Witness Name: Richard Lee
Statement No.: WITN4408007
Exhibits: 0
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INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF RICHARD LEE

I, Richard Lee, will say as follows: -

Section 1: Introduction

1. My name is Richard Lee and my date of birth is GRO-C 1950. My address is known to the Inquiry. I have the following professional qualifications: BSc (Hons); MBBS; FRCP; FRCPath.

2. After qualification in Physiology and Medicine in 1974 at King's College Hospital Medical School, London, and the University of London, my training as a junior doctor included General, Vascular and Urological Surgery at Dulwich Hospital (part of the King's College Hospital group) and General Medicine at the Kent & Sussex Hospital and Pembury Hospital, Kent, in 1975 and 1976. I then undertook further general medical training between April 1976 and July 1977 as Senior House Officer (SHO) in a medical rotation (Accident & Emergency, Respiratory Medicine, Neurology and Neurosurgery) at King's College Hospital; and as SHO in Medicine and Clinical Haematology at the Hammersmith Hospital, London, between August 1977 and January 1978. Thereafter I undertook specialist training in Haematology, first as Registrar at St George's Hospital, London, from February 1978 to March 1979, then as Lecturer/Senior Registrar in the St George's Hospital group from March 1979 to January 1985. My time at St George's entailed rotating

between St George's Hyde Park Corner and Tooting branches, St James Hospital, Balham and the Royal Marsden Hospital, Surrey.

From February 1985 to June 2010, I was Consultant Haematologist at the Royal Devon & Exeter Hospital NHS Trust and Director of the Exeter Haemophilia Centre. I retired fully from clinical practice in June 2010.

3. During my career my membership of organisations included:

- BMA (1975 – 2010) as ordinary member;
- Royal College of Physicians, London (1977 -1994) as Member;
- Royal College of Physicians, London (1994 – 2010) as Fellow;
- Royal College of Pathologists, London (1983 – 1995) as Member;
- Royal College of Pathologists, London (1995 – 2010) as Fellow;
- British Society for Haematology (1985 – 2010) for educational development;
- Association of Clinical Pathologists (1985 – 2010) for educational development;
- UKHCDO (1985 – 2010) as representative of the Exeter Haemophilia Centre in the national organisation;
- UKHCDO Working Party on Reorganisation of Haemophilia Care in the UK (1986? – ?) as representative of Centre Directors in the SW Region;
- SW Regional Haematology Committee (1985 – ?) as ordinary member. All Consultant Haematologists were members and the purpose of this committee was to coordinate development of services in clinical and laboratory Haematology under the auspices of the Regional Health Authority. I think it was disbanded when RHAs were reorganised and commissioners took over the role.

4. In 1989 I was involved in providing information to the South Western Regional Health Authority's legal team defending a group civil action against all the Haemophilia Centres in the SW. As far as I recall, all the cases I had knowledge of were of patients infected prior to my arrival in Exeter. I believe a settlement was agreed and the action did not reach the courts. I do not have any documents relating to this in my possession.

Section 2: My work at St George's Hospital ("St George's")

5. During my time at St George's I was a junior doctor training in Haematology, rotating between the hospitals in the group (St George's, St James, Balham and the Royal Marsden, Surrey). All the haemophilia care was centralised at St George's and much of the specialised leukaemia and chemotherapy services were based at the Royal Marsden.

6. Professor P Flute was Head of Department and Haemophilia Centre Director, Dr J Parker-Williams focused on laboratory and diagnostic services, Dr M Rose was lead clinician at St James, and Dr H Clink was Consultant Haematologist at the Royal Marsden. As Registrar, I learned the basics of haematological diagnosis in the laboratory, clinics and the wards. As Lecturer/Hon Senior Registrar, I took on teaching duties for medical students, nurses and laboratory scientists in addition to clinical duties. The research component of the post was largely abandoned because of the lack of time for senior staff to supervise. Both Professor Flute and Dr Rose were not in good health and had long periods of sick leave. The two Lecturers/Senior Registrars, Dr D Bevan and myself, bore the brunt of clinical cover at St George's and St James respectively.

7. My involvement with haemophilia care at St George's was largely confined to treating patients when they presented with bleeding episodes, often at night and weekends. I do not recall being involved in haemophilia clinics, nor was I involved in decisions regarding the selection of blood products, patient information or consent. Unfortunately, my memory is not clear enough to recall with any degree of certainty the number of patients registered at St George's

Haemophilia Centre, nor the proportion of children and adults. The data should be available through UKHCDO.

8. Decisions about the selection and purchase of blood products for patients with bleeding disorders were made by Professor Flute and his Consultant colleagues. I do not know for certain but I think it highly likely they took account of prevailing concerns about the risks of viral transmission associated with commercial products being higher, as well as advice from UKHCDO and the National Blood Service (NBS). The most widely used factor concentrates were those manufactured from UK blood donations and provided by BPL. However, supply shortfalls were common especially when demand increased further with the introduction of home treatment and prophylaxis. Inevitably St George's, in common with many other centres, had to seek supplies from commercial sources. Financial considerations, if they came into play at all, would have been a disincentive to purchase commercial concentrates as they were generally more expensive, I believe. As far as I knew, the centre at St George's maintained a relationship with pharmaceutical companies supplying blood products only to ensure alternative supplies of concentrate could be accessed if necessary. The department's training and conference expenses may have been supported by pharmaceutical companies from time to time but I am not certain. I do not recall what the selection criteria were for allocating products for patients, nor can I say whether patients were offered a choice of products. These decisions were taken by senior colleagues.

9. Alternatives to factor concentrates, such as Desmopressin (DDAVP) and Tranexamic Acid (TA), were used at George's when clinically indicated and appropriate. I do not know why they would not have been used as both pharmacological agents were readily available, inexpensive and effective in most patients with mild and moderately severe Haemophilia A and von Willebrand's disease (vWD). With the exception perhaps of major trauma (e.g. serious head injuries) these would be considered as the treatments of choice in these patients. The disadvantages of DDAVP are relatively minor. Side effects include transient hypotension, facial flushing, tachycardia, and rarely water retention with repeated doses. TA, being an antifibrinolytic agent,

stabilises clots. Its use is generally limited to arresting bleeding from mucosal surfaces, e.g. nose bleeds and after dental extractions. As evidence that it was used at St George's, I cite a case report published in the British Dental Journal 1984; 156: 450 – 452: "DDAVP and Tranexamic Acid for Dental Extractions in a Mild Haemophiliac – S Shankar and R Lee".

10. With regard to home treatment and prophylaxis, I believe the approach taken at St George's followed UKHCDO advice but I do not recall the dates when the policies were implemented or whether they changed over time.

11. At St George's and other centres cryoprecipitate was used extensively prior to the advent of factor VIII concentrate. The transfer of patients from cryoprecipitate to concentrate was driven largely by the perceived benefits of concentrate: ease of administration, faster and more predictable response, more suitable for home treatment and prophylaxis. The early forms of concentrate provided by BPL were essentially cryoprecipitate concentrated into a small volume. The starting material in both products was the same – UK blood donations. A potential downside of concentrates - infection risk associated with large pool batches – did not outweigh the benefits, particularly when heat treatment of concentrates was introduced. With commercial concentrates, the risk-benefit considerations became more complicated as account also had to be taken of the non-UK source of the plasma. I do not recall how the decisions were made concerning the use of cryoprecipitate for some patients and concentrate for others; they were taken by senior colleagues.

12. I was not involved in treating patients infected with hepatitis or HIV at St George's. Hepatitis patients were probably referred to the hepatologist. HIV had only just begun to affect our patients when I left in January 1985 and I do not know how they were managed.

Section 3: My work at Royal Devon & Exeter Hospital ("the Exeter Centre")

13. My role and responsibilities at the Exeter Centre were those of a Consultant Haematologist in the clinics, wards and laboratory providing services in a District General Hospital. I shared the workload with my Consultant colleagues

in all areas except for haemophilia, blood transfusion and paediatric haematology, for which I had sole responsibility. In the 1980s, Clinical Haematology was one of the newest and rapidly expanding sub-specialties in Medicine. When I was appointed in 1985, I replaced Dr Edgcumbe who was a laboratory haematologist, one of the last in his era. My remit was to assist a senior colleague, Dr M Joyner, who had arrived in 1979, to develop the clinical service to improve facilities for local patients with blood diseases. The majority of these patients suffered from leukaemia or other haematological malignancies. Treatment regimes were becoming more complex and increasingly demanding on patients and resources. At the same time, a significant proportion of the tasks normally undertaken by junior staff was now falling on consultants, a widespread problem within the NHS. Our first priority was to bring all haematology inpatients, including patients with bleeding disorders, who were scattered throughout the hospital in various medical wards, into a dedicated haematology ward, cared for by a dedicated team of nurses and doctors. Lack of space and resources forced my colleague and I to raise much of the funds to build a new unit through a charity that Dr Joyner had set up in 1980, the Exeter Leukaemia Fund (ELF). The new unit comprising inpatient beds and outpatient facilities was in use by 2000 or 2001. All patients including haemophiliacs were accommodated there. Since then an extension, entirely funded by ELF, has had to be added. Since retirement I have served as a Trustee of ELF, presently as Chairman. I mention this aspect of my work only to indicate how varied and stressful it was at a time when haemophilia care was also undergoing massive change. At no time was it possible to justify a separate Haemophilia Centre with its own specialist nurses and supporting staff. The numbers of patients were small compared to those with malignant diseases. I cannot recall the exact figures but as an estimate there were about 10 patients with severe haemophilia, amongst them 2 or 3 children, around 20 with moderate or mild disease, and numerous patients with vWD and rare disorders who were diagnosed by chance and rarely required treating. More precise numbers are available in UKHCDO records.

14. As the department grew, other Consultant colleagues were appointed. First Dr M Pocock took up a half-time appointment in around 1989 (a guess), then Dr C Rudin joined a few years later followed by Dr M Hamilton. Around 2006 - 2007, Dr J Coppell, Dr A Todd, Dr P Kerr, Dr J Ruell and Dr L Ngu were appointed in quick succession to address an impending crisis – Dr B Attock, Consultant Haematologist at the Northern Devon Healthcare NHS Trust, Barnstaple, had retired and no replacement could be found; and Dr Pocock, Dr Joyner and I were approaching retirement. A deal was struck by the two Trusts for all the haematology services in North Devon to be provided by the Exeter Consultants. I played my part in visiting Barnstaple twice a week to do clinics and look after inpatients and the laboratory while continuing my work at Exeter. I was lead clinician for North Devon Haematology from 2007 until I retired in 2010.

15. My role in the treatment of patients with bleeding disorders at the Exeter Centre is best described as a lonely one, albeit rewarding. All my colleagues preferred to focus on the rapidly developing areas, essentially the haematological malignancies (often referred to as 'haem-onc'). Although no one admitted it, I sensed that a desire for self-preservation was a factor in their decision. Once HIV and hepatitis, then vCJD, became well known as potential hazards of blood transfusion there was a noticeable decline in interest in subspecializing in Haemophilia and Blood Transfusion amongst trainees, and applications for consultant posts reflected this. Increasing workload without adequate support and the constant threat of litigation were powerful disincentives too. As a result, during my 25 years at the Exeter Centre the entire responsibility for Haemophilia and Blood Transfusion was carried by myself. The early years were most difficult as there were only two consultants with no external cover for leave or on-call commitments. Even when other colleagues joined the department, I had to be always contactable, even when on leave, to provide the necessary support for my colleagues should they have to attend to a patient with a bleeding disorder in my absence. Life became easier when mobile phones arrived.

16. The lack of interest in Haemophilia and bleeding disorders extended to all levels of staff. In the early years of HIV, junior doctors and nurses were often reluctant to carry out invasive procedures such as taking blood samples or intravenous cannulation in patients regarded as 'high risk' and these were tasks I found myself undertaking frequently. Sadly, needlestick injuries were not uncommon occurrences until better training, better equipment and improved techniques addressed the problem. But it was surprising how long it took.

17. In terms of provision of treatment for HIV and hepatitis, I recall there were no formal arrangements for referral to specialists for many years. There were no liver specialists or HIV specialists in Exeter until around 2000 (this is an estimate) and effective treatments did not become available much before then. Prior to this, patients with HIV or hepatitis were managed by those physicians under whom they were admitted, usually a general physician or respiratory physician. Patients with haemophilia and HIV were managed in Haematology by myself with the help of the appropriate colleague in another specialty according to the presenting problem.

18. Children with haemophilia were in a special category. Prior to 1985, they were managed mainly by the Paediatricians, with Dr Edgcumbe advising on treatment products and testing. Upon my arrival at Exeter, I arranged to do joint clinics in the paediatric department, initially with Dr J Tripp and Dr R L'E Orme, then Dr A McNinch when he was appointed around 1989/90(?). In the ensuing years, Dr McNinch and I worked closely to develop haemophilia care and oncology services for children in Exeter. A longstanding arrangement with the Bristol Children's Hospital for Consultant Oncologists to do outreach clinics at Exeter continued during my time and transfers to the Bristol unit for treatment were the norm for newly diagnosed oncology cases. Later, when some of the newer consultants were appointed to the Bristol unit who had wider haematology experience including Haemophilia, they undertook the visits and children with bleeding disorders were included in the clinics. My close cooperation with my paediatric colleagues meant that decisions regarding treatment products were always discussed. When recombinant

Factor VIII became available, we made a strong and successful case to the commissioners and hospital management to make it available for children as a priority.

19. Visiting haemophiliacs were another special category as they contributed significantly to the workload, especially during the summer as Devon was and is a popular holiday destination. If they arrived in the department or in the A & E department without warning I gave them priority as I believed that early treatment was crucial. It was not uncommon to find that the patient had not brought enough of their own treatment product with them and we had to provide for them from our stocks. For a few years before and after my arrival the Exeter Centre also provided for a steady stream of visiting haemophiliacs who attended a rehabilitation course at nearby St Loye's College. These courses usually lasted for months and our stock levels had to be managed to take account of this.

20. With reference to the selection and purchase of blood products, Dr Edgcumbe I believe followed UKHCDO advice closely, as I did. We prioritised the use of NHS products (although supplies were precarious) over commercial products. When heat treatment was introduced that was another factor to take into account. Heat treated NHS concentrate was the first choice for PUPs and children. Financial considerations were never a factor until recombinant products became available. It took considerable effort to convince the commissioners and the Trust that the costs were justified. Cryoprecipitate was always available to treat vWD patients and children but its use fell away when concentrates became available. The early version of BPL factor VIII concentrate was essentially cryoprecipitate in a concentrated freeze-dried form. Its ease of administration compared to that of cryoprecipitate and its faster and more predictable response made it a more effective product in the eyes of clinicians and patients. This product was also suitable for treating the rare patient with severe vWD as it contained significant amounts of vWfactor. On the whole patients were not offered a choice because supplies could not be guaranteed. They were informed of the risks and benefits and generally accepted what was available. Alternatives such as DDAVP and TA were

always considered and offered to appropriate patients if the clinical situation warranted.

21. Pharmaceutical companies had no influence on the Centre's decisions and actions. It was necessary to maintain a relationship only in so far as to ensure there was an alternative source of products to call on when NHS supplies could not meet our demands. There were never any financial inducements.

22. Home treatment had already been put in place by Dr Edgcumbe and I continued with this. Patients were kept under regular review and their usage was monitored to ensure doses were optimal. This entailed patients being supplied with treatment record sheets to document the type of product used, the batch numbers, the doses administered and the reasons, e.g. severity of bleed and joint affected. These records were required to be returned to the Centre monthly so that any major changes in use could be investigated promptly. With the children, Dr McNinch and I only considered home therapy when they and their parents showed signs of interest. Parents became aware from Haemophilia Society newsletters and other sources of the advantages of home treatment – having more control of their lives, freedom from the need to visit the hospital every time treatment was necessary. Those who chose to try home treatment had to be assessed as suitable and trained. This was a lengthy process taking months and sometimes years, given there were no specialist nurses in the haemophilia centre. The task fell to Dr McNinch and myself. Time was set aside to demonstrate cannulation techniques and safety precautions. I recall showing parents how to use an orange to practise cannulation to begin, then progressing to cannulating a vein in a human volunteer, invariably Dr McNinch or myself. Both the parents and the child had to want to undergo training and the pace was determined by them.

23. The approach taken in relation to prophylaxis followed UKHCDO guidelines. I do not remember all the details but I recall there was evidence that prophylaxis when compared with treatment on demand (only after bleeding had occurred) resulted in less chronic joint pain and better mobility in patients with severe disease, especially those with target joints. An added benefit in some studies was consumption of concentrate under a prophylactic regime was no greater

and often less than consumption under most on-demand regimes. This policy was not applicable to patients with mild or moderate disease as their infrequent need for any treatment made it unnecessary.

24. By 1985 the use of cryoprecipitate was largely confined to treatment of vWD patients, PUPS and patients with afibrinogenaemia (mostly following massive blood transfusions in the context of major surgery or trauma). My approach was based on considerations outlined earlier – faster and more predictable response as well as ease of administration of concentrates swung the balance in favour of concentrates for most patients. The move away from cryoprecipitate was accelerated by the introduction of heat treatment for concentrates.

Section 4: Knowledge of, and response to, risk

Hepatitis

25. In 1979 it was generally known that the hazards of blood transfusion included viral hepatitis, both HBV and NANBH. However, the extent and seriousness of the risk were not fully appreciated, probably because the tests were not as developed as they are now and also because many patients remained asymptomatic for years. At that time my understanding of the relative risks of infection from the use of commercial blood products and the use of NHS blood products was limited. I knew that blood products made from paid donors (applicable to most commercial products) were associated with a higher risk of hepatitis compared to those made from volunteer donors (applicable to NHS products). The differential risk was further highlighted by the arrival of HIV in the 1980s. The actions taken to reduce the risk to patients, both at St George's and at the Exeter Centre, were to use NHS products as far as possible if alternatives such as DDAVP and TA were not appropriate, and when heat treated NHS products were shown to be effective to adopt them.

26. Even by 1992 when a reliable test for detecting HCV became available we had a limited understanding of the disease. It was known that the disease remained silent for years and progression to cirrhosis and hepatocellular carcinoma (HCC) occurred in a minority of patients. The rate of progression

was highly variable and influenced by many factors including alcohol consumption, HIV or HBV coinfection as well as other comorbid conditions. In general, it was estimated that the time interval from infection to cirrhosis and HCC was in the region of 10 – 20 years, often longer. While it was well known that exposure to the hepatitis viruses by blood transfusion or inoculation was the main route of transmission, other transmission routes were not so well understood. HBV could be transmitted by the sexual route but it was not clear if this also applied to HCV. Most experts believed the risk of sexual transmission of HCV was low in normal heterosexual relationships. Nevertheless, in my consultations with patients and partners I generally advised that the precaution of practising safer sex using condoms could provide additional security. I do not know what the practice was at St George's. Other known infectious risks included non-viral agents such as bacteria and malaria, but these were very rare. My sources of knowledge were the usual ones: medical literature, educational/training resources provided by senior colleagues.

HIV and AIDS

27. I became aware of HIV and AIDS as a risk of blood transfusions when the first reports of the disease in haemophiliacs in the USA were published. I think it was around 1983 or 1984. The extent of the risk was not clear initially as adequate testing of blood donors was not in place. It was thought that blood products made from UK donors (exclusively volunteers) were at lower risk of contamination from HIV than those from commercial donors (mainly paid) and efforts were made, both at St George's and at Exeter, to only use NHS products. Unfortunately supplies of NHS products could not meet national demand and, faced with the choice of either not treating or using less effective alternatives such as cryoprecipitate, difficult decisions had to be taken. I do not recall how the decisions were made at St George's. At Exeter, I believe Dr Edgcumbe consulted NBS and UKHCDO and made patients aware of the dilemma. I recall similar difficult discussions with patients when I took over in 1985. There was agreement that a significant bleed had to be treated. Most clinicians including myself did not favour returning to cryoprecipitate wholesale

because it was cumbersome to use and it was not always possible to achieve a good clinical effect. The prevalence of severe joint problems leading to crippling in some cases was regarded as the legacy of years of undertreatment associated with cryoprecipitate use. The introduction of concentrates was viewed by patients as opening a new chapter in their lives. At last a product was available that could reliably raise the level of factor VIII to the desired level within minutes. Speed in treating bleeds was crucial. Delay led to irreparable joint damage with long term consequences. It is not surprising therefore that NHS concentrates continued to be used quite freely. When NHS supplies were not available the next best choice was heat treated commercial products, but they too were in limited supply, at least initially. Non-heat treated commercial products were avoided as far as possible. Alternatives such as DDAVP and TA were used whenever appropriate.

Response to risk

28. I believe that patients at St George's were informed of the risks of hepatitis and HIV but I have no certain knowledge of this. My memory of the steps I took at Exeter are clearer. On the first day in my post I was confronted with a file on the desk marked 'high priority' left by Dr Edgcumbe with a note that the enclosed results of HIV tests from about 12 or 14 haemophilia patients needed urgent attention. The results of these tests done in the previous weeks had just returned in the days before his retirement and he felt it would be more appropriate for me to deal with them. It was a baptism of fire that still haunts me today. I contacted the patients and saw them individually in clinic. I introduced myself as the new consultant and gently broke the news of their blood test results. Initial reactions varied from shock and silence to anger and hostility. As far as I recall, none elected to revert to cryoprecipitate; they understood the trade-off between risk and efficacy. Those on home treatment were particularly unenthusiastic because of the practical problems of administration and poorer response alluded to earlier. By February 1985, heat treated NHS factor VIII was just being introduced. My letters to Dr Snape at BPL [BPLL0010635 and BPLL0010628] list the patients for whom I wished to have supplies of the product and the estimated quantities. As far as I can

remember, these were the patients who were receiving regular treatment at the Exeter Centre at the time.

29. I do not know if senior colleagues at St George's decided to use heat treated products prior to the meeting of UKHCDO Reference Centre Directors on 10 December 1984 [HCDO0000394_117]. At the Exeter centre, shortly after taking up my post in February 1985, I decided to implement the recommendations made at that meeting. My letters to Dr Snape referred to in 28 reflect that decision.

30. I have no recollection of the meeting regarding Koate HT referred to in the letter dated 21 October 1986 [BAYP0000009_030]. Nor do I remember what the purpose of the meeting was, but it probably was to learn more about the product and its availability in the event we ran out of NHS products. I do not recall anything about the circumstances of the recall of a batch of Koate HT in March 1988 [BAYP0000005_057].

31. I do not recall that supplies of cryoprecipitate were difficult to obtain during my time at St George's and the Exeter Centre. They were generally sufficient. In my letter dated 4 February 1988 [RDET0000010_009] I was reassuring the Consultant Paediatrician that there would be adequate supplies of cryoprecipitate should it be needed following delivery of the child. I have already referred to the ongoing debate in haemophilia circles about the pros and cons of the different forms of treatment in earlier sections. It was a contentious issue and the information I would typically have given to adult patients and parents of a haemophiliac child has been rehearsed in an earlier section. It would appear from the last paragraph of the letter that the mother was not known to the Exeter Centre as a haemophilia carrier. Had she been known to us she would have had counselling at an early stage, ideally at the time she was considering starting a family, and been informed of what was available for treatment. As we had not had that opportunity I think I was implying we should make it a priority.

32. Even with hindsight, I consider the decisions and actions taken at St George's and Exeter were on the whole appropriate given the prevailing circumstances.

Had the NBS and NHS been better funded and better prepared, such that supplies of UK blood products were always adequate and of the highest quality, and clinical services better supported, the harm to patients and their families would have been mitigated and Haemophilia treaters would not have had to make such difficult choices.

Section 5: Treatment of patients

Provision of information to patients

33. I do not have detailed recollection of what information I provided to patients prior to commencing treatment. However, it was my normal practice to be open and to provide as much information as they wished. For example, I would have explained that NHS products and heat treated concentrates were probably safer than commercial and non-heat treated concentrates, and that there were alternatives that could be considered in some but not all circumstances, such as cryoprecipitate, DDAVP and TA. For those wishing to embark on home treatment, they could proceed if they wished, but I think I would have advised delaying prophylaxis until supplies were more reliable. I would also have suggested the Haemophilia Society as another source of information. As and when new information became available, I would adjust my advice accordingly.

HIV

34. I do recall knowing that there were patients testing positive for HIV at St George's towards the end of my time there. However, I do not have recollection of who arranged for the tests, how the patients were informed, what counselling was given and what the policy was in relation to testing partners/family members. As I have already stated, it is likely that senior colleagues were responsible for the decisions and actions. I do not know the number of patients affected or their distribution.

35. As indicated earlier, most patients at the Exeter Centre had just been tested by Dr Edgcumbe prior to my arrival in February 1985. It became my priority to contact them and see them individually in clinic within the first few weeks. I

told them what was known about HIV at the time - that it was a new virus that is transmissible by blood and other body fluids, that the rate of progression to AIDS is variable and influenced by many other factors such as co-infection with hepatitis, that there was no treatment available at the time, that their immune status could be closely monitored. I also advised them to report any new symptoms they could not explain and to do so directly to me or the nurses in Haematology. Shortly after arriving in Exeter I gave all haemophilia patients open access at all times to the haematology ward to avoid delays in treatment. Prior to this, patients had to report to A&E first and delays were inevitable. To address the possibility that some patients, especially visitors from other areas, would still present to A&E, I advised the A&E consultant to ensure that such patients were fast tracked to the haematology ward. At no time did I advise patients to keep their infections a secret but we were all aware that in the public's mind HIV was associated with a certain stigma.

36. I do not know if Dr Edgcumbe arranged for pre-test counselling. All the post-test counselling was carried out by myself. Patients were offered the opportunity for their partners/family members to be tested. Not many came to the hospital for testing, preferring mostly to consult their GPs. I explained to spouses/partners the risk of unprotected sex and advised the use of condoms for protection. I advised also not to share toothbrushes or razors and to cover open wounds to avoid contact with blood droplets.

37. The number of patients at the Exeter Centre infected with HIV varied with time. There was significant movement in and out of the area largely due to the patients attending the St Loye's rehabilitation centre. As an estimate: 6 had severe haemophilia A, none had moderate haemophilia A, 1 had mild haemophilia A, none had haemophilia B, none had vWD, and 1 was a child.

38. I do not remember any work undertaken at the Exeter Centre to establish the time period during which patients seroconverted. I do not recall any patient whose partner or family member became infected with HIV.

Hepatitis B

39. I do not know how the patients with HBV at St George's were informed of their infection or how many patients were infected. At the Exeter Centre, one patient was infected and he was among those I inherited from Dr Edgcumbe on his retirement. I informed him of the diagnosis and implications for him and his partner/family and the precautions to take. Unfortunately, there was no effective treatment available at the time. Because he was relatively young and keen for a second opinion I referred him to Dr P Kernoff at the Royal Free Hospital, London. From there he was enrolled into a trial of interferon alpha, a drug that was approved only for hairy cell leukaemia at the time but there were reasons to suppose it may be effective against HBV. Sadly, it did not produce a remission in his case. I continued to provide supportive care for him until a hepatologist took over on his appointment to the Royal Devon & Exeter Hospital in the late 1990s or early 2000s.

NANB Hepatitis/HCV

40. I do not recall how patients with NANB Hepatitis/HCV at St George's were informed of their infection. At the Exeter Centre, monitoring of liver function as an indicator of NANBH was in place before my arrival in 1985. Testing for HCV began in the early 1990s when a test became available. Those who were identified by the NBS as receiving blood transfusions (not concentrates) from implicated donors were managed separately by the NBS. Patients with bleeding disorders were seen in my clinic for testing and counselling. On the whole I informed patients of their results in person in the clinic. A few chose to be informed by phone or letter and were seen subsequently in clinic to discuss the result. I told them that the virus had been around for a long time and previously was known only as NANBH because it had not been identified until recently. It remained silent for many years. About 20% of patients eliminated the virus themselves. The remaining often were asymptomatic for 10 – 20 years, sometimes longer. It was known that some patients progressed to cirrhosis and hepatocellular carcinoma but the rate of progression was highly variable and was influenced by many factors including alcohol consumption, HIV or HBV co-infection and other comorbid conditions. Sexual transmission

was not generally thought to be a high risk in normal heterosexual relationships. Nevertheless, practising safer sex using condoms would provide additional security for partners. I also advised other precautions including not sharing toothbrushes and razors and covering open wounds. During my time at the Exeter Centre, I recall there were probably only 2 or 3 patients infected with HCV. When effective treatment became available these patients were transferred to the care of the recently appointed hepatologist in Exeter.

Delay/ public health/other information

41. As far as I recall, there were no delays in informing patients of their results. We were all aware of the public health implications of HIV, AIDS, HBV and HCV and they formed part of the discussions with patients at the time of diagnosis and in subsequent attendances. In the case of HBV, when an effective vaccine became available it was offered to family members of those patients infected with HBV as well as those patients not infected with HBV and to frontline staff.

Consent

42. I do not know how often blood samples were taken from patients attending St George's. At Exeter, patients on regular treatment were seen at 3 monthly intervals or more frequently if clinically indicated, e.g. bleeding frequency or intensity increasing. Those who required less treatment were seen at 6 monthly intervals. At these visits, routine blood checks were made testing for liver function, clotting factor levels, inhibitors (antibodies to clotting factors), HBV, HCV and HIV. Patients were told what the samples were for and that the viral samples would be stored in case of the need to look back at a future date. No formal consent was requested or recorded.

43. Most of the patients I took over from Dr Edgcumbe in February 1985 were already on concentrates. Subsequent new patients coming under my care were informed of the treatments available at the time and the pros and cons for each. At the time of the first treatment, the product, usually a concentrate, was reconstituted in their presence. The mode of administration and possible

side effects were explained again before treatment was administered. Written consent was not requested; it was not a requirement at the time. Treatment was recorded in the notes, implying that verbal consent had been given.

44. No patient under my care was tested for HIV or hepatitis without their agreement and knowledge of the purpose of the test. Patients were told that routine surveillance of viruses that they may become exposed to as a result of infected donations was important for them and their families.

PUPS

45. The actions taken with regard to PUPS differed according to the severity of the disease. In the case of patients with severe haemophilia, the choice was between cryoprecipitate and factor VIII concentrate. By 1985, heat treated NHS concentrate was becoming available and I was able to reserve a small stock for PUPS. I preferred this to cryoprecipitate for the reasons indicated earlier. In summary, concentrate was much easier and quicker to administer (a crucial factor in limiting damage from bleeding) and it produced a more predictable rise in the level of factor VIII (important for efficacy); it was also heat treated, thereby reducing viral risk. In contrast, cryoprecipitate was cumbersome to administer because it was a large volume and required thawing; it had to be infused slowly and the rise in factor VIII level was difficult to predict. It was not heat treated but it was made from small pool or single donations (limiting donor exposure was considered a possible advantage before products were heat treated). For patients with moderate or mild haemophilia, I always considered non-blood alternatives first, e.g. DDAVP and TA, if they were appropriate for the clinical situation. If not, or if tried and found to be ineffective, heat treated NHS concentrate would be the preferred choice.

Treatment of patients who had been infected with HIV or Hepatitis

46. I have no detailed recollection of how patients with HIV or Hepatitis at St George's were managed. I think they were referred to the appropriate specialist team there. At the Exeter Centre, patients with haemophilia and HIV were managed by myself in conjunction with the appropriate Physician and Microbiologist colleagues until an HIV specialist was appointed to the Royal

Devon & Exeter Hospital. As far as I remember there was only one child infected with HIV; he was managed by myself and the Paediatricians. He was one of the early cases I inherited from Dr Edgcumbe for whom sadly effective treatment did not come soon enough. Before effective anti-retroviral drugs became available, the only treatment was supportive care and this was available locally. Monitoring of CD4 counts was available locally. External referral, whilst possible, was not popular with patients because of the distances they would have to travel to London, Oxford or Cardiff. At the time there were no centres in the South West region able to offer the facilities to manage our patients. When treatments started to become available there was only one patient with HIV at the Exeter Centre, the others either had moved away or had passed away. This patient declined referral so I treated him (with frequent advice from other centres) until his care was transferred to a local HIV specialist when he was appointed around 2000. As mentioned in earlier sections, all the supportive care for patients with haemophilia and HIV, HBV or HCV, including counselling and applications for financial/social support were provided by myself as there were no dedicated services available within the Exeter Centre. The services within the hospital, such as they were, were overstretched and waiting times were very long.

Research

47. Patients with bleeding disorders constituted a tiny minority of my patients, the vast majority were patients with malignant haematological disorders. There was little time for research and my involvement in research studies was largely confined to entering patients with leukaemia into various trials run by the Medical Research Council and case reports. I was not involved in any research studies at the Exeter Centre relevant to the Inquiry's Terms of Reference unless you consider as relevant the annual patient data all Haemophilia centres were required to submit to UKHCDO, on which treatment guidelines were based.

48. In my opinion, the ethical principles that should guide research are benefits for patients and society, care to minimise harm, informed consent, respect and

integrity, no conflict of interest, confidentiality and protection of data, independent overview.

49. Relevant patient data was shared with UKHCDO. Consent was not sought or thought to be necessary. The system of data collection was already in place when I became Director of the Exeter Centre and it was the norm for Haemophilia Centres to contribute their data. I understood the national database formed the basis of a patient registry and its purpose was to provide an accurate measure of prevalence and patient and disease characteristics from which important information could be derived to assist planning and investment for future needs. Information provided to UKHCDO included name, age, type of bleeding disorder and severity, products used in treatment, infections, complications and date of death. Without this information, UKHCDO could not have performed its other function, that of providing valuable advice and guidance back to Centre Directors. I found this resource immensely helpful.

50. The only article I have published that is relevant to the Inquiry was published during my time at St George's and has been cited earlier in 9. It was a case report entitled "DDAVP and tranexamic acid for dental extractions in a mild haemophiliac – S Shankar and R Lee" (Br. Dental J, 1984, 156: 450 - 452). The purpose of this article was educational, to increase awareness of alternatives to blood products.

Records

51. At the Exeter Centre the policy with regard to death certificates of patients with HIV or hepatitis who died in hospital was to consult the coroner and to follow his/her instructions. For those patients who died at home I was not involved in their death certification.

52. My policy was to keep medical records indefinitely.

53. I recall that separate files were maintained in relation to

- Legal papers, not clinical files, pertaining to a group action brought by patients infected with HIV against the SW Regional Health Authority and hospitals in 1989. See 4.

- A register/book in which details of clotting factor products issued to patients were entered at the time of issue from the Blood Bank. This book ceased to be used when the Blood Bank became computerised.

I believe these files remain in storage at the Exeter Centre.

54. I did not and do not hold any records about my patients at home.

Section 6: UKHCDO

55. I was an ordinary member of UKHCDO representing the Exeter Centre between 1985 and 2010. As such I provided patient and treatment data to UKHCDO when requested and received information from UKHCDO in terms of advice and guidance. I had some, relatively minor, involvement in one of its working parties investigating reorganisation of haemophilia care. I represented the views of centres in the South West region from around 1986 to around the early 1990s when I think I shared the role with Dr S Davies, Centre Director for Taunton.

56. It was my understanding that UKHCDO was an organisation comprising Directors of all UK Haemophilia Centres and a smaller number of UK Reference Centres. The latter were usually Regional Centres. The South West region lacked both a Regional Centre and a Reference Centre and part of the remit of the working party was to address this anomaly. I believed the purpose of UKHCDO was to lead the development of the specialty by representing its members within the organisational structure of the NHS and to provide up to date advice and guidance on all matters relating to bleeding disorders. To achieve this, UKHCDO needed to have an accurate and complete picture of patient demographics, treatments used and outcomes. The annual returns from Centre Directors served this purpose and the data formed the basis of

planning for service improvements as well as guidelines for best practice. Information was disseminated to members by post, email, conferences and educational symposia. I was not involved in developing policies, guidance, actions or decisions of UKHCDO relating to the manufacture, importation, purchase, selection or use of blood products; self-sufficiency; the risks of infections associated with the use of blood products; the sharing of information about such risks with patients and/or their families; obtaining consent from patients; heat treatment and other measures to reduce risk; vCJD exposure; and treatments for HIV and HCV.

Section 7: Pharmaceutical companies/medical research/clinical trials

57. I have never:

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

58. I have no accurate memory of what regulatory requirements or guidelines were in place during this time concerning declaratory procedures for involvement with a pharmaceutical company and had no such involvement.

Section 8: vCJD

59. I became aware of the risks of transmission of vCJD by blood transfusion in the early 2000s.

60. I recall it was senior staff at the NBS, Bristol, who directed the look-back exercise to identify potentially exposed patients and who coordinated the process of providing appropriate information to patients. At the Exeter Centre the process for informing patients about possible exposure to vCJD followed guidance issued by NBS and UKHCDO.

61. I first notified patients of possible exposure to vCJD in early 2001 by letter. You have provided the evidence [HSCO0004246]. I do not remember what, if any, subsequent notifications were sent. The information I provided to patients about the risks of vCJD was summarised in the fact sheet that accompanied my letter [HSOC0004246].

62. There was no additional counselling available to offer beyond what I and my Paediatric colleague, Dr McNinch, were able to provide.

63. In relation to public health measures that were put in place, I informed hospital management, all relevant consultants in the hospital and the Infection Control Team and provided them with guidance including on sterilization and reuse of medical equipment.

Section 9: Involvement with the financial support schemes

64. My involvement consisted of assisting patients in their applications for financial support to the Macfarlane Trust and Skipton Fund. I provided them with the necessary information and as far as I can recall no other staff was involved. There was no formal policy as such for referral to these Trusts. I would raise the subject of financial support during my consultations and I would provide assistance if required, usually in the form a letter of support. As far as I can

recall, the type of information required by the Trusts included confirmation of diagnosis and severity and whether the patient was infected with HIV or hepatitis. The Exeter Centre did not act as a gateway for determining whether a particular patient met the eligibility criteria. That was for the Trusts to decide. Occasionally I was asked to check an application form or to assist the patient in filling out the form. I have no opinion as to whether the Trusts and Funds were well run. My own experience suggested they did their best to distribute their funds fairly. I did not understand why there were so many separate funds. Perhaps a single, well endowed, fund could have achieved more.

Section 10: Other issues

Reorganisation of Haemophilia Care

65. In so far as this was a contentious issue, particularly in the South West region, that I became aware of soon after I became Director of the Exeter Centre, I did my best to represent the views of fellow Directors in the South West in the Working Party on Reorganisation of Haemophilia Care. As a new consultant I was somewhat reluctant and surprised that other more experienced Directors were not prepared to take the lead. To ensure that South West had a voice in the debate I took on the role of spokesman. Minute 5 c) of the First Meeting of the UK Regional Haemophilia Centre Directors' Committee on 11 September 1989 [UKHCDO0000436] describes my position well. Document [TSFT0000002_001] summarises my concerns arising from earlier meetings of the Working Party, concerns that were shared by fellow Centre Directors in the South West.

66. At the time the South West region lacked a Regional Reference Centre and haemophilia care was provided by 8 separate centres – in Bristol, Bath, Taunton, Barnstaple, Exeter, Plymouth, Torbay and Truro. Patients received most of their care locally but when necessary Centre Directors, including myself, were able to access advice and care for their patients from specialist centres outside the region based on longstanding relationships developed over the years, e.g. Oxford for orthopaedic surgery, the Royal Free for liver disease. The proposal under discussion in the Working Party was to centralise

specialist advice and care in one large centre in the South West, a Comprehensive Care Centre, in line with the model in other regions. While this would streamline the service, it did not appear to be a feasible proposition, given that there was no one centre in the region that could, or wished to, fulfil that role. In terms of patient numbers, Bristol was the obvious candidate, but it was reluctant to take on this role or even to represent the South West in the Working Party. This was probably because the Bristol Centre recognised that it could not meet the other criteria of a Comprehensive Care Centre – leadership in developing services, quality of care, research and innovation, and not least enthusiasm. Patients were becoming aware of the proposals through Haemophilia Society communications and other patient networks. Those who had a view were mainly the most severely affected patients who attended frequently and often had experienced care in various centres in the region. The feedback from them was that the disadvantages outweighed the benefits. They did not like the idea of having to travel long distances, e.g. from Truro to Bristol, for care that they were used to having locally. The geography of the region was a unique problem. Many of these patients had severely restricted mobility and the practical difficulties of travel weighed heavily on them. It would have taken considerable investment in infrastructure and staffing for a Comprehensive Care Centre in the South West to be viable and I do not recall there was any indication this would be forthcoming. I believe the quality of service to my patients would have suffered, at least in the short to medium term. With hindsight, an alternative model based on the Paediatric Oncology model with Consultants from the Comprehensive Care Centre doing outreach clinics in the region might have been acceptable to patients.

67. I cannot recall any more details of the proceedings of the Working Party without consulting all the relevant minutes. It did not meet frequently and by the time I handed over the role to another Centre Director little progress had been made.

68. I am not aware of any complaints about me relevant to the Inquiry's Terms of Reference.

69. In my concluding remarks, I would like to emphasize that this statement is the result of much soul searching and examination of my fading memory. I have reached my cognitive limits in producing this statement and offer my sincere apologies in advance if it is found wanting in parts. Nevertheless, I would be satisfied if my report contributes to the knowledge that the Inquiry is seeking and helps to deliver the closure that longsuffering haemophilia patients and their families deserve.

Statement of Truth

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

Signed GRO-C

Dated: 30/9/20