors are the number of donors that have donated in 2007
9) Total number of registered donors = 241762
10) Number of first time donors only giving blood samples not available - they are registered together with all refused donors
11) In remote areas, a few first time donors will donate blood to a mobile unit

Table 1.1 – *Profile of donations*

Country	whole blood donations			red cell apheresis		plasmapheresis donations	platelet apheresis	
	% voluntary, non-remunerated	% from replacement donors	% from autologous donors	% voluntary, non-remunerated	% from autologous donors	% voluntary, non-remunerated	% voluntary, non-remunerated	
Armenia	4	44	0.25	11			3	1)
Austria	100	0	0.90	0	121	100	100	2)
Belgium	100	0	0.09	100	0	100	100	
Bulgaria	97	75	0.19			0	0	
Croatia	100	0	0.63			100	100	3)
Cyprus	100	0	0.00	98			100	
Czech Republic	100	0	4.26	37		93	37	4)
Denmark	100	0	0.00			100	100	
Estonia	100	0	0.00	0			98	
Finland	100	0	0.00			100	100	
France	100	0	0.42	100	0	0	100	5)
Georgia	5	2						
Germany			1.51		20			6)
Greece	49	51	0.95	55	1	43	51	7)
Hungary	100	0	0.47	100	0		100	
Iceland	100	0	0.00	100	0	100	100	
Ireland	100	0	0.00				100	
Italy	100	0	4.10			100	100	8)
Latvia	98	27	0.01	0		0	0	
Luxembourg	100	0	0.94	0		100	100	
Malta	100	0	0.00				100	
Moldova	16	1	0.17	0		74		
Montenegro	20	80	0.14					9)
Netherlands	100	0	0.02	100		100	100	
Norway	100	0	0.02	100	0	100	100	
Poland	100	8	0.28	100	0	1	100	
Romania	100			0		100	100	
Serbia	100		0.08			0	100	
Slovakia	100	0	0.84	100	0		5	10)
Slovenia	100	0	2.12	0		50	100	
Spain	100		0.88	100		100	100	
Sweden	100	0	0.03	100	1	100	0	11)
Switzerland	100	0	1.07	100	12	100	100	
United Kingdom	100	0	0.00	100	0	100	100	12)

1) The equipment for blood cells apheresis - Cobe Spectra have been newly established in Armenian Haematology Center, that is why the number of blood cells apheresis is low
2) -Multi-component apheresis: data not available
-Plasma collection:
°Industriepl.(fil.),L: 62201 61519 (Industr.)
°Quarantänepl.(fil.)L: 6722 6017 (Spitäler)
°Octaplas:L:
3) Multi-component apheresis donations = PLT + PLASMA
4) In about 1/6 platelet apheresis some plasma is also collected, exact figure is not known and the procedure is declared as “platelet apheresis”
5) Plasma (only) apheresis procedures : 262779 multi-component apheresis donations : red cells+platelets : 24528 plasma+platelets: 121910
6) Data not available to voluntary non-remunerated donations (%) and Number of granulocytes apheresis donations (procedures)
Replacement donations not allowed
7) Total number of whole blood donations
- In addition to the above national blood collection another 25624 RBCs were imported from Swiss Red Cross
8) Data on multi-component apheresis will be collected by the new national information system starting from 2009
9) Apheresis procedures are not performed in Montenegro yet
10) Stem cell donations 297
11) Platelet apheresis donors are recruited from the voluntary donors. They receive about 15-20€ per donation
12) NHSBT (England) – 1,096 multi-component procedures also counted as red cell and as platelet procedures

Table 2 – *Collection of whole blood, autologous blood and blood (apheresis) components*

Country	whole blood collections					apheresis collections						
	whole blood units	Transfused or distributed	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)	multi-component apheresis (U)	
Armenia	12 175	Trans.	4.1	30	0.2	135	0.05	4	4 314	4		1)
Austria	478 106	Distr.	57.5	4 295	0.9	6 722	0.81	29 685	2 753	81		2)
Belgium	535 349		51.0	472	0.1	53 089	5.06	4 715	2 576	35	22 614	3)
Bulgaria	152 116	Distr.	19.9	291	0.2	245	0.03	549	0	0		
Croatia	160 026	Distr.	36.1	1 011	0.6	38	0.01	1 756	0		1 756	4)
Cyprus	48 030		62.7	0	0.0	0	0.00	0	0	0	0	5)
Czech Republic	403 221	Distr.	39.0	17 159	4.1	65 822	6.37	16 276	1 800			6)
Denmark	363 655	Trans.	66.6	0	0.0	319	0.06	968	0	0	0	
Estonia	55 072	Trans.	41.1	0	0.0	0	0.00	755	0	0	0	7)
Finland	269 589	Distr.	50.8	0	0.0	2 520	0.48	885	0	0	0	8)
France	2 339 898	Trans.	36.7	9 904	0.4	157 664	2.47	23 502	1 629	321	145 448	9)
Georgia	34 924	Distr.	7.9									10)
Germany	4 778 500	Distr.	58.1	72 241	1.5	1 367 428	16.63	173 761	17 322		15 362	11)
Greece	624 994		59.5	5 930	0.9	706	0.07	17 882	1 985		2 206	12)
Hungary	422 168	Trans.	41.9	2 000	0.5	0	0.00	4 224	14	98	0	
Iceland	14 292	Distr.	46.5	0	0.0	24	0.08	445	127	0	0	
Ireland	151 219	Distr.	36.0	2	0.0	0	0.00	6 699	0	0	0	13)
Italy	2 437 000	Trans.	41.3	100 000	3.9	205 000	3.47	70 000				14)
Latvia	54 577	Distr.	24.8	5	0.0	879	0.40	1 373	0	0	0	
Luxembourg	21 684	Distr.	48.2	203	0.9	1 620	3.60	858	0	0	0	
Malta	14 125	Distr.	34.3	0	0.0	0	0.00	335	0	0	0	15)
Moldova	74 013	Distr.	20.6	129	0.2	1 337	0.37	0	0	0	0	
Montenegro	13 848	Trans.	22.2	20	0.1							16)
Netherlands	562 684	Distr.	34.2	113	0.0	175 323	10.67	4 000	0	400	50	
Norway	200 230	Trans.	42.3	36	0.0	4 503	0.95	4 327	4 619	0	1 477	17)
Poland	943 635	Distr.	24.8	2 685	0.3	18 344	0.48	18 456	173	88	3 977	
Romania	339 199	Distr.	15.8			126	0.01	2 233	0		0	
Serbia	17 054	Distr.	2.3	14	0.1	1 001	0.13	1 586	0	0	0	
Slovakia	184 682	Distr.	34.2	1 547	0.8	0	0.00	5 682	229	44	0	18)
Slovenia	84 103	Trans.	42.1	1 784	2.1	610	0.31	1 207	0	0	0	
Spain	1 681 945	Trans.	37.6	14 781	0.9	18 804	0.42	13 442	1 081	42	22 600	
Sweden	474 617	Trans.	51.7	126	0.0	50 211	5.47	6 531	534	72		
Switzerland	347 936	Distr.	45.8	3 723	1.1	1 651	0.22	7 931	1 404	0	7 395	19)
United Kingdom	2 313 961	Distr.	37.9	9	0.0	241	0.00	88 117	1 410	59	1 096	20)

1) The equipment for blood cell apheresis (Cobe Spectra) has only been recently established in the Armenian Haematology Center, hence the low number of blood cells from apheresis

   322 units of cryoprecipitate were prepared, but the FVIII IU quantity has not been analysed

2) -Multi-component apheresis: data not available

   -Plasma Collection:

   °Industriepl.(fil.): 62201 L 61519 L (Industry)

   °Quarantänepl.(fil.): 6722 L 6017 L (Hospitals)

   °Octaplas: Cryoprecipitate: data from hospital pharmacies

3) The number of red cell units includes 4,277 red cell units for neonates

4) Multi-component apheresis donations = PLT + PLASMA FVIII IU x 10^6 = 0.029

5) Single Donor Platelets are collected using a Haemonetics cell separator {MCS+}

6) In about 1/6 platelet apheresis procedures some plasma is also collected. The exact figure is not known and the procedure is recorded only as "platelet apheresis"

7) Amount of cryoprecipitate used is in units (1 unit consists of more than 70 IU)
8) The number of FFP includes both regular FFP/CSP as well as Octaplas distributed by the Finnish Red Cross BS and another distributor (total figure for Finland)
9) Plasma (only) apheresis procedures : 262,779

   Multi-components- apheresis donations: ?

   Red cells + platelets : 24,528

   Plasma + platelets: 121,910
10) Information based on statistics from 5 main blood centers where 24,585 donations of whole blood were collected. Information from remaining blood centers not available
11) Data not available for voluntary non-remunerated donations (%) and number of granulocyte apheresis donations (procedures). Replacement donations not allowed
12) In addition to the national blood collections, a further 25,624 RBC donations were imported from the Swiss Red Cross
13) Cryoprecipitate 2,313 units, of which 136 were single and 2,187 were pools of 5 units
14) Data on multi-component apheresis and platelets will be collected by the new national information system starting from 2009
15) Cryoprecipitate total refers to number of packs prepared, not FVIII IU
16) Apheresis procedures are not yet performed in Montenegro. Data on PLT and CP refer only to the BTC CC blood centre in Podgorica because only this Center prepares and uses these kinds of blood component
17) vWF/FI (SD-cryo, IE 58500
18) Stem cell donations = 297

   Granulocity = 38 T.U.
19) WB are exclusively autologous units
20) NHSBT (England) – 1,096 multi-component procedures also counted as red cell and platelet apheresis procedures. Cryoprecipitate figure given is not only for single unit equivalents for direct clinical use (some are pools of 5)

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)
Armenia	11 695		23 390		11 753	3.79.E+13	3.71.E+13	8.00.E+11	2.1	
Austria	0	0.0	437 986	52.7	128 789	30 028	3 353	26 675	88.8	
Belgium	0	0.0	509 610	48.5	85 999	63 960	37 817	26 143	40.9	0
Bulgaria	1 822		157 911		88 202	7 273	6 374	899	12.4	0
Croatia	2 740	1.7	159 252	35.9	79 310	12 166	10 504	1 662	13.7	0
Cyprus	0	0.0	46 506	60.7	16 361	8 056	7 814	242	3.0	0
Czech Republic	845	0.2	418 574	40.5	195 475	22 986	4 314	18 672	81.2	
Denmark	0	0.0	349 333	64.0	68 686	32 422	31 125	1 297	4.0	0
Estonia	32	0.1	52 981	39.5	33 899	6 037	1 407	4 630	76.7	643
Finland	4	0.0	256 031	48.3	50 883	38 427	37 661	766	2.0	0
France			2 175 121		312 272	245 326	55 177	190 149	77.5	0
Georgia	93		22 049		20 048	1 626				48
Germany	16 442	0.4	4 562 879	55.5	1 422 828	448 922	170 292	278 630	62.1	
Greece	250	0.0	582 637	55.5	301 569	152 138	134 691	17 447	11.5	
Hungary	0	0.0	398 279	39.6	87 210	18 042	13 818	4 224	23.4	0
Iceland	0	0.0	13 787	44.8	5 314	1 648	800	848	51.5	0
Ireland	0	0.0	148 425	35.3	660	22 426	12 049	10 377	46.3	2 313
Italy			2 426 000		540 000					
Latvia			53 274		55 583	4 396	1 826	2 570	58.5	5 105
Luxembourg	0	0.0	20 339	45.2	4 520	2 219	1 283	936	42.2	0
Malta	0	0.0	13 780	33.4	2 050	901	546	355	39.4	520
Moldova	41	0.1	27 986	7.8		44 105				12 308
Montenegro	2 357	20.6	11 454	18.3	7 200	1 893				183
Netherlands	0	0.0	554 824	33.8	92 568	53 701	49 701	4 000	7.4	0
Norway	110	0.1	191 869	40.5	39 867	19 001	12 730	6 271	33.0	
Poland	268	0.0	945 095	24.8	333 240	65 911	44 718	21 193	32.2	7 653
Romania	104 231		327 160		215 686	16 106	13 873	2 233	13.9	16 192
Serbia	17 054	7.4	230 510	30.5	148 616	12 200	10 907	1 293	10.6	3
Slovakia	4 100	3.0	136 634	25.3	52 533	19 193	13 133	6 060	31.6	0
Slovenia	0	0.0	76 369	38.2	30 953	29 537	27 364	2 173	7.4	0
Spain	138	0.0	1 520 637	34.0	245 043	223 944	115 030	108 914	48.6	2 529
Sweden	0	0.0	458 017	49.9	114 209	38 091	24 495	13 596	35.7	
Switzerland	3 012	1.0	312 257	41.1	69 822	22 937	1 672	21 265	92.7	0
United Kingdom	85	0.0	2 184 088	35.8	304 015	257 076	98 974	158 102	61.5	106 085

Table 4 – *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)	
Armenia				3.92		
Austria	61 519	7.40	0.00	15.50	0.29	
Belgium	169 194	16.11	69.18	8.19	0.17	
Bulgaria	13 544	1.77	0.00	11.54		
Croatia	19 708	4.44		17.87	0.50	
Cyprus	0	0.00		21.35	0.35	1)
Czech Republic	116 601	11.29	48.63	18.92	0.47	2)
Denmark	78 900	14.45	100.00	12.58	0.20	
Estonia	0	0.00		25.28	0.64	3)
Finland	59 584	11.24	100.00	9.59	0.20	
France	694 052	10.89		4.90		4)
Georgia				4.52		
Germany	2 248 034	27.34	43.27	17.31	0.31	
Greece	16 503	1.57		28.72	0.52	
Hungary				8.66	0.22	5)
Iceland	0	0.00		17.27	0.39	
Ireland	0	0.00		0.16	0.00	
Italy	608 000	10.31	64.47	9.15		
Latvia	1 030	0.47		25.27		
Luxembourg	7 400	16.44	69.32	10.04	0.22	6)
Malta	0	0.00		4.98	0.15	
Moldova	8 332	2.31	36.93			
Montenegro				11.53	0.63	7)
Netherlands	294 071	17.89	55.53	5.63	0.17	
Norway	48 661	10.27	92.00	8.42	0.21	8)
Poland	118 804	3.12	86.55	8.74	0.35	
Romania	0	0.00		10.03		9)
Serbia	9 500	1.26	0.00	19.66	0.64	
Slovakia	19 343	3.59	100.00	9.74	0.38	10)
Slovenia	10 324	5.16	97.05	15.48	0.41	
Spain	326 203	7.29		5.48	0.16	
Sweden	140 400	15.30	67.36	12.45	0.25	
Switzerland	87 412	11.51	0.00	9.19	0.22	
United Kingdom	0	0.00		4.99	0.14	

1) The plasma collected is not further fractionated to products
2) Only fresh frozen plasma either from whole blood collection or source plasma is sent for fractionation
3) No fractionation contract in 2007
4) Data for F VIII non available. See LFB for further data
5) In Hungary one private plasmapheresis establishment (it has been bought by the Kedrion Ltd) collected plasma with apheresis technique HNBTS has not got information about the quantity of the collected plasma
6) Other plasma = plasma of platelet apheresis
7) In Montenegro plasma is collected from the units of whole blood and in total use for clinical application. Donors plasmapheresis procedure is not performed in Montenegro yet
8) Some of the plasma is used for Octaplas production of approx. 40.000 bags of 200 ml
9) No contract for fractionation
10) We are not able to make different between plasma for FVIII and immunoglobulins - it is all together

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 %	path.inact. %	
Austria	100	10	100	2	100	51	0	1)
Belgium	100		100	0	100		17	
Bulgaria	4							
Croatia	13				69			
Cyprus	100	0	0	0	0	0	0	
Czech Republic	21	7	0	2	83	60	0	
Denmark	22	9	0	7	96	15	0	
Estonia	5	3	0	0	41	17	0	
Finland	99	3	100	0	100	37	0	2)
France	100		100	0	100		5	3)
Germany	100	4		0	100	34	0	4)
Greece	35	15	35	10	69	13		
Hungary	10	5	16	2	70	12	0	
Iceland	19	9	0	0	100	77	0	
Ireland	100	12	100		100	100	0	5)
Latvia	40	1			100	37	0	
Luxembourg	100	1	100	0	100	7	0	7)
Malta	100	1	100	0	100	1	0	8)
Montenegro	10	0			70	0	0	9)
Netherlands	100	10	100		100	25	0	
Norway	100	7			100	30	12	10)
Poland	7	4	0	0	79	32	0	
Romania					13		0	
Serbia	57	1	70	0	84	11	0	
Slovakia	10		5		27		0	11)
Slovenia	27	16	0	0	55	27	0	
Spain	95		27		97			
Sweden	85	4	92	6	100	58	5	
Switzerland	100		85		100			12)
United Kingdom	100	8	100	0	100	53	0	13)

1) Cryoprecipitate: no production at the BE
2) Hospitals also gamma irradiate red cells and sometimes platelets. Octaplas is virus-inactivated FFP that is available in Finland
3) 10% irradiated for all components (RBC and platelets)
4) Data on leucocyte-depleted plasma for transfusion is not collected. Cryoprecipitate-reduced plasma components and Cryoprecipitate not used
5) A small amount of FFP is LD-depleted. Majority of plasma (98.5%) is SD plasma
6) Data will be collected by the new national information system starting from 2009
7) SD plasma for transfusion is virus-inactived
8) Cryoprecipitate-reduced plasma is not used. FFP for clinical use is acquired from regular donors
9) Leucocyte-depleted components of blood are prepared in special cases, such as transplant patients and patients with reports of febrile non-haemolysis adverse reactions
10) Octaplas is the only plasma used for transfusion
11) Data on % of irradiated products not available - will form part of statistics next year
12) Data not available on irradiation in the hospitals
13) Scotland - cryoprecipitate for use in neonates and children under 16 is imported from North America
It is treated with Methylene Blue and supplied as individual donations (i.e. not pooled) – approx. 800 units per year

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 %	
Austria	19	81	0	0	0	0	1)
Belgium	0	100	0	0	0	0	
Cyprus	0	0	0	0	0	0	
Czech Republic	100	0	100	0	100	0	
Denmark	0	0	0	0	0	0	
Estonia	0	0	0	0	0	0	
Finland	0	70	4	0	0	0	2)
France	57	43	0	0	0	0	3)
Georgia							
Germany	93	7	0	0	0	0	4)
Greece	17	11					
Hungary	0	0	0	0	0	0	
Iceland	0	0	0	0	0	0	
Ireland		98	0	0	0	0	5)
Italy							6)
Latvia	40						
Luxembourg	0	100	0	0	0	0	7)
Malta	100	0			50	0	8)
Moldova							
Montenegro							9)
Netherlands	100	0					
Norway		100					10)
Poland	52	0	3	0	100	0	
Romania		0		0		0	
Serbia	0	0	0	0	0	0	
Slovakia	25	0	0	0	0	0	11)
Slovenia	10	0	0	0	0	0	
Spain	34	66					
Sweden	0	2	0	0	0	0	
Switzerland	85	15					12)
United Kingdom	0	3	0	0	0	1	13)

See notes Table 5.1

Table 6 – *Donation testing strategy for infectious agents*

Country	Type of test (% tested)										
	anti-HIV 1+2	HIVAg	HBsAg	Anti-HBc	anti-HCV	HCVAg	anti-HTLV I/II	Syphilis	Malaria	Other	
Armenia	100	100	100	100	100	0	0	100	0	Brucellosis: Testing every donation.	
Austria	100	100	100	17	100	0	0	100	0	Neopterin-Screening-Elisatest (Brahms, IBL): Testing every donation.	1)
Belgium	100	0	100	First	100	0	0	100			2)
Bulgaria	100	100	100	0	100			100	0		3)
Croatia	100	100	100	0	100	43	0	100	0		4)
Cyprus	100	0	100	0	100	0	0	100	0		5)
Czech Republic	100	100	100	0	100	30	0	100	0		6)
Denmark	100	100	100	0	100	0		0			7)
Estonia	100	100	100	0	100	100	0	100	0		
Finland	100	100	100	0	100	0	28	100			8)
France	100	0	100	100	100	0	100	100			9)
Georgia	100	0	100	0	100	0	0	100	0		
Germany	100		100	100	100	0	0	100	0		10)
Greece	100		100		100		100	100			11)
Hungary	100	0	100	First	100	0	0	100	0		
Iceland	100	100	100	0	100	0	0	0			12)
Ireland	100		100	100	100		100	100	0	CMV: Testing 82%.	
Italy	100	0	100	0	100	0	0	100	0		13)
Latvia	100	0	100	0	100	0	0	100	0	anti-CMV: Testing 12%. ALT: Testing every donation.	14)
Luxembourg	100	100	100	First	100	0	First	100	2		15)
Malta	100	100	100	100	100	0	0	100	0	ALT: Testing every donation.	16)
Moldova	100	100	100	0	100	0	0	100	0		
Montenegro	100	100	100	0	100	0	0	100	0		17)
Netherlands	100	0	100	0	100	0	100	100			18)
Norway	100		100	50	100	0		First	1		19)
Poland	100	100	100	0	100	0		100	0		
Romania	100	100	100	0	100	0	100	100	0	ALT: Testing every donation.	20)
Serbia	100	100	100	10	100	0	0	100	0		21)
Slovakia	100	100	100	0	100	0	0	100	0		22)
Slovenia	100	100	100	8	100	0	0	100	0		
Spain	100	0	100	0	100	0	0	100	0	Chagas`disease: Testing first donation only.	
Sweden	100		100	First	100		First	90	0		23)
Switzerland	100	50	100			100	0	100	1	ALT: Testing every donation. anti-CMV: Testing 2%.	24)
United Kingdom	100	100	100	1	100	0	100	100	1	Anti-CMV: Testing 30%. Chagas' Disease: Testing 1%.	25)

1) Anti-HBc: about 80,000 donors are tested at each donation
2) HIV Ag: not required. Anti-HBc when indicated. Malaria: in case of history of malaria. Anti-CMV: small % of red cells and PLT for patients with allogeneic stem cell or lung transplantation
3) HCV Ag: HCV Ag/Ab testing started in 2008
4) HCV Ag: only the Croatian Institute of Transfusion Medicine in Zagreb tested every donation in 2007 for HCV-Ag
5) (i) anti-HIV1+2, HBsAg and anti-HCV are performed using an enzyme immunoassay techique (ELISA), (ii) Syphilis is tested with a haemagglutination technique
6) Anti-HIV: combined Ab + Ag test. HIV Ag: combined Ab + Ag test. Anti-HCV: in 30% combined Ab + Ag test. HCV Ag: combined Ag + Ab test in some blood establishments. Syphilis: specific Ab
7) Anti-HTLV: first time donors and donors traveling to endemic areas. Malaria: donors travelling to endemic areas
8) Anti-HTLV: first time donors and repeat donors every third year. Malaria: only donors who have been in endemic areas
9) HIV Ag: complementary test in case of positive AC or NAT. Malaria: travellers, residents and those born in epidemic countries are tested with 4-month quarantine. Chagas disease: travellers, residents and those born in epidemic countries are tested with 4-months quarantine. CMV: on demand
10) HIV Ag: no data. Antibody-Antigen-Combitests for HIV-1+2 are used by some blood establishments. Anti-HBc: persons testing positive for anti-HBc can donate blood if a sensitive assay for HBV genome is negative and if the anti-HBs antibody-titer stays above 100 IU/l

11) HIV Ag: when required. Anti-HBc: when required. HCV Ag: when required. Malaria: when required
12) Malaria: only if donor travelled in malaria area (few tests/year)
13) A significant proportion of Blood Services (not yet defined) perform HIV Ag/Ab combo tests
14) Anti-CMV: for paediatric use
15) HIV Ag: combined detection of Ag HIV 1+2 + Ag P24. Malaria: deferral of 6 months after travel in an endemic area with malaria
16) ALT: this test will be discontinued as of 01/01/2009
17) Anti-HBc: In BTC CC in Podgorica, anti-HBc screening test is carried out in cases of HBsAg reactive samples
18) Malaria: only donors who have had malaria conform to 2004-33-EC. Anti-Parvovirus B19 antibodies: about 33% of the donor population tested and antibody-positive products are labelled as B/19 safe for use as requested by hospitals
19) HIV Ag: all except one blood bank use a combined Ag/Ab test, but this is not a requirement. Anti-HBc: new donors and repeat donors that donated more than six months previously are tested. Anti-HTLV: all new donors tested up to July 1st 2007 (i.e. approx. 6,000 tests performed in 2007). Malaria: voluntary
20) Anti-HIV: Ag/Ab Combo tests in use at national level. HIV Ag: Ag/Ab Combo tests in use at national level
21) Syphilis: ELISA test is applied in 100% of donations
22) Syphilis: TPHA and RPR
23) HIV Ag: combined antigen-antibody tests are used, but the extent is unknown. Anti-HBc: additional anti-HBc testing was performed after certain risk events . HCV Ag: combined antigen-antibody tests are used, but the extent is unknown. Syphilis: syphilis screening is performed according to demands from the fractionation industry
24) HIV Ag: possibility to use Ag/Ab combined tests. Anti-HBc: all donors with history of hepatitis are tested for anti-HBc and anti-HBs. Malaria: after exposure. Anti-CMV: in immuno-deficient patients and neonates
25) HIV Ag: NHSBT (England) – screened using HIV-Ab/Ag Combo assay; Wales – every donation and Combi test used on PRISM; Scotland – HIV Ag/Ab combo serological screen

    Anti-HTLV: Wales – pools of 48 samples tested by ELISA; Scotland – minipools of up to 48 donations ELISA tested

    Chagas' Disease: Wales – Only those donors considered to have visited an endemic area (<0.1%); NHSBT (England) – donation accepted if at least 6 months following the date of last exposure, a validated test for *T. cruzi* antibody is negative

Table 7.1 – *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	
Austria	0	5	47	6	29	14			15	28	
Belgium	0	2	43	2	21	6			10	13	
Bulgaria	2	0	1 672	332	149	102			192	84	
Croatia	0	1	21	8	15	4			7	11	
Cyprus	1	0	20	8	10	5	0	0	13	12	
Czech Republic	1	2	19	10	26	7			4	7	
Denmark		2	11	0	8	1	1				
Estonia	4	2	16	4	75	12			3	9	
Finland	0	3	1	0	11	2	0	0	0	4	
France	16	17	376	5	178	14	13	4	250	85	1)
Georgia											2)
Germany	44	38	727	36	381	52			202	104	
Greece	45	29	1 268	319	208	50	6	4	78	34	
Hungary	5	1	4	1	130	2			63	6	3)
Iceland	0	0	0	0	1	0					
Ireland	1	2	4	0	4	1	1	0	4	0	4)
Italy	61	64	676	73	486	85	0	0	343	183	5)
Latvia	10	1									
Luxembourg	0	0	2	0	0	0	0	0	0	0	
Malta	0	0	0	0	0	0			0	0	
Moldova	25	0	2 785	0	1 218	0	0	0	1 991	0	
Montenegro	1	0	25	1					18	1	6)
Netherlands	3	3	15	4	3	1	0	1	9	15	7)
Norway	1	1	4	0	3	0	0	0	4	0	
Poland	35	31	1 319	19	872	102			155	82	
Slovakia	3	0	51	6	20	6			7	4	
Slovenia	1	0	11	0	10	0	0	0	6	4	
Spain	38	50	373	28	301	32			291	286	
Sweden	1	0	13	1	30	2	1				
Switzerland	1	4	28	4	19	5			18	4	
United Kingdom	22	10	71	3	70	8	16	1	57	32	

1) HTLV I/II positives do not include overseas territories (West Indies)

2) Data not available

3) HBsAg+a-HBc positive - 75 donor samples were positive

4) Samples taken only from first-time new donors (SOND) born outside Ireland & UK. In 2007, 1,314 SOND donors were tested of whom 2 confirmed positive for HBsAG, 3 for HCV and 2 for syphilis. These are included in the first-time tested category above

5) Coverage: 92.9% of donations

6) Confirmatory testing of HCV has not been used during 2007

7) Seropositive syphilis serology includes those not diagnosed with syphilis

Table 7.2 – *Prevelance and incidence calculated per 100,000 donors*

Country	HIV 1 / 2		HBV		HCV		
	prevelance per 100,000 first time tested donors	incidence per 100,000 repeat donors	prevelance per 100,000 first time tested donors	incidence per 100,000 repeat donors	prevelance per 100,000 first time tested donors	incidence per 100,000 repeat donors	
Armenia							1)
Austria	0.00	1.13	87.14	1.36	53.77	3.17	2)
Belgium	0.00	0.69	86.71	0.69	42.35	2.08	
Bulgaria	6.14	0.00	5137.19	417.33	457.80	128.21	
Croatia	0.00	1.24	152.07	9.96	108.62	4.98	
Cyprus	17.07	0.00	341.47	18.75	170.74	11.72	3)
Czech Republic	3.80	0.77	72.23	3.85	98.84	2.69	
Denmark		0.87	31.75	0.00	23.09	0.44	
Estonia	43.30	8.06	173.22	16.12	811.95	48.36	
Finland	0.00	1.86	5.57	0.00	61.24	1.24	
France	4.16	1.38	97.82	0.41	46.31	1.14	4)
Georgia							5)
Germany	8.02	1.56	132.52	1.48	69.45	2.14	
Greece	64.70	8.59	1822.99	94.53	299.04	14.82	6)
Hungary	9.09	0.33	7.27	0.33	236.39	0.67	7)
Iceland	0.00	0.00	0.00	0.00	59.24	0.00	
Ireland	7.63	2.36	30.53	0.00	30.53	1.18	8)
Italy	21.79	4.96	241.43	5.66	173.57	6.59	9)
Latvia	58.79	2.61					
Luxembourg	0.00	0.00	196.66	0.00	0.00	0.00	
Malta	0.00	0.00	0.00	0.00	0.00	0.00	10)
Moldova	113.17	0.00	12607.51	0.00	5513.81	0.00	
Montenegro	23.81	0.00	595.24	16.34			11)
Netherlands	11.03	0.80	55.15	1.06	11.03	0.27	12)
Norway	8.20	1.07	32.81	0.00	24.61	0.00	13)
Poland	13.37	8.73	503.95	5.35	333.16	28.71	
Romania							14)
Slovakia	8.81	0.00	149.72	5.46	58.71	5.46	15)
Slovenia	9.74	0.00	107.10	0.00	97.36	0.00	
Spain	14.07	5.90	138.13	3.30	111.47	3.77	
Sweden	2.30	0.00	29.88	0.42	68.96	0.84	16)
Switzerland	3.83	1.86	107.37	1.86	72.86	2.33	
United Kingdom	8.96	0.84	28.92	0.25	28.51	0.67	

1) People passed blood testing but blood not donated had positive results for infection or other reason against donation
2) Repeat donors: data not available
3) 1st time donor selection policy is currently impossible to adopt due to our efforts to maintain levels of blood availability
4) HTLV I/II positives do not include overseas territories (West Indies). A 6% increase on 2006
5) Data not available. Information based on statistics from 5 main blood centers, where 24,585 donations of whole blood were collected. Information from rest of blood centers not available
6) Only in a few centers do donors give blood samples only for testing on first visit
7) HBsAg+a-HBc positive - 75 donor samples were positive
8) Sample taken only from first-time new donors (SOND) born outside Ireland & UK. In 2007, 1,314 SOND donors were tested of whom 2 confirmed positive for HBsAG, 3 for HCV and 2 for syphilis. These are included in first time tested category above
9) Coverage: 92.9% of donations
10) First time donors (total) includes all new donors, including those deferred
11) Confirmatory testing of HCV has not been used during 2007
12) Seropositive syphilis serology includes those not diagnosed with syphilis
13) Regular and repeat donors are the number of donors that have donated in 2007
14) Total number of registered donors = 241,762
15) Number of first-time donors giving only blood samples not available- they are registered together with all refused donors
16) In remote areas, a few first time donors donate blood to the mobile unit

Table 8.1 – *NAT testing*

Country	HIV NAT		HBV NAT		HCV NAT		Other NAT tests (separated by ';')		
	Donations tested	Size Minipool	Donations tested	Size Minipool	Donations tested	Size Minipool	Donations tested	Size Minipool	
Armenia	None		None		None				
Austria	All	96	All	96	All	96	All HAV: Frankfurt, Wiesenheid, Roche, Linz; All PB19:Frankfurt, Wiesenheid, Roche, Linz	96; 96	1)
Belgium	All	8	None		All	8			2)
Bulgaria	None		None		None				
Croatia	None		None		None				3)
Cyprus	None		None		None				
Czech Republic	None		None		None				4)
Denmark	None								5)
Estonia	All	12	None		All	12			
Finland	All	96	None		All	96	All Parvo B19	480	6)
France	All		All		All				7)
Germany	All	96			All	96			8)
Greece	All	6	All		All	24			9)
Hungary	None		None		None				10)
Iceland	None		None		None				
Ireland	All	8	None		All	8			
Italy	All		All		All				11)
Latvia	None		None		None				
Luxembourg	All	50	All	50	All	50			12)
Malta	None		None		None				
Moldova	None		None		None				
Montenegro	None		None		None				13)
Netherlands	All	48	None		All	48	All HBV for plasmafractionation; All HAV for plasmafractionation; All Parvo virus B19 for plasmafractionation	480; 480; 480	14)
Norway	None		None		All	24			15)
Poland	All	6	All	6	All	6			
Romania	None		None		None				16)
Serbia	None		None						17)
Slovakia	None		None		None		All Chiron HIV, HCV,HBV, single donation testing		18)
Slovenia	All		All		All				
Spain	All		All						19)
Sweden	None		None		None				
Switzerland	All	8	All	1	All	8			20)
United Kingdom	All		None		All				21)

1) HIV: pool size 3-96. HBV: pool size 3-96. HCV: pool size 3-96. HAV (Frankfurt, Wiesenheid, Roche, Linz) pool size 3-96. PB19: (Frankfurt, Wiesenheid, Roche, Linz) pool size 3-96
2) HIV: pool size = 8 (93.6 %), pool size = 24 (6.4 %). HCV: pool size = 8 (93.6 %), pool size = 24 (6.4 %)
3) NAT screening of blood donors is not mandatory in Croatia. NAT testing is in use for confirmatory testing in some patients, according to written procedures
4) HIV: plasma for fractionation is tested by the processing company and positive results are reported back. HBV: plasma for fractionation is tested by the processing company and positive results are reported back. HCV: plasma for fractionation is tested by processing company and positive results are reported back
5) HIV: ID NAT will be implemented 01 January 2009
6) Parvo B19
7) HBV: only for overseas territories and Army personnel on individual testing. WNV: if epidemic occurs. Chikungunya: if epidemic occurs. Dengue: if epidemic occurs
8) HIV: only HIV-1. HBV: no Data. HBV NAT Test performed by blood donation service on a voluntary basis
9) -HIV: data on 23,075 blood units tested with Roche Cobas Ampliscreen. Another 372,195 blood units tested with ID NAT testing for HCV-RNA/HIV-RNA/HBV-DNA with Procleix-Ultrio-Chiron. Data collected and analysed by the Coordinating Haemovigilance Centre (SKAE)

   -HBV: 372,195 blood units tested with ID NAT testing for HCV-RNA/HIV-RNA/HBV-DNA with Procleix-Ultrio-Chiron. Data collected and analysed by the Coordinating Haemovigilance Centre (SKAE). Results on NAT only positive cases will be sent at the end of November

- HCV: Data on 23,075 blood units tested with Roche Cobas Ampliscreen. Another 372,195 blood units tested with ID NAT testing for HCV-RNA/HIV-RNA/HBV-DNA with Procleix-Ultrio-Chiron. Results on NAT only positive cases will be sent at the end of November

10) NAT technique is used as one of the verification methods in the central conformation laboratory at BE headquarters

11) HIV: coverage = 89% of donations. HBV: coverage = 89% of donations. HCV: coverage = 100% of donations

12) HIV: DRK Frankfurt. HBV: DRK Frankfurt. HCV: DRK Frankfurt

13) NAT testing does not retool in TS in Montenegro

14) HBV for plasma fractionation. HAV for plasma fractionation. Parvo virus B19 for plasma fractionation

15) HCV: testing stopped in 2008

16) NAT has not been introduced in routine testing

17) HCV: HCV NAT tested only for plasma fractionation

18) Chiron HIV, HCV, HBV and single donation testing (pilot study): all donations were tested during a certain period (in total 5,596 donors). NAT testing is not performed in routine practice

19) HIV: size of minipools = 1- 48. HBV: size of minipools = 1- 48. HCV: size of minipools = 1- 48

20) HIV: size of minipool ranges from 8 to 24. HBV: NAT testing with Tigris in ID began to be performed since middle of 2007 for 3 markers (HIV, HBV and HCV) for about 60% of the blood donations. HCV: size of minipool ranges from 8 to 24

21) HCV: Northern Ireland – 96; Wales – 48; Scotland – up to 95; NHSBT (England) – 48

Table 8.2 – *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 donors
Austria	0	0	0	0	1	0
Belgium	0	0			0	2
Estonia	0	0			8	1
Finland	0	0			0	0
Georgia						
Germany	0	1	0	1	3	16
Greece		1				
Ireland	0	0			0	0
Italy	0	1	2	55	0	0
Luxembourg	0	0	2	0	0	0
Moldova						
Netherlands	0	0			0	
Norway					0	0
Poland	1	0	18	30	6	5
Slovenia	0	0	0	6	0	1
Spain	3		74		6	
Switzerland	0	0	0	1	0	0
United Kingdom	0	1			0	0

Table 9 – *Bacterial screening*

Country	total platelets issued (adult therapeutic doses)	% bacterial screened		% of platelet adult doses screened	% of screened units confirmed positive	
		recovered	apheresis			
Armenia	37 920 000 000 000					
Austria	30 028	18	16	34		1)
Belgium	63 960	90	71	83	0	2)
Bulgaria	7 273	1		1		
Croatia	12 166	7	8	7	0	3)
Cyprus	8 056	0	0	0	0	
Czech Republic	22 986	1	1	1		4)
Denmark	32 422			80	0	
Estonia	6 037	100	100	100	0	
Finland	38 427			0		5)
France	245 326			0		
Georgia	1 626					
Germany	448 922			1		6)
Greece	152 138	6	3	4	10	
Hungary	18 042	2	47	4	1	7)
Iceland	1 648	0	0	0	0	
Ireland	22 426	100	100	100		8)
Latvia	4 396					
Luxembourg	2 219	0	2	2	0	
Malta	901	20	20	20	0	
Moldova	44 105					
Montenegro	1 893					10)
Netherlands	53 701	100	100	100	100	
Norway	19 001	78	78	78	0	11)
Poland	65 911	2	1	1	1	12)
Romania	16 106					13)
Serbia	12 200			2		
Slovakia	19 193	0	0	0		14)
Slovenia	29 537				0	
Spain	223 944					
Sweden	38 091			36	0	15)
Switzerland	22 937			0		16)
United Kingdom	257 076	11	16	12	1	17)

1) Confirmed results: data not yet available
2) Percentage of platelet adult doses pathogen-inactivated = 17 %
3) Data available only for Croatian Institute of Transfusion Medicine in Zagreb, responsible for 43% of all donations in Croatia. Confirmed positive results = 0.15%
4) Bacteria screening is done as a part of routine (statistical) QC only
5) In-process microbiological cultures are not performed. All outdated platelet components are cultured: 4 out of 2,293 platelet doses (products) were positive (17%)
6) At the end of shelf life
7) Single platelet concentrates produced in Hungary. 3,004 single PLTs were screened for presence of bacteria last year
8) Overall positive rate = 0.421%. False positive = 0.29%. Unconfirmed positive = 0.084%. Confirmed positive = 0.047%. Confirmed and non-confirmed positive = 0.131
9) Screening of platelets for bacteria is not a national policy
10) Regular screening for the presence of bacteria in platelet preparations does not retool in TS
Checking of PLT for presence of bacterial contamination is carried out from time to time
11) 12 units found to be positive
12) About 50% of NAT tests are performed on single donations
13) Mandatory screening done on BactAlert or Hemoline. Figures by component not compiled
14) Presence of bacteria is tested only as a quality control, not as routine for prolongation of expiration
15) 0.13% of the screened units were confirmed positive
16) Only QC carried out on outdated units
17) NHSBT (England) – No routine bacterial screening performed
Northern Ireland – 97% bacterial screening
Wales – 100% bacterial screening
Scotland - as from September 2007, all platelets have been tested

Table 10 – *Organisation, registration and labelling*

Country	National Council or Expert Committee	National blood policy		National regulations	
		on quality and safety	implementing		
Austria	Yes	Yes	Yes	Yes	
Belgium	Yes	Yes		Yes	
Bulgaria	No	Yes	Yes	Yes	
Croatia	Yes	Yes	Yes	Yes	
Cyprus	No	No		Yes	1)
Czech Republic	Yes	Yes	Yes	Yes	
Denmark	Yes	Yes	Yes	Yes	
Estonia	No	Yes	No	Yes	
Finland	No	Yes	Yes	Yes	
France	Yes	Yes	No	Yes	
Georgia	Yes	No	No	No	
Germany	Yes	Yes	Yes	Yes	
Greece	Yes	Yes	Yes	Yes	
Hungary	Yes	Yes	Yes	Yes	
Iceland	No	No	No	Yes	
Ireland	No	Yes	Yes	Yes	
Italy	Yes	Yes	Yes	Yes	
Latvia	Yes	No	No	Yes	
Luxembourg	Yes	Yes	Yes	Yes	
Malta	No	Yes	Yes	Yes	
Moldova	Yes	Yes	Yes	Yes	
Montenegro	Yes	No		Yes	2)
Netherlands	Yes	No	Yes	Yes	3)
Norway	Yes	Yes	Yes	Yes	
Poland	No	Yes	No	Yes	
Romania	Yes	Yes	Yes	Yes	
Serbia	Yes	Yes	Yes	Yes	
Slovakia	Yes	Yes	No	Yes	4)
Slovenia	Yes	Yes		Yes	
Spain	Yes	Yes	Yes	Yes	
Sweden	No	Yes	Yes	Yes	
Switzerland	No	Yes	Yes	Yes	
United Kingdom	Yes	Yes	Yes	Yes	5)

1) All European Directives regarding blood and blood components have been transposed into national law and are awaiting full implementation
2) All these documents are foreseen by a new law and are in preparation
3) The National Blood Plan is a national law on Blood Transfusion
4) A national plan on blood policy implementation is in the process of preparation
5) Guidelines for the Blood Transfusion Services in the UK (7th Edition)

Table 11a – *Quality management related issues*

Country	QMS established and maintained#	% donations covered by			other procedures	Inspections every second year	Description of "Other" organisation/body	System of educ. and training
		GMP	ISO 9000	other				
Austria	Yes	100	100		Blutsicherheitsgesetz 1999,Blutspenderverordnung 1999, Richtlinien in der Blutgruppenserologie und Transfusionsmedizin, Verordnung: Arzneimittel aus menschlichem Blut	National	AGES PharmMed (Nationale Einrichtung)	Yes
Belgium	Yes	100	35			National+Other	If covered by 9000 series: also inspected by body for ISO certification.	Yes
Bulgaria	Yes	100				National		Yes
Croatia	Yes	100	43			No		Yes
Cyprus	Planned	0	0	0		No		No
Czech Republic	Yes	100	45			National		Yes
Denmark	Yes	100		15	ISO15189	National		Yes
Estonia	Yes	100				National		No
Finland	Yes	100			ISO 17025 for laboratory testing	National	National Agency for Medicines	Yes
France	Yes	100	100			National	AFSSaPS	Yes
Georgia	No					No		No
Germany	Yes	100				National		Yes
Greece	Yes	75	12			Other	EKEVYL, ELOT for some centres only.	Yes
Hungary	Yes	100				National+Other		Yes
Iceland	Yes		97			National	Icelandic Medicines Agency	No
Ireland	Yes	100				National		Yes
Italy	Yes	0	39	100	Regional authorisation and accreditation	No		Yes
Latvia	Planned					National		Yes
Luxembourg	Yes	100	100	100	AFSSAPS for FFP SD	National+Other	AFSSAPS for FFP SD	Yes
Malta	Yes					National+Other	Irish Medical Board (IMB)	Yes
Moldova	Yes					National		Yes
Montenegro	Planned							No
Netherlands	Yes	100	100	100	JACIE for stemcells	National+Other		Yes
Norway	Yes	100	41			National	Both by the National drugs agency and the Norwegian Board of Health	Yes
Poland	Yes	96	51			National+Other	Institute of Haematology and Blood Transfusion; Main Pharmaceutical Inspectorate	Yes
Romania	Planned					No		Yes
Serbia	Planned					National		Yes
Slovakia	Yes	100	0			National+Other	fractionator	Yes
Slovenia	Yes	100	70			National+Other	organisations accredited to perform the ISO 9001:2000 certification procedes	Yes
Spain	Yes		100			Other	CAT (Comité de Acreditación en Transfusión);	Yes
Sweden	Yes	100	0		ISO IEC 17025 or ISO/IEC 15189	National+Other	The technical accreditation body, SWEDAC	Yes
Switzerland	Yes	100	65	90	A majority of RBTS comply with ISO 17025 (accreditation of the laboratories)	National+Other	METAS: national accreditation body	Yes
United Kingdom	Yes	100	4	0	4 UK Blood Services each has its own National procedures. ISO 9000 - Wales only.	National+Other	Wales only – BSI ISO series every 6 months	Yes

Table 11b – *Quality management related issues*

Country	% donations labelled		component code		Comments	Haemovigilance system	
	ISBT 128	another system	SBT 128	another system		Available / organisation	Description of 'Other' organisation/body
Austria		100		100	Nicht näher spezifizierbar; Code ISBT 128: in Errichtung begriffen	National	AGES PharmMed (Nationale Einrichtung)
Belgium	93	7	93	7	in house developed system with codabar 39 or code 128; ISBT or ISBT 128-like;	National	
Bulgaria	0	100	0	100	National unified system	National	
Croatia	0	90	0		Codabar system	Other	Croatian Institute of Transfusion Medicine
Cyprus	0	0	0	0	ISBT is under the procedure of ordering	No	
Czech Republic		100		100	national blood labelling standard	National	
Denmark	100		85			National+Other	Danish Society for Clinical Immunology
Estonia	100		0		Component codes are local	National	
Finland	100		100			National+Other	National Agency for Medicines and Finnish Red Cross Blood Service
France		100		100	French national code (monarch)	National	AFSSaPS
Georgia					There is no labeling system on a national level.	No	
Germany					Any unique code, mostly used is Eurocode	National	
Greece		85		85	"Percentage donations labelled according to ISBT128 (% donation numbers)": Planned. ""Percentage components labelled according to another system* (% component codes)"": Blood Med and Blood-Pleroforiki."	Other	National Coordinating Haemovigilance Centre (SKAE) of the Hellenic Centre of Diseases Control and Prevention (KEELPNO) of the Ministry of Health and Social Solidarity.
Hungary		100			codabar	National	
Iceland	97	1	97	1	From May 2007 all donations/ components are labelled according to ISBT128	National	
Ireland	0	100	0	100	CODABAR	National	
Italy	0	100	0	100	National regulation (UNI 10529); A new regional and national inspection system will be implemented starting from 2010 in compliance with EU directives	National	
Latvia	70	30	70	30		National	
Luxembourg	0	100	0	100	local system; TOO EXPENSIVE	National+Other	CTS and HOSPITALS
Malta		100		100	CODABAR	National	
Moldova	100	100	100	100		National	
Montenegro		100				No	
Netherlands	100	0	100	0		National+Other	
Norway	95	5	95	5		National	
Poland	0	100	0	100	national system	Other	Institute of Haematology and Blood Transfusion
Portugal							
Romania	0	100	0	100	national procedure	National	planned, not yet functional
Serbia	100		100			No	These data is from National Blood Transfusion Institute
Slovakia					informations are not available	National	
Slovenia		100		100	codabar system	National+Other	Blood Transfusion Centre of Slovenia (collecting data and reporting to the national authority)
Spain	44	56	44	56		National	
Sweden	85	15	85	15	previous recommenden Swedish system "Blood-ID"; Non-ISBT 128 users have routines for reading the ISBT 128 codes and performing additional labelling into their own system and vice versa.	National+Other	Swedish Society for Transfusion Medicine
Switzerland	100		100			National	
United Kingdom	100	0	0	100	Codabar; Donation numbers ISBT 128, Product labels Codabar	National+Other	MHRA (SABRE) & SHOT

Table 12 – *Haemovigilance*

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 allo antibody	Non immun. Hemol.	PT Purpura	Anaphylaxis	TRALI	GVHD	TA-HBV	TA-HCV	TA-HIV	TA-Other viral	TA-Bacterial	TA-Malaria	TA-Parasitic	TA-TACO	TA-Other serious		
Austria	596 803	1	10	0	0	0	0	0	0	0	0	0	1	0	0	0	0	2.0	1)
Belgium	659 569	7	3	0	0	14	2	0	0	0	0	0	4	0	0	6	0	5.5	
Bulgaria	253 386																		2)
Croatia	250 728	1	9	17	13	11							2					21.1	3)
Cyprus	70 923	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0	
Czech Republic	637 035	0	0	0	0	5	2	0	0	0	0	0	0	0	0		2	1.4	4)
Denmark	450 441										1							0.2	
Estonia	92 917																		
Finland	345 341	7	5	0	0	0	1	0	0	0	0	0	0	0	0		0	3.8	
France	2 732 719	3	12	0	1	57	30	0	0	0	0	0	7	1	0	74	17	7.4	
Georgia	43 723																		
Germany	6 434 629	3	9		1	49	34		1		1		8					1.6	
Greece	1 036 344	6	11	1		6											6	2.9	5)
Hungary	503 531																		6)
Iceland	20 749					2												9.6	
Ireland	171 511	0	4	0	0	34	0	0	0	0	0	0	0	0	0	28	24	52.5	
Italy	2 966 000																		7)
Latvia	113 253	1				2												2.6	
Luxembourg	27 078	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0	8)
Malta	16 731	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	6.0	
Moldova	72 091																		
Montenegro	20 547																		9)
Netherlands	701 093	6	11			32	14						4			27		13.4	
Norway	250 737	1	2	0	0	2	0	0	0	0	0	1	0	0	0	7	0	5.2	10)
Poland	1 344 246																		
Romania	558 952																		
Serbia	391 326	1				1							2				2	1.5	11)
Slovakia	208 360	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	16	7.7	12)
Slovenia	136 859	0	0	0	0	1	0	0	0	0	0	0	0	0	0	7	2	7.3	
Spain	1 989 624	8	4		1	40	15						2		1	19		4.5	13)
Sweden	610 317																		14)
Switzerland	405 016		3			22	5		1				1			5	2	9.6	
United Kingdom	2 745 179	7	22	0	1	46	7	0	0	0	0	0	3	0	0		25	4.0	15)
Total		52	105	18	17	325	110	0	2	0	2	1	34	1	1	173	96		

1) Febrile transfusion reactions (Level 1) = 115
   Non-febrile transfusion reactions (Level 1) = 108
2) No serious adverse reactions and events have been reported for 2007 to the Bulgarian Drug Agency (National Authority) and to the National Center of Transfusion Hematology
3) Data on serious adverse reactions are not complete. Reports from some centers in Croatia awaited
4) TACO is not reported as a specific SAR in CZ, it is probably included in "other serious reactions"
5) Haemovigilance data associated with the transfusion of 738,872 blood products (429,728 RBCs, 198,522 FFP and 110,622 platelets).
6) Non-assessable level = 0
   Anaphylaxis/hypersensitivity = 159
7) Coverage = 57.5% of transfused units
8) Only 15 non-serious adverse reactions reported, with imputability level 0 (1), level 1 (4), level 2 (6), level 3 (4)
9) Reporting of adverse reactions is not routine behaviour in hospitals in Montenegro
10) Transmission of Varicella = certain
    Transmission of CMV = unlikely
    Other serious = vasculitis
11) A haemovigilance reporting system is being introduced at a national level
12) Other serious reactions = pyretic reactions.
13) Other parasitical infections: *T. cruzi*.
14) Imputability levels must be 1 or higher for inclusion in the report of the Society for Transfusion Medicine
15) Circulatory overload - not tested

APPENDIX

Questionnaire on the collection, testing and use of blood and blood components in Europe
The 2007 Survey

Strasbourg, 31 March 2006

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

THE 2007 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 and is copyright of Dr Olof Akerblom and Dr C.L. van der Poel. Revisions and additions have been made to comply with a World Health Organisation (WHO) questionnaire on selected indicators. 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 2006 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

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 according to the Council Recommendation 98/463/EC and Council of Europe Guide to the preparation, use and quality assurance of blood components, Appendix 1.

First time donor	Someone who has never donated either blood or plasma
Repeat donor	Someone who has donated before but not within the last two years in the same blood establishment
Regular donor	Someone who donated blood or plasma within the last two years in the same blood establishment

Comments to the data given in Table 1

2. Collection of blood and blood components

2.1	**Whole blood**, total **number** of donations	
2.1.1	**-** voluntary non-remunerated, **per cent** of donations	%
2.1.2	- replacement donations,[1] **per cent** of donations	%
2.1.3	**-** autologous donations**,** pre-deposit, **number**	
2.2	**Red cells apheresis**, total **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**, total in **litres**	
2.3.1	- collected from voluntary non-remunerated, **litres**	
2.4	**Platelets apheresis**, total **number** of donations (procedures)	
2.4.1	**-** voluntary non-remunerated, **per cent** of donations	%
2.5	**Granulocytes apheresis**, **number** of donations (procedures)	
2.6	**Multi-component apheresis**, [2] **number** of donations (procedures)	

[1] Replacement donations — Donations collected from donors recruited by patients to enable them to undergo therapy, which requires blood transfusion

[2] Multi-component apheresis — means the collection in one session of two or more different types of blood components, *i.e.* erythrocytes + plasma, platelets + plasma, etc.

Comments to the data given in Table 2

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], total number**	
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 volume of red cells or plasma collected by apheresis.

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

Comments to the data given in Table 3

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.

Comments to the data given in Table 4

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.	Plasma	%	%
5.2.2	**Cryoprecipitate reduced plasma**	%	%
5.2.3	Cryoprecipitate	%	%

Comments to the data given in Table 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.

6.1	**Screening test performed**	**only 1st time donation**	**Every donation**	(if not all donations tested:) **% donations tested**	**Comments**
6.1.1	anti-HIV 1+2	☐	☐		
6.1.1.1	HIV-Ag	☐	☐		
6.1.2	HBsAg	☐	☐		
6.1.2.1	anti-HBc	☐	☐		
6.1.3	anti-HCV	☐	☐		
6.1.3.1	HCV-Ag	☐	☐		
6.1.4	anti-HTLV I/II	☐	☐		
6.1.5	Syphilis[1]	☐	☐		
6.1.6	Malaria	☐	☐		
6.1.7	Others[2]	☐	☐		
		☐	☐		
		☐	☐		
		☐	☐		

[1] e.g. TPHA, RPR, VDRL, or other screening tests.

[2] Please specify, e.g. Chagas' disease, brucellosis, WNV, anti-CMV

Comments to the data given in Table 6.1

6.2	**The use of simple rapid tests** Are any of these screening test performed using a rapid test technique *ONLY*?				
	Screening test	**Yes,** all donations	**Yes,** % of donations	**No**	**Comments**
6.2.1	anti-HIV 1+2	☐	☐ %	☐	
6.2.2	HBsAg	☐	☐ %	☐	
8.2.3	anti-HCV	☐	☐ %	☐	

Comments to the data given in Table 6.2

7. Confirmatory testing

7.1	**Are repeatedly reactive screening test results subjected to confirmatory testing?** ☐ Yes, always ☐ Yes, approximately _____ % of them ☐ No

7.2 Confirmed seropositive test results

7.2	**Confirmed seropositive**[1]	HIV 1/2	HBsAg	HCV	HTLV I/II	Syphilis
7.2.1	First time tested donors[2], number					
7.2.2	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.

Comments to the data given in Table 7

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 plus repeat donors			

[4] NAT only positive:
Positive in a NAT assays 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.

Comments to the data given in Table 8

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 to the data given in Table 9

SECTION C: General Information

10. National co-ordination

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

10.2	**National Blood Policy**		
10.2.1	- is there a national blood policy on the quality and safety of blood and blood components?	☐ Yes	☐ No
	If yes,		
10.2.2	- is there a national blood plan on implementing the national blood policy?	☐ Yes	☐ No

10.3	**National Regulations** - are there national regulations, legally binding, for the collection, testing, processing, storage and distribution of blood and blood components?	☐ Yes	☐ No

Comments to the information given in Table 10

11. Quality management related issues

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

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

11.3	**Education and training** - is there a system of education and regular training of staff in blood transfusion medicine? ☐ Yes ☐ No

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

Comments to the information given in Table 11

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:

12.2 Haemovigilance data Serious adverse reactions* observed in recipients of blood or blood components:		Serious adverse reactions* reported				
		- total	- with imputability level*			
		number	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.

Comments to the information given in Table 12

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