

INFECTED BLOOD INQUIRY - LIST OF ISSUES

This is a List of Issues which has been prepared in order to help guide the Inquiry's investigative work. It is an evolving document and is highly likely to change over time as more information is analysed by the Inquiry team. Issues may be added, deleted or reformulated.

Nothing in the drafting of the List of Issues should be taken as indicating any view on the part of the Inquiry or the Chair as to the answer to any of the questions posed.

The List of Issues has not at this stage identified as an issue for determination the question of what recommendations should be made, since any recommendations will necessarily follow from, and be influenced by, the Inquiry's resolution of the issues in the List.

Any suggestions from Core Participants for additions to the List of Issues should be sent to Counsel to the Inquiry.

Decision-making: general

The role of Government

Knowledge of risk

Policy-making, decision-making and actions

Self-sufficiency

The role of the blood services

Knowledge of risk

Policy-making, decision-making and actions

Regulation

Viral inactivation/heat treatment and other measures to reduce risk

Viral inactivation/heat treatment

Donor selection/screening

Screening of donations

Other measures to reduce risk

The role of haemophilia centres and the UKHCDO

Knowledge of risk

Policy-making, decision-making and actions

Lord Mayor Treloar College (Treloar's)

The role of other NHS bodies

Knowledge of risk

Policy-making, decision-making and actions

The role of medical practitioners

Knowledge of risk

Provision of information to people about the risks of blood products

Provision of information to people about the risks of transfusion

Guidance

Consent

Policy-making, decision-making and actions

The role of pharmaceutical companies

The international market for blood products

Relevant companies and corporate structures

Communication of risk of HCV, HIV and other infections

The collection of blood for use in pooled plasma products

a. _____ the company/organisation obtaining the blood:

b. _____ the company/organisation that was producing the blood product?

Interaction with the UK regulatory and medical authorities

Pharmaceutical companies' interactions with the licensing authorities

a. _____ What was the extent of any such interaction?

b. _____ What was the purpose of any such interaction, so far as the company was concerned?

c. _____ What, if any, internal company policies or guidance governed such interactions?

d. _____ What, if any, external policies, guidance or regulations governed such interactions?

e. _____ What, if any, budget was allocated for such interaction, and how was it spent?

f. _____ How did these matters change over time, and, if they did, why?

Individual products

Intended use and licensing

Studies

Risks

Heat treatment

Response to infection

The role of the Haemophilia Society

Scale of infection and response

Cover up, lack of candour and openness

Impact on people infected and affected

Impact on people infected

[Impact on people affected](#)

[Stigma](#)

[Access to treatment, care and support](#)

[Response of Government and others](#)

[Trusts and Schemes](#)

[General](#)

[Establishment of the Alliance House Organisations](#)

[Funding](#)

[Operation of the Trusts and Schemes](#)

[Revised Schemes](#)

[Future](#)

Decision-making: general

1. Which organisations were, or should have been, responsible for taking key decisions as to the use of blood and blood products during the relevant period?[1]
2. What principles and/or policy objectives:
 - a. underpinned decision-making on the use of blood and blood products?
 - b. should have underpinned such decision-making?
3. In particular:
 - a. to what extent did considerations of public safety inform decision-making?
 - b. should public safety have been the overriding concern?
 - c. what approach was taken to the evaluation of risk(s)?
4. What decision-making structures were in place (and with what oversight) during the relevant period to ensure:
 - a. adequate information-sharing between the different organisations involved;
 - b. comprehensive assessment of the risks arising from the use of blood and blood products;
 - c. timely, coordinated and/or structured decision-making as to the nature and extent of any risks;
 - d. timely, coordinated and/or structured decision-making as to any steps that should be taken to reduce or mitigate such risks?

5. To what extent were decisions informed by (or should have been informed by) decisions and/or practices in other countries?

The role of Government

Knowledge of risk

6. What information and knowledge did the Government[2] as a matter of fact have during the relevant period about the risks of infection associated with blood and blood products?
7. In particular:
 - a. How did the Government's knowledge of the risks of the transmission of hepatitis from blood and blood products develop over time?
 - b. When and in what circumstances did the Government first become aware that HIV could be transmitted by blood and blood products?
 - c. What was the Government's understanding of the relative risks of infection from (i) the use of commercially supplied blood products and (ii) the use of domestically sourced blood and blood products?
 - d. When and in what circumstances did the Government become aware of any risks of transmission of vCJD associated with the use of blood and blood products?
8. How did the Government inform itself about the risks from blood and blood products, including any risks posed by the purchase of commercially supplied blood products?
9. What enquiries and/or investigations did the Government carry out in respect of these risks and what information was obtained as a result?
10. Was the extent of the enquiries and/or the level of the Government's knowledge appropriate or should further enquiries or investigations have been carried out?

11. Did the Government keep abreast of the growing awareness internationally about the risks arising from blood and blood products and the various national and international responses to such risks?

12. What advice did the Government receive (and from whom) about the risks of infection associated with blood and blood products?

13. What ought to have been known and understood by the Government at all relevant times about the risks of infection associated with blood and blood products, including the particular risks described in paragraph 7 above?

14. Was there a higher risk of infection from imported blood/blood products than domestic ones? If so: why; when was this known; and when should it have been known?

Policy-making, decision-making and actions

15. What decisions and actions were taken, and what policies were formulated, by the Government as regards:

- a. the importation;
- b. the manufacture; and
- c. the use;

of blood products during the relevant period?

16. What decisions and actions were taken, and what policies were formulated, by the Government as regards:

- a. the collection; and

b. the use;

of blood during the relevant period?

17. What decisions and actions were taken, and what policies were formulated, by the Government (whether alone or in conjunction with the blood services/NHS bodies/UKHCDO[3]/pharmaceutical companies/others), which caused or contributed to:

a. the use of infected blood;

b. the use of infected blood products;

to treat people in the United Kingdom (or in any of the constituent parts of the United Kingdom)?

18. What did the Government do in response to the risks arising from blood and blood products? In particular:

a. What decisions were taken by the Government during the relevant period?

b. What advice was given by the Government during the relevant period?

c. What steps did the Government take to satisfy itself that there were the right advisory and decision-making structures in place in response to the risks and scale of infection?

d. What did the Government do to ensure that NHS bodies, the medical profession and the public were informed and educated about the risks?

e. What did the Government do to ensure the safety of the blood collected in the UK?

- f. What did the Government do to ensure the safety of the blood products being used to treat people in the UK?[4]
- g. What did the Government do to provide access to treatment for infections?
19. Were the steps taken by the Government adequate and appropriate?
20. What should the Government have done in respect of each of the matters set out in paragraph 18 above, and by when should such steps have been taken?
21. What difference might such steps have made?
22. Why did the Government not do more?
23. What factors influenced the Government's decision-making and actions? What role did commercial and financial considerations play?
24. Did the Government delegate its responsibilities as regards the supply of blood and blood products to others? If so: to whom, when, and was such delegation appropriate?
25. Was there a belief that UK sourced blood was free from infection? If so, how did this belief come about and was it justified?
26. Why did the Government not impose a prohibition on the purchase and/or use of imported blood/blood products? Should the Government have done so; when; and what difference might this have made?
27. Why was there no centralised system for meeting the UK's requirements for blood and blood products? Should there have been? What difference might this have made?

28. Should the Government have issued guidance on the procurement of blood and blood products, when and what difference might this have made?

29. What was the relationship between the pharmaceutical companies manufacturing/supplying blood products and the Government? What influence did that relationship have on Government policy?

30. Did the various changes in responsibility for health in Northern Ireland, Scotland and Wales adversely affect the risks that people were exposed to and the treatment, care and support they received?

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

Self-sufficiency

32. Why did the Minister for Health commit to self-sufficiency in 1974-75?

33. What steps were taken towards self-sufficiency at this time and subsequently?

34. Were sufficient resources made available?

35. Why was self-sufficiency not achieved?

36. Should the demand for blood products have been better understood and predicted?

37. Should Parliament have been informed that self-sufficiency was not being achieved, and if so, when? Why was it not so informed?

38. When should self-sufficiency have been achieved? What steps and resources would have been required to achieve this?
39. What difference would self-sufficiency have made to the risk of infection?
40. Why did Scotland have the capability to be self-sufficient, but not the rest of the UK?
41. Why, if Scotland had spare capacity to manufacture blood products, was this not utilised by England, Wales and Northern Ireland?

The role of the blood services

Knowledge of risk

42. What were the roles, functions and responsibilities of the blood services[5] during the relevant period?
43. What information and knowledge did the blood services as a matter of fact have during the relevant period about the risks of infection associated with blood and blood products?
44. In particular:
 - a. How did their knowledge of the risks of the transmission of hepatitis from blood and blood products develop over time?
 - b. When and in what circumstances did the blood services first become aware that HIV could be transmitted by blood and blood products?

c. What was their understanding of the relative risks of infection from (i) the use of commercially supplied blood products and (ii) the use of domestically sourced blood and blood products?

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

45. What enquiries and/or investigations did the blood services carry out in respect of these risks and what information was obtained as a result?

46. Was the extent of the enquiries and/or the level of their knowledge appropriate or should further enquiries or investigations have been carried out?

47. What ought to have been known and understood by the blood services at all relevant times about the risks of infection associated with blood and blood products, including the risks described in paragraph 44 above?

Policy-making, decision-making and actions

48. What decisions and actions were taken, and what policies were formulated, by the blood services as regards:

a. the importation, manufacture and use of blood products;

b. the collection and use of blood;

during the relevant period?

49. What decisions and actions were taken, and what policies were formulated, by the blood services (whether alone or in conjunction with the Government/other NHS bodies/UKHCDO/pharmaceutical companies/others), which caused or contributed to:

- a. the use of infected blood;
- b. the use of infected blood products;

to treat people in the United Kingdom (or in any of the constituent parts of the United Kingdom)?

50. What did the blood services do in response to the risks arising from blood and blood products? In particular:

- a. What decisions were taken by them over the relevant period?
- b. What advice did they provide during the relevant period?
- c. What steps did they take to satisfy themselves that there were the right advisory and decision-making structures in place in response to the risks and scale of infection?
- d. What steps did they take to ensure that other NHS bodies, the medical profession and the public were informed and educated about the risks?
- e. What did they do to ensure the safety of the blood collected in the UK?
- f. What did they do to ensure the safety of the blood products being used to treat people in the UK?

51. Were the steps taken by the blood services adequate and appropriate?

52. What should the blood services have done in respect of each of the matters set out in paragraph 50 above, and by when should such steps have been taken?

53. What difference might such steps have made?

54. Why did they not do more?

55. What factors influenced their decision-making and actions? What role did commercial and financial considerations play? What role did crown immunity play?

56. What was the relationship between the blood services and the pharmaceutical companies? What influence did that relationship have on the actions or decisions of the blood services?

57. What consideration was given to increasing production of cryoprecipitate, or producing a product with lower risk, in response to the risks associated with factor products?

58. What steps were taken by the blood services in response to information that a particular donor or a particular product was infected? What should have been done?

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

Regulation

60. What was the regulatory regime in respect of blood donors, blood donations, blood banks and transfusion centres during the relevant period, and how did this change over time?

61. How effective was the regime in identifying and guarding against risks of infection? Should there have been a different, more effective regime, and if so by when?

62. What differences were there between the regulatory regime for NHS blood products and the regulatory regime for commercial blood products, and what were the reasons for any differences?

63. What was the system for keeping records of the blood or blood products used in the United Kingdom (both in relation to source and use)? How effective was the system in terms of identifying or guarding against the risks of infection?

Viral inactivation/heat treatment and other measures to reduce risk

Viral inactivation/heat treatment

64. What decisions and actions were taken in respect of heat treatment, by whom, when and how?

65. What were the relative roles and responsibilities, as regards heat treatment, of the Government, the blood services, the Blood Products Laboratory, the Plasma Fractionation Laboratory and the Protein Fractionation Centre, the UKHCDO, the haemophilia centres and other relevant NHS or regulatory bodies?

66. How effective and coordinated was the research, planning and decision-making as regards heat treatment? What direction or guidance was given to ensure effective research and/or effective production?

67. What research, decisions and actions should have been taken and when?

68. Could, and should, effective heat treatment have been achieved earlier than it was? If so, why was it not so achieved?

69. Should (and if so, when) untreated Factor VIII product have been recalled and replaced throughout the UK?

70. Why was a heat-treated product that deactivated HIV and was later also found to have deactivated HCV produced for use in England 18 months before it was made available in Scotland?

Donor selection/screening

71. What donor selection or screening policies and practices were in existence over the relevant period? Who was responsible for formulating and implementing such policies and practices?

72. To what extent was donor selection/screening regulated and/or subject to standards or guidelines? Should there have been different or better regulation and what difference might this have made?

73. What were the relative roles and responsibilities, as regards donor selection and screening, of the Government, the blood services, the Blood Products Laboratory, the Plasma Fractionation Laboratory and the Protein Fractionation Centre, the UKHCDO, the haemophilia centres and other relevant NHS or regulatory bodies?

74. What steps were taken to screen blood donors for risk of infection? Were the steps taken effective? What other steps should have been taken?

75. What steps were taken to discourage donors thought to be at higher risk of transmitting infection, or to prevent them from donating? Were the steps taken effective? What other steps should have been taken?

76. To what extent, over what period and why was blood taken in the UK from:

- a. prisoners (or other detainees)?
- b. UK and US armed forces?
- c. high risk groups such as intravenous drug users?

77. What was known, and when, about the risk of transmission of infection from these groups compared to the general donor population?

78. To what extent were these groups incentivised to give blood?

79. Was it cheaper to obtain blood from these groups than from the general population?

80. Should the collection of blood from such groups have stopped earlier and if so when?

Screening of donations

81. What decisions and actions were taken, and by whom, in relation to the testing of blood donations over the relevant period? What decisions and actions should have been taken?

82. To what extent was this regulated and/or subject to standards or guidelines? Should there have been different or better regulation and what difference might this have made?

83. What were the relative roles and responsibilities, as regards the screening and testing of donations, of the Government, the blood services, the Blood Products Laboratory, the Plasma Fractionation Laboratory and the Protein Fractionation Centre, the UKHCDO, the haemophilia centres and other relevant NHS or regulatory bodies?

84. When should the screening of blood donations for HIV have begun?

85. Was there a delay? If so, what caused that delay?

86. What difference might earlier screening for HIV have made?

87. Should surrogate testing for non-A, non-B hepatitis (NANB hepatitis) have been introduced across the UK and if so when?

88. What difference might surrogate testing have made?

89. Why, following the discovery, in 1989, of HCV and the development of a test to screen for it, was there a delay in the introduction of screening in the UK?

90. Why was there a further delay after the decision in principle had been taken before screening actually started?

91. When should screening have been introduced?

92. What difference might the earlier introduction of screening have made?

Other measures to reduce risk

93. Were there other measures to reduce risk that should have been considered? If so, what measures and when?

94. Were credible alternatives to heat treatment advanced and if so were they given sufficient consideration?

The role of haemophilia centres and the UKHCDO

Knowledge of risk

95. What were the roles, functions and responsibilities of the haemophilia centres[6] during the relevant period?

96. What were the roles, functions and responsibilities of UKHCDO (or its predecessor) during the relevant period?

97. What information and knowledge did (i) the haemophilia centres and (ii) UKHCDO as a matter of fact have during the relevant period about the risks of infection associated with blood products?

98. In particular:

a. How did the knowledge of (i) the haemophilia centres and (ii) UKHCDO as to the risks of the transmission of hepatitis from blood and blood products develop over time?

b. When and in what circumstances did they first become aware that HIV could be transmitted by blood and blood products?

c. What was their understanding of the relative risks of infection from (i) the use of commercially supplied blood products and (ii) the use of domestically sourced blood and blood products?

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

99. What enquiries and/or investigations did (i) the haemophilia centres and (ii) UKHCDO carry out in respect of these risks and what information was obtained as a result?

100. Was the extent of the enquiries and/or the level of their knowledge appropriate or should further enquiries or investigations have been carried out?

101. What ought to have been known and understood by (i) the haemophilia centres and (ii) UKHCDO at all relevant times about the risks of infection associated with blood products, including the risks described in paragraph 98 above?

Policy-making, decision-making and actions

102. What decisions and actions were taken, and what policies were formulated, by (i) the haemophilia centres and (ii) UKHCDO as regards the importation, manufacture and use of blood products during the relevant period?

103. What decisions and actions were taken, and what policies were formulated, by (i) the haemophilia centres and (ii) by UKHCDO (whether alone or in conjunction with the Government/the blood services/other NHS bodies/pharmaceutical companies/others), which caused or contributed to the use of infected blood products to treat people in the United Kingdom (or in any of the constituent parts of the United Kingdom)?

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

105. What alternative treatments to the factor products were available for people with bleeding disorders? What were the risks, advantages and disadvantages of those alternative treatments and should they have been used in preference to factor products?

106. What responsibility did (i) the haemophilia centres and (ii) UKHCDO have for the selection and purchasing of blood products over the relevant period? How did they make decisions about the selection and purchase of blood products? What were the reasons that led them to choose one product over another?

107. What did (i) the haemophilia centres and (ii) UKHCDO do in response to the risks arising from blood products? In particular:

a. What decisions did they take during the relevant period?

b. What advice did they give during the relevant period?

c. What steps did they take to satisfy themselves that there were the right advisory and decision-making structures in place in response to the risks and scale of infection?

d. What did they do to ensure that NHS bodies, the medical profession and the public were informed and educated about the risks?

e. What did they do to ensure the safety of the blood products being used to treat people in the UK?

f. What did they do to provide access to treatment for infections?

108. Were the steps taken by (i) the haemophilia centres and (ii) UKHCDO adequate and appropriate?

109. What should the (i) the haemophilia centres and (ii) UKHCDO have done in respect of each of the matters set out in paragraph 107 above, and by when should such steps have been taken?

110. What difference might such steps have made?

111. Why did they not do more?

112. What factors influenced their decision-making and actions? What role did commercial and financial considerations play?

113. What was the relationship between the haemophilia centres, UKHCDO and the pharmaceutical companies manufacturing/supplying blood products? What influence did that relationship have on their decisions and actions?

114. Why in light of growing evidence of the risks arising from pooled blood products, did the haemophilia centres and/or UKHCDO continue to use these products?

115. What decisions or actions of the haemophilia centres and/or UKHCDO could and/or should have avoided, or brought to an end earlier, the use of infected blood products?

116. What were the consequences of the variations in decision-making by haemophilia centres?

Lord Mayor Treloar College (Treloar's)

117. What blood products were administered to the pupils of Treloar's during the relevant period?

118. What information was provided to pupils and/or their families about the risks of such treatments?

119. How were the decisions taken as to what treatments to administer?

120. Was pressure put on Treloar's staff to use products which they would have preferred not to use, and if so why?

121. Were the pupils at Treloar's treated differently than other people with bleeding disorders? If so, in what respects and why?

122. What happened to the pupils at Treloar's in consequence of treatment with infected blood products?

The role of other NHS bodies

Knowledge of risk

123. What information and knowledge did other NHS bodies[7] in general have during the relevant period about the risks of infection associated with blood and blood products?

124. In particular:

a. How did their knowledge of the risks of the transmission of hepatitis from blood and blood products develop over time?

b. When and in what circumstances did they first become aware that HIV could be transmitted by blood and blood products?

c. What was the understanding of the relative risks of infection from (i) the use of commercially supplied blood products and (ii) the use of domestically sourced blood and blood products?

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

125. What enquiries and/or investigations did such NHS bodies carry out in respect of these risks and what information was obtained as a result?

126. Was the extent of the enquiries and/or the level of their knowledge appropriate or should further enquiries or investigations have been carried out?

127. What ought to have been known and understood by NHS bodies in general at all relevant times about the risks of infection associated with blood and blood products, including the risks described in paragraph 124 above?

Policy-making, decision-making and actions

128. What decisions and actions were taken, and what policies were formulated, by other NHS bodies as regards:

- a. the importation, manufacture and use of blood products;
- b. the collection and use of blood;

during the relevant period?

129. What decisions and actions were taken, and what policies were formulated, by other NHS bodies (whether alone or in conjunction with the Government/the blood services/haemophilia centres/UKHCDO/pharmaceutical companies/others), which caused or contributed to:

- a. the use of infected blood;
- b. the use of infected blood products;

to treat people in the United Kingdom (or in any of the constituent parts of the United Kingdom)?

130. What did the NHS in general do in response to the risks arising from blood and blood products? In particular:

- a. What decisions were taken over the relevant period?
- b. What advice was provided over the relevant period?
- c. What steps did they take to satisfy themselves that there were the right advisory and decision-making structures in place in response to the risks and scale of infection?

d. What steps were taken to share information and to ensure that other NHS bodies, the medical profession and the public were informed and educated about the risks?

e. What was done to ensure the safety of the blood collected in the UK?

f. What was done to ensure the safety of the blood products being used to treat people in the UK?

g. What did they do to provide access to treatment for infections?

131. Were the steps taken adequate and appropriate?

132. Should more have been done? If so what and by when? What difference might this have made?

133. What factors influenced decision-making and actions? What role did commercial and financial considerations play?

134. What decisions or actions of the NHS could and/or should have avoided, or brought to an end earlier, the supply of infected blood or infected blood products?

The role of medical practitioners

Knowledge of risk

135. What was the level of knowledge and understanding within the medical profession[8] about the risks of infection (in particular with hepatitis and HIV) associated with blood and blood products during the relevant period? How did it change over time?

136. What information, advice and guidance about these risks were available to medical practitioners? Where did such information, advice and guidance come from?

137. Did the level of knowledge and understanding differ depending on whether the practitioner was in a specialist centre or not?

138. What should the level of knowledge and understanding been?

Provision of information to people about the risks of blood products

139. What information was provided to people with a bleeding disorder (and to people 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 over the relevant period?[9]

140. Was sufficient and appropriate information provided?

141. What information should have been provided?

142. Was the failure to provide relevant information such that people receiving treatment were not in a position to give informed consent to their treatment?

Provision of information to people about the risks of transfusion

143. What information was provided to people receiving whole blood about the risks of infection in consequence of treatment with whole blood over the relevant period?[10]

144. Was sufficient and appropriate information provided?

145. What information should have been provided?

146. Was the failure to provide relevant information such that people receiving treatment were not in a position to give informed consent to their treatment?

Guidance

147. What guidance or advice about doctors' ethical obligations and the provision of information and consent was available to medical practitioners during the relevant period?

148. Even if medical practitioners' approach to the provision of information and the obtaining of consent was consistent with the standards of the time, were those standards (whether contained in guidance or advice or otherwise) wrong?

Consent

149. Were people experimented on without their consent? If so, how and why did this occur?

150. Were people treated without their consent? If so, how and why did this occur?

151. Were people tested without their consent? If so, how and why did this occur?

152. Were people used for research purposes without their consent? If so, how and why did this occur?

153. What treatment and testing decisions and actions were taken with regard to a category of people referred to as 'previously untreated patients' ('PUPS')? How and why did this occur?

Policy-making, decision-making and actions

154. To what extent were the risks associated with multiple transfusions considered by doctors treating people with thalassaemia and sickle cell anaemia?

155. To what extent were the risks of infection through immunoglobulin considered by doctors treating people with immunodeficiencies?

156. To what extent were factor products administered to people without bleeding disorders? How and why did this come about and were there alternative treatments?

157. Were medical treatments for HCV, HBV and HIV appropriately prescribed? In particular:

a. What information and advice was given to people about the side effects of these treatments?

b. Would people have been better advised to wait for the second generations of these treatments?

c. Were new drugs released to people quickly enough?

d. Were some of these treatments abandoned as too risky in some areas of the country while still being prescribed elsewhere?

158. Should medical practitioners have been actively encouraging people who had received blood or blood products over the relevant period to be tested?

159. Did medical practitioners wrongly refuse to test for infection people who had received blood or blood products?

160. Were medical practitioners testing people without their consent to establish whether they were infected with HIV, HCV and HBV? If so, why and what was done with this information once obtained?

161. Did medical practitioners remain silent about their suspicions or about evidence that blood and blood products were causing infections when they should have spoken up?

162. How, as a matter of good practice, should the results of blood testing have been communicated to people? In particular:

a. Once a test had been carried out, was it acceptable to keep the diagnosis from the individual?

b. Should results have been delivered in person?

c. Should information have been immediately available about the diagnosis and treatment options?

d. Should counselling have been available?

e. Should information have been given about the risk of infecting others?

f. Did medical practitioners decide not to inform people of their diagnosis because of a belief that their condition could not be treated?

163. To what extent did medical practitioners fail to act in accordance with good practice in this regard? Even if medical practitioners' conduct was consistent with the standards of the time, were those standards (whether contained in guidance or advice or otherwise) wrong?

164. What, if any, information or advice could and/or should medical practitioners have provided to partners or family members about any risks to them?

165. What was the level of knowledge amongst medical practitioners of the effects of HCV, HBV and HIV and of the prognosis for those infected with HCV, HBV and HIV?

a. What information was available and from where?

b. Should medical practitioners have availed themselves of this information before informing people of their diagnosis?

166. Were people encouraged to keep their infective status secret?

167. What practical advice, advice about living with HCV/HBV/HIV and advice about the implications of the diagnosis could and should medical practitioners have been providing? Was inappropriate or inaccurate advice given?

168. Was there a culture of not allowing people to ask questions about their diagnosis/the cause(s) of their illness/ their treatment?

169. Was there a culture or pattern of incorrectly attributing conditions to alcohol use, unsafe sex with multiple partners and/or drug use in respect of people who had received infected blood and blood products?

170. Was there a culture or pattern of recording inaccurate information on death certificates when the true reason, death caused by HCV or HIV or HBV, should have been clear from the known history of the deceased?

171. What was the nature and extent of the obligation on clinicians to report an infection or adverse events arising from the use of blood and blood products? Did this in fact happen?

172. How were people infected by blood or blood products and their families treated by the medical profession? In particular:

- a. Were there breaches of patient confidentiality?
- b. Were they treated with dignity and respect?
- c. Was there candour and openness?

173. Should there have been national/regional/organisational guidelines for medical practitioners on:

- a. ensuring that people who had received blood and blood products were provided with information about the risks of infection?
- b. encouraging such people to be tested for HCV, HBV and HIV?
- c. ensuring that once tested they were informed of their diagnosis?
- d. ensuring that people were informed about the risk of infecting others and how this risk could be minimised?

The role of pharmaceutical companies

The international market for blood products

174. How did the international market for blood products, in particular blood products (including Factor VIII and Factor IX) relating to bleeding disorders, develop in the post-war period?

175. In general terms, what were the key factors in determining supply and demand within the international market for blood products?

176. How significant was the United Kingdom and the NHS as (i) a market and (ii) a producer of blood products within the international market for blood products?

177. Which companies and/or state-owned organisations played significant roles in the international market for blood products, and in particular in respect of supplying products to the NHS or its regions?

178. How did the international market for blood products respond or alter in response to the growing knowledge of: (i) the risk of commercially supplied blood products transmitting HCV[11], (ii) the severity of HCV, (iii) the risk of commercially supplied blood products transmitting HIV, (iv) the risk of commercially supplied blood products transmitting other infections and diseases (e.g. HBV)?

Relevant companies and corporate structures

179. Which companies/organisations provided blood products manufactured from pooled plasma to the UK market during the relevant period?

180. What were the products that those companies provided?

181. How were decisions taken within the company about which pooled blood plasma products should be developed? What factors influenced those decisions?

Knowledge of risk of HCV, HIV and other infections[12]

182. What structures existed within each company to identify risks to health caused by its own products?

183. How was research about such risks commissioned, considered and disseminated by the company?

184. What internal and external practices, policies or obligations governed the identification of risks to health caused by the company's products?

185. What information and knowledge did the company in fact have throughout the relevant period about the risks of infection associated with the types of blood products it was producing? In particular, what information did the company have, and when, about the risks associated with (i) HCV, (ii) HIV and (iii) other infections and diseases?

186. What resources were devoted to researching and eradicating the risks identified in the previous question? In particular, what resources were devoted to:

- a. establishing methods for heat treating the products;
- b. other methods of viral deactivation;
- c. producing products for the treatment of bleeding disorders that were not manufactured from pooled plasma?

187. How were decisions made on the allocation of those resources?

188. How was research commissioned or undertaken by the company on the risks identified above disseminated (i) within the company and (ii) externally?

189. Are there instances of research relevant to the risks identified above being withheld from publication or dissemination? If so, for what reason?

190. How did the company contribute to the international debate on the risks identified above?

Communication of risk of HCV, HIV and other infections

191. What external and internal policies, guidance and/or obligations were placed on the company to provide information to:

- a. the UK national regulatory authorities;
- b. NHS bodies and healthcare professionals that might use its products;
- c. NHS patients who might use its products;

about the risk posed by its products relating to HCV, HIV and other infections during the relevant period?

192. How did the policies, guidance and/or obligations described above change over time?

The collection of blood for use in pooled plasma products

193. From where was the blood used in commercially produced blood products obtained? In particular, were donors voluntary or paid? How and from where were donors recruited?

194. What national legislation, regulations or policies governed the relevant blood donations?

195. How did the national legislation, regulations or policies change over time, and in particular in response to developing knowledge concerning the risk of HCV and HIV infection?

196. What criteria were applied in respect of the recruitment of donors by:

a. the company/organisation obtaining the blood;

b. the company/organisation that was producing the blood product?

197. Did the recruitment process and criteria described in the previous question above change over time, and in particular in response to developing knowledge concerning the risk of HCV and HIV infection?

198. What information was shared between those obtaining the blood and the companies producing the blood product about the source of the blood?

199. How did the number of donors contributing to a pool vary over the relevant period, and what were the reasons for any variations?

Interaction with the UK regulatory and medical authorities

The UK licensing regime

200. What was the licensing regime for blood products used by the NHS within the UK during the relevant period?

201. What information and knowledge did the licensing authorities as a matter of fact have throughout the relevant period about the risks of infection associated with blood products?

202. What enquiries and/or investigations did the licensing authorities carry out in respect of these risks and what information was obtained as a result?

203. What ought to have been known and understood by the licensing authorities at all relevant times about the risks of infection associated with blood products?

204. What decisions and actions were taken by the licensing authorities which caused or contributed to the use of infected blood products to treat people in the United Kingdom?

205. What did the licensing authorities do in response to the risks arising from blood products and to ensure the safety of the blood products being used to treat people in the UK?

206. Were the decisions and actions of the licensing authorities adequate and appropriate? What should the licensing authorities have decided and done? What difference might this have made?

Pharmaceutical companies' interactions with the licensing authorities

207. What information was the company required to produce in support of an application to supply a blood product within the UK?

208. How did that compare to information required by other national drug licensing authorities?

209. How was the information for the UK licensing authorities obtained and provided?

210. Which materials relevant to the production of a blood product were not required by or provided to the UK licensing authorities?

211. How did the system change over time?

212. Outside of the formal application process what, if any, interaction did the company have with the UK drug licensing authorities?

Pharmaceutical companies' interactions with medical authorities and the medical profession

213. What, if any, interaction did the company have with haemophilia centre directors/clinicians/administrators, individual doctors, and charitable and support organisations?

- a. What was the extent of any such interaction?
- b. What was the purpose of any such interaction, so far as the company was concerned?
- c. What, if any, internal company policies or guidance governed such interactions?
- d. What, if any, external policies, guidance or regulations governed such interactions?
- e. What, if any, budget was allocated for such interaction, and how was it spent?
- f. How did these matters change over time, and, if they did, why?

Individual products

Background

214. Which products did the company produce from pooled plasma which were used by the NHS in the UK in the period relevant to the Inquiry?

215. What was the decision-making process that led to the development of the product?

216. How was the product produced (including by reference to the size and selection of the donor pool, and the use of heat treatments and/or other methods of viral deactivation)?

217. From where was the plasma used in the product sourced?

Intended use and licensing

218. What was the intended therapeutic use of the product?

219. Was the product licensed for use in the UK, and if so, when?

220. What information was provided to the UK licensing authorities? Was any relevant information not so provided?

221. Was the product made available for use in the UK absent a relevant licence, and if so when and for what reason?

222. Were any applications made to vary the licence, and if so, when and why?

223. Was the product refused a licence at any stage by the UK licensing authorities, or by any other licensing authorities?

Profile and period of use

224. Over what period was the product available in the UK?

225. When and why did the product cease to be available in the UK?

226. When and why did the product cease to be available in countries other than the UK?

227. How much of the product was used in the UK (broken down by year, if possible)?

228. What were the national and regional variations in respect of the use of the product within the UK?

Price and profit

229. Is it possible to state the costs of the research, development and manufacturing processes that led to the product?
230. What was the price of the product to the NHS?
231. What was the profit margin for the product when sold to the NHS?
232. What was the total profit derived from sales of the product to the NHS, and how did this change over time?

Studies

233. What, if any, studies were commissioned by the company relating to or including the product (i) prior to and (ii) following its release to the UK market?
234. Were those studies published? If so, when and where? If not, why not?

Risks

235. What risks of infection were/are associated with the product?
236. When and how did the company become aware of these risks?
237. How and why did the risk profile change over time?
238. What was communicated by the company to the following about the risks identified above, and when: the UK licensing authorities; NHS bodies; NHS clinicians and administrators; NHS patients using, or potentially using, the product?

239. How did the nature and timing of the information provided above compare to information provided by the company to other licensing bodies, regulators, medical organisations, clinicians and patients elsewhere in the world?

Heat treatment

240. Where relevant, how did the product come to be heat treated?

241. When and why were decisions taken to pursue heat treatment?

242. What was the rationale for the chosen method of heat treatment?

243. How were decisions taken about the level of resource to be allocated to heat treating the product?

244. Is it possible to assess how much was spent in time and resource in providing a heat treated version of the product?

Response to infection

245. When did the company become aware that people within the UK had been infected with HCV/HBV/HIV by using its product?

246. What was the response of the company to such infections?

247. Did the company recall batches of the product? What influenced the decision on whether or not to do so?

248. What knowledge did the company have on rates of infection from its products? Did it conduct any monitoring or request information from the medical community?

249. Was any specific action taken in relation to the supply of products to the UK after the FDA changed its recommendations on donor selection in March 1983 and/or after product licenses were revoked by the FDA?

250. What litigation (actual or threatened) was there in respect of UK infections? If so, what was the outcome?

251. Were any ex gratia, compensation or other payments made by the company in respect of UK infections?

252. How does the company's response as regards people treated by the NHS in the UK compare with its response to infections in other countries from use of this product?

The role of the Haemophilia Society

253. What information and knowledge did the Haemophilia Society as a matter of fact have during the relevant period about the risks of infection associated with blood products?

254. What actions and decisions were taken by the Haemophilia Society in relation to the use of infected blood products during the relevant period? Should different actions or decisions have been taken? What difference might this have made?

255. What was the relationship (financial and otherwise) between the Haemophilia Society and the pharmaceutical companies manufacturing/supplying blood products? What impact did such a relationship have on the Society's actions and decisions?

256. What representations were made to Government by the Haemophilia Society in relation to self-sufficiency and why?

257. What representations were made to Government by the Haemophilia Society in relation to imported blood products and why?

258. Why did the Haemophilia Society continue to issue statements reassuring its members that the factor treatments were safe and to continue using them?

259. What should they have advised their members to do?

Scale of infection and response

260. What were the likely numbers of people infected (directly or indirectly) with HCV from transfusions:

a. between 1970 and 1991?

b. after 1991?

261. What were the likely numbers of people infected (directly or indirectly) with HBV from transfusions:

a. between 1970 and 1991?

b. after 1991?

262. What were the likely numbers of people infected (directly or indirectly) with HIV from transfusions:

a. between 1970 and 1991?

b. after 1991?

263. What were the likely numbers of people infected (directly or indirectly) with HCV from blood products:

a. between 1970 and 1991?

b. after 1991?

264. What were the likely numbers of people infected (directly or indirectly) with HBV from blood products:

a. between 1970 and 1991?

b. after 1991?

265. What were the likely numbers of people infected (directly or indirectly) with HIV from blood products:

a. between 1970 and 1991?

b. after 1991?

266. How many men, women and children were infected through blood transfusion?

267. How many women were infected through blood transfusions after giving birth?

268. How many men, women and children with haemophilia were infected through blood products?

269. How many men, women and children with thalassaemia were infected through blood transfusions?

270. How many men, women and children with sickle cell anaemia were infected through blood transfusions?

271. How many men, women and children with primary immunodeficiencies were infected through immunoglobulin?

272. How many people with haemophilia or other bleeding disorders have died in consequence of being given infected blood products in the UK?

273. How many people have died in consequence of being given infected blood or infected blood products, through transfusion or other means, in the UK?

274. Have people receiving blood products or blood been exposed to the risk of other diseases, such as vCJD? To what extent can this be assessed and quantified? What steps should be taken now to address such risks?

275. What are the clinical implications of being repeatedly infected through blood and blood products?

276. Do people receiving infected blood and blood products and treatment for the infections have a higher risk of other medical conditions?

277. Why has no comprehensive “look back” testing programme been introduced whereby all people at risk (those receiving a transfusion or blood products between 1970 and 1991) are traced and advised to seek a test?

278. Was there ever a Government policy or guidance that patients should not be informed of the possibility of contraction of infection through transfusion?

279. What if any steps were taken by the Government in response to reports about infected blood and blood products? In particular:

a. Were adequate steps taken to remove infected batches of product from circulation as a result of testing on people and tracing their treatment?

b. Were adequate steps taken to trace people at risk of infection?

280. Why has no accurate data on the number of people infected been kept and why has no accurate data on the cause of infections (particularly HCV) and cause of death been collected? Furthermore:

a. Has this caused additional distress for people and their families?

b. Has this caused difficulties in accessing support through the schemes?

c. What other impact has this had in terms of the ability of the Government or NHS to prevent harm to those infected and to ensure that events of this nature do not happen again?

281. What was the system of recording the cause of death from infection from blood or blood products in England, Scotland, Wales and Northern Ireland?

282. Did the system accurately capture information about cause of death?

283. Has there been a systemic failure on the part of the medical profession and/or coronial system and/or the system for the registration of deaths to investigate and/or certify accurately the cause(s) of death in the case of people who have died in consequence of treatment with infected blood or infected blood products?

Cover up, lack of candour and openness

284. Have relevant Government documents been destroyed? If so,

- a. When were the documents destroyed?
- b. What classes or description of documents have been destroyed and (insofar as can be ascertained) what information or kind of information was or might have been in those documents?
- c. Who gave the order for the documents to be destroyed?
- d. Under what authority or power were they destroyed?
- e. For what reason were they destroyed?

285. What relevant Government documents have been lost or are otherwise missing?

- a. What classes or description of documents have been lost or are missing? What information is thought to have been in those documents?
- b. When was it first appreciated that they had been lost or were missing?
- c. What were the circumstances surrounding the loss or disappearance of these documents?
- d. Who is or was responsible for their loss or disappearance?

286. What policies or guidance were in existence regarding the retention and/or destruction of documents during the relevant period?

287. Have relevant documents held by others (in particular, the blood services, the haemophilia centres, UKHCDO, licensing and regulatory authorities) and relevant to the issues being investigated in this Inquiry been destroyed or lost? If so:

- a. What classes or descriptions of documents have been destroyed or lost and what information or kind of information might have been in those documents?
- b. What are the circumstances in which such documents have been destroyed or lost?
- c. Who is or was responsible for their loss or destruction?
- d. In the case of documents that were destroyed, what was the reason for their destruction?

288. Have the medical records of people who were infected been lost? If so:

- a. Is this a common pattern?
- b. Does this suggest that the loss of these records was deliberate?
- c. If so, how, by whom and at whose instigation was this achieved and carried out?
- d. What was the purpose of deliberately losing medical records?
- e. What were the consequences of deliberately losing medical records?

289. Have the medical records of people who were infected been wrongfully interfered with? If so:

- a. What kind of information has been removed or altered and why?

- b. Is this a common pattern?
- c. What does this pattern suggest?
- d. What was the purpose of tampering with medical records?
- e. Did this adversely impact on people's treatment?

290. Has relevant information been omitted from the medical records of people who were infected? If so:

- a. What kind of information has been omitted and why?
- b. Is this a common pattern?
- c. What does this pattern suggest?
- d. What were the consequences of this?

291. Has the Government deployed crown immunity to prevent the true facts emerging?

292. Why did the Government not establish a UK-wide public inquiry before now?

293. Why did the Government not provide witnesses to the non-statutory Archer Inquiry?

294. Did the prosecutions in France trigger a cover up in the UK?

295. Has there been a lack of candour on the part of any governmental or public or other relevant organisation, or a failure on the part of any governmental or public or other relevant organisation to acknowledge fault?

296. Are all or any of these matters part of an attempt to prevent the true facts emerging?

297. Has there been, on the part of the Government, the blood services, the haemophilia centres, UKHCDO, the NHS more generally, the pharmaceutical companies, the licensing and regulatory authorities and/or the medical profession, a lack of candour and/or transparency in their dealings with the infected and affected, or in their response to the raising of concerns about infected blood and blood products?

Impact on people infected and affected

Impact on people infected

What is or has been:

298. The physical, medical and mental impact of receiving infected blood or blood products.

299. The physical, medical and mental impact of the treatments received for those infections.

300. The emotional and psychological impact of being infected and of the treatments received for the infections.

301. The impact of infection and treatment on the quality of life of people who were infected.

302. The impact of infection and treatment on their relationships with others and their private and family life. (To include consideration of the position of children who were taken into care; those who were advised to, or did, terminate pregnancies; and those who had to take difficult decisions about whether or not to have children or were only funded for sperm washing for one child).

303. The impact of infection and treatment on their ability to live their life fully as a member of society.

304. The impact of infection and treatment on the ability of people who were infected to access education, to work and earn money, to obtain insurance and to accrue a pension.

305. The financial effects of being infected with HIV and/or HCV and/or HBV and/or of the treatments received for those infections.

306. The impact on people who were infected of their dealings and interactions with the Trusts and Schemes.

307. The impact on people who were infected of having to seek welfare benefits and of their dealings and interactions with the welfare benefit system.

308. The extent to which medical and dental treatment and care for other conditions was compromised or adversely affected by the fact of their infected status.

309. The impact of being provided with inaccurate or insufficient information or advice.

310. The impact on those who were infected of any failure on the part of any relevant organisation to accept responsibility.

Impact on people affected

What is or has been:

311. The impact on people who were affected - family, carers and others close to those infected:

a. Physically.

b. Emotionally, mentally and psychologically.

c. Financially and on their ability to access education, work and earn money and to accrue a pension.

d. On their quality of life and their ability to live their life fully as a member of society.

e. On their private and family lives and on the quality of their relationships including with the infected person.

f. Of their dealings and interactions with the Trusts and Schemes.

g. Of having to seek welfare benefits and of their dealings and interactions with the welfare benefit system.

312. The impact on people who were affected of their dealings with hospitals and coroners after the death of their loved one.

313. The impact on people who were affected of any failure on the part of any relevant organisation to accept responsibility.

Stigma

314. What has the impact of the stigma of infection been on people who were infected or affected?

315. What could or should the Government, the NHS or other relevant bodies have done to reduce and counter the stigma?

316. Why were some people advised not to discuss their diagnosis?

317. What was the emotional burden of keeping a diagnosis secret on infected and affected people and what if anything should have been done to recognise or address this?

Access to treatment, care and support

318. Did people who were infected or affected face difficulties or obstacles in obtaining adequate treatment, care and support? What were those difficulties and obstacles?

319. What difficulties or obstacles do people who were infected or affected continue to face?

320. What should be done to address those difficulties and obstacles?

321. Was adequate counselling and/or psychological support made available to people who were infected or affected?

322. Is adequate counselling and/or psychological support now available to people who were infected or affected?

Response of Government and others

323. What practical steps could and/or should the Government, the NHS or other relevant bodies have taken to alleviate some or all of the burdens identified above?

324. Did the response of Government and others in fact exacerbate the impact on people who were infected or affected?

Trusts and Schemes

General

325. What was the purpose of setting up schemes to provide financial assistance? What principles or philosophy underpinned their introduction?

326. Were those who suffered infection or were affected by the infection of others (consequent upon transfusion of blood or administration of blood products) regarded by Government and/or the scheme administrators as having suffered without that suffering being the fault of anyone? If so, then given that those who suffer medical accidents, where fault is not established, do not generally receive payments from the State (or any private medical professional involved), on what basis was it decided that people who received blood-borne infections should receive financial payments?

327. Given the resolution of issues 1 to 324, what principles should have been adopted?

Establishment of the Alliance House Organisations

328. Should a scheme for financial assistance have been established earlier than it was?

329. Did the fact that the trusts and schemes were set up in response to large scale litigation, and the fact that the support provided through the Alliance House Organisations was always characterised by the Government as “voluntary” or “ex gratia”, have an impact on the way they operated?

330. What was the intended impact of the financial assistance and how was it formulated? In particular:

a. Who did the Government consult with and did they consult with the beneficiary community?

b. What (if any) expert evidence did they receive?

331. What was the underlying rationale for the scheme? What principles were intended to underpin its establishment and its operation?

332. Why:

a. were payments provided by (allegedly) arms-length organisations rather than directly by the Government?

b. were some payments made via a charitable trust and some via a limited company?

333. What impact did this set-up have on the culture of the organisations and the way in which they operated, and on beneficiaries?

334. Did the way the organisations were structured and/or operated contribute to stigma?

335. Were the charitable foundations (MacFarlane Trust, Eileen Trust, Caxton Foundation) sufficiently independent of Government? In particular,

a. What impact did the fact that the Government appointed 3/9 trustees to Macfarlane, Eileen and Caxton, have on their independence? Should there have been a different constitution of trustees?

b. What influence did the Government have on the organisations?

c. Were the organisations able to lobby the Government on behalf of their beneficiaries?

Funding

336. What variations were there between the schemes, with different groups of people receiving different levels of financial assistance and/or those in different parts of the UK being treated differently?

337. What was (and is) the rationale for those differences?

338. Were (are) any of those differences justified?

339. How did central Government set the budget for the trusts and schemes? In particular,

a. Who did they consult with and did they consult with the beneficiary community?

b. What (if any) expert evidence did they receive?

c. What mechanism was there for receiving submissions from the trustees and directors of the trusts and schemes?

340. To what extent was the decision to make payments by monthly instalments influenced by considerations of the limited life expectancy (at the time) of those with HIV?

341. Why was the model in the Republic of Ireland, of providing substantial lump sums which provided the ability to invest and to become financially independent, not adopted?

342. Were the trusts and schemes adequately financed throughout the period (1988-2019) to meet the needs of the beneficiary population? In particular:

- a. How and on what basis did the Government allocate resources to the trusts and schemes?
- b. What advice did the Government receive on the appropriate level of funds to allocate?
- c. Did the Government consult with the trusts and schemes and/or the beneficiary population?
- d. What mechanisms were in place to adjust the funding to respond to changing circumstances?

Operation of the Trusts and Schemes

343. Did the Trusts and Schemes reach all of the individuals they should? In particular:

- a. What if any steps did the Government take to advertise the existence of the trusts and schemes?
- b. What if any steps did the trusts and schemes take to advertise their existence?
- c. What is and has been the level of take up over the period of their existence?
- d. Should more have been done to reach people who were infected and affected? If so, what?

344. Was the application and decision-making process accessible for potential applicants and transparent? In particular,

- a. Were the criteria against which applications were determined publicly available and accessible?

b. Did the trusts and schemes unnecessarily require repeat applications to be made?

c. Was sufficient practical support and assistance given to applicants to make applications?

345. Was the application and decision-making process fair and appropriate? In particular:

a. Were the eligibility requirements fair and appropriate?

b. Were the requirements for proof of exposure to blood and/or blood products fair and appropriate?

c. Was the requirement for supporting evidence fair and appropriate?

d. Were decisions made fairly and in line with published guidelines?

e. Were medical judgments to inform decisions made fairly?

f. Was there a practice of securing loans against properties? If so, why and was there any justification for it?

g. How were applicants treated during the application and decision-making process? Were they shown respect?

h. Were decisions made in an efficient and timely manner?

i. Were applications decided in a consistent way or were there differences in the way applicants were treated?

j. Were adequate reasons given when applications were refused?

346. To what extent did the trusts and schemes rely on the haemophilia centres to put people forward and/or to undertake screening for eligibility for payment?

347. Should there have been a mechanism for review/appeal against decisions (apart from Skipton for which there was a mechanism)?

348. Were the payments at the right level? In particular:

a. How were these levels set?

b. Was there a medically-led and/or beneficiary-informed analysis of what the payments ought to be?

c. Did contemporary expectations about life expectancy etc. influence early quantum levels, and if so, was that reasonable? Do they continue to inform quantum?

d. What if any information was obtained from other jurisdictions when setting these levels?

e. What justification was there for having payments at a lower level to that in Republic of Ireland, in particular following the recommendations of the Archer Report and the judgment of Mr Justice Holman in *R (March) v Secretary of State for Health* in 2010?

349. What decisions were taken by the Government in response to the recommendations of the Archer Report and the judgment of Mr Justice Holman? What decisions should have been taken?

350. Did the trusts and schemes want to keep the number of beneficiaries down? If so, why?

351. Why were the ex gratia payments for HIV infection made conditional on waiving rights to bring any further proceedings, whether in respect of HIV or HCV, and was this appropriate? In particular,

a. At the time that this requirement was imposed, what did the Government know about HCV infection?

b. Did they provide this information to those being asked to sign the waiver, prior to the waiver being signed?

Revised Schemes

352. Should the trusts and schemes have been reformed prior to 2016-2017?

353. Was the 2016-2017 consultation fair? In particular,

a. Was there sufficient consultation?

b. Did the consultation overlook the main issues identified by the All-Party Parliamentary Group (quantum, evidence, and the relationship with the Government)?

354. Were the revised schemes an appropriate and adequate response to the All-Party Parliamentary Group's 2015 report? In particular, has there ever been a "comprehensive and holistic assessment of the precise level of payments and resources necessary to sufficiently provide for those affected" (APPG report)?

355. Was it right for the reformed schemes to carry over the eligibility test from the schemes and trusts?

356. What are the differences in the arrangements made for financial assistance between England, Wales, Scotland and Northern Ireland? Are any differences fair and justifiable? Is it fair and justifiable for people who were part of the same

settlement with the Government to receive different payments depending on their location?

357. Are there deficiencies in the current system, in terms of both the application and decision-making processes and the payments made?

358. How do each of the devolved administrations budget for their schemes?

359. How does the financial assistance in England, Wales, Scotland and Northern Ireland compare to schemes in other countries, for example Canada and EU nations?

360. What is the reason for any difference? Can it be justified?

Future

361. Should there now be a different system to replace the current schemes?

362. If so:

a. What should be the purpose(s) of the replacement system and on what principles and philosophy should it be based?

b. What should be its principal characteristics?

c. How should it operate?

d. How should the levels of financial assistance be determined?

JENNI RICHARDS QC

KATIE SCOTT

SARAH FRASER BUTLIN

18 December 2018

[1] 'The relevant period' is a phrase used throughout the List of Issues, as the Inquiry considers that it would be too prescriptive at this stage of its investigations to specify exact time periods. The 'relevant period' will in any event vary depending on the nature of the issues and organisations under investigation.

[2] References to 'the Government' in the List of Issues include as appropriate all relevant Government departments and devolved Governments. The extent to which the state of knowledge differed in the constituent parts of the UK over the relevant period, and the different decisions and actions taken (or not taken) at different times as regards England, Wales, Northern Ireland and Scotland, will be considered by the Inquiry when examining these issues.

[3] The United Kingdom Haemophilia Centres Doctors' Organisation.

[4] The Inquiry may also consider the position of members of the UK armed services posted abroad who were treated with blood products.

[5] References to 'the blood services' are to NHS Blood and Transplant, the Scottish National Blood Transfusion Service, the Northern Ireland Blood Transfusion Service, the Welsh Blood Service and to their predecessor bodies. The extent to which the state of knowledge differed in the constituent parts of the UK over the relevant period, and the different decisions and actions taken (or not taken) at different times as regards England, Wales, Northern Ireland and Scotland, will be considered by the Inquiry when examining these issues.

[6] Reference to 'the haemophilia centres' includes centres across the UK where decisions about the treatment of persons with haemophilia or other bleeding disorders were taken, as well as the NHS trusts, boards or authorities responsible for the centres during the relevant period. The extent to which the state of knowledge differed in the constituent parts of the UK over the relevant period, and the different decisions and actions taken (or not taken) at different times as regards England, Wales, Northern Ireland and Scotland, will be considered by the Inquiry when examining these issues.

[7] Excluding the blood services and haemophilia centres but including the range of different NHS bodies (trusts, boards, health authorities etc.) which over the course of the relevant period had responsibility for decision-making as regards the use of blood and blood products. The extent to which the state of knowledge differed in the constituent parts of the UK over the relevant period, and the different decisions and actions taken (or not taken) at different times as regards England, Wales, Northern Ireland and Scotland, will be considered by the Inquiry when examining these issues.

[8] It will not be practicable for the Inquiry to consider the decisions and actions of every medical practitioner who treated a person with infected blood or infected blood products, or diagnosed or treated a person who had been so infected (likewise it will not be practicable for the Inquiry to consider the decisions and actions of every hospital, trust, board or health

authority where people received treatment). Decisions will have to be made by the Inquiry in due course as to how best to meet the Inquiry's Terms of Reference.

[9] It will not be practicable for the Inquiry to examine the information provided to every individual. The Inquiry will therefore be looking at these issues more generally and looking in particular for themes and patterns of behaviour and misinformation.

[10] As set out in footnote 9 above, it will not be practicable for the Inquiry to consider the information provided to every individual.

[11] References to HCV (here and throughout the List of Issues) are intended to include knowledge of or relating to NANB hepatitis in the period before HCV was identified.

[12] These questions are directed to companies who produced commercial products from pooled plasma that were used by the NHS during the relevant period.