Witness Name: Dr Orla McNulty
Statement No.: WITN0921001
Exhibits: None
Dated: 4 November 2020

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR ORLA MCNULTY

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 30 June 2020

I, Dr Orla McNulty, will say as follows: -

Section 1: Introduction

1.1 My name is Orla Maire Clare McNulty, my current address is GRO-C GRO-C and my date of birth is GRO-C 1962.

1.2 After obtaining my medical degree MB, BCh, BaO from University College Dublin in June 1987 I completed my junior and senior house officer years in Craigavon Area Hospital from August 1987 to July 1989. I was interested in specialising in Paediatrics and was senior house officer in the Waveney Hospital, Ballymena from August 1989 to July 1990 and subsequently in the Royal Belfast Hospital for Sick Children from August 1990 to July 1991. As I was uncertain at that stage as to my best career path, I worked for six months in Obstetrics and Gynaecology in the Mid Ulster Hospital in Magherafelt, August 1991 to January 1992 and then six months as Clinical Medical Officer in Carrickfergus Health Centre up until June 1992. It was then I applied for and was appointed to a two-year post in the Haematology Department in the Royal Victoria Hospital as Research Registrar which was a post of two parts, one based at the Haemophilia Centre which involved coordinating clinical trials of high purity Factor VIII concentrates, and one involved studies and audits at the Blood Transfusion service as well as attending blood donor sessions.

1.3 I believe my growing interest in the sphere of haemophilia care was noted and in 1994 my contract was extended and I became more involved in the clinical aspect of the Haemophilia Centre as well as continuing to coordinate the clinical trials. In 2000 my job title became Staff Grade and in 2008 I became Associate Specialist to the Haemostasis and Thrombosis Unit, now based in Belfast City Hospital.

Throughout my time in the Haemophilia Department I was a member of the UKHCDO and would have attended a number of annual general meetings with other members of the Centre. I also attended a few meetings of the committee as representative of the Belfast Centre whenever the Centre Director was unable to attend.

I have not provided evidence to, or been involved in, any other inquiries, investigations, criminal or civil litigation in relation to HIV, and/or HBV and/or HCV infections and/or CJD in blood and/or blood products.

Section 2: The Northern Ireland Haemophilia Centre ("Centre")

2.1 Over the 26 years I worked at the Northern Ireland Haemophilia Centre there were many changes, some of them major, in location, facilities, staff, and services available.

2.2 When I began work in the Centre in 1992 Dr Elizabeth Mayne was the Director and the Centre was based in the Royal Victoria Hospital in an area which has now been demolished to make way for the new hospital building. There was one large outpatient ward for all haematology patients, but specific days were allocated for haemophilia clinics. The staff was comprised of a nursing sister and two staff nurses who cared for all haematology patients, a registrar and an SHO and then me.

2.3 Dr Mayne and the nurses were very keen to inform and instruct newcomers such as myself and their insight and knowledge of the patients' history and requirements was invaluable. To the best of my memory there are about 200 patients with bleeding disorders registered at the Centre and of these approximately 40 have severe Haemophilia A and I think the number has not varied much over the years. I only worked with adults so cannot comment on the numbers for the children's Centre.

2.4 Obviously, more severely affected patients became better known to the staff but I always felt there was a good relationship between staff and patients and at times some rather robust but affectionate banter!

2.5 During these years I learned a lot from Dr Mayne who was a firm but fair boss. I gained experience in managing bleeding episodes and also became aware of the developing problems due to the infective issues. At this stage the clinical trials had finished, and my main role was in the clinical management of patients with bleeding disorders. I very much enjoyed working with Dr Mayne and was very sad when she retired in 1999.

2.6 There was then a period of about a year before the next Centre Director was appointed and during that time Dr Frank Jones was acting Director although his main role was in the leukaemia and transplant team. Haemophilia clinics continued as before but Dr Jones had daily meetings with me and the nursing staff to discuss any particular issues arising and to draw up management plans for any surgical procedures that were anticipated. During this time, due to the redevelopment of the hospital, the outpatient department was relocated to a portacabin beside a carpark, fondly known as "the shack at the back". Obviously, this caused a lot of upheaval and inconvenience, but we did our utmost to ensure that the welfare of the patients was not compromised.

2.7 In 2001 Dr Julia Anderson was appointed as Centre Director and her arrival coincided with the transfer of the Centre to the Belfast City Hospital, initially to a ward in the tower block and after a couple of years to a dedicated area in the Bridgewater Suite. The team then was made up of Dr Anderson, myself, a senior house officer who was attached to the Centre for a three month stint, and a nursing sister and staff nurse.

2.8 Dr Anderson resigned as Director in 2005 - to the best of my recollection - and again Dr Jones acted in a supervisory capacity until the appointment of Dr Dennis O'Keeffe in 2006. His was a short reign and he left after six months for family reasons and again Dr Jones became acting Director. During these rather

unsettling years I was very grateful for the training and experience I had gained whilst working with Dr Mayne as my role had changed from one of collecting and collating data for clinical trials to one of clinical management of patients and liaison with other specialties involved in their care.

2.9 In 2008 Dr Gary Benson was appointed as Director and with his support I was upgraded to Associate Specialist. My duties changed to include more involvement with thrombotic disorders as with the establishment of prophylactic factor therapy and the appointment of more nursing staff with expertise in haemophilia care there were fewer acute problems and inpatient admissions.

2.10 I am not aware of any viruses or infections being transmitted to patients at the Centre in consequence of the use of blood products during the time I worked there. I cannot speak to anything that may or may not have occurred prior to my taking up post in 1992.

Section 3: knowledge of, and response to, risk; testing; diagnosis; and treatment

GENERAL:

3.1 When I applied for my job at the Centre in 1992 I spent some time preparing for the interview by reading around the subject of haemophilia as general medical training does not provide much experience in the subject and it wasn't high on the syllabus when I was a medical student. I had been aware of the risk of transmission of hepatitis and HIV via blood during my house officer years, but my preparatory reading opened my eyes to the specific problems affecting the haemophiliac population.

3.2 When I began work, I learned more about the situation from discussions with Dr Mayne and nursing staff who had been at the Centre for many years. I was aware that a number of patients had become infected as a result of treatment with blood products in the past and I could understand the distress and hurt suffered by the infected and the affected. It was a situation that everyone was struggling to come to terms with and everybody needed support, patients and

staff.

3.3 Over the years knowledge and understanding of HIV and HCV increased significantly as did the number and effectiveness of treatments available, but in the early 90s we could only deal with what information was available to us. At that time, monitoring was the key and regular blood tests were taken to assess the stability of the patient. If the results began to change an opinion was sought from the hepatology team or the HIV specialist and we worked carefully with them to ensure that the optimal treatment available at that time was provided.

3.4 As the treatments became more sophisticated, treatment regimes were instigated by the relevant specialty, but we endeavoured to provide as much monitoring as possible, in the form of blood testing, at the Centre. We tried to minimise inconvenience and upset to the patients by having to attend clinics in other departments or hospitals and we were very fortunate that the HIV specialists were happy to come to the Centre on a regular basis to assess the patients.

3.5 Throughout this time all the staff at the Centre were very conscious that despite progress in treatment the anxiety and upset felt by the infected and affected was ongoing. When I first started at the Centre, I was very impressed by the empathy and care shown by Dr Mayne and the nursing staff to the patients and their families, some of whom they had known for a long time. The importance of respect for everyone's privacy and dignity was repeatedly emphasised and all staff tried their utmost to counsel and support to the best of their ability.

3.6 There was always a social worker attached to the hematology department who was available when required and a number of patients were referred to the psychology team if they felt that this would be of some help to them.

3.7 I am unaware of any funding issues as the financial aspect of the Centre was not within my remit.

3.8 In my time at the Centre I was not aware of any patient with HBV which I

assume was a reflection of an effective vaccination campaign.

3.9 I cannot comment on care and treatment of infected children as I worked in the adult Centre only.

CONSENT and TESTING:

3.10 Blood sampling has always been an important part of haemophilia care and routine bloods were checked at review appointments - three monthly for those with severe haemophilia and six or twelve monthly for those with moderate or mild haemophilia. The basic tests, which would have been the same as taken by any GP carrying out a routine medical examination were full blood count and liver and kidney function. The particular test for the haemophilia population was a Factor VIII inhibitor test. Patients with infective issues had additional tests to monitor their particular problem and response to treatment. The patients were aware that blood samples were always taken at their review appointment and in many cases, they would contact us the next day to inquire about their results.

3.11 In the case of taking samples for carrier testing, this was only done after full discussion with the people involved and an explanation of a detailed consent form which was then signed by the person being tested and the practitioner doing the sampling. It was witnessed, and filed in the chart.

3.12 My experience of testing for HIV or hepatitis was limited to new patients registering at the Centre or partners of known infected patients as most of the registered patients at the Centre had been tested prior to my arrival. Certainly, this was the case with HIV. I think the HCV testing was being carried out in the early days of my employment when the first effective HCV test was available, around 1991/1992, but I was not involved in that testing. In the case of partners, they were fully aware of the test being carried out and, in many cases, had requested it themselves. New patients were informed of the viral screening that would be carried out and given ample time for discussion and questions.

3.13 To the best of my recollection approximately 60 patients at the Centre were

infected with HCV. In the early 90s knowledge of HCV was basic and nobody was yet fully aware of its natural history, significance or prognosis. As this information and treatment options became known patients were consistently updated, at their clinic appointments and at patient information sessions organised by Dr Mayne. She attended UK and European meetings to keep abreast of latest developments and passed on this information to staff and patients.

Witness Statements

3.14 Regarding the statement of W3209, (Q23), I am unable to assist the inquiry in clarifying this issue as I was not involved in this situation but can only comment that reliable testing for HCV only became available around 1994.

3.15 Regarding the comment in Question 49 I have no recollection of this consultation and cannot imagine why the statement maker's father's DNA would have been of any relevance.

3.16 Regarding the letters referred to in questions 24 and 25 I have tried to recall this situation but without a great deal of success. It is possible that a number of HCV PCR results which initially showed to be negative were subsequently found to be positive and this appears to have been an issue involving the virology lab in late 1999. As is apparent in Dr Jones' letter, as soon as this was drawn to his attention, he arranged for the patients involved to be retested and invited for discussion. There were many discussions between me and Dr Jones at that time as we were trying to set up a regular joint hepatology/ haemophilia clinic and were in regular contact with the hepatologists to press our case.

PUPS:

3.17 The Centre had a number of previously untreated patients who were younger in age and had mild to moderate haemophilia. I was trained to assess the severity of any bleeding episode they had and to manage the bleed with oral cyclokapron tablets and intravenous desmopressin when possible. If a bleed did not settle or in the case of major trauma or surgery and after full discussion with

the consultant the patient would have been treated with the most appropriate blood product available at that specific time, which in my earlier career was one of the high purity heat treated plasma products. In these cases, the patient was fully informed about the product they were receiving, that it was virally inactivated but that no blood product was completely without potential risk. They fully understood the benefit of controlling the bleed in serious situations outweighed any potential risk.

RESEARCH:

3.18 As I have explained in my introduction, my initial role in the centre was to coordinate clinical trials to assess the clinical efficacy of the high purity factor VIII products manufactured by SNBTS and BPL and subsequently recombinant factor VIII. All of these trials were approved by the hospital Ethics Committee and came with strict guidelines and protocols and each patient was fully consented and a consent form signed and witnessed. My role was to record the number and amount of treatments applicable to each involved patient, monitor the blood results, which were taken at the routine reviews, report any adverse events such as allergic reactions, increased bleeding or inhibitor development and pass on completed documentation to the trial headquarters.

RECORDS:

3.19 When dealing with the issue of death certificates it must be noted that Northern Ireland is a small place and it's difficult to go somewhere without meeting someone you know. This is particularly true in rural areas and the privacy and discretion which was paramount in the Centre did not always filter down to those places. It must also be noted that 25 years ago there was a lot of ignorance and fear associated with HIV and hepatitis and it was felt to be an act of humanity not to use those terms on the death certificate in order to protect the deceased and their relatives. Very often this was at the specific request of the patient or their family and was not done in any underhand way.

3.20 To the best of my knowledge medical records were retained and disposed of in accordance with the relevant Trust policy at the time. Documents and letters

regarding HIV testing and results were kept in a locked drawer in the Director's office as a privacy issue because the medical files were accessible by various members of staff including administrative. I do not know whether this is still the case.

3.21 I have never in the past, and certainly do not now, hold any records or information about any patient in my home.

Section 4: vCJD

4.1 I am uncertain about the exact date of becoming aware of the risks of transmission of vCJD associated with the use of blood and blood products, but I think it was initially in 2000 when the Centre was located in the portacabin in the RVH and Dr Frank Jones was acting Director. He received communication from the Department of Health regarding the risk of transmission of vCJD associated with the use of blood and blood products and we spent a considerable amount of time trawling through records to identify patients possibly at risk.

4.2 In 2004 the UKHCDO sent out a large information pack containing background information, patient and GP information sheets, and a reply form for the patients in which they could indicate whether they wished for an appointment for further discussion. These documents were sent out to all patients who had received blood products and a number of people requested further information and discussion.

4.3 They were given appointments with the consultant and I do not recall being at any of these consultations but was always happy to speak to any patients and pass on whatever information was available to us at the time.

Section 5: UKHCDO

5.1 When I became an established member of the haemophilia team I joined the UKHCDO and remained a member until my retirement. I understood their role to be one of setting guidelines and protocols, coordinating standards of treatment throughout all the Centres by carrying out regular audits, and as a forum for

sharing learning and supporting colleagues. However, I was never in the inner circle and merely attended five meetings as representative of the Belfast Centre at times when the Director was unavailable. I felt very out of my depth in those meetings and maintained as low a profile as possible.

Section 6: Pharmaceutical companies/medical research/clinical trials

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

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

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

6.4 I have never received any financial or non-financial incentives from pharmaceutical companies to use certain blood products. I have never received any funding to prescribe, supply, administer, recommend, buy or sell any blood products from a pharmaceutical company.

6.5 Declaratory procedures for involvement with a pharmaceutical company were not within my remit.

6.6 I have never provided a pharmaceutical company with results from medical r esearch studies.

Section 7: Involvement with the financial support schemes

7.1 Over the years I worked at the Centre I did not have any involvement in relation to the development of any criteria or policy relating to eligibility for financial assistance nor did I provide any advice to any trust or fund but I communicated with the Macfarlane Trust on a number of occasions to request funding for

respite breaks for patients who had been through a prolonged period of illness or inpatient treatment or who had suffered some other traumatic life event such as bereavement or significant family stress. I can remember also requesting financial assistance in a case of extreme need and to the best of my recollection these requests were met promptly and satisfactorily.

7.2 In recent years all members of the haemophilia team at our Centre made a point of ensuring that patients who had been infected with HCV were aware of the Skipton fund and we advised them on how to obtain the application form if they had not already done so. I completed many of these forms for patients and I felt that, when the criteria were met, the response of the fund was prompt.

7.3 If patients had other queries about assistance, benefits or insurance policies, the staff referred them to the Haemophilia Society for further advice.

Section 8: Other issues

8.1 There have been no complaints made about me to my employer, the General Medical Council, the Northern Ireland Public Services Ombudsman or any other body or organisation.

8.2 I would like to take this opportunity to express my sympathy with those infected and affected. I have known them for many years and been privileged to share in some of their good times as well as trying to help them through the bad times. Over the years there were many changes in the Centre but through it all I would like to emphasise that we all tried as best we could to do the best we could with the knowledge that was available to us at the time.

8.3 Looking back from more than a quarter of a century later it is hard to believe how little was understood about the ways the infections would progress and that treatments had not yet been developed or were quite unsophisticated. Perhaps, in thirty years' time when people look back upon this current pandemic, they will be stunned at how little was known in 2020 and unable to understand how the crisis was not prevented or better managed.

8.4 I would also like to put on record my respect and admiration for Dr Elizabeth Mayne with whom I had the privilege of working during some very difficult times. I was in awe of the breadth of her knowledge and her desire to share her experience of working with the haemophilia patients. She was dedicated to the patients and I do not think many people realised the distress she suffered as the infections progressed and caused so much grief and sorrow. She did whatever she could to offer comfort and support and on a couple of occasions when a patient had been transferred to London for assessment for liver transplantation, she dispatched me to London to visit the patient and spend time with the one relative who was allowed to accompany them. I really felt this was a great act of kindness and one which was never really acknowledged. I had hoped she would have a happy and healthy retirement and it saddens me that this is not the case.

Statement of Truth

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

Signed GRO-C

Dated 4th November 2020.