

File

Ref: MSL/1/1

12

Dr Field IMCD
Dr Sibellas IMCD
Mr Fanning CHD1
✓ Mr Winstanley HS1A
Dr Wolford MED SEC

COUNCIL OF EUROPE: DRAFT RECOMMENDATION ON PREVENTING TRANSMISSION OF
ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) FROM BLOOD DONORS TO PATIENTS

In view of increasing international concern about the rising number of AIDS cases in Europe the Committee of Experts on Blood Transfusion and Immunology will be submitting the attached draft recommendation (Appendix II) to the Council of Europe's Health Committee on 20 June and later that day the text will be submitted to Minister's Deputies for approval.

Foreign and Commonwealth Office have asked for briefing on the text indicating its acceptability to the UK and any amendments we propose, together with supporting arguments. Dr H Gunson, our representative on the expert committee, has already accepted the main principles of the draft recommendation.

I should be grateful for any response you may have by early on Monday morning 13 June for onward transmission to the FCO.

GRO-C

A T CUMMING
IR1B
Room D304 AFH
Ext GRO-C

7 June 1983

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

COMMITTEE OF MINISTERS

Strasbourg, 3 June 1983

Restricted
CM(83)119

DRAFT RECOMMENDATION NO. R(83)... ON PREVENTING THE
LIKELY TRANSMISSION OF ACQUIRED IMMUNE DEFICIENCY
SYNDROME (AIDS) FROM BLOOD DONORS TO PATIENTS RECEIVING
BLOOD OR BLOOD PRODUCTS

Secretariat memorandum
prepared by the Directorate of Economic and Social Affairs

1. The Acquired Immune Deficiency Syndrome (AIDS) was described for the first time in 1981. Since then 1,300 cases have been reported to the Centre for Disease Control in the USA. (Appendix I contains a brief description of the present knowledge of AIDS and its epidemiology.) Extensive research is being carried out to determine the causal factor of this syndrome, and the possible preventive and therapeutic measures.

2. In Europe AIDS has been discovered among patients who have received transfusion. Seven cases out of 69 have been reported to the Committee of Experts on Blood Transfusion and Immunohaematology (SP-HM). It is assumed that the syndrome is transmissible via blood (as is the case for hepatitis B). This explains the increasing concern which the syndrome is causing in blood transfusion circles and especially among haemophiliacs (1) and the consequent need to urgently implement preventive measures.

- (1) Haemophilia A and B are genetic diseases affecting approximately one individual in 10,000. They are due to a deficiency or anomaly of coagulation factors and result in bleeding disorders. Therapy consists in regular administration of missing factors obtained from plasma of blood donors. The quantitative needs are of about 50,000 I.U per year per haemophiliac. Depending on the purity of the preparation, this implies that 5%-20% of the general population need to donate blood once a year. The present average of voluntary donors hardly exceeds 10% of the population.

80.333
03

3. At its 6th meeting held in Lisbon on 16-19 May 1983 the SP-HM, the only Committee of Experts competent in this field at European level, reviewed the situation (see Appendix I) and prepared a draft Recommendation (see Appendix II), to be submitted to the Committee of Ministers for examination and adoption.

The draft Recommendation recalls the basic principles to minimise the hazard of transmission of infectious diseases (AIDS appears to belong to this category), and advocates that information on AIDS be given to all blood donors inviting those in high risk groups to refrain from donating. Furthermore, it recommends rapid implementation of the following Recommendations of the Committee of Ministers:

- Recommendation No. R(80)5 concerning blood products for the treatment of haemophiliacs
- Recommendation No. R(81)14 on preventing the transmission of infectious diseases in the international transfer of blood, its components and derivatives.

4. The SP-HM asked the Secretariat to submit urgently the text of the draft Recommendation to the Committee of Ministers for consideration, in particular, in view of the fact that the next International Congress of Haemophiliacs would be held in Stockholm in July 1983. If the draft Recommendation were to be adopted at the June 1983 meeting of the Ministers' Deputies it would be forwarded to the Congress before it started its work.

Moreover the Services for Communicable Diseases of the Regional Office of the World Health Organisation (WHO) have been urged by the governments to convene a meeting to study the epidemiological aspects of the AIDS problem. It is expected that this meeting will probably be held in August 1983. It would therefore be highly desirable that measures proposed for the prevention of AIDS in relation to blood transfusion, set out in the draft Recommendation, be officially available by that date.

5. According to normal procedure the draft Recommendation prepared by the SP-HM should first be approved by the European Health Committee (CDSP) before its submission to the Committee of Ministers for consideration and adoption. However, the Bureau of the CDSP (which has been consulted by the Secretariat) agreed that the text of the draft Recommendation should be submitted to the Committee of Ministers direct in view of the urgency of the matter and the reasons set out above in paragraph 4. The forthcoming meeting of the CDSP will be held in Strasbourg on 20-23 June 1983; all members of the CDSP have been informed of this procedure and the full text of the draft Recommendation has been communicated to them by telex.

6. Finally, the Secretariat wishes to point out that for the convenience of blood transfusion services an information leaflet prepared by the American Red Cross is appended to the draft Recommendation, it being understood that each member State is free to adapt it to fit its own situation.

APPENDIX I

EXTRACT FROM THE REPORT OF THE 6TH MEETING OF THE
COMMITTEE OF EXPERTS ON BLOOD TRANSFUSION
AND IMMUNOHAEMATOLOGY (SP-HM)
(Lisbon, 16-19 May 1983)

Agenda item 3.1 - Urgent Questions
Acquired Immune Deficiency Syndrome (AIDS)
(SP-HM(83)2)

The discussion was introduced by Prof. Dr. W Weise (Federal Republic of Germany) who reviewed the AIDS syndrome which is thought to impair the immune system of man and leave affected individuals susceptible to certain types of cancer and a number of infectious diseases. Since June 1981 about 1,300 cases of AIDS have been reported to the Centre for Disease Control (CDC) in the USA.

CDC defines a case of AIDS as a disease, at least moderately predictive of a defect in cell-mediated immunity, occurring in a person with no known cause for diminished resistance to that disease. Such diseases include Kaposi's sarcoma, pneumocystis carinii and serious other opportunistic infections.

The syndrome has been reported as striking mainly male homosexuals (75-80 per cent of all cases) but it also has affected male and female heterosexuals (60 per cent of whom admit intravenous drug abuse), and haemophiliacs. Two different ethnic groups are also involved: male and female Haitians and people from Central Africa (eg Tschad and Zaïre). No AIDS were observed in Japanese and Chinese.

The casual agent behind the AIDS epidemic is unknown at the present time. The distribution of AIDS cases parallels that of hepatitis type B virus infection, which is transmitted sexually and parenterally. Blood products or blood appear responsible for AIDS among hemophilia patients who require clotting factor replacement.

Several factors indicate that individuals at risk for transmitting AIDS may be difficult to identify. There is no specific laboratory test for AIDS so far. AIDS is characterised by a number of in vitro signs of cellular immune deficiency, such as abnormal ratios of helper to suppressor cells within the lymphocyte compartment. Such signs have also been observed among a significant proportion of homosexual men who were asymptomatic or had non-specific symptoms or signs. Similar findings have been reported among patients with haemophilia.

The most urgent need is to confirm or disprove the hypothesis that AIDS is caused by a transmissible agent present in the blood. Studies of T-lymphocyte sub-populations among similarly treated haemophiliacs in geographical areas to which AIDS has not yet been introduced would be an immense help for the resolution of this question.

Members of the committee up-dated the information they had provided upon AIDS concerning their country and it was generally agreed that this was an important and increasing problem on which the committee should prepare a draft recommendation to assist national health services in handling the consequences of AIDS related to the transfusion of blood and blood products. A working party, comprising Prof. Dr. P Cazal (France), Prof. Dr. W Weise (Federal Republic of Germany), Prof. R Masure (Belgium), Dr. H H Gunson (United Kingdom), Dr. B Gullbring (Sweden), Prof. A Hässig (Switzerland) and Dr. J Leikola (League of Red Cross Societies) was formed to prepare the draft Recommendation which was approved by the Committee of Experts for submission to the European Health Committee and adoption by the Committee of Ministers.

The Spanish delegation suggested that the Secretariat of the Council of Europe continue the collection of epidemiological data on AIDS in Europe on the basis of a uniform questionnaire based on the model in use in the Federal Republic of Germany. This would allow the Committee to be kept informed of the evolution of this condition in Europe.

Various members of the Committee pointed out that this question of a strictly epidemiological nature was outside the scope of the Committee's terms of reference.

In reply to a question as to whether there existed other Council of Europe committees which either were or could become competent for this field, the Secretariat replied that there were no such committees; however, further to a recent co-ordination meeting between the Council of Europe and the WHO Regional Office for Europe, it had been agreed that the study and control of the epidemiology of AIDS would be dealt with by WHO, while the Council of Europe's Committee of Experts on Blood Transfusion and Immunohaematology was requested to follow closely this question from the transfusional angle.

Mutual information on findings would be ensured by the Secretariats of the respective organisations. This was of importance especially as a meeting on the epidemiology of AIDS was going to be organised by WHO in Europe in August or November 1983.

The Committee endorsed this agreement and decided to invite all the members to keep the Secretariat constantly informed of any new developments on AIDS in relation to blood transfusion. Prof. Dr. W Weise (Federal Republic of Germany) accepted to continue to act as Rapporteur for this item.

In view of the fact that haemophiliacs were specially concerned by this problem and that their next international congress will be held in Stockholm in July 1983, the Committee asked the Secretariat to take all necessary measures to bring the proposed recommendation urgently to the attention of the Committee of Ministers so that it would be adopted in time for its transmission to both the above international congress on haemophilia and the WHO meeting on the epidemiology of AIDS.

APPENDIX II

DRAFT RECOMMENDATION NO. R(83)...
OF THE COMMITTEE OF MINISTERS TO MEMBER STATES
ON PREVENTING THE LIKELY TRANSMISSION OF
ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)
FROM BLOOD DONORS TO PATIENTS RECEIVING BLOOD OR BLOOD PRODUCTS

(Adopted by the Committee of Ministers on ...
at the ...th meeting of the Ministers' Deputies)

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

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

Considering the growing importance of a new and severe health hazard, Acquired Immune Deficiency Syndrome (AIDS), that may be caused by an infectious agent transmissible by blood and blood products;

Recalling the basic principles to minimise the hazard of transmissible infectious disease by blood or blood products drawn up in the context of the work of the Committee of Experts on Blood Transfusion and Immunohaematology:

1. to expose the recipient to a minimum number of donations of blood when the transfusion is of cellular and coagulation factor products,
2. to achieve national self-sufficiency in the production of coagulation factor products from voluntary, non-remunerated donors,
3. to avoid the importation of blood plasma and coagulation factor products from countries with high risk populations and from paid donors:

Recalling Recommendation No. R(80)5 concerning blood products for the treatment of haemophiliacs, with special reference to Section II of the operative part, and Recommendation No. R(81)14 on preventing the transmission of infectious diseases in the international transfer of blood, its components and derivatives;

Recognising the necessity to provide pertinent information to blood donors, attending physicians and selected recipient groups in order to avoid, as far as possible, donations by persons in high risk groups without inappropriate discrimination and emotive over-reaction amongst recipients;

Recommends the governments of member States

- I. to take all necessary steps and measures in respect to the Acquired Immune Deficiency Syndrome and in particular
 - to avoid the use of coagulation factor products prepared from large plasma pools except when such a product is specifically indicated for medical reasons; this is especially important for those countries where self-sufficiency in the production of such products has not been achieved;
 - to inform attending physicians and selected recipients, such as haemophiliacs, of the potential health hazards of haemotherapy and the possibilities of minimising these risks;
 - to provide all blood donors with information on the Acquired Immune Deficiency Syndrome so that those in high risk groups will refrain from donating (an example of an information leaflet for donors is appended);
- II. to pursue rapid and full implementation of Recommendations No. R(80)5 and No. R(81)14.

Appendix to Recommendation No. R(83)...

The present information leaflet for donors has been prepared by the American Red Cross and is given as an example for the convenience of National Blood Transfusion Services wishing to draw up their own information leaflet

AN IMPORTANT MESSAGE TO ALL BLOOD DONORS

This information is distributed to all potential blood donors to help prevent the spreading of certain illnesses from donors to patients by blood transfusions.

Please read this statement, and if you think that there is a risk that your blood could cause illness in a patient who might receive it, please refrain from donating blood at this time.

WHAT ARE THESE ILLNESSES?

Some persons may feel in excellent health but have viruses or other infectious agents in their blood that could cause illness in persons receiving a transfusion of their blood. If you think any of the following information pertains to you, please do not donate blood today:

1. Acquired Immune Deficiency Syndrome (AIDS)

This newly described illness of unknown cause is believed to be spread by intimate personal contact and, possibly by blood transfusion. Persons with AIDS have reduced defenses against disease and as a result may develop infections such as pneumonia, or other serious illnesses. At this time there is no laboratory test to detect all persons with AIDS. Therefore we must rely on blood donors' health histories to exclude individuals whose blood might transmit AIDS to patients who will receive that blood.

The Office of Biologics of the Food and Drug Administration has identified groups at an increased risk of developing AIDS. These groups are:

- persons with symptoms and signs suggestive of AIDS. These include severe night sweats, unexplained fevers, unexpected weight loss, lymphadenopathy (swollen glands) or Kaposi's Sarcoma (a rare cancer);
- sexually active homosexual or bisexual men with multiple partners;

- recent Haitian entrants into the United States;
- present or past abusers of intravenous drugs;
- sexual partners of persons at increased risk of AIDS.

2. Hepatitis

Persons with a past history of viral hepatitis are deferred permanently. Intimate contact with someone suffering from viral hepatitis requires deferral for six months.

3. Syphilis

Potential blood donors with active syphilis are deferred.

4. Malaria

Potential blood donors who have visited countries where malaria exists are deferred for six months after leaving the malarious area, or if anti-malarial drugs were taken, for three years after cessation of this drug therapy. Natives from countries where malaria exists are deferred for three years; Haiti is one of these countries.

WHAT SHOULD I DO?

If you believe that you may be carrying one of the above-mentioned illnesses, or if you are an individual in a group at increased risk of developing AIDS, we ask that you refrain from donating blood at this time. You may leave now without providing an explanation. Or, if you prefer, you may proceed to be deferred confidentially, without further questioning, by the health history interviewer.

If you would like additional information, Red Cross nurses and physicians will be pleased to answer any questions you may have.