Witness Name: Dr Kosh Agarwal
Statement No.: WITN3770001
Exhibits: WITN377002-006
Dated: 18th Feb 2021

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF KOSH AGARWAL

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 19 September 2019.

I, Kosh Agarwal will say as follows: -

Section 1: Introduction

My name is Dr Kaushik (Kosh) Agarwal and my date of birth is GRO-C 1967.
Professional Address: Institute of Liver Studies, Kings College Hospital, Denmark Hill, London SE5 9RS

My professional qualifications are listed below:
1991 - BmedSci (Hons) 2.1 University of Newcastle
1992- MBBS
Text
1995- MRCP
2003 - MD University of Newcastle
2006- FRCP (Edinburgh)
2009- FRCP (UK)

I am a consultant Hepatologist and Transplant Physician at the Institute of Liver Studies, Kings College Hospital and was appointed in March 2006. I am the Lead of the Viral Hepatitis Service. In this role I co-ordinate and clinically manage patients across an Operational Delivery Network (ODN) in South London and Kent and oversee the largest viral hepatitis service in the UK. Between 2016 - 2019 this equated to

responsibility for approximately 1100/ patients / year treated for Hepatitis C Virus (HCV). I am a member of the national Hepatitis Clinical Reference Group (CRG), which provides clinical advice on national policy and I am also currently a Co-Director of the NIHR South London CRN (Clinical Research Network). I was previously the Lead of Hepatology at Kings (2015-19).

I have been involved in the care of viral hepatitis patients, including HCV since I was a trainee registrar in 1998 in the Regional Liver and Transplant Unit, Freeman Hospital, Newcastle. I spent a year as an Advanced Hepatology Fellow at Mt Sinai Hospital, New York and was appointed as a consultant in the Regional Liver and Transplant Unit, Freeman Hospital, Newcastle between 2004-2006 prior to my consultant appointment at Kings College Hospital.

I have contributed to several national guidelines in this clinical area and delivered international, national lectures and teaching programs in Viral Hepatitis.

I have been involved in the clinical development and trials for directly acting agents (DAAs) against HCV and have worked with pharmaceutical companies such as AbbVie, Gilead, and MSD in a scientific advisory and speaker capacity.

Section 2: Responses to criticism of W0653

I have reviewed the clinical notes for this patient, (having obtained patient consent for these to be released), who has been under the care of Kings College Hospital between 2013 and 2019. These are enclosed (exhibit WITN3770002). These demonstrate consistent care and appropriate documentation.

1. **Comment on paragraphs 49 & 50 - fibroscan**

   There is no medical literature that I can find stating that fibroscan is 'ineffective on people with EDS'. Fibroscan is a non-invasive test using a probe to assess the stiffness of the liver that is performed in the clinic. It is not a perfect method and all types of patients may have occasional 'odd' or un-interpretable readings, but it has been validated for fibrosis assessment in many liver conditions and is best used at the extremes of fibrosis (ie differentiating minimal/ no scarring *versus* advanced fibrosis/ cirrhosis). The normal method is to obtain and then average out 10 readings and this results in a score in KPa. This is not a precise test but is reproducible, safe and has been demonstrated to correlate with fibrosis (scarring) in the liver in several liver conditions but mainly HCV. The European guidelines recommend fibroscan as the modality of choice for assessment of fibrosis in HCV.

Clinically, a reading less that 6.5KPa is normal (i.e. no fibrosis) and greater than 12.5 KPa indicative of established significant scarring (cirrhosis).

It is worth highlighting that the clinical assessment and laboratory markers (platelet count, albumin, liver function tests, APRI score) did not (and still do not) infer advanced liver disease in witness W0653. Radiological imaging with CT scan (a more precise radiological assessment than ultrasound) in 2015 and 2019 demonstrate a normal spleen re-emphasising the likelihood of mild/ minimal scarring. 'Fatty liver' on ultrasound merely infers there is some fat in the liver (which is an extremely common finding) and can account for a finely 'heterogenous appearance.' These are not 'indicative symptoms of cirrhosis'.

On review of W0653's fibroscan results from 2014, 2015 and 2017 the results are below 6.5 KPa (3.8, 4.1and 4.3 KPa respectively), and the range of the readings (interquartile range – IQR) is quite small (indicating reproducibility). It is quite common for some readings to be invalid but certainly overall my clinical view was that the repeated fibroscan readings and scores were representative of minimal underlying liver fibrosis (WITN3770002).

2. **Comment on paragraph 50 – liver biopsy**

All objective and qualitative clinical parameters demonstrated that W0653 did not have advanced liver disease (fibrosis). The laboratory markers (platelet count, albumin, liver function tests, APRI score) did not (and still do not) infer advanced liver disease. Radiological imaging with CT scan (a more precise radiological assessment than ultrasound) in 2015 and 2019 (WITN3770003, WITN3770005) demonstrate a normal spleen re-emphasising the likelihood of mild/ minimal scarring. I did not feel that a liver biopsy in this situation was indicated, nor would be indicated, in any patient with the clinical parameters exhibited by witness W0653. Liver biopsy is an invasive procedure and carries a risk of morbidity and mortality. In 2013 non-invasive modalities such as fibroscan, whilst not perfect, were adopted as our basis for fibrosis assessment. A liver biopsy was not recommended or done because he had a 'bleeding disorder' *per se*; but given the history of Ehlers-Danlos Syndrome (EDS), and bruising, and specifically minimal concern of significant fibrosis, the risk- benefit, 'safety first' viewpoint would have been not in favour of an invasive procedure.

Furthermore, in view of the advice he had received, and his clear wishes, I spoke with our Professor of Radiology (Prof P Sidhu) and arranged a more sensitive ultrasound examination (acoustic radiation force impulse imaging – ARFI, a different way to assess fibrosis/ scarring in the liver) specifically to reassure and to

delineate with confidence that a liver biopsy was not indicated and to be confident about the level of fibrosis/ scarring. Adequate and repeatable measurements were obtained (WITN3770004) and confirmed the clinical view that he had minimal fibrosis (or liver scarring).

This highlights that paragraph 56 of W0653's statement is incorrect. I am sorry that the patient has misunderstood the results of our investigations.

3. **Comment on paragraph 52 -drug interactions**

Treatments to cure HCV have steadily evolved. In 2013, it was correct that the licensed treatments had moderate side effects and included agents such as Interferon. Thus at that time-point, the stated wish to wait for better treatments was the right decision, as the patient had no significant liver damage.

However, in 2015 and onwards the advent of licensed combination Directly Acting agents (DAA) therapy was established for HCV. Indeed, we were treating patients with advanced liver disease and transforming patient care. Our multi-disciplinary team were keen to offer these treatments as quickly as possible to those infected through Blood Products as we understood the additional issues associated with this cohort of patients. As a clinician who was treating many patients, including those needing liver transplants or with liver cancer, and who had been involved in the successful development of DAAs I was confident that there were no interactions with the other medications W0653 was receiving. The medication stated was not an unlicensed drug (Midodrine) but licensed for other conditions but not typically 'indicated' for the symptoms the patient was demonstrating. He was under other specific follow up for this separate condition. Given my familiarity with the interactions and DAA HCV drugs I did not need to check the interactions (we were treating 50-60 patients/ month at this time).

4. **Comment on paragraph 53 – consultation comments**

I recall my consultation with W0653 in 12/ 2015. As stated in my clinic letter, I did not feel we offered a pathway to him understanding that we had curative HCV treatments that were safe and that we would most likely improve his health status. I had met this patient previously with my senior clinical fellow and was asked to see the patient specifically subsequently given the complexity of the discussion. W0653 highlighted significant symptoms of joint pains, and fatigue and I suggested that he should consider the treatments we now had so that we could cure him and hopefully improve his symptoms. W0653 stated that he would not have

'experimental' treatments as he had been 'experimented on by the NHS' previously. We continued a circular conversation where upon all his frustrations with his NHS care were aired. I felt that I was being blamed for his HCV infection and can recall stating that *'whilst I was here to offer him the best care and was sorry for events, I could not be held responsible for what had occurred'*.

W0653 was frustrated and seemed only to wish to have me state he had advanced liver fibrosis but conversely would not consider treatment that we were 'fast tracking' for him. I did state that if he did not have faith in our clinical care and advice that I would be comfortable referring him elsewhere for expert management. This is my usual practice. I did not use the language stated, as I would never swear at a patient. I note from the clinical records (WITN3770002) that W0653 was comfortable having a subsequent consultation with me in July 2017. I also observe in paragraph 56 that the patient states he has not undergone HCV treatment, which is solely his choice and a decision we have respected. We have attempted to explain our on-going clinical recommendation (made by several members of our multidisciplinary team) over the time he has been seen in the Kings Hepatitis Service. I also note he has had meticulous follow up, blood test monitoring and regular ultrasound scans (WITN3770002).

5. Comment on Paragraph 54 – contents of letter

My clinical letter was delayed as I spoke to radiology to organise the ARFI test (for some reason it had been cancelled- WITN3770006) and recall phoning the patient to explain our plan of investigation and to ensure he was in agreement. I reflected on this clinic interaction and thus articulated that I felt I had not offered a good consultation as the patient had mistrust in our current clinical care and misunderstanding despite our best efforts. My letter inferred my opinion that his fixation around his route of infection were impacting on our ability to now improve his health. I agree that W0653 is entitled to feel bitter about his route of infection. Having managed and cared for many patients infected with HCV who have died and struggled through traditional HCV treatment, as well as bearing the stigma of this diagnosis, (however acquired), I feel I have some insight. I (and the Kings Hepatitis team) have always strived to do our best for this and all our patients in offering the best care and options of treatment. I note that several other witnesses to this Inquiry have positively cited examples of our care.

Lastly, I note the comments in paragraph 57 around perceived misconceptions from clinical colleagues about W0653's treatment status. Sadly, these perhaps relate to the fact that W0653 is quite possibly the only patient in our service under

follow up who has not taken up the opportunity of DAA curative HCV treatment; as we have been treating all patients (regardless of fibrosis stage) for well over 2 years now.

Section 3: Other Issues

Statement of Truth

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

Signed GRO-C

Dated 18th February 2021

Table of exhibits:

Date	Notes/ Description	Exhibit number
2013-2019	W0653 Kings clinical letters	WITN3770002
2013-2019	W0653 Kings clinical results	WITN3770003 - 6