FURTHER SURVEY OF FACTOR VIII ASSOCIATED HEPATITIS 1976-7

OBJECT

To continue the survey of Hemofil associated hepatitis begun in 1974 and to compare the incidence of hepatitis after transfusions of Kryobulin and NHS Factor VIII with that after treatment with Hemofil.

METHOD

1) Directors of Haemophilia Centres who agree to participate will be asked to report cases of hepatitis associated with the use of these products to the Oxford Haemophilia Centre throughout the two year period. For this they should use the Hepatitis Survey Sickness Form C3. The only additional information required would be whether the patient had previously received transfusions of large pool Factor VIII concentrates (Elstree, Oxford, Hemofil, Kryobulin) before the transfusion thought to be implicated in this attack of hepatitis. Otherwise the same data would be recorded as in the previous survey. The transfusion record of each patients with hepatitis will be requested using a revised Form C.

2) At the end of each year Directors will be asked to report the total numbers of patients who have received previously designated batches of Factor VIII associated with cases of transfusion hepatitis to the Oxford Haemophilia Centre using Form C4 (a, b, or c). Where no cases occur particulars of 5 batches, i.e. total numbers of patients and bottles transfused will be included. The batch numbers of each product to be included in the survey will be notified to each Haemophilia Centre Director before the annual returns to Oxford are due. It is also requested that any cases due to these products associated with batch numbers not included in the survey, should be added to the annual return.

3) Details of the transfusion records for each batch will be recorded as before, using Form C4. For patients who do not develop hepatitis it may be more convenient to report the numbers of bottles of each batch transfused over a suitable period e.g., 1 month, instead of for each particular day.

4) For Elstree Factor VIII, the numbers of batches are now so large that it will be better to make returns on a selected number of batches at designated centres by arrangement with each individual Director. Dr. d'A Maycock has agreed in principle to a survey on these lines. If any cases of hepatitis occur where any batch of Lister Factor VIII may be implicated, then these should be reported by the same method as for Hemofil and Kryobulin.

5) It is hoped to do a postal survey of the sequelae of Non-B hepatitis and hepatitis B due to Hemofil over the past two years. A specimen of serum will be requested

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from each Haemophilia Centre from each patient who was considered to have had evidence of infection with hepatitis B or Non-B hepatitis. Details will be sought of the patient's general health and the results of any recent investigations with particular reference to liver function. Approaches will be made to individual Haemophilia Centre Directors by Dr. Craske.

RESULTS

At the end of the two year period, the results will be analysed to obtain the following data:-

1) The number of Non-B and hepatitis B cases related to each batch and to each product.

2) The attack rates of each type of hepatitis related to age, batch, severity of Factor VIII deficiency of each patient.

3) The mortality, incidence of chronic sequelae related to the above factors.

4) The incidence of hepatitis associated with the results of tests for HB_sAg on each batch of concentrate and with each product.

5) Whether any of the above factors are related to the fluctuations in the incidence of transfusion hepatitis in haemophiliacs.

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