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FURTHER DEVELOPMENT AND ESTABLISHMENT FOR ROUTINE USE IN THE BLOOD TRANSFUSION SERVICE OF A SCREENING TEST FOR ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS)

BACKGROUND

AIDS is an infectious disease that can be transmitted, among other ways, by blood transfusion or the administration of blood products such as the anti-haemophilia factor, Factor VIII. The best available serum marker for AIDS is the presence of antibodies to human T-lymphotropic virus type III (HTLV III). In a recent study HTLV III antibodies were found in 97% of patients with clinically-verified AIDS. Current concern about AIDS emphasises the need for a reliable, low cost, test that can be used to screen blood donors for AIDS markers.

of the Virology Department of the Middlesex Hospital Medical School and have, with colleagues, developed a radioimmunoassay (RIA) for HTLV III antibodies. This RIA, designated MH/CB RIA, was developed with the intention that it should be suitable for routine use in Blood Transfusion Centres (BTCs). Accordingly, the basic test protocol is identical to that of an RIA that is widely used for screening for hepatitis B surface antigen and the same range of equipment is used. The Middlesex Hospital played a big part in the development of the hepatitis test which has been supplied for some time by the Blood Products Laboratory (BPL). Antiserum for the MH/CB RIA is being produced by Wellcome Reagents Ltd in collaboration with the PHLS Centre for Applied Microbiology and Research, Porton Down. This is being done on a 'costs only, no profits' basis. There has been a Patent application in the names of the Middlesex Hospital and Chester Beatty Laboratory, where is based, and commercial exploitation is likely.

The MH/CB RIA is thus a product of the co-operation of British Science and British Industry. There is general agreement that it is the most sensitive RIA for HTLV III presently available.

There are firm plans to produce the MH/CB RIA in kit form-the same form as the hepatitis test-at BPL. However, work to scale up production will be needed before routine supply to BTCs can be started. Pilot studies on use and performance will have to be undertaken and throughout these studies the Middlesex Hospital will have to monitor the results. This will involve examination of all positive sera and detailed follow up of blood transfusions and blood products where positive material may have been used. Monitoring will have to continue when full scale

production starts. There are no plans to supply the MH/CB RIA outside BTCs.

Commercial kits for HTLV III are expected soon from the USA. It has been predicted that these will cost between £1 and £2 per test. This is considerably more than the MH/CB RIA will cost. It is likely that USA manufacturers will wish to use the UK as a proving ground for their products and thereby to gain support for performance submissions to the US Food and Drugs Administration. It is very important therefore to be able to assess these kits to ensure that the NHS can be told about unsatisfactory ones. Clearly, the Middlesex Hospital is uniquely qualified to assess HTLV III kits.

PROPOSAL FROM 1 AND

This is at Appendix 1. After it was submitted discussions were held with 1 to clarify some of the points made. As a result, some changes to the costings can be made and more information can be given.

1. Funds are being sought for a two-year project that will be subject to review after the first year.
2. A microtitre plate washing device will be required. This will cost between £2,000 and £3,000. The one currently in use is not satisfactory and is on loan from Dynatech Ltd. Purchase of a satisfactory washer will put the project on a firmer footing.
3. Up to £3,000 per annum will be required for consumable items including plastics ware and reagents.
4. The secretary is needed to perform all the clerical tasks involved in producing reports, keeping records and follow up studies. The Secretary will work at the Middlesex Hospital.
The MLSO will also work at the Middlesex Hospital and will do all the technical work involved in the project.
6. Given that funds are made available, it should be possible to start the pilot studies by June, 1985.

The revised costings are:-

Basic Grade MLSO		£8,165 + overheads per ann
Grade 2 Secretary		£7,633 " " "
Consumables		£3,000 + VAT per annum
Plate washer	maximum of	£3,000 + VAT
TOTAL FOR ONE YEAR		<u>£21,798 + VAT + overheads</u>
TOTAL FOR TWO YEARS		<u>£37,596 + VAT + overheads</u>

SUMMARY

The proposal, which is strongly supported by Medical Division and STB3A, offers the opportunity to develop further a very sensitive British test for HTLV III antibodies and to establish it for routine screening of blood donors for AIDS. The proposal also offers the opportunity to follow up in depth donations of blood from HTLV III antibody-positive people. Finally, there is an opportunity to assess commercial products which will inevitably be introduced to capitalise on an established need.

STB3A

4 January, 1985