International forum: an investigation of iron status in blood donors

Tomislav Vuk[1], Karin Magnussen[2], Wim de Kort[3], Gilles Folléa[4], Giancarlo M. Liumbruno[5], Harald Schennach[6], Giovani Vandewalle[7], Veerle Compernolle[7], Natalia Masharova[8], Georgia Karakatsiani[9], Isabella Argyrou[9], Vít Řeháček[10], Gulara Khanirzajeva[11], Johanna Castrén[12], Bruno Danic[13], Rachid Djoudi[14], Geneviève Woimant[14], Markus M. Mueller[15], Constantina Politis[16], Stefania Vaglio[17,18], Anita Daugavvanaga[19], Edita Vilutyte[20], Jean-Claude Faber[21], Denise Borg-Aquilina[22], Peter van den Burg[23], Arlinke Bokhorst[23], Ryszard Pogłód[24], Jolanta Antoniewicz-Papis[24], Mario Muon[25], Olivia L. Burta[26], Jana Rosochová[27], Polonca Mali[28], Miguel A. Vesga[29], Karin Schneider[30], Rut Norda[30], Nicky Anderson[31]

[1]Croatian Institute of Transfusion Medicine, Zagreb, Croatia; [2]Rigshospitalet/Hvidovre Hospital, University Hospital of Copenhagen, Copenhagen, Denmark; [3]Sanquin Blood Supply, Amsterdam, The Netherlands; [4]Établissement Français du Sang La Plaine St. Denis, France; [5]Italian National Blood Centre, National Institute of Health, Rome, Italy; [6]Central Institute for Blood Transfusion and Department of Immunology (ZIB), Innsbruck, Austria; [7]Belgian Red Cross-Flanders, Blood Services, Ghent, Belgium; [8]National Centre of Transfusion Haematology, Sofia, Bulgaria; [9]Cyprus Blood Establishment, Nicosia General Hospital, Nicosia, Cyprus; [10]Transfusion Department, University Hospital Hradec Králové, Hradec Králové, Czech Republic; [11]North Estonia Medical Centre's Blood Centre, Collection and Production Department, Tallinn, Estonia; [12]Finnish Red Cross Blood Service, Helsinki, Finland; [13]Etablissement Français du Sang Bretagne, Rennes, France; [14]Etablissement Français du Sang, La Plaine Saint Denis, France; [15]Institute for Transfusion Medicine and Immunohaematology, University Clinics of the Johann Wolfgang Goethe, University Frankfurt/Main, German Red Cross Blood Transfusion Service Baden-Wuerttemberg-Hessen, Frankfurt/Main, Germany; [16]Hellenic Centre for Disease Control and Prevention, Hellenic Coordinating Haemovigilance Centre, Athens, Greece; [17]Department of Clinical and Molecular Medicine, Sapienza University of Rome, Rome, Italy; [18]Immunohaematology and Transfusion Medicine Unit, Sant'Andrea Hospital, Rome, Italy; [19]State Blood Donor Centre; Riga, Latvia; [20]Medicine Public Institution, National Blood Centre, Vilnius, Lithuania; [21]Retired Luxembourg Blood Services, Luxembourg; [22]Malta National Blood Transfusion Service, G'Mangia Hill, Pietà, Malta; [23]Sanquin Blood Supply, Amsterdam, The Netherlands; [24]Institute of Haematology and Transfusion Medicine, Warsaw, Poland; [25]Coimbra Blood and Transplantation Centre, Coimbra, Portugal; [26]Blood Transfusion Centre, Bihor County, Romania; [27]National Transfusion Service, Bratislava, Slovak Republic; [28]Blood Donor Selection and Collection Unit, Blood Supply Department, Blood Transfusion Centre of Slovenia, Ljubljana, Slovenia; [29]Basque Country Blood Transfusion Service, Galdakao, Bizkaia, Spain; [30]Clinic of Immunology and Transfusion Medicine, Uppsala University Hospital, Uppsala, Sweden; [31]NHS Blood and Transplant, Filton, United Kingdom

Transfusion of blood components is an irreplaceable form of treatment for many patients[1]. However, besides providing sufficient amounts of blood components of excellent quality, blood transfusion services should protect the safety of blood donors. Numerous studies have proven that iron deficiency is common in frequent blood donors, particularly women[2-5]. Determination of the haemoglobin concentration is a routine part of the donor selection process both in order to ensure adequate quality of red cell concentrates collected and to protect the potential donor's health. Indeed, low haemoglobin is globally the most common reason for deferral of prospective blood donors. Nevertheless, only cases of manifest low haemoglobin levels and imminent anaemia are detected using this approach. More sensitive tests are needed to assess depletion of iron stores, particularly in non-anaemic individuals, with ferritin measurements being used most frequently.

Many studies to find the best approach to preventing iron deficiency in blood donors have been carried out or are still in progress[6-9]. These studies aim to re-evaluate current criteria in blood donor selection including the appropriateness of the interval between donations, to decide on the optimal testing strategy for determination of iron stores and to investigate the effect of iron supplementation in preserving them. The results of each study contribute to making decisions which should preserve an adequate blood supply without harming blood donors.

This international forum was initiated to evaluate the algorithms of donor selection and care to avoid iron deficiency as well as the methods used in the assessment of iron status in blood donors.

The request for participation was sent to experts in 28 member states of the European Union, together with a short questionnaire containing eight questions. The response rate was high with 26 countries (92.9%) having responded to the forum. The data obtained are summarised below and followed by the individual contributions with more details. Participants were asked to indicate whether the information relates to the national or institutional/local level and to provide respective data if haematocrit is also assessed. Participants from most

countries provided national data (17/26), while others provided local or institutional data.

Question 1

Please describe the method of haemoglobin (Hb) determination in donor selection:

- do you apply an invasive or non-invasive method for routine donor haemoglobin screening? Please specify the method(s) you are using.
- If you are using two or more screening methods, can you estimate the proportion of each method at the national (or institutional/local) level?
- Do you, and under what circumstances, use venous blood in donor haemoglobin assessment (e.g. pre- or post-donation? additional testing in the case of failing the initial screen? ...).

The methods used to determine haemoglobin in blood donors are summarised in Table I.

Four participants reported the use (or experience in using) non-invasive methods of haemoglobin determination. In two countries non-invasive technologies for determining haemoglobin concentration are under evaluation or are planned to be introduced in the near future.

Capillary blood is used for the determination of haemoglobin concentration in 24 of 26 countries that responded to the question. The copper sulphate test is used only in the United Kingdom, Spain and Croatia. A

Table I - Haemoglobin determination in donor selection.

Country	Reporting level	Method(s) in use			
		Non-Invasive	***Invasive***		***Sampling pouch***
			Capillary	*Venous*	*Venous*
Austria	National	Yes (minority)	Yes	Grey-zone/doubtful results	Yes (1 centre)
Belgium	National	No	Yes (all new donors and failed Hb on previous donation)	No	Yes (100%)
Bulgaria	National	No	Yes	No	No
Croatia	National	Yes (14% in 2014)	Yes (86% in 2014)	No	Yes (apheresis only)
Cyprus	National	No	Yes	Yes (apheresis only)	No
Czech Republic	Institutional	No	Yes	Yes (new WB donors)	Yes (regular WB and apheresis donors)
Denmark	Regional	No	No	Yes (low Hb on previous donation)	Yes
Estonia	National	No	Yes	No	No
Finland	National	No	Yes	Yes (deferred due to low capillary)	No
France	National	No	Yes (21%)	Yes (low capillary)	Yes (100%)
Germany	Regional	No	Yes	No	No
Greece	National	Yes (1 centre)	Yes	No	Yes (apheresis donors and some first time female donors)
Italy	Local	No	Yes	Yes (low capillary)	Yes (100%)
Latvia	National	No	Yes	No	No
Lithuania	Institutional	No	Yes	No	No
Luxembourg	National	No	Yes ("trigger events")	Yes (donor candidates and "trigger events")	Yes
Malta	National	No	Yes	Yes (low capillary and apheresis)	No
Netherlands	National	No	Yes	No (only special request)	No (for quality control purposes only)
Poland	National	Yes	Yes	Yes (once yearly for regular donors)	No
Portugal	Local	No	Yes	Yes (apheresis donors)	Yes (first time WB donors)
Romania	Institutional	No	Yes	Yes (apheresis donors or suspicious capillary level)	No
Slovakia	National	No	Yes (mobile collections)	Yes (donations at BE)	Yes (donors tested only from capillary blood)
Slovenia	National	No	Yes 98%	Yes 2% (apheresis)	No
Spain	Regional	No (starting 2016)	Yes	Yes (low capillary)	No
Sweden	National	No (under evaluation)	No	Yes (candidate donors)	Yes (registered donors)
United Kingdom	National	No	Yes	Yes (low capillary)	No

WB: whole blood; BE: blood establishment; Hb: haemoglobin.

photometric measurement of haemoglobin in capillary blood was reported by 21 participants, of which 14 use the HemoCue® method (HemoCue AB, Angelholm, Sweden). One country uses both methods, copper sulphate and HemoCue®.

Seventeen participants reported invasive sampling of venous blood for haemoglobin determination, almost exclusively in cases of donors deferred due to the low capillary haemoglobin and new/candidate donors, but seldom in apheresis donors. Non-invasive sampling of venous blood from the sampling pouch during donation is standard procedure for donors in apheresis programmes. However, this method is also in use for whole blood donors: nine participants reported such procedure for all donors and one participant for new donors.

Question 2

What are the minimum haemoglobin levels for male and female donors to donate:

- whole blood;
- platelets/plasma;
- red cells by apheresis.

In all countries except France (25/26), minimum haemoglobin levels for whole blood donations are the same: 125 g/L for female and 135 g/L for male donors. In France, these levels are 120 g/L and 130 g/L, respectively.

For plasma collection, 18 of 24 participants reported minimum haemoglobin levels of 125 g/L for female and 135 g/L for male donors, three participants 120 g/L and 130 g/L and two participants 115 g/L and 125 g/L, respectively. Only in Austria is the minimum value for both sexes the same, at 120 g/L.

For platelet apheresis, 22 of 26 participants reported minimum haemoglobin levels of 125 g/L for female and 135 g/L for male donors, two participants 120 g/L and 130 g/L, and one participant 115 g/L and 125 g/L, respectively. Romania reported two different standards in use, depending on the type of the apheresis machine (120-125 g/L for female donors and 130-135 g/L for male donors).

Seventeen participants reported minimum haemoglobin values for red cells obtained by apheresis: eight of them 140 g/L for both sexes, 150 g/L in Slovakia (only male donors) and Italy. Another six paricipants reported the same values as for whole blood donations (125 g/L and 135 g/L in female and male donors, respectively). Lithuania reported different values for male (140 g/L) and female donors (145 g/L).

Question 3

What is the donor deferral rate due to low haemoglobin? If possible, please provide the information for 2014, separately for male and for female donors.

Six participants could not provide data on donor deferral for low haemoglobin, while another seven participants did not have data separately for male and female donors. Among 13 participants reporting data for both sexes, the deferral rate for female donors ranged from 0.84% in Denmark to 15.9% in Croatia, while for male donors deferral rates ranged from 0.11% in Denmark to 3.24% in Croatia. For female donors, eight out of 13 participants reported deferral rates from 3.77 to 5.49%, three participants from 8.5 to 15.9% and two participants from 0.84 to 1.40%.

For male donors, three participants reported deferral rates below 1%, seven participants reported rates from 1.0 to 2.0% and three participants reported deferral rates from 2.8 to 3.24%.

Question 4

What is the minimal interval between whole blood donations (separately for males and females if different) and what is the maximum number of donations that can be collected from male and from female donors in a 1-year period?

The responses to this question are summarised in Table II, including reporting level.

In 17/26 countries intervals for blood donations are the same for male and female donors, while in the remaining nine countries intervals for male and female donors differ by 20-30 days. For female donors the interval between two donations is 2 months in 11 countries, between 2-3 months in two countries, 3 months in six countries, and 4 months in seven other countries. For male donors the interval between two donations is 2 months in 12 countries, between 2-3 months in three countries, and 3 months in 11 countries.

The annual frequency of whole blood donations ranges from two to four for female donors and from four to six donations for male donors. In Italy, females are allowed to donate only twice per year. In Austria, it is not the number of donations that is regulated by law but the maximum volume to be collected per year, which is 3,000 mL/year for men, 2,000 mL/year for women before the menopause and 3,000 mL/year for post-menopausal women. In Belgium, a fifth donation is allowed by law in case of special medical need.

Question 5

What is the acceptable range for the volume of whole blood donations? If possible, please specify both the volume of the unit and volume of the blood collected for laboratory testing.

Most participants (18/26) reported the target volume of 450 mL, while an additional 10-40 mL are collected for laboratory testing. The data are summarised in Table II.

Table II - Donation interval, frequency and volume.

Country	Reporting level	Interval[1]		Donations/year		Volume collected (mL)	
		Females	*Males*	*Females*	*Males*	*Units*	*Samples*
Austria	National	8 weeks	8 weeks	-	-	450±10%	40
Belgium	National/Institutional*	2 months	2 months	4	4	max 470*	max 30*
Bulgaria	National	2 months	2 months	4	5	450±10%	17
Croatia	National	4 months	3 months	3	4	450±10%	35
Cyprus	National	120 days	90 days	3	4	450±10%	≤10
Chech Republic	Institutional	10 weeks	10 weeks	4	5	450 target	max 20
Denmark	Regional	90 days	90 days	4	4	450±10%	approx. 40
Estonia	National	2 months	2 months	4	6	450±10%	approx. 35
Finland	National	91 days	61 days	4	6	465 target (415-515)	30
France	National	8 weeks	8 weeks	4	6	max 500 (not >13% TBV)	30-40
Germany	Regional	56 days	56 days	4	6	target 500	max 30
Greece	National	2 months	2 months	3-4	4-6	450±20	20-30
Italy	Local	90 days	90 days	2	4	450 target	max 40
Latvia	National	9 weeks	9 weeks	4	6	450	35
Lithuania	National/Institutional*	2 months	2 months	4	6	405-495*	20*
Luxembourg	National	4 months	3 months	3	4	500±10%	30
Malta	National	4 months	3 months	3	4	475±10%	10-15
Netherlands	National	8 weeks	8 weeks	3	5	450-550	30
Poland	National	8 weeks	8 weeks	4	6	450±10%	approx. 40
Portugal	Local	4 months	3 months	3	4	450±10%	35
Romania	Institutional	90 days	70 days	4	5	450±10%	approx. 18
Slovakia	National	4 months	3 months	3	4	450 target	25
Slovenia	National	4 months	3 months	3	4	450±10%	23
Spain	Regional	2 months	2 months	3	4	411-495	24
Sweden	National	12 weeks	12 weeks	3	4	450±10%	no data
United Kingdom	National	12 weeks	12 weeks	7 times in 2 years (advise)		475±10%	20-35

[1]: Data reported as per individual contributions; *Institutional data; TBV: total blood volume.

Question 6

Do you routinely use a ferritin test (or another appropriate test -in this case please specify) in assessing donor iron stores? If so, what algorithm are you using for detecting/monitoring iron deficiency (please describe briefly)? Please provide information on the frequency of iron deficiency detected in male and female donors. If not used routinely, are you aware of any research on donor iron stores in your country?

Ten participants reported varying degrees of ferritin testing. In Denmark, the Czech Republic and Italy ferritin is measured to a greater extent. In Denmark (regional data) ferritin testing is performed in all first time donors, on every tenth donation and in the case of previously low or high ferritin or haemoglobin. In the Czech Republic (institutional data), ferritin is measured in all new blood donors and in selected cases of repeat donors. In Italy (local data), ferritin is measured once yearly in regular donors, while in Cyprus different tests are performed once a year (complete blood count, iron, ferritin).

In seven countries (Austria, Croatia, France, Malta, The Netherlands, Portugal and UK) research on donor iron stores has been carried out or is in progress.

Question 7

Please describe briefly how you are managing donors with iron deficiency (donation intervals, future donations, counselling, dietary advice, treatment, etc.)

The most common answers to this question were: referral of donors to a general practitioner/specialist, donor deferral and prolongation of the donation interval, followed by donor counselling and giving dietary advice. Five participants reported determination of iron stores.

Iron supplementation practices were investigated further in the next question.

Question 8

If iron supplementation is given, please specify:

- whether the therapy is given orally or intravenously;
- who bears the costs of the iron therapy.

Respondents from 14 of the 26 countries reported the use of iron supplementation to varying degrees. Supplemental iron is administered orally, and, in most cases, the costs are covered by blood transfusion services.

Haematocrit measurements are not routine practice in donor selection in member states of the European Union. In Austria, haematocrit measurements are allowed but seldom performed (reference value for males is 0.4 and for females 0.38). In Denmark (regional data), if the haematocrit is >0.52 on two occasions, the donor is referred to a general practitioner or haematologist. For plasmapheresis the haematocrit should be <0.50, as long as the haemoglobin concentration is in the acceptable range.

Conclusion

Overall, the results indicate still limited use of non-invasive methods for determining blood donors' haemoglobin concentration and the predominance of photometric measurements in capillary blood samples. Minimum haemoglobin levels to donate blood and blood components are nearly identical among member states, which is not surprising given the corresponding requirements in the European Union Directive 2004/33/EC. However, clear differences exist when comparing the minimal intervals between whole blood donations and the maximum number of donations that can be collected annually. This may explain, at least partially, the different rates of donor rejections due to the low haemoglobin. Despite the great interest of professionals in this topic, relatively few studies have been conducted to investigate iron stores in blood donors in the European Union. Although 38% of participants use ferritin measurement, this method is implemented on a larger scale in only three countries. Although a majority of participants (14/26) use supplementation as a means to manage iron deficiency in blood donors, there are important differences in the approaches to administering supplementary iron to prevent or correct iron deficiency.

It would be useful to organise a consensus conference and issue guidelines to facilitate decision-making on the assessment, prevention and treatment of iron deficiency in blood donors. It is to be hoped that the results of this international forum will serve as an incentive for such an initiative.

The individual contributions from the 26 countries are presented below.

The Authors declare no conflict of interests.

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Guest Editors
Karen Magnussen
Centre for Donor Haemoglobin and Iron,
Copenhagen University Hospital, Rigshospitalet
Blood Centre sec 231 - Hvidovre Hospital
2650 Hvidovre, Denmark
e-mail: Karin.Magnussen@regionh.dk

Wim de Kort
University of Amsterdam
Department of Public Health
Amsterdam, the Netherlands
e-mail: w.dekort@sanquin.nl

Gilles Folléa
Établissement Français du Sang
La Plaine St. Denis, France
e-mail: Gilles.Follea@efs.sante.fr

International Forum Editor
Tomislav Vuk
Associate Editor Blood Transfusion
Croatian Institute of Transfusion Medicine
Petrova 3, 10000 Zagreb, Croatia
e-mail: tomislav.vuk@hztm.hr

Individual contributions

AUSTRIA

Introduction

Austria has nine federal states and 8,474,00 inhabitants (2013 census). The population of the federal states determines the size of the ten regional blood centres. The Red Cross started its first blood donation service in 1950. Since then 95% of blood donations have been carried out by the Red Cross. Approximately 60% of the annual 300,000 to 340,000 whole blood units are further prepared and tested in Red Cross blood centres. The remaining 40% are produced in hospitals, of which two sites are university institutes, one site a hospital-based institute in close relationship with a medical university and the remaining three sites are hospital-based centres[1]. The following statements refer to the situation in the whole of Austria.

Question 1 (Hb determination in donor selection)

Until 2012 Hb tests on Austrian blood donors were mostly performed using capillary blood gained by finger or ear sticks. In 2012 the Central Institute of Blood Transfusion in Innsbruck implemented the non-invasive Hb measurement method NBM 200 (OrSense ltd, NesZiona, Israel). The system was validated against an automated haematology cell analyser (Sysmex XS-1000i, Cobe, Japan) serving as a gold standard and was also compared to the invasive method in use (HemoCue®). After intensive training of the personnel, specificity of the system was 97.6% and sensitivity 98.6% with regard to the reference values, correlation to the gold standard was 0.761 for both methods, invasive and non-invasive (data presented as poster at the AABB annual meeting 2012). In 2015 the majority of the Austrian blood donor services changed to non-invasive methods. Two devices were in use: NBM 200 and Haemospect®(MBR Optical Systems, Wuppertal, Germany). Because of recent problems with the sensitivity and specificity of the Haemospect® system in 2016 users of this system changed back to invasive methods. One blood centre still takes intravenous blood samples drawn from the connector of the blood bag system and testing is performed by an automated haematology cell analyser. Tests giving grey-zone results or implausible results (obvious difference between the donor´s clinical appearance and Hb value or results of previous measurements) are repeated on site and, if necessary, confirmed by an automated haematology cell analyser in the blood establishment or in a specialised laboratory.

Question 2 (Minimum Hb levels)

According to the Blood Safety Act 1999[2] and the Blood Donor Order 1999[3] all blood donors must be tested on signs of anaemia. This must be done before the donation using a test measuring the Hb value. World Health Organisation reference values for cellular components and single unit red cell apheresis donors are 125 g/L for female donors and 135 g/L for male donors. For double unit red cell apheresis donations a minimum Hb level of 140 g/L is required for both sexes. For plasma the reference value for both sexes is 120 g/L. Haematocrit measurement is also allowed but is seldom performed (reference value for men: 0.4 and for women: 0.38).

Question 3 (Donor deferral rate for low Hb)

Exact numbers are not available, but the deferral rate is estimated to be in the range of less than 1%, including a high proportion of pre-menopausal women.

Question 4 (Donation intervals and frequencies)

The minimal interval between two whole blood donations for both female and male donors is 8 weeks. It is not the number of donations that is regulated by law but the maximum volume to be collected per year: men, 3,000 mL/year; women before menopause, 2,000 mL/year; and women after the menopause 3,000 mL/year.

Question 5 (Volume of whole blood donations)

The standard volume of whole blood collected is 450 mL±10%. Another 40 mL are drawn for testing by use of the device´s sampling bag.

Question 6 (Assessment of iron stores)

Routine measurement of ferritin or a comparable test is not mandatory in Austria. In 2013, for her master's thesis, Schuessler S enrolled 2,594 whole blood donors from the Austrian federal state Upper Austria. All of them had appropriate Hb levels and were tested for ferritin, transferrin saturation and various red blood cell indices. The overall prevalence of iron deficiency in this donor population was 22.8%: pre-menopausal women were iron deficient in 39.1% of cases and post-menopausal women in 23.6% of cases. The odds ratio for being iron deficient between female and male donors was 3.76. Men who donated more than four times per year showed a statistically significant higher prevalence of iron deficiency than men who made fewer donations.

Question 7 (Managing donors with iron deficiency) and Question 8 (Iron supplementation)

Donors who attract attention because of symptoms or low Hb levels undergo testing of their iron stores. If the results are outside the normal range the donor is first excluded from further donations and then referred to a general practitioner or a specialist in internal medicine. In most cases the donor will undergo more extensive investigation, followed by iron supplementation with oral or intravenous iron, usually prescribed by the general practitioner and only rarely by a specialist in transfusion medicine in the blood establishment. The Austrian health and welfare system bears the cost of the iron supplementation.

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Contact details
Harald Schennach
Central Institute for Blood Transfusion and Dept. of Immunology
Tirol Kliniken GmbH www.tirol-kliniken.at
Anichstrasse 35
6020 Innsbruck, Austria
e-mail:harald.schennach@tirol-kliniken.at

BELGIUM

The data reported refer to the national or institutional level.*

Question 1 (Hb determination in donor selection)

Belgian law prescribes that total blood counts, including Hb levels, should be determined at each donation (pre- or post-donation). Venous samples are collected by way of the integrated sample pouch. In mid-2015 a capillary method for Hb measurement (Compolab TS haemoglobin screening device, Fresenius Kabi) was added before collection for all new donors and for repeat donors with a low Hb level at the previous donation.

Question 2 (Minimum Hb levels)

In accordance with Directive 2004/33/EC, Belgian Law details that the minimal acceptable levels of Hb for whole blood and cellular components collected by apheresis should be 125 g/L for female donors and 135 g/L for male donors. A higher minimum Hb concentration of 140 g/L is required for double unit red cell apheresis. The minimum value for plasmapheresis is 120 g/L for female donors and 130 g/L for male donors. At present no red cells are collected by apheresis.

Question 3 (Donor deferral rate for low Hb)

Overall in 2014, 5.74% of whole blood donors were deferred because of low Hb levels (9.1% of female donors and 2.8% of male donors)*.

Question 4 (Donation intervals and frequencies)

Donors are allowed to donate whole blood four times a year. The interval between two whole blood donations should not be less than 2 months. No difference is made between males and females. In case of special medical needs, a fifth whole blood donation is allowed by law.

Question 5 (Volume of whole blood donations)

The maximum volume collected must not exceed 13% of the donor's estimated total blood volume, with a maximum of 500 mL per donation. At our Blood Service the maximum volume is 470 mL. In addition, up to 30 mL are collected for laboratory tests by way of the in-line diversion pouch.

Question 6 (Assessment of iron stores)

At present no tests to assess donor iron stores are in use and we are not aware of any such tests in Belgium.

Question 7 (Managing donors with iron deficiency)

Iron deficiency is indicated as a possible long-term adverse effect in our educational material given to all donors. In this material, special attention is given to female donors in their fertile period. Donors with a low venous Hb level are informed and referred to their physician for follow-up. At the next donation, these donors are screened before donation using a capillary method and dietary advice is given on how to prevent this in the future.

Question 8 (Iron supplementation)

A Ministerial Decree permits the supplementation of iron for female whole blood donors in the fertile age group. At our blood service a blister of 15 tablets containing 105 mg Fe^{++} per tablet is provided. The costs are borne by the Blood Service.

Contact details
Giovani Vandewalle
Belgian Red Cross-Flanders, Blood Services
Ottergemsesteenweg 413, B-9000 Ghent, Belgium

Veerle Compernolle
Faculty of Medicine and Health Sciences, Ghent University, Ghent
Belgian Red Cross-Flanders, Blood Services
Ottergemsesteenweg 413, B-9000 Ghent, Belgium
e-mail: veerle.compernolle@rodekruis.be

BULGARIA

The data reported refer to the national level.

Question 1 (Hb determination in donor selection)

An invasive method is applied to determine Hb levels. Only one method is used, the microcuvette method (HemoCue® system).

Question 2 (Minimum Hb levels)

- Whole blood: males ≥135 g/L; females ≥125 g/L;
- platelets/plasma: males ≥135 g/L; females ≥125 g/L;
- red cells by apheresis: red cells are not collected by apheresis.

Question 3 (Donor deferral rate for low Hb)

No data available.

Question 4 (Donation intervals and frequencies)

- Males: maximum five donations in a 1-year period; the minimal interval between whole blood donations is 2 months.
- Females: maximum four donations in a 1-year period; the minimal interval between whole blood donations is 2 months.

Question 5 (Volume of whole blood donations)

The accepted range of volume of a unit of whole blood is 450 mL±10%.

The volume of blood collected for laboratory testing is 17 mL.

Question 6 (Assessment of iron stores)

Ferritin is not measured and other tests are not performed.

Question 7: (Managing donors with iron deficiency)

When the Hb level is below the limit we apply the following measures:

- prolongation of donation interval;
- dietary advice;
- referral to general physician.

Question 8 (Iron supplementation)

Iron supplementation is not provided by blood transfusion services.

Contact details

Natalia Masharova
National Centre of Transfusion Haematology
112 "BratyaMiladinovi"str. 1202
Sofia, Bulgaria
e-mail: Nathalie_54@abv.bg

CROATIA

The data reported refer to the national level.

Question 1 (Hb determination in donor selection)

In Croatia, routine Hb screening in blood donors is performed before donation, mainly using an invasive method. In 2014, a copper sulphate test was used for 83% of donors, a further 3% were tested using the HemoCue® photometer. A non-invasive method (Hemospect®) was used in the remaining 14% of donors (one centre), but its use was interrupted in 2015. Hb in venous blood is determined as part of the complete blood count in donors participating in an apheresis programme. On rare occasions, Hb is determined in venous blood as part of different studies and validations. In all such cases samples are taken from the sampling pouch integrated in the collection system.

Question 2 (Minimum Hb levels):

To donate whole blood or platelets/plasma using apheresis technology, the Hb level should be at least 125 g/L for female and 135 g/L for male donors. At present, red cells are not collected by apheresis in our country.

Question 3 (Donor deferral rate for low Hb)

In 2014 the total rate of deferrals because of low Hb was 5.64% on the national level. The deferral rate was higher for female donors (15.9%) than for male donors (3.24%). All values are calculated as percentages of presenting donors.

Question 4 (Donation intervals and frequencies)

The minimum interval between whole blood donations is 3 months for male and 4 months for female donors. It is acceptable for both male and female donors to donate blood up to 7 days prior to the above mentioned periods. Accordingly, the maximum number of donations is four per year for male and three per year for female donors.

Question 5 (Volume of whole blood donations)

The acceptable range for the volume of whole blood donations is 405-495 mL (450 mL±10%) plus approximately 35 mL of blood in the diversion pouch used to collect samples for laboratory testing.

Question 6 (Assessment of iron stores)

No additional tests for the assessment of donor iron stores are in use so far. However, extensive research on iron status in Croatian blood donors was completed recently and the data obtained will be used to decide on the implementation of ferritin measurement.

Question 7 (Managing donors with iron deficiency)

Donor deferral and counselling are currently the routine measures at our blood establishments.

Question 8 (Iron supplementation)

No iron supplementation is prescribed at donor sessions.

Contact details

Tomislav Vuk
Quality Assurance
Croatian Institute of Transfusion Medicine
Petrova 3, 10000 Zagreb, Croatia
e-mail: tomislav.vuk@hztm.hr

CYPRUS

The data reported refer to the national level.

Question 1 (Hb determination in donor selection)

We apply an invasive method for routine donor Hb screening. A small drop of capillary blood is taken from the finger of a potential blood donor. The Hb concentration is

determined through a photometric method. This method uses a digital haemoglobinometer, which is a portable, battery-operated photometric device based on determination of azide methaemoglobin. This method is implemented on a national level always before a blood donation. Venous blood is only taken in the case of platelet donors before the apheresis procedure in order to run a full blood count. A separate puncture is done before the apheresis procedure itself.

Question 2 (Minimum Hb levels)

For whole blood and platelet/plasma donations, the minimum Hb levels are 13.5 g/dL for males and 12.5 g/dL for females.

Red cell apheresis is not performed in our blood centres.

Question 3 (Donor deferral rate for low Hb)

The total donor deferral rate for 2014 was 14%; in 5% of cases the deferral was due to low Hb level for both men and women. The deferral rate for women was 4%, while that for men was 1%. Thirty-seven percent of all deferrals (men and women) were because of low Hb levels.

Question 4 (Donation intervals and frequencies)

The minimal interval between whole blood donations is: 90 days for males and 120 days for females.

The maximum number of donations that can be collected in a 1-year period is four for males and three for females.

Question 5 (Volume of whole blood donations)

The volume of a unit of whole blood is 450 mL±45 (10%). The volume of blood for laboratory testing is ≤10 mL.

Question 6 (Assessment of iron stores)

Blood donors are offered a set of blood tests once a year and these include a full blood count, iron levels, ferritin levels and iron-binding capacity. Based on these results, blood donors are temporarily deferred from donation in the case of low iron and ferritin levels and are also advised on how to increase these parameters. The frequency of iron deficiency detected is approximately 7% in male donors and 15% in female donors.

Question 7 (Managing donors with iron deficiency)

Donors with iron deficiency are:

- temporarily deferred for 3 months, depending on their iron levels;
- future donations are postponed until iron levels return to normal;
- advised to increase their dietary iron intake by consuming specific groups of food;
- advised to start on oral iron supplementation for 3 months at least, if necessary;
- counselled and referred to their general practitioner (GP), in the case of any other blood loss or serious iron deficiency and anaemia.

Question 8 (Iron supplementation)

Iron supplementation is given orally. The blood donor bears the cost of iron therapy. The blood transfusion service does not prescribe iron supplementation, blood donors are referred to their general practitioners.

Comments and suggestions

We are interested in collecting some background information concerning the non-invasive methods for Hb estimation.

Contact details

Karakatsiani Georgia
Isabella Argyrou
Cyprus Blood Establishment
Nicosia General Hospital Nicosia
Limassol Old Road No. 215,
2029 Strovolos, Nicosia, Cyprus

CZECH REPUBLIC

The data reported refer to the Transfusion Department, University Hospitál Hradec Králové (annually 20,000 whole blood donations, 15,000 aphereses).

Question 1 (Hb determination in donor selection)

a) Whole blood first-time donors (6%):
   - complete blood count before donation;
   - invasive-venous blood.

b) Whole blood regular donors (94%):
   - Hb before donation (HemoCue®);
   - invasive-capillary blood + post-donation complete blood count from the tube withdrawn at the beginning of the whole blood donation.

c) Apheresis donors (plasma, platelets):
   - non-invasive, complete blood count is measured from the tube withdrawn at the beginning of the procedure (apheresis donors are "qualified" donors, never first-time donors).

d) Red cell apheresis = b) (never first-time donors).

Question 2 (Minimum Hb levels)

- Whole blood: males ≥135 g/L, females ≥125 g/L;
- plasma/platelets by apheresis: males ≥130 g/L, females ≥120 g/L;
- double red cell apheresis: males and females ≥141 g/L.

Question 3 (Donor deferral rate for low Hb)

In 2014 the donor deferral rates for low Hb were 1.40% among female donors and 0.24% among male ones.

Question 4 (Donation intervals and frequencies)

The minimum donation interval is 10 weeks for both male and female donors.

Males may donate a maximum of five times/year, female a maximum of four times/year.

Question 5 (Volume of whole blood donations)

The volume of a whole blood donation from both males and females is 450 mL + a maximum of 20 mL (from the satellite bag) for testing.

Question 6 (Assessment of iron stores)

Ferritin levels are determined in:

- all first time donors;
- repeat donors;

in the case of an unexpected drop of Hb, for the donation subsequent to a delivery (female), and for donors undergoing double red cell apheresis.

Question 7 (Managing donors with iron deficiency)

All donors with iron deficiency are given dietary advice and counselling, their next donations are postponed and they can make a maximum of one or two whole blood donations/year. Iron supplementation is given p.o. In the case of severe iron deficiency/anaemia, the individual is referred to the Haematology Department.

Question 8 (Iron supplementation)

Oral iron supplementation is given.

The costs are borne by the Transfusion Department. In the case of severe iron deficiency anaemia with referral of the donor to the Haematology Department, the expenses are covered by health insurance.

Contact details

Vít Řeháček
Transfusion Department,
University Hospital Hradec Králové
Sokolská 581
500 05 Hradec Králové, Czech Republic
e-mail: rehacekv@lfhk.cuni.cz

DENMARK

The data reported refer to regional data, from the Capital region in Denmark.

Question 1 (Hb determination in donor selection)

An invasive method is used to determine the donors' Hb.

An EDTA sample is taken from the pre-sample bag. The sample is sent to the Centre for Donor Haemoglobin and Iron, where it is analysed on a Sysmex XE2100-D (Sysmex Europe GmbH, Norderstedt, Germany) within 24 hours. If the Hb at the previous donation was low, the Hb is measured on a venous sample taken from the pouch, or directly from the arm and measured immediately on a PocH100i (Sysmex Europe GmbH, Norderstedt, Germany), and the donor is then only bled if the Hb is at least 7.8 mmol/L (125 g/L) for female donors and at least 8.4 mmol/L (135 g/L) for male donors. The donors whose Hb is measured pre-donation on the PocH100i will all have a control measurement on the Sysmex XE2100-D.

The measurement is routinely available post-donation. All donors routinely have a complete blood count, and in some ferritin is also assayed, so no testing is done beyond that.

Question 2 (Minimum Hb levels)

- whole blood: female donors 7.8 mmol/L and male donors 8.4 mmol/L;
- platelets/plasma: as for whole blood, but with the possibility of approving levels down to 7.0 mmol/L (113 g/L) for female donors and down to 7.8 mmol/L (125 g/L) for male donors, only if the donors are healthy and cleared by the Donor Haemoglobin and Iron physician;
- red cells by apheresis: not applicable.

The haematocrit is measured as part of the complete blood count, but is not our primary measure. If the haematocrit is >0.52 on two occasions the donor is referred to either a general physician (GP) or haematologist. Likewise, for plasmapheresis donors the haematocrit should be <0.50 and, as long as the Hb level is acceptable, the lower the haematocrit, the better.

Question 3 (Donor deferral rate for low Hb)

In 2014 the rate for female donors was 0.84%, while that for male donors was 0.11%.

Question 4 (Donation intervals and frequencies)

The intervals and frequencies are the same for male and female donors. The minimum interval is 90 days, which is equivalent to four times in 360 days; it is, therefore, possible for a few donors to donate five times in 1 year, if they donated during the first days of January.

Question 5 (Volume of whole blood donations)

The volume of a unit of blood is 450 mL±10%; an additional 40 mL sample is used for tests.

Question 6 (Assessment of iron stores)

Ferritin is measured in first-time donors and the measurement is repeated every tenth donation. A control ferritin determination is also made when the previous ferritin or Hb was low or high. This strategy was started in a few blood banks in February 2011 but with no electronic transfer of results. From February 1st 2012 the programme was fully implemented.

Unfortunately we do not have any data on the current frequency of iron deficiency.

Question 7 (Managing donors with iron deficiency)

The same management is applied to male and female donors.

In the case of normal Hb and

- ferritin <60 μg/L: the donor is offered 20 iron tablets with future donations;
- ferritin <30 μg/L: the donor is also sent 60 iron-tablets by post.

In the case of low Hb the donor is telephoned and
- if disease is suspected, the donor is referred to the GP;
- if there is no suspicion of disease, and
  - ferritin <60 µg/L: the donor is offered 20 iron tablets with future donations,
  - ferritin <15 µg/L: the donor is sent 100 iron tablets by post
  - ferritin 15-40 µg/L: the donor is sent 60 iron tablets by post
  - ferritin >40 µg/L or not done: the donor is almost always referred to the GP.

Question 8 (Iron supplementation)

Iron supplementation is given orally, either as ferrous fumarate (100 mg iron) with vitamin C, or as bisglycinate with 25 mg iron.

The blood centre bears the cost of the iron therapy.

Contact details
Karin Magnussen
Centre for Donor Haemoglobin and Iron
Copenhagen University Hospital, Rigshospitalet
Blood Centre sec 231 - Hvidovre Hospital
2650 Hvidovre, Denmark
e-mail: Karin.Magnussen@regionh.dk

ESTONIA

The data reported refer to the national level.

Question 1 (Hb determination in donor selection)

We apply an invasive method for routine donor Hb screening. We measure the level of Hb in donors' capillary blood (finger stick blood samples) using a Hb analyser. We do not use two or more screening methods. We do not use venous blood to assess donors' Hb concentration.

Question 2 (Minimum Hb levels)
- Whole blood: females 125 g/L, males 135 g/L;
- platelets/plasma: females 125 g/L, males 135 g/L;
- red cells by apheresis: females 140 g/L, males 140 g/L.

Question 3 (Donor deferral rate for low Hb)

In 2014 the donor deferral rate due to a low Hb was 7.2%.

Question 4 (Donation intervals and frequencies)

The minimal interval between whole blood donations is 2 months. The maximum number of whole blood donations that can be collected from male donors in a 1-year period is six and from female donors is four.

Question 5 (Volume of whole blood donations)

The volume of the unit is 450 mL±10%; the volume of the blood collected for laboratory testing is approximately 35 mL.

Question 6 (Assessment of iron stores)

We do not measure ferritin; as of present we do not have any research on donor iron stores in our country.

Question 7 (Managing donors with iron deficiency)

We advise an iron-rich diet, use donor deferral and extend donation intervals. If the Hb level is very low or the low Hb lasts a long time, we recommend that the donor contacts his or her physician).

Question 8 (Iron supplementation)

We do not administer iron to donors.

Contact details
Gulara Khanirzajeva
North Estonia Medical Centre's Blood Centre
Collection and Production Department
2 Ädalastr
10614 Tallinn, Estonia
e-mail: Gulara.Khanirzajeva@regionaalhaigla.ee

FINLAND

The data reported are provided by the Finnish Red Cross Blood Service.

Question 1 (Hb determination in donor selection)

Before every donation, a finger stick capillary blood sample is analysed with the point-of-care HemoCue® Hb201+ system.

A venous blood sample is used for blood count testing in deferred donors, when their Hb level in the screening test is <115 g/L (females) or <125 g/L (males).

Question 2 (Minimum Hb levels)

The minimal acceptable level of Hb in males (for all types of donation) is 135 g/L.

The minimal acceptable level of Hb in females (for all types of donation) is 125 g/L.

Question 3 (Donor deferral rate for low Hb)

The deferral rate due to a low Hb level in 2014 was 1.5% in males and 4.1% in females.

Question 4 (Donation intervals and frequencies)

The maximum number of whole blood donations per year for male donors is six, with a minimum interval between donations of 61 days.

The maximum number of whole blood donations per year for female donors is four, with a minimum interval between donations of 91 days.

Question 5 (Volume of whole blood donations)

The targeted volume in whole blood collection is 465 mL; the acceptable range of volume is 415-515 mL (+ 30 mL sample for the laboratory testing).

Question 6 (Assessment of iron stores)

We do not measure ferritin or other iron markers in donors.

Question 7 (Managing donors with iron deficiency)

We counsel donors with low Hb and send them to their own physicians and we provide educational material to all female donors in the age range of 18-50 years and all donors donating every fourth month or more frequently. In 2015 we started a cohort study, FIN Donor 10 000 with the goals of: (i) identifying/discovering the health effects of blood donation in the Finnish donor population, particularly with regards to iron status; and (ii) promoting the health of donors and preventing adverse events/effects, again mainly in relation to iron status.

Question 8 (Iron supplementation)

We provide iron supplementation to all female donors in the age range of 18-50 years and all donors donating every fourth month or more frequently. The first choice is HemoJern®(LongoVital, Lynge, Denmark) (dietary supplement) (350 mg hemoglobinpulver and 25 mg ferrous fumarate) (20 tablets): 1-3 tablets/day. The second choice is Retafer (ferrous sulfate, Fe^{++}) 100 mg, (30 tablets): 1-2 tablets/day. The Finnish Red Cross Blood Service bears the costs for iron supplementation.

Contact details

Johanna Castrén

Medical Support in Blood Donation - Finnish Red Cross Blood Service

Kivihaantie 7

FI-00310 Helsinki, Finland

e-mail: johanna.castren@bloodservice.fi

FRANCE

The data reported refer to the national level.

Question 1 (Hb determination in donor selection)

a) Hb is assessed on a capillary sample before donation in the following conditions:
   - first donation;
   - last donation more than 2 years previously;
   - Hb near the threshold (≥12 and ≤12.5 g/dL for women and ≥13 and ≤13.5 g/dL for men) at the previous donation;
   - Hb below the threshold (<12 g/dL for women and <13 g/dL for men) at the previous donation;
   - physician order (clinical symptoms of anaemia).

b) Hb is measured as part of a blood cell count on a sample from each donation (results available after donation). Invasive method.

   A HemoCue® photometer is used to test the capillary samples.

Proportion of different methods:

- predonation testing: 21% of candidates;
- blood count: 100% of donations.

Use of venous blood

Venous blood is tested immediately pre-donation in the case of low Hb with the capillary test; in addition, a venous blood cell count including Hb concentration is determined for each donation.

Question 2 (Minimum Hb levels)

- Whole blood: 12 g/dL (females); 13 g/dL (males);
- platelets/plasma: 12 g/dL (females); 13 g/dL (males);
- red cells by apheresis: 14 g/dL (males and females).

Question 3 (Donor deferral rate for low Hb)

In 2014, the donor deferral rate due to low Hb was 1.82% for men and 4.81% for women.

Question 4 (Donation intervals and frequencies)

The minimum donation interval is 8 weeks for both male and female donors.

In a 1-year period, male donors may donate up to six times, and female donors up to four times.

Question 5 (Volume of whole blood donations)

The amount of whole blood collected must not exceed 13% of the total blood volume, and in any case must not exceed 500 mL, blood samples not included.

The volume collected for blood samples for laboratory testing ranges between 30 and 40 mL.

Question 6 (Assessment of iron stores)

Ferritin is only measured at the first donation of red blood cells by apheresis, and must be higher than 20 ng/mL to authorise further blood cell apheresis donations.

The French Blood Establishment (EFS) is willing to investigate studies about blood donor management on this subject.

A study of the impact of donation frequency and Hb threshold is ongoing. The EFS is implementing an iron deficiency study in French overseas areas (the islands of Martinique and Guadeloupe).

Question 7 (Managing donors with iron deficiency):

Donors with a low Hb are deferred for 6 months and advised to consult their doctor. The similar management is applied in the case of iron deficiency.

Question 8 (Iron supplementation)

Not applicable.

Contact details

Bruno Danic

Etablissement Français du Sang Bretagne

rue Pierre Jean Gineste

35016 Rennes CEDEX, France

e-mail: bruno.danic@efs.sante.fr

Rachid Djoudi
Geneviève Woimant
Etablissement Français du Sang
20 Avenue du Stade de France
93218 La Plaine Saint Denis, France

GERMANY

The data reported refer to the regional level (17 institutes for transfusion medicine and their mobile teams).

Question 1 (Hb determination in donor selection)

An invasive method, the Haemocue® (Hb Donor Checker) is used. Venous blood is not used.

Question 2 (Minimum Hb levels)

- Whole blood: males: ≥13.5 g/dL females: ≥12.5 g/dL;
- platelets/plasma: males: ≥13.5 g/dL females: ≥12.5 g/dL;
- red cells by apheresis: this is not done routinely. The minimum body weight of donors for red cell apheresis is 70 kg; the minimum Hb levels are identical to whole blood.

Question 3 (Donor deferral rate for low Hb)

The donor deferral rate for low Hb is approximately 2%.

Question 4 (Donation intervals and frequencies)

The minimum interval is 56 days. The maximum number of donations for males is 6 times/year, whereas for females it is 4 times/year.

Question 5 (Volume of whole blood donations)

The volume of donated blood is 500 mL, plus a maximum of 30 mL for laboratory testing.

Question 6 (Assessment of iron stores)

Iron stores are not assessed.

Question 7 (Managing donors with iron deficiency)

Donors with iron deficiency are given dietary advice; if regular donors (>2 donations/year), they are given iron supplementation, if they accept this.

Question 8 (Iron supplementation)

Oral iron supplementation is supplied. The blood donor service bears the cost of this supplementation.

Contact details

Markus M. Mueller
Department Head Blood Donation
Institute for Transfusion Medicine and Immunohaematology
University Clinics of the Johann Wolfgang Goethe University Frankfurt/Main
German Red Cross Blood Transfusion Service Baden-Wuerttemberg -Hessen
Sandhofstrasse 1
60528 Frankfurt/Main, Germany
e-mail: m.mueller@blutspende.de

GREECE

The data reported refer to the national level.

Question 1 (Hb determination in donor selection)

Hb is determined by an invasive method. Only one blood establishment has been using a non-invasive method.

Use of capillary blood to assess the donors' Hb concentration: finger stick and a spectrophotometric method with portable devices (Hemocue®).

Venous blood is used for the examination of Hb using haematology analysers for aphaeresis donors and in some females donating for first time.

Question 2 (Minimum Hb levels)

- Whole blood: males ≥13.5 g/L, females ≥12.5 g/L;
- platelets/plasma: males ≥ 13.5 g/L and females ≥12.5 g/L;
- red cells by apheresis is rarely performed: males ≥13.5 g/L.

Question 3 (Donor deferral rate for low Hb)

Data not nationally available. In large centers this rate is less than 3%.

Question 4 (Donation intervals and frequencies)

The minimum interval between whole blood donations is 2 months for male and female donors.

The maximum number of donations that can be collected from male donors in 1 year is four to six and for female donors three or four if the Hb screening is normal.

The interval between a 2 units red cell apheresis must be 4 months for males.

Question 5 (Volume of whole blood donations)

The acceptable range for the volume of one unit of donated whole blood donation is 450±20 mL. The volume of the blood collected for laboratory testing ranges from 20 to 30 mL depending of the method in use at the various blood establishments.

Question 6 (Assessment of iron stores)

We do not routinely measure ferritin level as a pre-donation test.

Question 7 (Managing donors with iron deficiency)

Donors with low hemoglobin are advised to increase donation intervals. Donors with iron deficiency are referred to their physicians. They are accepted again as donors after complete recovery of the iron deficiency.

Question 8 (Iron supplementation)

Iron therapy in mostly administered orally. It is administered intravenously only if there is a contraindication to oral administration. Iron supplementation is prescribed by the physician of the blood transfusion service. The costs are covered by the blood donors' insurance fund.

Contact details
Constantina Politis
Hellenic Center for Disease Control and Prevention (H.C.D.C.P.)
Hellenic Coordinating Haemovigilance Centre (SKAE)
10 Averof Str.
10433 Athens, Greece
e-mail: cpolitis@keelpno.gr

ITALY

The data reported refer to the local level.

Question 1 (Hb determination in donor selection)

We apply an invasive method for routine donor Hb screening. The most common method used is a finger prick test. Data are not available on the proportion of different methods.

We routinely use venous blood to assess pre-donation Hb by taking the sample from the sampling pouch at the beginning of the donation (results available after the donation), and occasionally before donation if the finger prick test is indicative of a low pre-donation Hb concentration.

Question 2 (Minimum Hb levels)

- Whole blood: the minimum Hb level for male donors to donate is 135 g/L, while the minimum for female donors is 125 g/L;
- platelets/plasma: when the interval between two plasma aphereses is more than 90 days, the minimum Hb level for male donors to donate is 125 g/L and for female donors is 115 g/L. The same standards as those for whole blood donation are applied to platelet apheresis with no exceptions;
- red cells by apheresis: the minimum Hb level to undergo two-unit red blood cell apheresis is >150 g/L for both male and female donors.

In addition the minimal interval between two consecutive two-unit red blood cell aphereses or between a two-unit red blood cell apheresis and a whole blood donation is 180 days.

Question 3 (Donor deferral rate for low Hb)

Data not available.

Question 4 (Donation intervals and frequencies)

The minimal interval between two consecutive whole blood donations is 90 days equally for male and female donors, but the maximum number of donations that can be collected in a 1-year period is four from male donors and female donors of non-childbearing age and two for female donors of childbearing age.

Question 5 (Volume of whole blood donations)

The target volume of whole blood donations is 450 mL. The volume of the blood collected for laboratory testing must not exceed 40 mL.

Question 6 (Assessment of iron stores)

In accordance with Italian Law, we routinely measure serum ferritin once a year in regular blood donors to assess their iron stores.

Question 7 (Managing donors with iron deficiency)

As a first step, donors with iron deficiency are invited to lengthen the interval between whole blood donations. Iron supplementation is given only if the ferritin value declines significantly; this is not established by law but it is based on a clinical evaluation tailored on the donation programme (whole blood donation versus apheresis; male versus female).

Question 8 (Iron supplementation)

Iron supplementation is administered orally. The Italian National Health System bears the costs of the iron therapy.

Contact details
StefaniaVaglio
Dept. of Clinical and Molecular Medicine, Sapienza University of Rome
Immunohaematology and Transfusion Medicine Unit
Azienda Ospedaliera Sant'Andrea
Via di Grottarossa 1039
00189 Rome, Italy
e-mail: stefania.vaglio@uniroma1.it

LATVIA

The data reported refer to the national level.

Question 1 (Hb determination in donor selection)

An invasive method, HemoCue®, is used to determine donor Hb. Venous blood is not used.

Question 2 (Minimum Hb levels)

- Whole blood: males 135 g/L, females 125 g/L;
- platelets/plasma: males 135 g/L, females 125 g/L;
- red cells by apheresis: 140 g/L.

Question 3 (Donor deferral rate for low Hb)

The percentage of potential donors with a low Hb is 3% of males and 8.5% of females.

Question 4 (Donation intervals and frequencies)

In male donors the maximum number of donations per year is six (minimum interval, 9 weeks). In females the maximum number is four per year (minimum interval, 9 weeks).

Question 5 (Volume of whole blood donations)

The volume of a whole blood unit is 450 mL and an additional 35 mL are taken for testing.

Question 6 (Assessment of iron stores)

Iron stores are not assessed.

Question 7 (Managing donors with iron deficiency)

For donors with a low Hb level we recommend diet and at least a 1 month extension of the 9-week minimum interval between donations.

Question 8 (Iron supplementation)

Not applicable.

Contact details
Anita Daugavvanaga
State Blood Donor Centre
Str. Selpils 9
Riga, Latvia, Lv-1007
e-mail: anita.daugavvanaga@vadc.gov.lv

LITHUANIA

The data reported refer to national or institutional situations, as specified below.

Question 1 (Hb determination in donor selection)

Institutional level information (Public Institution, National Blood Centre): we use an invasive method for routine Hb screening. Only one method is used: capillary blood and a HaemoCue Hb 201 DM analyser.

We do not use venous blood for routine Hb screening. We use it for quality control, only four times per month for the whole blood donations and 30 times for filtrated red blood cells.

Question 2 (Minimum Hb levels)

National level information:

- whole blood: women 125 g/L, men 135 g/L;
- platelets/plasma: women 125 g/L, men 135 g/L;
- red cells by apheresis: women 145 g/L, men 140 g/L (we do not take red cells by apheresis in our centre).

Question 3 (Donor deferral rate for low Hb)

Institutional level information: donors are deferred for 1 month if they have a low Hb level.

With regards to 2014, among males there were 646 deferrals (1.42% of presenting donors or 0.91% of presenting donations) and among females there were 1785 deferrals (3.92% of presenting donors or 2.52% of presenting donations).

Question 4 (Donation intervals and frequencies)

National level information: the minimal interval between whole blood donations is 2 months for both males and females. The maximum number of donations that can be collected in a 1-year period from male donors is six, while the maximum number from female donors is four.

Question 5 (Volume of whole blood donations)

Institutional level information: the acceptable range for the volume of whole blood donations is 405-495 mL. The volume for laboratory testing is 20 mL.

Question 6 (Assessment of iron stores)

Institutional level information: we do not measure ferritin routinely. We are not aware of any research on donor iron stores in our country.

Question 7 (Managing donors with iron deficiency)

Institutional level information: if the Hb level is low, we defer the donor for 1 month. The doctor gives dietary advice and if necessary refers the donor to his or her GP for a full blood count and treatment.

Question 8 (Iron supplementation)

Institutional level information: we do not give iron supplementation.

Contact details
EditaVilutyte
Public Institution National Blood Centre
Zolyno 34
LT-10210 Vilnius, Lithuania
e-mail: e.vilutyte@kraujodonoryste.lt

LUXEMBOURG

The data reported refer to the national data from 2010.

Question 1 (Hb determination in donor selection)

In Luxembourg, the country's blood component needs are covered by approximately 20,000 whole blood donations, 1,000 plateletaphereses and 5,000 plasmaphereses for contract fractionation, all collected by one single blood establishment, with one fixed site and two mobile teams.

Low iron stores and iron deficiencies in blood donors have always been a concern in Luxembourg.

First-time donors are not accepted immediately for donation: they become "donor candidates". They undergo the extended medical questionnaire, by a medical doctor and blood samples are drawn (including a tube for a 15-parameter blood count) without a donation being taken.

In repeat donors, the eligibility is mainly based on haematological results of the past donations and on the recent donor history. If there is a "trigger event", a pre-donation check is performed with HemoCue® (especially in the mobile drives) and a Coulter STKS© (Beckman Coulter, Hialeah, FL, USA) (full blood count with 15 parameters in the blood centre).

At the beginning of the donation, a blood sample is collected from the diversion pouch of the collection kit to run a full blood count on the blood cell counter.

Invasive or non-invasive method

Invasive: if a pre-donation Hb test is required, a venous blood sample is taken.

Non-invasive: if no pre-donation Hb test is required, the routine testing is done using a blood sample taken from the diversion pouch of the collection kit, after venipuncture has

been performed for the purpose of the donation. See above for: before and after donation, fixed site and mobile drives.

Method specification

In general, the results of blood counts of former blood donations are the basis for donor acceptability and these data are found on the donor history file slip.

Proportion of different methods

At a national level, all procedures are the same as there is only one blood establishment in Luxembourg; two-thirds of all whole blood collections are taken in the fixed blood centre, one-third in the mobile drives. About 10-15% of donors coming to donate undergo a pre-donation Hb check, in the fixed centre with the blood counter, on the mobile drives with the HemoCue® instrument. All donations are rechecked systematically on a blood sample taken from the diversion pouch filled at the beginning of the donation (the latter is not considered invasive although there is venipuncture but for the purpose of collecting a unit of whole blood).

Use of venous blood

On all donations, a full blood count is performed on venous blood taken at the start of the donation. All haematology results are reviewed by a medical doctor. A computer programme allows for electronic selection and classification of the values of 15 haematological parameters and facilitates the work of the physician in charge of assessing a huge amount of data every day. If this evaluation gives suspicious results for a donor, additional steps may be ordered according to predefined procedures.

In cases of mild iron depletion (Hb and haematocrit are normal, but red cell morphology indices are lowered), additional ferritin and total iron binding capacity tests are performed on the existing blood sample. The red blood cell indices used are: mean corpuscular volume, mean corpuscular Hb, mean cell Hb concentration and red cell morphology index, giving the distribution curve of red blood cells).

In cases of severe iron deficiency (Hb and haematocrit are significantly lowered and the red blood cell indices are anyway abnormal), the donor is recalled and has a targeted and detailed history taken, has new blood samples drawn and gets some counselling on iron deficiency.

Question 2 (Minimum Hb levels)

- Whole blood: for female donors >125 g/L, for male donors >135 g/L;
- platelets/plasma: for female donors >115 g/L, for male donors >125 g/L;
- red cells by apheresis: this type of procedures is rarely performed as we believe that in Luxembourg it is not necessary and it is not cost-effective.

Question 3 (Donor deferral rate for low Hb)

In 2010, the overall deferral rate for whole blood donors was 6% in the blood centre and 8% on the mobile drives (temporary and permanent deferrals for any cause taken together). Of these deferrals, <10% were due to low Hb or abnormal haematology results, suspicious of iron deficiency. In that year, 17 donors were deferred permanently because of repeated Hb failures (0.63% of 2,682 permanent deferrals occurring during that year).

In 2010, the deferral rates were not separated according to whether the donors were female or male.

The data for plasma/platelet-pheresis donors are not really relevant in the present context, because these donors are selected exclusively for the plasma-/cytapheresis programme and both donor pools (whole blood and apheresis) are kept separate. These dedicated plasma donors (donating only plasma and/or platelets and plasma) are selected based on: gender (mostly female donors), low body weight (<50 kg), confirmed low iron stores, blood groups (preferentially blood groups B+ and AB+) and also donors with travel to malaria areas (during their temporary deferral from whole blood donations).

Question 4 (Donation intervals and frequencies)

For female whole blood donors, the minimum interval between donations is 4 months (with a maximum of 3 whole blood donations per year). For male whole blood donors, the minimum interval is 3 months (with a maximum of 4 whole blood donations per year).

For plasmapheresis donors, the minimum interval between donations is 1 month (with a maximum of 12 plasma donations a year).

Question 5 (Volume of whole blood donations)

Whole blood collection is standardised at 500 mL±10% plus 30 mL for blood samples.

For plasmapheresis donations, the volume is adapted to the donor's body weight and blood count (from 500 mL up to a maximum of 750 mL per plasma donation).

Question 6 (Assessment of iron stores)

Specific tests for iron reserves are not performed systematically (i.e. with each donation collected), but these tests are routine as supplementary tests in suspected cases of weakness/depletion of iron stores. A detailed algorithm is not available to this author. The frequency of iron deficiency in whole blood donors is directly reflected by and correlated with the donor deferral rates for this suspension (mostly temporary). Raw data on the iron issue in donors are available, but not used for research.

Question 7 (Managing donors with iron deficiency)

The approach for each iron-depleted donor is customised, individualised and depends on different aspects. In female

whole blood donors with iron deficiency, an initial temporary deferral for 6-12 months is applied; this may be extended according to the results of repeat testing. In relapsing cases of iron deficiency, permanent deferral is considered or, as an alternative, the donor is offered the possibility of being a plasmapheresis donor (with flexible volume collected and frequency of plasma donations).

Question 8 (Iron supplementation)

Iron supplementation is administered orally (drugs of different brands are used in order to ensure best tolerated oral treatment). If the blood centre hands over iron tablets to a donor, these are paid for by the blood centre. If a blood donor consults his doctor who prescribes iron supplement therapy, the costs for that medication is covered by the Social Security Service of Luxembourg.

Comments and suggestions

Iron deficiency in blood donors has been underestimated for a long time. The vast majority of resources have been concentrated on recipient safety, whereas donor safety was taken for granted by many. In my view, it is more than urgent to balance safety concerns and measures for donors and recipients at the same level. Iron deficiency is only one issue in the context of donor safety: others are delayed vasovagal reactions with severe accidents, protein depletion with aggressive plasmapheresis programmes, osteoporosis following repeated apheresis procedures, long-term side effects of mobilisation of peripheral progenitor cells for apheresis harvesting.

Contact details
Jean-Claude Faber
Retired Medical Director of Luxembourg Blood Services
Luxembourg
e-mail: jean.claude.faber@numericable.lu

MALTA

The data reported refer to the national level (there is only one Blood Establishment in the Maltese Islands, the Malta National Blood Transfusion Service).

Question 1 (Hb determination in donor selection)

An invasive method is used to determine Hb concentration.

A photometric method of measurement is applied to a drop of capillary blood obtained by finger prick. Venous samples are tested by a complete blood count analyser machine.

The photometric measurement of capillary blood is used for 100% of whole blood donors. Hb is assessed by a complete blood count of a venous sample in the following circumstances:

- additional testing in the case of failing an initial screen;
- pre-donation for platelet donors (a separate venipuncture for a venous sample is required for the platelet count).

Question 2 (Minimum Hb levels)

- Whole blood: males 13.5 g/dL, females 12.5 g/dL;
- platelets/plasma: apheresis platelet donations: males 13.5 g/dL, females 12.5 g/dL. Plasma is not collected by apheresis:
- red cells by apheresis: not collected.

Question 3 (Donor deferral rate for low Hb)

The total deferral rate from whole blood donation in 2014 was 24.05%. Of these deferrals, 18.52% were due to low Hb levels. This translates into 4.45% of total deferrals.

Of the total deferrals due to low Hb, 68.80% were female donors (686 donors) and 31.19% were male donors (311 donors).

Question 4 (Donation intervals and frequencies)

The minimal interval is 3 months for males and 4 months for females. The maximum number of donations in 1 year is four for males and three for females.

Question 5 (Volume of whole blood donations)

The volume of a whole blood unit is 475 mL±10%. Another 10-15 mL are collected for testing.

Question 6 (Assessment of iron stores)

Ferritin is assessed in regular donors who request other routine testing offered by the Malta National Blood Transfusion Service. However, this is not standard practice for all donors. Currently there is no formal research on this issue in Malta, although there has been some in the past few years.

Question 7 (Managing donors with iron deficiency)

Donors with iron deficiency are given dietary advice, oral iron supplementation, prescribed as necessary, and advised to leave more time between donations.

Question 8 (Iron supplementation)

Any iron supplementation is administered orally.

The donor bears the cost of iron therapy.

Contact details
Denise Borg-Aquilina
Malta National Blood Transfusion Service
G'Mangia Hill, Pietà, Malta
e-mail: denise.borg-aquilina@gov.mt

The NETHERLANDS

The data reported refer to the national level.

Question 1 (Hb determination in donor selection)

Hb is determined by an invasive method: finger stick and Hemocue®. Only this method is used.

Hb is not determined from venous blood, except for quality control purposes and special requests, e.g. piano players.

Question 2 (Minimum Hb levels)
- Whole blood: males 8.4 mmol/L, females 7.8 mmol/L;
- platelets/plasma: males 8.4 mmol/L, females 7.8 mmol/L;
- double red cells by apheresis: ≥ 8.7 mmol/L, haemochromatosis patients only.

Question 3 (Donor deferral rate for low Hb)

Females 5% deferral, males 2% deferral; mean deferral rate 3.3%.

Question 4 (Donation intervals and frequencies)

The minimal interval between donations is 56 days. Male donors can give a maximum of five whole blood donations/year, female donors can give a maximum of three whole blood donations/year.

Question 5 (Volume of whole blood donations)

The volume of a whole blood unit is 450-550 mL +30 mL collected into the deviation pouch/test tubes.

Question 6 (Assessment of iron stores)

No ferritin measurement.

Question 7 (Managing donors with iron deficiency)

Only temporary deferral or permanent deferral based on donor data and/or reduction of the maximal number of donations/year.

Question 8 (Iron supplementation)

No iron supplementation is administered.

Comments and suggestions

For the future a personalised donor interval based on previous Hb would contribute to the prevention of deferrals due to low Hb.

Contact details
Peter J.M. van den Burg
Transfusion Medicine Sanquin
Plesmanlaan 125
1066 CX Amsterdam, The Netherlands
e-mail: p.vandenburg@sanquin.nl

Arlinke Bokhorst
Medical Donor AffairsSanquin
Plesmanlaan 125
1066 CX Amsterdam, The Netherlands
e-mail: a.bokhorst@sanquin.nl

POLAND

The data reported refer to the national level.

Question 1 (Hb determination in donor selection)

Invasive or non-invasive method

Both invasive and non-invasive methods are applied for routine donor screening.

In general, a total blood count from venous blood (separate venipuncture) before donation is determined once a year in regular donors. In routine practice, the Hb concentration in repeat blood donors is determined before each donation by means of a haemoglobinometer on capillary blood or using the non-invasive method.

Method specification

We determine either Hb level or complete blood count following respective European Union Directives. Blood Transfusion Centres determine the complete blood count using haematology analysers or Hb concentration only using a haemoglobinometer. During mobile blood collections, Hb concentration is determined. The non-invasive method is performed with an optical measurement device combined with a finger-attached sensor probe. The measurement is performed directly on the donor's finger. This involves no drawing of a blood sample.

Proportion of different methods

Difficult to estimate.

Use of venous blood

Venous blood is used to assess the donor's Hb concentration pre-donation.

Question 2 (Minimum Hb levels)

The minimum Hb concentration is the same for whole blood, platelet and plasma donors and is 13.5 g/dL for male donors and 12.5 g/dL female donors. The minimum Hb concentration for donors of red cells collected by double erythroapheresis is 14.0 g/dL for men and women.

Question 3 (Donor deferral rate for low Hb)

The donor deferral rate in 2014 was 104.99/1,000 persons presenting for donation.

The donor deferral rate in 2013 was 107.43/1,000 persons presenting for donation.

Separate data for male and female donors are not available.

Question 4 (Donation intervals and frequencies)

The minimum interval for whole blood donations is 8 weeks for both males and females.

The maximum number of donations that can be collected per year is six for males and four for females.

Question 5 (Volume of whole blood donations)

The volume of blood donation is 450 mL ±45 mL and the volume for laboratory testing is approximately 40 mL.

Question 6 (Assessment of iron stores)

Iron stores are not assessed.

Question 7 (Managing donors with iron deficiency)

In the case of a Hb level below the limit we defer the donor, give dietary advice and refer the donor to his or her GP for prescription of iron supplementation and monitoring of its effect.

Question 8 (Iron supplementation)

Iron supplementation is given orally. Public funds cover the cost of this iron therapy.

Contact details
Ryszard Pogłód
Clinical Transfusion Medicine Laboratory
Department of Transfusion Medicine
Institute of Haematology and Transfusion Medicine
Indiry Gandhi 14
02-776 Warsaw, Poland
e-mail: rpoglod@ihit.waw.pl

Jolanta Antoniewicz-Papis
Institute of Haematology and Transfusion Medicine
Indiry Gandhi 14
02-776 Warsaw, Poland
e-mail: jpapis@ihit.waw.pl, j.antoniewiczpapis@gmail.com

PORTUGAL

The data reported refer to the Blood and Transplantation Centre in Coimbra.

Question 1 (Hb determination in donor selection)

Hb levels are measured invasively using the HemoCue® 301 system on capillary blood from a finger.

Hb is measured in venous blood in donors undergoing apheresis as part of the pre-donation complete blood count using a sample collected before the apheresis procedure and in first-time whole blood donors as post-donation testing of a sample from an integrated sample pouch at the beginning of the collection.

Question 2 (Minimum Hb levels)

- Whole blood: males 13.5 g/dL, females 12.5 g/dL;
- platelets/plasma: males 13.5 g/dL, females 12.5 g/dL;
- red cells by apheresis: males 13.5 g/dL females 12.5 g/dL.

Question 3 (Donor deferral rate for low Hb)

- Males: 1.11% (411/37,031) 0.54% (411/75,502);
- females: 5.49% (2112/38,470) 2.8% (2112/75,502).

Question 4 (Donation intervals and frequencies)

The minimum interval between donations for females is 4 months, who can make a total of three donations per year.

The minimum interval between donations for males is 3 months, who can make a total of four donations per year.

Question 5 (Volume of whole blood donations)

The volume of a whole blood unit is 450 mL±10%; an additional 35 mL are collected for laboratory tests.

Question 6 (Assessment of iron stores)

We do not perform routine measure of ferritin. There was a group that did some research on donor iron stores.

Question 7 (Managing donors with iron deficiency)

A donor with low Hb usually has counselling, with the suggestion to increase donation intervals and dietary advice. In repeated cases, the donor is advised to visit the family doctor.

Question 8 (Iron supplementation)

We do not prescribe iron supplements at donation sessions.

Contact details
Mario Muon
Centro de Sangue e da Transplantação de Coimbra
Quinta da Vinha Moura, S. Martinho do Bispo
Coimbra, Portugal
e-mail: Mario.chin@ipst.min-saude.pt

ROMANIA

The data reported refer to the Blood Transfusion Centre in Bihor.

Question 1 (Hb determination in donor selection)

We determine the Hb level on capillary blood from all donors, pre-donation using HemoCue® and on venous blood using a semi-automated medical device (pre- or post-donation).

Venipuncture is always performed in the case of an apheresis procedure and is performed in certain situations to compare capillary and venous Hb levels.

After the eligibility procedure (including the already mentioned ways of determining Hb) blood (for screening tests) is collected from the sampling pouch at the beginning of blood collection.

Question 2 (Minimum Hb levels)

We perform whole blood collection and platelet apheresis.

For whole blood collection, the thresholds are 12.5 g/dL for females and 13.5 g/dL for males.

For platelet apheresis:

- performed on MCS+ devices, the thresholds are 12.5 g/dL for females and 13.5 g/dL for males;
- performed on a TRIMA device, the thresholds are 12.0 g/dL for females and 13.0 g/dL for males.

Question 3 (Donor deferral rate for low Hb)

From the total number of potential donors (13,500), 1,282 were rejected (9.49%).

From the total number of rejected potential donors (1,282), 393 (30.6%) were rejected according to Hb level: 218 females (17.0%) and 175 males (13.6%).

Question 4 (Donation intervals and frequencies)

- 70 days for whole blood collection, in males (maximum 5 donations/year).
- 90 days for whole blood collection, in females (maximum 4 donations/year).

Question 5 (Volume of whole blood donations)

The volume of whole blood collected is 450 mL±10%, as indicated on blood bags.

About 18 mL of blood are collected at each donation session for laboratory testing.

Question 6 (Assessment of iron stores)

Never. I do not have any data regarding national research on iron deficiency.

Question 7 (Managing donors with iron deficiency)

We either refer the potential donors to family doctors or recommend iron substitutes; according to Hb levels and evolution we recall the potential donor, after a certain period of time, to check the Hb level and we also prolong the interval between donations.

Question 8 (Iron supplementation)

Iron supplementation is given orally, if indicated by us.

The iron supplementation is prescribed by either the blood transfusion service (when the cost is borne by the donor) or by the donor's physician (the cost is borne by the donor, or by the Health Insurance System).

Contact details
Olivia Ligia Burta
Bihor Blood Transfusion Centre
Louis Pasteur 30,
Oradea, Bihor County, Romania
e-mail: oliviaburta@yahoo.com

SLOVAKIA

The data reported refer to the national level.

Question 1 (Hb determination in donor selection)

In Slovakia, an invasive method is used for donor Hb screening before donations. The haemogram is controlled before each donation. In blood establishments venous blood is used in a Sysmex instrument and the sample is taken by separate venipuncture before donation. At mobile collection sites the Hb level is checked by Haemocue® on capillary blood, and then is re-checked on venous blood in the blood establishment by a Sysmex instrument on a sample taken from the integrated sampling pouch at the beginning of the donation.

Question 2 (Minimum Hb levels)

Minimum Hb levels for whole blood, plasma and platelet donations are 135 g/L for male donors and 125 g/L for female donors. For red cell apheresis in males, the minimum Hb level is 150 g/L.

Question 3 (Donor deferral rate for low Hb)

We do not collect data concerning the deferral rate due to low Hb level.

Question 4 (Donation intervals and frequencies)

The minimal interval between two whole blood donations is 3 months in males and 4 months in females. Males can give their blood four times/year and females three times/year.

Question 5 (Volume of whole blood donations)

We take 450 mL of blood per donation. The volume of blood for samples is about 25 mL.

Question 6 (Assessment of iron stores)

We do not routinely measure the ferritin level in donors. Donors are selected by a medical doctor in the blood establishments. The doctor has the blood count results before the donation. This physician informs the donor about the results, and asks the donor to go to his or her family doctor if there is evidence of anaemia or other blood count pathology. The blood establishment doctor can also investigate anomalies (measure ferritin, B12, folic acid) and can give iron treatment to the donor. Males are usually asked to see their doctors while females can be provided iron treatment directly in the blood establishment. In this case, the iron treatment is free and paid by the blood establishment. The donor is deferred for a certain period (6 months or 1 year) depending on the level of Hb. Practices may differ in different blood establishments. There is no legislative requirement regarding control of the ferritin level.

If a low Hb level is detected after the donation (normal Hb level before donation, but low Hb level in venous blood), the donor is informed by letter.

Question 7 (Managing donors with iron deficiency)

Donors with repeated low ferritin or Hb levels are invited to donate platelets or plasma or to decrease the frequency of donations or they are refused definitively.

Question 8 (Iron supplementation)

If iron substitution is given by a blood establishment, it is usually administered orally.

Contact details
Jana Rosochová,
Expert of the Ministry of Health in Transfusion
National Transfusion Service
Limbová 3
833 14 Bratislava, Slovak Republic
e-mail: rosochova@ntssr.sk

SLOVENIA

The data reported refer to the national level.

Question 1 (Hb determination in donor selection)

Only invasive methods are used to determine Hb. Hb concentration is determined by HemoCue® on capillary blood for whole blood and plasma donations. For platelet apheresis donations, the sample is taken by separate venipuncture before donation for a complete blood count using the Coulter method.

The Hemocue method is used in approximately 98% of cases, and the Coulter method in the remaining 2%.

Question 2 (Minimum Hb levels)

- Whole blood: males 135g/L and females 125 g/L;
- platelets/plasma: same as above;
- red cells by apheresis: not done in Slovenia.

Question 3 (Donor deferral rate for low Hb)

The rate in 2014 was approximately 30%. Separate data are not available for males and females.

Question 4 (Donation intervals and frequencies)

The minimum donation interval for males is every 3 months (4 collections) whereas for females it is every 4 months (3 collections). Donations can be made 2 weeks before the end of these intervals if the Hb level acceptable.

Question 5 (Volume of whole blood donations)

Whole blood: 450 mL±10% (theoretically 405-495 mL, but maximum value never taken in practice; in reality we only collect from 405 mL to 450 mL, especially for first-time donors and young donors).

The volume of blood taken for laboratory testing is 23 mL (standard volume into test-tubes).

Question 6 (Assessment of iron stores)

Iron stores are not assessed, but we are planning to introduce point-of-care ferritin testing in 2016 as a pilot study for some donors.

Question 7 (Managing donors with iron deficiency)

Donors with a low Hb (below 115 g/L) are referred to their GP.

For female donors with a Hb level 115-125 g/L and male donors with a Hb below 135 g/L, donation is postponed at least 1 month, and the donors are given counselling and dietary advice. No treatment is prescribed.

Question 8 (Iron supplementation)

Iron supplementation is not given.

Contact details
Polonca Mali
Blood Donor Selection and Collection Unit
Blood Transfusion Centre of Slovenia
Slajmerjeva 6
1000 Ljubljana, Slovenia
e-mail: polonca.mali@ztm.si

SPAIN

The data reported refer to the istitutional/regional level.

Question 1 (Hb determination in donor selection)

Hb is determined with an invasive method, but we are moving to a non-invasive method in January -June 2016. The copper sulphate method is used (density 1.053 for women and 1.055 for men).

Hb is determined on venous blood only when blood donors are considered as non-eligible for blood donation. In those cases complete venous testing is performed, including tests related to iron stores. When iron depletion is suspected for the first time, the donors are given the report and the recommendation to visit a GP for further investigation and iron therapy; the donor is deferred for 6 months. At the following donation a ferritin control is added to the pre-donation screening. In regular donors already studied for iron depletion, and once other reasons of blood losses have been discarded, the number of blood donations per year is adjusted to one or two depending on the individual case.

Question 2 (Minimum Hb levels)

- Whole blood: 12.5 g/dL for females and 13.5 g/dL for males;
- platelets/plasma: 12.5 g/dL for females and 13.5 g/dL for males;
- red cells by apheresis: 12.5 g/dL for females and 13.5 g/dL for males.

Blood donors with Hb below these levels can be accepted depending on the instructions of the responsible physician.

Question 3 (Donor deferral rate for low Hb)

The deferral rate for low Hb was 0.89% of all males offering to donate blood but 0.81% of male donors who had made one or more previous blood donations. The corresponding figures for females were 3.77% and 2.70%.

Question 4 (Donation intervals and frequencies)

The minimum donation interval is 2 months for both males and females with a maximum of three blood donations/year for females and four for males.

Question 5 (Volume of whole blood donations)

The volume of a whole blood unit is 411-495 mL. The volume of blood for laboratory testing is 24 mL.

Question 6 (Assessment of iron stores)

See answer to question 1.

Question 7 (Managing donors with iron deficiency)

See answer to question 1. We sometimes start iron therapy but usually the problem is resolved just by decreasing the frequency of blood donation.

Question 8 (Iron supplementation)

Iron supplementation is administered orally. The costs are borne by the Regional Health System.

Contact details

Miguel Angel Vesga
Centro Vasco de Transfusión y Tejidos Humanos (CVTTH)
Bilbao, Spain
e-mail: MIGUELANGEL.VESGACARASA@osakidetza.eus

SWEDEN

The data reported refer to the national level.

Question 1 (Hb determination in donor selection)

No blood donation is accepted from potential new donors. First, the history is taken, a physical evaluation performed and laboratory samples are collected for acceptance or deferral of the donor.

In registered donors, at blood donation the Hb is determined on a venous EDTA-blood sample taken from the sample pouch of the blood bag after the donation. Test results are available after the donation in accordance with Swedish standards. Non-invasive methods are under evaluation.

Question 2 (Minimum Hb levels)

- Whole blood: males 135 g/L or 125 g/L if taken after the donation, females 125 g/L or 115/g/L if taken after the donation;
- platelets/plasma: no difference according to the Standards;
- red cells by two-unit apheresis collection: 140g/L.

Question 3 (Donor deferral rate for low Hb)

Such data are not collected. The pre-qualification of donors leads to non-acceptance of approximately 20% of female and 4% of male applicant donors.

Question 4 (Donation intervals and frequencies)

The minimum interval is 12 weeks. The maximum numbers of blood donation per year are four for males and three for females.

Question 5 (Volume of whole blood donations)

The volume is 450 mL±10% and a maximum of 500 mL, including blood samples for laboratory testing, may be collected. Furthermore, the amount of blood collected must not exceed 13% of the donor's blood volume calculated according to sex, height and body weight.

Question 6 (Assessment of iron stores)

There are different practices in Sweden and efforts are being made to harmonise them. The more ambitious blood establishments test ferritin levels at pre-qualification and at regular intervals thereafter. In Uppsala, the cut-off level for accepting donors and donations is 25 µg/L for males and 20 µg/L for females. This is equal to the lower reference level for men but higher than that for women (20 µg/L instead of 10 µg/L). Applying these levels together with Hb level will defer about 30% of women and 5% of men in the pre-qualification stage.

Question 7 (Managing donors with iron deficiency)

Iron supplementation is provided and instead of a donation the donor is invited to a control visit at which a questionnaire is completed and blood samples taken for tests. Evaluation of the information leads to appropriate counselling.

Question 8 (Iron supplementation)

Iron supplementation is given orally. The costs are covered by the Blood Establishment.

Contact detail

Karin Schneider, Donor Selection and Care
Rut Norda, Clin Immunology and Transfusion Medicine
Uppsala University Hospital
751 85 Uppsala, Sweden
e-mail: rut.norda@akademiska.se

UNITED KINGDOM

These data apply to NHS Blood and Transplant (NHSBT) which is the organisation responsible for blood collection in England and North Wales and these data apply to the whole organisation.

Question 1 (Hb determination in donor selection)

Invasive testing is used with a copper sulphate screening test and two different solutions with specific gravity set to detect males with Hb 135g/L and females 125g/L. Donors who fail the copper sulphate screening test have a Hb measurement on a venous blood sample using the HemoCue®. They are accepted if the Hb ≥135 g/L for males and ≥125 g/L for females.

Question 2 (Minimum Hb levels)

- Whole blood: males 135 g/L, females 125 g/L;
- platelets - males 135 g/L, females 125 g/L;
- double red cell apheresis is not performed at present in the NHSBT.

Question 3 (Donor deferral rate for low Hb)

- The 2014 rate for males was 152 per 10,000 attendances.
- The 2014 rate for females was 406 per 10,000 attendances.

Question 4 (Donation intervals and frequencies)

Our UK Donor Selection guidelines state the following:

"A minimum interval of 12 weeks between donations

should normally be observed. Donors who regularly attend at intervals of less than 16 weeks should be informed that they are at increased risk of iron deficiency. They should be advised to reduce their frequency of donation to an average of 16 weeks or more. Donors with genetic haemochromatosis may donate at intervals of less than 12 weeks".

We advise our donors that they should not give more than seven whole blood donations in 2 calendar years. However this is not enforced by our computer system.

We currently have approximately 50,000 blood donors registered in the INTERVAL study who donate at 8, 10, 12 weeks (males) or 10, 12, 14 weeks (females).

Question 5 (Volume of whole blood donations)

A whole blood donation is 475 mL ±10% and the sample pouch contains 20-35 mL.

Question 6 (Assessment of iron stores)

The NHSBT does not routinely measure serum ferritin levels.

The INTERVAL study is currently underway in the NHSBT. Part of this study is to look at iron stores.

Question 7 (Managing donors with iron deficiency)

As we do not make a specific diagnosis of iron deficiency in our donors we do not manage this directly.

- Donors with a HemoCue® result of 125-134 g/L (males) and 115-124 g/L (females) are deferred for 3 months.
- Donors who have a HemoCue® result below 125 g/L (males) and 115 g/L (females) are deferred from donation for 12 months and referred to their GP for investigation and treatment.
- Male donors with a HemoCue® result <100 g/L and female donors with a HemoCue® result <80 g/L are advised to make an urgent appointment to see their GP.

Question 8 (Iron supplementation)

The NHSBT does not provide iron supplementation to blood donors.

Contact details

Nicky Anderson,
Associate Medical Director Blood Donation
NHS Blood and Transplant
500 North Bristol Park
Filton BS34 7QH, UK
e-mail: nicky.anderson@nhsbt.nhs.uk

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