ADVISORY COMMITTEE ON DANGEROUS PATHOGENS

ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)

BACKGROUND

Members will be well aware of the considerable publicity and the degree of public concern that has arisen since AIDS was first recognised as an apparently new clinical condition - characterised by the occurrence of Kaposi's sarcoma or of opportunistic infections in the absence of known causes of immunosuppression - with the potential for spread in the community.

While the majority of the 1800 plus cases of this condition now recorded in the United States (Aug 1983) has occurred in promiscuous male homosexuals, it is now clear that other groups can also be affected. So far, these include female sexual contacts, recipients of blood and blood products and some others including Haitians, whose route of acquisition is unknown. (Appendix A). To date no case has been recorded in health care personnel which has been conclusively attributable to contact at work (Appendix Bi). The Communicable Disease Surveillance Centre (CDSC) has taken on the task of recording and publicising notifications of confirmed cases in the United Kingdom and these now amount to 14, details of which are given in Appendix C.

The assumption to date has been that AIDS results from an infection which is most likely to be viral. Several viruses have been suggested as causal agents (cytomegalovirus, swine fever virus, human T cell leukaemia virus) but none has been positively incriminated. There is also a possibility that susceptibility to AIDS may be related to pre-existing immune dysfunction in the host.

There is now strong circumstantial evidence that AIDS may be transmitted by blood and blood products. In the USA some 20 haemophiliacs (August 1983) have developed AIDS and in Britain there is one confirmed case in a haemophiliac. Similarly in Spain, AIDS has been reported in three people treated with commercial Factor VIII concentrates and single cases have been reported in haemophiliacs in Germany, Austria and Canada. No haemophiliac has developed Kaposi's sarcoma. Perhaps the most significant case in relation to blood transfusion concerns a baby who developed AIDS several months after receiving transfusions of blood and platelet concentrates. One of the platelet donors was subsequently

discovered to have developed AIDS, although he had been apparently well at the time of donation. Some other less well defined instances of AIDS developing at long but variable periods after transfusion have been recorded. Although in these cases no other predisposing factor has been implicated, neither has a direct link been established with a donor suffering from AIDS.

There have been fears that the hepatitis B vaccine, which is prepared from the plasma of homosexual donors, might be capable of transmitting AIDS. To date, there is no evidence that this has occurred (Appendix D).

Guidance for blood donors in the UK is being issued with a view to reducing the possible risk of transmission by blood transfusion (Appendix E). Reassurance has been promulgated by the Haemophilia Society to those who regularly receive blood products (Appendix F).

In view of the circumstantial evidence for infectivity, in particular in relation to transmission by blood or body fluids, there is concern amongst health care staff about the possibility of contracting AIDS from patients or from contaminated materials and clinical samples for investigation. There is also concern lest hepatitis B vaccine or specific hepatitis B immunoglobulin - which is recommended for use after an inoculation accident - could be capable of transmitting AIDS. Guidance for the conduct of laboratory work and for patient care and general preventive measures, has been issued by the US Department of Health via the Centers for Disease Control and this was published initially in two editions of the Mortality and Morbidity Weekly Report. This is now available from the Communicable Disease Surveillance Centre at Colindale in a combined form (Appendix Bii).

REFERRAL TO ACDP

Although an infective aetiology for AIDS remains unproven, it would seem prudent at this time for ACDP to consider the need to provide guidance for the safe handling of clinical and other material from patients who either have AIDS or are at risk from the disease. Consultation on the draft ACDP Report No. 1 has produced a number of requests for ACDP to examine this matter, including requests from the Joint Consultants Committee and the TUC.

ACDP is therefore invited to consider whether there appears to be a case for the provision of guidance at this time and, if so, if it will:-

i. review the evidence in relation to the transmissibility of AIDS and

ii. in the light of that evidence, formulate guidance for the safe handling of potentially infective clinical and other material and

iii. advise on procedures to be adopted at the interface between clinical care and laboratory work and

iv. examine the evidence in relation to the possible transmission of AIDS by hepatitis B vaccine and specific hepatitis B immunoglobulin.

The Committee may wish to establish a working party for this purpose.

APPENDICES

A "Epidemiological Information on AIDS as currently known" - CDSC June 1983

Bi) "An Evaluation of AIDS Reported in Health Care Personnel" - MMWR July 15 1983

ii) "AIDS - Precautions for Clinical and Laboratory Staff" - MMWR Nov 5 1982
Prevention of AIDS: Report of Inter-Agency Recommendations - MMWR March 4 1983

C Surveillance of AIDS in the UK - definition and case analysis from CDSC, Aug 1983

D Hepatitis Surveillance: Safety of Hepatitis B Virus Vaccine - Wkly Epid Rec. WHO Aug 5 1983

E "AIDS and How it Concerns Blood Donors" - wording of leaflet for distribution by the NBTS

F Letter from the Haemophilia Society to haemophiliacs - 4 May 1983

EPIDEMIOLOGICAL INFORMATION ON AIDS AS CURRENTLY KNOWN (JUNE 1983)

Acquired Immune-Deficiency Syndrome

APPENDIX A

1. Identification

A serious, often fatal, illness (39% mortality). Patients may present with lesions of Kaposi's sarcoma - violaceous, cutaneous papules, sometimes also involving viscera, or with various opportunistic infections. These include Pneumocystis pneumonia, toxoplasmosis, cytomegalovirus infection, atypical mycobacterial infection and cryptococcal infection. A phase of unexplained extra-inguinal lymphadenopathy in two or more sites of three months duration, together with fever, weight loss, night sweats and diarrhoea commonly occurs, and may be prodromal. In order to make a diagnosis of AIDS, known causes of immunosuppression should be absent.

2. Infectious Agent

Thought to be a virus, possibly a slow virus. It has been postulated that repeated episodes of virus infection contribute to a state of defective cellular immunity.

3. Occurrence

Thought to be endemic in Haiti and possibly in Central Africa. A recent outbreak (1,600 cases, May 1983) has occurred amongst young homosexual males in the USA. There have been 120 cases (May 1983) in Europe, including 12 in England and Wales. Other groups thought to be at risk are intravenous drug abusers, consorts of bisexuals, and recipients of infected blood and blood products.

4. Mode of Transmission

Thought to be blood-borne and by intimate direct contact of mucosal surfaces. Homosexual practices involving trauma to the rectal mucosa and contact with faeces are thought to be important in the spread of infection.

5. Incubation Period

Thought to be from four months to two years, or longer. There may be a latent period between exposure and clinical illness, during which transmission can occur.

6. Susceptibility and Resistance

Epidemiological evidence suggests that identifiable groups are at increased risk of developing the disease. The majority of cases have occurred in homosexual men with multiple sex partners, IV drug abusers, Haitians and

sexual contacts of persons in these categories. Cases are thought to have occurred from perinatal or in utero transmission.

Several cases have been reported in persons without other known risk factors, who have received blood products from patients subsequently found to have AIDS. Cases have occurred amongst haemophiliacs receiving Factor VIII concentrate (11 in U.S.A., 1 in Wales and 3 in Spain).

7. Methods of Control

No cases have been reported amongst hospital or laboratory staff who have contact with affected patients or their clinical specimens. However, patterns of distribution and spread are similar to those seen with hepatitis B virus. It would seem wise to follow procedures used in the management of patients and handling of specimens known to be infected with hepatitis B. These procedures should be adopted for known cases of AIDS, for those in high risk groups and for those suffering from the Lymphadenopathy syndrome previously described.

Guidelines and precautions for clinical and laboratory staff have been described by CDC (Atlanta). These have been reproduced by CDSC.

Sexual contacts of patients diagnosed as having AIDS should be investigated. Blood and blood products donated by patients subsequently developing AIDS, should be destroyed. Patients are treated on an individual basis. There is a voluntary reporting scheme to CDSC.

CDSC
JUNE 1983

APPENDIX Bi

An Evaluation of the Acquired Immunodeficiency Syndrome (AIDS) Reported in Health-Care Personnel -- United States

As of July 11, 1983, physicians and health departments in the United States and Puerto Rico had reported a total of 1,831 patients meeting the CDC surveillance definition of the acquired immunodeficiency syndrome (AIDS) (*1*). Of these, four were reported to be health-care personnel not known to belong to groups at increased risk for AIDS. Onset of illness in these patients occurred between June 1981 and April 1983. The source of AIDS in these four patients is unclear, and none had documented contact with another AIDS patient. Additional cases have been reported in health-care personnel; however, these have either occurred in persons belonging to AIDS risk groups or in persons for whom information is insufficient to determine if they belong to such groups. The case histories for the four patients follow.

Patient 1: A 32-year-old black man living in Baltimore, Maryland, was in good health until January 1983, when he complained of lower abdominal discomfort, relieved by urination, and blood in his stools. Medical evaluation, which included a renal sonogram and an abdominal CAT scan, revealed no cause for his complaints, and his symptoms subsided without treatment. At the same time, he began to lose weight. On May 13, he presented to his private physician with complaints of fever and cough of 2-3 days' duration. His temperature was 37.8 C (100 F). Chest x-ray showed a questionable right upper lobe infiltrate, and he was given oral erythromycin.

On May 21, 1983, the patient went to a Baltimore hospital, where he was found to have bilateral pulmonary infiltrates. He was hospitalized and sulfamethoxazole/trimethoprim was added to his therapy. On May 24, a transbronchial lung biopsy showed *Pneumocystis carinii* pneumonia (PCP); results of immunologic studies were consistent with AIDS. Despite the addition of pentamidine isethionate to his therapy, his condition worsened, and he died on June 2. At autopsy, no evidence of malignancy was found.

The patient had worked for the housekeeping department of a hospital since 1968. Beginning in August 1981, he worked exclusively in the ambulatory surgery area, where his duties included removal of surgical drapes and disposable surgical equipment, which were often contaminated with blood. Reportedly, he usually did not wear gloves.

On February 26, 1982, the patient went to the employee-health nurse for treatment of a needlestick injury. The patient stated that, while disposing of a cardboard box containing used needles, he had been stuck on the hand by a needle protruding from the box. Blood samples were drawn for hepatitis B virus serologic tests, and a single 2-ml dose of immune globulin (IG) was given intramuscularly. (IG therapy has not been reported in other AIDS patients not belonging to known risk groups.) The serologic tests were positive for antibody to hepatitis B surface antigen but negative for the antigen. No other injuries had been recorded on his employee-health record.

When interviewed by his physicians, the patient denied homosexual activity, intravenous (IV) drug use, foreign travel, or transfusion. After the patient's death, interviews by the Baltimore City Health Department of his family and friends confirmed his history. Four of his female sexual partners were interviewed, and all denied IV drug use; none had a history compatible with AIDS. The patient had no history of treatment for venereal diseases, and serologic tests for syphilis (RPR, MHA-TP, FTA-ABS), done during his hospitalization for PCP, were negative.

No patient meeting the CDC surveillance definition of AIDS was reported to have been seen at the hospital where patient 1 worked. In June 1982, 4 months after the needlestick injury and 7 months before patient 1 became ill, a homosexual man with a history of chronic,

AIDS — Continued

unexplained lymphadenopathy underwent a lymph node biopsy in the ambulatory surgery area of the hospital. Although patient 1 was working in this area on the day of the biopsy, the extent of his contact, if any, with the lymphadenopathy patient or materials used in the biopsy procedure is unknown.

Patients 2-4: Less epidemiologic information is available for patients 2-4 than for patient 1. They appear either more likely to have belonged to AIDS risk groups or less likely to have had exposure to blood than patient 1. All had immunologic studies consistent with AIDS.

Patient 2, a 32-year-old American Indian woman, was living in New Jersey when she became ill in 1981. She was found to have PCP, recovered following treatment, but died of cerebral toxoplasmosis in 1982. She had worked in a hospital laundry since 1980. During her employment, a patient with possible AIDS had been admitted to the hospital where she worked, but she had no direct contact with this person. Although she used marijuana, cocaine, and mescaline, she denied IV drug use. She also denied foreign travel, receipt of blood, and sexual contact with men who were bisexual or IV drug users. (This patient has been previously reported elsewhere [2].)

Patient 3, a 34-year-old Jamaica-born man, was living in Miami, Florida, when he became ill in 1982. He was found to have PCP and recovered following treatment. He had come to the United States in 1979 and had worked as a private-duty nurse in Miami since then. He denied contact with AIDS patients; a subsequent review of his work assignments showed that he had not cared for any patients reported to have AIDS. He did not recall ever having a needlestick injury. He also denied homosexual activity, IV drug use, and receipt of blood. One of his female sexual partners was interviewed. She was in good health and denied IV drug use. Another of his female partners could not be located.

Patient 4, a middle-aged man, was living in New York City when he became ill in 1983. He was found to have PCP and recovered following treatment. He worked as a nurse's aide in the outpatient department of a hospital. AIDS patients had been seen at this hospital, but he apparently had not cared for any of them. In the past, he had had needlestick injuries and had received bites from patients, but could recall no such injuries for more than 2 years. Although he admitted to a homosexual encounter as an adolescent, he denied homosexual activity as an adult. He also denied IV drug use and receipt of blood and had no foreign travel since 1976. His serologic tests for syphilis (FTA-ABS) and hepatitis B virus (antibody to hepatitis B core antigen) were positive.

Reported by S Rosen, MD, Baltimore, M Levin, MD, R Berg, MD, D Dutta, MD, S Baker, Sinai Hospital, Baltimore, D Williams, C Campbell, R Dunning, D Glesser, MD, Baltimore City Health Dept, J Horman, DVM, E Israel, MD, State Epidemiologist, Maryland State Dept of Health and Mental Hygiene; U Setia, MD, R Kapila, MD, University of Medicine and Dentistry New Jersey, Newark, W Patkin, DVM, State Epidemiologist, New Jersey State Dept of Health; J Ehrenkrantz, MD, South Florida Hospital Consortium for Infection Control, Miami, R Morgan, MD, Dade County Health Dept, J Sacks, MD, Acting State Epidemiologist, Florida State Dept of Health and Rehabilitative Svcs; S Friedman, MD, New York City Dept of Health, R Rothenberg, MD, State Epidemiologist, New York State Dept of Health; Div of Field Svcs, Epidemiology Program Office, Hospital Infections Program, AIDS Activity, Center for Infectious Diseases, CDC.

Editorial Note: Although the etiology of AIDS remains unknown, epidemiologic evidence suggests that AIDS is caused by an infectious agent transmitted sexually or, less commonly, through exposure to blood or blood products. The disease has not been shown to be transmitted through casual contact with affected individuals.

Continuing surveillance of AIDS confirms earlier observations that 94% of patients come from the high risk groups previously described (3). The source of AIDS in the patients reported here is unknown. They denied belonging to known AIDS risk groups; however, the accuracy of data concerning sexual activity and IV drug use cannot be verified. None gave a history

AIDS – Continued

of caring for an AIDS patient, and none had known contact with blood of an AIDS patient; however, the possibility that these patients had forgotten or unknown exposure to the blood of AIDS patients cannot be entirely excluded.

These four cases provide no new information regarding occupational risk related to health-care personnel. Transmission of AIDS within hospitals has not been reported. Recommendations for prevention of AIDS in health-care personnel have been previously published (4), and these personnel are urged to become familiar with and adhere to these recommendations.

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The *Morbidity and Mortality Weekly Report* is prepared by the Centers for Disease Control, Atlanta, Georgia, and available on a paid subscription basis from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402, (202) 783-3238.

The data in this report are provisional, based on weekly reports to CDC by state health departments. The reporting week concludes at close of business on Friday; compiled data on a national basis are officially released to the public on the succeeding Friday.

The editor welcomes accounts of interesting cases, outbreaks, environmental hazards, or other public health problems of current interest to health officials. Such reports and any other matters pertaining to editorial or other textual considerations should be addressed to: ATTN: Editor, *Morbidity and Mortality Weekly Report*, Centers for Disease Control, Atlanta, Georgia 30333.

☆U.S. Government Printing Office: 1982 740-185/1003 Region IV

UNITED STATES GOVERNMENT PRINTING OFFICE
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Washington, D.C. 20402

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ACDP - AIDS -

APPENDIX B ii

ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) : PRECAUTIONS FOR CLINICAL AND LABORATORY STAFFS

The etiology of the underlying immune deficiencies seen in AIDS cases is unknown. One hypothesis consistent with current observations is that a transmissible agent may be involved. If so, transmission of the agent would appear most commonly to require intimate, direct contact involving mucosal surfaces, such as sexual contact among homosexual males, or through parenteral spread, such as occurs among intravenous drug abusers and possibly hemophilia patients using Factor VIII products. Airborne spread and interpersonal spread through casual contact do not seem likely. These patterns resemble the distribution of disease and modes of spread of hepatitis B virus, and hepatitis B virus infections occur very frequently among AIDS cases.

There is presently no evidence of AIDS transmission to hospital personnel from contact with affected patients or clinical specimens. Because of concern about a possible transmissible agent, however, interim suggestions are appropriate to guide patient-care and laboratory personnel, including those whose work involves experimental animals. At present, it appears prudent for hospital personnel to use the same precautions when caring for patients with AIDS as those used for patients with hepatitis B virus infection, in which blood and body fluids likely to have been contaminated with blood are considered infective. Specifically, patient-care and laboratory personnel should take precautions to avoid direct contact of skin and mucous membranes with blood, blood products, excretions, secretions, and tissues of persons judged likely to have AIDS. The following precautions do not specifically address out-patient care, dental care, surgery, necropsy, or hemodialysis of AIDS patients. In general, procedures appropriate for patients known to be infected with hepatitis B virus are advised, and blood and organs of AIDS patients should not be donated.

The precautions that follow are advised for persons and specimens from persons with: opportunistic infections that are not associated with underlying immunosuppressive disease or therapy; Kaposi's sarcoma (patients under 60 years of age); chronic generalized lymphadenopathy, unexplained weight loss and/or prolonged unexplained fever in persons who belong to groups with apparently increased risks of AIDS (homosexual males, intravenous drug abusers, Haitian entrants, hemophiliacs); and possible AIDS (hospitalized for evaluation). Hospitals and laboratories should adapt the following suggested precautions to their individual circumstances; these recommendations are not meant to restrict hospitals from implementing additional precautions.

A. The following precautions are advised in providing care to AIDS patients:

1. Extraordinary care must be taken to avoid accidental wounds from sharp instruments contaminated with potentially infectious material and to avoid contact of open skin lesions with material from AIDS patients.
2. Gloves should be worn when handling blood specimens, blood-soiled items, body fluids, excretions, and secretions, as well as surfaces, materials, and objects exposed to them.
3. Gowns should be worn when clothing may be soiled with body fluids, blood, secretions or excretions.
4. Hands should be washed after removing gowns and gloves and before leaving the rooms of known or suspected AIDS patients. Hands should also be washed thoroughly and immediately if they become contaminated with blood.
5. Blood and other specimens should be labeled prominently with a special warning, such as "Blood Precautions" or "AIDS Precautions". If the outside of the specimen container is visibly contaminated with blood, it should be cleaned with a disinfectant (such as a 1:10 dilution of 5.25% sodium hypochlorite (household bleach) with water). All blood specimens should be placed in a second container, such as an impervious bag, for transport. The container or bag should be examined carefully for leaks or cracks.
6. Blood spills should be cleaned up promptly with a disinfectant solution, such as sodium hypochlorite (see above).
7. Articles soiled with blood should be placed in an impervious bag prominently labeled "AIDS Precautions" or "Blood Precautions" before being sent for reprocessing or disposal. Alternatively, such contaminated items may be placed in plastic bags of a particular color designated solely for disposal of infectious wastes by the hospital. Disposable items should be incinerated or disposed of in accord with the hospital's policies for disposal of infectious wastes. Reusable items should be reprocessed in accord with hospital policies for hepatitis B virus-contaminated items. Lensed instruments should be sterilized after use on AIDS patients.
8. Needles should not be bent after use, but should be promptly placed in a puncture-resistant container used solely for such disposal. Needles should not be reinserted into their original sheaths before being discarded into the container, since this is a common cause of needle injury.
9. Disposable syringes and needles are preferred. Only needle-locking syringes or one-piece needle-syringe units should be used to aspirate fluids from patients, so that collected fluid can be safely discharged through the needle, if desired. If reusable syringes are employed, they should be decontamined before reprocessing.

10. A private room is indicated for patients who are too ill to use good hygiene, such as those with profuse diarrhea, fecal incontinence, or altered behavior secondary to central nervous system infections.

Precautions appropriate for particular infections that concurrently occur in AIDS patients should be added to the above, if needed.

B The following precautions are advised for persons performing laboratory tests or studies on clinical specimens or other potentially infectious materials (such as inoculated tissue cultures, embryonated eggs, animal tissues, etc) from known or suspected AIDS cases:

1. Mechanical pipetting devices should be used for the manipulation of all liquids in the laboratory. Mouth pipetting should not be allowed.
2. Needles and syringes should be handled as stipulated in Section A (above).
3. Laboratory coats, gowns, or uniforms should be worn while working with potentially infectious materials and should be discarded appropriately before leaving the laboratory.
4. Gloves should be worn to avoid skin contact with blood, specimens containing blood, blood-soiled items, body fluids, excretions, and secretions, as well as surfaces, materials, and objects exposed to them.
5. All procedures and manipulations of potentially infectious material should be performed carefully to minimize the creation of droplets and aerosols.
6. Biological safety cabinets (Class I or II) and other primary containment devices (eg centrifuge safety cups) are advised whenever procedures are conducted that have a high potential for creating aerosols or infectious droplets. These include centrifuging, blending, sonicating, vigorous mixing, and harvesting infected tissues from animals or embryonated eggs. Fluorescent activated cell sorters generate droplets that could potentially result in infectious aerosols. Translucent plastic shielding between the droplet-collecting area and the equipment operator should be used to reduce the presently uncertain magnitude of this risk. Primary containment devices are also used in handling materials that might contain concentrated infectious agents or organisms in greater quantitites than expected in clinical specimens.
7. Laboratory work surfaces should be decontaminated with a disinfectant, such as sodium hypochlorite solution (see A.5 above), following any spill of potentially infectious material and at the completion of work activities.
8. All potentially contaminated materials used in laboratory tests should be decontaminated, preferably by autoclaving, before disposal or reprocessing.
9. All personnel should wash their hands following completion of laboratory activities, removal of protective clothing, and before leaving the laboratory.

C. the following additional precautions are advised for studies involving experimental animals inoculated with tissues or other potentially infectious materials from individuals with known or suspected AIDS.

1. Laboratory coats, gowns, or uniforms should be worn by personnel entering rooms housing inoculated animals. Certain nonhuman primates, such as chimpanzees, are prone to throw excreta and to spit at attendants; personnel attending inoculated animals should wear molded surgical masks and goggles or other equipment sufficient to prevent potentially infective droplets from reaching the mucosal surfaces of their mouths, nares, and eyes. In addition, when handled, other animals may disturb excreta in their bedding. Therefore, the above precautions should be taken when handling them.
2. Personnel should wear gloves for all activities involving direct contact with experimental animals and their bedding and cages. such manipulations should be performed carefully to minimize the creation of aerosols and droplets.
3. Necropsy of experimental animals should be conducted by personnel wearing gowns and gloves. If procedures generating aerosols are performed, masks and goggles should be worn.
4. Extraordinary care must be taken to avoid accidental sticks or cuts with sharp instruments contaminated with body fluids or tissues of experimental animals inoculated with material from AIDS patients.
5. Animal cages should be decontaminated, preferably by autoclaving, before they are cleaned and washed.
6. Only needle-locking syringes or one-piece needle-syringe units should be used to inject potentially infectious fluids into experimental animals.

The above precautions are intended to apply to both clincial and research laboratories. Biological safety cabinets and other safety equipment may not be generally available in clinical laboratories. Assistance should be sought from a microbiology laboratory, as needed, to assure containment facilities are adequate to permit laboratory tests to be conducted safely.

Reported by Hospital Infections Program, Div of Viral Diseases, Div of Host Factors, Div of Hepatitis and Viral Enteritis, AIDS Activity, Center for Infectious Diseases, Office of Biosafety, CDC; Div of Safety, National Institutes of Health.

PREVENTION OF ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) : REPORT OF INTER-AGENCY RECOMMENDATIONS

Since June 1981, over 1,200 cases of acquired immune deficiency syndrome (AIDS) have been reported to CDC from 34 states, the District of Columbia, and 15 countries. Reported cases of AIDS include persons with Kaposi's sarcoma who are under age 60 years and/or persons with life-threatening opportunistic infections with no known underlying cause for immune deficiency. Over 450 persons have died from AIDS, and the case-fatality rate exceeds 60% for cases first diagnosed over 1 year previously(1,2). Reports have gradually increased in number. An average of one case per day was reported during 1981, compared with three to four daily in late 1982 and early 1983. Current epidemiologic evidence identifies several groups in the United States at increased risk for developing AIDS(3-7). Most cases have been reported among homosexual men with multiple sexual partners, abusers of intravenous (IV) drugs, and Haitians, especially those who have entered the country within the past few years. However, each group contains many persons who probably have little risk of acquiring AIDS. Recently, 11 cases of unexplained, life-threatening opportunistic infections and cellular immune deficiency have been diagnosed in patients with hemophilia. Available data suggest that the severe disorder of immune regulation underlying AIDS is caused by a transmissible agent.

A national case-control study and an investigation of a cluster of cases among homosexual men in California indicate that AIDS may be sexually transmitted among homosexual or bisexual men(8,9). AIDS cases were recently reported among women who were steady sexual partners of men with AIDS or of men in high-risk groups, suggesting the possibility of heterosexual transmission(10). Recent reports of unexplained cellular immunodeficiencies and opportunistic infections in infants born to mothers from groups at high risk for AIDS have raised concerns about in utero or perinatal transmission of AIDS (11). Very little is known about risk factors for Haitians with AIDS.

The distribution of AIDS cases parallels that of hepatitis B virus infection, which is transmitted sexually and parenterally. Blood products or blood appear responsible for AIDS among hemophilia patients who require clotting factor replacement. The likelihood of blood transmission is supported by the occurrence of AIDS among IV drug abusers. Many drug abusers share contaminated needles, exposing themselves to blood-borne agents, such as hepatitis B virus. Recently, an infant developed severe immune deficiency and an opportunistic infection several months after receiving a transfusion of platelets derived from the blood of a man subsequently found to have AIDS (12). The possibility of acquiring AIDS through blood components or blood is further suggested by several cases in persons with no known risk factors who have received blood products or blood within 3 years of AIDS diagnosis (2). These cases are currently under investigation.

No AIDS cases have been documented among health care or laboratory personnel caring for AIDS patients or processing laboratory specimens. To date, no person-to-person transmission has been identified other than through intimate contact or blood transfusion.

Several factors indicate that individuals at risk for transmitting AIDS may be difficult to identify. A New York City study showed that a significant proportion of homosexual men who were asymptomatic or who had nonspecific symptoms or signs (such as generalized lymphadenopathy) had altered immune functions demonstrated by in vitro tests (2, 13, 14). Similar findings have been reported among patients with hemophilia (2, 15, 16). Although the significace of these immunologic alterations is not yet clear, their occurrence in at least two groups at high risk for AIDS suggests that the pool of persons potentially capable of transmitting an AIDS agent may be considerably larger than the presently known number of AIDS cases. Futhermore, the California cluster investigation and other epidamiologic findings suggest a "latent period" of several months to 2 years between exposure and recognizable clinical illness and imply that transmissibility may precede recognisable illness. Thus, careful histories and physical examinations alone will not identify all persons capable of transmitting AIDS but should be useful in identifying persons with definite AIDS diagnoses or related symptoms, such as generalized lymphadenopathy, unexplained weight loss, and thrush. Since only a small percentage of members of high-risk groups actually has AIDS, a laboratory test is clearly needed to identify those with AIDS or those at highest risk of acquiring AIDS. For the above reasons, persons who may be considered at increased risk of AIDS include those with symptoms and signs suggestive of AIDS; sexual partners of AIDS patients; sexually active homosexual or bisexual men with multiple partners; Haitian entrants to the United States; present or past abusers of IV drugs; patients with hemophilia; and sexual partners of individuals at increased risk for AIDS.

Statements on prevention and control of AIDS have been issued by the National Gay Task Force, the National Hemophilia Foundation, The American Red Cross, The American Association of Blood Banks, the Council of Community Blood Centers, the American Association of Physicians for Human Rights, and others. These groups agree that steps should be implemented to reduce the potential risk of transmitting AIDS through blood products, but differ in the methods proposed to accomplish this goal. Public health agencies, community organizations, and medical organizations and groups share the responsibility to rapidly disseminate information on AIDS and recommended precautions.

Although the cause of AIDS remains unknown, the Public Health Service recommends the following actions:

1. Sexual contact should be avoided with persons known or suspected to have AIDS. Members of high risk groups should be aware that multiple sexual partners increase the probability of developing AIDS.

2. As a temporary measure, members of groups at increased risk for AIDS should refrain from donating plasma and/or blood. This recommendation includes all individuals belonging to such groups, even though many individuals are at little risk of AIDS. Centers collecting plasma and/or blood should inform potential donors of this recommendation. The Food and Drug Administration (FDA) is preparing new recommendations for manufacturers of plasma derivatives and for establishments collecting plasma or blood. This is an interim measure to protect recipients of blood products and blood until specific laboratory tests are available.

3. Studies should be conducted to evaluate screening procedures for their effectiveness in identifying and excluding plasma and blood with a high probability of transmitting AIDS. These procedures should include specific laboratory tests as well as careful histories and physical examinations.

4. Physicians should adhere strictly to medical indications for transfusions, and autologous blood transfusions are encouraged.

5. Work should continue toward development of safer blood products for use by hemophilia patients.

The National Hemophilia Foundation has made specific recommendations for management of patients with hemophilia (17).

The interim recommendation requesting that high-risk persons refrain from donating plasma and/or blood is especially important for donors whose plasma is recovered from plasmapheresis centers or other sources and pooled to make products that are not inactivated and may transmit infections, such as hepatitis B. The clear intent of this recommendation is to eliminate plasma and blood potentially containing the putative AIDS agent from the supply. Since no specific test is known to detect AIDS at an early stage in a potential donor, the recommendation to discourage donation must encompass all members of groups at increased risk for AIDS, even though it includes many individuals who may be at little risk of transmitting AIDS.

As long as the cause remans unknown, the ability to understand the natural history of AIDS and to undertake preventive measures is somewhat compromised. However, the above recommendations are prudent measures that should reduce the risk of acquiring and transmitting AIDS.

Reported by the Centers for Disease Control, the Food and Drug Administration, and the National Instutes of Health.

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SURVEILLANCE OF AIDS IN THE UK

For their purposes, the Communicable Disease Surveillance Centre at Colindale has adopted, from the Centers for Disease Control, the following definition as the criterion for acceptance of a genuine case of AIDS:

> ".... for the limited purposes of epidemiological suveillance a case of acquired immune deficiency syndrome is defined as one in which a person has a reliably diagnosed disease that is at least moderately indicative of an underlying cellular immune deficiency (such as an opportunistic infection, or Kaposi's sarcoma in a person aged less than 60 years) but who, at the same time, has had no known underlying cause of cellular immune deficiency nor any other cause of reduced resistance reported to be associated with that disease."

The so-called "extended lymphadenopathy syndrome", characterised by unexplained lymphadenopathy in two or more extrainguinal sites for more than 3 months with fever, malaise, night sweats, weight loss and hepatosplenomegaly, is not included in the definition because of the current doubts about its implications.

By 31 July 1983, 14 cases of the acquired immune deficiency syndrome had been reported to the Communicable Disease Surveillance Centre. All the patients were white men. There were 6 cases of Kaposi's sarcoma without pneumocystis, 5 cases of pneumocystis pneumonia without Kaposi's sarcoma, and 3 cases of other opportunistic infections. The other infections reported were toxoplasmosis and cytomegalovirus in two patients and the third had oesophageal candidiasis.

Patients ranged in age from 20-45 with a median of 39. The youngest patient had haemophilia A. There were 5 deaths, two from Kaposi's sarcoma and three from pneumocystis pneumonia, all in homosexual patients aged between 35 and 45.

Of the 14 patients 12 were homosexual, one was also a drug abuser; 10 were reported from London, one from Bristol and one from Oxford. The haemophilic patient was from Wales, and had received Factor VIII imported from the United States; a patient from Lancashire did not come within the known risk groups.

Seven patients are thought to have had sexual contact with Americans. Two of the homosexual men reported had had sexual contact with each other. No cases were reported in laboratory staff or others working in other areas of health care.

[from Surveillance of the Acquired Immune Deficiency Syndrome in the United Kingdom January 1982 - July 1983 CDSC BMJ Vol.287 Aug 6th 1983 pp407-8]

ACQUIRED IMMUNE DEFICIENCY SYNDROME: CASE SUMMARY (ENGLAND AND WALES)

Case No.	Where reported	Date reported	Date confirmed	Nationality/ Ethnic group	Sex	Age (yrs)	Diagnosis	Date onset	Date diagnosis	Date death	Sex orientn	Travel (5 years)/ USA contacts	Blood or blood products	Drug abuse
1.	Oxford	1.2.83	28.2.83	British	M	40	CMV; neuro-toxo; KS			GRO-A 83	Homo-sexual	USA contacts	N/K	N/K
2.	London	1.3.83	10.3.83	S African	M	39	KS	1982	1982	GRO-A 83	N/K	N/K	Nil	N/K
3.	London	Dec 1982	Dec 1982	British	M	22	CMV, AIDS	Jan 83	Jan 83	alive	Homo-sexual	USA contacts	N/K	N/K
4.	Bristol	Feb 1982	Feb 1982	British	M	25	CMV; toxo; AIDS	Dec 82	Dec 82	alive	Homo-sexual	Poss. USA contacts	Nil	Amyl nitrite
5.	London	Dec 1982	May 1982	British (Italian origin?)	M	41	KS; AIDS	Jul 82	Jul 82	?	Homo-sexual/ Bisexual	N/K	Nil	N/K
6.	London	1982	Feb 1983	British	M	41	KS; AIDS	Jan 83	Jan 83	alive	Homo-sexual	USA contacts Greece & USA 1982	Nil	N/K
7.	London	Mar 1983	Mar 1983	British	M	43	ITP; PCP, CMV	Autumn 1981	Dec 81	GRO-A 82	Homo-sexual	Close USA contact	Nil	N/K
8.	Cardiff	May 1983	May 1983	British	M	20	Candida; AIDS epididymo-orchitis	Dec 1982	May 1983	alive	Hetero-sexual	Nil	Haemophiliac USA FVIII 1981 NBS FVIII since 1981	Nil
9.	London	May 1983	May 1983	British	M	36	PCP; toxo	Apr 82	Apr 82	GRO-A 82	Homo-sexual	Poss. USA contact	Nil	IV drugs
10.	London	May 1983	May 1983	British	M	45	PCP, CMV; pro-gressive multifocal leucoencepha-lopathy	early 1982	early 1982	GRO-A 82	Homo-sexual	USA contacts Florida 1981	Nil	N/K
11.	London	May 1983	May 1983	British	M	36	KS	Feb 83	Mar 83	alive	Homo-sexual	Nil	Nil	Recreational drugs
12.	London	May 1983	May 1983	Canadian (returned to Canada)	M	28	Candida; PCP	Dec 82	Dec 82	alive	Homo-sexual	USA contacts + contact with case No.4. Travelled to Los Angeles, Florida 1981	Nil	IV drugs plus recreational drugs

Sl.No.	Where Reported	Date Reported	Date Confirmed	Nationality Ethic Group	Sex	Age Year	Diagnosis	Date of onset	Date diagnosis	Date of death	Sex orien-tation	Travel (5 yrs) USA con-tacts	Blood or blood products	Drugs abuse
13	Preston (Lancs)	20.6.83	23.6.83	English	M	43	PCP/ Oeso-phageal Candida/ H Zoster encepha-litis	Jan '83	Feb '83	Alive	Hetero sexual	None	Blood transfusion during abdominal surgery 1979. Transfusion records being checked.	-
14	London	1.7.83	4.7.83	German	M	32	KS/ Oeso-phageal Candidiasis	May '83	June '83	Alive	Homo-sexual	Under investi-gation	None	None

AIDS CASE SUMMARY (ENGLAND AND WALES)

KEY TO THE TABLE ATTACHED

KS	=	Kaposi Sarcoma
CMV	=	Cytomegalovirus
Neurotoxo	=	Neurotoxoplasmosis
Toxo	=	Toxoplasmosis
ITP	=	Idiopathic Thrombocytopenic propura
PCP	=	pneumocystis pneumoniae

APPENDIX D

HEPATITIS SURVEILLANCE

Safety of Hepatitis B Virus Vaccine

UNITED STATES OF AMERICA. — Since its licensure in 1981 and its general availability in July 1982, hepatitis B virus vaccine has been administered to over 200 000 individuals, mostly health care workers. In a collaborative effort, the Centers for Disease Control, the Food and Drug Administration, and the firm producing the vaccine have collected information on illnesses that developed after receipt of HBV vaccine. Serious illnesses have been followed up by telephone or personal interviews. Some illnesses, especially minor ones, have probably not been reported, and many reported illnesses have not been causally related to the vaccine.

As of 1 March 1983, illness had been reported in 118 vaccinees (most illnesses began within 4 weeks of the first vaccine dose). Of the 118 cases, 56 (47.5%) were considered not likely to be attributable to vaccine use because: (1) another specific cause was identified, (2) onset of illness occurred before receipt of vaccine, or (3) the reported event was unrelated to the vaccine (e.g., deltoid pain after gluteal injection). Many of the remaining 62 illnesses may represent "background" disease rather than adverse reactions to the vaccine.

Of these 62 persons, 57 (91.9%) had mild or moderate illness that included: 6 neurological conditions (5 persons with tremors and 1 with recurrent Bell's palsy); 11 skin or mucous membrane lesions (hives, herpes zoster, psoriasis, and nonspecific lesions); 10 musculoskeletal ailments (including generalized aches, joint pain, and joint inflammation); 5 hepatitis-like illnesses (with increased liver enzyme levels and no other identified cause); and 25 miscellaneous complaints (14 persons with an influenza-like syndrome, 4 with injection-site reactions, 4 with diarrhoea, 1 with headache, 1 with vomiting, and 1 with self-limited chest pain with a normal cardiac evaluation).

Six persons had serious illness; illness was defined as serious when it caused hospitalization or other intensive medical care, lasted 14 days or more, caused permanent disability, or was life-threatening. Five of these serious illnesses included 1 case each of erythema multiforme, aseptic meningitis, grand mal seizure, possible transverse myelitis, and Guillain-Barré syndrome (GBS). A second case of GBS was also reported in a person with antecedent febrile illness, presumptively caused by cytomegalovirus; febrile illness began 11 days after receipt of HBV vaccine, and GBS began 10 days after onset of febrile illness. This case was thus counted among the 56 illnesses not likely to be attributable to the vaccine. The numbers of vaccinees and GBS cases are too few on which to base firm conclusions; nevertheless, 2 cases of GBS do not exceed the number expected by chance alone within 6 weeks of vaccinating 200 000 people (23 GBS cases per million adults per year).

Whether acquired immune deficiency syndrome (AIDS) could be associated with HBV vaccine has been questioned, since the vaccine is made from human plasma. Since 1979, homosexual men, including those from cities with reported AIDS cases, have been the source for much of this plasma. Vaccine produced from these sources has been used in various investigative studies since 1980 and has been commercially available since 1982. To date, no AIDS in vaccine recipients has been reported outside groups with high AIDS incidence. Specifically, no cases have occurred among the several thousand individuals, other than male homosexuals, who participated in vaccine studies from 1980 to date. In addition, no cases have been reported from the over 200 000 individuals who have received HBV vaccine since its general availability in July 1982. (The latent period for AIDS, if an infectious agent is involved, appears to be between 8 and 18 months.) Two homosexual men who participated in the original HBV vaccine field trials have developed AIDS. This occurrence is not significantly different from that observed among men who were screened for participation in these trials but who were ultimately not vaccinated. Furthermore, the manufacturing process for HBV vaccine includes several procedures that inactivate representative viruses of all known types. Thus, microbiological and empirical data currently available provide no support for the suggestion that HBV vaccine might carry an etiological risk for AIDS.

AIDS AND HOW IT CONCERNS BLOOD DONORS - NBTS

Recently there has been considerable publicity in the newspapers and on radio and television about a new, serious, but rare disease called AIDS.

Since AIDS may be transmitted by transfusion of blood and blood products, the National Blood Transfusion Service wants blood donors to have the facts about the disease.

WHAT IS AIDS?

AIDS is short for Acquired Immune Deficiency Syndrome. As its name implies, AIDS destroys the body's immune system which normally protects against infections and other illnesses. A person with the disease is there at risk of developing serious infections such as pneumonia, or even cancer. AIDS is probably caused by a virus, but this is not known for certain.

WHO IS AT RISK FROM AIDS?

Most of the information about AIDS has come from the USA where approximately 1,500 patients have been found to be suffering from the disease up to the middle of 1983. Certain groups of people appear to be particularly susceptible; these are:

1. Homosexual men who have many different partners.

2. Drug addicts, male and female, using injections.

3. Sexual contacts of people suffering from AIDS.

It has also been found in a number of immigrants to the USA from the island of Haiti.

Patients with AIDS also seem more likely to have suffered, at some time, from various other diseases such as hepatitis B, syphilis or other sexually transmitted diseases.

HAS AIDS OCCURRED IN THE UNITED KINGDOM?

Yes, about a dozen cases have been reported, by the middle of 1983. No-one knows whether more people in the United Kingdom will develop AIDS and a careful watch is being kept for possible cases.

CAN AIDS BE TRANSMITTED BY TRANSFUSION OF BLOOD AND BLOOD PRODUCTS?

Almost certainly yes, but there is only the most remote chance of this happening with ordinary blood transfusions given in hospital. However, in the USA a very small number of patients suffering from haemophilia, an illness in which the blood will not clot, have developed AIDS. Haemophiliacs are more susceptible to AIDS because they need regular injections of a product called Factor VIII. This is made from plasma obtained from many donors. Should just one of the donors be suffering from AIDS, then the Factor VIII could transmit the disease.

HOW CAN THE RISKS BE REDUCED?

At present, there is no screening test the Transfusion Service can use to detect people with AIDS. So, until there is and until more is known about this disease, donors are asked not to give blood if they think they may either have the disease or be at risk from it.

WILL DONORS BE QUESTIONED ON SEXUAL MATTERS WHEN THEY ATTEND TO GIVE BLOOD?

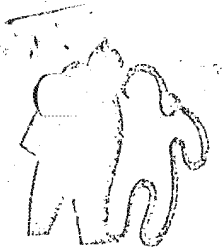
DEFINITELY NOT.

The National Blood Transfusion Service has a very high regard for donors as extremely responsible people who give blood for the benefit of others and is confident that they would not knowingly put patients at risk from such a serious disease.

WHERE CAN DONORS OBTAIN FURTHER INFORMATION ON AIDS?

Any donor can discuss in confidence whether to give blood, with the doctor on the blood collection session, their own doctor or the Director of their local Blood Transfusion Centre.

Please remember, AIDS is a rare disease but a serious one.



THE
HAEMOPHILIA
SOCIETY

P.O. Box 9
16 Trinity Street
London SE1 1DE
Telephone: 01-407 1010

APPENDIX F

In view of the unduly alarmist reports on AIDS which appeared in the press over the weekend, we are writing to reassure members of the Society about the true position. We have been in touch with PROFESSOR ARTHUR BLOOM, Chairman of the Haemophilia Centre Directors, senior member of our own Medical Advisory Panel and a member of the Central Blood Laboratories Authority, who has kindly written to us all as follows:-

Reports from America of the acquired immune deficiency syndrome (AIDS) in persons with haemophilia are causing anxiety to members of this Society and to their relatives. Haemophiliacs, their parents and doctors have always balanced the quality of life and the dangers from bleeding against the risks of treatment. We are no strangers to infective diseases, such as hepatitis, which can be transmitted by factor concentrates. Recent evidence indicates that in this respect at any rate concentrates prepared from British blood are not necessarily safer than those prepared in the United States. Even so we welcome the fact that the government is investing over twenty million pounds in the Blood Products Laboratory (i.e. factory) at Elstree so that this country shall become self-sufficient in blood products. Bearing this in mind it is important to consider the facts concerning AIDS and haemophilia. The cause of AIDS is quite unknown and it has not been proven to result from transmission of a specific infective agent in blood products. The number of cases reported in American haemophiliacs is small and in spite of inaccurate statements in the press we are unaware of any proven case in our own haemophilic population. Neither have any cases been reported from Germany where massive amounts of American concentrates have been used for many years. Nevertheless the situation is being closely monitored by the Haemophilia Centre Directors and in a more general way by the Communicable Disease Surveillance Centre in London. In addition the importation of licensed blood products has always been strictly monitored and controlled. Thus whilst it would be wrong to be complacent it would equally be counter-productive to alter our treatment programmes radically. We should avoid precipitate action and give those experts who are responsible a chance continually to assess the situation.

We are most grateful to Professor Bloom for this statement. If you have any further questions about AIDS and your own treatment programme then, of course, your Centre Director will be able to help you.

The Revd. Alan J. Tanner, MA
Chairman

4 May 1983