Witness Name: Dr Kenneth Donaldson
Statement No.: WITN7716001
Exhibits: None
Dated: 18/07/2023

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR KENNETH DONALDSON

I provide this statement in response to a request under Rule 9 Request of the Inquiry Rules 2006 dated 14 February 2023.

I, Dr Kenneth Donaldson, will say as follows: -

Section 1: Introduction

Please set out your name, address, date of birth and professional qualifications

1. My name is Kenneth Donaldson, my date of birth is GRO-C 1971, and my professional qualifications are MBChB FRCP MSc. My address is NHS Dumfries and Galloway, Mountainhall Treatment Centre, Bankend Road, Dumfries DG1 4AP.

Please set out your current role at Dumfries and Galloway Health Board and your responsibilities in that role.

2. My current role is as Executive Medical Director with consequent responsibilities and as Responsible Officer for NHS Dumfries and Galloway.

Please set out the position of your organisation in relation to the hospital/other institution criticised by the witnesses (for example "NHS Foundation Trust ('the Trust') operates from Hospital X and Hospital Y (formerly Hospital Z)").

3. NHS Dumfries and Galloway is responsible for healthcare provision for the population of Dumfries and Galloway.

Section 2: Responses to criticism by witness W2264

The criticisms the Board has been asked to address set out at paragraph 13 (page 4), paragraph 34 (page 8) and paragraph 36 (page 9) of the witness statement of witness W2264 which state:

Paragraph 13

> **Going through all of this, [W2264's late husband] didn't trust the medical profession. He did develop trust in one specialist nurse, however even that turned out to be a big mistake in the end as this was the medical professional who missed the cancer diagnosis that ultimately killed him. [W2264's late husband] was routinely monitored every 3 months. He attended Dumfries Royal Infirmary in December 2019 for his routine blood tests and to see Dr Jones and the specialist nurse GRO-D. They decided during this appointment that they wouldn't see [W2264's late husband] again until May 2020 and give him a bit longer this time. We thought this was good news, so we booked a holiday to Gran Canaria in February 2020.**

Paragraph 34

> **[W2264's late husband] was doing quite well during April and May, however there was an incident where he fell out of the bath and that is when everything changed. Two days later he became jaundiced and he was admitted back to Dumfries and Galloway Royal Infirmary. Again because of covid-19 restrictions I wasn't allowed in to see him, so I**

couldn't be sure he was getting the right care. When I spoke to him on the phone, he was all over the place, he sounded totally out of it. His medication kept getting mucked around so he barely knew what was going on.

Paragraph 36

This issue was addressed. I wrote all the medication down for Dumfries and Galloway Royal Infirmary. I have no idea why they made such a negligent mistake over my husband's care. [W2264's late husband] asked me before he died to not drop this and get answers as to why the care was so appalling. I promised him I would, and I will.

4. The Board identified Dr Gwyneth Jones and Consultant Nurse GRO-D GRO-D as the most appropriate people to respond to the criticisms made. Dr Jones is a Consultant Physician and Specialist in Infectious Diseases at NHS Dumfries and Galloway who has recently retired. Her response is below, in her own words. CN GRO-D is a Specialist Nurse in Infectious Diseases and Blood Borne Viruses and is currently working for NHS Dumfries and Galloway. Her response is below, in her own words.

Response of Dr Gwyneth Jones

Paragraph 13

5. When I set up the clinic for people with Hepatitis C I was very aware from my previous training and experience that many people did not feel comfortable with the medical profession. We designed simplified referral pathways and phone follow up for those who did not attend appointments. Recruitment of a nursing team with similar background and experience enabled us to work together to provide holistic care and retain people in follow up despite the poor outcomes from early interferon based treatment. We built a close relationship with the Tertiary centre (Scottish

Liver Transplant Unit SLTU) to optimise care for any patient with liver failure.

6. I provided care for this man alongside the Hepatitis C nursing team for more than 9 years.

7. At initial referral he had cirrhosis with severe pancytopenia. Bone marrow had been performed to exclude other pathology. Scans revealed portal hypertension. Alpha feto protein (AFP) was elevated at 74 ku/l in keeping with advanced cirrhosis. Further imaging including MRI liver revealed no liver lesion.

8. We supported him through 3 courses of treatment for Hepatitis C including an Interferon based regimen requiring careful blood monitoring and dose adjustments.

9. We ensured he had early access to more effective treatment as soon as new drugs became available and licensed. We even explored options for participation in trials. Ultimately, he had a sustained viral response and cleared Hepatitis C. We liaised closely with the Tertiary centre (Edinburgh) both at start of treatment in 2013 because of risk of liver decompensation and when his condition deteriorated in 2019. He was under surveillance for Hepatocellular cancer as per national protocol with US and AFP monitoring. He also had regular endoscopy and banding of oesophageal varices. His care involved multiple hospital appointments.

10. I was also aware during some of this period that he was juggling work, sometimes away from home and challenges in his personal life. The nursing team provided ongoing support throughout a period when Hepatitis C treatment was changing rapidly. I have summarised key events below.

11. 2013 he had at least 5 clinic reviews. He did not respond to the standard Interferon treatment regimen. I liaised with Edinburgh SLTU to determine

if he could be included in any trials of newer direct acting antivirals but he did not meet criteria.

12. 2014/2015 he defaulted several appointments but we became aware of personal difficulties and he was referred for additional support to Alcohol services to ensure he could maintain abstinence given his advanced liver disease.

13. He was seen urgently at his GP's request with decompensated liver disease which was stabilised and he commenced treatment on a newly licensed dual antiviral + ribavirin regimen in May 2015. He did not respond.

14. 2016 I was involved in his care when admitted with E coli sepsis

15. 2017 We liaised through West of Scotland viral resistance group (part of national treatment strategy) to determine best treatment option with Q30R mutation. He was then successfully treated with Epclusa+ Ribavirin

16. 2014/2016/2018 he had UGIEndoscopy with banding of oesophageal varices (barely noticeable on last scope) He was also treated with carvedilol to reduce portal hypertension and did not experience further GI bleeding.

17. 2018 Head injury whilst intoxicated

18. Feb 2019 Support letter for PIP (composed by CN Specialist)

19. April 2019 Medical clinic review reporting fatigue, reduced physical activity, increased BMI. He had no ascites.

20. He complained of feeling breathless and I organised ECG/CXR/ECHO and pulmonary function tests. He received support from dietetics.

21. Benefits had been re-established.

22. I referred him back to SLTU (Scottish Liver Transplant Unit) with UKELD score 50 and increasing fatigue. He was seen in Edinburgh July and Dec 2019. He had well compensated liver disease and from a liver perspective was considered to have low symptom burden. It was therefore felt there was no indication/benefit to liver transplantation. Edinburgh arranged 12 month follow up appointment. He was still undergoing investigation for chest pain and breathlessness initiated by our team and highlighted as a concern by Edinburgh.

23. He was seen in DGRI Jan 20 (Hepatology Speciality doctor) and follow up appointment in May 20 was arranged to alternate with Edinburgh (6 monthly reviews). There were no new symptoms.

24. He had been seen by cardiology and further investigations were arranged. There had been some improvement with isosorbide mononitrate.

25. CXray, ECHO and pulmonary function tests had been normal. He had missed an appointment with Cardiology that we re-arranged. Following ETT he was referred for angiography (performed 24.4.20)

26. From clinic bloods 9.1.20 AFP was 8 and repeat 3.3.20 was 12 (he had previous raised levels) He had no new abnormality on last imaging or change in symptoms or liver function tests. This was discussed with me and we planned a repeat in 3 months.

27. By now we were aware of COVID-19 and we had been involved in pandemic planning. During this period, we had to suspend all Hepatocellular US screening.

28. I would highlight that AFP is a screening test for hepatocellular carcinoma and not the Cholangiocarcinoma that was subsequently diagnosed. He was however admitted within a month of the repeated AFP. At that time, he presented with acute pain such that the triage doctor considered rib fractures or pulmonary embolism as possible diagnoses. Imaging revealed the cholangiocarcinoma and boney metastases.

29. I find the language used in the publicly available witness statement of W2264 extremely distressing. Our team had provided continuous care for almost a decade. This was not an expected complication. He had been reviewed by a Tertiary centre. He was well enough to travel abroad during this period. Cholangiocarcinoma is associated with poor outcome and sadly treatment options were limited with risk from toxicities felt to outweigh possible small benefit.

30. I would clarify that we have not received a complaint about our care. I had seen his wife as a patient following his death.

31. I must clearly document that there was no action taken by CN GRO-D GRO-D that would support an assertion that she had 'missed a cancer diagnosis'. All patients at that time were discussed with me and together we formulated follow up plans.

32. The comment around the May appointment is inaccurate (I had not seen him in Dec 19) the timing related to alternating appointments with SLTU. He was usually monitored 6 monthly but we arranged additional blood tests because of the mild rise in AFP.

33. CN GRO-D had previously ensured that we found further information for a successful application to the Skipton fund despite initial disappointment with destroyed records. She also prepared a detailed letter to ensure benefits were restored and wrote an emergency request to support a marriage application during his last illness. She provided holistic care throughout the difficult journey through Hepatitis C treatment

and co-ordinating investigations for the cancer including liaising with the Lothian Hepato-biliary team and Oncology services. This was more challenging than usual because of new restrictions around COVID-19 that impinged on many aspects of care and included the introduction of virtual clinics.

34. During the admission and cancer diagnosis in April 2020 I was unable to see W2264 as I was in quarantine for 14 days with a sick family member with COVID-19 and another in protective isolation. There was much uncertainty regarding outcomes and indeed mortality from this new illness. Medical services were severely affected.

35. I did however 'meet' W2264's wife in a subsequent virtual clinic appointment. I spoke with W2264 and his wife who showed us their recent wedding photos.

Paragraphs 34 and 36

36. I was not involved in the subsequent short admission following a fall (10.7-13.7) when 'His medications kept getting mucked about'

37. From case records I note that initially he declined anything stronger than paracetamol. But pain worsened and he required increasing breakthrough doses of oral MST (oramorph) solution. He received the most on 11.7 (5 doses). It is usual practice this would then lead to recalculation of the background twice daily long-acting MST. His dose of MST was increased and dexamethasone had also been increased. He received intravenous zoledronate for bone disease. He had a single dose of lorazepam when he felt agitated.

38. I note that his wife did express concern about medication and he was seen by a member of the Specialist Palliative care team. He was keen to be at home and opted for outpatient radiotherapy. He didn't want to know further blood results.

39. I can speculate from experience that it can be challenging to titrate pain relief in someone with advanced liver disease as opiate medication can accumulate and cause unwanted drowsiness. This would also be a very distressing period as he became aware his disease had progressed, was experiencing pain and his wife was not able to be present because of COVID-19 restrictions. He did not want to spend time in hospital. I can only express my great sadness that they had to navigate through this difficult period apart.

40. I did not identify an error in prescribing although medication was changed because of increased pain. Some doses were given later than usual timings which will happen in a ward setting with multiple patients.

41. I am not clear what is being referred to by the comment 'why they made such a negligent mistake' On reviewing documentation I believe we did provide good quality care. In the latter stages this was more challenging as we were all affected by the COVID-19 pandemic. It is difficult to comprehend how difficult this was for those with terminal illness and for those caring for a loved one dying during this period.

Response of Consultant Nurse GRO-D

42. As a registered nurse I realise that I must cooperate with this investigation. However, I feel uncomfortable and distressed to be discussing a deceased patient whom I had the privilege of nursing since April 2013 without his knowledge. I will provide the documented facts in response to this claim.

Background

43. The patient was referred to our team for treatment of chronic Hepatitis C Virus by his Consultant in April 2013. At that time, he was also diagnosed with portal hypertension, splenomegaly, oesophageal varices, cirrhosis,

and deranged liver function tests including an Alpha Feta Protein (AFP) level of 74. These are all indicators of advanced chronic liver disease, with a risk of developing hepatoma. The patient was aware of this (clinic letter copied to patient). Excess alcohol intake was also a problem for him.

44. I was eventually able to inform him that directly acting antiviral treatment (DAA) had cleared his Hep C in 2018.

45. At no time did he ever raise a concern about his ongoing treatment and care with me or our clinical team. He continued to be followed up in our care for routine hepatoma surveillance, consisting of 6 monthly ultrasound scans (USS) of liver, 6 monthly clinic review and 6 monthly blood tests including AFP.

Paragraph 13

46. I have explored a timeline and can provide these documented facts:

- 5/12/2019; the patient was reviewed by the Scottish National Liver Transplant Unit (SNLTU) team (liver experts) in Edinburgh. All bloods were taken, including AFP. His liver condition was described as stable, with a planned review in one year.

- 09/01/2020-Patient attended his 6 monthly reviews in our liver clinic. He was seen that day by a speciality doctor in hepatology. His AFP was 8, his most recent, routine liver scan showed no lesions. Patient was aware of this. All clinic letters were routinely copied to SNLTU team for their information and review. Plan; repeat AFP in 3 months.

- 03/03/2020-Patient was in clinic by nurse to review and repeat bloods. AFP 12, liver function tests stable. Local liver team discussed these results; outcome; review in 3 months with usual USS liver. Patient informed of this.

- 22/03 2020; Decision was made to redeploy some clinical nurse specialists by the lead nurse in this acute trust to support the “surge” of expected patient admissions with Covid-19. I was redeployed from my substantive post to work as a registered nurse in medical and surgical wards across the acute site. This was in preparedness for the Covid-19 pandemic and national lockdown.

- 24/03/2020; our clinical team sent a letter to the patient informing him of changes to hospital appointments, clinic appointments and redeployment of our medical and nursing staff because of Covid-19 restrictions and national lockdown. This included alternative “ways of working” and clinical contact numbers for the team for the patient.

- 01/04/2020; Dr Jones then had to go into home “quarantines” caring for a family member who tests positive for Covid-19. Nursing and medical team adapt to “virtual/remote” working practices. This was in keeping with NHS local Covid-19 task force.

- 06/04/2020-Telephone call to me from patient’s partner concerned about patient’s condition. Patient complained of; new, severe right upper quadrant pain and cough. I arranged for him to be triaged through the “Covid-19 Hub”. It was considered that he may have a possible rib fracture or pulmonary embolus. This prompted an emergency admission by ambulance to a medical ward and an urgent CT scan. This CT scan of chest abdomen and pelvis revealed a lesion on his liver and two lesions on his vertebrae.

- 07/04/2020-Patient was informed of this by his ward consultant prior to discharge. I was present in the room. He was informed that they may be malignant lesions on the liver and on the bones and that could represent cancer. He was informed that an urgent referral was sent to Edinburgh Hepato-biliary (HPB) multi-disciplinary team and copied to SNLTU for review of this finding.

- 08/04/2020; patient was keen for discharge and went home, with follow up plan (await review and recommendations from Edinburgh HPB team).

- 10/04/2020; I telephoned the patient to update him of news from Edinburgh HPB team, with an interim decision and plan of care. They recommended a liver biopsy to be done locally; to establish if this was a cancerous lesion and to determine what type of cancer this was. In my documentation of this telephone conversation, I reminded the patient that this was possibly a cancerous tumour.

- During this conversation I also informed him that this clinical finding routinely generated a referral to the Cancer consultant based in Edinburgh as well as the local cancer specialist nurse on site here.

- I provided the name and telephone contact for this nurse. I informed him that this nurse would make contact with him by telephone. (I was also able to inform him that she remained in her substantive post and was not redeployed to wards). He was happy about this.

- I requested an urgent ultrasound guided biopsy of liver on that day. I planned to speak to the patient again on Tuesday 14th April. This was Easter weekend; Monday was a public holiday.

- 14/04/2020; I telephoned patient as planned, who was able to attend later that day for his urgently arranged liver biopsy at hospital. Unfortunately, this procedure was abandoned by the consultant because of the location of tumour and potential risk to patient. An alternative CT guided liver biopsy was immediately organised by the consultant for 16/04/2020. Patient went home. He was determined to remain out of hospital.

- 16/04/2020. Patient was admitted to hospital for planned CT guided liver biopsy and discharged home the same day with a follow up plan. He was aware that the cancer nurse would be following him up with this result and would contact with him by telephone.

- 22/4/2020. Pathology report was received by ward consultant suggesting a primary cholangiocarcinoma arising in the background of liver cirrhosis. This was automatically sent to HPB team in Edinburgh for expert opinion and further discussion; this included the oncology team.

- 29/4/22 Further expert pathology report was received by ward consultant and oncology team confirming diagnosis of intrahepatic cholangiocarcinoma. The local cancer nurse had been in contact with patient by telephone and arranged an "attend anywhere" consultation for him with the consultant oncologist on 29/4/2020. This was to discuss his diagnosis of intrahepatic cholangiocarcinoma diagnosis which was confirmed by biopsy.

47. I did not "miss" this diagnosis and I am mortified to think that this is what this patient's partner has stated.

Paragraph 34

48. I cannot comment on this paragraph I was not involved in this episode of care.

Paragraph 36

49. I cannot comment on this paragraph I was not involved in this episode of care.

Section 3: Other Issues 5

If there are any other issues in relation to which you consider that you have evidence which will be relevant to the Inquiry's investigation of the matters set out in its Terms of Reference, please insert them here.

50. None

Statement of Truth

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

Signed GRO-C

Dated 18/07/2023