Witness Name: Dr Andrew COLE

Statement No.: WITN7694001

Exhibits: WITN7694002-WITN7694003

Dated: 27 April 2022

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR ANDREW COLE

I provide this statement on behalf of the University Hospitals of Derby and Burton NHS Foundation Trust in response to the request under Rule 9 of the Inquiry Rules 2006 dated 11 October 2021.

I, Dr Andrew Cole, will say as follows: -

Section 1: Introduction

1. I am Dr Andrew Cole, Consultant Gastroenterologist at the University Hospitals of Derby and Burton NHS Foundation Trust (UHDB) and I am also an Honorary (Consultant) Assistant Professor at the University of Nottingham School of Medicine. I was also the Clinical Lead for the Endoscopy Service at the University Hospitals of Derby and Burton (formerly Derby Teaching Hospitals NHS Foundation Trust) until 1 April 2019.

Section 2: Response to Criticism by witness W2982

2. I am aware that witness W2982 has provided a statement to assist the Inquiry dated 30 May 2019 which relates to the care her husband received at the Royal Derby Hospital and specifically in relation to the use of the Endoscopy service in 2018/2019.

3. I have been asked to prepare a statement addressing the concerns raised by witness W2982 in my capacity as clinical lead for the Endoscopy service during this period. Witness 2982 states as follows:

   "I do not believe there was any problem in accessing the treatment, but he has had issues with some of his treatment. I remember one occasion where GRO-A *went to have an endoscopy but when* GRO-A *got to Derby Royal Infirmary, they refused to carry out the procedure. They claimed that* GRO-A *was a liar and that the procedure would never have been offered due to his infection due to the cost of the machinery.* GRO-A *was told that they would have had to use the machine on* GRO-A *only and then no one else could use it. This incident happened in 2018 and then again this year but no one believed me at the hospital when I tried to tell them"*

4. I firstly wanted to provide an apology to both Mr GRO-A and his wife for the difficulties they experienced in obtaining an Endoscopy at the Royal Derby Hospital. I have

tried to ascertain what happened on these occasions but unfortunately, I have not found any note made by the Endoscopy team relating to a failed Endoscopy appointment at this time. I have reviewed Mr GRO-A s records between 1 January 2017 and 31 December 2019 and the only reference I could locate relating to an Endoscopy being declined was in Mr GRO-A s GP referral on 5 June 2019 which states:

"He says the last time he was referred for endoscopy it was refused because of the risk of CJD and I think he had quite a battle over this and never had the endoscopy done".

5. The fact that Mr GRO-A would have been deemed increased risk of CJD should not have been a block to him receiving treatment and as can be seen below, hasn't been a block to him having other treatment such as a Gastroscopy in 2019. I am sorry that this has caused Mr GRO-A and his wife distress. I have addressed in this statement what I believe should take place and have explained the policies and procedures we have at the Trust to ensure all patients requiring an Endoscopy receive safe care.

Section 3: Trust and National Guidelines

6. I have set out below the Trust's current policies and protocols relating to Clinical Guidelines for hereditary bleeding disorders the Trust uses local protocols for patients who are haemophiliacs, HIV+ve and HCV+ve and regularly do procedures on all these patient groups.

7. The Trust has guidelines for hereditary bleeding disorders and bleeding disorders in surgical procedures, attached marked Exhibit "WITN7694002".

8. The aim of this Policy is to ensure that patients who received British plasma derived in clotting factor concentrate or antithrombin concentrate between 1980 and 2001 were designated "at risk" for vCJD for public health purposes. All such patients have an alert sticker in the front of their notes. Infection control have a list of identified patients.

9. If these patients required surgical or endoscopic interventions special measures may need to be taken to decontaminate/quarantine the instruments/scope used. When in doubt, or for emergencies, instruments used must be quarantined until the next working day when a decision about cleaning the instrument and or quarantining can be made.

10. The British Society of Gastroenterology guidance for decontamination of equipment that was available in 2018 and remains unchanged in the 2020 guidance and is as follows:

BSG GUIDANCE FOR DECONTAMINATION OF EQUIPMENT FOR GASTROINTESTINAL ENDOSCOPY

"14. The agent of variant Creutzfeldt-Jakob disease (vCJD) is believed to be resistant to all forms of conventional sterilisation. The risk of transmission of this agent is

extremely low provided that scrupulous attention to detail is routinely employed in the decontamination process after every patient. In particular, all accessible endoscope channels should be brushed through with a single use purpose-made device or brush tipped wire assembly that has an appropriate length and diameter for each channel.

15. Any endoscopic procedure that breaches gut mucosa and is followed by the withdrawal of an unsheathed accessory through the working channel of an endoscope is deemed "invasive". Procedures that cause tissue vaporisation (e.g. diathermy) are also deemed "invasive". If an invasive procedure is undertaken in i) a patient with definite or probable vCJD, ii) a patient in whom a diagnosis of vCJD is being considered or iii) a patient at increased risk of vCJD (in whom infection should be presumed) through receipt of labile blood products, such as red cells from a donor who later developed vCJD, it will necessitate the subsequent quarantining of the endoscope used.

16. The performance of an "invasive" procedure (defined in 14 above) in a patient at risk of vCJD due to receipt of pooled plasma concentrates is no longer deemed to confer a increased risk of endoscope contamination. A single quality assured decontamination cycle according to these guidelines is considered sufficient, but the endoscope should be decontaminated separately from other equipment within an EWD and with a single-use disinfectant. There is no longer a requirement to quarantine the endoscope provided that routine traceability data can demonstrate thorough reprocessing".

11. The Trust also now has a flow chart for CJD and/or vCJD questions that the patient is asked at the pre assessment/inpatient admission. A copy of that is attached and marked Exhibit "WITN7694003". This outlines the process for performing endoscopies in patients that are at increased risk of CJD and follows the guidance from the BSG noted above.

Section 4: The Trusts' standard practice

12. The Trusts' current practice is now as follows:

- Referral completed
- Endoscopy Pre-Assessment (This service was not in situ in 2018 but the same rules applied to all of our patients on the day of admission)
- Confirmation obtained from infection control of risk status (if positive answer received to the pre assessment blood products/plasma/transfusion questions)
- Procedure booked and placed at the end of the list
- Nursing and Decontamination teams informed
- Infection control policies followed for decontamination
- If biopsies/therapeutics are required then the scope is quarantined and assigned to the patient for life)

The Trust holds a list of scopes that are allocated to patients for life and scopes that are available for allocation. The staff have a folder to refer to with the relevant information and policies.

If the patient is deemed at increased risk of CJD, preparations will be made in accordance with the BSG guidance noted above and arrangements for scopes to be quarantined and/or decontaminated depending on whether the patient requires a biopsy or other invasive procedure. This ensures that clinics run smoothly and that patients are able to be booked in an appropriate slot to allow for them to have their endoscopy procedure.

Section 5: Endoscopy/Gastroscopy

13. I can see from Mr GRO-A 's medical records that he underwent an Endoscopy on 18 July 2019 where his increased risk of CJD had been noted prior to the procedure. Biopsies were not taken during the Endoscopy and so in accordance with the guidance the scope was decontaminated appropriately after use, rather than being quarantined.

Statement of Truth

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

Signed GRO-C

Dated: 27 April 2022

Table of exhibits:

Date	Notes/ Description	Exhibit number
2018/2019	Clinical Guideline for Hereditary Bleeding	WITN7694002
Current	Flow Chart for vCJD Pre Assessment and Admissions	WITN7694003