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COAGULATION FACTOR WORKING PARTY FOR SCOTLAND AND NORTHERN IRELAND

2002/2003

15th ANNUAL REPORT

Membership

The current members of the Working Party are:

Dr J Anderson
Dr P Cachia
Dr E Chalmers
Dr P Clark
Professor I M Franklin
Dr E H Horn
Professor G D O Lowe
Professor C A Ludlam (Chairman)
Dr W Murray
Miss J Pelly (Secretary)
Dr R J Perry
Dr C V Prowse
Dr C Tait
Dr A E Thomas
Professor I D Walker
Dr H G Watson

In attendance:

Mrs D Evans
~~Mr A Macmillan Douglas~~ + Mr Keith Thompson
Dr A Keel

Provision of Coagulation Factor Concentrates in Scotland and Northern Ireland

In Scotland and Northern Ireland all appropriate haemophilia patients are being offered recombinant factor VIII and XI concentrate and there are only a few patients who remain on plasma derived products, either for medical reasons or for patients personal preference. We continue to review the supply situation for recombinant factor VIII and to appraise SNBTS of any potential forecast increased need for plasma derived concentrate.

Factor VIII Concentrate

SNBTS factor concentrate (Liberate) is still used in an small number of patients, particularly those with acquired haemophilia. The estimated annual demand rests at about 2 million units per annum.

The recently developed Liberate HT (80^0C for 72 hours and solvent/detergent treated) has completed its pharmacokinetic evaluation in Poland and a product license application has been submitted.

Factor XI Concentrate

SNBTS high purity factor XI concentrate (HIPFIX) has a product license, but as the majority of patients in Scotland are treated with recombinant factor XI concentrate the anticipated use in Scotland is small.

Prothrombin Complex Concentrates

The current SNBTS prothrombin complex concentrate, Defix (factor II, XI and X) is heat treated and used predominately for warfarin reversal and occasionally coagulopathy of liver disease. A further development of this concentrate has been to add a solvent detergent step during the manufacture and this concentrate is under assessment in a study for warfarin reversal by SNBTS. Recruitment has been slow. We have drawn the availability of this concentrate to the attention of our colleagues in England on the UKHCDO Rare Coagulation Disease Working Party as a potential treatment for II and X deficiency

A four factor prothrombin complex concentrate is required for warfarin reversal and this is under development by SNBTS and will be ready for clinical trial early in 2004.

Fibrinogen Concentrate

The SNBTS fibrinogen concentrate continues under evaluation for the treatment of congenital hypofibrinogenaemia and acquired hypofibrinogenaemia in liver disease for patients undergoing hepatic biopsies. We have also drawn this concentrate to the attention of our colleagues in England who may have patients with congenital hypofibrinogenaemia.

Risks of Transfusion

The CFWP in conjunction with SNBTS, Haemophilia Directors, UKHCDO Executive and the Scottish Executive responded to the notification that three batches of SNBTS concentrate received contributions from a patient who developed vCJD. The concentrates were given to patients in the period 1987 – 1989. All patients who received clotting factor concentrates during this period were written to and invited to contact their local Haemophilia Centre if they wished to find out more about the incident and whether they received any of the "implicated" batches. About 25% wished counselling and only a percentage of these after discussion wished to know whether they had received the implicated batch.

Haemophilia Directors in conjunction with other partners in the Haemophilia Alliance, particularly Haemophilia Nurses Association and patients wish to devise a suitable model for informing patients next time an implicated batch is identified.

UKHCDO has established a surveillance programme (MRC funded) in conjunction with the CJD Surveillance Unit in Edinburgh to monitor patients who received the implicated batches and to test autopsy and operative samples for abnormal prion.

Recombinant VIIa (NovoSeven)

This recombinant concentrate is used primarily for treating acute bleeds in patients with haemophilia A and B with inhibitory antibodies. As it is not part of the NSD National Contract, Health Boards are charged individually for its use.

There is increasing evidence that recombinant VIIa can be successful in arresting life threatening haemorrhage in non-haemophiliacs and it is used for this purpose occasionally in predominately the teaching hospitals with Haemophilia Centres in the UK. There is potentially an increasing demand for its use in this way particularly if the systematic studies underway demonstrate clinical benefit. Scotland and Northern Ireland Haemophilia Directors have compiled a protocol for use of recombinant VIIa in non-haemophiliacs. This highlights the issues and has been sent to Medical Directors of Trusts with Haemophilia Centres. We await responses.

Acknowledgement
I should like to acknowledge the prompt and very efficient way Miss Jane Pelly fulfils her secretarial commitment to the CFWP.

CAL
May 2003