Witness Name: Francis Eric Preston
Statement No.: WITN4002001
Exhibits: WITN4002002 - WITN4002003
Dated: 15 September 2020

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF FRANCIS ERIC PRESTON

I, Francis Eric Preston, will say as follows: -

Section 1: Introduction

1. Francis Eric Preston, (address known to the Inquiry), DOB GRO-C 35, MB CHB MD FRCPATH FRCP

2. 1963-64: SHO Liverpool;

   1964/1972: RAMC;

   1972: Senior Registrar in Haematology, Royal Infirmary, Sheffield;

   1974: Consultant in Haematology, Royal Infirmary, Sheffield then Royal Hallamshire Hospital, Sheffield;

   1986: Professor of Haematology, University of Sheffield and Royal Hallamshire Hospital, Sheffield.

   See CV Exhibit WITN4002002.

   A list of my publications relevant to this Inquiry are Exhibit WITN4002003.

3. As WITN4002002.

3(a) WHO, 1994 - 2003. I provided advice relating to developments in the treatment of haemophilia and its complications. Also advice relating to haemostasis.

DOH, 1997 - 2000. I advised on all aspects of the infection of the Hep C virus and especially haemophilia.

4. I gave evidence to the Lindsay Tribunal in Dublin in May 2000. I do not have a copy of my statements or a transcript of my evidence.

Section 2: Decisions and actions of those treating patients with haemophilia at the Royal Hallamshire Hospital, Sheffield

5. There was a haemophilia centre of which I was director. There was a senior registrar and two senior haemophilia nurses. There was no change over time. Senior colleagues Dr K K Hampton, who was senior registrar then consultant and there was Dr Michael Makris, [who followed the] same progression. The functions and responsibilities of the above remained constant over time.

6. I was director of the centre and responsible for all aspects of haemophilia care.

7. I cannot remember

7(a) yes

8. This was decided at meetings of the directors of haemophilia reference centres.

9. I had total control.

9(a) I decided which treatments were to be used based on the evidence available at that time.

9(b) Safety and efficacy.

9(c) none

10. The companies had no influence on the selection of products used.

11. Not relevant

12. DDAVP was recommended for mild haemophilia.

13. For mild haemophilia, DDAVP had no disadvantages and so it should have been used here to reduce the risk of infection. In severe haemophilia it was of no use.

14. Cryoprecipitate was not an option for the treatment of sever haemophiliacs. It did not change over time.

15. It did not change over time. Home treatment was recommended for those patients who could understand its principles and how to use it.

16. Prophylactic treatment was recommended for those patients who demonstrated that they could understand what they had to do. This did not change over time.

17. No children were ever treated at Royal Hallamshire Hospital.

    17(a) ditto

18. Mild haemophiliacs were always treated with DDAVP.

19. We were always alert to the dangers of any virus which may be transmitted through blood products. These events occurred 34 years ago. I only have a vague recollection of them but not in detail.

Section 3: Knowledge of, and responsible to, risk

General

20. In 1972 minimal knowledge. It was not a problem then. The problem became apparent during the early 1980s. My knowledge was derived from observation of affected patients and attendance at national and international haemophilia meetings.

21. At the Royal Hallamshire Hospital I was totally responsible for all decisions. I frequently attended national and international meetings in respect of

haemophilia and the potential infectivity of different blood products. I was aware of what was happening nationally.

22. The hepatitis risk of commercial products was substantially greater than the risk from NHS products. Unfortunately there were insufficient NHS products for the treatment of Royal Hallamshire Hospital patients. There was no obvious change in risk over time.

23. To choose the safest product with respect to Hepatitis and to carefully monitor our patients and to keep abreast of the literature.

24.

24(a) Yes this is accurate.

24(b) Yes

24(c) This was true of the very early days. Later more thought was given to the potential problem.

Hepatitis

25. At that time as a senior registrar I had little knowledge of this issue. Through interaction with other UK haemophilia centre directors and perusing the medical literature my knowledge and understanding developed in this way.

26.

26(a) Yes

26(b) Because they had received no training in these disciplines.

26(c) It is still my view.

26(d) There was a greater understanding at the time of my retirement. I cannot comment on the present day.

27. I agree

28.

28(a) Yes

28(b) Haemophilia centre directors had experience in the treatment of haemophilia, but not in liver disease.

28(c) We did not share that view at the time and we published a papers showing the dangers of NANB Hepatitis. Please refer to the paper Lancet 1978 Sept 16th.

28(d) In this context I believe we were world leaders.

28(e) It was discussed at meetings of haemophilia reference centre directors and we presented our data at haemophilia meetings nationally and internationally.

28(f) We drew attention to the seriousness of liver disease in haemophilia. For instance we were able to use evidence from autopsies, whereas in smaller haemophilia centres they could not.

29.

29(a) The Royal Hallamshire Hospital was a university hospital. Dr Triger was a distinguished liver doctor with whom we worked closely.

29(b) Dr Peter Kernoff at the Royal Free Hospital.

<u>The 1978 article</u>

30. Because of increased transaminase levels in haemophiliacs.

31. No

32. I was aware of this through close collaboration with Dr Triger and Prof Underwood. Generally no, but there may have been odd exceptions.

33. Please refer to the paper. The final sentence of the summary of the paper should be taken as the salient conclusion.

34. Very well. The Lancet was and still is recognised as an important medical journal.

34(a) Yes

34(b) Not relevant

34(c) No

35. Haemophilia clinics at the Royal Hallamshire Hospital included a member from Dr Triger's department. I was not aware of what happened elsewhere.

36. No it did not. There was a general apprehension and fear of liver biopsies by doctors responsible for patients with bleeding disorders.

37.

37(a) Yes

37(b) Because these views are correct

37(c) No, there was greater knowledge of this among haemophilia reference centre directors. This was their responsibility.

37(d) This was the responsibility of virologists.

37(e) Only two materials were available to haemophiliacs, these were blood products or DDAVP.

<u>The 1982 letter</u>

38. Dr Hay was not involved in this letter. The authors were Preston, Triger and Underwood. The last sentence of the letter tells you the reason why we decided to write it.

39. Is this not clear in the letter?

40. I cannot remember exactly how the views of my colleagues were expressed, we were a reference centre and it would have been that our views would have been respected. My views have not changed over time.

41. This quotation does not come from the letter of Preston, Triger & Underwood as shown in your references. Have you not confused a letter from Preston, Triger and Underwood with an occasional survey from Hay, Triger and Underwood?

42. To which article do you refer?

The 1985 article

43. We were drawing attention to the role of liver disease in patients with haemophilia who had been treated with clotting factor concentrates.

44. Please see the final two sentences in our summary of this paper.

45. There is no way of assessing this.

45(a) Yes because we were the acknowledged experts in this area. B Not relevant. C. No.

46. (i) This did not result in any change to practice at the RHH.

(ii) There was no information from other centres.

The July 1985 letter

47. We wrote the letter to show that certain heat treated factor concentrates may transmit NANB hepatitis.

48. Please refer to the last sentence of our letter, which goes from 'whilst…to disappointing.'

49. With interest.

49(a) Yes

49(b) Not relevant

49(c) No

50.

50(a) I believe so but I do not recall precisely

50(b) I believe it was Factorate. It was an Armour product. At that time it was what we were using.

50(c) I believed it to be safe at that time, but this was later shown not to be the case.

50(d) The state of knowledge which I had at that time, and the basis upon which I prescribed it, was on the basis that it was thought that the heat treated factor concentrate was safe to administer.

50(e) No, the treatment was standard.

50(f) It was not a trial.

50(g) No

50(h) This was not a trial.

50(i) No

Professor Mannucci's research

51. I cannot give you the exact timeline in my current situation. I know that we discontinued using certain products but I cannot recall the details.

52.

52(a) It is not appropriate to compare these papers because they were carried out at completely different dates.

52(b) See answer to (a)

52(c) We had no discussions with Professor Mannucci. Our findings were discussed at meetings of haemophilia reference centre directors.

Autopsies

53.

53(a) Information from autopsies was important because they would review important information about cause of death in these patients.

53(b) I cannot remember this.

53(c) An enormous amount of important information was generated.

General

54. Careful consideration of the blood products that were used in the treatment of haemophilia.

55. It was part of my job to keep up to date with all of these issues.

56.

56(a) Yes

56(b) Yes

56(c) I cannot remember.

56(d) Any differences would relate to the size of the donor pool the risk would be greater with larger donor pools.

56(e) Unheated blood products carried the risk of transmitting hepatotropic viruses.

56(f) in absolute terms no, there was a greater risk of transmission of hepatitis from paid as opposed to volunteer donors.

57.

57(a) Yes

57(b) Yes

57(c) On the basis of our patient population.

57(d) My views remain unchanged.

57(e) During the 1980s.

HIV and AIDS

58. My knowledge improved through regular meetings and discussions through regular meetings with UK haemophilia reference centre directors.

59. Through the medical literature as in 58 above. It would be in the early 1980s but I am not entirely sure of this.

60. I was convinced that I should only treat with UK blood products.

61. Frequent and constant discussions with other experts in this field, with both UK and non-UK reference centre directors. This allowed us to keep up to date.

62. We used heat treated clotting factor concentrates.

63. Yes. I cannot remember what products were used.

Response to risk

64. Yes, individually and collectively, and we had meetings where we met with the patients and discussed these problems.

65. We were already doing this.

66.

66(a) Yes

66(b) Because it was appropriate to use DDAVP in the selected patients.

66(c) Some were, some were not, we did not discuss it. I cannot comment on whether other centres changed their approach over time.

66(d) Following discussions at meetings of haemophilia reference centre directors, this would be a date close to a meeting.

66(e) All advice to the haemophilia centre directors would have come from the haemophilia reference centre directors.

66(f) I have no information about treatment used in centres other than my own in Sheffield.

67.

67(a) We used all available products apart from the Behring.

67(b) Yes, because to my knowledge it was the safest product.

67(c) No

67(d) Patients with mild haemophilia were treated with DDAVP. With reference to 8Y, wherever possible all of them

67(e) Not my area.

67(f) I do not have the answer.

67(g) Please see my answer to 67 (f)

68. Yes I was aware of it, I believe that I did use it.

69. I used heat treated material when it became available.

70.

70(a) Yes

70(b) Following Colombo et al published article 'Transmission of NANB Hep by heat treated factor viii concentrate' 6 July 1985.

70(c) Yes

71. Because heat treatment is known to inactivate hepatotropic virus which would have persisted in non-heat treated products.

72. Yes it is. I can only comment on my own use of these products.

73. I am aware that the memorandum was written, but I cannot recall the outcome.

74. This is a question for the fractionaters

75. Yes I do because this was one of my functions.

76. At all times we paid particular attention to the safety of blood products.

77.

77(a) Yes

77(b) On the results of blood tests.

77(c) I have no idea

77(d) Quite possibly

77(e) It became clear from publication in medical journals.

78. Decisions were taken at the regular meetings of the haemophilia reference centre directors.

79. Prior to 1980 this role was that of those who manufactured blood products.

Section 4: Treatment of patients at the Royal Hallamshire

Provisions of information to patients

80. Our department held regular meetings with patients and their families in respect of the relationship between the use of blood products and hepatitis / HIV. This was a continuous process.

81. For severe haemophiliacs none, for mild haemophiliacs we advised the use of DDAVP.

82. We spoke to each patient individually before they embarked upon home therapy.

HIV

83. With respect to HIV we held a meeting to which all patients and their families were invited. I cannot remember the exact date, but it was in the early 1980s.

84. Samples were taken from all our patients and sent for HIV antibody testing. I cannot recall the exact date, again it was in the early 1980s.

85. They were told in person as soon as the results were available.

86. We did not tell them to keep it a secret, we spoke to them personally and provided them with all the information that was available at that time. We answered all their questions.

87. This was provided by our two haemophilia nursing sisters.

88. I was not aware of this.

89. We did not test family members.

90. We discussed the question of the sexual transmission of HIV with the patients and their partners.

91. I do not have this information.

Hepatitis

92. I do not have this information.

93. I do not have this information.

94. I do not have this information.

NANB Hepatitis / Hepatitis C

95. Yes, verbally.

96. These patients were seen by Dr David Triger, consultant liver specialist.

97. These patients were told in person, I cannot remember the exact date.

98. They were provided with the information re Hep C that was available at the time of their diagnosis.

99. I do not have this information.

Delay / public health / other information

100. All patients were informed promptly.

101. Public health implications did not form part of my decision-making process.

102. None

103. Full information was given.

Consent

104. Full information was given to all patients from whom blood samples were taken. Informed consent was obtained from all patients. Frequency of blood samples depended on their earlier results.

105. No. Consent to the treatment was obtained after discussion.

106. Express and informed consent was obtained after discussion.

107. No. Consent was obtained following discussion with the patient.

Research

108. I do not have this information.

109. I do not have this information.

110. All of our research was approved by the ethical committee of the RHH.

111. Yes. Patients were not mentioned by name, therefore consent was not necessary.

112. Patient data was anonymised. We took this approach in epidemiological research.

113. Yes. Important issues arising out of patient data was discussed at meetings of the haemophilia centre directors.

114. See WITN4002002.

Previously Untreated Patients

115. They were followed up in exactly the same way as all our other patients.

Treatment of patients who were infected with HIV or Hepatitis

116. Patients with HIV / AIDS were treated appropriately by my team in the RHH.

116(a) Where appropriate further discussions took place with genito-urinary consultants at RHH.

116(b) Treatment options were identical to those offered to non-haemophilic patients with HIV.

116(c) Full information was given to all affected patients.

117. Exactly as with non-haemophiliac patients infected with HIV.

118. In exactly the same way as non-haemophiliac patients infected with hepatitis B.

119. As above.

120. Exactly the same.

121. In exactly the same way as non-haemophiliacs with NANB hepatitis.

122. As above.

123. Our department was responsible for the treatment of haemophiliacs with HIV / Hepatitis. We were not involved in clinical trials in respect to these disorders.

124. I had no involvement in the treatment of children.

125. All of this was offered by our department, which included two SRNs.

126. No.

127. We did not seek funding in this respect.

Records

128. It was the same as for all other patients.

129. All the medical records of all patients living or deceased were kept permanently at the haemophilia centre.

130. We maintained separate files for all patients attending the haemophilia centre, and these files were stored in the centre itself. I have been retired since 2000 and so I cannot say.

131. No I did not.

132. No, I retired 20 years ago.

Section 5: Self-sufficiency

133.

133(a) Yes

133(b) Royal Hallamshire Hospital did not exist in 1974.

134. The provision of prophylactic Factor VIII and bleeding incidents.

135. No

136. In my opinion all these bodies viewed the term 'self-sufficiency' in exactly the same way.

137. See my answer to question 136.

138. This information was provided at meetings of haemophilia reference centre directors.

138(a) I had no role except with reference to the RHH.

138(b) The UKHCDO had no role. This was the role of the UK haemophilia reference centre directors.

138(c) Individual reference centre directors would be influenced in their assumptions by factors such as number of patients, the difference in severity, and the amount of Factor VIII used.

138(d) The estimate was provided by the reference centre director, usually over a 12-month period.

138(e) at meetings of the haemophilia reference centre directors.

138(f) These processes did not change over time.

139.

139(a) This was provided by individual reference centre directors, and I was responsible for Sheffield adults

139(b) Every centre had to submit annually the amount of Factor VIII and Factor IX which had been used, and this was the basis upon which future predictions were made. It did not change over time.

139(c) Calculations were made by the individual centre director on the basis of previous experience.

139(d) These were national figure and treated as such.

139(e) This information was held at the Oxford Haemophilia Centre and to the best of my knowledge it was not shared.

139(f) They did not change over time.

140. I only know about the Royal Hallamshire Hospital and the estimates provided were appropriate.

141.

141(a) Yes

141(b) This is a question for the UK providers of the concentrates.

141(c) It was not achieved.

142. It is incorrect that haemophilia clinicians did not provide timely and accurate estimates of the future demand of Factor VIII blood products. I have no knowledge of Factor VIII and Factor IX use in Scotland. It was not possible for haemophilia clinicians to look into the future with relation to the use of factor VIII blood products.

143. There would have been no increase in associated HBV, HCV and HIV infections with self-sufficiency. Self-sufficiency might have reduced these infections but since it was not achieved it is impossible to know.

Section 6: The blood services

144. We only contacted the manufacturers of the blood products if there was an unwanted side effect in any of patients who had received that particular product.

145. There was no possibility that cryoprecipitate could replace Factor VIII concentrate for severely affected haemophiliacs.

146. These issues were discussed at regular meetings of haemophilia reference centre directors, which also included a senior member from BPL.

147. I was totally involved but only in respect of my own centre in Sheffield.

148. Careful records were kept in reference to all aspects of haemophilia care.

Section 7: UKHCDO

149. I was a member of the UK Haemophilia Reference Centre Directors working party on chronic liver disease in Haemophilia.

150. The role was the study of the aetiology of, impact and treatment of liver disease in haemophilia.

150(a) Totally effective.

150(b) No

150(c) No change.

151. Again, I assume you mean UK Haemophilia Reference Centre Directors.

151(a) To provide and produce information regarding all aspects of haemophilia care and the complications of haemophilia.

151(b) The composition of individual working parties comprised those individuals with special knowledge or expertise relevant to that working party.

151(c) This varied from centre to centre.

151(d) Decisions were taken individually, not by groups in respect to their own practise.

151(e) Regular meetings of all UK haemophilia reference centre directors. Information relating to meetings of the reference centre directors was transmitted to haemophilia centres throughout the UK.

151(f) This is a poorly constructed question and I cannot fully understand it, and therefore I cannot answer it.

Section 8: Pharmaceutical companies / medical research . clinical trials

152. Yes I have. I recall the following companies: Immuno, Armour and Grifols. I was consulted by these companies from time to time on issues relating to haemophilia care.

153. Monies received from these companies were for the Sheffield Haemophilia Reference Centre and our Haemostatis Research Charity and not for personal gain.

154. Yes, Immuno. I received some remuneration from this company, I cannot remember the exact details.

155. No

156. No

157. No

158. At that time there were no declaratory procedures of which I was aware.

159. Yes, we conducted research into the half-life of blood products. I recall conducting this research for Immuno and BPL. There were others but I cannot recall the details.

160. Yes, only in respect of a product's half-life.

161. No, at that time it was not necessary.

162. Please be aware that these events took place over 30 years ago. I do not have any documents available to me and my answers are to the best of my recollection.

162(a) The initial request would have come from Revlon Health.

162(b) I cannot recall the exact details of this research, I conducted numerous research collaborations with Dr Triger at that time.

162(c) I took the decision to apply for that grant, we wanted to know more about haemophilia and liver disease.

162(d) No

162(e) I cannot recall.

162(f) No

162(g) I do not have these records, however Revlon Health did not seek to influence my findings in any way.

162(h) I would have informed Dr Christie of the antibody status of the two patients in question. It is courteous to respond transparently to questions of this nature. The trial did not include provisions of this nature. The patients were not consulted on this matter, it was not

deemed necessary to inform patients of this conversation. Their details were anonymised.

163.

163(a) Yes

163(b) I cannot recall who reported it. It is not clear from the paragraph who should have done the reporting, just that it should have been reported. I am confident that it would have been reported.

164.

164(a) Yes

164(b) I believe so

164(c) We were unable to participate because we were already involved in a similar study with Armour.

164(d) I was very concerned to understand the relationship between haemophilia and its complications, and so I would have collaborated with the first feasible research project in this area.

164(e) This is so long ago I cannot remember.

165.

165(a) Yes

165(b) They were effective

165(c) No

166.

166(a) I do not have this information and therefore I cannot recall. It would have been severe haemophiliacs.

166(b) This would not have been a trial, merely routine treatment of severe haemophilia.

166(c) For all trials patients were fully informed of the reasons for the trial, and all of them gave their written consent to their participation.

166(d) I cannot recall

166(e) We decided to use the Alpha product because they were safer in respect of NANB Hepatitis. That was our reasoning.

Section 9: vCJD

167. Around 1996 it was brought to the attention of the haemophilia reference centre directors.

168. I believe that this was following discussions between haemophilia reference centre directors including information relating to vCJD was given to patients by staff of the individual haemophilia centres.

169. It has always been our custom to keep our patients and their families fully informed about all issues relating to the infectivity of blood products.

170. Frequent and regular meetings were held between haemophilia members of staff and haemophiliacs and their families concerning all aspects of their care, including possible exposure to vCJD.

171. Please refer to the answer to question 170 above.

172. I am not aware that any of our patients fell into this category.

173. We had no responsibility in respect of public health activities.

Section 10: Involvement with financial support schemes

174.

174(a) My role with the other medical experts was to describe and evaluate the treatments for HCV and the impact that it made on the lives of people with haemophilia.

174(b) To the best of my knowledge the deliberations of this working party were not conveyed to the Department of Health.

174(c) I was more concerned with the medical issues and so I would not have been very involved with matters to do with levels of compensation and expenses. I certainly would have agreed to the propositions.

175. I was not involved in any way with any of these funds, this is because I had retired from the NHS in 2000.

176. My answers to this and to 177, 178 and 179 relate solely to Sheffield regional haemophilia centre and not to the Royal Hallamshire Hospital Trust. I had no involvement with these trusts but I cannot exclude the possibility that relevant information was given by the two haemophilia nursing sisters.

177. To the best of my knowledge, no.

178. I provided no information to these trusts although I cannot exclude the possibility that information was given by the two haemophilia nursing sisters.

179. I was not involved in any way with such a process. I cannot exclude the possibility that the nursing sisters may have been involved in this process.

180. I had no involvement in this, but I cannot exclude the possibility that some other members may have been involved.

181. I have no comment in respect to these questions.

Section 11: Other issues

182. I am unaware of any complaints against myself.

183. I have nothing to add.

Statement of Truth

I believe that the facts stated in this witness statement are true.

Signed GRO-C

Dated: 15/09/20