Worldwide policies on haemochromatosis and blood donation: a survey among blood services

N. S. Pauwels, E. De Buck, V. Compernolle & P. Vandekerckhove
Belgian Red Cross-Flanders, Mechelen, Belgium

Background and Objectives Haemochromatosis (HC) is a disorder of iron metabolism, requiring frequent phlebotomy to normalize high serum iron levels. There is currently no consensus relating to the eligibility of these patients to donate blood for transfusion. To gain a better understanding of the policies worldwide, a survey amongst blood services was performed.

Materials and Methods A web-based questionnaire was developed and distributed among 44 blood services in 41 countries to identify the different policies relating to patients with HC and blood donation.

Results Respondents from 35 blood services (80%) of 33 countries completed the questionnaire. In 24 blood services among them (69%), individuals with genetic susceptibility for HC and/or patients with HC are accepted as blood donors. In approximately one-third of these blood centres (33%), genetic carriers/patients are allowed to donate blood more frequently than regular donors. Prescription from/approval by the patient’s treating physician and/or a donor physician is required in the majority of the blood services (87%). Similar policies were identified in a few countries; however, in general, the policies regarding blood donation from patients with HC remain widely variable.

Conclusion The results of our survey demonstrate large differences in the blood donation policies regarding carriers/patients with HC illustrating the need for uniform evidence-based and cost-effective policies which could benefit both HC patients and the blood supply around the world.

Key words: blood donation, blood donor, haemochromatosis, phlebotomy, policy.

Introduction

Haemochromatosis (HC) is characterized by abnormalities in iron homoeostasis and is related to a deficiency of the iron regulatory hormone hepcidin which results in excessive absorption of iron from the diet [1, 2]. Over time, the excess iron accumulates in tissues and organs (e.g. liver, heart, endocrine organs) throughout the body, leading to iron overload. Early identification and treatment of HC can prevent complications like cirrhosis of the liver and diabetes mellitus [1, 3].

Haemochromatosis is in most cases inherited, but can also be acquired. Hereditary or primary HC is a common genetic disorder in Caucasians, especially in people of North European descent [4], with a genetic susceptibility of 1 per 220–250 individuals [5, 6]. Multiple genetic defects are identified among people, but mutations in the HFE gene (High Fe) are the most common [5]. C282Y homozygotes account for more than 80% of patients with hereditary HC [3].

The initial clinical diagnosis of HC is based on biochemical screening tests for serologic iron markers (serum ferritin and transferrin saturation) [6]. Periodic therapeutic bloodletting (phlebotomy) is the primary treatment of HC as blood cells contain an abundance of iron [6, 7]. Considering the shortage of blood (donors) [8],
the potential to use blood from people with this disorder is an issue of major interest.

Distinct clinical presentations of HC occur (irrespective of the genotype) and are described in an evidence-based guideline concerning the diagnosis and management of HC [6]. The different phenotypes (or stages, in some cases) range from asymptomatic carriers (i.e. no increase in iron stores, but with genetic susceptibility), iron-overloaded patients without tissue or organ damage (i.e. uncomplicated HC) to patients with tissue or organ damage [6].

For many years, there has been debate concerning the eligibility of carriers/patients with HC as blood donors [8–11]. The two main considerations are whether the blood of patients with HC is safe for recipients and whether the blood donation can be considered voluntary. Recently, a systematic review of De Buck et al. [12] addressed the first question about the safety and effectiveness of blood from patients with uncomplicated HC for transfusion. The altruistic nature of blood donation is questioned, because the benefits of blood donation for the patient with HC is twofold (e.g. the patient benefits both financially and medically as the ‘donation’ can replace the need for bloodletting by a physician and its associated fees) [13]. In addition to this debate, other factors like logistical issues, which require changes in operational policy, might influence the policy concerning the acceptability of this target group for blood donation.

Until now, an overview of the individual regulations related to allowing carriers/patients with HC to donate blood by country has not been carried out. In this study, the policies from different blood services around the world were gathered and evaluated, using descriptive analysis from a cross-sectional survey developed from the results of a web-based questionnaire. Additionally, the policies are linked to the prevalence of the disease.

Materials and methods

A cross-sectional survey using a web-based questionnaire (SurveyMonkey® software) was distributed in May 2012 to 44 representatives of blood services of 41 countries. All representatives are members of the European Blood Alliance (EBA, [14]) and/or Alliance of Blood Operators (ABO, [15]). The data were collected and analysed from May until August 2012. Descriptive analysis was used to evaluate the data.

Questionnaire

The questionnaire consisted of 8 multiple choice questions including the ability to select multiple applicable answers and to add a comment if necessary. The online survey was designed to ensure that respondents answered all questions, not only questions that pertained specifically to them. Additionally, the respondents were asked to fill in their name, affiliation, city and country.

The purpose of the questionnaire was to gain important information concerning the worldwide policies of accepting carriers/patients with HC as blood donors. All survey questions are shown as online supporting information and take into account the assumption that all other requirements for blood donation have been fulfilled.

The first question of the questionnaire focused on whether or not carriers with a documented HFE mutation/patients with HC are allowed to donate blood. This question was posed to gather information about the genotypes and phenotypes of individuals that are allowed to donate blood in the blood service or to assign ‘none’ if not applicable. A distinction was made between the eligibility of asymptomatic carriers of a documented HFE mutation and symptomatic patients with HC. Additionally, a distinction was made between potential HC donors with normal versus increased ferritin/transferrin saturation levels and patients with HC in iron depletion versus maintenance therapy.

If at least one group of carriers of a documented HFE mutation or HC patient group was entered as eligible to donate blood at the centre, the following six questions explored the situation further: why the patients were included (or not), the percentage of donations coming from carriers/patients with HC from total blood capacity, the policy concerning the frequency of donation and whether or not there was patient guidance by a treating and/or donor physician.

The goal of the final question ‘Which tests are performed on blood from blood donors?’ was to determine whether all blood samples (including blood from both healthy donors and patients with HC) are routinely tested for a HFE mutation and/or abnormal levels of haemoglobin, mean corpuscular volume (MCV), serum ferritin, transferrin saturation and/or serum liver enzyme. This question elicited whether blood was only screened for the above-listed blood parameters at their first donation, always screened before each donation or never screened.

Results

A total of 35/44 (80%) respondents representing blood services in 33 countries on five continents (Africa, America, Asia, Australia and Europe) participated in the survey (Table 1). The data are presented in Figs 1 and 2. Figure 1 shows an overview of answers to questions 1–3, 6 and 8 from respondents, thereby reporting the policy of each blood centre included in this study. Figure 2 presents the blood centres grouped according to their common policy.
concerning the main questions. The answers to each question are described in detail below.

**Question 1:** ‘Which individuals do you accept as blood donors, assuming that all other requirements for donation are fulfilled?’

Detailed information about the genotypes and phenotypes of individuals that are allowed to donate blood in the blood service are recorded in Fig. 1 and summarized in Fig. 2. In general, the policies can be subdivided into two main groups, that is, some centres accept neither carriers nor patients with HC on one hand (31%), and other centres accept some carriers and/or patients on the other (69%).

In detail, approximately one-third (11/35, 31%) of the blood centres (located within 10 European countries and Hong Kong) accept neither carriers (with a documented mutation) nor patients with HC. Twenty per cent (7/35) of the blood centres allow both carriers of a documented mutation and symptomatic patients with HC (in both maintenance and depletion therapy) to donate blood. In 17% (6/35) of the surveyed blood services (including services located within Canada [Montréal], Austria, Czech Republic, Norway, Republic of Ireland and Scotland), only carriers with a documented HC mutation and...
asymptomatic patients are included in the donor pool. The policies of the remaining 11 centres are described in detail in Fig. 1 and cannot be classified under one of the three groups described above. The results indicate a high variability regarding the eligibility of these HC carriers/patients to donate blood.

Question 2 and 3: ‘Why do you accept/refuse (some) HC carriers or patients as blood donors?’

These questions were designed to elicit the rationale behind the policies regarding eligibility of carriers/patients with HC to donate blood. As the policy of accepting some individuals is linked to the reasons of refusal, the answers were combined (below and in Fig. 1). Additionally, the answers ‘expert consensus’ and ‘personal opinion/preference’ were combined, as suggested during the peer review process, as these reasons seem to be related.

Regulation (partially) as a result of personal preference/expert consensus was the most common reason (i.e. indicated by 20 blood services). Internal regulations were also frequently listed by the respondents (i.e. 18 blood centres). Based on the survey, in only three blood services (located in Belgium, Estonia and Spain), the policy was solely based on legislation. Interestingly, in five other blood services, other reason(s) (e.g. internal regulations

Table 1  Representatives of blood services who participated in the study

<table>
<thead>
<tr>
<th>Last name and first name of respondent(s)</th>
<th>Country</th>
<th>City</th>
<th>Affiliation</th>
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<tbody>
<tr>
<td>Anderson Laurel</td>
<td>South Africa</td>
<td>Johannesburg</td>
<td>South African National Blood Services (SANBS)</td>
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<td>Aquilina Alex</td>
<td>Malta</td>
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<td>National Blood Transfusion Centre</td>
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<td>Benjamin Richard</td>
<td>USA</td>
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<td>American Red Cross</td>
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<td>Blanco Lydia</td>
<td>Spain</td>
<td>Valladolid</td>
<td>Centros de Transfusion Sangüinea de Castilla Y León</td>
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<tr>
<td>Briel Irena</td>
<td>Slovenia</td>
<td>Ljubljana</td>
<td>Blood Transfusion Centre of Ljubljana</td>
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<tr>
<td>Bux Jürgen</td>
<td>Germany</td>
<td>Hagen</td>
<td>German Red Cross Blood Service West</td>
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<td>Canada</td>
<td>Ottawa</td>
<td>Canadian Blood Services</td>
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<td>Luxembourg</td>
<td>Luxembourg</td>
<td>Red Cross Luxembourg</td>
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<td>Canada</td>
<td>Montréal</td>
<td>Héma-Québec</td>
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<tr>
<td>Wim De Kort, Jeroen De Wit and Ed Slot</td>
<td>The Netherlands</td>
<td>Amsterdam</td>
<td>Sanquin Blood Supply Foundation</td>
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<tr>
<td>Dobrota Alina Mirella</td>
<td>Romania</td>
<td>Constanța</td>
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<td>Saint-Denis</td>
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<td>Dublin</td>
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<td>Reykjavík</td>
<td>Blood Bank</td>
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<td>Sweden</td>
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<td>Uppsala University Hospital</td>
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<tr>
<td>Poole Geoff and Field Stephen</td>
<td>UK – Wales</td>
<td>Pontyclun</td>
<td>Welsh Blood Service</td>
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<td>Hradec Králové</td>
<td>Transfusion Department, University Hospital</td>
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<td>Shinar Eliat</td>
<td>Israel</td>
<td>Ramat Gan</td>
<td>Magen David Adom Blood Services</td>
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<td>Turner Marc and Wells Angus</td>
<td>UK – Scotland</td>
<td>Edinburgh</td>
<td>Scottish National Blood Transfusion Service</td>
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<td>Vandekerkhove Philippe</td>
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<td>Mecelen</td>
<td>Belgian Red Cross–Flanders</td>
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<td>Velati Claudio and Grazzini Giuliano</td>
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<td>Bologna</td>
<td>Italian National Blood Centre</td>
</tr>
<tr>
<td>Williams Jennifer and Bell Barbara</td>
<td>Australia</td>
<td>Melbourne</td>
<td>Australian Red Cross Blood Service</td>
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and/or personal preference/expert consensus) in addition with legal regulations was/were listed as basis of the current policy.

Question 4: ‘What is the contribution of blood donors with a documented HFE mutation?’

Respondents were asked to indicate the percentage of blood donations originating from both carriers with a documented HC mutation and patients diagnosed with HC. The contribution of these individuals to the general pool of blood donors is less than 1% in 50% (12/24) of the surveyed blood centres (located within Austria, Canada [Ottawa and Montréal], Finland, Israel, Italy, Japan, Scotland, South Africa, Spain, the Netherlands and USA [Portland, OR]) and between 1 and 5% in approximately 21% (5/24) of the blood centres surveyed in Australia, France, Norway, Northern Ireland and Republic of Ireland. Seven blood services were not able to provide an estimate.

Question 5: ‘Frequency of donation?’

Of the surveyed blood centres which accept some subgroups of carriers and/or patients (n = 24), one-third (8/24, 33%) allow genetic carriers of HC and patients with HC to donate more frequently than regular blood donors. This particular trend was noted in blood centres located within Australia, England, France, Northern Ireland, Norway, Republic of Ireland, Sweden (Uppsala) and USA (Portland, OR).

Question 6: ‘Guidance by physician?’

This question identified whether guidance by a physician was required for carriers with a documented HC mutation and/or patients with HC when donating blood. Additionally, respondents were asked to clarify whether the guidance came from the treating physician (i.e. most frequently a hepatologist managing their condition or their general practitioner) and/or the blood centre donor physician.

As shown in Fig. 2, the policies regarding the physician's approval to donate blood is variable. In blood services in only two countries (Canada and the Netherlands), carriers and/or patients with HC can donate blood without approval or prescription by a physician. Interestingly, in 83% (19/23) of the blood services, approval by the donor physician is required (Fig. 1). In addition to the donor physician, in 8 (of 23) blood services (35%), also prescription from the treating physician is required for a carriers/patients with HC to donate blood (Fig. 1).

Question 7: ‘Place of blood donation?’

Some blood services organize mobile blood collections in addition to their fixed donation centre. In the majority of

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the surveyed blood centres [68% (15/22), located in Australia, Canada (Ottawa and Montréal), England, Finland, Germany, Israel, Italy, Malta, Norway, Scotland, Sweden (Uppsala), Switzerland, the Netherlands and Wales], carriers and patients with HC are authorized to donate at both fixed donation centres and mobile blood collections. The results also demonstrated great diversity within the policies concerning the location at which carriers and patients with HC are allowed to donate blood.

**Question 8: ‘Which tests are performed on blood from blood donors?’**

The question elicited information concerning which screening tests relevant to pathophysiology of HC are performed on a routine basis (‘always’) and which are only performed at the first donation. This question refers to the screening of blood from all donors, not specifically to carriers (with a documented HC mutation) or patients with HC. The results are described in Fig. 1.

All surveyed blood centres routinely test the haemoglobin levels in donated blood samples, and none of them performs genetic screening for a HFE mutation as part of their routine testing. Rarely, two serologic iron markers (serum ferritin and transferrin saturation levels) are screened [i.e. only at blood services located in Czech Republic, France, Iceland, Italy, Norway, Sweden (Uppsala)]. In all blood services except for blood service located in France, these particular screening tests are only performed on blood collected at the first donation.

**Discussion**

In this publication, policies regarding the eligibility of carriers with a documented mutation and/or patients with HC to donate blood were assessed. Thirty-five blood services within 33 countries, on five continents, completed a questionnaire regarding the eligibility of HC carriers/patients to donate blood. Although this survey does not present a complete overview of all blood services of all countries, it serves as a useful representation of the larger situation. The results of this study demonstrate a large variability in the policies, not only across countries but also between blood centres within the same country, and highlight the need for uniform policies.

Thirty-five blood services (of 44) completed the survey. As a result, the article does not represent the policy of blood services in Cyprus, Greece, Hungary, Latvia, Poland and Romania (in contrast to Iceland, Spain and USA, represented by another respondent/blood service). The prevalence of HC in these countries is <5%, according to the data described in Merryweather-Clarke et al. [16]. In detail, the allele frequencies of C282Y HC are between 0% and 1% in Cyprus, Latvia, Poland and Romania. In Greece and Hungary, the allele frequencies of C282Y HC are between 1% and 5%. In general, the countries of which no data were added in the publication (due to non-response) have low frequencies of HC.

This study indicates that either asymptomatic carriers with a documented HC mutation or asymptomatic patients are accepted in 69% of the surveyed blood centres (24/35). In 9 of these blood centres, symptomatic patients with HC are also eligible to donate blood. Of particular interest, the policies not only vary between countries but sometimes also between blood centres within a country, that is, in Canada, Sweden and USA. For the latter country, the policy concerning HC donors is dependent on whether a blood service applied for the US Food and Drug Administration (FDA) variance. For example, the American Red Cross (ARC) defers donors with a history of HC in 35 of its blood centres. At one Red Cross centre (in Portland, OR), an FDA variance to collect and utilize HC blood for transfusion was implemented, without special labelling as being sourced from a donor known to have HC. Additionally, America’s Blood Centres (ABC) have no uniform policy, as was stated by the ABC respondent as reason to be unable to fill in the survey. In summary, a list of blood centres and healthcare systems in the US that have approval from the US FDA to collect blood from HC donors can be consulted at:


In Europe, donor eligibility criteria are described in Commission Directive 2004/33/EC, implementing Directive 2002/98/EC of the European Parliament and of the Council. In detail, no specific criteria for neither carriers with a documented HC mutation nor patients with HC are described in this Directive. However, a general statement concerning haematological and metabolic disease is listed (i.e. prospective donors with serious active, chronic, or relapsing haematological or metabolic disease are permanently deferred for allogeneic donations).

The results of the survey illustrate that the contribution of individuals with genetic susceptibility, or having the disease, to the total blood pool is <5% in all surveyed blood centres which were able to provide an estimate. However, the actual contribution of carriers with a documented mutation of HC is probably underestimated. This theory is based upon two assumptions. First, many individuals are not aware of their genetic HC status. For example, within the Welsh Blood Service, 950 of 140 000 people (approximately 8%) who give blood each year are homozygous for the C282Y mutation [17]. These individuals show no physical signs of iron overload and are unaware of any family history of iron overload. Second,
in some countries where carriers and/or asymptomatic patients are allowed to donate blood, the prevalence of C282Y mutation is higher than 5% [16, 18, 19]. In detail, the allele frequency of C282Y is >5% in France (7-1%) and countries of the Northern part of Europe, that is in Republic of Ireland (10-1%), UK (8-1%), Norway (7-3%), Sweden (5-2%) and Iceland (5-1%) [16, 18, 19].

Interestingly, results of the survey about the policy can be linked to data about allele frequency [16] and thus prevalence of HC, because the geographic distribution of the C272Y allele and disease are similar [4]. The highest frequency of the C282Y allele was mainly found in the general population living in countries in the Northern part of Europe [16, 18, 19]. In 73% (8/11) of the blood centres that accept neither carriers nor patients, the C282Y allele frequency in the respective countries was reported to be £3-6% [16]. In detail, those blood centres are located in Hong Kong (C282Y allele frequency of 0%), Belgium (estimated frequency <1%), Estonia (3-5%), Latvia (2-6%), Luxembourg (estimated frequency <1%), Portugal (2-8%), Romania (1-75%) and Slovenia (3-6%) [16]. On the other hand, in multiple countries with high (>5%) C282Y allele frequency (i.e. Republic of Ireland, UK, Norway, Sweden and France, but not Denmark and Iceland [16]), asymptomatic carriers/patients are allowed to donate blood in the surveyed blood centres.

An overview of the reasons for accepting/rejecting (this potential subgroup of) patients with HC as blood donors was created, revealing that the basis for the policies was also highly variable. Expert consensus and personal opinion/preference are incorporated for decision-making in several blood centres with regard to the eligibility of carriers/patients with HC. Internal regulations and in lesser extent legislation were also used to develop the policies regarding the eligibility of carriers/patients with HC to donate blood. The authors put forward the need for evidence-based policies. Recently, a systematic review about the safety of blood from uncomplicated patients with HC was published [12]. The authors concluded, from six observational studies, that there is no evidence that blood from patients with uncomplicated HC is unsafe to be used as donor blood, on the condition that iron levels are normalized. However, other factors like logistical issues might affect the implementation of an adapted policy concerning the acceptability of this target group for blood donation.

The respondents of the survey were asked about whether a medical review performed by a physician (either or both treating or donor physician) was required prior to carriers/patients with HC donating blood. The results indicate that the policy concerning pre-donation medical review is highly variable.

Policies relating to standard lab tests performed on donor blood (from both healthy donors and carriers/patients with HC) across the surveyed blood centres were more uniform, when compared to eligibility criteria. For example, in 100% of the blood centres surveyed, haemoglobin levels are measured as a part of routine testing. However, the measurement of haemoglobin levels alone does not always provide information about abnormal iron storage and might therefore result in the inclusion of carriers/patients within the donor pool who are unaware of their genotype or disease status (even within blood centres with a policy to refuse them).

In conclusion, this study illustrates the large variability within the policies concerning blood donation by carriers with a documented HC mutation and patients with HC and thus calls for uniform evidence-based and cost-effective policies, which could be beneficial for both patients and blood services around the world.

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**Supporting Information**

Additional Supporting Information may be found in the online version of this article:

**Data S1** Worldwide policies on haemochromatosis and blood donation: a survey among blood services (complete survey).