

3053

## Aids Immune Deficiency Syndrome [AIDS] - Current Developments

1. This paper sets out the current position with regard to AIDS and points to the urgent need for the Department to obtain advice from the professional groups involved on the numerous problems thrown up as a result of recent developments following the identification of a causal virus. It is proposed that a Working Group should be set up to provide this advice.

### 2. Background

AIDS was first reported in the USA in 1981 although retrospective studies indicate that the first cases occurred there as early as 1978. Soon after its recognition in the USA cases were identified in the United Kingdom, again retrospective studies identified cases occurring in 1979. Since that date up to the end of June 1984 some 51 cases of AIDS have been identified in the UK. 28 of these have died. The disease affects the immune system producing the deficiency in the body's defences which because it is unable to respond normally is manifested by opportunistic infections and/or malignancies. Fewer than 20 per cent of patients have survived two years after AIDS has been diagnosed.

AIDS is prevalent amongst homosexual men, intravenous drug abusers, sexual partners of these two groups. It is also prevalent in Central Africa and Haiti. The disease has also arisen in patients suffering from haemophilia who are treated with Factor VIII derived from large pools of plasma. A number of cases have been reported in the USA which have developed after receiving massive blood transfusions. Whilst there are some patients who do not fit into any of these high risk categories there is little evidence of the disease being transmitted by ordinary day-to-day contact and no substantiated evidence of the infection being transmitted to staff who deal with AIDS patients or their specimens.

### 3. Cause of the Disease

Towards the end of 1983 two teams of researchers, one in the USA and one in France isolated a retrovirus from AIDS cases and from patients with the extended lymphadenopathy syndrome which is believed may precede full blown AIDS. Subsequent research has confirmed that the viruses isolated by the two groups (known as HTLVIII/LAV virus) are similar. A lot of further research is required to characterise the virus and to define whether it is the only causal

agent or if there others. As the disease has now affected 5,500 patients in the USA, a number which is expected to double within the next six months, considerable effort and resources are being put into developing a test to detect whether or not individuals have been infected with the agent and a vaccine. The importance of a screening test for the UK National Blood Transfusion Service is paramount. Whilst the risk calculated so far of AIDS being transmitted through ordinary blood transfusions is minimal, recipients of blood derivatives such as Factor VIII which are mainly extracted from large plasma pools are at greatly increased risk of having the disease transmitted.

#### 4. Development of Screening Tests in the UK

By collaboration with Dr Gallo in the United States and Dr Montaignier in France, Dr Robin Weiss at the Cancer Research Institute and Dr R S Tedder virologist at the Middlesex Hospital Medical School have obtained isolates of the causal virus. They expect to isolate a similar agent in the UK shortly. Using the USA agent they have been able to devise a test which uses a radio immunoassay technique to identify antibody to HTLV 3 virus in the blood of AIDS patients. Arrangements are being made at the Middlesex Hospital to increase the production of the reagent needed for the test. To do this Category 3 accommodation is required and a laboratory is being converted to achieve this. Once sufficient test reagent is available it is planned to extend the test to blood donors at the North London Transfusion Centre probably at the beginning of October to ascertain the prevalence of positive cases in the blood donor population. The sensitivity, specificity and practicability of the test for blood donors will also be assessed. The initial stages of developing this test have been financed through the Medical School and MRC funds but it is likely Dr Tedder will be looking to us to provide funds to enable the test reagent production to be scaled up sufficiently to extend the screening test to two more Regional Transfusion Centres (RTC's).

5. Once the availability of a screening test becomes public knowledge there will be pressure to institute its use in all Regional Transfusion Centres and to extend its use for screening purposes to STD clinics and possibly by general practitioners. If in the preliminary trials the UK test is found to be accurate there will be a need to scale up the production of the reagent further.



It would be appropriate that the scale up should be carried out CAMR who have the equipment and the expertise. In any case production of the reagent either by CAMR or possibly by British industry will be facilitated if the agent has been isolated by research teams working in the UK. Clearance would have to be sought to use the United States isolate for any extended production of the reagent (the French agent is currently difficult to propagate). The same clearance would apply to the tissue culture used to grow the reagent although Dr Weiss is expects to be able to adapt an existing line to do this.

6. It is currently estimated that the test reagent developed by Drs Tedder and Weiss will cost 20p per test whereas reagents likely to be produced by USA pharmaceutical companies, 5 of whom have been given the isolate to develop, may cost up to £5 per test.

7. It should be noted that the Middlesex Hospital team were involved in devising the radio immunoassay test for hepatitis B now used by all Regional Transfusion Centres. There has been more than a little disappointment at the Middlesex that the Department has not been able to find some means of financial recognition of the Middlesex Hospitals contribution to the development of this assay. It must be expected that some assurance will be sought that the AIDS test will receive some financial recognition, not I hasten to add for individual research workers, but for the Department as a whole.

8. Problems will arise once the test identifies carriers of the antibody. In the first place it will not be immediately apparent if the carriers have the disease, are incubating it or if they have been infected and have overcome it. Examination of the carriers and their follow-up will be necessary. As it is known that incubation of the disease can take many months the follow-up will take careful and prolonged arrangements. It will be necessary to plan how this surveillance can be undertaken and by whom it would be done. It will also be necessary to have a policy about informing donors who have been found to have the antibody. There will need to be decisions about the donations of blood which the carrier donors have provided at earlier attendances. It may well be necessary in some cases to follow-up the recipients of the donations given by carriers.

9. Donors identified of being antibody carriers at the Regional Transfusion Centre will require further confirmatory tests as for Hepatitis B cases. It will probably be appropriate for the PHLS to provide a reference service for these cases. In view of the cuts currently faced by PHLS, funding for a reference service is likely to be sought.

10. The Department will need to have professional advice on many of the points raised in the preceding paragraphs. Health authorities will also need advice on how to deal with the screening of blood donors and others at risk. It is suggested that an expert group should be drawn together to consider the problems and provide guidance. In forming such a group the interests of the whole of the United Kingdom should be kept in mind.