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CRYOPRECIPITATE PRODUCTION

The attached memorandum focuses attention on a number of related problems the solutions to which must be found if the Factor VIII production programme is to be completely meaningful. It does not purport to be an exhaustive examination of the subject, the full implications of which can only be known to those engaged in cryoprecipitate production and standardisation. Nevertheless, it seems to point to the need for urgent study of all aspects of cryoprecipitat production. Perhaps the first thing to be decided is whether we must wait for improvements to emerge from the natural processes of scientific discussion, experimentation and emulation or whether there are steps which the Department can take to speed up the development of more uniform, standardised cryoprecipitate preparation. A first step has already been made with the setting up of the Working Party of RTDs which will investigate the amount of activity in the cryoprecipitates which the various RJCs produce but there appears to be much to be done in addition. Views on any aspects of these problems would be welcome.

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CRYOPRECIPITATE PRODUCTION

1. In an attempt to compare current output of the various forms of Factor VIII with the 35 million iu of Factor VIII which the experts now consider will be required per annum, the available data on purchases of commercial concentrate and blood donations devoted to the preparation of cryoprecipitate and National Health Service freezedried concentrate in the 6 months ending June 1976 have been tabulated, tables annexed.

Part A shows the amounts of Factor VIII available to clinicians in each of the 6 months in question, the amounts of commercial concentrate being expressed in international units. The quantities of NHS cryoprecipitate and freezedried concentrate are expressed in terms of donations as has been the practice hitherto. Cryoprecipitate is being produced at the annual rate of about 250,000 donation equivalents per annum and freezedried concentrate at much the same rate if the latest figures are typical. The NHS is therefore preparing Factor VIII at the rate of about 500,000 donation equivalents a year compared with the target of 375,000 donations by mid 1977/adopted when the £½ million was injected. Despite this progress, large amounts of commercial concentrate are still being purchased although there are signs that purchases are now beginning to drop.

2. While it is important for the NBTS to know how many blood donations they must collect and process to produce a specific amount of Factor VIII, the clinician is more interested in the number of international units of activity in the container. Whilst NHS freezedried concentrate is so labelled this is not always the case with cryoprecipitate.

3. The figures contained in table B express the current "availability" of Factor VIII in termsof international units, three assumptions being made about the amount of activity obtained from one donation of blood when cryoprecipitate is prepared ie 50, 60 and 80 iu per donation. It now seems possible from information provided by Dr Maycock that yields as low as 40 iu per donation are not uncommon and there is a reference in a minute by Dr Waiter to levels as high as 100 iu. The result is a situation in which a large part of NHS Factor VIII is in a form the "potency" of which can vary by 100% and more. Apart from the inherent waste if low yields are avoidable, this leads to uncertainty on the part of clinicians and over administration to ensure that an adequate blood level is maintained.

4. FOUR ~~Three~~ possibilities appear to require urgent consideration.

a) Whether it is possible to bring the cryoprecipitate yield per donation of all centres more into line with that of the best centres

b) Is it possible to improve still further the yield of those centres which are most successful in this respect.

c) Should preparation of cryoprecipitate be carried out at fewer centres where maximum precautions can be taken to avoid loss of activity and possibly, where selected high yield donors can be used.

*Variations in the amount of plasma taken from each donation may account for some of the difference.

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d) Whether it is possible to present cryoprecipitate in a more standardised form with the number of international units, if necessary within limits, stated on the container, so that clinicians will always know what they are administering.

5. It is apparent that none of these tasks will be easy but there is considerable inducement to succeed. Each unit of cryoprecipitate lost or never garnered has to be made up at present with commercial freezedried concentrate at 8 pence to 12 pence a unit and it may be possible to so improve yields as to go some way towards achieving self sufficiency in Factor VIII without collecting more blood. Furthermore, unless the activity of cryoprecipitate can be established within reasonably precise limits it will not be possible to explain to Ministers how close the NHS is to achieving the self sufficiency in Factor VIII by which he sets such store.

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