Dr Mark Winter Rule 9 - List of Questions

Section 1: Introduction

1. Please set out your name, address, date of birth and professional qualifications.

2. Please set out your employment history, including the various roles and responsibilities that you have held throughout your career, as well as the dates. Please include a description of the six months you spent at the North London Blood Transfusion Centre in the 1970s.

3. Please set out your membership, past or present, of any committees, associations, parties, societies or groups relevant to the Inquiry's Terms of Reference, including the dates of your membership and the nature of your involvement.

4. Please confirm whether you have provided evidence to, or have been involved in, any other inquiries, investigations, criminal or civil litigation in relation to the human immunodeficiency virus ("HIV") and/or hepatitis B virus ("HBV") and/or hepatitis C virus ("HCV") infections and/or variant Creutzfeldt-Jakob disease ("vCJD") in blood and/or blood products. Please provide details of your involvement and copies of any statements or reports that you provided (please note that there is no need for you to supply the Inquiry with a further copy of your written submission to the Archer Inquiry or your written submission to the Penrose Inquiry).

Section 2: Your employment at Guy's Hospital

5. Your CV states that you were a Lecturer and Honorary Senior Registrar in Haematology at Guy's Hospital between 1979 and 1983 and that during your time there you introduced a home therapy programme for patients with severe haemophilia and set up a system for comprehensive care. Please state who was the director of the haemophilia centre at Guy's between 1979 and 1983 and answer, to the extent that you are able to, the following questions with regards to haemophilia care and treatment at Guy's during that period.

6. What decisions and actions were taken, and what policies were formulated, at Guy's regarding the importation, manufacture and use of blood products (in particular factor concentrates)?

7. Who was responsible for the selection and purchase of blood products for use at Guy's, and what decisions were taken as to which products to use? In addressing this issue, please answer the following questions:

    a. How, and on what basis, were decisions made about the selection and purchase of blood products?

    b. What were the reasons or considerations that led to the choice of one product over another?

    c. What role did commercial and/or financial considerations play?

8. What was the relationship between Guy's haemophilia centre and the pharmaceutical companies manufacturing/supplying blood products? What

influence did that relationship have on the decisions and actions described above?

9. If the responsibility for the selection and purchase of blood products lay with an organisation other than the haemophilia centre at Guy's, please specify which organisation and provide as much information as you can about its decision-making.

10. Did you have a role in deciding which products to use for particular patients at Guys, or was that decision taken by others (and if so whom)? If the decision was yours, how did you decide which products to use for particular patients?

11. What alternative treatments to factor concentrates were available for people with bleeding disorders and used at Guy's during this period?

12. What was the policy and approach at Guy's as regards the use of cryoprecipitate for the treatment of patients with bleeding disorders? Did that policy and approach change over the four years that you were there and if so how?

13. What was the policy and approach at Guy's in relation to home treatment? Please describe the setting up of the home therapy programme referred to in your CV. How many patients (approximately) participated in the programme? What factor concentrates were used? What information was provided to patients about their treatment and any risks?

14. What was the policy and approach at Guy's in relation to prophylactic treatment?

15. What was the policy and approach at Guy's in relation to the use of factor concentrates for children?

16. To what extent, and why, were people with mild or moderate bleeding disorders treated at Guy's with factor concentrates?

17. Please describe the "system for comprehensive care" which you set up at Guy's.

Section 3: Decisions and actions of the Kent Haemophilia Centre

18. Please describe the roles, functions and responsibilities of the Kent Haemophilia Centre ("the Centre") during the time that you worked there.

19. Please describe your role and responsibilities as consultant haematologist at, and as the director of, the Centre.

20. Approximately how many patients with bleeding disorders were under the care of the Centre when you became director in 1983 and over the years that followed? (If you are able to give exact rather than approximate figures, please do so).

21. On 7 February 1984 you wrote to Miss Spooner, at Oxford Haemophilia Centre, stating that you were not able to provide information about material used in the home treatment of the Centre's patients, because "there was a serious lack of local funding a few years ago and, for these reasons, an arrangement was made whereby all Haemophiliacs on home treatment received Factor VIII concentrate from their General Practitioners on prescription". You explained that you had no data on the type or amount of Factor VIII that had been used

by the Centre's patients on home treatment. Do you have any more information about the arrangement described in the letter? Did Dr Sterndale (your predecessor) decide what products the patient should receive, or was this decision left to the GP? Did you subsequently obtain data on the type or amount of Factor VIII that had been used by the Centre's patients on home treatment?

22. What decisions and actions were taken, and what policies were formulated, by the Centre and, following your appointment in 1983, by you, regarding the importation, manufacture and use of blood products (in particular factor concentrates)?

23. What responsibility did the Centre, and you as its director, have for the selection and purchase of blood products, and what decisions were taken by you or the Centre as to which products to use? In addressing this issue, please answer the following questions:

    a. How, and on what basis, were decisions made about the selection and purchase of blood products?

    b. What were the reasons or considerations that led to the choice of one product over another?

    c. What role did commercial and/or financial considerations play?

24. What was the relationship between the Centre/you and the pharmaceutical companies manufacturing/supplying blood products? What influence did that relationship have on the Centre's and your decisions and actions?

25. If the responsibility for the selection and purchase of blood products lay with an organisation other than the Centre, please specify which organisation and provide as much information as you can about its decision-making.

26. How did you decide which products to use for particular patients?

27. What alternative treatments to factor concentrates were available for people with bleeding disorders?

28. What were, in your view, the advantages and disadvantages of those alternative treatments? What use did you make of them? Do you consider that they should have been used in preference to factor concentrates so as to reduce the risk of infection? If not, why?

29. What was your/the Centre's policy and approach as regards the use of cryoprecipitate for the treatment of patients with bleeding disorders? How did that policy and approach change over time?

30. What was your/the Centre's policy and approach in relation to home treatment? How did that policy and change over time?

31. What was your/the Centre's policy and approach in relation to prophylactic treatment? How did that policy and approach change over time?

32. What was your/the Centre's policy and approach in relation to the use of factor concentrates for children? How did that policy and approach change over time?

33. To what extent, and why, were people with mild or moderate bleeding disorders treated with factor concentrates?

34. What viruses or infections, other than HIV, HCV and HBV, were transmitted to patients at the Centre in consequence of the use of blood products?

Section 4: Knowledge of, and response to, risk

General

35. In 1979, when you became a senior registrar at Guy's, what did you know and understand about the risks of infection associated with blood and/or blood products? How did your knowledge and understanding then develop over time?

36. What advisory and decision-making structures were in place, or were put in place, at the (Kent) Centre and/or within the area covered by the Centre, to consider and/or assess the risks of infection associated with the use of blood and/or blood products?

37. What was your understanding of the relative risks of infection from (i) the use of commercially supplied blood products and (ii) the use of NHS blood products?

38. In your oral evidence to the Penrose Inquiry (transcript, 26 April 2011, p. 108) you referred to patients not wanting to have any concentrate of American origin and stated that at the Centre "we had great difficulty in getting supplies of NHS concentrate. So it took us quite a bit of work to persuade patients in some cases to continue to receive commercial concentrate because of this same perception". Why did you want to "persuade" patients to continue to receive commercial concentrate, and what did you do or say to persuade them?

39. What decisions and actions were taken by the Centre and by you to minimise or reduce exposure to infection?

Hepatitis

40. When you became a senior registrar at Guy's in 1979, what was your knowledge and understanding of the risks of the transmission of hepatitis, including hepatitis B and NANB hepatitis (hepatitis C), from blood and/or blood products? How did that knowledge and understanding then develop over time?

41. What if any enquiries and/or investigations did you, as director of the Centre, carry out or cause to be carried out in respect of the risks of transmission of hepatitis? What information was obtained as a result?

42. What if any actions did you take to reduce the risk to patients of being infected with hepatitis (of any kind)?

43. What was your understanding of the nature and severity of the different forms of blood borne viral hepatitis and how did that understanding develop over time?

44. In your written submission to the Archer Inquiry, you stated that "Very shortly after the introduction of these concentrates [in the early 1970s], it became apparent that nearly all regularly treated patients displayed biochemical abnormalities of liver function of a type that would be compatible with a form of Hepatitis virus" and that "it was assumed that these patients might prove to have a third Hepatitis virus", named as non-A, non-B Hepatitis". What if any steps were taken (i) by you and (ii) more generally in response to that knowledge and assumption?

45. Your written submission to the Archer Inquiry suggested that "these biochemical abnormalities of liver function" were not held at the time to be "of particular significance" and in your oral evidence you stated that the third hepatic virus (i.e. NANB hepatitis) was "not thought to be of very great significance" (transcript, p. 68). What was the basis for the view that the abnormalities were not "of particular significance"? What was the basis for the view that NANB hepatitis was not "of very great significance"?

HIV and AIDS

46. What was your knowledge and understanding of HIV (HTLV-III) and AIDS and in particular of the risks of transmission from blood and blood products? How did your knowledge and understanding develop over time?

47. How and when did you first become aware that there might be an association between AIDS and the use of blood products?

48. What steps did you take in light of that awareness?

49. What if any enquiries and/or investigations did you carry out or cause to be carried out in respect of the risks of transmission of HIV or AIDS? What information was obtained as a result?

50. You said in your evidence to the Archer Inquiry that "when HIV or AIDS broke in 1982 in haemophilia patients, then obviously enough it must be a transmissible agent". In your oral evidence to the Penrose Inquiry you described December 1982 as "a really critical moment" and that any doctor "would have to believe that AIDS was a transmissible disorder and that it could be transmitted by blood and blood products" (transcript, 27 April 2011, p. 108-9). What if any steps did you take at that point in relation to the treatment of your patients? What

information did you provide to patients who were receiving, or were due to receive, treatment with factor concentrates?

51. You explained in your written submission to the Archer Inquiry that in December 1983 the question of a switch to cryoprecipitate was raised at the UKHCDO AGM and that the minutes recorded that "after discussion, it was agreed that patients should not be encouraged to go over to cryoprecipitate for home therapy but should continue to receive the NHS or commercial concentrates in the usual way". Did you agree with the outcome of that discussion? Why?

52. Did you continue to use factor concentrates to treat patients, after becoming aware of the possible risks of infection of HIV? If so, why?

53. You stated in your written submission to the Archer Inquiry that there was a "great reluctance among both the medical and patient communities to consider a move away from concentrates". What is the factual basis for your claim that there was "great reluctance" among "patient communities" to consider a move away from concentrates?

54. You stated in your oral evidence to the Penrose Inquiry (transcript, 26 April 2011, p. 81) that there was "very significant patient opposition and Haemophilia Society opposition" to the proposal of switching back from concentrate to cryoprecipitate. What is the factual basis for your claim that there was "very significant patient opposition" to switching back to cryoprecipitate?

Response to risk

55. Did you take any steps to ensure that patients and/or the public were informed and educated about the risks of hepatitis and HIV? If so, what steps?

56. You suggested in your oral evidence to the Archer Inquiry that there was "open discussion" about the likelihood of US concentrates transmitting viruses, and that such discussion extended to "the patient group". What discussions with patients took place and when?

57. Do you consider that your decisions and actions and those of the Centre in response to any known or suspected risks of infection were adequate and appropriate? If so, why? If not, please explain what you accept could or should have been done differently.

58. What decisions or actions by you and/or by the Centre could and/or should have avoided, or brought to an end earlier, the use of infected blood products?

59. Did you revert to treatment with cryoprecipitate for some or all of your patients in response to the risk of infection? If so, how did you decide which patients would be offered a return to cryoprecipitate and which would not? If not, why not?

60. What actions or decisions or policies of other clinicians or other organisations, within your knowledge, played a part in, or contributed to, the scale of infection in patients with bleeding disorders? What, if anything, do you consider could or should have been done differently by these others?

61. Do you consider that greater efforts should have been made to inactivate viruses in blood or blood products prior to 1980? If so, who should have made or coordinated those efforts and what steps should have been taken and when? If not, why?

62. In your written submission to the Archer Inquiry, you observed that there was, at the time (in 1983 and 1984), no overarching advisory body with a remit for the new virus and no national advice available to haematologists. Do you consider that there should have been such a body? If so, when should it have been established and by whom? What steps do you consider that such a body could and/or should have taken?

63. Please provide details of the discussions that you had with Professor Savidge, and the discussions that you and Professor Savidge had with Alpha Therapeutics, about using their heat-treated product on a named patient basis.

64. At what point in time did you and Professor Savidge decide that there was "compelling evidence" that the currently available concentrates not only transmitted NANB hepatitis but were also very likely to contain HTLV III (see your Written Submission to the Archer Inquiry)? What steps did you take to communicate and/or share your view with (i) patients, (ii) other clinicians and (iii) others?

65. Is it correct that from May 1984 you used heat-treated factor concentrates (Profilate) on a named patient basis and that from 1 July 1984 only heat-treated factor VIII and factor IX were used in the Centre? Was this also the position, to your knowledge, in any other Centres and if so which? Were any of the Centre's patients who were treated with heat-treated product infected with HIV?

66. In your oral evidence to the Penrose Inquiry (transcript, 27 April 2011, p. 100-101):

    a. You reported that in April 1984, one month before you first used heat-treated Factor VIII, a four year old boy (who subsequently came under your care) with mild haemophilia was given non-heat-treated Factor VIII at a hospital 12 miles from the Centre and got HIV. Please identify the

hospital at which the boy was given the non-heat-treated Factor VIII which infected him.

b. You reported that the first person to whom you gave heat-treated Factor VIII in May 1984 was, a month later, given non-heat-treated Factor VIII in the casualty department of a hospital west of the Centre and got HIV. Please identify the hospital at which the man was given the non-heat-treated Factor VIII.

67. You record in your written submission to the Archer Inquiry that "there were a number of Haemophilia doctors who continued to express the view that UK plasma was safe and that HIV infection would never happen if patients were exclusively treated with factor VIII derived from UK plasma". Which doctors, to your knowledge, held this view at the time?

Section 5: Treatment of patients at the Centre

Provision of information to patients

68. What information did you provide or cause to be provided to patients with a bleeding disorder (and to any patients who did not have a bleeding disorder but were treated with blood products for other conditions) about the risks of infection in consequence of treatment with blood products (in particular, factor concentrates), prior to such treatment commencing? Please detail whether and if so how this changed over time.

69. Do you accept that patients should have been informed that it was well known that there were hepatitis viruses within blood?

70. What information did you provide or cause to be provided to patients about alternatives to treatment with factor concentrates? Please detail whether and if so how this changed over time.

71. What information did you provide or cause to be provided to patients before they began home treatment/home therapy?

HIV

72. When did you first discuss AIDS or HIV (HTLV-III) with any of your patients?

73. Please describe how and when you learned that patients under your care had been infected with HIV.

74. In your written submission to the Archer Inquiry you state that performing HTLV-III tests without consent from patients was part of the "culture of medicine at that time". You also state that in your Centre patients were informed that their blood was being sent to UCH for testing.

    a. Please explain what you meant by "the culture of medicine at that time".

    b. What information did you give to patients at the Centre about the testing process? Were they explicitly informed that the blood test was in relation to HTLV-III? Were they asked to consent before the blood was sent to UCH, or informed after the event that it had been done?

75. How and when were patients told that they had been, or might have been, infected with HIV? Were they told in person, by letter or by telephone? Did you see patients individually or in groups? What information was given to them

about the significance of a positive diagnosis? Did you tell patients to keep their infection a secret?

76. What was the Centre's/your policy in relation to testing partners/family members of people known or suspected to be infected with HIV? Under what circumstances were tests carried out?

77. What if any information or advice did you provide to partners or family members of people that were at risk of infection with HIV or were infected with HIV?

78. How many patients at the Centre were infected with HIV (your evidence to the Archer Inquiry was that, of 31 patients with severe haemophilia at the Centre, 30 were infected with HIV, that the average age of those infected was 18 and that 18 were children)?

79. In your written submission to the Penrose Inquiry, you stated at 1.17 that "We know now that most patients with Haemophilia were infected with HIV between 1981 and 1984". Do you have any more precise information as to when the patients at the Centre were infected with HIV?

Hepatitis B

80. Were patients infected with hepatitis B informed of their infection and if so how? What information was provided to patients infected with hepatitis B about the infection, its significance, prognosis, treatment options and management?

81. How many patients at the Centre were infected with hepatitis B?

NANB Hepatitis/Hepatitis C

82. Were patients infected with NANB hepatitis informed of their infection and if so how? What information was provided to patients infected with NANB hepatitis about the infection, its significance, prognosis, treatment options and management?

83. You told the Archer Inquiry that it was apparent following the introduction of commercial and NHS concentrates that they were likely to transmit NANB hepatitis. Did you inform your patients of that likelihood before commencing treatment? If so, what information did you give them? If not, why?

84. When did the Centre begin testing patients for hepatitis C? How were patients told of their diagnosis of hepatitis C? Were they told in person, by letter or by phone? What information was provided to patients infected with hepatitis C about the infection, its significance, prognosis, treatment options and management?

85. How many patients at the Centre were infected with hepatitis C?

Delay/public health/other information

86. Were the results of testing for HIV and hepatitis (of all kinds) notified to patients promptly, or were there delays in informing patients of their diagnosis? If there were delays in informing patients, explain why.

87. To what extent, if at all, did you take into account the public health implications of HIV, AIDS, hepatitis B and NANB hepatitis/hepatitis C, when taking decisions as to what information or advice to provide to patients or what treatment to offer patients?

88. What information was provided to patients about the risks of other infections?

89. What information was provided to patients about the risks of infecting others?

Consent

90. How often were blood samples taken from patients attending the Centre? What information was given to patients about the purposes for which blood samples were taken? Did you obtain patients' informed consent to the storage and use of those samples?

91. Were patients under your care treated with factor concentrates or other blood products without their express and informed consent? If so, how and why did this occur? What was your approach to obtaining consent to treatment? If it is your position that patients did give express and informed consent to treatment with factor concentrates, please explain the basis for that position.

92. Were patients under your care tested for HIV or for hepatitis or for any other purpose without their express and informed consent? If so, how and why did this occur? What was your approach to obtaining consent for testing?

PUPS

93. Detail all decisions and actions taken by you or with your involvement with regard to a category of people referred to as 'previously untreated patients' (PUPS).

Research

94. Please detail all research studies that you were involved with during your time as a consultant at, or director of, the Centre. In relation to those research studies that could be relevant to the Inquiry's Terms of Reference, please:

a. describe the purpose of the research;
b. explain the steps that were taken to obtain approval for the research;
c. explain what your involvement was;
d. identify what other organisations or bodies were involved in the research;
e. state how the research was funded and from whom the funds came;
f. state the number of patients involved;
g. provide details of the steps taken to inform patients of their involvement and seek their informed consent; and
h. provide details of any publications relating to the research.

95. What do you understand to be the ethical principles that should guide research? Did you apply those principles to the research studies referred to above and if so how? If not, why not?

96. Were patients involved in research studies without their express consent? If so, how and why did this occur?

97. Was patient data (anonymised, de-identified or otherwise) used for the purpose of research or for any other purpose without their express consent? If so, what data was used and how and why did this occur?

98. Was patient data (anonymised, de-identified or otherwise) shared with third parties (e.g. UKHCDO or Oxford Haemophilia Centre)? If so how and why did this occur and what information was provided to whom?

99. Please provide details of any articles or studies that you have published insofar as relevant to the Inquiry's Terms of Reference.

Treatment of patients who were infected with HIV and/or hepatitis

100. How was the care and treatment of patients with HIV/AIDS managed at the Centre? What steps were taken to arrange for, or refer patients for, specialist care? What treatment options were offered over the years to those infected with HIV? What information was provided to patients about the risks and benefits of specific treatments and about side effects?

101. What follow-up and/or ongoing monitoring was arranged in respect of patients who were infected with HIV?

102. How was the care and treatment of patients with hepatitis B managed at the Centre? What steps were taken to arrange for, or refer patients for, specialist care? What treatment options were offered over the years? What information was provided to patients about the risks and benefits of specific treatments and about side effects?

103. What follow-up and/or ongoing monitoring was arranged in respect of patients who were infected with hepatitis B?

104. How was the care and treatment of patients with NANB hepatitis managed at the Centre? What steps were taken to arrange for, or refer patients for, specialist care? What treatment options were offered over the years? What information was provided to patients about the risks and benefits of specific treatments and about side effects?

105. How was the care and treatment of patients with hepatitis C managed at the Centre? What steps were taken to arrange for, or refer patients for, specialist care? What treatment options were offered over the years? What information was provided to patients about the risks and benefits of specific treatments and about side effects?

106. What follow-up and/or ongoing monitoring was arranged in respect of patients who were infected with hepatitis C?

107. What arrangements were made for the care and treatment of children infected with HIV and/or hepatitis? How did those arrangements differ (if at all) from the arrangements made for adults?

108. Your written submission to the Archer Inquiry stated that co-infection with HIV and HCV was "currently leading to very significant problems in their management". Please explain these problems further.

109. What if any arrangements were made to provide patients infected through blood products with counselling, psychological support, social work support and/or other support?

110. Was the Centre allocated, whether by the Department of Health and Social Security or another source, any funding to help with counselling of patients infected with HIV?

111. What kind of counselling if any was made available to patients?

Records

112. What was the Centre's policy or practice as regards recording information on death certificates when a patient had been infected with HIV or hepatitis?

113. What were the retention policies of the Centre in regards to medical records during the time you were director?

114. Did you maintain separate files for some or all patients? If so, why; where were those files located; and where are those files now?

115. Did you keep records or information (e.g. information being used for the purpose of research) about any of your patients at your home or anywhere other than the Centre? If so, why, what information and where is that information held now?

116. Do you still hold records or information about any of your patients? If so, explain why and identify the records or information that you still hold.

Section 6: Treloar's

117. In your oral evidence to the Archer Inquiry (transcript, p. 66) you stated that some of your patients went to Lord Mayor Treloar College ("Treloar's"). Did you recommend any patients under your care attend Treloar's and/or refer them to Treloar's and/or have any involvement with Treloar's? If so:

    a. How many patients did you recommend or refer to Treloar's?
    b. What prompted the recommendation(s) or referral?
    c. What involvement did you have in the arrangements for them to attend Treloar's?

d. What involvement did you have with the ongoing care and treatment of boys attending Treloar's?
e. Please describe any research and/or trials and/or experimental treatment that you are aware of involving pupils at Treloar's, including any involvement that you had in such research/trials/treatment.

Section 7: Self-sufficiency

118. In December 1974 the Department of Health announced additional funding with the primary aim of making the NHS self-sufficient in Factor VIII blood products within two to three years. The Inquiry recognises that in your written submission to the Archer Inquiry you stated that you were "not able to make detailed comments about the political initiatives of the 1970s towards self-sufficiency, since I was only a Haematology Registrar at that time". To the extent that you are able to please address the following questions.

a. When did you become aware of this announcement?
b. What did you understand the term "self-sufficiency" to mean? In particular, did you understand it to mean self-sufficiency in providing Factor VIII blood products prophylactically, or solely in response to bleeding incidents?
c. Did your understanding of what "self-sufficiency" meant change at any time? If so, when and why?
d. What was your understanding of how others defined "self-sufficiency"?
e. What if any role did you play (at Guy's between 1979 and 1983 or at the Centre from December 1983) in any arrangements or initiatives designed to help achieve self-sufficiency?

119. How were estimates made of how much Factor VIII blood product would be required for use in England and Wales? In particular:

a. What was your role (as director of the Centre) in making such estimates, and how did this change over time?
b. What was the role of UKHCDO and how did this change over time?
c. What assumptions would underpin the estimates (including assumptions as to how the blood products would be used)?
d. How would the estimate be made (e.g. by whom were they made, when and through what process)?
e. How were the estimates shared with other interested parties?
f. How did any of these processes change over time?

120. How were annual figures derived for how much Factor VIII blood product had been used over the course of a year?

a. What was your role (as director of the Centre) in providing such figures, and how did this change over time?
b. What was the role of UKHCDO and how did this change over time?
c. How would the calculations be made (e.g. by whom were they made, when, through what process and using what data)?
d. How were those figures broken down geographically (e.g. by country, region or any other unit)?
e. How were the figures shared with other interested parties?
f. How did any of these processes change over time?

121. Were there significant differences between the estimates that were made and actual use? If so, why?

122. It may be suggested that England and Wales never achieved self-sufficiency of Factor VIII blood products, in the sense that clinicians were always reliant on commercially imported products to meet the actual demand of patients for such products.

a. Is this correct, to the best of your knowledge?

b. If so, why, in your opinion, was self-sufficiency was never achieved?

c. If, in your view, self-sufficiency was achieved, when was it achieved and why it was not achieved earlier?

123. It may be suggested that a significant contributory factor to England and Wales not achieving self-sufficiency (or not doing so earlier) was a failure by haemophilia clinicians to provide timely and accurate estimates of future demand for Factor VIII blood products. In particular, it may be suggested that haemophilia clinicians failed to identify the foreseeable increase in use of such products once they became available. How would you respond to these suggestions?

124. If self-sufficiency had been achieved in Factor VIII products, what, in your view, would have been the effect on the numbers of patients infected with (i) HBV, (ii) HCV, and (iii) HIV. Please comment on when self-sufficiency would have needed to be achieved (in your view) in order for any material difference to have been made in respect of each of these viruses.

125. It may be suggested that England and Wales did achieve self-sufficiency in respect of Factor IX blood products. To the best of your knowledge, is this correct? Please explain your answer.

126. If self-sufficiency in respect of Factor IX blood products was achieved, did you nonetheless use commercially produced products in preference to domestically produced products? If so, why?

Section 8: Blood services and BPL

127. Please outline the interactions and dealings you had with the blood services, whether on a regional or national level, and/or with BPL in your capacity as director of the Centre.

128. What if any consideration was given to increasing production of cryoprecipitate, or producing a product with lower risk, in response to the risks associated with factor products, and what if any involvement did you have with any blood service (regionally or nationally) and/or BPL in relation to this?

129. What if any discussions or meetings or interactions did you have with any blood service (regionally or nationally) and/or BPL in relation to:

    a. the risk of infection with hepatitis from blood products;
    b. the risk of infection with HIV/AIDS from blood products;
    c. the steps to be taken to reduce the risk of infection?

130. What if any involvement did you have with any decisions or actions taken by any blood service (regional or national) and/or BPL in response to the risks arising from blood and blood products?

Section 9: UKHCDO

131. Please describe your involvement with UKHCDO (including any of its working parties, committees or groups).

132. During the period that you were involved with UKHCDO, please outline:

    a. the purpose, functions and responsibilities of UKHCDO, as you understood them;

b. the structure, composition and role of its various committees or working groups;
c. the relationships between UKHCDO and pharmaceutical companies;
d. how decisions were taken by UKHCDO;
e. how information or advice was disseminated by UKHCDO and to whom;
f. any policies, guidance, actions or decisions of UKHCDO in which you were involved and which relate to:
    i. the importation, purchase and selection of blood products;
    ii. the manufacture of blood products;
    iii. Self-sufficiency;
    iv. alternative treatments to factor products for patients with bleeding disorders;
    v. the risks of infection associated with the use of blood products;
    vi. the sharing of information about such risks with patients and/or their families;
    vii. obtaining consent from patients for the testing and storage of their blood, for treatment and for research;
    viii. heat treatment;
    ix. other measures to reduce risk;
    x. vCJD exposure; and
    xi. treatments for HIV and hepatitis C.

Section 10: Pharmaceutical companies I medical research clinical trials

133. Have you ever provided advice or consultancy services to any pharmaceutical company involved in the manufacture and/or sale of blood products? If so, please list the names of the companies and give details of the advisory or consultancy services that you provided.

134. Have you ever received any pecuniary gain in return for performing an advisory/consultancy role for a pharmaceutical company involved in the manufacture or sale of blood products? If so, please provide details.

135. Have you ever sat on any advisory panel, board, committee or similar body, of any pharmaceutical company involved in the manufacture or sale of blood products? If so, please provide details of your involvement and of any financial or other remuneration you received.

136. Have you ever received any financial incentives from pharmaceutical companies to use certain blood products? If so, please provide details.

137. Have you ever received any non-financial incentives from pharmaceutical companies to use certain blood products? If so, please provide details.

138. Have you ever received any funding to prescribe, supply, administer, recommend, buy or sell any blood product from a pharmaceutical company?

139. What regulations or requirements or guidelines were in place at the time concerning declaratory procedures for involvement with a pharmaceutical company? If you were so involved, did you follow these regulations, requirements and guidelines and what steps did you take?

140. Have you ever undertaken medical research for, or on behalf of, or in association with, a pharmaceutical company involved in the manufacture or sale of blood products? If so, please provide details.

141. Have you ever provided a pharmaceutical company with results from medical research studies that you have undertaken? If so, please provide details.

142. If you did receive funding from pharmaceutical companies for medical research, did you declare the fact that you were receiving funding and the source of the funding to your employing organisation?

Section 11: vCJD

143. When and in what circumstances did you become aware of the risks of transmission of vCJD associated with the use of blood and blood products?

144. What was the process at the Centre for informing patients about possible exposure to vCJD?

145. How and when were patients told of possible exposure to vCJD?

146. What information was provided to patients about the risks of vCJD?

147. What counselling, support and/or advice to be offered to patients who were informed that they might have been exposed to vCJD?

Section 12: The Centre's involvement with the financial support schemes

148. To what extent, during your time as director of the Centre, did the Centre and its staff inform patients about the different trusts or funds (the Macfarlane Trust, the Eileen Trust, the Macfarlane and Eileen Trust, the Caxton Foundation and the Skipton Fund) which were set up to provide financial support to people who had been infected?

149. Did the Centre have any policy or any guidance for staff members in relation to referring patients to the trusts and funds for support?

150. What kind of information did the Centre (whether through you or otherwise) provide to the trusts and funds about or on behalf of patients who were seeking assistance from the trusts and funds?

151. Did the Centre, or any of its staff (including you), act as a gateway for determining whether a particular patient met the eligibility criteria for the receipt of assistance from any of the trusts and funds? If so, please explain who set the criteria, what they were and how they were applied.

152. Was the Centre or any of its staff (including you) involved in determining applications made by patients for assistance from the trusts or funds? If so, please describe that involvement.

Section 13: Your involvement with the financial support schemes

Macfarlane Trust

153. You were a Trustee of the Macfarlane Trust from 1996 until 2009. Please explain:

a. how you came to be appointed as a Trustee;
b. the functions that you carried out and the responsibilities that you held in this capacity;
c. the role, purpose and functions of any internal committees or groups you were involved in at the Macfarlane Trust (such as the Strategic Review Group, the Partnership Group and the National Support Services

Committee) and the nature of your involvement in those committees or groups.

154. You were identified in the trust deeds as a "DOH Trustee". Please explain what was meant by this; whose interests you were representing in your role as a DOH-appointed Trustee; whether you received any instructions or guidance from the DOH as to how to perform your role (and if so what instructions or guidance); and whether you had any reporting obligations to the DOH.

155. Were you involved in the development of any criteria or policies of the Macfarlane Trust relating to eligibility for financial assistance or for determining applications? If so please provide details.

156. Did you provide advice to the Macfarlane Trust? If so please provide details.

157. Were you involved in assessing, approving and/or rejecting applications for assistance that were made to the Macfarlane Trust? If so please provide details.

158. Do you consider (from your perspective as a Trustee) that the Macfarlane Trust was well run? Do you consider that it achieved its purposes? Were there difficulties or shortcomings in the way in which the Macfarlane Trust operated or in its dealings with beneficiaries and applicants for assistance?

159. In your view was the Macfarlane Trust in receipt of sufficient funding from the Department of Health? What steps did the Trust take to attempt to obtain more funding and what was the Department's response?

160. The minutes of several trustees' meetings record your concern that patients receiving treatment for HIV and/or hepatitis through haemophilia centres were having to pay prescription charges: see, e.g., the minutes of meetings dated 12 February 2002 (MACF0000011_001) and 17 July 2001 (MACF0000013_037), and in May 2002 you prepared a letter to be sent to haemophilia centres to request exemption codes be applied for patients in these circumstances (HCDO0000264_155).

    a. When and how did you first become aware that patients infected with HIV were being required to pay prescription charges for medication prescribed through haemophilia centres?

    b. How did the Department of Health and haemophilia centres respond to the concerns raised by you about prescription charges?

    c. How was this issue resolved?

161. In a meeting on 12 July 1999, the minutes record that a "lively discussion" took place between trustees about the possibility of a user Trustee joining the board (MACF0000007_179). You suggested that it would be "difficult not to be inhibited in provision of medical advice to the Board if 'user trustees' were present at a meeting".

    a. Please explain why you considered that medical advice would be inhibited if a user Trustee was present at Trustee meetings.
    b. Did you support a user Trustee's inclusion on the board? Why or why not?
    c. In your opinion, did the inclusion of a user Trustee on the board alter the way in which the Trust operated and decided cases? If so, how?

162. According to the minutes of a meeting held on 28 April 1999, the Chairman proposed that you attend a small group meeting with Baroness Hayman on behalf of the Trust to present medical issues (MACF0000007_189). It was suggested that the group include user representation, but the Chairman felt that this meeting was only for Trustees, and user representatives could meet with other levels within the Department. In another meeting dated 2 May 2000, the Chairman reported that you accompanied the Chief Executive and the Treasurer to a meeting with Lord Hunt (MACF0000013_03). At this meeting, it was put to him the need to increase payments to registrants to which it was reported his reaction was neither 'positive nor negative.' Please answer the following questions about meetings between the DOH and the Trust:

a. How often did you attend meetings with the relevant Minister or with civil servants at the Department of Health and what was the purpose of these meetings? What was your role at these meetings?
b. Were user representatives invited to attend future meetings with the Department? If not, what avenue was available to user representatives to voice concerns directly to the Government? Did the Trust facilitate user representatives attending such meetings?
c. Can you please clarify what was meant by Lord Hunt's reaction to the statement that further funds were needed as not being 'positive nor negative'?

163. In several trustees' meetings, you raised the lack of support available to the bereaved (see, e.g., MACF0000002_037; MACF0000009_008; MACF0000014_124, enclosed). Please summarise your concerns about support available to the bereaved. Do you consider the level of support available to the bereaved improved during your time as a Trustee?

164. In an undated report by the Chairman, Peter Stevens, it was reported that you had expressed doubts about the role of Partnership Group meetings. (MACF0000006_028). What was the purpose of these Partnership Group

meetings, who determined membership of the group and what specific concerns did you hold?

165. In a meeting dated 11 October 2004, you outlined to other Trustees the impacts that vCJD would have on the beneficiary community (MACF0000019_126). It was agreed during this meeting that a letter would be sent to the Minister outlining these impacts, along with a revival of a business case about additional payments. Please explain what impact you consider the announcement about vCJD had on beneficiaries, what submissions were sent by the Trust to Ministers about vCJD and what response was received, if any.

166. Please consider the following documents which are enclosed with this letter: minutes of a UKHCDO meeting on 10 January 1993 (HCDO0000015_007); the minutes of a Trustees' meeting dated 21 May 1996 (MACF0000017_052); the minutes of a Trustees' meeting dated 15 September 1998 (MACF0000005_030); the minutes of a Trustees' meeting dated 24 November 1998 (MACF0000005_078); the minutes of a Trustees' meeting on 23 February 1999 (MACF0000007_263); and the minutes of a Trustees' meeting on 21 October 2001 (MACF0000002_037). Please answer the following questions about the Trust's policy on assistance with reduced risk conception for beneficiaries:

a. What was the policy on reduced risk conception when you first commenced as Trustee? How did the policy change over time?
b. Approximately how many applications for reduced risk conception were considered by the Trust while you were a Trustee?
c. What concerns did you hold about funding for reduced risk conception?
d. What procedures relating to assisted conception were considered by the Trust? Was any funding provided for any of these procedures, and if not, why not?

e. What was the outcome of the test case submitted to the health authority for funding of sperm washing? If refused, what reasons were given by the authority for refusing funding?
f. Did the Trust subsequently review its policy on sperm washing after the 21 October 2001 meeting, and if so, what was the outcome?

Eileen Trust

167. You were a Trustee of the Eileen Trust from 1996 until 2009. Please explain:

a. how you came to be appointed as a Trustee;
b. the functions that you carried out and the responsibilities that you held in this capacity.

168. Were you involved in the development of any criteria or policies of the Eileen Trust relating to eligibility for financial assistance or for determining applications? If so please provide details.

169. Did you provide advice to the Eileen Trust? If so please provide details.

170. Were you involved in assessing, approving and/or rejecting applications for assistance that were made to the Eileen Trust? If so please provide details.

171. Do you consider (from your perspective as a Trustee) that the Eileen Trust was well run? Do you consider that it achieved its purposes? Were there difficulties or shortcomings in the way in which the Eileen Trust operated or in its dealings with beneficiaries and applicants for assistance?

Other trusts and funds

172. Have you had any involvement with any of the trusts or funds apart from the Macfarlane Trust and the Eileen Trust? If so, please provide details of your involvement, role and responsibilities including:

a. any involvement you had in relation to the development of any criteria or policies relating to eligibility for financial assistance;
b. any involvement you had in providing advice;
c. any involvement you had in assessing applications.

173. On 9 December 2004 you sent Dr Hill (in his capacity as Chair of UKHCDO) a draft letter concerning the Skipton Fund.

a. In your covering letter to Dr Hill, you described the Skipton Fund as "the servant of the DoH". What did you mean by that?
b. The draft letter referred to "significant disquiet" amongst haemophilia centre directors about the criteria being used under the scheme, suggested that all patients who are hepatitis C positive should be offered the part 1 payment and recommended that patients who acquired hepatitis B from treatment should also be included for payment. Do you have anything to add to the concerns expressed in the draft letter?

General

174. You stated in your written submission to the Archer Inquiry that those living with HIV and hepatitis continued to need "the very best of support". Do you consider that the Macfarlane and Eileen Trusts and the Skipton Fund provided "the very best of support"? Please explain your reasons.

Section 14: Haemophilia Society

175. Please provide details of your involvement with the Haemophilia Society. In particular:

a. Describe your involvement with the Haemophilia Society's campaign for recompense for those infected (your CV describes you as the nominated campaign medical contact for the media and members of Parliament).
b. Describe the work undertaken as a member of the Society's Medical Advisory Panel, insofar as relevant to the Inquiry's Terms of Reference.
c. Describe the work undertaken as a member of the Society's Treatment and Care Committee, insofar as relevant to the Inquiry's Terms of Reference.
d. Describe the work undertaken as a member of the Society's General Services Committee, insofar as relevant to the Inquiry's Terms of Reference.

Section 15: Involvement with the National Haemophilia Alliance

176. Please outline how and why the National Haemophilia Alliance was established and what its objectives were.

Section 16: Other issues

177. In March 1996 you wrote an article in The Bulletin entitled "Recombinant Blood Products – and why they are important". In your view:

a. Should recombinant blood products have been made available to all haemophiliacs earlier than they were?
b. When should recombinant products have been available to all?

178. When were recombinant products available to people treated at the Centre?

179. Please provide details of any complaints made about you (insofar as relevant to the Inquiry's Terms of Reference) to your employer, to the General Medical Council, to the Health Service Ombudsman or to any other body or organisation which has a responsibility to investigate complaints.

180. Please explain, in as much detail as you are able to, any other issues that you believe may be of relevance to the Infected Blood Inquiry.