

DRAFT

Submission to MinistersAIDS and Blood Transfusion - Introduction of HTLV III Antibody Screening Test for all Blood DonationsSummary

1. This Submission sets out the latest position on the transmission of AIDS virus by transfusion of blood and blood products', and seeks
  - (i) Ministers' agreement that a Screening test for all blood donations in the National Blood Transfusion Service (NBTS) is necessary and
  - (ii) Ministers' approval that officials should actively pursue its uniform introduction into the NBTS.

Background

2. The annex to this paper sets out the details of the growing prevalence of AIDS in the UK and describes the developments to date in the UK and USA of a test for the antibody to HTLV III, the virus associated with AIDS. Preliminary results of such screening tests indicate that a large proportion of haemophiliacs have antibody to HTLV III as a result of receiving contaminated Factor VIII, and the first cases in this country have recently been reported of the exposure of patients to AIDS virus through blood transfusion. Whilst heat-treatment of certain blood products (eg Factor VIII) to reduce the risk of AIDS transmission is being pursued, such action cannot be taken for transfusion of blood itself and other blood derivatives.

Needs for a Screening test

3. The campaign to dissuade high-risk groups from donating blood, (by leaflet distribution, interviews at sessions etc) is an important interim measure whilst screening is not possible, but it is recognised that such donor selection methods by themselves, are not enough. It is known that some homosexuals insist on giving blood even when aware that the NBTS asks them not to do so. Unless all blood donations are screened for AIDS infection, the confidence of those patients who need blood transfusion will be lost, with a consequential increase in morbid and prolonged hospitalisation and even mortality of those who refuse to have blood which they fear may transmit AIDS. In order to prevent the transmission of AIDS via blood and blood products it is therefore considered necessary to adopt routine screening of all blood donations in the NBTS. At a meeting of

NBTS Advisory Committee's Working Group on AIDS (a panel of experts) on 27 November 1984, the Department was advised that the screening test for HTLV III antibody should be introduced into all Regional Transfusion Centres as soon as possible.

4. To put the problem into context it should be noted that at present all blood donations in the UK are screened for hepatitis and syphilis - the incidence of hepatitis is about 1 in every 1000 donations, whereas syphilis occurs in 1 in every 100,000 donations. To introduce screening tests for AIDS is equally if not more essential than for hepatitis and syphilis because of its high mortality, lack of treatment, and the consequences of spreading it into the general population.

#### Financial Implications

5. All versions of the screening test are still at the developmental/evaluation stages, and accurate costs are not yet known. Estimates vary between £1 and £2 per donation tested; these are mainly revenue costs, there being little capital outlay needed, at least for those versions compatible with existing NBTS equipment. The NBTS collects around 2 million donations per annum, and thus RHAs would need to find a total of between £2-£4 million pa to fund this test.

#### Development of Test

6. The annex sets out some of the problems currently identified for the introduction of a suitable test throughout the NBTS - the various versions will need development/evaluation work, and there is a need for pilot trials in the NBTS itself. Officials have received approaches from all interested parties, and would wish to take an active part in promoting discussions to ensure that the most suitable test is chosen, and is introduced uniformly throughout the NBTS as soon as possible.

#### Decision Required

7. Ministers are asked:

- (i) to agree that a screening test for HTLV III antibody is necessary for all blood donations collected by the NBTS
- (ii) to agree that officials may pursue actively the uniform introduction of such a test with all speed.

NEX

Background(a) Cases in the UK

Since 1981 up to the end of December 1984 108 cases of AIDS had been identified in which of whom forty-six have died. The majority of cases (93) are male homosexuals. However three heterosexual males had haemophilia A and two of these have died.

(b) Antibody Testing

Since the retrovirus HTLV III has been associated with AIDS rapid progress has been made in the detection of antibodies to the virus in the blood of patients with AIDS or with AIDS related complex. In the UK a key seroepidemiologic study (using a sensitive and specific test which was developed by at the Chester Beatty Laboratories and at the Middlesex Hospital) showed the antibody to be present in :-

- 30/31 AIDS patients
- 89 per cent patients with persistent lymph gland enlargement
- 17 per cent symptomless homosexual men
- 34 per cent haemophiliacs receiving pooled clotting factors
- 1.5 per cent intravenous drug abusers
- None of more than a thousand unselected blood donors was sero positive.

Since then further tests have shown that whilst the overall incidence of antibody to HTLV III is of the order of thirty-four per cent in all haemophiliacs 75 per cent of severe haemophiliacs have this antibody. Additionally antibody tests carried out on symptomless homosexuals attending STD clinics in London have confirmed the figure quoted in the initial survey and also confirmed that symptomless homosexuals attending STD clinics elsewhere in the country are also presenting with AIDS antibody.

2. Significance of the Test

The antibody test identifies an individual who has been exposed to the virus. It does not mean that the patients will develop AIDS but it must be assumed that those who are antibody positive are infectious.

3. Development of the Screening Test for AIDS Antibodies

The UK test was based on the original isolate of HTLV III made at the National Institute of Health USA and sent to on a research basis. The US Government have licensed five pharmaceutical companies all of whom are using this

same isolate to develop screening tests and vaccines. All five companies have made tentative approaches to the UK either to DHSS or to Regional Transfusion Directors (RTDs) or about setting up evaluation studies of their tests which they hope to market in the UK in the spring.

Despite an approach by DHSS officials to the US Government it has not been possible to obtain permission to use the isolate sent to on any other than a 'research' basis. has now isolated a virus from a British patient and this is being developed to provide a test and eventually a vaccine by Wellcome who have sub-contracted the scale up of its production to CAMR Porton.

#### 4. Blood Transfusion and AIDS

AIDS is transmitted by transfusion and the development of the test to detect carriers of AIDS has been seen as a priority. There are already a hundred cases of AIDS amongst recipients of contaminated blood transfusions in the USA. This number of AIDS cases does not truly represent the number of recipients to whom the AIDS virus has been transmitted. AIDS infection is therefore spreading outside the high risk groups into the general population.

Whilst the chance of transmitting AIDS through blood transfusion is low in the UK and no one has yet developed AIDS, there are already three recipients who have been infected by one donor now suffering from AIDS. All three have positive tests as pregnant after she was transfused and<sup>has</sup>/delivered a child who also has antibodies to virus. Plasma from the same donor contaminated a pool from which a batch of Factor VIII was prepared which 38 haemophiliacs have been given. There will almost certainly be other similar incidents unless there is a means of detecting carriers who for one reason or another do not wish to declare that they are in high risk groups.

#### 5. Introduction of a Screening Test

At a meeting of the National Blood Transfusion Service Working Group on AIDS (a panel of experts) on the 27 November the Department were advised that the screening test for HTLV III antibody should be introduced to all RTCs as soon as possible. Pilot trials are needed before the UK tests can be introduced to all centres. There are difficulties because it is known that homosexuals will come to give blood in order to be tested. Expert advisers will consider, later this month what arrangements need to be made for the demand for tests by those in high risk groups and how those found to have positive tests are to be counselled and kept under surveillance and what other resources are required to contain this communicable disease.

It is fortunate that scientists in the UK have so quickly developed a sensitive and specific test which is particularly appropriate to introduce into Regional Transfusion Centres (RTCs) who are using a similar technology to detect hepatitis B carriers. Preliminary approaches already made by four of the USA pharmaceutical companies licensed to use the US isolate indicate that their tests are based on a different technique which is probably less sensitive and certainly unfamiliar to RTCs. Furthermore confirmation of positive findings by the US tests would require testing by the UK method. From information so far received it seems certain that US tests will be more expensive than the UK test. A uniform test throughout the RTCs would also be of value in establishing a reliable base line for the detection of antibody carriers. If an effort is not made to make one test universally available to RTCs then Regional Transfusion Directors (RTDs) will individually introduce tests as they become available on the market first from the US or later from Wellcome who intend to produce a test for NHS laboratories in due course.

It is therefore considered that officials should promote the co-ordination of the research teams, Wellcome, CAMR and BPL in order to hasten the development and application of a properly evaluated screening test for AIDS in the NBTS. The desirability of supporting UK based invention of industry will be borne in mind, but the over-riding policy must be the urgent needs of the NBTS for a reliable screening test.