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### **Increasing the obligatory age limit for blood donations by regular donors**

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#### **1. INTRODUCTION AND ISSUE**

On 19 October 2009, the Superior Health Council received a request for advice from the Minister of Social Affairs and Public Health concerning the obligatory upper age limit for regular blood donors.

The progress made in transfusion practice is closely connected with that in medicine and medication. With increasingly less invasive procedures being developed in surgery, the use of blood products can be predicted to decrease. Also in haematology, the demand is expected to stabilise. Still, this does not apply to medical issues in which the needs of patients over 70 should evolve (Rouger, 2005).

In less than 30 years, life expectancy has risen by an average of ten years in Europe (the Belgian population statistics show that on 1 January 2008, 17% of the population were over 65). Age-related diseases are therefore bound to increase, which means that the needs for transfusion will too (Ali et al., 2010).

Each year the blood establishments lose some 10% of their donors because the latter reach the age limit or suffer from a disorder that is a counter-indication for blood donation. Moreover, the average rate of (temporary or definite) deferrals in blood donation sessions amounts to about 14% (Custer et al., 2004). Ensuring that the amount of blood collected meets hospital requirements is a daily challenge.

The selection procedures regarding donor eligibility pursue a variety of aims: avoid harming the donor, detect a potential pathology in the donor, optimise the therapeutic quality of the final blood product and avoid harming the recipient (Boulton, 2008).

The policies concerning donor selection and deferral should be based on medical scientific evidence. As regards transfusion, there are, however, but few randomized clinical trials. The scientific foundation should therefore originate from other experience-related sources (risk analyses, follow-up of side-effects after blood donations ...). However, as the “donor” factors on the basis of which side-effects can be predicted are not fully understood, some of the criteria selected to protect donors are arbitrary (Goldman et al., 2007). Some selection criteria that were introduced several years ago have even become dogmas. They have not been subject to critical review and remain applicable in spite of the fact that there is no certainty that these measures increase donor safety. Conversely, their influence on the supply of blood products can be considerable (Eder et al., 2009).

With the average age of the population in general and of blood donors in particular (Zou et al., 2008) on the increase, raising the blood donation age limit can have a significant impact on blood supplies.

An answer is requested to the following questions:

1. Can the obligatory upper age limit for regular blood donors be raised beyond the age of 65?
2. Are there any specific criteria for assessing donor eligibility in over 65-year-olds?

This advisory report only deals with whole blood donations, not with apheresis donations nor donations of other blood components.

This advisory report is based on an overview of the knowledge on this subject and on the opinion of the experts.

## **2. ADVICE**

The upper age limit for blood donors can be raised to the donors' 70<sup>th</sup> birthday because older donors

- are particularly regular, which increases transfusion safety;
- are safer donors who are less often excluded because of risk behaviour with respect to the transmission of infectious diseases;
- do not present more adverse reactions when donating blood. Yet, as for all changed criteria, there should be a tightened follow-up of the haemovigilance among these blood donors.

As is the case with all blood donors, the occurrence of anaemia through iron shortage should be monitored.

There is no need to introduce any new specific criterion regarding donor eligibility: it suffices to select these donors on the basis of a questionnaire, an interview and a clinical examination and with permission of the physician in the blood establishment, in agreement with the European directive 2004/33/EC and the Belgian legislation.

However, increasing the age limit should only apply to registered donors. The SHC believes that it is not wise to enrol new blood donors who are over 65.

## **3. FURTHER DETAILS AND ARGUMENTATION**

### **3.1. Methodology**

This advisory report is based on an evaluation of the European recommendations and an examination of the scientific literature.

### **3.2. Regulations: state of affairs**

There is neither a consensus nor a general rule for setting the upper age limit for blood donors (Klein et al., 2005; COE, 2008). The relevant rules and practices still differ from one country to another: there are no uniform recommendations; the latter are usually local or national (Rouger, 2005).

The Belgian Act of 5 July 1994 stipulates that in order to give blood, potential donors must be aged between 18 and 65; blood may only be collected from over 65-year-olds if the conditions fixed by the King are met.

According to European directive 2004/33/EC, the acceptance criteria for donors of whole blood or blood components set the authorised age between 18 and 65. Beyond the age of 65, donations must be authorised by the physician of the blood establishment. This permission must be renewed each year.

In France, the decree of 12 January 2009 has revised the selection criteria for blood donors as follows (section 1): “*De 18 à 65 ans révolus, tout type de don est possible, sauf le don de granulocyte, qui n’est autorisé que jusque 50 ans révolus. Le premier don après 60 ans est soumis à l’appréciation d’un médecin de l’établissement de transfusion sanguine. Après 65 ans, seul le don de sang est autorisé et sous réserve que chaque don soit autorisé par un médecin de l’établissement de transfusion sanguine. Après 70 ans, aucun don n’est autorisé, sauf dérogation prévue au VII du présent article.*” (VII. Dispositions spécifiques au prélèvement de sang rare). (i.e. “From the age of 18 to the donor’s 65<sup>th</sup> birthday, every type of donation is possible, except for granulocyte donations, which are only authorised until the donor’s 50<sup>th</sup> birthday. First-time donations after the age of 60 are subject to the appreciation of a physician of the blood establishment. After the age of 65, blood donations only are authorised, provided that each donation is approved by a physician of the blood establishment. Beyond the age of 70, no donations are allowed, except as regards the derogations provided under VII of this section” (VII. Specific provisions concerning rare blood donations).

Other countries, such as the United Kingdom, Germany, Austria, Denmark, Portugal, Australia, the United States, and Canada, have also raised the upper age limit for blood donations beyond the age of 65 (see reviews in Stainsby & Butler, 2008).

The setting of this age limit is therefore arbitrary. A case in point is Florida, where the number of elderly inhabitants over 65 doubled between 1970 and 1980. They then constituted more than 17 % of the population. The eligibility criteria were reviewed in 1980 and the age limit was raised to 85. Today, there is no longer any upper age limit in Florida.

Taking into consideration the greater average life expectancy of the population and the improved health of over-65-year-olds, as well as the fact that the age limit of 65 is both arbitrary and medically unfounded, it is justified to review this limit. This would allow to increase the pool of regular donors, thus contributing towards a better prevention of blood component shortages, such as those that occur during holidays or in the event of an epidemic.

### **3.3. Can the obligatory upper age limit for regular blood donors be raised beyond the age of 65?**

The experience of our colleagues from other countries enables us to draw the following conclusions:

*Elderly donors are exceptionally regular blood donors.*

The annual donation frequency increases with age. Before the age of 20, people donate their blood 1.5 times a year on average. Between the ages of 50 and 54, this frequency rises to 2.5 and for those aged between 66 and 70, it reaches 3 (Goldman et al., 2007). In the same publication, 26 % of donors aged over 70 had donated blood between 100 and 200 times and 4.5 % had already donated blood more than 200 times. Crucially, donor regularity is known to contribute towards improving transfusion safety.

*Elderly donors are safer donors who are less often excluded during medical screening.*

American studies have shown that allogeneic blood donation by elderly people is safer (Garry et al., 1991; Schmidt, 1991; Simon et al., 1991; Popovsky, 2002). In Goldman (2007), a study involving 659 elderly donors aged at least 71, not a single temporary or permanent deferral on account of risk behaviour with respect to the transmission of HIV or hepatitis was noted. As a matter of fact, not a single infection marker was discovered in the 615 blood units that were collected.

*Elderly donors present less adverse reactions when donating blood.*

Taking all ages together, 3 to 10 % of blood donors show adverse reactions, most of which are mild (Eder et al., 2008). The experience with programmed autologous pre-donations has shown that donation-related morbidity is very limited in the elderly, including those of a fairly advanced age (Mann, 1983).

Among regular blood donors (more than 7 donations in Shehata et al., 2004), the incidence of donation-related adverse effects is much lower in elderly people than in younger people (0.61 % in donors under 20, 0.03 % in those between 60 and 65, 0 % in those between 66 and 71). This had already been shown in a previous study (Pindyck et al., 1987), which had suggested that there may be a “survival”-effect caused by donors who had suffered an adverse reaction after a previous donation excluding themselves.

Elderly donors are also more haemodynamically stable (Imholz et al., 1990; Kuchel et al., 1991) and show fewer vasovagal reactions than younger donors (odds ratio adapted to 0.66 for donors above 60, compared with donors between 30 and 39) (Trouern-Trend et al., 1999).

Yet, as is always the case when criteria are changed, there should be a tighter follow-up of the haemovigilance among blood donors aged over 65.

#### **3.4. As is the case with all blood donors, the occurrence of anaemia through iron shortage in elderly donors should be monitored**

Donating blood triggers a depletion of the iron supply (500 mL of blood contains about 220 mg of iron), which causes an increased intake of iron through food. In 78 % of donors, the haemoglobin levels return to normal after 8 weeks (Newman, 2006). However, the serum ferritin concentration decreases steadily as a result of regular blood donation (Milman et al., 1998). Other studies (Punnonen et al., 1999; Boulton et al., 2000) have shown that serum soluble transferrin receptor concentrations increase in regular donors, which is also indicative of iron shortage.

The period of time that is required for the iron supplies to be restored after donation depends on the quantity of blood that was collected, donation frequency, diet and possible supplements, age and gender (Boulton, 2008). Since the iron supply is fairly high in elderly people, they could be good candidates for regular blood donations (Garry, 1983). However, the haemoglobin level decreases in men over 80. In women, it rises after the menopause, but falls again after the age of 80 (White et al., 1993).

In elderly people, especially women, the adaptation phenomenon may not be sufficient after 4 to 5 blood donations (Garry et al., 1991). It is therefore not only important to detect early any anaemia that may have been induced by regular blood donations, especially in elderly people, but also to provide iron supplements.

### 3.5. Are there any specific criteria for assessing donor eligibility in over 65-year-olds?

Although they are meant to protect individual health, divergent views on donor eligibility or donor deferral cause confusion, disappointment and fear among donors, especially when GPs have different opinions on the same physical condition. However, some donor selection criteria, which are well-known to blood establishment physicians, are not always well understood by the general public and are equally unknown to some GPs.

Since the questionnaire, the interview, and the clinical examination carried out before each donation make it possible to assess the donor's state of health and detect any cardiovascular or neurological disease which the donation might cause to worsen, it does not appear to be useful to perform any additional medical evaluations. Indeed, one study has shown that there can be no supplementary value attached to this (Eder et al., 2009). On the contrary, according to the Canadian study by Goldman (2007), this examination has proven to be useless because most donors who were excluded by their GPs would also have been deferred merely on the basis of the questionnaire.

Older donors have a longer medical history and take more medicine than younger donors (analgetic/antipyretic drugs and substitutive hormonal treatments were taken most frequently by 63 to 80-year-old donors) (Simon, 1991). They are also deferred more frequently than younger donors on account of cardiovascular or oncological problems. These elements are highlighted by the questionnaire that is traditionally used for donors: it is therefore unnecessary to draw up a specific questionnaire for donors aged over 65 or to introduce special restrictions (Simon et al., 1991).

In Canada, the obligatory upper age limit for blood donors is the donor's 70<sup>th</sup> birthday. There is no need to apply any specific criteria between the ages of 65 and 70. The same applies to the United States and the European countries: all that is required is the opinion of the blood establishment physician. As is the case in France and the United Kingdom, it is, however, considered wise to limit the age for enrolling new donors to their 65<sup>th</sup> birthday.

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## 5. COMPOSITION OF THE WORKING GROUP

All experts joined the working group *in a private capacity*. The names of the members and experts of the Superior Health Council are indicated with an asterisk\*.

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