NORTH WESTERN REGIONAL HEALTH AUTHORITY

National Blood Transfusion Service

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Date: 3rd July, 1984

Dr. A. Smithies,
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Dear Alison,

Anti-HTLV III and A.I.D.S.

I write to you to give you details of the meeting that I held on 28th June, with Dr. David Tyrrell, Chairman of the MRC Committee on A.I.D.S., Dr. Richard Tedder, Consultant Virologist at the Middlesex Hospital, Dr. T. Wallington, Consultant Immunologist at the Bristol B.T.S. and Dr. Marcella Contreras.

The meeting took place following a letter that Dr. Tyrrell sent to me at the end of May when he suggested that the MRC could be helpful in setting up a study on blood donors using the detection of anti-HTLV III as a possible marker for donors who may be at high risk of transmitting A.I.D.S.

The work of Montagier of France and Gallo of the U.S.A. has suggested that HTLV III virus is the causative agent of A.I.D.S. although further work still needs to be carried out before this is firmly established. However, Dr. Tyrrell pointed out that it could be the causative agent and it may be particularly useful for the detection of the pre-A.I.D.S. condition. Therefore, a study on blood donors undertaken at the present time could be a useful practical step.

One of the major problems is that considerable pressure will be put on the Transfusion Service if this test is introduced in the U.S.A. However, we all agreed that at the present time this test should be regarded as a research project and that it should not be introduced as a routine screening test on blood donations without proper appraisal. It is important, however, that a study should be started as soon as possible so that it would be possible from a practical point of view to answer questions on the use of the test in the U.K.

The most important development in the study is the availability of a viable test for anti-HTLV III. In this regard, the work of Dr. Robin Weiss of the Chester Beatty Institute in co-operation with Richard Tedder is very promising. Although these are early days, there is some reason to believe that a radio-immune assay may be available within the foreseeable future.

Studies will be performed upon patients in high risk groups with respect to A.I.D.S., but with respect to studies on blood donations, we agreed the following general protocol.

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STAGE I. Following successful development of the test, donor serum sa would be sent from the N.W. Thames Regional Transfusion Centre to the Middl Hospital where the performance of the test will be proved and evaluated.

STAGE II. The performance of the test will be transferred to the N.W. Thames R.T.C. and experience gained on its use.

At this stage, the tests will be retrospective and donations which are fo to be positive may well have been used prior to the knowledge of the result of the test. This approach can be defended ethically without problem and is entirely justifiable at this stage.

STAGE III. Donations will be tested at the Manchester R.T.C. and the Bristol R.T.C. while tests will continue at N.W. Thames R.T.C. The combinatio of these three regions should give a broad view of the country as a whole, viz London, a N.W. Industrial area and a largely rural community.

At this stage, donations will be tested prior to issue and plasma will be saved from the donation and donors will be followed up. In Manchester, if donors found positive have given blood within the previous 8-9 months, a previous sample of serum stored frozen will be available for testing. If this should prove positive then identification of patients receiving the products will be made and follow-up pursued.

At the R.T.C.'s, we agreed that we could absorb this work without additiona funding since the major effort in the study will be carried out by Robin Weiss and Richard Tedder. Positive samples from the R.T.C.'s will be sent to Richar Tedder for confirmation and he will receive additional samples when the donor is interviewed. His work is to be supported by the MRC.

Of course we will not know whether routine application of this test is justified until the results of the study have been assessed. However, it is important that the implications for routine screening should be considered early, since it will be important that if the results are satisfactory there should not be an undue delay before this takes place.

There will be some developmental work to be performed to improve the reagents for the test, but production of the antigen will be required and this may be possible in collaboration with Industry or possibly at CAM-R at Porton. When the reagents are available it will be necessary to make test kits. It would be an advantage for the NBTS if this was in the format of the BPL RIA test for HBsAg and this concept is being considered by Richard Tedder at present. We briefly discussed the possible role of the C.B.L.A. in the preparation of the test kits and whilst this is an option which may be available, there are others, such as collaboration with Industry, which will have to be considered. Within the financial arrangements entered into, I think it is important that the contributions made by Robin Weiss and Richard Tedder should be recognised.

I have written at length about the possibilities of developing the test in the U.K., since the alternative will be to purchase kits from an American company such as Abbot Laboratories. I dread to think what the cost to the NHS will be under these circumstances.

Other considerations will have to be made also. To carry out such routine screening I should think that every R.T.C. will require additional staff and equipment, and some will require additional space.

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It will, therefore, require a major decision to proceed to routine screening, particularly when the incidence of positive reactors will probably be very low. Pressures will come from various sources and I doubt that it will be possible to resist them when dealing with a condition which carries a potentially fatal outcome.

If you are agreeable, I think that this topic should be placed on the agenda for our meeting on 7th August.

Sorry for the length of this letter but I thought it best to set it down in detail since it will give you the opportunity to consider these matters before we have the chance to discuss them.

With kind regards.

Yours sincerely,

GRO-C

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Director

c.c. Dr. D. Tyrrell
Dr. R. Tedder
Dr. T. Wallington
Dr. M. Contreras
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