Witness Name: Dr Patricia Hewitt
Statement No.: WITN3101001
Exhibits: NIL
Dated: 4 June 2019

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR PATRICIA HEWITT

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 16 May 2019.

I, Patricia Hewitt, will say as follows: -

Section 1: Introduction

1. **Name:** Dr Patricia Hewitt
   Address: NHSBT Colindale Centre, Charcot Road, Colindale, London NW9 5BG
   DOB: GRO-C 1951
   Qualifications: M.B., Ch.B., 1975, Fellow of the Royal College of Physicians (England) and Fellow of the Royal College of Pathologists.

Positions held as a Consultant and Roles and Responsibilities

2. I was appointed to a Consultant Haematologist post at the (then) North London Blood Transfusion Centre (NLBTC) in 1984. NLBTC was one of 14 Regional Blood Transfusion Centres which together made up the National Blood Transfusion Service. I occupied a role in charge of donor health and blood collection. One of my first responsibilities was to implement within NLBTC the Confidential Unit Exclusion (CUE) questionnaire, based on one in operation at the New York Blood Centre, designed to encourage blood donors at risk of HIV infection to confidentially indicate to the blood service that their blood donation should not be used. In 1985, on introduction of HIV screening of blood donations, I managed the HIV lookback

programme for NLBTC, which covered the area of central and north west London and the Home Counties.

3. Subsequently, I was Lead Consultant in Transfusion Microbiology for the London and South East Zone of the National Blood Service (NBS) from 1995 to 2000, and National Lead Consultant in Transfusion Microbiology from 2000 to 2005. In these positions, I managed the HCV lookback programme for NLBTC (1995) and the national HTLV lookback programme (2002). I contributed, with colleagues, to a submission to the Department of Health proposing a cost-effective method for the introduction of screening of blood donations for Human T-cell Lymphotropic Virus 1 (HTLV 1). I also was Principal Investigator, with Professor Robert Will of the National CJD Research and Surveillance Unit, of a research project (the Transfusion Medicine Epidemiology Review [TMER]) which commenced in 1997 and was designed to investigate whether there was any link between blood transfusion and vCJD.

4. After formation of the National Blood Authority (NBA) and then the current organisation NHS Blood and Transplant (NHSBT), I retained the National (clinical) lead role for Transfusion Microbiology until my retirement from full time employment in June 2018. I continued in the work of the TMER, and also contributed to a study (2012/2013) looking at the blood safety implications of hepatitis E virus (HEV). The results of this study led to the introduction of HEV screening of blood donations.

5. The National (clinical) lead role for Transfusion Microbiology involved overall responsibility for the management of blood donors who were found through the routine screening of blood donations to be infected with blood-borne infections, and overall responsibility for managing reported cases of possible transfusion-transmitted infection. In addition, I was required to ensure that clinical matters relating to transfusion microbiology were represented in any relevant NHSBT initiatives and projects.

6. Prior to my employment with NHSBT and its predecessor organisations, I was employed as a Lecturer in Haematology at Middlesex Hospital Medical School, and was involved in treatment of patients with a variety of Haematological disorders, including clotting disorders.

7. I am now retained by NHSBT to provide occasional assistance and advice as and when required.

Membership of past or present Committees/groups relevant to the Inquiry's Terms of Reference.

- JPAC (Joint UK Blood Transfusion and Tissue Transplantation Services) Specialist Advisory Committee on Care and Selection of Donors
- JPAC Specialist Advisory Committee on Transfusion Transmitted Infection
- UK Blood Services Prion Assay Working Group
- Serious Hazards of Transfusion (SHOT) Steering Group
- CJD Clinical Incidents Panel
- ACDP (The Advisory Committee on Dangerous Pathogens) Transmissible Spongiform Encephalopathy (TSE) Risk Assessment Working Group
- ACDP TSE Risk Management Working Group
- ACDP TSE Sub Group
- Council of Europe Committee of Experts on Blood Transfusion and Immunohaematology
- English Infected Blood Support Scheme (EIBSS) Appeal Panel

Section 2: Response to criticism

8. I have been asked to explain a statement made in my letter of 5th May 2005 to Dr Christopher Tibbs. My letter was in response to a letter from Dr Tibbs of October 2004, when he provided me with information relating to the blood transfusions given to Mr GRO-B in 1990. In my letter, I stated the NHS Blood and Transplant (NHSBT) policy that no investigation would be conducted into reported cases of hepatitis C (HCV) infection where individuals had received blood transfusion prior to the introduction of routine blood donation screening for HCV on 1st September 1991. I am happy to assist the Inquiry in explaining in greater detail the reasons for this policy, and I trust that this statement will be of help in this, and possibly other, cases.

9. To deal with the specific issues raised in Mr GRO-B case, it is, of course, a matter of regret that when his case was first raised in 1999, my enquiry to the Consultant in charge of the blood transfusion laboratory at St Helier Hospital produced a negative response, in that they had not located any records of him receiving a blood transfusion. In the light of the information which Mr GRO-B subsequently obtained from his medical notes, I would have expected the blood transfusion laboratory to have located records relating to his blood transfusions, as only 9 years had then elapsed. I would not normally expect that laboratory records would have been destroyed after this period of time. I very much regret that I interpreted the inability to locate any such records as evidence that no transfusion had taken place. My letter, in retrospect, should have been more cautious as I was reporting back on second-hand information. I am usually much more circumspect in correspondence when I am relying on information provided by others.

10. I admit to some confusion in the exhibits provided and the information contained in Mr GRO-B witness statement. I note that, on the basis of the copies of labels (which would have been attached to the bags of red cells and plasma received by Mr GRO-B) sent to me by Dr Tibbs, I calculated that Mr GRO-B had been exposed to 17 different blood components (red cells and fresh frozen plasma), as well as quantities of HAS (Human Albumin Solution). Mr GRO-B statement refers to "137 bags of blood". It is not clear to me where this figure comes from, and as I do not have access to Mr GRO-B medical records, I cannot comment other than to note this discrepancy. I should, at this stage, point out that HAS is a pasteurised product produced from pools of human plasma, and pasteurisation (heat treatment) renders the product free from the risk of virus transmission, so I am excluding HAS from any further discussion.

11. In my experience, when cases of hepatitis C infection associated with blood transfusion prior to 1st September 1991 are reported to the blood service by patients and/or their clinicians, it is with one, or all, the following purposes:

- To establish a definite answer as to whether the hepatitis C infection can be positively assigned to an infected blood donor
- To establish whether other patients may have also been infected, but not yet be aware of their infection (a point raised by Mr. GRO-B in his statement), and whether any other individuals are at risk of infection.

- To provide information to support a claim to the HCV payment scheme, initially the Skipton Fund, subsequently the English Infected Blood Support Scheme (EIBSS).

I would like to deal with each of these points in turn.

12. First, it is completely understandable that infected people would wish to have definite evidence that their HCV infection had been traced to an infected blood donor, rather than be left with the knowledge that blood transfusion is the likely, but not definitely proven, source of the infection. We would all prefer certainty. Unfortunately, I cannot recollect any case in these circumstances where an investigation by NHSBT has provided that certainty. I will explain why this should be. After the introduction of more widespread use of HCV testing in patients with liver disease in the early 1990s, a number of cases were reported to NHSBT where a patient found to be infected with HCV had a history of blood transfusion prior to September 1991. Investigation of such cases involves first the identification of all blood components transfused to the infected person. This information is held in the hospital blood transfusion laboratory, in the form of the unique identifying number allocated to each blood component, and it is this information which NHSBT requests. The request is made to the blood transfusion laboratory as this is where the primary record is held. NHSBT can, from that information, identify the blood donors from whom those components were obtained. A check in NHSBT records will reveal whether the blood donors in question had attended and donated blood **after** 1st September 1991, and therefore had a known (negative) HCV status. As explained in my letter to Dr Tibbs, if any donor had been found to be infected with HCV through the screening of their blood donation, we would already have taken action to identify previous (unscreened) donations, and carried out a lookback into those previous donations, to trace such donations through to the patients who had received these earlier donations, who could then be notified and offered testing. Inevitably, not all blood donors who donated blood prior to the introduction of blood donation HCV screening would have returned after 1st September 1991. Each year, approximately 18% of donations are made by first time donors, who are recruited to replace those donors who have not returned (lapsed). The reasons for donors lapsing are many, but include ill-health, frequent overseas travel, moving home, either within the UK or moving abroad, moving job, pregnancy, loss of opportunity to donate, and others. Once a donor has lapsed, it becomes unlikely that donor will return, despite best efforts. Especially difficult is the donor who moves home, and fails to notify the blood service of a new address. In the 1990s, modern forms of communication such as mobile phone numbers and e mail

addresses were not available. We were therefore dependent on addresses to contact people. Once a person had moved from their last known address, our only means of tracing them was through the NHS Register of patients registered with GPs in England. Blood donors by definition are fit, healthy people, and these are the very people who may not register with a new GP when moving home. Inevitably, in any case where we are trying to trace and contact donors after a lapse of some years, there will be a proportion who cannot be traced/ contacted. As a rough estimate, this could be 20-25% of donors after a lapse of a few years. In Mr GRO-B case, even if we had been able to obtain his transfusion records in 1999, when his case was first referred to us, it is fair to say that 4-5 of the 17 donors who I believed he had been exposed to would probably have lapsed before September 1991, and could be uncontactable. If, as Mr GRO-B states, the number was 137, then we would have been faced with a correspondingly much larger number of lapsed donors. In cases where reports reach us within 3 years of the transfusion, we have the facility to retrieve the sample which is retained in frozen storage from all blood donations, and subject that to testing, but samples are not retained longer term through reasons of cost and available storage space. In summary, therefore, investigation of cases such as Mr GRO-B were always unsatisfactory because we were never able to provide the certain answer, and were left with being able to exclude a number of donors (who had a subsequent negative HCV test result) but not identify an infected individual. This outcome is frustrating to all.

13. The second point is that if an infected donor could be identified, other patients exposed to blood components obtained from that blood donor could be identified, traced, notified, and offered testing, as was done through the large-scale HCV lookback programme after the introduction of routine screening of blood donations. It goes without saying that if we are unlikely to identify an infected donor through investigation of cases such as Mr GRO-B then any form of lookback is impossible. But to explain further the difficulties, lookback depends on the blood service identifying the donor and then all "at risk" blood components. Through NHSBT records, the fate (whether issued for clinical use, and if so, the destination) of those blood components can be traced, to identify to which hospital laboratory(ies) they were issued. Once the hospital laboratory has been notified, the laboratory records can be interrogated to determine whether the blood component was used, and, if so, the names of patients. Those patients can then be traced, notified, and offered testing. NHSBT many years ago determined a policy of keeping records which established the audit trail from donor through to point of issue of the resultant blood

components, and from unique component number back to donor names as far back as 1980. Most hospitals, at the time in question, kept records only 10-12 years (as referred to in Mr GRO-B statement in relation to his medical records), so that if NHSBT had initiated a search in 2004/5 for pre-1991 records, while it should have been possible for NHSBT to identify the fate (final destination) of blood components produced, it is likely that no hospital would have records to establish what had happened to the blood components which they received. So any investigation would reach a blank. We have ample experience of this in lookback programmes which have been carried out, both in relation to HCV and other infections. It was not until the Blood Safety Quality Regulations (BSQR) were introduced in 2005 that hospitals were required to keep blood transfusion laboratory records for 30 years (going forwards).

14. The third aspect to be considered is the ability of an infected person to bring a claim under the various payment schemes (for HCV, The Skipton Fund, and now EIBSS). Of course, NHSBT would not wish to introduce a policy which could cause disadvantage to potential claimants. The Skipton Fund was set up with the provision that a definite source of transfusion–transmitted HCV infection was not necessary for a successful claim. This provision was precisely in recognition that the expected number of claims would overwhelm the UK blood services if all such cases had to be investigated and positive donors identified before payment could be made. This is in contrast to the payment scheme for HIV infection. HIV has been much less commonly transmitted through blood transfusion, and a blood service investigation would generally be necessary before payment is made. Furthermore, HIV screening of blood donations began in 1985, so most HIV-related claims involve screened blood. It goes without saying that cases of HCV (or other) infection believed to be associated with blood transfusion but involving screened blood would always be subject to scrutiny by NHSBT, and would generally be investigated unless there was overwhelming evidence for an alternative source of infection. This is because, while there is no assurance that any screening method will be 100% effective, and in very rare cases infection can be transmitted through blood transfusion even with modern donor selection procedures and donation screening tests, it is vitally important that blood services fully understand when, and why, screening tests may fail, and this knowledge is only possible through thorough scrutiny and investigation of every reported case of possible transfusion-transmitted infection.

Section 3: Other Issues

15. I have sought to deal, in appropriate detail I hope, with the specific matters raised in the Rule 9 Request. I have also set out on detail my background and involvement in matters relevant to the Inquiry's Terms of Reference. I have considered the invitation to set out other pertinent matters if they arise, and have sought to address some which are relevant to this request but also anticipate that there will be other areas where I may be of assistance to the Inquiry, because of my roles and responsibilities within NHSBT up to the time of my retirement, as specified in Section 2 of this statement. If so, I look forward to being able to assist the Inquiry further.

Statement of Truth

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

Signed GRO-C

Dated 4th June 2019