LOTHIAN HEALTH BOARD

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Lothian Health Board
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Your Ref
Our Ref CAL/NP
Date 20/11/92
Enquiries to
Ext. No. GRO-C

Dear Helen,

Hepatitis A Vaccination for Children with Haemophilia and related disorders.

Recently there have been several outbreaks of hepatitis A infection amongst patients with haemophilia in different parts of Europe. There is strong epidemiological evidence backed up with laboratory testing of factor VIII concentrates to suggest that hepatitis A virus is transmitted by concentrates prepared by iron exchange chromatography and sterilised by the solvent/detergent technique. As you will probably know, traditional dogma is that hepatitis A virus is virtually never transmitted by blood but this appears now not to be true!.

Over the past few weeks I have had discussions with various individuals from Europe who have first hand knowledge and experience of the outbreaks. One of the factors in common has been the mode of manufacture of the concentrates. Unfortunately the method is very similar to the one used in Scotland for producing the new high purity concentrate. To date we have no evidence that it has transmitted hepatitis A but clearly this is now apparently a possibility.

I have therefore decided to vaccinate all anti-hepatitis A negative individuals who may receive poolled coagulation factor concentrates. As you will know a hepatitis A vaccine has recently been licensed and apparently has a good safety record.

Unfortunately the product licence does not cover the use of the hepatitis A vaccine for children, I understand this is because no studies have been done in these individuals.

My purpose in writing is to let you know that I think it would be prudent to vaccinate all potentially at risk children against hepatitis A (if they are anti-HAV negative) with half the dose recommended for adults. Such vaccinations would be on a named patient basis because the product license does not cover children.

I thought I should write and let you know of this proposed course of action because it potentially increases the liability of the LHB when a product is used on a named patient basis, particularly for many individuals. Of course if I do not vaccinate the children and hepatitis A virus is transmitted by factor VIII concentrate I might be judged less than prudent not to have given the vaccine despite the absence of a CSM licence!.

I apologise for adding to your in-tray but as the LHB now carries my indemnity I thought you might like to have the opportunity to comment on my proposed course of action.

With best wishes

Yours sincerely

C A Ludlam
Consultant Haematologist

c.c. Prof M R Lee
Chairman, Drugs & Therapeutics Committee