Reference

(2596)

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UP-DATE ON AIDS

1. Aids in Haemophiliacs in the UK

There is one suspect case in Cardiff. Although CDSC states that this case meets the USA criteria for AIDS, the clinician in charge does not consider that it should be regarded as a confirmed case. There is also a possible case at Bristol Royal Infirmary but it may not meet all the criteria. Further details are being sought. There is still no trace of the London case which was mentioned in the press.

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. Action proposed by Regional Transfusion Directors

At their meeting on 18 May 1983 the Regional Transfusion Directors agreed to prepare an information leaflet on AIDS which would be available for 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 is being discussed with Information Division.)

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.

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.

4. FDA regulations on donor screening

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.

vii) Plasma from a donor known or suspected to have AIDS must be quarantined and destroyed or otherwise handled according to specified procedures for bio-hazardous materials.

5. Relevance of FDA regulations for UK imports

A disproportionately high percentage of plasma from "high-risk" donors is likely to find its way into imported albumin, PPF and gamma globulin preparations on the totally unsubstantiated premise that heat-treatment of these products will inactivate the AIDS agent. Medicines Division will presumably be considering the implications of this.

There are presumably large stocks of Factor VIII concentrates in the USA prepared before the 23 March guidelines came into force. It is possible that concentrates made from the "safer" plasma may be retained for use in the USA while the older stocks may be dumped on export markets such as the UK. Medicines Division has been asked to consider if there is any way - perhaps by means of new labelling requirements - to prevent this.

Medicines Division have also been asked to consider whether it would be possible to identify products manufactured from plasma taken outside the areas where AIDS is most prevalent eg New York, San Francisco, Los Angeles etc and whether it would be feasible - in terms of the amount of material currently available - to restrict imports of Factor VIII concentrate to those batches made from plasma collected after 23 March.

As a long stop, Immuno or other European manufacturers could be asked if they would be able to supply up to 30 million i.u. of Factor VIII made wholly from European plasma. Presumably Supply Division would wish to take the lead on this.

6. Implications of the introduction of heat-treated Factor VIII concentrates

A number of commercial manufacturers of Factor VIII are hoping to introduce Factor VIII concentrates which have undergone an additional heat-treatment step which is designed to reduce viral infectivity. Although originally

aimed at reducing the risk of transmission of hepatitis, it is now being suggested that heat-treated concentrates might also reduce the risk of the transmission of AIDS.

As far as I am aware, there have been no controlled clinical trials to substantiate a reduced hepatitis risk from the heat-treated concentrates and nor, of course, is there any information on the transmission of AIDS. Nevertheless, should they be licensed for use in this country, it seems more than likely that there will be a heavy clinical demand for them. Not only would this have cost implications for the NHS, since the heat treatment substantially reduces the yield of Factor VIII per litre of plasma and therefore increases production costs, but the BPL may find itself obliged to manufacture heat-treated concentrates for which up to 60% more plasma might be needed simply to produce the current output of Factor VIII.

Clearly, there is a need for a controlled clinical trial of heat-treated concentrates in respect of hepatitis infectivity. However, such a trial could pose ethical problems at the present time. In earlier discussions on a protocol for such a clinical trial, Haemophilia Centre Directors had been of the opinion that a meaningful trial could only be conducted in patients who had not previously been treated with Factor VIII ie newly diagnosed mild haemophiliacs. However, this is a particular group of patients for whom the Directors have recommended (see para 2 above) that only NHS material should be used.

7. Genetically engineered Factor VIII

The prospects for genetically engineered Factor VIII still seem to be several (5-10) years in the future.

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