Patients’ Right to Health Protection and Quality and Safety of Blood(Products)

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1. Introduction

In December 2003, the Health Secretary of the United Kingdom informed the parliament of the death of a person who was probably victim of the variant Creutzfeldt-Jakob disease (vCJD). This because of transfusion of blood in 1996 from a donor who had been incubating vCJD. As a precautionary measure, the United Kingdom decided to exclude from blood-donation all those who had received a blood transfusion since January 1980. Following this event, the Dutch organisation in charge of the blood supply, Sanquin, asked the Minister of Health, Welfare and Sport to apply the same measure in the Netherlands. This request did not receive a positive answer because the measure was considered inefficient, the risks for the health of blood recipients were considered extremely low as sofar no cases of vCJD had been detected in the Netherlands yet, and the chance that cases would occur was considered very small. After a second case of infection with vCJD through blood in the United Kingdom, also in the Netherlands, recipients of blood transfusions since January 1980 were barred as blood donors. This change of position was due to the fact that with the second event in the United Kingdom, the risk of infection was considered higher then expected. Since the outbreak of vCJD, the United Kingdom had to invest in a New York based company that procures plasma for human use in order to secure the availability of life saving blood products.

This case shows how difficult it is to estimate with sufficient precision the risks for the patients who are in need of blood and blood products. And, in case risks are established that require donor deferral, how to cope with a shortness in blood supply.

Safety of the provision of blood, blood components and plasma derived medicaments to the patient is influenced by many factors. The chain of blood supply from donor to patient involves many actors and hence many responsibilities. Each step
The weakest link in the chain is determinant for the safety in blood medicine.

The purpose of this article is to analyse and discuss the difficulties in finding the right balance between a policy for blood medicine that is safe and a supply of blood, blood components and plasma as a source for medicines that is sufficient to meet the demands, nationally and in the context of the European Union.

2. Dilemmas with blood based therapeutics

Blood is life saving, but also life-threatening. The patient has a right to safe blood and blood-products whenever medically necessary. The right to health care of good quality is an essential part of the right to care for health. The patient has also the right to be informed about the therapeutic measures envisaged, the choices they have (if any alternatives are available), the prospects and risks involved with therapeutic measures based on blood as a source material. In principle whole blood and perishable-blood products1 are less safe than the plasma-products that are ‘non-perishable”, made on the basis of plasma-pools (medicaments). But plasma products are not 100% safe either, despite the many treatments the source material undergoes. Thus, for instance in 2003, a class action lawsuit was launched against Bayer and Baxter corporations on behalf of people with haemophilia in Asia and Latin America who contracted HIV or hepatitis through contaminated blood products supplied by the companies. The safety of blood, blood components and plasma derived medicaments stays or falls with the safety policy in donor recruitment, and selection and in the testing of the plasma-pool. Moreover, plasma products are not a substitute for transfusions with perishable blood products. Patients must rely on adequate donor selection procedures ant the application of safety measures necessary to prevent health risks. In that respect, the scientific state of the art plays an important role. Every safety measure has its own price. As financial resources available for health care are limited, safety measures have to be evidence-based and hospitals and medical doctors should only apply a blood-therapy when it is proven to be safe and effective.2

On the other hand, the more risks for diseases that may be transmitted through blood, blood components and plasma are discovered that can only be avoided by donor-deferral, the more the availability of sufficient blood supply comes under pressure. The decline in donors with the increase in the number of a-specific tests and the increasing need for specific donors makes blood-medicine clearly a “double-edged” sword.