Witness Name: Dr Saad Al-Ismail
Statement No.2: WITN3761005
Exhibits: WITN376100 - WITN3761033
Dated: 09 September 2020

INFECTED BLOOD INQUIRY

SECOND WRITTEN STATEMENT OF DOCTOR SAAD AL-ISMAIL

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 4 June 2020.

I, Saad Al-Ismail, of GRO-C will say as follows:

Section 1: Introduction

1. My date of birth is GRO-C 1947. My Professional Qualifications are:

   i. M.B; Ch.B (1970) Baghdad Medical School (First Graduate)

   ii. MRCP Ireland 1975

   iii. MRCP UK – 1976

   iv. FRCPath – 1980

   v. FRCP (London) 1990

2. I have reviewed the information I provided in my first witness statement to the Blood Inquiry dated 24 September 2019. To the best of my knowledge the information I provided then was correct. I will describe in more detail the role and duties I performed from the date of my appointment as a consultant haematologist in June 1982 until my retirement in February 2018.

3. Many of patients receiving haemophilia services in Swansea were under the care of the lead Haemophilia Centre in Cardiff, the Cardiff Reference Haemophilia Centre (later named Cardiff Comprehensive Care Haemophilia Centre) before the appointment of the first consultant haematologist in Swansea. Other patients were also looked after by Cardiff for major bleeds.

4. The first Consultant Haematologist for the Swansea area was Dr M. Kurshid who took up his post in February 1975. Dr Kurshid was given the notional title of the first Director of Haemophilia Services. The terms Swansea Haemophilia Service and Swansea Haemophilia Centre were used interchangeably over the years.

5. Later in 1975, Swansea became a designated "sub haemophilia centre" working under the lead Haemophilia Centre in Cardiff. The Swansea Haemophilia Centre was later identified by the United Kingdom Haemophilia Centre Directors (later Doctors) Organisation ("UKHCDO") as Centre Number 151.

6. I was appointed to the substantive post of full time consultant haematologist in West Glamorgan Health Authority ("WGHA") in 1982. I started my duties on 2 June 1982. I joined Dr Kurshid and shared with him the responsibilities of looking after patients with inherited bleeding disorders with the guidance and direction of the Senior Haemophilia Specialist in the lead Haemophilia Centre in Cardiff, the late Professor Arthur Bloom. We provided clinical and laboratory haematology services in WGHA on three hospital sites: Morriston Hospital, Singleton Hospital and Neath General Hospital. We both provided services on the three hospital sites in haematological cancers (both children and adults), general non-malignant haematology and thrombosis and haemostasis including haemophilia and inherited bleeding disorder services. We delivered both

outpatient services in general haematology and haematological cancers as well as in-patient clinical haematology in the three hospitals.

7. As a consultant haematologist, I supervised and interpreted laboratory haematology services on the three hospital sites. Initially the haemophilia services constituted less than 5% of my clinical responsibilities.

8. I have not worked as a consultant haematologist in any other hospital or haemophilia treatment centre apart from Swansea.

9. Dr Khursid left Swansea to take up a post in Karachi, Pakistan in 1985. I then became the Director of Swansea Haemophilia Services/Centre from 1985 and shortly after Dr A. C. Beddall was also appointed as a consultant haematologist in 1985. Dr Beddall and I shared the responsibilities of looking after all haematology patients including those with inherited bleeding disorders. I continued in this role until 21 September 2015.

10. Doctor Charles Percy took up the post of full time consultant in Haemophilia, Thrombosis and Haemostasis on 21 September 2015. I subsequently relinquished the role of Director of the Haemophilia Centre in Swansea on his appointment. Dr Percy subsequently left to take up the post of Consultant Haematologist in Birmingham on 30 December 2016. At that point, I resumed the role of Director of the Swansea Haemophilia Centre and lead in Thrombosis and Haemostasis in addition to my other clinical and laboratory responsibilities on 30th December 2016.

11. Subsequently, I retired from full time NHS service on 20 February 2018.

12. As a member of the following organisations, I received regular written communications, journal extracts and invites to update meetings on various specialisms. I also had voting rights for the appointment of various officers and received papers in relation to this:

Organisation	Period	Capacity
Medical and Dental Defence Union of Scotland	1976 - to date	Member
Royal College of Physicians	1976 - 1990	Member
British Society of Haematology	1980 - 2018	Member As Senior registrar for first two years
British Medical Association	1980 - 2018	Member
Royal College of Pathologist	1980 - to date	Fellow
Blood Transfusion Society	1982- 2018	Member
Haemophilia Doctors Organisation	1985 - 1990	Member
American Society of Haematology	1986 - to date	Member
Royal College of Physicians (London)	1990 - to date	Fellow
European Society of Haematology	2012 - to date	Member

13. I have also participated as a member or Chair of the Following Committees which shows that during my working life I was predominantly involved in general haematology and treating related cancers. I was not primarily involved in treating haemophilia patients unlike colleagues at the Cardiff Haemophilia Centre (which I refer to below). My main specialism is Haemato-oncology. My involvement in each of the following roles is briefly explained below:

Organisation	**Period**	**Capacity**	**Involvement in role**
Swansea NHS Trust	1998 – 2000	Lead Cancer Clinician	Supervised the development of Cancer Multidisciplinary Teams and developed Cancer Directory
South West Wales Cancer Network	2000 – 2011	Lead Cancer Clinician and Medical Director	Clinical Direction and responsible for Clinical Guidance
South West Wales Network Advisory Group	2000 – 2011	Chair	Unified services and developed the Clinical Governance Strategy for the South West Network
Advisory Group on Haematological Cancers in Wales	1999 – 2015	Member (one of six) of Core Advisory Group	Advised on the Haematological Cancers Strategy Group on issues related to Standards in Haematological Cancers in Wales

All Wales Cancer Drugs Group	2007 – 2008 2011 – 2012	Chair	To address issues related to cancer drugs that were outside the remit of the All Wales Medicine strategy Groups.
Chemotherapy Network System in Wales	2008 – 2011	Chair	The implementation of the Electronic Chemotherapy Prescribing System in South West Wales - Currently the only Chemotherapy Network System in Wales improving the safety and accountability on the use of chemotherapy in South West Wales
SIFT Committee in Abertawe Bro Morgannwg University Health Board ("ABMU") Health Board	2011 – 2018	Chair	To proportion resources for teaching undergraduate medical students
Ministerial Task and Finish Group	2011 – 2012	Member	To review the services of people with inherited

			bleeding disorders in Wales
Task and Finish Group of ABMU Health Board	2011 – 2012	Chair	For planning and delivery of haemophilia and inherited bleeding disorder services
Task and Finish Group for Low Molecular Weight Heparins of ABMU Health Board	2012 - 2013	Chair	To review services and make recommendations on the use of Low Molecular Heparin in the Health Board
New Medicine Group to advice the All Wales Medicine Strategy Group	2015 - April 2018	Chair	To advise on the introduction of new drugs in Wales
Cancer Commissioning Group- ABMU Health Board	January 2015 - 2018	Co-Chair	To identify priorities for Commissioning Cancers in ABMU University Health Board

14. I have neither provided evidence to, nor been involved in any other Inquiries, investigations, criminal or civil litigation in relation to the human immunodeficiency virus ("HIV") and/or hepatitis B virus ("HBV") and/or hepatitis C virus ("HCV") and/or variant Creutzfeldt – Jakob disease ("vCJD") in blood and/or blood products.

Section 2: Decisions and actions of those treating patients with bleeding disorders at the Swansea Haemophilia Centre

15. In this section, I shall set out the facilities, organisation, roles, functions and responsibilities of the Swansea Haemophilia Centre during the time I worked there between 1982 and 2018.

16. As set out earlier in this statement, initially in 1975 Haemophilia services provided in Swansea, managed by WGHA was considered a "sub haemophilia centre". However as UKHCDO had provided it with a Centre number it operated as a Centre in its own right but still under the direction of the lead Centre in Cardiff.

17. Initially the majority of Haemophilia services were provided at Morriston Hospital and so most haemophilia patients were treated there before the commissioning of Swansea Haemophilia Centre accommodation in Singleton Hospital in 1991/1992 (as set out below):

18. At Morriston Hospital children were managed as in-patient or day cases on the children ward. Dr Kurshid and I supervised their haematology and haemophilia care while consultant paediatrician and paediatric junior staff managed their general paediatric care and infused the Cryoprecipitate and clotting factors concentrate as requested by the consultant haematologist.

19. Adults were managed as day cases or in-patients on one of the adult wards. There were no designated rooms for haemophilia patients or haemophilia day centre for adults in Morriston Hospital and initially there was no haemophilia nurse.

20. The main coagulation laboratory for specialised clotting tests and coagulation factors assay and inhibitors assays has always been in Morriston Hospital. The Medical Laboratory Scientific officers ("MLSOs") kept records and stocks of factor concentrates and Cryoprecipitate in the Blood Bank in Morriston Hospital.

21. The MLSOs kept a record of products used per patient and other information required by the Haemophilia Directors Organisation in Oxford at that time.

22. Patients were reviewed in the general haematology clinics mainly in Morriston Hospital where most of the patients had their blood tests, management and treatment both as day cases on the appropriate ward or as in-patient.

23. Patients who received home treatment collected their supplies of factors concentrate from the blood bank in Morriston hospital. Occasionally patients were seen or admitted to Neath General Hospital or Singleton Hospital if they had presented there.

24. In 1991 the Paediatric services moved from Morriston to Singleton Hospital.

25. My clinical, nursing and laboratory colleagues and I were successful in making the case for a further designated space to be able to see and treat haemophilia and allied disorder patients and to manage their needs in Singleton Hospital. Around 1991/1992 we were given two rooms on the upper ground floor in Singleton Hospital with easy access from the road. These two rooms were designated for use by the Swansea Haemophilia Centre. This led to Singleton hospital becoming the administrative and main treatment hub for the Haemophilia Centre and the hospital under which all haematology consultants operated in Swansea. Day cases, out-patient and day treatments were provided in Singleton hospital as well as all Haematological cancer treatments. Therefore, patients were no longer treated at Morriston hospital or indeed Neath and if emergency haemophilia treatment was provided at either of those two hospitals, Singleton hospital would oversee this

26. The expression of "Swansea Haemophilia Centre" used by the Inquiry to cover the treatment of patients with inherited bleeding disorders within the catchment boundaries of Singleton Hospital, Morriston Hospital and Neath General Hospital is correct. Most of the services were provided in Singleton and Morriston hospitals. Neath only provided management for patients with

haemophilia who may be admitted as an emergency or had surgery in Morriston Hospital.

27. Consultant Haematologists that were responsible for the management of patients with inherited bleeding disorders for the period 1975 - March 2018 and their roles are listed in *Swansea Haemophilia Centre - Consultant Haematologists and their responsibilities in Haemophilia Care 1975 – 2018* ("Consultant List") **[WITN3761006]**. All of the consultants covered all three hospitals in Swansea during on-call rotas. General haematology outpatient clinics took place at all three hospitals.

Role and responsibilities at the Swansea Haemophilia Centre

28. When I became the Director of the Swansea Haemophilia Centre in 1985 and therefore Lead in Haemophilia for Swansea and after Dr A.C. Beddall was appointed in 1985, he and I both looked after and treated all haematology patients including those with inherited bleeding disorders. For around three months each year only one of us would have treated all haematology patients as the other consultant would have been on annual leave or study leave.

29. I continued with the same management plans for individual patients and regularly liaised with the lead Haemophilia Centre in South Wales in Cardiff.

30. When I undertook on call rotas for after hours, I undertook this for Singleton Hospital, Dr Beddall was on call for Neath general Hospital and we both shared the on-call for Morriston Hospital. The inherited bleeding disorders/haemophilia workload constituted less than 5% of my overall clinical workload which included general haematology clinics and haematological cancers.

31. Prior to the commissioning of the Haemophilia Centre accommodation in Singleton Hospital in 1991/1992, Patients were reviewed in the general haematology clinics mainly in Morriston Hospital where most of the patients had their blood tests, management and treatment both as day cases on the appropriate ward or as in-patients. Patients receiving home treatment collected

their supplies of factors concentrate from the blood bank in Morriston hospital. Occasional patients were seen or admitted to Neath General Hospital or Singleton Hospital if they had presented there.

32. A new purpose built wing was created on the Singleton hospital site for Women and Children services and after this the Paediatrics and neonatal services were transferred from Morriston to Singleton in 1991.

33. Once Singleton hospital became the administrative and treatment hub in 1991 for the Haemophilia Centre in Swansea, my day to day responsibilities were mainly undertaken at Singleton hospital. This meant that I could treat and manage patients with haemophilia coming to the Centre for a bleed.

34. In addition, Dr Beddall and I started monthly haemophilia out-patient clinics at Singleton hospital with the Haemophilia Nurse. Initially we undertook the clinic together then we started undertaking this on alternate months. This helped improve the clinical care for Haemophilia patients in the area

35. When Dr Sian Lewis was appointed as a Consultant Haematologist in November 1997, she joined the monthly rota for the haemophilia out-patient clinic with myself and Dr Beddall. That gave the opportunity for each consultant haematologist to review and become more familiar with inherited bleeding disorder patients and their families.

36. In 2005, Dr Peter Collins from the Cardiff Haemophilia Centre, who had overtaken Professor Bloom's former role as the Lead in Haemophilia, started undertaking joint haemophilia clinics with me and he saw patients in Swansea. As with Professor Bloom, the Swansea Haemophilia Centre followed the advice and guidance of Haemophilia Consultant colleagues in Cardiff in relation to treatment of haemophilia patients given their greater specialist expertise in this area. Patients were reviewed and any planned intervention for a patient or the delivery plan of a haemophilia carrier were discussed and made available to fellow health care workers involved in that patient's treatment. My haemophilia workload increased in 2004/2005 to approximately 20% of my overall workload

as other colleagues did not undertake haemophilia out-patient clinics in Singleton, with the advent of the vCJD risk becoming known (which I cover in further detail under section 9) and the National tendering programme for recombinant factors concentrates.

37. More than 10 years before I retired I produced a business case relating to the need for a consultant haematologist with a sub-specialism in inherited bleeding disorders, thrombosis and haemostasis.

38. Further in 2011 a Ministerial Task and Finish Group was established to review the services for those with inherited bleeding disorders in Wales (papers relevant to this, I believe, were included in the evidence list/exhibits provided to the Blood Inquiry with the response of the Chief Executive of ABMU Health Board in 2018). This recommended a further consultant haematologist specialising in bleeding disorders, the appointment of a part-time psychologist and part-time physiotherapist to the Haemophilia Centre in Swansea. Please see *Ministerial Task and Finish Group on Haemophilia Services - Report and recommendations arising from Review of services for people with inherited bleeding disorders June 2011* ("the Task and Finish Group recommendations") **[WITN3761007]**. The part-time psychologist and part-time physiotherapist were appointed in August 2014.

39. After the Consultant haematologist specialising in bleeding disorders, Dr Charles Percy was appointed in Swansea in September 2015, I stepped down from my role as Director for the Swansea Haemophilia Centre and gave to Dr Percy the lead role in thrombosis and haemostasis on his appointment. I acted and supported him in his absence and after he left in December 2016, I resumed the lead responsibility for the Swansea Haemophilia Services/Centre. I continued in that role, in addition to my main duties in general haematology and haematological cancers until my retirement.

Numbers of patients with bleeding disorders

40. I do not have a full record of the exact number of patients with bleeding disorders who were under the care of the Swansea Haemophilia Centre when I first started working as a Consultant Haematologist in 1982. However, the *Abertawe Bro Morgannwg University Health Board - Swansea Haemophilia Centre – Infected Blood Inquiry* ("ABMU Health Board – Infected Blood Inquiry") **[WITN3761008]** contains *Swansea Annual returns* sent to UKHCDO in 1980-1987 (which are part of the exhibit). These returns record the number of patients treated per year during this period.

41. The total number of patients with bleeding disorders in 2006 was 127 as indicated by *Swansea Haemophilia Centre, Patient with Inherited Bleeding Disorders 2006* **[WITN3761009]**, this was made up of 47 patients with Haemophilia A; 2 with Haemophilia B;78 with other inherited bleeding disorders.

42. The document entitled *Swansea Haemophilia Centre, Patient with Inherited Bleeding Disorders 2019* **[WITN3761010]**, indicates that the total number of patients with bleeding disorders registered with the Swansea Haemophilia Centre then was 248. This was made up of 61 Haemophilia A, 9 Haemophilia B, 4 patients with acquired haemophilia, 17 female carriers, 157 with other inherited bleeding disorders. The number of patients being treated had increased significantly from 2006 due to new diagnoses and other categories of patients with bleeding disorders which had not previously been identified.

43. I believe that the full list of patients registered with the Centre over the years could probably be obtained by the Inquiry from UKHCDO files.

Policies and procedures

44. From when I first started and throughout the time I was in charge of the Haemophilia Centre in Swansea, both I and the other haematology consultants in Swansea followed the advice and guidance of the late Professor Arthur Bloom and his successors in the lead Haemophilia Care in Cardiff. His and their

guidance as well as the recommendations made by UKHCDO and any published guidelines shaped the policies in the Swansea Haemophilia Centre.

45. To the best of my knowledge we undertook the following:

a. We followed the advice communicated to us by colleagues in the Cardiff Centre in relation to which products should be ordered for patients. I set out below in paragraphs 52 to 56 further detail of which organisation had responsibility for selection and purchase of blood products;

b. In general, the policy was to adhere to one concentrate per patient unless directed by Cardiff or there a product that had been linked to the transmission of blood borne viruses ("BBV") by certain concentrate batch. To the best of my knowledge, we acted on all information communicated by the lead Haemophilia Centre in Cardiff;

c. We followed the principle of avoiding the use of coagulation concentrates for patients with mild and moderate haemophilia. Instead, we relied on Cryoprecipitate and Desmopressin ("DDAVP") (a synthetic product which could stimulate Factor VIII production in mild and moderate haemophiliacs) whenever such treatment achieved the desired clotting levels in individual patients;

d. I honestly do not remember any guidance being given by the Cardiff Haemophilia Centre to us about the importation or manufacture of blood products;

e. Avoided the use of more than one batch or product of concentrate per patient;

f. Regular testing for responses and inhibitors;

g. Monitored for BBV transmitted diseases when tests became available for such viruses. Patients and guardians of patients tested for counselled and their informed consents were obtained;

h. Informing patients or their guardian of the results of such tests when the results became available;

i. Identified patients exposed to factors concentrates that were later identified as a possible source of transmitting BBV and monitored such patients;

j. I communicated all the directives and advice I received about any issue related to haemophilia to my colleagues working at the Centre.;

k. We communicated all test results to patients or their guardian(s) in a sensitive manner and in person for HIV results;

l. Patients with altered liver function tests were counselled about the need for tests for HCV when the test became available. To the best of my recollection most of such communications were undertaken by the haemophilia nurse who later informed patients about the results.

46. In 1997, recombinant factor VIII products were made available to all patients in Wales. Wales was the first country to do this, as outside Wales, most centres adopted a policy to introduce recombinant products initially for children and non-infected patients.

47. The Haemophilia Centre arranged for list and management plans for patients with inherited bleeding disorders to be available in all admission rooms and medical wards in all three major hospitals in Swansea. More detailed and individual patient management plans and the name of product to be used for their care were kept in individual patients' notes. The style of these management plan sheets and details of products to use for individual patients were modified over the years to offer details that were more comprehensive. Patients were made aware of these plans and were given copies of their management plan

sheets if they requested this. Examples of these management care plans for individual patients, for children, pre-operative plans and the dental care plan are included as well as Information sheets for patients relating to looking after their teeth and guidance for dental teams **[WITN3761011]**.

48. With the support of the Haemophilia nurse, we produced response curves for treatment with factors concentrates. We also produced response curves to treatment with DDAVP for patients with mild and moderate haemophilia as well as patients with Von Willebrand disease (a genetic disorder caused by missing or defective Von Willebrand factor ("VWF") a clotting protein). The aim and the details of the assessments were explained to individual patients including children and their guardians.

49. Inherited bleeding disorder patients were provided with a "haemophilia card" with the details of the patient and the contact details of the Centre and other details. These cards were given after the diagnosis was confirmed and patients or the guardians were encouraged to carry the card with them at all times.

50. All patients/guardians had open access to the Haemophilia Centre during working hours and were provided with details of telephone contacts after hours. After normal working hours and at weekends, guardians of children were asked to take a child in need of attention to a specific paediatric ward and adults to the adult haematology ward in Singleton.

51. The clinicians and Haemophilia Nurse in the Haemophilia Centre in Swansea supported patients with the help of the social workers employed by the organisation.

Selection and purchase of blood products

52. Products for the management of patients with haemophilia in Swansea were obtained after receipt of advice and directives from the lead Haemophilia Centre in Cardiff. Factor VIII and Factor IX concentrates, derived from UK volunteer donors have been available from Blood Product Laboratory located

in Elstree ("BPL") since the early 1960s. Commercial Factor VIII concentrates became available in the UK from the early 1970s. I believe that these products were supplied free of charge to haemophilia centres until 1993. In 1993, budgets were developed for haemophilia centres.

53. I continued to follow advice from the Cardiff Haemophilia Service about which blood product to use when I took on the role of Director of the Haemophilia Services in Swansea in 1985. To the best of my knowledge, both prior to 1985 and in 1985 blood products were ordered directly by the Swansea Haemophilia Centre through WGHA but I personally did not authorise any invoice for the purchase of such products. I continued to follow the advice of the late Professor Bloom in the Cardiff Haemophilia Centre until the Blood Transfusion service took over responsibility for ordering products for South Wales on the recommendation of the Cardiff Centre.

54. In 2006, the Swansea Haemophilia Centre joined other centres in Wales in the National tendering programme to commission recombinant clotting concentrates. From then, the Swansea Haemophilia Centre ordered recombinant products agreed for individual patients receiving home treatment directly from manufacturers. The other recombinant blood supplies for patients not receiving home treatment were purchased centrally via by the Welsh Blood Service. However, I do not know the history of the exact dates when the National Blood Transfusion Service and later the Welsh Blood Service took on the purchase of products on behalf of the Haemophilia Services in South Wales before recombinant products were available.

Choice of blood product

55. The selection of a particular product purchased for use by patients being treated in Swansea was decided by the Cardiff Haemophilia Centre under the direction of Professor Bloom.

56. I do not recall in any detail the basis of decisions made about the selection of a particular product or particular concentrate for an individual patient. However, I do recall that the following general principles were applied:

i. All products used in Swansea were licenced products. Swansea did not take part in any assessment of a product prior to it being licenced;

ii. Safety and efficacy of a selected product for a patient would have to be a priority;

iii. Patients with mild/moderate haemophilia and Von Willebrand disease were treated by Cryoprecipitate or DDAVP if possible;

iv. Patients requiring coagulation factors concentrates should be kept on one concentrate unless there is a clear reason for changing to a different concentrate.

57. I can provide very little information as to the role of commercial or financial consideration in the choice of blood products purchased for patients. However, having discussed the issues with colleagues at the time, it would appear that perhaps financial pressures may have played a part. However, as to how much, I do not know. In any event, I do not recall, any obstacles in providing what was communicated to me by colleagues in Cardiff to my colleagues in Swansea about the use or avoidance of certain blood products or particular concentrates.

58. The only involvement I had was to confirm the choice of a particular concentrate as communicated to me by Specialist Haemophilia colleagues in Cardiff and request that WGHA obtain them for the Swansea Haemophilia Centre or subsequently that they be acquired and supplied by the Blood Transfusion Service/Welsh Blood Service.

Relationship with Pharmaceutical companies

59. I had no specific relationship with pharmaceutical companies manufacturing or supplying blood products other than contact with them when the Centre purchased blood products through WGHA. I did not have then or now any conflict of interest in my duties as a consultant haematologist working for the National Health Service in the Swansea Haemophilia Centre.

60. I have seen the letter dated 16 August 1985 from a representative of Cutter Laboratories to me which suggests a meeting had taken place between us (BAYP0000007_080). I do not recall that meeting however I suspect it was in relation to when I took over the lead role for Haemophilia Services in 1985.

61. As explained above, Professor Bloom in the Cardiff Haemophilia Centre recommended the usage of factor concentrates which was initially obtained directly from manufacturers by the Cardiff Centre, then the WGHA until the time the Blood Transfusion Services took over purchasing the products on behalf of haemophilia centres in South Wales. This was why the letter from Cutter Laboratories contained price information.

    a. I set out below the information contained in the Annual returns submitted to UKHCDO which records the products from Cutter Laboratories which were given to patients in Swansea.

    b. To the best of my recollection, the supplied vials referred to by Cutter Laboratories in this letter were for assessment i.e. to check the ease of constitution of the products referred to and their solubility.

    c. Even though the Swansea Haemophilia Centre followed the policies and advice communicated by Professor Bloom, I cannot recall if there was any specific policy communicated about reserving batches of product in order to minimise patients' exposure to a large number of batches.

62. I have seen a copy of the letter dated 16 December 1985 from a different representative of Cutter Laboratories to me (BAYP0000007_180) which stated

that from 1 January 1986 the price of Koate HT heat-treated Factor VIII Concentrate would increase due to testing costs carried out on each donor.

63. The products used by the Haemophilia Centre in Swansea for the years 1980-1987 are referred to in the *Swansea Annual returns* 1980 -1987 which forms part of ABMU Health Board – Infected Blood Inquiry **[WITN3761008]**. I recall Cutter Koate was acquired for Swansea patients in 1982, 1985, 1986 and 1987 (see separate returns as part of this exhibit). I believe that the Swansea Haemophilia Centre would have accepted the uplifted price charged by Cutter.

64. As explained above, the Haemophilia Centre in Swansea received blood products acquired on its behalf by the Cardiff Haemophilia Centre initially, then later on products were acquired via the WGHA and then latterly the Blood Transfusion Service. The Haemophilia services in Swansea followed the recommendations of the main Haemophilia Centre in South Wales in Cardiff over the specific selection of certain blood products. I am not aware of the reasons of why or how Professor Bloom selected these products.

65. Please refer to paragraphs 52 to 56 above in relation to selection of products for patients based on the advice of Professor Arthur Bloom and the Haemophilia Centre in Cardiff. I and my colleagues in Swansea followed this advice and, in keeping with it, tried to keep the patient on the same product wherever possible. Any discussion with patients regarding the choice of products that could be used, if documented, would have been in the patients' notes.

Alternatives to factor concentrates

66. The alternatives to factor concentrates available for patients with bleedings disorders were Cryoprecipitate and DDAVP particularly for mild to moderate haemophiliacs and patients with Von Willebrand Disease. Cryoprecipitate was also used for patients with hypo fibrinogenaemia (a rare bleeding disorder for patients with lower than normal levels of fibrinogen which can prohibit a stable clot to form).

67. The advantage of Cryoprecipitate is that units are collected from single donation from donors in the UK. DDAVP is a chemical drug and is not sourced from human plasma. The disadvantage with using Cryoprecipitate is that one needs a large number of Cryoprecipitate units to achieve a good level for blood clotting in severe haemophiliacs. Therefore, it is not practical for home treatment and is only used for mild/moderate haemophilia on demand. DDAVP is also only used in mild and moderate haemophilia and can only achieve a limited rise in Factor VIII level for blood clotting. Both Cryoprecipitate and DDAVP were given to haemophiliacs treated by the Swansea Haemophilia Centre. However severe haemophiliacs required treatment with Factor concentrates to achieve a good blood clotting level.

68. The Swansea Haemophilia Centre's policy, in line with the advice from the Cardiff Haemophiliac Centre was to use Cryoprecipitate or DDAVP to treat mild and moderate haemophilia and Von Willebrand disease. Currently DDAVP and factors concentrates are used for both.

Home Treatment

69. Home treatment has been in place for patients with inherited bleeding disorder since before 1982. I continued with the policy of offering it to patients with severe haemophilia who were either able to self-administer the treatment or was a guardian of a child with severe haemophilia who agreed to be trained and certified as capable of administering the treatment safely at home. When recombinant concentrates became available, they were prescribed from 1997 to all patients in Wales requiring such treatment. Patients receiving home treatment initially collected their treatment from the Haemophilia Centre in Swansea. Later, with the advent of National Contracts, the supply of recombinant concentrates were delivered to patients by Health Care services at home.

70. Severe haemophiliacs receiving home treatment were offered the option of prophylactic treatment (regular treatment to stop bleeds) rather than on

demand. I cannot recall specifically when this was offered but I know it was soon after the Cardiff Haemophilia Centre introduced this perhaps in 1990s. The benefit of such treatment was explained to the patients before it was provided. Patients were monitored carefully. Levels were measured in individual patients in Swansea and trough level (i.e. pre-dose levels) were documented to help inform and direct the further dose and frequency of prophylactic treatment. The individual patient made the final decision whether or not to accept prophylactic treatment.

Factor concentrates for children

71. I could not find any documents referring to the policy/approach relating to the use of factor concentrates for children although I recall that these concentrates were used before I was appointed in 1982. I believe that the Swansea Haemophilia Centre would have adopted the same practice as Cardiff Haemophilia Centre for sourcing mainly NHS concentrates for children if possible.

Factor concentrates for mild/moderate bleeding disorders

72. Many patients with mild to moderate haemophilia/bleeding disorders were treated with Cryoprecipitate and DDAVP only, if the clotting levels achieved were sufficient to deal with a bleed or for a procedures to be undertaken. However, very occasionally patients with mild and some patients with moderate haemophilia received factors concentrate if there was a need to keep the clotting factors level between 50-100% (for example in the case of surgery) and they had had an inadequate clotting factor response to DDAVP or Cryoprecipitate.

73. To the best of my knowledge, no other BBV or infections, other than HIV, HCV and HBV, were recorded as being transmitted to patients treated in the Haemophilia Centre in Swansea.

Section 3: Knowledge of, and response to, risk

General

74. I sat my final examination of the Royal College of Pathologists for Haematology in 1980. The knowledge I had then about the risk of infection associated with blood and/or blood products would have been that published in peer reviewed publications that I came across as I was preparing for my final examination. I cannot be certain as to the exact details or depth of my knowledge at that time. Since then, my knowledge and understanding in relation to HCV, HIV and vCJD disease has developed and increased over the years as more information became available (and was communicated to me by the Cardiff Haemophilia Centre, UKHCDO and via peer reviewed publications, attending scientific meetings, and discussions with colleagues in Cardiff and other centres.

75. As explained previously, the main source of advice that shaped the decision-making in the Haemophilia Centre in Swansea was from the Haemophilia Centre in Cardiff and particularly the late Professor Arthur Bloom regarding which product to use per patient. The minutes, advice and publications by UKHCDO provided national guidance and was another source of information relating to how to consider and/or assess the risk of infection associated with the use of blood and/or blood products. Guidelines published by the British Society of Haematology, UKHCDO and other National and International guidelines were also considered.

76. At some stage it became known that commercial coagulation concentrates were more likely to transmit infection or could not reduce the risk of infection as much as NHS concentrates or single donations like Cryoprecipitate. I am not sure as to when I acquired this knowledge but it may have been on or around the time that I first became aware of how the HIV infection may be transmitted. However, there was no adequate supply of NHS concentrates for all the patients that needed them and that resulted in the NHS having to rely on Commercial products. However, confidence would stem from the fact that products licenced to be used in the United Kingdom would have been shown to be safe in accordance with the Medicines Act 1968.

77. The practice adopted at the Haemophilia Centre in Swansea was that patients with mild haemophilia and Von Willebrand Disease should be treated by Cryoprecipitate and DDAVP. We also implemented a policy that patients on coagulation factor concentrates should receive only one specific product and not be subjected to multiple products or batches to reduce the risk of development of inhibitors to treatment. I continued the same policy and maintained close liaison with the lead Haemophilia Centre in Cardiff in relation to this.

Hepatitis

78. I understood before I was appointed as a consultant haematologist in 1982 that HBV can be transmitted by Blood/blood products. When observing raised liver enzymes for patients receiving coagulation concentrates (NANB hepatitis) there was no clarity as to the cause of such changes, whether it was an infection by a virus and the medium and long term prognosis in these patients. The HCV was identified in 1989. Patients with Non A and Non B ("NANB") hepatitis were offered the tests for HCV when it became available. The majority of such patients were found to be HCV antibody positive. My knowledge and understanding continued to develop as by the time the antibody test became available, there were multiple peer reviewed publications that suggested the majority of NANB hepatitis detected was the HCV infection. I refer to some of the peer reviewed publications I became aware of below.

79. It was the practice in the Haemophilia Centre in Swansea for haemophilia patients to have regular blood tests for full blood count, factors level, antibody to clotting factors, HBV tests and liver function tests. When HCV antibody tests became available in Swansea on or around 1990, all haemophilia patients were offered the tests. To the best of my recollection, the Haemophilia Nurse offered the patients the test when it became available and for those who accepted to have it, arranged the test request form and gave it to the patient or guardian to have the sample collected to determine whether the patient had been exposed to HCV or not. The nurse communicated the results to patients either face to

face or via telephone call. Patients who requested to see my colleagues or I regarding that information were seen in person in outpatient clinics.

Action to reduce risk of Hepatitis infection

80. As stated above, the policy adopted at the Swansea Haemophilia Centre (upon guidance from the Cardiff Haemophilia Centre) was that patients with mild haemophilia and Von Willebrand Disease should be treated by Cryoprecipitate and DDAVP, a chemical drug that did not expose patients to BBV. For those that were treated with coagulation factor concentrates, we determined that the patient should be treated with only one product and avoid being subjected to multiple products. We followed this policy throughout my involvement in the Swansea Haemophilia Centre.

81. The information I would have about the nature and severity of the different forms of viral hepatitis when I first started as a consultant haematologist in 1982 was mainly related to HBV. I was not sure as to the causative agent or changes in liver function tests, the natural history and the prognosis in NANB hepatitis (later diagnosed as HCV) until publications on the issue became available in the mid-nineties and beyond. It is probably worth stating that none of the patients treated by the Swansea Haemophilia Centre had an active HBV infection and there was no treatment available for NANB hepatitis. However, I include as an exhibit an article entitled *Chronic Hepatitis* published in the Blood Review 1993 by M Makris and FE Preston which is undated ("Chronic Hepatitis article") **[WITN3761012]**. The Chronic Hepatitis article indicates that ever since the availability of assays for the detection of hepatitis A and B it was recognised that at least one other virus existed which was responsible for the majority of post transfusion hepatitis, hence the name NANB hepatitis. The article further states that a number of groups around the world have different HCV viral strains and the virus undergoes frequent mutations. Some areas of the virus mutate much more rapidly than others and this could explain how the virus escapes host immunological surveillance and the development of chronic infection. The developing of chronic infection is a remarkable feature of HCV in that it occurs in 50 to 85% of infected subjects. Also included as an exhibit is an article

published in the BMJ Journal entitled *Hepatitis C and haemophilia* BMJ 1995; 310:1619 by Christine A Lee **[WITN3761013]**. This article explained that the high incidence of hepatitis (i.e. HCV) after treatment with clotting factor concentrate form a large pool was first identified in 1972. It was found that infection was more common in young patients having their first treatment and it was now known that there was virtually a 100% rate of transmission of HCV to previously untreated patients with haemophilia until effective procedures to inactivate the virus were introduced in 1985-6. This paper further stated that alpha Interferon (which I refer to further below in this statement) was a promising treatment for HCV as it led to a change in dominance of the genotype but the clinical importance of this was unclear. A further international publication also provided helpful updates (see *EASL International Consensus Conference on Hepatitis C – Consensus* statement Journal of Hepatology 1999;30;956-961 February 1999 ("February 1999 Conference") **[WITN3761014]**. The February 1999 Conference indicated that the incidence of new infections was declining due to the transmission by blood products reducing to near zero and universal precautions reducing transmission in medical settings. However, this further stated HCV is a dichotomous disease in which a subset of patients will die from liver-related causes, but in which the majority will probably live out their normal life span. As a result of the above publications I understood that once HCV was identified, the infection could progress to severe liver disease as cirrhosis or liver cancer. This showed how my understanding developed over time as more information became available.

HIV and AIDS

82. I came to know the following information at some stage but I am not sure exactly when. First of all, the Centre of Disease Control in Atlanta published its first report about AIDS in Haemophiliacs soon after I started my post as a consultant haematologist in Swansea in 1982. I recall that August 1983 was the first report of death of a UK haemophiliac in Cardiff as a result of AIDS.

83. I do not recall as to the exact time I became aware and familiar with the fact that there was an association between HIV infection and blood and blood products.

I believe that I became aware of them at the time that I read relevant publications in the British Journal of Haematology, New England Journal of Medicine, British Medical Journal, and others. I cannot say as to when and where I came across the different issues. My knowledge and understanding also increased as a result of discussing the issues with my colleagues. I have found out subsequently that in 1985 the first HIV test became available and the screening of all blood donors for HIV occurred from October 1985.

84. I followed the advice communicated to me personally and to the Swansea Haemophilia Centre from the Haemophilia Centre in Cardiff, UKHCDO and peer reviewed publications regarding the risk of transmission. The following steps taken in the Centre were:

    a. Counselling patients and guardians about the tests for HIV (HTLV-III) and explaining the results when available. HIV positive patients and guardians were informed about the way the infection can be transmitted to others. Confidentiality for individual patients was maintained throughout.

    b. The Swansea Haemophilia Centre used approved products, limited the exposure of patients with severe haemophilia to one product whenever possible, did not use any products known to have been contaminated or recalled and regularly tested and monitored patients, participated in recoding and provided information to UKHCDO.

    c. For mild and moderate haemophilia, the Centre used Cryoprecipitate and DDAVP and avoided factor concentrates. There was regular testing of patients that received treatment with plasma derived products such as concentrates, Cryoprecipitate or any other products after counselling them. The results were explained in person in the Haemophilia Centre. All the above, if documented, would have been in patients' notes.

85. The enquiries or investigations undertaken by the Swansea Haemophilia Centre related to regular testing of patients for the HIV virus. The Centre provided the

results of tests for HIV and the products used for individual patients to the Cardiff Centre and UKHCDO on regular basis. Patients treated with a particular product that had seroconverted, suggested that the product is responsible for the infection. In immunology, seroconversion is the time period during which a specific antibody develops and becomes detectable in the blood. After seroconversion has occurred, the antibodies can be detected in blood tests for the disease. This outcome is compared to what others have reported on the product so that appropriate action could be taken to ensure that the product was no longer used.

Action in light of a possible association between AIDS and use of blood products

86. I continued to follow the advice that was communicated to the Swansea Haemophilia Centre from the Haemophilia Centre in Cardiff, the UKHCDO and published British guidelines (including the British Society of Haematology and Haemophilia Society) and International guidelines (such as those published by International Societies of Thromboses and Haemostasis, European Haematology Association, American Society of Haematology, and others).

87. As a result of this advice, we took steps to recall and return any batches or product that patients had at home or which were stored in the Blood bank that were suspected or known to have been contaminated with the HIV virus as it was sourced from untested donors.

88. Both I and my colleagues in Swansea stopped using factor concentrates that were implicated as having been contaminated. However we continued to use factor concentrates that were not implicated as advised by Cardiff.

Response to risk

89. Throughout my career as a consultant haematologist, I adopted the ethos that patients needed to know the facts related to them and their ailments. The exception were patients who specifically asked not to be told about certain

aspects of their condition including prognosis. I had no hesitation at any time to explain to patients and their carers that I did not know the answers to all questions asked. I made clear to all my patients throughout my career that I did not speculate about a likely outcome unless I was certain of the most likely prospect or outcome of a condition or its treatment.

90. To the best of my knowledge, all patients and guardians were given information/leaflets when they attended the Centre produced by UKHCDO and other bodies (which were communicated to the Swansea Haemophilia Centre) about the risks of hepatitis and HIV. We also cascaded to our patients the information that was within the public domain about HIV. There was a leaflet and publication stand in the Centre and the Haemophilia Nurse passed such leaflets to patients. The information provided to individual patients or guardians would be present in patients' notes if documented.

91. I used heat-treated products when they became available on or around 1984/85 as per the advice of the Late Professor Bloom and the Haemophilia Centre in Cardiff. The details of such use and the category of patients that received these products such as HTLV III (HIV) negative patients and children would have been detailed in patients' notes and would have been sent to UKHCDO by the Swansea Haemophilia Centre on an annual basis. As an example, in a letter to Dr Napier, Director at the Welsh Regional Transfusion Centre (BPLL0002378_003) dated 11 April 1985, I supplied a list of patients considered eligible for Heat treated Factor VIII concentrate who were likely to require treatment with this product over the next 6 months. The criteria used to select the patients, was in line with Professor Bloom's advice, i.e. HIV (HTLVIII) negative patients, children and those under the age of 20 that were mildly affected with haemophilia but likely to need treatment with concentrates to achieve sufficient blood clotting levels.

92. I have reviewed the Letter from a representative of Cutter Laboratories dated 16 December 1985 which makes reference to testing each donor unit of Koate UT for HTLV-III (BAYP0000007_180).

93. When I took the lead in Haemophilia in 1985 after Dr Kurshid left, the Swansea Haemophilia Centre was using Cutter Laboratories' products as detailed in Swansea Haemophilia Centre returns to UKHCDO. The *Swansea Annual Returns* 1980 -1987 which forms part of ABMUHB – Infected Blood Inquiry **[WITN3761008]**. indicates Cutters Factor VIII (Koate) was used for Haemophilia A patients in 1982, 1985, 1986 and 1987. I do not recall what information was provided to the Centre about HTLV III testing for individual products used by the Centre before receipt of Cutter Laboratories' 16 December 1985 letter, apart from the fact that the products were licensed for use in United Kingdom.

94. I do not recall whether patients were informed about HTLV-III testing on individual products including Cutter's products or Koate UT. If the patients or guardians were informed and if such information was documented, the information would have been detailed in their medical notes.

95. I cannot recall whether there was a change of policy in relation to reverting to the use of Cryoprecipitate in response to the risk of infection. I cannot recall which (if any) patients were offered a return to Cryoprecipitate. Patients' notes and UKHCDO returns could provide a source for such information.

96. I do consider that the actions taken by my colleagues and I were adequate and/or appropriate in the light of the known risks of infections as we acted upon all the information communicated to us by the lead Haemophilia Centre in South Wales, run by the late Professor Bloom and National bodies such as UKHCDO, about the products to use and the products to avoid. To the best of my knowledge and recollection, any information that was communicated to the Swansea Haemophilia centre regarding safety or otherwise of a product would have been acted upon.

97. In hindsight, and if I and my colleagues were informed about a risk of any infection that may result from a particular product we would have avoided the use of such product(s) and would have informed patients and guardians about the risks associated with the use of each product.

98. Companies using human product concentrates played a part in or contributed to the scale of infection in patients with bleeding disorders. Those companies should have not used any plasma donated by at risk donors and should have screened the donations. In addition, they should have provided explicit details about their products and their donor sources and the risk to patients from such donations so that treatment centres could have made a more informed choice about use of their products. The UK government and Medicine Safety and licensing authorities at the time should not have agreed to allow any products at risk to be used in the UK. Safer donor pools for concentrates should have been ensured by Commercial firms as well as UK fractionation centres. Patients and guardians should have been kept informed about any possible risks of using different blood products due to donor source or safety. Patients and guardians as well as Haemophilia Centre staff should have been given the information so that patients could make their own choice of whether to accept any products or not based on concern about its donor source or safety.

Section 4: Treatment of Patients at the Centre

Provision of Information to patients

99. The information that both I and my colleagues provided in the Haemophilia Centre in Swansea to patients prior to commencing treatment were as follows (this did not change significantly over time):

    a. Once a diagnosis of inherited bleeding disorder is made, the patient or guardian would be provided by myself or my colleagues with information about the nature of the condition. That would have been undertaken in a meeting with the patient and family in an appropriate environment and in the presence of the haemophilia nurse. Written information about the condition, its inheritance would have been provided in easy to understand forms including booklets for children. The family would have been given contact details if they had further queries for the staff at the Centre. They would have been informed about the lead Haemophilia Centre in Cardiff and offered the chance to be seen there as well. They

would have been given contact details of patient support group and the Haemophilia Society and other organisations.

b. The management plan of the condition would have been discussed with the patient/guardian including any replacement therapy. The choice of replacement therapy, the benefit as well as the potential risks known at the time would have been discussed.

c. The patient and family would have been empowered by the information provided to make choices and a detailed management and care plan.

d. The nature of blood tests needed, vaccinations and any other intervention recommended would have been explained.

e. The patient, guardian and family would have been encouraged to have another meeting soon after the first for an opportunity to clarify and answer any question they could have.

100. I do believe that I and my colleagues in Swansea Haemophilia Centre adopted the above best practice for many years. However, I cannot be certain as to the definite time that all of the above was provided to individual patients. However, I do not believe that such practices changed significantly over time.

101. All options for treatment including alternatives to factor concentrates, and non-human products, if appropriate, like DDAVP for mild and moderate haemophilia and Von Willebrand disease would have been explained to the patient and guardian. Patients with severe haemophilia would have been told about the different products available for treatment including Cryoprecipitate. The advantages and disadvantages of each therapeutic product would have been explained from the information available at the time. Once again, I cannot be certain as to when such practice became the prevalent practice in the Swansea Haemophilia Centre.

HIV

102. I discussed AIDS and HIV (HTLV-III) with patients at the Swansea Haemophilia Centre when I learned about the facts of the infection and the tests for the virus antibody became available on or around 1985, however I am not certain of this date. I would have told them about the infection and the benefits and the draw backs of having the test.

103. It was only after the result of the virus antibody test came back that I and my colleagues learned that a patient under the care of Swansea Haemophilia Centre had been infected with HIV. After counselling, the Swansea Haemophilia Centre gave the vast majority of patients the request form for the test. The patient or guardian would take the request form for a sample to be collected for the HIV test by the phlebotomy service which was sent to the Virology Laboratory. I believe the Virology Department initially sent the test to London (Colindale) for processing but at some stage, later on, the Public Health Laboratory in Cardiff took on responsibility for processing the test and then latterly Swansea. This format for HIV tests was undertaken during the entire period that I was working in Swansea.

104. Each patient and/or guardian of a relevant patient would have been given pre-counselling about the HIV (HTLV-III) virus antibody test as soon as it became available. The information the test could provide, the significance of the information, the possible consequences to the patient and the possible consequences for other family members as well as possible social stigma and consequences were all discussed. Such information if documented would have been in patients' notes.

105. Patients or guardians who consented to have the test done would have been tested. Each patient or guardian of a patient with positive results for HIV was told in person and individually in the Haemophilia Centre in Singleton hospital. When the result of the test became available, patients or guardians were called back and given the results individually in person usually in the presence of the haemophilia nurse. It was explained to patients that the results would be written in their notes and were considered highly confidential.

106. Once a positive diagnosis was confirmed the patient or guardian was told the significance of this, i.e. that they had contracted the HIV infection from infected blood. There were also told any other information available to the Centre in terms of results, the prognosis known at the time for the average patient, the options in terms of interventions, how the patient would be monitored clinically and immunologically and advice in terms of prophylactic medications. Referral to appropriate specialist services was also undertaken for example dental, ophthalmology, gastrointestinal and other services if needed.

107. To the best of my recollection no patient was ever told to keep their infection a secret, however whether the patient wished their HIV status to be disclosed to others was left to the discretion of the patient or the guardian of the patient. However, the risk of infection to others was discussed in detail.

108. Patients were urged to come to the Centre to discuss any issue related to HIV or indeed any other issue they experienced after their positive test result. Adults were counselled about the mode of sexual transmission of HIV were urged to involve their partner in discussions when the patient came to the Haemophilia Centre for counselling services. Adult patients were told about the need to adopt safe sex practices. The risk of transmission to households via needle pricks was also explained. For guardians of young children the decision to discuss the information with their child was also explored. For HIV infected children coming to an age where they were likely to become sexually active, guardians were informed of the importance of informing the young person about the risk of sexual transmission of HIV infection to others.

109. I do not know of any discussion among clinicians in Swansea or with colleagues in Cardiff relating to withholding information about HIV status from patients or indeed any matter related to a patient with haemophilia or the guardian of patient.

110. Parents administering home treatment to HIV infected children and partners of HIV infected adults were counselled about having tests for HIV if they wished.

Partners of HIV infected adults took the option when they had had unprotected sex with their partner. Parents or guardians generally took up the offer of having an HIV test if they had needle stick injury or they were concerned about the possibility that they may have been exposed to the infection.

111. Households and family members of HIV infected patients were provided with the information that the Centre had at the time about HIV. Information about an adult patient with haemophilia in a family was only discussed with family members after obtaining consent of a patient. I have already set out earlier in this statement at paragraphs 104 and 108the nature of the pre and post-test counselling that was undertaken by the Swansea Haemophilia Centre.

112. Dr Forbes (Chair of the AIDS Group) and Dr Rizza (Secretary to the AIDS Group) wrote to me on behalf of the Aids Group and UKHCDO on 15 May 1986 *Letter from Oxford Haemophilia Centre to Haemophilia Directors* **[WITN3761015]** which indicated that a survey of patients in the UK with Haemophilia would be repeated to find out the number of patients who are HIV (HTLVIII) positive in May 1986. Dr Forbes and Dr Rizza provided a printout of the patients that we had previously included in Annual returns as having received plasma, Cryoprecipitate, Factor VIII or Factor IX concentrates since January 1980. I was asked to populate this print out with details of the antibody test. This print out indicates that Eight patients tested positive for HIV (HTLV III) this was made up of:

a. Six adults with severe haemophilia A.

b. None with moderate haemophilia

c. None with mild haemophilia

d. None with haemophilia B or von Willebrand disease.

e. Two Children with severe Haemophilia.

113. Work was undertaken at the Centre to establish the time period during patients seroconverted. Patients receiving treatment for haemophilia were tested on a regular basis. To the best of my recollection this was undertaken at 1-3 monthly intervals. Patients or guardians were informed of the results and the Haemophilia Centre in Cardiff was informed of any new positive result to help assess whether any product responsible for seroconversion and a specific timeframe for this could be detected. The treatment received by individual patients was communicated to UKHCDO.

114. In the letter from me to Dr Rizza at the Oxford Haemophilia Centre (on behalf of UKHCDO) dated 18 December 1986 (HCDO0000132_039) I provided details of the seroconversion dates for several patients that were treated under the auspices of Swansea Haemophilia Centre. The purpose was to help identify the possible product that could have contributed to the seroconversion of a patient and was responsible for HIV infection in patients. We monitored all patients that were seen in the Centre and/or who received treatment in Swansea or shared care under other treatment centres such as Cardiff and West Wales. Information on shared patients were communicated to the clinicians looking after these patients in these three treatment centres. All patients or guardians of patient under the care of Swansea were informed of the sero-conversion in person and in the presence of the Haemophilia Nurse. Patients and guardians were informed and did not object to their data/information being shared with UKHCDO and the Cardiff Haemophilia Centre.

115. The Inquiry has asked me to comment on the letter I sent to Dr R.B. Christie, Director of Clinical Sciences, Armour Pharmaceutical Company Ltd. ("Armour") which was a response to a letter of 4 June 1985 (ARMO0000402). In this letter, I confirmed that each patient had received Factorate Batch No. Y69402 and provided a summary of the amount that each received and the symptoms they had. In my letter dated 13 August 1986 to Dr Christie (ARMO0000574) I confirmed the HTLVIII status of patients that had received the Heat Treated Factorate Batch No. Y69402 which updated the information that I had provided in my letter of 7 June 1985. To the best of my recollection, patients and guardians were kept informed about the actions and communications the Centre

undertook on their behalf with Armour. If that information was documented, it would be in patients' notes.

116. Dr Christie from Armour wrote to me on 22 August 1986 (ARMO0000573) and she confirmed that what was then the Department of Health and Social Security ("DHSS") (now Department of Health and Social Care) had asked her to follow up the progress of and history of all other patients who were sero-negative after one patient following previous treatment with non-heat-treated Factor VIII sero-converted yet remained clinically well. Unfortunately, I cannot recall the circumstances concerning the content of the letter or the DHSS's request and perhaps DHSS's records could help the Inquiry in this respect. I cannot recall any other possible reason for Armour's request for an update on these patients other than the DHSS's request.

117. Dr Christie did ask me to provide to Armour a patient's pattern of previous treatment with heat-treated and non-heat-treated Factor VIII. I cannot recall whether I provided this information to Armour. To the best of my recollection I was careful not to disclose information to a pharmaceutical company about products of other companies. The detail of any information that I might have provided, if documented, would have been in patients' notes.

118. To the best of my recollection, patients and guardians were kept informed about the actions and communications the Centre undertook to share information with Armour and other pharmaceutical companies including the issues about seroconversion after treatment with non-heat-treated Factor VIII. If that information was documented, it would be in patients' notes.

119. During May 1986 to August 1987 I was involved in correspondence with Professor Bloom and Dr Keith Myers of West Wales General Hospital (CVHB0000004_121 - CVHB0000004_127) in which we attempted to establish the date that a patient seroconverted and the treatment received by the patient that could have contributed to the seroconversion. To the best of my recollection all patients with Swansea Haemophilia Centre receiving active treatments were monitored regularly to detect any seroconversion to HTLV III

positive status. If a patient did seroconvert, the patient or guardian would have been called to the Centre and informed. After all the treatment that they had received was identified this was checked with information the Centre or Cardiff Haemophilia Centre had against the patients who had treatment with the same batch in Swansea, Cardiff or West Wales. Any suspected batch would have been withdrawn and the UKHCDO and manufacturer would have been informed. The aim was to ensure that possible contaminated batches were identified early and no longer used

120. GRO-D

Hepatitis B

121. As far as I can recall, any adult patient or guardian of a child with confirmed BBV infections were informed of the diagnosis in person. The patient/guardian would have been given all the information known to Swansea Haemophilia Centre. The patient would have been offered a referral to the specialised clinician.

122. The information provided to those with BBV about the infection they had been diagnosed with, its significance, prognosis, treatment options and management if documented, would have been in patients' notes.

123. I do not remember any patient with haemophilia being treated by the Swansea Haemophilia Centre being diagnosed with an active hepatitis B infection during the time I worked in Swansea.

NANB Hepatitis / HCV

124. To the best of recollection, any abnormal tests results suggesting NANB hepatitis were disclosed to patients or guardians in person at the Centre.

125. Any information given to patients concerning raised liver enzymes (NANB) hepatitis if documented would be in patients' notes. To the best of my recollection, if patients asked about the significance of raised liver enzymes I would have said that I did not know the exact cause and significance of such changes. In terms of management of the condition, adults with raised liver enzymes (NANB) were advised about the need to avoid or minimise alcohol intake. I would have encouraged patients to refer any other queries regarding the significance of the infection, prognosis, treatment options and management to the specialist hepatologist as (NANB) hepatitis was not my specialist area.

126. I do not exactly recall when the test for HCV was first made available to patients in Swansea but we did conduct this test from then on throughout my entire period of working in Swansea. The virologist in charge at the time in the Singleton hospital in Swansea has passed away. I posed this question to colleagues currently in charge of the virology section in Swansea but they could not provide me with a definite answer. The request form for such tests would have been given to the patient or guardian, after putting the appropriate risk stickers on the form, to take to phlebotomy services in the hospital. Some of the patients receiving home treatment preferred to take the request home and collect the sample for the test themselves when injecting the coagulation concentrate which was undertaken using a "butterfly". To the best of my personal recollection, initially HCV tests were processed in the Public Health Laboratory in Colindale London. One of my current colleagues in Virology asked his colleagues in Colindale as to the date the laboratory service in Colindale first received samples from Swansea and I have not received an answer yet. When

the result of tests for HCV became available, patients were immediately informed as soon as the test was received. To the best of my recollection, the Haemophilia Nurse at the time phoned the patient or met with the patient in person to confirm the positive antibody result.

127. I have reviewed the minutes of the 24th meeting of the UK Haemophilia Centre Directors on 18 September 1992 UKHCDO meeting (HCDO0000248_013) which reflects me asking, when chronic liver disease was discussed, about the frequency of testing for HCV and it being agreed that patients should be tested annually. I cannot recall specifically the main purpose of my question, but I reckon it was in the context of there being no clear guidelines as to the frequency of testing. To the best of my knowledge, prior to 18 September 1992, Swansea Haemophilia Centre was testing patients negative for HCV at their three monthly visits if they received treatment for bleeding disorders. I do not have any recollection of how often individual patients were tested (but this should have been documented in their medical notes) or why generally three months was considered a sufficient frequency for testing. During this meeting, there was a discussion about annual testing for patients who were already antibody positive or had not received any treatment in the interim period, as they would not require three month testing. Following this meeting, we adopted this practice at the Swansea Haemophilia Centre.

128. Patients with HCV who had need for any other hepatology services were referred for assessment and monitoring, treatment and advice, to the gastroenterologist with an interest in liver disease. Prior to 2006, the Hepatology services in Swansea for patients with haemophilia and allied disorders was delivered by Dr J Kingham. In 2006 Dr Chin Lye Ch'ng was appointed as the consultant physician with a special interest in liver disease and tasked with setting up a chronic viral hepatitis service (the BBV Service).

129. I believe that patients would have received information relating to the HCV infection, its significance, prognosis, treatment options and management from the consultant gastroenterologist in the Hepatology Department at the relevant

time but cannot confirm for certain. The specific information provided to individual patients, if documented, would be available in patients' notes.

130. Out of the total number of patients with bleeding disorders in 2006 as indicated by *Swansea Haemophilia Centre, Patient with Inherited Bleeding Disorders 2006* **[WITN3761009]**, 22 had BBV infections which was made up of 4 patients with HIV and HCV and 18 that had HCV only. The document entitled *Swansea Haemophilia Centre, Patient with Inherited Bleeding Disorders 2019* **[WITN3761010]**, indicates that 25 patients, at that time had BBV infections, this was made up of 4 patients with HIV and HCV and 21 with HCV only (all patients that previously were diagnosed with HCV had been successfully treated and the infection eradicated).

Delay/public health/other information

131. To the best of my recollection, all results of patients tested for HIV or had a serological or antibody or other tests for hepatitis (of all kinds) had their results explained to them as soon as reasonably practicable but usually within a week. To the best of my recollection, patients known to have NANB hepatitis who later had the HCV antibody test were informed of the positive result by the Haemophilia Nurse by telephone or in person. For patients infected with HIV, the results would have been explained to them direct or the patient's guardian (in the case of children) in person by a consultant haematologist and any information available at the time would have been passed to them. Any details of the date of such tests and the explanation given, if documented, would have been in patients' notes. I do not believe that there was any delay in patients being informed of these test results.

132. To the best of my recollection, my colleagues and I took into account the public health implications of BBV i.e. HBV, HIV and HCV once tests became available to diagnose such infections and information was available on their mode of transmission. Individual patients or guardians would have been advised to take appropriate measures with regard to the risk of transmission of such viruses (once diagnosed) to any other person including their partner, households, health

care workers dealing with the patient or their friendship groups and any other member of the public that could be put at risk. The above measures would not have had any detrimental impact at all or lead to a change to the decisions made for the care and treatment offered to these patients.

133. I can recall that information was provided to patients about the risk of other infections as it would have been known at the time and if documented would have been in patients' notes.

134. To the best of my recollection, the information provided to patients about infecting others would have been to those known to the health care profession at the time and would have included risks from sexual transmission, needle stick injury and any other known risk of transmission of that particular virus. Such information if documented would have been in patients' notes.

Consent

135. Frequency of blood tests for specific patients if documented would be in the relevant patients' notes. To the best of my recollection, all patients receiving regular treatment from the Swansea Haemophilia Centre would have had blood tests at 1-3 monthly intervals with their consent. Any blood test needed would have been requested after informing the patient of the purpose for example, to assess blood count, clotting factors level, inhibitor to coagulation factor, biochemical profile, immunology tests (CD4 counts and immunoglobulins) and virology tests that are provided on a separate virology test form. The blood test request forms would have been marked with the appropriate infection risk stickers, folded and given to the patient to take to phlebotomy. Some patients receiving home treatment preferred to collect the samples for testing themselves to avoid additional venepunctures. To the best of my recollection, samples were neither held nor stored by the Haemophilia centre for any other purpose.

136. During the time that I worked in Swansea and to the best of my knowledge no patient was ever treated in the Swansea Haemophilia Centre with Factor

concentrates or other blood products without their express or informed consent or the consent of their guardian being obtained first.

137. The purpose of the treatment would have been explained to the patient i.e. it could help them achieve a good level of clotting factors. This information and the consent provided verbally, if documented, would have been in the relevant patient's notes.

138. To the best of my knowledge, no patient was tested at the Centre for HIV or received a specific serology test for hepatitis or for any other purpose without the consent of the patient or guardian being obtained first after the purpose of the test was first explained.

PUPS

139. To the best of my knowledge, previously untreated patients (PUPS) would have been jointly managed by the Swansea and Cardiff Haemophilia services. These patients would have received a detailed assessment from the Swansea Haemophilia Centre which included pre-treatment virology tests. Once the outcome of the virology tests were known, they would have been treated using one product which would have been considered "safest" at the time for them. Initially, that would most probably be an NHS product. We would always have consulted the Haemophilia Centre in Cardiff over the choice of product given their specialist expertise to try to avoid or minimise the development of inhibitors.

Research

140. I did not participate in any Research Studies or epidemiological or similar studies in Haemophilia or Allied disorder during my time as a consultant haematologist in Swansea. I did, however, participate in data collection and annual returns provided to the National Register of patients with bleeding

disorders. I believe that the Register was first started in 1968. Later the Register was run by UKHCDO operating out of the Oxford Haemophilia Centre. Throughout its existence, Swansea Haemophilia Centre provided the data to UKHCDO as required to provide a full database for haemophilia and related disorders in the UK. To the best of my knowledge, all patients or guardians of patients with haemophilia and inherited bleeding disorders were informed about the database and their informed consent was obtained as soon as a diagnosis of inherited bleeding disorder was made. I also shared information with colleagues at other Centres who enquired about patients previously under their care. To the best of my recollection, I notified patients on or around the time that information was due to be shared. Such information included the wellbeing of such patients. I did not do this as part of any research project or epidemiological study it was merely part of the data collection as required by UKHCDO.

141. To the best of my knowledge no research study was undertaken by me in the Swansea Haemophilia Centre on inherited bleeding disorders. However, since 2005 it is possible that the Cardiff Haemophilia Centre may have sought consent for patients in Swansea to be included in research studies but I cannot recall the nature of such studies. I set out below my limited or lack of involvement in the following:

    a. I have had regard to the Clinical trial exemption application for 8Y Factor VIII at (OXUH0003657). The protocol for the trial on 8Y Factor VIII would have been put to the Local Medical Ethical Committee as required in the study. Section 1.1.2 of (OXUH0003657) states that contribution to this 2-year trial would potentially be sought from some or all of the other haemophilia centre directors under whose control various unspecified physicians may administer the product to the patient. I understand from section 1.2 more than 20 patients took part. Even though my name and the Hematology Department at Morriston hospital is mentioned under section 9 as a potential contributor, I do not recall, however, that any patient from Swansea was recruited in that trial. The UKHCDO would have the details of the patients recruited and the haemophilia centre that recruited the patients.

b. I note that the publication of, "*Mortality before and after HIV infection in the complete UK population of haemophiliacs*" in Nature, Vol 377, 7 September 1995 (PRSE0003657) was a study that scrutinised the death rates of those haemophiliacs infected with HIV during the 1970s. It states that it included the status of males in the UK with Haemophilia on the National register for Haemophiliacs from 1977-1991. The article further states that several smaller cohorts from the UK were included in the present study and their vital status was obtained from individual haemophilia centres and NHS Registers. I did not know about this letter in Nature prior to its publication, I did not directly contribute to the data summarised within it albeit data I supplied to UKHCDO may have been sent by UKHCDO to the authors. The UKHCDO acknowledged that all haemophilia centre directors had provided information which was collated in the database held by UKHCDO not that we contributed to this study directly. The Inquiry should note that this article is credited to the Sarah C. Darby et.al as the authors.

c. I have had regard to the Lancet Article published on 15 November 1997, "*Mortality from liver cancer and liver disease in haemophiliac men and boys in UK given blood products contaminated with hepatitis C*" (HCDO0000264_150). I had no previous knowledge of this article prior to its publication in the Lancet. The article is again, credited to the authors cited in the publication Sarah C. Darby et.al. Again I did not directly supply any data for inclusion in this article. The UKHCDO acknowledged the contribution of all Haemophilia Centres Director to the database held by UKHCDO.

d. The Haemophilia article published on 28 February 2001, "*Treatment of Haemophilia in the United Kingdom 1981-1996*" (HVDO0000012_173)- is credited to the authors cited in the publication C.R. Rizza, J.D Spooner and P.L.F Giangrande. I did not know about this article prior to its publication in the Haemophilia journal. The UKHCDO acknowledged the contribution of all haemophilia centres director to the database held by

UKHCDO. Again, I did not contribute any data directly to the authors, however UKHCDO may have supplied information from the annual returns I previously submitted to it.

142. My understanding of the ethical principles that should guide research are based on:

e. Protection of patients' rights.

f. Informed and express voluntary consent.

g. Independent approval.

h. Scientific/Medical basis.

i. Appropriate risk benefit.

j. The subject's wellbeing taking precedence over other considerations.

I believe that I applied these principles throughout my years of practice and that I underwent the appropriate training and certifications that were in place during the time I participated in research related to haematological cancers under the Medical Research Council and later the Cancer Institute.

143. I did not involve any patient under my care in any research study in Haemophilia. I took part in the Medical Research Council studies in Haematological Cancers as Haemato-oncology is my main sub-speciality. I did not, however, involve any patient under my care in any cancer research study without their express consent.

144. As stated above, I have not used patient data whether anonymised, de-identified or otherwise) for the purpose of research or for any other purpose without a patient's or their guardian's consent (as appropriate).

145. Patients' data was shared by the Swansea Haemophilia Centre with UKHCDO as agreed by all participating haemophilia centres in the United Kingdom since 1968. In the time I was the Director of the Haemophilia Centre in Swansea, I explained to patients at the time of the diagnosis that their data would be shared with UKHCDO and obtained their (or their guardian's) informed consent. I did not provide any patient data (whether anonymised, de-identified or otherwise) to Dr Craske of the Public Health Laboratory however information could have been provided by UKHCDO.

146. I have had regard to the letter from myself to Professor Lee at the Royal Free hospital dated 31 March 1998 (WITN2384026) in which I provided information about this patient to Professor Lee and Professor Lee's letter to me dated 7 April 1998 (WITN2384022). Mr Michael O'Driscoll was originally a patient under the care of Professor Lee in the Royal Free Hospital before his care was transferred to Swansea. Professor Lee wrote a letter to the Haemophilia Centre in Swansea on 25 March 1998 to enquire about Mr O'Driscoll and the progress of his HIV infection (see redacted version **[WITN3761016]**). She explained that she had been following and reporting on the natural history of cohorts of patients infected with HIV. She explained that she was still looking after GRO-A in the Royal Free Haemophilia Centre. She explained that half of the cohort she had been following had died and it was important that they chart the natural history in order to develop better knowledge and approach to care for haemophilia patients with HIV. Professor Lee did state in this letter that she would be happy to acknowledge my help in any future publication but I did not provide information for the purpose of publication and did not seek any credit for this. I have no knowledge of whether I am referred to in any paper or article produced by Professor Lee. I provided the information she requested in my letter of 31 March 1998 (WITN2384026) as the patient was known to her and she enquired about his wellbeing. I felt that any knowledge acquired by following the natural history and treatment of haemophilia patients infected with HIV could help in the management of Mr O'Driscoll, GRO-A and other patients with Haemophilia and HIV infection. I confirmed in this letter that the patient was well but he had severe hemophiliac arthropathy. I provided details of his CD4, CD8 and lymphocyte account and confirmed that he was on AZT/DDI medication

which the GU Physician with expertise in HIV started him on in November 1997. His main complaint, at the time, related to HIV was severe seborrheic dermatitis.

147. My recollection is different to that of Mr O'Driscoll. I do remember telling Mr O'Driscoll that Professor Lee was enquiring about him. I believe I mentioned this to Mr O'Driscoll when he called at the Centre to collect treatment or forms. If Mr O'Driscoll had said he was unhappy about any information being provided to Professor Lee I would not have gone against his wishes. I remember that I was rather proud that a small centre like Swansea was monitoring HIV infected patients with a regular CD4 count.

148. I wrote to Mr O'Driscoll on 20 September 2004 to provide him with a copy of the letter sent out to all patients that gave information about the possible risk of vCJD **[WITN3761017]**. The Haemophilia Centre in the Royal Free Hospital also wrote to me on 20 October 2004 to update our records with regard to vCJD and plasma product exercise (see section 9 below) and to inform me about the batch numbers and type of products that Mr O'Driscoll received when he was under their care. This helped the Haemophilia Centre in Swansea to decide whether Mr O'Driscoll would be in a low risk or a high risk category in relation to vCJD. The Royal Free Hospital wrote to me again on 18 November 2004 to confirm that Mr O'Driscoll and GRO-A had been notified by the Royal Free hospital that they were at risk of vCJD (see "Redacted letter from Royal Free hospital relating to Mr O'Driscoll" **[WITN3761018]**). This perhaps emphasises that Mr O'Driscoll's care was still being supported by the Royal Free Hospital even after his transfer to Swansea and that information would be shared with me as his treating consultant.

149. I neither co-authored nor had any prior knowledge of the following article quoted by the Inquiry "Falcao R.P., Ismael S.J & Donadi E.A. (1987), "*Age associated changes of T Lymphocytes subsets", Diagnostic and Clinical Immunology*,5, 205-208".One of the authors quoted, Ismael S. J, had a name that sounds similar to my family name but is definitely not my family name. The initials of that author are different to my initials as mine are Dr S Al-Ismail. I have seen this article subsequently when I requested a copy of the article from the

British Library on 20 July 2020. I found that the authors were from the Department of Clinical Medicine, School of Medicine, Ribeirao Preto, Brazil. Unfortunately, I cannot provide a copy of the digital reprint that I obtained as the Library Service informed me due to copyright issues:

"Please be aware that other than for patients, carers or guardians of patients, all copies made under the NHS Wales CLA license should only be made for NHS Wales' own internal information purposes."

I enclose a copy of the email dialogue with the British Library in this regard entitled *Article* **[WITN3761019]**. The Inquiry may wish to obtain a copy of this article direct from the British Library instead.

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

150. The first HIV clinical team established in Swansea around 1985 to monitor and look after HIV infected patients (including Swansea Haemophilia patients consisted of the GenitoUrinary ("GU") physician the late Dr Reif Cobbald, respiratory consultant physician, Dr John Banks and myself as the consultant haematologist. Dr K Yoganathan was appointed as a GU physician in 1994. Initially his services were to look after HIV infected patients attending the GU services. However, as he developed his services to encompass all HIV infected patients, I referred to him all HIV infected patients with haemophilia after having counselled patients first and sought their approval to be referred to Dr Yoganathan in the GU Department . Patients would have then been monitored clinically, haematologically, biochemically and immunologically with regular CD4 count.

151. To the best of my recollection, the treatment available for patients initially were AZT and Zidovudine. Later specific anti-retroviral therapy became available. Patients were informed about the nature and benefits of treatment and possible side effects as known at the time by the HIV clinical team.

152. Over time, I came to understand, from my involvement in the HIV Clinical team in Swansea that HIV therapy is crucial in HIV management which included the appointment of an HIV Pharmacist as an independent prescriber which resulted in further improvement. A recently published audit showed that 98.5% of the Centre's patients achieved complete HIV suppression (national average 71%). Dr Yoganathan's team informed me on or around 2018, that a further audit of HIV in pregnancy revealed that all of 61 babies born to HIV positive mothers under his care were HIV negative which is fully in line with British HIV Association standards. A counsellor from the Terence Higgins Trust attends the HIV clinic and helps HIV positive patients regarding benefits, safer sex practice and accommodation.

153. The information provided to patients about the risks and benefits of treatment would have been that known to me and my colleagues at the time. The information provided would be available in patients' notes if it was documented. The benefits we would have discussed with the patients centred around how the treatment could slow down the progress of the infection. The possible side effects were also explained in consultation as well as via leaflets provided by pharmacy on dispensing drugs to the patients.

154. Initially HIV patients attended the Haemophilia Centre for the monitoring of their HIV infection and discussed their treatment options with the HIV team (as set out above). Patients were assessed in the Haemophiliac clinics at regular intervals and had the option to drop into the Haemophilia Centre at other times if they needed to address any issues. On attendance, patients received clinical assessment and had blood tests including T-Lymphocytes subsets. The details of these tests can be found in individual patient notes. After the HIV regional services were established by Dr Yoganathan, all tests and treatment related to HIV infection were carried out by Dr Yoganathan' s team and communicated to the haematology team/Swansea Haemophilia Centre.

155. The Swansea Haemophilia Centre and HIV and HCV clinical teams worked with patients and families to notify them about how to manage HIV, and HCV. The relationship between the Centre and patients, families and their support groups

has been very positive. The Haemophilia Nurse, and my other senior colleague in the Haemophilia Centre in Swansea, Dr Beddall would have been informed of test results. The results were also shared with the lead Haemophilia Centre in Cardiff and with UKHCDO. The patient or guardian of the patient would have been informed and consented to information being shared. The patients were also consulted about switching their treatment to recombinant products, if this was considered appropriate, and their agreement sought when the allocation of recombinant products was available.

Care and Treatment of patients with HBV/NANB Hepatitis/HCV

156. As stated above at paragraph 128, prior to 2006, patients identified with HBV, or NANB Hepatitis (later identified as HCV) were referred for assessment and management to the consultant gastroenterologist Dr J. Kingham. After 2006 patients were referred for specialist treatment to Dr Chin Lye Ch'ng the consultant physician with a special interest in liver disease who headed up the Swansea BBV Service.

157. The BBV service(other than HIV) initially started with one gastroenterologist consultant who held weekly clinics and part-time Clinical Nurse Specialist ("CNS") based in Singleton Hospital. The service has since expanded to include up to potentially 4 CNS and a managerial role in light of the specialist service they provide.

158. There are now three consultant physicians in, Singleton Hospital; Neath/Port Talbot ("NPT") Hospitals and Princess of Wales ("POW") Hospital) managing patients with chronic viral hepatitis including HBV, HCV and NANB hepatitis within Swansea Bay including patients with bleeding disorders or those given infected blood. Patients in the three boroughs currently have easy access to the service. There are now clinics in Singleton, Morriston, NPT and POW Hospitals. They also provide community clinics in the Swansea area and including the Swansea and Parc prisons and they run a monthly Multi-Disciplinary Team ("MDT) (Physicians, Clinical Pharmacists, CNS with administrative support) to facilitate access to the right regimen of therapy.

159. The BBV/Hepatology service has liaised with the Haematology Department on a regular basis to offer treatment to haemophiliac patients infected with any form of hepatitis. Initially the service was treating about 50 patients a year (2017) including all infected patients with inherited bleeding disorders and those infected through infected blood products. The number has now increased to 200 patients a year. The service achieved its target for two years running, treating patients with HCV as set out in the All Wales Hepatitis C Treatment Roll Out Program.

160. General haematologists used interferons over the years to manage certain haematological cancers. Most general haematologists of my generation would have been very familiar with the different side effects of interferons. It is worth restating that there was no treatment for NANB Hepatitis prior to identification of the HCV virus and the Swansea Haemophilia Centre had no patients with haemophilia and an active HBV infection. NANB patients would have instead been advised to reduce or refrain from alcohol. When evidence became available that alpha interferon was an option for treatment, it was offered to HCV patients. The side effects of interferon would have been explained. Some patients declined the treatment based on that while others accepted it. The Swansea Haemophilia Centre referred all patients that would have received pegylated interferon and ribavirin, which had more serious side effects, to the Haemophilia Centre in Cardiff or to the Hepatology service in Swansea as this would have been more intensive treatment. HCV patients would have been offered treatment with interferon, until ribavirin became available but they unfortunately have a lot of significant and sometime serious side effects (which I set out below).

161. The Hepatology department acquired a Fibroscan within the last 3-5 years, a non-invasive scan to assess patients with hepatitis and liver disease prior to treatment, during and post treatment for their condition. The therapy landscape has changed over the last decade with new therapies now available. The new therapies (known as direct acting anti-viral agents) can achieve eradication of viral HCV with a near 100% success rate. Only 8 to 12 weeks of treatment is

required and the therapy is now pan-genotypic i.e. regardless of the genotype of HCV, the treatment offers near 100% eradication rate. There is also no need to use ribavirin and interferon medication, which would have been traditionally offered to hepatitis patients. Since the introduction of new antiviral therapy for HCV, all patients in Swansea that needed the treatment were offered the new treatment and accepted it. Currently there are no patients with haemophilia in Swansea with active HCV.

162. The Hepatology service works closely with other departments in secondary care, primary care physicians, homeless health, Genito-Urinary Medicine (GUM) clinic, Integrated Sexual health clinics, and community drug and alcohol teams to link patients with chronic viral hepatitis for care. All, treatment options offered to individual patients would have been documented in patients' notes.

163. The risk and benefits of any specific treatment offered to an individual patient, if documented, would be in patients' notes. It is worth restating that the Swansea Haemophilia Centre were not treating any patient with an active HBV and there was no specific treatment for NANB until HCV was identified. A discussion about the benefits, since the introduction of new antiviral therapy for HCV, was had and all patients in Swansea that needed the treatment were offered the new treatment and accepted it. Currently there are no patient with haemophilia in Swansea with active HCV. Discussion would have centred on how treatment could slow down the progress of the infection. There would also have been a detailed discussion on the risks related to the possible side effects. This would have been discussed with the patient by the treating consultant and included in the leaflet that was given by the pharmacy service on dispensing the treatment. The only treatment that would have been prescribed by the Swansea Haemophilia Service to patients under the guidance of gastroenterologists was alpha Interferon. The benefit was that it could successfully clear the HCV. The side effects could range from flu like symptoms to extreme lethargy, mood changes, depression of bone marrow function etc. As I explained above, some patients with HCV infection refused treatment with Interferon after explaining the possible side effects. I did not recall initiating pegylated interferon and Ribavirin treatment myself for any patient with HCV. Such treatment would have

been prescribed by the Cardiff Haemophilia Centre or a consultant hepatologist in Swansea as this would have been more intensive treatment. I am aware that Ribavirin can cause haemolytic anaemia, a very low level of red blood cells.

164. As the Swansea Haemophilia Centre had no patients with HBV, it had no involvement in the follow up and/or ongoing monitoring of the treatment of HBV. Follow ups in relation to hepatitis care (in relation to HCV) were arranged by the gastroenterologist or consultant physician with expertise in liver disease managing the hepatitis in individual patients. Patients being treated with alpha interferon were monitored by the Haemophilia Centre initially before their treatment for HCV was led by the Gastroenterologist/hepatologist in Swansea.

165. Given the passage of time since the UKHCDO Meeting of 18 September 1992 (HCDO0000248_013) I cannot recall the specific details of that meeting except what I have subsequently read in the minutes provided by the Blood Inquiry. The minutes reflect me asking for recommendations for treatment of patients who had HCV presumably, as this was not clear at the time (however I cannot say for certain). The minutes further indicate that one doctor said they use interferon and Professor Bloom agreed. A paper recommended the use of alpha interferon. Any recommendation for the management of hepatitis for any patients treated by the Swansea Haemophilia Service, I believe, would have been determined after discussing the issue with Dr Kingham as he was the lead clinician for managing hepatitis in Swansea at the time or with the Haemophilia Centre in Cardiff.

166. I have had regard to pages 139 to 143 of the oral evidence transcript of Mr Michael O'Driscoll from 30 October 2019. To the best of my recollection I would not have described the side effect of a drug like Interferon as simply just "mild flu-like symptoms". On a balance of probabilities, I think it was more likely that I said, "*the most common side effect could be flu like symptoms but patients may experience much more severe side effects*". I usually explain to any patient to be started on any medication that the side effect of any particular drugs varies between patients. I would explain the common effects and the not so common as well as the more serious side effects. This is good practice. The source of

information relating to interferon would have been the Chronic Hepatitis article published in the Blood Review 1993 **[WITN3761012]** which recommended alpha interferon. The Chronic Hepatitis article indicates that, in an uncontrolled study, 8 out of 10 patients treated with recombinant alpha interferon given three times a weekly had normalised their previously persistent abnormal transaminases enzymes. I also would have referred the patient to the leaflet dispensed with the drug and suggested that the patient talk to other patients within the Haemophilia Society and other support groups. I explained to patients under my care that the decision to continue with any medication or to stop it was their choice and theirs only. I usually also explain that I view the role of a clinician looking after a patient is to give enough information to empower a patient and their carer to take a decision about the management of the patient's condition and their decision would be respected by me and the haematology team.

167. I reviewed Mr O'Driscoll on 21 April 1994 and explained the abnormal liver function tests he had as demonstrated by my handwritten notes **[WITN3761020]**. I explained that interferon was an option and stated in the notes "*Explained the rationale behind interferon and possible benefits and side effects*". Then the out-patients note stated "*...wanted to start on interferon*". The letter I sent to the West Cross Medical Centre dated 21 April 1994 also part of **[WITN3761020]** indicated that I discussed the ins and outs of interferon treatment with the patient and he expressed a wish to start on this. He was started on alpha interferon. That is given three times a week. He was reviewed in the out-patient clinic on a regular basis. I recall that he maintained that he did not have any significant side effects.

168. In 2002/2003, Mr O'Driscoll was referred to Cardiff Haemophilia Centre where he was offered treatment with pegylated interferon plus Ribavirin. Professor Peter Collins informed me at that time that he completed a fourteen-week course but he did not respond fully and it did not clear the HCV. Professor Collins may be able to provide further information about that treatment. I believe full details about the severe side effects of this medication would have been explained to him prior to his decision to accept this treatment.

169. I have had regard to the letter I sent to Dr Kingham on 17 April 2003 (WITN3691021) which was a referral for him to see the patient mentioned in the letter and for Dr Kingham, as the specialist for Hepatology services in Swansea, to counsel the patient about the need for treatment with Interferon or otherwise. I enclose a copy of the Review Article entitled *Guidelines on the diagnosis, management and prevention of hepatitis in haemophilia* (2001), 7, 339±345 ("the Guidelines") **[WITN3761021]**. The Guidelines included *inter alia* guidance for diagnoses of HCV, sexual transmission, testing of sexual partners for HCV, follow up, treatment and co-infection with HIV which I referred to in my letter. I would have discussed with the patient what the guidelines said and sought his consent to be referred before I made the referral to Dr Kingham. I note that Dr Kingham has written by hand "OPD-Soon". That note was intended for his team to ask the patient to attend his outpatient clinic. The notes of the patient would probably provide further detail about the counselling he received from the Hepatology team.

170. The letter from Dr Kochar dated 22 September 2003 (WITN3691011) is in fact about the same patient that was referred to in my letter to Dr Kingham 17 April 2003 (WITN3691020). The patient was seen in Dr Kingham's outpatient clinic on 22 September 2003 by the specialist registrar in gastroenterology, Dr Kochar. The Hepatology team checked the HCV viral load and performed the other tests as stated in the letter. My understanding of Dr Kochar and Dr Kingham's "wait and see policy" rather than to offer him treatment, which is referred to in the letter, is to monitor the patient for viral load and liver tests. The letter indicates that Dr Kochar and Dr Kingham suspect that the patient had had chronic HCV for 20 years but he had no enzymatic abnormalities or significant signs of symptoms pertaining to liver damage. I expect that the decision and management plan, i.e. the outcome of the referral for HCV would have been communicated to the patient by Dr Kingham and his team. If that was done and documented by the Hepatology Team, it would probably be in patients' notes. Alternatively, it may be open to the Inquiry Team to request further information from the Hepatology Team.

171. HCV patients were followed up initially and prescribed interferon in the Swansea Haemophilia Centre. Later as the Hepatology service took over all the care for patients with HCV, any follow ups were undertaken entirely by the Hepatology team and would have been documented in hospital notes. Some patients received their treatment in Cardiff. Either Dr Kingham or later Dr Chin Lye's team would arrange the follow-up and monitoring of patients with HCV in the gastroenterology department. Letters from the Haemophilia team to the Hepatology team and vice versa would have been sent to ensure that certain treatment or health issues were addressed by the respective department

172. To the best of my knowledge, the haematology team in Swansea was not involved with any clinical trial in relation to treatment for HIV and HCV.

173. For children infected with HIV and/or Hepatitis to the best of my recollection these children would have been referred to the HIV services and the Paediatric Services in Swansea. Details would be in individual patients' notes. I did not treat any child with haemophilia and HCV, and unfortunately the two children with HIV and haemophilia died before any treatment was available for HIV. To the best of my knowledge, children with HIV would have been treated as outlined above at paragraphs 103 to 111.

174. Prior to commencement of full Hepatology services and Regional HIV services in Swansea, Haemophilia patients infected with BBV were looked after jointly by the Haemophilia Centres in Swansea and Cardiff (with Cardiff taking the lead on treatment options etc). However, consultant haematologists and haemophilia specialist nurses in both Swansea and Cardiff offered counselling services to the Swansea Haemophilia Centre patients. In 2014, a part-time psychologist was appointed in Swansea. The Haematology Department in Swansea had a social worker who provided support to haematology in-patients on the haematology ward in Singleton Hospital. Most of those in-patients had haematological malignancy and conditions other than haemophilia. However, the haematology social worker, when she was in post, also offered some haemophilia patients social care support. Patients with haemophilia infected

with BBV in Swansea called on the support of the Hepatology services and HIV services in Swansea when they attended these specialised services.

175. In 2011 a Ministerial Task and Finish Group was established to review the services of people with inherited bleeding disorders in Wales. It recommended a further consultant haematologist specialising in bleeding disorders be appointed in Swansea and the appointment of part-time psychologists and part-time physiotherapist to the Haemophilia Centre in Swansea. The latter two part-time posts were appointed in 2014 **[WITN3761007]**.

176. To the best of my knowledge, the Haemophilia Centre in Swansea was not allocated specific resources to help with the counselling of patients with haemophilia infected with HIV and/or hepatitis until 2014, after the Task and Finish Group recommendations from 2011 were implemented (see further below).

177. Until the appointment of part time psychologists for the Haemophilia Services in Swansea, the counselling services available to patients with haemophilia infected with BBV were as set out in paragraph 174 above.

178. Before 2011 there was no separate funding for the Haemophilia Centre to treat patients who had been infected with HIV and/or HCV. The Haemophilia Centre therefore relied on the support of the HIV and Hepatology services (which may have received special funding) in Swansea to look after patients with Haemophilia infected with BBV. It was not until 2011 that the Ministerial Task and Finish Group recommended additional funding to the Centre for a further Consultant Haematologist specialising in bleeding disorders in Swansea and the appointment of a part-time Psychologist and Physiotherapist specifically for the treatment of those who had been infected with HIV and/or HCV. This was implemented in 2014.

Records

179. To the best of my knowledge, the Haemophilia Centre in Swansea did not have a specific policy or practice for recording information on death certificates for patients infected with HIV or hepatitis. To the best of my knowledge, such infections were recorded on the death certificate appropriately.

180. The Haemophilia Centre in Swansea had no separate or specific retention policy for records. The Centre followed the retention policy of the WGHA / the Swansea NHS Trust and/or the ABMU Health Board, the Swansea Bay University Health Board at the time the Centre operated under these organisations. I believe records were retained at the Centre for up to eight years after the death of the patient or the last contact and thereafter would have been destroyed.

181. Notes for patients with Haemophilia and inherited bleeding disorders were kept in the Haemophilia Centre and were accessible at all times by all services whenever needed. These notes were kept safe by a combination lock. The Centre kept handwritten records of home treatment and hospital treatment in the early and mid-1980s and then electronically to provide the data needed by UKHCDO and the Health Board finance department. I did not maintain separate files for any patients.

182. I did not keep any records or information about my patients in my home or any place other than the Haemophilia Centre and Hospital services. All information about any of my patients are those available in the Swansea Haemophilia Centre and held at Singleton Hospital or those held by Swansea Bay University Health Board's IT systems. I do not hold any records or information relating to any of my previous patients separate to this.

Section 5: Self –Sufficiency

183. If the Department of Health announced in 1974 additional funding would be made available for the primary aim of making the NHS self-sufficient in Factor VIII blood products over the next few years in the UK, this was well before I was

appointed as a consultant haematologist in 1982. To the extent that I am able I can confirm the following:

a. I am not certain as to when I first became aware of the Department of Health's aim however, that awareness most probably developed after I was appointed as a consultant haematologist.

b. My understanding of the term "self-sufficiency" in this context was that the UK wanted to be able to collect enough blood donations in the UK and be able to process them within the UK to provide the UK population with all of its need for blood and blood products including coagulation factors concentrates for whatever treatment needs (whether that be replacement therapy for haemophilia, blood transfusions for anaemia , surgery etc) that could arise. I do not recall whether others or myself considered the UK was aiming to become self-sufficient in Factor VIII products prophylactically or solely in response to bleeding incidents. My guess would be that the UK wanted to have sufficient supplies such that it could respond to any need for blood products without relying on products from outside the UK.

c. I am not sure whether my understanding changed over time or not.

d. I do not know how others may have defined self-sufficiency as I did not discuss this with others.

e. I had no role in any arrangements or initiatives designed to help achieve self-sufficiency for Factor VIII or blood products within the UK.

184. I set out below the knowledge I have of how estimates were made of how much Factor VIII blood products would be required for use in England and Wales.

a. The directors of haemophilia centres provided figures for the usage of different coagulation factors in their respective centres to UKHCDO. I am not aware of any other role of a director of a centre had in making

estimates needed to plan for self-sufficiency or how this changed over time.

b. I did not have a specific role in making estimates needed to plan for self-sufficiency other than providing the annual data of use in Swansea as requested by UKHCDO.

c. The role of the UKHCDO was explained well in the paper entitled: *Treatment of haemophilia in the United Kingdom 1981-1996* ; C.R. Rizza, R.J.D Spooner and P.L.F. Giangrande ; Haemophilia (2001), 7 , 349-359 ("UK Haemophilia treatment paper 1981-1996")(HCDO0000012-173). This paper provides data at page 353 which was collated by UKHCDO relating to the increase in use of blood products: "*There has been a consistent rise each year of approximately 10% in the usage of both FVIII and FIX. A total of 63.2 million units were used in 1981 to treat Haemophilia A patients but consumption had risen to 149.7 million units by 1996...Factor IX consumption rose from 9.9 million units to 23.2 million over the same period."* The annual report of UKHCDO showed the number of patients, Haemophilia severity, the annual rise in the use of products including concentrates and Cryoprecipitate. I enclose extracts from *the UKHCDO Annual Report 2018* ("2018 Annual report") **[WITN3761022]** which included Factor VIII units issued by UK haemophilia centres to treat haemophilia A 1973 - 2017/18 and Market share of Factor VIII concentrates issued by UK haemophilia centres. These figures then help to build a good forecast on the likely demand of blood products in the short, medium and long term. UKHCDO's role changed over time in terms of analysing data and over time it sought more information and produced more guidance and understanding to help with planning of short, medium and long term for haemophiliacs.

d. I am not sure as to all assumptions that were used to underpin the estimates. However, I believe it could have included the yield from blood

donations, the loss of potency during processing and the increasing yearly demands for haemophilia concentrates.

e. I do not know how exactly the estimates were made, who made them, when were they were made or the process for making them.

f. I do not know how the estimates were shared with other interested parties such as the Department of Health.

g. I do not know how any of the above processes changed over time.

185. I believe that UKHCDO produced the annual figure of the usage of Factor VIII concentrates and other products. I believe that UKHCDO derived this figure from the data collected regarding usage of Factor VIII products from the haemophilia centres in the UK.

a. The haemophilia centre directors provided to UKHCDO the details of usage as well as details relating to untoward events, such as the development of inhibitors by patients. These figures were provided initially in paper format then changed to electronic submissions over time.

b. My role was to check on the figures collected by the MLSOs and later by the Haemophilia Nurse in the Haematology Department and ensure that they were provided to UKHCDO in a timely manner.

c. The role of the UKHCDO was explained well in the "UK Haemophilia treatment paper 1981-1996") (HCDO0000012-173). The paper states that every year information is collected regarding patients who had received treatment during the year including the type of blood products used and inhibitor status. Data was also collected on the date and cause of death. A card was sent from the Oxford Haemophilia Centre to every other Haemophilia Centre every 3 months requesting details of any adverse events including viral transmission, developing of an inhibitor,

thrombotic event or allergic reactions to concentrate. Please see paragraph 184.c above for a summary of the information contained within this paper relating to the increase in demand for Factor VIII and Factor IX blood products. There was been no change in UKHCDO's role other than over time they have asked for more details and provided more information and produced more guidance.

d. Prior to 1987, the figures for coagulation factor concentrates and Cryoprecipitate in Swansea were initially collected by the MLSOs in the Haematology Department as they kept records and stocks of factor concentrates, Cryoprecipitate used by individual patients and the coagulation factor concentrates in the Blood Bank in Morriston Hospital. The Haemophilia nurse took over this role when appointed in 1987.

e. The UKHCDO is the body that can provide the details of how the figures supplied by the Haemophilia Centres were broken down by county, region or any other unit as I am not aware of this information.

f. The UKHCDO provided an annual summary on all the figures collected to the Directors of Haemophilia Centres. I do not know how UKHCDO shared the figures with others apart from Haemophilia Centres, however I suspect it would have shared figures with the Department of Health.

g. I do not know how any of the above processes changed over time. Please direct this question to the UKHCDO.

186. I do not know whether there were significant differences between the estimates that were made and actual usage as this was not within my knowledge.

187. The information I can provide relating to whether England and Wales achieved self-sufficiency of Factor VIII blood products is as follows:

a. I believe that it is accurate to state that England and Wales never achieved self-sufficiency of Factor VIII products as clinicians were reliant

on commercially imported products from abroad to meet the actual demand of patients for such products.

b. I believe that several factors contributed to the lack of ability to achieve self-sufficiency due to:

    i. An insufficient number of donations of blood were obtained;

    ii. An insufficient yield from individual donations;

    iii. The loss of potency during manufacturing;

    iv. The capacity of processing facilities;

    v. The rising demand for concentrates;

    vi. The advent of vCJD in the UK and its effect on avoiding plasma collected in the UK.

c. As stated above, in my view, self-sufficiency was never achieved.

I believe that haemophilia clinicians provided accurate data of usage of coagulation products for the management of patients in their establishments to UKHCDO in a timely manner. We provided accurate details of adverse events to UKHCDO every three months as well as the annual returns. The data provided by us showed there was a progressive increase in the demand for products on an annual basis. This is data that would have been included in the UKHCDO's annual report. I honestly cannot see any shortfalls in haemophilia's clinicians efforts to assist in planning the need for blood products in short, medium and long term basis.

188. I think if self-sufficiency in Factor VIII products was achieved, all donations would have been UK sourced from voluntary donors which would result in less risk of transmission of BBV. Therefore, it is possible that that the number of

patients infected with either HBV, HCV or HIV would have been less. I do not know the answer as to when self-sufficiency would have needed to be achieved in order for any material difference to have been made in respect of each of the above viral infections.

189. I have no knowledge of whether England and Wales achieved self-sufficiency in respect of Factor IX blood products.

190. If self-sufficiency would have been achieved in relation to Factor IX concentrates, I would not have used commercial products until the advent of recombinant concentrates which are not human derived and therefore pose less risk of contamination.

191. I have had regard to the minutes of the 21 September 1990 UKHCDO meeting (HCDO0000015_021) and page 3 in particular, which mentions Professor Bloom's comments on self-sufficiency and the Department of Health being pushed to import blood products. The Haemophilia Centre in Swansea was guided by the Haemophilia Centre in Cardiff in relation to the policies it adopted and the products used. However from when I started working in Swansea in 1982 and even after, I did not think that the Haemophilia Centre Directors and the Haemophilia Society were urging the Department of Health to purchase imported blood products. I do not know of other Haemophilia Centres pushing for the purchase of imported products.

192. I believe that when Professor Bloom stated that "everyone knew the result of..." importing products that he was reminding the audience and the haemophilia directors at that meeting the lessons learned from using imported products to treat patients with haemophilia i.e. that some products were sourced from high risk paid donors and the result was increased transmission of BBV to patients.

Section 6: Blood services, BPL, and PFL

193. During the time I was a consultant haematologist, initially the Blood Transfusion Service in Wales, later named Welsh Blood Services, provided support for the

patients in Swansea in terms of blood and blood products. I did not have any regular interactions with the BPL or the Plasma Fractionation Laboratory ("PFL") during the time that I worked at the Haemophilia Centre other than receipt of updates on their products.

194. I do not know if any consideration was given by UKHCDO, the Department of Health or other organisations as to increasing production of Cryoprecipitate, or producing a product with lower risk, in light of any risks associated with factor products. It is probably worth reiterating that Cryoprecipitate was mainly used to treat those with mild or moderate haemophilia and Von Willebrand disease. I had no involvement with any blood services, BPL or PFL in relation to the production of Cryoprecipitate at all.

195. Updates about the risk of infection from blood products was communicated to me by the Cardiff Haemophilia Centre and I gained further knowledge via peer reviewed publications, attending scientific meetings, UKHCDO and discussions with colleagues in Cardiff and other centres. I relied on the Blood Transfusion Service/Welsh Blood Service in providing blood and blood products for my patients. I did not have any direct interaction with BPL or PFL. To the best of my knowledge, I did not have any discussions or meetings with any blood service (regionally or nationally) and/or BPL/PFL in relation to:

    a. The risk of infection with hepatitis from blood products;

    b. The risk of infection from HIV/AIDS from blood products;

    c. The steps to be taken to reduce the risk of infections.

196. To the best of my knowledge, I had no involvement with any decisions or actions taken by any blood service (regional or national) and/or BPL/PFL in response to the risks arising from blood and blood products. Albeit, as stated above, I did receive updates from the Blood Transfusion Service/Welsh Blood Service about the services or products they provided.

197. I have reviewed the letter from Dr Napier of the National Blood Transfusion Service (Wales) to Professor Bloom, Dr H Jones, a Consultant Haematologist at Cardiff Royal Infirmary and myself dated 29 January 1985 (BPLL0001351_011). I note that Dr Napier stated he had (previously) circulated to each of us a copy of a letter from Mr N Pettett (from BPL) dated 14 December 1984 concerning supplies of non-heat treated Factor VIII material. Given the passage of time, I cannot recall this letter at the time or whether the Swansea Haemophilia Centre required non-heat treated Factor VIII during this period. However, Dr Napier suggests in this letter that as he had not heard from us that he assumed that the supplies of non-heat treated material were not required in the Welsh region and also that we were happy to use heat treated materials as and when it became available as described in the letter from Mr Pettett dated 23 January 1985 which was also enclosed. This suggests to me that perhaps the Swansea Haemophilia Centre has not requested non-heat treated products.

198. I have already referred to my letter of 11 April 1985 (BPLL0002378_003) to Dr Napier in paragraph 91 and as I explained before, the Haemophilia Centre in Swansea followed the advice given to it by the main Haemophilia Centre in Cardiff and by the lead in Haemophilia in Wales at the time, the late Professor Bloom. I therefore followed the criteria communicated to me, namely, mildly affected patients, those under 20 and children to ensure that patients not previously exposed to infected concentrates should be given priority to receive NHS heat-treated products if they needed such products. Heating up blood products to higher temperatures tended to be more effective in killing viruses however, this could lead to a reduction in clotting-factor potency.

199. The Haematology Department in Swansea kept records of blood and blood products used to treat an individual patient in the patient's hospital notes, the blood bank and in the case of haemophiliac patients, the Haemophilia Centre to provide updates to UKHCDO.

Section 7: UKHCDO

200. I was a member of UKHCDO from 1985 as I was the Director of Swansea Haemophilia Centre. I did not participate in or work on any of its working parties, committees or groups. My involvement with UKHCDO related to providing the information requested from all haemophilia centre directors and I attended some of the UKHCDO meetings.

201. During the period that I was involved with UKHCDO I can confirm the following:

    a. The purpose, functions and responsibilities of the UKHCDO is explained well in UK Haemophilia treatment paper 1981-1996 (HCDO0000012-173). The UKHCDO was established in 1991. Its purpose and function was to update the national database relating to haemophiliacs which provided an invaluable tool for gathering and disseminating information that guided the care for patients. It was responsible for developing important understanding of the clinical and therapeutic issues and challenges in providing a good level of care to patients with haemophilia and other inherited or acquired bleeding disorders. The UKHCDO produced valuable publications and guidance to help direct the care of haemophilia and allied disorders in the UK.

    b. I was not involved with any of UKHCDO's various committees or working groups. However, my understanding was that they collected information and data that helped direct the care of patients. An example of such working groups included the HIV group, Hepatitis Group, Inhibitor Group Data Analysis group etc. I enclose further extracts from the 2018 Annual report including the contents page – which lists out various working parties and groups and a redacted copy of the Data Analysis group report **[WITN3761023]**. This indicates that the Data Analysis Group was a subgroup of the Data Management working Party and its role was to assess and prioritise applications to analyse data. The group met once a month by teleconference from April 2017 onwards. It provided feedback to the applicant and worked with them to refine their proposal.

Guidelines were produced by the various committees and working groups and these were published and disseminated once approved by UKHCDO. I attended some of the meetings of UKHCDO and followed their publications and guidance. I have no in-depth knowledge of the structure or composition of such committees or working groups however I am aware that they would meet on a regular basis to determine how they could collate data and produce a final outcome.

c. I am not aware of a relationship between UKHCDO and pharmaceutical companies.

d. In the meetings I attended, decisions were made after discussions on various topics and were based on the consensus of members.

e. The UKHCDO used to disseminate advice and guidance by sending minutes of its meetings, and information about the findings or conclusions of its working groups and producing guidelines. These and other information were posted to directors in the early years. Later on this information was provided electronically by e-mails. They also started producing an Annual book about all the information they had gathered.

f. I was not involved in producing any of the policies, guidance, actions or decisions of UKHCDO which may have been disseminated to all directors of the haemophilia centres or any other third parties such as the Department of Health.

202. I have had regard to the letter I sent to Professor Bloom on 16 July 1986 which is contained within (CVHB0000004_126). This letter indicates that I stated that I had missed the Haemophilia reference Centre Director AIDS group meeting. It is worth pointing out that Swansea is a Haemophilia Centre and not a Haemophilia Reference Centre unlike the Cardiff Reference Haemophilia Centre (later named Cardiff Comprehensive Haemophilia Care Centre). I did not work as a member of the Reference Centre Directors' AIDS Group. I cannot recall whether I was invited to the meeting referred to above and could not

attend or whether my reply to Professor Bloom was an error, in the sense, I may have thought he was referring to the Haemophilia Centre Directors Meeting and not Haemophilia Reference Centre's meeting. The Infected Blood Inquiry Team may need to look in the minutes of that meeting and assess whether I was expected to attend the meeting and if so in what capacity. I do not have any documents relating to the Haemophilia Reference Centre Directors' AIDS group meeting or any other Reference Centre Directors' meetings as I was not involved in any of these.

Section 8: Pharmaceutical companies/medical research/ clinical trials

203. I have not provided advice or consultancy services to any pharmaceutical company involved in the manufacture and/or sale of blood products.

204. In light of my response above, I have neither been offered nor received any pecuniary gain as I have never performed an advisory/consultancy role for a pharmaceutical company involved in the manufacture or sale of blood products.

205. I have never sat on an advisory panel, board, committee or similar body of any pharmaceutical company involved in the manufacture or sale of blood products. Accordingly, I would never have received any financial or other remuneration for this.

206. I have not received any financial on non-financial incentives from pharmaceutical companies to use certain blood products.

207. To the best of my knowledge, I have not received any funding to prescribe, supply, administer, recommend, buy or sell any blood products from a pharmaceutical company. The specific blood products given to individual patients was always undertaken upon the recommendation of Professor Bloom from the Cardiff Haemophilia Centre given his specialist expertise in the area.

208. I cannot recall the regulations or requirements or guidelines that were in place concerning declaratory procedures for involvement with a pharmaceutical

company. As I explained above, and to the best of my recollection and knowledge, I was not involved in any such activities and therefore these were not likely to be at the forefront of my mind as I did not need to take steps to comply with them. I cannot recall either any colleagues declaring any involvement with pharmaceutical companies at any UKHCDO or other Haemophilia meetings I attended.

209. To the best of my knowledge, I have not undertaken medical research for or on behalf of, or in association with a pharmaceutical company involved in the manufacture or sale of blood products.

210. The only research work I have been directly involved in, during my career, related to blood cancers and were research projects run by the Medical Research Council and Cancer Research Institute. These included different Acute Myeloid Leukaemia studies in Adult patient (AML trials) and trials in Multiple Myeloma and myeloproliferative and lymphoproliferative diseases. To the best of my knowledge, I have never provided a pharmaceutical company with results from medical research studies that I was involved in, in the field of blood cancers and I have not been directly involved in any research projects or studies relating to haemophilia at all.

211. As I have never provided pharmaceutical companies with results from blood cancer research studies I have been involved in, accordingly I have not received any funding from them.

Section 9: vCJD

212. I cannot recall exactly when I first found out about the risks of transmission of vCJD associated with the use of blood and blood products but I do recall it was in relation to a patient notification exercise. The information I received through official channels in relation to vCJD were mainly from UKHCDO. It included information jointly provided by: the National Public Health Services for Wales, Health Protection Agency, Scottish Centre for Environmental Health, NHS National Services of Scotland and Directorate of Health, Social Services and

Public Safety. There is a large hard copy folder in the Haemophilia Centre in Singleton Hospital and I scanned some of the information there (which are exhibited below). The details of the communications from UKHCDO included an action plan and protocols to inform patients or their guardians, General Practitioners of patients and colleagues in secondary care. The full details and timelines of these letters by UKHCDO to Haemophilia Directors and actions plans set by UKHCDO should be available, I would have thought, from UKHCDO files.

213. The decisions relating to the information that should be provided to patients was communicated to haemophilia centre directors and made by UKHCDO in response to different announcements made by the Government, Public Health bodies in England, Scotland and Wales and by BPL and BFL. Initial communications were made on or around 2001. Then UKHCDO sent letters to Haemophilia Centre Directors on 7 September 2004 entitled *Variant Creutzfeldt-Jakob Disease (vCJD) and Plasma Products* ("7 September 2004 letter) and 9 September 2004 entitled *Notification of patients with haemophilia and bleeding disorders of the changed perception of risk of vCJD by British sourced plasma products and institution of health protection measures* ("9 September 2004 letter") **[WITN3761024]** giving information about the risk of transmission of vCJD associated with the use of blood and blood products and providing an action plan to inform patients and health care workers of their responsibilities.

214. In the 7 September 2004 letter the UKHCDO stated "*... that patients who are exposed to a 1% or greater potential additional risk of infection, should be considered 'at-risk' of vCJD for public health purposes (i.e. certain special precautions need to be taken to reduce any possible risk of onward transmission of vCJD). Treatment with UK-sourced factor VIII (here the plasma concentrate used in the manufacturing process has been implicated), factor IX...is highly likely to expose patients to this potential additional risk. This is because a single dose of these products, as used in clinical practice is estimated to contain sufficient potential vCJD infectivity to cross the 1% threshold."* The 7 September letter asked us to inform patients that they should inform any clinicians and other healthcare professionals with whom they have dealings of their 'at-risk' status,

so that special infection control precautions can be taken before surgery and other invasive procedures should they require future medical care.

215. The 9 September 2004 letter asked all Haemophilia doctors in the UK to read the letter to clinicians and post letters to patients including patient information sheets by first class post before 20 September 2004 and enclosed a template letter for this purpose. The Haemophilia Centre in Swansea acted on all action plans received in a timely manner and provided letters and leaflets to patients which identified the risks (see further below). I believe that there could have been earlier communications from UKHCDO about vCJD in 2001 and 2002, however I do not have a copy of these. I do however have a copy of a memorandum I sent to colleagues on 21 June 2002 entitled *Variant CJD* which states that there was no national policy as to the precautions needed to deal with surgery and surgical instruments used in operations on such patients. However, future surgery would need to be discussed with the microbiologist as well as the surgeon involved and the Variant CJD Panel in Edinburgh **[WITN3761025]**. The content of this memorandum would have been guided by information received by UKHCDO and others. The Infected Blood Inquiry may wish to approach UKHCDO for a full list of communications sent to the Haemophilia Centres including Swansea Haemophilia Centre.

216. I enclose some of the other communications I received from UKHCDO and others **[WITN3761026]**. These comprise the following:

a. An email from the then Chair of UKHCDO dated 14 November 2006 entitled *Variant Creutzfeldt-Jakob disease (vCJD) and plasma products* 2006;

b. A letter to UK Haemophilia Centre doctors from UKHCDO entitled *Variant Creutzfeldt-Jakob disease (vCJD) and plasma products* dated November 2006. This indicated that a batch of Factor VIII and a batch of Factor IX was manufactured using plasma including that from donors who later developed vCJD;

c. A UKHCDO publication entitled *Variant Creutzfeldt-Jakob disease (vCJD) and plasma products* – Clinical Information November 2006;

d. A copy of the Health Protection Agency letter to Medical Directors of Trusts entitled *Variant Creutzfeldt-Jakob disease (vCJD) and plasma products: look back and patient notification* dated November 2006;

e. A Health Protection Agency leaflet entitled *Variant Creutzfeldt-Jakob Disease and clotting factors* dated November 2006 ("Health Protection Agency leaflet"); and

f. A Health Protection Agency and Health Protection Scotland leaflet entitled *Information for people who have an increased risk of CJD* dated February 2009 ("Health Protection Agency/Health Protection Scotland leaflet").

217. I have had regard to the incomplete draft letter purported to be dated February 2009 for patients which provides further detail of a haemophilia patient who died of unrelated issues yet tested positive at post mortem for vCJD ("February 2009 letter")(ARCH0000202).This letter is one of several sent to patients or guardians and was based on the recommendations of UKHCDO. Please see earlier letters sent to patients and guardians on 20 September 2004 entitled *Important Information – Variant Creutzfeldt-Jakob disease (vCJD) and Plasma Products* ("20 September 2004 letter") **[WITN3761027]** (page 4). It read:

"Does this affect my care?

If you are 'at-risk' of vCJD for public health purposes, your clinical care should not be compromised in any way. Healthcare professionals need to know you are 'at-risk' so that if any surgical instruments are used in your care they can be treated differently."

218. The intention behind the statement in the February 2009 letter (ARCH0000202) that the information would not change the way patients would be treated, was to assure patients and the guardians of patients. I wanted to make clear that their care or their childcare would not be compromised but certain measures needed to be taken to protect them, for example, in relation to surgical instruments being prepared in a different manner and to protect other members of the public.

219. The Haemophilia Centre in Swansea followed the process communicated to it by UKHCDO. The Centre informed patients by letters as requested by UKHCDO. I offered each individual patient or guardian an appointment to discuss the content of the letter. In addition, in my communications to patients (including the 20 September 2004 letter **[WITN3761027]** the Health Protection Agency leaflet sent to patients in 2006 contained in **[WITN3761026]** and February 2009 letter (ARCH0000202)) as I realised that the information about vCJD was worrying for patients I wanted them to feel that they could contact the Haemophilia Centre for advice. I held additional clinics just for this purpose.

220. As specified by UKHCDO's 7 September 2004 letter and 9 September 2004 letter **[WITN3761024]**, patients were sent letters on 20 September 2004 **[WITN3761017]**. Patients were also sent further communications in 2006 (which contained the Health Protection Agency leaflet in **[WITN3761026]** and the vCJD letter of February 2009 letter (ARCH0000202) and other information in a timely manner including the Health Protection Agency/Health Protection Scotland leaflet dated February 2009 **[WITN3761026]**. The content of these communications were explained to each patient or guardian in individual out-patient appointments.

221. The information provided to patients about the risks of vCJD were those detailed in UKHCDO communications. Further information about risks was contained in the Health Protection Agency leaflet and other publications within **[WITN3761026]**. This provided details about vCJD and indicated that to help stop the spread of vCJD, patients with bleeding disorders who had received clotting factors (either Factor VIII or Factor IX) derived from UK sourced plasma

between 1980 and 2001, following a decision taken in 2004, would be considered at risk of vCJD. This leaflet provided further information about how vCJD could not be easily passed to friends and family and however vCJD may be spread by blood transfusions (as three people had died from vCJD after acquiring it from blood donors who had died of the disease). The Health Protection Agency leaflet further indicated that unfortunately no blood test had been developed to detect vCJD. However, if a patient developed an illness then samples of tissues could be tested. In addition, the leaflet indicated that a patient's medical and dental treatment should be the same as if the patient was not at risk of vCJD, however surgical instruments for surgery or complex dental treatment may need to be prepared differently. Finally the leaflet indicated that patients' medical treatment should not alter as a result of being at risk of vCJD but they should seek advice from their medical practitioners if they were worried about their health.

222. I saw individual patients or guardians in outpatient clinics that were created specifically to discuss the content of letters the Swansea Haemophilia Centre would have sent to them regarding vCJD. I explained the information provided in the letter and addressed questions that I knew the answers to. I offered patients who needed further counselling, support or advice to be seen by my colleagues in the lead Haemophilia Centre in Cardiff if they wished. At the time we did not have a counsellor or psychologist providing services to patients with haemophilia and the carers of patients with haemophilia but we have had a psychologist since 2014.

223. The measures put in place were those specified by the documents circulated by UKHCDO. For example the 7 September 2004 letter indicated that a letter and an information leaflet should be sent to patients by 20 September 2004 to explain that they were considered 'at-risk of vCJD for public health purposes and that this status would be recorded in their hospital medical records and primary care notes. The extent of exposure to implicated batches, and whether or not a patient has asked to know if they have received implicated batches, would also be recorded on a Patient vCJD Exposure Assessment Form to be placed in their hospital records. Patients who had not received UK-sourced

pooled factor concentrate between 1980 and 2001 would also have this fact clearly recorded on the form. Further patients were advised that they should not donate blood, organs or tissues due to their 'at-risk' status. Regular updates were sent by the Swansea Haemophilia Centre upon receipt of further communications from UKHCDO.

224. I have had regard to the email (ABMU0000050) and attachment (ABMU0000062) dated 21 October 2005 that Peter Collins provided to me regarding a protocol for managing the risks related to vCJD for patients with bleeding disorders who may undergo surgery and when surgical instructions should be quarantined:

a. Patients were told that those with inherited bleeding disorders who had been treated with UK pooled coagulation factor concentrates between 1980 and 2001 had been designated as being at risk for public health purposes with regard to vCJD. This was communicated to patients via the template letter that UKHCDO circulated in September 2004 (as set out above). The letter sent to Mr O'Driscoll dated 20 September 2004 is included **[WITN3761017]**. Patients were told the same when they were seen in the outpatient clinics in the Haemophilia Centre to discuss the content of the letter.

b. The Swansea Haemophilia Centre did not implement a separate protocol, the advice and guidance for colleagues was to follow the Department of Health advice as was reflected in the memorandum to staff entitled *Variant CJD* dated 11 November 2005 **[WITN3761028]** and contact the variant CJD Panel in Edinburgh. Further interim guidance was given by the Medical Director in a letter dated 12 November 2010 entitled *Interim Guidance regarding action to be taken in the event of a suspicion of CJD and/or an incident relating to CJD within ABM University Health Board* **[WITN3761029]**. This stated that the Health Board CJD Policy and Standard Operating Procedure ("SOP") for CJD was being revised and the letter outlined for colleagues the process to follow which had been agreed with the Health Protection Unit in Public Health Wales in the event

of a suspected or confirmed case of vCJD or an incident relating to a CJD patient (for example having undergone surgery where used instruments may have to be quarantined). If any such incident occurred, the consultant in Communicable Disease Control and the relevant site Infection Control Doctor needed to be informed whilst copying in the Medical Director and Assistant Director of Nursing. This shows that the guidance on protocols was changing all the time. I would not have received a copy of the revised SOP as this would have been developed and retained by the Surgical Theatre and Endoscopy teams.

225. In relation to my letter of 10 January 2006 to Dr W Aird (Consultant Otolaryngologist) (WITN2384020), I can confirm that the responsibility to inform the otolaryngology team about the risk from vCJD was that of the referring clinician, the hospital notes and the patient to ensure that operations could go ahead whilst minimising public health risks. I have the following other observations about why Dr Aird was not aware of Mr O'Driscoll being at risk of vCJD.

    a. Mr O'Driscoll was informed in 2004 about his risk of vCJD as were all other patients who had been treated with UK pooled coagulation factor concentrates between 1980 and 2001. He was informed by letter **[WITN3761017]** and when seen in the outpatient clinic, to communicate his at risk status to Health Care workers if he needed intervention like an endoscopy, biopsy or surgery. If the Otolaryngologist knew of Mr O'Driscoll being at risk of vCJD he would have contacted the virologist who would have in turn contacted the vCJD panel in Edinburgh about the measures to implement in relation to Mr O'Driscoll's endoscopy.

    b. It was not possible to remind Mr O'Driscoll again about the need to inform Health Care workers that he is at risk of vCJD. This was because the Swansea Haemophilia Centre did not know about the initial Ear Nose and Throat ("ENT") outpatient appointment. I was only alerted to this by Mr Aird's letter to me dated 29 December 2005 **[WITN3761030]**. Mr Aird indicated that Mr O'Driscoll would be admitted for micro laryngoscopy and

excision of a legion from his vocal cord and asked me whether it was advisable that Mr O'Driscoll would need blood product support (prior to any intervention/biopsy) and that was when I first learnt about the intended procedure.

c. GPs looking after patients at risk of vCJD were informed as per the UKHCDO letters of 7 September 2004 of action needed in the event of intervention. It is not clear whether he was referred by his GP or he made self-referral to ENT.

226. I have had regard to my letter dated 11 October 2006 to Dr Thomas, Consultant Gastroenterologist (ABMU0000064). In this letter I stated that there was a need to develop a plan for the management of patients with inherited bleeding disorders undergoing endoscopy in Swansea. This plan needed to be developed by the colleagues performing the endoscopy procedures on patients at risk of vCJD. It could not to be produced by the Haemophilia Centre in isolation. The example protocol provided by Professor Collins dated October 2005 (ABMU0000062) could have been used as a prototype but it would need to refined by the endoscopy colleagues. Please refer back to paragraph 224b. for further information about the changing guidance and developing protocols that were implemented by the Swansea Haemophilia Centre with other colleagues.

Section 10: Involvement with the financial support schemes

227. During my career, I supported patients and carers in their applications for specific trusts and funds established in order to provide financial support people who had been infected by blood products. For example, I prepared documentation for the Skipton fund or Caxton Foundation for support for haemophilia patients who contracted HCV, and gave support letters for applications to the Macfarlane Trust which supported HIV patients. If patients gave me written consent to prepare support letters I would have no hesitation in putting in the time and effort to assist their applications.

228. My comments about the Swansea Haemophilia Centre's support for patients' applications to trust/funds are below:

a. The Specialist Haemophilia Nurse, my fellow colleagues and I, informed patients about the different trust funds when we became aware of them and their purposes. We also encouraged patients to contact patient support groups like the Haemophilia Society for any additional information.

b. The Haemophilia Centre supported all patients in their applications if they wished to pursue them. I do not think the Haemophilia Centre in Swansea had a written policy or guidance in relation to referring patients to the trusts and funds other than information communicated to it perhaps by the funds, trusts and UKHCDO.

c. The Haemophilia Centre completed the sections in application forms that asked for information about a patient's health. I only wrote letters of support to different funds after receiving the authorisation from patients or when requested by patients and their careers.

d. To the best of my knowledge or recollection, neither the Centre nor any of its staff acted as a gateway in determining whether a particular patient met the eligibility criteria for support from a trust or fund.

e. To the best of my knowledge or recollection, neither the Centre nor any of its staff including me were involved in determining applications made by patients for assistance from trusts or funds.

f. Some patients/applicants attending the Centre were satisfied with the response of the trust or fund they applied to while others were not, however I do not know the precise detail as to why. I did not know enough about the trusts and funds to be able to form a view on whether they were well run, or if there were any difficulties or shortcomings in the

way they operated or whether they achieved the purposes they were set to achieve.

g. I have had no involvement with the Wales Infected Blood Support Scheme ("WIBSS").

229. I wrote many letters to support haemophilia and allied disorder patients in their applications for different funds or trusts. Copies of these letters would be filed in patients' notes. However, due to the passage of time I cannot recall the context of these letters.

230. I have had regard to my letter of 18 March 2004 letter to Dr Morgan (WITN3691021) in which I stated that I provided information to a patient about the HCV compensation programme announced by the Government. I cannot recall exactly what I would have told the patient at the time. On the balance of probabilities, I probably explained what was announced and what was provided in the leaflets distributed following the announcement. Unfortunately, I do not have a copy of any of these leaflets or any other information provided.

Section 11: Current haemophilia care and treatment

231. After my retirement in 2018, the Swansea Bay University Health Board asked me in September 2018 to assist the Health Board in addressing matters related to the Infected Blood Inquiry. I was appointed as a locum consultant haematologist for this purpose only and I did not take on any clinical roles, responsibilities or duties with that appointment.

232. The treatments provided to patients with bleeding disorders at the Centre, before my retirement are as set out throughout this statement. The inquiry may want to contact Swansea Bay University Health Board and Professor Peter Collins and/or colleagues in the Comprehensive Care Haemophilia Centre in Cardiff to find out more about the current treatment offered for the management of inherited bleeding disorders as well as thrombosis and haemostasis in Swansea Bay University Health Board following my retirement.

233. My practice in the management of patients with different haematological conditions, and not just haemophiliacs, has been to convey the information I knew at the time to the patient and their carer to empower the patient and his/her carer to be the decision maker(s) or partners in decision(s) related to their care. I believe that has always been my practice and this has not significantly changed throughout my career. Patients and their families valued such an approach and reflected this in the different feedback I received from them. I enclose a copy of the results of *360 Feedback analysis for Dr Saad Al-Ismail Haematology dated 12 March 2011* ("2011 Feedback") and *360 Feedback analysis for Dr Saad Al-Ismail Haematology* dated 12 May 2016 ("2016 Feedback") **[WITN3761031]**. The 2011 Feedback indicated 14 colleagues considered my verbal communication and empathy towards patients, families and carers was outstanding and that colleagues considered feedback from patients was positive and that I communicated well with them. The 2016 Feedback reflects 10 colleagues considering my communication with patients with patients, families and carers was also outstanding and that I was professional, respectful and compassionate towards them. In addition, the reflections and feedback from patients was excellent. One patient stated "*Dr Al-Ismail is a first class consultant Haematologist who always puts my care as a priority. He explains my treatment plan, answers all my questions and includes me and my mum in the decision making. He is extremely professional, polite, caring and always has time for me. He has looked after me for the last 17¢* [sic] *years and I have never doubted his treatment, care or decisions. I have total confidence in him and it's a privilege to be his patient."*

234. I, in line with other medical professionals undertook regular courses every two years to ensure I was up-to-date with best practice in terms of research and obtaining consent. The process of obtaining consent changed over the 36 years I worked in Swansea in that it became better documented during the last 20 years. Patients would always give informed consent after being told about the treatment options and the proposed treatment (which would be reflected in patients' notes) but that would have been better documented in later years. Nowadays, once a decision for treatment is reached and agreed by the patient

that was documented in the patients' notes and communicated by a letter to their primary care provider.

a. The information I gave to patient about the risk of any treatment would have been the information I knew at the time in relation to that treatment together with any leaflets that had been produced on the subject.

b. I always explained to patients, that in my view, there is no medicine without potential side effects. I explained the known common side effects of medications, the known possible serious side effects I knew at the time. I have always held the view that the patient is the decision maker in as far as whether to accept, continue or to decline or stop any treatment. I made it clear to patients that I would always respect their decisions and continue to support them.

c. I explained that not accepting a treatment is an option but explained the possible consequences of such a choice.

d. I explained what I knew about the benefits of having treatment and would also provide that in the context of any possible side effects or disadvantages of treatment. To the best of my knowledge the way I obtained consent or discussed the issues referred to in paragraph 135 to 138 does not significantly differ with current practice at the Haemophilia Centre.

235. The consent for some treatment was recorded as informed consent. The consent for other types of treatment such as chemotherapy, invasive procedures and intervention likely to have common serious side effects could have been recorded as a signed consent on the appropriate form. To the best of my knowledge, this does not significantly differ with current practice at the Swansea Haemophilia Centre.

236. The only blood samples asked for routinely were those needed to monitor and manage the patient conditions. Requests at the Centre are transcribed on

request forms and given to patients or guardians by hand to be taken for blood collection. Please see paragraphs 79, 103, 126 and 135 for further detail on this.

237. Patient consent for testing are obtained after informing the patient of the need for certain tests and the patient agreeing to have the test. Some tests like genetic testing required a signed consent form whereas others may have been undertaken after recording there had been informed consent in the patient's medical notes.

238. The document entitled *Swansea Haemophilia Centre, Patient with Inherited Bleeding Disorders 2019* **[WITN3761010]**, sets out details of the total number of patients with bleeding disorders registered with the Swansea Haemophilia Centre in 2019. From this information it would appear that the Centre was treating the following category of patients:

    a. 0 infected with just HIV

    b. 4 co-infected with HIV and HCV through blood products

    c. 21 infected with HCV

    d. 0 infected HBV (as there is no reference to HBV in the list of patients due to none of the patients treated at the Swansea Haemophilia Centre being diagnosed with HBV)

239. Please see paragraphs 103 to 108] regarding the involvement either I or the Swansea Haemophilia Centre had in the treatment for HIV patients and as stated previously, we treated no patients diagnosed with an active HBV infection. Please refer back to paragraphs 124 to 134 in relation to my and the Centre's involvement in treatment for NANB Hepatitis and HCV. As explained above, there was a multi-disciplinary approach relating to BBV both in relation to HCV and HIV. Such multi-disciplinary approaches were feasible and beneficial for patients so that they received a more rounded service and could

cut down on the administration involved with seeking specific treatment from certain specialists.

240. A part-time psychologist was appointed at the Centre in 2014 to provide psychological support to patients particularly those infected with HIV and/or Hepatitis.

241. A part-time physiotherapist has also been appointed at the Centre since 2014 to provide support to any patients that require it.

242. I set out below my comments on the impact of the infection with HIV and/or hepatitis through blood products:

    a. Upon patients - HCV had a major impact in that most of the severe haemophiliacs treated with concentrates prior to 1990 were infected. Few of those patients died with liver failure. HIV had a devastating impact on the haemophilia population and some patients succumbed to the infection before 1990.

    b. Decisions about treatment and care – such decisions have always been based on the information available to health care workers at the time. Over the course of the last three decades, patients have progressively been given more information on the available evidence for specific treatments by health care workers including the source of blood products such as whether they were recombinant or plasma derived. Patients have also been empowered more to make decisions about their own care. In addition, there has been a tendency to avoid products that have been sourced from human plasma and recombinant therapy and innovative therapy in the care of patients has made the management of patients more effective and safer than before.

243. The information I now know about the infection of patients with HIV and/or HBV and/or HCV through blood products has:

a. Influenced my professional practice in that I sought to avoid, as much as possible, blood products that are sourced from blood donations. It also influenced my preference for more innovative and safer products such as those that have a longer lasting benefit for a patient for a longer period and innovative approaches to products that mimic the function of Factor VIII;

b. I suspect, influenced the practice and approach of my colleagues in similar ways in that they also probably seek to avoid treating haemophilia patients with blood products sourced by blood donations if at all possible;

c. Led to improvements in haemophilia care through a better multidisciplinary team approach particularly in relation to HIV and HCV, better replacement therapy and more resources for the service to include a better range of services including access to a psychologist and physiotherapist.

Section 12: Other issues

244. To the best of my knowledge virtually no complaints were made against me or the Haemophilia Centre in Swansea throughout entire my career. However, I do recall the daughter of a patient raising a complaint about the destruction of her father's medical records. Upon searching the electronic folders kept about haemophiliacs on the NHS drive, I found letters relating to a patient with mild haemophilia who received Factor VIII concentrates in 1980. An Adverse Event report was filed with UKHCDO about this patient on or around 14 November 1997. The redacted letter exhibited shows that Dr Paul Giangrande at the Oxford Haemophilia Centre contacted me on 20 November1997, **[WITN3761032]** and confirmed that this patient never tested positive for HBV but he had failed to attend HCV testing on a number of occasions. However, he was admitted with symptoms related to cirrhosis which was likely to be secondary to HCV. My redacted response to a memorandum sent by the Consumer Relation Manager, dated 18 January 2000, about the same patient is also attached ("CRM Memo") **[WITN3761033]**. In this CRM Memo I set out

the history of this patient, i.e. that investigations in 1985 and 1986 indicated he had raised liver enzymes and he was diagnosed with liver cirrhosis in 1997 and he was under the care of Dr Kingham. I cannot recall any further action being taken in relation to this complaint and I had no further involvement in this.

245. In concluding this statement, I wish to make the final comments. I firmly believe that my colleagues and I in the Haemophilia Centre provided the best possible care to patients with Haemophilia in Swansea given the information we knew at the time and the information provided to us by the Cardiff Haemophilia Centre, UKHCDO and any other organisation. We never performed any test on patients without explaining it was necessary and obtaining the patients' consent. This is a fundamental tenet of good medical practice. Also staff in the Haemophilia Centre in Swansea did not keep information from patients about their conditions and any untoward event that patients encountered (such as being infected) as a result of treatment given to them. We always made sure our patients were provided with the best and most up-to-date information available so that they could make informed choices about their care.

Statement of Truth

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

Signed GRO-C

Dated 09 September 2020

Table of exhibits:

Date	Notes/ Description	Exhibit number
1975 - 2018	Swansea Haemophilia Centre - Consultant Haematologists and their responsibilities in Haemophilia Care 1975 – 2018 ("Consultant List")	WITN3761006
2011	Ministerial Task and Finish Group on Haemophilia Services - Report and Recommendations arising from Review of services for people with inherited bleeding disorders June 2011 ("the Task and Finish Group recommendations")	WITN3761007
1980-1987	Abertawe Bro Morgannwg University Health Board - Swansea Haemophilia Centre – Infected Blood Inquiry ("ABMU Health Board – Infected Blood Inquiry") which contains Swansea Annual returns sent to UKHCDO in 1980-1987	WITN3761008
Undated	Swansea Haemophilia Centre, Patient with Inherited Bleeding Disorders 2006	WITN3761009
Undated	Swansea Haemophilia Centre, Patient with Inherited Bleeding Disorders 2019	WITN3761010
Undated	Management plan sheets and guidance for patients and dental teams	WITN3761011
Undated	Blood review article entitled Chronic Hepatitis by M Makris and FE Preston ("Chronic Hepatitis article")	WITN3761012

1995	BMJ Journal entitled Hepatitis C and haemophilia BMJ 1995; 310:1619 by Christine A Lee	WITN3761013
February 1999	EASL International Consensus Conference on Hepatitis C – Consensus statement Journal of Hepatology 1999;30;956-961 February 1999 ("February 1999 Conference"	WITN3761014
15 May 1986	Letter from Oxford Haemophilia Centre to Haemophilia Directors	WITN3761015
25 March 1998	Redacted letter from Professor Lee to the Haemophilia Centre	WITN3761016
20 September 2004	Letter to Mr O'Driscoll relating to the risk of vCJD	WITN3761017
18 November 2004	Redacted letter from Royal Free hospital relating to Mr O'Driscoll	WITN3761018
20 July 2020	Email dialogue with the British Library in this regard entitled Article	WITN3761019
21 April 1994	Handwritten medical notes relating to Mr O'Driscoll and letter to the West Cross Medical Centre	WITN3761020
2001	Guidelines on the diagnosis, management and prevention of hepatitis in haemophilia (2001), 7, 339±345 ("the Guidelines")	WITN3761021

2018	Extracts from the UKHCDO Annual Report 2018 ("2018 Annual report")	WITN3761022
2018	Extracts from the UKHCDO Annual Report 2018 ("2018 Annual report")	WITN3761023
7 September 2004 9 September 2004	Letters to Haemophilia Centre Directors	WITN3761024
21 June 2002	Memorandum to colleagues entitled Variant CJD	WITN3761025
November 2006 February 2009	Various UKHCDO communications and Health Protection Agency letters/leaflets	WITN3761026
20 September 2004	Letter to patients and guardians entitled Important Information – Variant Creutzfeldt-Jakob disease (vCJD) and Plasma Products ("20 September 2004 letter")	WITN3761027
11 November 2005	Memorandum to staff entitled Variant CJD	WITN3761028
12 November 2010	Letter from the Medical Director entitled Interim Guidance regarding action to be taken in the event of a suspicion of CJD and/or an incident relating to CJD within ABM University Health Board	WITN3761029

29 December 2005	Letter from Dr Aird	WITN3761030
2011 and 2016	360 Feedback analysis for Dr Saad Al-Ismail Haematology dated 12 March 2011 ("2011 Feedback") and 360 Feedback analysis for Dr Saad Al-Ismail Haematology dated 12 May 2016 ("2016 Feedback")	WITN3761031
20 November 1997	Redacted letter from Dr Paul Giangrande at the Oxford Haemophilia Centre	WITN3761032
18 January 2000	Redacted response to a memorandum sent by the Consumer Relation Manager, dated 18 January 2000, ("CRM Memo")	WITN3761033