Witness Name: Stephen Murray

Statement No: WITN4409001

Exhibit No: WITN4409002

WITN4409002

University Hospitals of Leicester NHS
NHS Trust

Caring at its best

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20th September 2018

Mr Brian Stanton,
Solicitor To the Inquiry,
Infected Blood Inquiry,
Fleetbank House,
1st Floor, 2-6 Salisbury Square,
London EC4Y 8AE

Dear Mr Stanton,

Report from Haemostasis and Thrombosis team Leicester Royal Infirmary
Subject: Infected Blood Inquiry

Report prepared by Prof Ann Hunter on behalf of the Trust

Professor Hunter is a Consultant Haematologist who is Head of Service for Haematology. She has prepared this report on behalf of the Director of Haemophilia who is on extended leave. Professor Hunter qualified in 1982 and has worked as a Consultant at University Hospitals of Leicester since 1997. Her primary area of expertise relates to acute leukaemia and stem cell transplantation but she has significant experience in management. The report was prepared with input from the Haemophilia Centre staff and assisted by the Trust Solicitor.

Background
The Trust received a letter from Mr Brian Stanton, Solicitor to the National Infected Blood Inquiry on 15th August 2018.

The letter requested the retention of all documents and information and for the production of specified documents and information under Rule 9(2) of the inquiry Rules 2006.

Process

On receipt of the letter the Chief Executive delegated this work to the Trust Solicitor and Professor Ann Hunter, Head of Service for Haematology, with support from the CMG Senior Staff.

Professor Hunter and Mr Murray met with staff in the Haemophilia Centre to ascertain what sources of information were available. Both paper copies of documents stored and the Centre hard drive were reviewed. It was acknowledged that prior to the development of the shared hard drive previous individual members of staff may have stored information within their own Trust drive. This information is not available to current staff.

Many of the documents alluded to by the Inquiry either never existed or are no longer available but I can give an assurance that steps have been taken to ensure that no further destruction of records including patient's notes, minutes of meetings, policies, correspondence, instructions, notes, advice, reports, briefings, guidance regarding the remit of the Inquiry will be destroyed from this time point.

In our effort to comply with the Inquiry we have performed a look back through the computer systems and looked at hard copies of documents stored within the Haemophilia Centre. Not all of the documents identified by the Trust fall within the scope of the inquiry and any documents not referenced in this report are felt to contain information which is outside the scope of this inquiry or to contain duplicated information. Relevant documents are annexed to this report.

I can confirm to the Inquiry that we have not identified any minutes of meetings relating to this issue. There are no protocols available within the Unit prior to 2009. I have requested information from our IM&T department as to whether there may be archived material available from computer backups previously made but this would require access to drives related to staff who have retired or no longer work within UHL. My understanding is that information is stored for only 12 months after departure of a member of staff. This information is then deleted. I am awaiting confirmation of this position. If further relevant information should come to light we will disclose this to the Inquiry.

The Haemophilia Unit moved in 1997 to new premises within the hospital. During the move we have no information to suggest data or documents of any relevance were stored elsewhere, either on site or in an off-site facility.
The data identified does not relate to policies or procedures related to HIV infection and the management of patients infected with HIV or at risk of HIV. A previous look back at this issue was carried out nationally and Leicester participated in this process but no information regarding this has been found within the Trust.

In terms of the list of conditions covered by the letter received from the Inquiry to take each point in order:

a. **The treatment of men, women and children with haemophilia or other bleeding disorders who were given infected blood products.**
This issue was part of previous look backs regarding HIV, Hepatitis C and risk of new variant CJD. We have identified lists of products by

batches and the names of the individuals who received these individual batches but it is not possible to say if the batches listed were infected or not. Although the batch number is listed the name of the manufacturer is not.

We also have a file listing all patients who were potentially at risk of HCV infection to be screened as part of the look back. Not all patients were available for screening and not all patients screened were found to be infected. Please refer to File 50.

We also identified a file which is a spreadsheet provided by the National Haemophilia Database listing UHL's patients, their HCV risk and confirming compliance by UHL in returning data for uploading on to the National database as part of the look back for HCV infection. (File 52)

In parallel to this information we have identified the Policy and Standard Operating Procedures which describe the care of patients within the Centre. These documents written in 2009 /10 are the oldest such documents we were able to identify. They have subsequently been updated and newer versions are available if required. These documents are numbered OHQS-P-50, OHQS-P-68, OHQS-P-69. This is the first documentation of a quality management system being utilised within the Centre with retention of obsolete versions of documents.

b. The risks of infection associated with blood products

The risk of individual products used at that time are not known to us but information on this can be sought from other sources such as UKHCDO, haemophilia register and suppliers of the individual products.

Once the risk of HCV was recognised, samples of serum for future testing of patients were collected in some patients going back to 1983 prior to testing being available. In 1985 the department listed those patients who had received commercial factor from Jan 1980 to December 1984, NHS supplied concentrate Jan 1975-mid 85, those treated with commercial concentrate 1975-Dec 79 and those patients who received cryoprecipitate or fresh frozen plasma in the centre. This document also identifies for many patients the Hepatitis C status and when testing was done. Some of the patients had had samples stored as early as 1983 prior to testing being available and these samples were subsequently tested. Most infections appear to have occurred between 1983 and 1985. Looking at the list what is clear is that only a small proportion of patients 34 out of a total of 148 patients listed received non-NHS concentrates. 13 of the 34 patients receiving commercial concentrates became Hep C positive but none of the other patients are recorded on the data list to have developed hepatitis C following NHS concentrates or treatment with cryoprecipitate or fresh frozen plasma (File 22). In addition single documents listing individual patient's exposure to specific concentrate batch numbers were identified.

c. **The extent to which people given infected blood products were warned (or not warned) beforehand of the risk that they might be exposed to infection.**

There is no documentation regarding the information to be given to patients prior to treatment before 2000. No policy or protocols have been identified. There are no patient leaflets available with regard to the risk of infection for patients and their relatives from this period if they ever existed. It may be possible from accessing relevant sets of notes to identify what staff have recorded regarding advice given to individual patients and this may give some understanding of the procedures in place at that time. Many of the notes of patients who have died will have been destroyed by now so only a limited amount of information would be likely to be available from patient records.

Following the Department of Health concerns regarding new variant CJD in 2004 there is evidence that patients potentially at risk were identified and contacted. The Centre received the correspondence issued by the CJD Incidents Panel dated 7th September 2004, the Tables of vCJD implicated batch numbers and advice on the care of these patients. All Patients received the NHS information for Patients and risk assessments were carried out on potentially affected patients. Included in our documentation is a list of patients and the products they received, copies of the telephone log documenting information given to patients who phoned the centre concerned as well as example letters sent to patients. (File 27, 28 & 29)

d. The systems adopted for the screening of donors and the collection, testing, licensing and supply of blood products.

To the best of my knowledge we do not and have never procured donors nor have we ever manufactured any product for use in treating patients with bleeding disorders and so this issue is not applicable to our organisation

e. **The testing of those who were infected with infected blood products and how their infection status was recorded.**

No protocols to identify the Centre's policy regarding testing have been found prior to 2009. The current Policy sets out clear guidelines that all new patients should be screened for known blood borne infections at the initial appointment. All patients are checked for immunity to Hepatitis B and offered vaccination if non-immune. Patients who have received blood derived products are tested annually for blood borne infections. All such patients are counselled and are aware of both risk and testing procedures and the results of all screens are shared with patients. (OHQS 50, 68 & 69)

In the data available reports to the Hepatitis survey were found. We do not know if this data is complete but it shows an awareness of the issue of a hepatitis risk in this patient group. It does not inform us of the information patients received. (File 12, 13 & 14)

f. **How the results of tests or information about their infection was communicated to those infected and affected.**

There is no written policy regarding how patients should be informed of the test results and when this should be done. It would require a look at the Hospital notes for individual patients to establish what occurred for each of them. For those patients who have deceased more than 8 years ago the notes are unlikely to be available as they should have been destroyed in line with Trust policy in this area. So this is unlikely to be possible. In the two sets of notes reviewed there is clear documentation of patients being informed of the Hepatitis C status and advice about protection of sexual partners given.

g. **The level of information that should be provided to those who were infected, when this should be provided and how.**

Again there is no written information about the Centre's Policy. On looking at several sets of notes available at the moment there is evidence that patients were informed in clinic and given advice regarding methods of transmission and about protecting other family members and the general public. A File also exists listing family members who were tested for infection. There is no information regarding screening for HIV infection or look backs for HIV infection on the systems searched. Patients have been routinely tested for blood borne infections at their annual review if they are still receiving blood based factor treatment.

In 2011 there was a National look back for HCV infection and the setting up of the Skipton fund. There is data found about individual patient's applications to the fund and generic emails from the Chairman of the UKHCDO advising the Centre on processes and procedures. (File 7 & 8).

In 2004 there was a new look back regarding risk of nvCJD. The CJD incident Panel ran this review and provided information to the Trust. Attached are copies of files related to this look back. (File 17, 18, 27, 28, 29). Since 2004 the Trust has received further guidance from the Department of Health regarding the risk of CJD and this information has been retained.
In addition the Centre informed patients of the death of a patient with CJD who had haemophilia using information provided to it from the Health Protection Agency. The Centre also set up a telephone helpline

to answer patient's calls and kept a log of the phone call received. (File 70 & 71)

h. The extent to which financial considerations affected decision making when treating people with haemophilia and bleeding disorders.

The data identified does not allow me to comment on this question. The list detailing product concentrate use during 1975-85 show a majority of patients received NHS derived concentrates, cryoprecipitate or fresh frozen plasma products. Only a small number of patients received commercial concentrate and the data does not inform me how these decisions were arrived at. It appears from the data that patients with mild bleeding disorders were treated with single unit cryoprecipitate or fresh frozen plasma and not pooled concentrates.

i. The treatment, care and support provided to those infected and their families.

The Haemophilia Centre had a dedicated clinic with a Hepatologist and+ Infectious Diseases Consultant present to manage patients with HIV and Hepatitis Infection. The care of individual patients would require a review of the available notes. Within the documentation identified are applications to the Skipton fund and evidence of payments made and evidence of a look back to identify the patients eligible to receive compensation. There is also a list of family members tested for HCV along with some of these results. It would require review of individual patient notes to know what treatment, care and support was provided to those infected and their families.
The department completed an audit around 1994 sent to Prof Preston regarding the number of patients with Hepatitis. This lists the number of cases, modes of transmission, partner testing which shows all sexual partners at the time were offered testing but only 3 agreed. It also describes the overall policy regarding treatment, surveillance and testing of children of women affected. Linked to this is a patient information sheet which sets out what a patient attending the Centre can expected and some information about the Skipton fund. (File 1)

During our investigation we identified individual applications from patients and their families to the Skipton Fund supported by the Medical staff confirming patient eligibility. These files all contain patient and family identification. We don't believe that these files fall within the ambit of your request but should we be wrong about this we assume that full information can be obtained via the Skipton fund.

j. The destruction of documents and information described above.

The investigation has identified that in line with the Trust Medical Records Retention Policy notes of adult patients are retained for 8 years after last treatment or death. For children it is until 25th birthday or 8 years after death. The full medical notes of patients who have died or left the area more than 8 years ago will therefore not have been retained. Within the information identified some individual patient

Centre summary sheets have been found covering approximately 200 patients. These individualised patient specific sheets list patient's diagnosis, identifying parameters, next of kin, GP address, family history and coagulation factor affected. Hepatitis status is listed but not completed for many patients. Past medical history, allergies and space to document admissions or significant events is available and completed for some patients.
The Centre has a shared computer drive but this is a relatively new acquisition and it is presumed that prior to this senior staff kept information on their own drives within the UHL system. No access to this information was available and so any documentation which might previously have been written is no longer obtainable. The same issue relates to any potential minutes or other documents, protocols, policies etc.

In addition to the information requested and referred to above we identified the following which we think may assist the Inquiry:
Lists of patients who have died between 1979 and 2002 with cause of death (File 19). This file does not appear to have been updated recently but this information is available via the National haemophilia Database.
We also identified several files listing patient names and whether serum samples were available in virology which had been stored for future testing, a list of batches of concentrate and the patients who had received them (File 20). During the HCV look back exercise consideration was given to the HCV status of all individuals treated within the Centre.
The National haemophilia database has sent a number of files detailing patients related to the HCV look back This information includes patients from other Centres and can be obtained via the database administration team. It is not included in the data sent to the Inquiry.

The data provided does not include individual's medical records including locally held treatment records in line with the advice given in the letter sent on 15th August.

Summary
The information provided for this report is a true reflection of the data identified. If on review of the Report the inquiry wishes to seek clarification or additional information please don't hesitate to contact us.

GRO-C

Professor Ann Hunter
Honorary Professor of Genetics and Genomic Medicine