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CENTRAL CONSULTATIVE COMMITTEE ON BLOOD TRANSFUSION
WORKING PARTY ON PRODUCTS CONTAINING FACTOR VIII AND IX
NOTE OF FIRST MEETING AT ABERDEEN ON THURSDAY 21 SEPTEMBER 1972

Present: Professor A S Douglas (Chairman)
Dr G A McDonald
Dr J Wallace
Mr J G Watt
Dr I S Macdonald

1. The Working Party has been established by the Central Consultative Committee with the following terms of reference.

"To consider the production, laboratory and clinical evaluation of the various factor VIII and IX products in relation to the overall produc ion capacity of the Blood Transfusion Service and to report".

2. It was noted that the supply of preparations containing Factor VIII had been considered on a number of previous occasions. The problem was partly one of determining the quantity to be prepared but quality was also important and increasing attention is being paid to this aspect. Consideration must be given to how much Factor VIII should be provided in the form of cryoglobulin precipitate and how much in the form of an AHF concentrate prepared by the Fractionation Unit. In these considerations the quality of all factor VIII preparations presently available requires to be considered; the discussion was also influenced by the recent appearance of a commercially prepared "Super-Concentrate" which has not yet been licensed for use in this country.

3. It was therefore opportune that the position should be reviewed and that attention should be paid to recent advances with a view to preparing better products.

4. Mr Watt reported that at the present time the ~~Protein Fractionation~~ Centre prepares a Cohn Fraction I. Work is proceeding on another product similar to that prepared by Doctor Alan Johnson of New York but development is slow and it will be at least another year before this is available for trial. The introduction of this new product will require a considerable amount of animal work followed by clinical trials which would be best carried out in the haemophilia centres.

5. This means that for the foreseeable future most patients in Scotland will receive treatment in the form of cryoglobulin precipitate. The group considered whether present production of cryoglobulin precipitate is adequate. This question cannot be answered with certainty but it was concluded that the level of production is reasonable. The question of prophylactic treatment of haemophilics was raised but it was considered that it would be wrong to begin to offer this treatment until supplies of Factor VIII preparation were in more plentiful supply. Already in hand.

6. In the longer term it would be ~~desirable to replace~~ cryoglobulin precipitate and the present Cohn Fraction I with ~~a~~ potent AHF concentrate. One of the major advantages of this would be the greater reliability of the product and the possibility of subjecting it to more rigorous quality control. This must however await the development of a suitable product and also the resolution of the logistic problems in converting production from the present products to a new one. The best estimate which can be made at present is that approximately 30,000 donations of blood per annum should be used for production of Factor VIII concentrate. This was on a "guess at best" basis.

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7. Mr Watt reported that products containing Factor IX were now available and problems concerning antibodies and pyrogens were being overcome. There is now a need for extended clinical trials and for liaison between the Blood Transfusion Service and clinicians. There had been difficulty in obtaining clinical information about the use of Factor IX but help with this had been received from Glasgow Royal Infirmary. The possibility of introducing licensing procedures into the Blood Transfusion Service, in accordance with the Medicines Act 1968, which would impose a requirement for clinical trials was mentioned.

8. The Group concluded that there is need for a mechanism for subjecting new Factor VIII and Factor IX products to further clinical trial. Time and effort would be needed in the design of effective trials. In practical terms these would be better carried out in the Western and South Eastern Regions because of the larger number of patients available in these areas. This would have funding implications for the SNBTA in the near future.

9. Difficulties in determining the production level of Factor IX products, and in determining which products to produce were mentioned. At present the PFC were producing two products. The first contained Factors II, VII, IX and X and had to be prepared from EDTA plasma. The second product contained Factors II, IX and X and was prepared from ACD plasma. The collection of EDTA plasma was troublesome because it was outwith the routine and it would therefore be useful to know how important the present of Factor VII was and if the second product is clinically as effective as the first. Some experience has been gained with the first product but not with the second. It was thought difficult to estimate the requirement of Factor IX products, but the products at present available were not meeting the demand and it is necessary to rely on fresh frozen plasma in the management of some of the haemorrhagic events in Christmas disease.

10. It was agreed that the Chairman and Mr Watt would co-operate on the production of a protocol for clinical trial for Factor IX products.

11. Covering further discussion of production problems it was agreed that there is a need to provide on the site of the PFC a facility for the assay of coagulation factors as part of the quality control procedures. This would be a limited function related to the routine production requirements and should not be confused with the need for similar facilities in hospitals to assist with diagnostic, research and treatment problems.

12. The production of these factors needs to be considered in relation to the other activities of the Blood Transfusion Service and if an adequate level of production is to be achieved and maintained there is a need to encourage a greater use of red cell concentrate. The Blood Transfusion Service should therefore undertake a forceful compaign to encourage the use of concentrated red cells with appropriate fluid supplements.

It was reported that a proposal to undertake an evaluation of cryoglobulin precipitates and other coagulation factor preparations at Glasgow Royal Infirmary was presently being considered for funding by the Western Regional Hospital Board and the Scottish Home and Health Department. It was agreed that this project should be recommended.