

SDC. 40

EDINBURGH AND SOUTH-EAST SCOTLAND REGIONAL BLOOD TRANSFUSION SERVICE



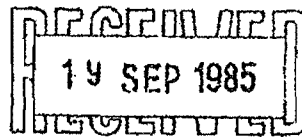
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DBLMcC/IMcK

18th September 1985.

Dr A McIntyre  
Scottish Home & Health  
Department  
St. Andrew's House  
EDINBURGH



Dear Dr McIntyre

PROPOSAL FOR SELF REFERRAL FACILITY FOR HTLV-III TESTING

Following Dr Forrester's recent letter I now enclose this proposal. This proposal has been discussed fully by the CAMO of Lothian, the Board's AIDS Group.

I can confirm that the Group and the CAMO welcome and support the proposal. It is recognised that if funding is provided by the CSO this will be strictly for a six month period to assess the need for this service.

Yours sincerely

Dr D B L McClelland  
Director

Encl.

cc Dr J A Forrester  
Dr G E Bath

SNBTS DOCUMENT REQUEST No:

2011/00098

Director Dr D B L McCLELLAND  
Consultant Dr P L YAP  
Consultant Dr J GILLON

Deputy Director Dr F E BOULTON  
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A STUDY TO ESTIMATE THE EXTENT OF HTLV-III INFECTION AMONGST  
SELF REFERRED SUBJECTS IN THE LOTHIAN AREA.

R. P. BRETTE

CITY HOSPITAL  
INFECTIOUS DISEASES UNIT

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COMMUNITY COMMUNICABLE DISEASES  
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REGIONAL VIRUS LAB  
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AN INVESTIGATION INTO THE EXTENT OF HTLV-III INFECTION AMONGST SELF REFERRED SUBJECTS IN THE LoTHIAN REGIONAL.

ABSTRACT

The aim of this investigation is to determine the extent of infection with HTLV-III virus amongst individuals who choose to attend a self-referral facility for testing, which will be provided on a trial basis to supplement testing which may be available through STD clinics and GP's. From a preliminary survey it is anticipated that there will be a significant number of antibody positives among the Lothian population of IV drug abusers and their contacts. It remains to be determined if other groups such as undeclared homosexual men will also come forward to be tested in significant numbers. It is hoped that this study will help to indicate whether Health Boards will need to set up similar screening programmes, firstly to prevent the Blood Transfusion Service from being used as a diagnostic screening facility, secondly to deal with individuals found to be HTLV-III positive and thirdly to help target health education material to high risk individuals.

INTRODUCTION

The Acquired Immune Deficiency Syndrome or AIDS is a new infection caused by a newly described lentivirus presently designated LAV or HTLV-III. It is spreading rapidly throughout the world and has now affected the UK. In July 1985 a total of 14,000 cases had been recorded world wide. Recorded cases in the UK have increased from 3 in Jan 1983 to 206 in Sept 1985. The number of cases is expected to continue doubling in the UK every six months for the next three years and it has been suggested that there will be an estimated 2000 patients diagnosed by the end of 1986. The high risk groups have been well identified and in most series 75% are male homosexuals and 15% are IV drug abusers. A small but important group are the recipients of blood products who currently represent only 5% of reported cases.

For every case of AIDS there are estimated to be 25 infected individuals. As defined by HTLV-III antibody positivity this would suggest that there are at present 5,000 infected individuals in the UK. There is no information about the natural history of this infection in those not progressing to AIDS but the recent work showing that the virus is neurotropic as well as lymphotropic raises the possibility that there are other medical problems associated with HTLV-III infection yet to be described.

The virus spreads by intimate contact between individuals i.e. sexual intercourse, blood products, shared needles etc. There has been considerable concern about spread by Blood Transfusion and a screening programme for donated blood is being introduced in October. There are fears however that if alternative screening facilities are not made available the BTS will be used by some individuals as a confidential diagnostic/

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diagnostic service. It is not known what groups would be reluctant to attend either GP or STD services for testing but experience reported from Denmark indicates that there may be a significant population of undeclared homosexual men in this situation. Also, it is likely that some IV drug abusers and their contacts may not wish to attend GP's or STD clinics. Thus an alternative, confidential route of access to testing may be required.

In Lothian recent work suggests that an unprecedented 34% of drug addicts are positive for HTLV-III. Furthermore, an episode of contamination of Scottish Factor VIII concentrate suggests that the virus has been present locally for some time. Work is now in progress at the University Department of Bacteriology and at the Regional Virus Laboratory, City Hospital to determine when the infection reached the Lothian Region and to plot its rate of spread. There is at present no explanation for this apparent high prevalence of infection and of even more concern is the fact that individuals are now presenting in Lothian with HTLV-III infection who are not IV drug abusers but are connected with the drug scene. This suggests that heterosexual spread is occurring (despite recent statements that this route of spread is not important).

#### PROPOSAL

A facility will be set up for a six months evaluation period to provide open access to HTLV-III antibody testing for individuals who wish to refer themselves.

Data will be collected to assess the size and nature of the demand for this service in Lothian, to attempt to estimate the likely demand beyond the six month period, and to estimate the resources needed if it was decided that continued operation was required.

This facility will be based at the Infectious Diseases Unit, City Hospital. Staff will be recruited on a short term, part time or sessional basis. Laboratory support will be provided within the existing staffing resources of the Regional Virus Laboratory and University Department of Bacteriology.

#### METHOD - GENERAL ARRANGEMENTS

Potential screening subjects will be informed of the availability of the service by providing information through channels which would include local drug help groups, local gay switchboard and by low key media publicity (local radio and local newspapers). The medical community would be informed of the project through the weekly CDC Bulletin. Final arrangements for publicisation would be made with the advice of the Communicable Diseases Service (Community) of the Lothian Health Board.

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The first contact point would be a telephone number giving access to an answering machine. This will give the caller information about the times when the telephone is manned for making appointments and will emphasise the confidential nature of the arrangements.

All subjects would be counselled before any sample was taken for testing to inform them of the possible implications of a positive test, and written consent to be tested would be obtained before withdrawing blood.

A case record sheet with the subject's given name and address would be retained in a secure file. All other records, including lab requests would be identified only by an attendance number. (This is standard practice in the STD Clinic, RIE) Subjects would be requested to identify themselves by their attendance number at all future visits.

Subjects would be required to complete a brief questionnaire designed to elicit the following information:

- Age
- Sex
- Membership of any recognised high risk group (and which group)
- How subject heard of the screening facility
- Reason for attending
- Reason for not going to GP
- Reason for not going to STD Clinic
- Membership of blood donor panel.
- Would the subject attend other existing services to be tested if this facility were not available
- Number of probable contacts (sexual partners or needle sharing).

During interview by the medical officer an assessment would be made as to the presence or absence of possible HTLV-III related symptoms.

It is not intended that a full clinical assessment would be carried out at the initial attendance.

For all subjects, a follow up appointment would be made: it would be emphasised to the subject that the onus is on him or her to re-attend to obtain test results. Test results would only be given in person by a member of clinical staff to the correctly identified subject.

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It is anticipated that some antibody positive subjects will require prolonged counselling. Since this need cannot be anticipated at the time of scheduling follow up appointments, it is expected that in some cases full counselling will be given on the day of the test or over two days. All information concerning the test results. At the time of the initial counselling antibody positive individuals will be given a package of literature reinforcing the preliminary counselling, and providing advice about seeking further help from the study participants and voluntary organisations.

#### TESTING FOR HTLV-III ANTIBODY

Testing by one of the available antibody screening ELISA procedures will be done by the Regional Virus Laboratory. Confirmatory testing by additional techniques will be done by the Regional Bacteriology Laboratory.

#### STAFFING

Reception, appointments, lab results etc will be managed by a part time receptionist operating specified hours.

Initial counselling will be undertaken by the Nursing Sister, who may be post-reg. counselling.

The Medical Officer will undertake counselling of antibody positive subjects and essential initial clinical assessment or advice.

Two Consultant Physicians (Dr Brettie and Dr Gillon) will share in the consultation and provide Consultant care. Their service will be the clinical support of Dr Brettie.

Dr Brettie or Dr Gillon will decide on and arrange appropriate referral for further medical care to be offered to all antibody positive subjects.

#### AVAILABILITY OF STAFF FOR SHORT TERM DUTIES

The difficulties are recognised. It is believed that suitable medical and nursing staff can be recruited on a sessional or temporary basis from within the local area. Some medical and nursing staff have already been identified. Initial counselling is available at St. Mary's Hospital, London, and staff involved would attend the appropriate short course.

#### EVALUATION OF THE STUDY

It is recognised that the nature of the likely subject population will make it difficult to collect fully satisfactory epidemiological data. We would therefore set limited objectives, attending



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It is anticipated that some antibody positive subjects will require prolonged counselling. Since this need cannot be anticipated at the time of scheduling follow-up appointments, it is expected that in some cases full counselling will be necessary. It is hoped that this will be completed within 30 days of the receipt of the test results. At the time of the initial counselling, antibody positive individuals will be given a package of literature reinforcing the preliminary counselling, and providing advice about seeking further help from the study participants and voluntary organisations.

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Initial counselling will be undertaken by the Nursing Sister, who may also provide post-test counselling.

The Medical Officer will undertake counselling of antibody positive individuals and essential initial clinical assessment or advice.

Two Consultant Physicians (Dr Brettle and Dr Gilson) will share in the counselling and provide consultant care. Their service will be the clinical responsibility of Dr Brettle.

Dr Gilson will advise on and arrange appropriate referral for further medical care to be offered to all antibody positive subjects.

#### AVAILABILITY OF STAFF FOR SHORT TERM DUTIES

The difficulties are recognised. It is believed that suitable medical and nursing staff can be recruited on a sessional or temporary basis from within the local area. Some suitable individuals have already been identified. Initial counselling in AIDS counselling is available at St. Mary's Hospital, London, and staff involved would attend the appropriate short courses.

#### EVALUATION OF THE STUDY

It is recognised that the nature of the likely subject population will make it difficult to collect fully satisfactory epidemiological data. We would therefore set limited objectives, after which

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attempting to answer the following questions using information obtained from subject questionnaires and interviews.

1. Having taken the steps outlined to publicise the facility in Lothian, what total number of individuals came forward?
2. What is the pattern of attendance over the six month period and does this help predict future demand?
3. What proportion of subjects are assessed as being unlikely to have been tested if the facility had not been available?
4. How many antibody positive subjects are assessed as unlikely to have been detected in the absence of the facility?
5. How many persons could be put at risk of exposure by the antibody positive subjects detected by this study assuming no preventive measures were taken?
6. What proportion of the attending subjects and of the antibody positive subjects belong to each recognised risk category (or other categories)?
7. What were the most effective routes of communicating the existence of the facility?
8. What were the reasons, given by subjects for not wishing to attend GP or STD services?
9. What proportion of subjects attending might have gone to the Blood Transfusion Service for testing if this facility did not exist?

#### RESOURCES AVAILABLE

Testing would be done on site at the Regional Virus Laboratory and no extra equipment or staff are required other than the purchase of the kits. Positive samples would be confirmed at the University Department of Bacteriology.

The clinic would be located in the Infectious Diseases Out Patient facility. Clinic space is available in the afternoons or evenings and it is envisaged that these would be the best times to attract individuals. The IDU of the City Hospital is used to dealing with the medical problems of drug addiction and is also currently dealing with AIDS patients. There is an on going education programme for all staff at the City Hospital into the problems of AIDS. The unit is therefore ideally suited to this type of investigation.

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The number of addicts or their sexual contacts that need to be screened in the Lothian Region is unknown and it is therefore difficult to gauge the resources required to mount the study. The best estimates available are that there are around 5,000 addicts in the Lothian Region and but it is expected that it will be possible to screen only a proportion of these. No estimates are available to indicate the size of other potential subject populations.

Resources Required for Six Month's Study

Part time Medical Officer	£ 8,075.62
Part time Nursing Sister with unsocial hours (evenings)	£ 5,534.20
Part time Secretary/Receptionist	£ 2,872.12
Testing Kits (2,000 at £1.00/Test)	£ 2,000.00
Cost of two people to attend counselling course at St. Mary's Hospital	£ 500.00
Cost of Ansaphone Machine	£ 100.00
Telephone Installation/Rental	£ 135.00
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TOTAL	<u>£19,216.94</u>

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