BLOOD PRODUCTS - HEPATITIS A INFECTION

THE PROBLEM:

There have been reports of some 80 cases of hepatitis A infection occurring in haemophilia A patients in Italy, Ireland, Germany and Belgium. The infections have occurred in patients receiving Factor VIII prepared by ion exchange chromatography and incorporating the solvent detergent method for ensuring viral safety. To date, the Factor VIII product concerned has been manufactured either by Octapharma in Vienna or in Italy by a company using the same technology under licence from Octapharma. So far there have been no reports of hepatitis A infection in haemophilia A patients in France and CRTS Lille use the identical technology to Octapharma. As yet there have been no cases of hepatitis A infection reported in patients with haemophilia B.

There are many hypotheses as to the reasons for the occurrence of these cases of hepatitis A infection:

1. With improving hygiene and changing socio-economic factors, the epidemiology of hepatitis A has changed during the past years. Now fewer children are infected and infections tend to occur within the age group of the blood donor population.

2. The changes described in 1. have led to a decrease in the presence of neutralising antibody to hepatitis A in existing plasma pools.

3. Previously, neutralising HAV antibody was present in intermediate purity Factor VIII and this has now been lost from the high purity products.

4. The ion exchange technology could possibly concentrate the virus, which may later then be released into the product. The methodology for manufacturing Factor IX has significant differences which might explain the absence, as yet, of reported cases in patients with haemophilia B.

5. The solvent detergent technology does not eliminate non-lipid envelope viruses. Hepatitis A is a small virus without a lipid envelope and it is debatable and even possible that it could get into the final end product if present in the original plasma pool.
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RECOMMENDATIONS:

1. Until investigations have resolved the cause of the cases of hepatitis A, it is recommended that United Kingdom recipients of pooled plasma products should be tested promptly for antibody to HAV.

2. If found to be negative, they should be offered a course of hepatitis A vaccination as soon as practicable.

3. Any case of hepatitis A occurring in a patient receiving blood products should be reported to the Chairman of the Adverse Events Working Party and to the Chairman of the Regional Committee. If the product has a licence in the United Kingdom, yellow cards should be sent to the Committee on Safety of Medicines.

NB: It should be pointed out that Octapharma products are not licensed in the United Kingdom.

E E Mayne
Chairman
UK Haemophilia Centre Directors’ Organisation

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To: Regional Haemophilia Centre Directors, UKHACDO
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