APPENDIX VI

Documents in the Personal Possession of Dr Peter R Foster

I have a number of documents concerning AIDS and blood products relating to correspondence with the trades union, The Association of Scientific Technical and Managerial Staffs (ASTMS), now incorporated into the trades union UNITE.

Date	Type	Author	Recipient	Subject
09/06/83	letter	P Foster	G Craig (ASTMS)	AIDS and blood products
28/07/83	letter	S McKechnie(ASTMS)	P Foster	Re. letter of 09/06/83 to G Craig and questions on health and safety concerning AIDS
05/08/83	letter	P Foster	S Mckechnie(ASTMS)	Reply to letter of 28/07/83 with information on blood products from the USA
26/08/83	letter	Glenarthur (DHSS)	C Jenkins (ASTMS)	AIDS and blood products
19/09/83	letter	S McKechnie(ASTMS)	P Foster	Invitation to comment on a letter from The Lord Glenarthur (DHSS) to C Jenkins (Gen Secretary, ASTMS) on AIDS and blood products from the USA.
20/09/83	Memo + papers	P Harper (ASTMS)	P Foster	Invitation to comment on the agenda papers for a meeting of the Advisory Committee on Dangerous Pathogens (ACDP) on AIDS.
29/09/83	letter	P Foster	S McKechnie(ASTMS)	Comments on the letter of August 1983 from The Lord Glenarthur to C Jenkins.
12/10/83	letter	P Foster	P Harper (ASTMS)	Comments on the ACDP agenda papers on AIDS
27/10/83	letter	C Jenkins (ASTMS)	Glenarthur (DHSS)	AIDS and blood products, reply
03/11/83	letter	S McKechnie(ASTMS)	P Foster	C Jenkins reply to The Lord Glenarthur; ACDP meeting
21/11/83	letter	P Foster	S McKechnie(ASTMS)	AIDS and ACDP
30/11/83	letter	S McKechnie(ASTMS)	P Foster	AIDS and ACDP
15/12/83	letter	S McKechnie(ASTMS)	P Foster	ASTMS AIDS Working Group
05/01/84	letter	P Foster	S McKechnie(ASTMS)	AIDS and ACDP
18/01/84	letter	Glenarthur (DHSS)	C Jenkins (ASTMS)	AIDS and blood products; reply to letter of 27/10/83 from C Jenkins.
18/01/84	letter	S McKechnie(ASTMS)	P Foster	AIDS and blood products: invitation to comment on The Lord Glenarthur's reply to letter of 27/10/83 from C Jenkins
23/01/84	letter	P Foster	S McKechnie(ASTMS)	Comments on reply from The Lord Glenarthur to C Jenkins letter of 27/10/83
14/02/84	letter	C Jenkins (ASTMS)	Glenarthur (DHSS)	AIDS and blood products: reply
02/03/84	letter	S McKechnie(ASTMS)	P Foster	AIDS , ACDP guidance
02/04/84	letter	Glenarthur (DHSS)	C Jenkins (ASTMS)	AIDS and blood products; reply to letter of 14/02/84 fro C Jenkins
17/04/84	letter	S McKechnie(ASTMS)	P Foster	AIDS and blood products; reply from The Lord Glenarthur of 02/04/84
14/05/84	letter	J MacKay (Scottish Office)	C Jenkins (ASTMS)	AIDS and blood products; the function of the Protein Fractionation Centre
10/07/84	letter	S McKechnie(ASTMS)	P Foster	AIDS and blood products; letter from J MacKay to C Jenkins dated 14/05/84

CONFIDENTIAL

[redacted]

9th June, 1983

Mr. G. Craig
ASTMS
[redacted]

Dear Gordon,

BLOOD PRODUCTS AND AIDS

At our last branch meeting the correspondence included minutes of a meeting of the Parliamentary Committee held on 4th May (copy attached) at which the above topic was discussed. I am not sure of the mechanism for commenting on such discussions, however as the issue does effect our Scottish members I feel that it might be helpful to provide some comments on the Scottish situation, particularly as a briefing is being prepared for the committee.

1. There is still very little known about AIDS, but there does seem to be increasing evidence that an infectious agent is involved and that this can be transmitted by blood and at least some blood products.

2. In this situation the use of blood or blood products from the USA and/or from paid donors probably represents a higher risk than from non-USA unpaid donors. However it should be recognised that the risk from UK unpaid donors may still represent a problem.

   This balance of risks is likely to continue until non-infective products can be guaranteed either by donor screening or by treatment of the products to render them non-infective.

3. It is now common knowledge that over half of the blood products used in the UK are imported and that this costs about £10 million per year. It seems to be less well appreciated that the importation is required for England and Wales and not for the UK as a whole. In fact Scotland is now virtually self-sufficient in blood and blood products and there is little or no requirement for importation.

4. While I fully support the need for a new and enlarged NHS facility at BPL, Elstree, I am very concerned that the equivalent NHS facility in Scotland (PFC, Edinburgh) remains seriously underused, despite the above situation South of the border.

   I would estimate that the capacity of the Scottish Centre could be increased 3-fold almost immediately (with the introduction of shift-working) and about 10-fold with provision of extra warehousing, cold storage and services.

I/

I understand that the DHSS Advisory Committee on BPL decided, about a year ago not to utilise the Scottish Centre at all and that at least one eminent member of the committee (Dr. P. Dunnill, University College London) resigned in protest at that decision.

The Scottish Centre has been operational since 1976 and I would estimate that the policy of neglecting this facility has probably already cost the NHS about £50 million, as well as resulting in the importation of disease (hepatitis, AIDS).

5. It may also be of interest to note that one approach to the problem of infectious products is to treat them (as part of the manufacturing process) to render them non-infective. At PFC we are well advanced in developing methods to achieve this and we are sharing this information with our colleagues at BPL Elstree. Hence, if the UK NHS Centres are given full and proper support, then both self-sufficiency and freedom from the risk of disease transmission could be achieved. This would represent an achievement which other countries could follow and might ultimately lead to the demise of the commercial blood industry internationally.

Yours sincerely,

PETER R. FOSTER

P.S. Our research on item (5) above is not yet public, but I will be presenting much of this information at an International Congress on 5th July.

asms

HEALTH AND SAFETY OFFICE

Whitehall Office, Dane O'Coys Road, Bishops Stortford, Herts. Tel: 0279-58111

SMcK/DPP.

28th July, 1983.

Mr. P.R. Foster,
[redacted]

Dear Peter,

Gordon Craig has sent me copies of your letters on AIDS. I represent the TUC on the Advisory Committee on Dangerous Pathogens and it is likely that the matter will be discussed by them at the December meeting. The information on the Scottish PFC will be very useful and I think that ACDP could be persuaded to recommend to the DHSS a policy of 'self-sufficiency' in blood products.

At the present time I am particularly concerned about the hazards to hospital staff and others who may have contacts with AIDS patients and specimens. At the moment we have circulated the CDC advice (attached) which essentially says treat any specimens etc. with the same care as hepatitis B. However, this has been based on the evidence that health care workers have not contacted the disease. I have now been told that there are 4 cases of AIDS affecting health care workers in the USA. None of these to my knowledge is a laboratory workers. If you have any information on this I would like to have it.

A further problem has arisen concerning the hepatitis B vaccine. Do you have any views on the safety of this vaccine? Would it be possible to ensure that a vaccine made from the blood of an AIDS patient was absolutely safe? How would you check that the AIDS agent (?) was ineffective if you don't know what the agent is? Could the manufacturing process be guaranteed to render them non-infective?

I would be very grateful if you could help on these points and suggest anyone else I should be in touch with. I will certainly keep you informed of any developments in ACDP in respect of AIDS.

Yours sincerely,

Sheila McKechnie,
Health and Safety Officer

Enc: CDC Advice.

cc: Gordon Craig - DO.

[redacted]

5th August, 1983

Sheila McKechnie
Health & Safety Office
ASTMS Whitehall Office
Dane O'Coys Road
Bishops Stortford
Herts

Dear Sheila,

Thank you for your letter of 28th July concerning AIDS and the ACDP. I'm not sure how much you know of the blood products situation and of the Scottish PFC. I have therefore enclosed an article on PFC (written by Gordon Craig for Medical World) and recommend the book "Blood : Gift or Merchandise" by P.J. Hagen (Publ. Alan Liss Inc) if you want some background information on the international blood industry.

In considering AIDS and blood products the ACDP should be aware that potentially contaminated materials (ie related to USA blood donors) may enter the U.K. in a number of forms:

1) As finished products (eg Factor VIII) from the USA (eg Armour).

2) As finished products manufactured in Europe but prepared from blood plasma collected in the USA (eg Immuno).

3) As unfinished materials (eg plasma, cryoprecipitate) imported for the manufacture of products in the UK on a commercial basis (eg Speywood).

Before I comment on the points in your letter I should perhaps make it clear that I do not consider myself an "expert" in virology or even in microbiology. I am a biochemical engineer with formal qualifications (BSc, MSc, PhD, C.Eng. FIChem.E) mainly in chemical engineering however, as head of the PFC R&D Department, much of my time is spent in interpreting and acting on information from specialists in a wide range of disciplines. I have therefore appended the names of some genuine "experts" who may be able to help you further.

My views on the questions posed in your letter are as follows:-

1. HAZARDS TO HOSPITAL STAFF

It is my understanding that the CDC view that the AIDS risk is similar to that of hepatitis B is based on the early observation that AIDS was being found in certain "high risk" groups and that the only common factor between these groups was that they were also known to be high risk groups for hepatitis B infection. Because of this, CDC decided to "put a flag out on haemophiliacs", another known HB high risk group. Aids was duly found amongst haemophiliacs and it is conceivable that if CDC had not done this, that the risk to haemophiliacs may not have been noticed so soon (ie still only 16 cases out of 1831).

Following/

Following the same logic CDC have now "put a flag out" on health care workers. As you note, 4 cases have now been reported (MMWR 15/7/83, enclosed) but I suspect that with an incubation period of up to two years then it is probably far too early to draw any conclusions.

Meanwhile the equivalence with HB appears fairly strong, however there could be variations in the modes of transmission (we are still dealing largely with conjecture) hence HB-type precautions should perhaps be seen as a minimum requirement until further information is available. This would seem to be relatively straightforward for confirmed AIDS cases. The really big problem is what to do with say specimens from high risk groups. The very long incubation period now being proposed suggests that AIDS victims may be infectious for at least 1 year with no symptoms and for another 1 to 2 years with non-specific symptoms. In the first period the AIDS victim could well be using health care facilities for non-AIDS purposes (eg dentist) while in the second period the victim will certainly present to their GP and may undergo intensive investigation before AIDS is even suspected.

One option would be to apply HB-type precautions to all high risk groups, clearly a very difficult and massive undertaking.

For the U.K., the critical question is how prevalent is AIDS here (or will it become)? If it can be restricted to a small number of cases then it may be only a relatively minor problem. It is possible that the USA publicity, together with different lifestyles in Europe, may have checked the spread of the disease in the U.K. However, it is equally possible that the incubation period is such that the disease is already with us. We should know the answer in the next 6-18 months.

2. SAFETY OF HB VACCINE

Until we know more about AIDS then the view that the methods used to inactivate HBV will also inactivate the AIDS "agent" is to some extent conjecture. The virologists I have spoken to do seem to believe that the various inactivation methods are so severe that all possible infectious agents will be destroyed.

However, it is necessary to be aware that different manufacturers (eg French, Dutch) are all using different methods for viral inactivation (eg BMJ 286, 1305-8, 1983) and the requirement that each lot of the USA product be tested in chimpanzees (MMWR Oct, 1982) suggests that confidence in the manufacturing process is not particularly high. There would seem to be other questions, concerning the validity of chimp testing (and also the possibility that the chimp may now be an endangered species). The report of various side effects associated with the USA vaccine (MMWR 18/3/83, enclosed), particularly "five hepatitis-like illnesses", may also be relevant.

The blood and blood product situation may provide useful information on the sensitivity of the AIDS "agent". Albumin, immunoglobulin and factor IX are all prepared from the same plasma used to manufacture factor VIII. The factor IX situation is uncertain (see my letter to Gordon), immunoglobulin is traditionally considered non-infective (reasons not fully understood) but albumin has to be pasteurised (ie heating at 60°C for 10 hrs) to prevent hepatitis infection. There have been no AIDS cases associated with albumin infusion and if this continues to be the case then it would suggest that the AIDS "agent" is inactivated by this procedure. Alternatively if AIDS does become associated/

associated with Albumin infusions then it would be clearly more resistant to heat than hepatitis B.

I suspect that the best course of action for the ACDP might be to wait a little longer for some better information on the nature of AIDS to emerge. Activity on this in the USA is now so intense that we could conceivably have a much clearer picture of the disease in 6-12 months time.

Best wishes.

GRO-C

PETER R. FOSTER

c.c. Gordon Craig

AIDS EXPERTS

The expertise on AIDS is really all in the USA. The rest of the world is probably 2 years behind and has substantially less resources commited to research in this area.

As you know the USA situation is being monitored by CDC and their MMWR are going to be invaluable over the next few months. For more detailed information from CDC the best person to contact is:-

Dr. Bruce Evatt
Centre for Disease Control
Atlanta

Aids is still located in key urban areas and I believe that each area has its own local committee. I do not know the route for formal contact but one member of the New York Committee is:-

Professor Alan Johnson
Department of Medicine
New York University Medical Center
550 First Avenue
New York 10016
(Telephone [redacted]

For detailed information on blood products you should contact:-

Dr. David Aronson
Director, Coagulation Branch
Division of Blood and Blood Products
Bureau of Biologics
Food and Drug Administration
Bethesda
Maryland 20205
(Telephone [redacted])

For the U.K. I understand that DHSS advisors include:-

Dr. Philip Mortimer
PHLS, Colindale

Dr. John Craske
PHLS, Withington Hospital, Manchester

ps. I understood that are now have a local expert who has just come from the USA to work in Edinburgh
is. Dr Ray Brettle
Senior Registrar
infectious diseases unit
City Hospital, Greenbank Drive, Edinburgh.

COMMERCIAL SALE OF FACTOR VIII IN U.K.

1981/1982

ABBOTT	1.9
ARMOUR	14.6
CUTTER	3.8
HYLAND	3.5
IMMUNO	7.3
SPEYWOOD (CUTTER)	1.5
	32.6 million I.U.

note: A 3-fold increase of PFC (see my letter of 9/6/83) could produce an extra 20 million iu FVIII.

DEPARTMENT OF HEALTH AND SOCIAL SECURITY

Alexander Fleming House, Elephant & Castle, London SE1 6BY

Telephone 01-[redacted]

From the Joint Parliamentary Under Secretary of State

PO(6)4801/7

Clive Jenkins Esq
General Secretary
Association of Scientific Technical
and Managerial Staffs
79 Camden Road
London
NW1 9ES

26 AUG 83

Dear Mr Jenkins,

Thank you for your further letter of 7 July to Lord Trefgarne concerning AIDS.

I think that I should emphasise, firstly, that there is no conclusive evidence that AIDS is transmitted through blood products. Nevertheless we are taking all practicable measures to reduce any possible risks to recipients of blood and blood products. Our scope for action in this is limited, as there is no means of testing for the presence of AIDS in blood donors or in blood products.

With regard to blood donation in the UK a leaflet is in the course of preparation which will be circulated through the National Blood Transfusion Service seeking to discourage potential donors in high-risk groups from giving blood until more is known about what causes AIDS.

Regarding blood products from the USA, in March this year the US Food and Drugs Administration (FDA) initiated new regulations for the collection of plasma designed to exclude donors from high-risk groups. Although future supplies of F.VIII both for export and for use in America will of course be manufactured from plasma collected in accordance with these regulations, there is still a quantity of stock, some already in this country and more in America awaiting shipment here, which has been made from "pre-March" plasma. The FDA has recently decided not to ban the use of similar stocks intended for the USA market because to do so would cause a crisis of supply. Obviously the same considerations apply here. We have to balance the risk of AIDS against the severe risks to haemophiliacs of withdrawing a major source of supply of F.VIII which cannot be made good from elsewhere in sufficient volume. In view of this I am satisfied that the decision to carry on using the current stock of F.VIII is justified, but it is also worth bearing in mind that some of the American manufacturers had, well in advance of the FDA, instituted their own precautions which were at best as demanding as those later contained in the new regulations. Haemophilia Society is aware of the situation and has in fact made known to me its opposition to any move to ban American F.VIII.

R.

So far as Hepatitis B vaccine is concerned the one vaccine which is licensed for use in this country is imported from the USA. This vaccine is treated by approved inactivation methods and we are not aware of any evidence that it carries any risk of transmitting AIDS. A recent review of the safety of Hepatitis B vaccine by a WHO Expert Group has also failed to find any such evidence.

I can assure you that we are not in any way complacent about the threat posed by AIDS. The Communicable Disease Surveillance Centre (CDSC), part of the Public Healt Laboratory Service at Colindale, is operating a national surveillance system in whic all cases are monitored. A special survey to report early information on possible cases has also been instituted by Haemophilia Centre Directors. In addition, CDSC i making available a summary of information about the incidence, identification and method of control of AIDS for use by doctors. Also, the latest epidemiological information and criteria for identification of the syndrome - supplied by the Communicable Disease Surveillance Centre - was published in the British Medical Journal on 6 August.

Yours ever,

GRO-C

THE LORD GLENARTHUR

astms

HEALTH AND SAFETY OFFICE

Whitehall Office, Dane O'Coys Road, Bishops Stortford, Herts. Tel: [redacted]

SMcK/DPP.

19th September, 1983.

Mr. P.R. Foster,
[redacted]

Dear Peter,

Thank you for your very helpful letter. I do in fact get the MMWR and monthly CDC reports from Colingdale and I hope I am keeping up with most current information. I attach a note I did for the last Health Care Section of the Journal about a meeting with Morsons on the vaccine which was not published. Other than that the NHS Health and Safety Committee has decided that we need take no further action at present but keep our members as fully informed as possible. So I would be very grateful to you if you would keep me up to date on any developments you think are significant.

I would be particularly grateful if you could comment on the letter that Clive Jenkins recently received from Lord Glenarthur. There is no great hurry to reply as in my experience such correspondence goes on for months not weeks. I have also written to Dr. Jones of the Haemophiliac Society to try and establish if they have any principled objection to Britain being self-sufficient in Factor VIII.

Finally and most urgent, the Advisory Committee on Dangerous Pathogens will be setting up a Working Party at its next meeting. I would like to nominate you on behalf of ASTMS. Can you phone Pam Harper in my office and let her know if it's OK as I will be on holiday. If I am not there I cannot guarantee that I will succeed in nominating you but will certainly have a try.

Many thanks for your help both past and I hope future. I have ordered the Hagen book - I am sure it is exactly the kind of bedtime reading I need.

Yours sincerely,

GRO-C

pp Sheila McKechnie,
Health and Safety Officer

Encs: Hep.Vac. Morsons (article)
p/c letter from Lord Glenarthur.

AIDS AND THE HEPATITIS VACCINE

On Friday 29th July, the General Secretary, the Health and Safety Officer and ASTMS specialists, met the scientific representatives of Thomas Morson (the British arm of the US Merck manufacturers) to discuss the safety of the Hepatitis 'B' vaccine.

Following the refusal of the DHSS to assure us about the absolute safety of this vaccine, we had advised members that, in the absence of information, we did not advise them to have the vaccine.

This concern was further underlined when the West German Government was reported to have banned vaccine imported from France.

The Company was at pains to emphasize that the French vaccine was quite different to that developed by Merck and that the criticism recently published in 'Nature' of that vaccine, could not be applied to the Merck 'HB' vaccine.

The reason for the concern about any Hepatitis 'B' vaccine made by current techniques, is that some of the plasma used to produce the vaccine is harvested from Hepatitis 'B' positive male homosexuals who are the highest risk group for AIDS.

ASTMS' view was that there is no way to stream donors currently available that would absolutely preclude any donor who has AIDS.

We fully accept however, the company's assurances that their screening procedures are thorough. The safety of the vaccine therefore depends on the various inactivation procedures and three different methods of inactivation are used by Merck.

This compares very favourably with the other manufacturing procedures.

The estimation of risk therefore, ultimately depends on concrete evidence of actual cases.

There has now been a number of years use of this vaccine and there is no evidence of AIDS developing in any of the non-risk groups who have been vaccinated. Only two cases of AIDS in male homosexuals who had been vaccinated, have been reported; a lower number than developed in the non-vaccinated cases.

Any risk from the vaccine remains at present theoretical and given the number of persons vaccinated any significant risk would appear unlikely. However, the theoretical possibility remains that the AIDS agent could survive techniques which deal effectively with known viral agents if indeed we are dealing with a single agent.

When balancing the risk of AIDS from the use of the vaccine however, the important factor is the risk of contracting Hepatitis 'B'. In male homosexual and drug abusers, the case for provision of the vaccine on the NHS is overwhelming. With respect to these groups, the current DHSS failure to provide vaccine smacks of moralism.

However, no one argues that the risk to laboratory staff is of this order and that makes it more difficult to justify the use of the vaccine in these circumstances. What is, however, reprehensible, is that certain health authorities and academics are arguing that the vaccine makes it unnecessary to take precautions with Hepatitis 'B' specimens. Will the lessons of the Birmingham smallpox disaster never be learned?

The choice to have the vaccine is clearly a personal decision. The standards of safety for all health workers should however be such that the risk to workers of contracting Hepatitis 'B' continued to be reduced by <u>prevention</u> and not a policy of vaccination.

We will be watching and monitoring.

ASTMS **Health & Safety Office**

To: Peter Foster
Re. ACSP / ATOS

This came in 19/9/83. If anyone to say we haven't on file already - please let me know. Otherwise hang on to the copy pending decision on committee if you do decide to be nominated.

From: GRO-C: P Harper
Date: 20/9/83

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 transmissi 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 occurre in homosexual men with multiple sex partners, IV drug abusers, Haitians and

2.2 ACDP is therefore asked to advise the Department and the HSE if there is a case for the provision of guidance at this time and, if so, the Committee is invited to establish a Working Party to:-

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.

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

Bii) "AIDS - Precautions for Clinical and Laboratory Staff" - MMWR Nov 5 1982
Prevention of AIDS: Report of Inter-Agency Recommendations - MMWR Mar 1

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

[illegible] SYNDROME: CASE SUMMARY (ENGLAND AND WALES)

Case No.	Where reported	Date reported	Date confirmed	Nationality/ Ethnic group	Sex	Age (yrs)	Diagnosis	Date onset	Date diag-nosis	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			20.1.83	Homo-sexual	USA contacts	N/K	N/K
2.	London	1.3.83	10.3.83	S African	M	39	KS	1982	1982	4.2.83	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 nitrate
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	Mar 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 NHS FVIII since 1981	Nil
9.	London	May 1983	May 1983	British	M	36	PCP; toxo	Apr 82	Apr 82	4.7.82	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	18.6.82	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.	[illegible]on	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	Nil	IV drugs plus Recreational

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 diag-nosis	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			20.1.83	Homo-sexual	USA contacts	N/K	N/K
2.	London	1.3.83	10.3.83	S African	M	39	KS	1982	1982	4.2.83	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 nitrate
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	Mar 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 NHS FVIII since 1981	Nil
9.	London	May 1983	May 1983	British	M	36	PCP; toxo	Apr 82	Apr 82	4.7.82	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	18.6.82	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	Nil	IV drugs plus recreational

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

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 surveillance 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.

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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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 epidemiologic 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.

ACDK / HDS

APPENDIX 1

MMWR 5 November 1982

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 A5 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.

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 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.

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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.

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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

APPENDIX E

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 GRO-A GRO-A. 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,

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

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.

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

1.6 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). Reasssurance has been promulgated by the Haemophilia Society to those who regularly receive blood products (Appendix F).

1.7 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).

2. REFERRAL TO ACDP

2.1 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.

ADVISORY COMMITTEE ON DANGEROUS PATHOGENS
JOINT PAPER FROM DHSS AND HSE

19 SEP 1983

ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)

1. BACKGROUND

1.1 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.

1.2 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 20, details of which are given in Appendix C.

1.3 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.

1.4 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 commercia 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

NOT FOR PUBLICATION

ACDP/83/ P22

ADVISORY COMMITTEE ON DANGEROUS PATHOGENS

ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)

Interim guidelines for Clinical and Laboratory Staff

A. 1. These Guidelines are intended as a basis for the formulation or revision of written local codes of practice in those institutions where patients with AIDS or suspected AIDS are housed or where specimens and other potentially contaminated materials arising from them may be handled.

2. Until such time as a causal agent is positively identified and assessed, specimens and contaminated materials from patients with AIDS or suspected AIDS patients must be treated as if they contained a pathogen capable of causing severe human disease for which there is no effective prophylaxis or treatment. The incubation period may be up to four years and the estimated mortality is 82% within two years of diagnosis. There is a potentially serious risk to those who handle pathological materials or items contaminated by them without due care.

3. At present there is no epidemiological evidence of AIDS transmission to hospital or laboratory personnel from contact with affected patients or clinical specimens. American experience as expressed in the Morbidity and Mortality Weekly Report (CDC ATlanta November 5 1982, March 4 1983) appears to show that infection through casual contact is unlikely , since persons with AIDS are living in the community.

4. Since the disease appears to be parenterally transmissible, the utmost care must be taken to avoid contamination of wounds, skin lesions and mucosal surfaces with blood or other potentially infectious material from any patient known or suspected to be suffering from AIDS. The application of hospital and laboratory codes

of practice designed to minimise the risk of accidental percutaneous inoculation or infection via mucosal surfaces is therefore essential.

5. For all work with AIDS cases it must be assumed that blood, tissues, body fluids, excreta and secretions and items soiled by them as well as surfaces, materials and equipment exposed to them are all potentially hazardous. It follows that items for disposal or sterilisation must be handled with gloves and safely contained.

6. Patients in whom AIDS has been diagnosed or suspected must be nursed in isolation. This should ordinarily imply the use of a single room and a strict barrier nursing regime.

7. It will be the responsibility of the Control of Infection Officer or a senior member of the medical or nursing staff in conjunction with the laboratories to ensure that all those who have direct dealings with AIDS patients (or materials arising from them) are aware of the diagnosis and are familiar with the prescribed precautions set out in local codes of practice relevant to each situation. They should also advise staff that provided these are followed there is believed to be no undue risk of infection.

B. 1. The following protective measures are recommended for the prevention or possible infection which might arise from direct or indirect patient contact when a diagnosis of AIDS is possible and when pathological investigations are required.

2. Gloves and disposable plastic apron must be worn when blood is taken; the latter should be worn over a gown which is to be discarded safely before moving on to other activities.

3. Only the minimum essential quantity of blood should be withdrawn and then only by experienced medically qualified staff who must ensure that the outside of specimen containers is free from contamination. All specimens must be in robust containers which must carry either a

"Danger of Infection" label or a biohazard symbol.

4. Specimens should be kept upright and must be transported to the laboratory without spillage in a sealed secondary enclosure (e.g an intact plastic bag). Pins, staples or metal clips must not be used to make the seal. the accompanying request form, which must be kept separate from the specimen, must show the diagnosis of AIDS or suspected AIDS. Such specimens must not be sent to the laboratory without previous agreement between the clinician and senior laboratory staff.

5. Disposable syringes and needles must be used at all times for blood collection. Used needles should not be bent or re-inserted in their sheaths, but immediately discarded in a puncture-proof container used solely for that purpose and designed for incineration. Only needle-locking syringes or one-piece needle-syringe or similar units should be used to aspirate fluids from patients. Accidental puncture wounds must be treated immediately by encouraging bleeding and liberal washing with soap and water . Any such incident or contamination of broken skin or mucous membrames must be promptly reported to and recorded by the person with overall responsibility for the work.

6. Protective clothing, soiled linen or bedding, surfaces and objects soiled by blood, fluids, secretions etc must immediately be safely contained for disposal or treated with a freshly prepared dilution of a suitable disinfectant. The following disinfectants are known to be active against a wide range of infectious agents e.g freshly prepared hypochlorite solutions containing 2500 ppm available chlorine, and freshly activated 2% glutaraldehyde but their activity against the cause of AIDS is unknown. For blood spills and gross contamination with organic matter, a higher concentration of 10,000 ppm available chlorine may be necessary. Hypochlorite solutions may damage metals.

7. All material leaving the patient's room must be handled in accordance with the policies of the District Control of Infection Committee for highly infectious patients. Non disposable items such as lensed instruments must be disinfected after use. deleted

8. It may be necessary for patients to go to specialist departments of the hospital for investigation such as X-ray but this should be allowed only after prior arrangement so that the control of infection policy for that department can be operated. A trained nurse should accompany the patient on such visits.

9. It must be borne in mind that patients with AIDS may also have other infections requiring additional precautions.

10. If surgical or dental procedures are necessary, all those concerned must be informed of the diagnosis of AIDS and the additional precautions required by the hospital's codes of practice for work on infectious cases applied.

C. 1. The following measures are required for laboratories handling pathological material from patients suffering from AIDS or suspect AIDS patients.

General Requirements

2. From receipt, all specimens from patients with AIDS must be handled in a room other than the routine diagnostic laboratory so that they can be kept separate from the general work. There must be adequate space ($24m^3$) for each worker.

3. A Class 1 Microbiological Safety Cabinet must be available for all laboratory work ~~and used for any operation in~~ which there is any potential for aerosol or droplet formation.

4. All pathological specimens from AIDS cases must be handled separately from routine work by a small number of trained staff who must be made fully aware of the diagnosis, Specimens should be processed either individually or in batches with other danger of infection specimens at the end of a period of routine work.

5. Laboratory workers must wear gloves, gown and disposable plastic apron whilst handling and processing AIDS specimens and great care must be taken to avoid contamination of equipment control knobs and surfaces. The latter should be routinely disinfected (glutaraldehyde) as soon as possible after use and immediately if contamination is suspected. Eye protection will be required when splashing is a possibility. Clothing for laundering must be made safe to handle before despatch to the laundry.

6. Full attention must be given to containment and disposal measures at all work sites and arrangements made for the autoclaving, chemical disinfection or incineration of discarded materials as appropriate. An immediate review of the relevant local code of practice for containment and disposal is therefore essential.

7. The use of sharp instruments must be avoided but any puncture wound which does occur must be immediately treated by encouraging bleeding and liberal washing with soap and water. Any such incident or contamination of broken skin or mucous membranes must be promptly reported to and recorded by the person responsible for the work. The local code of practice should state what further action needs to be taken.

8. A microbiological safety Cabinet (Class I BS 5726., or a unit with equivalent protection factor or performance) must be used for work such as fluid harvesting, vigorous shaking, mixing or ultrasonic disruption etc where the equipment in use is not designed to contain aerosols.

For roller mixing, specimen containers may be simply enclosed in another screw-capped or stoppered container.

9. All materials from AIDS patients for centrifugation must be enclosed in sealed centrifuge buckets. These should be routinely disinfected after use by filling with 2% activated glutaraldehyde, regardless of whether or not breakages have occurred.

10. All specimens, extracts of specimens or passage material to be stored must be separately labelled and placed in a secondary sealable container which must be clearly marked "CAUTION - AIDS" and surface - decontaminated..

11. Laboratory work surfaces, equipment used for AIDS specimen transport, processing preparation and testing should be regularly disinfected by whatever means is appropriate and safe to use. Used graduated pipettes must be totally immersed in fresh hypochlorite solution overnight before draining and processing for re-use (glass) or incineration (plastic). Disposable plastic Pasteur pipettes and dispenser tips must be safely contained, preferably by dunking in hypochlorite solution, until ready for autoclaving or incineration. The use of glass Pasteur pipettes for dispensing AIDS materials is most strongly discouraged. Where surface contamination is known to have occurred, disinfection must be undertaken immediately. Discarded specimens must be safely contained until ready for autoclaving or incineration.

12. All personnel engaged in specimen handling must wash their hands immediately following completion of work and after removal of gloves and protective clothing and before moving on to other activities.

13. Protective clothing must be used for no more than one day and dealt with safely after use (e.g. bagged and autoclaved before laundering). A fresh supply must be available at all times.

14. Specimens and request forms to be sent by post to other laboratories for e.g specialised investigations must be clearly labelled "AIDS" and then packed in accordance with the recognised regulations for the transmission of all pathological material. Details of the packing etc are laid out in the Code of Practice for the Prevention of Infection in Clinical Laboratories and Post Mortem Rooms (HMSO 1978) Section 17, and later Bulletin No 2 (DHSS 1981) Section 2.b.i and iv. It is prudent to take note of any change in requirements, by regular reference to the Post Office's latest regulations. Specimens for external transport (other than by post) are referred to in Section 16c of the same Code.

15. Microbiology

The general requirements for containment and disposal in all laboratory work are outlined above.

16. Microbiological work must be undertaken in a Category B1 laboratory (Code of Practice for the Prevention of Infection in Clinical Laboratories and Post Mortem Rooms (HMSO 1978): Containment Level 3, ACDP - Report No 1). A microbiological safety cabinet Class I (BS 5726) must be available and used for any operation in which there is any potential for aerosol or droplet formation.

17. Automated or semi-automated equipment should be disinfected as described below.

18. Clinical Chemistry, Haematology and Blood Transfusion

The general requirements for containment and disposal in all laboratory work are outlined above.

19. All manipulations in manual tests and preparation of material for analysis in a closed circuit analytical system must be performed in a microbiological safety cabinet ClassI (BS 5726 or unit with an equivalent protection factor or performance).

20. Tests should wherever possible be confined to those which can be performed in a closed system i.e an autoanalyser, cell counter etc which can be easily decontaminated and which operates without aerosol or droplet dispersal.

21. Effluent from analytical equipment must either be trapped in bottles containing hypochlorite or glutaraldehyde or discharged directly into the waste water plumbing system. In the latter case a discharge tube should project at least 25cm into the pipework. Water must flow down the waste pipe while the machine is operating and the waste system (preferably plastic to avoid corrosion problems) must be treated with a solution of hypochlorite (2500 ppm available chlorine) when the work is finished.

22. Whenever practicable analytical systems should be treated after use with glutaraldehyde or hypochlorite solution or when these are not applicable, flushed through with the manufacturer's recommended wash fluid.

23. Gloves should be worn when dismantling or servicing equipment used for processing AIDS materials.

HISTOPATHOLOGY AND CYTOLOGY

25. Arrangements should be made for most small specimens from AIDS or suspected AIDS patients to arrive at the histopathology laboratory in a fixative solution. Wherever possible whole organs or large tissue masses should not be examined in the laboratory except under conditions of containment.

26. Examination and cutting up of specimens in fixative should be delayed as long as possible to minimise operator exposure, but in any circumstances should be done by pathologists wearing suitable protective clothing (gloves, gowns, plastic aprons and eye protection). Due attention must be paid to containment and disposal or disinfection of these items along with instruments

and cutting boards in accordance with local rules for thehandling of infectious materials and the general recommendations outlined above.

27. Particular care must be exercised in this work to avoid cuts and puncture wounds, skin or mucous membrane contamination and splashing. (See paragraph C 7 above).

28. Frozen sections must not be made on unfixed material from AIDS cases. (See Code of Practice for the Prevention of Infection in Clinical Laboratories and Post Mortem Rooms HMSO 1978 Paragraph 29b).

29. Specimens for the cytology laboratory must be handled in accordance with the local code of practice for infectious material. The use of gloves, protective clothing, sealed centrifuge buckets or rotors (including the Cytospin centrifuge) and where necessary a microbiological safety cabinet Class I (BS 5726) or equivalent is required. Centrifuge buckets and rotors should be opened in a safety cabinet.

D. 1. <u>The following requirement is to be observed when animals are to be inoculated with materials arising from AIDS or suspect AIDS patients.</u>

2. No work involving the inoculation of experimental animals with tissues or other potentially infectious materials from individuals known or suspected to have AIDS should be undertaken without consultation with the DHSS and HSE.* , who will be able to recommend appropriate containment measures.

[This section is worded in this way as there are as yet no published requirements for animal work and containment which are thought to be suitable. As these guidance notes are likely to be available before ACDP Report No 1 appears it was thought to be simpler to ask prospective animal users to contact the department's officers who would then supply details of animal containment level 3.]

FOR ACDP ONLY

* DHSS 703-6380 ext
HSE 262-3277 ext

GRO-C

E. !. Requirements for Post Mortem Examination and Body Disposal.

When a diagnosis of AIDS has been established during life, a full scale post mortem examination should not be undertaken to confirm the cause of death.

2. It is recognised that AIDS as a disease is under intense investigation and that post mortem examination of confirmed and suspect cases may be required for research purposes. However, a strictly limited examination involving discrete tissue sampling may suffice for this purpose. Full scale post-mortem examination if held to be imperative, should be conducted only under the conditions described on pages 41-43 Section g. iv of the Code of Practice for the Prevention of Infection in Clinical Laboratories and Post Mortem Rooms (HMSO 1978).

3. Precautions for Body Handling and Disposal

Recommendations appropriate for handling the bodies of AIDS patients are contained in Appendix 12 of the same code of practice.

What about immunopathology
culturing cells may be hazardous

Para needed on immunopathology
Should there be class 3 containment
for immunology — ie same as
microbiology.

ASTMS COMMENTS ON ACDP/83/P22 REVISED AIDS

A6 To repeat a point I have made a number of times; I think a number of hospitals should be designated for the treatment of AIDS. There are overwhelming arguments for this on clinical grounds i.e. quality of treatment and considerable arguments for supposing that trained staff familiar with procedures in relation to AIDS samples or patients are much less at risk than staff who have only one odd case.

I accept that hospitals without the required facilities will not be able to admit AIDS patients but this seems a rather circumstantial approach for such a dangerous disease.

What about guidance for medical staff dealing with AIDS patients in the community?

B2 This does not make sense. Paragraph A6 refers to nursing in isolation.

B3 I have a number of reservations about the use of a biohazard label in such circumstances. These have become quite down-graded because of irresponsible overuse in some areas. 'Danger of Infection' is much preferable and I would like this to be the only acceptable label.

I was sure we had agreed to insert 'screw cap' between 'robust' and 'containers'. Other types of cap considerably increase the risk of aerosols or splashes in the laboratory. This is required for hepatitis B specimens.

B5 Re-order this paragraph to come after paragraph 3 for a more logical sequence. One comment I received was that needle stick accidents 'often' occur as a result of walking across the room to dispose of the syringes and needles. Insert after 'puncture proof container, which should be immediately adjacent to the patient when blood is taken, used solely for that purpose' etc.

B6 A number of reservations have been made to me on this point. Linen grossly contaminated with blood is unlikely to be adequately sterilized by treatment with hypochlorite, nor do hospitals have the facilities for this. The emphasis should be on disposable items and grossly contaminated linen should be incinerated.

B10 Should patients themselves be warned about this and what to do when accidentally cut?

C2 This does not match the guidance we are about to issue on hepatitis B specimens. (See paragraphs 40-42 of current draft). Two main points have been omitted; they must not be unpacked by reception staff and the room must allow a spillage and breakage procedure to be put into operation i.e. essentially it must be able to be disinfected.

C5 I am completely opposed to the use of Class II cabinets for reasons which I will not repeat. I eventually accepted the relevant appendix in ACDP Report 1 because of the arguments about certain kinds of research work having to be done in Class II to preserve the purity of the material.

Under what circumstances would such a reason arise in the case of specimens from AIDS patients? Unless there is evidence that this is required then no Class II cabinets should be used. This guidance is specific to AIDS and I do not consider that ACDP Report 1 sets a precedent on this point.

C15 The use of glass Pasteur pipettes should be forbidden. I can think of no good reason for using glass pipettes in most situations in the laboratory and not at all with AIDS specimens.

C16 This document is meant to be free-standing. Could the requirements related to AIDS not simply be specified instead of referring to a number of other documents all of which are difficult to obtain.

C17 Reference to a B1 laboratory on its own is not satisfactory. I also think reference should be made to ACDP Category 3 containment for all research.

C23 This is not really acceptable. For the time being would it not be better to suggest that systems which cannot be disinfected cannot be used. This is unpractical in relation to hepatitis B but not in relation to AIDS. (See paragraph 55 hepatitis B Guidance for further additions).

C24 Most MLSO's in my experience are not familiar with the term 'permit to work' system. Insert: 'The essential purpose of a permit to work system is to protect service engineers and other staff from commencing work on any equipment before steps are taken to eliminate any infectious hazard. Such permits usually require the signature of the person in the laboratory to certify that decontamination has taken place before work commences'.

C28 It is important to say who will 'deem it essential for research purposes'. If such research has to be done we should require a written protocol to be prepared specifying exactly what should be done to minimize any hazards.

D2 It is my impression that pathologists and staff will refuse to undertake such postmortems but this paragraph does not protect us against the odd Maverick who wants to leap beyond the 'frontiers of science' etc. I think the minimum we should require is notification as per paragraph D2.

ADDITIONAL POINTS

1) Please reproduce the CDC (now WHO) definition of AIDS.

2. There should be a warning concerning exposure of pregnant women or immuno-suppressed people to contact with AID specimens or patients.

3) There are a number of points from the current draft on hepatitis B which could usefully be incorporated. To save time I have just listed the paragraphs and what they cover:-

Paragraph 19

Eye protection - required for hepatitis B not for AIDS.

Paragraph 28

Use of forceps (if it applies).

Paragraph 29

Instruction of medical staff.

Paragraph 31 - B4

Should we say 'by means of an integral sealing strip?

Paragraph 35

Instruction to staff transporting specimens.

P62/63/64

Procedures for accidents, spillages etc.

ASTMS
Health and Safety Office

SMcK/DPP
29/2/84

THE
HAEMOPHILIA
SOCIETY

P.O. Box 9
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London SE1 1DE
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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 these 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

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.

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.

APPENDIX

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-Barre 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 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

[redacted]

29th September, 1983

Sheila McKechnie
Health & Safety Officer
ASTMS
Whitehall Office
Dane O'Coys Road
Bishop Stortford
Herts

Dear Sheila,

Thank you for your letter of 19th September concerning the ACDP and their AIDS working party. I am rather reluctant to become involved in this primarily because I am extremely busy and do not want to take on such an important commitment just now. I suspect that people on AIDS working parties are going to find it a full time occupation.

I would like to comment on the letter from Lord Glenarthur to Clive Jenkins. I found the letter surprisingly complacent about the blood products situation and there are a number of points to take up:-

1) Glenarthur "There is no conclusive evidence that AIDS is transmitted through blood products"

   Comment: The evidence is very strong. There are now about 20 haemophiliacs with AIDS. This figure is likely to underestimate the risk because of the apparently long incubation period. Haemophiliacs in Europe (using USA derived products) are contracting AIDS in locations where the disease had not previously existed. (This is also the case in the USA where the haemophiliacs with AIDS tend to live outside those areas affected by the epidemic).

2) Glenarthur "In March this year the US Food and Drugs administration (FDA) initiated new regulations for the collection of plasma designed to exclude donors from high risk groups"

   Comment These regulations rely on the use of interviews and questionaires to identify donors from high risk groups. The success of this approach is unlikely to be high because of the fact that all donors are paid and a donor who really needs the money may not be truthful. Paid donors are usually recruited from low income groups; 50% of the USA commercial collection centres are in the 10 Southern most states and over 25% are located in the 4 states bordering on Mexico (see Hagen p145). Also the companies do not intend to recall contaminated lots after manufacture (see AABB Newsletter).

   If AIDS continues to grow exponentially in the USA then I would not expect the current FDA regulations to help very much. They are simply a stopgap until progress is made in screening donors or in treating products to render them non-infective.

3) Glenarthur "There is still a quantity of stock..... made from pre-March plasma"

Comment It seems that despite the introduction of the above regulations we are still to carry on as before. There must be a real danger that the UK could become a dumping ground for USA companies to get rid of their non-regulated products.

4) Glenarthur "..... which cannot be made good from elsewhere in sufficient volume"

Comment The key limitation to the UK becoming self-sufficient in Factor VIII is supposed to be the lack of fractionation capacity. The fact that the Scottish fractionation plant is substantially underused seems to be being ignored. As I have mentioned before, the simple introduction of shift-working at PFC would increase our capacity such that we could manufacture over 2/3 rds of the factor VIII currently purchased from the USA.

This should not in any way effect the plans to build a "new" Elstree as the usage of factor VIII in the UK is still well below the level considered appropriate for proper clinical treatment (see Hagen pp 70-74).

5) Glenarthur "Haemophilia Society is aware of the situation and has in fact made known to me its opposition to any move to ban American FVIII"

Comment I am not sure that the Haemophilia Society are fully aware of the UK situation and particularly the true capacity of the Scottish Fractionation Centre and the reasons for its neglect (in my opinion this is a scandal which deserves an inquiry in its own right).

In seeking the views of users of FVIII (eg clinicians & patients) one should be aware that many users are associated with commercial companies (eg clinicians who act as paid consultants to the companies).

I notice that you have written to the haemophilia society about "self-sufficiency". The situation is that there is a clear division of interests. On one hand there are those whose objective is national self-sufficiency using unpaid donors (eg WHO, Blood Transfusion Services and Governments internationally). On the other hand there are the commercial companies who say that self-sufficiency is very nice in theory but is not feasible in practice. They argue that adequate quantities can only be achieved using paid donors and commercial manufacturers. They point to the UK to prove their case. However, if self-sufficiency can be achieved internationally then they would be out of business, hence considerable efforts go into trying to prevent the UK (or other countries) from actually achieving self-sufficiency. Techniques include the sale of cut price FVIII, the cultivation of local clinicians and the promotion of higher and higher quality products (prepared with lower and lower yields). I suspect that the haemophilia society may be heavily influenced by the commercial companies and they probably have a low opinion of the NHS.

I/

I hope these comments might be helpful; many of the points are covered in detail in Hagens book.

Yours sincerely,

GRO-C

PETER R. FOSTER

P.S. I understand that WHO are convening a meeting on AIDS for 22-25 November in Geneva.

c.c. G. Craig

[redacted]

12th October, 1983

Pam Harper
Health & Safety Officer
ASTMS
Whitehall Office
Dane O'Coys Road
Bishop Stortford
Herts

Dear Pam,

ACDP/AIDS

Thank you for the papers on AIDS (ACDP/83/P9). Most of the points have already been covered in previous correspondence but there are some further comments that I would like to make:-

1. Background, section 2.2.IV

The possibility that specific hepatitis B immunoglobulin might transmit AIDS is now being introduced because the selected blood donor population are a high risk group. However, this product should not be imported as the UK is self-sufficient. It is therefore the risk from UK blood donors that has to be considered.

2. Appendix A, Final Paragraph

CDSC advice here is that "Blood and blood products donated by patients subsequently developing AIDS, should be destroyed". This is not the position that the USA blood product manufacturers have taken (see AABB newsletter sent previously).

3. Appendix F

Obviously Arthur Bloom's letter is intended to reassure haemophiliacs in the face of a certain amount of press hysteria. Nevertheless I found some of his statements surprising.

(i) "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".

This is a highly contentious statement as there is considerable evidence that products from paid donors are worse than those from unpaid donors. It is also irrelevant to the AIDS situation as this disease is much more advanced in the USA than elsewhere (paid donors will make this inbalance even stronger).

(ii)/

(ii) "In addition the importation of licensed blood products has always been strictly monitored and controlled".

This is misleading. It suggests that there is some control of AIDS "contaminated" lots. In the absence of any tests and with the policy outlined by Lord Glenarthur then not only is there no control, but "contaminated" lots could enter the UK preferentially.

I hope these comments will be helpful.

Yours sincerely,

PETER R. FOSTER

FO (6) 4201/7

CS

2834

Association of Scientific Technical and Managerial Staffs
General Secretary
79 Camden Road, London NW1 9ES telephone 01 [redacted]
telex no [redacted]

Ref:

27th October 1983.

Dear [redacted]

9 7/4

See para 5.

ACQUIRED IMMUNE DEFICIENCY SYNDROME

Thank you for your detailed response to my queries on AIDS which was received in this office on the 26th August. I have been making a number of detailed enquiries among ASTMS experts on this issue and I would like to put on record my disagreement with a number of the statements made in your letter.

2. You say that there is no conclusive evidence that AIDS is transmitted through blood products. I would argue that the evidence is very strong. There are now about twenty American haemophiliacs with AIDS, and this figure is likely to underestimate the risk because of the apparently long incubation period. Haemophiliacs in Europe (using U.S. derived products) are contracting AIDS in locations where the disease has not previously existed. I also draw your attention to a paper prepared jointly by DHSS staff and the HSE which was submitted to a recent meeting of the Advisory Committee on Dangerous Pathogens (ACDP/83/P9). This paper states quite specifically that "there is now strong circumstantial evidence that AIDS may be transmitted by blood and blood products". I am tempted to ask you what you would consider to be conclusive evidence, particularly in the circumstances where the agent or agents for AIDS are as yet unidentified?

3. I think you are placing undue reliance on the Regulations introduced by the U.S. Food and Drugs Administration. These Regulations rely on the use of interviews and questionnaires to identify donors from high risk groups; the success of this approach is unlikely to be high because of the fact that all

donors are paid and a donor who really needs the money may be untruthful; half of the U.S. commercial collection centres are in the ten southern-most States, a quarter are located in the four States bordering on Mexico. The companies also do not intend to recall contaminated lots after manufacture.

I have attached a copy of the Newsletter of the American Association of Blood Banks which makes this point.

4. I do not regard the situation concerning "pre-March" plasma to be satisfactory because, in effect, it means that despite the introduction of the above Regulations we are essentially carrying on as before. In such circumstance there must be a real danger that the U.K. could become a dumping ground for U.S.A. companies to get rid of their non-regulated products. I think for this reason your Department should reconsider its rather passive response to the need for Regulations.

5. The key issue in all this is, of course, the question of the ability of the U.K. to become self-sufficient in Factor VIII. I am still far from satisfied that we could not achieve this situation in the very near future by realistic investment. The Scottish Fractionation plant is substantially under used and this seems to be being ignored by your Department. I am advised by my members that PSC could increase its capacity to a level where we could manufacture over two-thirds of the Factor VIII currently purchased from the U.S.A. This in no way would affect the plans to build further facilities at Elstree as we must take into account that the usage of Factor VIII in the U.K. is still well below the level considered appropriate for proper clinical treatment. It is on this point, specifically, that I think you should reconsider your approach.

Is this so!

6. I am concerned that you quote in support of your policy the statements of the Haemophilia Society. There is a haemophiliacs group in ASTMS and I have been in contact with a number of officials of the Society. As far as I can establish the Haemophilia Society would welcome Britain becoming self-sufficient in Factor VIII. But they cannot be expected to support a ban on American blood products until we are self-sufficient.

7. On the question of the hepatitis vaccine, we have had a meeting with the agents of the manufacturers in this country and while we accept that the standards of safety in the manufacture of this vaccine should ensure that the agent is not transmitted by this means, we have a substantial scientific problem in actually establishing this conclusively in the absence of a definite agent having been identified. I am sure you will be aware that there are a number of theories concerning the nature of the AIDS agent, and I have certainly heard it stated that it may not be "active" in the normal sense. I am, therefore, concerned that there is a complacency over this vaccine which concerns ASTMS members who may have it administered. The sooner we can manufacture the vaccine by techniques which do not involve using the plasma of hepatitis patients, the safer it will be for all those involved. I would certainly like to know what steps the Government are taking to support the development of the genetically manipulated vaccine.

8. I do understand that views concerning AIDS are evolving rapidly and that it is quite possible that you may have a revised view since you last wrote to me. I would be grateful if you would bring me up-to-date on the view that you now take on the various points raised in my letters as I am receiving many queries.

Yours sincerely,

GRO-C

Joint Parliamentary Under Secretary of State,
Department of Health & Social Security,
Alexander Fleming House,
Elephant and Castle,
London SE1 6BY.

astms

HEALTH AND SAFETY OFFICE

Whitehall Office, Dane O'Coys Road, Bishops Stortford, Herts. Tel: [redacted]

SMcK/DPP.

3rd November, 1983.

Mr. P. Foster,
[redacted]

Dear Peter,

If all ASTMS members with expertise were as helpful as you I think I might be out of a job. A reply to Glenarthur has been drafted on the basis of your letter and will go off shortly. Clive has redrafted my version about three times! When I get a copy of what was actually sent I will send it on.

The Committee set up by ACDP is a bit of a non-event. Neither MRC of PHLS really wanted ACDP in on the act other than in relation to the handling of patient specimens. A Committee has been set up to re-write the CDC guidance in 'English'. I think the DHSS is just 'pissed-off' that ASTMS circulated the CDC advice to all NHS laboratories as soon as it arrived. I have got a meeting next week with the ASTMS London membership on AIDS and I really think further advice is unnecessary at the present time.

I shall have great pleasure in correcting the ACDP paper and I would love to know the outcome of the WHO Conference. If you are passing through London and I can meet you for a meal or a coffee let me know.

Thanks again for your help.

Yours sincerely,

GRO-C

Sheila McKechnie,
Health and Safety Officer.

[redacted]

21st November, 1983

Sheila McKechnie
Health & Safety Office
ASTMS
Whitehall Office
Dane O'Coys Road
Bishops Stortford
Herts

Dear Sheila,

AIDS AND ACDP

Thank you for your letter of 3rd November. I'm glad that I've been able to be of some help.

The latest on the AIDS/haemophilia situation is that both UK patients (ie Bristol and Cardiff) have died - a report of the Bristol case has now been published in the Lancet (enclosed).

I do not get to London very often but I will be at a symposium on the 5th December at the Society of Chemical Industry, Belgrave Square. The lunch break will be from 12 - 1.30 and the meeting finishes at 4.30. The last flight back to Edinburgh is at 7.40 (Heathrow) and I would be pleased to have a chat with you (either lunchtime or early evening) if you are likely to be in the vicinity.

Yours sincerely,

PETER R. FOSTER

astms

HEALTH AND SAFETY OFFICE

Whitehall Office, Dane O'Coys Road, Bishops Stortford, Herts. Tel: [redacted]

SMcK/DPP.

30th November, 1983.

Mr. Peter R. Foster,
[redacted]

Dear Peter,

It looks as if there is going to be quite an argument at the next meeting of ACDP on AIDS and I think it would be very helpful if I could talk to you before that meeting.

However, I cannot make either of the times you have suggested. Do you think it would be possible for us to have a chat on the phone some time on Friday the 9th of December? I should by then have the papers that will be tabled at ACDP and can discuss the problems with you.

If there are problems about phoning you at work could you let me know and I will try and make some other arrangement.

Yours sincerely,

GRO-C

Sheila McKechnie,
Health and Safety Officer.

astms

HEALTH AND SAFETY OFFICE

Whitehall Office, Dane O'Coys Road, Bishops Stortford, Herts. Tel: [redacted]

15th December 1983

ASTMS AIDS Working Group

Joe Ashley	Brian Gee
Bob Bunnell	Colin Kenny
James Erdman	Paul Noon
Peter Foster	Pamela White
	Bob Williamson

Dear Colleague,

Tha attached document was submitted to the last meeting of ACDP. I did not receive it until the day before the meeting and therefore, reserved our position.

Can you review the document in detail and let me know by the beginning of January what changes if any you would like made. It will be issued eventually by the HSE as guidance to be followed. We must therefore, ensure that it is satisfactory to us.

The main issues are the containment levels required. Research will be ACDP Category 3 containment but it is not easy in practice to distinguish between clinical and research work.

Seasons Greetings

Yours sincerely,

GRO-C

Sheila McKechnie
Health and Safety Officer

enc

SMK/ph

5 St. Stephen Street
[redacted]

5th January, 1984

Sheila McKechnie
Health & Safety Officer
Whitehall Office
ASTMS
Dane O'Coys Road
Bishop Stortford
Herts

Dear Sheila,

AIDS AND ACDP

I have nothing to add to the draft ACDP guidlines except to reinforce the handwritten comment concerning the need for immunology guidelines (eg in the use of cell-sorters for T-cell estimations).

I have enclosed the first draft of the WHO report following their November meeting. This is clearly not for publication as it is not the final document. I understand that the CDC safety group are reviewing the section concerning precautions for health-care workers. This is being coordinated by Mr. Vinse Oviatt of CDC.

Best wishes.

PETER R. FOSTER

DEPARTMENT OF HEALTH & SOCIAL SECURITY

Alexander Fleming House, Elephant & Castle, London SE1 6BY

Telephone 01-[redacted]

From the Joint Parliamentary Under Secretary of State

PO(6)4801/22

Clive Jenkins Esq
General Secretary
Association of Scientific Technical and
Managerial Staffs
79 Camden Road
London
NW1 9ES

Dear Mr Jenkins,

Thank you for your letter of 27 October in which you record a number of areas of disagreement with points which I made in my earlier letter. Let me deal with your paragraphs in numerical order.

Para 2. It remains the case that there is no conclusive evidence of the transmission of AIDS through blood products, although the circumstantial evidence is strong. These two statements in no way contradict one another as you will readily appreciate from an analysis of a similar argument which you use in paragraph 7. Whilst there is strong evidence to suppose that the hepatitis vaccine will not transmit AIDS, the evidence is not conclusive and cannot be so until a means of testing for AIDS has been devised. In both cases, the conclusive evidence awaits the development of a test which can identify the AIDS agent (or agents).

Para 3. There is no question of placing 'undue reliance' on the new Regulations introduced by the US Food and Drugs Administration. We take the view that any improvements in donor selection procedures, whatever their limitations, must, to some extent, improve the safety of the products. Therefore we feel that products which have been prepared from plasma collected in accordance with the new regulations may carry a small additional margin of safety - not simply from the point of view of the transmission of AIDS, but also for the transmission of other diseases.

Para 4. I find it difficult to see how you can reconcile the statements in your third paragraph with those in the fourth. If the FDA Regulations are as useless in improving the safety of products as you say they are, then surely it is of no consequence that the UK might become the "dumping ground" of products made from plasma collected before these regulations came into force!

We, on the other hand, take the view that were it possible to obtain sufficient supplies of the 'regulated' products to treat the UK's haemophiliacs, we would take the necessary steps to do so. Regrettably, we have established that at the present time this is not the case and that to insist on only 'regulated' products would be to pose an absolute risk to the health and safety of haemophiliacs. This known risk factor must be weighed against the potential risk to haemophiliacs of acquiring AIDS. Many of your members are in the business of 'risk assessment' in relation to work place safety; they will know that the balance of risks is often more finely drawn than it is in this case.

Para 5. With regard to the United Kingdom becoming self-sufficient in blood products, you are of course aware of the new laboratory at present under construction at Elstree which will enable England and Wales to become self-sufficient. 'At present however the existing laboratory at Elstree is capable of fractionating all the plasma currently available.

Should the situation arise where the plasma supply builds up beyond the fractionating capacity of the existing laboratory, we should need to examine whether any surplus capacity at the Protein Fractionation Centre could be used.

At present, however, PFC would not have the storage, filling and packaging facilities to handle a substantial amount of extra plasma, even if it were available.

Para 6. The statements made by the Haemophilia Society are a matter of fact. It has been necessary to quote from them in order to illustrate to those who are ill-informed on these matters, that to demand a total ban on the imports of US Factor VIII, so far from safeguarding the lives of haemophiliacs, would put them at greater risk.

Para 7. Concerning the MSD plasma derived hepatitis B Vaccine, the Department accepts that the standards of safety in the manufacture of the vaccine should ensure that there is no transmission of any putative agent causative of AIDS; yet acknowledges, with you and the medical research community in general the substantial scientific problems of conclusively proving this in the absence of a definite identified causative agent.

The Department also shares your view that we should not expect plasma derived hepatitis B vaccines to provide a long-term solution but rather should expect this to be provided by biotechnologically manufactured alternatives eg genetically engineered or synthetic oligopeptide products. We have reached this view not just because of the AIDS problems, but have taken note of the world-wide developments in biotechnology generally. To this end the Department is encouraging (under the auspices of the British Technology Group) a collaborative project involving a DHSS funded research group and the University of Uppsala, Sweden into synthetic vaccine production in general and including Hepatitis B work in particular.

I hope that, by answering your questions fully, I have been able to provide you with the necessary information with which to respond to your members' queries.

Yours sincerely,

GRO-C

THE LORD GLENARTHUR

astms

HEALTH AND SAFETY OFFICE

Whitehall Office, Dane O'Coys Road, Bishops Stortford, Herts. Tel: [redacted]

SMK/ph

18th January 1984

Mr P R Foster
[redacted]

Dear Peter,

A reply has been received eventually from Lord Glenarthur. I attach it for your comments. I am sure his comments on PFC would be particularily interesting.

Thanks for your comments on containment proposals for AIDS and WHO report.

Yours sincerely,

GRO-C

pp Sheila McKechnie
Health and Safety Officer

enc

[redacted]

23rd January, 1984

Sheila McKechnie
Health & Safety Officer
Whitehall Office
ASTMS
Dane O'Coys Road
Bishop Stortford
Herts

Dear Sheila,

AIDS

Many thanks for a copy of the reply from Lord Glenarthur. I have not seen the letter that was finally sent to him but I would like to comment on some of the points that he makes.

1. "No Conclusive Evidence" (Para 2 comment)

I think Glenarthur is just being pedantic. The essential point is that a risk of contracting AIDS from blood and/or blood products is recognised to the extent that many agencies (eg Governments, Transfusion Services, manufacturers) are all taking action. There are times when evidence is sufficiently strong that it is necessary to take action prior to scientific proof being absolute and certain. I'm sure this is commonplace in the world of health and safety.

2. FDA Regulations (Comments on paras 3 & 4)

I would agree with Glenarthur's statement "Therefore we feel that products which have been prepared from plasma collected in accordance with the new regulations may carry a small additional margin of safety----".

From this it follows that "Regulated" USA products are clearly preferable to non-regulated products but that the FDA regulations will not in themselves remove the risk, at best they will only reduce the risk somewhat. I still believe that non-USA products (using unpaid donors) will have the lowest risk, because the disease is so much more advanced in the USA. This may change of course if AIDS takes off in the UK (as most experts are now predicting).

3. "Elstree is capable of fractionating all the plasma currently available" (Comment on para 5)

This may well be the case but it begs the question of plasma supply in England and Wales. To achieve selfsufficiency a substantial increase in Fresh Frozen Plasma is required (about 2-3 fold). Much of this can be achieved by replacing whole blood usage with concentrated red cells (leaving the plasma free for fractionation). Hence more plasma can be supplied from existing blood donations. It is conceivable that changes in practice like this are not being pursued at the moment in England and Wales because the Transfusion Centres have nowhere/

nowhere to send their extra plasma (they know exactly how much BPL can process). There are a number of other ways in which plasma supplies can be increased and again it is conceivable that nothing is being done because the BPL capacity problem is well known.

4. Protein Fractionation Centre (Comment on para 5)

I'm not sure where Glenarthur gets his information. The current position at PFC is:

4.1 Filling. This includes sterile filtration and aseptic dispensing. PFC facilities have recently been considerably upgraded (at a cost of over £ ¼M) and the capacity is now very substantial.

4.2 Packaging. The packaging department has been relocated and expanded over the last 18 months and is now operating well below capacity.

4.3 Storage. This is a real problem. Storage facilities at PFC are inadequate due to cuts imposed on building plans in the early 1970's. There are deficiencies in storage for plasma (-40°C), products (+4°C,+ 20°C) and dry goods (20°C). There are plans in the pipeline to build a PFC extension to cover these areas but, at the rate that the NHS moves, this will be a relatively long term project. However it should not be beyond the wit of man to provide some temporary solution to these storage problems (eg prefabricated cold stores are readily available).

4.4 PFC Staffing. Glenarthur has not mentioned the major problem at PFC. As I have noted previously we can increase our FVIII production 3-fold without difficulty, but to recover other blood products (eg albumin, also purchased by England and Wales) from this extra plasma we would require more staff plus a means of working more than an 8 hour day (ie a 2 or 3-shift system according to the plasma quantity). This latter point derives from the fact that our mainstream fractionation (for albumin) is carried out by a computer-controlled continuous-flow process. Currently this process operates for 5-6 hours/day and the capacity can therefore be increased about 4-fold simply by operating fully continuously rather than intermittently.

5. My major concern about Glenarthur's reply is that there is no indication that any positive steps are being taken, at least for the immediate future. Instead there seems to be an air of fatalism; that nothing else can be done therefore nothing is being done. Yet some questions do seem worth pursuing. Why is England so short of plasma? What can be done about it? What would it take to achieve more plasma? What would it take to bring PFC capacity up? Surely the DHSS should be investigating and costing these options with some urgency.

Best wishes

PETER R. FOSTER

c.c. G. Craig

P. Fosrer

c.c. Sheila McMechnie
H & S (Officer)

16 FEB 1984

14th February 1984

Dear Lord Glenarthur

I do not wish to prolong our correspondence unnecessarily and therefore will not go over old ground. I do, however, think you should ask for your information on PFC to be reconsidered. (Paragraph 5)

I am advised that the current position at PFC is as follows:-

1 Filling. This includes sterile filtration and aseptic dispensing. PFC facilities have recently been considerably upgraded (at a cost of over £1/4m) and the capacity is now very substantial.

2 Packaging. The packaging department has been relocated and expanded over the last 18-months and is now operating well below capacity.

3 Storage. We accept that this is a real problem. Storage facilities at PFC are inadequate due to cuts imposed on building plans in the early 1970's. There are deficiencies in storage for plasma (-40°C), products (+4°C, + 20°C) and dry goods (20°C). There are plans in the pipeline to build a PFC extension to cover these areas but, unless you give this item priority, this will be a relatively long term project. However, it should not be beyond human ingenuity to provide some temporary solution to these storage problems (e.g. prefabricated cold stores are readily available).

4 PFC Staffing. You have not mentioned the major problem at PFC. PFC can increase its FVIII production 3-fold without difficulty, but to recover other blood products (e.g. albumin, also purchased by England and Wales) from this extra plasma more staff would be required plus a means of working more than an 8-hour day.

/...

asms

HEALTH AND SAFETY OFFICE

Whitehall Office, Dane O'Coys Road, Bishops Stortford, Herts. Tel: [redacted]

Mr. P. Foster

2nd March 1984

Dear Colleague,

RE: AIDS, ACDP GUIDANCE

I attach the comments I have sent to the ACDP secretaries on the draft guidance. A second draft was made available to me for comment about two weeks ago but there were very few changes. However, this means the paragraph numbers do not relate to the draft that you have.

I am satisfied that I have taken everyones comments on board or that they were already incorporated in the second draft. However, if I have erred please let me know!

I do not expect the final version to be available until the end of March. I will then distribute it as widely was possible.

GRO-C

Sheila McKechnie,
Health and Safety Officer.

Enc: comments.

DEPARTMENT OF HEALTH & SOCIAL SECURITY
Alexander Fleming House, Elephant & Castle, London SE1 6BY
Telephone 01-[redacted]
From the Joint Parliamentary Under Secretary of State

PO(6)4801/51

Clive Jenkins Esq
General Secretary
Association of Scientific Technical
and Managerial Staffs
79 Camden Road
London NW1 9ES

Dear Mr Jenkins,

Thank you for your letter of 14 February in which you raise further matters about the supply of blood plasma and the facilities at the Protein Fractionation Centre (PFC) at Liberton, Edinburgh.

The detailed points you make about the PFC are matters for the Secretary of State for Scotland, and I have forwarded copies of your letter and our previous correspondence to the Scottish Office.

You raised some more general points about the supply of plasma needed for the manufacture of blood products. In 1982, when we decided to increase UK based production so as to make the UK self-sufficient in blood products, various options in the ways of achieving the necessary production capacity were considered. It was decided to build a new production unit at BPL, Elstree, with a capacity to meet the needs of England and Wales, and to have PFC, Liberton concentrate on the needs of Scotland and Northern Ireland. The construction of the new BPL unit is now well under way.

We are aware of the need for an increased supply of plasma from the National Blood Transfusion Service to feed the new BPL unit, and Regional Health Authorities have been set increased plasma production targets. I recognise this has resource implications for Health Authorities in the short term, but the longer term returns will benefit the whole NHS. The Secretary of State recently decided that income from the handling charges for blood and blood derivatives supplies to non-NHS hospitals should be used specifically to help fund the collection of more plasma.

GRO-C

THE LORD GLENARTHUR

astms

HEALTH AND SAFETY OFFICE

Whitehall Office, Dane O'Coys Road, Bishops Stortford, Herts CM23 2JN Tel: 0[redacted]

SMcK/DPP. 17th April, 1984.

Mr. P. Foster,
[redacted]

Dear Peter,

Thanks for your note and I hope you are not being put under pressure. I am very sorry if I inadvertently identified you by the content of our draft letters.

The latest reply from Glenarthur is attached. I do not want to phone you at work, but if you have a phone at home I could phone you some evening if that was convenient.

I raised the subject on ACDP and was told that the DHSS has 'an expert Committee' who reviewed the issue of blood products and AIDS and I now have to follow this up. It does not, of course, have trade union representatives.

Thanks again for all your help.

Yours sincerely,

GRO-C

Sheila McKechnie,
Health and Safety Officer.

Enc: p/c Glenarthur letter.

FROM THE MINISTER FOR HEALTH AND SOCIAL WORK

SCOTTISH OFFICE
WHITEHALL, ~~LONDON~~ SW1A 2AU
TELEPHONE: 01 [redacted]

Clive Jenkins Esq
General Secretary
Association of Scientific, Technical and
Managerial Staffs
79 Camden Road
LONDON
NW1 9ES

14 May 1984

Dear Mr Jenkins

Simon Glenarthur has let me see copies of your correspondence with him regarding the supply of blood plasma in which you have raised the question of the facilities at the Protein Fractionation Centre at Liberton.

The function of the PFC is to concentrate on the needs of Scotland and Northern Ireland. It performs this role satisfactorily: we are virtually self-sufficient in Factor VIII. As Simon Glenarthur explained in his letter of 2 April, the needs of England and Wales are to be met by a new production unit being built at BPL Elstree, and not by looking to any expansion of production at PFC. There is thus no need to consider your interesting suggestions whereby this could be achieved.

Yours sincerely

GRO-C

JOHN J MacKAY

DATE

asms

HEALTH AND SAFETY OFFICE

Whitehall Office, Dane O'Coys Road, Bishops Stortford, Herts CM23 2JN Tel: 0279-[redacted]

SMcK/DPP.

10th July, 1984.

Mr. P.R. Foster,
[redacted]

Dear Peter,

Thank you for the report you have recently sent me on AIDS.

I was going to get in touch with you before the recent dispute to find out how you were getting on. I was very pleased to hear that there has been a change in the management and that you were quite hopeful about developments. I have now received the attached letter from Clive Jenkins which makes me think that you might have been being rather optimistic. I found the nationalistic attitude behind John MacKay's letter very offensive, although I can understand the reasons for it.

I was thinking of replying and simply repeating the points about the risk from commercially manufactured Factor 8 from blood products that are obtained from the US, and repeating our recommendation on self-sufficiency. I do not think in the circumstances we should accept the geographical division of the country if PFC is able to ensure self-sufficiency for the rest of the country. Do you have any other points that you think I should make?

Are the recommendations listed at the end of the papers you sent me from the World Health Organization, or are they the recommendations that the Danish government has made? It is not clear from the document itself.

Yours sincerely,

GRO-C

Sheila McKechnie,
Health and Safety Officer.