APPENDIX VIII

REPORTS ON AIDS DEVELOPMENTS IN MEMBER STATES, FINLAND AND AUSTRALIA

(NB NUMBERS OF AIDS CASES SO FAR ARE SET OUT IN TABLE AT END OF THIS APPENDIX)

AUSTRIA

Blood donation organisations are starting to test for LAV/HTLV III antibodies.

BELGIUM

Selection of donors had been aided, for the past year, by the use of a questionnaire signed by the donor, certifying that he does not belong to a risk group which is advised against donating blood. It had been decided that, from now on, serological screening of all plasmapheresis donors would be carried out at least four times a year, and that only tested plasma from regular donors would be used in the preparation of coagulation factors. Positive results would not be passed on immediately.

To date, only 3% of haemophiliacs are anti-LAV/HTLV III positive, these cases being the result of imported concentrates. No cases of AIDS have so far resulted from transfusion and none has been identified in haemophiliacs.

CYPRUS

Since no AIDS cases have been reported in Cyprus, and the incidence of homosexuality is very low, there is currently no screening for LAV/HTLV III antibodies. Due to the fact that many tourists visit Cyprus, it is thought that, as well as excluding homosexuals and other high risk groups from giving blood, a LAV/HTLV III antibody test will need to be introduced in the near future.

The representative felt that, after confirmation of a positive test, the person concerned should be informed in a proper way.

DENMARK

Folders with information on AIDS and risk groups were prepared in 1983 by the National Health Service, in collaboration with blood banks and the Danish Voluntary Donor Association, and distributed to all active donors. People from risk groups are asked to refrain from giving blood.

A committee has been created, involving members from the National Health Service, epidemiologists, microbiologists, blood bank physicians, from the National Society for clinical immunology, and representatives from the homosexual community. This committee is now considering the testing of donors for LAV/HTLV III antibodies and heat-treatment of national Factor VIII

products. No final decisions have yet been taken concerning antibody screening of donors. Informing antibody-positive donors of this result is a major problem and is one reason for delaying the screening of donors.

A preliminary screening of 2,300 blood donors from the greater Copenhagen area (Rigshospitalet) has been performed by a cancer laboratory, using home-made ELISA tests with materials from Gallo. Thirty eight were positive or doubtful after first testing. Retesting showed 8 (0.35%) positive or doubtful. Confirmatory tests (Western blot) showed that none of these were positive.

In a second phase, two or three commercial tests are being examined in various Danish transfusion centres.

So far, 45-50 cases of AIDS have been diagnosed in total in Denmark (5 million inhabitants). None have been transfusion-associated.

Several clinics round the country already offer anonymous screening for LAV/HTLV III antibodies on demand.

FRANCE

The following measures are the main features of French policy:

i. Informing donors by means of leaflets and brochures, so that those belonging to risk groups refrain from donating;

ii. Providing doctors with specific information and supporting the establishment of a medical committee on AIDS at national level;

iii. Assessment of available testing techniques (Abbott, Organo-Technica/ HTLV III, Institut Pasteur/LAV). 6000 samples have all been tested with the three kits and the assessment procedure is in the process of being completed;

iv. Once the assessment under (iii) is completed, testing for all donations will be introduced. This decision will soon be made official by the Ministry of Health and it has also been decided that Social Security will bear the relevant costs;

v. In accordance with the opinion expressed by the national ethical committee, chaired by Prof. J Bernard, donors with a confirmed positive result will be informed accordingly; it is felt that such information constitutes a right of the donor and will also avoid any possible social discrimination;

vi. Appropriate measures will also be taken with respect to stable products which have not undergone such testing. Additionally, research will be sponsored to determine the effect of heat treatment of stable products on viral activity.

FEDERAL REPUBLIC OF GERMANY

Information about AIDS and the risk groups is provided to all donors, who are obliged to sign a form to the effect that they have read and understood it.

Testing for LAV/HTLV III antibodies is carried out in the majority of donors and will be compulsory from 1st October 1985. A number of different tests are used. Donors who are found positive are asked for a second specimen, a process which can take up to 6 months. If the result is confirmed, the donor will be informed through his physician.

GREECE

All the blood transfusion services in the country have been kept informed about AIDS.

The selection of donors has to be done very thoroughly, taking account of the country of origin, occupation and possible suspicious symptoms, but the rejection of any donor is handled discreetly and based on a pretext.

No information is being given to donors because of special considerations applying, eg, family and social problems. It has been decided to give out information only when the validity of the test will be known and medical assistance available.

Testing for LAV/HTLV III antibodies has been carried out on the majority of haemophiliacs.

A month ago, a pilot study was set up, using the Abbott and Organon kits, at the Second Regional Blood Transfusion Centre in Athens, but the results so far obtained are not yet sufficient for evaluation.

A committee on AIDS was set up at the beginning of 1983, with transfusionist representation, in the Ministry of Health. All suspected cases have to be reported to the committee and registered following confirmation.

Up to April this year, 8 fatal cases have been registered (5 foreign - Africa and USA, 2 Greek sailors and 1 associated with transfusion of imported concentrates).

ICELAND

A decision has been taken by the Department of Health to start testing all blood donors for LAV/HTLV III antibodies from September 1985. At the same time, testing will also be made available to individuals in the risk groups. No decision has yet been taken about whether to tell donors who eventually are found to be LAV/HTLV III antibody positive.

IRELAND

Ireland has a relatively low case incidence. For the past two years, all those wishing to donate blood have been required to read the explanatory pamphlet entitled "An important message to Donors" and are required to indicate on the donor registration form that they have read and understood the "message". In this regard, the Gay Health Action Group has produced an official information leaflet requesting that homosexuals refrain from giving blood. Similar information is also included in the envelope with the donor 'call-up' card.

As yet, no decision has been taken to test donations for the presence of anti-LAV/ HTLV III since there are several unanswered questions:

- will it be necessary to ask a donor's consent to perform the test? This is not presently the case in respect of venereal disease and Hepatitis B, which are screened routinely.

- given the high incidence of "false positives" with newly introduced tests, at what point in time, after repeated testing, should they be advised of results?

- will it be necessary to establish a donor counselling service to prevent further transmission of the virus?

In common with other Blood Transfusion Services, account must be taken of the psychological and social repercussions arising from the reporting of positive results, as these relate to the donor's family and friends. The question of "confidentiality" poses a further problem.

By the end of 1985, Ireland will have achieved self-sufficiency in respect of haemophilia concentrates.

ITALY

Blood Transfusion Centres have been asked to advise donors not to give blood if they are in the risk categories and this has been done. A committee of experts has been set up at the Consiglio Superiore di Sanità which has suggested that all donors should be tested for LAV/HTLV III antibodies. Some blood transfusion centres have introduced the test experimentally.

No decision has been taken as to whether to inform blood donors found to have positive markers.

LUXEMBOURG

1. Information for the donor.

The donor is informed on each occasion, by means of a form which he has to sign.

This information covers malaria, hepatitis and AIDS. The system has been in operation for more than a year and a half.

2. Screening

A study is underway into the ELISA method of screening. No date has yet been fixed for the introduction of routine screening for each donation.

MALTA

Screening blood donors for antibody to LAV/HTLV III is intended to be introduced in the coming months, following a preliminary exercise comparing results in the random donor population, with the most accessible high risk groups, the country's 22 severe haemophiliacs. 3 haemophiliac A patients have clinical evidence of AIDS Related complex - these patients and others have been infused with commercial Factor VIII concentrate which was subsequently withdrawn after the company informed the Health Department that one of the donors contributing to the batch had developed AIDS. Efforts are being made to substitute heat-treated concentrate for that traditionally used.

NETHERLANDS

Since the beginning of 1983, all blood donors have received a brochure which explains what AIDS is, which groups are at risk of acquiring it and the risks associated with transfusion of blood from these individuals. A committee of the National Health Council has regularly informed all physicians in the Netherlands about the epidemiology, symptomatology and prevention of AIDS. The organisation of homosexuals has also advised promiscuous male homosexuals not to donate blood.

Tests for antibodies to LAV/HTLV III became available in 1985. The Minister of Health has recommended that all blood banks and blood transfusion services, as well as the Central Laboratory, should start to use such a test on all blood and plasma donations. Starting from 11 April the Central Laboratory has tested all the donations obtained by mobile teams. The blood banks expect to have introduced anti-LAV/HTLV III testing by mid-1985. The government has made funds available to test facilities on alternative sites. Tests (eg Western blot) are now being evaluated by the National Institute of Health and the Central Laboratory. In addition, a comparison is being made of all available Elisa methods for anti-LAV/HTLV III. A decision about informing donors of positive anti-LAV/HTLV III results awaits the results of these studies.

NORWAY

Up to now 8 cases of AIDS have been diagnosed in Norway, all occurring in homosexual or bisexual males.

An advisory group on AIDS has been organised by the Norwegian health authorities. Following a recommendation from this group, the health authorities asked all blood banks to inform all donors about the disease. Persons belonging to any of the risk groups are asked to refrain from blood donation.

Organisations of homosexuals have been very co-operative, bringing information about the disease to their members and asking the male members not to donate blood.

Screening of blood donors for the presence of LAV/HTLV III antibodies has started recently at a few larger centres. The tests have so far been done anonymously, as part of a pilot project.

Before a systematic screening of all donors for anti- LAV/HTLV III is started, it is considered important to establish a parallel service (outside the transfusion service) where people belonging to the risk groups can be examined. A clinical counselling service for persons found to have LAV/HTLV III antibodies should also be available.

A major proportion of Norwegian haemophiliacs has now been tested for the presence of anti-LAV/HTLV III. Antibodies were identified in 12% of the patients. However, the Western blot technique has not yet been applied as a confirmatory test. Anti-LAV/HTLV III occurred more frequently in haemophilia A patients than in haemophilia B patients. In Norway, most haemophilia A patients are treated with single donor cryoprecipitate or with small pools (up to 6 donor units) of freeze-dried cryoprecipitate. In 1980, because of problems in processing a sufficient amount of cryoprecipitate, it became necessary to import Factor VIII preparations from abroad. It is known that nearly all the haemophilia patients having LAV/HTLV III antibodies had received such imported preparations.

PORTUGAL

Tests for anti-LAV/HTLV III have only been available for the last few weeks. Screening programmes are now starting on haemophiliacs and on chronic persons under haemodyalisis.

The possibility of extending the screening programme to include blood donors is dependent on available finances and has yet to be decided.

SPAIN

A committee on AIDS has been set up by the Ministry of Health, which includes clinicians, microbiologists and experts on blood transfusion.

The committee is planning a study to find out the positivity rate for LAV/HTLV III antibodies among the donor population. 10 blood banks are involved in the study which will start after the summer. Blood units

that are repeatedly positive will be referred to the Magadahonda Virology Centre for confirmation. No decision has been made whether or not to tell the donor about a positive result.

SWEDEN

In Sweden, a national AIDS group has been set up with the Minister of Health as Chairman. A decision has been taken that facilities should be organised for the testing of anti-LAV/HTLV III in risk groups starting from 1 June 1985. An information brochure has been distributed to public institutions. It has been decided that all blood and blood products should be tested for anti-LAV/HTLV III as from 1 August 1985. To the risk groups are added those who have had sexual contact with prostitutes later than 1979, parents of haemophiliacs, individuals who have antibodies to LAV/HTLV III. In the region of Stockholm, LAV/HTLV III testing will be carried out as a control of products and the donors will not be informed of the result if it is positive. This is to avoid people in high risk groups coming to blood banks for the purpose of LAV/HTLV III testing.

SWITZERLAND

Current testing: the main problem is to exclude false positive test results and to build up the reference system which will be centralised in the Central Laboratory of the Red Cross Blood Transfusion Service in Berne. Anti-HTLV III testing will be declared compulsory, by the Federal Health Authorities, and the other problem of how to inform and counsel LAV/HTLV III positive donors must be studied.

Up to now, 52 cases of AIDS have been found, but no transfusion-associated cases. No haemophiliac patient has shown full-blown AIDS up to now.

UNITED KINGDOM

The position on routine screening of blood donations for anti-LAV/HTLV III was as follows:

i. the test kits which have been licensed in the USA are undergoing evaluation in the Public Health Laboratory Service for sensitivity;

ii. satisfactory tests will then be subjected to a trial in the Blood Transfusion Service in order to assess the integration of the test into the service and to determine the prevalence of positive anti-LAV/HTLV III samples. Each test system will be tested against aliquots of approximately 6,000 blood samples.

The DHSS have established an Expert Advisory Group on all aspects of Acquired Immune Deficiency Syndrome. In particular, it is considering two major problems in relation to the Blood Transfusion Service, viz: the availability of alternate testing centres apart from the transfusion service and the manner in which the donor should be handled.

The United Kingdom Government was committed to the introduction of routine screening of blood donors once a satisfactory test was available, as determined by the evaluations being carried out.

AUSTRALIA

Transfusion related (8) and haemophiliac (2) AIDS account for a high proportion of the 78 cases notified in Australia up to 9 May 1985.

Donors sign a statement concerning their suitability to donate in the knowledge that:

i. the blood will be tested for LAV/HTLV III antibodies

ii. there are penalties for false or misleading information.

LAV/HTLV III screening began in mid-April, simultaneously in blood centres and public health centres in each state. The incidence of tests requiring reference laboratory investigation is 1/1,000. The incidence of anti-LAV/HTLV III in haemophiliacs is 28%, in a country which uses no commercial concentrate. Abbott and ENI (macro- and micro- methods) are appropriate for use.

Donors who are ultimately declared positive, following confirmatory testing, are informed.

Heat treatment of Factor VII concentrate has occurred since February 1985, requiring a significant increase in fresh frozen plasma processing for Factor VIII concentrate manufacture.

FINLAND

The policy:

i. All donors are informed about AIDS and those in risk groups are asked to refrain from donating;

ii. Several haemophiliacs have been studied: 2/150 had LAV/HTLV III antibodies

iii. A pilot study of male donors has begun: one positive out of 4,000 has been found. The study is anonymous.

iv. Donors with a positive test result were not informed.

NUMBER OF AIDS CASES IDENTIFIED SO FAR (MAY 1985)

Country	Total No.	Haemophiliacs	Transfusion-associated
Austria	start IV/83 till V/85:15 (12 died)	2 registered 2-3 weeks back	
Belgium	81	0	0 in Belgium (4 in Africa)
Cyprus	0	0	0
Denmark	45-50	0	0
France	350	⟶ 8 ⟵	
Federal Republic of Germany	180	5	0
Greece	8	1	
Iceland	0		
Ireland	5 (2 deceased)	1 ⟶	
Italy	39		1
Luxembourg	1	0	no
Malta	0		
Netherlands	52	0*	1**
Norway	8	0	0
Portugal	5	1	0
Spain	14	3	3
Sweden	22 (11 died)	1	0
Switzerland	52	0	0
United Kingdom	157	5	2 (transfused outside UK: 1 in USA, 1 in Dubai)
Australia	76	2	8
Finland	5	0	0
TOTAL	1,067 (approx)	26 (approx)	26 (approx)

* Except wife of 1 haemophiliac person (himself anti LAV but not yet symptomatic)

** transfused in the USA