Witness Name: Professor Ian Hann
Statement No.: WITN3497005
Exhibits: WITN3497006-009
Dated: 19 August 2020

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF PROFESSOR IAN HANN

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 11th May 2020.

I, Professor Ian Hann, will say as follows: -

Section 1: Introduction

2. I am Professor Ian Malcolm Hann of GRO-C, Republic of Ireland GRO-C

   Professional Qualifications:
   - MD BS LRCS
   - FRCPUK
   - FRCP, Glasgow
   - FRCP Edinburgh
   - FRCPI
   - FRCPATH
   - FRCPCH

3. Previous Posts

   1983 – 1988: I was Consultant Haematologist, Haemophilia Comprehensive Care Haemophilia Centre Director and Head of National Paediatric Bone Marrow Transplant Centre, Royal Hospital for Sick Children, Yorkhill, Glasgow. I was head of Department and Director of the hospital's large

children's Haemophilia Centre, Head of Haematology and blood bank laboratories for this hospital, the Queen Mother's Maternity Hospital and another Children's Home Hospital. I was head of the national bone marrow transplant centre for children in Scotland and shared the care of all of the children with blood and malignant diseases, leukaemia and solid tumours with one other consultant, Brenda Gibson.

1988 – 2006: I was Consultant Haematologist and latterly Professor of Paediatric Haematology and Oncology and Head of Department and Clinical Director at the Hospital for Sick Children, Great Ormond Street, London and University College London / Institute of Child Health. Throughout the majority of this period I was Haemophilia Comprehensive Care Centre Director, Head of the Haematology and blood bank laboratories, and shared the clinical care of all patients with blood diseases, leukaemia and lymphoma. Throughout most of that time I was Clinical Director for my areas and for periods I acted as deputy or actual Medical Director of Great Ormond Street.

Until the present, I have worked part time as haematologist to the Irish Blood Transfusion Service, based in Cork, Munster. For one six month period 3 years ago I was full time Medical and Scientific Director of the Irish Blood Transfusion Service. I am also Chair of the Children's Health Ireland National Paediatric Academic Health Group, bringing together all of the Universities in Ireland for the first time, under a legal entity. I am also a member of the Irish National Transfusion advisory Group with special responsibility for CMV screened blood products and blood product irradiation.

I attach a copy of my current CV to this Response which sets out in greater detail the positions held by me.

4. Relevant Committees:

Between 1983 and approximately 2001 I was a member of the UK Haemophilia Doctors' / Directors' Organisation (UKHCDO) and on its Central Committee for Directors. I was an expert advisor to the Haemophilia Society and regularly gave advice during a period of several years between 1988 and 2000. I was the Paediatric Haematology and Oncology Advisor to the Scottish Government throughout 1983 - 1987, via the Strategic Advisory Group of the Scottish Home and Health Department.

5. Previous relevant inquiries, investigations and litigation:

I have not been involved in any litigation with regard to HIV, HBV, HCV or vCJD. Other than the Penrose Inquiry, my only other involvement was with an Inquiry which, to the best of my recollection, was led by Lord Justice Ognall. This was early in my time at Great Ormond Street Hospital (GOSH) and about 1987-1988. I was asked to provide certain detailed information on the patients at GOSH, mainly in regard to blood test results and blood product transfusions (including factor concentrate batch numbers for instance).

6. My oral and written statements to the Penrose Inquiry are true and accurate to the best of my knowledge

7. My answers to subsequent questions will also include any relevant experience during my years 1987 – 2006 at GOSH

Section 2: Decisions and actions of those treating patients with bleeding disorders

8. The Royal Hospital for Sick Children Glasgow (RHSC), also known as Yorkhill, was essentially the children's hospital for the West of Scotland. It also had a national role, for instance as the National Bone Marrow Transplant (BMT) Centre. Although a small number of haematology, blood diseases, leukaemia and solid tumour patients were treated in Edinburgh and Aberdeen, the majority of such children within Scotland were under my care. After one year I had appointed a colleague Dr Gibson, who was proleptic (exempted from duties at RHSC) so that she could have additional full-time training in Manchester. During my time there I obtained additional funding and resources and official designation for the BMT work and transferred all of the care of the brain tumour patients to us.

   I was also responsible as haematologist and head of the haematology lab service to the Children's Home Hospital which I think was in Strathblane, for the Drumchapel Geriatric Hospital, and for the onsite Queen Mother's Maternity hospital which had a very active fetal medicine unit, managing complex issues such as those related to haematology e.g. haemolytic and haemorrhagic disease of the newborn. The RHSC provided a good general paediatric service and some specialised services such as renal, cardiac and neurology.

   Scotland was very slow to emerge into specialised paediatric care. This was partly due to resistance from the generalist paediatricians and especially some of the surgeons. When appointed I was the only trained paediatric haematologist in Scotland. I was initially a sole consultant in haematology and oncology at RHSC and about a year later there were two of us, Dr

Gibson and myself. Today there are eight consultants, which gives one some idea of our workload. There were no specialists in the areas of infectious diseases, hepatology, immunology and virology (for instance) at RHSC, which did produce challenges with optimal patient management. The situation at GOSH was quite different in that all paediatric specialties were provided, with excellent teams. However, Haematology and Oncology just had three consultants, one of whom was a full academic and medical director. Now, even excluding the large bone marrow transplant team, there are twenty consultants in haematology-oncology, which I hope gives one some idea of the burden on us in those years.

9. I was the Haemophilia Director, head of the haematology labs for four hospitals and head of the BMT unit. I subsequently appointed Dr Brenda Gibson who developed a special interest in late effects of cancer / leukaemia therapy and shared the malignant disorders workload. She took over as Director when I left. I was the specialist advisor for paediatric haematology and oncology to the Scottish Home and Health Department. I worked closely with our radiotherapists Dr Anna Gregor and Prof Ann Barrett and our surgeon Mr Amir Azmy . Mr Fred Jewell was our senior chief lab scientist who was initially responsible for clotting tests and for ordering and storing therapeutic blood products. Prior to my appointment my role was filled by Dr Michael Willoughby, with assistance from Mr Azmy and part of the time of a radiotherapist.

10. Initially I was sole consultant at Yorkhill with responsibilities to RHSC, Queen Mother's, Drumchapel and Strathblane. I was Haemophilia Centre Director and head of the haematology labs and head of the national BMT Centre throughout my four years there. Dr Gibson started after about a year and shared the workload of malignancy and bone marrow disorders. I looked after all of the children with blood and bleeding disorders and all of the brain tumours and the majority of children with solid tumours. Dr Gibson shared the workload of the malignant and bone marrow and non-malignant blood disorders when she took up her post. I provided, with Dr Gibson, a service to the perinatal patients and Dr Gibson took the lead in that area and with late effects of treatment.

11. I do not have exact figures for the number of children with bleeding disorders during my time at Yorkhill. My memory is that there were approximately 35 children with severe haemophilia and possibly another 40 with other coagulation disorders. The number increased slightly during my time there but I have no exact data available to me.

12. We were not involved in the manufacture of any blood products. My policy, based on my previous training at the Royal Free Haemophilia

Comprehensive Care Centre at the Royal Free Hospital (RFH) and GOSH was to use British manufactured products (Scottish in this instance) wherever possible. We were in regular contact with the SNBTS (usually Dr R Crawford) with regard to supplies. I spent my first six months in the post creating Standard Operating Procedures (SOP's) for the management of the wide array of patients for whom I was responsible, as no written SOP's existed before my appointment. The fall-back position, on the relatively rare occasions when Scottish derived product was not available was to ask Mr Jewell, our senior chief lab scientist, to source available American product e.g. to cover surgical procedures; my memory being that he continued the same process and sources as Dr Willoughby as there was no perceived difference between the commercial products by Haemophilia Directors at the time.

13.

a. Selection of blood products was made on the basis of clinical need, laboratory diagnosis, age and severity of bleeding e.g. whether or not this was simple mucosal bleeding such as epistaxis or major internal bleeding such as psoas bleed. *Vide supra:- if a product required to be used,* my policy was Scottish product first and foremost unless it was not available.
b. Prior to my taking up the post there had been a preference for commercial product from America as it was deemed to be more readily available and purer thus easier to draw up as it had less tendency to form fibrin strands. My training was that British product was inherently safer as the donor population was more reliable, not remunerated and altruistic throughout. I thus switched all patients whenever possible. SNBTS always did their very best to fulfil orders and rarely were unable to do so. It may have been the case that supplies had improved, but I am not in possession of that data
c. *Vide supra:- .* I do not know what proportion of product that we used was from the SNBTS, but would expect it to have been greater than 90%.
d. The choice of product used depended on the underlying disorder e.g. Haemophilia A, or B or von Willebrand's disorder. I have explained above that my preference throughout my career was to use product from British donors wherever possible, until recombinant-produced product became available and solved the problem.
e. Commercial and financial considerations never played any part in my decisions with regard to patient management
f. The policy towards therapy for bleeding disorders was ultimately mine, following discussion with our multidisciplinary team and on the best available evidence and guidelines, where available.

14. On rare occasions I would speak with representatives of the commercial companies manufacturing and supplying blood products, to determine if, for instance, longer acting and thus more easily applicable product development was progressing, what pathogen-reduction processes were developing, what was the chance of recombinant products becoming available etc. I had no commercial interests other than requesting funding to attend meetings for which I could not secure funding, such as the American Society of Haematology and World Federation of Haemophilia. In order for this never to become an issue, I ensured that this occurred on a rotational basis with the pharmaceutical companies who in fact supplied very little product for us.

15. The SNBTS always made it very clear that they wished to supply all of our patients' needs. There was no other organisation involved in product selection.

16. Many of the patients that I managed had already been treated, the majority for a number of years, and their treatment plans were already in existence as determined by Dr Willoughby and enacted by Dr Pettigrew. The great majority of patients who required concentrates attended regularly and on many occasions for review of bleeds, supplies, collection of therapy documents and had many opportunities to discuss any issues at all. I set up a new regular formal review clinic, within a few months of taking up my post, and the main aim was to review progress, talk about therapy and dosing and give families an opportunity to discuss whatever they wished to discuss. In addition, they were all advised to join the Haemophilia Society and were distributed literature from that organisation. Plus, we began for the first time to set up parent groups at which therapy and other issues could be discussed. The policy was always for complete transparency. We adopted a team approach with a social worker and specialist nurse who was available in day care so that further discussion could occur. I supplied (through the use of charitable donations) all newly diagnosed families with the excellent book Living with Haemophilia by Dr Peter Jones; written precisely for the purpose of keeping families fully informed. All patients were informed of the therapeutic options which were clearly described in all of the provided literature and when delivering supplies and attending clinic reviews. They would have been informed that we advised the use of NHS product for the reasons already stated. It may have been the case initially and possibly subsequently that some families may have chosen to return to purer commercial product because of ease of use.

17. Alternative treatments for people with haemophilia consisted of various modalities. Physiotherapy to strengthen muscles and joints was developed and could be accessed at clinics, along with booked regular dental

preventative checks. Topical therapies for mucosal bleeds such as nose and mouth bleeds consisted of tranexamic acid, DDAVP and topical thrombin. Cryoprecipitate could be used to treat factor VIII and rarely other deficiencies but was unreliable with regard to response and not suitable for home therapy and of often unacceptably large volume and length of infusion in hospital.

18. DDAVP was useful in treating some patients with von Willebrand's disorder (vWD) as long as it was not type 3, and also some patients with 'mild' haemophilia. Its advantage was that it was not a blood product. It required treatment in hospital as a day case and was not suitable for children below the age of 3 and those with seizures due to the development of hyponatraemia. It was often not useful for more serious bleeds or persistent bleeding, due to tachyphylaxis and unreliable responses which were very difficult to accurately monitor in a timely manner. Topical thrombin and tranexamic acid were only useful for simple epistaxis and lip / mouth bleeds. These were also not blood products. Cryoprecipitate had the advantage of being from a restricted number of donors and thus transfusion of infection was less likely but still an issue. It had been used for a large number of years for treating people with haemophilia but was of relatively large volume, required careful freezing and thawing, infusion over a relatively prolonged time in hospital, and was subject to quite frequent and sometimes severe transfusion reactions. It could not be used for home therapy, other than in rare cases. Home therapy revolutionised and empowered the lives of persons with haemophilia. I always practiced on the very clear understanding that ALL blood and blood products could, and many still do, carry a significant risk of transfusion-transmitted infection (TTI). Thus, the balance of risks in the choice of product and therapies used were clearly presented in the literature provided and in discussions with every bleeding episode.

19. The use of cryoprecipitate, before the HIV tragedy, for haemophilia therapy had largely fallen out of favour for the reasons described. Measurable responses of factor VIII levels were very difficult in a timely manner at the best of times and during the early HIV era getting specialised lab tests done was even more challenging. Where factor responses could be measured, it was often clear that responses were sub-optimal. I trained in the era before factor concentrate therapy and frequently experienced all the difficulties and side effects that I have detailed when using cryoprecipitate. During the HIV era some families chose after discussion, to try this approach again and they did experience the described problems with its use. It was not safe to use for any serious bleed as responses could not be predicted nor easily calibrated and large volume therapies were very difficult to manage, especially in young children and if reactions occurred. It meant being tied to

the hospital again, which was especially difficult for those who did not live nearby. Infusions via 'drip' meant often severe difficulties with venous access in young children who often became very distressed. Infusions also required extra resources of nursing and medical time, which was very challenging.

20. The institution of home therapy occurred during my time in training and was a 'game changer'. At last the patient and family were empowered and could hope to live a normal life; an expectation that we all had until it came crashing down in the 1980's. Dr Willoughby had instituted this approach with Dr Pettigrew at an early stage, a few years previously, and I continued that process, which was widely accepted as the standard of care. This did not change other than for the rare change to cryoprecipitate therapy for a relatively short phase in the HIV era.

21. Dr Willoughby was an early convert to prophylactic therapy and a few patients were on two or three times weekly treatment. Although results from Sweden were very encouraging, I was initially very sceptical as I had seen in London, and then in the Yorkhill patients, that those with target joints apparently did not do well. In fact, a few years later, I became an advocate of this therapy, including in patients with inhibitors to factor concentrate, at a time when many remained sceptical. We published our results in the worst affected patients at GOSH, in the early 1990's (Liesner R et al; exhibit WITN3497006) and championed this approach. The fact that this would cost a great deal more and require a greatly increased supply, which would not have been available in the 1980's was not the issue. That was a battle still to be won.

22. Children with mild or moderate bleeding disorders were usually managed without the use of factor concentrates. However, it had been pointed out in the very early days at the Royal Free Haemophilia Centre by the pioneering doctor Katherine Dormandy, that such patients did bleed and did suffer severe morbidity and mortality if they were not treated after injuries or following inappropriate procedures not covered with haemostatic therapies such as surgery / lumbar punctures etc. We would treat most injuries with DDAVP or sometimes cryoprecipitate or with the other non-factor products discussed above. Severe injuries such as head injuries / eye injuries / continued bleeding/ blunt force trauma could only be treated with concentrate because immediate predictable cessation is required.

23. I am unaware of any TTI in the Glasgow population during my time period, due to organisms other than HCV, HBV and HIV.

24. During my 20 years at GOSH our policy was always to use British pathogen – treated products initially and when they were available. However, within a relatively short time we were able to take part in pioneering studies with the new and inherently safer recombinant products. Thereafter we were able to institute recombinant concentrate prophylaxis for all eligible patients, as one of the first places in the world to achieve this comprehensive approach. Our aim was to reduce spontaneous bleeds to less than one per year in non-inhibitor patients, and we achieved that high bar.

Section 3: Knowledge of, and response to, risk

25. My knowledge of the infection risks associated with blood and blood products, upon taking up my post in Glasgow, was based mainly on my training and education. I had looked after persons with haemophilia of all ages throughout my 12-year career up to this point, including in major centres in Manchester, Royal Free (RFH), Liverpool and GOSH. Part of my training for the MRCPath examinations was in relation to coagulation and management of people with bleeding disorders. I was familiar with the major haematology and haemostasis textbooks of the time.

    In the era leading up to 1983 the major concern was related to the transmission of Hepatitis B. Testing of donors and vaccination of staff and patients gradually made this less of an issue, but at the RFH under Dr Peter Kernoff and Prof Tuddenham, there was a particular emphasis on the need to avoid the use of donors who had been at higher risk of Hepatitis B. To this day, there is still a risk from such donors as there is a 'window' through which such donations can escape and be transmitted if pathogen reduction techniques have not been applied.

    Prof Dame Sheila Sherlock was a world-renowned head of the liver unit at RFH and her teaching at the time as stated in her textbook was that non-A and non- B hepatitis was not a serious health issue (Dame Sheila Sherlock: 6th Edition of Diseased of the liver and biliary system 1981). We had no specific test or gold standard diagnosis and no available product treatment process to further reduce risks. We were in the early stages of collecting information on NANB hepatitis, and nobody that we were aware of predicted the emergence of HIV. My understanding was predicated throughout upon developments on understanding of the virology and epidemiology, and in particular the discovery of the HIV virus and Hepatitis C virus, the latter in approximately 1990.

26. The advisory and decision-making structures with regard to transfusion transmitted infection (TTI) in place at RHSC or nationally, depended in large part upon the collective advice produced by the United Kingdom

Haemophilia Doctors' Organisation (UKHCDO). I have previously pointed out (before the Penrose Inquiry) that we lacked an expert national advisory group with governmental input from expert virologists with clinical interest (of which there were very few at the time) as well as epidemiologists, public health doctors, hepatologists, infectious disease doctors etc. In addition to UKHCDO meetings, there was regular and frequent consultation with the other Directors in Scotland and especially Prof Lowe and Prof Forbes.

27. As previously stated, the relative risks of TTI from commercial versus British blood products were not explicit in available (to me) data. The mantra, based on the risks of a donor being Hep B positive, were interpreted by my mentors as indicating that unpaid, altruistic donors with no inducements were likely to be safer in this context.

28. In order to minimise the risk of TTI my policy and educational approach to all staff was that transfusion of blood products should be used conservatively and only when absolutely necessary in all patients with whatever diagnosis. Wherever possible, within the children with bleeding disorders, the clear policy was to use alternative therapies as described above, where those therapies could provide adequate haemostasis.

29. Training and advice to clinical staff at RHSC with regard to TTI risk of blood products is and was an integral part of haematology training through lectures, examination and day to day patient management discussions. Dr Pettigrew and the nursing staff had managed persons with bleeding disorders for years and were already expert in their field. Updates occurred by supporting their attendance at national and international scientific meetings.They had excellent interpersonal skills when explaining all of the many risks and benefits of therapies of various types. We frequently discussed as a team, the updates from the UKHCDO, World Federation of Haemophilia (WFH) and the Haemophilia Society.

30. From 1987 until 2006 at GOSH the risks and benefits of therapies and pathogen reduction measures developed apace. It was always my goal, and that of all other treaters, to be able to manage our patients with recombinant products with no risk of TTI. The understanding of Hepatitis C (Hep C) risk developed rapidly after 1990 and thankfully by then we had concentrates shown at last to be effectively treated for pathogen reduction, plus the development of recombinant products. It became clear that Hep C was a chronic serious disease which required major therapeutic intervention, but initially the drug therapies were very limited and largely ineffective.

31. The initial policy at GOSH, when I took over in 1987, was unchanged from that of my predecessor Prof Hardisty and similar to that used at RHSC with regard to risk of TTI. Clearly by then we had safer product and took part in recombinant therapy trials as soon as they were available.

Hepatitis

32. My knowledge of TTI with regard to Hep B and NANB hepatitis when I began at RHSC was derived from my extensive training as described, in large internationally-renowned Haemophilia Centres. The question implies that NANB hepatitis is Hep C, which is not the case. Not only was there no standard test, but also the virus had not been described.Rises in liver transaminases are associated with numerous causes such Hepatitis E (also described subsequently), cytomegalovirus (CMV) etc. The greatest fear was of Hep B transmission which was often a serious illness which could be life threatening. NANB was widely thought to be a minor issue with no good evidence that it had more serious import until later. It was known that most, if not all, persons with treated large pool concentrates of any derivation would develop this ill – defined biochemical abnormality.

33. The knowledge about Hep C, and of the many other causes of so-called NANB, gathered pace slowly in the 1980's and then accelerated in the 1990's when the virus was discovered. It became clear that it became much more serious in an individual over a prolonged period of years, than previously supposed and that it was sometimes associated with major morbidity and mortality. This made it even more important than previously realised, that reduction of TTI risk, as already described was of paramount and urgent importance.

34. Transmission of hepatitis by TTI was always regarded as a risk since the occurrence of Hep B in persons transfused with infected blood and blood products. As with all other UKHCDO members we followed the advice of that organisation and regularly (every 3 – 6 months usually, depending on product usage) tested children at their routine appointments or when they attended for clinical assessment or product supplies. I cannot remember exactly, but I believe that episodes of Hep B were reported to the UKHCDO annual data collection, and that may also have been the case for patients who had persistent transaminitis. I am not in possession of relevant information and cannot recall if further investigation with regard to product allocation was carried out.

35. RHSC reduced the risk of TTI hepatitis by using alternative therapies to blood products as already stated, and by using products sparingly and appropriately.

36. As previously stated, knowledge of the nature and severity of different blood-borne hepatitis types is developing to this day. We, for instance still do not know the full panoply and consequences of Hepatitis E. In the period of the early and mid 1980's we knew of the severity of Hep B, and we knew that CMV caused hepatitis and other conditions and was one of the commoner causes of death following BMT. The evidence with regard to NANB was as Dame Sheila Sherlock said in her seminal work (Dame Sheila Sherlock: 6th Edition of Diseased of the liver and biliary system 1981) "uncertain but probably benign", a statement that had been changed radically ten years later in 1990 when she recorded the 20% development of liver cirrhosis over a 20-year period of infection. This reflects my own knowledge development.

HIV and AIDS

37. Our knowledge of AIDS was very limited and very uncertain by 1983. I was present at the Immunocompromised Host Symposium in Stirling approximately 6 months previously. I attended because my expertise was in the management of children with immunocompromise and infection, particularly leukaemia. Most non-American delegates were stunned to hear of the ravages of a new disease which had come out of a clear blue sky. Various theories of causation were proposed, including non infectious causes and predispositions, until the virus was discovered by Montagnier and others about a year later. I heard about the various serious complications of the disease and its high mortality and severe morbidity, mainly in homosexual men, at the meeting.

38. My knowledge and understanding of HIV infection whilst at RHSC developed exponentially, as it did with all Haemophilia Directors. We learnt about the virus, its modes of transmission and its clinical sequelae, especially Pneumocystis pneumonia. At the time this was thought to be a protozoan named Pneumocystis (Pn) carinii; now it is renamed Pn jirovecii and is correctly redesignated as a fungus. We also recognised descriptions of a wasting syndrome and Kaposi sarcoma. Information became available about some methods of preventing clinical sequelae, such as Co-trimoxazole prophylaxis for Pneumocystis. Unfortunately, effective therapy for the primary cause was otherwise several years away.

39. Initial knowledge of TTI HIV was not clear until close to the time of discovery of the virus. Initially it was thought to be a disease of homosexual people and intravenous illicit drug users. At the Stirling meeting a very small number of persons with haemophilia and other underlying disorders was presented,

but it was not clear until at least 6 – 12 months into my time at RHSC that this was a blood borne TTI.

40. With regard to investigation of the association of HIV and TTI, I did not carry out any such investigations initially, until it became clear that this was an issue. When the virus was found and a reliable test validated, then we were supplied with details of the positivity or otherwise of our bleeding disorder patients. The information was collated with the factor batch histories, I believe through the UKHCDO and possibly SNBTS and regulatory agencies. I am not in possession of the outcome data which could be obtained from previous chair persons and the SNBTS.

41. As soon as we were aware of the association of TTI and HIV, we ensured that families were informed of the risks of sexual and blood exposures and the possible known consequences to the afflicted person. Some parents chose to reduce their use of factor concentrates and we ensured that concentrates and other blood products were only used when absolutely necessary. My recollection is that a few families chose to switch to the use of cryoprecipitate because of the reduced exposure to large numbers of donors.

42. Did we continue to use factor concentrates after becoming aware of the risks of TTI HIV? Yes we did, after full and continuing discussions with the parents. Whenever possible, and in almost all or all instances this would be with SNBTS concentrate. The management of haemophilia without factor concentrates is very difficult and can lead to long term sequelae such as neurological dysfunction, severe arthritis and can be life – threatening. I have discussed the pros and cons of alternative therapies above.

43. The management of children with bleeding disorders at GOSH from 1987 was initially the same as that employed at RHSC and followed UKHCDO policies as discussed. As already stated, all was to change when recombinant products became available.

Response to Risk

44. Did we at the RHSC take steps to inform parents and / or the public about the risks of hepatitis and HIV? The information of hepatitis risk from TTI and blood and blood products was supplied by the SNBTS through donor health life questionnaires (HLQ) and other public health measures, the details of which I cannot recall. The Haemophilia Society produced leaflets on various subjects including therapy issues, which we and they distributed. Sections of the book 'Living with Haemophilia' which we supplied contained all information in great detail, specifically targeted at parents and children. We

had a clinic, parents' support groups and access to social workers, a specialist nurse, Dr Pettigrew and myself, through an 'open door' policy in Day Care and the clinic area.

45. It was my opinion, as already stated and based upon my training, that American sourced plasma-derived products might carry a higher level of risk of TTI than domestic product. There was no actual data to support this that I can remember, although I believe that there had been reported higher levels of Hep B detected amongst American remunerated donors. In essence, I still believe that the best policy includes a system based on no inducement of any kind and rigorous HLQ application, as still exists in UK and Irish donors, for instance. When I started at RHSC there was a small amount of American product remaining as I believe that the majority used by my predecessor was American. I cannot state exact proportions, but I would expect that I used more than 90% domestic product and changed over completely as soon as existing stocks were used.

46. I cannot recall exactly when we started using heat treated and solvent-detergent treated products. The answer is straightforward – it was as soon as they were shown to be safe and available and to have a probable effect as advised by the SNBTS (and maybe also the UKHCDO). We always used the safest available product when available.

47. We explained all changes of product as they were introduced individually. This was done mainly by Dr Pettigrew and other members of the haemophilia team and was simply described upon the basis that safety and efficacy had been shown to be superior to existing products, for example that they were not associated with demonstrable increases in inhibitor incidence or transfusion reactions. Every family had ample opportunity to question any aspect of management, and were never discouraged from asking questions. There were multiple attendances for bleeds, clinic attendances, supplies and treatment record discussions.

48. As stated above, a few patients were treated with cryoprecipitate with the difficulties described and usually for short periods of time. When the families learned of the diagnosis and the risk of acquiring HIV they were given the opportunity of discussing again the various therapeutic options for the bleeding disorder and HIV. There was never a paternalistic or controlling approach from our team and they could access other members of the team e.g. the social worker if they had specific or unresolved concerns.

49. I am aware that some families believe that we did not make enough effort to make them aware of TTI risks. This was never to my knowledge expressed at the time or over the subsequent three years. Our belief was

that our infrastructure of a dedicated permanent team, open door policy, access to nurse and social work, psychology referral when required, new parent support groups, new multidisciplinary clinics and contacts with the Haemophilia Society and leaflets from same and access to printed literature such as Living with Haemophilia *would* suffice. Clearly, this was not enough for some and I should have foreseen that. This was at a time when I had my many other serious duties that I managed such as those related to the high global death rate amongst malignant disease affected children. However, with the benefit of hindsight, I should, I think, have made specific set extra times available for them to see me personally outside of their regular clinic appointments and concentrating on 'inherited patients'.

50. With the benefit of hindsight and now three Inquiries, I have for more than three decades asked myself what could have been done differently. If there was anything known that I could have done to bring the use of infected blood products to an earlier conclusion, then I hope it is obvious that I would have done so. To the best of my knowledge I was never responsible for a product that transmitted HIV. With regard to Hepatitis C, I simply do not know as the virus had not been found whilst I was at the RHSC and I do not know who seroconverted and when. None of my GOSH patients seroconverted during my period as Haemophilia Director there. As soon as safer products were available we used them. The SNBTS pulled out every stop to address the issue and I hope it is clear that we delivered safer care as soon as it was available, and I dedicated a significant part of my career to delivering safer and more effective products at the RHSC and GOSH.

51. I have considered blame for the scale of TTI very carefully over the years. It is easy to blame Pharma, but it should in my view be recognised that they ended up solving the problem, which is one of the reasons why I moved to Bayer and the development of recombinant products (along with other haematology products) after clinical retirement. It must also be understood that domestic product also caused some TTI, possibly due to inadequate HLQ questioning and acceptance of donors that was too lax. I believe that there was a failure to produce domestic product in adequate quantities. Decisions were made which were against the advice of haemophilia treaters who desired greatly increased production so that prophylaxis could begin properly, inhibitor patients treated with high dose tolerance therapy, and purer product provided. Decisions were made at some level of government or transfusion service management (I do not know which) not to greatly ramp up therapy. My memory which may not be accurate is that other countries such as Germany had achieved greater success in production. I am not aware of calculations which would elucidate whether or not this greater production would have reduced exposure or otherwise.

52. With regard to pathogen reduction of blood products and when this should have happened, it is important to understand that this remains to this day, a major issue in blood transfusion, particularly in relation to platelets and blood. The technology and science have been painfully slow to develop and we are still currently wrestling with the issues, c.f. the issues produced by Zika virus infection in the Americas. In the 1980's little had been achieved, despite what appeared to be tentative efforts to heat treat and possibly solvent-detergent treat plasma products. It is possible that this could have been ramped up but it usually requires a crisis like Covid19 for rapid medical progress to occur. The fact was that clinical virology was essentially in its infancy and infectious diseases dealt mainly with bacteria. Once the immediate Hep B problems had been resolved then the imperative fell away. I am not aware of any other reasons to explain slow progress until HIV hit everyone.

Section 4: Treatment of patients

Provision of information to parents and their families

At the RHSC

53. Information about risk of TTI was provided to parents and families of children with haemophilia through regular verbal contact at opportunistic visits for bleeds and supplies,at other consultations, at planned new clinic visits and at parent support groups. The majority of patients were diagnosed and treated and their management plan instituted by Dr Willoughby before my appointment. When I or Dr Pettigrew saw them, we discussed any such issues when brought up and they were advised about Hep B testing and the need for vaccination when it became available. At that time this was the only extant serious infectious threat.

    When taking their routine (usually quarterly) blood samples for factor assays, Hep B testing, blood counts and biochemistry tests the intention would have been to explain that we were looking to see if their liver function indicated hepatitis through transaminase testing. In statements and testimony given to this Inquiry, I am aware that some families felt that we had not been detailed enough about the latter information. It was in fact the case that we knew little about NANB and there was no standard of care or accepted standard of diagnostic testing other than some conventions which stated that a persistence of at least doubling of the transaminase levels may indicate NANB hepatitis.

    There was no specific therapy and no viable alternatives to factor concentrate for the severely affected patients. We followed UKHCDO policies throughout. However, in retrospect I believe that we should have been more proactive in describing the current uncertainties of what was

thought to be a minor issue. I had assumed that there was ample time for parents to bring this up at the multiple visits, clinics, support groups and through contacts and information from the Haemophilia Society. I could have done better in this respect and regret that I was not more proactive in identifying families by some means, where information prior to my arrival had not been fully understood. To the best of my knowledge I did speak to all newly diagnosed families and provided literature such as the book 'Living with Haemophilia' which described the best standards of care at the time. In subsequent years I ensured that I personally spent time detailing all the possible outcomes and always made clear that we were there to answer all queries without judgement. There was never anything other than a desire for full transparency and there was never any motive to do otherwise on the part of any member of the team.

54. The question of alternative therapies for bleeding disorders was discussed at all of the opportunities provided as described as above and in the literature provided. Taking over the care of long-established patients is not always straightforward as one is not fully aware of their level of knowledge. In this respect it was of immense value to have Dr Pettigrew as my lead clinical assistant. She knew the patients very well and often knew other affected relatives and had established excellent open relationships. However, I believe that in hindsight I could have done more to start again 'from scratch' in order to refresh memories and update information myself.

55. Home treatment had already been instituted for all eligible patients before I arrived. It was often several years before my own newly diagnosed families could gain reliable venous access themselves and thus the information provided was carried out some time after I began and consisted mainly of multiple discussions and demonstrations with Dr Pettigrew, the specialist nurse and her colleagues on Day Care. I cannot remember the actual written detail that was provided other than the excellent descriptions in the Living with Haemophilia book and the written information and group discussions provided by the very helpful Haemophilia Society.

At GOSH

56. Whilst I was at GOSH I was very fortunate to have an excellent full time Haemophilia Clinical Nurse Specialist with first class family therapy training. She and I spoke at regular intervals to all patients, initially those managed by Professor Roger Hardisty and subsequently by myself. We were assisted by the senior registrar trainee doctors who all had haemophilia care experience via the RFH in the main. By this stage TTI was a major concern for all families and we provided written information that we and the Haemophilia Society had produced in abundance and again we

recommended becoming members of that patient / parent organisation. By this stage we knew a great deal more about HIV, although treatment was still very unsatisfactory. We also had access to what the RHSC did not have, which was a very well-established specialist paediatric infectious disease department with two dedicated consultants and a first-rate clinical nurse specialist also with family therapy training, plus social workers. They were involved from the outset once Hep C was described and provided a great deal of oral and written information. However, like the RHSC and other Centres, we did not have dedicated space for a Haemophilia Centre and had very little or any space for private conversations.

HIV

57. Discussion of HIV positivity of patients was planned to be within a few weeks and no longer than three weeks of receipt of reliable antibody test results. The majority of such discussions were carried out by Dr Pettigrew although I believe that I may have seen a very limited number myself. Such discussions would, if possible, take place with the Haemophilia Day Case nurse and social worker where feasible.

    The decision, however, as to how and by what means the discussion should be set up was a very difficult one. Time and transparency was of the essence but as a team we believed that a telephone call or letter was not an appropriate way to pass on this devastating news. The majority of infected patients attended regularly and the opportunity was taken to interview the parent in as private a way as possible. I have no recollection of ever imparting such serious information in a corridor, to any of my patients with malignant disease, blood diseases or bleeding disorders. There was however a severe shortage of private interview rooms, meaning that the circumstances were not always ideal; something I addressed when I was the Clinical Medical Director responsible for the redevelopment of GOSH. The discussion was about the disease and what we knew about it at the time, the need to prevent household, blood and other transmission and the need to address prophylactic antimicrobial therapy.

58. The transmission of test results came from Dr Follett in a letter I received at a date that I cannot recall. We and the families knew that a number of attempts to set up testing in Scotland and elsewhere were under way and that full validation of the techniques had taken some time, as it always did and still does, with new virology serology tests. The tests were carried out on stored serum samples which had been taken at the routine (usually quarterly) testing which it was standard to perform, looking specifically for Hep B. It was standard virology lab practice at the time, and still is, that viral samples were stored and kept for some years to facilitate essential lookback

programmes. Nowadays permission to store samples for possible future testing e.g. from blood donors is consented and ethically approved, but that was not the practice at the time. It is regrettable that it took a crisis for this level of consent to become standard medical practice. I did not, to the best of my recall, request retrospective serology testing but it was in fact essential that we knew the results, for the patients' sake.

59. As stated above, prospective consent for storage of virology samples was not the standard of the time and was not sought. I did not request the retrospective tests results but it was our expectation, and I would expect that of most if not all of the families, that it was essential for the diagnosis to be made. As stated above, we informed the families as rapidly as possible, and there was a requirement for repeat sampling and confirmatory testing using other methods, as this was a novel test. The families were informed that confirmation was required.

60. Pre-test counselling was not as robust as it should have been when applying today's standards, although all families by this time were very well aware of the serious risk of HIV positivity in haemophilia children treated with factor replacement. Discussions took place with the majority of the families prior to the results as there was a significant interregnum before we were sure of the diagnosis.

61. I have no memory of a meeting on 24th November 1984 between Haemophilia Directors and SNBTS. I have reviewed the minutes of that meeting and see that Dr Gibson deputised for me, as she did on the infrequent occasions when I could not be available. I am clear that our first communication about valid HIV results was the letter received from Dr Follett and that I had discussed those results with Dr Pettigrew and presumably had communicated as usual with Dr Gibson.

62. As stated above, parents and some patients were told in person as we believed at the time that telephone, and letter communication or group talks would not be the best way for the families to hear. We believed at the time that this was the best way to communicate with the families. However I appreciate now that the down side to opportunistic day care and clinic room discussions was that it was often the case that only one parent was present. I was not informed at the time that this was a problem, and I had assumed that the other parent would understandably take the opportunity of our open-door policy to pursue any further questions. I have subsequently learnt that this caused considerable distress to some families and again, with hindsight, I wish that we had taken more steps to ensure that the other parent could be contacted and attend without causing greater stress in advance. I regret that our communication was not as good as we would have wished.

63. Informing children about their illnesses, and how and when, was an issue that I faced throughout my career. It is important to understand that our policy always was to transfer children to adult haemophilia centre care once they were established in secondary education and thus the relevant patients would have been all or nearly all below the age of 13 years. Our policy was always to offer to speak to the children individually or along with their parents, and with a social worker if possible. Most families chose to do this themselves, but the availability was always there. We would offer advice as to how to explain in simple terms and in a way that expressed truthful but not distressing future prospects and management.

64. The significance of an HIV positive result was explained at a number of visits and over time we were able to be more explicit with regard to prognosis, outcomes and therapies. At diagnosis, all of that was very uncertain and that situation was conveyed plus the assurance that developments would be communicated. It was not our business to advise parents to keep secrets. We always strongly advised appropriate truth with their children and we all fought extremely hard, often against the odds, to maintain absolute confidentiality. That latter was an ongoing battle for years due to the extreme anxiety within the population and the desire of some to disseminate personal information, and others to pursue victimisation.

65. Prognosis and life expectancy were extremely uncertain in this population at that time and for some years to come and this was clearly explained to families through the various means already described. As expected, therapy options altered that considerably. Families were more than aware of the media hype about what was often called a plague at the time and were aware that a fatal outcome was a possibility.

66. Families were very well aware and fully informed that HIV was a TTI and that their factor therapy was the culprit.

67. Post-test counselling for children and their families was provided at the RHSC by the team including social workers and referral to the very good psychology and psychiatric services at Yorkhill. Such referrals were recommended when deemed necessary and when requested, and were readily available. Otherwise, families had access to the Haemophilia Society and parent support groups. The medical / clinical aspects of counselling occurred with Dr Pettigrew, and sometimes myself, on what were usually numerous visits over the next period.

68. I am not aware of any discussions anywhere amongst clinicians who did not want to inform families or adult patients of their diagnosis. Such an approach would never have been acceptable or feasible. Many initial discussions took place as to how best to go about this and there was in my view no easy answer. As I have said, with the benefit of hindsight, I did not manage that in an ideal manner despite my very best intentions, *vide supra* Q62.

69. HIV testing of family members was not a major issue in the paediatric setting. I have no recollection of our approach to such testing and in view of the age of our patients I don't understand why it would have been necessary. Known adults with haemophilia would have been managed in an adult haemophilia setting. We would not have refused to test an immediate family member if they had genuine concerns over their own status.

70. Our discussions with regard to family members of children with HIV was confined to their parents. That would include reinforcement of the already essential practices of antisepsis and avoidance of needle stabs or blood spillages, disposal of clinical waste, managing any overt bleeding, which had already been discussed throughout the years of therapy at home and in hospital.

71. The numbers at RHSC infected with HIV to the best of my knowledge and after review of previous data:-

    a. Severe haemophilia 19 children
    b. Moderate haemophilia 2 children
    c. Mild haemophilia A 0 children
    d. Haemophilia B 0 children. von Willebrand's 0
    e. All were children. Adults were managed at GRI

72. The dates of the last negative and first positive HIV test are know for 12 of the 21 patients (as determined by Dr Chalmer's subsequent review – WITN3497008 and WITN3497009). Two seroconverted between January 1980 and January 1981, one child seroconverted in 1981, Three seroconverted in 1981-82, four in 1982-3, one at some stage between 1981 and 1983, and one at some stage between 1982 and 1984. Thus, about 5 were infected before the first cases of AIDS were reported in haemophilia persons and up to 16 infected before the first cases of AIDS in a UK haemophilia person in the UK. It was possible to establish that one child was infected by NHS product, 6 with either NHS or commercial product and 14 were infected by commercial product. The 21 children were infected with HIV relatively early in the HIV crisis, probably as a result of the widespread use of commercial product.

73. When I commenced my role at GOSH all of the patients with haemophilia and HIV infection had already been jointly managed with the expert infectious diseases team described above. A number of them already had symptoms of infection such as low platelet counts and were being considered for antiviral trials. When AZT became available they were eligible for treatment trials through the normal ethical and consent processes.

74. With regard to testing and diagnosis of HIV

    a. As stated above, HIV results were received through retrospective sample testing via a letter from virology. To the best of my knowledge I did not request such. The plan and policy was to request tests once they were valid and available. Then the policy was to do confirmatory testing, I think by Western blot, once seropositivity had been shown. The stored samples were taken as per the policies in most Haemophilia Centres, as described
    b. Testing for HIV consisted, as already stated, of confirmatory tests once we had been informed of retrospective serology results.
    c. Pre test counselling per se did not occur as retrospective sample results came through to some extent unexpectedly as described. Prior to that event, families were counselled at their regular attendances at day care and clinics when they were encouraged to ask questions. The storage of samples and consent for their use should have required more explanation; they were informed that Hep B testing was being performed, and these were the samples that were retrospectively tested.
    d. As already stated, testing of other family members was not a relevant consideration at RHSC. If there was concern amongst such persons then they were counselled and immediate family members could be tested if requested. However, I do not recall that we came across such requests.
    e. How and when patients seroconverted at GOSH is an issue about which I have only very vague memories. As far as I can remember lookback studies were going to be carried out through public health auspices, but I am not certain. As far as I recall, all seroconversions happened before 1983.

75. By the time that I had arrived at GOSH, I and many others had realised that consent processes were not adequately applied. We instituted fully informed consent for all transfusions and all testing procedures which basically consisted of an explanation of what was happening, why it was happening

and the risks of such. Much of that had been in existence for many years but there were gaps e.g. the consent to test stored samples, consent to proceed with straightforward procedures such as essential blood and platelet transfusions etc.

Hepatitis B

76. My memory is that we did not have any Hep B infected patients with haemophilia, but I am not certain. No case of Hep B TTI occurred during my time at Yorkhill or GOSH.

77. See question 76. Actual Hep B acquisition was not an issue.

78. See question 76. To the best of my knowledge there were no Hep B infected haemophilia children at RHSC.

NANB Hepatitis

79. I have no detailed recollection of how many children with haemophilia had a designation of NANB hepatitis. It is important to understand that this is not actually a diagnosis, but rather a description of a 'ragbag' of a series of conditions leading to persistently raised liver transaminases. Some of us at the time requested that the situation would more accurately be called persistent transaminitis of unknown cause.

    I think that there may have been a small number of patients at the time that had doubling of their enzymes over a six month period previously to my coming to the RHSC. There may have been a very small number more whose results changed in this way during my time. The policy was that Dr Pettigrew would inform them, or myself, at their opportunistic or clinic visits. The intention was that they would be informed at each visit that we were checking liver function as well as all of the other necessary standard tests, and abnormalities fed back. There was never any intention of not informing families about test results.

80. As already stated, the information about NANB hepatitis was extremely limited. It was not an accurate diagnosis and there was no therapy, no certain causes, no known prognosis and no specific management. The families were informed if the liver enzymes were elevated persistently and that we would follow that up and ensure that actual liver dysfunction would be managed appropriately. To the best of my knowledge no actual liver dysfunction, other than transaminitis, occurred whilst I was at the RHSC.The level of information giving has been criticised by families. In retrospect we should have spent more time explaining this very uncertain and very unclear

situation, which was thought to be a minor issue. The real-life issue about unknown test result consequences is the need to inform without causing unnecessary distress, which in this instance would be long-term and clouded by uncertainty.

81. During my time at GOSH no patient acquired a significant TTI. A number of patients did have persistent transaminitis of unknown cause and most were aware of that. Approximately three years later we were able to confirm Hep C in some of the patients that I inherited. Extensive efforts were made to inform them pre and post testing about all of the consequences. This was carried out by two clinical nurse specialists, myself, the infectious diseases team and social work / psychology support teams.

82. GOSH began testing for Hepatitis C, immediately after validated tests became available, which I believe was in 1990. Following counselling, all patients with haemophilia were tested over a period of a few months starting with those who had persistent transaminitis of unknown cause. In this instance, and unlike HIV, our patients were informed why the test was being done and that they would be called back to clinic or day care appointments. It was, as before, not thought good practice to inform such complex information by letter or telephone.

83. As before, the clinical science behind Hep C was still uncertain by 1990 and therapies were unproven and initially unsatisfactory. Accurate prognostication was impossible, but we did know by then that a proportion of affected people, after a number of years, did develop very serious liver disease, and the families were fully informed and expertly followed up.

84. Pre and post test counselling at GOSH is described in full above.

85. I cannot recall how many patients with haemophilia were Hep C infected. My memory is that some were and that no new cases appeared during my time.

Delay/Public Health/other information

86. There were no significant delays in informing the families of TTI. The clear policy of the team was to be open, transparent, accurate and timely. As far as I know we always tried to impart information in less than three weeks from confirmation of serology, so that information and confirmatory testing could take place. I am not aware of any delays.

87. The public health implications of HIV and Hep C were at the forefront of our minds. Prior to 1990 the public health implication of persistent transaminitis

was unknown. During that period the policy was confined to the desire of every haemophilia treater to have pathogen reduced blood products to prevent known and unknown TTI risk. We did everything we could to encourage that development, through the UKHCDO and other national organisations.

With regard to HIV, we were in the middle of a maelstrom of a crisis and battled every day to stop our patients becoming pariahs. Maintaining confidentiality whilst providing the best care was a constant challenge, and media bad behaviour was a perpetual strain on everyone.

We collaborated fully with Public Health (PH) initiatives, although I have to say that their help to us and support was minimal. We also had to refuse their requests on several occasions, for non-anonymised personal detail which they wished to distribute to e.g. dentists. As an example of how challenging this was, I was brought to the Home and Health Department by a Deputy Chief Medical Officer, to explain my refusal to assist PH with distribution of non-anonymised information. One of my enduring beliefs is that in future epidemics, the expertise of public health, epidemiologists, therapeutics, clinical and experimental virologists etc., should be brought together in governmental committees. Until recently this happened in far too haphazard a fashion and we were often left out on a limb.

During the Hep C era there was little intervention from Public Health officials. Throughout both periods, one of our first priorities was to reinforce the training that families had already received, as already stated, in order to avoid transmission within the family and elsewhere. That would include sexual health training where appropriate.

88. I am not sure what is meant by the risk of other infections. The question is very open ended. As already stated several times, antisepsis and i/v training was the basis of what we did. Transmission of infections, sexually and otherwise, was discussed and explained using leaflets, literature or orally. The risk of Pn pneumonia was explained as was therefore the need for prophylaxis. Other infections in HIV patients were discussed with infectious diseases experts.

89. As stated above the risk of haemophilia persons transmitting infections onwards was the basis of therapy and management from the onset of treatment. We were dealing with children and thus sexual transmission did not arise.

Consent

90. Blood samples were taken usually on a quarterly basis from patients with bleeding disorders who were receiving therapy; continuing the practices that I had observed in four other Centres. Patients who required very infrequent treatment might have annual blood tests unless their situation was very mild and not requiring any active treatment, when repeat testing would only occur when events occurred. The range of tests was those that other Centres carried out routinely and consisted of biochemistry, liver transaminases, full blood count and Hepatitis B testing. The sampling was almost always performed by Dr Pettigrew who communicated the need for testing throughout patient management. Consent was not specifically sought for storage of virology samples, although all virus labs did this at the time as a matter of rote. Consent was not sought at the time in any scenario where I had trained, for the storage and subsequent use of these samples, an omission which was corrected after this episode.

91. I have previously made the point in answering these questions that fully informed consent to all aspects of management of these children and their families is a continuing process. It was not the practice at the time to seek written consent for every aspect of therapy, not least because a single signature to an open-ended management period of years was in my view meaningless, especially when taken at a time of maximum stress for families. I have pointed out that haemophilia is a lifelong disorder and that the majority of the RHSC patients had attended many times before I arrived and had spoken many times to the team members, and especially Dr Pettigrew, who had excellent interpersonal skills. She also had long – term knowledge and knew the families, and indeed some of their relatives, very well over years. In addition, there was an open-door policy, routine review clinics and support groups. We encouraged questions to be asked, and parents frequently challenged medical approaches and sometimes chose not to accept advice. The approach was always to not impose a controlling and paternalistic environment. All families were encouraged to join the Haemophilia Society and were supplied with literature as stated above.

92. Consent for testing for Hep B and persistent transaminitis of unknown cause was obtained usually by Dr Pettigrew, assisted by the specialist nurse, when taking the samples. I do remember being present on several occasions when Dr Pettigrew did indeed explain what was being taken and why, and that Hep B and liver testing was included. I would also have done the same on the infrequent occasions when I took tests.

    I have previously explained above that HIV testing occurred in retrospect and to the best of my knowledge was not requested by myself. However, as I have already said, all families would have been acutely aware that testing was essential, as indeed it was. Many, if not all, of them would have been

aware that tests were developing and if asked we told them that tests would be performed when available and validated. In fact, repeat testing was required and the families were fully informed at that subsequent stage. In retrospect it would have been better if we had had more time to begin the information dissemination prior to result testing, although some families did discuss such issues in advance.

93. Consent, testing and therapy at GOSH was managed in a very similar way to that described above, at the RHSC. In addition, we had realised as a consequence of the sequence of events in Glasgow with retrospective testing, that explicit consent should be obtained before testing stored samples. The debate was, should we get that consent at the outset, for all possible studies whatever they might be? (as blood transfusion services still do) or would it not be better to ensure that any retrospective testing on our patients' samples should be consented at the time of that testing when we could explain what was actually happening and ensure ethics review? The latter depends on the lab not 'going it alone', but in fact I know of no subsequent occasion when this latter system failed.

PUPS (previously untreated patients)

94. I cannot remember the detail of any PUP haemophilia therapy trials at the RHSC. It would usually only be the case that a very few new severe patients per annum were diagnosed. I do not have any memory of precise numbers. The only relevant studies during that period would have been related to the ultimately much safer pathogen reduction treated concentrates. For a period of time, severely affected PUP's were considered for use of cryoprecipitate as there should be a lesser TTI risk, albeit many more difficulties with therapy as described. I cannot recall for certain if any families availed of this approach. If those studies had been available we would have proposed to the parents that we should treat new patients with the new concentrate if sufficient adult safety and efficacy studies had been performed. At GOSH, many of our newly diagnosed PUP's were entered into trials of the new recombinant products, which proved a Godsend.

95. I have no recollection of the PFL Oxford meeting in 1991 whereby GOSH was supplied with 8Y domestic concentrate for clinical trial support. I have no recollection of any trial, or policy of that nature. The Director in Oxford was Dr Paul Giangrande and maybe he will know.

Research

96. I do not have a full list of research studies that I was involved with between 1987 and 2006. I would not have retained such data and it should be recognised that I was Chair of the National Childhood Leukaemia Trials (A.L.L.) and national lymphoma trials working parties throughout most of this period. The great majority of my patients with disorders such as leukaemia, lymphoma, aplastic anaemia, and other blood disorders were entered into national and international trials. Scores of trials were performed and if required the Ethics Committee and the Medical Research council (MRC) and the national Children's Cancer and Leukaemia Group (UKCCLG) would have records. With regard to trials in children with bleeding disorders, these mainly consisted of studies in the introduction of recombinant concentrates, and also of specific therapies for HIV and Hep C which were run and coordinated by the Infectious Diseases Team. I will answer below with regards to bleeding disorders:

a) The purpose of research was to determine the safety and efficacy of clotting factors and anti-infection agents. I was not directly involved in the latter as the infectious diseases team co-managed the patients and managed all anti-infection therapies.
b) Research approval was via the Research and Development (R&D) Office of the Institute of Child Health (ICH) and University College London (UCL) as well as the Research Ethics Committee of GOSH – ICH.
c) I was the lead local investigator responsible for the trials until about the year 2000
d) ICH, UCL, UKCCLG and MRC were involved. Plus the Pharmaceutical companies which supplied the concentrates and drugs. In main part the companies were Bayer, Baxter, Pfizer, Centeon, Novo Nordisk and possibly FDA and MHRA.
e) Research funding from the Pharmacutical companies was for the cost of the concentrates and I believe, some administrative costs via the R&D office. The staff received no direct payments.
f) I am not certain as to how many patients were involved. The records would be with the companies developing the products and the regulatory authorities, and could be in the order of 10 – 30.
g) Fully informed consent was obtained by myself and the Clinical Nurse Specialist and in latter years, also with my new consultant haemostasis colleague.
h) I have not retained any of the publications which ensued from such studies. They were used for formal licensing purposes

I was only ever indirectly involved in epidemiological studies as these were run through the UKHCDO, and maybe also the Department of Health. We contributed anonymised data annually where required.

97. The ethical principles of research apply irrespective of the place or time and without exception. During periods of crisis such as pandemics, research ethics can be challenged and certainly prove challenging but have stood the test of time. Essentially, to my mind, it is the application of morals and professional codes of conduct to all aspects of research including collection, analysis and publication. It should always respect the subjects' right of privacy, confidentiality and informed consent. I am not a philosopher, but I would add to the many definitions that I have seen over the years, that there must be no element of futility and application of only the highest scientific principles of necessary discovery. I always tried to live up to these high principles.

98. I am aware of no research studies with which I was involved whereby consent of the family was not obtained.

99. I am not aware of any instance whereby patient data was used for the purpose of research, without consent.

100. Anonymised patient data from clinical trials is regularly shared with other parties involved in the studies and named within the ethical applications, including the biostatisticians and regulatory authorities. Any distribution thereafter is via publications in the public domain.

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

Management of HIV and NANBH at RHSC and GOSH

101. Management of HIV and NANBH at the RHSC and GOSH.

a. Specialist care of HIV at the RHSC was mainly arranged by Dr Gibson after my departure. During my time at this hospital there was no requirement for specialist assistance and specialist paediatric infectious diseases,immunology and hepatology did not exist within Scotland at the time.Initially specialist assistance was not necessary.

After I started at GOSH and not before, possible specific therapies for HIV gradually became available and specialist counselling and diagnostic services were provided in collaboration with the infectious diseases and immunology teams. Their ranks at GOSH had been bolstered by doctors and specialist nurses with a direct interest in that disorder. Hepatitis and its sequelae were not an issue until after Hep C was discovered. At that stage the Infectious Diseases Team again made arrangements to jointly manage all such patients with us.

b. Initially the only treatment for HIV was prophylactic Co-trimoxazole as stated above, along with symptomatic management of infections and other sequelae, none of which occurred during my time. After a short time at GOSH, trials of antiretroviral therapy, initially I believe with AZT, became available and thereafter the Infectious Diseases Teams managed that therapy in appropriate patients. After 1990, and in patients with established Hep C and indications for therapy, trials of interferon and other therapies were managed by that team and we managed their coagulation problems.
c. Information for families about therapeutic trials came via the Infectious Diseases Team, using the written patient information leaflets approved by the Ethics Committee. They also provided regular expert counselling which covered all aspects such as toxicities of therapy.
d. The difference between management of children and their families versus adults is a very big subject and is the basis for much of paediatric care. It involves the age specific written and verbal communication for the children and the varying dosages and toxicities in the paediatric age groups.

102. Follow-up management and monitoring of HIV infected patients was jointly with the Infectious Diseases and Haemophilia Teams, who had access to specialist advice e.g. social work / immunology/ family therapy / psychology / psychiatry / hepatology.

103. Hepatitis B management

a. To the best of my knowledge, as already stated, we did not have patients with Hep B. If we had , we would have jointly managed at GOSH with Infectious Diseases. At the RHSC it would have been necessary to seek expert help from adult treaters
b. I was never in a position where I needed to offer specific therapy
c. Specific treatments were not offered as not indicated
d. Treatment for children with Hep B required expert paediatric Infectious Diseases input if ever required.

104. I do not recall managing any children with Hep B. It would have required joint Infectious Diseases management

105. How was NANB hepatitis managed at the RHSC and GOSH?

a. Transfer to specialist care was not required at the RHSC as the virus for Hep C had not been found and no specific therapies were required or available. Once Hep C was diagnosable, joint management with

Infectious Diseases at GOSH was transitioned, initially for those with symptomatology or other treatable indications.

b. As stated above, NANB hepatitis is not a diagnosis and there was thus no specific therapy. Hep C patients were offered entry in clinical trials as therapies became available and the indications for therapy were extant. This was in the early years difficult to manage and not very successful, using mainly interferon and then ribavirin and combinations. Later on drugs such as sofosbuvir/ledipasvir became available. All required expert Paediatric Infectious Diseases management.
c. Information about risks and benefits of Hep C therapy was supplied orally by the infectious diseases team, by supplied literature and Ethics committee approved information leaflets.
d. Information especially directed for the level of child's understanding of Hep C was developed along with appropriate level discussion.

106. Management of Hep C at GOSH
Please see answers to Question 105.

107. As stated above Hep C patients were jointly followed up between the Haemophilia and Infectious Diseases Team, with the clinical nurse specialists providing the point of contact and ensuring continuity and cross-communication

108. Answers in relation to involvement with HIV and Hep C trials are stated clearly in previous questions.
At the RHSC there were none whilst I was there
At GOSH I had no direct involvement in specific antiviral treatments.

109. Please see answers to previous questions about counselling, social work and psychological support for patients with TTI and bleeding disorders. The policy which I developed at both sites was to enhance and broaden the Haemophilia Team approach. This was much easier at GOSH as we already had on-site access to world-class paediatric infectious diseases, clinical nurse specialists, trained dedicated counsellors and hepatologists, for instance. At the RHSC, Haemophilia was just one part of the range of responsibilities that I performed. Initially that was the case at GOSH until I was able to appoint an expert haemostasis consultant colleague. At the RHSC there was limited social work and specialist nurse time, but they did all that they could in that era to provide a very good service along with the excellent clinical assistant Dr Pettigrew. There was good access on both sites to expert psychology and psychiatric help which was invaluable when required. Both hospitals initially suffered from the lack of any dedicated

space and it took years of effort on my part to solve that problem at GOSH, such that they now have world-class facilities.

110. Funding for the treatment of HIV and Hep C infected children was not an issue, to my knowledge. The huge issue was getting the funding which these families needed to maintain an adequate lifestyle and manage their child's care. I took this on as a personal crusade, along with support from GOSH and ICH, including formally meeting with the Health Minister, Mrs Bottomley. The outcome of my and other advocates' sustained efforts was the setting up of the McFarlane trust in 1988 which was intended to support the persons afflicted with TTI.

Records

111. To the best of my recollection, none of my patients with bleeding disorders died at the RHSC. I believe that there may have been some deaths in latter years at GOSH, but those patients would by then have transitioned to adult care. As far as I am concerned, death certificates would always be completed with the full known truth.

112. Retention of medical records at the RHSC and GOSH was that they should be retained until the person was at least 25 years. Haemophilia case notes were usually kept separately and I determined, in view of litigation and Inquiries that they should be retained throughout my employ.

113. I do not have good recall of the system of records and log books at RHSC; others will have a better memory. As far as I can remember, the parents were asked to bring log books when they made any attendances as described above. The main reason would be to assess the bleeding history and responses. We already had a log of factor concentrate issued within the department. I cannot remember whether or not we asked the parents to return their log books and they may well have retained them.

114. As stated above there was a departmental log of factor supplies, and treatments given in hospital. Treatments given in hospital, day care and clinic visits would also be recorded in the usual way in the hospital case notes. I cannot recall where the case notes were kept but they were readily available. None of these records were disposed of during my time.

115. I never kept records or information about patients off-site or at home.

116. I do not have any records or information about my patients.

Section 5: Self-sufficiency

117. Regarding a 1974 DoH announcement of the aim to be self-sufficient in Factor VIII concentrates: -

a. In 1974 it is unlikely that I was aware of this announcement and I do not recall it. I was training in various aspects of paediatrics including haematology-oncology. My only memory was later in the late 1970's when I heard from my mentors in RFH and GOSH that this was the plan and that they were very disappointed that it had not been achieved despite a long period since that announcement.
b. Self-sufficiency was always an ill-defined term. I understood it ultimately to mean that we would have complete domestic supply to treat haemophilia optimally by internationally benchmarked standards. It should be understood that the greatest use eventually was for prophylactic therapy, and for immune tolerance therapy for persons with inhibitors to factor VIII and IX.

   Prophylaxis was very slow to be accepted as the standard of care and in many Centres was not adopted until the late 1980's or even later. Thus judging demand in retrospect is very difficult as we could not start prophylaxis if supply were to be subsequently compromised. Similarly, immune tolerance therapy was not well established and all jurisdictions (maybe apart from Germany) would have struggled to cope with the dramatic increase in demand that that produced. The fact is that even by 1983 in England, domestic supplies were inadequate for standard therapy. The situation in Scotland was considerably better in my experience and we rarely required deviating to commercial product.
c. My understanding of what self-sufficiency meant only changed significantly when the problem was solved by the development by Pharma of recombinant products.
d. I expect that all Haemophilia treaters regarded self-sufficiency as the supply of NHS product required to treat all bleeds. Some like myself and probably all over time, would add to that the greatly enhanced amounts required for prophylaxis and immune tolerance therapy for inhibitor patients.
e. I was not in a position to achieve self-sufficiency as that was the role of Government and Blood Transfusion Services initially. The Directors, through the UKHCDO, maintained constant pressure on those responsible for supply, in order to achieve this goal.

118. How were estimates made for the projected supply of concentrates? This of course included both factor VIII and IX concentrates.

a. The planning and monitoring of supplies in Scotland was the role of the SNBTS and its Director at the time, Dr John Cash. The Directors assisted in that by regular contact with that organisation's consultants (Dr Crawford in my case) if it was known that a significant deviation from the norm was expected e.g. surgery, major injury, inhibitor development with increased dosing. In my opinion they were always very helpful and did all in their power to sustain supply to the RHSC.
b. There was an annual data return to the UKHCDO and my memory is that the trends were graphically displayed at the meetings. I have not retained any UKHCDO meeting minutes or documentation.
c. As far as I know, I never saw the data from the SNBTS. They would look at usage (as they were the licensed supplier) and its increase compared with previous years. As already stated, they also took into account the very high 'users'. I am unaware as to who actually did the work, but it was under the auspices of that organisation and its Director.
d. I did not see this data, but imagine that it was broken down by the four Haemophilia Centres
e. I do not know what sharing of manufacturing and supplies data occurred. I did not see it.
f. I do not know how changes occurred in manufacturing and supply equations changed over time.

119. Usage of Factor VIII blood products per annum.
a. At RHSC I would make annual returns to the Oxford Haemophilia Centre which at the time correlated all inherited bleeding disorders therapy and some outcomes, for the UKHCDO
b. The UKHCDO correlated and presented the data on inherited bleeding disorders therapy and outcomes which were presented at annual meetings
c. The data was collected by Dr Rizza and Dr Giangrande and their team in Oxford, looking at causes of serious outcomes and trends in usage.
d. I do not recall what geographical compartmental analysis was carried out
e. Data was presented at annual meetings of haemophilia doctors and at more regular meetings of haemophilia directors
f. Changes in the format of processes over time may have occurred but I cannot recall any significant changes.

120. The difference between supply and demand for factor concentrates, during my time at RHSC, was very small and usually only occurred when an unforeseen circumstance occurred, e.g. when an inhibitor developed or surgeries became necessary. I cannot remember the actual figure but would

expect that we used domestic product more than 90% of the time, once the American product upon which some patients were already established at the inception of my post, had been used up.

121. Scotland made major steps towards self-sufficiency in my time, and I believe that that process had probably started prior to 1983. I am not in possession of that data.

Section 6: Blood services

122. Myself and the RHSC had a very close working relationship with the SNBTS and I believe that the latter always did their very best to help with supplies. Communication was very good and the processes were efficient

123. My communication from the RHSC was with the SNBTS HQ in Edinburgh. Discussions were about supply requirements and extra requirements as described. We also regularly discussed the strenuous efforts that they were making to produce a safer pathogen-reduced product.

124. To the best of my knowledge there was never a shortage of cryoprecipitate. As stated above, I had frequent consultations with the SNBTS consultants, discussing when heat treated, safer and efficacious products were expected to be available.

125. Discussions/meetings/interactions with any blood service in relation to TTI: -
Discussions about TTI risks occurred between Haemophilia Centre Directors and within the UKHCDO on a very regular and increasing basis. The ideal was to develop a safe product and there were many discussions about methodology e.g. how to heat treat, would solvent-detergent treatment work, was a recombinant technology feasible? I was not directly involved in the discussions that Directors had with Blood Transfusion Services, other than as described above, when it was clear that they had a very good understanding of the requirements.

126. Other than that which I have already described, I was not involved in decisions or actions taken by the Blood Transfusion Service.

127. My recollection of record keeping at the RHSC is not complete. I think that the system was that there was a log close to the factor concentrate store in the haematology laboratory, within which the patient details, batch number details and amounts given / taken and for what reason were documented. I think that the patients had hand held records whereby they

recorded bleeds and dosing, for reviews as described. A record of the same or similar was also made in the hospital case notes at clinics and day care attendances.

Section 7: UKHCDO and the Haemophilia Society

128. Please see answer 129.

129. With regard to my involvement with UKHCDO: -

a. The purpose of the organisation was to assist Haemophilia Directors, and later on other health care professionals, with the management of persons with all types of bleeding disorders. It provided expert guidance through its various expert committees, education materials, guidelines (I produced one on prophylaxis for children which I have not retained), collection of data relating to TTI, inhibitors, mortality, and the production of peer-reviewed publications on various aspects of bleeding disorders care. In addition, there was an external audit scheme with site visits by other Directors. Initially. I carried out external audits of other Centres as part of my membership of the organisation.
b. The membership, to the best of my memory, was for many years Haemophilia Directors and then it was widened at some stage to involve "haemophilia doctors". There were various committees dealing with aspects of therapy and especially TTI. I do not recall any further detail.
c. I know of no relationship between the UKHCDO and commercial companies, but I was never in an administrative position in the organisation.
d. Decisions taken by the UKHCDO were by consensus.
e. Dissemination of information and advice by the UKHCDO was, I think solely, initially through the Directors. There were Minutes and Position Papers, but I cannot recall any of those and I am in possession of none.
f. I was never a member of any of the committees or final decision-making bodies or groups of the UKHCDO other than my advocacy and development of prophylaxis guidelines for the organisation. In particular I was not involved in policies, guidance, actions or decisions of any of the following, other than taking part in discussions on occasions where strictly relevant to my practice: importation, purchase and selection of blood products, manufacture of blood products, self-sufficiency, alternative treatments to concentrates, TTI risk, sharing of TTI risk with families, consent for blood storage for treatment and for research, heat treatment of concentrates, other

measures to reduce TTI risk, vCJD exposure, treatments for HIV and Hep C.

130. Throughout my career I strongly advised families to join the Haemophilia Society and the majority did so. We always distributed the Society's literature and supported their patient / family support groups whenever asked. My impression was that they were an excellent support organisation and that we had a very good relationship with them and relied upon them to support our communication strategies.

A few years into my time at GOSH I was approached by Dr DIK Evans who was their main medical advisor, asking that I consider becoming one of the two-three advisors to the Haemophilia Society UK based in central London. His message to me was that Society members perceived myself as someone not afraid to speak "truth to power" (to use the modern language usage) and who was able to uphold the best interests of children and families with bleeding disorders at heart. I agreed, and continued to give advice for several years. They did indicate that they appreciated that advice, especially on subjects such as prophylaxis and TTI risk reduction. It was an honour to work with them.

Section 8: Pharmaceutical companies/medical research/clinical trials

131. During my time at the RHSC and GOSH I met infrequently with representatives of all blood product Pharma companies including Bayer, Centeon, Novo-Nordisk, Pfizer, and Baxter. This was for the purpose of exchanging information within ABPI (Association of the British Pharmaceutical Industry) rules with regard to progress being made with therapies, timescales etc. In particular, we needed to inform them of what was required and we needed to know about vital developments such as pathogen reduction modalities, their efficacy and safety, progress with development, supply and trials with recombinant products, and longer lasting factor concentrates. I did not provide consultancy services in any other way.

132. Prior to my retirement from clinical medicine I did not receive any pecuniary gain from blood product companies. Following my departure in 2006, I worked as Medical Head of Haematology for Bayer UK for four years and was salaried throughout from that source. My role was to assist with development of longer acting factor concentrates, develop antifibrinolytic compounds and develop one of the new oral anticoagulant drugs.

133. At some stage after the development of recombinant products, Bayer set up an International Board which I think was called the Paediatric Haematology Network or 'PedNet', Membership involved Paediatric Comprehensive Care Centre Directors from around Europe and Scandinavia. Other than sponsorship to attend the international venues my memory is that we did not receive honoraria for such attendances, although I am not certain on this point. Such payment would not in any case have breached ABPI guidelines. The meeting carried on until I stepped down as Director and my successor took over. It was a highly successful and vital scientific support to paediatricians who often are not involved in the adult treaters communications and experiences, which are in any case different.

134. I have never received financial incentives to use blood products.

135. I have never been offered, and neither did I ever take, non-financial incentives to use certain blood products

136. I have never received any funding to prescribe, supply, administer, recommend, buy or sell any blood product from Pharma whilst I was in clinical medicine.

137. I always was aware of the ABPI guidelines and the GMC (General Medical Council) guidance on the subject of involvement with Pharma. I always complied and was never the subject of a complaint to either body.

138. I was not involved with Pharma blood product studies at the RHSC. We began recombinant factor studies as soon as the products became available to GOSH. Initially this was with Bayer and subsequently with Pfizer and Baxter as products became available. These were approved by the Ethics Committee, the R & D Office and with fully informed consent.

139. *Vide supra* – The trials performed were regulatory in nature and thus the anonymised data was collected by the companies for presentation to the regulators.

140. Any funding through trials at GOSH was monitored and approved by the R & D Office (jointly GOSH and ICH) and the office of the CEO via the clinical directorships; the latter because of other potential resource implications and the potential to be locked-in to ongoing costs once the product was marketed.

Section 9: Involvement with the financial support schemes

141. My only involvement with the different Trust Funds was in championing the setting up of the McFarlane Trust, through advocacy to the DoH and its Minister, as already described. Once set up the trust funds were applied and used by the Infectious Disease Team and the various clinical nurse specialists and social workers.

142. In 1988, as already stated, the social workers, Infectious Diseases Team and clinical nurse specialists dealt with Trust funding application. I do not recall being asked for a list of infected patients to be supplied to any organisation. However, I trusted the families and their extensive support network to get access as required.

143.

a. As already stated, the extensive support network informed families of their rights with regard to trusts and funds, in the same way as we did on a continuing basis for many years for children with malignant disease.
b. Expert social workers, infectious disease teams, clinical nurse specialists do not need to be re-educated in how to provide resources for needy families, wherever it is available. There was no need for policies and guidelines in that respect; it was an integral part of their training and experience and day-to-day job.
c. Contacts with the Trust funds were by the staff I have already described.
d. I very much doubt that any impediment was placed in the way of families, by any member of the extensive and excellent support staff. Their job, of which they were very well aware, was to provide information regarding eligibility and to provide support with applications. I cannot remember the criteria of 32 years ago.
e. I am not aware of any instance in which GOSH staff determined the outcome of applications for funds
f. I never received any complaints about the trust funds and their standards. However, I would only have been told if there were major issues.

Section 10: Other issues

144. I have never been the subject of any complaints from any of the following: - My employer, the GMC, the Health Service Ombudsman, or any other body or organisation which has responsibility to investigate complaints. I was lead medical advisor to the Ombudsman on two occasions.

145. I would like to take the opportunity of giving my own view, with the wisdom of insight, of the years between 1983 and 2006. When one is a paediatrician, one's whole aim is to do the best that we possibly can for the patients and families. I never knew a haemophilia director who did less than his or her best in that respect. The standards within haemophilia care at the time and in 1983 were generally good and many were full of optimism about the future. That various crises then occurred was shocking and devastating to us and this has been a cause for constant reflection over the last 37 years. The anxiety, stress and regret that I have are nothing compared to the suffering of the families concerned, and where I failed to live up to the highest standards I have done my best to apologise for my failings. At the Penrose Inquiry I was asked what we should learn from the past. I would like to say a few things again, with the caveat that these are very different times;

a. Communication in the 1980's was very challenging. There was no internet, no e mails and the shortest length of time to publication of new papers in journals was usually three months, and usually much longer. We had to rely upon governmental sources which were slow and few and far between, attendance at meetings of Directors and crucially attendance at international meetings for which study leave funding was scant, and time off on leave very limited. Communication standards did improve over the years but even with Hep C and vCJD, provision of information was very tardy. In any future crisis, as well as the current pandemic, emphasis has to be on this area so that everyone can keep up with events, and Government has to take a very active role, usually through Public Health and Epidemiology sources along with clinical experts.
b. We lacked expert advice despite making gargantuan efforts to acquire it, and were usually left in a maelstrom of events 'swinging in the wind'. Public Health and Epidemiology resources were very limited and frankly not very helpful. Medical education still needs to improve in this area and given greater emphasis in training and in developing these specialties, with an emphasis on scientific research. Clinical virology was in its infancy and we had very little timely helpful advice. This has improved, but again it does not play enough of a role in training or in the resources allocated, which is disquieting considering the now widely predicted risks of enduring risk from zoonoses. The same can be said of prion diseases. It is essential, in all future episodes, that urgent advice from government is disseminated along with directives without delay, and that all available experts are at the forefront of any episode. That did occur to an extent with vCJD, but was not wholly satisfactory and as before we were left at least in part to our own devices with questions like,

can we do ENT operations?, should we ask surgeons to use plastic instruments?, what do we do with expensive endoscopes? etc. It is vital that expert advice from all relevant areas is urgently provided and would usually include experts in the following areas, some of which are still not always included – Infectious diseases, virology, zoonoses, epidemiology, public health, immunology, behavioural scientists, sociologists and economists.

c. Staffing levels at the time were poor in many areas of medicine and the development of so-called super-specialties such as haemophilia and paediatric haematology-oncology was far too slow. The numbers of such patients that I managed has not greatly increased but the numbers of staff have more than quadrupled in most Centres, reflective of the fact that we were grossly understaffed and could only spend limited time in each area of responsibility, making it even more difficult to keep up and keep control. Despite working 12 hour days with few holidays and one in two on call throughout the first 20 years of my consultant career, there were times when the workload was impossible to manage optimally. Health services move much too slowly when developments occur, as for instance occurred with the difficulty in developing and adequately resourcing bone marrow transplants in the late 1980's.

d. Regulation of blood and blood products improved greatly after the HIV and Hep C eras, and is one of the good things to come out of the crises. The Consumer Protection – Product Liability legislation was a 'game-changer' and permanently improved the situation, as has the governance applied by authorities that licence products and Quality organisations such as INAB (Irish National Accreditation Board) and HIQA (Health Information and Quality Authority) in Ireland. Traceability of products was inadequate prior to these arrangements and often imputability impossible. Now in my present blood transfusion practice in Ireland, 100% traceability is a legal requirement.

   In the current era, the levels of governance and quality assurance and quality control of blood transfusion services seems light years away from the 1980's, and the development of National Blood Services has been hugely helpful, compared with the 1980's when in England blood transfusion centres seemed to function like individual fiefdoms.

   Training of all clinical staff with regard to blood and blood products and TTI is still not satisfactory, however, and we have to spend much time retraining staff and validating their work processes. For some reason this area is still not taken seriously enough and mistakes such

as wrong and inappropriate transfusions continue. However, thankfully these are now monitored by the excellent relatively new organisation SHOT (Serious Hazards of Transfusion). This group provides first rate governance and manages to affect national policies and guidelines. In addition, there has been genuine improvement in general governance, through the development of haemovigilance trained specialist dedicated staff in every hospital; another good thing to emanate from that era.

e. Finally, we learnt a great deal about communication and consent, neither of which was adequate leading up to these crises. Medical education was inadequate in taking this seriously enough and in enough detail using modern methods. Interactive skills training had been available since the 1970's but few, if any, medical schools adopted such approaches.

   I took part in such training and encouraged all that I could to do so. Some medical schools adopted such approaches, but my experience in the recent past in UK and Ireland with trainee doctors, and even some nurses, is that this has not been given enough emphasis. It was almost as if, in the 60's and 70's much more effective therapies became available and it seemed that a holistic approach became unimportant. Sadly, I often felt that Vets and Dentists were better at managing their clients.

   My adopted principle was that consent, particularly in the paediatric field, was a continuing process. In most instances the mantra of the time was that you only needed to get written informed consent by attaining a signature on a piece of paper pre-surgery. That information was scant at best and often vague and open-ended and rarely dealt with any potential pitfalls. It felt like 'covering one's back'. We did begin the development of appropriately directed, understandable and comprehensive literature, and relied upon opportunistic visits to explain and answer questions. We set up clinics for this purpose in part, and parent support groups and supported family support organisations. But, some people, including those with chronic illness diagnosed before I started, fell through the net and we did not do as much as we should to plug those gaps, however difficult that might have been.

   Issues such as storage of samples was an example whereby very few doctors would have obtained specific consent, and in fact such storage went ahead, especially in virology without our knowledge, although we had an inkling that it was happening. In the post HIV era, ethical committees became much better established and were much

better staffed and with a wide range of independent expertise. Patient information was officially vetted through this and other processes within hospitals, including through the establishment of Patient Advocacy offices, which I championed at GOS. We did what we thought was right and maintained an open and transparent approach throughout, but it was not always adequate. Again, I believe that these aspects of patient care deserve more emphasis in medical education, although that area has definitely improved throughout the British Isles.

Statement of Truth

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

GRO-C

Signed _____

Dated 19 August 2020

Table of exhibits:

Date	Notes/ Description	Exhibit number
	The impact of prophylactic treatment on children with severe haemophilia	WITN3497006
	CV	WITN3497007
	Methodology for Collation of HIV patients in Glasgow (RHSC) – Prepared by Elizabeth Chalmers dated 28th March 2011	WITN3497008
	Table submitted to the Penrose Inquiry with Methodology for collation of HIV patients in Glasgow (RHSC)	WITN3497009