2005 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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European Directorate for the Quality of Medicines & HealthCare

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2005 Report

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The Collection, Testing and Use of Blood and Blood Components in Europe is published by the Directorate for the Quality of Medicines and HealthCare of the Council of Europe (EDQM).

Director of the Publication: Dr S. Keitel

Page layout and cover: EDQM

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Printed on acid-free paper by Druckerei C. H. Beck, Nördlingen (Germany)

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, autologus blood and blood components 22

Table 3 - Use of blood and blood components for transfusion 23

Table 4 - Plasma for fractionation 24

Table 5.1 - Special processing of blood components 25

Table 5.2 - Pathogen reduction or quarantine of plasma 26

Table 6 - Screening for infectious agents, serological test methods 27

Table 7.1 - Confirmed seropositive donors 29

Table 7.2 - Prevalence and incidence of infectious diseases 30

Table 8.1 - Nucleic Acid Amplification Techniques (NAT) testing 31

Table 8.2 - NAT-only confirmed positive donors 32

Table 9 - Bacterial screening 33

Table 10 - Organisation and registration 34

Table 11 - Quality management 35

Table 12 - Haemovigilance 37

Appendix 39

Questionnaire on the collection, testing and use of blood and blood components in Europe, the 2005 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 CoE 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 2005. In its present form it follows a series of similar reports which have assessed such data in 1989, 1991, 1993, 1995, 1997, and in its present revised form in 2001, 2002, 2003 and 2004.

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. As of 2004, the format of the questionnaire was reviewed and re-designed by the authors and the CoE experts belonging to 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 2005, as for former years, not all relevant information was obtained from each MS as a consequence of difficulties in implementation of data retrieval from automated blood banking systems, and in collating data from many Blood Establishments (BE) on a national level within the MS. However, the process is designed so that annual repetition will lead to improvements.

In contrast to the 2001-2003 surveys, the proportion of donations by voluntary non-remunerated and replacement donors was requested as of 2004 in the questionnaire. The European Commission (EC) has acknowledged its importance in its *Directive 2002/98/EC*.

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

In MS and in BE, data may be administered in different formats, and different definitions may have been operational. This could result in discrepancies when reporting the data in another format. Some data may not be available. It is anticipated that consistency, improvements and persistence in these CoE survey methods in agreement with the EC will result in better data and higher response rates among MS, where the questionnaires are used annually. In order to facilitate uniformity, definitions quoted in the EC Directives and CoE Guidelines were used whenever possible (*Council Recommendation 98/463/EC, Directive 2002/98/EC, Guide to the Preparation, use and Quality Assurance, 9th edition, 2002*). 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 the data.

In total 33 questionnaires were received, the response rate (for year 2005) was 72%. (For the 2001, 2002, 2003 and 2004 surveys, the response rates were 84%, 60%, 67% and 73%, respectively).

The average number of donors in relation to the general population is 24 (range 1-54) per 1,000 inhabitants. On average 25% of the donor base consists of first time donors.

The number of Whole Blood (WB) collections is on average 36 per 1,000 inhabitants, and the average use of Red Blood Cells (RBC) is 37 per 1,000 inhabitants. On average 3 Litres (L) of plasmapheresis plasma per 1,000 inhabitants are collected.

The use of RBC varies considerably (range 2–64) but averages 37 total RBC Units (U) per 1,000 inhabitants. In 2 of the reporting MS less than 20 U per 1,000 inhabitants are used, most likely reflecting an insufficient supply. On average in the reporting MS, 35% of the total platelet volume is supplied by (random) single donor platelets by apheresis, in 8 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; an average yield of 7 L of plasma for fractionation per 1,000 inhabitants is found. However 5 / 28 (18%) of reporting MS deliver 15 L or more per 1,000 inhabitants. In Europe on average 72% of the plasma for fractionation is from recovered plasma.

In 11 / 32 (34%) of MS, 100% leucocyte depletion of RBC products is carried out. Platelet concentrates are 100% leucodepleted in 15 / 30 (50%) of MS. In 12 / 25 (50%) reporting MS, 100% of Fresh Frozen Plasma (FFP) is additionally safeguarded by either quarantine or pathogen reduction methods.

In all 33 reporting MS, each donation is tested for anti-HIV-1/2, HBsAg and anti-HCV. In 29 / 33 (88%) reporting MS, all donations are tested for syphilis. Anti-HTLV-I/II testing is performed on all donations in 9 / 33 (27%) of reporting MS, and on first time donors in 4 / 33 (12%) MS. Anti-HBc is performed on all donations in 4 / 33 (12%) of reporting MS, and only on first time donors in another 5. Prevalence and incidence of infectious diseases vary greatly among MS, and it is noted that in Europe a North-South gradient exists for hepatitis B (HBV) and C (HCV) virus.

Nucleic Acid Amplification Techniques (NAT) testing for HCV is performed on each donation in 17 (51%) of 33 reporting MS; whereas HIV NAT on each donation is performed in 11 (33%) and HBV NAT in 4 (12%) of MS, respectively. The NAT yield is given in Table 8.2.

Bacterial screening of platelet concentrates is a new data set added in this 2005 report. Haemovigilance data have repeatedly demonstrated the importance of bacterial safety of platelet concentrates. Data were reported by 18 MS. In 2 / 18 (11%) MS, 90-100% of the recovered platelet concentrates are bacterially screened. Apheresis platelet concentrates are 90-100% screened in 3 (17%) of MS. Among 16 reporting MS, the average rate of confirmed positively cultured platelet concentrates was 0.25% (ranging from 0-1%), which is in agreement with the literature. Other MS reported having Quality Control (QC) programmes of bacterial testing in place.

In 28 / 33 (85%) of the reporting MS (73% in 2003) a National Council or Expert Committee to advise the Ministry of Health on transfusion related policy issues exists.

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

Labelling according to International Society for Blood Transfusion (ISBT)-128 for the donation number is partially performed in 7 countries, and 5 (25%) countries have 100% ISBT-128 code implementation for the donations. ISBT-128 labelling of the issued component is partially implemented in 7 countries, and 4 countries (20%) have 100% ISBT-128 coding at the donation as well as the component level.

Haemovigilance reporting i.e. reporting of serious adverse events, is a new data set collected as of the 2004 survey. The format for data acquisition on haemovigilance in the 2004 CoE questionnaire in its basic form was developed in collaboration with CoE, experts and the EC

and adapted into *Directive 2005/61/EC*. Reporting of serious adverse reactions as performed in haemovigilance programmes is a high level of surveillance, as these reactions are not unexpected untoward effects but well known complications of blood transfusion. In this report only those serious adverse reactions are presented that are probably or certainly ascribable to the transfusion process (imputability grade 2 to 3), together with data from conditions not caused by the blood component itself, such as TACO (Transfusion Associated Circulatory Overload). Taking account of the possibility of under-reporting and the differences in national reporting systems, an average incidence of 1–30 serious adverse reactions per 100,000 distributed blood components is estimated. Higher incidences may reflect better reporting rather than lower quality. Haemolysis due to blood group incompatibilities such as ABO, anaphylaxis, Transfusion Related Acute Lung Injury (TRALI) and TACO appear to stand out as the more frequent serious adverse reactions.

Acknowledgements

The CoE/ EDQM (European Directorate for the Quality of Medicines and Healthcare) and the authors are grateful to all colleagues and experts who collated data at a national level and provided it for inclusion in this report.

Data collection and analysis and preparation of this manuscript was coordinated by Dr Marie-Emmanuelle Behr-Gross (Scientific officer, EDQM) supported by Ms Alison Harle (secretarial assistant, EDQM) and by Ms Isabelle Vernay and Mr John O'Brien (editorial assistants, EDQM).

LIST OF ABBREVIATIONS

Ag	Antigen
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 Autologus 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 Creutzfeld Jacob Disease
WB	Whole Blood
WHO	World Health Organisation

STUDY METHODS

The methods used in this survey were, in principle, the same as those described in the 2001 survey report. Briefly, the Council of Europe (CoE) / European Directorate for the Quality of Medicines and Healthcare (EDQM) Secretariat circulated the questionnaire to the experts in charge in each Member State (MS) requesting that the completed forms be returned to the Secretariat. Completed questionnaires were received by the authors up to May 2008. After meetings with GTS (Ad hoc working group on the guide to the preparation, use and quality assurance of blood components) and CD-P-TS (European Committee (Partial Agreement) on Blood Transfusion), corrections and additions were provided by MS, which were accepted up to November 2008, after which the report was finalised.

The data in the completed questionnaires were reviewed by the authors after submission by the MS. Request for additional information or clarification from national experts were posed by the authors where incomplete or incomprehensible data sets were returned. The absence of a response could also be attributed to lack of clarity or inconsistent questioning in the questionnaire, unfamiliarity with the query format, or adaptations that need to be made to computer data systems in Blood Establishments (BE) in order to allow retrieval of the exact data requested. At the stage of evaluation some data did not comply to the definitions, and were deleted. A qualitative evaluation report on the questionnaire with recommendations for improvement of the process had previously been reported by the authors to SP-HM (Committee of Experts on Blood Transfusion) and discussed in November 2004.
A revision of the questionnaire with new additional questioning was thereafter implemented for the 2004 survey and the subsequent 2005 and 2006 questionnaires were similar.

Trend analysis and incomplete data

Comparisons of results from the annual surveys in a trend analysis is envisioned. Not all information requested in the Questionnaire is included in the tables, but these provide detail where sufficient information is available to justify presentation. Occasionally totals in the tables may not precisely match the contributing figures because of rounding. It was assumed that information was not available when information was not provided. Non-availability of the data or data not fitting the format is represented by empty fields in the tables.

Remarks to the data

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

RESULTS

Response rate

The 46 MS of the CoE were invited to send completed questionnaires and replies were received, as of May 5th 2008, from 33 MS; a response rate of 72%. For the 2001, 2002, 2003 and 2004 surveys, the response rates were respectively 84, 60, 67 and 73%.

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 in the short term. Therefore it is not certain whether this requirement was always met in generating the data for this survey. If this detail is deemed necessary in future, the 'inactive' number of donors (i.e. the number of donors in the databases that did not donate during the reporting year) would also need to be reported. This problem of definition has 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. all donors whose last previous donation was done less than 2 years ago), and for repeat donors (i.e. those donors whose last previous donation was done more than 2 years ago). The total of the two categories represent those donors, who are known to the system or establishment and in many countries form the basis 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*.

The term in this survey 'first time donors' includes all donors who are actually tested for the first time or who donate for the first time. There are systems where 'applicant donors' (*98/463/EC*) are only tested, and come back for a first donation 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.

It should be taken into account that 'first time donors' are already a selected population and therefore the prevalence of infectious diseases markers in the general population of a given MS may be different. The ratio of first time donors to the total number of donors in general reflects the annual donor recruitment or, more generally, the turn-over rate in the donor base. This figure may however be influenced by recruitment programmes. The number of first time donors, as compared to the total number of donors, becomes less meaningfull in systems that only register donations and less so, the (uniquely identifiable) donors.

Excluding MS where first time donors and repeat plus regular donors were not reported separately, 25% (range 6-95) of the total donor base consists of 'first time' donors. It is known that first time donors may have higher incidences of infectious diseases as compared to regular or repeat donors (Schreiber *et al.* 2001).

The average number of donors in relation to the general population is 24 (range 1-54) 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 may indicate an insufficient donor base. Not all countries with a relatively high number of donors per 1,000 inhabitants deliver as high a number of Red Blood Cells (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 33 reporting MS is, on average, 36 (range 0.02-68) 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 25 countries where autologous donations are given, they contribute on average 1% (range 0-5%) to the WB donations. This is in agreement with the literature. However it should be taken into account that surgery and anaesthesiology techniques, such as pre-operative hemodilution and intra-operative blood salvage, are not included in the presented data. In this survey only the Pre-operative Autologous Blood Donations (PABD) are taken into account.

- **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

programmes. On average, in 28 reporting MS 3 Litres (L), with a range of 0.01 – 18 L of plasma per 1,000 inhabitants, is collected by plasmapheresis.

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 33 reporting MS on average 35% (range 0-100) of the adult therapeutic doses of platelets are produced by apheresis. There is a wide range reflecting different supply models. Platelet apheresis may be applied for only a limited number of indications such as HPA/HLA typed platelets, or platelet apheresis may be applied towards providing 100% of platelets supply.

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 may 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 issued to hospitals by BE. This depends on the source of the data and the national infrastructure. Data on the exact use in hospitals are generally not available in most MS. As component losses in hospitals are limited, the number of blood components issued by BE to hospitals represents an acceptable proxy to the blood use estimate. When used in the denominator of a ratio, the difference between 'issue' and 'use' becomes less relevant.

WB 'must be considered as a source material and has no, or only a very restricted, place in transfusion therapy' (*Guide to the Preparation, Use and Quality Assurance of 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 26 reporting countries, on average 1% (range 0–5%) of the total RBC are issued as WB. Some low residual frequencies may represent the use of WB for non-transfusion purposes.

The use of RBC per 1,000 inhabitants varies considerably. In 26 reporting MS it averages 37 total RBC products per 1,000 inhabitants (range 2-64). 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. RBC 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 been implemented 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 'optimal use' programmes. If usage below 20 U per 1,000 inhabitants is reported, this may likely reflect insufficient supply of blood and/or limited resources for heath care. A more precise benchmark may be achieved by including the number of hospital beds in a future survey, and link this to RBC use.

The use of plasma for transfusion has been discouraged during the last decade, mainly because its clinical indications are limited and because more plasma was needed as source material for fractionation into medicinal products. However, for 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. However, in some countries, data on the use of pooled plasma for transfusion registered as a

medicinal drug, may not be included in the present survey. On average the FFP/RBC ratio is 0.39 (range 0.12 – 1.4).

In Europe, platelets are generally recovered from 4-5 buffy-coats of WB donations. Discussions on blood safety in relation to Variant Creutzfeld Jacob 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 in practice no supply reaches 100% apheresis platelets. On average, in 33 reporting MS, 35% of the adult therapeutic doses of platelets are produced by apheresis, and in 8 / 33 (24%) apheresis accounts for more than 50% of supply (Table 3).

Plasma for fractionation: Table 4

The total amount of plasma issued for fractionation into medicinal products differs among MS. This becomes more clear if the figure is related to the population size. In 28 reporting MS, on average 7 L (range 0–21 L) per 1,000 inhabitants of plasma for fractionation into medicinal products are issued. Five out of 28 reporting MS (18%) deliver 15 L or more plasma per 1,000 inhabitants (Table 4).

In Europe, the main supply of plasma for fractionation is recovered plasma; on average 72% of the plasma for fractionation is from recovered plasma in 19 reporting MS (Table 4).

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 and may have to be reconsidered in future surveys.

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

In 11 / 32 (34%) of reporting MS, 100% leucocyte depletion of RBC products is carried out. This is the case for platelet concentrates in 15 / 30 (50%) reporting MS. Hundred percent leucocyte depletion is applied for plasma for transfusion in 8 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 / 25 (50%) reporting MS, 100% of FFP is safeguarded by either method, in 4 MS for 100% by quarantine, and in 3 by 100% pathogen reduction.

Screening for infectious agents, serological test methods: Table 6

In all 33 reporting MS, all donations are tested for anti-HIV-1/2, HBsAg and anti-HCV.
In 29 / 33 (88%) reporting MS, all donations are tested for syphilis. It is debated in the literature

whether syphilis testing is necessary; mainly in the north of Europe only new donors are tested for syphilis or syphilis testing is not performed.

Testing for anti-HTLV-I/II is performed on all donations in 9 / 33 (27%) reporting MS, and only on first time donors in 4 / 33 (12%) countries.

Testing for anti-HBc is performed on all donations in 4 / 33 (12%) reporting MS, and only on first time donors in 5 other countries. This is a slight increase compared to 2003. Testing for Nucleic Acid Amplification Techniques (NAT) is reported separately in Table 8.

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.

- **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, if calculated from the provided data sets, ranges from 0 to 500 for HIV-1/2, from 0 to 21,000 for HBV and 11 to 9,000 for HCV. 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 the southern countries.

The incidence per 100,000 repeat tested donor years, if calculated from the provided data sets, ranges from 0 to 86 for HIV-1/2, from 0 to 596 for HBV and 0 to 293 for HCV. Although considerable differences in geographical 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 17 / 33 (51%) reporting MS. NAT for HIV is performed on each donation in 11 / 33 (33%) reporting MS. NAT testing for HBV is performed on each donation in 4 (12%) 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 reported the importance of bacterial safety of platelet concentrates. This is due to the fact that the storage temperature of platelets is around 22°C, thus allowing bacterial growth more easily. Data on bacterial testing were reported by 18 MS.
In 2 / 18 (11%) MS, 90–100% of platelet concentrates recovered from WB donations are bacterially screened, and in 13 MS this is performed on 3–50% of recovered platelet concentrates. Between 90–100% of the apheresis platelet concentrates are screened for bacteria in 3 (17%) of reporting MS.

Overall, more than 10% of platelet concentrates are bacterially screened in 11 / 18 (61%) reporting MS. This suggests that in these 11 MS, BE are gradually expanding their bacterial testing programme from a Quality Control (QC) level (testing of 1% of concentrates) to a higher level, albeit not in all establishments within a given country. Among 16 reporting MS, the average rate of confirmed positively cultured platelet concentrates was 0.25% (ranging from 0-1%), which is congruent with the literature. Other MS reported having QC programmes for bacterial testing in place.

Organisation and registration: Table 10

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

Quality management: Table 11

In 28 / 33 (85%) of the reporting MS, a Quality System (QS) is established and maintained by BE. In 4 (12%) countries the implementation of such a system is planned.

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

In 27 / 33 (81%) of the reporting MS, a haemovigilance system is installed and, in 17 / 33 (51%), haemovigilance systems are organised by or in collaboration with 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 partially performed in 7 countries, and 5 (25%) countries have 100% ISBT-128 code for the donations. Labelling of the finished component code is more complex, 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 partially implemented in 7 countries, and 4 countries (20%) have 100% ISBT-128 coding at the donation as well as the component level. Other systems of automated labelling exist, and are summarised in Table 11, and specified below the table.

Haemovigilance: Table 12

As of the 2004 report, haemovigilance reporting i.e. reporting of serious adverse reactions, was added as a new data set. The format for data acquisition on haemovigilance in the 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*, that came into force in August 2006. Reporting of serious adverse reactions as performed in haemovigilance programmes can be considered a high level of surveillance, as most of these serious reactions are not unexpected side effects but well known complications of blood transfusion and commonly indicated in the 'product information leaflets' for physicians and patients. Most recipients of blood transfusions are seriously 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 product 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 19 MS, are presented in Table 12.

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.

As haemovigilance is still in development, the data should be regarded with some caution. Taking into account the possibility of under-reporting and the differences in national reporting systems, the incidence varies between of 1–30 serious adverse reactions per 100,000 issued blood components, where the higher incidences may reflect better reporting rather than lower quality. Haemolysis due to blood group incompatibilities anaphylaxis, Transfusion Related Acute Lung Injury (TRALI) and TACO appear to stand out as the more frequent serious adverse reactions.

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TABLES

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

Armenia, Belgium, Bosnia / Herzegovina, Bulgaria, Croatia, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Moldova, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, United Kingdom.

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

Country	regular and repeat donors#	first time donors#	% first time donors#	total donors#	inhabitants x 1,000	donors per 1,000 inhabitants	
Armenia	325	5,993	94.9	6,318	3,200	2.0	
Belgium	252,303	54,357	17.7	306,660	10,289	29.8	
Bosnia / Herzegovina	13,842	15,062	52.1	28,904	2,100	13.8	
Bulgaria	120,965	32,372	21.1	153,337	7,719	19.9	
Croatia	76,853	13,979	15.4	90,832	4,438	20.5	
Czech Republic	313,300	31,700	9.2	345,000	10,300	33.5	
Denmark	229,246				5,430		1)
Finland	143,647	16,322	10.2	159,969	5,237	30.5	
France	1,153,734	352,348	23.4	1,506,082	62,519	24.1	
Germany	2,057,887	544,713	20.9	2,602,600	82,465	31.6	
Greece	312,335	57,203	15.5	369,538	10,500	35.2	
Hungary	300,000	64,620	17.7	364,620	10,142	36.0	
Iceland	7,546	2,360	23.8	9,906	300	33.0	
Ireland	71,124	26,357	27.0	97,481	4,240	23.0	
Italy	1,254,000	239,000	16.0	1,493,000	57,000	26.2	2)
Latvia	35,096	12,327	26.0	47,423	2,290	20.7	
Lithuania	20,388	21,785	51.7	42,173	3,414	12.4	
Luxembourg	13,520	1,802	11.8	15,322	440	34.8	
Moldova	37,020	16,724	31.1	53,744	3,830	14.0	
Montenegro	8,877	4,647	34.4	13,524	623,278	0.0	
Netherlands	468,846	30,011	6.0	498,857	16,306	30.6	
Norway	76,800	16,185	17.4	92,985	4,640	20.0	
Poland	300,138	198,888	39.9	499,026	38,191	13.1	
Portugal		287,491			10,356		3)
Romania	159,996	73,495	31.5	233,491	21,000	11.1	
Serbia		43,346			7,478		
Slovak Republic	91,017	23,338	20.4	114,355	5,300	21.6	
Slovenia	95,523	10,812	10.2	106,335	1,964	54.1	
Spain	780,601	328,962	29.6	1,109,563	43,066	25.8	
Sweden	216,842	29,914	12.1	246,756	9,048	27.3	
Switzerland	216,536	20,059	8.5	236,595	7,360	32.1	
Turkey					75,000		
United Kingdom	1,304,927	261,914	16.7	1,566,841	58,803	26.6	

 # expressed as absolute numbers

1) First time donors not registered
2) Only repeat donors counted
3) All donors counted as first time donors

Table 1.1 – *Profile of donations*

Country	WB donations			RBC 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	3	1	0.28					1)
Belgium	100	0	0.21	100	0	100	100	
Bosnia / Herzegovina	82	0					100	
Bulgaria	28	0	0.27			0	0	
Croatia	100	0	0.71			100	100	2)
Czech Republic	100	0	4.34	32	0	79	32	
Denmark	100	0	0.01			100	100	3)
Finland	100	0	0.00	0		100	100	
France	100	0	1.50	100	54	100	100	
Germany		0	3.00		21			
Greece	46	0	0.79	34		26	41	
Hungary	100	0	0.32	100			100	
Iceland	100	0	0.01	100	0	100	100	
Ireland	100	0	0.01				100	
Italy	100	0	5.11			100	100	
Latvia	97					40		
Lithuania	16						15	
Luxembourg	100	0	0.97			100	100	
Moldova	13	0		0		0	0	
Montenegro	20	1						
Netherlands	100	0	0.05	100	0	100	100	
Norway	100			100		100	100	
Poland	95	0	0.16	100		88	100	
Portugal	99	0	0.62	100	0		100	
Romania	100	0				100	100	
Serbia	83	0	2.24			0	100	
Slovak Republic	99	0	0.60	0		100	95	
Slovenia	100	0	2.42	0		100	100	
Spain	100		1.32	100		100	100	
Sweden	100	0	0.06	100	0	100	0	
Switzerland	100	0	4.03	100	20	100	100	
Turkey	36	0						4)
United Kingdom	100	0	0.01	100	0	100	100	

1) Also 386 remunerated donors donated 1612 U of WB

2) 3.096 L plasma collected from paid donors

3) <50 autologous donations

4) Data obtained from 189 of 360 blood centers

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

Country	WB collections				apheresis collections					
	WB (U)	WB per 1,000 inhabitants	autologous (U)	% autologous WB (U)	plasma apheresis (L)	plasma in L per 1,000 inhabitants	platelets apheresis (U)	RBC apheresis (U)	granulocytes apheresis (U)	
Armenia	7,839	2.4	22	0.3	67	0.02				1)
Belgium	554,317	53.9	1,150	0.2	82,229	7.99	27,023	2,283	0	
Bosnia / Herzegovina	30,417	14.5					330			
Bulgaria	153,337	19.9	407	0.3	117,900	15.27	837	0	0	
Croatia	156,231	35.2	1,112	0.7	376	0.08	1,747	0	0	2)
Czech Republic	421,500	40.9	18,300	4.2	54,200	5.26	15,100	1,000		
Denmark	366,817	67.6	50	0.0	400	0.07	919	0	0	3)
Finland	271,411	51.8	0	0.0	1,699	0.32	628	0	0	
France	2,143,879	34.3	32,139	1.5	161,069	2.58	172,084	3,257	403	
Germany	4,632,294	56.2	138,812	2.9	951,922	11.54	164,297	36,634		
Greece	623,556	59.4	4,942	0.8	873	0.08	25,380	2,824		
Hungary	434,259	42.8	1,407	0.3			5,591	89	19	
Iceland	14,631	48.8	2	0.0	16	0.05	319	46	0	
Ireland	154,906	36.5	12	0.0	0	0.00	6,131	0		
Italy	2,347,000	41.2	120,000	4.9	200,000	3.51	68,000		500	
Latvia	52,235	22.8			656	0.29	1,559			
Lithuania	90,132	26.4					783	36		
Luxembourg	22,160	50.4	216	1.0	2,942	6.69	787	0	0	
Moldova	57,067	14.9			1,150	0.30	0	0	0	
Montenegro	13,527	0.0								
Netherlands	596,107	36.6	280	0.0	172,956	10.61	4,123	88	645	
Norway	200,890	43.3			400	0.09	3,784	4,085	0	
Poland	935,415	24.5	1,509	0.2	683,744	17.90	20,253	58	113	
Portugal	361,935	34.9	2,250	0.6	0	0.00	1,964	130	3	
Romania	352,564	16.8			227	0.01	1,059			
Serbia	228,982	30.6	5,135	2.2	3,270	0.44	942		0	
Slovak Republic	165,084	31.1	986	0.6	20	0.00	2,999	0	1	
Slovenia	84,017	42.8	2,035	2.4	536	0.27	1,102	0	6	
Spain	1,556,637	36.1	20,496	1.3	16,133	0.37	14,810	555	86	
Sweden	480,261	53.1	290	0.1	59,695	6.60	9,086	630	53	
Switzerland	347,720	47.2	14,000	3.9	1,760	0.24	10,000	1,109	0	
Turkey	1,272,075	17.0					44,695			4)
United Kingdom	2,456,457	41.8	150	0.0	750	0.01	72,997	1,026	77	

1) Also 386 remunerated donors donated 1612 units of WB

2) 3.096 L plasma collected from paid donors

3) <50 autologous donations

4) Data obtained from 189 of 360 blood centers

Table 3 – *Use of blood and blood components for transfusion*

Country	WB (U)	% WB of total RBCs	RBC concentrates (U)	RBC (U) per 1,000 inhabitants	plasma for transfusion (U)	platelets total (U)	platelets recovered (U)	platelets apheresis (U)	% platelets apheresis	CP (10^6 IU FVIII)	
Armenia	8	0.1	7,301	2.3	7,603	369	0	369	100.0		
Belgium	0	0.0	516,245	50.2	90,708	71,864	33,131	38,733	53.9	0	
Bosnia / Herzegovina			12,144		4,145	2,996	2,336	660	22.0		
Bulgaria	1,736	1.1	156,682	20.3	89,783	5,389	4,531	858	15.9	0	
Croatia	2,026	1.4	148,453	33.5	83,223	13,563	11,816	1,747	12.9	0	
Czech Republic	1,300	0.3	432,800	42.0	283,500	21,600	4,300	17,300	80.1	0	1)
Denmark	0	0.0	344,833	63.5	60,133	28,401	25,637	2,764	9.7	0	
Finland	859	0.3	254,964	48.7	38,185	33,619	33,045	574	1.7	0	2)
France	0	0.0	2,009,111	32.1	281,409	218,863	33,734	185,129	84.6	0	3)
Germany	18,122	0.4	4,341,042	52.6	1,243,888	367,170	138,146	229,024	62.4	0	
Greece	827	0.1	628,498	59.9	267,279	156,950	131,570	25,380	16.2		4)
Hungary	10		427,474		92,851	14,819	9,227	5,592	37.7		
Iceland	0	0.0	14,125	47.1	5,400	1,097	530	567	51.7	0	
Ireland	25	0.0	139,326	32.9	25,626	19,777	11,273	8,504	43.0	1,765	5)
Italy	21,000	0.9	2,446,000	42.9	521,000	157,000	89,000	68,000	43.3	4,000	6)
Latvia	0	0.0	47,133	20.6	46,750	3,988	1,057	2,931	73.5	2,546	
Lithuania	9		86,797		30,049	4,624	3,856	768	16.6	912	
Luxembourg	0	0.0	21,166	48.1	4,472	2,108	1,340	768	36.4	0	
Moldova	57	0.2	22,947	6.0	32,481	3,586	3,586	0	0.0	5,956	
Montenegro	80		6,760		5,697	1,877	1,877	0	0.0	120	
Netherlands	0	0.0	578,687	35.5	67,700	52,043	48,142	3,901	7.5	0	
Norway			189,452		39,551	15,729	10,486	5,243	33.3		7)
Poland	790	0.1	876,731	23.0	339,975	61,878	32,388	29,490	47.7	1	
Portugal	0	0.0	352,387	34.0	1,729	18,040	15,937	2,103	11.7	600	8)
Romania	135,519		347,602		191,680	65,709	64,650	1,059	1.6	17,917	
Serbia	11,628	5.0	234,117	31.3	116,345	12,631	11,689	942	7.5	2	
Slovak Republic	8,686	5.4	159,800	30.2	73,053	9,899	4,057	5,842	59.0	0	
Slovenia	0	0.0	76,340	38.9	33,419	27,423	25,535	1,888	6.9	0	
Spain	539	0.0	1,420,359	33.0	228,032	112,237	75,413	36,824	32.8	5,770	
Sweden	0	0.0	448,922	49.6	109,507	33,174	19,481	13,693	41.3		
Switzerland	4,919	1.6	307,855	41.8	69,595	19,814	1,793	18,021	91.0	0	
Turkey	412,719		1,122,349		422,016	146,093	105,575	40,518	27.7	1,366	
United Kingdom	1,160	0.0	2,324,767	39.5	343,672	258,293	157,293	101,000	39.1		

1) Plasma kept in quarantine and smaller amount actually issued for transfusion

2) In addition to FFP, 5482 U of 200 mL SD plasma. Figures relate to blood components delivered by EFS to patients (85%) plus distributed to hospital blood banks (15%)

3) The figures relate to blood components delivered by EFS to patients (85%) plus distributed to hospital blood banks (15%)

4) 24.000 RBC units imported from Switzerland

5) 24880 plasama O^+ + 455 FFP + 291 CSP

6) WB distributed between hospitals not to be transfused but for further preparation

7) Plus approx. 1000 units 200 mL pooled SD plasma8) About 99% of FFP is pooled SD plasma: 75000 U of 200 mL

Table 4 – *Plasma for fractionation*

Country	plasma for fractionation (L)	plasma for fractionation per 1,000 inhabitants (L)	% fractionation plasma recovered	FFP per 1,000 inhabitants (U)	FFP / total RBC ratio (U/U)	
Armenia				2.38	1.04	
Belgium	200,571	19.49	56.91	8.82	0.18	
Bosnia / Herzegovina	3,905	1.86	92.11	1.97		
Bulgaria	12,726	1.65		11.63	0.57	
Croatia	20,607	4.64	0.00	18.75	0.56	
Czech Republic	87,300	8.48	58.88	27.52	0.66	
Denmark	80,720	14.87	100	11.07	0.17	
Finland	64,454	12.31	100	7.29	0.15	
France	631,627	10.10	78.19	4.50	0.14	
Germany	1,754,404	21.27	50.65	15.08	0.29	
Greece	18,242	1.74		25.46	0.43	
Hungary	72,638	7.16	100	9.16		
Iceland	0	0.00		18.00	0.38	
Ireland	0	0.00		6.04	0.18	
Italy				9.14	0.21	
Latvia	0	0.00		20.41	0.99	
Lithuania	12,343	3.62	100	8.80		
Luxembourg	7,190	16.34	69.49	10.16	0.21	
Moldova	14,228	3.71	93.03	8.48	1.42	
Montenegro				0.01		
Netherlands	298,902	18.33	55.23	4.15	0.12	
Norway	52,555	11.33		8.52		1)
Poland	103,689	2.72	58.00	8.90	0.39	
Portugal				0.17	0.00	2)
Romania				9.13		
Serbia	12,090	1.62	84.58	15.56	0.50	
Slovak Republic	23,532	4.44	100	13.78	0.46	
Slovenia	10,702	5.45	94.99	17.02	0.44	
Spain	295,646	6.86		5.29	0.16	
Sweden	151,000	16.69	60.93	12.10	0.24	
Switzerland	75,726	10.29	7.40	9.46	0.23	
Turkey	0	0.00		5.63		
United Kingdom	0	0.00		5.84	0.15	

1) Most plasma for fractionation is recovered plasma

2) No plasma fractionation in 2005

Table 5.1 – *Special processing of blood components*

Country	RBC		plasma for transfusion		platelets		
	% leucocyte depleted	% irradiated	% leucocyte depleted	% irradiated	% leucocyte depleted	% irradiated	
Armenia							
Belgium	100		100		100		
Bosnia / Herzegovina	2		2			50	
Bulgaria	6	1				1	
Croatia	8				55		1)
Czech Republic	16	8	0	6	78	43	2)
Denmark	18		0		93		
Finland	100	2	100	0	100	22	
France	100	8	100	0	100	40	
Germany	100	3			100	29	
Greece	36	12	32	6	7	12	
Hungary	6	4		27	62	10	
Iceland	20	6	1	1	100	59	
Ireland	100	3			100	75	
Italy	29	8	9	0	56	30	3)
Latvia	74	1	76	0	100	18	
Lithuania	4				14		
Luxembourg	100	2	100	0	100	2	
Moldova	0	0	0	0	0	0	
Montenegro							
Netherlands	100	4	100	0	100	30	
Norway	100	6			100	30	
Poland	5	4	0	0	54	48	
Portugal	100	15	100	0	100	100	
Romania	6	2				1	4)
Serbia	1	0	1		4	2	
Slovak Republic	14	25	14	0	66	35	
Slovenia	20	15			35	20	
Spain	92						
Sweden	69	3			76	53	
Switzerland	100		100		100		
Turkey							
United Kingdom	100		100	0	100		

1) Red cells and platelets leucocyte depleted on indication

2) Bed-side leucocyte depletion of ca 4% of red cells and 10% of platelets, irradiation of ca 3% components in clinical wards

3) Data refer to 70% of collected units

4) Platelets leucocyte depleted upon request

Table 5.2 – *Pathogen reduction or quarantine of plasma*

Country	FFP		CP reduced plasma		cyroprecipitate		
	% quarantined	% virus inactivated	% quarantined	% virus inactivated	% quarantined	% virus inactivated	
Armenia							
Belgium		100					1)
Bosnia / Herzegovina							
Bulgaria							
Croatia							2)
Czech Republic	100	0	100	0			
Denmark	0	0	0	0	0	0	
Finland	2	0	0	0	0	0	3)
France	60	40					4)
Germany	90	10	0	0	0	0	
Greece	21	11					
Hungary	0	0	0	0	0	0	
Iceland	0	0	0	0	0	0	
Ireland	0	100	0	0	0	0	5)
Italy							
Latvia	65	0		0		0	
Lithuania	100	0				0	
Luxembourg	0	100					
Moldova	0	0	0	0	0	0	
Montenegro							
Netherlands	100						
Norway	3	0,1					
Poland	57,44	0	100	0	100	0	
Portugal							6)
Romania	100		100		100		
Serbia	0	0	0	0	0	0	
Slovak Republic	60	0	0	0	0	0	
Slovenia	15	0	0	0	0	0	
Spain	92		36	64			
Sweden	0	0					7)
Switzerland	85	15					
Turkey							
United Kingdom				0			

1) Irradiation of blood components in the hospitals.
2) No national decision for quarantine or virus inactivation of plasma or cellular products
3) Some hospitals irradiate components.
4) CSP plasma and CP no longer produced in France.
5) Plasma mostly from USA
6) About 99% of SD FFP–about 75 000 units/year
7) CSP plasma only used for therapeutic plasma exchange in some cases

Table 6 – *Screening for infectious agents, serological test methods*[#]

Country	anti-HIV 1+2		HIVAg		HBsAg		Anti-HBc		anti-HCV		HCVAg		anti-HTLV I/II		syphilis		Other tests		
	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	
Armenia	Y				Y				Y						Y		Y		1)
Belgium	Y				Y			Y	Y				N	N	Y				2)
Bosnia / Herzegovina	Y		Y		Y		Y		Y		Y		Y		Y				
Bulgaria	Y		Y		Y				Y						Y				
Croatia	Y		Y		Y				Y						Y				3)
Czech Republic	Y		Y		Y				Y						Y				4)
Denmark	Y		Y		Y				Y					Y	N	N			5)
Finland	Y				Y				Y					Y	Y	N			6)
France	Y				Y		Y		Y				Y		Y				7)
Germany	Y				Y				Y						Y				
Greece	Y				Y				Y				Y		Y				
Hungary	Y				Y			Y	Y						Y				
Iceland	Y		Y		Y				Y										
Ireland	Y				Y		Y		Y				Y		Y				8)
Italy	Y				Y				Y						Y		Y		9)
Latvia	Y				Y				Y						Y				10)

**A = each donation** **B = first time donors** **Y = Performed** **N = Not performed**

1) 8170 donations tested
2) 0.41% donations HIV Ag tested 5.5% donations tested for a-HBc 0.41% donations tested for a-HTLV
3) HIV Ag/Ab combined test 45% of donations tested for HCV Ag
4) Ab / Ag combined test in some establishments
5) Most centres Ab / Ag combined test, national fraction not known. HIV-Ag not mandatory
6) 29% donations tested + every 3 donations or at least annually in repeat donors
7) 40.4% donations CMV tested
8) 75% donations CMV tested
9) Alamine Amino Transferase
10) a-CMV IgM platelet apheresis for pediatric use

Table 6 (continued) – *Screening for infectious agents, serological test methods*#

Country	anti-HIV 1+2		HIVAg		HBsAg		Anti-HBc		anti-HCV		HCVAg		anti-HTLV I/II		syphilis		Other tests		
	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	
Lithuania	Y				Y				Y						Y				
Luxembourg	Y	Y			Y			Y	Y				Y		Y				
Moldova	Y		Y		Y				Y						Y				
Montenegro	Y		Y		Y				Y						Y				11)
Netherlands	Y				Y				Y				Y		Y				11)
Norway	Y				Y			Y	Y					Y		Y			12)
Poland	Y		Y		Y				Y						Y				
Portugal	Y		Y		Y		Y		Y		Y		Y		Y		Y		13)
Romania	Y		Y		Y				Y			Y	Y		Y				14)
Serbia	Y				Y				Y						Y				
Slovak Republic	Y				Y				Y						Y				
Slovenia	Y				Y				Y						Y				15)
Spain	Y				Y				Y						Y				16)
Sweden	Y				Y			Y	Y					Y		Y			17)
Switzerland	Y				Y				Y						Y		Y		18)
Turkey	Y				Y				Y						Y				
United Kingdom	Y				Y				Y				Y		Y				19)

 # A = each donation B = first time donors Y = Performed N = Not performed

11) Anti-B19 antibodies in selected donors
12) Many centres use HIV Ab / Ag combi test–anti-HBc test repeated if donor has not donated in 12 months
13) ALT
14) HIV Ab / Ag combi tests
15) As of Oct 2005 HIV Ab / Ag combi test implemented: about 10% donations
16) Trypanosome Cruzi risk donors, about 0.25% donations tested
17) Anti-HBc also in at-risk donors
18) 20% of all donations tested for anti-HBc, donors with history of hepatitis tested for anti-HBc and anti-HBs
19) England performs HIV Ag testing–Diverse testing for Ghagas disease, Malaria and CMV in UK regions

Table 7.1 – *Confirmed seropositive donors*[#]

Country	HIV 1 / 2		HBV		HCV		HTLV-I/II		syphilis		
	first time donors	repeat donors	first time donors	repeat donors	first time donors	repeat donors	first time donors	repeat donors	first time donors	repeat donors	
Armenia											
Belgium	0	2	31	1	33	4			13	5	
Bosnia / Herzegovina	0	0	12	0	3	0			1	0	
Bulgaria	6		1666	853	275	110			395	219	
Croatia	0	3	29	12	8	5			10	12	
Czech Republic	0	2	21	30	42	56			15	35	
Denmark	0	0	15	0	5	3	0	0			
Finland	0	1	7	0	6	0	0	0	0	1	
France	18	23	346	5	210	14	32	4	76	37	
Germany	33	54	785	46	441	73			194	131	
Greece	69	19	1741	292	364	98	0	0	54	12	
Hungary	1	0	1	2	178	43			71	7	
Iceland	0	0	2	0	4	0					
Ireland	2	0	5	0	4	1	0	0	1	2	
Italy											1)
Latvia	5	12									2)
Lithuania											3)
Luxembourg	0	0	2	0	1	0	0	0	0	0	
Moldova	10	0									
Montenegro	1		40	1	32	2			23	3	
Netherlands	1	2	26	9	10	1	1	0	17	29	4)
Norway	0	0	4	0	10	0	0	0	3	0	
Poland	22	9		18		17			112	44	
Portugal											5)
Romania	13	6	3154	788	2412	249	43	4	1272	253	
Serbia											
Slovak Republic	0	0	45	5	14	8			7	11	
Slovenia	0	2	10	2	2	0			4	3	
Spain	55	42	469	52	438	32					6)
Sweden	0	3	18	5	29	2	0				
Switzerland	2	2	29	4	17	1			16	11	
Turkey											
United Kingdom	23	17	94	8	110	15	16	1	77	29	

 # expressed as absolute number

1) Data for 2005 not yet available
2) Only for HIV 1/2
3) Data on conformed positive donors not available nationally, blood centers required to provide information only on reactive screening test results.
4) Not all FTA positive donors diagnosed with syphilis
5) Positive confirmed results on 200 000 blood collections only
6) Syphilis confirmation not available

Table 7.2 – *Prevelance and incidence of infectious diseases*

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							
Belgium	0.00	0.79	57.03	0.40	60.71	1.59	
Bosnia / Herzegovina	0.00	0.00	79.67	0.00	19.92	0.00	
Bulgaria	18.53		5146.42	705.16	849.50	90.94	
Croatia	0.00	3.90	207.45	15.61	57.23	6.51	
Czech Republic	0.00	0.64	66.25	9.58	132.49	17.87	
Denmark		0.00		0.00		1.31	1)
Finland	0.00	0.70	42.89	0.00	36.76	0.00	
France	5.11	1.99	98.20	0.43	59.60	1.21	
Germany	6.06	2.62	144.11	2.24	80.96	3.55	
Greece	120.62	6.08	3043.55	93.49	636.33	31.38	
Hungary	1.55	0.00	1.55	0.67	275.46	14.33	
Iceland	0.00	0.00	84.75	0.00	169.49	0.00	
Ireland	7.59	0.00	18.97	0.00	15.18	1.41	
Italy							2)
Latvia	40.56	34.19					3)
Lithuania							4)
Luxembourg	0.00	0.00	110.99	0.00	55.49	0.00	
Moldova	59.79	0.00					
Montenegro	21.52		860.77	11.27	688.62	22.53	
Netherlands	3.33	0.43	86.63	1.92	33.32	0.21	5)
Norway	0.00	0.00	24.71	0.00	61.79	0.00	
Poland	11.06	3.00		6.00		5.66	
Portugal							6)
Romania	17.69	3.75	4291.45	492.51	3281.86	155.63	
Serbia							
Slovak Republic	0.00	0.00	192.82	5.49	59.99	8.79	
Slovenia	0.00	2.09	92.49	2.09	18.50	0.00	
Spain	16.72	5.38	142.57	6.66	133.15	4.10	7)
Sweden	0.00	1.38	60.17	2.31	96.94	0.92	
Switzerland	9.97	0.92	144.57	1.85	84.75	0.46	
Turkey							
United Kingdom	8.78	1.30	35.89	0.61	42.00	1.15	

1) First time donors not registered nationally

2) Only repeat donors counted

3) Only for HIV 1/2

4) Data on confirmed positive donors not available nationally, blood centers required to provide information only on reactive screening test results.

5) Not all FTA positive donors diagnosed with syphilis

6) All donors considered as first time

7) Syphilis confirmation not available

Table 8.1 – *Nucleic Acid Amplification Techniques (NAT) testing*

Country	HIV NAT		HBV NAT		HCV NAT		
	each donation#	Size Minipool	each donation	Size Minipool	each donation#	Size Minipool	
Armenia							1)
Belgium	Y	8			Y	8	2)
Bosnia / Herzegovina							
Bulgaria							
Croatia							3)
Czech Republic							4)
Denmark							
Finland	Y	96			Y	96	
France	Y	8 or 24			Y	8 or 24	5)
Germany	Y	up to 96			Y	up to 96	
Greece					Y	24	6)
Hungary							
Iceland							
Ireland	Y	8			Y	8	
Italy					Y	10-24	7)
Latvia							
Lithuania		1		1		1	8)
Luxembourg	Y	96	1	96	Y	96	
Moldova							9)
Montenegro							
Netherlands	Y	48			Y	48	
Norway					Y	24	
Poland		24		24		24	
Portugal							10)
Romania							11)
Serbia							
Slovak Republic							
Slovenia					Y	24	
Spain	Y	1-48			Y	1-48	
Sweden							12)
Switzerland	Y	8–24			Y	8–24	
Turkey							13)
United Kingdom		48–96			Y	48–96	14)

 # Y = Performed N = Not performed

1) No NAT used
2) 94% of donations in minipools of 8
3) No national decision yet on NAT
4) NAT only by fractionators, positive results reported to establishment
5) HBV ID NAT only in overseas areas
6) 11 BE tested SD NAT for HCV and HIV, and 14 tested for HIV, HBV and HCV
7) HIV NAT carried out in some regions and HBV NAT carried out in some regions
8) Approximatively 60% of donations HIV, HCV and HBV NAT tested
9) NAT testing in preparation
10) NAT planned for 2006
11) No NAT testing
12) NAT only performed by fractionators, positive results fed back to establishment
13) No NAT performed
14) Northern-Ireland tests for HIV NAT

Table 8.2 – *NAT-only confirmed positive donors*#

Country	HIV 1		HBV		HCV		
	first time tested donors	repeat donors	first time tested donors	repeat donors	first time tested donors	repeat donors	
Armenia							
Belgium	0	2			2	0	
Bosnia / Herzegovina							
Bulgaria							
Croatia							
Czech Republic							
Denmark							
Finland	0	0			0	0	
France	1	1			0	1	
Germany	0	1	0	3	2	6	
Greece					0	0	
Hungary							
Iceland							
Ireland	0	0			0	0	
Italy							1)
Latvia							
Lithuania	0		3		15		2)
Luxembourg	0	0	0	0	0	0	
Moldova							
Montenegro							
Netherlands	0	0			0	0	
Norway					0	0	
Poland	0	0	7	18	1	7	
Portugal							
Romania							
Serbia							
Slovak Republic							
Slovenia					0	0	
Spain	4				3		3)
Sweden							
Switzerland	0	0			0	0	
Turkey							
United Kingdom	0	0			0	0	

 # expressed as absolute number

1) Data for 2005 not avaible
2) All donations NAT tested in National Blood Center being 60% of WB donations
3) HIV NAT on 1,066,880 donations (66%) HCV NAT on 1,335,890 donations (83%)

Table 9 – *Bacterial screening*

Country	total platelets issued (adult therapeutic doses)	% platelets U screened			% total platelets U confirmed positive	
		recovered	apheresis	total		
Armenia	369			0		1)
Belgium	71864	100	80		0.1	2)
Bosnia / Herzegovina	2996			0		
Bulgaria	5389	0.4			0	
Croatia	13563	5.83	10.13	6.39	0.46	3)
Czech Republic	21600					4)
Denmark	28401			67		5)
Finland	33619					6)
France	218863			0		
Germany	367170			1		
Greece	156950					
Hungary	14819	16.21	9.4	13.65	0.059	
Iceland	1097			0		
Ireland	19777	100	100	100	0.08	7)
Italy	157000	3	5	3		8)
Latvia	3988	100	94	98	0	
Lithuania	4624	1.7	0.5	1.5	0	
Luxembourg	2108					
Moldova	3586	0	0	0	0	
Montenegro	1877					
Netherlands	52043	100	100	100	0.38	
Norway	15729			80		9)
Poland	61878			0		
Portugal	18040			100		
Romania	65709	50	100	50		
Serbia	12631	0.96	1	0.95		
Slovak Republic	9899	14	3	7.5	0	
Slovenia	27423					
Spain	112237					
Sweden	33174			24	0.3	
Switzerland	19814					10)
Turkey	146093					
United Kingdom	258293				0.2	

1) 131 U WB tested, 0 positive
2) 14% of apheresis platelets pathogen reduced
3) Bacterial testing only at CITM being 48% of supply
4) Bacterial testing as a statistical process control procedure
5) 67% is an estimate
6) All outdated platelets cultured
7) 0.08% confirmed positive from nov 2004–dec 2006
8) Data correspond to 70% Italian Transfusion Centres, range 0.5–26% tested
9) Most centres test for bacteria, 2 centres use pathogen reduction
10) Screening for bacteria performed only. QC procedures on outdated platelets

Table 10 – *Organisation and registration*[#]

Country	National Council or Expert Committee	national blood policy		national regulations	
		on quality and safety	implementing		
Armenia	N	N		N	1)
Belgium	Y	Y		Y	
Bosnia / Herzegovina	Y	Y	Y	Y	
Bulgaria		Y	Y	Y	
Croatia	Y	N		Y	2)
Czech Republic	Y	Y	Y	Y	3)
Denmark	Y	Y		Y	4)
Finland	N	Y	Y	Y	5)
France	Y	Y	N	Y	
Germany	Y	Y	N	Y	
Greece	Y	Y	Y	Y	
Hungary	Y	Y	Y	Y	
Iceland	N	N		N	6)
Ireland	N	N	N	Y	7)
Italy	Y	Y	Y	Y	
Latvia	Y	Y	Y	Y	
Lithuania	Y	Y	Y	Y	
Luxembourg	N	N	N	Y	
Moldova	Y	Y	Y	Y	
Montenegro	Y				
Netherlands	Y	Y	Y	Y	
Norway	N	Y	Y	Y	
Poland		Y	Y	Y	
Portugal	N	Y	Y	Y	
Romania	Y	N	Y	Y	
Serbia	Y	Y	Y	Y	
Slovak Republic	Y	Y	Y	Y	
Slovenia	Y	N	N	Y	8)
Spain	Y	Y	Y	Y	
Sweden	N	Y	Y	Y	
Switzerland	N	Y	Y	Y	
Turkey	Y	N		Y	
United Kingdom	Y	Y	Y	Y	

 # Y = Performed N = Not performed

1) National regulations installed in 2006
2) Government oriented system with 34 centres
3) Revision of national policy expected
4) CoE Guide implemented
5) National Agency for Medicines advises
6) National regulations in 2006
7) National Steering Committee for EU Blood Directives. Blood Policy Unit in Dept of Health.
8) Bacterial testing only as QC

Table 11 – *Quality Management*

Country	QMS established and maintained#	% donations covered by			Inspections each second year, by*	system of education and training#	% donations labelled according to		% component coded according to		Haemovigilance system operated by*	
		% GMP	% ISO 9000	% other			ISBT 128	another system	ISBT 128	another system		
Armenia	N				0	N	100		0		no	
Belgium	Y	65.2	35.3		nat aut + other org	Y	93.6	6.4	93.6	6.4	nat aut	1)
Bosnia / Herzegovina					0	N		100		100		
Bulgaria	Y	100			nat aut	Y	100				nat aut	
Croatia	Y	100	48		nat aut	Y		100		80	other org	2)
Czech Republic	Y	100	40		nat aut	Y		100		100	nat aut	3)
Denmark	Y	100	0		nat aut		100		85		other org	4)
Finland	Y	100			nat aut & other org	Y	100		100		nat aut	5)
France	Y		100		nat aut	Y		100		100	nat aut	6)
Germany	Y	100			nat aut	Y					nat aut	
Greece	Y	70	0.02		nat aut	Y	0.05	99.95	0.22	99.78	other org	7)
Hungary	Y	100			nat aut + other org	Y		100		100	nat aut	8)
Iceland	Y		92		other org	Y	92		92		no	9)
Ireland	Y	100			nat aut	Y		100		100	nat aut	10)
Italy					no	Y	95		82		nat aut	11)
Latvia			30		nat aut	Y					nat aut	
Lithuania	Y				nat aut	Y		100			nat aut	12)

 # Y = Established and maintained N = Not established * nat aut = national authority other org = other organisation no = no haemovigilance system in place

1) Inspections by plasma fractionator and ISO in some centres–haemovigilance started in 2005
2) CITM has ISO 9001:2000–inspections in CITM–CODABAR–Croatian Society of Haematology and Transfusion Medicine
3) ISBT compatible system since 1995–mandatory reporting in 2005
4) Haemovigilance by DART
5) ISO 17025 in laboratories–inspections also by FINAS
6) Coding by MONARCH
7) National coding system–haemovigilance by SKAE
8) Barcode
9) Inspections by ISO and BSI–Akureyri no computer system for labeling
10) Inspections by Irish Medicines Board–Codabar
11) Planned
12) 100% of donations covered by SOP's–local systems blood centres

Table 11 (continued) – *Quality Management*

Country	QMS established and maintained#	% donations covered by			Inspections each second year, by*	system of education and training#	% donations labelled according to		component code		Haemovigilance system operated by*	
		% GMP	% ISO 9000	% other			ISBT 128	another system	ISBT 128	another system		
Luxembourg		100	100		nat aut + other org	Y	0	100	0	100	nat aut + other org	
Moldova	N				nat aut	Y		100		100	nat aut	13)
Montenegro						N	0	100			no	
Netherlands	Y	100	25		nat aut	Y	100	0	100	0	other org + nat aut	14)
Norway	Y	100	33		0	Y	80		80		other org	15)
Poland	Y	100	59		nat aut	Y	0	100	0	0	nat aut	
Portugal	Y		100		other org	Y	100		100		no	16)
Romania	N				0	Y		100		100	no	17)
Serbia	Y	13.3	13.3		ant aut + other org	Y	7.33	92.67	5.6	94.4	no	18)
Slovak Republic	Y	90	1,2		nat aut + other org	Y		90		90	nat aut	19)
Slovenia	Y	100			nat aut + other org	Y		100			other org	20)
Spain	Y		95		other org	Y	28	72	28	72	nat aut	21)
Sweden	Y	100		57	nat aut + other org	Y	89	11	89	11	nat aut + other org	22)
Switzerland	Y	100	65		nat aut	Y	100		100		nat aut	23)
Turkey	N				0	Y					no	24)
United Kingdom	Y	100			nat aut	Y	100			100	nat aut + other org	25)

 # Y = Established and maintained N = Not established * nat aut = national authority other org = other organisation no = no haemovigilance system in place

13) Planned–national coding system
14) ISO planend 100% in 2006–national TRIP programme in colalboration with Inspectorate of Health
15) Inspections planned–Norwegian association for immunology and transfusion medicine
16) Data on haemovigilance remain in hospitals
17) Planned–national coding system
18) QMS being implemented
19) Establishments of NTS have uniform QMS, other establishments various QMS, 1 with ISO 9001–labelling compliant with CoE recommendations
20) Codabar–haemovigilance by Blood Transfusion Centre of Slovenia
21) 100% centres have SOP's–Codabar–Codabar
22) EN ISO/IEC 17025 or EN ISO 15189. 57% of BE specific QMS for transfusion medicine, while 26% have this in overall laboratory QMS–also by ISO–11% on older national coding system
23) Majority of BE complies with ISO 17025
24) QMS planned–Inspections irregular
25) Codabar

Table 12 – *Haemovigilance*

Country	total number components transfused: WB + RBC + FFP + Platelets (U)	Absolute number of serious adverse reactions with likely, probable or certain imputability (level 2 or level 3)														Incidence high imputability serious adverse reactions per 100,000 component U	
		haemolysis ABO	haemolysis other	PTP	Anaphylaxis	TRALI	GVHD	HBV	HCV	HIV	Other viral	Bacterial	Malaria	Parasitic	TACO	Other serious	
Armenia	15,273																
Belgium	678,817																
Bosnia / Herzegovina	19,285																
Bulgaria	251,854	0	0	2	49	0	0	0	0	0	0	0	0	0	0		20.2
Croatia	245,239	1	8	0	9	0	0	0	0	0	0	3	0	0	3	0	9.8
Czech Republic	737,900	0	2	0	38	0	0	0	0	0	0	0	0	0	0	22	8.4
Denmark	433,367	1	1	3	1	0	0	0	0	0	0	0	0	0	0	0	1.4
Finland	326,768						0	0	0								1)
France	2,509,383	2	3	1	36	15					0				67	6	5.2
Germany	5,952,100	4	0	1	5	16	0	3	1	0	0	12	0	0	0	0	0.7
Greece	1,052,727	4	1	0	14	1	0	1	1	0		1	0			1	2.3
Hungary	535,144	0	6	1	17	3	0	0	0	0	0	0	0	0	0	2	5.4
Iceland	20,622																
Ireland	184,729	1	2	0	17	0	0	0	0	0	0	0	0	0	21	16	30.9
Italy	3,124,000	2	2		9	0	0			0					4		0.5 2)
Latvia	97,871																
Lithuania	121,470																3)
Luxembourg	27,746	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	

1) Imputability submitted only since 1 January 2006

2) Data as of October 2005

3) Haemovigilance data available as of August 2006

Table 12 (continued) – *Haemovigilance*

Country	total number components transfused: WB + RBC + FFP + Platelets (U)	Absolute number of serious adverse reactions with likely, probable or certain imputability (level 2 or level 3)														Incidence high imputability serious adverse reactions per 100,000 component U	
		haemolysis ABO	haemolysis other	PTP	Anaphylaxis	TRALI	GVHD	HBV	HCV	HIV	Other viral	Bacterial	Malaria	Parasitic	TACO	Other serious	
Moldova	59,014	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Montenegro	14,334																
Netherlands	698,430	4	1	0	16	8	0	0	0	0	0	5	0	0	3	17	7.7
Norway	244,732	1	0	0	1	1	0	0	0	0	0	0	0	0	0	0	1.2
Poland	1,278,584	3	12	0	32	18	0	0	0	0		0	0	0	0	35	7.8
Portugal	372,156																
Romania	604,991																
Serbia	363,093																
Slovak Republic	242,752	2	2	0	29	1	0	0	0	0	0	0	0	0	0	18	21.4
Slovenia	137,182	0	0	0	3	0	0	1	0	0	0	0	0	0	1	0	3.6
Spain	1,760,628																4)
Sweden	591,603																5)
Switzerland	397,264	1	5	0	11	3	0	0	0	0	0	4	0	0	4		7.0
Turkey	1,690,458																
United Kingdom	2,926,732	3	15	2	25	9	0	1							7	4	2.3

4) Haemovigilance data on 81% of component units, 2 Chagas infections in recipients reported

5) Only cases with imputatibility of 1-3 included in reporting by Swedish Society for Transfusion Medicine.

APPENDIX

QUESTIONNAIRE ON THE COLLECTION, TESTING AND USE OF BLOOD AND BLOOD COMPONENTS IN EUROPE THE 2005 SURVEY

Strasbourg, 31 March 2006

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

THE 2005 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

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

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