Witness Name: Dr Ron Kerr
Statement No.: WITN4749001
Exhibits: WITN4749002-14
Dated: 8 March 2021

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR RON KERR

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

I, Ron Kerr, will say as follows: -

Section 1: Introduction

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

   Name: Dr Ronald Kerr

   Address: Department of Haematology, Ninewells Hospital and Medical School, Ninewells Avenue, Dundee, DD1 9SY

   Date of birth: GRO-C 1972

   Professional qualifications: MBChB with Commendation 1995
   MRCP 1998
   DipRCPath 2000
   FRCPath 2003
   MD 2004

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

   CURRENT POST

   Consultant Haematologist and Haemophilia Director, NHS Tayside (March 2005 – present) and Clinical Lead for NHS Tayside Clinical Haematology Service (2009 to present)

   PREVIOUS POSTS

   Acting/Locum Consultant Haematologist and Haemophilia Director, NHS Tayside (December 2003 – April 2004 and September 2004 – March 2005)

Specialist Registrar, Haematology, East of Scotland Deanery (August 1998 – January 2001 and November 2002 – August 2004)

Clinical Lecturer in Haematology, The University of Edinburgh (January 2001 – November 2002)

Senior House Officer, General Medicine, Stracathro Hospital (February 1998 – August 1998)

Senior House Officer, Vascular, Cardiology and Renal Medicine, Ninewells Hospital (August 1997 – February 1998)

Senior House Officer, Haematology, Ninewells Hospital (February 1997 – August 1997)

Senior House Officer, Infectious Disease Medicine, Kings Cross Hospital (August 1996 – February 1997)

Pre-Registration House Officer, General Surgery, Stracathro Hospital (February 1996 – August 1996)

Pre-Registration House Officer, General Medicine, Ninewells Hospital (August 1995 – February 1996)

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

I have served as a member of the Scotland and Northern Ireland Haemophilia Directors Group (latterly Scottish Haemophilia Directors Group) since my appointment as a Locum Consultant and subsequent Consultant Haematologist (September 2004 – present) and acted as Secretary for the group from 2008 to 2018. I also attended these meetings on occasion as deputy for Dr Cachia from December 2003 to September 2004.

I have been a Fellow of the Royal College of Pathologists since 2003.

I have been a member of the UK Haemophilia Centre Doctors' Organisation since approximately 2001.

I have been a member of the British Society on Haemostasis and Thrombosis (since approximately 2001.

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

I provided evidence which was any relevant documents held by myself or our centre to the Penrose Inquiry as well as a written statement to the Penrose Inquiry. I have submitted all of these documents again to this Inquiry following a Rule 9 request in July 2018. I have not been involved in any other inquiries, investigations or litigation in relation to HIV, HBV, HCV or vCJD.

5. **The questions below focus on your time working at Dundee Haemophilia Centre but if you have information relevant to the decisions, policies or practices at Edinburgh Haemophilia Centre where you previously worked, please also set that out.**

I worked at Edinburgh Haemophilia Centre from January 2001 to November 2002. This was a Clinical Lecturer post supervised by Professor Christopher Ludlam. The main focus was laboratory research (cell culture studies and molecular biology rather than clinical trials involving patients) and teaching of undergraduates. The laboratory research was supervised by Professor Ludlam's Senior Clinical Scientist Dr David Stirling. I had weekly clinics where I reviewed patients with bleeding and thrombotic disorders and was on the Royal Infirmary of Edinburgh Haematology Specialist Registrar on call rota. I was not involved in making policy decisions. My research work was successfully presented as a Thesis on 'Cytokines and Haemostasis' for the postgraduate degree of Doctor of Medicine (MD).

Section 2: Decisions and actions of Dundee Haemophilia Centre

6. **Please describe the roles, functions and responsibilities of Dundee Haemophilia Centre during the time that you have worked there. Please provide an account of the Centre's history, its establishment and its activities during this time.**

The first time that I worked in the Department of Haematology in Ninewells Hospital Dundee was as a Senior House Officer in 1997. The format of a Haemophilia Centre in Dundee had been established prior to that time by Dr (now Professor) Philip Cachia who was my predecessor as Consultant Haematologist and Haemophilia Director. Dr Cachia was appointed in 1992 and had managed to establish a dedicated space for the Dundee Haemophilia Centre and importantly established a part time Specialist Haemophilia nurse post in 1995. I have very little knowledge of facilities prior to that time.

The Dundee Haemophilia Centre is a designated Haemophilia Treatment Centre (HTC) rather than a Comprehensive Care Centre (CCC). Partly this is due to patient numbers (see section 9) falling below those generally expected to attend a CCC which is related to the population that the centre serves (across Tayside and Fife this is less than 750 000). However, due to its geographical location and being situated within a University Teaching Hospital, Dundee HTC has always provided a spectrum of clinical activities similar to those provided by a CCC during my time working there. All urgent and review patient appointments, surgery and management of complications of treatment such as Hepatitis C have been provided at the Dundee Centre. The patients did not attend the linked CCC in Edinburgh for clinical care. The main relationship with Edinburgh CCC related to the stock control and monitoring of coagulation factor concentrate usage.

In-patient work is within the Dedicated Haematology ward (currently ward 34 and previously ward 16 which was shared with the Department of Renal Medicine then ward 31) where patients with Haematological Malignancies are managed. This allows specialist Haematology care 24 hours a day, 365 days per year with the Haemophilia Director and Specialist nurse working together with a team of Haematology Consultants, Specialist Registrars and dedicated Haematology nurses.

Both myself, and previously Dr Cachia, have always worked with Consultant Paediatricians (Previously Dr Rosalie Wilkie and recently Dr Margaret Peebles and colleagues) to provide joint clinics in the Tayside Children's Hospital within Ninewells Hospital for assessment and treatment of children with bleeding disorders. We have also worked with a local Hepatologist (Professor John Dillon) to manage Hepatitis C (see more details in section 6), an Orthopaedic surgeon (Mr Ben Clift) to manage haemophilia arthropathy, as well as local dental, obstetric, genetics and physiotherapy specialists. During my time at the centre there has always also been a data manager who collates information regarding factor concentrate usage as required by the purchasers of factor concentrate (National Specialist and Screening Services Division (NSD) within NHS National Services Scotland (NSS)) who purchase factor concentrate centrally on behalf of all Scottish Health Boards. Amongst other duties our data manager has also been invaluable in helping with patient notification exercises as described in section 5.

7. **Please identify senior colleagues at the Dundee Haemophilia Centre and their roles and responsibilities during the time that you worked there.**

As above, during my period as a trainee the Haemophilia Director was Dr Cachia until he moved to the Post of Postgraduate Dean and I replaced him in this role. There were periods between December 2003 and September 2004 when Dr Cachia was Acting Postgraduate Dean and during those periods I covered his role as an Acting Consultant.

The Specialist Haemophilia nurse was Mrs June Ward from 1995 to June 2018 and since June 2018 to present has been Mr Lee Newman. Other colleagues whom we have worked closely with have been mentioned in section 6 above.

Dr Cachia appointed a Clinical Assistant 1 or 2 days a week from around 1997 to see patients together with the Specialist Haemophilia Nurse in routine clinics as he had taken on additional sessions working in the Postgraduate Deanery. At my time of appointment this was Dr Helen Murrie. Shortly after my appointment Dr Murrie returned to work in a more full time role in General Practice and I did not replace this post as I was able to attend those clinics myself and our Specialist nurse was able to practice more independently having gained significant experience over the previous 9 or 10 years.

8. **Please describe:**

   a. **your role and responsibilities at Dundee Haemophilia Centre and how, if applicable, this changed over time;**

b. your work at the Centre insofar as it has involved the care of patients with bleeding disorders and/or patients infected with hepatitis and/or HIV in consequence of infected blood or blood products.

During my time as a trainee (initially a Senior House Officer and then as a Specialist Registrar) my main role within the Haemophilia Centre was the occasional assessment of patients attending with acute bleeding episodes, and performing routine clinics when the Clinical Assistant was not available. The majority of my time during that period was spent managing patients with haematological malignancies.

Following my appointment as Consultant Haematologist and Haemophilia Director I assumed responsibility for the Haemophilia Centre. I also have a patient case load that includes patients with Haematological Malignancy (Leukaemia, Lymphoma, Myeloma), general non malignant haematological conditions and thrombotic disorders. I am responsible for the Tayside anticoagulation service (the monitoring of over 6000 patients on warfarin within a community service and I oversee the training and medical support to the community anticoagulant practitioners (nurses and pharmacists) and laboratory quality control for this service. I also have laboratory clinical duties. I have also had significant managerial responsibility as Clinical Lead for the Clinical Haematology service since 2009. I continue in all of these roles although in the last few years I no longer take on new patients with haematological malignancies as we have balanced the workload across the Consultants within our department. I would estimate that on average I spend around 25% of my time on matters relating to patients with bleeding disorders.

Since my appointment as a Consultant Haematologist and Haemophilia Director I have been responsible for the investigation, prevention and management of both bleeding and the long term complications of Haemophilia and bleeding disorders and their treatment. From the start of my time in this role all Haemophilia patients were already established on recombinant factor concentrates. The only patients that have received blood (plasma) derived concentrates (all of which are virally inactivated) during my time as Haemophilia Director are a small number of patients with von Willebrand's disease (and very occasionally those with rare bleeding disorders such as dysfibrinogenaemia, prothrombin deficiency and factor XI deficiency) where alternative treatments such as DDAVP or tranexamic acid were ineffective, contra-indicated or would provide inadequate cover for eg surgery. No patients have acquired transfusion transmitted infection in the time that I have been looking after them. No existing Dundee HTC patients (or to my knowledge previous and now deceased patients treated in Tayside) had HIV or chronic Hepatitis B infection. All Dundee HTC patients who had previously received plasma derived coagulation factor concentrates prior to the introduction of viral inactivation steps had chronic Hepatitis C infection (further details on numbers of patients in section 6 below) with no apparent cases of spontaneous clearance in our population. Together with Professor John Dillon we have now successfully treated all current patients with Hepatitis C infection following the development of novel direct acting antiviral therapies. Although earlier treatment with Interferon +/- Ribavirin was effective for some patients, this was not the case for many and it is very sad that several of our patients died of the complications of HCV prior to the availability of these subsequent highly effective novel therapies.

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

From the UKHCDO database –
In 2002 when I returned to Dundee from Edinburgh there were 167 patients registered at Dundee HTC (28 with Haemophilia A, 10 with Haemophilia B, 98 with von Willebrand's disease and 31 with other congenital bleeding disorders).

Currently in 2020 there are 541 patients registered at Dundee HTC (46 with Haemophilia A, 10 with Haemophilia B, 189 with von Willebrand's disease and 296 with other congenital bleeding disorders).

Whilst patient numbers have increased substantially I suspect that there were also a number of patients were attending clinics but not registered on the UKHCDO database in 2002, particularly those with bleeding disorders other than Haemophilia.

Section 3: Treatment of Patients at Dundee Haemophilia Centre

Research

10. **Please list all research studies that you were involved with during your time as a consultant at Dundee Haemophilia Centre insofar as relevant to the Inquiry's Terms of Reference, please:**

    a. **Describe the purpose of the research.**

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

    c. **Explain what your involvement was.**

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

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

    f. **State the number of patients involved.**

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

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

Please provide the same details in relation to any epidemiological or similar studies in which you were involved, insofar as relevant to the Inquiry's Terms of Reference.

A. Studies in which I was involved leading to publication –

(copies of the following papers and abstracts will be submitted along with this statement) Full Papers (published in peer reviewed journals)

i. *WITN4749002* - Sims M, Mayer L, Collins J, Bariana T, Megy K, Lavenu-Bombled C, Seyres D, Kollipara L, Burden F, Greene D, Lee D, Rodriguez-Romera A, Alessi M, Astle W, Bahou W, Bury L, Chalmers E, Da Silva R, De Candia E, Deevi S, Farrow S, Gomez K, Grassi L, Greinacher A, Gresele P, Hart D, Hurtaud M, Kelly A, Kerr R, Le Quellec S, Leblanc T, Leinøe E, Mapeta R, McKinney H, Michelson A, Morais S, Nugent D, Papadia S, Park S, Pasi J, Podda G, Poon M, Reed R, Sekhar M, Shalev H, Sivapalaratnam S, Steinberg-Shemer O, Stephens J, Tait R, Turro E, Wu J, Zieger B, Kuijpers T, Whetton A, Sickmann A, Freson K, Downes K, Erber W, Frontini M, Nurden P, Ouwehand W, Favier R, Guerrero J (2020) Novel manifestations of immune dysregulation and granule defects in gray platelet syndrome *Blood* **136(17)**: 1956-1967

   This research, led by Professor Ouwehand in Cambridge, sought to further explore clinical and laboratory features of the very rare inherited platelet disorder, Gray Platelet Syndrome. It was a multicentre, international study with full ethical approval. Professor Ouwehand's group invited any centre with patients known to have Gray platelet Syndrome to participate. It is a very rare disorder with only a few known affected patients in the whole of Scotland. I informed our Centre's single known patient with this disorder of the study and invited them to participate. They wished to do so and I obtained full informed and written consent. Professor Ouwehand's centre funded the study. I sent clinical information regarding the patient and their blood test results to Professor Ouwehand's research group with the fully informed consent of the patient. The patient also chose to attend their centre in Cambridge in person to provide further information. I reviewed the paper prior to submission and did not have any significant suggested modifications to its content. The research discovered novel clinical associations with the Gray Platelet Syndrome disorder which are important and will be very helpful in managing such patients. The patient involved has reported to me that they found participating very rewarding.

ii. *WITN4749003* - Buckley F, Norris A & Kerr R (2018) Management of abdominoperineal excision of the rectum in a patient with Glanzmann thrombasthenia *Acta Haematologica* **139**:243-246

   This was a case report of the management of one of my (anonymised) patients with a rare and severe inherited platelet function disorder, Glanzmann's thrombasthenia, who had major life saving cancer surgery which had not previously been described in a patient with this disorder. This was a major undertaking and required significant co-ordination with our Scottish National Blood Transfusion Service (SNBTS) colleagues across the country as the patient required 62 pools of platelets which were highly matched and required specific donors to be called to allow this.

The patient's fully informed and written consent was obtained prior to submission. The patient was provided with a copy of the published paper at their request which they have proudly shown to their family. No funding was required. I co-authored the paper with one of my trainees and a Blood Transfusion Service colleague.

iii. *WITN4749004* - McLaughlin D & Kerr R (2017) Management of type 2B Von Willebrand Disease during pregnancy *Acta Haematologica* **137**:89-92

This was a case report of the management of one of my (anonymised) patients with type 2B von Willebrand's disease during pregnancy and delivery and also included a literature review. The case was novel as it was the first report in the literature of the baby having been also affected by this disorder and requiring treatment at delivery. The patient's fully informed and written consent was obtained prior to submission. The patient provided this on behalf of herself and her baby. No funding was required. I co-authored the paper with one of my trainees.

iv. *WITN4749005* - Simeoni I, Stephens J, Hu F, Deevi S, Megy K, Bariana T, Lentaigne C, Schulman S, Sivapalaratnam S, Vries M, Westbury S, Greene D, Papadia S, Alessi M, Attwood A, Ballmaier M, Baynam G , Bermejo E, Bertoli M, Bray P, Bury L, Cattaneo M, Collins P, Daughert LC, Favier R, French D, Furie B, Gattens M, Germeshausen M, Ghevaert C, Goodeve A, Guerrero J, Hampshire D, Hart D, Heemskerk J, Henskens Y, Hill M, Hogg N, Jolley J, Kahr W, Kelly A, Kerr R, Kostadima M, Kunishima S, Lambert M, Liesner R, Lopez L, Mapeta R, Mathias M, Millar C, Nathwani A, Neerman-Arbez M, Nurden A, Nurden P, Othman M, Peerlinck K, Perry D, Poudel P,Reitsma P, Rondina M, Smethurst P, Stevenson W, Szkotak A, Tuna S, van Geet C, Whitehorn D, Wilcox D, Zhang B, Revel-Vilk S, Gresele P, Bellissimo D, Penkett C, Laffan M, Mumford A, Rendon A, Gomez K, Freson K, Ouwehand W & Turro E (2016) A comprehensive high-throughput sequencing test for the diagnosis of inherited bleeding, thrombotic and platelet disorders *Blood* **127(23)**:2791-2803

This research was performed by Professor Ouwehand as described in the paper (i) above and the patient recruited from our centre was the same patient as in that paper with exactly the same process followed as described there. The focus and outcome of the study was the development of improved diagnostic testing for platelet function disorders.

v. *WITN4749006* - Khan MM, Tait RC, Kerr R, Ludlam CA, Lowe GD, Murray W, Watson HG (2013) Hepatitis C infection and outcomes in the Scottish Haemophilia population *Haemophilia* **19(6)**:870-875

This research was a retrospective, anonymised study to report the outcomes of Hepatitis C infection in the Scottish Haemophilia population. It was led by Dr Khan and Dr (now Professor) Watson in Aberdeen. As part of the Scottish Haemophilia Directors Group I discussed the study design

with them, provided anonymised patient data for the study and reviewed the paper prior to submission. All of the other Scottish Haemophilia Centres also provided this information. No funding was required for this study. The primary data used was obtained from the UKHCDO database and our patients had provided written informed consent for that data to be collected. From the UKHCDO database 455 patients were identified as having been infected with Hepatitis C in Scotland. From across Scotland we were able to provide data regarding the long term consequences of infection and responses to treatment for 255 patients from this cohort as well as an additional 47 patients (giving a total of 302 patients) who had been infected from treatment received outside Scotland but now living in Scotland. Of those 302 patients, 26 were from the Dundee Haemophilia Centre. The consequences of Hepatitis C infection were described as were the responses to available therapies. Our patients were all fully informed as to any complications that they had encountered and their responses to treatment. I did not specifically request express consent from each individual patient regarding using this information for the study report as this is not a requirement for an anonymised, retrospective study. This is discussed further in section 12 below. The information from this study has been very helpful when discussing hepatitis C infection, its consequences and its treatment with our patients.

Published Abstracts (of research presented at Conferences as either a poster or oral presentation)

vi. *WITN4749007* - Chalmers E, Bagot C, Tait RC, Anderson J, Rodgers R, Khan M, Watson H, Craig J, Kerr R and McLaughlin D (2018) Scottish experience introducing extended half-life factor concentrates in Haemophilia A and Haemophilia B patients *Haemophilia* **24 (5)**: 27

This was a retrospective, anonymised report of the use of extended half life recombinant factor concentrates to treat Haemophilia patients. These were new (but fully licenced and approved) treatments for Haemophilia and the purpose was to examine any benefits or concerns from their use in routine care. As this was simply a report of experience with no additional information or blood samples than those required for standard patient care, ethical approval was not a requirement. All patients were aware of the treatments that they were receiving and the outcomes of that treatment in terms of effectiveness in preventing bleeding, any adverse effects and the results of any blood tests as part of their standard treatment. All Haemophilia centres in Scotland took part and reported on all 22 patients that had received these treatments at the time of the study, 5 of whom were from the Dundee Haemophilia Treatment Centre. As it was an anonymised, retrospective report, written informed consent is not a requirement but as a matter of good practice all of our patients were aware that we were collating and presenting this data and verbally agreed to this. It was co-ordinated by my Specialist Registrar, David McLaughlin with my supervision. The reported abstract was circulated to all named authors above that

contributed for approval prior to submission and subsequent presentation at the World Federation of Haemophilia Meeting. The report was reassuring in demonstrating that these new treatments were effective in controlling bleeding with the significant advantage to patients of less intravenous infusions. Such information is collected much more quickly when collated across all Scottish centres rather than relying on just your own centre's experience and is invaluable for our patient population to be aware of when they are deciding about which treatments that they wish to receive. No funding was required for this study.

vii. *WITN4749008* - McGaffin G, White A, McLuskey J, O'Brien D, Kerr R, Horn L & Stirling D (2011) MLPA analysis in routine molecular diagnostics – a cautionary tale. *British Journal of Haematology* **153 (1)**: 188

This was an anonymised report from Dr David Stirling's genetics laboratory at the Royal Infirmary of Edinburgh that was presented at the British Society of Haematology. It highlighted an issue that was noted when using a laboratory technique known as MPLA analysis to determine the underlying genetic mutation that causes von Willebrand's disease. This technique was noted to give a misleading signal in certain circumstances and was noted in 2 patients having MPLA analysis as part of their routine care. One of these patients was from the Dundee Haemophilia Centre. The testing was part of routine genetic testing and full informed written consent is always taken for genetic testing. The noted issue was picked up and an accurate report was provided for the patient and the patient was informed of this report.

I reviewed the abstract prior to submission. No funding was required. The highlighting of this issue to other laboratories helps other molecular genetic laboratories to be vigilant to these issues which is beneficial to patient care.

viii. *WITN4749009* - Ward J, Maddox J, Kerr R (2010) Glanzmann's thrombasthaenia – a single centre experience of different therapeutic approaches to achieve haemostasis in 3 patients. *Haemophilia* **16** (suppl 4): 123

This anonymised, retrospective report from our Haemophilia Centre treatments used in the management of the rare, severe platelet function disorder Glanzmann's thrombasthaenia. It particularly highlighted alternatives to platelet transfusion with the use of recombinant factor VIIa and tranexamic acid. It was presented as a poster at the World Federation of Haemophilia by our Specialist June Ward and co-authored by myself and our Specialist Registrar Dr Maddox.

As an anonymised, retrospective report ethical approval and informed written consent is not a requirement but the patients were informed that this was being presented and consented to this. They had given fully informed consent regarding the treatments that they had received and were fully

aware of the outcomes. No funding was required. The report highlighted the available alternatives to platelet transfusion which reduce the risk of transfusion transmitted infection and alloimmunisation (which makes future platelet transfusions less effective when required).

ix. *WITN4749010* - Ward J, Craig J, Kerr R (2010) A case presentation of an unusual intramural small bowel bleed in a patient with severe Haemophilia B. *Haemophilia* **16** (suppl 4): 28

This anonymised case report from our Haemophilia Centre highlighted an unusual bleeding episode which occurred in one of our patients with Haemophilia. It was presented as a poster at the World Federation of Haemophilia by our Specialist nurse June Ward and co-authored by myself and our Specialist Registrar Dr Craig.

As part of the report was a radiological image (MRI) of the patient it is good practice to obtain written consent and this was obtained. The patient was shown the poster prior to it being taken for presentation. No funding was required. Raising awareness of unusual presentations are helpful to clinicians and patients for future management of haemophilia patients. It has been my experience that our patients are very keen to contribute in this way to help others with bleeding disorders.

x. *WITN4749011* - Hay AE, Kerr R, Watson HG (2010) Perinatal management of pregnancies at risk for haemophilia. *British Journal of Haematology* **149(1)**: 27

This anonymised, retrospecitve report from Aberdeen and Dundee Haemophilia Centres was presented by Dr Hay at the British Society of Haematology meeting.

It reported on the variation in management of such patients that can be seen in the absence of established guidelines. Dr Hay was the lead author with her supervisor Dr Watson and I provided data and reviewed the manuscript. No funding was required. As an anonymised, restrospective report that did not involve anything other than a report on the clinical course from the routine management of patients ethical approval and patient consent was not required. Again this is further discussed in section 12. Highlighting variations in practice from such studies is beneficial to establish areas where guideline development would be beneficial.

xi. *WITN4749012* - Khan MM, Chalmers EC, Dennis R, Horne L, Kerr R, Lowe GDO, Ludlam CA, Murray W, Tait RC, Thomas AE, Walker ID, Watson HG (2009) Outcomes of hepatitis C infection in a large haemophilia population. *British Journal of Haematology* **145(1)**: 5-6.

This is an earlier report of study (v) with the same approach as documented in study (v) above. There was less complete data at that time. Note that the

related document that I have in my records that I have submitted as evidence was titled 'The Hepatitis C outbreak in Scottish haemophiliacs' rather than 'Outcomes of hepatitis C infection in a large haemophilia population' and the title must have been changed by Dr Khan prior to submission (which I subsequently note was agreed at a Haemophilia Directors Meeting prior to the meeting from the minutes provided to me by the Inquiry as evidence relating to this statement [Document – GGCL0000222_001] – agenda item 4a).

xii. *WITN4749013* - Maddox J, Ward J, Kerr R (2008) Application of the UK Haemophilia Centre Doctors Organisation (UKHCDO) diagnostic criteria for type 1 von Willebrand disease to patients seen in a UK Haemophilia Centre. *Haemophilia* **14** (suppl 2): 116.

This anonymised, retrospective report examined the classification of patients with von Willebrand's disease in Dundee Haemophilia Centre. It was presented as a poster at the World Federation of Haemophilia meeting by my trainee, Dr Maddox and was co-authored by myself and June Ward. The data used was obtained from the UKHCDO database and our patients had provided written informed consent for that data to be collected. No funding was required. The study reported the findings that a number of patients had historically been classified as having von Willebrand's disease but did not meet the updated diagnostic criteria. This had important implications for the patients. Any patients where the review found a patient's diagnosis of von Willenbrand's disease may not meet the criteria led to the patient being reviewed, informed of this and in a number of cases such a diagnosis removed which is important for both their future management and in some cases restrictions regarding occupation and insurance. We have received very positive feedback from patients regarding this and it is part of ongoing routine care to review the diagnosis of any patient with a previously made diagnosis of von Willebrand's disease.

xiii. *WITN4749014* - Maddox J, Ward J, Kerr R (2008) Blood group distribution of baseline factor levels in von Willebrand disease. *Haemophilia* **14** (suppl 2): 116.

This report was linked with study (xii) above and followed the same procedure. It examined the known interaction of blood group on levels of von Willebrand factor which need to be taken into account when reviewing the data as described above.

B. In addition to the studies above I can recall 2 additional clinical studies which our centre recruited patients to but for which we were not involved in the study design, analysis or publication.

xiv. Liplong Study – This was a commercial study sponsored by Bayer PLC which was a randomized, active-controlled, double-blind, parallel design

study to evaluate the efficacy and safety of a once-a-week prophylaxis treatment with BAY 79-4980 compared to three times-per-week prophylaxis with rFVIII-FS in previously treated patients with severe Haemophilia A.

The process for such studies is that the sponsoring pharmaceutical company, in this case Bayer PLC, approached the Ninewells Hospital Clinical Research Centre (CRC) as one on many Centres to potentially recruit patients to the study. CRC would then have brought the study to my attention asking if we had any patients who may fulfil the eligibility criteria. On confirmation that this is the case it is submitted through the process of central and local ethical approval and eligible patients are invited to participate if they wish with fully informed written consent. From memory I think that only 1 or 2 of our severe Haemophilia A patients took part starting in 2010. Our centre staff – predominantly our Specialist Haemophilia nurse, would have taken the required blood samples to assess the safety and efficacy of this treatment as well as collecting the required clinical information regarding any bleeding or complications. There were also health and pain questionnaires completed by the patients who took part. All information regarding the study is subsequently held centrally by the sponsor out with the Haemophilia Centre. There is an agreed renumeration per patient to cover the costs of the study which is paid to NHS Tayside. There is a saving to NHS Scotland in that the patient receives the study factor concentrate free of charge instead of their usual factor concentrate which as described in section 2 part 6 above is centrally funded in Scotland. None of the centre staff received any renumeration for taking part in the study. I was not involved in the publication of the study findings.

xv. Ankle arthropathy study (HAP II). Our specialist Haemophilia nurse (June Ward) recruited patients to this questionnaire study which was led by a Haemophilia Centre Physiotherapist (Richard Wilkins) from Leeds Infirmary. Patients were recruited to the study with full informed written consent which had the required central and local ethical approval and returned questionnaires regarding effects of Haemophilia on their ankles. I think that this study was in 2017/18. I believe that 4 patients were recruited and again the information is held centrally by the Principal Investigator rather than by myself. There was no renumeration for this study and neither myself or June were involved in the publication of the study findings.

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

No, other than in anonymised, retrospective studies (see question 12 below).

12. Was patient data (anonymised, de-identified or otherwise) used for the purpose of research or any other purpose without their express consent? If so, what data was used and how and why did this occur?

There is not a requirement to obtain express consent for anonymised, retrospective data to be used. The most common use of such data in recent years is out with clinical studies and relates to Freedom of Information (FOI) requests. Frustratingly we are increasingly inundated with such requests which appear to be from pharmaceutical companies looking to gain information regarding the treatment of patients. I would prefer not to share such data which is an intrusion that is not for the primary benefit of the treatment of our patients and also wastes considerable NHS resource in collating the data for this purpose. There is a clear legal framework around this and as above it proceeds without express patient consent. The perceived misuse of FOI requests is a significant issue which may fall out with the remit of this Inquiry although it would be very helpful if the Inquiry may be able to at least highlight this issue.

The clinical studies which I have reported above which were retrospective and anonymised were all designed with the express purpose of being of benefit to the future care of patients with bleeding disorders. It is often impractical to obtain express consent from many of the patients as the studies (such as study (v) above) can be retrospective over long periods and patients may no longer be attending our centre or may have sadly died. Anonymisation protects the confidentiality of individual patients. It has always been my clinical practice to inform patients of any aspect of their illness, treatment and investigation results. In these studies I have not included information for any patients that I care for that I have not informed them of in the course of their routine clinical care. I accept that for patients that have died this may not have always been the case historically, although I would expect this to be rare. As stated above their confidentiality is protected by anonymity. It is important for accurate data to help patients in their future management that data for patients that have died is not removed as this would lead to a very significant reporting bias.

13. **Was patient data (anonymised, de-identified or otherwise) shared with third parties without their express consent? If so how, and why did this occur, and what information was provided to whom?**

This has been answered in questions 10 and 12 above.

14. **Please provide details of any articles or studies that you have published insofar as relevant to the Inquiry's Terms of Reference. (your articles entitled "Assessment of hepatitis C infection and outcomes in the Scottish haemophilia population" [PRSE0003319] and "Hepatitis C infection and outcomes in the Scottish haemophilia population" [GRAM0000025] are attached to this letter).**

I shall submit with this statement copies of the publications and abstracts for studies (i) to (xiii) above [WITN4749002-14]. The paper for study (v) [WITN4749006] is already held by the Inquiry as document [GRAM0000025] and duplicated as document [PRSE0003319].

Section 4: Pharmaceutical companies/medical research/clinical trials

15. **Have you ever provided advice or consultancy services to any pharmaceutical company involved in the manufacture and/or sale of blood products? If so, please**

list the names of the companies and give details of the advisory or consultancy services that you provided.

No

16. **Have you ever 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? If so, please provide details.**

    No

17. **Have you ever sat on any advisory panel, board, committee or similar body, of any pharmaceutical company involved in the manufacture or sale of blood products? If so, please provide details of your involvement and of any financial or other remuneration you received.**

    No

18. **Have you ever received any financial incentives from pharmaceutical companies to use certain blood products? If so, please provide details.**

    No

19. **Have you ever received any non-financial incentives from pharmaceutical companies to use certain blood products? If so, please provide details.**

    As outlined in section 2, question 8 none of the Dundee HTC patients with Haemophilia have received blood product concentrates in the time that they have been under my care. The main patients that have received blood (plasma) derived concentrates during my time as Haemophilia Director are a small number of patients with von Willebrand's disease where alternative treatments such as DDAVP or tranexamic acid were ineffective, inadequate cover for eg surgery or contra-indicated. The 2 pharmaceutical companies that manufacture/sell the von Willebrand factor (vWF) Concentrates that I have used are CSL Behring (their vWF concentrate is Voncento and formerly Haemate P) and Octapharma (their vWF concentrate is Wilate).

    When I have attended Conferences such as the International Society for Thrombosis and Haemostasis these companies have occasionally organised educational symposia on the subject of von Willebrand's disease at these Conferences. These symposia tend to be at lunch time or in the evening and a meal is generally provided either before or after the symposium. I have accepted meals in such circumstances on a few occasions. I cannot remember specific details and it is at least 5 years since I have last attended such as sponsored symposium. The symposia are supposed to be non promotional as governed by ABPI rules (the Association of the British Pharmaceutical Industry). There has been tightening of such regulations over my career but it is my opinion that such meetings are never truly non promotional as presentations tend to be slanted towards studies that have demonstrated the benefit of the sponsoring company's product. I always consider such bias when attending and interpreting any data presented.

It is my opinion that these non-financial incentives described above have not influenced my prescribing. The final decision regarding the availability of coagulation factor concentrates for use in our patients is determined nationally by National Services Scotland (NSS) who purchase the concentrates on behalf of all of the Scottish Health boards. NSS ask Scottish Haemophilia Directors for clinical input when determining which products they will purchase and during such a process each Clinician is appropriately required to submit any Declaration of Interests. In the vast majority of cases the primary reason for the choice of products purchased is price as there have rarely been significant clinical differences between available products for specific clinical indications.

20. **Have you ever received any funding to prescribe, supply, administer, recommend, buy or sell any blood product from a pharmaceutical company? If so, please provide details.**

    No.

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

    As a Consultant I have always made a Declaration of Interests annually to UKHCDO and also to my employer NHS Tayside through annual appraisal. This is an addition to a declaration of interests that is always made when involved in discussions regarding adding any medicine to the hospital formulary (or NSS formulary as described above).

22. **Have you ever undertaken medical research for or on behalf of a pharmaceutical company involved in the manufacture or sale of blood products? If so, please provide details.**

    No.

23. **Have you ever provided a pharmaceutical company with results from medical research studies that you have undertaken? If so, please provide details.**

    Only for the pharmaceutical company sponsored study (Bayer Liplong study) described above in section 3, question 10 (study (xiv)) which was obviously a prerequisite for participating in the study and involved fully informed patient consent.

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

    I have not received such funding.

Section 5: vCJD

Knowledge & Actions Taken re: Risk of vCJD

Most of the questions in this section relate to events that occurred around 20 years ago. It appears that it is desired that I provide answers from how I remember events rather than I review literature to provide a specific documented timeline and I will do so but must qualify by stating that my memory of events and particularly timelines may well not be completely accurate given the amount of time that has elapsed. I have also added additional information at the end of question 32 that I have recalled after reading the further information (mostly minutes of Scottish Haemophilia Directors meetings) that was provided to me by the Inquiry in relation to this statement.

25. When and in what circumstances did you become aware of the risks of transmission of vCJD associated with the use of blood and blood products? How did this knowledge develop over time?

I have never encountered a case of vCJD at any point during my career and I do not consider myself a particular expert in this area. I recall becoming aware of vCJD as a potential disease during my General Medical postgraduate training (around 1997-1998) and a confused patient being considered to potentially have this by a Consultant I worked for at that time. The patient did not have vCJD and in fact had a haematological malignancy (myeloma) causing their confusion. I was subsequently involved in their care as a Haematology Registrar which is why I remember this case and subsequent approximate time point. During my early Haematology Specialist Registrar Training (1998 to 2000) I recall the introduction of universal leucocyte depletion of red cells for transfusion with a primary driver for this change being precautionary in case of the risk of transmission of vCJD by blood transfusion. I recall that I answered an essay question regarding this (or prepared an answer in case it was a question – I cannot recall which it was) for the part 1 written examination for membership of the Haematology Royal College of Pathologists in 2000. I recall that a major precipitant for the introduction of universal leucocyte depletion was the reporting of a case of vCJD in a patient who had received a red cell transfusion from a blood donor who was well at the time of donation but subsequently developed vCJD. I think that there were eventually 4 such cases. In all cases the transfused blood was prior to the introduction of universal leucocyte depletion. I can no longer recall the specific timelines for these events.

26. Please outline your knowledge of the events that led to vCJD being recognised as a risk to the UK blood supply, in chronological order.

By the time that I was working as a Consultant Haematologist (initially as a locum/acting Consultant from December 2003) and this became a focus for me it was fairly well established that vCJD was recognised as a potential risk to the UK blood supply. Prior to that point it was not a significant focus for me and I can really just recall that a perceived risk was there from the time I was in my early training as a Specialist Registrar from 1998 to 2000 and that as stated above this was the reason for the introduction of universal leucocyte depletion of red cells which was thought to reduce the risk as lymphocytes were felt to be the likely source of transmission of vCJD if it occurred due to a predilection of the prion protein for lymphoid tissue.

27. **Please outline any steps which were taken in response to the developing knowledge of risk. Do you think adequate action was taken to safeguard the risk of potential transmission through blood and blood products in line with what was known at the time? Please give your reasons.**

As stated above I recall the introduction of universal leucocyte depletion of red cells at the time of my early Specialist Registrar training. At the time it was felt that the risk of transmission of vCJD by blood was mainly focussed on cellular blood products rather than plasma due to the available information suggesting that if there was transmission it would be by lymphocytes. At that time it was felt that the introduction of this step alone was a major undertaking and expense for a perceived low risk of transmission of vCJD. However, there were not significant clinical disadvantages to this process that I can recall and there were additional potential clinical advantages including a reduction in febrile non haemolyitic transfusion reactions and alloimmunisation (which can cause future transfusion reactions and reduced effectiveness of future transfusions) both of which have been demonstrated to be the case. It was therefore felt appropriate to proceed with this and I thought that was appropriate. My recollections on subsequent steps taken for plasma products will be answered in the following questions.

28. **What was your understanding of the relative risks of vCJD infection from:**

    a. **The use of commercial or foreign produced blood and blood products; and**

    b. **The use of domestically produced blood and blood products?**

It was recognised that the prion protein that caused vCJD was predominantly found in the UK food chain (and I recall Northern France) and therefore it was logically assumed that the UK donor population that consumed UK meat was at higher potential risk of acquiring and subsequently transmitting vCJD than the donor population for foreign blood.

29. **What steps, if any, did you take to ensure that patients were informed about the risk of vCJD transmission via blood and blood products?**

During my entire career as a doctor it has always been my practice to have a discussion with every patient regarding the potential risks of transmission of transfusion transmitted infection (and other side effects of transfusion) prior to a transfusion of blood or blood products. The only exception to this is the urgent life saving transfusion of an extremely unwell/unconscious patient with severe acute blood loss. There remains a risk, albeit small, of HIV and Hepatitis with any transfusion of cellular products and there is a risk of transmission of currently unknown pathogens with any blood or blood products. When vCJD emerged as a potential risk this was added to the discussion. The discussion has centred around such risk being small but life threatening and in view of this alternatives to transfusion are always sought with transfusion being the last resort. Transfusion proceeds if and when the patient consents on the basis that they agree that the benefit of transfusion outweighs this risk.

30. **Did you have any involvement in decisions as to what information to provide to patients about vCJD in a general sense? If so, what steps were taken, and continue to be taken, to provide information to patients about the risk of vCJD?**

My involvement in providing information to patients regarding vCJD risk has mostly centred around the risk notification exercises as discussed in the following questions. Other than that my only involvement is to for me to inform any patient under my care that is receiving a blood product of the potential risk as outline in Question 30 above.

31. **Please describe what, if any, impact a patient's vCJD "at risk" status had on their clinical care and whether there is any ongoing impact.**

I have always been a very strong advocate that the 'at risk' status of a patient should not have an impact on their clinical care. This was clear from the outset of defining patients as being 'at risk'. Any patients with bleeding disorders having procedures have a plan letter to those clinicians involved from myself and I have always made it very clear for any classed as 'at risk' the precautions required and emphasised strongly that there should not be any delay or modification from standard treatment on account of the 'at risk' classification of the patient. I emphasised that it had been made clear that any additional cost of quarantining or disposing of equipment had been approved from the outset. The most frequent procedure involving lymphoid tissue where this was relevant was gastroscopy and my colleague, Professor Dillon, who worked in the endoscopy suite was always also very supportive of this. The process also had support of my colleagues in Infection Control. I do not recall any specific resistance from any colleagues to this approach or any significant alterations or delays to patient treatment.

Notification between 2003 and 2009

32. **The Inquiry is aware of patient notification exercises between 2003 and 2009, in particular the large-scale notification exercises commencing 2004, notifying patients they were 'at risk' of vCJD. Please explain your involvement, if any, in those notification exercises between 2003 and 2009, giving as much detail as possible and focusing on:**

I will first outline my personal recollection of events and at the end of this section have also added additional recollections from having read documents (minutes of meetings, most of which I attended and others which I would have received if I did not attend) that were sent to me by the Inquiry in relation to this written statement.

a. **Details of the circumstances in which you were advised to notify patients of their at risk status, if at all;**

I recall that this was an exercise that I had to undertake very shortly after taking over from Dr Cachia as Haemophilia Director in September 2004. I have subsequently checked my records of when these letters were sent and confirmed that it was later that same month. It was a clear national policy that I was informed of through the Haemophilia Directors Group and also formal correspondence from the Department of Health and UKHCDO.

b. **What guidance and/or toolkit/s and/or pack/s were given to clinicians in relation to notifying patients, if any;**

There were standard 'at risk' and 'not at risk' letters and accompanying information.

c. **What steps were taken at the Dundee Haemophilia Centre for informing patients about their vCJD at risk status?;**

We put together a list of all of our known bleeding disorders patients. We then assessed from the UKHCDO database, patient notes and our local Blood Transfusion Service which patients had received UK sourced plasma products in the relevant period of 1980 to 2001. We then had 2 lists of patients those had received such products and were deemed 'at risk' and those who had not and were not deemed 'at risk'. The relevant letters and information packs were then sent out to each of these groups. This was a major undertaking and I was very grateful to our Specialist Haemophilia nurse (June Ward) and Data Manager (Jane Prior) who worked extremely hard and many extra hours to achieve this as quickly as possible. I recall some resistance from the printing and postal departments but an explanation to those staff as to the urgency (and some boxes of chocolates) overcame that fairly promptly. We did not receive any additional funding for this exercise.

d. **What mode of notification was chosen to notify patients and why? Namely whether patients were told in person, by letter or by telephone, and whether patients were seen individually or in groups;**

Patients received letters as outlined above with an invitation to make an appointment to discuss this further at the Haemophilia Centre. If they did not make a specific appointment this would be discussed at the next routine appointment. We are in close regular contact with those that have received plasma derived products and deemed 'at risk' and they were seen fairly quickly. The other patients with bleeding disorders that had received a letter reassuring them that they were not 'at risk' would phone if they had any queries (a number weren't sure if they had perhaps had plasma derived products in the past and we would see them and investigate further – there were a few patients who had mistakenly thought that DDAVP was 'clotting factors' (not too unsurprisingly as they would have likely recalled discussions about it raising their clotting factors)).

e. **What specific information was provided to at risk patients and/or partners/family members about vCJD, its significance, prognosis, treatment options and management?;**

I delivered the majority of this information personally but it was also reinforced by my Specialist Haemophilia nurse so I will refer to 'we' rather than 'I' throughout. As outlined above patients were sent a letter explaining the situation and whether or not they had received UK sourced plasma derived coagulation factor concentrates in the defined period of 1980 to 2001.

They were informed that if they had not then they did not require to take any other action other than to let us know at the Haemophilia Centre if they thought that this information (ie that they had not received UK sourced plasma derived coagulation factor concentrates in that period) was incorrect and also to contact us if they had any concerns at all.

If the patient had received UK sourced plasma derived coagulation factor concentrates in the defined period of 1980 to 2001 then these patients were informed that they were classified as 'at risk' of vCJD in both the written information and subsequent clinical consultation and the implications of this were discussed. The Inquiry has a copy of the written information that was sent to all patients from evidence that I provided as part of a Rule 9 request in July 2018. At consultation we explained that the implications were 2 fold – risk to themselves and risk of onward transmission to others.

For personal risk we explained that there had been a very small number of cases where there had been transmission of vCJD to a patient who had received a red cell transfusion from a blood donor who was well at the time of donation but subsequently developed vCJD as a result of ingestion of infected meat prior to the blood donation. We explained that we thought that this was due to the blood cells in the transfusion rather than the plasma and that there were no cases of known transmission of vCJD from plasma derived coagulation concentrates. We explained that there may be 'implicated batches' of factor concentrate where one of the many donors to the batch of factor concentrate was subsequently discovered to have developed vCJD from the food chain and we asked our patients if such information came to light and they had received such an 'implicated batch' would they wish to be informed. As part of this discussion we explained that there was no test (blood test or otherwise) to tell who might have been infected and no current treatment available. There was a variable response from patients as to whether they would wish to know this. I recall that the majority expressed that they would wish to know. None of our patients have received any implicated batches that were identified and I was able to tell them all at the initial consultation that that was the case at that point.

We also discussed the public health implications. We discussed that although the perceived risk of them being infected with vCJD was low it was not zero and that as they had received a lot of blood products they were identified as a group where it would be appropriate to take certain precautions to prevent onward possible infection. I emphasised to patients that this would not affect their care in anyway. I explained that they should always let us know if they were having any invasive procedures. This was already standard as we arranged haemostatic cover but it was emphasised again. I informed them that I would liaise with whoever was doing the procedure (as usual) but that they should also inform them of their 'at risk' status and that this was a specific question in some departments' consent procedures eg neurology or Ear, Nose and Throat (ENT) surgery. I explained that if the procedure involved lymphoid tissue that the instruments used would be disposed of or quarantined, again emphasising that this would not prevent any

treatment or investigations that they would usually have as any additional costs involved would be covered. They were also informed that they could not be blood or organ donors but it would have already been likely that they had been excluded from this for other clinical reasons.

f. What follow-up and/or ongoing monitoring and/or psychological counselling and/or financial support was arranged in respect of patients who were told they were at risk of vCJD?;

All follow up was provided by the Haemophilia staff – myself and the specialist Haemophilia nurse – there was no specific psychological support or funding. We could have accessed psychological report through psychology services if any patients did not appear to be coping with the information but this did not appear to be the case. It has become apparent to me over time that many patients could benefit from psychological support even if they do not overtly express or show symptoms of anxiety and I have a much lower threshold for referral to psychology services now that I did at that time.

g. What funding was provided by the Department of Health and Social Security or any other source to help with the counselling of at risk patients?

I am not aware of any funding that was provided by the Department of Health for counselling of 'at risk' patients.

Additional comments following having read the related documents that were sent to me by the Inquiry –
I note that I attended a Scotland & Northern Ireland Haemophilia Directors Group meeting on 13th December 2002 [Document - GRAM0000102]. I was a Specialist Registrar at this time and deputising for Dr Cachia. In item 3 of the minutes I note that 'letters regarding the vCJD donor incident were finally dispatched on 26th November. Glasgow Royal Infirmary, Royal Infirmary of Edinburgh and Ninewells Hospital all reported similar responses.' I presumably reported on behalf of Dr Cachia for Ninewells. I am sorry that I do not recall this at all and the first notification letter that I recall was the letters sent in September 2004.

I note that I attended a Scotland & Northern Ireland Haemophilia Directors Group meeting on 12th January 2004 [Document – LOTH0000082_013] again deputising for Dr Cachia. I note that Professor Ludlam reported on an incident that had been reported in December (presumably 2003) where there had been a case of transmission of vCJD by red cell transfusion and the vCJD Incidents panel had begun looking at how patients should be notified at that point. I note that Professor Ludlam had drafted an initial letter for patients at this point which was reviewed and I now have some recollection of this.

I note that I attended a Scotland & Northern Ireland Haemophilia Directors Group meeting on 18th February 2004 [Document – GGCL0000202]. At this point I was working as a Locum/Acting Consultant to cover whilst Dr Cachia was Acting Post Graduate Dean. It was unusual to meet as often as monthly and the frequency of

meetings reflected the vCJD situation and planning the notification exercise. I recall following reading these minutes that the group decided to hold off sending out the letter drafted by Professor Ludlam as an update on vCJD for Scottish patients as it was now known that there was going to be guidance on the matter from the UKHCDO Advisory Committee.

I subsequently attended a Scotland & Northern Ireland Haemophilia Directors Group meeting on 10th June 2004 [Document – GGCL0000204], received minutes of a Scotland & Northern Ireland Haemophilia Directors Group meeting on 26th August 2004 that I did not attend [Document – LOTH0000082_006], and attended a Scotland & Northern Ireland Haemophilia Directors Group meeting on 6th September 2004 [Document – GGCL0000206]. In these meetings (particularly 6th September) the formal plan as sent by the UKHCDO Advisory Committee with direction from the Health Protection Agency (HPA) is set out in some detail. I recall that I closely followed the detailed instructions as set out in these minutes regarding which documents were to be sent including the precise timing of sending out the documents (9am on Tuesday 21st September 2004) so that all patients in Scotland received these at the same time.

I could not recall immediately from memory the specific details of the 2009 notification exercise. Following reading the minutes of the Scotland & Northern Ireland Haemophilia Directors Group, Directors of Regional Planning, National Services Division and National Procurement meeting which I attended on 30th October 2009 [Document – GGCL0000179] I now recall that this notification exercise was to share further information with our patients regarding the finding of prion protein in the spleen of a haemophiliac patient that had died of other causes. I recall that this reflected a promise in the 2004 notification exercise to update patients if any further significant information regarding vCJD came to light. This was further information but it did not change the management of patients. The notification process followed that of 2004 with letters sent to patients and appointments to discuss the information offered. I recall that this was less well received than the 2004 notification exercise. Patients understood the need for information in 2004 as there were actions to be taken by both them and us for public health purposes and they were also given the option as to whether they wished to be informed of 'implicated batches'. I recall the feedback from patients during consultations in 2009 was generally that they would prefer only to be informed if there was information such as a reliable screening test or treatment for vCJD available or a change that required a change in our practice or their behaviour. In relation to this I recall that there was a subsequent proposed notification exercise regarding a possible (but not confirmed and validated) blood test for vCJD in development. On reflection from the 2009 notification exercise feedback we decided not to proceed with a further notification letter until there was an actual confirmed and validated blood test to detect vCJD (which as yet still does not exist). Information sharing with a wide and diverse patient group can be a difficult balance. Whilst we would always inform patients about any specific information about their illness and investigations and answer any questions openly and honestly, notification exercises can impose general information on patients which causes them anxiety and as above some have expressed that they would

prefer not to know. There has been a significant change in how information is shared over the last 50 years. It may be easiest for the clinical staff to simply give as much information as possible to patients so that they are not retrospectively accused of 'hiding' information but the anxiety that can be caused is significant, especially so with 'unknown' factors. The context is also important. We commonly explain that a patient is at risk of life threatening complications prior to operations or prior to chemotherapy for cancer treatment but these are well defined risk with a specific period that the patient gets past and can then put this behind them. Explaining a risk of vCJD with no test, treatment or defined end point when the risk may be past is much more difficult for a patient to cope with. Clearly past circumstances where many patients were reassured of 'small' risks of HCV and HIV will also have a significant bearing as to their interpretation of such risk and subsequent anxiety caused. Unfortunately I do not think there is a simple answer as to the best approach to this problem. I believe that we would tend to err on the side of proceeding with sharing information where there is any doubt as to what the majority of patients would wish but do need to be cognisant of the harm that can occur from notification exercises.

33. **Please explain whether you are aware of any circumstances when individuals were not informed of their risk status or with considerable delay and if so, why they were not informed, or were informed after considerable delay.**

I do not recall any significant delays in advising individuals of their 'at risk' status.

34. **Please explain whether you conveyed any view on patient notification to any relevant entity, and if so, explain what these views were, when they were conveyed and what response you received, if any.**

I do not recall conveying views on patient notification out with discussing the feedback received from patients at Haemophilia Directors meetings to inform the decisions regarding future notification exercises as just outlined above in question 32.

Notification - 2009

35. **The Inquiry is aware that during a meeting of the Scotland and Northern Ireland Haemophilia Directors Group on 24 March 2009, which you were present at, concerns were raised that haemophilia centre directors were 'not informed earlier' by the UKHCDO with regard to this notification exercise in 2009 [GGCL0000222_001]. Please explain, giving as much detail as possible, your knowledge of the concerns raised and the outcome of those discussions.**

I do not recall any further information in addition to that given in the minutes and do not recall the concern even after reading the minutes. I cannot recall if it was confirmed that Professor Ludlam raised this at the UKHCDO meeting as proposed in the minutes or any subsequent response.

CJD Incidents Panel

36. **The Inquiry is aware of the CJD Incident Panel, which was set up in 1990 to assess the level of risk of exposure of vCJD to recipients through blood products. Please explain, giving as much detail as possible:**

    a. **Whether, and if so to what extent, you had any involvement in reporting any incidents to the CJD Incidents Panel;**

    b. **Whether, and if so to what extent, you requested advice from the CJD Incidents Panel in relation to any matter concerning vCJD;**

    c. **The nature of any advice sought and any response which you received.**

    I do not recall ever having any involvement in reporting any incidents to the CJD Incidents Panel or requesting advice from the CJD Incidents Panel.

Questionnaires in 2007

37. **The Inquiry is aware that in 2007 the Edinburgh Haemophilia Centre developed a questionnaire, including questions for patients, with respect to vCJD. This was mentioned at a meeting of the Scotland and Northern Ireland Haemophilia Directors Group Meeting on 16 February 2007, which you were present during [GGCL0000216]. In your capacity as a director at the Dundee Haemophilia Centre, please explain, giving as much detail as possible:**

    a. **What the purpose and objective of this exercise was;**

    b. **The nature and content of these questionnaires;**

    c. **How many patients received these questionnaires and how many completed responses were received;**

    d. **Information about the process for returning the questionnaires and whether you/the Dundee Haemophilia Centre received any information with respect to the outcome of the questionnaires;**

    e. **At point 4 of these minutes, reference is made to 'situations of near miss being reported'. Please explain the background to this discussion and the nature of the concern.**

    I do not recall these questionnaires. It appears from the minutes that this was a proposal but was not taken forward. I do not recall this being progressed and I do not recall sending out such questionnaires to patients.

    The 'situations of near miss' is a separate bullet point under the heading of vCJD and does not relate to the questionnaires mentioned above. I do not recall the specifics of the cases of near miss above but do recall a general concern that despite all of the processes which we had put in place to notify patients and any clinicians carrying out procedures that required precautions for those 'at risk' that

there could be occasions where the 'at risk' status was not picked up at every stage (hence 'near miss') but one of the steps had led to notification and appropriate precautions instituted prior to the procedure being performed (hence avoiding an actual adverse event). We use such 'near miss' incidents as a flag to tighten procedures and avoid an actual adverse event but as stated I cannot recall the specifics that were discussed at a meeting 13 years ago.

Testing

38. The Inquiry is aware that during the meeting of Scottish Haemophilia Centre Directors on 25 November 2011 [GGCL0000188], which you were not present during, reference was made to the 'Coleridge diagnostic test' and the recruitment of haemophilia patients to evaluate its use. Please explain your knowledge, if any, with respect to the nature and development of this test and any conclusions which were reached as to its viability and effectiveness.

I do not recall this test. The referenced meeting (GGCL0000188), at which I was not present, was the annual meeting of Haemophilia Directors and nurses with patients and the minuted statement was made by a patient rather than a Clinician and I suspect (but cannot be certain) that the patient may have been referring to research work taking place elsewhere in the UK reported through the UK Haemophilia Society. Neither myself or anyone at our centre were ever involved with the evaluation of this proposed diagnostic test and it did not become a routine test. I therefore do not have any further information regarding this.

Denotification – 2013 onwards

39. The Inquiry is aware of a de-notification process which occurred in 2013 following a change in the defined at-risk period, discussed during a Scottish Haemophilia Directors Group meeting on 4 June 2013, which you were present at [GRAM0000074]. Please explain, giving as much detail as possible:

a. The circumstances in which you became aware of the change in the defined at-risk period, the reasons for the change and what those changes were;

b. What steps were taken/put in place at the Dundee Haemophilia Centre for informing patients that they were no longer deemed at risk of contracting vCJD;

c. Further details with respect to the notification of two patients identified by the Dundee Haemophilia Centre, referred to during the meeting [GRAM0000074];

d. Whether you are aware of any further patients having been notified of no longer being at risk of vCJD by the Dundee Haemophilia Centre and if so, an estimate of how many patients have been de-notified to date;

e. Any details with respect to whether any patients have provided any feedback about this de-notification, or any further details about how de-notification was received by patients;

Answers a to e:
In 2013, there was a re-evaluation of the 'at risk' period by the Department of Health. I recall that it was indicated to myself and other Directors, I believe through UKHCDO, following a review of the number of cases of vCJD and the likely incubation period, that the period when patients that had received UK sourced plasma derived coagulation factor concentrates that deemed them as 'at risk' of vCJD could be shortened from 1980 to 2001 to 1990 to 2001.

As we already had a list of all patients identified as 'at risk' from our previous notification exercise, we were able to review this list and assess if any patients could be notified that they were no longer 'at risk'. It was obvious to us that the majority of our patients that receive coagulation factor concentrates would not be changed as recombinant factor concentrates were only available from the mid 1990s so any of our patients on regular treatment would still have received UK sourced plasma derived concentrates at the start of the 1990s. However, it was also recognised that those not on regular treatment may have only received UK sourced concentrate between 1980 and not between 1990 and the introduction of recombinant concentrates. We examined the treatment records of all such patients closely and 2 such patients were identified. We have not identified any further patients since that fall into this category.

Once these patients were identified, myself or our Haemophilia nurse telephoned them to let them know and subsequently discussed this further at their next clinic appointment. We were happy to give good news such as this by telephone and the patients understandably appeared pleased that their risk was now assessed as significantly lower due to the emerging data on the incidence of vCJD.

f. Any further details, if any, with respect to the concerns raised during the meeting [point 4.1 GRAM0000074] about the inaccuracy of the UKHCDO 'lists' and reference to 'confusion in relation to a possible change in the need to quarantine endoscopes due to a reassessment of risk.'

With regard to concern regarding inaccuracy of UKHCDO lists, these centrally held lists do not always contain the full and up to date information regarding our patients. This is why, as described in Question 32c, we would use the UKHCDO list in conjunction with our patients' medical notes and any transfusion records from our local Blood Transfusion service.

Additionally UKHCDO often sent lists to every centre that a patient may have previously been treated at rather than just their current treatment centre. Our data manager would inform UKHCDO to rectify any incorrect information.

I cannot recall further details regarding discussion regarding the 'confusion in relation to a possible need to quarantine endoscopes due to a reassessment of

risk'. To try and clarify I have checked the minutes of the following Haemophilia Directors meeting of 22nd November 2013 but this was not referred to again at that meeting. However, I am aware that the UKHCDO/HPA guidance did change in 2013 in that quarantining of endoscopes used for patients classified as 'at risk' of vCJD was now no longer deemed necessary unless the patient had received an 'implicated batch' (which as stated earlier none of our patients had). Presumably we were seeking clarification around this point at that time.

Section 6: Current haemophilia care

40. Please describe:

a. how the provision of care and treatment for bleeding disorders is currently organised at the Dundee Centre; and

b. your current roles and responsibilities at the Dundee Centre.

Answer 40 a and b. Describing provision of care and roles and responsibilities.

This has already been outlined in my answers to section 2 so I will not repeat this here.

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

All patients with Haemophilia A that require coagulation factor concentrates have received recombinant factor concentrates in my time as Haemophilia Director. The majority of severe Haemophilia A patients receive this as prophylaxis to prevent bleeds. As is the case at many other centres we have recently began to introduce an alternative to factor concentrates in the form of Emicizumab (HemLibra). This is a biphasic antibody that mimics the function of factor VIII and has advantages which include it being given less frequently (usually once per fortnight rather than on alternate days) and being administered subcutaneously rather than intravenously. Only 2 patients receive this currently. There have been some delays in the planned introduction due to limited attendance of patients at the centre with COVID restrictions.

All patients with Haemophilia B that require coagulation factor concentrates have received recombinant factor concentrates in my time as Haemophilia Director. All patients with severe Haemophilia B receive this as prophylaxis. Since 2016/17 all of these patients are receiving extended half life concentrates which have the advantage of being administered once every one to two weeks rather than around every 3rd day.

Although none of these concentrates are blood products we still use DDAVP and tranexamic acid as alternatives for patients with milder forms of Haemophilia in situations where these agents are clinically effective.

Due to lack of availability of recombinant products for other bleeding disorders, plasma derived concentrates (all of which are virally inactivated) are used for a small number of patients with von Willebrand's disease (and very occasionally those with rare bleeding

disorders (dysfibrinogenaemia, prothrombin deficiency and factor XI deficiency)) where alternative treatments such as DDAVP or tranexamic acid are ineffective, contra-indicated or would provide inadequate cover for eg surgery. No patients have acquired transfusion transmitted infection from these products during my time caring for them. It remains our objective to use recombinant products whenever these are available (as is set out in UKHCDO guidelines) and at the time of writing this is likely to be very soon in the case of recombinant von Willebrand factor concentrates which are undergoing the required approval process.

42. Please describe how you typically obtain your patients' consent to treatment. In particular:

a. What information do you give patients about the risks of the treatment?

b. What information do you give patients about the side-effects of the treatment?

c. What information do you give patients about the risks of not having the treatment?

d. What information do you give patients about the benefits of having the treatment?

All patients are asked at least verbally to consent prior to treatment. If the treatment involves an invasive procedure then written consent would also be taken, generally by the individual performing the invasive procedure.

When discussing treatment all common side effects are discussed. Less common side effects are discussed if they can potentially lead to serious harm. I also discuss potential 'unknown' side effects particularly in the context of plasma derived concentrates. These conversations usually occur early at the time of diagnosis and often prior to actually requiring the treatment. To be specific in that regard, I would explain that it is always our aim to avoid using blood products wherever we can. As these patients may well require these products in the future I begin with reassurance that the products are treated to prevent viruses such as Hepatitis and HIV and that I have used these products for the last 20 years with none of these infections caused by using these products in that time. I then explain that we (as health professionals) always remained concerned regarding any currently unknown infections that may not be treated by the viral inactivation procedures and for that reason we only use these products when absolutely necessary and in circumstances where the risk of bleeding would appear to outweigh this potential, but likely small, risk of such an adverse event. The final decision regarding the treatment received is always made by the patient or a parent/guardian, or in the case of an adult with incapacity their welfare guardian.

Information given about treatments is given verbally in the clinic and supplemented by information leaflets regarding the treatments which the patients are encouraged to read. If there are not good information leaflets I send a copy of the clinic

consultation letter to the patient so that they have this to refer to as I am very aware that it is difficult to retain all information that is given verbally. Also for this reason the information is not generally only given once but on several occasions at clinic visits and repeated by our Specialist Haemophilia nurse.

The various alternative treatments that can be used in any given situation are discussed with patients so that they can come to a decision. For the vast majority of treatment decisions the risk/benefit balance of having treatment and what type of treatment to use is clear. In some cases additional factors such as religious beliefs need to be considered – for example a Patient who is a Jehovah's witness may prefer to accept risks of using a non blood product alternative that another patient would not. Where there are difficult decisions to be made we are always happy to make additional time to discuss such issues further.

43. Please describe how you typically record your patients' consent to treatment.

I typically record patient's consent to treatment in writing the medical notes including details of discussion of the reasons for treatment and potential side effects of the treatment as described above. This is then also repeated in a type written letter to the GP.

44. Do you routinely take blood samples from patients attending the Dundee Centre? If so, what information do you provide to patients about the purposes for which the samples are being taken? Do you obtain patients' consent to the storage and use of the samples and if so how and is that recorded?

Patients routinely have blood samples taken at clinic. At any time that myself or our Haemophilia nurse take blood samples we explain which blood samples we are taking and the reason for doing so. We always ask if the patient is happy for us to proceed prior to doing so. Apart from being appropriate and polite it is also part of the ongoing process of educating the patient regarding their illness. Routine blood samples are not stored other than for a few weeks in case there is, for example, a laboratory issue with the assay being performed.

45. Please describe how you typically (a) obtain and (b) record your patients' consent to testing (of any kind).

For 'routine' blood tests such as checking the patients' full blood count, renal and liver function tests, coagulation factor and inhibitor assays the procedure is described in Question 44 above. The specific tests performed are recorded in the medical notes. I do not specifically write in the notes that there has been consent from the patient for testing of these samples. This is common accepted practice.

For any virology testing I do specifically document in the notes that the patient has consented to testing. If a sample is being sent to the virology laboratory for 'serum to store' (this is rarely done but is standard practice if the patient is initiated on a plasma derived coagulation factor concentrate or changes to a different plasma derived coagulation factor concentrate) I explain this to the patient and record consent for that in the notes also. It

forms part of the discussion of receiving plasma derived concentrates as outlined in question 42 above.

For any genetic testing (to identify the underlying gene mutation causing a bleeding disorder) there is a specific written consent process with accompanying information booklet and includes consent for sample testing, storage and use of the information gained for subsequent identification of relatives (with options to opt in or out of the separate components).

46. How many current patients at the Dundee Centre (a) were infected with HIV through blood products; (b) were infected with HCV through blood products; (c) were infected with HBV through blood products; (d) were co-infected with HIV and HCV through blood products?

(a) Infected with HIV through blood products – none

(b) Infected with HCV through blood products – 17 (From the 26 patients described earlier (section 10, question 3, paper (v)) at the Dundee Centre who were infected with HCV 16 are still alive and resident in the area and attending the Centre and 1 additional patient has subsequently been identified who had been infected many years previously and lost to follow up. All of our current patients have had successful treatment for HCV and are HCV PCR negative. One was infected elsewhere and prior to transferring to our centre was known to be HCV PCR negative through natural immunity ie without requiring treatment.

(c) Infected with HBV - there are no patients with chronic HBV infection. Some will have been infected and developed natural immunity but I do not have specific figures for this.

(d) Co-infected with HIV and HCV through blood products – none

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

We have never had any patients that have had HIV or chronic HBV requiring treatment.

Patients with HCV have been monitored and treated as a multi-disciplinary team (MDT) approach. The MDT comprises our Haemophilia team and the Hepatology team led by Professor John Dillon. Most of the routine monitoring for liver disease is arranged through the Haemophilia Centre team. We have always closely liaised with Professor Dillon and as soon as any therapies for HCV have become available we have arranged assessment and treatment as soon as possible. Initially this was with Interferon +/- Ribavirin. At that time the usual approach would be that our patients would be seen by Professor Dillon and an appropriate treatment schedule made and initiated. These were very often joined consultations where Professor Dillon and myself (or formerly Dr Cachia) would see the patients together. On going treatment, delivery and monitoring would then be supervised by the Haemophilia team with close consultation with the Hepatology team. The latter,

highly successful Direct Acting Antiviral therapies which are given orally and over a shorter course were entirely delivered by the Hepatology team following referral by myself to them. Any complications of liver disease detected such as portal hypertension leading to varices, decompensated cirrhosis or hepatoma are immediately discussed with the Hepatology team and Professor Dillon has led decisions regarding when liver transplant was appropriate. I believe that the multi-disciplinary approach described is very beneficial for patient care.

48. What if any psychological services are available at the Dundee Centre? Do you have a psychologist as part of the staff team? Is there psychological support specifically for those infected with HIV and/or hepatitis in consequence of infected blood products?

There is a national Scottish Psychology service comprising a Psychologist (Grainne O'Brien) and Psychiatrist (Sarah Kennedy (part time) (previously Nadine Cossett until January 2019)). These staff will see any patient (or relative) that we refer with a bleeding disorder. They offer local clinic appointments within our centre and also a telephone consultation service. The service is not only for those infected by blood products - other roles include, for example, the management of needle phobia in young children. This is a relatively recent service in the last few years and I feel that it has been very beneficial for our patients.

49. What if any other support services are available at the Guy's Centre?

This appears to be a typographical error and I assume it is meant to be the Dundee centre that is referred to. I have never worked at the Guy's centre.

The Dundee Haemophilia Centre is part of the Department of Haematology for which I am Clinical Lead and we have access to the established services that are provided for our patients with Haematological malignancies which is beneficial, as well as any services expected in a University teaching Hospital. There are great benefits for Haemophilia care from our situation that all services in Ninewells Hospital are on one site so that we are closely available for any patients having surgery, during childbirth etc.

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

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

None of our patients were infected with HIV or chronic HBV.

The effect of HCV has been devastating and is difficult to express in words. The clinical course has been well described in the paper referred to in section 10, question 3, paper (v) [Document - GRAM 0000025] which refers to the Scottish Haemophilia population. This retrospective overview of the Scottish population reflects an overview of the clinical course in our patients in Dundee. Of course, the clinical course has been highly variable in different patients and an overview cannot express just how difficult it has been for individual patients. The individual patient witness statements can express this

far more eloquently than I ever could. The report of the clinical course that I refer to also does not reflect the incredible psychological impact from having an infection with initially unknown and subsequently known life threatening complications throughout the course of a patient's life. This has affected every patient that I have cared for with Hepatitis C. The effect can be variable and is often very severe. Many of these effects have taken many years to become known to me and many will still be unknown to me. The psychological support referred to in section 48 is vital in this regard. The clinical and psychological effects for individual patients and their families has been absolutely heart breaking. I am sorry that I am unable to put anything further in words and really feel that this is best expressed by the patients and families that have been affected.

b. the ways in which decisions about treatment and care are taken, and treatment and care are provided, at the Dundee Centre?

The clinical impact of infected blood products has been clearly known for the entire time that I have been working at Dundee Haemophilia Centre. Practices have therefore not changed considerably over that period but the knowledge of the impact of previous infection has clearly informed many of the established practices that have been described by me earlier. The main evolving change over my time working has been the increased realisation of the extent of the psychological effects of coping with HCV infection and the potential benefit to improving psychological services to help with this. I feel that there has already been a direct benefit on my own clinical practice from this Inquiry in hearing patients' stories. In some cases I have historically felt that HCV was 'dealt with' in a patient who is HCV PCR negative after treatment, has no significant long term liver damage and the patient appears happy and healthy at clinic review. This overlooks the long term psychological effects of having carried worries of HCV infection and its subsequent outcome for many years which could have had long lasting effects on their behaviour, relationships and life opportunities and I have a heightened awareness to explore this with more patients and refer to psychology services as appropriate.

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

a. changed or influenced your professional practice and approach and if so how?

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

c. changed or influenced the way in which haemophilia care is now provided and if so how?

I do not have anything additional to add to the answer given above in question 50.

Section 7: The financial support schemes

52. **What if any involvement have you had with the different trusts or funds (the Macfarlane Trust, the Eileen Trust, the Macfarlane and Eileen Trust, the Caxton Foundation, the Skipton Fund, EIBSS) which were set up to provide financial support to people who had been infected?**

My involvement has been to provide reports to the Skipton Fund for our patients that have been infected by HCV.

53. **To what extent, during your time at Dundee Haemophilia Centre, have staff (including you) informed patients about the different trusts or funds?**

Our Haemophilia Centre staff, including myself, have always pro-actively informed any of our patients regarding any trusts or funds that they are eligible for. This has predominantly been the Skipton Fund for HCV but also includes supporting patients applying for other benefits such as Disability Living Allowance.

54. **Does the Centre have any policy or any guidance for staff members in relation to referring patients to the trusts and funds for support?**

Our policy is as above in question 53. We have a written policy which I produced for the monitoring of complications of HCV and I included within that policy assessments that were both clinically valuable for assessment of liver disease and also directly related to assessment for the Skipton Fund (such as the AST/ALT (different liver enzymes) ratio and APRI (Aspartate aminotransferase to Platelet Ratio Index)).

55. **What kind of information has the Centre provided to the trusts and funds about, or on behalf of, patients who were seeking assistance from the trusts and funds?**

I have completed the Medical assessment part of the Skipton fund applications for any patients (or relatives in the case of deceased patients) that have requested that I do so. This has mostly followed proactive discussion as described in Question 53 above.

56. **Has the Centre, or any of their staff, acted as a gateway for determining whether a particular patient met the eligibility criteria for the receipt of assistance from any of the trusts and funds? If so, please explain who set the criteria, what they were and how they were applied.**

I am not clear as to what is meant by 'acting as a Gateway'. I have completed the medical section of Skipton form applications with truthful and accurate clinical information and the fund makes a decision as to the appropriate level of payment.

57. **Has the Centre or any of its staff been involved in determining applications made by patients for assistance from the trusts or funds? If so, please describe that involvement.**

As stated in Question 56 my involvement has been to complete the medical section of Skipton form applications with truthful and accurate clinical information and the fund makes a decision as to the appropriate level of payment. I am not aware of any other

members of staff from the Haemophilia Centre having any involvement other than that Dr Cachia would have completed forms in the same way prior to me taking over from him.

58. **Based on your own dealings with any of the trusts or funds and/or based on your knowledge of the experiences of your patients in relation to the trusts or funds, do you consider that the trusts and funds have been well run? Do you consider that they have achieved their purposes? Were there difficulties or shortcomings in the way in which they have operated or in their dealings with beneficiaries and applicants for assistance?**

My dealings have been with the Skipton fund. I found it relatively straightforward to complete the medical assessment section. My patients did not report significant problems with the process beyond that to me and seemed to receive payment relatively promptly. I did not have personal interaction with the organisers of the fund. The fund has to a degree achieved the purpose of providing financial support to individuals with HCV. In my opinion, the extent of that support has clearly fallen well short of the financial effect that the consequences of HCV infection has had for some patients that have been infected and their families.

Section 8: Other issues

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

I have not received any such complaints.

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

I have nothing further to add.

Statement of Truth

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

GRO-C

Signed _____

Dated 8 March 2021

Table of exhibits:

Date	Notes/ Description	Exhibit number
2020	Sims M, et al., Novel manifestations of immune dysregulation and granule defects in gray platelet syndrome *Blood* **136(17)**: 1956-1967	WITN4749002
2018	Buckley F, Norris A & Kerr R, Management of abdominoperineal excision of the rectum in a patient with Glanzmann thrombasthenia Acta Haematologica 139:243-246	WITN4749003
2017	McLaughlin D & Kerr R, Management of type 2B Von Willebrand Disease during pregnancy *Acta Haematologica* **137**:89-92	WITN4749004
2016	Simeoni I, et al., A comprehensive high-throughput sequencing test for the diagnosis of inherited bleeding, thrombotic and platelet disorders *Blood* **127(23)**:2791-2803	WITN4749005
2013	Khan MM, et al., Hepatitis C infection and outcomes in the Scottish Haemophilia population *Haemophilia* **19(6)**:870-875	WITN4749006
2018	Chalmers, E, et al., Scottish experience introducing extended half-life factor concentrates in Haemophilia A and Haemophilia B patients Haemophilia 24 (5): 27	WITN4749007
2011	McGaffin G, et al., MLPA analysis in routine molecular diagnostics – a cautionary tale. British Journal of Haematology 153 (1): 188	WITN4749008
2010	Ward J, Maddox J, Kerr R, Glanzmann's thrombasthaenia – a single centre experience of different therapeutic approaches to achieve	WITN4749009

	haemostasis in 3 patients. Haemophilia 16 (suppl 4): 123	
2010	Ward J, Craig J, Kerr R, A case presentation of an unusual intramural small bowel bleed in a patient with severe Haemophilia B. *Haemophilia* **16** (suppl 4): 28	WITN4749010
2010	Hay AE, Kerr R, Watson HG, Perinatal management of pregnancies at risk for haemophilia. British Journal of Haematology 149(1): 27	WITN4749011
2009	Khan, MM, et al., Outcomes of hepatitis C infection in a large haemophilia population. British Journal of Haematology 145(1): 5-6.	WITN4749012
2008	Maddox J, Ward J, Kerr R, Application of the UK Haemophilia Centre Doctors Organisation (UKHCDO) diagnostic criteria for type 1 von Willebrand disease to patients seen in a UK Haemophilia Centre. Haemophilia 14 (suppl 2): 116.	WITN4749013
2018	Maddox J, Ward J, Kerr R, Blood group distribution of baseline factor levels in von Willebrand disease. Haemophilia 14 (suppl 2): 116.	WITN4749014