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[redacted]

31st May, 1985.

[redacted]

CONFIDENTIAL

Expert Advisory Group on Aids,
D.H.S.S., Hannibal House,
Elephant & Castle, London SE1 6BY.

Dear [redacted]

I am just writing to you to re-inforce the views that I have expressed at the Meeting on 29th May, concerning the rapid introduction of HTLV III antibody screening of blood donors. My anxiety is compounded by the paper from the Middlesex Hospital Group, published this week in the Lancet about the rising prevalence of HTLV III antibody positivity in London. I think that not only haemophiliacs receiving cryoprecipitate but also other groups such as some patients undergoing open-heart surgery or with acute leukaemia etc., could be at a real risk of infection by HTLV III. I therefore think that one or more of the FDA approved tests should be introduced immediately to test donations. Those which test as positive should be discarded and the logistics of re-testing, confirmatory testing and donor counselling could then be dealt with as separate issues. I think that donors would readily accept witholding of all ~~positive~~ results as an interim measure because after all, they are themselves potential recipients. I feel that such testing should be implemented immediately in order to preserve confidence in the Blood Transfusion Service and any temporary increase in expense would just have to be borne.

Finally, I think you should know that I plan to submit a letter to the BMJ along these lines.

Yours sincerely

[redacted]

cc [redacted]

(RUS") TESTING IN ENGLAND & WALES (SITUATION AT JUNE 1985)

TRAINING

First meeting of PHLS anti-HTLV3/LAV testing group.

Demonstration of commercial assays to staff of confirmation laboratories.

First training course at VRL for staff of BTS and clinical laboratories.

STANDARDISATION AND QUALITY CONTROL

Preparation of first panel of control standard sera for issue to laboratories.

Panel made available to BTS and clinical laboratories.

Preparation and distribution of PHLS Standard and "cut-off" sera.

Second panel of sera prepared.

Distributed to all testing laboratories.

Analysis of results.

Process repeated six-monthly.

CONFIRMATION OF RESULTS

"Request for confirmation of anti-HTLV3/LAV result" form drafted.

Designation of VRL and six other large PHLS laboratories as confirmation laboratories. Bid to DHSS for funding submitted 22 May, 1985.

Agreement on request form.

Agreement on uniform confirmation system, provisionally by indirect competitive solid phase assay, immunofluorescence, and Western blotting.

Discussion of performance of commercial assays based on feed-back from requests for confirmatory tests.

REPORTING RESULTS TO COMMUNICABLE DISEASE SURVEILLANCE CENTRE

Reporting system for anti-HT tests set up.

First monthly reports of an HTLV3/LAV tests in Communic Disease Report.

Monthly reports and analyses continue.

PHLS
4.6.8

FLOW CHART FOR THE INTRODUCTION OF ANTI-HTLV3/LAV

PRODUCTION, EVALUATION & INTRODUCTION OF SCREENING TESTS

SUMMER '84

"In house" anti-HTLV3/LAV assays developed in a few foreign and UK research laboratories. PHLS Virus Reference Laboratory (VRL) and the Middlesex Hospital available as primary testing centres.

WINTER '84/85

Antigen producer cell lines made available by US National Cancer Institute to five US companies.

CEM-J producer cell line developed at Chester-Beatty Institute, London.

APRIL '85

Licensing of first US commercial assays by FDA (Abbott, Electronucleonics, ENI).

CEM-J line made available to Wellcome UK.

MAY '85

Licensing of other commercial assays by US FDA (Litton, Travenol).

Demonstration of Abbott, ENI and Wellcome assays to PHLS staff and DHSS officers.

JUNE '85

Demonstration of further assays to PHLS and DHSS.

PHLS evaluation of first three assays available (Abbott, ENI and Wellcome). (1)

JULY '85

Presentation of PHLS findings to DHSS Subgroup.

AUGUST '85

PHLS evaluation of Litton and Travanol assays, if available.

SEPTEMBER '85

Presentation of PHLS findings to DHSS Subgroup.

Introduction of anti-HTLV3/LAV assays in clinical laboratories designated as confirmation centres. (2)

OCTOBER '85

Introduction of anti-HTLV3/LAV screening tests in PHLS clinical laboratories. (2)

NOVEMBER '85

DECEMBER '85

1986

BTS

Visit to PHLS by BTS officer who is organising BTS evaluation, 12 June 1985.

BTS evaluation of suitable assay begins. (3)

BTS evaluation continues. (3)

Introduction of anti-HTLV3/LAV screening in BTS.

1 First batches delivered by manufacturers were withdrawn (on 23 May by ENI and 29 May by Abbott). Replacements expected 3 June (Abbott) and at a date to be notified by ENI, who have no agent in the UK. Wellcome kits expected on 21 June.

2 The "Confirmation Laboratories" other than VRL all require upgrading to meet current ACDP safety guidelines, and will need some new equipment. A bid for the funding needed was submitted to DHSS on 22 May 1985.

3 The two intermediate steps introduce a degree of duplication, and therefore delay.