Witness Name: Christine Mary Loran

Statement No.: WITN4043001

**Exhibits: None** 

Dated: 1st May 2020

INFEC'	TED I	BLO	OD I	NOL	JIRY

# FIRST WRITTEN STATEMENT OF CHRISTINE MARY LORAN

# I, Christine Mary Loran, will say as follows: -

- 1. My date of birth is GRO-C 1961. My professional qualifications are Registered Nurse, Adult (1983), Diploma of Nursing 2002, MSc Nursing Studies 2006, B-tech Counselling 1994.
- My employment history is set out below:

July 1983, qualified as registered general nurse, Cardiff (South Glamorgan Area Health Authority)

July 1983 – Jan 1986, staff nurse, Care of the Elderly, Cardiff Royal Infirmary Jan 1986 – Sept 1992, staff nurse, Haematology (Bone Marrow Transplant Unit), University Hospital of Wales Cardiff. (Maternity leave, July 1986 – ? Dec 1986. Unsure of exact date.)

27<sup>th</sup> Sept 1992 – 28<sup>th</sup> May 1995, senior staff nurse (F grade), 32 hours per week, Haemophilia Reference Centre, University Hospital of Wales, Cardiff. (Maternity leave 28<sup>th</sup> May 1995 – Feb 1996.)

Feb 1996 – Feb 10<sup>th</sup> 1997, staff nurse (E grade), Bone Marrow Transplant Unit, University Hospital of Wales, Cardiff, 15 hours per week.

Feb 1997,returned to the Haemophilia Centre, University Hospital of Wales as senior staff nurse F Grade on 24.5 hours per week

Jan 2001, Haemophilia Nurse Manager (as above) G grade 37.5 hours per week

April 2006, Agenda for Change, re-banded as Band 7

May 31st 2019, retired

3. I have never been a member of any committee, group, association, society or working party relevant to the Inquiry's Terms of Reference. I have never provided any evidence or been involved in any other inquiries, investigations, or criminal or civil litigation in relation to HIV, hepatitis B or C virus, or variant CJD in blood and/or blood products.

#### The haemophilia centre at the University Hospital of Wales Cardiff

- 4. I have listed below the staff at haemophilia centre ('the centre') during my 3 periods of employment there, so far as I can remember.
  - A. Employment period 27<sup>th</sup> Sept 1992 to 28<sup>th</sup> May 1995, 32 hours pw, as Senior staff nurse F Grade
- My colleague and senior nurse was Ms Jennifer Jones Clinical Nurse
   Specialist (CNS) Grade I, who had been in post since mid 1980s.
- 6. The consultant in charge when I started was briefly Professor Arthur Bloom until his death on 12 November 1992. At the time of Professor Bloom's death, the senior registrar Dr Simon Davies took over as locum consultant until Dr Eddie Hampton was appointed consultant; this was before I went on maternity leave in 1995—I cannot recall the precise date Dr Hampton started. Dr Has Dasani was the clinical fellow throughout this period and managed the majority of clinical care within the haemophilia centre. A haematology registrar on rotation was also part of the team. Other members of the multi-disciplinary

- team were physiotherapist, Mrs Fiona Hall, and social workers Mr Tim Hunt and Nia (I cannot remember Nia's surname).
- 7. My role and responsibilities, in conjunction with the CNS, were to deliver nursing care primarily to patients who attended the centre as outpatients, although some care was also delivered to individuals with haemophilia during inpatient stays. My responsibilities included administration of clotting factors, blood sampling, general nursing support of patients and families during clinic visits.
  - B. Employment period Feb 1997 to Jan 2001, 24.5 hrs per week, as Senior staff nurse F grade
- 8. During this period, Ms Jennifer Jones remained as CNS in charge of the centre. Consultant haematologist was Professor Peter Collins; Dr Has Dasani remained as Staff Grade specialist in haemophilia. My role and responsibilities were the same as before.
  - C. Employment period Jan 2001 to May 31<sup>st</sup> 2019 37.5 hours per week, Haemophilia Nurse Manager G grade (band 7 after 2006)
- 9. Ms Jennifer Jones remained in post as CNS until 2003 when she retired. Alison Robinson was employed as Paediatric CNS to replace Jennifer Jones's post. Anne Gallacher and Joanna Popham had started the previous year as part-time staff nurses on a job share and Alan Eldridge as staff nurse with clinical trials responsibilities. This increase in nursing establishment staff reflected the increased demands of the haemophilia centre.
- 10. Medical cover continued to be provided by Professor Peter Collins throughout the whole of this period; a further consultant appointment was Dr Rachel Rayment around 2004 (I don't recall the exact year) and later Dr Raza Alikhan. Haematology registrar support on rotation was maintained. Dr Has Dasani left the centre in 2007.

11. As haemophilia nurse manager, I had responsibility for the day to day running of the haemophilia centre, ensuring nurse cover was available at all times covering the clinic open times, in-patient treatments were administered as required and community care delivered.

#### Knowledge of risk

- 12. At the time of the commencement of my employment in the centre in 1992, as I recall, all clotting factors used for the treatment of haemophilia A and B were the Bio Products Laboratory Ltd(BPL) products, 8Y, 9A and 8SM. We obtained these from the Welsh Blood Service. I was informed by the clinical nurse specialist that these were now virally inactivated by heat treatment processing (since 1985) and therefore the risk of any contamination from known viruses of Hepatitis and HIV had almost certainly been eliminated.
- 13. Recombinant factor concentrates were discussed from 1997 and, as soon as available (licensed), were used in Wales for haemophilia A, initially children then adults at a later date. I recall Professor Collins was keen that these products should become available to patients as they were thought to eliminate the risk of any further viral transmissions. Patients who did require a plasma based product (e.g. patients with Von Willebrand disease) were counselled by medical staff prior to first exposure and signed a consent form stating that they were aware of the risks from unknown viruses—this relates to the period of employment from Feb 1997 onwards.
- 14. Decisions about treatment were made primarily by the medical staff, particularly in the early part of my employment. Latter experience has been a more MDT approach to obtaining consensus of opinion on treatments, particularly once Dr Rachel Rayment was in post as consultant.
- 15. When I started work in the centre there was a programme commencing prophylaxis for children; adults were intermittently on prophylaxis but not as routine. To enable prophylaxis, parents regularly attended the centre to learn

- the skills to treat their children. Over time older patients were introduced to prophylaxis, but it always remained a choice for them to make.
- 16. Once recombinant factor concentrates became available, as I recall, children were started on prophylaxis at an earlier age, in accordance with expert opinion at that time, due to the smaller volume of the concentrate.
- 17. We had no specific standard operating procedures (SOPs). United Kingdom Haemophilia Centre Doctors Organisation (UKHCDO) guidelines were followed with regard to the introduction of recombinant factor concentrates.
- 18. When I started at the centre, I was aware of the risk of transmission of HIV, hepatitis B (HBV), and hepatitis C (HCV—then known as 'hepatitis non-A non-B') though plasma concentrates. I believed at the time that the viral inactivation steps carried out eliminated thisrisk of transmission.
- 19. All our factor concentrates were obtained from the Welsh Blood Service. None of them was obtained commercially. I understood that, historically, some concentrates had been obtained from commercial sources. I did not know the details.
- 20. Medical staff informed patients/ families of the potential risk from plasma products. Patients were offered vaccination with hepatitis B vaccine from diagnosis. Hepatitis A vaccine was also offered. The explanation provided for the benefit of vaccination was that, due to the medical diagnosis of a bleeding disorder, the risk of exposure to blood products at any point in their life was probably greater. There was also considered the slight theoretical risk of viral transmission if a problem developed during the manufacturing process.
- 21. I recall from 1997 patients signing a consent form before first dose of a plasma concentrate being given. I cannot recall this in place prior to this date, but it may have been the case.

- 22. The consultant or registrar would advise patients about potential risks of plasma products before they signed the consent form. The consent form included a written summary of the risks. The main risk from plasma derived concentrates was thought to be due to unknown infectious agents which could not be tested for. When administering a first dose of plasma concentrates, I would make sure that patients understood the risks, as set out on the consent form.
- 23. From my first experience in centre in 1992 onwards, it was stressed to me by the CNS how important it was to try to minimise exposure to multiple batches of plasma products. To ensure this, careful records were kept of all batches of factor concentrate in stock and in the patients' records, and every effort was made to maintain the same batch, as much as possible. This practice continued even when recombinant factors became the dominant factors used, and remains good practice.

# Testing, treatment and care of patients

- 24. As stated above, patients were advised about the risks of plasma-based products before signing a consent form. For most of our patients, there was not a realistic alternative, until the recombinant factor concentrates became available. Where an alternative such as desmopressin could be used effectively, patients were informed of this, and this would be the preferred choice—this applies to those patients with mild haemophilia or Von Willebrand disorder.
- 25. This information was given by the consultant, staff grade or registrar. I did not have training in obtaining consent, and never performed this task.
- 26. Home treatment would not normally be started unless the patient had already received treatment at the centre. The patients/carers would have training before this started. When home therapy was provided, that patients/ carers signed a consent form for a 'period of home therapy', and these were filed in

- the patients notes. I cannot remember the contents of this consent form. I think that this may have included an account of the risks of the treatment.
- 27. Patients had blood samples taken for a variety of tests—mainly factor levels around treatment doses to measure response. In clinic appointments patient would receive blood forms from the consultant which they would give to the nurses for sampling. The doctor would inform the patient which tests were to be taken for what purpose. As a nurse, I always confirmed that the patients were aware what they were being tested for and agreed to the testing.
- 28. I recall liver function tests being done routinely, from when I started at the centre, as part of the 6-monthly review of treatment. When the tests came back, they would be reviewed by the medical staff. If there was cause for concern, then the patient would be called back; the doctor would discuss the results with the patient. I recall that there were patients whose liver function was affected by a known hepatitis.
- 29. There were patients at the centre with existing diagnoses of hepatitis B, hepatitis C and HIV. While I was working at the centre, I am not aware of any patients who had a new diagnosis of HIV, HBV or HCV, acquired through treatment at the centre. However, I remember that there were a few patients who moved into the area, and were diagnosed with HIV or HCV when they first attended the centre.
- 30. Patients who were tested for HIV, HBV and HCV would be counselled about the implications of the test by the doctor, before the test was ordered. The discussion would be documented in the medical notes. Before taking the blood, nursing staff would make sure that the patients understood what they were being tested for and the implications of the test.

- 31. The patient would be asked to come back in a few days' time for the results.

  We did not normally like to give out the results on the telephone. The patient would have a private meeting with the doctor to discuss the results.
- 32. I cannot recall ever being told to withhold information from a patient or patients about risks, or treatment, or testing, or diagnosis, or their condition. This was not suggested in any way to my knowledge.
- 33. Patients with HIV, HBV or HCV were given advice about the risks of infecting others. They were advised to use barrier contraception. They were also given advice about how to deal with blood spillages, not to share toothbrushes etc. Patients with HCV were given the same initial advice as patients with HIV, but this may have become more relaxed once the hepatitis specialists were involved in giving the advice.
- 34. During the 1990s and early 2000s, partners of HIV positive pts would often request a HIV test during clinic appointments; it was policy to ask them how they wanted the result relayed. This was generally by telephone call as soon as the results were available. I often personally ensured that these results were given to the relatives as soon as possible. Fortunately, no partners became infected, to my knowledge, during my time in the centre.
- 35. Counselling and psychological support was provided in Cardiff continually by the social workers throughout my employment as a haemophilia nurse. Cardiff and Vale UHB ensured that funding remained in place for a HIV specialist social worker to be employed until the mid 2000s, then a more general role for the haemophilia social workers emerged. Psychologists were available from around 2004, with full-time support from about 2015, with Welsh Assembly funding.
- From 1992, I recall that initially care for patients with HIV, HBV and HCV was delivered through the haemophilia centre, primarily by Dr Dasani. From about

1996 or 97, care was shared with infectious disease specialists as these services became available. Joint clinics were held in the centre for many years with HIV specialist and haemophilia doctors in attendance. In recent years, patients with HIV have attended specialist clinics away from the centre. A joint clinic remains in place for patients to be reviewed in the haemophilia centre every 2 -3 months, or as required.

- 37. The specialist CNS in the infectious diseases multidisciplinary team provided a lot of the support to infected patients, once this service became available around 2000. In addition, the haemophilia nurses have always provided as much support to patients and families as they are able.
- 38. Infected patients were not treated differently by the haemophilia centre staff, but on occasions staff would need to advocate on their behalf to ensure appropriate treatments were not delayed e.g. surgery listing or endoscopies. I recall an incident where HIV patient was placed in isolation following surgery on the orthopaedic ward, and was distressed by this. I attended the ward during the immediate post-operative period and informed the nursing staff straight away that this was inappropriate; the measures were removed. A formal complaint was issued to the ward by the patient's relative. Training was given to the nursing staff concerned.
- 39. Measures to address risk of cross-infection were the use of universal precautions in accordance with hospital policy at any given time. We would use gloves for testing; we would double-bag blood samples. For a time, we would take the samples to the lab ourselves, rather than give them to the porter.
- 40. From 1997, all blood results were filed in the medical notes and included on clinic letters. I cannot recall practice during my previous employment period Oct 1992–May 1995. Clinical staff at the centre would be aware of the diagnosis. Other departments of the hospital were informed if they were

providing treatment to the patient. As far as I am aware, none of our patients ever asked for this information to be withheld. I remember that some patients told me that, in the early days, they were uneasy about their GP being informed of the diagnosis. The doctors discussed their concerns with them. I cannot say whether the GPs actually were informed or not.

- 41. As a haemophilia nurse, for many years I was fully involved in the care of patients and families who were affected with HIV and HCV. Patients experiences varied a lot so it is hard to generalise; some patients became very sick, especially during the 1990s and I recall many who tragically died. This had an effect on the other patients as they were a close-knit group at that time and nurses, staff and patients attended many funerals during these years, which was devastating. In my experience, in the 1990's, as treatments were limited, patients' health could deteriorate very quickly; alternatively, some were sick for several years and gradually lost weight, were unable to fight infections and had increasing hospital admissions.
- 42. Individuals' opinion on whether to inform family members varied greatly, with some happy to share the reasons, others desperate to keep it all quiet. Some were not even happy for GPs to be informed as they lived in small communities where even the GP receptionist would know them personally. This led to a lot of secrecy and fear throughout the patient community. I am aware that, prior to my appointment, a few patients who were HIV negative chose to attend the haemophilia centre as infrequently as possible, preferring to manage joint bleeds themselves at home. This in turn impacted on their health by causing severe joint damage and haemarthropathy.
- 43. HCV treatments once commenced were very harsh and led to a great deal of physical and emotional illness, patients suffering intense flu-like symptoms, weight loss, anaemia and psychological effects such as agitation, depression and even suicidal thoughts. I recall quite a few patients who suffered 12 months of debilitating HCV treatment with interferon, only for it not to work.

- 44. It was hard supporting patients through these experiences and seeing the fear and loss of hope as treatments failed, or friends they had known since childhood were passing away. As a nurse, they were difficult years to work through especially due to the nature of the long-term relationship which is established with patients with chronic medical conditions and their families.
- 45. In later years when cirrhosis and liver cancer (HCC) became more common in HCV patients, it felt like yet another blow to those families who had survived initial diagnosis only to watch the slow impact of these conditions and inevitable outcomes.

#### Research

- 46. Dr Has Dasani carried out the Bayer Kogenate study from 1990 onwards. This was a study of recombinant Factor 8. I cannot recall the details of any other studies he may have been involved in.
- 47. Prof. Peter Collins carried out multiple pharmaceutical clinical trials from 1998 onwards as the Cardiff Haemophilia centre continues to be a centre for haemophilia research, primarily pharmaceutical clinical trials. I did some of the study-nurse work for the Factor 9 benefits study in about 1997. I was also study-nurse for the KG2 recombinant Factor 8 study from around 2000.
- 48. In my experience patients have always been informed fully of the basis of any clinical trials they have participated in, and full consent obtained beforehand. Patients would be given information sheets about the studies they were participating in before they signed a consent form to proceed.
- 49. In my experience 'PUPS' refers to mainly children who commenced clinical trials before they had received any other clotting factors (or minimal dose). I am not aware of it being used in any other context. Full written information was given to the parents of the children involved and parents would sign a consent form if they wished to proceed.

# Variant CJD (vCJD)

- 50. I became aware of the risk of vCJD at the time the Department of Health informed the UKHCDO. A list of affected batches of the BPL concentrates was sent around the centres, either direct or via the Blood Transfusion service. I think this was 2003/04. I was aware of media coverage prior to this, as all members of the public were.
- 51. As I recall, the haemophilia centre was sent a standard letter from the Department of Health, which we were told had to be sent to all affected patients by a certain date. The letter informed them if they were at risk of potential vCJD infection due to their having received pooled plasma products. I think there was also a separate letter for those who were not considered at risk because they had not received the affected plasma batches.
- 52. As a multidisciplinary team in Cardiff, we met to discuss this request from the Department of Health. We were not entirely happy with the way it was written and were concerned that the letter would cause additional stress to patients/families; we would have preferred to inform them personally. We understood the need for information to be given due to the possible risk to other members of the public. Our decision was to compose our own letter to go alongside that from the Department of Health, explaining in more detail that this was a request we could not ignore, but offering all patients opportunity to come and discuss the matter in person at their earliest opportunity.
- 53. Patients were informed that they must inform any medical person who would provide them with care which involved an invasive procedure e.g. dental procedures and endoscopies. They were informed that there was at that time no blood test available which would indicate if they would go on to develop vCJD.

- 54. The social workers who were part of the multidisciplinary team at this time were available to offer additional support to any who requested it, alongside the medical/clinical staff.
- 55. There were no confirmed cases of vCJD at the centre.

#### Effect on clinical staff

- 56. Staff would protect themselves by following hospital guidelines for the prevention of cross-infection. These applied to all patients, not just to those known to have a serious infection. For example, we would normally wear gloves when obtaining blood samples from any patient, not only from those known to have hepatitis or HIV.
- 57. Regarding patient complaints, I am not sure whether or not there was a written complaints policy in 1992, when I first started working at the centre. I believe that patients were always aware of their right to complain.
- 58. As I recall, for about the last 10 years, there has been a formal Health Board written complaints policy. Patients are informed of their right to complain, and how their complaints would be dealt with. There were posters about this in the centre and distributed around the hospital sites.
- 59. Any patient complaints were dealt with by the manager of the centre, and escalated as necessary. Patients knew that they could write to the chief executive of the hospital if they wished.
- 60. Nurses and other staff would sometimes raise concerns. I remember raising concerns about the management of infected patients in other parts of the hospital, and about delays in endoscopies for patients who were at risk of vCJD. I did not have occasion to raise any concerns about the safety of the treatments we were giving at the centre.

61. Fortunately, I never had the experience of treating a haemophilia patient who subsequently became infected from his treatment. I knew staff who had worked at the centre in the 80s, who were devastated when they found out that treatment they had given had resulted in a patient becoming seriously ill.

### Other Issues

- 62. I was aware that patients received payments from the Macfarlane Trust. I was involved with the initial and subsequent Skipton Fund payments, mainly by supporting patients and relatives to submit the completed claim forms.
- 63. Centre social workers dealt primarily with the Macfarlane Trust payments.

  Once the Skipton Fund decided to include widows and relatives of deceased patients, I spent a great deal of time tracing family members to ensure they were aware of their eligibility to claim. I also searched through medical notes to find any relevant entries or blood results which would assist the application. The consultants completed the forms and then copies were kept in the centre for reference.
- 64. As far as we were able, we retrieved all medical notes of (haemophilia) deceased patients from the clinical areas as soon as possible, and stored them in the haemophilia centre archive. This included medical notes from previous decades. We kept these records indefinitely.
- 65. Current patients' notes continue to be kept in the centre for those with inherited bleeding disorders, unless they are required in other clinical areas. This remains current practice to my knowledge.
- 66. A handwritten book containing a record of all HIV testing from 1984/85 was present from the start of my employment in 1992, although it was no longer in use. It was retained in the centre and submitted to the Inquiry via Cardiff and Vale UHB in 2018. Factor concentrate use for each patient is documented on separate 'Treatment sheets'; these are kept indefinitely in the haemophilia

archive. Annual returns/database records of concentrate usage to UKHCDO are ongoing.

67. I retired as haemophilia nurse in May 2019 therefore was aware of the Inquiry during my employment, and would have been party to many discussions. I have not discussed the contents of this statement with any clinicians at the centre. The contents of this statementare my own personal reflections.

The contents of this statement are true to the best of my knowledge and belief.

