Submission to Ministers

AIDS and Blood Transfusion - Introduction of HTLV III Antibody Screening Test for all Blood Donations

1. Summary

This submission describes the public health problem that the spread of AIDS presents and the need to reduce as far as possible the risk of its transmission by blood and blood products. It seeks Ministers agreement in principle to the introduction of a test to screen all blood donations for evidence of infection with the AIDS virus.

2. Background

a. 108 patients have been diagnosed as suffering from AIDS in the UK since 1981. 46 of these patients have died. 93 of the cases were in homosexual males and 8 cases in heterosexual males of whom 3 were haemophiliacs.

b. The number of reported cases has doubled every 8 months in the UK.

c. AIDS can be transmitted by sexual contact and by transfusion of blood and blood products. Whilst no cases of AIDS have arisen in the UK yet as a result of blood transfusion 3 recipients of blood donations given by a patient who now has AIDS are known to have been infected with the virus. Plasma from one of these donations has contaminated a pool of plasma from many other donors and used to make Factor 8. In Scotland a batch of Factor 8 has similarly been contaminated by an undetected donor.

d. In the United States a hundred cases of AIDS are believed to have been caused through blood transfusion and there are over fifty haemophiliacs with AIDS out of a total of 7,669 AIDS cases diagnosed since 1980.

e. No method of treating the disease has been developed although some consequential infections can be controlled with antibiotics. Eventual mortality from the disease is believed to be in the region of 80 per cent.

3. Current Action

Research on AIDS in the UK has been co-ordinated by the Medical Research Council whose Expert Advisory Group is closely in touch with the work of AIDS in the USA, Europe and elsewhere.

Expert advice has already been obtained by the Department at a meeting of the NBTS AIDS Working Group on the application of the screening test and the need to heat treat Factor VIII. A more widely based Expert Advisory Group is meeting at the end of the month to consider the implications of the disease and the need to prevent its spread. The Advisory Committee on Dangerous Pathogens has prepared guidelines for hospital staff which are to be distributed to Health Authorities within the next few days.

A revised leaflet is shortly to be issued to all blood donors individually.

4. Need for a Screening Test

Whilst the campaign to dissuade high risk groups from donating blood is an important interim measure it is not enough. Experience has shown that people with the active disease and others who are infected have been donors. The confidence of patients will be lost if they cannot be assured that they will not contract AIDS infection from transfusions. Prolonged hospitalisation, increased morbidity and mortality will be the consequences of patients refusing transfusion.

Moreover if patients receive contaminated transfusions the disease will no longer be confined to the high risk groups but be transmitted to the population at large.

5. The Screening Test

This test will identify people who have been infected with AIDS virus but a positive test will not mean that the disease will develop. Only about 10 per cent of those infected with the virus apparently develop the disease. Nevertheless it must be assumed they will be infectious. A small proportion of carriers will be undetected by the test. Until a test for the virus itself is developed certain blood products made from large pools of plasma can be heat treated to make them safe. Heat treatment cannot be applied to blood itself.

All blood donations are currently screened for Hepatitis B virus and for Syphilis. The incidence of positives is 1:1000 for Hepatitis B and 1:100,000 for Syphilis. The number of donors found positive for AIDS antibody will lie between the two, probably nearer to that of Syphilis.

6. Financial Implications

No tests are yet available for use in Regional Transfusion Centres. They are expected to be ready in the Spring. Both American and British tests are still being developed but the likley cost will be between 75p to £2.00 for each donation. The British test is more sensitive and more suitable to install at Transfusion Centres and is likely to be cheaper. The NBTS collect more than 2 million donations per annum and thus the RHAs would need to fund between them a total of £2-4 million per annum. There will be consequential resource implications for the provision of counselling those found to have the antibody.

7. Development of the Test

Details are provided in the Annex.

8 . Decision Required

The tests for AIDS antibodies will not guarantee the purity of donated blood. There is a time lapse between infection and development of a detectable antibody. Complete assurance will have to await development of a test for the AIDS virus itself. There is no doubt that despite these problems the balance of advantage lays clearly with the introduction of a routine test of donations as soon as possible.

Ministers are asked to agree in principle to the introduction of a screening test for AIDS antibody for all blood donations and to an announcement made to this effect at the appropriate moment indicating that the development of a test is being backed by the Department.

ANNEX

Test for HTLV III Antibody

1. Antibody Testing

The Re trovirus HTLV III is associated with AIDS. In the UK a sensitive and specific test to detect antibodies to the virus has been developed by Professor Weiss at the Chester Beatty Laboratories and Dr Richard Tedder at the Middlesex Hospital.

They found the antibody in:-

30 out of 31 AIDS patients
89 per cent patients with persistent lymph gland enlargement
17 per cent symptomless homosexual men
34 per cent haemophiliacs receiving pool clotting factors
1.5 per cent intravenous drug abusers
None of more than 1000 unselected blood donors was sero positive for antibody.

Since then further tests have shown that whilst the overall incidence of antibody in all haemophiliacs is of the order of 34 per cent, 75 per cent of severe haemophiliacs have the antibody. Tests carried out on symptomless homosexuals attending STD Clinics outside London confirm that they also have 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 they will develop AIDS. Only about 10 per cent of those infected with the virus are thought to develop the disease. However it must be assumed that those who are antibody positive are infectious.

3. Development of the Screening Test for AIDS Antibodies

The UK test is based on the original isolate of HTLV III made at the National Institute of Health USA and sent to Professor Weiss on a research basis. The US Government have licenced 5 Pharmaceutical Companies all of whom are using this same isolate to develop screening tests and vaccines. The US Government has made it clear in a response to DHSS officials that use of this isolate for the development of a test reagent could only be arranged on a commercial basis with one of the licenced firms. Professor Weiss has now isolated a virus from a British patient and this is being developed to provide a test by Wellcome who have sub-contracted CAMR Porton to scale up its production. It will take at least 3 to 4 months for sufficient test reagent to be available for testing blood specimens on a large scale.

4. Blood Transfusion and AIDS

In addition to sexual contact AIDS is transmitted by transfusion of blood and blood products. There are already 100 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.

Whilst the chance of transmitting AIDS through blood transfusion is low in the UK and no-one has yet developed AIDS there are already 3 recipients who have been infected by 1 donor now suffering from AIDS. All 3 have positive tests and 1 who was transfused in March 1983 has since had a baby who also antibodies to AIDS virus. Plasma from one of the same donations contaminated a pool made from many donations which was used to prepare a batch of Factor 8. Some of this batch has been given to 38 haemophiliacs in Wales and Wessex. In Scotland 15 haemophiliacs have been found positive for AIDS antibody having received Factor 8 from a batch contaminated by a donor in Scotland. There will almost certainly be other similar incidents unless carriers are detected.

5. Introduction of a Screening Test

At a meeting on 27 November the Department were advised by the expert Working Group on AIDS of the National Blood Transfusion Service that the screening test for HTLV III antibody should be introduced to all Regional Transfusion Centres (RTCs) as soon as possible. Pilot trials are needed before these tests can be introduced to all Centres. There are difficulties because it is known that homosexuals will come to give blood in order to find out whether they are carriers of the antibody.

Expert advisers will consider, later this month, what arrangements need to be made for the demand for tests by those in high risk groups, 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.

The UK test is sensitive and specific and particularly appropriate to introduce into RTCs who are using a similar technology to detect Hepatitis B carriers. Preliminary approaches already made by the Americal Pharmaceutical Companies licenced to develop tests indicate that their tests are based on a different technique which is probably less sensitive,unfamiliar to most RTCs and requiring more capital equipment. Furthermore, confirmation of positive findings by the US tests will require testing by the UK method. It also seems certain that the US tests will be more expensive than the UK testing. A uniform test throughout the RTCs would be of value in establishing a reliable baseline for the detection of antibody carriers throughout the UK. If an effort is not made to make one test universally available to RTCs then Regional Transfusion Directors will individually introduce tests as they become available on the market almost certainly first from

the USA and later from Wellcome.