Witness Name: Dr David Roy Edwards
Statement No.: WITN5491001
Exhibits: 0
Dated: 04/03/2021

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR DAVID ROY EDWARDS

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 28 January 2021.

I, Dr David Roy Edwards, will say as follows: -

Section 1: Introduction

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

1.1. Name: Dr David Roy Edwards
Address: GRO-C
Date of Birth: GRO-C 1948

1.2. Qualifications: BSc; MB BS; LRCP MRCS; FRCPath (Haematology) formerly FRCP (HC)

2. Please set out your employment history including the various roles and responsibilities that you have held throughout your career, as well as the dates.

2.1. Employment History

2.1.1. House Physician St Bartholomew's Hospital: Jan '74 – June '74

2.1.2. House Surgeon Luton & Dunstable: July '74 – December '74

2.1.3. SHO in Neurosurgery St Bartholomew's Hospital: Jan '75 – June '75

2.1.4. RAF Medical Officer: July '75 – June '80

2.1.5. Station MO RAF Leeming & RAF Valley '75 – '76

2.1.6. Trainee Pathologist RAF Halton '76 – '77

2.1.7. Junior Pathologist RAF Wroughton Hospital '77 – '80

2.1.8. Senior Registrar Oxford rotation: July '80 – May '82

2.1.9. Consultant Haematologist Ysbyty Glan Clwyd: June '82 – Feb '06.

2.1.10. I was the first Consultant Haematologist appointed to Ysbyty Glan Clwyd. Prior to my appointment there were no clinical services provided there. All cases were directly referred to Liverpool or Manchester and the laboratory service was provided by the General (Histo)Pathologists. I was single-handed until 1988, when I was joined by a Consultant colleague and subsequently an Associate Specialist in 1989 or 1990 as I recall. My colleague became Medical Director around 2000, I don't recall the precise date and the Associate Specialist took early retirement to pursue a career as an artist around the same time. For a short while I was again single-handed but subsequently attracted 2 further Consultant colleagues who were still in post when I resigned in 2006 in order to take up my present post. My main function throughout this time was providing a laboratory diagnostic service and a clinical service that was predominantly haemato-oncology, which has always been my area of specialisation.

2.1.11. Consultant Haematologist Ysbyty Gwynedd: March '06 – present.

2.1.12. My job specifically carried the responsibility for being director of the autologous stem-cell transplant service. My only involvement with Haemophilia is in emergency/on-call situations.

3. **Please set out your membership, past or present, of any committees, associations, parties, societies or groups relevant to the Inquiry's Terms of Reference, including the dates of your membership and the nature of your involvement. If applicable, please ensure your answer addresses your involvement with the UKHCDO.**

3.1. I was a founder member of the British Blood Transfusion Society (BBTS) from its inception until now.

3.2. I was seconded to the National Blood User Group (NBUG) as a North Wales representative at a time when there was a possibility that blood for North Wales would be supplied from Cardiff rather than Liverpool because of the proposed closure of the Liverpool Centre. My main function was to lobby for the continued existence of the Liverpool Centre as a source of supply for the 3 North Wales hospitals because of the impossibility of a timely response for platelets and blood in an emergency from Cardiff. I cannot recall the precise dates but the documentation you have quoted would suggest it was '97 – '98. Once the continued supply to North Wales via NBTS was secured I had no further role.

3.3. All my other activities centre on my main specialisation of Haemato-Oncology. I have never been a member of nor had any involvement with the UKHCDO. I am currently working from home and do not have access to documentation that would enable me to give accurate dates

4. **Please confirm whether you have provided evidence to, or have been involved in, any other inquiries, investigations, criminal or civil litigation in relation to human immunodeficiency virus ("HIV") and/or hepatitis B virus ("HBV") and/or hepatitis C virus ("HCV") infections and/or variant Creutzfeldt-Jakob disease ("vCJD") in blood and/or blood products. Please provide details of your involvement and copies of any statements or reports which you provided.**

4.1. I confirm I have never provided evidence nor been involved in any previous inquiries, investigations or criminal proceedings in relation to HIV, HBV, HCV or vCJD in blood or blood-products.

5. **The questions below focus on your time as a consultant haematologist at Glan Clwyd Hospital, however, if you have information relevant to the decisions, policies or practices at Gwynedd Hospital where you subsequently worked, please include this information in your answer.**

5.1. My role in Ysbyty Gwynedd has been focussed on haematological cancer treatment and being Clinical Director of the autologous transplant service. Unlike Ysbyty Glan Clwyd, Ysbyty Gwynedd was designated as a Haemophilia Centre with a Clinical Director role and I have had colleagues specifically tasked with providing that service. My own involvement has been minimal, providing ward and emergency cover if my colleagues were unavailable.

Section 2: Decisions and actions of the Haemophilia Centre at Glan Clwyd Hospital

6. **Insofar as relevant to the Terms of Reference, please:**
   a. **describe the roles, functions and responsibilities of the Haemophilia Centre at Glan Clwyd Hospital ('the Centre') during the time that you worked there.**
   b. **outline the facilities and staffing arrangements for the care of patients with bleeding disorders;**
   c. **identify senior colleagues at the Centre and their roles and responsibilities during the time that you worked there, insofar as they were involved with the care of patients with bleeding disorders and/or patients infected with hepatitis and/or HIV in consequence of infected blood or blood products.**

6.1. The title of this section is misleading and inaccurate based on the incorrect assumption that Glan Clwyd Hospital was designated a Haemophilia Centre and I functioned as its Clinical Director. Glan Clwyd Hospital had no clinical services prior to my appointment there as a general haematologist in 1982. It did not become a Haemophilia Centre on my appointment nor did it become one during the time I worked there. The patient numbers were very small (see later) and I would not have accepted the post had it involved the role of Haemophilia Centre Clinical Director as this is not my area of expertise. All the Haemophiliacs and patients with congenital bleeding disorders were already registered with the Liverpool or Manchester Centres. Glan Clwyd

offered a storage and distribution facility for factor provided by the main centre(s) to save the patients having to travel. I and subsequently my colleagues were able to deal with acute bleeds and problems but were not able to offer a comprehensive care service. This was always provided by the main Centre – predominantly Liverpool. The laboratory offered a diagnostic service to patients with a bleeding history or a family history and they were subsequently referred to Liverpool for confirmation if testing suggested a bleeding disorder.

6.2. There were no specific facilities for the care of patients with bleeding disorders since Glan Clwyd Hospital was not a designated Haemophilia Centre. Patient numbers were too small to justify such a designation. The Blood Bank kept a record of the known patients; their factor levels; the factor they were receiving from Liverpool and exercised stock control, keeping a slight "float" to cover emergencies. They also carried a stock of Fresh Frozen Plasma (FFP); Cryoprecipitate, FEIBA and platelets when specifically ordered. A&E or the wards could telephone the consultant on call for advice on a 24/7 basis. The laboratory was capable of performing pre and post-dose factor assays. There were no specialist Nurses or Social Workers and no comprehensive multidisciplinary clinics or teams.

6.3. Initially I was single- handed. In 1988 I was joined by Dr D.I.Gozzard, Consultant and subsequently Dr A.Craig, Associate Specialist a year or so later as I recall. Dr Craig was fully qualified in Haematology but opted to work as an Associate Specialist. Dr Craig had less of an interest in malignancy and myeloproliferative disorders than Dr Gozzard and myself so she developed the shared-care approach for bleeding disorders with Liverpool. She undertook combined clinics with the visiting Liverpool Consultants Dr P.Bolton-Maggs and subsequently Dr V.Martlew that included paediatric cases. Her role was essentially to provide a focus for communication and liaison as the direction of care came from Liverpool and we provided local support. When Dr Gozzard became Medical Director and Dr Craig retired around 2000, I was single-handed again until the appointment of Dr C. Hoyle – another Haemato-Oncologist and Dr J.Goodrick a general haematologist who took over the shared-care of the patients with bleeding disorders.

7. **Please describe:**

   a. **your role and responsibilities at the Centre and how, if applicable, this changed over time;**
   b. **your work at the Centre insofar as it involved the care of patients with bleeding disorders and/or patients infected with hepatitis and/or HIV in consequence of infected blood or blood products.**
   c. **your role and responsibilities at the Centre and how, if applicable, this changed over time;**
   d. **your work at the Centre insofar as it involved the care of patients with bleeding disorders and/or patients infected with hepatitis and/or HIV in consequence of infected blood or blood products.**

7.1. As Glan Clwyd was not a Centre and I was not a Clinical Director I had no specific role or responsibility for patients with bleeding disorders. As Head of Department I was responsible for running the laboratory and blood bank and managing the departmental budget.

7.2. As a clinician I was responsible for my own general patients but managed patients with bleeding disorders on a shared-care basis under advice from the Liverpool centre. My involvement in this role became less after Dr Craig's appointment as my own malignancy practice expanded.

7.3. I was appointed in 1982 as a new, single-handed consultant initially with no staff, no beds and no clinics. Prior to my appointment there had not been any clinical service and the Hospital Medical Staff Committee was rather taken aback that I would want such things. I managed to secure 4 beds on a medical ward and a theoretical share in a medical SHO prior to taking up the post and then some outpatient clinics. The majority of patients were myeloproliferative disorders, anaemias, CLL, low-grade lymphomas and myelomas requiring oral medication. Haemophilia and bleeding disorders were and remained a tiny proportion of the work.

7.4. When Dr Gozzard was appointed we started to give intravenous chemotherapy and the proportion of haematological malignancy cases increased as we no longer sent these patients to Liverpool for treatment. Haematology became part of the medical SHO rotation and eventually we got some middle-grade support in the form of a Staff-Grade doctor. This enabled

us to develop a shared-care service with Ysbyty Gwynedd for high-dose therapy and stem-cell transplantation in 1998. We were not directly involved in managing the complications of infected blood in the small numbers of cases we had except for managing acute bacterial and fungal infections when they occurred.

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

8.1. To the best of my recollection when I started there were initially 4 patients with severe and 1 with mild Haemophilia A and 1 with severe Haemophilia B. All the severe cases were well-established on lyophilised factor before I arrived. There was 1 extended family of von Willebrand's but I cannot remember any details and have no access to past records. I was not involved with Paediatric cases, who were initially managed by the Paediatricians with outreach Consultants from Alder Hey Hospital in Liverpool. Dr Craig subsequently attended these clinics but I was never involved.

8.2. By the time I left all 4 severe Haemophilia A patients that I was directly involved with were dead:

8.2.1. Patient 1.) Lung Cancer. – Infected.

8.2.2. Patient 2.) Crushed when a lorry-jack failed. Not infected

8.2.3. Patient 3.) Brought in dead from the back streets of Rhyl. Definitely not infected

8.2.4. Patient 4.) Progression of HCV & HIV.

8.3. I cannot recall the fate of the patient with severe Haemophilia B.

9. **To the best of your knowledge, what decisions and actions were taken, and what policies were formulated by the Centre, regarding the selection, purchase and use of blood products (in particular factor concentrates) during the time that you worked there? In addressing this issue, please answer the following questions:**

   a. **How, and on what basis, and by whom were decisions made about the selection and purchase of blood products?**
   b. **What (if any) other bodies or organisations or individuals (e.g. other centres in the same region, or the Regional Health Authority) were involved in the arrangements for the selection, purchase or use of blood products?**
   c. **What were the reasons or considerations that led to the choice of one product over another?**
   d. **What role did commercial and/or financial considerations play?**[1]
   e. **What if any involvement did you have?**
   f. **What products or treatments were generally used for treating (i) patients with severe haemophilia A; (ii) patients with moderate haemophilia A; (iii) patients with mild haemophilia A; (iv) patients with haemophilia B; (v) patients with von Willebrand's disease? Who had responsibility for the selection and purchase of blood products?**

9.1. a) All factor was provided from the Liverpool Centre and presumably the decisions about selection and purchase were made by Mersey Region Health Authority. We were not party to those discussions or decisions, we merely ordered supplies against the requirements of the patients in our area.

9.2. b) Mersey Regional Health Authority to the best of my knowledge.

9.3. c) I do not know.

9.4. d) I do not know.

[1] In answering this question, you may wish to consider the enclosed minutes from a meeting of the North East Thames Regional Association of Haematologists Haemophilia Working Party dated 9 October 1990 [BART0000666]. The minutes record that you were present at this meeting, and that Dr Kernoff raised the issue of how financial considerations may have affected product choice (p2). Please also consider the enclosed letter from Dr Kernoff to Dr Colvin (copied to you) dated 27 April 1979 discussing regional funding of factor VIII [BART0002487].

9.5. e) None.

9.6. f) To the best of my recollection -

9.6.1. (i) Home treatment with lyophilised factor VIII concentrate or heat-treated factor when this became available. Recombinant factor VIII for children and negative-testing adults once these became available.

9.6.2. (ii) Ad hoc treatment as for (i) with bleeds.

9.6.3. (iii) Ad hoc DDAVP and Tranexamic Acid if not a urological bleed.

9.6.4. (iv) Lyophilised factor IX concentrate, heat-treated once available.

9.6.5. (v) Cryoprecipitate and subsequently Haemate P when this became available. Choice of product was not in our remit, we took what we were given from Liverpool. The departmental budget referred to in 7a) was for running the laboratory and paying for services from Mersey Region. It did not include funding for direct purchase of blood products.

10. What was the relationship between the Centre and the pharmaceutical companies manufacturing/supplying blood products? What influence did that relationship have on the Centre decisions and actions?

10.1. As I had no ability to purchase factor, I declined to see any pharmaceutical representatives promoting those products.

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

11.1. Mersey Regional Health Authority. I have no knowledge of their decision-making processes.

12. What alternative treatments to factor concentrates were available in the 1970s and 1980s for people with bleeding disorders? What were, in your view, the advantages and disadvantages of those alternative treatments? What use did the Centre make of them? Do you consider that they should have been used in preference to factor concentrates so as to reduce the risk of infection? If not, why?

12.1. My main interest and expertise lies in treating haematological malignancy. As a corollary of this I have some expertise in acquired bleeding disorders such as DIC and thrombocytopenia. I was aware of the use of DDAVP and it was occasionally used but I cannot recall the specific details. I was also aware of the potential use of Tranexamic Acid and the risks if it was used with urinary-tract bleeds. As I became aware of the risks of infected blood and I followed the advice of the Haemophilia Centre and national guidelines on these matters. I do not feel I have the knowledge or background to debate whether what they recommended was correct or not.

13. What was the Centre's policy and approach as regards:

a. the use of cryoprecipitate for the treatment of patients with bleeding disorders? Did that policy and approach change over time and if so how?

b. home treatment? When was home treatment introduced?

c. prophylactic treatment? To what extent and when was treatment provided on a prophylactic basis?

13.1. a) There was no "Centre Policy" as such in Glan Clwyd. Cryoprecipitate was used to replace fibrinogen in cases of DIC and for the occasional bleeds in von Willebrand's patients if I recall correctly. I have no awareness of how it might have been used in children.

13.2. b) All the severe Haemophilia A patients were already on home treatment from Liverpool when I took up the post.

13.3. c) I had no involvement with the care of children where I suspect prophylaxis may have been introduced. None of the adult patients which I dealt with had long-term ongoing prophylaxis as I recall.

14. What was the Centre's policy and approach in relation to the use of factor concentrates for children? Did the policy and approach change over time and if so how?

14.1. Children were managed under the policies of the Alder Hey children's hospital in Liverpool. As far as I am aware they were given priority for the safer recombinant or virally inactivated concentrates once these became available.

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

15.1. I am not aware of any other viruses being transmitted as a consequence of the use of blood products in Glan Clwyd Hospital.

Section 3: Knowledge of, and response to, risk

16. When you began work as a consultant haematologist at the Centre, what did you know and understand about the risks of infection associated with blood and/or blood products? What were the sources of your knowledge? How did your knowledge and understanding develop over time?

16.1. I was aware of the transmission of HBV and "NonA-NonB hepatitis" which subsequently became known as HCV by blood and blood products. My knowledge came from journals and educational meetings. As time went on I became aware of the risks of HIV and vCJD. I learnt that the risks from concentrates was much higher because red cells, platelets, and cryoprecipitate were all derived from a single donor whereas lyophilised concentrate effectively exposed the recipient to thousands of donors.

17. What advisory and decision-making structures were in place, or were put in place at the Centre, to consider and assess the risks of infection associated with the use of blood and/or blood products?

17.1. This applies primarily to the Liverpool Centre not Glan Clwyd Hospital as we could only obtain products approved by them. We followed NBTS guidance on blood transfusion practice and tried to limit unnecessary transfusions.

18. What was your understanding of the relative risks of infection from commercially supplied factor concentrates and NHS factor concentrates?

18.1. I was aware that NHS factor concentrates were obtained from motivated, voluntary, unpaid donors. All donors were screened to the best available level at the time and the only risk was the sensitivity and scope of the screening testing. This was particularly true for the initial lack of a specific test for HCV and the initial reluctance to test for HIV in groups that were not considered to be "at risk" because of social and insurance implications. In the UK screening for HIV was introduced in 1985 but did not become available for HCV until 1991.

18.2. In contrast commercial products were derived from paid overseas donors in the USA and Africa where the level of screening was far less certain and far less rigorous. Commercial batches also tended to be from larger pools so one infected donor would have a greater impact. Commercial products were therefore potentially much riskier than the NHS products.

19. How did you keep up-to-date with relevant scientific and medical developments in knowledge? What journals did you regularly read?

19.1. I read journals and attended meetings and conferences as well as having discussions with colleagues.

19.2. BMJ, Lancet, Blood Transfusion (BBTS journal) and sometimes the BJHaem and Blood.

20. When you began work as a consultant haematologist at the Centre, what was your knowledge and understanding of:

a. the risks of the transmission of hepatitis (including hepatitis B and NANB hepatitis/hepatitis C) from blood and blood products?

b. the nature and severity of the different forms of blood borne viral hepatitis?

20.1. a) HBV was thought to be highly infectious. HVC was thought to be less infectious.

20.2. b) HBV was initially thought to be severe and symptomatic, HVC (NonA-NonB) was initially thought to be a less serious condition diagnosed by exclusion of other causes of hepatitis.

21. What were the sources of your knowledge? How did that knowledge and understanding develop over time?

21.1. See 19). Better testing for HBV revealed there were asymptomatic cases, recovered cases and cases with chronic infection. Development of a specific test showed HCV was more widespread and infectious than initially thought and gave rise to chronic infection with serious long-term effects such as cirrhosis and hepatocellular carcinoma.

22. What, if any, actions did you and/or the Centre take to reduce the risk to patients of being infected with hepatitis (of any kind)?

22.1. We actively discouraged unnecessary use of blood and factor concentrates.

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

23.1. In the mid 80s as I recall, when the spread amongst iv. drug users sharing needles suggested a blood-borne transmission. It had previously been considered a sexually transmitted infection primarily affecting gay men.

24. What was your knowledge and understanding of HIV (HTLV-III) and AIDS and in particular of the risks of transmission from blood and blood products during your time working at the Centre? What were the sources of your knowledge? How did your knowledge and understanding develop over time?

24.1. See 19) & 20) above. AIDS was thought to be less infectious than the hepatitides in terms of viral load needed to create an infection. It became apparent there was a long subclinical course where the patient was “well” but infectious. This increased the risk from factor concentrate as described above. Routine screening of donors was introduced in the UK in 1985.

25. What, if any, actions did you and/or the Centre take to reduce the risk to your patients of being infected with HIV?

25.1. See 22) above.

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

26.1. This is a question for the Liverpool Centre since they issued the treatment given to patients in Glan Clwyd.

27. Did you and/or your colleagues at the Centre take steps to ensure that patients were informed and educated about the risks of hepatitis and HIV? If so, what steps?

27.1. This was a function of the Liverpool Centre. We answered questions raised by the patients in the light of the information they had received via the centre or through the Haemophilia Society.

28. Did you or your colleagues at the Centre revert to treatment with cryoprecipitate for some or all of the patients in response to the risk of infection? If so, when and how was it determined which patients would be offered a return to cryoprecipitate?

28.1. I do not recall this happening with the adult patients and I have no knowledge of the decisions made for the paediatric patients. Any such decisions would have been made in Liverpool.

29. When did the Centre begin to use heat treated factor products and for which categories of patients? Please set out what steps were taken to obtain heat treated products. Please also set out whether steps were taken to recall any stores of unheated products which patients had.

29.1. When the Liverpool Centre made it available. I cannot recall a date. I have no knowledge of the steps taken to acquire it but I understand priority was given to children and those adults who tested negative for viruses. I have no

recollection of a recall of unheated products after this passage of time but that does not mean it did not happen.

30. Looking back now, what decisions or actions by you, the Centre or any other relevant organisations or individuals, could have avoided, or brought to an end earlier, the use of infected blood products?

30.1. None that I am aware of at an individual level. See 31) below.

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

31.1. A ban on the use of imported commercial products or at the very least an insistence on tightening of the testing criteria applied to them applied at national level by the Department of Health. I suspect the main reason this was not done was because the NHS production at the time was insufficient to support the national demand. There had been a lack of investment in developing recombinant factor which had been a British invention that ended up being commercially developed in the USA.

Section 4: Treatment of patients at the Haemophilia Centre at Glan Clwyd Hospital

31.2. I reiterate: Glan Clwyd Hospital was not a Haemophilia Centre when I worked there.

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

32.1. This was done in Liverpool.

33. How many patients at the Centre were infected with HIV in consequence of the treatment with blood products? Of those infected,

a. How many had severe haemophilia A?

b. How many had moderate haemophilia A?

c. How many had mild haemophilia A?

d. How many had haemophilia B?

e. How many had von Willebrand's disease?

f. How many were children?

33.1. To my recollection: 2 – both with severe Haemophilia A. I cannot recall whether a third severe Haemophilia A patient was infected or not as we hardly ever saw him. No other adult patients were infected to my knowledge. I have no knowledge of paediatric cases.

34. How and when did you learn that patients under your care/the Centre's care had been infected with HIV?

34.1. From the patients themselves.

35. How and when were patients told that they had been, or might have been, infected with HIV? What if any involvement did you have in this process?

35.1. As far as I remember, they were told by the Liverpool Centre. I played no part in the process.

36. Please describe the Centre's process for HIV testing, including pre-test and post-test counselling.

36.1. We did not test Haemophiliacs for HIV. This was done in Liverpool and I have no knowledge of their process.

37. What information was given to them about the significance of a positive diagnosis? Were patients told to keep their infection a secret?

37.1. See above: I do not know if they were told to keep it a secret or not. I never told them to do so.

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

38.1. See 33) above – the same 2 patients had HCV.

39. Were patients infected with hepatitis C informed of their infection and if so, how and by whom? What information was provided to infected patients about the infection, its significance, prognosis, treatment options and management? What if any involvement did you have in this process?

39.1. See 35) above.

40. When did the Centre begin testing patients for hepatitis C? Please describe the Centre's process for HCV testing, including pre-test and post-test counselling. What involvement did you have in this process?

40.1. We did not test Haemophiliacs for HCV. See 36.) above.

41. Were the results of testing for HIV and hepatitis C notified to patients promptly, or were there delays in informing patients of their diagnosis? If there were delays in informing patients, explain why.

41.1. As we did not test or give results I cannot comment about delay.

42. How often were blood samples taken from patients attending the Centre and for what purposes? What information was given to patients about the purposes for which blood samples were taken? Were patients asked to consent to the storage and use of the samples? Was their consent recorded and if so, how and where?

42.1. When patients presented for treatment, samples for pre and post dose testing were taken on an ad hoc basis to manage the acute bleeds along with routine haematology and biochemistry samples when clinically indicated. The fact the patient had presented requesting treatment was taken as implied consent that was confirmed verbally at the time. The patients were all on factor already and knew the risks. No other samples were taken and no samples were stored.

43. Did the Centre have a bank of stored samples? If so, was that storage undertaken with patients' knowledge and consent?

43.1. No

44. Were patients under your care/under the Centre's care treated with factor concentrates or other blood products without their express and informed consent? If so, how and why did this occur? What was your approach to obtaining consent to treatment? Was their consent recorded and if so, how and where?

44.1. No. Patients occasionally presented requesting treatment with a bleed that had failed to respond to home treatment. Details were recorded in the notes. See 42) above.

45. Were patients under your care tested for HIV or hepatitis or for any other purpose without their express and informed consent? If so, how and why did this occur? What was your approach to obtaining consent for testing? Was their consent recorded and if so, how and where?[2]

45.1. No.

46. Please detail all decisions and actions taken at the Centre by you or with your involvement with regard to a category of people referred to as 'previously untreated patients' (PUPS).

46.1. We were never involved with this category of patient beyond the point of screening testing. If their testing suggested a bleeding disorder they were immediately referred to Liverpool for confirmatory testing and initiation of treatment if necessary.

[2] In answering this question, you may wish to consider comments surrounding consent made in the enclosed meeting minutes [BART0000674]. These minutes are from a meeting of the North East Thames Region Association of Haematologists Working Party dated 27 November 1985, at which you were present.

47. How was the care and treatment of patients with bleeding disorders and HIV/AIDS managed at the Centre? In particular:

a. What steps were taken to arrange for, or refer patients for, specialist care?

b. What treatment options were offered over the years?

c. What information was provided to patients about the risks and benefits of specific treatments and about side effects?

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

47.1. a) Patients were already under a specialist centre in Liverpool.

47.2. b) I have no direct knowledge as I wasn't involved.

47.3. c) See b) above.

47.4. d) This was carried out at visits to the Liverpool Centre as far as I know.

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

48.1. As far as I can recall we had no patients infected with HBV.

49. How was the care and treatment of patients with bleeding disorders and hepatitis C managed at the Centre? In particular:

a. What steps were taken to arrange for, or refer patients for, specialist care?

b. What treatment options were offered over the years?

c. What information was provided to patients about the risks and benefits of specific treatments and about side effects?

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

49.1. The same as 47) a, b, c and d above.

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

50.1. This was arranged through Liverpool as far as I know.

51. Did the Centre receive funding from the Department of Health and Social Security or from any other source to help with the counselling of patients infected with HIV?

51.1. No.

52. What, if any, difficulties did you/the Centre encounter in obtaining sufficient funding for the treatment of people who had been infected with HIV and/or hepatitis C?

52.1. N/A.

53. What, if any, involvement did you or your patients have with clinical trials in relation to treatments for HIV and/or hepatitis? Please provide full details.

53.1. None as far as I am aware. I don't know if they were involved via Liverpool.

54. What was the Centre's policy with regards to recording information on death certificates when a patient had been infected with HIV or hepatitis? Were you involved with any inquests in relation to patients who had been infected with HIV or hepatitis in consequence of their treatment? If so, please provide details.

54.1. As far as I know, it was recorded on the death certificate. I was not involved in any inquests.

55. What were the retention policies of the Centre in regards to medical records during the time you were practising there?

55.1. The Policy of the then Conwy & Denbighshire Trust. As far as I know this policy followed Welsh National Guidelines. The organisation has now been

subsumed into the Betsi Cadwaladr University Health Board. Deceased notes were initially archived, I do not know at what point they would have been destroyed.

56. As far as you are able to recall, did you:

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

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

56.1. a) Each patient had an individual set of notes, there was not a separate Haemophilia file. The notes were kept in Medical Records when the patient was alive and archived on death. I would be very surprised if these notes were still in existence ~30 years later and I do not know whether they were microfiched.

56.2. b) No.

57. Please list all research studies that you were involved with as a consultant haematologist at the Centre (or any other relevant positions of employment) insofar as relevant to the Inquiry's Terms of Reference, and please:

a. Describe the purpose of the research.

b. Explain the steps that were taken to obtain approval for the research.

c. Explain what your involvement was.

d. Identify what other organisations or bodies were involved in the research.

e. State how the research was funded and from whom the funds came.

f. State the number of patients involved.

g. Provide details of steps taken to inform patients of their involvement and to seek their informed consent.

h. Provide details of any publications relating to the research.

57.1. I have had no involvement in trials relating to Haemophilia or other bleeding disorders.

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

58.1. N/A – see 57) above.

59. Was patient data (anonymised, de-identified or otherwise) used for the purpose of research or shared with third parties without their express consent? If so, please explain what data was used, and how/why it was shared.

59.1. N/A – see 57) above.

Section 5: Current care at the Haemophilia Centre at Gwynedd Hospital

60. Please describe:

a. how the provision of care and treatment for bleeding disorders is currently organised at the Haemophilia Centre at Gwynedd Hospital ('the Centre); and

b. your current roles and responsibilities at the Centre.

60.1. As already described, I have no formal role in the management of bleeding disorders in Ysbyty Gwynedd, just ad hoc emergency cover. I feel questions 61 – 68 should be answered by those who have a more comprehensive knowledge of what is done than I.

61. Please outline the treatments currently provided to patients with bleeding disorders at the Centre.

61.1. As already described, I have no formal role in the management of bleeding disorders in Ysbyty Gwynedd, just ad hoc emergency cover. I feel questions 61 – 68 should be answered by those who have a more comprehensive knowledge of what is done than I.

62. Please describe how you typically obtain your patients' consent to treatment.

a. What information is provided to patients by you or others regarding the risks, benefits and potential side-effects of treatment options?

b. What information is provided to patients by you or others regarding the consequences of forgoing treatment?

c. How is patient consent typically recorded?

62.1. As already described, I have no formal role in the management of bleeding disorders in Ysbyty Gwynedd, just ad hoc emergency cover. I feel questions 61 – 68 should be answered by those who have a more comprehensive knowledge of what is done than I.

63. Do you routinely take blood samples from patients attending the Centre? If so, what information is provided to patients by you or others about the purposes for which the samples are being taken? Do you obtain patients' consent to the storage and use of the samples and if so, how?

63.1. As already described, I have no formal role in the management of bleeding disorders in Ysbyty Gwynedd, just ad hoc emergency cover. I feel questions 61 – 68 should be answered by those who have a more comprehensive knowledge of what is done than I.

64. If applicable, how many current patients at the Centre were infected with HIV, HCV, HBV through blood products or were co-infected with HIV and HCV through blood products?

64.1. As already described, I have no formal role in the management of bleeding disorders in Ysbyty Gwynedd, just ad hoc emergency cover. I feel questions 61 – 68 should be answered by those who have a more comprehensive knowledge of what is done than I.

65. What if any involvement do you have in the treatment of the Centre's patients for HIV and/or HCV and/or HBV? Are there multidisciplinary clinics (e.g. haematology and hepatology), and if not, would such arrangements be beneficial?

65.1. As already described, I have no formal role in the management of bleeding disorders in Ysbyty Gwynedd, just ad hoc emergency cover. I feel questions 61 – 68 should be answered by those who have a more comprehensive knowledge of what is done than I.

66. What if any psychological services are available at the Centre to patients infected with HCV/HBV/HIV?

66.1. As already described, I have no formal role in the management of bleeding disorders in Ysbyty Gwynedd, just ad hoc emergency cover. I feel questions 61 – 68 should be answered by those who have a more comprehensive knowledge of what is done than I.

67. What has been the impact of the infection of patients with HIV and/or hepatitis through blood products:

a. upon patients at the Centre (without identifying any individual patient); and

b. how treatment is decided, arranged and provided at the Hospital?

67.1. As already described, I have no formal role in the management of bleeding disorders in Ysbyty Gwynedd, just ad hoc emergency cover. I feel questions 61 – 68 should be answered by those who have a more comprehensive knowledge of what is done than I.

68. Has the infection of patients with HIV and/or HBV and/or HCV through blood products:

a. changed or influenced your professional practice and approach, and/or that of your colleagues, and if so, how?

b. changed or influenced the practice and approach of your colleagues and if so, how?

68.1. As already described, I have no formal role in the management of bleeding disorders in Ysbyty Gwynedd, just ad hoc emergency cover. I feel questions

61 – 68 should be answered by those who have a more comprehensive knowledge of what is done than I.

Section 6: Pharmaceutical companies/medical research/clinical trials

69. Have you ever:

a. **provided advice or consultancy services to any pharmaceutical company involved in the manufacture and/or sale of blood products?**
b. **received any pecuniary gain in return for performing an advisory/consultancy role for a pharmaceutical company involved in the manufacture of sale of blood products?**
c. **sat on any advisory panel, board, committee or similar body, of any pharmaceutical company involved in the manufacture or sale of blood products?**
d. **received any financial incentives from pharmaceutical companies to use certain blood products?**
e. **received any non-financial incentives from pharmaceutical companies to use certain blood products?**
f. **received any funding to prescribe, supply, administer, recommend, buy or sell any blood product from a pharmaceutical company?**
g. **undertaken medical research for or on behalf of a pharmaceutical company involved in the manufacture or sale of blood products?**
h. **provided a pharmaceutical company with results from medical research studies that you have undertaken?**

69.1. No to all.

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

70.1. No to all.

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

71.1. No to all.

Section 7: Interaction with the financial assistance trusts and schemes

72. Please explain as fully as you can any involvement you have had in relation to any of the trusts or funds (the MacFarlane Trust, the Eileen Trust, the MacFarlane and Eileen Trust, the Caxton Foundation, the Skipton Fund) which were set up to provide financial assistance to people who had been infected. Relevant involvement may include:

a. Occupying a formal position with any of the trusts or funds;

b. Providing any advice to any of the trusts or funds, including for the development of any eligibility criteria or policies;

c. Informing patients about or referring patients to the different trusts or funds;

d. Determining or completing any part of applications made by patients.

72.1. I have had no interaction with these organisations.

Section 8: vCJD

73. When and in what circumstances did you become aware of the risks of transmission of vCJD associated with the use of blood and blood products? You may wish to consider the enclosed minutes of a meeting of the National Blood Service User Group held on 30 October 1997, which discusses emerging knowledge of the risk of vCJD transmission by blood/blood products [NHBT0005945].

73.1. I vaguely recall the media interest in "Mad Cow Disease" and some speculation of the possibility of blood-borne transmission as well as eating contaminated beef products. I got a clearer picture from the documentation from NBUG prior to the meeting in October 1997.

74. Did you have any involvement in decisions as to what information to provide to patients about vCJD? If so, please answer the following:

a. What steps were taken/put in place a process at the Centre for informing patients about the risks of or possible exposure to vCJD?

b. What steps were taken to arrange for counselling, support and/or advice to be offered to patients who were being informed that they might have been exposed to vCJD?

74.1. Only as recorded in the minutes of the NBUG meeting (NHBT0005945). It was felt there was no need to trace recipients of products that may have become contaminated as there was no test that could be done at that time to detect infection and no treatment to offer either. Imparting such information would have only caused distress which, as it has turned out, would have been totally unnecessary.

74.2. a) In the light of the above – none.

74.3. b) In the light of the above – none.

75. What measures were put in place from a public health perspective at either of the institutions at which you have worked in relation to the care and treatment of patients?

75.1. There have been no patients in either institution with vCJD.

76. Please consider the enclosed minutes of National Blood Service User Group meeting held on 22 January 1998 [NHBT0005944]. The minutes record a discussion regarding whether UK Haemophilia Directors should avoid the use of Factor VIII made from British plasma. Please comment on this, including whether you agreed with this recommendation and why, and whether it was implemented by you or your colleagues.

76.1. I was not a Haemophilia Centre Director and I would have supported the view that making an exception for only one group would not be justifiable. If British plasma was to have been avoided for one, it should have been avoided for all pooled products. I have no recall of the content of the NBS position statement

referred to by Dr Robinson. I was not in a position to have implemented the suggestion if it had been supported.

77. **The minutes also state that the Department of Health did not require clinicians to inform recipients of blood products from donors who developed nvCJD as there was no test or implications for treatment, and little information was known as to the level of risk [NHBT0005944].**

a. Did you ever discuss the risk of vCJD with patients under your care?

b. Please comment on this approach to informing patients of the risks of developing vCJD outlined in the enclosed minutes [NHBT0005944].

77.1. a) No

77.2. b) See 74). Transfusion is never absolutely "risk free" and as with all medical interventions the risks must be weighed against the benefits. However, when the risk is unknown and may be minimal or only theoretical, what benefit is it to give incomplete information to patients? There is probably a greater risk to their mental and physical wellbeing from the information than the purported threat.

Section 9: Look-back and tracing exercises

78. **In as much detail as you are able to, please explain your knowledge and involvement in hepatitis (of any kind) look-back or tracing exercises. In answering this question, you may find it useful to refer to the enclosed letters between you and Dr Martlew concerning donor tracing exercises in 1990 [NHBT0076930_004, NHBT0076930_015 and NHBT0082478_041]. Additionally, the enclosed letter from you to Dr Shepherd discusses a donor tracing exercise in 2001 [NHBT0082478_041].**

78.1. It is good transfusion practice to investigate any untoward reactions following a blood transfusion. This would happen in the hospital where the transfusion took place by initially looking at incompatibility testing or for the development of new antibodies in multiply-transfused recipients. In delayed reactions the presentation is often jaundice and deranged LFTs, so unconjugated bilirubin, viral serology and a DAT would also be tested. If the serology proved positive,

it would require notifying the Transfusion Centre that supplied the product so they could identify and test the donors.

78.2. If the converse occurred and a donor unexpectedly tested positive, the Transfusion Centre would check if the donations had been issued and notify the recipient hospital. The hospital would then check if the product had been transfused and then counsel and test the recipient.

78.3. The letters refer to two separate incidents reflecting this practice. You will note my signature block refers to Consultant Haematologist and Lead Cancer Clinician.

79. In as much detail as you are able to, please explain your knowledge and involvement in HTLV-III/HIV look-back or tracing exercises.

79.1. Because of the long interval between becoming antibody positive for HIV and becoming clinically unwell, it would be more likely that this change would first be picked up in the donor on routine testing and follow the second scenario outlined above. I have never been involved in this situation.

Section 10: National Blood Transfusion Services

80. Please describe your involvement with the National Blood Service User Group (NBSUG). During the period that you were involved with the NBSUG , please outline:

a. The purpose, functions and responsibilities of the NBSUG, as you understood them.

b. The relationships between NBSUG and other organisations, such as regional transfusion centres, haemophilia centres, pharmaceutical companies and/or government departments.

c. Any policies, guidance, actions or decisions of the NBSUG in which you were involved and which relate to:

- **the purchase, selection and use of blood products;**
- **the care and treatment of haemophilia patients;**
- **the risks of infection associated with the use of blood products;**
- **the sharing of information about such risks with patients and/or their families;**

- **obtaining consent from patients for the testing and storage of their blood, for treatment and for research;**
- **measures to reduce risks of viral transmission;**
- **vCJD exposure; and**
- **treatments for HIV and hepatitis C.**

80.1. I believe the National Blood User Group (NBUG) was set up by the Secretary of State in 1996 with an initial remit of 2 years. I was very surprised to be asked to be part of it but I supposed it was on account of my activities trying to secure the blood supplies for North Wales which were in jeopardy with the proposed closure of the Liverpool Regional Transfusion Centre. The group was the national body comprising I believe of representatives from the Zonal user groups with observers from the National Blood Service, NHSE and Welsh Office. I do not recall any specific representation for Haemophilia Centres.

80.2. a) As a user group it was to address problems experienced by users with the supplies of blood and blood-products involving issues such a stock-control; donor issues; the impact of new infective threats; the proposed reorganisation of the National Blood Authority to replace the NBS. It also took an interest in information that would lead to the better and safer usage of blood.

80.3. b) Some members of NBUG were from regional Transfusion Centres and reported the actions back to their Centres and their Zonal user groups. I do not recall a specific representation from Haemophilia Centres but there were people on the group whose precise role I did not know. There was no involvement with pharmaceutical companies and the nearest thing to government representation were the observers from NHSE and the Welsh Office. The group sent written reports back to the Secretary of State.

80.4. c) The only decisions I was involved in are reflected in the minutes of the meetings you have sent to me. I had no involvement outside those meetings.

81. The enclosed minutes from a meeting of the NBSUG held on 30 January 1997 record a discussion about the need to receive SHOT statistics, without which "some clinicians felt unable to give patients an informed indication of risks involved in blood transfusion" [DHSC0004164_117]. Please explain the information provided by SHOT statistics, when they were made available to clinicians (if at all), and the benefits afforded by this data to clinicians and patients (for instance, as a method of increased awareness and reduced risk of viral transmission by blood or blood products).

81.1. SHOT (Serious Hazards Of Transfusion) reports are made available to hospitals via their blood banks and usually to the haematologist in charge of the bank as well. They are based on the reports filed by the hospitals throughout the UK when a serious adverse event is recorded that is deemed to be due to transfusion. As such they tend to be focussed on red blood cell and platelet donations rather than factor concentrates. Whilst they do record incidents where infection has occurred, there is much more in them about clerical error, poor clinical practice when storing or checking blood prior to transfusion, unexpected transfusion reactions etc. They do have a benefit in detailing infection and raising awareness but they also inform on improving clinical practice in general and reinforcing the fact that blood is not hazard-free and the benefits of the transfusion must always be carefully weighed against the known risks.

82. The enclosed document is a letter from Dr Wagstaff to you dated 25 October 1994 responding to your concerns regarding the reorganisation of the blood services [NHBT0009875_076]. These concerns are also raised in the enclosed letter from K J Guinness to Dr Gilmore dated 2 April 1996 in which you are mentioned [DHSC0020763_123]. Please consider these documents and explain in as much detail as you are able to[3]:

a. the proposed changes to the organisation of the blood services;

b. the concerns held by you or others, and the basis for these concerns;

c. whether the existing organisation of the blood services, and/or the proposed changes had or could have had any consequences for the treatment and care of haemophilia patients; and

[3] In answering this question, please consider the enclosed NBSUG First Report to the Secretary of State [DHSC0004725_053] which provides an overview and evaluation of the reorganisation of the National Blood Services. You may also be assisted by the enclosed article published in The Guardian on 26 October 1994 titled 'Blood shed in the service of the nation', in which you are quoted [DHSC0004586_003].

d. what steps were taken (if any), and by whom, to address these concerns.

82.1. a) In 1994 a consultation document was circulated about the proposed reorganisation of the NBS to form the new NBA. This document suggested closure of the Liverpool Regional Transfusion Centre and consolidation of all transfusion services, both clinical and laboratory at the centre in Manchester.

82.2. b) North Wales hospitals were already at the extreme end of timeliness for emergency blood delivery (blue-light deliveries) from Liverpool. Moving the source of blood-supplies fifty miles further away would make the timely delivery of blood or platelets impossible and put patients with life-threatening haemorrhage at unacceptable risk. As secretary of the Glan Clwyd Hospital transfusion committee, I wrote to Dr Wagstaff expressing these concerns in response to the consultation document. This was further clouded by a bid from Cardiff for Welsh Blood Services to take over the donor base and supply blood to North Wales. This was also unacceptable to colleagues in North Wales and led to my being invited to the meeting referred to in the second letter and probably also led to my being invited to join NBUG.

82.3. c) The proposed changes did not affect the Liverpool Haemophilia Centre and would have had no impact on the supply of factor. The only impact of the proposed changes on haemophiliacs would have been if they were suffering a life-threatening haemorrhage.

82.4. d) Lobbying by North Wales and Northwestern clinicians who relied on the Liverpool Transfusion Centre was eventually successful and the Centre remained as a source of blood supply although some of the laboratory testing was moved to Manchester.

83. The enclosed document is a letter from Dr Duguid to Professor Bellingham dated 18 September 1998 expressing concerns about changes in the supply of BPL finished products to hospitals in North Wales [NHBT0093334].

a. Please explain the changes that were made to existing arrangements, who was responsible for these changes, why these changes were made, and the consequences, if any, for the treatment and care of haemophilia patients.

b. Did you share Dr Duguid's concerns? If so, please explain the basis for your view and what steps, if any, were taken to address the concerns expressed by Dr Duguid.

83.1. a) I'm afraid I cannot recall the precise detail of the issues raised. I suspect it reflects the change in the production of BPL protein fractions – albumin and globulin – from pooled to single-donor products in response to the growing concerns about infected blood products, in particular vCJD. The changes were made with very little warning at national level and presented as a fait accompli. There was an interim period when commercial products needed to be bought at greater cost necessitating different ordering and delivery programmes. You will have to confirm with Dr Duguid's statement to see if my assumptions are correct. If I am correct, the changes would have had more impact on patients with burns, immunodeficiency, nephrotic syndrome, shock and eclampsia etc. rather than haemophilia.

83.2. b) If I'm right, the proposed changes should have resulted in a safer product but the disruption caused by the interim arrangements would have been considerable. I don't think there were any steps we could have taken, we had to put up and shut up. Supplies eventually stabilised.

Section 11: Other Issues

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

84.1. I am not aware of any complaints past or pending.

85. Please explain, in as much detail as you are able to, any other matters that you believe may be of relevance to the Infected Blood Inquiry, having regard to its Terms of Reference and to the current List of Issues.

85.1. The whole business of infected blood is extremely upsetting for all parties. Few, if any, aspects of medicine are entirely risk-free and even when we think we know all the risks, it often turns out that we don't, knowledge is never static. Actions and decisions need to be judged against what was known at the time, not what we know now.

Statement of Truth

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

Signed: David Roy Edwards

Dated: 11/03/2021