



Review

Hemochromatosis and blood donation

Turid Aarhus Braseth^{a,e}, Tor Hervig^{b,c,*}, Anne Synnove Rosvik^d^a Faculty of Engineering and Business Administration, Department of Biomedical Laboratory Sciences and Chemical Engineering, Bergen University College, pb 7030, 5020 Bergen, Norway^b Institute of Clinical Sciences, University of Bergen, 5021 Bergen, Norway^c Department of Immunology and transfusion medicine, Haukeland University Hospital, 5021 Bergen, Norway^d Department of Biological Sciences Aalesund, Faculty of Natural Sciences and Technology, The Norwegian University of Science and Technology (NTNU) in Aalesund, PB1517, N-6025 Aalesund, Norway^e Western Norway University of Applied Sciences, Postbox 7030, 5020 Bergen, Norway

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ABSTRACT

The voluntary, unpaid, altruistic blood donor is a cornerstone of current transfusion medicine. The complexity of medical and ethical issues related to blood donation and hemochromatosis has led to a large number of studies related to the safety of the hemochromatosis donor and the quality of the blood components produced from these donations. The issue of accepting persons with HC as blood donors is diverting, both in Europe and worldwide and without joint guidelines. A questionnaire-based study was performed and mailed to all 25 blood bank leaders in Norway. Descriptive analysis was used to evaluate the data. Eight of 22 blood banks strictly followed national guidelines concerning persons with hemochromatosis. Other blood banks make local adjustments. 16 of 22 responding blood banks accept hemochromatosis donors and five do not, and one answered partly yes. The reasons the blood bank leaders supported the acceptance of hemochromatosis donors differ. Based on published papers and the present questionnaire, we believe that a clear definition of the "hemochromatosis donor" and guidelines with more detailed information on an acceptable donation regime would be important to overcome the weak points in blood donor eligibility criteria.

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1. Introduction

The voluntary, unpaid, altruistic blood donor is an important part of transfusion safety [1–4]. Nevertheless, under some circumstances other options may be both needed and beneficial since blood bank availability is not equally distributed throughout the world [5]. In general, blood donation should be for the benefit of the patient, not for the donor [3,6]. Regardless of donor motives, blood donation causes significant iron loss, and it has been a long-standing medical issue as to whether iron depletion could reduce

* Corresponding author at: Faculty of Engineering and Business Administration, Department of Biomedical Laboratory Sciences and Chemical Engineering, Bergen University College, pb 7030, 5020 Bergen, Norway.

E-mail addresses: jseghatchian@btopenworld.com, tor.audun.hervig@helse-bergen.no (T. Hervig).

the risk of contracting diseases such as myocardial infarction [7,8]. Such possible advantages of blood donation have not raised any storm of “self-care motivated” donors although “pure altruism” may not be sufficient to define donor motivation [9].

For persons with diagnosed iron overload – hemochromatosis – the situation is different. Despite substantial disagreements concerning “safe” s-ferritin concentration limits [10], bloodletting is unanimously the therapy – or prophylactic measure – of choice [11,12]. The possible ethical conflicts are accordingly obvious; the hemochromatosis blood donor may have financial benefit by donating free in a blood center rather than paying for the same service in an outpatient clinic [3,4]. In addition, many patients with hemochromatosis want frequent bloodletting although the treating physician does not find this indicated [10,12,13]. Accordingly, it could be argued that blood centers should defer donors with hemochromatosis [6].

The issue of accepting persons with hemochromatosis as blood donors is nevertheless much more complicated [3,14]. First, the definition of the term hemochromatosis varies. Iron overload is mostly due to HFE-gene mutations [15–17]. The term preclinical hemochromatosis indicates that there is only an elevated s-ferritin concentration and the condition is named clinical hemochromatosis when organ-injury is diagnosed. Due to extensive screening programs and knowledge of familiar occurrence, many people know that they have iron overload or they are at risk of developing iron overload. Thus, new blood donors may be motivated by knowledge of a personal risk of having iron overload – and registered blood donors may be diagnosed through the blood centers’ screening program.

The complexity of medical and ethical issues related to blood donation and hemochromatosis has led to a large number of studies concerning the safety of the hemochromatosis donor and the quality of the blood components produced from these donations [11,14,18]. The hemochromatosis donor exposed to the normal selection program for blood donor does not seem to represent any additional risk of transmitting an infection to the patient [18,19]. In addition, the quality of the blood components produced from donors with iron overload is not inferior to components produced from other donors. [15,18,20].

Based on published papers, the ethical dilemmas and multinational legal documents as in the European Blood Directive [21], it could be anticipated that common acceptance criteria for donors with iron overload were available. In reality, the situation is heterogeneous as demonstrated by a world-wide survey in 2013 [3].

Norway is a country with 5.2 million inhabitants. The blood transfusion service is decentralized and there are 25 hospital-based blood banks. The country has four health regions and there is formal and informal contact between the blood banks in each region. Only a minority of the blood donation sites has a transfusion medicine specialist working in the facility. To investigate the blood banks’ practice concerning people with hemochromatosis, we conducted a questionnaire-based study with the primary aim to describe the situation for the hemochromatosis donor in Norway. Our secondary objectives were to evaluate if daily supervision by a specialist in transfusion medicine, the size of the blood bank or geographical position (health region) influenced the policy as we hypothesized that these factors are relevant.

2. Material and method

2.1. Subjects and design

We performed a questionnaire-based study in November 2014, and mailed this to all 25 blood bank leaders in Norway. Blood bank size was categorized based on the number of donations per year.

Data was collected and analyzed through 2015. Descriptive analysis was used to evaluate the data.

2.2. Questionnaire

The questionnaire consisted of 20 multiple-choice questions. It was possible to select more than one alternative for each question and to add comments. The purpose of the questionnaire was to collect relevant information concerning the policies of accepting persons with HC focusing on the aims of this study as described in the introduction.

Our main question focused on whether or not blood bank leaders accepted persons with HC as donors. If the answer was yes, follow-up questions clarified their reasons for the acceptance. If the answer was no, the respondents were asked to choose among various options for not accepting this blood donor. We also asked about the frequency of donations where persons with HC are accepted and if economic aspects could be of importance.

A draft of the questionnaire was validated by three specialists in transfusion medicine and by research colleagues with expertise in survey methodology. Corrections of the questionnaire included some new questions and rephrasing several others.

2.3. Ethical concerns

The study complied with the Declaration of Helsinki and was submitted to the Regional Committees for medical and health research ethics of Western Norway (REC) as a disclosing evaluation. The respondents were invited to participate as leaders of the blood bank. The invitation contained information about the project and by responding to the survey, they gave their informed consent. No approval by NSD (Norwegian national institution for data security in research) was needed.

3. Results

Leaders from 22 of 25 blood banks (88%) from the four health regions of Norway participated. The participating blood banks were divided into small, medium and large, separated by number of donations per year: S=small, <1000 donations per year, M=medium 1000–9999 donations per year, L=large 10000+ donations per year. An overview of responses is presented in Table 1. Descriptions of the accepting blood banks are presented in Table 2. Comments from each participating blood bank are reported separately.

As shown in Table 1, there is a considerable variation in how the hemochromatosis donors are treated in Norwegian blood banks. In general, 16 of 22 responding blood banks accept hemochromatosis donors. Eight of 22 blood banks follow national guidelines concerning persons with hemochromatosis. Other blood banks [15] make local adjustments, 1 blood bank reports not to comply with the guidelines and 5 blood banks answers that persons with hemochromatosis are not accepted as donors.

The reasons for accepting hemochromatosis donors differ (see Table 1) but a common denominator is that no risk of “infectious blood” is recognized.

The blood bank leaders advocating hemochromatosis donor deferral highlight the aspects of donor motivation; a person with hemochromatosis may not have “correct motivation” and the need for bloodletting may cause dishonest answers. Some key statements are cited within the framework below.

Table 2 also shows that among the blood banks allowing persons with hemochromatosis to donate, there are substantial differences concerning blood donation policies. Nine blood banks allow more frequent donations from persons with hemochromatosis.

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