

**SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE**

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JDC/EP

2nd August 1985

Dr W Whitrow
Director
Blood Transfusion Service
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Dear Bill

HTLV-III antibody testing: Recent developments

Events are moving rather fast now and as our meetings together are less frequent at this time of the year I thought it might be helpful to write to let you know some of the more recent developments.

1. Kit Evaluation

The PHLS (phase 1) study has revealed that, at the present time, the kits manufactured by Organon and Wellcome Diagnostics are the only ones they can recommend for field (phase 2) evaluation in the two NBTS Regional Transfusion Centres (Edgware and Manchester). A full PHLS report will be released in mid-August. The phase 2 evaluation has started but the full report will not be available until the end of October.

2. Familiarisation Plans

(a) You will see from the above that the two companies you need to contact urgently with regard to technical familiarisation studies are Organon and Wellcome.

(b) You have been advised separately of the PHLS proposal.

3. Start of Full Scale Donation Screening

(a) The commitment for the SNBTS/NBTS to start "simultaneously" still stands. More details will be sent to you as soon as they are available.

(b) It would, at the present time, be appropriate to plan a commencement date some time in the first week of October 1985. It should be emphasised that there are still a large number of variable and complex operational problems to be resolved and that this time schedule remains tentative, pending further advice.

4. Contracts for kits

It is my intention to discuss this topic with you on August 20th with a view to us making some "national" decisions. However, various consultations lead me to conclude the following:-

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- (a) That in the latter weeks of September 1985 your Centre should be slowly introducing selected donor screening at a low grade level of activity so that the change to full screening in the weeks ahead, "early October", is an operationally smooth exercise.
- (b) In order to be in this position you will need, by the first week of September, to have made up your mind about the kit you wish to purchase. Arrangements to contract appropriate supplies should be made soon thereafter.
- (c) Your contract, in the first instance, should be for a full 4 months worth of kits - assuming full donation testing and no repeats. (The purpose of this short contract is to provide you with sufficient flexibility to change suppliers if problems arise. However, I would suggest after 2 months (or less) running you will need to consider either an extension of the contract or a change.)
- (d) I would like to see, if at all possible, the 2 suppliers getting equal access to the SNBTS. This has considerable potential advantages to us in the event of problems and in ensuring pricing competition. The easiest approach would be for Inverness, Aberdeen, Dundee and Edinburgh to opt for 1 kit and Glasgow another. I will leave you to dialogue with your colleagues.
- (e) I would strongly recommend at the present time that offers of "free" equipment should be accepted and that it wouldn't be advisable to purchase any one company's equipment in order to get cheaper disposables. We can explore such levels of marketing sophistication at a later date when we have a good deal more information on technical/supply performances. The possibility of securing whole batches of reagents can also be explored at a later date (for instance, Wellcome think each batch will be 60,000 tests).
- (f) I have already taken steps to advise the Treasurer to seek the extra (reagent) funds from SHHD and in due course to see that your allocations are adjusted appropriately.

5. Kit/Equipment performance monitoring

You can expect, soon after or before, the whole of the UK Transfusion Centres go "fully live" to hear from Harold Gunson. Harold intends to establish for a few (? 6) months at the Manchester Centre a constant (2 weekly) update from all RTCs on the performance of kits and equipment and to make this information widely available.

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This is an exceedingly important exercise and should be supported.

6. Donor Counselling

This development has, perhaps inevitably, been less well planned by central authorities and I have now decided that the most appropriate further action we can take is to make arrangements for Dr Jack Gillon (SEBTS) to go to St Mary's (London) to work for a few days in Dr Pinching's Department and for Dr Gillon and Dr McClelland to run a HQ Seminar/Teach-in for Directors and all relevant RTC medical/nursing staff. We are heavily boxed in for dates (because we are but weeks away from full testing) and the date selected is Friday, 13th September, 10.30 a.m. start at HQ.

It is essential that you and/or your medical/nursing colleagues are there. Please let Elizabeth know your Centre's numbers.

7. Action Flow chart for screening

All the work we put into this exercise has been of much help. The basic plan devised by the SNBTS has been accepted by the Expert Advisory Group. Small polishings will be necessary and Brian will, in good time, provide you with the 'final solution' - which, of course, will be recommendations.

8. Letters to Donors

It has been agreed that all donors will be informed of the commencement of HTLV-III antibody screening. This necessitates a letter. I enclose my draft for starters. It is important that we agree a suitable text on 20th August because it has to be printed and catch the mail drop (? 2nd week in September) - so please have a good look at it well in advance.

9. Adjustment of Existing signed forms

In addition to the donors signing that they have read the 'old' message and that, to the best of their knowledge, they are not in one of the high risk groups, there will be an addition required (? separate signature) to the effect, "I agree that my donation can be HTLV-III antibody tested." We need to think about this - it will be discussed on the 20th August.

10. HTLV-III A/B Reference Centres

Brian and I, with SHHD colleagues, are making steady progress. Right now we don't have anything specific to report that needs to bother your good self.

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Apologies for the length of this missive. I suggest you go back and digest the most immediately important items (viz. 2, 3, 4, 6, 8 and 9).

Best wishes and kindest regards,

Yours sincerely

John D Cash

Encl.