Witness Name: Dr Lynne Margaret Ball
Statement No.: WITN4739001
Exhibits: None
Dated: 21 March 2021

INFECTED BLOOD INQUIRY

FIRST WRITTEN STATEMENT OF DR LYNNE MARGARET BALL

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 7 December 2020,

I, Lynne Margaret Ball will say as follows: -

SECTION 1: Introduction

1.

1(a) Personnel details:

Name: Dr. Lynne Margaret Ball, MB BS, PhD., Dip Pall Med, FRCP., FRCPath., FRCPCH.

Address known to the Inquiry.

DOB: GRO-C 1953

1(b) Professional qualifications:

1979	MB BS (1979), Royal Free Hospital School of Medicine, London University.

1985	Membership of the Royal College of Physicians (UK)
1987	Membership of the Royal College of Pathologists (UK) specialist subject - Haematology. Membership number 0605651
1990	Member of British Pediatric Association (pre-RCPCH. Membership number: 10560)
1996	(Founder) Membership of the Royal College of Paediatrics and Child Health
1997	Fellow of the Royal College of Pathologists (UK)
1997	Fellow of the Royal College of Paediatrics and Child Health (UK)
1998	Fellow of the Royal College of Physicians (Edinburgh, UK)
2010	PhD. Clinical and Laboratory Features of Mesencyhmal Stromal Cells in Pediatric Stem Cell Transplantation (March 4th 2010 - Leiden University, Leiden the Netherlands)
2011	JACIE accredited pediatric SCT inspector (Re-accreditation 2013/2015)

2015	Postgraduate Diploma in Palliative Medicine (Paediatric Option) Awarded with Distinction, Cardiff University, Wales UK. (enrolled September 2013)

2. Employment history:

Training appointments:-

01-07-1979 to 31-12-1979	House Officer (Medical/Haemtology), Addenbrookes Academic Teaching Hospital, Cambridge, United Kingdom.
01-01-1980 to 31-01-1980	Locum House Officer (Haematology), Addenbrookes Academic Teaching Hospital, Cambridge, United Kingdom.
01-02-1980 to 31-07-1980	House Officer (Surgical/ENT including pediatrics), Royal Free Teaching Hospital, London, United Kingdom.
01-08-1980 to 31-07-1981	Senior House Officer (Pediatrics), Royal Free Teaching Hospital, London, United Kingdom.
01-08-1981 to 28-02-1982	Senior House Officer, Royal Liverpool Children's Hospital, Alder Hey, Liverpool, London, United Kingdom. (Paediatrics)
01-03-1982 to 31-08-1982	Senior House Officer (Oncology), Royal Marsden Hospital, London, United Kingdom.

01-09-1982 to 31-08-1983	Senior House Officer (Medicine), Royal Liverpool University Teaching Hospital, Liverpool, United Kingdom.
01-08-1983 to 31-08-1983	Locum Registrar, Royal Liverpool University Teaching Hospital, Liverpool, United Kingdom.
01-09-1983 to 31-12-1984	Registrar (Haematology), Western Infirmary Teaching Hospital, Glasgow, Scotland, United Kingdom.
01-01-1985 to 28-02-1986	Registrar (Pediatrics), Yorkhill Hospital, Glasgow, Scotland, United Kingdom.
01-03-1986 to 31-03-1988	Honorary Senior Registrar (Pediatrics Haematology/BMT), Hospital for Sick Children, Great Ormond Street, London, United Kingdom

Specialist appointments:

16-01-1989 to 31-01-1996(unless otherwise stated)	Consultant Clinical and Laboratory Paediatric Hematologist / Hematopathologist, Head of Hematology Department, RLCH Alder Hey, Liverpool, United Kingdom. Director of Paediatric Bone Marrow Transplantation Unit, RLCH Alder Hey, Liverpool, United Kingdom.

	Director of Paediatric Haemophilia and Haemostasis Unit (1989-1993), RLCH Alder Hey, Liverpool, United Kingdom. Consultant Paediatric Haematologist (part-time), Regional Neonatal Special Care Baby Unit, Liverpool, United Kingdom. Consultant Paediatric Haematologist (part-time), Regional Foetal Medicine Centre, Liverpool Women's Hospital, Liverpool, UK. Consultant Haematologist, Liverpool Hospital for Women and Babies, Liverpool, UK. Clinical Advisor Abercrombie Health Centre for Inherited Blood Disorders (1989-1993), Liverpool, UK.
01-12-1995 to 31-05-98	Active Staff, Departments of Pathology and Paediatrics, IWK Grace Health Centre, Halifax, Nova Scotia, Canada
01-06-98 to 31-10-99	Consultant Paediatrician and Haemato-oncology, POS General Hospital, Trinidad and Tobago.
01-11-1999 to 31-08-2018 (retired)	Senior Academic Medical Specialist, Paediatric Hemato-oncology and Stem Cell Transplantation, Department of Paediatrics, Willem Alexander Children's Hospital, Leiden University Medical Centre, Leiden, the Netherlands.

University appointments:

01-03-1986 to 15-01-1989.	Lecturer (Haematology), Institute of Child Health, University of London, Guilford St., United Kingdom.
01-04-1988 to 15-01-1989.	Lecturer (Research Haematology), Department of Haematology, Royal Free Teaching Hospital, London, United Kingdom. Investigations into cell signalling and cell cycling.
15-01-1989- 01-12-95	Clinical Lecturer in Paediatric Haematology, Institute of Child Health, University of Liverpool, UK.
01-12-95-31-05-1998	Associate Professor of Haematology, Dalhousie University, Halifax, Nova Scotia, Canada
01-06-98 to 31-10-99	Clinical lecturer and Consultant Paediatrician and Hematolo-oncologist, University Hospital, University of the West Indies, Trinidad and Tobago

3. Memberships of organisations allied to medicine:

Member of the UK Haemophilia Society. (1990-1995)

Member of the British Paediatric Association. (1987 -1996 until RCPCH founded)

Member of the British Society of Haematology. (1990-1999)

Member of the British Paediatric Haematology Forum (Founding Member) (-1999).

Member of the North-West Paediatric Haematology Group. (1989-1995).

Member of the North-West Haemostasis Group. (1989-1995).

Member of the North-West Bone Marrow Transplant Group. (1989-1995)

Member of the Medical Women's Federation. (1989-1995)

Member of the Liverpool Medical Institute. (1989-1995)

Member of the North-Wales Paediatric Association. (1989-1995).

Member of the American College of Toxicology. (1997-1999)

Member of the American Society of Clinical Oncology. (1996-2009)

Member of the Canadian Research Association. (1996-1998)

Member of the Trinidadian Paediatric Association. (1998-1999)

Member of the United Kingdom Children's Cancer Study Group. (1990 – 2018)

Member of the European Bone Marrow Transplantation Organisation. (1990-2018)

Member of the European Haematology Association. (1996-2018)

Member of the American Society of Haematology. (1996-2018)

Member of the Dutch Paediatric Association. (NVK)(2000-2018)

Member of Dutch Paediatric Oncology Association (SKION). (2000-2018)

Member of SIOP (2000-2018)

Member of ISCT (2006-2018)

Member of the European Association for Palliative Care (EACP) (2013 –2018)

4. I have never provided evidence (or been asked to) to any other inquiries, investigations, criminal or civil litigation in relation to human immunodeficiency virus ("HIV") and/or hepatitis B virus ("HBV") and/or hepatitis C virus ("HCV") infections and/or variant Creutzfeldt-Jakob disease ("vCJD") in blood and/or blood products.

5. It is the Inquiry's understanding that your haematology career has involved positions as Honorary Senior Registrar at Great Ormond Street Hospital ("GOSH") during 1986-1988, and Consultant Paediatric Haematologist and Director at Alder Hey Children's Hospital ("Alder Hey") from 1988, before relocating overseas in 1995.

The statements above are globally correct but from 01-04-1988 until 14-01-1989 I was working as a research SR at the Royal Free Hospital London as part of the established training rotation. I was appointed as consultant at Alder Hey in October 1988 but only took up position on 15-01-1989.

SECTION 2: Decisions and actions of those treating patients with bleeding disorders at the Great Ormond Street Hospital and Alder Hey Children's Hospital, and your decisions and actions

6.

6(a) GOSH:

During my appointment as senior registrar at GOSH which extended over the period from 01-03-1986 to 31-03-1988 I was assigned for one year to provide day to day inpatient and outpatient care for children with coagulopathies. This included but not exclusively those children aged 0-18 years with haemophilia. I worked under the direct supervision of Professor Dr. Roger Hardisty and later Prof Dr Ian Hann. I worked also with a dedicated haemophilia specialist nursing sister(s) and we had a dedicated treatment area, on-site specialist laboratory diagnostic facilities and weekly outpatient clinics attended by Prof Hardisty and myself together with the haemophilia sister. Children were regularly reviewed and monitored according to

standard practice for inhibitors, hepatitis B and HIV. During my attachment there were no new cases of HIV diagnosed and all sero-positive children had been infected by tainted blood products and identified before I took up my appointment. I am not aware of the circumstances whereby this was undertaken, namely informed consent etc but none of the parents ever discussed with me their concerns if any as to how the tests had been carried out or the results presented. The cases as far as I can recollect included those boys who had received multiple units of Factor 8 with some cases related to the presence of inhibitors or those with life threatening bleeds including post-operative and intracranial bleeds who had subsequently a higher usage of factor 8. It was policy for patients with mild haemophilia and non-life threatening bleeds to either preferentially receive cryoprecipitate or DDAVP if they had been shown to be sufficient responders in pre-treatment assessments. I cannot recall if any patients were treated with these products during my attachment. At that time hepatitis C monitoring was not routinely available but children liver functions were regularly monitored (as an indicator of non A non B hepatitis). Children receiving regular blood product support were vaccinated against hepatitis B. All haemophilia patients registered with GOSH if required were admitted to the haematology/oncology unit without exception.

As considered essential part of my training as a paediatric haematologist as well as the clinical aspect I was required to undertake and interpret laboratory findings related to clotting dysfunction and the treatments thereof. I provided diagnostic assistance to other members of the hospital medical staff for in-patients undergoing complex treatments that led to coagulation and transfusion related problems.

In addition to these standard aspects of my appointment I, with the complete and full support of Prof Hardisty, established a parents' support group initially for those families affected by HIV and tainted

blood products. These were held approximately every 1-2 months together with the haemophilia sister and occasionally Prof Hardisty, and were conducted out of hours in the hospital board room, with refreshments provided by the hospital. There was no financial or other time related remuneration for the staff involved but the positive feedback from the parents led to an extension of the support group to other families of children with coagulopathies but non-HIV infection who required additional psychosocial support from the team. This initiative was complemented by several family days where children with haemophilia, brothers and sisters and parents, were funded by the department and were able to enjoy outings or special occasions and meet other families, the idea being to offer mutual support.

I also liaised with Prof Roland Levinsky, from the Institute of Child Health, Professor of Immunology, to establish regular immune function screening of HIV affected boys so that we could offer prophylaxis for opportunistic infection in those at risk due to severely reduced CD4 T cell numbers. Fortunately, during my attachment, although approximately six boys were affected (I have no access to documentation and my recollection may be wrong in respect to the numbers of children affected) although HIV related symptoms such as lymphadenopathy, night sweats and weight loss had been documented, none of the boys fulfilled the criteria for AIDS as defined by the CDC.

During the latter part of my attachment, I took part in an ongoing clinical trial of the pharmacokinetics of Zidovudine in boys with haemophilia who were HIV positive, initiated by Prof Hardisty and later supervised by Prof Ian Hann. My responsibility was, after parents had given informed written consent, to ensure that sequential bloods were taken, anonymised, preserved and later sent for analysis and I was involved in the subsequent publication and presentation of the results. To my knowledge there was no financial remuneration to any medical staff, but the pharmaceutical company provided the study drug

formulation free of charge and undertook the analysis, but had no say in the final publication of the results. Parents of the children participating in this study were informed of the results.

References

(1) Ball LM, Harper J. Atopic eczema occurring in HIV positive haemophiliacs. Lancet. 1987; 2(8559): 627-628.

(2) Ball LM. Zidovudine experience at the Hospitals for Sick Children, Great Ormond Street, London. J Infect. 1989; 18 Suppl 1: 83.

(3) Ball LM. The use of Zidovudine in HIV positive haemophiliac boys - a pilot study. Proceedings of the Welcome Symposium: Aspects of HIV Infection. Queen Elizabeth II Conference Centre, London, UK, September 1988.

(4) Ball LM, Fox J, Hann IM. the beneficial effects of zidovudine in HIV positive haemophiliac children.

Proceedings of the Combined Annual Scientific Meeting of the British Society of Haematology and the Netherlands Society for Haematology, Canterbury, UK, April, 1989. British Journal of Haematology Supplement, April, 1989.

(5) Ball LM, Fox J, Byrne M, Levinsky R, Hann IM. The use of Zidovudine in HIV positive haemophiliac boys: Clinical response and pharmaco-kinetic studies. Proceedings of the British Paediatric Association Annual Scientific Meeting, Warwick, UK, April, 1989.

(6) Ball LM. Treatment aspects of adolescents with HIV infection. Proceedings of the National Symposium on Paediatric HIV Infection, Royal College of Physicians, Glasgow, UK, April, 1989.

Having completed one year in this capacity I was then superseded by Dr Elaine Simpson who assumed similar responsibilities. I was then assigned to co-ordinate and execute the care of children undergoing stem cell transplantation, which was a continuation of my training in paediatric oncology and stem cell transplantation. However, I maintained my involvement with children with coagulopathies requiring acute care as necessary in a 1:2 out of hours rota shared with Dr Simpson as well as continuing the support group and my involvement in the zidovudine trial, only discontinuing these involvements on taking up my appointment as consultant at Alder Hey in January 1989.

6(b) Alder Hey:

I was appointed consultant Paediatric Haematologist to Alder Hey Children's Hospital in October 1988 contracted as a FT clinical and laboratory consultant with a 20% research commitment. On uptake of my position in January 1989 I was one of only 13 specialist trained paediatric haematologists in the UK, and as such, and not unusual, single handed.

I was appointed with the specific remit to establish stem cell transplantation for children which had been undertaken in a limited capacity at the adult facility (Royal Liverpool Hospital), together with assuming care of children with malignant and non-malignant haematological conditions including children with coagulation disorders. I also assumed responsibility for all laboratory diagnostics which at the time was on two sites (Alder Hey and Myrtle Street, the latter serving supra-regional paediatric cardiac surgery, neonatal intensive care and the recently established department of foetal medicine). Oncology services other than haematological disorders for children would continue under the auspices of Dr John Martin who had until my appointment been responsible for the all the clinical care of the above but had no diagnostic laboratory commitments. I initially held the budget responsibility for laboratory services including staff

but had no budgetary control for the provision of medications including factor replacement therapies.

I started mid-January as Dr Martin took vacation commencing the first day of my tenure. I was not provided with any overview or patient summaries but was none the less required to take on all acute clinical inpatient and outpatient care for the whole unit as well as all diagnostic responsibility for the haematology laboratory including the on-call commitment single handed until his return to duties.

In stark contrast to my experience at GOSH the provision of clinical and laboratory services offered to children with haemophilia especially those with HIV at the time of my appointment was severely compromised.

There had been no investment in laboratory facilities or equipment for a decade. The automated cell counter was out of date and on loan from Coulter and there was no onsite facility for monitoring anything other than basic coagulation screening. Pre-operative and therapeutic monitoring of Factor 8/9 levels had to be transported to the Royal Liverpool Hospital (a thirty minute transport time) for analysis and any suspected inhibitors similarly analysed off site. Laboratory staff had no protective area to prepare contaminated samples prior to analysis and there were no facilities to monitor immunological parameters for affected children.

Clinically there were as I recollect approximately 12 boys with haemophilia who were HIV positive. As I recollect as a proportion of children registered per treating centre in the UK this was one of the highest (if not the highest) proportion of HIV positive haemophiliacs. Unlike the boys in GOSH, a number of children at the beginning of 1989 were already beginning to show evident signs of severe immune dysfunction as a result of the virus manifesting in the development of opportunistic infections.

During my attachment there were no new cases of HIV diagnosed and all sero-positive children had been infected by tainted blood products and identified before I took up my appointment. I am not directly aware of the circumstances whereby this was undertaken, namely informed consent etc but parents informed me they were not counselled before testing and received a "positive" outcome by means of a letter addressed to the parents. There was no copy of the letter in any of the case notes but at least two sets of parents had retained the letter.

The cases as far as I can recollect were not limited to those boys who had received multiple units of Factor 8 due to the presence of inhibitors or those with life threatening bleeds.

There was no established treatment centre, no specialist nurse or social worker provision, no outpatient clinics, no immunological monitoring or screening and the majority of children had not received routine vaccination against Hepatitis B and there was a paucity of successful home treatment and self-administration programmes. This meant that for acute minor bleeds boys accessed the haematology-oncology ward (C3) and were treated with concentrate ordered and supplied ad hoc from the Royal Liverpool Hospital. As there was no batch reservation to reduce donor exposure it was difficult to determine what the individual usage per child had been prior to my appointment. A large proportion of the clinical notes of children affected by HIV were on close inspection missing essential treatment and decision-making details. As far as I could ascertain there were no protocols for the use of alternatives such as cryoprecipitate or DDAVP.

One of my first priorities was to establish good clinical practice not only for boys who were HIV positive but for all children with coagulation abnormalities. This was no mean feat as I was informed by the then newly established Trust hospital manager, Mr Pearce Butler, that there was no budget to develop additional services, even though I wrote an extensive case of need for a second consultant

which I submitted to him and the newly appointed Medical Director, the former consultant in charge of haemophilia care, Dr John Martin.

Fortunately, and at the advice of Dr Charles Hay, who had been recently appointed as haemophilia director at the adult unit at the Royal Liverpool Hospital and was invaluable in helping my efforts to establish an independent children's centre, I was able to access a regional fund (the name of which I forget) that had been set up by the UK government in response to the AIDS controversy, to provide additional funding for the provision of care for peoples with HIV. This fund had been active for a number of years but not accessed by the Children's Hospital. I was able to make a successful case for the complete funding for a specialist haemophilia nurse (3 years FTE), a dedicated social worker (3 years FTE), personal computer support, laboratory equipment including flow cabinet, closed system coagulation monitoring and part funding for a flow cytometer for immune function cell monitoring and storage facilities for factor replacement which I intended to relocate with budget from the Royal Liverpool Hospital.

Once the funding was approved, I was able to develop the services accordingly including the training of dedicated senior laboratory staff for the additional support required modelled on my experiences at GOSH, including participation in NEQAS coagulation quality control which repeatedly gained positive assessments.

I was also able to build up regular outpatient clinics, which were dedicated for children with coagulation disorders, the first three appointments being reserved in duplo for the boys who were HIV positive, being one of five out-patient clinics that I ran per week. Parents were given an explanation and informed that children would be regularly assessed clinically and screened for blood borne infection which at that time was limited to hepatitis and HIV, as well as regular monitoring for the presence of inhibitors and verbal consent was required at every blood evaluation. The haemophilia sister and social

worker were integral in the information process with additional time being given to parents and children at the out-patient clinic to discuss their concerns and any particular difficulties. As was routine for all other out-patient contacts, GPs were advised about the outpatient clinical follow up by letter, which was a new development.

We were able to order and provide heat treated factor 8 with the required budget being transferred to the Alder Hey pharmacy which was the main store of the products. This was essential for the accurate documentation of Factor usage both qualitatively and quantitatively, as well as completing the required Oxford returns.

Together with the Haemophilia sister we began an intensive programme to help families establish home treatment and together with the dedicated social worker school and home visits to support the children and their families in the wider community. As had proved so effective in GOSH we established a parents support group attended regularly by myself, the haemophilia sister and social worker but unlike GOSH not financially supported by the hospital administration but rather from personal contribution for the provision of refreshments (in parallel I was involved in a similar action with the Malcolm Sergeant social worker to establish a group for parents of children with cancer and adolescents with cancer, which was supported by C3 ward funding).

With the immune function monitoring it became evident that a significant proportion of the HIV affected boys were severely immune compromised, which at the time was not the experience of many paediatric haematology colleagues I consulted. In discussion with Prof Levine he confirmed my clinical judgement to start a number of these children with the PCP prophylaxis as well as treatment with Zidovudine, which was the only antiviral treatment available at that time but fortunately with the experience from our GOSH studies we felt this might offer some advantages to the most severely affected boys, especially as they were now being regularly monitored.

Around this time the situation with the hospital management deteriorated. This resulted from one of the boys being acutely admitted to C3 with severe pneumonia as a result of "full-blown AIDS." He was 8 years old. After his mother made it known to another parent that her son was HIV positive there was a distressing moment for all the parents who were very frightened and concerned about the infectivity risk and welfare of their children with cancer. Together with the ward senior sister, Doris Hackel, who had nursed these children from diagnosis to adulthood, we met the parents individually and felt that we had reassured the them not only to safety issues, but also to the necessity of the child with a highly immune compromised state being cared for in a ward with expertise and surrounded by staff that he knew and trusted. I found that without consultation the child under my care was moved to a general paediatric medical ward the following morning under the instructions of the acting senior ward consultant and Medical Director. No appeal by myself or the nursing staff could assuage him to change his decision. In fact, I was accused of deliberately influencing the nursing staff to be openly hostile to his decision. I have never understood why his animosity towards me manifested itself in such a way, but the nursing staff independently opposed this decision as one might expect from professionals who had for years provided care for this sub-group of children. I appealed directly to the Hospital Manager who refused to be involved in what he determined was a purely clinical matter.

The edict didn't stop there as from that moment all children with haemophilia were no longer to be treated or admitted to ward C3 but would be instead be seen on a general paediatric ward, with nurses who had no experience in the management of immune compromised children or bleeding disorders. The dismay and distress this caused the parents of these boys was in my mind then as it is now as being cruel and unnecessary. The parents asked me to mediate but I was unable to convince my colleague to reverse this decision, but the hospital manager agreed to meet with the parents (I think this was

around Feb 1990). He subsequently agreed to the provision of a dedicated haemophilia unit (which he had previously resisted because of budget concerns), training of the nursing staff and the guaranteed continuation of funding for the specialist nurse and social worker. This was how the Paediatric haemophilia centre was finally established at Alder Hey and provided a central storage facility for factor replacement, office space for medical, nursing and secretarial staff, a dedicated treatment room where inhaled pentamidine could be safely administered and a counselling rest room for parents and children.

After a period of two years and a severe debilitating illness requiring a period of hospitalisation following the birth of my only child in GRO-C 1991, I felt I could no longer physically or emotionally continue in my role as Director of Haemophilia Services especially given the adversarial and toxic environment that had persisted following the afore mentioned difficult issue. As such I made a case of need for a full time second paediatric haematologist based upon the increasing clinical needs of the HIV affected children, the increasing demands of stem cell transplantation both unrelated and high dose chemotherapies and autologous stem cell rescue for solid tumour patients and my expanding role in developing palliative care for children with malignancy. A second part-time consultant was appointed 1993/94, Dr Paula Bolton Maggs, who had been as a senior register on secondment from The Royal Liverpool Hospital and as my locum very much involved with haemophilia care. She took over the management of haemophilia and transfusion related problems (other than neonatal and ICU), as I continued as head of laboratory services, Haemato-oncology and Stem cell transplantation until my departure in Dec 1995. I of course continued to provide emergency cover and additional support to the further improvements for treatment provision, expansion of laboratory diagnostics and resistance to the clinical transfer of children aged under 16 years with high usage factor 8 to the adult unit in order to reduce budgetary deficits.

I also helped facilitate additional staff support for the haemophilia unit from the newly established McMillan Paediatric Palliative care team as toward the end of my tenure a significant proportion of the children affected were dying from AIDS

Together with Dr Bolton Maggs and Dr Hay we were able to develop transition teams to the adult unit which paralleled my efforts to establish together with Dr McDowell, as newly appointed FTE paediatric oncologist, a transition team to the adult unit for survivors of childhood cancer.

7. I am unable to give exact numbers of patients with bleeding disorders who were under the care of (a) GOSH and (b) Alder Hey as this would be after so many years and without access to any documentation speculative on my part.

8. Children on reaching adulthood (18 years) at GOSH as far as I recollect were transferred to the nearest adult haemophilia centre, which varied as GOSH was a supra regional paediatric centre, During the year I spent actively involved no child to my recollection was eligible on the basis of age to be transferred to an adult unit.

Children from Alder Hey were transferred to the adult Haemophilia unit of the Royal Liverpool hospital, initially from the age of 18 years but later Trust policy I think changed to include children from the of 16 years, but I am not sure if that is a correct recollection. At least on one occasion the Trust attempted to force the transfer of one child with inhibitors (non-HIV positive) to the adult unit at the age of 14 years solely to on the basis of "excess" cost incurred by increased concentrate usage. I do not know if that had ever occurred before my appointment but together with Dr Bolton Maggs and Dr Hay we were able to prevent this from happening, on the grounds that it was not in the best medical interest of the child.

9. I was not involved in the decision-making process or choice of product at GOSH but we used heat treated concentrate, including 8Y and porcine derived products as well as cryoprecipitate and DDAVP based on the recommendations and availability of products at the time. Other blood

products were supplied from regional BTS according to standardised protocols and availability, screened in accordance with National policies

At Alder Hey, prior to my appointment products were ordered and supplied by the Royal Liverpool Adult Haemophilia Centre. I do not know who was responsible for purchase or product selection but historically Alder Hey received concentrate for acute care by telephoning the on-call Haematologist at the Royal Liverpool Hospital who organised the transfer of the required product for immediate treatment. If subsequent injections were required for an on-going bleed there was no guarantee that the same batch would be supplied as there was no individual reservation of batches per patient

As soon as feasible and with budget transfer the provision of factor concentrate was located in the pharmacy at Alder Hey. With the establishment of a dedicated paediatric Haemophilia centre the storage of factor concentrate was transferred to the unit but the purchasing budget remained with pharmacy. Batch reservation per patient was introduced to minimise donor exposure.

10. I cannot recollect which products were chosen or why other than we continued to use the same supplier as the Adult unit to ensure continuity and also benefit from the expertise shared with Dr Hay.

I was not involved in the decisions after the appointment of Dr Bolton Maggs, other than supporting her application for adequate budget for products costed from annual usage figures and best clinical practice recommendations by the BSH and College of Pathologists

11. I do not know of any relationship between GOSH and any pharmaceutical companies manufacturing/supplying blood products

At Alder Hey, drug representatives could make appointments to inform staff of developments in product formulations but no financial or personal incentives were offered or requested to influence choice of products.

12. There were always lengthy discussions with Alder Hey hospital management and finance department around budget considerations for any change in treatment that incurred additional costs. Provision of blood products is costly but inherent in providing adequate haemophilia care.

Annual budget projections had to be submitted via pharmacy to justify expenditure.

13. Dr Hay refers to bad advice from Finance regarding the budget availability for coagulation products. (letter from Dr Charles Hay to Mr D. G. Watters dated 16 October 1991[HSOC0011048]). I have no recollection of the event alluded to in his letter and cannot remember discussing this with him. The Finance department at Alder Hey were not qualified to determine which products we used but they were repeatedly obstructive in advancing the funding for many aspects of treatment and support for children with haemophilia, which required me to find external funding to support levels of care that I felt were necessary, as previously described.

14. As previously stated, during my directorship we did not use any different product than that used by the adult unit, except for alternatives as recommended for mild/moderate haemophiliacs with non-life-threatening bleeds. Ultimately the decision of product purchase was that of the specialist in charge of the care of the patient but to say that this conferred control of the budget is by no means accurate. Rather a case of need had to be annually made to justify expenditure but neither myself or later Dr Bolton Maggs were prepared to accept any product we felt inferior to the clinical requirements of our patients, even if this incurred additional costs for the Trust. This not only included products but continued funding for specialist nursing, continued training of nursing staff, secretarial support and advances in on-site laboratory diagnostics including the costs associated with quality assurance. All requests had to be justified in writing, financially analysed and presented to the head of finance and hospital management together with an annual audit of laboratory expenditure and performance. “Clinical freedom” came at a personal cost because many of these meetings were by nature confrontational as the over-riding determining factor or pressure for management was continued cost

reduction whereas the clinicians' was one of provision of quality care. Obviously in light of this and subsequent events there were considerable delays in providing the quality of care I wished to deliver and had there been more cooperation from Hospital management, the centre and its staff and laboratory support would have materialised, much sooner.

However, it would not have prevented the high rate of HIV infection as this was already well established before I took up my position. It did however, in the time of fear and stigmatisation of the late eighties add to the distress and anger that many parents experienced, which I tried together with my support staff to minimise. I think one statement I offered to Mr Butler after the decision to "evict" the boys from accessing continued care in the Haematology ward was that even if he felt no moral imperative to establish a centre of excellence for the care and treatment of Haemophilia and HIV patients he could at least view it as a means to avoid bad publicity for the hospital, as at that time the parents were threatening to go to the press. It was an invidious position and one ultimately very damaging to the families, but I think the care we were able to offer compensated to some extent the feelings of abandonment and isolation these children and families experienced.

We experienced similar budgetary constraints when trying to initiate multi-satellite packs for neonatal blood transfusion in an attempt to reduce donor exposure and conserve blood products. This could only be achieved by reduction of expenditure in other laboratory areas and is yet another example of how cost reduction drove management decision making rather than striving to optimise patient care and safety. This was a continual source of conflict between myself and hospital management but eventually with the support of the neonatology department and Liverpool BTS director we were able to initiate this level of support without funding reduction in other areas

There was no stage, either at GOSH or Alder Hey, when commercial interest or any pharmaceutical incentive played a role in determining treatment options.

15. I have addressed the issues regarding alternative treatments offered as standard at GOSH but not to my knowledge ever offered at Alder Hey prior to Jan 1989 despite the recommendations to treat children with moderate haemophilia with non-life-threatening bleeds with cryoprecipitate.

This practice was changed at my appointment following national guidelines although I cannot recollect any use of cryoprecipitate in our patient population. The use of DDAVP was also introduce during my tenure. These alternatives were discussed with parents and the children if they were old enough to comprehend.

Parents were aware of different manufactured products for the treatment of haemophilia related events but I cannot recollect how that was discussed with them but it probably was one of the topics for a parents' evening as well as being one of the areas the specialist nurse would further discuss with them.

16. Alternatives to multiple donor factor concentrates were thought to be useful in reducing exposure and thus risk of infection. This was more relevant for HIV as testing became available but did not eradicate risks of hepatitis C. However, severe bleeding episodes or inter-operative interventions even in small children may require higher factor levels over a sustained period of treatment that could in effect preclude the option of using cryoprecipitate of DDAVP, so there was always a balance of risks. With the advent of reliable testing for HIV and Hepatitis together with effective heat treatment strategies concentrates became a safer option and we would have then followed the national guidelines in relation to treatment preferences, especially with regards to prophylaxis. However, these later decisions would not have been made by me personally as I was no longer the haemophilia director.

17. The choice of alternatives was a national recommendation communicated to all heads of departments at a time when I was in training at GOSH and Dr Simpson and I were instructed by Prof Hardisty to follow this recommendation to the letter. Any deviation from his recommendation had to be discussed with him beforehand and only he could authorise any deviation from the protocol. To my knowledge this never occurred. He was also an expert in coagulation

and platelet disorders and actively involved in the elucidation of different forms of Von Willebrands disease so his knowledge and teaching of the use of DDAVP in selected cases of haemophilia and platelet aggregation disorders was very cutting edge at the time. I had a very good working relationship with Prof Hardisty and his successor Prof Ian Hann and they were invaluable sources of support. I also established a working relationship with Dr Evans at Pendlebury Children's Hospital in Manchester before his retirement and later his successor Dr Dick Stevens. Together we later formed a NWest Paediatric haematology group which met monthly and included Dr Sally Kinsey from Leeds where we could present individual cases and discuss management issues. These informal relationships together with the expertise of Dr Hay and later Dr Bolton Maggs were instrumental in supporting my attempts at initiating and introducing many of the clinical and laboratory advances into Alder Hey.

18. Home treatment was the standard aim at GOSH and teaching of parents and children was established by the haemophilia sister assigned to the unit. I cannot recollect what proportion of children were successfully assigned to home treatment programmes.

At Alder Hey on taking up my appointment, home treatment was less established and many children accessed care via acute presentation to the haemato-oncology ward. One of my priorities with the newly appointed specialist haemophilia nurse was to establish a home treatment programme, which due to her dedication and expertise was successful with the majority of children with suitable venous access being assigned to home treatment regimes, which she supervised with frequent home and school visits.

19. I am not aware of the changes to practice at GOSH as they would have been initiated after my tenure

Changes to treatment options such as recombinant factor concentrates and prophylactic use of factor 8 were introduced by Dr Bolton Maggs as she assumed directorship of the unit at her appointment as consultant.

20. AT GOSH, mild or moderate haemophilia would have been treated according to the severity and clinical indications as previously discussed, in line with the

recommendations at that time. I cannot comment on what decisions were made in relation to treatment prior to my tenure or subsequent to my departure.

At Alder Hey factor concentrates were used in mild cases before my tenure but again I cannot comment on the indications as I cannot recollect the details. I do know that the use of DDAVP for potentially treating moderate cases was introduced after my appointment, but I cannot recollect if or how many children ever required this therapeutic intervention during my tenure.

21. During my tenure at GOSH and Alder Hey there were no other documented infections other than HIV, HCV and HBV, transmitted to patients as a consequence of the use of blood products.

However, patients with HIV related to blood product contamination at Alder Hey developed PCP as a result of being severely immune compromised (despite prophylaxis) together with immune related opportunistic skin and gastrointestinal problems.

SECTION 3: Knowledge of, and response to, risk

General

I find it difficult to determine a timeline as to when I was aware of infection risks during specific periods of my training and appointments as a paediatric haematologist because I have accrued a knowledge base over 35 years in the field. With that caveat in mind I shall try and answer to the best of my recollection.

22. I was aware of the risks of infection associated with blood and/or blood products. I had trained at the Royal Free and during my tenure as SHO I was seconded to the Katherine Dormandy Haemophilia Centre for one month in an observational capacity but was fortunate to be schooled by Dr Peter Kernoff who pioneered the work in the identification of non A non B hepatitis later recognised as hepatitis C. I also received hepatitis B vaccination as I was working with blood products. Also, as a registrar in the early 1980's, transfusion related HIV infection was being recognised. As I was undertaking

MRCP examination these were also topics which were being included in the examination. Working alongside haematologists and immunologists at GOSH when HIV was first affecting children by vertical transmission, I was fortunate enough to learn from Prof Levinsky and his team who were developing HIV specialist care and liaised with them over management issues. Also, my work as a paediatric transplant specialist focused my expertise on the care and treatment of severely immune compromised children and those with life threatening conditions and the care of their families.

At GOSH patients were being regularly screened for infections at their outpatient as well as immune function introduced during my tenure as part of the establishment of out-patient contacts

23. I cannot recollect any formal structure at GOSH to consider risk assessment of infection associated with the use of blood and blood products, but at Alder Hey together with Dr Bolton Maggs, we set up a risk management strategy which included regular meetings with the blood transfusion authority based in Liverpool, I cannot recollect when his started or how frequent the meetings took place.

24. It was my understanding during my training as a SR in Blood transfusion (Brentwood) that NHS derived single donor or reduced donor products (such as cryoprecipitate) had less risk of viral transmission that pooled plasma product concentrates mainly originating from the USA where paid blood donation was common. Single donor products may have reduced the risk but did not abrogate the risk of hepatitis and often could not provide sufficient levels of factor replacement required for life threatening bleeds, even in young children.

However, it was also my understanding that despite repeated calls for central government funding to enable self-sufficiency in blood products, particularly concentrate for haemophilia treatments, had not been successful and that commercially produced products would be required. This was despite the initial production of 8Y by the BTS in the hope of producing a viable heat-treated product.

Initially there was more focus on the prevention of HIV during the 1980's because Hep C was felt to be less life altering. It was only later that the chronic liver disease was identified as a result of this blood transmitted infection. Donor screening for HIV and Hep C relied on reliable laboratory diagnostics which took time to introduce and I remember the initial tests for Hep C proved less reliable until refinements were established.

Initial attempts at heat treatment of factor concentrates for the inactivation of potential virus transmission proved ineffective but later refinements were successful. As I recollect, there were also concerns that the initial heat-treated products potentially induced inhibitor formation, which later proved not to be significant nor an impediment to offering safer treatment.

Hepatitis

25. When I began work at GOSH, I was aware of the risks of the transmission of hepatitis (including hepatitis B and NANB hepatitis/hepatitis C) from blood and blood products as previously described

That is why all children were offered routine vaccination against hepatitis B at GOSH as well as staff regularly handling blood products. Children with haemophilia were also regularly monitored for infections at six monthly intervals. This was not undertaken at Alder Hey but was one of the protocols that I as Haemophilia Director introduced as well as vaccination to reduce the risk of hepatitis B

26. I was aware of the acute and chronic nature of hepatitis B and non A non B hepatitis but until reliable serological determination and treatment options were available for hepatitis C only supportive care could be offered. Under Dr Bolton Maggs, reliable screening for hep C became routine and added to the routine viral screening following discussions with the parents and children. I believe patients testing positive were discussed with the gastroenterologist/hepatologist both in Alder Hey and the Royal Liverpool Hospital with regards to treatment options. I was not involved at that time with those clinical decision-making processes.

27. I think the processes at GOSH were consistent with the knowledge base and recommendations at the time but the standard of care at Alder Hey up to my appointment in relation to the overall care of children with haemophilia fell below the standards I had experienced during my tenure at GOSH.

I think nationally there was no self-sufficiency of blood products that left physicians no choice other than to use imported commercial concentrates. Prior to the recognition of severe viral complications these had been life transforming for patients. Many mothers I met and listened to who had experienced brothers with severe debilitating haemophilia and had chosen to have children based on the relatively "normal" life injection of factor concentrates allowed.

Hepatitis B vaccinations at GOSH and this was introduced as standard of care at Alder Hey from 1989.

28. Initially there was a general consensus that HIV was the most life-threatening risk to patients with haemophilia treated in the 1970/1980's and that effective vaccination against hep B was sufficient to protect against the worse risk of hepatitis. The liver dysfunction associated with chronic hepatitis C I feel was initially underestimated in light of the urgency of the HIV problems but was later recognised as yet another blood borne disease that would have life altering consequences in long-term survivors of recipients of contaminated blood and blood products. All efforts were made to screen donors and patients, but the early antibody tests were unreliable

As with HIV, once reliable testing became available this was offered to patients but the natural history of the infection, especially in children surviving to adulthood, would take time to manifest and there were no national or international studies to determine interventions which might prevent or ameliorate the worst of hepatic dysfunction at the time I was in charge of the haemophilia care.

30. No action I could have individually taken would have prevented the transmission of HIV from contaminated blood products as I was not in any consequential position when these were introduced. I cannot comment on hep

C as I am not aware if any new patients developed hep C as a result of contaminated blood products after I was appointed to Alder Hey. Again, most of the boys I treated after 1989 had already received numerous doses of factor concentrate. I established good medical practice standards of care following the recommendation at the time and with the product availability at the time.

My positions both at GOSH and Alder Hey were ones of caring for the consequences of previous treatments and trying to improve services directed at the care for children and families with haemophilia and life-threatening infection. This also required not only direct medical care but psycho-social support in a time when nationwide fear and stigmatisation were rampant and supportive care requirements were sadly lacking

31. When I chose to specialise in paediatric haemato-oncology there was no recognised training programme and very few specialists who had completed any form of specialist attachments which gave insights into the care of children with haemophilia. HIV was a new and relatively unknown infection as was hepatitis C and as such there was also a lack of awareness as to the clinical trajectory of infections in these children. At GOSH, Prof Hardisty had developed a unit striving to provide the recognised high standard of care but even he was unable to prevent the unpreventable in children requiring massive doses of life saving factor 8 as this was HIV contaminated at source. Alder Hey failed because there was insufficient staffing and attention to detail by those charged with the care of these patients. My appointment was in part to correct some of these deficiencies but lack of adequate funding and a hospital management team including the Medical Director were unwilling to assist in prioritising the care of these children, even though the government at the time was promising families and patients with haemophilia that they would as "compensation" receive the highest quality of care the NHS could offer. No amount of reasoning, cajoling, or adversarial tactics or any other means I could muster affected a change in this institutional attitude.

SECTION 4: Treatment of patients

Provision of information to patients

32/33. I cannot comment on what information was given to patients diagnosed before I took up tenure either at GOSH or Alder Hey. At GOSH parents and cognisant children must have been aware of the risks of hep B and HIV as they were regularly seen and counselled. No new patients as far as I can recollect were started on factor concentrate when I was at GOSH. Once we established out-patient and regular review at Alder Hey parents and children were informed of the risks of infections and the need for regular monitoring. As hep C screening became available and the relative risks and treatments (which in the early 1990's wasn't fully elucidated) parents were informed prior to testing as far as I am aware. Unlike the original screening for HIV subsequent monitoring was always discussed beforehand with parents and children as appropriate and at a later stage informed consent either verbally and/or written was included (as was standard practice for all patients being tested for HIV)

Similarly, patients and their families were informed of treatment options and reasons for using concentrates or other alternatives, as appropriate, but I cannot comment on how this was communicated before my appointment as consultant.

34. At Alder Hey, in contrast to GOSH, very few patients were taught to self-inject and many parents were either reluctant or unable to inject factor concentrates precluding for many boys the possibility of home treatment. This was prioritised at the appointment of the nurse specialist and to her credit and expertise she effectively taught all capable boys and/or parents to safely and correctly administer concentrates within a year of her appointment, as well as the safe disposal of waste. She organised the home documentation of concentrate use which we could then monitor at the out-patient visits. Her home appraisals were invaluable and together with the social worker this became a regular part of their duties. She provided information for schools about safe handling of blood products and injection waste so that emergency

treatments for children could be safely administered on most school premises. She also gave short talks to schools to help with the integration of children into normal school curricula.

HIV

35. All families I cared for at GOSH and Alder Hey were aware of the HIV diagnosis but not all the children infected were aware of their status. The information had already been given to the families before I took up my position. We informed all parents of the importance of monitoring not only for HIV but other potential infections every time we sampled blood taking the opportunity to stress the importance of good surveillance in order to document any infection related to the injection of blood products for the clinical management but also as evidence of direct infection from administered treatments should there ever be any future "contamination" problems.

36. I cannot recollect how patients were specifically identified as being HIV other than to think there must have been some obvious entry in their clinical notes. I may have been provided with a list of names but at GOSH they were known to the haemophilia sister and Prof Hardisty and when I looked after them I was informed accordingly, interestingly, many of the parents informed me too.

At Alder Hey, there must have been some clinical entry in the notes to identify the HIV status but I can no longer remember. There was however no copy of the letter sent to the parents in any of the notes of the affected children.

38. I am not sure how families were counselled pre-testing at GOSH but they were individually informed of the positive test and implications by Prof Hardisty and the haemophilia sister.

At Alder Hey, I was informed by the parents that they were not counselled before testing and received no personal post testing counselling. The information regarding the positive test outcome was sent by letter to an affected boy's parents. One mother felt a "positive test" was in fact a good outcome and one mother hearing that letters had been sent was so distressed

that she was unable to open the letter for months. These incidents were related to me by the parents involved at one of the parents evening meetings

I had no involvement in the process either at GSOH or Alder Hey as this took place before I was appointed at either institute.

39. I don't recollect any parent being told to keep the diagnosis secret but many if not most were wary of sharing this with anyone outside their immediate family circle because of the stigma attached to the diagnosis. Even close family members weren't very often aware (e.g. grandparents) and many families were very isolated as a result. This was one of the motivations of setting up the parent support groups both at GOSH and Alder Hey.

40. As I was not working at either institute at the time of the initial testing or involved in any counselling of the results, I was not involved in any of these decisions or subsequent discussions of results.

41. As discussed above all patients in accordance with the directive of the 7 October 1991 UKHCDO meeting [HCDO0000491_001], were routinely tested for HIV at six monthly intervals and the reasons for so doing is as stated above. However, my routine testing predated this edict as I felt, following the guidance of Prof Levinsky, this was an important screening tool for those boys receiving blood products

42. I can no longer remember the accurate figures of HIV infected children with haemophilia and I have no documentation or clinical information related to that time, but I would estimate 6 boys at GOSH and 12 at Alder Hey. I can no longer be certain of the levels of severity or factor deficiency of those boys affected.

43. They were all aged under 16 years of age. I do not recollect any attempt to document the moment of sero-conversion either at GOSH or Alder Hey and to my knowledge there were no stored serum samples to retrospectively analyse this time point. I did not initiate any storage of tissues or materials from children with haemophilia.

Hepatitis B

44/45. I have no documentation or recollection as to any cases of hepatitis B so I am unable to answer this request

NANB Hepatitis/Hepatitis C

46. I have no documentation or recollection as to any cases of hepatitis C so I am unable to answer this request

47. When did (a) GOSH or (b) Alder Hey begin testing patients for hepatitis C?

I have no documentation or recollection as to the definitive date. At GOSH, the testing would have started after my tenure and I think at Alder Hey, this was during the tenure of Dr Bolton Maggs. I cannot recollect having any direct involvement other than monitoring liver function test as a surrogate marker.

48. As I was not directly involved (see above) I cannot comment on this other than to be confident that Dr Bolton Maggs would have openly discussed the issue and support would have been in line with national guidelines, British Society of Haematology and RCPath.

49. Please refer to 48

50. I cannot recollect when HCV testing was introduced but would have been subject to the availability of the relevant test being made available by the regional reference laboratory. I was however shortly after this recommendation absent on maternity leave which was followed by a period of protracted illness, during which time Dr Bolton Maggs acted as locum and if available would have introduced this as part of the regular screening we had already established for other infections.

51. I do not recollect this meeting (Alder Hey Blood Transfusion Committee meeting held on 25 March 1994 [AHCH0000039]) nor can I say when testing for hepatitis C antibodies would have been introduced. Finger pricks in children are often more traumatic than venous puncture and yield small amounts of blood for testing. Also, if blood testing is being performed regularly,

it can be part of a routine venous puncture. "High risk" probably refers more in relation to causing soft tissue damage in the fingers of children with coagulation disorders rather than high risk due to infection. These children would be identified in the front cover of their clinical notes as a child with a coagulopathy together with warnings not to receive aspirin NSAID or IM injections. In 1994 there would be a centralised list in the Haemophilia Centre with the child's diagnosis and factor level

I don't know what the basis of the arguments were for the numbers of expected infections, perhaps because of the expectation that these children being considered had received products after the routine screening of donors for hep C thus exposure would be presumed to be low.

I do not know how many children were found to be infected.

I do not have a copy of the information sheet and consent form referred to in the minutes nor can I described them

52. I do not recollect how many children were found to be infected with hepatitis C at Alder Hey

Delay/public health/other information

53. As previously stated, I was not in tenure when patients were informed of their HIV status and cannot comment as to the timing of information being provided to patients and families.

Hep C infections were to my recollection discussed at Alder Hey once they became available as patient and families were being regularly seen and followed up as well as counselled by the Haemophilia Centre staff

54.

54(a) I do not know what the policies were regarding informing children of their test results when initially diagnosed because I wasn't involved in their care at those specific times.

There was no specific policy as far as I can remember but in line with all practice at that time parents would be informed, and a discussion would be undertaken as to how and when the children would be informed. My experience was that many families had found it very difficult to communicate the diagnosis of HIV to the affected children. Even grandparents, friend, religious communities, who would otherwise provide a support system, were often unaware. This left families very isolated and added to the psychological burden. This was a time of extreme fear and stigmatisation. Some examples may attest to the difficulties we were encountering: A parent confided in me that they were terrified of their son's diagnosis becoming known. They had heard of a family whose child had haemophilia and whose house had AIDS graffiti painted on the door and fire bombed. He was erroneously presumed to have AIDS because of his haemophilia. The government at that time was showing public information advertisements on TV showing large black gravestones with AIDS chiselled onto the side tumbling into dust emphasising the lethality of the condition. One family confided that their religious community only acknowledged HIV as a result of homosexuality which was a sin, so they feared being ostracised. One young boy I cared for wished to visit Disneyland and this was granted by the Make a Wish foundation, but at the last moment he was refused an US entry visa because he was HIV positive. I visited the US embassy in Grosvenor Square and held a frank discussion with the then ambassador. He arranged for the visa but it cost so much time the child died before he could fulfil his wish. With no treatment and real fears about social stigmatisation and backlash many parents sought to protect their child, I could understand this and worked alongside them to find age appropriate ways to communicate with the children. This became important as treatment intervention was required, especially if the child had siblings with haemophilia who were HIV negative and weren't receiving these specific treatments (such as regular inhaled pentamidine).

Of course, there were also a number of adolescent boys initially unaware of their HIV and we had to work with the parents to assist them as any sexual activity required a knowledge of transmission risk and prevention. In the eighties, for many parents discussing sexual activity with their adolescent offspring was embarrassing and difficult. In chronically ill children, parents can infantilise their children's emotional development as part of the protective nature of being a parent with a seriously ill child. We were able to systematically inform the boys and instruct them and this was achieved with the help of the haemophilia sister, unit social worker and adult physician from the sexual health unit in the Royal Liverpool hospital, who was involved in the care of young men with HIV.

54(b) Other than following national guidelines the assistance of the adult physicians and instructing parents and schools about safe handling of blood spillage, I cannot recollect any further specific guidance.

54(c) "Back-up facilities" meant dedicated social workers, HIV counsellors, clinical psychologists and family therapist including play therapists. Paediatric numbers were very small and the funding to provide these services didn't exist, (also for other paediatric diseases). In GOSH this support was an extension of the haematology/oncology unit, which was well established and up until the edict of displacing the haemophilia boys to a general unit was also the support system offered at Alder Hey. As a consequence, until the establishment of the dedicated haemophilia unit at Alder Hey, there was a predictable and considerable disruption to this aspect of essential ancillary support. Through the efforts of the staff we did re-establish a better service, but adequate funding was always contentious as I have already discussed.

55.

55(a) Please refer to answer Q54c

55(b) b. At GOSH, Professor Hardisty provided funding for parent counselling and in support of the meetings.

At Alder Hey, I raised my concerns with the Trust Manager (Mr P Butler), Medical Director (Dr J Martin) as well as the Director of Laboratory Services (Dr Helen Carty) at numerous and repeated meetings as well as with the director of finance (whose name I cannot recollect) that these services in light of the severity of the children's condition and the displacement from the experienced and similarly staffed haematology ward were imperative to provide the improved support they and their families required. I was repeatedly informed there was no budget to provide this level of support.

55(c) I do not recollect all the differences in support and funding provided for children and adults

56. I cannot recollect specific information given at the time other than the generic risks associated with blood products

57. I cannot remember specific advice given but it would have included the risk associated with blood contamination (open wounds needle stick injury), good practise in handling of blood contaminated needles etc and disposal (home treatment) as well as risk of sexual transmission.

We were able to reassure parents treating children at home with factor replacement that their risk of being infected with HIV was negligible if guidelines were followed as that research was published. We also emphasised the lack of transmission, e.g. sharing crockery, toilet seats etc. Basically, we used the opportunity of regular follow up to continually inform families of the knowledge base of HIV/ hepatitis as it became known to us

Consent

58. Blood would be taken at the follow up clinic to monitor general health, renal liver function immunological and infection parameters. I don't think at that time there was any specific protocol but I personally always tell parents why I am

taking blood and for what purpose. This would be in the clinic and the information at that time was only verbal. They would not be asked for written consent but would be able to discuss and refuse to have blood drawn if they so wished, as all tests undertaken on children must be with parental assent. Tests for HIV would have to be consented but probably in those days it would be verbal consent only.

I do not recollect any samples being taken other than for diagnostic purposes and there was no storage of samples.

My recollection is that the Zidovudine study was conducted under written informed consent

59. Children presented with bleeding episodes were for the large part already registered and had received numerous factor replacement treatments before I was involved in their care. Subsequent treatments were based on clinical assessment and needs. I do not recollect ever asking parents for consent to treat these acute bleeds but obviously would have discussed the reasons for initiating any treatment. I cannot recollect any new patients during my tenure at GOSH but there will have been PUPs at Alder Hey, I assume the parent were informed of the diagnosis and treatment options as well as alternatives, prognosis and results of investigations but I cannot say definitively how and when this was documented

60. Patients under my care were tested along national guidelines and they would have been informed and consent to testing required, However, as previously stated the children with HIV infection were all infected and tested before I was involved in their care and I do not know how this was explained or consent (if any) obtained.

PUPS

61. I cannot recollect any decisions and actions taken at the (a) GOSH and (b) Alder Hey by me or with my involvement with regard to a category of people referred to as 'previously untreated patients' (PUPS), other than the preferential use of cryoprecipitate (or DDAVP in mild cases).

I cannot remember any PUP at GOSH and by the time of my appointment at Alder Hey, newly diagnosed children were probably receiving HIV/HEP screened heat-treated factor replacement, this being viewed as a safer option. Subsequently, recombinant factor prophylaxis was introduced to try and eliminate spontaneous bleeds. I cannot be sure of the timeline or when any new patients presented at Alder Hey

62. As far as I can recollect, there was no provision at Alder Hey for entering PUPS into clinical trials prior to my tenure and up to the appointment of Dr Bolton Maggs. As far as I recollect, there were no on-going UK trials or eligible patients at Alder Hey. Any national trial initiated should have been notified to the registered Haemophilia Centre and if eligible children would be included under the guidelines which would include informed consent

Research

63. I do not have a printed or electronic copy of the article published in January 1989 in the Journal of Infection "Zidovudine experience at the Hospitals for Sick Children Great Ormond Street, London"

64. GOSH was involved in the 8Y study but my involvement was peripheral. I was not involved in setting up the study or analysing the data or in any subsequent publication. If I was involved at any level it would be as part of my standard clinical duties in administering care and taking blood samples which may have been included in the study analysis. As such I am not in a position to answer more specific details about 8y study

In relation to the Zidovudine study, please seem under Q6a where I detail my involvement and other parties involved. I cannot remember the name of the pharmaceutical company involved but they provided the drug and pharmacokinetic analysis but no direct monetary funding. It included as far as I can recollect the 6 boys who were HIV positive.

65. I personally have never included a child in a study without informed consent of the child if of an age or parental/guardian assent.

66. Patient specific details would not be shared with any other third party and all children would be ascribed a UPN for purposes of the study and subsequent analyses. The pharmaceutical firm had no influence on the results of publication thereof.

67. See above answer to Q66.

68. Please see answer to Q6a

69.

69(a) I cannot recollect the process of inclusion of patients in the 8Y trial but all participants at GOSH would be children.

69(b) I cannot recollect procedure regarding obtaining consent for inclusion in the 8Y trial.

69(c) I cannot recollect what procedure was in place to deal with adverse events.

Treatment of patients who had been infected with HIV and/or Hepatitis

70. I have discussed in previous comment sections differences in care aspects between GOSH and Alder Hey and my involvement.

70(a) In the 1980s, there were no specialist in AIDS care for children with haemophilia. As discussed in previous answers, I consulted with other paediatric specialists including haematologists, immunologists as well as pulmonologists, infectious disease specialist, gastroenterologists, dermatologists, neurologists. I also actively sought support from specialist caring for young adult HIV patients. The children had complex multi system complaints and as there was very little general knowledge in this field there was no expert so I, like most paediatricians caring for these children, was guided by best practice, This was difficult especially in a field where epidemiologists were publishing that AIDS related symptoms in children where rare when at that time they were considering newborns and vertical transmission

as we were being confronted with symptomatic children unfortunately dying of AIDS.

70(b) During my tenure, apart from supportive care including psycho-social support, the only available treatment specifically directed against HIV was Zidovudine, which required careful dosing and monitoring.

70(c) All available information was provided to patients and their families but this was limited as few children had been treated in the 1980's, which was one of the motivations for undertaking a limited study at GOSH to determine the pharmacokinetics and to document any immunological improvements. However, this was a small observational study and it would be many years before advances in knowledge and treatment options evolved, by which time I was no longer involved in the direct management of these children

71. As previously stated, I established regular outpatient follow up and monitoring by full clinical examination and serological testing inclusive of immune function parameters. They were also offered additional counselling by the specialised nursing staff and social worker attached to the centre.

72. I cannot recollect any patient with hep B and as such I cannot provide further information about this specific request.

73. I cannot recollect any patient with hep B and as such I cannot provide further information about this specific request.

74. I cannot recollect any patient with hep C and as such I cannot provide further information about this specific request.

75. I cannot recollect any patient with hep C and as such I cannot provide further information about this specific request.

76.

76(a) I am no longer aware of the specific treatments related to adults at that time, but I was dealing with children who require specific

approaches to therapies rather than a "mini adult" approach. I followed international CDC guidelines and national BSH and RCPath publications, but these were often not specific enough for the patient population I was dealing with. As there was no evidence based advice it was only by widespread consultation with other specialists, especially Dr D Stevens in Manchester, and Prof Levine Institute of Child Health, that I could offer the best available support pertinent to the time period.

76(b) Not really but I did the best I could considering the limitations of knowledge at the time (see above).

76(c) There was only one therapeutic available which was zidovudine and as indicated and in discussion with the families this was used if children had symptomatic disease. Additional supportive care to limit opportunistic infections was also given.

77. I have answered this in previous sections at some length and would reiterate that I tried to provide this level of support but during my time at GOSH this was provided as an extension of the services given to oncology patients and at Alder Hey I had to find external funding as the Trust would not financially support these services and the oncology unit services were withdrawn from the children.

78. I do not know of any funds at GOSH that provided services although the haematology ward charitable fund did provide for the parents' meetings and covered the costs of various organised hospital excursions

At Alder Hey, I received regional funding on application for a specialised nurse and dedicated social worker who acted as counsellors. The Haematology ward fund did not provide any financial contributions to the support of the families.

79. I do not know of any funds at GOSH that provided services or if there were any difficulties in accessing these funds

Despite being appointed specifically to improve haemophilia patient services, especially for those boys infected with HIV, I was not provided with any funds from the Trust to achieve these improvements. The Regional Health Authority through the AIDS allocation was my only means to advance the clinical care, laboratory diagnostics and supportive care. The establishment of a dedicated haemophilia centre would not have been possible without the ultimate support of the Trust. The establishment of the unit was only agreed to after the decision to withdraw the clinical support offered by the haematology oncology unit and following a meeting between the hospital manager and the parents of children affected by HIV.

80. The only HIV study involvement I and patients under my care were involved in were the Zidovudine study.

Records

81. During my tenure at GOSH there were no deaths related to HIV or Hepatitis

My policy at Alder Hey was to state the underlying reason as a result of immune deficiency related to haemophilia as that would be the correct diagnosis.

82. All records should have been retained. There were no computerised records in those days so at GOSH paper records were stored in the centre.

At Alder Hey records were kept on the oncology ward until the establishment of the haemophilia centre when they would have been transferred.

In contrast to GOSH, when I was first appointed to Alder Hey, many of the case notes of HIV infected boys were missing large parts of relevant documentation either within the body of the notes or in the section reserved for correspondence. I was unable to locate these sections nor was I able to determine when or by whom sections had been removed but it wasn't an isolated case note that was incomplete and this was in stark contrast to the oncology notes kept in the same unit which were by and large complete inclusive of treatment decisions

83. I did not keep any separate files.

84. I have never kept any patient records at home or anywhere other than within the hospital.

85. I hold no records or information related to the patients either on paper or electronically.

SECTION 5: UKHCDO

86. I cannot recollect my involvement with the UKHCDO, and I was not on any working party committee or group.

I probably attended some meetings, but I cannot specifically remember when or where these would be held and what the content of those meeting entailed.

I have no information regarding the structural organisation, relationships with pharmaceutical companies or decision-making processes.

In light of this, I feel it would be inappropriate for me to try and answer any specifics related to the organisation

SECTION 6: Pharmaceutical companies/medical research/clinical trials

88. I have never provided advice or consultancy services to any pharmaceutical company involved in the manufacture and/or sale of blood products

89. I have never received any pecuniary gain in return for performing an advisory/consultancy role for a pharmaceutical company involved in the manufacture or sale of blood products.

90. I have never sat on any advisory panel, board, committee or similar body, of any pharmaceutical company involved in the manufacture or sale of blood products.

91. I have never received any financial incentives from pharmaceutical companies to use certain blood products.

92. I have never received any non-financial incentives from pharmaceutical companies to use certain blood products

93. I have never received any funding to prescribe, supply, administer, recommend, buy or sell any blood product from a pharmaceutical company

94. As far as I recall there were no regulations or requirements or guidelines were in place at the time concerning declaratory procedures for involvement with a pharmaceutical company but in any presentation I would mention if a company had been involved and to what extent they had provided support.

95. I have never undertaken medical research for or on behalf of a pharmaceutical company involved in the manufacture or sale of blood products.

96. The pharmaceutical company from the Zidovudine study as part of the research contract to provide support had access to the results but no patient was identified other than by a designated UPN known only to Prof Hardisty (GOSH) as head of the study and myself as co-ordinator and the company had no influence on the publication of the data.

97. I did not during the period receive funding from pharmaceutical companies for medical research other than stated above

SECTION 7: The financial support schemes

98. I do not recall any involvement in these specific funds but I know that there were funds accessed by the parents during my tenure at Alder Hey which when granted were put into trust until the boys reached 18 years of age. I probably wrote in support of the application if a medical documentation was required but I cannot recollect.

99. I cannot recollect what information was given to parents, but this would have been one of the tasks of our Centre dedicated social worker who would have assisted the parents in any application that were available. As in most cases if a medical declaration was necessary in support of any application, I would have written a letter to the trust fund requesting them to support the parents'

application. I cannot answer in any more detail as I no longer can recall what processes we undertook.

The one occasion that I remember was a family who were granted financial assistance (I cannot recollect from which Trust) but it would have been in 1989 and this was to be held in trust until the child reached adult age. He died the same year and we tried to facilitate the support to be released to provide his mother and family with the much-needed financial assistance. I do not think we were successful but in my opinion in this instance the trust proved not fit for purpose.

SECTION 8: Other Issues

100. In relation to the Inquiry's Terms of Reference, I have not had any complaints made about me to any of the bodies listed.

101. I wish to state to the Inquiry that my experiences of trying to provide quality care for haemophilia and HIV infected boys and their families at Alder Hey was the worst period of my 40-year career. The constant refusal by senior hospital management to provide me with even the basic resources went beyond budgetary considerations. No financial or medical reasoning could ever justify the way these families were prevented from accessing the ward and experienced staff who had treated them all of their lives and whom they had trusted to provide continued care when they became infected with HIV. Never one to back down from defending the rights of my patients the subsequent toxic and adversarial approach by senior management took its toll on my health and ultimately my decision to leave the NHS and the UK. I took up a research position and completely divorced myself from the direct clinical care of children for almost three years. I was fortunate enough to very successfully re-establish my clinical role in paediatric stem cell transplantation in the Netherlands, where I happily worked and flourished academically and clinically for twenty years. My experiences at Alder Hey insured that I never again would be involved in the management of children with haemophilia. I cannot imagine if this was the impact it had on me, how terrible it must have been for the parents and the boys. My only consolation is that I left them a

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Statement of Truth

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

Signed

GRO-C

Dated:

21. March 2021

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