



Recommendation Rec (2001)4 of the Committee of Ministers to member states on the prevention of the possible transmission of variant Creutzfeldt-Jakob Disease (vCJD) by blood transfusion

(Adopted by the Committee of Ministers on 7 March 2001 at the 744th meeting of the Ministers' Deputies)

The Committee of Ministers, under the terms of Article 15.b of the Statute of the Council of Europe,

Considering that the aim of the Council of Europe is to achieve greater unity between its members and that this aim may be pursued, *inter alia*, by the adoption of common action in the health field;

Taking account of the ethical principles set out in Recommendation No. R (88) 4 on responsibilities of health authorities in the field of blood transfusion concerning voluntary, non-remunerated blood donation;

Recalling its Recommendation No. R (95) 14 on the protection of the health of donors and recipients in the area of blood transfusion;

Recalling the guidelines and principles defined in Recommendation No. R (95) 15 on the preparation, use and quality assurance of blood components;

Considering the identification of a new form of Creutzfeldt-Jakob Disease (CJD) that differs from previously recognised types of the disease, known as variant Creutzfeldt-Jakob Disease (vCJD);

Taking into account that much of the scientific basis concerning transmission routes and mechanisms is uncertain in CJD as well as in the new vCJD;

Considering nonetheless that there are indications that vCJD may be transmissible by blood or blood products;

Given that the length of the incubation period will make it extremely difficult to establish scientific certainty within a reasonable time limit;

Considering that it has been established beyond reasonable doubt that the transmissible agent for vCJD is indistinguishable from that of Bovine Spongiform Encephalopathy (BSE) and that vCJD most probably results

from the exposure to bovine products derived from BSE infected cattle;

Taking into account that at present there is as yet no evidence that vCJD has been transmitted by blood or blood products; Taking note of the information provided in the explanatory report to this recommendation,

Recommends that governments of member states take the following measures in order to prevent the possible transmission of variant Creutzfeldt-Jakob Disease (vCJD) by blood transfusion:

1. Initiatives need to be taken to promote the appropriate use of blood to minimise the unnecessary exposure of patients to blood transfusion.
2. Care should be taken to ensure that any measure proposed will not have a negative impact on the donation and supply of blood necessary to meet patients' needs. Any measures under consideration for the purpose of minimising the theoretical risk of transmitting vCJD to a recipient by blood transfusion must take into account the balance of risk between maintaining an adequate blood supply and minimising the theoretical risk.
3. Member states should have a centralised CJD surveillance system in place, with access to a European CJD reference centre facility, and a system of traceability of donations in order to initiate a recall if necessary.
4. Member states should determine, on the basis of the prevalence of BSE within individual countries, of the endogenous exposure of the population to bovine products imported from countries with a high BSE prevalence and of the incidence of cases of vCJD, what precautionary measures they may need to take to minimise the theoretical risk of transmission of the vCJD infective agent through blood transfusion.
5. Efforts must be made to develop and implement a sensitive and specific test for diagnostic and screening purposes as soon as practically feasible.