

JDC/EP

25th January 1985

CONFIDENTIAL

Dr R Mitchell
Director
Blood Transfusion Service
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CARLUKE
Lanarkshire

Dear Ruthven

HTLV-III Antibody Testing: SNBTS Evaluations

Many thanks for your letter of the 21st January and for your most helpful contributions to our discussions with Ewa, Bill and Brian last week at TPH.

From these and other discussions and the points raised in your letter the following conclusions can be made:-

1. That the WBTS should undertake, on behalf of the SNBTS, initial evaluation studies of commercial HTLV-III antibody kits, but that current pressure from commercial organisations to meet their deadlines should be resisted and priority given to SNBTS interests - particularly in terms of confidentiality and ethical clearance.
2. That retrospective studies (on donor samples) currently in store should be used provided:-
 - (a) Steps are taken to ensure that no one can identify the donors.
 - (b) That the selection of donor samples is representative and random (not exclusively high risk donors and does not deliberately exclude high risk donors by virtue of previous tests).
 - (c) That the donors associated with factor VIII batch 023110090 are not used for these evaluation studies.
 - (d) That the donor samples would come exclusively from the WBTS donor panel.
3. That initial donor samples should be of sufficient volume to enable the following:-/

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- (i) Initial test
- (ii) Repeat test if necessary
- (iii) Reference test (? Western Blot) if necessary
- (iv) As many residual 1 ml aliquots (at least 2) so that the same samples can be tested with other emerging kits and the results compared.

4. Professor Girdwood is back from China and I would strongly advise that you prepare a short protocol (with explanation) for Ethics Committee approval. I am confident he will give clearance himself (without calling a full Committee) and will give you every assistance to secure this if necessary.

Again, I would emphasise, that we must not be stampeded by any of these companies nor enter into this exercise seeking quick scientific publications. I'm certain, after last week's NBTS Directors' meeting you would fully support these comments.

Please keep me informed of your progress. If I can be of any further assistance, it will be a pleasure. I've copied this to all colleagues for I feel as this is an SNBTS exercise they should all be briefed.

Good hunting!

Kindest regards,

Yours sincerely

John D Cash

Copy to:
Transfusion Directors

se J Bell