Opinion on information to be given to patients regarding the possibility of transmission of the infective agent of Creutzfeldt-Jakob disease by blood components

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Opinion

In a letter dated 17th April, 1997, on the possibility of transmission of the infective agent of Creutzfeldt-Jakob disease by blood components, Monsieur Hervé Gaymard questioned the National Consultative Ethics Committe (CCNE) on the following points :

"1° - are conditions specified for the information of patients in circular DGS n° 96-504 of 31st July 1996 still pertinent ?

2° - if the *Académie Nationale de Médecine* (National Medical Academy) were to consider that systematic information is required, what should it consist of and what kind of follow-up action should be instituted ?".

The CCNE felt the use of blood components should be considered in the general context of a risk-benefit ratio evaluation of blood transfusion and management of that risk.

Known risks of acute, subacute or chronic transfusion accidents are those of an immunologic or infectious nature.

According to data supplied by the *Institut National de la Transfusion Sanguine* (National Institute for Blood Transfusion) for 1996, they are presently assessed as follows :

A. IMMUNOLOGIC RISK (averages) :

ABO incompatibility : 1/53,000 units

accidents connected to the presence of irregular antibodies : 1/47,000 units.

B. INFECTIOUS RISK (averages)

HIV : 1/700,000

HBV : 1/120,000

HCV : 1/150,000

HTLV : 1/3 million

In the present state of scientific knowledge, risk of transmission through the blood of transmissible spongiform encephalopathy agents is purely theoretical. No human clinical case has been reported.

The possibility of transmission of non-conventional agents through blood derived medicinal drugs or through human origin labile blood products cannot however be neglected.

It is therefore now necessary to complement existing arrangements with prospective measures which would make it possible when the time comes to organise screening or even treatment for CJD if that becomes available.

This presupposes that information be given to physicians and patients, as follows :

A. Information to physicians.

Reference must first of all be made to risks which are completely known and evaluated. It is sad to find that the most frequent accidents involving the use of blood products are still related to protein or red blood cell incompatibility. Transfusion safety rules must be unflaggingly repeated in regulatory texts, in particular those addressed to health institutions.

Similarly, reminders should be given of the indications of the various transfusion blood products. Not only would that bring about better medical management of the risk, but also substantial savings.

For these reasons, the conclusions of the Consensus Conference organised on December 16th, 1996 by the *Société Française d'Anesthésie et de Réanimation* (French Society of Anaesthesia and Resuscitation), could be widely circulated. This conference stated clearly how human albumin solutions should be used for adult patients. Their conclusions, which pointed out that indications for the use of albumin solutions are very limited, are published in the *Annales Françaises d'Anesthésie-Réanimation* (AFAR, vol 15-n°4-1996). They could be the subject of a DGS (1) text.

A prospective register for identification of patients who have received this type of product should be started now in view of future epidemiological studies, and so that patients can be traced easily if necessary.

Monsieur Hervé Gaymard has decided to defer permanently prospective blood donors who have been transfused. This decision became operational on October 1st, 1997. Similarly, disqualification from blood donation of those who are at increased risk of developing a TSE is already implemented. This is the case for patients treated with hormones extracted from pituitary glands, or who have been recipients of a dura mater graft, and those presenting clinical signs of neuro-degenerative pathologies.

In the circumstances, an evaluation must be made of the risk/benefit ratio of deferring other blood donors for whom, unlike those previously mentioned, there is no documented risk. If cause for disqualification is extended there could be a risk of scarcity of the blood supply and thereby, a risk of deaths due to severe haemorrhage as has been observed in obstetrics or traumatology.

B. Information to patients.

Giving information to patients about the therapy they are undergoing is a deontological and ethical obligation. It would be unacceptable to deny them information about their own health to which they are entitled. The decision to inform about treatment must be systematic and not left to the physician's discretion. The administration of blood products to a patient implies that his state of health is or has been critical. Communication of the medical file is all the more imperative because there is a potential risk of later therapy which may be incompatible with certain blood products or drugs previously administered. This is the case not just for blood derived pharmaceuticals but is also true of certain antibiotics or some anaesthetics which present a risk of immunisation or secondary effects.

Information on the potential risk of some therapies, when it is not based on scientifically confirmed facts, is not the same thing as information on the treatment itself. Once a risk is

known and scientifically demonstrated, there is an obligation to inform the patient. If, however, the risk is virtual and theoretical, there is no ethical justification to giving information since it may be perceived as a vague unidentified threat which could lead to irrational behaviour, possibly dangerous to both patient and society. This is the case for TSE at present.

C. Conclusion

The CCNE therefore considers it necessary, in the specific case of blood contamination by non conventional agents, to create a scientific and ethical surveillance unit to monitor scientific publications on this subject on a regular basis. Once scientifically established facts make it possible to state that the risk is a reality, then information in medical files collected on a prospective basis would be processed and used to trace potentially contaminated patients. They would then be systematically informed according to well defined protocols.

Notes

1. *DGS - Direction Générale de la Santé,* French Public Health Authorities