Superior Health Council

ADVISORY REPORT OF THE SUPERIOR HEALTH COUNCIL

Guidelines for autologous transfusion

7 February 2007

SHC no 8195

1. INTRODUCTION AND ISSUES

The extensive use made of human blood and of derived blood products for therapeutic purposes, as well as the wide discrepancies that can be observed amongst Belgian hospitals in their transfusion practice, have made it necessary to develop guidelines for the optimal use of these products. The recommendations made by these programmes aim at guaranteeing a safe, permanent supply in accordance with ethical rules, as well as ensuring an adequate and rational clinical use of the donated blood. However, blood transfusions can entail a risk of immediate or future complications and can transmit infective agents (bacteria, viruses, non-conventional agents, ...). Encouraging a rational clinical use of blood components reduces the number of transfusions performed to a minimum and increases their overall safety.

The risks associated with transfusions can be lessened by making judicious use of simple alternatives to transfusion (salvaging, haemodilution, planned autologous transfusion…).

Transfusions are a necessary part of healthcare: not only are they needed when dealing with medical and surgical emergencies (road accidents, burn victims…), they are also required for surgical operations and therapies aiming at improving the health of the recipient (leukaemia patients, haemophiliacs…). Transfusion Committees have been set up in Belgian hospitals as a result of the Royal Decree of April 16th, 2002 and have been ordered to draw up transfusion guidelines for hospitals. In addition, these Committees closely monitor the use of every blood component in the hospital. This surveillance, as well as large-scale studies carried out in some European countries, reveals that hospitals exhibit a great lack of consistency with respect to the indications for transfusions. Finally, if strict rules are implemented in transfusion establishments, a particular effort will also be required to standardise and rationalise clinical indications.

In order to remedy these divergences and to provide a scientific basis to the Transfusion Committees, the Superior Health Council (SHC) has organised two expert meetings on blood components with the *Belgian Haematological Society*.

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These meetings were designed to collect the most recent knowledge on the subject of blood component transfusion as well as its alternatives in order to enhance the harmonisation of transfusion practice in Belgium. Thus, the Superior Health Council is required to draw up a code of good practice concerning the correct administration of blood or blood products, in keeping with article 3 of the law of July 5th, 1994 on blood and blood products of human origin, modified by the programme law of April 8th, 2003, Chap. X, Art 158.

These issues were discussed during the meetings of the working group « blood and blood products» that took place on September 21st and November 23rd, 2006, as well as on January 18th, 2007. The provisional advisory report of the members of the working group was approved on January 23rd, 2007 and validated by the SHC Board on February 7th, 2007.

Assignment

1. The organisation of expert meetings on the indications for blood component transfusions, including autologous transfusions;

2. The assessment of the most recent knowledge on the subject of autologous transfusions;

3. The drawing up of guidelines for autologous transfusions.

2. CONCLUSIONS

Assignment 1. The Superior Health Council (SCH) set up a working group, which met on several occasions in 2005 and 2006 in order to prepare two expert meetings devoted to «*Guidelines for the transfusion of red cells* » and «*Transfusion Guidelines: Pathogen reduction, products and indications for the transfusion of plasma* ». These conferences, which were held in collaboration with the *Belgian Haematological Society*, took place in Brussels on November 18th, 2005 and May 11th, 2006, respectively. The speakers discussed the indications for transfusing these blood components and subsequently turned to the alternatives to carrying out blood transfusions.

Assignment 2. Assessing the most recent knowledge on the subject of autologous transfusions was performed in numerous steps. On the one hand, there were papers and subsequent discussions, followed by the final discussion of the meetings, on the other, there were (a) the preparation of transfusion guidelines by the rapporteurs and (b) the validation of the recommendations proposed by the members of the working group “blood and blood products” of the SHC.

Assignment 3. The working group has been able to draw up a substantial series of recommendations aiming at standardising and rationalising clinical indications for autologous transfusions in Belgium. These recommendations are included in the report entitled ”*Guidelines for autologous transfusion* “, which is to be published in a scientific journal.

3. FURTHER DETAILS AND ARGUMENTATION

a) *The organisation of expert meetings on the indications for blood component transfusions, including autologous transfusions*

The expert meetings «*Guidelines for the transfusion of red cells*» and «*Transfusion Guidelines: Pathogen reduction, products and indications for the transfusion of plasma* » were held in Brussels on November 18th, 2005, and May 11th, 2006, respectively. Their aim was to rationalise the prescription of red cells and fresh frozen plasma by providing guidance for

practitioners in their decision-forming processes, thus enhancing the quality of transfusions and providing help in homogenising the practice under discussion. In order to achieve this goal, the organising committee gleaned the most relevant contributions from the literature and asked that, in preparing their papers, the speakers pay particular attention to the available meta-analyses and the *evidence based medicine* approach. Moreover, the speakers were asked to clearly identify any opinions of their own. A printed version of the papers was given to the chairmen (M. Lamy, Liège, Z. Berneman, Antwerp, K. Jochmans, Brussels and Ph. Baele, Brussels) and the rapporteurs (Ph. Baele, Brussels, L. Muylle, Brussels, D. De Backer, Brussels, and B. Vandekerckhoven, Ghent) in order to enable them to prepare the discussions, for which a large amount of time had been programmed.

Several of the papers were more directly concerned with the alternatives to transfusions:

1. « *The medical indications for red cell transfusion* » (J. Isbister, Sydney);
2. « *Clinical use of red cells in critical patients: Surgery & Intensive Care* » (Ph.Van der Linden, Brussels);
3. « *Indications and levels of evidence for clinical transfusion of fresh frozen plasma* » (S. Stanworth, Oxford);
4. « *Alternatives to allogeneic transfusion: indications for the transfusion of autologous products* » (Ph. Van der Linden, Brussels).

b) The assessment of the most recent knowledge on the subject of autologous transfusions

Each paper was immediately followed by an in-depth discussion of the analyses put forward. Next, during the discussion following the set of papers, each recommendation suggested was re-examined and assessed during an intense exchange involving both the experts and the doctors in charge of transfusions who attended the meeting.

Thanks to these meetings, it was possible to set up guidelines for autologous transfusions. These reflected the expertise of the members of the working group “blood and blood products” of the SHC, who based them both on the analyses outlined in the papers and on the arguments or opinions expressed during the discussions on the report, which goes into the details of the principles behind autologous transfusions compared to blood component transfusions. The members of the working group adapted this document and produced a final version, which was approved on January 23rd, 2007 (reference a).

c) The drawing up of guidelines for autologous transfusions.

These recommendations do not provide a description of user requirements, but can be used as a means of assessing minimum standards of good practice.

1. Preoperative autologous predeposit donations should be restricted to patients who are scheduled to undergo a surgical procedure that usually requires a blood transfusion.

2. There are little or no relative indications for the autologous donation of blood components. Patient populations that are likely to benefit from such donations should be identified on the basis of preoperative haemoglobin levels as well as the estimated preoperative blood volume, the expected blood loss and the transfusion trigger.

3. There are few absolute indications for the autologous donation of blood components. The patients concerned should be identified and advised to donate blood for autologous and allogeneic use. Patients with few or no compatible donors should be given the option of donating autologous blood for red cell cryopreservation.

4. As is the case for all transfusion practices, autologous transfusion techniques must always follow written Standard Operating Procedures.

5. Given the fact that autologous transfusions are not risk-free, the transfusion triggers for autologous and allogeneic transfusions should be identical.

6. All autologous transfusion techniques reduce the need for allogeneic transfusions.

7. Blood retrieval techniques are technically complex and require the supervision of a specially trained team.

The recommendations above constitute one of the appendixes to the « *Good transfusion practice for hospitals*» (SHC no 8167).

4. REFERENCES

a) Report « *Guidelines for autologous transfusion* », 18/01/07, 4 pages.

5. APPENDIXES

None.

6. COMPOSITION OF THE WORKING GROUP

The following experts were involved in issuing this advisory report:

- BAELE Philippe (anesthesiology);
- BONTEZ Walter (blood, tissues and cells);
- DE BACKER Daniel (intensive care);
- DE PAEP Rudi (intensive care);
- FERRANT Augustinus (clinical haematology);
- LAMBERMONT Micheline (transfusion);
- LATINNE Dominique (haematological biology);
- MUYLLE Ludo (blood, tissues and cells);
- PEERLINCK Kathelijne (internal medicine, haematology);
- SCHOTS Rik (haematology);
- THOMAS Isabelle (TSE, virology);
- TOUNGOUZ Michel (immunology, haematology, transfusion);
- VANDEKERCKHOVE Bart (clinical biology, cell therapy);
- VOETS Ellen (blood and blood products, TSE, virology).

This working group was chaired by Mr. TOUNGOUZ Michel, the scientific secretary was Mr. HÜBNER Roland.