Witness Name: Dr Helena Daly

Statement No.: WITN4685008

Exhibits: 0

Dated 9/6/21 :

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF HELENA DALY

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 2 March 2021

I, Helena Daly, will say as follows: -

Section 1: The Bristol Patient

National AIDS Surveillance

- 1. On 22 March 1983, Drs Craske and Rizza and Professor Bloom wrote to all Haemophilia Centre Directors about a system for the reporting of possible AIDS cases [HCDO0000517_001]. They enclosed three documents: "AIDS/1", a background paper on the syndrome [HCDO0000517_002]; "AIDS/2", a paper containing diagnostic criteria [HCDO0000273_078]; and "AIDS/3", a form for reporting suspect cases [HCDO0000517_004].
 - a. Were you aware of these documents around the time they were sent to BRI?
 - b. If not, were you aware more generally of the existence of a UKHCDO surveillance system for AIDS cases from late March 1983?

- c. Did you discuss these documents or the system more generally with Dr Scott or any other BRI clinicians?
- 1.1 The letter is addressed to Haemophilia Centre Directors. I was not a Haemophilia Centre Director at the time. My consultant was a Haemophilia Centre Director at the time and likely received the letter. I believe I was aware at some stage. I don't remember as early as March 1983. I did know people were looking out for cases.
- 1.2 N/A
- 1.3 I believe I would have discussed the documents/system with my consultant Dr G L Scott.
- 2 On 23 April 1983 the British Medical Journal published a letter from Drs Connor, McEvoy and Galbraith of the Communicable Disease Surveillance Centre ("CDSC") [RLIT0000368]. The letter asked all doctors in England and Wales to report AIDS cases to CDSC.
 - a. Were you aware of this letter, or more generally of the CDSC AIDS surveillance programme, in late April 1983? If you became aware of the programme subsequently, please explain when to the best of your recollection.
 - b. Did you discuss the April 1983 letter or the CDSC AIDS surveillance programme more generally with Dr Scott or any other BRI clinicians?
 - 2.1 I don't remember.
 - 2.2 I don't remember.

Diagnosing and reporting the Bristol Patient

- 3 When did you first consider the possibility that the Bristol patient had or was developing AIDS? Did you do so at any point during 1982?
 - 3.1 I believe May 1983. Not in 1982.
- 4 In your and Dr Scott's letter to The Lancet [PRSE0004509], published on 19 November 1983, you described the Bristol patient's symptoms in May 1983 and wrote that AIDS was suspected at that time. Which of the patient's symptoms led you and/or Dr Scott to suspect that he had developed AIDS?
 - 4.1 The symptoms which led us to suspect the patient was developing AIDS are described in PRSE0004509.
- 5 In a later article published in the British Journal of Haematology [GLEW0000677], you stated that you suspected that the patient had developed AIDS in "early 1983". Were you referring to a date earlier than May 1983? If so, when and which symptoms led you to suspect AIDS?
 - 5.1 No.
- 6 Did you, Dr Scott or any other BRI clinician complete form AIDS/3 for the patient and return it to UKHCDO? If so, when? If not, why not?
 - 6.1 I believe Dr Scott and I did complete an AIDS/3 form for UKHCDO. I don't remember when after we suspected the diagnosis and before Dr J Craske referred to its content in his surveillance update dated 10/9/83 [CBLA0001758] which he presented at the 17th meeting of Haemophilia Reference Centre Directors 19/9/1983.
 - 6.2 It is clear from this document that Dr Craske had received all the clinical and pathological details of our patient (Patient A/4) as per AIDS/3 form and updated to include the post mortem diagnosis.

- 7 Did you, Dr Scott or any other BRI clinician notify CDSC of this suspected case of AIDS? If so, when? If not, why not?
 - 7.1 I did not inform CDSC directly. We reported to PHL and to National Haemophilia Centre/UKHCDO.
- 8 In your November 1983 letter to The Lancet [PRSE0004509], you and Dr Scott described the patient's symptoms over the course of several days in August 1983. Before he died, did you, Dr Scott or any other BRI clinician report his case to UKHCDO and/or CDSC? If not, why not?
 - 8.1 Yes. See answer to Q6 above.
 - 8.2 I believe we had submitted an AIDS/3 form to UKHCDO. We reported possible transfusion transmitted infections (hepatitis) in patients with haemophilia to the National Haemophilia Centre Oxford and therefore I would have done the same for HIV.
 - 8.3 Dr J Craske wrote, 1/3/1983, cases (of AIDS possibly associated with transfusion of US commercial FVIII concentrate) will also be notified to CDSC at the Central Public Health Laboratory Colindale. Dr Craske was a PHL Director and Chair of the UKHCDO Hepatitis Working Party. He was the lead on AIDS in haemophilia. I don't remember being expected to inform the CDSC also.
- 9 You have explained that The Lancet initially rejected the letter published in November 1983 [PRSE0004509]. When did you and Dr Scott first submit it? As far as you are aware and can recall, what reasons did The Lancet give for initially rejecting it?
 - 9.1 I do not remember. It was likely late September/October 1983.
 - 9.2 We submitted a paper. I received a letter from the Lancet Editor rejecting it.

 I believe it was considered not to merit publication.

- 9.3 Dr Scott spoke with the Editor by telephone. The outcome of that was I was advised to resubmit the paper as a letter which I did.
- 9.4 Dr Scott was anxious that the information be published. He told me that he had advised the Editor that if it was not published he would authorise me to release the information publicly.
- 9.5 I suggest you ask the Lancet Editor.
- 10 The Bristol patient's case was discussed at the 19 September 1983 meeting of Reference Centre Directors [PRSE0003196], with details provided in a report by Dr Craske [CBLA0001758]. Dr Galbraith, director of CDSC, was reported to be "somewhat concerned that he had not heard about the Bristol case until after the patient's death", and there was a discussion of reporting mechanisms to Drs Craske and Galbraith. The minutes of the 17 October 1983 Haemophilia Centre Directors meeting, during which Dr Scott gave details of the Bristol case, are also provided for information [PRSE0004440].
 - a. When and how were details of the Bristol patient's case provided to Dr Craske?
 - b. To the best of your knowledge, why was the case not reported to CDSC until after the patient's death?
 - 10.1 I do not remember. Either via PHL Bristol or AIDS/3 form to UKHCDO. Dr Craske clearly had an update after the patient's death as he had the full post mortem results. He may have spoken with Dr Scott. Dr Scott gave details of the index Bristol patient at the HCDO meeting at Cardiff 17/10/83
 - The diagnosis was made by histological examination of post mortem tissue.

 I don't know who reported to CDSC. According to the minutes of meeting PRSE0003196 it was agreed by a majority that reporting to CDSC should be through Dr Craske after discussion with the (Haemophilia) Director involved in the patient management. I was not the Haemophilia Centre Director.

- 11 In a letter published in The Lancet on 10 December 1983 [PRSE0004506], Drs McEvoy and Galbraith corrected your and Dr Scott's reference to an earlier report of a haemophilic with AIDS, explaining that they had referred to this patient who was in Wales as a definite case.
 - a. Were you aware of this letter at the time it was published?
 - b. Had you learned by any other means that the Welsh patient was considered to be a definite case earlier in 1983? If so, when and how?
 - 11.1 I don't remember.
 - 11.2 No, when I spoke with Professor Bloom by telephone about our patient I was advised of a suspected case at the Welsh Centre.
 - 11.3 In Dr Craske's report 10/9/83 [CBLA0001758] Patient A/1 is described as 'in reasonable health' following Herpes Labialis with no other complications.

 This was after the death of patient 4.
 - 11.4 In the same report Dr Craske referred to patient A/4 as the first confirmed diagnosis of AIDS possibly associated with transfusion of blood products in the UK.

Surveillance of BRI patients

- 12 You have explained that in May-October 1983 you undertook a clinical and immunological review of 43 patients regularly attending BRI, and that this resulted in an article published in the British Journal of Haematology ("BJH") in February 1985 [GLEW0000677].
 - a. Were any individuals or bodies outside of BRI aware that you were undertaking this review? For example, CDSC/Dr Galbraith, the Public Health Laboratory Service/Dr Craske or UKHCDO?
 - b. If so, when and how did you share the results?

- c. Your review was carried out between May and October 1983. Your article was received by the BJH on 2 April 1984. Other than the time it took to analyse the results and draft the paper, did any other factors delay its submission to the BJH?
- d. Was the article amended or otherwise discussed with the BJH between 2 April 1984 and 17 July 1984, when it was accepted for publication?
- e. To the best of your knowledge, why was the article only published in February 1985, when it had been accepted for publication in July 1984?
- 12.1 Yes. The study was supported by the Bristol District Medical Research Committee and ethical approval obtained from the Ethics Committee of the Bristol & Weston Health Authority many of whose members were from outside of the BRI. Ms G Lee Chief MLSO Haematology Department Southmead Hospital Bristol performed the T cell subsets and was a coauthor of the paper.
- 12.2 I do not think any of CDSC, Dr Galbraith, Dr Craske or UKHCDO.

 Throughout our patients illness samples were sent to PHL Bristol and I discussed him with the Medical Director of PHL Bristol.
- 12.3 On publication.
- 12.4 No.
- 12.5 I don't remember. I believe that was the time taken for peer review of the paper.
- 12.6 In my experience that would not be an undue delay but the question should be directed at the Editorial Board of the British Journal of Haematology.
- 13 What, if any, involvement did you or other BRI clinicians have in Dr Craske's follow-up of patients who had received the same batches as the Bristol patient? The patient was referred to as case A/4 when this follow-up was initially proposed (see the document at CBLA0001758), and when an update

was provided to Haemophilia Centre Directors at a meeting in September 1984 [CBLA0001884_007 and PRSE0003659].

- 13.1 I do not remember. According to the minutes [PRSE0003196] Dr Craske knew the batches of NHS/Commercial FVIII concentrate received by the index Bristol patient. I, or possibly Dr Scott, must have informed him.
- 13.2 Dr Craske stated that the donors of the cryo received by this patient 'were being traced' at that time. I, Dr Scott or the blood transfusion staff at the BRI must have supplied the batch numbers.
- 13.3 At the 15th meeting of UKHCD 27/9/84 Dr Craske presented information on other patients at the BRI who received the same batches as the index patient [CBLA0001884]. I, or possibly Dr Scott, must have informed him. Dr Scott attended that meeting.
- 14 Please explain, in as much detail as you are able to, any other issues that you believe may be of relevance to the Infected Blood Inquiry.
 - 14.1 None.

Statement of Truth

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

Signed	GRO-C		
Dated 9 th Jur	ne 2021		