

PAPER II

ACTION ALREADY TAKEN BY RELEVANT AUTHORITIES OUTSIDE THE DEPARTMENT

1. Action by Regional Transfusion Directors

At their meeting on 18 May the Regional Transfusion Directors agreed to prepare an information leaflet on AIDS which would be available to donors to read at donor sessions and could be sent to donors phoning in with enquiries. (Directors asked if the Department would pay for the printing of such a leaflet and this has been agreed with Information Division. A draft has been circulated for comment).

The Directors further proposed to make an approach to the Medical Gay Society (an association of homosexual doctors) to enlist their help in the dissemination of information on AIDS to homosexual groups. The Society's initial reaction has been favourable.

Directors were adamant that there would be no direct questioning of donors about their sexual habits nor about the presence of symptoms such as night sweats, weight loss etc.

2. Recommendations of Haemophilia Reference Centre Directors

At their meeting on 13 May 1983, the Haemophilia Reference Centre Directors agreed that on the evidence available and because of the benefits of treatment, no restriction should be placed on the use of imported Factor VIII concentrate other than to continue with the present policy of using only NHS material for children under the age of 4 years and for mild haemophiliacs.

3. New Regulations on Donor Screening by the Food and Drugs Administration (FDA) in the USA

As from 23 March 1983, FDA regulations have required that:

- i. Educational programmes be instituted for potential donors from defined high risk groups asking that they refrain from donation. (High risk groups are defined as: persons with symptoms and signs suggestive of AIDS; sexually active homosexual or bisexual men with multiple partners; Haitian immigrants, intravenous drug abusers and sexual partners of individuals at increased risk of AIDS).
- ii. All plasma donors to receive information on AIDS.
- iii. Plasma taken from a donor in a high-risk group should be labelled to indicate that it should only be used in the preparation of albumin, PPF, globulin or for non-injectable products. (NB: the use of such plasma for albumin, PPF etc production is extremely dubious. If an infectious agent is involved, there is no means of knowing that the heat treatment, to which these products are subjected, will inactivate it - DW).
- iv. The donor's medical history should include specific questions designed to detect possible AIDS symptoms eg night sweats, unexpected weight loss etc.

- v. Donors should be examined for lymphadenopathy (a limited examination to be made by "an adequately trained individual" at each donation and annually by a physician).
- vi. The donor's weight should be recorded before each donation. A donor with unexplained weight loss should be referred to a physician and any plasma stored from that donor should be quarantined.
- viii. Plasma from a donor known or suspected to have AIDS must be quarantined and destroyed or otherwise handled accordingly to specified procedures for bio-hazardous materials.

4. Council of Europe

Dr Gunson attended a meeting of the Council on 16-19 May. AIDS was discussed at length and Dr Gunson has sent a summary report for most of the European countries. (The report from Belgium is interesting because of the preponderance of patients originating in Zaire and the suggestion in the Lancet that the disease may be caused by a variant of the African Swine Fever Virus may well be pertinent). Most countries reported additional cases following the preparation of their reports but there are very few cases following transfusion, even in W. Germany.

Dr Gunson reports that there is going to be a resolution put to Ministers of the Council of Europe. This has not yet been finalised but the gist is as follows:-

1. To expose the recipient to a minimum number of donations of blood in the case of transfusion of cellular and coagulation factor products.
2. To achieve national self-sufficiency in the production of coagulation factor products.
3. The avoidance of the importation of plasma and coagulation factor products from countries with high risk population.
4. To provide information to all donors so that those at risk will abstain from donating.
5. To inform all attending physicians and selected patient groups of the potential hazard and the possibilities of minimising this risk.

Dr Gunson draws attention to 1 above as indicating the probability of a greater use of cryo-precipitate in Europe since this tends to be the standard product in many European countries. This will have far-reaching implications for BPL as it would cause great difficulties to change to the production of freeze-dried cryoprecipitate. The CBLA will need to consider the interim period before completion of the new plant and the path to a solution of the problem is as yet unclear.