

EDITORIAL

Is there a limit to the normality of blood products?

The emotional shock and trauma experienced by patients who have received contaminated blood is so dramatic that not only patients, but also other individuals, including politicians, blood bank directors, indeed all of us remain scarred. Precautions for blood selection are on the increase and each country has its own elaborate rules.

Efforts to minimise contamination are clearly a priority for blood banks and existing policies restrict donations from any person whose blood could infect or damage a recipient. These preventative measures have been designed to obtain safe blood from normal donors, in order to provide for the needs of recipients. But what do we mean by 'normal' in this context? Current screening procedures are extensive and, while they are aimed at protecting recipients, they do actually exclude potential donors. The result is extravagant expense with a low return in life-years saved. It is clear that we need to reconsider the cost/benefit equation and reassess the actual risks for recipients.

Consider the example of hemochromatosis abnormalities, which are frequently encountered in blood bank screenings. Phenotypic and genotypic methods are used to screen not only the family members of individuals with this disease, but also the large-scale population. In the USA, healthy homozygotes are excluded from donating blood under the pretext of being non-volunteers. In some countries, even individuals who are heterozygous for hemochromatosis are excluded from donating blood are considered to be non-normal donors. What is the actual risk when a blood unit is taken from a healthy individual with this disease? If analyses show that a potential donor has a genetic anomaly that manifests no phenotypic trait, should this person be necessarily excluded from donating blood? It seems more appropriate to consider carefully the needs of potential recipients. No one is genetically 'normal' and it is time for blood banks to identify anomalies that are incompatible with the philosophy of blood donation. Too many precautions can only lead to a dearth of potential donors.

Consider as well the selection of donors according to their past history. The USA has a policy to exclude donors who have spent more than 6 months in the UK. In France, people who have already received blood transfusions (one or more) are automatically excluded from donating their blood. One has to ask what the limits are. What should be tested for, and on what basis? Indeed, one may ask how many laboratory tests should be performed on blood products? Costs for blood screening seem to have no limit. While the risks cannot be completely eliminated, residual risks must be minimised, yet no one has a clear idea of the limit. The extensive, high-cost blood screening programme implemented by the French Ministry of Health in 1999 is a prime example. A study comparing the cost of Hepatitis C screening (using current 3rd generation ELISA vs ELISA and PCR tests on individual and pooled blood donations with the benefit to recipients, as measured by the number of life-years saved) prompted the ministry to implement a wide-scale screening programme using expensive detection techniques (PCR). This study defined 'benefit' as the number of life-years saved, taking into account not only the reduction of infection and the survival time of the recipients, but also the natural history of the Hepatitis C-infected patients. The incremental cost per additional life-year saved was estimated to be in the region of 80 million Euro/US dollars. Another example is HTLV-1 detection, systematically performed on blood of individuals who live outside a given endemic area. Should we not, then, screen for all types of viral and parasitic infections using expensive molecular tools on each individual unit of blood? Should politicians compare the price of additional life-years saved with that of other innovations actually limited in medical practice?

It has now become urgent for blood banks to reassess common criteria for the selection of donors and to establish clear guidelines for the tests to be performed on blood donations.

L Degos