Witness Name: DR NICHOLAS KENNEDY
Statement No.: WITN5580001
Exhibits: WITN5580002-007
Dated: 6 April 2021

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR NICHOLAS KENNEDY

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 17 March 2021.

I, Dr Nicholas Kennedy, will say as follows: -

Section 1: Introduction

1. My name is Dr Nicholas Kennedy. My date of birth is GRO-C 1963 and my professional address is: Infectious Diseases Unit, University Hospital Monklands, Monkscourt Avenue, Airdrie, ML6 0JS. My home address is known to the Inquiry. My professional qualifications are: MB ChB (bachelor of medicine and surgery, Bristol University, 1988), MRCP (membership of the Royal College of Physicians, 1991), Dip Nutrition (Diploma in Nutrition, University of the West Indies, 1985), DTM&H (Diploma in Tropical Medicine and Hygiene, London, 1993), MD (Doctorate of Medicine, Bristol University, 1995). I have been elected to fellowship of Royal College of Physicians of Edinburgh (1999) and Royal College of Physicians and Surgeons of Glasgow (2006), with FRCP Edin and FRCPSG (2006) awarded respectively. I hold certificates of completion of specialist training in General Medicine, Infectious Diseases and Tropical Medicine.

2. A curriculum vitae [WITN5580002] has been provided to the Inquiry which contains detailed information regarding the various professional positions that I have held

since I qualified as doctor, along with the organisations in which I held these positions and my responsibilities in these positions. My curriculum vitae also contains full details of relevant past and present committees that I have been a member of.

3. I took up my current position as Consultant in Infectious Diseases and General Medicine, Monklands Hospital, Airdrie, in November 1997. I am also an Honorary Clinical Senior Lecturer (University of Glasgow). I have held various clinical managerial roles, including Lead Clinician for our Lanarkshire Bloodborne Viruses Prevention and Care Network (BBV PCN) from 2008 until the present time.

4. I have been actively and extensively involved in viral hepatitis and HIV work, including research, service provision and service development, since the mid-1990s. This has included work at a hospital, health board and national level (details provided in curriculum vitae). Throughout this period I have worked hard in my professional life, as well as in my personal time, to promote and improve care for people infected by Hepatitis C and other blood borne viruses.

Section 2: Responses to criticism of W2298

5. Thank you for providing me with the opportunity to respond to the written statement from Mr Thomas Hanley, brother of the late Mr Robert Hanley. I, Dr Nicholas Kennedy, have written the response myself. With the written permission of the Inquiry, I have shared and discussed this response with my colleague, Dr Claire McGoldrick, Consultant in Infectious Diseases, as Dr McGoldrick was more directly involved than I was in Mr Robert Hanley's case in the period leading up to his re-treatment. However, as per standard good clinical practice, his treatment would have been discussed at, and supported by, a multi-disciplinary team (MDT) meeting. Hence the treatment decision made should be regarded as a multi-professional and multi-disciplinary team decision.

6. At paragraph 18 of his statement, witness W2298 states that his brother was on a medication called Telaprevir which should not be taken by people with heart or

blood pressure issues. Witness W2298's brother had both of these conditions and they were recorded in his medical notes. He believes that this medication was inappropriate for his brother yet, he was still prescribed the drug.

7. At paragraph 18, witness W2298 states that a nurse described Telaprevir as a "new" and "aggressive" hepatitis treatment. Witness W2298 does not believe his brother's notes were comprehensively read, meaning his brother could not have been given full information about Telaprevir in light of his pre-existing heart and blood pressure conditions. At paragraph 19, witness W2298 states that he suspects that his brother was given Telaprevir for research purposes.

8. The first thing we would like to do is to offer our condolences to Mr Thomas Hanley on the sad loss of his brother in March 2013. It is clear from his statement that this loss is still very raw, with unhappiness and outstanding questions relating to his medical care, social circumstances and employment matters around the time of his death.

9. The response below regarding his medical care is based on the evidence that is available to us. Unfortunately, as indicated by Mr Thomas Hanley in his statement, the previous paper case records appear to have been destroyed when NHS Lanarkshire transitioned to electronic case records (I have also tried, unsuccessfully, to locate any paper case records). However, there are fortunately a number of clinic letters stored electronically from the period December 2011 to January 2013 [WITN5580003] that give a reasonably complete picture of Mr Robert Hanley's assessment prior to commencing re-treatment for Hepatitis C (HCV) with a 3-drug regimen of Pegylated Interferon, Ribavirin and Telaprevir in February 2013. In addition, a copy of the 'Yellow Card' report that was submitted to the MHRA after his death is available [WITN5580004], as well as a copy of the death certificate itself [WITN5580005].

10. Mr Robert Hanley had been under clinical follow-up for Genotype 1 chronic HCV by the Blood Borne Viruses (BBV) team at University Hospital Monklands for a number of years. In 2003 he underwent HCV treatment under our care with Pegylated Interferon and Ribavirin, but unfortunately this did not clear the virus

and he remained HCV PCR positive. This was a concern as there was evidence of progressive liver damage, as judged by his climbing Fibroscan liver stiffness scores, progressing towards the cirrhotic range. Thus when the first new effective drugs for HCV (Telaprevir and Boceprevir) became available for NHS prescription in 2012, we offered Mr Hanley the option of more effective HCV re-treatment, on the NHS, to arrest this progressive liver damage. He was never enrolled in a clinical trial.

11. We had a detailed and comprehensive guideline that was in use in 2012-13, 'Hepatitis C infection: The Lanarkshire Management Guideline', a copy of which is provided [WITN5580006]. All patients, including Mr Hanley, were assessed and treated in accordance with this guideline along with the relevant Summary of Product Characteristics (SPC) for the drugs to be administered. As stipulated in the guideline, all patients were assessed very carefully prior to HCV treatment with the benefits and risks of treatment explained. All patients were also discussed at a multi-disciplinary team (MDT) meeting, which included Consultants, Specialist Nurses and a Clinical Pharmacist, prior to the commencement of treatment. Treatment was only commenced if supported by the MDT and with a patient's informed consent.

12. During the period December 2011 to January 2013 Mr Hanley was reviewed on 6 occasions by doctors from the Blood Borne Viruses team (Dr Kennedy in 2011, then by Dr McGoldrick and other colleagues in 2012-13) [WITN5580003], as well as by a BBV Specialist Nurse (now retired). In addition to considering his HCV and liver disease, a general pre-treatment health evaluation was performed. This included: a full physical examination; assessment and optimisation of his diabetic control (this had been sub-optimal); assessment of his blood pressure treatment and control (which was good); cardiac assessment by ECG and echocardiogram (minor abnormalities only); a careful assessment of any potential drug-drug interactions between his proposed HCV re-treatment regimen and his existing medications.

13. No contra-indications to HCV treatment were identified at the time. Reviewing this now, in light of Thomas Hanley's written statement, we are still not able to

see any contra-indications to his HCV treatment, although careful assessment and close monitoring would be indicated (and both were indeed undertaken). Specifically, there is no mention in the archived Telaprevir SPC (the drug is no longer in use) of high blood pressure being a contra-indication to treatment [WITN5580007]; Robert Hanley's blood pressure was also well controlled. Equally, there is no suggestion from our clinic letters that Mr Robert Hanley had a documented history of clinical heart failure (the heart not working adequately as a pump resulting in fluid accumulating in the lungs or elsewhere in the body) or ischaemic heart disease (heart disease due to narrowed arteries and inadequate blood supply to the heart muscle). There was also no suggestion that he had any symptomatic heart disease during the period of evaluation pre-treatment. He did certainly have risk factors (diabetes and hypertension) for asymptomatic underlying ischaemic heart disease and it is possible that the minor abnormalities on ECG and echocardiogram were due to this. However, even if this was the case then the SPC again does not suggest that this would constitute a contra-indication to treatment with Telaprevir and Pegylated Interferon and Ribavirin.

14. As per our standard practice at the time, we checked his ECG carefully both before and during the first weeks of treatment. The primary aim of this careful ECG monitoring was to look for evidence of so-called QTc prolongation (an electrical abnormality on the ECG which can be caused by some drugs, including Telaprevir, and which can lead to heart rhythm abnormalities; QTc prolongation is not the same as either heart failure or ischaemic heart disease). Significant pre-existing or evolving QTc prolongation would have constituted a contra-indication to Telaprevir, but there was no evidence of this.

15. With regards to the drug Telaprevir itself (which has now been withdrawn and superseded by other HCV drugs), whilst it was certainly more effective than preceding treatments for HCV, we would not regard it as 'very aggressive'. It was widely used world-wide for HCV treatment for a period and generally well tolerated. The main concern was potentially severe skin reactions, rather than heart problems (see Section 4.8 of Telaprevir Summary of Product Characteristics (SPC), [WITN5580007]).

16. The arrival of the first 2 new drugs from the so-called directly acting antiviral (DAA) class, Telaprevir and Boceprevir, meant that many patients such as Mr Robert Hanley who had failed previous HCV treatment now at last had a chance of a cure for their HCV. However, Hepatitis C treatment has advanced very rapidly over the last decade and newer drugs are now available that are even more effective, can be given once daily, have fewer food restrictions and do not need to be given together with Interferon injections. Hence Telaprevir and Boceprevir have become obsolete.

17. After a full assessment and MDT discussion, Mr Robert Hanley was commenced on treatment with Pegylated Interferon, Ribavirin and Telaprevir on February 20th 2013. His treatment was closely supervised (weekly appointments) by a BBV Specialist Nurse over the following weeks, including review of symptoms and potential medication side-effects, blood tests and repeat ECGs (to check for QTc prolongation). There were no concerns until he failed to attend for a scheduled clinic appointment on March 26th 2013. The following day our Specialist Nurse was informed by his brother that Mr Robert Hanley has sadly been found dead in the house. There were no witnesses to the death.

18. We are not sure exactly what was said to Mr Thomas Hanley at that point by our now retired Specialist Nurse, but we are certain that sincere condolences would have been offered. We suspect (as this would be our usual practice) that an offer was made for a meeting and further discussion with a Consultant from the Blood borne Virus (BBV) team. However, there is no documentary evidence to confirm this (the nursing notes were contained in the main paper case records which are no longer available). We do not think that any such further discussion did take place, but equally there was certainly no attempt to avoid this. There would also have been the opportunity for Mr Thomas Hanley to raise a formal or informal complaint with the hospital about his brother's care if he had concerns, where these concerns would have been addressed in a timely manner and with all records available. Our complaints department have confirmed that no complaint was received.

19. As this was a sudden unexpected death in the community, the case was referred (by the police we assume) to the Procurator Fiscal and a Post Mortem was performed to establish cause of death. This Post Mortem was not reported until May 2013. However, from the outset it appeared most likely that this was a sudden myocardial infarction (heart attack) without any clear connection to his hepatitis C treatment. As previously mentioned, Mr Robert Hanley did have risk factors for ischaemic heart disease and hence for a sudden heart attack, with his diabetes (which he had struggled to control well) probably being the main risk factor.

20. The post mortem report does confirm that ischaemic heart disease (heart disease due to inadequate blood supply to the heart muscle) was the immediate cause of death, with probable focal haemorrhage (bleeding) into a plaque (fatty deposits causing narrowing of the arteries) of one of the main arteries supplying blood to the heart. This appears to have caused a sudden severe obstruction to the blood supply to the heart, resulting in myocardial infarction (heart attack) and there were changes on microscopy consistent with a very early acute infarction (i.e a very recent heart attack). The post mortem also showed evidence of a bronchopneumonia (lung infection) as well as of quite severe liver disease, although not yet amounting to liver cirrhosis. The post mortem report conclusion does state that the presence of bronchopneumonia may well have put additional strain on his heart, with the severity of his liver disease potentially making him more susceptible to infections such as bronchopneumonia, thus making the liver disease a potential contributing factor in death. The Cause of Death is recorded as: 1a: Ischaemic Heart Disease. 2: Bronchopneumonia; Chronic Liver Disease [WITN5580005].

21. As this was clearly a serious clinical event occurring in a patient who was taking a recently licenced medication (Telaprevir), as per standard UK practice we reported his death to the MHRA using the 'Yellow Card' procedure. A copy of the report submitted is enclosed [WITN5580004]. Dr Kennedy completed this in his capacity as Lead Clinician, as Dr McGoldrick was on maternity leave by this stage. In is important to note that 'Yellow Card' reporting does not mean that the doctor making the report thinks that the drug was responsible for the serious

clinical event: it is a mechanism to ensure full transparency and to make sure that post-marketing safety information on new drugs is gathered.

22. We are aware that there were conversations between the Procurator Fiscal's office and the family (we assume Mr Thomas Hanley) later on in 2013 to discuss the cause of death. We do not know the detail of these conversations. However, the Procurator Fiscal's office did subsequently contact Dr Kennedy to clarify clinical details relating to Mr Robert Hanley's underlying medical problems and his HCV treatment. As far as we are aware the Procurator Fiscal was satisfied with the correctness of the established cause of death, as identified at Post Mortem and recorded on the death certificate, which was presumably relayed to the family.

23. With regards to question of whether or not Mr Robert Hanley ever received compensation for his HCV infection, we are unfortunately not in a position to answer this. Our standard practice at that point in time would have been to encourage and support all of our patients with suspected transfusion associated HCV to complete an application for Stage 1 payment from the Skipton Fund. Mr Robert Hanley's case does certainly appear to have been known to the Skipton Fund, as evidenced by correspondence between ourselves and the Skipton Fund in 2015 (see [WITN5580003]). The Skipton Fund may potentially also have further documentary details relating to the circumstances leading to his original HCV infection (we can unfortunately not help with this now due to his case-notes not being available). Further direct enquiry with the Skipton Fund should hopefully clarify these points.

Section 3: Other Issues

24. In conclusion, we would again like to extend our condolences to Mr Thomas Hanley regarding the sudden loss of his brother Mr Robert Hanley in 2013. We hope that this detailed account clarifies some misunderstandings of the events leading up to his death, and indeed the cause of death itself.

Statement of Truth

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

Signed ___ GRO-C

Dated ___6 April 2021_____

Table of exhibits if including:

Date	Notes/ Description	Exhibit number
February 2021	Curriculum Vitae	WITN5580002
	Clinical Notes of Mr R Hanley	WITN5580003
2013	Yellow Card submission	WITN5580004
9 May 2013	Post Mortem report of Mr R Hanley	WITN5580005
March 2012	Hepatitis C Infection, the Lanarkshire Management Guideline	WITN5580006
	INCIVO : Summary of Product Characteristics	WITN5580007