

E/46



ACQUIRED IMMUNE DEFICIENCY SYNDROME

AIDS

BOOKLET 2

**INFORMATION FOR DOCTORS CONCERNING THE
INTRODUCTION OF THE HTLV III ANTIBODY TEST**

October 1985

CMO(85)12



DEPARTMENT OF HEALTH AND SOCIAL SECURITY
ALEXANDER FLEMING HOUSE
ELEPHANT AND CASTLE LONDON SE1 6BY
TELEPHONE 01-407 5522 EXT
G7N 12915

Your reference:

Our reference:

To: All Doctors in England

Copies to: Regional Medical Officers
District Medical Officers
General Managers of Special Health Authorities
for London Postgraduate Teaching Hospitals
Regional Transfusion Directors

1 October 1985

Dear Doctor

INTRODUCTION OF A TEST FOR HTLV III ANTIBODY

Further to my letter of 15 May, CMO(85)7, which accompanied the blue booklet "AIDS: General Information for Doctors", I now enclose information about the introduction of a test for antibody to HTLV III. [AIDS: BOOKLET 2]

From a date in mid October to be announced, all blood donations will be screened at Regional Transfusion Centres (RTCs) for HTLV III antibody.

At the same time, alternative facilities for providing antibody tests on a confidential basis will become available -

- a. at Genito Urinary Medicine (GUM) clinics.
- b. by arrangement with the patients' general practitioner at certain other clinics as arranged and publicised by the District Health Authority. (I have written under separate cover to District Medical Officers asking them to let all general medical practitioners know about local arrangements.)

The synchronous provision of these arrangements is to ensure that people who believe themselves at risk of infection do not donate blood in order to be tested. This is crucial because even a reliable test cannot detect very early infections to which an antibody response has not yet been generated. In conjunction with the alternative testing facilities, arrangements will be made to advise those who attend requesting the test, of the implications that it might have for them.

It is essential that all individuals who are found to have positive antibody tests receive counselling both in order that they may understand the meaning of the results and to advise them how to avoid transmitting the infection to others.

E. R.

Health Authorities have been asked to provide counselling services, and such services will also be available at the Regional Transfusion Centres for blood donors found to be seropositive. A brief summary of counselling which should be given is attached at appendix 2. This is for patients with AIDS and their families and friends, and also for individuals with a positive antibody test.

Training courses for counsellors are taking place initially at St Mary's Hospital, Paddington. Details can be obtained from the NHS Training Authority (Ms J Vaughan-Smith, NHS Training Authority, Headquarters, St Bartholomew's Court, 18 Christmas Steps, Bristol BS15).

The antibody test is an important tool, in the control of the spread of HTLV III infection. If it is to be used effectively, very strict confidentiality must be maintained in respect of positive results (see paragraph 11).

Yours sincerely



E D ACHESON DM FRCP FFCM MFOM

Enquiries to: 01-407 5522 Ext 7340 (medical)
or Ext 6699 (administrative)

or: 01-703 6380 Ext 3487 (medical)
or Ext 3574 (administrative)

Further copies of this letter and annex may be obtained from DHSS Store, Health Publications Unit, No 2 Site, Manchester Road, Heywood, Lancs OL10 1PZ quoting the code and serial number appearing at the top right-hand corner.

INTRODUCTION

1. Arrangements have been made in the National Blood Transfusion Service (NBTS) for the screening of all blood donations for HTLV III antibody. This will safeguard blood supplies and will identify donors who are anti-HTLV III positive. Testing facilities are also being made available through genito-urinary medicine (GUM) clinics and elsewhere depending on local arrangements made and publicised by District Health Authorities for people concerned about possible exposure to HTLV III. The arrangements are described below.

INTRODUCTION OF SCREENING TESTS FOR BLOOD DONORS

2. In 1983 and January 1985 the Department of Health in conjunction with the NBTS issued a leaflet warning those in AIDS risk groups not to donate blood. The leaflet, now entitled "AIDS : Important Information for Blood Donors", has been revised and will be re-issued. Steps are now being taken further to reduce the risk of transmission of AIDS through blood transfusion by testing blood donations to identify antibody to HTLV III, the virus which causes AIDS. The tests will be used routinely to screen all blood donations (as is presently done for hepatitis B and syphilis). Donors will be informed that the test is being done and they will be asked to agree to the test before their blood is taken. The tests introduced have been the subject of careful evaluation by the Public Health Laboratory Service (PHLS) and NBTS.

PROCEDURE

3. Blood donations which are found to react positively will not be used for transfusion. Repeat tests will be carried out and a sample from the donation will be sent for confirmation to a Reference Laboratory where another test method will be employed. If the sample is also confirmed as positive at the Reference Laboratory, the Regional Transfusion Director (RTD) will contact the donor, asking him/her to attend the Regional Transfusion Centre (RTC) or a local collection centre to discuss the results of the test. Recalled donors will be interviewed and counselled about the significance of test results by senior NBTS medical staff who have received training in counselling. A further sample of blood will then be taken to confirm the results given by blood from

the donation. This second sample will be tested at the Reference Laboratory which confirmed the original test. These donors will be asked to consult a medical practitioner (their general practitioner or GUM clinician), who with their consent, will be informed of the test results and will arrange any follow-up required.

INTERPRETATION OF RESULTS

4. It is necessary to be cautious in the interpretation of the test results. Occasionally serum from an individual without HTLV III infection will react positively. However the schedule for testing described above is intended to eliminate as far as possible the incorrect assignment of a positive result to a healthy blood donor. As persons infected with HTLV III do not produce antibodies for a few weeks after the infection has taken place, 'false-negative' results will also occur in rare instances. Positive results are expected to be very rare. In Australia testing of blood donations has so far yielded positive results in fewer than 1 in 20,000 donations. Nevertheless, although an appeal has been made to all individuals in high-risk groups not to donate blood, there may be some members of these groups who do not regard themselves as having been at risk. Others could unwittingly have become infected through heterosexual contact.

5. Donors with a confirmed positive result should be offered a full clinical evaluation. As seroconversion generally antedates the development of clinical signs and symptoms, such donors may be asymptomatic. Others may have conditions such as persistent generalised lymphadenopathy, thrombocytopenic purpura of the AIDS-related complex (ARC) (a clinical syndrome comprising weight loss, unexplained fevers and oral candidiasis). These, and the clinical features of AIDS, are described in the booklet accompanying the CMO letter (85)7. Clinical assessment will determine whether or not a patient should be referred for any further investigation and treatment, and how frequently follow-up is required.

ALTERNATIVE TESTING FACILITIES FOR INDIVIDUALS WHO ARE NOT BLOOD DONORS

6. It is extremely important that individuals do not donate blood simply to determine whether they are or are not HTLV III antibody positive. Facilities for blood samples to be tested outside the NETS will be available locally so that people who believe themselves to have been exposed to the virus can have

their blood tested for HTLV III antibody. Such people need counselling about the test, information about the implications for them personally and advice on measures which can be taken to avoid transmission of the AIDS virus. If they are then content for a blood sample to be taken, this can be done by referral to a GUM clinic or other centre designated by the District Health Authority. PHLS will provide the laboratory service required to test samples collected from such patients. The PHLS has designated a number of laboratories that will undertake tests for HTLV III antibody and the number of laboratories will be kept under review as demand for the test becomes apparent. Every effort must continue to be made to dissuade members of high risk groups from donating blood because even a reliable test cannot detect very early infection to which an antibody response has not yet been generated.

ADVICE FOR GENERAL PRACTITIONERS

7. Many of the general practitioners who are consulted by patients worried that they may have been exposed to infection will wish to refer them to Health Authority facilities for advice and testing. Health Authorities will provide details of GUM clinics which provide these services. In the case of patients who do not wish to attend GUM clinics (eg persons who have received blood transfusions) District Health Authorities have been asked to consider providing some alternative facilities and Authorities will be able to provide details of these. For these alternative facilities it will probably be necessary for an appointment to be made, for example at an out-patient clinic. All Health Authority clinics providing HTLV III antibody tests for those who think they have been exposed to infection should also provide patients with advice and counselling both before they have the test and subsequently if the result is positive. Those general practitioners who themselves wish to provide the test for their own patients will need to contact the Director of their local PHLS laboratory about arrangements for collecting and testing blood samples. The precautions outlined in Appendix 1 for obtaining, labelling and transporting blood samples must be observed. In such circumstances it will also be necessary for the GP to provide advice and counselling before and after the test. Where the patient has a confirmed positive result a full clinical examination will be required and if necessary referral for investigation and treatment.

COUNSELLING FOR SEROPOSITIVE INDIVIDUALS

8. Whether or not donors or patients are members of a high risk group the news that they are HTLV III antibody positive may be difficult for them to accept, and careful counselling will be required. It will be important to stress that the test is not a test for AIDS, and that a positive result indicates that a person has been infected by the virus, not that he has or is necessarily about to develop AIDS. From information currently available, up to 10 per cent of infected (antibody-positive) people have subsequently developed AIDS. A further 30 per cent have developed less serious HTLV III-related disorders. The remainder have remained well within the period of time in which the disease has been under study. All HTLV III positive individuals, whether or not asymptomatic, must be regarded for the time being as capable of transmitting infection through sexual contact or through transfusion or inoculation of blood. Their counselling should include the guidance given in CMO(85)7, the relevant extract from which is given in Appendix 2.

SEROPOSITIVE WOMEN OF CHILD-BEARING AGE

9. Particular problems may arise in women of child-bearing age. It is possible that pregnancy may lead to the expression of the disease in the seropositive women, and likely that the infant will become infected with HTLV III. A substantial proportion of such infants may develop AIDS. It may be appropriate to counsel a patient to delay a planned pregnancy until more is known about the factors involved in transmission. Expert opinion will be needed. There is also some evidence that transmission of HTLV III infection is possible through breast milk.

EMPLOYMENT OF HTLV III ANTIBODY POSITIVE INDIVIDUALS

10. Health education measures supported by the Department, and public statements made by the Ministers and the Chief Medical Officer, have stressed the limited means by which HTLV III can be spread. It is hoped that this will encourage the public and employers in general not to regard the employment of people with AIDS, ARC or with HTLV III antibody as posing risks.

CONFIDENTIALITY

11. The strictest confidentiality must be maintained when an HTLV III antibody positive individual is identified. Where a person is tested for HTLV III infection or for its complications and it is thought to have been sexually transmitted, health authorities have an obligation to maintain confidentiality of information under the terms of the National Health Service (Venereal Diseases) Regulations 1974 (SI 1974.9). Unless the patient has given his consent, personal health data relating to him must not be disclosed to anyone for any purpose other than the health care of that patient, except where the disclosure is necessary to prevent the spread of infection. Disclosure of this information for purposes other than medical or public health reasons could lead to serious consequences for the informant. Adequate safeguards to protect individuals against unauthorised disclosure must be adopted.

LABORATORY INVESTIGATIONS

If blood is taken from a person suspected of having AIDS or an HTLV III related condition then the following procedures outlined in the ACDP Guidelines issued by the DESS (HC(85)2) should be observed.

- a. When blood or other specimens are to be taken, gloves and a disposable plastic apron and/or gown must be worn and discarded safely after use. Eye protection is recommended.
- b. Only the minimum essential quantity of blood should be drawn and then only by designated staff who are trained and experienced. Those who withdraw blood or other body fluids must ensure that the outside of any specimen container is free from contamination.
- c. Disposable units must be used for blood collection. Needles and syringes should be immediately discarded into a puncture-proof disposable bin used solely for that purpose and designed for incineration. Only needle-locking syringes or similar units should be used to aspirate fluid from patients. Accidental puncture wounds in staff must be treated immediately by encouraging bleeding and liberal washing with soap and water. Any such accident or contamination of broken skin or mucous membranes must be promptly reported to and recorded by the person with overall responsibility for the work.
- d. Specimens must not be sent to the laboratory without a standing agreement between the clinician and senior laboratory staff. They must be in robust screw-capped and leak-proof containers (evacuated or not) bearing a hazard warning label. Securely capped specimen containers should be sent in separate sealed plastic bags, kept upright if possible and transported to the laboratory in a sound secondary container which can be disinfected. The accompanying request forms must be kept separate from the specimen to avoid contamination and also clearly indicate the hazard. Pins, staples or metal clips must not be used to seal the bags and for safety, the carrying handles of the secondary container should not be attached to the lid.
- e. Specimens when sent by post or otherwise must conform to Post Office Regulations.
Further advice on transport of specimens should be obtained from the Director of the designated laboratory.

APPENDIX 2

GUIDANCE TO INDIVIDUALS ON MEASURES TO CONTROL THE SPREAD OF HTLV III

This guidance is not only for patients with AIDS and their families and friends but also for persons with positive HTLV III antibody tests and members of the risk groups. HTLV III appears to be transmitted principally by sexual intercourse - predominantly but not exclusively between male homosexuals - or by transfusion or inoculation of blood or blood products. There is no evidence that social contact with others presents a risk of transmission of infection. Furthermore, there is no evidence that the infection is transmissible by airborne droplets resulting from coughing, or sneezing, nor by sharing washing, eating and drinking utensils, other articles commonly in general use or sharing of toilet facilities. Infection has not been detected in family contacts apart from sexual partners or children born to infected mothers.

There is a risk of infecting others by sexual intercourse. Sexual partners should be restricted where possible to established relationships. In the present state of knowledge both homosexual and heterosexual anal intercourse should be avoided. Although spread by saliva has not been documented, intimate exposure of others by oral-genital contact or by intimate kissing should be avoided. Mutual masturbation appears to be safe. The efficacy of condoms in preventing infection with HTLV III is not proven, but the consistent use of protective sheaths will probably reduce transmission and is therefore recommended.

Infection may also be transmitted by the sharing of needles and syringes. Devices which have punctured the skin, such as hypodermic needles, ear piercing and electrolysis equipment, tattooing needles and acupuncture needles must be safely discarded unless proper facilities (for instance in a hospital) for steam sterilisation by autoclave are available. Needles and equipment coming into contact with blood should whenever possible be disposable. Razors, toothbrushes or other implements which could become contaminated with blood must not be shared. After accidents resulting in bleeding, contaminated surfaces should be cleaned liberally with household bleach, freshly diluted one part bleach to 10 parts water.

PERSONS INFECTED BY HTLV III AND IN THE GROUPS AT RISK SHOULD NOT DONATE BLOOD, PLASMA, OTHER BODY TISSUES (EG BONE MARROW,) BODY ORGANS, OR SPERM. THEY SHOULD NOT SIGN OR CARRY ORGAN DONOR CARDS.

Individuals with a confirmed sero-positive test should inform doctors and dentists who are treating them that they are antibody positive prior to any blood samples being taken or surgical procedures including dental work being undertaken so that appropriate precautions can be taken. Advice for surgeons, anaesthetists and dentists dealing with individuals infected with HTLV III is in preparation.

COUNSELLING

Within Genito Urinary Medicine/Sexually Transmitted Diseases clinics multi-disciplinary collaboration involving social workers, clinical psychologists and health advisers is usually available to assist the proper counselling and support of AIDS sufferers and their contacts. Support is also available from some community based groups, such as the Terrence Higgins Trust Ltd, BM AIDS, LONDON WC1N 3XX and the Haemophilia Society, PO Box 9, 16 Trinity Street, LONDON SE1 1DE