Witness Name: Charles Hamilton Massey
Statement No.: WITN3365011
Exhibits: WITN3365012-WITN3365031
Dated: 30 August 2019

INFECTED BLOOD INQUIRY

EXHIBIT WITN3365029 OF MR CHARLES HAMILTON MASSEY

WITN3365029 – Exhibit: Complaint by GRO-A against Professor Christopher Ludlam. GMC Case Reference: 2005/1881

General
Medical
Council

Case Examiner Decision Form

Investigation Officer: Grumberg

File Reference No 2005/1881 / Date 19/1/06

Dr's Name Ludlum Reg No 1325999

Part 1.

Nature of Allegations

Date complaint first received by the GMC: 24/6/05

Year alleged events took place: 1983 onwards

The following are the allegations raised by the complainant and/or employer: (TO BE NUMBERED)

1. That Professor Ludlum performed, or allowed to be performed, an HIV test on the complainant, without proper counselling or consent. Further, that this was part of a clinical study, about which the patient had not been informed. Neither the complainant nor his parents were informed about the test results, which placed both the family and the public at risk, and possibly denied the complainant access to treatment.
2. That neither the complainant nor his family were ever warned about the risk of contracting infectious diseases from factor VIII therapy.
3. That Professor Ludlow deliberately misled the GMC about the ethical approval for his study.

Nature of Allegations: presumption of impaired FTP

1.1 Do the allegations fall within one of the categories where there is a presumption, if proven, of impaired fitness to practise to a degree justifying action on registration?

Sexual Assault or indecency	**Yes**	**No**
a. Indecent behaviour	☐	☒
b. Indecent assault	☐	☒
c. Rape/attempted rape	☐	☒
d. Female circumcision	☐	☒
e. Child pornography	☐	☒
Violence		
f. Assault	☐	☒
g. Attempted murder	☐	☒
h. Firearms offence	☐	☒
i. Murder/manslaughter	☐	☒
j. Robbery	☐	☒
Improper sexual/emotional relationship	☐	☒
Dishonesty		
k. False claims to qualifications/experience	☐	☒
l. Financial fraud/deception	☐	☒
m. Forgery/improper alteration of documents	☐	☒
n. Research misconduct	☐	☒
o. False certification, false reporting	☐	☒
p. False claims about effectiveness of treatment	☐	☒
q. Other serious incidence(s) of dishonesty not covered above	☒	☐

Part 2.

Nature of allegations: Good Medical Practice

2.1 Do the allegations relate to one or more of the principles of Good Medical Practice set out below? If yes, please tick and cite the relevant paragraph in the right hand column then go to Part 3.
If no, please tick ' None of the above' then go to Part 3.

(For more detail on the principles of GMP, refer to the GMP booklet and the guidance provided.)

		Para(s) in GMP
a. Good Clinical Care	☒	2,3
b. Maintaining Good Medical Practice	☐	
c. Teaching and Training	☐	
d. Relationships with patients	☒	17,19,21,22,23
e. Working with colleagues	☐	
f. Probity	☐	
g. Health	☐	
i. None of the above GMP allegations	☐	

Part 3

Criteria for assessing the seriousness of allegations

Questions 3a to 3g will help to identify whether the allegations are sufficiently serious to meet the Investigation stage test: 'Is there a realistic prospect of establishing that a doctor's fitness to practise is impaired to a degree justifying action on registration?'

Please tick yes or no in each section

Do the allegations indicate that:

	Yes	No
a. the doctor's performance has harmed patients or put patients at risk of harm?	☒	☐
b. the doctor has shown a deliberate or reckless disregard of clinical responsibilities towards patients?	☒	☐
c. the doctor has abused a patient's right or violated a patient's autonomy or other fundamental rights?	☒	☐
d. the doctor has behaved dishonestly, fraudulently or in a way designed to mislead or harm others?	☐	☒
e. the doctor's behaviour is such that public confidence in doctors generally might be undermined if the GMC did not take action?	☒	☐
g. the doctor's health is compromising patient safety?	☐	☒

Part 4

Realistic prospect test

4.1 Is there a realistic prospect of establishing that the doctor's fitness to practise is impaired to a degree justifying action on registration

Yes ☐

No ☒

4.2 Please give reasons for your decision

Background

Haemophilia is a bleeding disorder in which patient's lack clotting factor VIII. Factor VIII was prepared from pooled blood transfusions, and in the eighties it became apparent that infectious diseases, including the newly identified HIV, could be spread in this manner. In 1983, the exact course of HIV infection was not fully elucidated, and there was no effective treatment available. Current standards state that HIV tests should only be performed after counselling and with very specific patient consent due to the effects the diagnosis, or even the admission of having a test, can have on the patient's social circumstances, employment, insurance etc. This guidance did not exist in the same form in 1983.

GRO-A alleges that neither he nor his family were made aware of the risks of factor VIII therapy; that they were not counselled or consented regarding an HIV test; that they were not made aware of the results of the test until 1991; that this situation arose only because Professor Ludlum was performing a study on his patients.

1. That Professor Ludlum performed, or allowed to be performed, an HIV test on the complainant, without proper counselling or consent. Further, that this was part of a clinical study, about which the patient had not been informed. Neither the complainant nor his parents were informed about the test results, which placed both the family and public at risk, and possibly denied the complainant access to treatment.

Professor Ludlum states that his study was not about AIDS/HIV per se. Rather it was undertaken to assess effects on the immune system of Scottish haemophiliacs (who were presumed not to have been exposed to the virus) after being exposed to repeated injections of Factor VIII. In addition, the blood tests in the file are clearly labelled "haemophilia AIDS study". However, in his response to the GMC, Professor Ludlum states that the testing was not for a research project: it was introduced as a monitoring process for this group of patients that was thought to be high risk of immunosuppression, but that the risk had not been qualified. The blood samples were labelled "AIDS study" as a shorthand to ensure that they were handled correctly, and identified appropriately.

Professor Ludlow is correct in stating that in 1983 there was not a specific test for HIV. However, white cell counts were taken to determine if there was immunosuppression and in the absence of other causative pathology to infer possible HIV infection. It would seem that the tests indicated that GRO-A was immunosuppressed is as early as 1983. This left

Professor Ludlum with an ethical dilemma, especially when GRO-A was finally identified as HIV positive. He is correct in stating that at the time, the full implications of a positive HTLV /HIV test were not known, and that the situation evolved rapidly over the next few years. Standard practice today is not what was thought necessary in the early 1980's. Today, patients receive intensive counselling before being tested. However, Professor Ludlum was now faced with a group of patients who were known to be HIV positive due to monitoring of their immune state, but who did not know themselves that this was the case. It became clear that it was not best practice to present the patient with a positive result, but to encourage them to ask for it. It is clear that GRO-A did not wish to know his result. One could argue that Professor Ludlum did not try hard enough to "put him in the right frame of mind", but there is enough evidence available to suggest that he took appropriate steps to try and suggest that GRO-A should know what his status was; and also to try and alert the entire group pf patients. This situation arose because of the rapidly evolving situation with regards to knowledge of AIDS, and cannot be laid solely at the door of Professor Ludlum.

In the interim, some advice had been issued by the Public Health Department, giving doctors two options. either inform the patient, or not. Pros and cons are set out in this memo (21/11/84), and Professor Ludlum seems to have opted for the latter course (option (c) ii), although he admits himself becoming uneasy about the situation in later years.

Professor Ludlum certainly continued to give specific advice to GRO-A without confirming that he was at particular risk, because GRO-A continued to not want to know about his HIV status. In 1989 he wrote: "aware we have been doing HIV tests. Does not want to know result. Consents to continue HIV testing." There is some indication from the records that some appropriate counselling was given in the interests of protecting GRO-A and his relations, and the public with regards to blood spillage and sexual intercourse. When Mr GRO-A was finally given the result in 1991, Professor Ludlum wrote: "I have told him his HIV status. He had not really suspected that he might be positive, and seemed therefore quite taken aback."

The documentary programme has evidence from another of Professor Ludlum's patients that exactly mirrors the story given by GRO-A. However, it is notable that NHS Lothian wrote a strongly worded letter to the BBC on 11/8/05 decrying the accuracy of both the content and presentation of the documentary.

It is always difficult to judge someone for actions done 20 years ago and to not apply today's standards. HIV was a new illness in 1983, and not much was known about it. There was uncertainty amongst the medical community as a result, and practice evolved as more knowledge was acquired. Professor Ludlum's response does suggest that he tried to act in the best interests of patients given the rapidly changing information available to him regarding HIV and the constraints of confidentiality. The Case Examiners are satisfied that the so called "AIDS study" was did in fact start as a monitoring exercise of immune status in haemophiliac patients receiving certain blood products, and that publication of the findings was a necessary way of informing the wider medical community of a possible problem. The ethical consent letter from the MRC is for a follow up study that it funded, not the original longitudinal monitoring, and this has confused the issue somewhat. There is no realistic prospect of showing impaired fitness to practise.

2. That neither the complainant nor his family were ever warned about the risk of contracting infectious diseases from factor VIII therapy.

At the time, it was felt that the risk to British haemophiliacs was minimal, as only a few cases had been reported in the USA. Although patients should be fully informed of the risks and benefits of any treatment or therapy they are receiving, situations evolve with

time. It was not clear in 1983 that the risk was substantial. However, after this time, it is clear that attempts were made to alert patients to the risks. There is no realistic prospect of showing that fitness to practise is impaired.

3. That Professor Ludlow deliberately misled the GMC about the ethical approval for his study.

Professor Ludlow states that his study was not about AIDS/HIV per se. Rather, it was initially to assess effects on the immune system of Scottish haemophiliacs (who were presumed not to have been exposed to the virus) after exposed to repeated injections of Factor VIII. Dr Ludlum has explained why the forms were labelled "haemophiliac AIDS Study" and has explained that this was not a clinical trial or research, merely a monitoring exercise, that was later published to alert the wider medical community to a potential problem. It is regrettable that this choice of wording caused so much upset later on. There is no realistic prospect of establishing that his fitness to practise is impaired.

Summary for Closure Letter

"It is always difficult to consider cases where there has been considerable passage of time. Standards of practice change, and what is valid best practice today may contrast sharply with established practise decades ago. The situation with regards to HIVAIDS has evolved considerably since the 1980's. The Case Examiners accept that Professor Ludlum established a monitoring system to assess the incidence of immunosuppression in haemophiliac patients in response to events in Scotland, and that, once some of the patients were identified as being HIV positive, he was in a difficult position. They are satisfied that he acted in accordance with the standards of practice that were accepted at the time, bearing in mind that practice rapidly evolved as more information became available. As a consequence, the Case Examiners do not feel that there is a realistic prospect of establishing that Professor Ludlum's fitness to practise is impaired."

General
Medical
Council

Case Examiner Decision Form

Investigation Officer: Grumberg

File Reference No 2005/1881 / Date 3/11/05

Dr's Name Ludlum Reg No 1325999

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k. False claims to qualifications/experience	☐	☒
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b. the doctor has shown a deliberate or reckless disregard of clinical responsibilities towards patients?	☒	☐
c. the doctor has abused a patient's right or violated a patient's autonomy or other fundamental rights?	☒	☐
d. the doctor has behaved dishonestly, fraudulently or in a way designed to mislead or harm others?	☐	☒
e. the doctor's behaviour is such that public confidence in doctors generally might be undermined if the GMC did not take action?	☒	☐
g. the doctor's health is compromising patient safety?	☐	☒

Part 4

Realistic prospect test

4.1 Is there a realistic prospect of establishing that the doctor's fitness to practise is impaired to a degree justifying action on registration

Yes ☒

No ☐

4.2 Please give reasons for your decision

Background

Haemophilia is a bleeding disorder in which patient's lack clotting factor VIII. Factor VIII was prepared from pooled blood transfusions, and in the eighties it became apparent that infectious diseases, including the newly identified HIV, could be spread in this manner. In 1983, the exact course of HIV infection was not fully elucidated, and there was no effective treatment available. Current standards state that HIV tests should only be performed after counselling and with very specific patient consent due to the effects the diagnosis, or even the admission of having a test, can have on the patient's social circumstances, employment, insurance etc. This guidance did not exist in the same form in 1983.

GRO-A alleges that neither he nor his family were made aware of the risks of factor VIII therapy; that they were not counselled or consented regarding an HIV test; that they were not made aware of the results of the test until 1991; that this situation arose only because Professor Ludlum was performing a study on his patients.

1. That Professor Ludlum performed, or allowed to be performed, an HIV test on the complainant, without proper counselling or consent. Further, that this was part of a clinical study, about which the patient had not been informed. Neither the complainant nor his parents were informed about the test results, which placed both the family and public at risk, and possibly denied the complainant access to treatment.

Professor Ludlow states that his study was not about AIDS/HIV per se. Rather it was undertaken to assess effects on the immune system of Scottish haemophiliacs (who were presumed not to have been exposed to the virus) after being exposed to repeated injections of Factor VIII. He claims to have had full ethical approval for this, and that it was funded by the MRC. The ethical consent letter from the MRC is for a follow up study that it funded, not the original longitudinal study. In addition, the blood tests in the file are clearly labelled "haemophilia AIDS study".

Professor Ludlow is correct in stating that in 1983 there was not a specific test for HIV. However, white cell counts were taken to determine if there was immunosuppression and in the absence of other causative pathology to infer possible HIV infection. It would seem that the tests indicated that GRO-A was immunosuppressed is as early as 1983, but no attempt was made until 1989 to inform GRO-A

In the interim, some advice had been issued by the Public Health Department, giving doctors two options. either inform the patient, or not. Pros and cons are set out in this memo

(21/11/84), and Professor Ludlum seems to have opted for the latter course (option (c) ii), although he admits himself becoming uneasy about the situation in later years.

Professor Ludlum certainly continued to give specific advice to GRO-A, without confirming that he was at particular risk. In 1989 he wrote: "aware we have been doing HIV tests. Does not want to know result. Consents to continue HIV testing." There is no indication from the records that any counselling, other than precautions relating to the haemophilia and sexual intercourse were given. When GRO-A is finally given the result in 1991, Professor Ludlum writes: "I have told him his HIV status. He had not really suspected that he might be positive, and seemed therefore quite taken aback."

Finally, the documentary programme has evidence from another of Professor Ludlum's patients that exactly mirrors the story given by GRO-A

It is always difficult to judge someone for actions done 20 years ago and to not apply today's standards. HIV was a new illness in 1983, and not much was known about it. There was uncertainty amongst the medical community as a result, and practice evolved as more knowledge was acquired. However, the evidence suggests that Professor Ludlum did not in fact take into account what might be in the best interests of his patients, or the public health, for some time. There is no alternative, therefore, but to refer this case to a fitness to practice panel.

2. That neither the complainant nor his family were ever warned about the risk of contracting infectious diseases from factor VIII therapy.

At the time, it was felt that the risk to British haemophiliacs was minimal, as only a few cases had been reported in the USA. Although patients should be fully informed of the risks and benefits of any treatment or therapy they are receiving, situations evolve with time. It was not clear in 1983 that the risk was substantial. However, after this time, it is clear that attempts were made to alert patients to the risks. There is no realistic prospect of showing that fitness to practise is impaired.

3. That Professor Ludlow deliberately misled the GMC about the ethical approval for his study.

Professor Ludlow states that his study was not about AIDS/HIV per se. Rather, it was initially to assess effects on the immune system of Scottish haemophiliacs (who were presumed not to have been exposed to the virus) after exposed to repeated injections of Factor VIII. He claims to have had full ethical approval for this, and that it was funded by the MRC. The ethical consent letter from the MRC is for a follow up study that it funded, not the original longitudinal study. In addition, the blood tests in the file are clearly labelled "haemophilia AIDS study". It may be that events have become confused with the passage of time. However, it would appear to be reasonable to conclude that Professor Ludlum is deliberately misleading the GMC.

Reasons for referral to FTP

The Case Examiners acknowledge the importance of assessing past actions in the light of the clinical standards in place at the time and not current standards. They also acknowledge that clinical practice relating to HIV/AIDS has changed substantially since 1983. However, the evidence suggests that Professor Ludlum did not in fact take into account what might be

in the best interests of his patients, or the public health. In addition, the evidence suggests that Professor Ludlum has misled the GMC about the nature of the longitudinal study that included the complainant. There is, therefore, no alternative but to refer this case to a Fitness to Practice panel for a determination.

Part 5

Undertakings

5.1 Do you consider that this is a case where undertakings should be offered to the doctor?

Yes ☐

No ☒

5.2 If you answered yes, please give reasons for your decision

Part 6

Warnings

6.1 Do you consider that this is a case where a warning should be given to the doctor?

Yes ☐

No ☒

6.2 In either case, please give reasons for your decision

There has not been sufficient departure from Good Medical Practice to warrant such a warning

Part 7

Decision

a. Refer to a FTP panel for determination	☒
b. Agree undertakings	☐
b. Issue a warning	☐
c. Conclude	☐

Name of Case Examiner (1) GRO-C

Signature of Case Examiner (GRO-C

Name of Case Examiner (2) GRO-C

Signature of Case Examiner (2) 10/11/05

Date 3/11/05

Date

Case Examiner Referral Form

Section 1: Case Details

See Notes on Completion at end of form

FPD reference **RG/FPD/2005/1881**

Date complaint made to the GMC: **24 June 2005**

Doctor's name **LUDLAM, Christopher**

Registration no. **1325999**

Date **1 November 2005**

Investigation Officer Richard Grumberg

File location: E:\.... E:\CONDUCT\Manchester Screening\Grumberg R\Ludlum, Christopher 2005 1881\CERF.doc

Section 2: Previous History

See Note 1

Previous history? Yes

FPD Reference	Nature of complaint	Outcome/current status
2003/1173	Substandard Clinical Practice/Consent Issues	Closed: No realistic prospect
2003/2726	Substandard Clinical Practice/Consent Issues	Closed: No realistic prospect

Section 3: Index complaint – background and summary

See Note 2

1. **Specialty/field of practice of the doctor:** Medicine/Haematology

2. **Chronology of events**

The complaint is made by GRO-A regarding his past treatment by Consultant Professor Ludlum in relation to becoming infected by HIV/AIDS and Hepatitis C.

GRO-A received his medical records in 2003 however due to medical problems he has impaired sight and was unable to read them. Due to the stigma surrounding HIV/AIDS and Hepatitis C he did not inform anyone that he had the diseases and did not let anyone read his medical notes for him. Only after having recently informed a friend that he has AIDS did he have someone read his notes.

GRO-A was informed that an AIDS study was carried out on him from April 1983. He became positive for HTLV III when he was 14 years old in 1984. GRO-A states that he finds it unacceptable that Professor Ludlum informed neither him nor his parents at that time. GRO-A was also not informed of the risks of contracting HIV/AIDS from Factor VIII prior to his infection when a named AIDS study was carried out on him 1983.

Professor Ludlum did not inform GRO-A of GRO-A 's HIV/AIDS status until January 1991, almost six years later, during a routine appointment in which Professor Ludlum told GRO-A that it had come to his attention that he was HIV positive. GRO-A received no counselling prior to being informed of his HIV status and as mentioned in his notes, Professor Ludlum stated that "he had not really suspected that he might be positive and he was therefore quite taken aback."

GRO-A has since learned that according to research papers published in medical journals that a total of 18 haemophiliacs contracted HIV/AIDS from the one batch giving Professor Ludlum "the opportunity to study a unique group of haemophiliacs" from the onset. GRO-A s group is mentioned as "one of the most researched group in the world."

GRO-A and others featured recently in a documentary by BBC Scotland, Frontline Scotland "Blood and Tears," and neither he nor the BBC have received satisfactory answers from Professor Ludlum to explain why Mr. GRO-A or his parents were not told that he was HTLV III positive. GRO-A encloses copies of AIDS studies and Professor Ludlum's comments regarding being told of being HIV positive.

Flag 2 is a transcript of the BBC Scotland documentary "Blood and Tears" broadcast on 1 June 2005.

Flag 3 is Professor Ludlum's response wherein he states that in December 1984/January 1985 all patients and parents of children with haemophilia were invited to an open meeting in Edinburgh to explain to patients what was known about AIDS in individuals with haemophilia. Professor Ludlum claims that GRO-A 's parents received an invitation to the meeting.

Subsequent to the meeting, all haemophiliacs and parents were written to with an "Advice Sheet for Adult Patients and Families about Acquired Immune Deficiency." This set out what was known in 1985. An explicit invitation was made to anyone who wanted to have more information or to know the result of their Anti-HTLV III test to telephone to make an appointment. GRO-A 's parents did not take up this opportunity.

GRO-A was also asked in 1986 whether he wanted to know his anti-HTLV III result. He was adamant that he did not want to know. In 1989 GRO-A consented to serial HIV tests but told Professor Ludlum he did not want to know the result. When it became clear in 1991 that prophylaxis against PCP was effective and Zidovudine was beneficial, Professor Ludlum was keen to offer GRO-A these therapeutic options and a meeting was arranged for 15 January 1991 during which GRO-A was informed of his anti-HTLV III status.

Flag 4 is GRO-A 's response to Professor Ludlum's comments. GRO-A states that his parents have no recollection of being invited to the meeting Professor Ludlum mentions. GRO-A also states that according to Professor Ludlum GRO-A was asked in 1986 if he wished to know his anti-HTLV III result, when, as the medical records point out, GRO-A was actually asked whether he wanted to know his "antibody result." GRO-A explains that in 1986 it was not explained what exactly an antibody test was or what it was for. GRO-A assumed it was a just a routine test that was carried out on all haemophiliacs.

In summary, GRO-A states that his parents did not know of the risks as they were always assured by Professor Ludlum and his staff that the Scottish Factor VIII was the safest in the world, and as they did not attend either meeting in 1984 or 1985. They also did not receive a copy of the AIDS Advice Sheet, and Professor Ludlum never ensured that they went to the meetings, received the sheet or mentioned the risks to them personally. His parents did not know that there was a possibility that GRO-A was infected.

GRO-A believes that Professor Ludlum should have followed the Council of Europe Recommendation No R(83)8 which states "-to inform attending physicians and selected recipients, such as haemophiliacs, of the potential health hazards of haemotherapy and the possibilities of minimising these risks." GRO-A believes that his parents should have been informed of the possible risks of Factor VIII to enable them to decide on any future treatment he received and to possibly prevent his infection as according to Professor Ludlum and his retrospective tests, GRO-A was in June 1983, HTLV III negative.

Further, when GRO-A tested positive in 1984 it was Professor Ludlum's responsibility to inform his parents as soon as possible to prevent the spread of AIDS throughout his family as by 1984 GRO-A 's mother was injecting him with Factor VIII and thereby risking her own life.

Flag 5 is a letter from GRO-A enclosing a letter in relation to MRC funding and Ethics Committee approval for the "Named Patient AIDS Study" carried out on GRO-A in 1983. Professor Ludlum in his comments at Flag 3 states that the studies had full ethical approval from the Lothian Health board Ethics Committee and were funded by the MRC, Scottish Office and the Wellcome Trust." In fact, the MRC did not fund the original study but rather a follow-up study, and it is unclear whether there was any ethical backing for Professor Ludlum's study involving GRO-A . It therefore appears that Professor Ludlum's statement to the GMC in his response is mistaken at best, and misleading at worse.

Travelling with the blue file is a folder marked "Patient Medical Rcords GRO-A GRO-A Current Records"; 7 lever arch files, and a video tape marked "Frontline Scotland Blood and Tears"

3. Brief summary of the allegations/issues complained about to the GMC

Failure to inform a minor's parents of the HIV/Hep C status of the minor; failure to inform the patient of his HIV/Hep C status; failure to inform the patient or his parents of the risks of contracting HIV/Hep C from Factor VIII; providing misleading statements to the GMC.

Section 4: Additional information

See Note 3

Section 5: Performance Assessments/Health Examinations

See Note 4

Section 6: Summary of Allegations

See Note 5

A	B	C	D
No	**Allegation**	**Presumption of impaired FTP?**	**Breach of GMP?**
1	Failure to inform a minor's parents of the HIV/Hep C status of the minor	No	Yes
2	Failure to inform the patient of his HIV/Hep C status	No	Yes
3	Failure to inform the patient or his parents of the risks of contracting HIV/Hep C from Factor VIII	No	Yes
4	Providing misleading statements to the GMC.	Yes	Yes

Other relevant guidance? No

See Note 6

Section 8: Conclusion/Suggested Action

With respect to the first allegation, Failure to inform a minor's parents of the HIV/Hep C status of the minor, given the life-threatening risks of the spread of the infection it appears that Professor Ludlum should have specifically informed the parents rather than relying on an invitation to a meeting or mailing a fact sheet. The realistic prospect test therefore appears to be satisfied.

With respect to the patient, once GRO-A became of age, rather than being asked whether he wanted to know of the results of his "antibody tests" he should have specifically been informed of what the terms meant, the risks involved, and of his status. Failure to adequately inform the patient meets the realistic prospect test.

Regarding the allegation of failing to inform the patient or his parents of the risks of contracting HIV/Hep C from Factor VIII, Professor Ludlum did not take adequate steps to inform GRO-A or his parents of the risks of Factor VIII so as to provide a foundation for informed consent. Rather, they were told that Scottish Factor VIII was the safest in the world. The realistic prospect test is therefore satisfied.

Finally, with respect to the misleading statement to the GMC, it is apparent that, contrary to Professor Ludlum's clear statement to the contrary, the MRC did not fund his original study, and there is a real question as to whether there was ethical backing for such a study as well. It therefore appears that the realistic prospect test is satisfied in this instance as well.

Based on the above the case should be forwarded to a fitness to practise panel.

General
Medical
Council

Case Examiner Decision Form

Investigation Officer: Grumberg

File Reference No 2005/1881 / Date 3/11/05

Dr's Name Ludlum Reg No 1325999

CE DECISIONS
SCANNED & SENT TO
GRO-C 31. EMML

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Year alleged events took place: 1983 onwards

The following are the allegations raised by the complainant and/or employer: (TO BE NUMBERED)

1. That Professor Ludlum performed, or allowed to be performed, an HIV test on the complainant, without proper counselling or consent. Further, that this was part of a clinical study, about which the patient had not been informed. Neither the complainant nor his parents were informed about the test results, which placed both the family and the public at risk, and possibly denied the complainant access to treatment.
2. That neither the complainant nor his family were ever warned about the risk of contracting infectious diseases from factor VIII therapy.
3. That Professor Ludlow deliberately misled the GMC about the ethical approval for his study.

Nature of Allegations: presumption of impaired FTP

1.1 Do the allegations fall within one of the categories where there is a presumption, if proven, of impaired fitness to practise to a degree justifying action on registration?

Sexual Assault or indecency	**Yes**	**No**
a. Indecent behaviour	☐	☒
b. Indecent assault	☐	☒
c. Rape/attempted rape	☐	☒
d. Female circumcision	☐	☒
e. Child pornography	☐	☒
Violence		
f. Assault	☐	☒
g. Attempted murder	☐	☒
h. Firearms offence	☐	☒
i. Murder/manslaughter	☐	☒
j. Robbery	☐	☒
Improper sexual/emotional relationship	☐	☒
Dishonesty		
k. False claims to qualifications/experience	☐	☒
l. Financial fraud/deception	☐	☒
m. Forgery/improper alteration of documents	☐	☒
n. Research misconduct	☐	☒
o. False certification, false reporting	☐	☒
p. False claims about effectiveness of treatment	☐	☒
q. Other serious incidence(s) of dishonesty not covered above	☒	☐

Part 2.

Nature of allegations: Good Medical Practice

2.1 Do the allegations relate to one or more of the principles of Good Medical Practice set out below? If yes, please tick and cite the relevant paragraph in the right hand column then go to Part 3.
If no, please tick ' None of the above' then go to Part 3.

(For more detail on the principles of GMP, refer to the GMP booklet and the guidance provided.)

		Para(s) in GMP
a. Good Clinical Care	☒	2,3
b. Maintaining Good Medical Practice	☐	
c. Teaching and Training	☐	
d. Relationships with patients	☒	17,19,21,22,23
e. Working with colleagues	☐	
f. Probity	☐	
g. Health	☐	
i. None of the above GMP allegations	☐	

Part 3

Criteria for assessing the seriousness of allegations

Questions 3a to 3g will help to identify whether the allegations are sufficiently serious to meet the Investigation stage test: 'Is there a realistic prospect of establishing that a doctor's fitness to practise is impaired to a degree justifying action on registration?'

Please tick yes or no in each section

Do the allegations indicate that:

	Yes	No
a. the doctor's performance has harmed patients or put patients at risk of harm?	☒	☐
b. the doctor has shown a deliberate or reckless disregard of clinical responsibilities towards patients?	☒	☐
c. the doctor has abused a patient's right or violated a patient's autonomy or other fundamental rights?	☒	☐
d. the doctor has behaved dishonestly, fraudulently or in a way designed to mislead or harm others?	☐	☒
e. the doctor's behaviour is such that public confidence in doctors generally might be undermined if the GMC did not take action?	☒	☐
g. the doctor's health is compromising patient safety?	☐	☒

Part 4

Realistic prospect test

4.1 Is there a realistic prospect of establishing that the doctor's fitness to practise is impaired to a degree justifying action on registration

Yes	☒
No	☐

4.2 Please give reasons for your decision

Background

Haemophilia is a bleeding disorder in which patient's lack clotting factor VIII. Factor VIII was prepared from pooled blood transfusions, and in the eighties it became apparent that infectious diseases, including the newly identified HIV, could be spread in this manner. In 1983, the exact course of HIV infection was not fully elucidated, and there was no effective treatment available. Current standards state that HIV tests should only be performed after counselling and with very specific patient consent due to the effects the diagnosis, or even the admission of having a test, can have on the patient's social circumstances, employment, insurance etc. This guidance did not exist in the same form in 1983.

GRO-A alleges that neither he nor his family were made aware of the risks of factor VIII therapy; that they were not counselled or consented regarding an HIV test; that they were not made aware of the results of the test until 1991; that this situation arose only because Professor Ludlum was performing a study on his patients.

1. That Professor Ludlum performed, or allowed to be performed, an HIV test on the complainant, without proper counselling or consent. Further, that this was part of a clinical study, about which the patient had not been informed. Neither the complainant nor his parents were informed about the test results, which placed both the family and public at risk, and possibly denied the complainant access to treatment.

Professor Ludlow states that his study was not about AIDS/HIV per se. Rather it was undertaken to assess effects on the immune system of Scottish haemophiliacs (who were presumed not to have been exposed to the virus) after being exposed to repeated injections of Factor VIII. He claims to have had full ethical approval for this, and that it was funded by the MRC. The ethical consent letter from the MRC is for a follow up study that it funded, not the original longitudinal study. In addition, the blood tests in the file are clearly labelled "haemophilia AIDS study".

Professor Ludlow is correct in stating that in 1983 there was not a specific test for HIV. However, white cell counts were taken to determine if there was immunosuppression and in the absence of other causative pathology to infer possible HIV infection. It would seem that the tests indicated that GRO-A was immunosuppressed is as early as 1983, but no attempt was made until 1989 to inform GRO-A .

In the interim, some advice had been issued by the Public Health Department, giving doctors two options. either inform the patient, or not. Pros and cons are set out in this memo

(21/11/84), and Professor Ludlum seems to have opted for the latter course (option (c) ii), although he admits himself becoming uneasy about the situation in later years.

Professor Ludlum certainly continued to give specific advice to GRO-A , without confirming that he was at particular risk. In 1989 he wrote: "aware we have been doing HIV tests. Does not want to know result. Consents to continue HIV testing." There is no indication from the records that any counselling, other than precautions relating to the haemophilia and sexual intercourse were given. When GRO-A is finally given the result in 1991, Professor Ludlum writes: "I have told him his HIV status. He had not really suspected that he might be positive, and seemed therefore quite taken aback."

Finally, the documentary programme has evidence from another of Professor Ludlum's patients that exactly mirrors the story given by GRO-A .

It is always difficult to judge someone for actions done 20 years ago and to not apply today's standards. HIV was a new illness in 1983, and not much was known about it. There was uncertainty amongst the medical community as a result, and practice evolved as more knowledge was acquired. However, the evidence suggests that Professor Ludlum did not in fact take into account what might be in the best interests of his patients, or the public health, for some time. There is no alternative, therefore, but to refer this case to a fitness to practice panel.

2. That neither the complainant nor his family were ever warned about the risk of contracting infectious diseases from factor VIII therapy.

At the time, it was felt that the risk to British haemophiliacs was minimal, as only a few cases had been reported in the USA. Although patients should be fully informed of the risks and benefits of any treatment or therapy they are receiving, situations evolve with time. It was not clear in 1983 that the risk was substantial. However, after this time, it is clear that attempts were made to alert patients to the risks. There is no realistic prospect of showing that fitness to practise is impaired.

3. That Professor Ludlow deliberately misled the GMC about the ethical approval for his study.

Professor Ludlow states that his study was not about AIDS/HIV per se. Rather, it was initially to assess effects on the immune system of Scottish haemophiliacs (who were presumed not to have been exposed to the virus) after exposed to repeated injections of Factor VIII. He claims to have had full ethical approval for this, and that it was funded by the MRC. The ethical consent letter from the MRC is for a follow up study that it funded, not the original longitudinal study. In addition, the blood tests in the file are clearly labelled "haemophilia AIDS study". It may be that events have become confused with the passage of time. However, it would appear to be reasonable to conclude that Professor Ludlum is deliberately misleading the GMC.

Reasons for referral to FTP

The Case Examiners acknowledge the importance of assessing past actions in the light of the clinical standards in place at the time and not current standards. They also acknowledge that clinical practice relating to HIV/AIDS has changed substantially since 1983. However, the evidence suggests that Professor Ludlum did not in fact take into account what might be

in the best interests of his patients, or the public health. In addition, the evidence suggests that Professor Ludlum has misled the GMC about the nature of the longitudinal study that included the complainant. There is, therefore, no alternative but to refer this case to a Fitness to Practice panel for a determination.

Part 5

Undertakings

5.1 Do you consider that this is a case where undertakings should be offered to the doctor?

Yes ☐

No ☒

5.2 If you answered yes, please give reasons for your decision

Part 6

Warnings

6.1 Do you consider that this is a case where a warning should be given to the doctor?

Yes ☐

No ☒

6.2 In either case, please give reasons for your decision

There has not been sufficient departure from Good Medical Practice to warrant such a warning

Part 7

Decision

a. Refer to a FTP panel for determination ☒
b. Agree undertakings ☐
b. Issue a warning ☐
c. Conclude ☐

Name of Case Examiner (1) GRO-C

Signature of Case Examiner GRO-C

Name of Case Examiner (2) GRO-C

Signature of Case Examiner (2) 10/11/05

Date 3/11/05

Date

Complainant	Doctor	GMC	Comment
1. Did not obtain consent for Aids Study and accompanying tests	Clinical studies set up in 1980's in direct response to AIDS threat. Investigation colloquially known as the 'AIDS' study although no known cases of AIDS at that time. Therefore not a study on AIDS as such, but a clinical assessment of immune function of patients with haemophilia. Acknowledge that it was debatable whether the investigations should be termed as research or as immune surveillance set up in response to the AIDS threat. Not an AIDS study. Blood samples for the immune studies were likely taken at the same time as blood was being taken for other routine surveillance investigations. **It was our standard practice, ... to let the patient know that we would ... and to seek his explicit verbal consent.** **Believe it was generally known within the patient group that serum was stored for the purpose of investigating retrospectively...** **Both mother and patient would have heard about proposed blood tests.** **Consent not recorded in notes as not standard practice to do so at**	Prof L is correct in stating that in 1983 there was not a specific test for HIV. However, white cell counts were taken to determine if there was immunosuppresion and in the absence of other causative pathology to infer possible HIV infection. Prof L faced with an ethical dilemma when patient positively identified as HIV positive. It became clear that it was not best practice to present the patient with a positive result but to encourage them to ask for it. This situation arose because of the rapidly evolving situation with regards to the knowledge of AIDS, and cannot be laid solely at the door of Prof L Some advice from Public Health Dept – 2 options – inform or not – Prof L took	Not sure CEs have dealt with this point. Complainant says consent not given for AIDS study and accompanying tests. Prof L says not AIDS study, though called this and that would have obtained verbal consent for tests – did not say did obtain. CEs don't appear to deal with consent issue. Leaving aside the issue of whether it was an AIDS study or not, the Complainant says that consent was not obtained for the tests or study and Prof does not dispute that no consent was obtained for the study and says it would have been for the blood tests. **This appears to be a matter of evidence which the CEs have resolved.**

Complainant	Doctor	GMC	Comment
	that time. **In 1985 Lothian Health Board agreed not necessary to record verbal consent for the taking of small blood samples.** **No objection raised to blood being taken by patient or mother.**	latter option.	
2. Did not give the patient or family counselling in respect of tests	Need to clarify what counselling means given the change in meaning and practice. Patient and his mother knew of Dr's concerns about blood safety and the need for surveillance. Patient issued with a small information leaflet to kept in his Haemophilia Card The initial anti-HTLVIII tests were carried out without either the patient's or his mother's specific consent. This was carried out in the autumn of 1984 before the necessity for HIV pre-test counselling was appreciated and at a time when consent was not considered appropriate for other viral tests. GMC published guidance on the need for counselling in relation to HIV testing in 1988	Prof L continued to give specific advice to Patient without confirming he was at risk. Some indication in the records that some appropriate counselling was given in the interests of protecting Patient and his relations and the public with regards to spillage and sexual intercourse.	It appears that at the time, counselling was not best practice so Prof L cannot be criticised for not doing so. CEs don't deal with specific point on counselling.

Complainant	Doctor	GMC	Comment
3. Did not inform patient or family that tests were part of AIDS study	Term 'clinical study' may be interpreted in a number of different ways. It is Dr's belief that patient would have been informed and consulted. It was standard practice at time and no reason to believe patient would be treated differently. Setting up these tests was viewed as good clinical practice... Both patient and mother would have understood that additional test were being undertaken and it is likely they might well have been told that the investigations were part of the study of his immune system. Forms were labelled 'AIDS Study' so no wish to keep investigations secret.	Case Examiners satisfied that the so called 'AIDS Study' was did (sic) in fact start as a monitoring exercise of immune status in haemophiliac patients receiving certain blood products, and that publication of the findings was a necessary way of informing the wider medical community of a possible problem.	CE focus on what Dr says and accept this. They have not dealt with the fact that regardless of what the study or investigations were called, the family/patient say they were not informed. Dr says, they would have been and no reason to believe they were not but can't say for certain. Again, this appears to be a resolution of conflict of evidence by CEs.
5. Did not take proper steps to inform patient or parents about HIV positive result	Should be borne in mind that the inference of an anti-HTLVIII result in December 1984 was very different from what is now understood by an HIV positive test result. Patient's parents were invited to an open meeting in December 1984 – would have learned that patients had been anti-HTLVIII tested and that patients could obtain the results by arranging a meeting with myself	See above	There is a comment from the Dr that the patient had been 'tested without his consent'... and assumptions are made about the patient complying with protocols. It is clear that the Prof did not take pro-active steps to inform patients or parents about HIV positive result. However, can rely on advice

Complainant	Doctor	GMC	Comment
	Patient's parents sent the 'Advice Sheet on Adult patients and families on AIDS' which made explicit offer of a meeting with Dr to discuss individual circumstances. Letter dated 31 January 1985 sent to Patient's GP who could have contacted Dr. **As Patient had been tested without his consent and we believed he had appreciated the safety precautions which were set out in the information sheet, we considered that there was no immediate need to actively seek out and inform patients of their anti-HTVIII status.** **Believed that all patients should eventually know their results but provided the safety precautions were being followed, it was not essential to insist that patients know given that there was no effective treatment or specific therapy.** **Would have discussed with patient in a general way concerns about HIV and AIDS on 2 occasions in 1985**		from Public Health Dept which gave option of not disclosing. CEs appear to have accepted at face value the Drs response.

Complainant	Doctor	GMC	Comment
	and 1 in 1986. **Was keen to open up a discussion about the subject of his status with the hope that he might consider knowing his result.** **Patient made it clear in 1986 that he did not wish to know result. Took care to inform him about the safety precautions.** **14 August 1988, Dr Auger wrote to patient telling him about visit to discuss HIV and AIDS - ? cancelled by patient.** **Patient seen 1989 – made aware that he had been HIV tested – did not wish to know result.** **Told result on 15.01.91** **In discussion on 27 June 06 – patient said he was glad not to have known result as he had 6 extra years without worry...**		
6. Did not take steps to warn the patient or parents of the risks of contracting infectious diseases from Factor VIII therapy	Patient and parents were aware from a number of sources	At the time it was felt that the risks to the British Haemophiliacs was minimal, as only a few cases had been reported in the USA.	Again the CEs appear to have accepted the Drs response that there were a number of sources to warn the patient/parents.

Complainant	Doctor	GMC	Comment
		Although patients should be fully informed of the risks and benefits of any treatment or therapy, situations evolve with time. It was not clear in 1983 that the risk was substantial. However after this time it is clear that attempts were made to alert patients to the risks.	The issue not addressed is that Prof L did not take steps to warn this patient.
7. Over the course of treating the patient did not confirm he was as any particular risk	Made every effort to advise patient of his status, gave advice about risks and offered access to a social worker and counsellor	See above	See above
8. Did not give/Offer any counselling	See above	See above	See above
9. Did not give any advice in respect of the risks involved	See above	See above	See above
10. Did not take proper steps to inform him of the HIV positive result	See above	See above	See above
11. Made in accurate and/or misleading claims about ethical approval	Did not seek ethical approval for the investigations Not intention to mislead. No patient had AIDS so was not an AIDS study	Prof L states that this was not about AIDS/HIV per se. Prof L has explained why the forms were labelled as they were. It is regrettable that this choice of wording caused so much upset later on.	It is clear that there is some confusion here. In his initial response, Prof L is unequivocal that 'the studies' had full ethical approval... The Prof did not at this stage seek to clarity what study he was referring to.

Complainant	Doctor	GMC	Comment
			There is an issue here about whether this reply could mislead although it was subsequently corrected but only because it was picked up by the Complainant.
		Case Examiners accept that Prof L established a monitoring system to assess the incidence of immunosuppression in haemophiliac patients. They are satisfied that he acted in accordance with the standards of practice that were accepted at the time bearing in mind that practice rapidly evolved as more information became available.	It is clear that there are issues about what was appropriate at the time and it was not at all clear what was good practice in what was a clearly developing area. It would appear from the doctor's response that he was very much responding to the situation and made decisions at the time that he felt were appropriate. There are however clear contradictions between the complainant and the Dr as to the issues of consent, counselling, and keeping the patient informed. There is also an issue about the claim in relation to the AIDS Study which in my view are not matters that the CE should have resolved.

RECEIVED
24 JUN 2005

GRO-A

Edinburgh
GRO-A

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350 Regents Place
Euston Road
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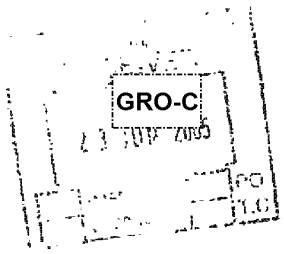

22 June 2005

Dear Sir/Madam

I am a 35 year old haemophiliac, I am infected with HIV/AIDS and Hepatitis C, I attend the Haemophilia and Thrombosis Centre, Edinburgh Royal Infirmary, and I am writing to complain about my past treatment by my consultant Professor CA Ludlum in relation to becoming infected with HIV/AIDS.

I received my medical records in 2003, unfortunately due to medical problems I have impaired sight and was unable to read them. Due to the incredible stigma surrounding HIV/AIDS and Hepatitis C I had not informed people that I had these fatal diseases. Therefore I was unable to let anyone read my notes for me, and it is only recently after having informed a friend that I have AIDS I have had someone to read them to me.

I have been informed that an AIDS Study was carried out on me from April 1983. I became positive for HTLV III when I was 14 years old (1984). I find it unacceptable that neither my parents or myself were informed by Prof Ludlum at this time, or indeed informed of the risks of contracting HIV/AIDS from Factor VIII prior to my infection when a named AIDS Study was carried out on me in 1983. Prof Ludlum did not inform me until January 1991 (almost six years) of my HIV/AIDS status during a routine appointment, where he proceeded to tell me that it had come to his attention that I was HIV positive. I received no counselling before being informed of my HIV status and as mentioned in my notes Prof Ludlum stated that "he had not really suspected *that he might be positive and he was therefore quite taken aback.*"

I have learnt that according to research papers published in medical journals that a total of 18 haemophiliacs contracted HIV/AIDS from the one batch giving Prof Ludlum "the opportunity to study a unique group of haemophiliacs" from onset. We are mentioned as "one of the most researched group in the world".

Along with others, I featured recently in a documentary by BBC Scotland, Frontline Scotland "Blood and Tears", and neither the BBC or myself have received satisfactory answers from Prof Ludlum to explain why I or my parents were not told I was HTLV III positive. I find this totally unacceptable.

Please find encloses copies of AIDS Studies and Prof Ludlum's comments re: being told of being HIV positive.

Due to my impaired sight, I ask that any correspondence regarding this complaint be done by telephone and confirmed by letter marked STRICTLY CONFIDENTIAL.

Yours sincerely

GRO-A

GRO-A

GRO-A

Copy: GMC, Edinburgh

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RECEIVED
12 AUG 2004

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Date: 02.08.05
Your Ref: EB/FPD/20005/1881
Our Ref: CAL/NS

CONFIDENTIAL
Emily Barry
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Dear Emily Barrie

I have received a copy of GRO-A 's letter dated 22nd June 2005 to the GMC. To aid clarity I shall respond to the issues raised in each paragraph individually.

Para 1
I have looked after GRO-A since 1980. I can confirm that he has severe haemophilia A and has been infected with HCV and HIV.

Para 2
He is visually impaired as a result of HIV-related brain damage, which he sustained sometime ago.

Para 3
GRO-A refers to an "AIDS Study", which was carried out from April 1983. The background to this research project was to investigate the immune status of haemophiliacs in Edinburgh who had been treated exclusively with factor VIII concentrate prepared from Scottish blood donors. The reason for undertaking this project was

that immune abnormalities had been reported in many haemophiliacs without AIDS in the United States. These might have been due to either a putative virus for AIDS, or a secondary immune "reaction" to the infusion of proteins in the factor VIII concentrates, or to another viral infection or hepatitis. As there were no known cases of AIDS in Scotland in 1983 I hypothesised that the chance of local haemophiliacs being infected by a putative AIDS virus was small. Subsequent studies when anti-HTLVIII testing became available proved that most patients were not infected until 1984. Our study demonstrated similar immune abnormalities in Edinburgh patients to those in US patients and this was therefore evidence that the immune changes in the North American patients may have been due to the clotting factor concentrates per se, and that they were not necessarily solely due to infection with a putative virus (Carr, Lancet, 1, 1431).

The above research project was part of a more extensive research programme into infections transmitted by clotting factor concentrate. For example I had earlier published a study, with colleagues on hepatitis B infection in haemophiliacs (Stirling et al J Clin Path, 1983, 36, 577). The "AIDS Study" referred to above used serum samples for measurement of total immunoglobulin levels, $\beta 2$ microglobulin and samples were also assessed for CD4 and CD8 lymphocyte counts. At this time in 1983 there was no blood test to detect the putative virus of AIDS and therefore no such investigation could be undertaken. This study was to try and grapple with the very serious emerging issues relating to immune dysfunction in haemophiliacs and their relationship, if any, to the few cases of AIDS, which had been diagnosed in haemophiliacs in North America.

In late 1984, when the first anti-HTLVIII antibody tests became available on a research basis in the UK, I sent some samples from some of my patients to Professor Richard Tedder at the Middlesex hospital. Mr GRO-A was found to be anti-HTLVIII positive and using stored serum samples it became apparent that he had probably seroconverted in spring of 1984. On reviewing his transfusion records and those of other patients it seems likely that he was infected by a batch of Scottish National Blood Transfusion Factor VIII concentrate, which he received. This was given to him for a knee haemarthrosis.

I was keen to ensure that patients and their families were kept informed about developments in respect of AIDS and haemophilia. In December 1984/January 1985 all patients and parents of children with haemophilia were therefore invited to an open meeting in Edinburgh to explain to patients what was known about AIDS in individuals with haemophilia. Mr and Mrs GRO-A (GRO-A 's parents) received an invitation to this meeting. At this meeting Professor Forbes (Director, Haemophilia & Thrombosis Centre in Glasgow) and I explained what was known about AIDS in those with haemophilia. There were very many uncertainties about the viral infection and especially about the clinical significance of a positive anti- HTLVIII antibody result.

Subsequent to this open meeting all haemophiliacs and parents were written to with an "Advice Sheet for Adult Patients and Families about Acquired Immune Deficiency" [copy enclosed - Appendix 1]. This sets out what was known at the beginning of 1985. An explicit invitation was made to anyone who wanted to have more information or to know the result of their anti-HTLVIII test to telephone to make an appointment. Mr and Mrs GRO-A did not take up this opportunity, although many other patients and parents did and I saw them all personally. GRO-A 's GP was also written to (Appendix 2).

As neither GRO-A nor his parents had enquired about his anti - HTLVIII status and because I knew him to be positive and thought he should know his status I saw him on 13th November 1986 and asked him whether he wished to know his anti-HTLVIII result (Appendix 3). He was adamant that he did not wish to know. I reiterated the advice given in our information sheet about the potential for sexual transmission if he did have the virus and that we were advising all haemophiliacs, irrespective of anti-HTLVIII status, to use condoms. Furthermore he was advised that blood spills should be cleaned using rubber gloves and dilute bleach. We were concerned that GRO-A did not wish to know his anti-HTLVIII status, but as a competent adult that was his legal right. Furthermore he told me that neither his parents nor his GP were to be informed. At this time he was also referred to Mrs Geraldine Brown, Social Worker with experience and expertise in haemophilia and AIDS issues.

Over the succeeding years we became increasingly uncomfortable that he did not know that he was anti-HTLVIII positive particularly as the

clinical significance of being positive became apparent. At this time he consented to serial HIV tests, but told us he did not want to know the result (clinical notes 20/03/89, Appendix 4). During this time he was working away from Edinburgh and we had less contact with him. In the mid 1980s there was no effective therapy for those infected with the virus, but when it became clear that prophylaxis against pneumocystis carinii pneumonia (PCP) was effective and Zidovudine was beneficial, we were keen to offer him these therapeutic options. You will see from the copy of his case notes (Appendix 4) that we had tried over some considerable period of time to arrange to see him and this was difficult to arrange, because we did not wish to alert his parents that there was an important matter to discuss with him. As he was working away from his home area his GP was not in touch with him. The record of my meeting with him to tell him on 15th January 1991 of his anti-HTLVIII status is recorded in his case notes (Appendix 4). You will note that I made arrangements on the same day for him to see Mrs Geraldine Brown.

In summary GRO-A 's parents were given the opportunity to know of their son's HTLVIII result, but chose not to enquire and GRO-A himself at the age of 16 gave clear instructions he did not wish to know.

Para 4

GRO-A refers to my research activities in relation to HIV and in particular the cohort of haemophiliacs who became infected by a single batch of factor VIII concentrate. The blood samples for these research studies were small (5-10ml) and were taken at the same time as blood for other routine blood tests to monitor their haemophilia and its treatment. The studies had full ethical approval from the Lothian Health Board Ethics Committee and were funded by the MRC, Scottish Office and the Wellcome Trust.

Para 5

The reasons he was not told his anti-HTLVIII result are explained above. Subsequent to the television programme on BBC Frontline Scotland "Blood and Tears" I had two meetings with GRO-A and his father (on Monday 27th June and Friday 1st July 2005), at which we had a wide ranging discussion about HIV and HCV infection in haemophiliacs and about events in relation to GRO-A during the 1980's. I felt we had a very useful discussion and I was able to

provide more information about the uncertainties during the evolution of the AIDS epidemic and the attempts to isolate and identify a putative virus. I was also able to outline in particular the uncertainties about the significance of a positive anti-HTLVIII test results. I hope as a result of these recent meetings that GRO-A and his father now have a clearer understanding of the complexities and difficulties in relation to HIV in the 1980s. GRO-A s letter to the GMC was written on 22nd June 2005, prior to our recent meetings. The first I learnt that he had written to the GMC was when I received your letter of 12th July 2005.

As viral infection transmission by blood products has been a major research interest since the early 1980's I have been very conversant with many of the legal, medical, social and ethical issues related to HIV including the difficulties of counselling patients and respecting their autonomy. I believe my actions during this time in relation to Mr GRO-A were reasonable response and in keeping with good medical and ethical practice at the time.

If you would like further information or clarification I would be keen to try to provide this.

Yours sincerely

GRO-C

Christopher A Ludlam
Professor of Haematology and Coagulation Medicine

RECEIVED
24 AUG 2005

GRO-A
EDINBRGH
GRO-A

Emily Barry
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Fitness to Practise Directorate
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22 August 2005

Your ref: EB/FPD/2005/1881

Dear Ms Barry

Further to your letter of 12 Aug, and Prof Ludlum's reply, I have the following points I wish to make

In 1983 when Prof Ludlum carried out an AIDS Study, he states that there "were no blood test to detect the putative virus of AIDS and therefore no such investigation could be undertaken", then why was this research entitled "AIDS Study", and why was this named patient study still being carried out on me at the end of November 1984 after I was known to be infected, also why did Prof Ludlum not inform my parents of the "very serious emerging issues relating to immune dysfunctions in haemophiliacs"?

Prof Ludlum states that my parents were invited to a meeting in which parents/patients were to be informed about developments, my parents have stated that they have no recollection of receiving this invitation, and therefore did not attend, at that time (1984/85) they did not know of the threat to haemophiliacs through contaminated blood products, they also have no recollection of receiving a copy the AIDS Advice Sheet. Did Prof Ludlum ensure my parents attended either of the meetings held, did he ask my parents if they received the Advice Sheet? Prof Ludlum also states that "an explicit invitation was made to anyone who wanted to have more information or to know the results of their anti-HTLVIII test to telephone to make an appointment". As my parents neither attended any meeting nor received the relevant information regarding AIDS, they did not know that they were to make an appointment to speak to Prof Ludlum. Was it not Prof Ludlum's' job to make an appointment to speak to my parents and ensure they knew all

about the risks to me and my family? As my mother was at that time injecting me with my Factor VIII was it not Prof Ludlum's duty to inform her of the potential risk to her own health/life? Was the onus not on Prof Ludlum to ask my parents either by a clear and precise letter or personally at a pre-arranged meeting if they understood the knowledge about HTLVIII at the time, and if they wanted to know my HTLVIII status.

It seems that the fact that neither of my parents enquired about my HTLVIII status for almost 2 years was not cause for concern to Prof Ludlum, as this matter was never mentioned again until 13 November 1986, when according to Prof Ludlum I was asked whether I "wished to know my anti-HTLVIII result" as you will note in my medical note of 13/11/86 I was asked if I wanted to know my "antibody result". In 1986 it was not explained to me exactly what an "antibody test" was, or what it was for, I assumed that it was just a routine test that was carried out on all haemophiliacs, as for being adamant that I did not wish to know, I would like to know where this information came from. The point about condoms and blood spills being cleaned using rubber gloves, I would have thought that if I or anyone else was at risk of any infection, I would have been supplied with rubber gloves and plastic aprons with my home treatment (according to AIDS Advice Sheet). As for me not wanting my parents or GP to know, I do not know where Prof Ludlum obtained this information from at this time as I see no record in my medical notes. As for being referred to Geraldine Brown, I knew her as being the Social Worker for haemophiliacs, not a counsellor for AIDS and I felt that I had no need for a Social Worker.

It is also stated that they became "increasingly uncomfortable" that I did not know I was HTLVIII positive, if this was the fact, why did it then take almost a further 3 years before being discussed again. By this time I knew that some haemophiliacs were HIV positive and in fact I had heard of haemophiliacs dying of AIDS, and mistakenly assumed that all HIV positive haemophiliacs had by now been informed, and thought that the tests I agreed to being taken were routine, that every haemophiliac received these tests, when I was asked if I wished to know the results, I said "Tell me if there is anything wrong" and since I was not informed of something being "wrong" I took it that my HIV tests were negative.

In 1991 when Prof Ludlum eventually told me of my HIV status, he notes that I had not really suspected that I might be positive and therefore seemed quite taken aback. I find it absolutely unbelievable that I was HIV positive for almost 6 years without being told, if, as Prof Ludlum states "I did not want to know" then why at what I took to be a regular appointment did he decide to inform me of my HIV, this he proceeded to do without any counselling before he went on to tell me that it had come to his attention that I was HIV positive, and that there was an ex-gratia payment going, and since I have only about 18 months to live he suggested I accept it and have a bit of fun.

In summary my parents did not know of the risks as they were always assured by Prof Ludlum and his staff that Scottish Factor VIII was the safest in the world, and as they did not attend either meeting in 1984 or 1985, did not

receive a copy of the AIDS Advice Sheet, and Prof Ludlum never ensured that they were at any of the meetings, or received the advice sheet, or mentioned the risks to them personally, they did not know that there was a possibility that I could have been infected. Prof Ludlum should have followed the Council of Europe Recommendation No R(83)8 which states "- to inform attending physicians and selected recipients, such as haemophiliacs, of the potential health hazards of haemotherapy and the possibilities of minimising these risks; and informed my parents of the possible risks to Factor VIII to enable them to decide on any future treatment I received to possibly prevent my infection, (according to Prof Ludlum and his retrospective tests I was at that time [June 1983] HTLVIII negative). I also think that when I tested positive in 1984, it was Prof Ludlum responsibility to inform my parents as soon as possible to help prevent the spread of AIDS throughout my family, as already stated in 1984 my mother was injecting me with Factor VIII, and it seems, risking her own life.

Just because the studies had full ethical approval from the Lothian Health Board Ethics Committee and were funded by the MRC, Scottish Office and the Wellcome Trust, I find that a named patient AIDS Study on me without my knowledge or consent throughout 1983, 1984 and for an unknown amount of years after is totally unacceptable.

My father and I have had two meetings with Prof Ludlum since the BBC Frontline Scotland "Blood and Tears" only for Prof Ludlum to tell me that he "gave me at least 6 good years" before informing me of my AIDS status and I found Prof Ludlum to be rather evasive with answers to any of my questions.

If as Prof Ludlum says "I believe my actions ... were reasonable response and in keeping with good medical and ethical practice at the time" why was the advise of Dr J Craske (29.10.84) not followed when he stated the moral and ethical problems of not informing patients (a copy enclosed), or the Haemophilia Centre Directors Organisation AIDS Advisory Document (Dec 1984) which states "Ab positive people should be informed, reassured and counselled, regarding transmission to spouses etc., " (a copy enclosed).

I still do not understand why the haemophiliacs in Edinburgh are a "unique group" and why we have become one of the most researched group in the world.

Yours sincerely

GRO-A

GRO-A

GRO-A

Public Health Laboratory Service

Public Health Laboratory
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PROTEIN FRACTIONATION CENTRE
Received 21 NOV 1984

23rd October 1984

Our ref JC/PH File No: Your ref AIDS

SEO LANDON DR G.J. PERRY

Dear

Factor VIII batch HL 3186: Possible risk of infection with Human T-cell lymphotropic virus type 3 (HTLV-3) with subsequent development of the acquired immune deficiency syndrome (AIDS)

You will have already heard that one of the donors who contributed to the plasma pool used in the manufacture of the batch of factor VIII is a practicing homosexual, and was recently admitted to hospital with clinical features consistent with the diagnosis of AIDS. I am afraid that this has now been confirmed. The patient has developed Pneumocystis carinii pneumonia and two specimens of serum collected in September and October 1984 have been found to be positive for antibody to HTLV-3 by competitive radioimmunoassay (RIA).

I have responsibility for the epidemiological follow-up of recipients of this batch to confirm whether any hazard exists, and to assist in the investigation of patients where required. I hope that we can obtain the maximum information from this unfortunate incident, and devise methods for the prevention of the disease. We also need to confirm the association of HTLV-3 infection and transfusion of factor VIII concentrate.

From studies already underway on recipients of batches of factor VIII transfused to the two haemophilia A patients who contracted AIDS in 1983, we have already provisionally identified one batch of factor VIII which was transfused to one of the AIDS patients and was associated with seroconvertion to HTLV-3 antibody positive in seven out of thirteen recipients . One of the patients who acquired HTLV-3 infection subsequently developed AIDS, a second developed thrombocytopenia, and the other five have remained symptomless. There was no correlation between the number of bottles of factor VIII each patient received and the chance of contracting HTLV-3 infection. The most likely explanation for this is that only a small proportion of the total bottles of the batch were contaminated with HTLV-3.

contd/...

Risk to the patient

From the forgoing discussion you will see that it is difficult to be certa of the precise risk of any recipient contracting AIDS, but the following facts may help you to appreciate the position.

1) Only a proportion of the patients transfused with an infected batch are likely to contract HTLV-3 infection.

2) Some patients who have received commercial factor VIII since 1.1.80 will already have contracted HTLV-3 infection from other infected batches.

3) The proportion of patients who are infected with HTLV-3 who eventually contract AIDS is unknown, but as serum from 34% of symptomless haemophiliacs are positive for HTLV-3 antibody, it is likely that a significant proportion of patients will remain in good health. So far 21 patients are known to me who have clinical features of AIDS (4) or the AIDS related complex. It is likely that the proportion of patients who contract HTLV-3 infection who contract AIDS will be of the order of 1/100 - 1/500.

4) The long term prognosis for patients with HTLV-3 infection is unknown. The incubation period of AIDS based on projection of the epidemic curve at C.D.C. Atlanta is from 9 months to 6 years, with a mean of 4 years.

5) There is evidence that HTLV-3 infection can be transmitted by sexual contact. Therefore some sexual partners of recipients of factor VIII contaminated with HTLV-3 may be at risk.

6) We cannot yet distinguish those patients who are likely to transmit infection, or who are likely to contract AIDS by means of laboratory tests.

Methods of Investigation

With the above facts in mind, I propose the following strategy.

a) Identify all patients who have received factor VIII batch HL3186
If a serum specimen taken before the date of transfusion of factor VIII HL 3186 is available, then this should be tested for HTLV-3 antibody. This will identify persons already exposed to infection. If no specimen is available then a specimen of serum (2.0ml) should be collected as soon as possible to exclude the possibility of prior HTLV-3 infection.

b) Follow up of patients
Patients identified should be followed up at least at four monthly intervals for 6 years. Further review should be undertaken if a patient becomes ill to exclude the possibility of an AIDS related illness. A control patient who has not received batch number HL3186 should be selected for each index patient. These should be matched as far as possible for age, severity of disease and transfusion history.

Returns for each patient can be made after each clinic visit by filling in a case record form (a specimen copy enclosed) and returning it to me at Manchester PHL together with a specimen of serum (2.0ml) for HTLV-3 antibodies.

cont'd/...

Follow up should be carried out even if a patient is found to b positive for HTLV-3 antibody in the first specimen tested. This will assess whether exposure to more than one batch of factor VIII contaminated with HTLV-3 have any effect on the chance of contracting AIDS.

c) Four monthly review Forms (A/1) should be completed and sent to Miss Spooner at Oxford. This history and medical examinatior should be designed to exclude AIDS related disease. Laboratory investigations should include haemoglobulin, E.S.R., white count, absolute lymphocytic count and differential, platelet count, and total serum IgG, IgA and IgM estimations. Blood should be taken for hepatitis B, and other viral antibodies as appropriate. Two mls of serum should be retained for HTLV-3 antibody tests and sent to Dr. Craske at Manchester PHL.

The follow-up may be carried out using the alternative of two different strategies:-

i) If the patient has been informed of the risk associated with this contaminated batch of factor VIII, testing could be carried out on each specimen as it is obtained at each four monthly review. In addition, it would be wise to warn the index patient that his spouse may be at risk from contracting HTLV-3 infection as a result of any sexual contact. An antibody test for HTLV-3 antibodies can be offered at the time of follow-up of the index case for the contact. Alternatively they can be referred to their own doctor and follow up can be arranged through him as thought necessary by the Haemophilia Centre Director.

ii) An alternative strategy would be not to tell the patient of the risks involved but to observe him at regular clinical review four monthly, to collect serum specimens for HTLV-3 antibody examination and send them to me at Manchester. These would not be examined until two years after the initial exposure, or until the patient develops clinical features suggestive of AIDS, or testing is requested by the Haemophilia Centre Director.

The ethical problems involved in these two alternative methods of follow up are discussed in an appendix at the end of this letter.

Further investigations can be carried out as local facilities and these could include virus isolation specimens of faeces, urine and a throat swab for virus isolation. Assessment of immune response by examination of T-cell subsets, the response of T-cells in vitro to transformation using mitogens and the response to intradermal injection of skin test antigens as an assessment of cell mediated immunity.

d) Investigation of spouses This will be at the discretion of the Haemophilia Centre Director, and will depend upon whether it is decided to inform the index patient of the possibility that the batch of factor VIII was contaminated with HTLV-3 virus. (see page 4 "other preventative measures")

Should the patient be told?

Ideally I think he should, but this will depend on many factors, including the amount of anxiety concerning AIDS there is already present at the Centre, and the degree to which the patient is capable of understanding the situation. An alternative might be to inform the patient's spouse or other close relative, as is done when patients develop malignant diseases. This will be at the discretion of the local Haemophilia Centre Director.

Other preventative measures

1) When a patient is told of the risk of exposure to HTLV-3 infection he should also be warned that his sexual partner might also be exposed to infect The use of 'barrier' forms of contraception, e.g., a sheath should be recommende It would be advisable to offer the sexual partner and any other members of the family tests for HTLV-3 antibody where appropriate. Regular follow up either by the Haemophilia Centre Director or by the relatives G.P. should be encouragec The G.P. should be informed of the situation subject to the patient's consent.

2) Preliminary information suggests that HTLV-3 is readily inactivated by heat at $60^{o}C$. It is possible that a heat treated factor VIII will be available before long.

J. Craske
23.10.84.

Appendix

ETHICAL PROBLEMS ASSOCIATED WITH HTLV-3 INFECTION IN HAEMOPHILIACS

The accompanying letter details a protocol with 2 alternative strategies for the follow up of patients who have received a batch of factor VIII contaminated with plasma collected from a donor who subsequently is shown to have AIDS or to have acquired HTLV-3 infection.

1) Informing the patient and his family of the risks This allows information of the development of HTLV-3 infection to be available to the caring physician as soon as possible, and thereby to identify and treat all complications as they arise where treatment is available.

It also allows the patients spouse to be informed of the risk of contracting infection through sexual intercourse, for advise to be given as early as possible after the patient has been exposed to HTLV-3 infection. Such measures as using 'barrier' types of contraception, e.g., a sheath may lessen the chances of transmission.

It also maintains a trusting relationship between the physician and his patient which is essential if difficult problems arising from HTLV-3 infection are to be surmounted.

2) Restricted follow-up In this strategy the identification of patients who contract HTLV-3 infection will not be made for 2 years or at the request of the Centre Director. It will be impossible to warn spouses and advise preventative measures to limit the risk of transmission of infection, since it will not be known when the index patient first contracts HTLV-3 infection. If a patient develops AIDS related illness it will be too late, as the period of maximum infectivity will already have passed.

Any benefit or peace of mind for the patient will be temporary if any other persons exposed develops AIDS. If the patient finds out that he has had this batch, then the trust of the patient will be lost, and the Haemophilia Centre Director placed in a delicate situation.

It is quite likely that any patient who has received commercial factor VIII since 1980, and thus had already possibly been exposed to HTLV-3 infection will not have a greatly increased chance of contracting AIDS, compared with a patient who has received only NHS concentrate until now.

In my view option (1) is the only one tenable on moral and ethical grounds.

J. Craske
29.10.84.

HAEMOPHILIA CENTRE DIRECTORS ORGANISATION

AIDS Advisory Document

At a recent meeting of Reference Centre Directors the following observations were discussed and recommendations made in consultation with Drs. Richard Lane, John Cash, Harold Gunson, Phillip Mortimer, Richard Tedder, John Craske and others.

Background

1. In U.S.A. There are over 6,000 cases of AIDS including 52 haemophiliacs.

   In U.K. There have been 102 cases with three reported haemophiliacs. No doubt other cases are developing in the haemophilic population.

2. Tests for HTLV III antibody are available for haemophiliacs via:
   Dr. Phillip Mortimer
   Central Public Health Laboratory Service
   175 Colindale Avenue
   Colindale, London NW9 5HT

   Dr. Richard Tedder,
   Department of Virology
   School of Pathology,
   The Middlesex Hospital Medical School,
   Riding House Street,
   London W1P 7LD.

   Antibody positivity probably correlates with exposure to imported concentrates but there have been two notable recent episodes concerning U.K. concentrates.

3. Antibody tests indicate prior infection but do not imply immunity as antibodies may not be neutralising. Infective carriers can be antibody positive and there may also be a variable period of antigen positivity before seroconversion occurs.

   Antibody positive persons should therefore be considered at risk of transmitting or developing AIDS but antibody negativity does not exclude infectivity.

General Precautions

Donors

(a) the BTS is making increased efforts to ensure exclusion of donors at risk by questionnaires or leaflets or both.

(b) HTLV antibody tests either commercial or home grown should become available during 1985 but cannot be instantaneously implemented. Equipment, space and staff may be needed at Regional Transfusion Centres.

It seems probable that HTLV III has been incorporated into at least one BPL and one Scottish batch of factor VIII. Recipients are being followed up.

Concentrates

Factor VIII. Evidence is accruing that HTLV is heat labile but the data from "spiked" concentrate is entirely related to U.S. concentrates and is minimal. It seems that in concentrates HTLV III is inactivated by dry heat at 68°C for 24 hours. It is unlikely that this process completely inactivates Non A Non B hepatitis . Loss of yield is 15% for dry heat. Wet heat with stabilisers is probably more effective but evidence is lacking and loss of yield is up to 50%. Of current products heat treated Koate HT and Factorate HT are dry heated and sell at 12p a unit. Travenol Hemofil T is dry heat treated and sells at 15p a unit. Alpha Profilate (heated) is wet-treated (14p a unit). Immuno also have heated preparations.

Factor IX Profilnine (heated) (Alpha), heated Konyne (Cutter) and Immuno (heated Prothromplex) are available at prices up to 20p a unit but the effects on efficacy and thrombogenicity are unpublished. Since AIDS and laboratory changes seem (controversially) to be less common in Christmas disease than haemophilia A no firm recommendation can be given on heated factor IX.

Heated Feiba is also available from Immuno at 30p a unit but is probably not cost-effective.

BPL Factor VIII BPL can dry heat 30% of its output available from January 30th, 1985 and the rest in two months time when two more ovens are installed to supplement the existing one. The process produces an acceptablein vitro product but extensive clinical trials have not been undertaken.

Edinburgh From now on all Scottish factor VIII will be dry heated to supply Scotland and N. Ireland.

Options in probable decreasing order of safety from AIDS for Haemophilia A

1. Heated U.K. concentrate (note: still NANB hepatitis risk)
2. Single donor cryo. or FFP
3. Heated imported conc. (note: still NANB hepatitis risk)
4. Unheated U.K. conc.
5. Unheated imported conc - almost certain to be contaminated.

Note: Heated concentrates may still transmit hepatitis. Some of the distinctions e.g. between 3 and 4 are debatable and the long-term effects (e.g. immunogenicty) of using heated plasma proteins in this way are unknown. Even pasteurised albumin is not given as frequently to individuals as will be factor VIII.

RECOMMENDATIONS

1. Concentrate is still needed; bleeding is the commonest cause of disability and death.

2. Use DDAVP in mild Haemophilia A and vWd if possible.

3) For Haemophilia A needing blood products

(a) "Virgin" Patients those not previously exposed to concentrate, and childre use cryo or heated NHS factor VIII (if available).

(b) Severe and Moderate haemophiliacs previously treated with factor VIII use heat treated NHS factor VIII, if available or heat treated US commercial.

4) Haemophilia B

(a) Mild Christmas Fresh frozen plasma if possible (otherwise NHS Factor IX.

(b) "Virgin" Patients and those not previously exposed to concentrate use fresh frozen plasma (or NHS factor IX concentrate if essential)

(c) Severe and Moderate Christmas Disease previously exposed to factor IX concentrate continue to use NHS factor IX.

In individual patients there may need to be a choice. In general heated concentrate appears to be the recommendation of virologists consulted but individual Directors may wish to make up their own minds. This is particularly true of unheated NHS material. The evidence that heated U.S. factor VIII is safer than unheated NHS is debatable and some Directors may wish to continue using unheated NHS material until all supplies are heated. This is valid for carefully selected patients but must be on individual decision based on the assumption that some batches of NHS materials will be contaminated with HTLVIII. The argument that HTLV III positive patients have already been infected and could receive unheated American material is probably scientifically true but this material would pose an additional risk to staff and families and its continued use would pose logistic problems.

Supplies

It seems that as from January 30th, 1985 a limited supply of BPL heat treated British factor VIII will be available. Preference will be given (a) to treat patients defined in recommendation 3a above and possibly (b) to those willing to participate in clinical trials.

NOTES

1. The Blood Products Laboratory cannot take back for reissue unused unheated concentrate. Do not ask your BTS to order more of this than you are willing to use because this would prejudice supplies of heated material later in the year.

2. If the bill for heated commercial concentrate is heavy at first it can be put to your Authority that increased supplies of heat treated BPL material could be available later in the Summer as stockpiled unheated material at BPL is heated.

3. Funding will need to be negotiated at local level although strong representations are being made to DHSS for central funding if needed. Please inform the Chairman (Prof A.L. Bloom) and Secretary (Dr. C.R Rizza) if you are experiencing difficulties. They cannot promise individual help but the information will be useful.

4. The need for elective surgery etc., should be assessed in the light of supplies of heated concentrate.

ANTIBODY TESTING

It is recommended that patients be HTLV III Ab tested.

Test should be repeated if positive.

Ab positive people should be informed, reassured and counselled regarding transmission to spouses etc., including the possible use of barrier contraception. This seems to be the most practical method available. Facilities are only available at present for HTLV III Ab studies on contacts as part of organised projects. Please note that sample bottles of serum must be leak-proof. The Laboratory Directors would prefer to liase with a small number of haemophilia doctors. Thus where possible samples should be chanelled through Reference Centres or the nearest large Haemophilia Centre from where suitable sample bottles may be obtained.

ORDINARY LABORATORY TESTING

Samples from patients with AIDS or PGL will be subject to the regulations promulgated by the AdvisoryCommittee on Dangerous Pathogens. Although very restrictive draft instructions have been circulated in an unauthorised fashion in various quarters we were assured that the definitive document is less so. Careful safety auditing of laboratory procedures is recommended. The recommendations apply to AIDS and high suspect patients. The rules for samples from healthy HTLV III Ab positive patients have not been specifically addressed but presumably these are also potentially dangerous.

CLINICAL

Plastic aprons could be used for preparing and administering all treatments (including home treatment). Home treatment procedures should be revieved. Use of butterfly needles may be safer than ordinary syringe and needle as the risk of 'walk on' injury is reduced.

In the wards patients with AIDS or high risk thereof should be nursed in single rooms. Gloves and aprons should be worn by nurses when carrying out practical procedures. In general hepatitis B-like precautions should be taken. HTLV III Ab pos. patients should be dealt with for Dental care as for hep. BAg pos. In case of needle injuries virological advice from PHLS at Colindale should be obtained after applying the usual first aid measures. Aerosols and casual contacts do not constitute a risk and there is no need to isolate routinely HTLV III Ab positive patients.

STAFF

HTLV III Ab testing of staff is not recommended routinely but it could be useful to have organised studies in certain larger centres.

These recommendations will obviously need to be modified in the light of rapidly changing experience.

December 14th, 1984

COUNCIL OF EUROPE
COMMITTEE OF MINISTERS

RECOMMENDATION No. R (83) 8

OF THE COMMITTEE OF MINISTERS TO MEMBER STATES

ON PREVENTING THE POSSIBLE TRANSMISSION OF ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) FROM AFFECTED BLOOD DONORS TO PATIENTS RECEIVING BLOOD OR BLOOD PRODUCTS

(Adopted by the Committee of Ministers on 23 June 1983 at the 361st meeting of the Ministers' Deputies)

The Committee of Ministers, under the terms of Article 15.*b* of the Statute of the Council of Europe,

Considering that the aim of the Council of Europe is to achieve greater unity between its members and that this aim may be pursued, *inter alia*, by the adoption of common regulations in the health field ;

Considering the growing importance of a new and severe health hazard, Acquired Immune Deficiency Syndrome (AIDS), that may be caused by an infectious agent transmissible by blood and blood products ;

Recalling the basic principles to minimise the hazard of transmissible infectious diseases by blood or blood products drawn up in the context of the work of the Committee of Experts on Blood Transfusion and Immunohaematology :

1. to expose the recipient to a minimum number of donations of blood when the transfusion is of cellular and coagulation factor products,

2. to achieve national self-sufficiency in the production of coagulation factor products from voluntary, non-remunerated donors,

3. to avoid the importation of blood plasma and coagulation factor products from countries with risk populations and from paid donors ;

Recalling Recommendation No. R (80) 5 concerning blood products for the treatment of haemophiliacs, with special reference to Section II of the operative part, and Recommendation No. R (81) 14 on preventing the transmission of infectious diseases in the international transfer of blood, its components and derivatives ;

Recognising the necessity to provide pertinent information to blood donors, attending physicians and selected recipient groups in order to avoid, as far as possible, donations by persons in risk groups, without inappropriate discrimination and emotive over-reaction amongst recipients,

Recommends the governments of member states :

I. to take all necessary steps and measures with respect to the Acquired Immune Deficiency Syndrome and in particular :

— to avoid wherever possible the use of coagulation factor products prepared from large plasma pools ; this is especially important for those countries where self-sufficiency in the production of such products has not yet been achieved ;

— to inform attending physicians and selected recipients, such as haemophiliacs, of the potential health hazards of haemotherapy and the possibilities of minimising these risks ;

— to provide all blood donors with information on the Acquired Immune Deficiency Syndrome so that those in risk groups will refrain from donating (an example of an information leaflet for donors is appended) ;

II. to pursue rapid and full implementation of Recommendations No. R (80) 5 and No. R (81) 14.

Appendix to Recommendation No. R (83) 8

The present information leaflet for donors has been prepared and is used by the American Red Cross ; it is given as an example for the convenience of National Blood Transfusion Services wishing to draw up their own information leaflet

An important message to all blood donors

This information is distributed to all potential blood donors to help prevent the spreading of certain illnesses from donors to patients by blood transfusions.

Please read this statement, and if you think that there is a risk that your blood could cause illness in a patient who might receive it, please refrain from donating blood at this time.

What are these illnesses ?

Some persons may feel in excellent health but have viruses or other infectious agents in their blood that could cause illness in persons receiving a transfusion of their blood. If you think any of the following information pertains to you, please do not donate blood today :

1. *Acquired Immune Deficiency Syndrome (AIDS)*

This newly described illness of unknown cause is believed to be spread by intimate personal contact and possibly by blood transfusion. Persons with AIDS have reduced defences against disease and as a result may develop infections such as pneumonia, or other serious illnesses. At this time there is no laboratory test to detect all persons with AIDS. Therefore we must rely on blood donors' health histories to exclude individuals whose blood might transmit AIDS to patients who will receive that blood.

The Office of Biologics of the Food and Drug Administration has identified groups at an increased risk of developing AIDS. These groups are :

— persons with symptoms and signs suggestive of AIDS. These include severe night sweats, unexplained fevers, unexpected weight loss, lymphadenopathy (swollen glands) or Kaposi's Sarcoma (a rare cancer) ;

— sexually active homosexual or bisexual men with multiple partners ;

— recent Haitian entrants into the United States ;

— present or past abusers of intravenous drugs ;

— sexual partners of persons at increased risk of AIDS.

2. *Hepatitis*

Persons with a past history of viral hepatitis are deferred permanently. Intimate contact with someone suffering from viral hepatitis requires deferral for six months.

3. *Syphilis*

Potential blood donors with active syphilis are deferred.

4. *Malaria*

Potential blood donors who have visited countries where malaria exists are deferred for six months after leaving the malarious area or, if anti-malarial drugs were taken, for three years after cessation of this drug therapy. Natives from countries where malaria exists are deferred for three years ; Haiti is one of these countries.

What should I do ?

If you believe that you may be carrying one of the above-mentioned illnesses, or if you are an individual in a group at increased risk of developing AIDS, we ask that you refrain from donating blood at this time. You may leave now without providing an explanation. Or, if you prefer, you may proceed to be deferred confidentially, without further questioning, by the health history interviewer.

If you would like additional information, Red Cross nurses and physicians will be pleased to answer any questions you may have.

I.19 769

GRO-A

EDINBURGH

GRO-A

Emily Barry
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3 October 2005

Ref: EB/FPD/2005/1881

Dear Emily Barrie

Further to my correspondence of 22 August 2005 I wish to enclose a copy of correspondence in relation to MRC funding and Ethics Committee approval for the "Named Patient AIDS Study" carried out on me from April 1983

I feel that Prof Ludlum has been misleading in his statement of 2 August 2005 where he states that his "research activities in relation to HIV and in particular the cohort of haemophiliacs ... The studies had full ethical approval from the Lothian Health Board Ethics Committee and were funded by the MRC, Scottish Office and the Wellcome Trust", as the enclosed correspondence shows that ethical approval or funding was not given until a much later date, this was given for a follow-up study and not the actual "Named Patient AIDS Study" carried out on me in 1983.

Yours sincerely

GRO-A

GRO-A

Enc: Correspondence from Nicola Wiseman (MRC)

Ms C Leckie MSP

GRO-C

Scotland

22 September 2005

Dear Ms Leckie

Thank you for your letter of 5 September to Dr Joan Box about the "Edinburgh Haemophilia Cohort" in which you requested documents relating to the MRC-funded research proposal from Professor Ludlam.

The MRC did not fund the original study which you mentioned but did fund a follow-up study which aimed to continue and substantially extend a longitudinal study, started in 1983, of the immune function of a cohort of people with haemophilia. It is not clear to us which documents you might require, but I have enclosed a copy of the abstract of the research, as submitted to us as part of Professor (then Dr) Ludlam's application for funding.

We do not have a record of the Ethical Committee deliberations, and nor would we expect to. I suggest you contact the appropriate Ethics Committee - i.e. the Lothian Health Board. However, we do have a letter confirming that the MRC-funded work did have Ethics Committee approval; a copy of this letter is enclosed.

For details of published research papers, I recommend you contact Professor Ludlam directly as we do not hold copies of these. Alternatively, details of current published medical research are available on the web at http://www.ncbi.nlm.nih.gov/entrez/query.fcgi or at http://scholar.google.com/.

Kind regards

GRO-C

Nicola Wiseman
Knowledge Management Group

cc Professor Ludlam

Encs

Medical Research Council 20 Park Crescent London W1B 1AL
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tel: (direct line) GRO-C direct fax: GRO-C email: GRO-C

Title of Project

Clinical and Immunological Study of Haemophiliacs treated exclusively with NHS Factor VIII/IX Concentrates

Abstract of research

This application seeks support to continue and substantially extend a longitudinal study, started in 1983, of the immune function of a cohort of haemophiliacs. During the study period to date a single batch of NHS factor VIII introduced the HTLVIII virus into this population of previously unexposed haemophiliacs. The initial investigation of this unique and serious transfusion reaction revealed important data concerning the risk of developing anti-HTLVIII and the relationship to the pre-existing immune status of the patients (9). We wish to continue to monitor, in detail , the clinical condition of the patients as well as their in vivo and in vitro immune function. The project will also include studies to attempt to indentify the components (s) in factor VIII/IX concentrates responsible for immunomodulation. It is also proposed to seek evidence of the HTLVIII infection in the patients who received the infected factor VIII but who remained anti-HTLVIII negative as well as those who sero-converted.

Your ref
Our ref MCO/85
calling/ask for Mr. Redmond
Date [illegible]

Astley Ainslie Hospital
Grange Loan
Edinburgh EH9 2HL
Tel. 031-447-3399

Dr. C. A. Ludlam,
Department of Haematology,
Royal Infirmary of Edinburgh,
Lauriston Place,
Edinburgh,
EH3 9YW

Dear Dr. Ludlam,

CLINICAL AND IMMUNOLOGICAL STUDY OF HAEMOPHILIACS TREATED EXCLUSIVELY WITH NHS FACTOR VIII/IX CONCENTRATE

With reference to your application for ethical approval of the above project, I am pleased to advise you that this has been granted by the Ethics of Medical Research Sub-Committee for Medicine and Clinical Oncology.

Yours sincerely,

GRO-C

G. M. Redmond,
Secretary,
Ethics of Medical Research Sub-Committee
(Medicine and Clinical Oncology)

Guy's and St Thomas' NHS
NHS Foundation Trust

HAEMATOLOGY DEPARTMENT
4th Floor, Thomas Guy House

GRO-C (Direct)
GRO-C (Fax)

email: GRO-C

Guy's Hospital
St Thomas Street
London SE1 9RT

Tel: 020 7188 7188

9th January 2006

Professor C.A. Ludlam,
Department of Haematology,
Royal Infirmary,
51 Little France Crescent,
Edinburgh
EH16 4SA
Fax: GRO-C

RECEIVE

.....

Dear Professor Ludlam,

You have asked me if I remember the laboratory study we undertook on the Edinburgh Haemophiliacs in 1983, while I was a Junior Haematology Registrar at the Edinburgh Royal Infirmary. I understand a complaint has been made to the GMC about a blood test which was taken in 1983, as part of this study. Specifically you have asked if I remember what consent I obtained at the time of taking these blood samples.

The study was to look at the immune profile, as assessed simply by the peripheral blood lymphocyte CD4/CD8 ratios, in the Edinburgh Haemophiliacs who had not been exposed to factor VIII manufactured from plasma sourced in the USA. This was the time when AIDS had just been recognised in American homosexuals and in some haemophiliacs in the US. Our hypothesis was that the haemophiliacs treated in Edinburgh would not have been exposed to the then putative AIDS agent, because they had always been exclusively treated with FVIII prepared by the Scottish Blood Transfusion Service, and so would not show the immune dysregulation being described in those exposed to the American product.

I was your registrar at the time and, as part of my routine clinical duties, was responsible for taking most of the blood samples from the patients under our care.

In truth, I do not remember the specific discussions I had with the patients about this particular study; probably because we did not see it as being particularly contentious at the time. It was of course before formal written consent was the norm. However there was a culture of openness with this patient group, engendered by yourself and your predecessor Howard Davies. It was practice to store down plasma from each of the haemophiliacs at intervals and I well remember saying to the patients I bled, "an extra tube for Dr Ludlam's store today", or some such.

You have retrieved from the files some of the blood request forms which I filled in for the samples related to this particular immune profile study, and these have "AIDS Study" written prominently upon them. This suggests openness about the reason for taking the blood, as I would have tended to write the forms as I talked to the patients in the clinic or ward.

31 January 2006

In reply please quote: EB/FPD/2005/1881

General Medical Council

GRO-A

GRO-A

Edinburgh

GRO-A

5th Floor, St. James's Buildings
79 Oxford Street, Manchester M1 6FQ

Telephone: 0845 357 8001
Facsimile: 0845 357 9001
Email: gmc@gmc-uk.org
www.gmc-uk.org

Dear GRO-A

I refer to our previous correspondence regarding your complaint about Professor Ludlam.

We have now completed our enquiries into your complaint and both a medical and a non-medical case examiner have considered the case. Case examiners are senior GMC staff, appointed to make decisions on cases.

The case examiners have now reviewed your complaint and the information we have obtained during our investigation. They have decided to conclude your complaint with no further action.

The Case Examiners said;

"It is always difficult to consider cases where there has been considerable passage of time. Standards of practice change, and what is valid best practice today may contrast sharply with established practise decades ago. The situation with regards to HIVAIDS has evolved considerably since the 1980's. The Case Examiners accept that Professor Ludlum established a monitoring system to assess the incidence of immunosuppression in haemophiliac patients in response to events in Scotland, and that, once some of the patients were identified as being HIV positive, he was in a difficult position. They are satisfied that he acted in accordance with the standards of practice that were accepted at the time, bearing in mind that practice rapidly evolved as more information became available. As a consequence, the Case Examiners do not feel that there is a realistic prospect of establishing that Professor Ludlum's fitness to practise is impaired."

I hope that I have been able to explain clearly our reasons for concluding this case. Please contact me on my direct dial number if you have any questions.

CLOSURE LETTERS DID HAVE PD WRITTEN ON THEM WHEN THEY WENT OUT.

Yours sincerely

GRO-C

Emily Barry
Investigation Officer
Fitness to Practise Directorate
Direct Dial: GRO-C
Fax No: GRO-C
Email: GRO-C

GRO-A

Edinburgh

GRO-A

9th March 2005

Emily Barry
Fitness to Practise Directorate
General Medical Council
5th Floor
St James's Buildings
79 Oxford Street
Manchester
M1 6FQ

Dear Ms Barry,

I was disappointed to hear that the case examiners have decided to conclude my complaint with no further action. Your letter of 31st January 2006 is flatly inadequate, not answering the initial question in my letter dated 22nd June 2005; namely, why I was not informed that I had contracted HIV from the infected blood products administered whilst under the care of Professor Ludlam.

I, therefore, insist on having this question satisfactorily answered. I recently acquired over thirty relevant articles published by Ludlam and his cohorts in the Lancet. The dates for these publications start from 3rd August 1985; it seems incomprehensible to me that this information was published worldwide, yet I was not informed either of the diagnosis or its implications for many years afterwards.

As stated in my letter dated 22nd August 2005, the only attempts to inform me were doctors asking me if I wanted to know my "antibody result". As I did not understand what an antibody was at the age of fourteen, let alone the implications of it, I do not consider that I was giving informed consent. I feel that Professor Ludlam should have attempted to ascertain my levels of understanding before dismissing my response; also, at the age of fourteen or fifteen, my parents should have been informed. I feel it is inconceivable that ***any*** child would be able to comprehend the implications of a diagnosis of HIV.

If you are still unable, or perhaps reluctant, to answer this question I would like to know what the procedure for an appeal is, and if there is an ombudsman or other form of independent body who could look into your findings.

I look forward to hearing from you shortly.

GRO-A

GRO-A

Ms Juliet Oliver
The General Medical Council
Regent's Place
350 Euston Road
London NW1 3JN

18 April 2008

Dear Ms. Oliver,

Inquiry into Contaminated Blood

When we corresponded last July (your ref: JS/JO/Rule 12/GRO-A v Ludlam) you kindly said that if the Inquiry found it necessary to request the assistance of the GMC, you would do your best to provide that assistance.

Certain questions have arisen in the course of the evidence, on which we would be most grateful for your help. If someone from the GMC were prepared to give evidence publicly, that would be our preference, but if that would cause a difficulty, we would be grateful for a reply either by post, or an interview in private.

I set out the questions below.

1. Does the GMC lay down rules of professional conduct for general practitioners, or are they in the form of guidance?
2. Is there statutory provision for the rules, or are there professional sanctions for an infringement?
3. Have there been any changes between the situation in the mid 1970s and the present day?
4. Did any such rules or guidance apply to the testing of patients for the purposes of research. If a patient was to be subjected to a test, was the consent of the patient required, when the test was for the purpose either of treatment, or of research?
5. One witness stated : "We asked the GMC to investigate the matter of testing without permission along with the cases of several other patients. The GMC concluded that it wasn't that what we said hadn't happened but because the doctors had failed to document matters like pre and post

test counselling and written consent they couldn't reach a conclusion through lack of information in the medical records, so doctors had to be given the benefit of the doubt." We appreciate that complaints would be treated confidentially, and we are not concerned to investigate the conduct of individual doctors, but we may need to comment on the existence of the practice in the period between the mid 1970s and the mid 1990s, and we would be most grateful for any light which you could shed on the matter.

With best wishes,

Yours sincerely,

GRO-C

Anna's draft response

Response to Queries relating to the Inquiry into Contaminated Blood

1. Does the GMC lay down rules of professional conduct for general practitioners, or are they in the form of guidance?

The General Medical Council ("The Council") does not lay down rules of professional conduct but sets standards for doctors in the form of guidance in a document called 'Good Medical Practice' which sets out the principles and values on which good medical practice is founded. The guidance applies to all doctors and not just general practitioners.

2. Is there statutory provision for the rules, or are there professional sanctions for an infringement?

'Good Medical Practice' is not a code of practice set up under statute but s.35 of the Medical Act 1983 gives the Council power to give advice to doctors about standards of conduct and medical ethics.

> *S.35. General Council's power to advise on conduct, performance or ethics*
>
> *The powers of the General Council shall include the power to provide, in such manner as the Council think fit, advice for members of the medical profession on –*
>
> *(a) standards of professional conduct;*
> *(b) standards of professional performance; or*
> *(c) medical ethics.*

Fitness to practise sanctions apply where a doctor has seriously or persistently failed to follow the guidance in 'Good Medical Practice'.

The Council provides guidance to panels on the determination of sanctions to ensure consistency, which has been welcomed by the courts. The 'Indicative Sanctions Guidance' is on our website.

3. Have there been any changes between the situation in the mid 1970s and the present day?

The Council's statutory power to advise on conduct, performance and ethics was introduced in 1978 (The Medical Act1978). At that time the Council gave guidance which focused more on the forms of misconduct which would lead to action against a doctor's registration rather then positive advice about what standard we expect of doctors. In 1995, when the first edition of 'Good Medical Practice' was published we moved away from a focus on misconduct. 'Good Medical Practice' sets out the standards expected of a competent doctor.

4. Did any such rules or guidance apply to the testing of patients for the purposes of research. If a patient was to be subjected to a test, was the consent of the patient required, when the test was for the purpose of either treatment or research?

In 1988 the Council issued guidance about HIV and AIDS (see attached) and it was in this guidance that the Council gave specific guidance on consent for the first time. The guidance covers testing for *'investigative procedures including the removal of samples or invasive techniques, whether for the purpose of routine screening, for example in pregnancy or prior to surgery, or for the more specific purpose of differential diagnosis'*.

The Council now provides specific guidance on consent, which is currently being updated. This guidance is supplementary to the guidance contained in 'Good Medical Practice' and is available on our website. The updated version will be available by the end of May.

include link?

5. One witness stated: "We asked the GMC to investigate the matter of testing without permission along with the cases of several other patients. The GMC concluded that it wasn't that what we said hadn't happened but because the doctors had failed to document matters like pre and post test counseling and written consent *they couldn't reach a conclusion through lack of information in the medical records*, so doctors had to be given the benefit of the doubt." We appreciate that complaints would be treated confidentially, and we are not concerned to investigate the conduct of individual doctors, but we may need to comment on the existence of the practice in the period between the mid 1970s and the mid 1990s, and we would be most grateful for any light which you could shed on this matter.

[A search of our records has revealed records relating to a complaint by patients about the matter of testing without permission in relation to investigations into the risk of HIV infection carried out by Professor Ludlum in 1983. The Council's case examiners decided not to refer the case to a Fitness to Practise hearing because Professor Ludlum was able to demonstrate that the patients were tested in accordance with the guidance that existed at that time. In considering the case, the case examiners were assessing his behaviour based on the standards that existed at the time the research was carried out and not when the complaint was made.]

Response based on draft documentation located by one of the case examiners. Case file has been requested.

A

31 January 2006

In reply please quote: EB/FPD/2005/1881

General Medical Council

GRO-A

Edinburgh
GRO-A

5th Floor, St. James's Buildings
79 Oxford Street, Manchester M1 6FQ

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Dear GRO-A

I refer to our previous correspondence regarding your complaint about Professor Ludlam.

We have now completed our enquiries into your complaint and both a medical and a non-medical case examiner have considered the case. Case examiners are senior GMC staff, appointed to make decisions on cases.

The case examiners have now reviewed your complaint and the information we have obtained during our investigation. They have decided to conclude your complaint with no further action.

The Case Examiners said;

"It is always difficult to consider cases where there has been considerable passage of time. Standards of practice change, and what is valid best practice today may contrast sharply with established practise decades ago. The situation with regards to HIVAIDS has evolved considerably since the 1980's. The Case Examiners accept that Professor Ludlum established a monitoring system to assess the incidence of immunosuppression in haemophiliac patients in response to events in Scotland, and that, once some of the patients were identified as being HIV positive, he was in a difficult position. They are satisfied that he acted in accordance with the standards of practice that were accepted at the time, bearing in mind that practice rapidly evolved as more information became available. As a consequence, the Case Examiners do not feel that there is a realistic prospect of establishing that Professor Ludlum's fitness to practise is impaired."

I hope that I have been able to explain clearly our reasons for concluding this case. Please contact me on my direct dial number if you have any questions.

Yours sincerely

GRO-C

Emily Barry
Investigation Officer
Fitness to Practise Directorate
Direct Dial: GRO-C
Fax No: GRO-C
Email: GRO-C

B

General
Medical
Council

Case Examiner Decision Form

Investigation Officer: Grumberg

File Reference No 2005/1881 / Date 19/1/06

Dr's Name Ludlum Reg No 1325999

Part 1.

Nature of Allegations

Date complaint first received by the GMC: 24/6/05

Year alleged events took place: 1983 onwards

The following are the allegations raised by the complainant and/or employer: (TO BE NUMBERED)

1. That Professor Ludlum performed, or allowed to be performed, an HIV test on the complainant, without proper counselling or consent. Further, that this was part of a clinical study, about which the patient had not been informed. Neither the complainant nor his parents were informed about the test results, which placed both the family and *the public at risk, and possibly denied the complainant access to treatment.*
2. That neither the complainant nor his family were ever warned about the risk of contracting infectious diseases from factor VIII therapy.
3. That Professor Ludlow deliberately misled the GMC about the ethical approval for his study.

Nature of Allegations: presumption of impaired FTP

1.1 Do the allegations fall within one of the categories where there is a presumption, if proven, of impaired fitness to practise to a degree justifying action on registration?

Sexual Assault or indecency	**Yes**	**No**
a. Indecent behaviour	☐	☒
b. Indecent assault	☐	☒
c. Rape/attempted rape	☐	☒
d. Female circumcision	☐	☒
e. Child pornography	☐	☒
Violence		
f. Assault	☐	☒
g. Attempted murder	☐	☒
h. Firearms offence	☐	☒
i. Murder/manslaughter	☐	☒
j. Robbery	☐	☒
Improper sexual/emotional relationship	☐	☒
Dishonesty		
k. False claims to qualifications/experience	☐	☒
l. Financial fraud/deception	☐	☒
m. Forgery/improper alteration of documents	☐	☒
n. Research misconduct	☐	☒
o. False certification, false reporting	☐	☒
p. False claims about effectiveness of treatment	☐	☒
q. Other serious incidence(s) of dishonesty not covered above	☒	☐

Part 2.

Nature of allegations: Good Medical Practice

2.1 Do the allegations relate to one or more of the principles of Good Medical Practice set out below? If yes, please tick and cite the relevant paragraph in the right hand column then go to Part 3.
If no, please tick ' None of the above' then go to Part 3.

(For more detail on the principles of GMP, refer to the GMP booklet and the guidance provided.)

		Para(s) in GMP
a. Good Clinical Care	☒	2,3
b. Maintaining Good Medical Practice	☐	
c. Teaching and Training	☐	
d. Relationships with patients	☒	17,19,21,22,23
e. Working with colleagues	☐	
f. Probity	☐	
g. Health	☐	
i. None of the above GMP allegations	☐	

Part 3

Criteria for assessing the seriousness of allegations

Questions 3a to 3g will help to identify whether the allegations are sufficiently serious to meet the Investigation stage test: 'Is there a realistic prospect of establishing that a doctor's fitness to practise is impaired to a degree justifying action on registration?'

Please tick yes or no in each section

Do the allegations indicate that:

	Yes	No
a. the doctor's performance has harmed patients or put patients at risk of harm?	☒	☐
b. the doctor has shown a deliberate or reckless disregard of clinical responsibilities towards patients?	☒	☐
c. the doctor has abused a patient's right or violated a patient's autonomy or other fundamental rights?	☒	☐
d. the doctor has behaved dishonestly, fraudulently or in a way designed to mislead or harm others?	☐	☒
e. the doctor's behaviour is such that public confidence in doctors generally might be undermined if the GMC did not take action?	☒	☐
g. the doctor's health is compromising patient safety?	☐	☒

Part 4

Realistic prospect test

4.1 Is there a realistic prospect of establishing that the doctor's fitness to practise is impaired to a degree justifying action on registration

Yes ☐

No ☒

4.2 Please give reasons for your decision

Background

Haemophilia is a bleeding disorder in which patient's lack clotting factor VIII. Factor VIII was prepared from pooled blood transfusions, and in the eighties it became apparent that infectious diseases, including the newly identified HIV, could be spread in this manner. In 1983, the exact course of HIV infection was not fully elucidated, and there was no effective treatment available. Current standards state that HIV tests should only be performed after counselling and with very specific patient consent due to the effects the diagnosis, or even the admission of having a test, can have on the patient's social circumstances, employment, insurance etc. This guidance did not exist in the same form in 1983.

GRO-A alleges that neither he nor his family were made aware of the risks of factor VIII therapy; that they were not counselled or consented regarding an HIV test; that they were not made aware of the results of the test until 1991; that this situation arose only because Professor Ludlum was performing a study on his patients.

1. That Professor Ludlum performed, or allowed to be performed, an HIV test on the complainant, without proper counselling or consent. Further, that this was part of a clinical study, about which the patient had not been informed. Neither the complainant nor his parents were informed about the test results, which placed both the family and public at risk, and possibly denied the complainant access to treatment.

Professor Ludlum states that his study was not about AIDS/HIV per se. Rather it was undertaken to assess effects on the immune system of Scottish haemophiliacs (who were presumed not to have been exposed to the virus) after being exposed to repeated injections of Factor VIII. In addition, the blood tests in the file are clearly labelled "haemophilia AIDS study". However, in his response to the GMC, Professor Ludlum states that the testing was not for a research project: it was introduced as a monitoring process for this group of patients that was thought to be high risk of immunosuppression, but that the risk had not been qualified. The blood samples were labelled "AIDS study" as a shorthand to ensure that they were handled correctly, and identified appropriately.

Professor Ludlow is correct in stating that in 1983 there was not a specific test for HIV. However, white cell counts were taken to determine if there was immunosuppression and in the absence of other causative pathology to infer possible HIV infection. It would seem that the tests indicated that GRO-A was immunosuppressed is as early as 1983. This left

Professor Ludlum with an ethical dilemma, especially when GRO-A was finally identified as HIV positive. He is correct in stating that at the time, the full implications of a positive HTLV /HIV test were not known, and that the situation evolved rapidly over the next few years. Standard practice today is not what was thought necessary in the early 1980's. Today, patients receive intensive counselling before being tested. However, Professor Ludlum was now faced with a group of patients who were known to be HIV positive due to monitoring of their immune state, but who did not know themselves that this was the case. It became clear that it was not best practice to present the patient with a positive result, but to encourage them to ask for it. It is clear that GRO-A did not wish to know his result. One could argue that Professor Ludlum did not try hard enough to "put him in the right frame of mind", but there is enough evidence available to suggest that he took appropriate steps to try and suggest that GRO-A should know what his status was; and also to try and alert the entire group pf patients. This situation arose because of the rapidly evolving situation with regards to knowledge of AIDS, and cannot be laid solely at the door of Professor Ludlum.

In the interim, some advice had been issued by the Public Health Department, giving doctors two options. either inform the patient, or not. Pros and cons are set out in this memo (21/11/84), and Professor Ludlum seems to have opted for the latter course (option (c) ii), although he admits himself becoming uneasy about the situation in later years.

Professor Ludlum certainly continued to give specific advice to GRO-A without confirming that he was at particular risk, because GRO-A continued to not want to know about his HIV status. In 1989 he wrote: "aware we have been doing HIV tests. Does not want to know result. Consents to continue HIV testing." There is some indication from the records that some appropriate counselling was given in the interests of protecting GRO-A and his relations, and the public with regards to blood spillage and sexual intercourse. When GRO-A GRO-A was finally given the result in 1991, Professor Ludlum wrote: "I have told him his HIV status. He had not really suspected that he might be positive, and seemed therefore quite taken aback."

The documentary programme has evidence from another of Professor Ludlum's patients that exactly mirrors the story given by GRO-A However, it is notable that NHS Lothian wrote a strongly worded letter to the BBC on 11/8/05 decrying the accuracy of both the content and presentation of the documentary.

It is always difficult to judge someone for actions done 20 years ago and to not apply today's standards. HIV was a new illness in 1983, and not much was known about it. There was uncertainty amongst the medical community as a result, and practice evolved as more knowledge was acquired. Professor Ludlum's response does suggest that he tried to act in the best interests of patients given the rapidly changing information available to him regarding HIV and the constraints of confidentiality. The Case Examiners are satisfied that the so called "AIDS study" was did in fact start as a monitoring exercise of immune status in haemophiliac patients receiving certain blood products, and that publication of the findings was a necessary way of informing the wider medical community of a possible problem. The ethical consent letter from the MRC is for a follow up study that it funded, not the original longitudinal monitoring, and this has confused the issue somewhat. There is no realistic prospect of showing impaired fitness to practise.

2. That neither the complainant nor his family were ever warned about the risk of contracting infectious diseases from factor VIII therapy.

At the time, it was felt that the risk to British haemophiliacs was minimal, as only a few cases had been reported in the USA. Although patients should be fully informed of the risks and benefits of any treatment or therapy they are receiving, situations evolve with

time. It was not clear in 1983 that the risk was substantial. However, after this time, it is clear that attempts were made to alert patients to the risks. There is no realistic prospect of showing that fitness to practise is impaired.

3. That Professor Ludlow deliberately misled the GMC about the ethical approval for his study.

Professor Ludlow states that his study was not about AIDS/HIV per se. Rather, it was initially to assess effects on the immune system of Scottish haemophiliacs (who were presumed not to have been exposed to the virus) after exposed to repeated injections of Factor VIII. Dr Ludlum has explained why the forms were labelled "haemophiliac AIDS Study" and has explained that this was not a clinical trial or research, merely a monitoring exercise, that was later published to alert the wider medical community to a potential problem. It is regrettable that this choice of wording caused so much upset later on. There is no realistic prospect of establishing that his fitness to practise is impaired.

Summary for Closure Letter
"It is always difficult to consider cases where there has been considerable passage of time. Standards of practice change, and what is valid best practice today may contrast sharply with established practise decades ago. The situation with regards to HIVAIDS has evolved considerably since the 1980's. The Case Examiners accept that Professor Ludlum established a monitoring system to assess the incidence of immunosuppression in haemophiliac patients in response to events in Scotland, and that, once some of the patients were identified as being HIV positive, he was in a difficult position. They are satisfied that he acted in accordance with the standards of practice that were accepted at the time, bearing in mind that practice rapidly evolved as more information became available. As a consequence, the Case Examiners do not feel that there is a realistic prospect of establishing that Professor Ludlum's fitness to practise is impaired."

Case Examiner Referral Form

Section 1: Case Details

See Notes on Completion at end of form

FPD reference **RG/FPD/2005/1881**

Date complaint made to the GMC: **24 June 2005**

Doctor's name **LUDLAM, Christopher**

Registration no. **1325999**

Date **1 November 2005**

Investigation Officer Richard Grumberg

File location: E:\.... E:\CONDUCT\Manchester Screening\Grumberg R\Ludlum, Christopher 2005 1881\CERF.doc

Section 2: Previous History

See Note 1

Previous history? Yes

FPD Reference	Nature of complaint	Outcome/current status
2003/1173	Substandard Clinical Practice/Consent Issues	Closed: No realistic prospect
2003/2726	Substandard Clinical Practice/Consent Issues	Closed: No realistic prospect

Section 3: Index complaint – background and summary

See Note 2

1. **Specialty/field of practice of the doctor:** Medicine/Haematology

2. ***Chronology of events***

The complaint is made by GRO-A regarding his past treatment by Consultant Professor Ludlum in relation to becoming infected by HIV/AIDS and Hepatitis C.

GRO-A received his medical records in 2003 however due to medical problems he has impaired sight and was unable to read them. Due to the stigma surrounding HIV/AIDS and Hepatitis C he did not inform anyone that he had the diseases and did not let anyone read his medical notes for him. Only after having recently informed a friend that he has AIDS did he have someone read his notes.

GRO-A was informed that an AIDS study was carried out on him from April 1983. He became positive for HTLV III when he was 14 years old in 1984. GRO-A states that he finds it unacceptable that Professor Ludlum informed neither him nor his parents at that time. GRO-A was also not informed of the risks of contracting HIV/AIDS from Factor VIII prior to his infection when a named AIDS study was carried out on him 1983.

Professor Ludlum did not inform GRO-A *of* GRO-A *'s HIV/AIDS status* until January 1991, almost six years later, during a routine appointment in which Professor Ludlum told GRO-A that it had come to his attention that he was HIV positive. GRO-A received no counselling prior to being informed of his HIV status and as mentioned in his notes, Professor Ludlum stated that "he had not really suspected that he might be positive and he was therefore quite taken aback."

GRO-A has since learned that according to research papers published in medical journals that a total of 18 haemophiliacs contracted HIV/AIDS from the one batch giving Professor Ludlum "the opportunity to study a unique group of haemophiliacs" from the onset. GRO-A 's group is mentioned as "one of the most researched group in the world."

GRO-A and others featured recently in a documentary by BBC Scotland, Frontline Scotland "Blood and Tears," and neither he nor the BBC have received satisfactory answers from Professor Ludlum to explain why GRO-A GRO-A or his parents were not told that he was HTLV III positive. GRO-A encloses copies of AIDS studies and Professor Ludlum's comments regarding being told of being HIV positive.

Flag 2 is a transcript of the BBC Scotland documentary "Blood and Tears" broadcast on 1 June 2005.

Flag 3 is Professor Ludlum's response wherein he states that in December 1984/January 1985 all patients and parents of children with haemophilia were invited to an open meeting in Edinburgh to explain to patients what was known about AIDS in individuals with haemophilia. Professor Ludlum claims that GRO-A 's parents received an invitation to the meeting.

Subsequent to the meeting, all haemophiliacs and parents were written to with an "Advice Sheet for Adult Patients and Families about Acquired Immune Deficiency." This set out what was known in 1985. An explicit invitation was made to anyone who wanted to have more information or to know the result of their Anti-HTLV III test to telephone to make an appointment. GRO-A 's parents did not take up this opportunity.

GRO-A was also asked in 1986 whether he wanted to know his anti-HTLV III result. He was adamant that he did not want to know. In 1989 GRO-A consented to serial HIV tests but told Professor Ludlum he did not want to know the result. When it became clear in 1991 that prophylaxis against PCP was effective and Zidovudine was beneficial, Professor Ludlum was keen to offer GRO-A these therapeutic options and a meeting was arranged for 15 January 1991 during which GRO-A was informed of his anti-HTLV III status.

Flag 4 is GRO-A 's response to Professor Ludlum's comments. GRO-A states that his parents have no recollection of being invited to the meeting Professor Ludlum mentions. GRO-A also states that according to Professor Ludlum GRO-A was asked in 1986 if he wished to know his anti-HTLV III result, when, as the medical records point out, GRO-A was actually asked whether he wanted to know his "antibody result." GRO-A explains that in 1986 it was not explained what exactly an antibody test was or what it was for. GRO-A assumed it was a just a routine test that was carried out on all haemophiliacs.

In summary, GRO-A states that his parents did not know of the risks as they were always assured by Professor Ludlum and his staff that the Scottish Factor VIII was the safest in the world, and as they did not attend either meeting in 1984 or 1985. They also did not receive a copy of the AIDS Advice Sheet, and Professor Ludlum never ensured that they went to the meetings, received the sheet or mentioned the risks to them personally. His parents did not know that there was a possibility that GRO-A was infected.

GRO-A believes that Professor Ludlum should have followed the Council of Europe Recommendation No R(83)8 which states "-to inform attending physicians and selected recipients, such as haemophiliacs, of the potential health hazards of haemotherapy and the possibilities of minimising these risks." GRO-A believes that his parents should have been informed of the possible risks of Factor VIII to enable them to decide on any future treatment he received and to possibly prevent his infection as according to Professor Ludlum and his retrospective tests, GRO-A was in June 1983, HTLV III negative.

Further, when GRO-A tested positive in 1984 it was Professor Ludlum's responsibility to inform his parents as soon as possible to prevent the spread of AIDS throughout his family as by 1984 GRO-A 's mother was injecting him with Factor VIII and thereby risking her own life.

Flag 5 is a letter from GRO-A enclosing a letter in relation to MRC funding and Ethics Committee approval for the "Named Patient AIDS Study" carried out on GRO-A in 1983. Professor Ludlum in his comments at Flag 3 states that the studies had full ethical approval from the Lothian Health board Ethics Committee and were funded by the MRC, Scottish Office and the Wellcome Trust." In fact, the MRC did not fund the original study but rather a follow-up study, and it is unclear whether there was any ethical backing for Professor Ludlum's study involving GRO-A . It therefore appears that Professor Ludlum's statement to the GMC in his response is mistaken at best, and misleading at worse.

Travelling with the blue file is a folder marked "Patient Medical Rcords, GRO-A GRO-A Current Records"; 7 lever arch files, and a video tape marked "Frontline Scotland Blood and Tears"

3. Brief summary of the allegations/issues complained about to the GMC

Failure to inform a minor's parents of the HIV/Hep C status of the minor; failure to inform the patient of his HIV/Hep C status; failure to inform the patient or his parents of the risks of contracting HIV/Hep C from Factor VIII; providing misleading statements to the GMC.

Section 4: Additional information

See Note 3

Section 5: Performance Assessments/Health Examinations

See Note 4

Section 6: Summary of Allegations

See Note 5

A	B	C	D
No	**Allegation**	**Presumption of impaired FTP?**	**Breach of GMP?**
1	Failure to inform a minor's parents of the HIV/Hep C status of the minor	No	Yes
2	Failure to inform the patient of his HIV/Hep C status	No	Yes
3	Failure to inform the patient or his parents of the risks of contracting HIV/Hep C from Factor VIII	No	Yes
4	Providing misleading statements to the GMC.	Yes	Yes

Other relevant guidance? No

See Note 6

Section 7: Charges

See Note 7

None.

Section 8: Conclusion/Suggested Action

With respect to the first allegation, Failure to inform a minor's parents of the HIV/Hep C status of the minor, given the life-threatening risks of the spread of the infection it appears that Professor Ludlum should have specifically informed the parents rather than relying on an invitation to a meeting or mailing a fact sheet. The realistic prospect test therefore appears to be satisfied.

With respect to the patient, once GRO-A became of age, rather than being asked whether he wanted to know of the results of his "antibody tests" he should have specifically been informed of what the terms meant, the risks involved, and of his status. Failure to adequately inform the patient meets the realistic prospect test.

Regarding the allegation of failing to inform the patient or his parents of the risks of contracting HIV/Hep C from Factor VIII, Professor Ludlum did not take adequate steps to inform GRO-A or his parents of the risks of Factor VIII so as to provide a foundation for informed consent. Rather, they were told that Scottish Factor VIII was the safest in the world. The realistic prospect test is therefore satisfied.

Finally, with respect to the misleading statement to the GMC, it is apparent that, contrary to Professor Ludlum's clear statement to the contrary, the MRC did not fund his original study, and there is a real question as to whether there was ethical backing for such a study as well. It therefore appears that the realistic prospect test is satisfied in this instance as well.

Based on the above the case should be forwarded to a fitness to practise panel.

D

A

Complainant	Doctor	GMC	Comment
1. Did not obtain consent for Aids Study and accompanying tests	Clinical studies set up in 1980's in direct response to AIDS threat. Investigation colloquially known as the 'AIDS' study although no known cases of AIDS at that time. Therefore not a study on AIDS as such, but a clinical assessment of immune function of patients with haemophilia. Acknowledge that it was debatable whether the investigations should be termed as research or as immune surveillance set up in response to the AIDS threat. Not an AIDS study. Blood samples for the immune studies were likely taken at the same time as blood was being taken for other routine surveillance investigations. **It was our standard practice, ... to let the patient know that we would ... and to seek his explicit verbal consent.** **Believe it was generally known within the patient group that serum was stored for the purpose of investigating retrospectively...** **Both mother and patient would have heard about proposed blood tests.** **Consent not recorded in notes as not standard practice to do so at**	Prof L is correct in stating that in 1983 there was not a specific test for HIV. However, white cell counts were taken to determine if there was immunosuppresion and in the absence of other causative pathology to infer possible HIV infection. Prof L faced with an ethical dilemma when patient positively identified as HIV positive. It became clear that it was not best practice to present the patient with a positive result but to encourage them to ask for it. This situation arose because of the rapidly evolving situation with regards to the knowledge of AIDS, and cannot be laid solely at the door of Prof L Some advice from Public Health Dept – 2 options – inform or not – Prof L took	Not sure CEs have dealt with this point. Complainant says consent not given for AIDS study and accompanying tests. Prof L says not AIDS study, though called this and that would have obtained verbal consent for tests – did not say did obtain. CEs don't appear to deal with consent issue. Leaving aside the issue of whether it was an AIDS study or not, the Complainant says that consent was not obtained for the tests or study and Prof does not dispute that no consent was obtained for the study and says it would have been for the blood tests. **This appears to be a matter of evidence which the CEs have resolved.**

Complainant	Doctor	GMC	Comment
	that time. **In 1985 Lothian Health Board agreed not necessary to record verbal consent for the taking of small blood samples.** **No objection raised to blood being taken by patient or mother.**	latter option.	
2. Did not give the patient or family counselling in respect of tests	Need to clarify what counselling means given the change in meaning and practice. Patient and his mother knew of Dr's concerns about blood safety and the need for surveillance. Patient issued with a small information leaflet to kept in his Haemophilia Card The initial anti-HTLVIII tests were carried out without either the patient's or his mother's specific consent. This was carried out in the autumn of 1984 before the necessity for HIV pre-test counselling was appreciated and at a time when consent was not considered appropriate for other viral tests. GMC published guidance on the need for counselling in relation to HIV testing in 1988	Prof L continued to give specific advice to Patient without confirming he was at risk. Some indication in the records that some appropriate counselling was given in the interests of protecting Patient and his relations and the public with regards to spillage and sexual intercourse.	It appears that at the time, counselling was not best practice so Prof L cannot be criticised for not doing so. CEs don't deal with specific point on counselling.

Complainant	Doctor	GMC	Comment
3. Did not inform patient or family that tests were part of AIDS study	Term 'clinical study' may be interpreted in a number of different ways. It is Dr's belief that patient would have been informed and consulted. It was standard practice at time and no reason to believe patient would be treated differently. Setting up these tests was viewed as good clinical practice... Both patient and mother would have understood that additional test were being undertaken and it is likely they might well have been told that the investigations were part of the study of his immune system. Forms were labelled 'AIDS Study' so no wish to keep investigations secret.	Case Examiners satisfied that the so called 'AIDS Study' was did (sic) in fact start as a monitoring exercise of immune status in haemophiliac patients receiving certain blood products, and that publication of the findings was a necessary way of informing the wider medical community of a possible problem.	CE focus on what Dr says and accept this. They have not dealt with the fact that regardless of what the study or investigations were called, the family/patient say they were not informed. Dr says, they would have been and no reason to believe they were not but can't say for certain. Again, this appears to be a resolution of conflict of evidence by CEs.
5. Did not take proper steps to inform patient or parents about HIV positive result	Should be borne in mind that the inference of an anti-HTLVIII result in December 1984 was very different from what is now understood by an HIV positive test result. Patient's parents were invited to an open meeting in December 1984 – would have learned that patients had been anti-HTLVIII tested and that patients could obtain the results by arranging a meeting with myself	See above	There is a comment from the Dr that the patient had been 'tested without his consent'... and assumptions are made about the patient complying with protocols. It is clear that the Prof did not take pro-active steps to inform patients or parents about HIV positive result. However, can rely on advice

Complainant	Doctor	GMC	Comment
	Patient's parents sent the 'Advice Sheet on Adult patients and families on AIDS' which made explicit offer of a meeting with Dr to discuss individual circumstances. Letter dated 31 January 1985 sent to Patient's GP who could have contacted Dr. **As Patient had been tested without his consent and we believed he had appreciated the safety precautions which were set out in the information sheet, we considered that there was no immediate need to actively seek out and inform patients of their anti-HTVIII status.** **Believed that all patients should eventually know their results but provided the safety precautions were being followed, it was not essential to insist that patients know given that there was no effective treatment or specific therapy.** **Would have discussed with patient in a general way concerns about HIV and AIDS on 2 occasions in 1985**		from Public Health Dept which gave option of not disclosing. CEs appear to have accepted at face value the Drs response.

Complainant	Doctor	GMC	Comment
	and 1 in 1986. **Was keen to open up a discussion about the subject of his status with the hope that he might consider knowing his result.** **Patient made it clear in 1986 that he did not wish to know result. Took care to inform him about the safety precautions.** **14 August 1988, Dr Auger wrote to patient telling him about visit to discuss HIV and AIDS - ? cancelled by patient.** **Patient seen 1989 – made aware that he had been HIV tested – did not wish to know result.** **Told result on 15.01.91** **In discussion on 27 June 06 – patient said he was glad not to have known result as he had 6 extra years without worry...**		
6. Did not take steps to warn the patient or parents of the risks of contracting infectious diseases from Factor VIII therapy	Patient and parents were aware from a number of sources	At the time it was felt that the risks to the British Haemophiliacs was minimal, as only a few cases had been reported in the USA.	Again the CEs appear to have accepted the Drs response that there were a number of sources to warn the patient/parents.

Complainant	Doctor	GMC	Comment
		Although patients should be fully informed of the risks and benefits of any treatment or therapy, situations evolve with time. It was not clear in 1983 that the risk was substantial. However after this time it is clear that attempts were made to alert patients to the risks.	The issue not addressed is that Prof L did not take steps to warn this patient.
7. Over the course of treating the patient did not confirm he was as any particular risk	Made every effort to advise patient of his status, gave advice about risks and offered access to a social worker and counsellor	See above	See above
8. Did not give/Offer any counselling	See above	See above	See above
9. Did not give any advice in respect of the risks involved	See above	See above	See above
10. Did not take proper steps to inform him of the HIV positive result	See above	See above	See above
11. Made in accurate and/or misleading claims about ethical approval	Did not seek ethical approval for the investigations Not intention to mislead. No patient had AIDS so was not an AIDS study	Prof L states that this was not about AIDS/HIV per se. Prof L has explained why the forms were labelled as they were. It is regrettable that this choice of wording caused so much upset later on.	It is clear that there is some confusion here. In his initial response, Prof L is unequivocal that 'the studies' had full ethical approval... The Prof did not at this stage seek to clarity what study he was referring to.

Complainant	Doctor	GMC	Comment
			There is an issue here about whether this reply could mislead although it was subsequently corrected but only because it was picked up by the Complainant.
		Case Examiners accept that Prof L established a monitoring system to assess the incidence of immunosuppression in haemophiliac patients. They are satisfied that he acted in accordance with the standards of practice that were accepted at the time bearing in mind that practice rapidly evolved as more information became available.	It is clear that there are issues about what was appropriate at the time and it was not at all clear what was good practice in what was a clearly developing area. It would appear from the doctor's response that he was very much responding to the situation and made decisions at the time that he felt were appropriate. There are however clear contradictions between the complainant and the Dr as to the issues of consent, counselling, and keeping the patient informed. There is also an issue about the claim in relation to the AIDS Study which in my view are not matters that the CE should have resolved.

Our ref: JS/JO/Rule 12 GRO-A v Ludlam

19 November 2007

GRO-A

Edinburgh
GRO-A

Your complaint against Professor Ludlam

I refer to previous correspondence in relation to the above.

I write further to my letter of 28 November 2006 notifying you of my decision to undertake a review of the decision that your complaint against Professor Ludlam should be concluded with no further action.

I have considered carefully the representations received, and all relevant material, and have now concluded my review. I am sorry to have taken so long, but it has been necessary for me to make inquiries as to accepted criteria in relation to what is now known as the HIV/AIDS virus of many years ago.

Under rule 12(5) of the GMC's Fitness to Practise Rules 2004, I have decided that the case examiner's original decision should stand.

Yours is undoubtedly a most unfortunate case. I am confident that what occurred in your case could not happen today. However, I have had to come to a decision by reference to standards as they were in the early 1980s at a time when the virus had only recently been discovered and its ramifications were unknown. I have made inquiries, and it is evident that at this early period there was no consensus as to the proper approach either towards warning patients of risks associated with HIV/AIDS (insofar as they were known) or towards the information which should be given to patients who had tested positive. Indeed, it was not until 1988 that the GMC first issued guidance to the medical profession on ethical considerations arising in relation to HIV/AIDS (please see copy attached). In the early 1980s there was limited understanding of the virus and no general agreement as to what information should be imparted either to patients who might be subject to a test or to those suspected or diagnosed as having contracted the virus.

Times have, of course, moved on since the 1980s. But I have had to form a judgment whether your complaint should be referred to case examiners in the light of the professional standards of very many years ago. The institution of GMC disciplinary proceedings against Professor Ludlam would only be appropriate if in the light of those

standards his conduct was such as raised a question whether his fitness to practise medicine is impaired.

I have therefore come to the conclusion that the original decision not to refer your allegations to a Fitness to Practise Panel should stand. I have come to this decision in the light of:

(a) the inevitable difficulties in investigating events of so long ago;
(b) the lack of clear applicable standards at the material time; and
(c) the lack of any realistic prospect on the known information that a Panel would now find that Professor Ludlam's fitness to practise is impaired.

A letter is being written in parallel terms to Professor Ludlam.

Memorandum

General Medical Council

Regulating doctors
Ensuring good medical practice

Aide-memoire

From: Juliet Oliver **Date:** 9 November 2006

Title: GRO-A v Professor Christopher Ludlam

GRO-A – v – Prof Ludlam

1. This is a memo in response to a request for advice regarding the grounds under Rule 12 General Medical Council (Fitness To Practise) Rules 2004 to review the Case Examiners' decision to conclude the above case with no further action. The decision was communicated to the complainant, GRO-A, by letter of 31 January 2006. GRO-A has since written on 9 March [2006] requesting information about an appeal or other form of review of the GMC's procedures. His MP, Mike Pringle MSP wrote on 13 July 2006 chasing a reply to that letter.

Background

2. GRO-A wrote to the GMC on 22 June 2005 with allegations regarding his treatment by Professor Ludlam. He is a haemophiliac who was infected with HIV / AIDS and Hepatitis C following receipt of Factor VIII therapy. He alleges that Professor Ludlam included him in an "AIDS study" without consent, from April 1983 onwards, and that he was not informed of the risks of contracting HIV / AIDS from Factor VIII therapy prior to his infection in 1984. He was not informed of his positive HIV status until January 1991 and received no counselling at the time.

3. Professor Ludlam provided comments to clarify that he conducted a study to investigate the immune status of haemophiliacs in Edinburgh treated exclusively with Factor VIII and their relationship with a few cases of AIDS diagnosed in haemophiliacs in North America. In late 1984, there were uncertainties around the clinical implications of the positive anti-HTLVIII antibody test, however all patients and parents were invited to an open meeting to explain issues surrounding AIDS in relation to haemophiliacs, and an advice sheet was sent out to all patients and parents regarding what was known at the time. This invited the recipient to make an appointment if they wished to seek the results of individual tests. Patients' GPs were also written to in equivalent general terms. Professor Ludlam stated that GRO-A in particular was invited to ask for the results of his test in 1986, but he said that he did not wish to know. In 1989 he consented to serial HIV tests, but once again said that he did

not wish to know the results. Finally on 15 January 1991, once it became clear that effective therapies were available, he told GRO-A of his positive result.

4. In further correspondence, GRO-A alleged that his parents never received an invitation to a meeting or the fact sheet referred to by Professor Ludlam, that he did not understand in 1986 what test was being referred to (the medical records indicate he was asked whether he wanted to know his "antibody results") and that, in 1989, he asked Professor Ludlam to tell him if anything was "wrong" and assumed therefore that nothing was.

5. He further states that it was Professor Ludlam's responsibility to inform his parents in order to prevent the spread of AIDS throughout his family as GRO-A GRO-A's mother was injecting him with Factor VIII and thereby risking her own life.

6. Professor Ludlam states that the studies had full ethical approval from the Lothian Health Board Ethics Committee and were funded by the MRC, Scottish Office and the Wellcome Trust. However, a letter dated 22 September 2005 from the Medical Research Council confirms that the MRC did not fund the original study but did fund a follow-up study *"which aimed to continue and substantially extend a longitudinal study, started in 1983, of the immune function of a cohort of people with haemophilia."* The MRC-funded works did have Ethics Committee approval and a letter dated 9 October 1985 confirms approval for *"clinical and immunological study of haemophiliacs treated exclusively with NHS Factor VIII/IX concentrate"*.

7. The five-year rule was waived in the initial processing and assessment form – there is a note by the Case Examiner stating *"waive 5 y rule as with other Hep C / AIDS haemophilia cases "public interest". Needs investigation plus check name of Dr"* - and the case was progressed under stream one and the patient's medical records and employer information obtained.

8. A CERF was prepared on 1 November 2005, and this appears to recommend that the case be forwarded to a Fitness to Practise Panel on the following grounds:

    1. *"It appears that Professor Ludlam should have specificallyb informed the parents rather than relying on an invitation to a meeting or mailing a fact sheet"*;

    2. *"...once* GRO-A *became of age, rather than being asked whether he wanted to know of the results of his "antibody tests" he should have specifically been informed of what the terms meant, the risks involved and of his status"*;

3. *"Professor Ludlam did not take adequate steps to inform* GRO-A *or his parents of the risks of Factor VIII so as to provide a foundation for informed consent.";*

4. *"...it is apparent that, contrary to Professor Ludlam's clear statement to the contrary, the MRC did not fund his original study, and there is a real question as to whether there was ethical backing for such a study as well.".*

The Case Examiners considered the case accordingly and decided on 3 November 2005 to refer the matter for adjudication. A full CEDF was completed and the decision made that:

"The Case Examiners acknowledge the importance of assessing past actions in the light of the clinical standards in place at the time and not current standards. They also acknowledge that c,inical practice relating to HIV/AIDS has changed substantially since 1983. However, the evidence suggests that Professor Ludlum [sic] did not in fact take into account what might be in the best interests of his patients, or the public health. In addition, the evidence suggests that Professor Ludlum has misled the GMC about the nature of the longitudinal study that included her complaint. There is therefore no alternative but to refer this case to a Fitness to Practise Panel for a determination."

That decision having been made, allegations were disclosed to Professor Ludlam under Rule 7(1) and he submitted representations accordingly. The Case Examiners were referred to their earlier "draft CEDF" and asked formally to consider the allegations and reach a decision. They did so on 26 January 2006 and decided to close the case with no action on the basis that:

"Standards of practice change, and what is valid best practice today may contrast sharply with established practice decades ago. ... the Case Examiners accept that Professor Ludlam established a monitoring system to asses the incidence of immunosuppression in haemophiliac patients in response to events in Scotland, and that, once some of the patients were identified as being HIV positive, he was in a difficult position. They are satisfied that he acted in accordance with the standards of practice that were accepted at the time, bearing in mind practice rapidly evolved as more information became available. As a consequence, the Case Examiners do not feel that there is a realistic prospect of establishing that Professor Ludlam's Fitness to Practise is impaired."

Criteria under Rule 12

8. As you will be aware, the President's power to undertake a review only arises where the criteria under Rule 12 of the GMC (FTP) Rules 2004 are met.

9. The Case Examiners decision in this case is one that he is able to review in that it comprises a decision not to refer the allegations raised by GRO-A to a panel (Rule 12 (1)(a)).

10. There are two possible grounds for review. First, under Rule 12 (2), the President may consider that "new evidence or information", emerging after the decision in question was taken, makes the review necessary either for the protection of the public, the prevention of injustice to the practitioner, or in the public interest. Such information must be substantively different and bring a real chance of a different outcome. Following the decision, GRO-A contacted the GMC to express his disappointment with the Case Examiners decision, however this correspondence essentially repeats elements of his original complaint. I do not therefore consider that the criteria under this ground are met.

11. In addition, the President is able to review a decision where he has received information that the GMC has erred in its administrative handling of the case and he is satisfied that it is necessary in the public interest to do so (Rule 12 (3)). I would advise that this ground applies.

12. Specifically, rule 7(1) requires the GMC to notify the doctor of the allegation and the documents in support as soon as reasonably practicable after referral to the Case Examiners. This was not done. After the Case Examiners had made their decision, a rule 7 letter was then sent and the Case Examiners made a second decision. From a strict legal perspective, the GMC had no power, the Case Examiners having exercised their discretion, to re-take the decision. The failure initially to comply with rule 7, and the subsequent re-taking of the Case Examiners' decision comprise administrative errors fro the purposes of rule 12(3). However, given that the second decision essentially corrects the defect in process – the failure to allow the doctor the opportunity to submit representations – it is hard to identify a public interest in reviewing the (re-taken) decision on this basis.

13. In addition, however, whilst the Case Examiners in the re-taken decision particularise the allegations in full, their detailed reasoning does not address the allegations of lack of consent and/or counselling in relation to the performance of the original tests. They simply state *"standard practice today is not what was thought necessary in the early 1980s. Today, patients receive intensive counselling before being tested. ..."*. Further they do not address the allegation that the patient was not informed that the tests were part of a clinical study. The Case Examiners simply repeat Professor Ludlam's admission that the testing was not for a research project but simply a monitoring process, and that the blood samples were labelled "AIDS study" as a short hand to ensure that they were handled correctly. The President may wish to review the decision in this case in view of the public interest in ensuring that an administrative error does not prevent the GMC from considering and

determining allegations of misconduct in relation to consent to testing, particularly in such a sensitive area.

14. **NB. The Case Examiners refer to a memo 21/11/84 issued by the Public Health Department advising doctors on whether to inform patients of positive tests – this memo is not on the file and it is not clear where this information arises from.**

Juliet Oliver

Our ref: JS/JO/Rule 12/ GRO-A v Ludlam

9 November 2006

GRO-A

Edinburgh
GRO-A

Your complaint against Professor Ludlam

I refer to previous correspondence in relation to the above, and to your letter dated 9 March 2005. Please accept my sincere apologies for the delay in providing you with a substantive response.

As you will be aware from the letter from Emily Barry dated 31 January 2006, the GMC decided to conclude your complaint against Professor Ludlam with no further action. I can tell you that I have decided to review that decision. The purpose of this letter is to explain the reasons for that decision and to describe the procedure and timetable to be followed from now on.

Rule 12 of the General Medical Council (Fitness to Practise) Rules 2004 empowers the President of the GMC to review certain decisions. A decision not to refer a complaint to a Fitness to Practise Panel is one such decision: see Rule 12(1)(a). There are two possible grounds for a review. First, under Rule 12(2) I may consider that "new evidence or information" (emerging after the decision in question was taken) makes a review necessary. I do not consider that this applies here.

Second, under Rule 12(3), I may review a decision where I receive information that the GMC has erred in its administrative handling of the case, and I am satisfied that it is necessary in the public interest to do so. This, I consider, does apply here.

I note that in the reasons for their decision, the Case Examiners have not addressed all of your allegations that Professor Ludlam. Specifically, in relation to your allegations that he did not obtain your consent or provide counselling in relation to the tests taken by him, and that he did not inform you or your family that the tests were part of a clinical study, the Case Examiners noted that the testing was not for a research project but a monitoring process, and that the blood samples were labelled "AIDS study" as a short hand to ensure that they were handled correctly, and they stated *"standard practice today is not what was thought necessary in the early 1980s. Today, patients receive intensive counselling before being tested. ..."*. I am not however satisfied that this adequately addresses the issues raised, and cannot therefore be satisfied that these have appropriately been considered.

I am satisfied, in all the circumstances, that it is necessary in the public interest to review the decision.

Rule 12(4) provides that where I have decided to review a decision falling within Rule 12(1)(a) I must seek representations from the complainant and the doctor regarding that review. Accordingly, you are invited to make any representations that you consider appropriate, dealing with the matters raised in this letter or otherwise. You are not obliged to submit any such representations but any that are submitted will be taken into account.

When preparing any representations, you should bear in mind that three courses will be open to me under Rule 12(5): First, I may determine that the decision should stand; second, I may refer any of your complaints for consideration by Case Examiners under Rule 8 (general consideration); third, I may refer any of your complaints for reconsideration by Case Examiners under Rule 10(2)(undertakings).

I emphasise that I have so far decided only to *undertake* a review. It is impossible to predict its outcome. If, however, the review were to result in reconsideration by Case Examiners, it would be appropriate for both you and Professor Ludlam to be given a further opportunity to submit representations. In accordance with the GMC's normal procedures, Professor Ludlam would be given the opportunity to have the last word.

As regards timing, I would like to complete the review process as quickly as possible. Accordingly, I would appreciate receipt of any representations within 21 days of the date of this letter. That decision will then be promulgated in accordance with Rule 12(6).

A letter is being written in parallel terms to Professor Ludlam.

1777

7 DEC 2006

GRO-A

Tel: GRO-A

The President
Sir Graeme Catto
General Medical Council
Regent's Place
350 Euston Road
London
NW1 3JN

3 December 2006

Dear Sir

I have just been informed by GRO-A, GMC Ref: 2005/1881 and JS/JO/Rule 12/GRO-A v Ludlam, that you have decided to undertake a review of his original case against Prof Ludlam.

I am therefore requesting for my own original case GMC Ref: 2003/2726 to be reconsidered. I feel that as both GRO-A and my own case are very similar in that we were both treated by Prof Ludlam, that the events surrounding our infection, the lack of counselling in relation to the tests taken by him from March 1983, the fact that he did not inform me that I was part of a clinical AIDS study even though this study was being carried out on me without my knowledge or consent at a time when I was asking Prof Ludlam and other treating doctors about a new disease (now known as AIDS) which was happening in America and then other countries. Although I was continuously asking from the beginning of 1983 about this disease and any risks to and from Factor VIII I was never told I was HTLV III positive until 1987 even though I tested positive in October 1984.

I also feel that since the Freedom of Information (Scotland) 2002 Act, which came into effect from 1 January 2005, I have received information which would have helped my case – information which I was not in possession of, such as Prof Ludlam giving false information in his request to the Ethics Committee for research of HTLV III positive haemophiliacs in Edinburgh infected through NHS Factor VIII.

As the Case Examiners concluded "... the allegations were serious ..." I feel that my case should have been dealt with individually and not "... together with other haemophiliac complaints ..." I also feel that I have been dealt with unjustly by the GMC as I was informed that there was no appeal system on my original complaint. I therefore await a decision on this request for a review.

Yours faithfully

GRO-A

GRO-A

General
Medical
Council

Our ref: JS/JO/Rule 12/GRO-A v Ludlam

28 February 2007

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GRO-A

GRO-A

Your complaint against Professor Ludlam

I refer to previous correspondence in relation to the above and to your letter dated 3 December 2006.

As you will be aware from the letter from Surupa Sarkar dated 20 April 2005, the GMC decided to conclude GRO-A 's complaint against you with no further action. I can tell you that I have decided to review that decision. The purpose of this letter is to explain the reasons for that decision and to describe the procedure and timetable to be followed from now on.

Rule 12 of the General Medical Council (Fitness to Practise) Rules 2004 empowers the President of the GMC to review certain decisions. A decision not to refer a complaint to a Fitness to Practise Panel is one such decision: see Rule 12(1)(a). There are two possible grounds for a review.

Under Rule 12(3), I may review a decision where I receive information that the GMC has erred in its administrative handling of the case, and I am satisfied that it is necessary in the public interest to do so. This, I consider, does apply here.

I note that in the reasons for their decision (a full copy of which can be found in the Case Examiner Decision Form (CEDF) dated 18 April 2005, attached), the Case Examiners have not addressed all of your allegations against Professor Ludlam. Specifically, they failed to address the following allegations:

(i) That, when informing you of your HIV status in 1987, he played down the seriousness of the diagnosis and suggested that the cause may not be the use of blood products;

(ii) That he gave your stored blood samples to an informal Lothian AIDS group.

I cannot therefore be satisfied that these have appropriately been considered and am satisfied, in all the circumstances, that it is necessary in the public interest to review the decision.

Second, under Rule 12(2) I may consider that "new evidence or information" (emerging after the decision in question was taken) makes a review necessary. In your letter of 3 December 2006, you claim that you have, since the decision in question, received information that would have helped your case, including information that Professor Ludlam gave false information in his request to the Ethics Committee for research on HTLV III positive haemophiliacs in Edinburgh infected through NHS Factor VIII. Your letter did not enclose the information referred to. However, any further information sent by you during the course of this review will be considered carefully to identify whether it is substantively new and brings a real chance of a different outcome.

Rule 12(4) provides that where I have decided to review a decision falling within Rule 12(1)(a) I must seek representations from the complainant and the doctor regarding that review. Accordingly, you are invited to make any representations that you consider appropriate, dealing with the matters raised in this letter or otherwise. You are not obliged to submit any such representations but any that are submitted will be taken into account.

When preparing any representations, you should bear in mind that three courses will be open to me under Rule 12(5): First, I may determine that the decision should stand; second, I may refer any of your complaints for consideration by Case Examiners under Rule 8 (general consideration); third, I may refer any of your complaints for consideration by Case Examiners under Rule 10(2)(undertakings).

I emphasise that I have so far decided only to *undertake* a review. It is impossible to predict its outcome. If, however, the review were to result in consideration by Case Examiners, it would be appropriate for both you and Professor Ludlam to be given a further opportunity to submit representations. In accordance with the GMC's normal procedures, Professor Ludlam would be given the opportunity to have the last word.

As regards timing, I would like to complete the review process as quickly as possible. Accordingly, I would appreciate receipt of any representations within 21 days of the date of this letter. That decision will then be promulgated in accordance with Rule 12(6).

A letter is being written in parallel terms to Professor Ludlam.

Yours sincerely

Sir Graeme Catto
President

GRO-C

Our ref: JS/JO/Rule 12 GRO-A v Ludlam

13 April 2007

GRO-A

Dear GRO-A

Your complaint against Professor Ludlam

I refer to previous correspondence in relation to the above and to your letter dated 3 December 2006.

As you will be aware from the letter from Surupa Sarkar dated 20 April 2005, the GMC decided to conclude your complaint against Professor Ludlam with no further action. I understand that you would like the GMC to review that decision. Rule 12 of the General Medical Council (Fitness to Practise) Rules 2004 empowers the President of the GMC to review certain decisions in specified circumstances.

I note that, on 19 February 2007, Lord Morris of Manchester announced the setting up of a public Inquiry, with terms of reference as follows:

"*To investigate the circumstances surrounding the supply to patients of contaminated NHS blood and blood products; its consequences for the haemophilia community and others affected; and further steps to address both their problems and needs and those of bereaved families.*"

The Inquiry is to be chaired by Lord Archer of Sandwell QC, and he will be calling on, amongst others, patients and bereaved dependants to assist the Inquiry.

In the circumstances, in view of the fact that the public interest will not be served by the GMC conducting parallel investigations in relation to matters that are likely to be covered during the course of the public Inquiry, the President has decided not to undertake a review of the decision to conclude your complaint against Professor Ludlam at this time, and will revisit the matter following the conclusion of the Inquiry.

In the meantime please do not hesitate to let me know if you would like to discuss.

Yours sincerely

Jackie Smith
Head of Investigation
Fitness to Practise Directorate
Direct Dial: GRO-A
Fax: GRO-A
Email: GRO-A

THE ROYAL INFIRMARY OF EDINBURGH

HAEMATOLOGY DEPARTMENT

Dr. A. C. Parker (Ext. GRO-C
Dr. C. A. Ludlam (Ext.

Senior Chief M.L.S.O.
Mr. P. F. J. Newman (Ext. GRO-C

LAURISTON PLACE
EDINBURGH EH3 9YW

Telephone. 031-229 2477

Your Ref.
Our Ref. CAL/PMC

25th June, 1985

The Medical Adviser
Committee of Safety of Medicine,
Market Towers,
1 Nine Elms Lane,
LONDON.

IN STRICT MEDICAL CONFIDENCE

Dear Sir,

Scottish National Blood Transfusion Factor VIII
Batch [illegible]

I write to formally report that it would appear that the above batch of factor VIII transfused during the Spring of last year to patients under my care may have contained the HTLVIII (AIDS) virus. Most of our patients were negative for anti-HTLVIII before the Spring of last year and during the succeeding few months a number of patients developed antibodies to HTLVIII. We have examined the transfusion records carefully of all the patients who developed this specific antibody and the above batch would appear to be the one that was most likely to have caused the infection.

I send you the names of the individual haemophiliac infected in very strict confidence. No doubt you will wish to undertake your own enquiry but I should be grateful if the list of patients concerned was not passed to any other organisation without my personal consent. Although some of the patients realise they have received a contaminated batch and know that they have developed anti-HTLVIII, other patients do not know of this and do not wish to know.

Yours faithfully,

C.A.Ludlam
Consultant Haematologist

P.S. I enclose the complete transfusion records for 1984 on the infected patients.

Our ref: JO/Rule 12/GRO-A v Ludlam

10 May 2007

General Medical Council

Vijay Mehan
c/o Fentons Solicitors LLP
19 Bloomsbury Square
London
WC1A 2NS

Regents Place
350 Euston Road, London NW1 3JN

Telephone: 0845 357 8001
Facsimile: 020 7819 5001
Email: gmc@gmc-uk.org
www.gmc-uk.org

Dear Mr Mehan

Contaminated Blood Products: Public Inquiry

I write to you in your role as a solicitor to the above inquiry, established by The Right Hon Lord Morris of Manchester, President of the Haemophilia Society.

The GMC has had brought to its attention matters regarding the fitness to practise of a doctor involved in treating haemophiliacs contaminated by blood products in the early 1980s. Whilst the details of any complaint remain confidential, it is necessary for the GMC to understand whether evidence submitted to the Inquiry and/or any of its findings will be relevant to the GMC's consideration. In this respect, I should be most grateful if you would please respond at your earliest opportunity to the following:

1. I note that the Inquiry's terms of reference are "To investigate the circumstances surrounding the supply to patients of contaminated NHS blood and blood products; its consequences for the haemophilia community and others afflicted; and suggest further steps to address both their problems and needs and those of bereaved families". Please could you confirm whether you envisage evidence being submitted and/or relied upon in relation to the treatment of any individual patient with haemophilia and, if not, whether steps have been/will be taken to limit the evidence considered by the Inquiry.

2. I note that the Inquiry is funded by private donors. It has been termed an "independent public inquiry" (19 February 2007 press statement from the Chair of the Inquiry, The Right Hon Lord Archer of Sandwell QC). Please could you let me know what steps have been/will be taken to ensure that it is independent.

3. I note that the Inquiry has no statutory basis. Please would you confirm to me any rules of evidence and other codes or principles guiding its procedures.

4. The Inquiry website refers to evidence being called from patients and bereaved dependants, former Health Ministers and members of the medical scientist community, amongst others. The website invites submissions from the general public. Please can you let me know the way in which submissions are scrutinised to assess their relevance, and the mechanisms for testing evidence both oral and written (eg. cross examination/written questions).

5. Please would you confirm that the oral and written evidence considered by the Inquiry will be made publicly available. Please would you let me have any information available regarding witnesses whose evidence (either oral or in writing) will be considered by the Inquiry.

6. I understand that the Inquiry will report in late summer 2007 to the Secretary of State for Health. Please would you clarify the involvement of the Department of Health in the Inquiry and whether this is in fact the case.

I look forward to hearing from you at your earliest opportunity.

Yours sincerely

Juliet Oliver
Principal Legal Adviser
Direct Dial: GRO-C
Direct Fax:
Email: GRO-C

GENERAL MEDICAL COUNCIL

44 HALLAM STREET, LONDON, W1N 6AE
TELEPHONE: 071 580 7642

from the President
Sir Robert Kilpatrick, CBE, MD, FRCP
and the Chairman of the Standards Committee
Dr D.H. Irvine, CBE, MD, FRCGP

April, 1991

Dear Colleague,

In August 1988 the attached statement was sent to all doctors on the Principal List of the Register and to those holding limited registration. It contains important material offering guidance to doctors in approaching a number of ethical questions which arise in relation to the management and control of HIV infection and the diseases associated with it. These questions are both sensitive and difficult, and warrant the careful attention of every doctor.

The statement stands as an expression of the Council's views in four main areas where ethical difficulties can arise:

- the doctor's duty towards patients;
- duties of doctors infected with the virus;
- consent to investigation or treatment;
- confidentiality.

We believe that the policy adopted by the Council in these matters is well understood by doctors and has been widely accepted by both the profession and the public. The statement expresses the Council's confidence that the generality of doctors had been tackling these problems with compassion, understanding and good sense and, as time has passed, we are sure that this confidence was not misplaced. We believe, however, that the principles enshrined in the statement deserve to be drawn to the attention of all doctors embarking on practice in this country, and this document is therefore being sent to doctors when they are first granted registration by the Council and to any who inform us that they wish to return to practice in the UK following a period overseas.

The statement should be read as a whole, but we would draw particular attention to paragraphs 8-11, which discuss the duties of doctors who are infected with the virus, or who think there is a possibility that they may have been infected. We regard the risk of a doctor transmitting the virus to a patient as extremely small, but the matter is one of public concern, and it is important that all doctors are aware of the Council's guidance and that it is followed in all relevant circumstances.

[redacted]

Doctors have long been familiar with the need to make judgments, in the course of everyday medical practice, which they may later have to justify. That principle is particularly important in the handling of complex ethical problems to which there may be no clear-cut answer. Any doctor who is experiencing difficulty in resolving a problem in the areas covered by this document should seek the advice of an experienced colleague, a professional association, a medical defence society or the Council.

GRO-C

Robert Kilpatrick
President

GRO-C

Donald Irvine
Chairman, Standards Committee

HIV INFECTION AND AIDS: THE ETHICAL CONSIDERATIONS

INTRODUCTION

1. This paper brings together the Council's guidance to the medical profession on some of the ethical considerations which arise in relation to HIV infection and AIDS. It deals first with general principles and then discusses specific matters in relation to the duties of doctors towards infected persons, the duties of doctors who may themselves be infected, the need to obtain patients' consent to investigation or treatment and the need to observe the rules of professional confidence.

THE DOCTOR/PATIENT RELATIONSHIP

2. The doctor/patient relationship is founded on mutual trust, which can be fostered only when information is freely exchanged between doctor and patient on the basis of honesty, openness and understanding. Acceptance of that principle is, in the view of the Council, fundamental to the resolution of the questions which have been identified in relation to AIDS.

3. The Council has been impressed by the significant increase in the understanding of AIDS and AIDS-related conditions, both within the profession and by the general public, which appears to have occurred within the past 18 months. It seems that most doctors are now prepared to regard these conditions as similar in principle to other infections and life-threatening conditions, and are willing to apply established principles in approaching their diagnosis and management, rather than treating them as medical conditions quite distinct from all others. The Council believes that an approach of this kind will help doctors to resolve many of the difficulties which have arisen hitherto.

4. In all areas of medical practice doctors need to make judgements which they may later have to justify. This is true both of clinical matters and of the complex ethical problems which arise regularly in the course of providing patient care, because it is not possible to set out a code of practice which provides solutions to every such problem which may arise. The Council would remind the profession of the statements of general principle which are set out for the guidance of doctors in its booklet, "Professional Conduct and Discipline: Fitness to Practise". In the light of that general guidance the Council has formed the following views on questions of particular significance in relation to HIV infection and the conditions related to it.

THE DOCTOR'S DUTY TOWARDS PATIENTS

5. The Council expects that doctors will extend to patients who are HIV positive or are suffering from AIDS the same high standard of medical care and support which they would offer to any other patient. It has however expressed its serious concern at reports that, in a small number of cases, doctors have refused to provide such patients with necessary care and treatment.

6. It is entirely proper for a doctor who has a conscientious objection to undertaking a particular course of treatment, or who lacks the necessary knowledge, skill or facilities to provide appropriate investigation or treatment for a patient, to refer that patient to a professional colleague.

7. However, it is unethical for a registered medical practitioner to refuse treatment, or investigation for which there are appropriate facilities, on the ground that the patient suffers, or may suffer, from a condition which could expose the doctor to personal risk. It is equally

unethical for a doctor to withhold treatment from any patient on the basis of a moral judgement that the patient's activities or lifestyle might have contributed to the condition for which treatment was being sought. Unethical behaviour of this kind may raise a question of serious professional misconduct.

DUTIES OF DOCTORS INFECTED WITH THE VIRUS

8. Considerable public anxiety has been aroused by suggestions that doctors who are themselves suffering from AIDS or who are HIV positive might endanger their patients. There is no known case anywhere in the world of HIV having been transmitted by an infected doctor to a patient in the course of medical treatment.

9. Nevertheless it is imperative, both in the public interest and on ethical grounds, that any doctors who think there is a possibility that they may have been infected with HIV should seek appropriate diagnostic testing and counselling and, if found to be infected, should have regular medical supervision. They should also seek specialist advice on the extent to which they should limit their professional practice in order to protect their patients. They must act upon that advice, which in some circumstances would include a requirement not to practise or to limit their practice in certain ways. No doctors should continue in clinical practice merely on the basis of their own assessment of the risk to patients.

10. It is unethical for doctors who know or believe themselves to be infected with HIV to put patients at risk by failing to seek appropriate counselling, or to act upon it when given. The doctor who has counselled a colleague who is infected with HIV to modify his or her professional practice in order to safeguard patients, and is aware that this advice is not being followed, has a duty to inform an appropriate body that the doctor's fitness to practise may be seriously impaired. There are well-tried arrangements for dealing with such cases. They are designed to protect patients as well as to assist the sick doctor. If the circumstances so warrant the Council is empowered to take action to limit the practice of such doctors or to suspend their registration.

11. These arrangements also safeguard the confidentiality and support which doctors when ill, like other patients, are entitled to expect. The principles underlying this advice are already familiar to the profession, which has well-established policies and procedures designed to prevent the transmission of infection from doctors to patients.

CONSENT TO INVESTIGATION OR TREATMENT

12. It has long been accepted, and is well understood within the profession, that a doctor should treat a patient only on the basis of the patient's informed consent. Doctors are expected in all normal circumstances to be sure that their patients consent to the carrying out of investigative procedures involving the removal of samples or invasive techniques, whether those investigations are performed for the purposes of routine screening, for example in pregnancy or prior to surgery, or for the more specific purpose of differential diagnosis. A patient's consent may in certain circumstances be given implicitly, for example by agreement to provide a specimen of blood for multiple analysis. In other circumstances it needs to be given explicitly, for example before undergoing a specified operative procedure or providing a specimen of blood to be tested specifically for a named condition. As the expectations of patients, and consequently the demands made upon doctors, increase and develop, it is essential that both doctor and patient feel free to exchange information before investigation or treatment is undertaken.

Testing for HIV infection: the need to obtain consent

13. The Council believes that the above principle should apply generally, but that it is particularly important in the case of testing for HIV infection, not because the condition is different in kind from other infections but because of the possible serious social and financial consequences which may ensue for the patient from the mere fact of having been tested for the condition. These are problems which would be better resolved by a developing spirit of social tolerance than by medical action, but they do raise a particular ethical dilemma for the doctor in connection with the diagnosis of HIV infection or AIDS. They provide a strong argument for each patient to be given the opportunity, in advance, to consider the implications of submitting to such a test and deciding whether to accept or decline it. In the case of a patient presenting with certain symptoms which the doctor is expected to diagnose, this process should form part of the consultation. Where blood samples are taken for screening purposes, as in ante-natal clinics, there will usually be no reason to suspect HIV infection but even so the test should be carried out only where the patient has given explicit consent. Similarly, those handling blood samples in laboratories, either for specific investigation or for the purposes of research, should test for the presence of HIV only where they know the patient has given explicit consent. Only in the most exceptional circumstances, where a test is imperative in order to secure the safety of persons other than the patient, and where it is not possible for the prior consent of the patient to be obtained, can testing without explicit consent be justified.

14. A particular difficulty arises in cases where it may be desirable to test a child for HIV infection and where, consequently, the consent of a parent, or a person in loco parentis, would normally be sought. However, the possibility that the child may have been infected by a parent may, in certain circumstances, distort the parent's judgement so that consent is withheld in order to protect the parent's own position. The doctor faced with this situation must first judge whether the child is competent to consent to the test on his or her own behalf. If the child is judged competent in this context, then consent can be sought from the child. If however the child is judged unable to give consent the doctor must decide whether the interests of the child should override the wishes of the parent. It is the view of the Council that it would not be unethical for a doctor to perform such a test without parental consent, provided always that the doctor is able to justify that action as being in the best interests of the patient.

CONFIDENTIALITY

15. Doctors are familiar with the need to make judgements about whether to disclose confidential information in particular circumstances, and the need to justify their action where such a disclosure is made. The Council believes that, where HIV infection or AIDS has been diagnosed, any difficulties concerning confidentiality which arise will usually be overcome if doctors are prepared to discuss openly and honestly with patients the implications of their condition, the need to secure the safety of others, and the importance for continuing medical care of ensuring that those who will be involved in their care know the nature of their condition and the particular needs which they will have. The Council takes the view that any doctor who discovers that a patient is HIV positive or suffering from AIDS has a duty to discuss these matters fully with the patient.

Informing other health care professionals

16. When a patient is seen by a specialist who diagnoses HIV infection or AIDS, and a general practitioner is or may become involved in that patient's care, then the specialist should explain to the patient that the general practitioner cannot be expected to provide adequate clinical management and care without full knowledge of the patient's condition. The Council believes that the majority of such patients will readily be persuaded of the need for their general practitioners to be informed of the diagnosis.

17. If the patient refuses consent for the general practitioner to be told, then the doctor has two sets of obligations to consider: obligations to the patient to maintain confidence, and obligations to other carers whose own health may be put unnecessarily at risk. In such circumstances the patient should be counselled about the difficulties which his or her condition is likely to pose for the team responsible for providing continuing health care and about the likely consequences for the standard of care which can be provided in the future. If, having considered the matter carefully in the light of such counselling, the patient still refuses to allow the general practitioner to be informed then the patient's request for privacy should respected. The only exception to that general principle arises where the doctor judges that the failure to disclose would put the health of any of the health care team at serious risk. The Council believes that, in such a situation, it would not be improper to disclose such information as that person needs to know. The need for such a decision is, in present circumstances, likely to arise only rarely, but if it is made the doctor must be able to justify his or her action.

18. Similar principles apply to the sharing of confidential information between specialists or with other health care professionals such as nurses, laboratory technicians and dentists. All persons receiving such information must of course consider themselves under the same general obligation of confidentiality as the doctor principally responsible for the patient's care.

Informing the patient's spouse or other sexual partner

19. Questions of conflicting obligations also arise when a doctor is faced with the decision whether that fact that a patient is HIV position or suffering from AIDS should be disclosed to a third party, other than another health care professional, without the consent of the patient. The Council has reached the view that there are grounds for such a disclosure only where there is a serious and identifiable risk to a specific individual who, if not so informed, would be exposed to infection. Therefore, when a person is found to be infected in this way, the doctor must discuss with the patient the question of informing a spouse or other sexual partner. The Council believes that most such patients will agree to disclosure in these circumstances, but where such consent is withheld the doctor may consider it a duty to seek to ensure that any sexual partner is informed, in order to safeguard such persons from a possibly fatal infection.

CONCLUSION

20. It is emphasised that the advice set out above is intended to guide doctors in approaching the complex questions which may arise in the context of this infection. It is not in any sense a code, and individual doctors must always be prepared, as a matter of good medical practice, to make their own judgements of the appropriate course of action to be followed in specific circumstances, and able to justify the decisions they make. The Council believes that the generality of doctors have acted compassionately, responsibly and in a well-informed manner in tackling the especially sensitive problems with which the spread of this group of conditions has confronted society. It is confident that they will continue to do so.

Complaint by GRO-A

GMC Reference RG/FP/2005/1881

Responses by Professor Christopher Ludlam

1. Response to the allegations
2. GRO-A s medical history (paper apart 1)
3. Response to GRO-A s letter of 22 August 2005 (paper apart 2)
4. Response to the Council of European Committee of Minister Recommendations No R(83)8 (paper apart 3)
5. Response to the Frontline Scotland programme (paper apart 4)
6. Shortened resume for Professor Ludlam (paper apart 5)
7. Assessment of immune function of persons with haemophilia in Edinburgh (paper apart 6)
8. Consent form (annexation 1)
9. Information sheet re factor VIII (annexation 2)
10. Factor VIII concentrate label (annexation 3)
11. Hepatitis C information sheet (annexation4)
12. Literature from the Haemophilia Society (annexation 5)
13. Letter to the BBC from the Medical Director, Lothian NHS (annexation 6)
14. Questions from the BBC (annexation 7)
15. Responses from Professor Ludlam (annexation 8)
16. Additional notes from Professor Ludlam (annexation 9)

Response to Schedule of Allegations

1. *That from 1980 to date you have been working at the Royal Infirmary of Edinburgh firstly as a Consultant Haematologist and then in a number of different posts.*

I confirm that I have been working as a consultant haematologist at the Royal Infirmary of Edinburgh since 1980 when I was also appointed as Director, Haemophilia Centre. I was Head, Department of Haematology, Royal Infirmary of Edinburgh 1990 - 2004. In 1999, in addition, I was appointed as Professor of Haematology and Coagulation Medicine at the University of Edinburgh.

2. GRO-A , *a Haemophiliac has been under your care since that date.*

I confirm that I have been the responsible Consultant Haematologist for Mr GRO-A from 1980 until August 2005 after which his care was taken over by a colleague, as a result of the allegations by GRO-A in the Frontline Scotland programme Blood and Tears. I met with him along with his father to consider the issues that had been raised in the programme on 27th June and 1st July,

both at my instigation, when I suggested that another haemophilia consultant should take over his care, for the time being, as it seemed to me that there had been an apparent serious breakdown of trust in our relationship. He had never previously mentioned to me the criticisms he raised in the television programme. From my perspective the allegations he made were inaccurate and misleading. His action in taking part and what he said in the programme seemed to me to be so out of character and unreflective of our relationship. At our meeting on 27th June he indicated that he would be quite happy for me to continue to look after him and at no time has he asked for, or indicated that he would like another consultant to look after him. These two meetings took place after his letter to GMC dated 22nd June and at neither did he indicate that he had made a formal complaint.

3. *In the 1980's* GRO-A *'s mother was injecting* GRO-A *with Factor VIII to treat the condition.*

GRO-A was taught, in 1980, how to set up infusions of cryoprecipitate. The teaching was mainly given at GRO-A and she was viewed by the staff there as being competent to give the treatment. She gave cryoprecipitate at GRO-A because it was considered unsafe to give it at home, because of

the risk of allergic reactions. As she was able to give the therapy it was much quicker to get him treated at anytime of day or night rather than having to wait for one of the hospital doctors to attend. This made treatment of his acute bleeds much easier and avoided frequent journeys to Edinburgh a distance of approximately 30 miles. In August 1981 I was able to provide factor VIII concentrate for home treatment and she was shown how to make it up and administer it. As evidence of her understanding of the procedure and the risks she signed our standard consent form on 11th August 1981 (copy attached - Annexation 1).

In April 1982 during an admission to the Royal Infirmary GRO-A was shown how to administer cryoprecipitate (which was being given for an acute bleed) and he readily learned to do this. The synopsis of GRO-A 's medical history (paper apart 1) outlines how during 1982 he took over from his mother the administration of factor VIII concentrate, although when he had a difficulty during the first year she would help him. By mid 1983 he was giving the factor VIII regularly and effectively to himself for acute bleeds and for prophylactic therapy, particularly for problems associated with his right knee.

4. *From April 1983 you began an AIDS study on* GRO-A

The clinical studies I set up in the early 1980's were in direct response to the AIDS threat. The reasoning behind the need for immune surveillance is briefly set out in answer to allegation 3 at page 13. Similar investigations were being undertaken in other large Haemophilia Centres in the UK and were considered an appropriate clinical response to the immune abnormalities which had been reported in those with haemophilia elsewhere. Our investigation was colloquially know as the "AIDS study", although there were no known cases of AIDS either in the patients in Edinburgh at that time, or in the population of Scotland from which the blood donors were drawn and from which the factor VIII concentrate was made. It was not therefore a study on AIDS as such, but a clinical assessment of immune function of patients with haemophilia.

In my previous letter to the GMC of 2nd August 2005 I referred to the "AIDS Study" as a "research project". It was set up as a project, or special study, so that the correct investigations would be carried out on the samples. The request forms were labelled "AIDS study" so that when the samples were received in the Royal Infirmary, Department of Haematology Laboratory they would be handled differently from routine blood test requests. This was because they required different investigations and also they needed to be

couriered by taxi across Edinburgh to the Western General Hospital for measurement of lymphocyte CD4 and CD8 subsets. See the paper apart 6 - "Assessment of immune function of persons with haemophilia in Edinburgh".

I acknowledge it is debatable whether the investigations should be termed as research or as immune surveillance set up in response to the AIDS threat. I did not seek ethical approval for these investigations (see response to Allegation 5).

In summary for reasons set out above this was not an AIDS Study on Mr GRO-A

5 *You:-*

(a) performed a test on GRO-A *to determine whether there was immunosuppression;*

(b)allowed a test to be performed on GRO-A *as described in 5(a) above.*

Standard tests of immune function were arranged on peripheral blood samples taken from GRO-A, which consisted of measurement of the lymphocyte

count, lymphocyte subset CD4 and CD8 numbers, and serum components, eg immunoglobulins and beta2 microglobulin.

The haematology request forms in the clinical details section were labelled 'Aids study' or 'haemophilia aids study'. The forms containing the results were not initially put in the patient's case notes because I did not wish anyone reading the case notes to consider that GRO-A (or any patient) might have AIDS. When anti-HTLVIII testing became available and it became known that some individuals were infected, such speculation might have been very detrimental to the patient's care, because of the extreme anxiety felt by many about the possibility of AIDS virus transmission to staff during medical investigation and treatment in hospital.

6. *The blood tests at paragraph 5 were recorded in the medical notes as:-*

(a) Aids study

(b)haemophilia aids study

The request forms were labelled as "Aids Studies" or "Haemophilia Aids Studies" but no record of such studies being carried out was made in the notes for the reasons mentioned in the response to Allegation 5 (above).

7. In 1984 you arranged to be carried out an anti-HTLVIII antibody test on Mr GRO-A *s blood.*

Stored serum samples of GRO-A 's blood were sent to Dr R S Tedder, consultant virologist at the Middlesex Hospital for anti-HTLVIII testing probably in October/November 1984.

8 (a). *You did not obtain appropriate consent for the tests at paragraphs 5 and 7.*

Blood samples for the immune studies were likely taken at the same time as blood was being taken for other routine surveillance investigations, e.g. liver function tests, or anti-factor VIII antibody assay, or a sample for serum storage, or when GRO-A had a needle in a vein when he was receiving treatment for an acute bleed. It was our standard practice, if we were wishing to take extra samples, to let the patient know that we would like to do so and to seek his explicit verbal consent. If no verbal consent was given then the extra sample would not be taken. I believe it was generally known within the patient group that serum was stored for the purpose of investigating retrospectively any infection or potential infection that might be transmitted by treatment.

At that time there was only a single haemophilia room in the ward in which patients were reviewed with acute bleeds. It therefore served both as a waiting room and treatment facility. GRO-A brought her son to hospital by car and would have been present when he was being examined, investigated and treated. Furthermore when GRO-A attended the review clinics in the hospital outpatient department, his mother always came into the consulting room with him. This enabled me to get a rounded picture from both GRO-A and his mother of how his haemophilia was affecting him and how the treatment arrangements were working out in practice. Thus GRO-A was usually seen in the presence of his mother, so that both would have heard about the proposed blood tests. Consent for tests was not recorded in the case notes as it was not standard practice at that time to do so. In 1985 the Lothian Health Board Ethics Committee agreed that it was not necessary to record verbal consent in patients' case notes for the taking of small blood samples, even if they were part of a formal research project with clinical approval.

We had a very open and explicit policy about issues related to blood safety and viral infections and were happy to discuss our investigations with patients (see the answer to allegation 8 (d) and (e), pages 12 and 13 below. At no time do I recall GRO-A, or his mother, who accompanied him to the Haemophilia Centre and who took a keen interest in his treatment and welfare, ever raising

any objection to the blood being taken for full blood count, liver function tests, anti- factor VIII inhibitors, storage, immune surveillance, or research. Had Mr GRO-A or his mother done so, the blood would certainly not have been taken.

8 *You did not*

(b) give the patient counselling in respect of the test at paragraphs 5 and 7;

(c) give the family counselling in respect of the test at paragraphs 5 and 7

A full response to this allegation invites clarification of exactly what is meant by the term "counselling" since its meaning and practice in the health service have changed considerably during the past thirty years. Indeed counselling as it practised today as an integrated part of our Centre's service to patients with haemophilia has been developed largely as a response to the complex ethical issues and traumatic impact of blood-borne infections, as well as being shaped by the developments in practice and values of counselling in other health settings. There is a risk therefore of applying 21st century expectations anachronistically to practice of 20 years ago which was not then thought of as 'counselling'.

Nevertheless in our haemophilia service from the time of my appointment we considered it important in respect of patients to

- Offer full information and explanation about procedures and treatment;
- Discuss with the patient the implications of undergoing or of choosing not to undergo procedures or treatment;
- Listen to the patient's concerns;
- Observe the patient's need for confidentiality;

Attention was also paid to the needs of patient's family members and to the particular needs of parents of minors.

GRO-A and his mother knew of my concerns about blood safety and the need for surveillance. It would have been explained to GRO-A and his mother in 1980, when I had wanted to give him home treatment with factor VIII, but could not do so because of a shortage of SNBTS NHS concentrate, that I considered it better to wait a short while until there was more NHS concentrate available than to expose him to the additional hepatitis risks from US commercial concentrates.

He was also issued with a small information leaflet to keep in his Department of Health Haemorrhagic States Card (a Haemophilia Card - which gave details of

his haemophilia so that he could get treatment readily at other Haemophilia Centres he might visit with an acute bleed if away from Edinburgh). This small information sheet was composed by me and requested that if treatment was needed at another centre GRO-A should receive cryoprecipitate or NHS factor VIII concentrate and that commercial concentrates should be avoided if possible. This information sheet was given to all patients who had been treated only with NHS blood products. At my meeting with GRO-A and his father on 1st July 2005 he volunteered that he remembered this "letter" (see clinic note). GRO-A and his mother and father would therefore have known of my particular concerns about blood safety.

The initial anti-HTLVIII tests were carried out without either GRO-A or his mother's specific consent. The samples would have been taken from the bank of serum samples. It should be borne in mind that this was carried out in the autumn of 1984 before the necessity for HIV pre-test counselling was appreciated and at a time when consent was not considered appropriate for other viral tests e.g. those for hepatitis B. It was not until 1985 that the necessity for pre-test counselling started to become apparent. In my capacity as Chairman of the Lothian ADIS Advisory Committee which was set up early in 1985, I became acutely aware of the need for pre-test counselling. I spent a considerable effort trying to promote it in various non-haemophilia clinical

settings. It was not until three years later in 1988 that the GMC published guidance on the need for counselling in relation to HIV testing.

It should be noted that when I saw GRO-A in November 1986 he was aware that I had an anti-HTLVIII result on his blood and he did not indicate that we should not have tested him previously. In March 1989, when he was seen by Dr Auger, it was made very explicit that we were testing him for HIV and he gave his consent for us to continue to do so. When I told him in February 1991 that he was HIV positive he did not indicate that he objected to having been tested.

8 *You did not:-*

(d) inform the patient that the test was part of a clinical study;

(e) inform the parents that the test was part of a clinical study

The term 'clinical study' may be interpreted in a number different ways. I understand this term in this context to describe the clinical monitoring of patients' immune status over a period of time. It is my belief that GRO-A would have been informed and consulted. It was our standard practice to inform all such patients about the investigations which we wished to undertake and there is no reason to believe that GRO-A was treated in any different

way from fellow patients with haemophilia. If either of his parents was present they would have received the same information.

The rationale for the immune tests was as follows. They were to assess the immune status of each individual person with haemophilia, as immune tests were being reported to be abnormal in other patients with haemophilia and a few persons with haemophilia had developed clinical evidence of immune suppression (AIDS). Therefore to have set up these investigations was viewed as good clinical practice to try and monitor patients' response to a new and ill understood threat.

When it became clear that the results in some patients were outwith the normal range, in a clinical setting where it was very unlikely that they would have been infected by a putative AIDS agent it was important that this should be brought to the attention of other haemophilia treaters and hence the results were published.

Both GRO-A and his mother, when present, would have understood that we were undertaking additional tests (see the answer to allegation 8a above) and I think it likely they might well have been told that the investigations were part of a study of his immune system. Evidence of our open policy for informing

patients about our investigations is the fact that the words 'AIDS study' had been explicitly written on the form. These forms may well have been seen by the patient, or parent, when the blood was being collected as the forms would be beside the patient when the tubes were being filled with his blood. Had we wished to keep our investigations a secret from the GRO-A or his mother, we could certainly have labelled the forms in a different and very less explicit way.

8 You did not

(f) take proper steps to inform the patient about the HIV positive test results;

(g) take proper steps to inform the parents about the HIV positive test result

It should be borne in mind that the inference of an anti-HTLVIII result in December 1984 was very different then from what is now understood by an 'HIV positive test result'

GRO-A 's parents were invited to an open meeting in December 1984, the invitation for which was explicit in stating that it would be about the AIDS issues in haemophilia. Had they attended, they would have learned that many

patients had been anti-HTLVIII tested and that the patients could obtain the results by arranging a meeting with myself.

Nevertheless GRO-A 's parents were also sent the 'Advice sheet on Adult patients and families on Acquired Immune Deficiency (AIDS)'. This alerted recipients to the fact that individuals with haemophilia in Scotland had been tested for anti-HTLVIII and it made an explicit offer of a meeting with myself to discuss individual circumstances. A letter dated 31st January 1985 was also sent to GRO-A GRO-A GP, who could have either contacted me for further information or seen GRO-A . I assumed that GRO-A 's parents received the letter and that they would have discussed its contents with him.

As GRO-A had been tested without his consent and we believed he had appreciated the safety precautions which were set out in the information sheet, we considered that there was no need immediately to actively seek out and inform patients of their anti-HTLVIII status. At this time there was no treatment for those with HIV infection. Our experience was that most haemophiliacs knew that they had been anti-HTLVIII tested but many did not wish to have the result immediately. They wanted some time to consider the issues and Mrs Geraldine Brown, Social Worker and AIDS Counsellor played a crucial role in counselling patients about the issues. We believed it important

that all patients should eventually know their anti-HTLVIII result, but, provided the safety precautions, which were recommended for all haemophiliacs (both anti-HTLVIII negative and positive) were being followed it was not essential to insist that patients knew their anti-HTLVIII result immediately, given there was no effective treatment or specific therapy for those who were anti-HTLVIII positive.

In addition to the above, I would have discussed with GRO-A in a general way that we were concerned about HIV and AIDS and that safety precautions were appropriate when I saw him on 25th March 1985, 30th June 1985, 28th January 1986. The notes disclose that it was in my mind, as I was examining him for enlarged lymph nodes, (a known feature of HIV infection at the time) which was not previously part of the routine examination of a patient with haemophilia. It is likely I mentioned the concerns about AIDS because I was anxious for him to know the result and I was keen to open up a discussion about the subject of his anti- HTLVIII status with him in the hope that he might wish to consider knowing his result. I also recall my ethical dilemma in wanting him to know; he was preparing for his Higher exams which he took in April/May 1986 and I remember thinking when I saw him on 28th January 1986 that it would be inappropriate to volunteer the information about his HIV status just before his forthcoming exams.

As there had not been any enquiry by the end of 1986 from either GRO-A or his parents, about his anti-HTLVIII status, I arranged to see him on 13th November 1986. I told him about the risks to people with haemophilia of HTLVIII infection and that anti-HTLVIII tests had shown that some people with haemophilia in South East Scotland had been infected. An account of the session is in paper apart 1 in the synopsis of his medical history (page 4). He made it very clear to me that he did not wish to know his anti-HTLVIII result. I took care therefore that he was informed about the safety precautions which were appropriate for all patients with haemophilia.

During the next two years he was working away from home and presented with few bleeds. At this time, as set out in the medical history (paper apart 1), we considered his situation repeatedly and very carefully in our weekly multi-disciplinary meetings to discuss the overall help and medical treatment we could offer patients with HTLVIII.

On 14th August 1988 Dr Auger, Clinical Assistant, Haematology Centre and Dr Richardson, AIDS Clinical Psychologist wrote to GRO-A telling him they were planning to visit him at home to discuss HIV and AIDS related matters. (paper apart 1 - page 5) The visit is not noted so it appears he cancelled it. He was eventually seen by Dr Auger on 20th March 1989 (paper apart 1 - page 6) when

the notes make clear he was aware he had been HIV tested, that we could continue to do so, but that he did not wish to know the result. As is documented in the medical history (paper apart 1 - page 8) I saw him on 15th January 1991 and told him the result. By this stage there was therapy of demonstrable and proven benefit, which could be offered eg zidovudine and so it was essential to give him the opportunity to be treated. As is clearly set out in his medical history he was very reluctant to accept the offer of therapy and failed to attend many clinic appointments. He only agreed to take septrin as PCP prophylaxis two years later in 1993 (and then only intermittently). He declined the offer of zidovudine for 5 years, even when he had advancing severe neurological disease.

In my discussion with GRO-A and his father on the 27th June 2005 after the "Blood and Tears" programme, GRO-A very explicitly stated he was glad not to have known his anti-HTLVIII result until 1991 as he had had six extra years without the worry of knowing about his HIV status. See paper apart 2 - page 3.

When the anti-HTLVIII result on GRO-A was available he was almost 15 ½ years old. In my view at that time, and in the considered view of my colleagues, it would have been inappropriate to have volunteered the anti-HTLVIII result

to his parents. They were invited to the open meeting, sent the information sheet on AIDS, and his father was aware that individuals with haemophilia were at risk of AIDS. At that time GRO-A 's father was a blood donor who was declined because of his son's haemophilia, although they made no enquiry about their son's anti-HTLVIII status. Had they done so, this would have opened up a further discussion in our team about whether we should have encouraged Mr GRO-A to seek to know his anti-HTLVIII status. If he did not want to know the result (and all the evidence set out above is that he did not want to), it is extremely unlikely that he would have given his consent to his parents knowing the result, particularly given his persistent reluctance to inform his parents after 1991 even when he had rapidly progressive HIV-related brain damage in 1997 -paper apart 1 - page 15. Had we told his parents the anti-HTLVIII result without his consent I think we might have been censured for disregarding his wishes and for breaching confidentiality.

Since his parents were informed in 1997 by GRO-A I have had several discussions with his father (and at least one with his mother) about the long delay in them knowing about his HIV status. My clear recollection is that they appreciated the difficulty, suspected that their son might be HIV positive long before he was told and were not critical of my not telling him.

8(h) and (i) *You did not:-*

(h) warn the patient of the risks of contracting infectious diseases from Factor VIII therapy;

(i) warn the parents of the risk of contracting infectious diseases from Factor VIII therapy

GRO-A and his parents were aware that factor VIII therapy might transmit viral infection from the following sources.

1) The information sheet enclosed with each bottle of factor VIII concentrate states there are "generalised complications of hepatitis" (see annexation 2 - Page 2 "side effects").
2) The bottles of SNBTS factor VIII concentrate state on the label that "this preparation of human origin cannot be assumed to be free of hepatitis virus" (see annexation 3).
3) The consent form about home treatment that GRO-A signed in 1981 specifically mentioned that factor VIII concentrate may transmit infections (annexation 1).
4) I will have discussed the issues of hepatitis with them particularly in relation to:

a) My delay in giving GRO-A home treatment because I wished to avoid use of commercial factor VIII concentrate because of the hepatitis risk.

b) The insert I provided for the Haemophilia Card stating that if he visited another Haemophilia Centre he should be treated with NHS concentrate or cryoprecipitate and commercial concentrate should be avoided if possible.

c) It would have been known from our requests for storage of blood samples that these were being collected because of the possibility of infections being acquired from the factor VIII treatment.

d) I was keen for patients to have access to literature produced by the patients' Haemophilia Society and their information material was made available to patients in the Haemophilia Treatment room in the ward. In the 1980's they were very active in offering information about viral or other possible infections. The Haemophilia Society notice board in the Haemophilia Room also posted information about haemophilia and encouraged patients to join the

Society based in London as well as the local Edinburgh group. There was a regular bulletin and also Haemofact Sheets were produced specifically about viral infections.

e) GRO-A 's parents were sent the "Information Sheet for Adults and Families on Acquired Immune Deficiency Syndrome".

f) Serial attempts that were made from 1985 onwards to encourage GRO-A to know his anti-HTLVIII status. At each of these he will have been reminded that factor VIII concentrate could transmit infections.

9 - *Over a number of years you continued to treat* GRO-A *and in following consultations you did not:-*

(a) confirm he was at any particular risk

(b) give/offer any counselling;

(c) give any advice to his family relating to the risks involved;

(d) take proper steps to inform him of the HIV positive result.

This allegation covers ground which I have already addressed elsewhere and in particular in my responses to allegation 8. Rather than repeat information already given I can confirm that I made every effort to advise GRO-A of his status, gave advice about the risks inherent in the use of factor VIII both to GRO-A and to his family and offered him access to the social worker and AIDS Counsellor.

10. *You informed* GRO-A *that he was HIV positive in 1991.*

I confirm I advised GRO-A at a consultation on 15th January 1991 that he was HIV positive - see paper apart 1 - page 8.

11. *By acting as you did in paragraphs 4-10 above you failed to:-*

(a) provide GRO-A *with appropriate treatment;*

(b) give appropriate advice

(c) safeguard against the risk that GRO-A *'s family and the public could be infected;*

(d) allow GRO-A *access to appropriate treatment by not informing him of his HIV status.*

Prior to 1991 there was little in the way of proven effective therapy. Had he known his anti - HTLVIII status in the late 1980s then it is likely that he would have been offered pentamidine as a prophylaxis to PCP. As he never developed PCP subsequently he would have gained no benefit from that. When he was offered the PCP prophylaxis (pentamidine) in 1991 he declined it for a period of two years, and only took septrin intermittently thereafter. It seems likely from subsequent events that if he had been offered pentamidine in the late 1980s he would have declined it.

All of the advice given to all of the Haemophiliac patients (whether anti-HTLVIII positive or negative) ensured that the risks to their families or the public were minimised.

12. *On 2nd August you wrote to the GNC in response to the complaint made against you.*

I confirm that I wrote to the GMC in a letter dated 2nd August 2005 about a complaint made against me.

13. *In that letter you stated that the studies had full ethical approval from the Lothian Health Board Committee.*

I stated in my letter of 2nd August 2005 in response to para 4 of GRO-A 's letter of 22nd June 2005 (page 4 of my letter) that 'my research activities in relation to HIV and in particular the cohort of haemophiliacs who became infected by a single batch of factor VIII....had full ethical approval from the Lothian Health Board'. This is correct and it was granted in 1985. I did not claim that the immune studies we carried out in 1983 and 1984 had ethical approval. I did not seek ethical approval for these as at that time it was doubtful whether it would have been considered necessary because the investigations were viewed as part of individual patient assessment in response to the developing AIDS situation in the United States. In addition only a small

sample of extra blood was being taken at a time when the patients were having blood taken for other routine tests, or receiving treatment and for which we were seeking patient's verbal consent. Furthermore, even for formal research studies it was acceptable practice not to record verbal consent in the case notes. Additionally the information obtained from the immune tests might be directly useful for benefit of the individual patients. I believe similar studies were being undertaken in other large Haemophilia Centres as part of the routine clinical immune surveillance in 1983.

I have been very conscious of the need to obtain ethical approval for research studies and the necessity and arrangements for these have evolved over the last 25 years. I have obtained appropriate consent for my research studies.

14. *Your claims at paragraph 13 were: -*

(a) inaccurate;

(b) misleading;

(c) intended to mislead.

I do not believe my statement that the HIV studies had ethical approval was inaccurate or that it was intended to mislead. I can see however how my

response might have been misinterpreted, and I apologise if it was not clear, but it was never my intention to be misleading in my response. In retrospect it is unfortunate that the haematology request forms were labelled in 1983 with 'AIDS study' as I can see how this has led to misunderstanding subsequently. As I have indicated above, the labelling of the investigations as 'AIDS Study' was a shorthand, or colloquial expression, for the immune investigations that were we were undertaking. It could not be considered a study on AIDS, because none of the patients in Edinburgh had AIDS in 1983/4.

15. *Your conduct as set out above was: -*

(a) unacceptable;

(b) inappropriate;

(c) inadequate;

(d) not of a standard expected of a Medical Practitioner;

(e) not in the best interests of your patient.

As evidenced by the information I have provided above I believe that my conduct was acceptable, appropriate, adequate, of the standard expected of a Medical Practitioner and I tried to act sensitively and in the best interests of

GRO-A

2

GRO-A 's medical history

GRO-A was referred for advice about his haemophilia to the Royal Infirmary, Edinburgh in 1979 by Dr Alison Thomson, Consultant Paediatrician at Peel Hospital, Galashiels. He had recently moved to GRO-A having previously lived in both GRO-A and GRO-A At the time of referral to us his principal clinical difficulty related to a chronic haemarthosis of his right knee. On investigation his basal factor VIII level was 2.2% and he thus had moderate haemophilia A. He had evidence of prior hepatitis B infection, as antibody was detected to the virus in 1980. His liver function test results revealed an intermittently elevated alanine amino transferase which reflected the presence of non-A non-B hepatitis. There was no history of an anti-factor VIII inhibitor.

I first met GRO-A when he came with his mother to my clinic on 7th February 1980 shortly after I took up my appointment at the beginning of that year. As he lived some distance from Edinburgh he was treated at the more local GRO-A I had hoped to be able to let him have home treatment for his acute bleeds, but I could not do that because of the shortage of NHS factor VIII concentrate. I explained this to GRO-A and his mother and that I was reluctant to recommend commercial factor VIII because of the extra hepatitis risk that I perceived. Arrangements were therefore made for

him to be treated with cryoprecipitate at GRO-A for acute bleeds. Mrs GRO-A was taught how to set up the infusions and, according to the correspondence clearly became *'both competent and confident about giving the intravenous injections'*. During 1980 he had many more bleeds typical of haemophilia than had occurred previously.

This local treatment arrangement seemed to work well.

In August 1981, as he was about to start secondary school, and because the supply of NHS factor VIII had increased, I arranged for him to have home treatment, which his mother was competent to give. This arrangement worked well. He continued to have bleeds and his right knee was still troublesome. In April 1982 GRO-A was admitted to the Royal Infirmary because of the continuing bleeds into his right knee. He was treated with cryoprecipitate which he was *'encouraged to give this himself, which he learnt to do with little problem'* and on discharge *'he will give himself alternate days factor VIII and continue with physiotherapy'*.

Over the following year GRO-A took over giving himself the factor VIII, although occasionally his mother did so if there was a difficulty. In 1983 the case notes record that he was giving himself treatment and Dr Logie at GRO-A

GRO-A noted that when he attended there with a bruise to his back *'he was observed to give himself 40mls of Factor VIII solution with admirable efficiency'.* During 1983 and 1984 he continued under regular review in Edinburgh and was admitted to hospital on several occasions because of bleeds, which responded well to treatment.

In approximately December 1984 he was found to be anti HTLVIII positive as a result of blood samples having been sent to Dr Tedder in London.

On 31st January 1985 I sent a letter to Dr GRO-A, his GP, letting him know that some patients with haemophilia were anti-HTLVIII positive and outlining the safety precautions which were necessary, including barrier contraceptives. The letter indicated that this would be an anxious time for his patient and I invited Dr GRO-A to contact me if he wished to discuss his patient further. GRO-A's parents were sent a copy of the "Information for Patients and Families about Acquired Immune Deficiency Syndrome".

On 25th March 1985, I reviewed GRO-A and noted that on examination he had some lymph nodes palpable in both axillae and a few in his neck. In June 1985 I recorded that he had a small lymph node in his right axilla. In January 1986, when I reviewed him at the clinic, I noted that he had had a recent sore

throat and on examination he had small tonsillar and axillary nodes, but his liver and spleen were not palpable. I noted that he was working for his Higher exams in April and May (these are the final school leaving exams) and that he was hoping to get a job as a wood turner.

(Comment: When I reviewed him on these occasions I was clearly aware of his anti HTLVIII status because of the entry in the case notes about the lymph nodes and I would have used the opportunity enquire whether he wanted to discuss issues related to HIV. It is likely that I would also have mentioned to him that we were recommending all patients to use safety precautions for sex).

He was seen on three occasions for review or with bleeds in 1986, but as Mr GRO-A appeared to be reluctant to wish to know more about HIV, I invited him to come and see me on 13th November 1986 at the Haemophilia and Thrombosis Centre. The record of this meeting did not form part of his normal clinical case notes until recently, because of issues related to confidentiality. The record of this counselling session was kept in a separate confidential file. The entry reads: *'Invited for counselling. Does not want to know antibody result. Knows precautions of sex/blood. Working as a carpenter - started 9/52 ago. Employer knows he has haemophilia. Advised about have gloves/bleach. ---- Geraldine'*

(Geraldine Brown was the Social Worker and Aids counsellor.

(Comment: I remember the occasion because he had not given any indication of wanting to know his HTLVIII status previously and I was keen that he should know. He made it very clear however that he did not wish to know and it would therefore have been inappropriate to give him the information. At this time there was no therapy for HIV from which he could have benefited).

During 1987 he was seen on four occasions. In February 1987 it was noted that he had some axillary lymph nodes.

In February 1988 he presented with a splinter in his finger and I suggested that he be referred to casualty. The record states that if an invasive procedure is required he would need to be treated as a 'high risk patient'.

On 14th June 1988 Dr Auger, Clinical Assistant Haemophilia Centre and Dr Alison Richardson, Clinical Psychologist wrote to GRO-A as follows:

"Dear GRO-A

We are hoping to visit all the people that attend this unit and who may have worries about the AIDS virus at the present time. We would therefore like to

visit you at home at about 10.30 am on Tuesday the 28th June 1988. If this time is not convenient for you or if you would prefer not to be visited please leave a message for us with Dr Ludlam's secretary on extension 2099, or bleed me on bleep no. 1714 and we will change the arrangements to suit you.

Look forward to seeing you,

Yours sincerely

Dr Auger and Dr Richardson did not visit GRO-A I assume therefore that he must have been in touch to indicate he did not want a visit.

He was not seen in the Haemophilia Centre again until 20th March 1989 when he was reviewed by Dr Auger. The case notes record the following '

'Seen in Centre. Bleeds approximately once/fortnight,' Record describes bleed in left elbow the previous day and recent one in left ankle. Had run out of home treatment. He was given factor VIII infusion and 20 bottles of factor VIII to take home.

'Aware we have been doing HIV tests.

DOES NOT WANT TO KNOW THE RESULT (in capitals in the casenotes)

Consents to continuation of HIV testing. I have told him that if he ever wants to discuss this HIV results he can contact one of the doctors in the Centre and arrange to see them at any time.

I have advised him to assume that he is at risk of passing on HIV infection and therefore should use protection for intercourse and be especially careful with the disposal of needles and blood spillages.

He enquired about possible loans for home purchase, I said that a bank/insurance company would probably want to know his HIV result, but that we would never disclose this information to anyone, including his GP. I advised him to contact the Haemophilia Society for the most recent information on loans etc' (signed) B. Auger (Clinical Assistant).

In 1989 he was seen with two bleeds, one of which into his right knee required a three-day admission to hospital in September. I requested physiotherapy at Bridge of Earn Hospital because he had been living away from Edinburgh in GRO-A for several years.

Follow up appointments were sent to his home address in 1990 (as he never gave us his address in GRO-A), but as he failed to attend his parents were

contacted. They did not have his address. We contacted his GP who reported that he was still registered as his patient but *'had not seen him for years. GP will contact parents'*. On 9th October 1990 I have written in his case notes *'GP does not know anti-HIV status. Dr Hughes to ring GP to tell HIV result'*.

In January 8th 1991 Dr Hughes telephoned GRO-A 's parents and his father told her that GRO-A had returned to live with them because he was without a job, had financial difficulties and had had a recent car crash without injury. The record continues by noting that his father said that he seems to be going through a period of *'denial of his haemophilia'*. His father suggested phoning later in the day to speak to GRO-A . Later in the day Sister Reynolds (Haemophilia Sister) spoke to him on the phone - he was *'very reluctant to come to Centre. Importance of the review was stressed and appointment given for Tuesday 15th at 10.30 to see Dr Ludlam.'*

GRO-A attended on 15th January 1991 when I saw him. He had not had many bleeds in the recent past. I told him of his HIV status and arranged for him to see Mrs Geraldine Brown the same day. I reviewed him the following week when I noted that he reported that he had been able to *'cope with the knowledge of HIV status better than he expected. Reassured that it is not transmissible by*

social contact but knows it can be sexually. Does not want his GP to know at present particularly as he is a family friend. Discussed indications for AZT (zidovudine)*/pentamidine and told it depends on his CD4 cell count - this to be repeated in 2/52 when reviewed again.'*

He was reviewed again on 19th February when the notes record *'AZT + pentamidine discussed. Needs pentamidine +/- AZT'*. He failed to keep two further appointments and was seen again on 28th May 1991 when he agreed to pentamidine, but wished to think further about AZT. He *'Refused to have pentamidine'* on that visit. He failed to keep four follow up appointments and therefore never received pentamidine. He was eventually reviewed on 6th December 1991 at which time he was working as a cabinetmaker in GRO-A He agreed to take septrin 960mg on alternate days and he was given 60 tablets, which were to last two months.

(Comment: By this time monthly pentamidine inhalations had been replaced by tablets of septrin as prophylaxis against PCP).

He again failed to keep two follow up appointments and was seen again after four months on 19th March 1992. On this occasion he had lymphadenopathy in this left neck and axilla, which was still present a month later on 16th April. I

was consulted after his visit and considered that a lymph node biopsy might be needed. He did not attend his monthly follow up appointment and I reviewed him on 18th June and on examination I found that his enlarged lymph nodes had regressed substantially.

(Comment: this is a feature of HIV in which lymph nodes care vary in size markedly over a period of time).

He failed to keep three follow up appointments and attended next on 6th October with a large psoas bleed. His was a major bleed and he was admitted to hospital for factor VIII and strict bed rest. On 15th October he took his own discharge against our advice because he '*found the bed rest on the ward intolerable,*' but he agreed to rest and continue to treat himself at home. He was reviewed on 27th October and an ultrasound examination revealed the haematoma had diminished markedly in size to only 1x1 cm. On 29th October the notes record that he was discussed at *'review meeting'* and should be offered AZT or Delta trial. This was an MRC trial of AZT and DDI. (Comment: another anti HIV drug).

He was reviewed on 10th November 1992 when AZT/Delta were discussed, but he wished to think further about these. He was offered and agreed to have

hepatitis A vaccine. On 1st December he was reviewed and indicated he did not want AZT or the Delta trial. On 21st December he presented with a severe bleed in the floor of his mouth and was admitted to hospital. With treatment, he made a good recovery.

In 1991 he failed to keep six follow up appointments. He was seen on 13th August 1993 with a post-traumatic bleed in his right forearm. Presented on 15th December 1993 with a broken tooth. He had stopped septrin 1 month previously because of diarrhoea, which had settled. Dr Andrews, Clinical Assistant, had a long discussion with him about hepatitis C and he was given our information sheet on the topic (annexation 4). He failed to keep three appointments for the liver clinic with Professor Hayes in May and June 1994. In December 1994 he was seen very fully by Dr Dennis, Clinical Assistant, about various aspects of his situation relating to haemophilia, HIV and hepatitis C – he again declined septrin and AZT.

I reviewed him on 25th January 1995 when I noted he was '*keeping reasonably well although R knee intermittently swelling especially after motor cycling*'. I gave him pethedine tablets for the pain in his knee and encouraged him to take factor VIII prophylactically to prevent bleeds. As he was considering giving up work, I arranged for him to see Mrs Geraldine Brown. During the remainder of

the year he was seen on five occasions and on the fifth, a fortnight after he had been in Dundee Royal Infirmary having unfortunately amputated the ends of the 3rd and 4th fingers of his left hand. His wounds were redressed and when reviewed a week later they had healed well. Septrin PCP prophylaxis was again discussed and offered, but he declined to restart it or take any other medication.

In January 1996 his situation was discussed at a meeting with Dr Brettle, consultant in Infectious Diseases, who suggested offering AZT but starting at a low dose of 100mg and gradually increasing it to 300mg. After not keeping two appointments, he attended in July 1996 with a generalized rash on arms and thighs. A fungal infection was diagnosed and he was given canestan 1%cream which rapidly produced improvement.

On 16th January 1997 GRO-A had a long discussion about HIV related matters with Dr Hanley, Lecturer in Haematology, who was working in the Haemophilia Centre. Even although his CD4 count was approximately 50, and he knew that he was at high risk of PCP and other infections, he did not want antibiotic prophylaxis. He agreed to eye examinations and a baseline brain MRI scan as recommended by Dr Brettle. He was feeling isolated because of his fears of the social stigma if neighbours and others knew of his HIV status. He

was therefore offered the opportunity to be put in touch with other HIV positive individuals and he agreed to consider this option. Present knowledge and experience of the benefits of anti-HIV drug therapy were discussed, but GRO-A said that he would rather wait until he ran into problems than have therapy at that time.

A week after this discussion with Dr. Hanley, he presented because his eyesight was rapidly deteriorating, he had a headache, some unsteadiness and clumsiness and was bumping into things. He was admitted immediately and reviewed urgently by Dr Dhillon, Ophthalmologist. A brain CT scan was reported as not showing any focal abnormality. Subsequently his condition was discussed with Dr Clifford Leen, consultant in Infectious Diseases, who strongly suspected progressive multi-focal leukoencephalopathy (PML). As his condition had stabilized, he was seen as an outpatient. An MRI brain scan on 6th August demonstrated abnormalities in the left parietal lobe, right occipital lobe and left thalamus. The scan was reported as strongly suggestive of PML.

I reviewed him on 7th August 1996 when I noted his vision was continuing to decline. We made arrangements to try and support him in the community along with assistance from Mrs Geraldine Brown. At this time he still did not want to let his parents know the diagnosis and he was fully conversant with the possibility of serious progressive neurological impairment. The following day he

was admitted to hospital and reviewed by neurologists again who discussed his situation with Prof Harrison (a neuro-HIV expert in London). A further lumbar puncture was suggested, as the previous one was negative for JC virus. (Comment: one of the causes of PML), to seek evidence of fungal infection. On further discussion with GRO-A, he decided against a further lumbar puncture. He was told that there was some doubt about the diagnosis, but if PML was established it was likely to progress rapidly. It was suggested that AZT would be the best option as it might slow progression, but GRO-A decided against it because of the possible side effects, saying that he preferred homeopathy. Arrangement was made for him to see Dr Linda McCallum who had homeopathic experience. GRO-A did not want to tell his parents the diagnosis until he was re-housed in GRO-A and Dr Hanley pointed out that his condition might deteriorate such that he might not be able to tell his parents. He continued to be seen as an out-patient. He was reviewed by Dr Grant, Consultant Neurologist, in early October, after a further MRI scan revealed some worsening of brain appearance, which Dr. Grant viewed as consistent with a diagnosis of PML. GRO-A still declined antiviral treatment.

I reviewed him on 20th November 1996 as an outpatient and noted that his vision was possibly a little worse, and that *'he seems little disinhibited and memory poor'*. A month later there was a marked deterioration in his condition with speech difficulties mainly of a marked nominal expressive dysphasia. He

was admitted to the Western General Hospital. He could only communicate by nodding or shaking his head and it was recorded that he – '*still does not want his parents informed*'. His symptoms were consistent with an intracranial bleed, but GRO-A refused factor VIII therapy. I visited him in the Western General Hospital where, after discussion, he agreed to have an injection of factor VIII. The next day he was much improved mentally and he was reviewed by Dr Grant who noted progressive visual field problems of right homonymous hemianopia, memory loss, olfactory hallucination and intermittent jerking. He considered that the features were that of PML which was taking its usual course with seizures as an aggravating factor and he recommended sodium valporate 200mg twice daily.

Subsequently GRO-A was managed as an outpatient and I reviewed him again on 8th January 1997 when he had deteriorated neurologically. He had not taken the valporate during the previous week. He planned to tell his parents as soon as he moved into his new flat, but he gave me permission to tell his parents his diagnosis if he became incapable. He indicated that he would like his parents to make decisions for him and that he did not want his life prolonging if its quality was to be poor. He was seen approximately weekly and then fortnightly at the Haemophilia and Thrombosis Centre and his general condition declined, but he

was managing at home with assistance. I reviewed him on 9th April when his condition seemed to have stabilized and after a long discussion he considered that he might start AZT and I gave him a prescription for 250mg daily. After some delay, he started the AZT and I recommended that he increase the dose to 500mg per day; he was given a dosette to try and help him to remember to take the dose each day. By the end of April when reviewed again he agreed to take a further anti-HIV drug, didanosine, 200mg twice daily and he was subsequently changed to 3TC shortly thereafter. Following his agreement to take the anti-HIV treatment he was referred to Dr Brettle at the Infectious Diseases Unit at the City Hospital (which subsequently moved to the Western General Hospital) for further management of his HIV infection.

He had been reluctant to register with a GP because he was concerned about confidentiality, but in 1997 he registered with GRO-A who had previously offered him homeopathic advice. He was seen at the Infectious Diseases Unit on 15th May by Dr Andrews (who had previously worked in the Haemophilia and Thrombosis Centre) on behalf of Dr Brettle and she noted that his condition appeared to have improved a little although he still had difficulty walking. He told her that his memory was very poor but it had improved so that he could now hold a conversation. On examination, he had a rash on his forehead, right thigh,

abdomen, left flank and wrists. *'His affect was somewhat inappropriate if not euphoric... he had signs of upper motor neurone weakness affecting his right arm and leg which was worse in his arm'.* He agreed to continue his anti-HIV drugs. He was subsequently followed up regularly by Infectious Diseases Unit, Neurology and Haemophilia and Thrombosis Centre. I reviewed him on 6th August 1997 and was pleased to note good progress. Subsequently he agreed to take septrin again as PCP prophylaxis.

As concerns had been raised that BSE was the probable cause of variant CJD and that it was under discussion that it might be transmissible by blood products, in December 1997 I wrote to Dr Grant to enquire whether it possible that GRO-A 's neurological problem could in anyway be a manifestation of variant CJD. Dr Grant replied indicating that he did not think GRO-A 's neurological features were compatible with variant CJD.

GRO-A continued to be closely followed after 1997 at both the Infectious Diseases Unit and the Haemophilia and Thrombosis Centre and community social work support helped him live in his flat. Subsequently, with support from the hospital and community teams he moved to new accommodation, which was

modified because of his physical disability. His neurological situation continued to cause difficulty. Although his PML had become static, he was troubled with episodes, which were probably complex partial seizures and also a peripheral neuropathy. An EEG revealed a moderate increase in regular slow activity consistent with HIV encephalopathy. A further MRI scan on 5th August 1997 revealed mild cerebral atrophy and bilateral occipital white matter high signals. The left thalamic 1.0 cm lesion was less well defined and there was a new right thalamic lesion of 1.0 cm. The occipital horn of the left ventricle had dilated and there was atrophy of the left occipital lobe and widening of the cortical sulci.

His right knee was causing him considerable difficulty because of recurrent bleeds and some arthritic pain. After much discussion and review by a number of experts he had a right knee prosthesis inserted in 2004. This was a great success as it abolished the arthritic pain and bleeds and walking was much easier. His haemophilia was mostly treated by himself with factor VIII concentrate, as his vision improved.

As referred to above, one of the other evolving issues after 1997 in relation to blood safety was the possibility that variant CJD might be transmitted by clotting factor concentrate. He, like many patients, was informed by letter on

7th February 2001 that some batches of factor VIII concentrate manufactured at the Blood Product Laboratory at Elstree were retrospectively found to have contained plasma donations from a donor who subsequently developed variant CJD. So far as we knew GRO-A had not received any of the batches, but he was informed, as were other patients in Scotland, in case unknown to us he might have had treatment for a bleed with one of the batches at an English Haemophilia Centre.

He was started on recombinant factor VIII in February 2000, but had to revert to plasma-derived factor VIII in July 2001 (because of a work shortage of recombinant VIII). Of various therapeutic options offered to him at this time, he opted to be treated with SNBTS high purity factor VIII concentrate, Liberate. He was reinstated on recombinant factor VIII in February 2002.

He was also informed by letter dated 22nd November 2002 about batches of factor VIII used in Scotland in 1987-89 to which a donor who subsequently developed vCJD had contributed. His infusion records however do not indicate that he received any of the relevant batches. On the 21st September 2004 he received a further letter on "Haemophilia treatments and vCJD - important information" and accompanying literature to bring him up to date with the evolving situation. A similar letter was sent to all patients in Scotland.

3

Response to GRO-A 's letter of 22nd August 2005

I shall respond to the issues raised in each of the paragraphs of GRO-A 's letter.

Page 1. Para 2, beginning at Line 3.

I have explained in answer to allegation 5 why the investigations were titled 'AIDS Study' on the haematology request forms. It was well known that AIDS had occurred in individuals with haemophilia initially in the United States and that this was likely to be as a result of immune dysfunction. The cause of the immune dysfunction in Edinburgh patients was uncertain and I did not think it was likely in 1983 to be due to a putative AIDS virus, this was later proved to be correct. GRO-A 's parents have never sought, nor in retrospect complained about a lack of, information from me, whether about immune dysfunction or AIDS in persons with haemophilia.

Page 1, Para 3.

I have recorded above what steps I took to inform GRO-A 's parents about the situation, which I believe, were reasonable. I assumed that they would have discussed the contents of the Information Sheet, sent in January 1985, with their son. The GP had also been informed that some patients were anti-HTLVIII

positive and he could have enquired further of the GRO-A 's situation or talked to him or his parents. GRO-A 's father has told me recently that he was aware of the AIDS risk because, as stated earlier, he was declined as a blood donor because his son had haemophilia. I do not believe it would have been appropriate to have informed his parents of GRO-A 's anti-HTLVIII status without his approval. Moreover it is very clear from subsequent events that he did not want his parents to be informed until he was very ill in 1997. It is my understanding that GRO-A was not injecting her son with factor VIII after he became infected with HTLVIII as he managed his own injections from 1982/3 onwards.

Page 2, Para 2.

I made it very clear to GRO-A in 1986 what the significance of a positive anti-HTLVIII test was because its significance was then much clearer than it had been at the beginning of 1985. I remember being as explicit as I could be because I was keen for him to know that he was positive. I did my best to try to persuade him that he should know his status. He was quite adamant that he did not want to know. His response when Dr Auger saw him in March 1989 was similar and she documented in his case notes very fully what had been discussed.

The attempts to inform GRO-A of his HIV status are set out in the summary of his medical history in paper apart 1. Again GRO-A stated in 1989 that he did not wish to know his HIV status.

Page 2, Para 4

GRO-A made it quite clear to me at our meeting on 1st July 2005that he was pleased that he had not known of his HIV status for 6 years, as he had been able to enjoy himself during this time. This does not accord with his view as stated here. I certainly did not tell him that he had "*only about 18 months to live and suggested I accept it and have a bit of fun*".

Page 2, Para 5.

I believed at the time, and subsequent studies have supported my belief, that Scottish factor VIII concentrate in 1983 and 1984 was one of the safest in the world.

I respond to the Council of Europe document separately in paper apart 3. It was clear that AIDS did not spread through families by ordinary social contact and therefore GRO-A 's family were not at risk of infection. By 1983, as described in the summary of GRO-A 's medical history, (paper apart 1) he

was confidently treating his haemophilia by injecting himself with factor VIII concentrate and his mother had ceased to do.

Page 3, Para 2

The reason for the forms being labelled as "AIDS Study" is set out in my answer to allegation 5.

Page 3 Para 3.

At my suggestion, I had two meetings with GRO-A along with his father after the Frontline Scotland programme. I thought that these meetings had been productive and useful. It was in fact GRO-A who told me he was pleased not to have known that he had HIV for 6 years and that he was able to enjoy himself during that time. (This conversation was witnessed by Staff Nurse Shea.) I was not evasive and I considered that I had given very direct answers and responses to GRO-A

Page 3 Para. 4.

The letter from Dr Craske of 23rd October 1984 and also an appendix entitled 'Ethical problems associated with HTLV-3 infection in haemophiliacs' relate to a specific batch of factor VIII concentrate manufactured by the Blood Products Laboratory at Elstree. In these documents Dr Craske points out that the issues are complex in relation to patients who have received a batch of NHS factor VIII to which a blood donor, whose plasma had contributed to the plasma pool from which the concentrate was manufactured, was subsequently found to have developed AIDS. This is a rather different circumstance to the general one of having to advise all haemophilacs. The circular of 14th December 1984 does recommend that patients should be tested for anti-HTLVIII and if positive *"informed, reassured and counselled ...."*

The policy we developed in Scotland, we believe, was rather more forward looking than the one set out in the circular of 14th December. Firstly, as patients had been tested without their consent, each was now entitled to have the result when he felt ready to receive it. By this means we were returning some autonomy to the patient. Such autonomy had previously been denied by testing the patients in a manner which was now being recommended in the circular. In fact our policy in Scotland foresaw the one that developed generally in 1985 of offering patients pre-test counselling to discuss the issues, benefits

and drawbacks of knowing their result before the blood was taken for the test. Secondly, we were keen to offer the same safety advice, e.g. condoms, to both anti-HTLVIII positive and negative patients for the dual reasons, that

- it was uncertain at that time whether or not an anti-HTLVIII negative patient might be chronically viraemic (without development of antibody),
- and also an anti-HTLVIII negative patient, at time of testing, might have become infected shortly before or after testing and subsequently would become viraemic before seroconverting; he would, therefore, be infectious, although he would consider himself not to be. He might thus have been falsely reassured about his potential infectivity.

For these reasons our policy in Scotland was a very precautionary one and sought to ensure maximum safety.

Page 3, Para 5.

I have repeatedly made it very clear to patients, as set out above in detail, why those treated in Edinburgh were an almost unique group because they had not been exposed to commercial factor VIII concentrate. Subsequently very unfortunately a number of patients became infected from a single batch of SNBTS factor VIII concentrate. Had it not been for this single batch very few patients in Edinburgh would have become infected with HIV. As a result of

my policy of using NHS factor VIII concentrate preferentially, many fewer patients became infected with HIV in Edinburgh than if we had used commercial factor VIII concentrate which would have led to many more becoming infected in the late 1970s and early 1980s, as was in fact the case in England.

4

Paper Apdx 3

Response to Council of European Committee of Minister Recommendations No R (83) 8. Adopted 23rd June 1983.

Despite taking part in national discussions in 1983 about blood safety and AIDS, I only saw this document for the first time a few months ago. I do not believe it was made available to UKHCDO or haemophila treaters in 1983. It 'recommends member states to inform attending physicians and selected recipients, such as haemophiliacs, of the potential health hazards of haemotherapy and the possibility of minimising these risks'. I do not recall the Departments of Health offering any advice about the potential transmissibility of AIDS by clotting factor concentrates to haemophilia physicians at this time. In June 1983 it was unclear what the risks were of transmission of a putative agent. As evidence of this I enclose a circular issued only one month before the EU document and approved by the chairman of the Haemophilia Society in conjunction with Professor Bloom (chairman UKHCDO) which states,

'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'.

In this circular the chairman states that

'we are not strangers to infective diseases, such as hepatitis, which can be transmitted by factor concentrates'

As has been described earlier, GRO-A and his parents were aware of the potential for virus transmission by concentrates, but in mid 1983 it was not possible to give more specific information about the risks.

5

Frontline Scotland programme "Blood & Tears"

This television production was misleading in its contents and contains little of the responses to various questions put to me in writing (annexation 7). The producers chose to ignore the information I provided in response to their questions (annexation 8) In addition they were alerted prior to transmission that it was considered possible that the programme might contain inaccurate information but they declined to accept my offer to review it.

As I had kept a note of the 1986 meeting when he was offered knowledge of his anti-HTLVIII status I wanted to make that available to him in case he could not remember the occasion. I contacted GRO-A by telephone as set out in my contemporaneous note of 21st May 2005 and arranged to see him on the 25th May. He agreed to meet. Unfortunately he was unable to attend, leaving a message for me to that effect. I tried again to contact him on two occasions by telephone but was unable to do so. I therefore sent him a copy of the note relating to the 1986 meeting by special delivery (annexation 9 - all handwritten notes and copy letter).

Further, after transmission of the Frontline Scotland programme the Medical Director, NHS Lothian wrote to the Head of News and Current Affairs of BBC

Scotland, pointing out that the programme gave an "unbalanced view and contained serious inaccuracies in relation to the case of patients with haemophilia" (annexation 6).

As such, it is not reasonable to consider programme as evidence, particularly as it was been edited after recording.

6

Professor Ludlam's Management, Research, Education (for NHS Staff and those with Haemophilia) activities in relation to blood safety, HIV and AIDS.

The following is a brief summary of some of my clinical activities to promote blood safety

Some of my early research was into the mode of action of the drug desmopressin which in 1977 was reported to be useful for raising the factor VIII level in patients with mild haemophilia. My research demonstrated its value for treating such patients, including to cover sugery, and this avoided the use of blood products and the possible transmission of viruses. My studies were published and I gave lectures to promote its use, for example in 1980 I lectured on it use as an effective and safe form of treatment at the UKHCDO annual meeting in Glasgow.

In the early 1980s in Edinburgh I completed a project started by my predecessor to assess the continuing hepatitis B infection in patients with haemophilia, despite excluding blood donors in whom the virus was detected. This retrospective study was possible using the serum bank which had been established. This study demonstrated the importance of offering hepatitis B to patients to offer protection against this virus when it became available in 1985.

With the advent of AIDS my investigative effort was put into trying to understand the immune status of those with haemophilia and to try and limit the exposure of patients to commercial concentrates. Apart from the studies and clinical activities described in detail elsewhere in this document I also worked, with others, to raise the amount to NHS factor VIII concentrate manufactured in Scotland. The studies, I and colleagues, undertook in the field of HIV ensured that we were at the forefront of diagnostic techniques which could be of benefit to patients, e.g. being able to detect evolving resistance to AZT, and we were in a position to monitor the safety of the newly developed heat treated factor VIII concentrates.

When hepatitis C virus was characterised in 1989, I and colleagues, were able to set up the appropriate testing early. This led to further characterisation of the virus. With our clinical work we were able to offer patients appropriate

investigation and therapy with interferon early after it became available and hence offer guidance to other clinicians looking after individuals with haemophilia.

As Chairmen, UKHCDO, in 1997 following the emergence of variant CJD, I helped lead the UK away from the use of UK plasma and towards its importation from non-BSE countries.

The following are some of the positions I have held in the field of haemophilia and blood safety.

Chairman: UK Haemophilia Centre Directors Organisation (UKHCDO) (1996-1999)

This organisation oversees the provision of care in the UK for people with haemophilia and their families.

Chairman: UKHCDO Genetics Working Party

Chairman: Coagulation Factor Working Party of Scottish Executive Health Department/Scottish National Blood Transfusion Service/Haemophilia Directors Scotland and Northern Ireland

Chairman, Task Force UKHCDO to revise Therapeutic Guidelines for Treating Haemophilia. This was a major responsibility to oversee the production of the UK recommendations for treating haemophilia in 1996 and 2001

Co-Chairman, Haemophilia Directors Committee for Scotland and Northern Ireland.

Member, UK Haemophilia Reference Centre Directors AIDS Committee (1984 - 1991 when it ceased to be a separate committee)

Member, UKHCDO Working Parties

1. Platelets

2. HIV

3. Chronic Liver Disease

4. Genetics Working Party

5. Factor VIII Inhibitors

These are influential national committees of UKHCDO which publish guidelines for the treatment of haemophilia and related disorders.

President (1992 - 1993) British Society for Haemostasis and Thrombosis.

Member, U.K. Haemophilia Society Medical Advisory Panel.

I helped the patients' organisation nationally not only with advice but also with its regular Bulletin. I also assisted the local Edinburgh Haemophilia Society group with its meetings especially during the 1980s. I also attended the Scottish Haemophilia Group meetings and gave talks for their members

Vice Chairman, Medical Advisory Board, World Federation for Haemophilia

Member, Factor VIII/IX Subcommittee of the Scientific and Standards Committee of the International Society for Thrombosis and Haemostasis

Member, von Willebrand Factor Subcommittee of the Scientific and Standards Committee of the International Society for Thrombosis and Haemostasis.

Chairman, Lothian Aids Advisory Committee.

This committee was established in early 1985 following our finding of some patients with haemophilia were anti-HTLVIII positive. This multi-disciplinary committee met frequently to try and address the many issues that arose in relation to HIV, what ever their risk group, in the provision of hospital, and to some extent community services. It was essential to ensue that the complete range of hospital services were available to those with HIV infection. We sought to help promote the provision of counselling and support for patients with HIV and their families. There was a great deal of anxiety amongst staff about their risks of infection from patients and much effort was expended in trying to ensure that there were appropriate arrangements and resources available.

Publications

I have been the author of over 200 articles, reviews and chapters mainly related to haemophilia, its treatment and complications.

7

Assessment of immune function of persons with haemophilia in Edinburgh.

The clinical immune studies I set-up in 1983 were in direct response to the AIDS threat. At this time I asked a colleague (Dr C M Steel) to help set-up the technology.

It may be helpful to describe the technological constraints and complexities involved in undertaking these immunological assessments, so as to explain the means and arrangements by which we managed them.

Our endeavour was colloquially know as the "AIDS study," although in fact there were no known cases of AIDS in either the patients in Edinburgh at that time, or in the population of Scotland. For this reason, blood donors (and factor VIII concentrate) were likely be free of a putative virus, if such was the cause of AIDS. The arrangements were set up as a special, or research, project to help to ensure that the samples were subjected to the correct investigations when they were received in the Royal Infirmary Department of Haematology laboratory. The request forms were labelled with "AIDS study" so that they could be readily identified when the samples arrived in the laboratory.

In the laboratory, as well as a Coulter instrument full blood count, a manual (i.e. microscopic examination of blood film) white blood cell differential count was required to assess the number of lymphocytes.

(Comment: In 1983 automated blood counter could not perform differential white cell counts).

For routine clinical practice the standard was to count 100 white cells visually. It was important that we had a lymphocyte count which was as accurate as possible, as this was necessary to enumerate the CD4 and CD8 cells which are sub-populations of the lymphocytes, and to this end, we therefore arranged for 200 white cells to be counted visually. This is why it states "200 cell differential" on the haematology request forms.

We had to establish a technique and facility for counting the CD4 and CD8 cells and Dr C M Steel at the Western General Hospital in Edinburgh kindly collaborated in setting up the methodology which initially was by visual counting of cells on a specially stained blood film. For this each blood sample had to be couriered by taxi from the Edinburgh Royal Infirmary to the Western General Hospital and this too was facilitated within the laboratory by the request being clearly labelled "AIDS study".

The results of these investigations surprised us. As there were no AIDS in the population in Scotland in 1983 my expectation was that patients attending the Edinburgh Haemophilia Centre would have normal immune systems. What we discovered was that some patients had evidence of immune disturbance similar to that in individuals with haemophilia in North America.

Having discovered that some of the Edinburgh patients with haemophilia had immune abnormalities, it became imperative to monitor their evolving immune status. One of the paradoxes, of the results of the surveillance programme was that the patients exhibited evidence of both immune deficiency, e.g. reduced CD4 helper cell numbers, as well as evidence of immune stimulation, e.g. increased beta 2 microglobulin and immunoglobulin levels. Having found a range of immune abnormalities in Edinburgh patients, it might have been viewed as poor clinical practice not to have continued to monitor them especially at this time when the cause of AIDS was uncertain. Patients therefore had their immune status monitored when they were having blood taken for other routine investigations.

FRONTLINE SCOTLAND

Statement by Professor Ludlam

I am only able to make general comments on the issues raised by Frontline Scotland. This is because referring to individual patients could prejudice certain ongoing matters which we cannot discuss publicly. This must remain true even where a patient has signed the consent forms which, under normal circumstances, allow us to reveal details of their case.

The national guidelines were followed for the treatment of patients with haemophilia.

From the late 1970s patients were aware that treatments could lead to hepatitis. However, it was not until 1985 that evidence emerged to show that Non A Non B hepatitis might be serious and progressive.

It has also been suggested that patients who were infected with serious illnesses following Factor VIII treatment were not kept properly informed.

Yet at the end of 1984 when the first anti-HTLVIII (HIV) results became available patients, and their carers, were invited to an open meeting to explain what was then known about Factor VIII and AIDS. As Director of the Haemophilia Centre I arranged the meeting in Edinburgh.

Patients were also encouraged to make an appointment to see their haemophilia doctor for more information and to discuss their own test results. It was patients who decided whether they wanted to know the results. Counselling was also made available.

Patients were sent a fact sheet explaining what was known about AIDS and making it clear that it could be contracted through concentrates used in the

treatment of haemophilia. This leaflet also gave straightforward advice on sex. This included a recommendation that all patients should always use a condom.

A letter was sent to GPs in January 1985 to ensure they had the latest information on Factor VIII and AIDS. Again, this also stressed the importance of using condoms to protect sexual partners.

It is essential to remember that HIV/AIDS was still new to medical science during the period being discussed. And little was known of the long-term effects of Non A Non B hepatitis. Treatment of haemophilia patients In Lothian developed and changed in line with advances in medical knowledge. I and my unit took seriously our responsibilities for the pastoral care of patients.

ENDS

18 May 2005