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Current issues in transfusion medicine in Norway

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Abstract

Important current issues in transfusion medicine in Norway are discussed. Current patient legislation specifically defines blood donors as patients, and blood and blood products are defined as drugs. Donor selection is controversial, especially deferral of all persons born in, or having lived for more than one year in areas with high prevalence of infections that are transmitted by blood. The threshold for becoming a blood donor is high, but registered donors donate frequently, e.g. 2,4 whole blood donations per year on average. Some blood banks have specialized in multicomponent aphereis technology, in particular collection of two units of red cells.
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1. Introduction

Transfusion medicine is continuously evolving, with new developments both in terms of the legal, administrative and economical aspects with emphasis on three pointers of quality: namely procurement, process, and patient surveillance. The Norwegian Red Cross Blood Program recently arranged its third course in Transfusion Medicine to update participants on some new developments. This paper summarises some of the issues discussed.

2. Legal and administrative aspects

2.1. Structure

During recent years, the Norwegian health service has been restructured and new legislation introduced. Hospitals are now organised in a corporate structure where the Department of Health owns five regional corporations. Each corporation in turn owns all of the hospitals in their region,

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and each hospital in turn is considered a separate company. Parallel to this restructuring, all directorates/institutes and registers in the health service have also been reorganized. Because all the blood banks in Norway are individual departments within hospitals this has also influenced the blood banks. There has been a period of uncertainty about who does what in the transfusion service.

2.2. Blood law

Norway does not currently have a specific blood law. Best practice in transfusion medicine is based on seven-year-old Guidelines in Transfusion Medicine and nine-year-old Guidelines for GMP in Blood Banks. The professionals have suggested new guidelines in 2000 and 2002, but due to the reorganization it has been unclear as to who was responsible for issuing the guidelines and progress has been very slow. Early in 2004 a new attempt was made to obtain new guidelines and the Directorate of Health took on this responsibility. However, various topics in the guidelines are considered too sensitive to public opinion and the politicians also want their say. Therefore, the guidelines are waiting for political evaluation [1]. The inability of the authorities to produce new guidelines in a timely manner has led to a strong wish for guidelines based solely on professional opinion, without attempt to obtain the approval of the authorities.

Two topics related to donor exclusion are particularly causing problems; namely the exclusion of males that have had sex with males, and exclusion of all persons born in, or having lived for more than one year in areas with a high prevalence of infections that are transmitted by blood.

2.3. The donor

One interesting point in the current patient legislation in Norway is that blood donors are specifically defined as patients. This is counterintuitive to most people working in the transfusion service, as well as to blood donors. The concept is that even if the donor gives blood for altruistic reasons, he or she also expects some benefit from being in contact with the health service, here represented by the blood bank. In practical terms, however, it means that the blood donor is regarded as a donor and the blood bank must follow the transfusion medicine guidelines and the blood directive. In other instances the donor is regarded as a patient and must be treated as such. This creates problems in several ways, in particular when using computer systems. Should the donor be registered in the blood bank system, the hospital's patient system or both?

The advantage for the donor is that in the case of an adverse event there is no question about the donor's right to treatment.

This strategy has also considerable economic consequence, as everything related to outpatient treatment should be paid for by social security. To date, the hospital blood bank has paid for everything related to the blood donors, including blood tests.

2.4. Blood as drugs

Despite criticism from the professionals, the health authorities have been very specific about blood being drugs, and the Norwegian Medicines Agency have had an important role to play by inspecting blood banks, issuing licences to blood banks, and receiving reports on the complications of blood transfusion. In a surprise move, the Department of Health has modified its opinion and will be moving blood-related issues to it is public health sector.

3. Haemovigilance and safety surveillance

Haemovigilance has been covered by several general compulsory reporting systems, e.g. reports about accidents and near accidents to patients, go to the Surgeon General, those about technical errors without patient accidents go to the health directorate, and those about infections go to the Institute of Public Health. Despite compulsory reporting, the reports have been few and far between. Analysis of the reports and suggestions for improvement, have been lacking. The Norwegian Association for Immunology and Transfusion Medicine, which is a professional body under the

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