Witness Name: Dr Aileen Marshall
Statement No.: WITN7660001
Exhibits: WITN7660002-007
Dated:

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR AILEEN MARSHALL

I provide this statement in response to the request under Rule 9 of the Inquiry Rules 2006 dated 31 August 2022.

I, Dr Aileen Marshall of The Royal Free London NHS Foundation Trust, Pond Street, London, NW3 2QG, will say as follows: -

Section 1: Introduction

1. I am a Consultant Hepatologist who qualified with (MBChB) from the University of Aberdeen in 1994. After obtaining my medical degree I completed my pre-registration House Officer rotations between 1994 and 1995 at Aberdeen Royal Infirmary and Raigmore Hospital in Inverness. Thereafter I worked in a range of Senior House Officer positions at Addenbrooke's Hospital between 1995 and 1997.

2. I undertook my specialist training in gastroenterology between 1997 and 2009.

3. I obtained my Certificate of Completion of Training (CCT) in gastroenterology and general medicine, with a sub specialism in hepatology in 2009, whereupon I was eligible to take up Consultant posts.

4. Thereafter from 2009 to 2011 I was Clinical Lecturer in gastroenterology at Addenbrooke's Hospital. I took up my first Consultant position as Consultant Hepatologist at Peterborough City Hospital in 2011 working there until 2013. Between 2011 and 2014 I also held the post of Honorary Consultant at Addenbrooke's Hospital.

Between 2011 and 2013 I also held the post of Clinical Fellow at Cancer Research UK working at the Cambridge Research Institute.

5. In January 2013 I took up my present post as Consultant Hepatologist and Honorary Senior Lecturer at Royal Free London NHS Foundation Trust. In addition to my medical degree I obtained Membership of the Royal College of Physicians (MRCP medicine) in 1997. I obtained a PhD in clinical medicine from the University of Cambridge in 2006. In addition I also hold a BSc in medical science which I obtained from the University of Aberdeen in 1991.

6. I became Clinical Lead for Hepatology at the Royal Free London NHS Foundation Trust in 2014.

7. The contents of this witness statement concern the treatment of W0491's late spouse. Information provided within my witness statement is based upon facts within my knowledge, save where I have indicated the source of my information or belief. Where matters are not directly within my knowledge, I believe them to be true.

Background to W0491's late spouse's treatment

8. Relevant to my response to the criticisms of W0491 at paragraphs 9-12, 15 and 34-35 of his witness statement dated 14 December 2020 is the system which was in place for treating patients such as W0491's late spouse with antiviral medication for Hepatitis C. In this regard, it should be noted that treatment with antiviral medication for Hepatitis C during the period which is the subject of this statement, was centrally funded, rather than being funded by an individual NHS Trust. In order to assess whether a patient was eligible for treatment, in November 2014 NHS England set up Operational Delivery Networks (ODN's) throughout the country to assess who could be considered for treatment according to the criteria laid down by NICE in their Technology Appraisal Guidelines and according to the eligibility criteria laid down by NHS England. There were a number of ODN's which covered different regions of the country. The Royal Free London NHS Foundation Trust fell within the North Central London ODN. W0491's late spouse would have fallen within the ODN covering the South of England/Portsmouth area, where she lived.

9. The ODN for the relevant region in which a patient lived would assess whether that patient could be considered for treatment, applying the relevant criteria. Where a patient was potentially suitable for treatment, these patients would then go on to be

considered for treatment at local multi-disciplinary team meetings (MDTs). The MDT would consider whether the patient was suitable for treatment, taking into account their various comorbidities and past medical history and if so which particular treatment regime would be most appropriate for the patient.

10. Prior to the ODN's coming into existence, each individual NHS Trust would fund antiviral Hepatitis C treatment on a local basis. The introduction of the ODN's was meant to centralise funding of this treatment and came about as a result of a number of new Hepatitis drugs such as Sofosbuvir being developed and approved for treatment.

11. With regard to funding of anti-viral Hepatitis C treatment, from March 2016 each NHS Trust had a target for how many patients could be treated. Where patients were eligible for treatment there was a considerable incentive for NHS Trusts to treat those patients, in order to maximise the funding available to the Trust. Therefore where patients were eligible and would benefit from treatment, they would be recommended for treatment, because clinicians were keen to use the full allocation of funding available to the Trust to benefit their patients.

12. In addition, prior to formal NICE approval for a particular drug, certain patients would be eligible for treatment via NHS England funded Early Access Programme. Treatment for patients in trials of antiviral Hepatitis C drugs was based on urgent clinical need. To be eligible for treatment on this early access programme they needed to be suffering from decompensated cirrhosis or life threatening disease, such as cryoglobulinaemia. W0491's late spouse did not meet the eligibility criteria for the early access programme, after her transplant on 23 March 2014, because she did not have decompensated cirrhosis or any other life-threatening condition caused by hepatitis C.

Chronology of NICE and NHS England approvals for antiviral treatment for Hepatitis C with Sofusbuvir

13. It is noted that W0491's criticism of me in relation to his late spouse's treatment relate to the alleged failure to treat his wife with Sofosbuvir, a new antiviral treatment for Hepatitis C which became available as part of certain specific treatment regimes prior to W0491's late spouse's death. In order to respond to W0491's criticisms it is therefore necessary to understand the chronology in relation to when drug treatments including Sofosbuvir were approved by NICE and in relation to which category of patient the NICE approval applied to. In addition, because NHS England was the body

which implemented the NICE Technology Appraisal guidance and laid down the criteria for which patients would be eligible for treatment based on the Nice appraisal, it is important to also to know when the various NHS England circulars confirming which new treatment regimes could be given to patients were published.

14. The first NICE Technology Appraisal guidance relevant to Sofosbuvir was NICE TA 330 published on the 25 February 2015. I attach a copy of this to my statement as **Exhibit WITN7660002**. This technology appraisal related to treatment of patients with Sofosbuvir for treatment of chronic Hepatitis C. The relevant sections of this document are found at page 5 where at Table 1 it confirmed that NICE did not recommend treatment with Sofosbuvir with Peginterferon alfa and Ribavirin for Hepatitis patients with genotype 1. In this regard it should be noted that W0491's late spouse was genotype 1. NICE's conclusions are found at paragraph 4.25 at page 63 of TA 330 and states as follows:

    "However, the committee concluded that based on the very uncertain evidence presented and the high ICERs, treatment with Sofosbuvir plus ribavirin for 24 weeks does not represent a cost effective use of NHS resources for people with genotype 1 treatment – experienced HCV who are intolerant to or ineligible for interferon treatment and therefore could not be recommended in this group".

15. For reasons which I will explain below, W0491's late spouse was treatment experienced and ineligible for interferon treatment and she therefore fell within the category of patients who would not have been eligible for this treatment regime. At the time this was the only treatment regime available using Sofosbuvir.

16. The situation was confirmed by the NHS England *"Clinical Commissioning Policy Statement Treatment of Chronic Hepatitis C in patients with cirrhosis"* published in June 2015, a copy of which I attach as **Exhibit WITN7660003**. The relevant section of this document is the table which runs from pages 7 to 19. This confirms that no treatment with Sofosbuvir as a constituent part was approved by NHS England for patients without cirrhosis. I will explain below why patient W0491's late spouse was not cirrhotic.

17. This was the situation which pertained until 25 November 2015 when NICE published TA 363. A copy of NICE TA 363 is appended to this statement as **Exhibit-WITN7660004**. The relevant section of the guidance is found at pages 55/56 at paragraph 4.20 and states as follows:

"On balance, the Committee concluded that only 12 week ledipasvir-sofosbuvir treatment could be considered a cost effective use of NHS resources in people with previously treated genotype 1 or for HCV without cirrhosis".

18. NICE TA 363 therefore confirmed that the newly available treatment with Ledipasvir and Sofosbuvir which became known as the Harvoni regime was effective for patients such as W0491's late spouse, who were genotype 1, not cirrhotic and were not treatment naïve. It should be noted that once NICE has published a Technology Appraisal approving a particular drug for use for a particular group of patients it usually takes 90 days for the guidance to be implemented locally.

19. In this case NICE TA363 was approved on 1st March 2016 by NHS England. I attach a copy of NHS England's Specialised Services Circular dated 1st March 2016 as **Exhibit WITN7760005** for ease of reference. The relevant section of this circular is found at page 4 where under the heading *"Implementing NICE guidance"* it is stated as follows:

"The NICE guidance recommends that the treatment decisions will be made by the Operational Delivery Network (ODN) Multidisciplinary teams (MDTs) prioritising patients with the highest unmet clinical need. Thousands of patients with cirrhosis are yet to be treated, and will face the highest risk of further progression. It is expected that as these highest levels of unmet clinical need are addressed the ODN MDTs access to an oral treatment for the following new groups of Hepatitis C Patients

- *Sofosbuvir – Ledipasvir-GT1 and GT4 patients, without cirrhosis, treated or untreated"*

20. It can be seen from this circular that from 1 March 2016 patients such as W0491's late spouse would be eligible for treatment with the Harvoni regime, but this would be subject to whether the patient had any comorbidities or medical history which made them ineligible for treatment.

21. In this regard, it is important to note that the European Association for the Study of the Liver (EASL) Recommendations on treatment of Hepatitis C dated 2015 which were in force until September 2016, a copy of which is attached to this statement as **Exhibit** WITN7660006 states as follows at page 206 (paragraph 2):

"While no does adjustment of sofosbuvir and ledipasvir is required for patients with mild or moderate renal impairment, the safety of the sofosbuvir-ledipasvir combination has not been assessed in patients with severe renal impairment (eGFR<30ml/min/1.73m2) or end stage renal disease requiring haemodialysis. Relative to patients with normal renal function (eGFR >80ml/min/1.73m2) sofosbuvir AUC was 61%, 107% and 171% higher in patients with mild, moderate and severe renal impairment, while the GS-331007 AUC was 55%, 88% and 451% higher, respectively. Thus no dose adjustment is required for patients with mild or moderate renal impairment, but no dose recommendation can currently be given for patients with severe renal impairment (eGFR <30 ml/min/1.73 m2) or with end-stage renal disease.".

22. Therefore the Harvoni regime was not suitable for patients with renal impairment. I will explain the significance of this for W0491's late spouse's treatment below.

23. The only other treatment including Sofosbuvir which was available from 1 March 2016 was Daclatasvir. The NHS England Specialised Services Circular published on 1 March 2016 (see **Exhibit WITN7660005**) is clear at page 4 that this treatment was only approved for genotype 1 patients without cirrhosis, treated or untreated, if the person had significant fibrosis. For the reasons which I will explain below this did not apply to W0491's late spouse.

W0491's late spouse's treatment

24. W0491's late spouse was a patient who lived in West Sussex. She was being treated at St Richard's Hospital in Chichester. Patients who lived in W0491's late spouse's area would be referred to the Royal Free London NHS Foundation Trust if they were on the transplant waiting list, in need of a transplant, or in the case of W0491's late spouse had already undergone a transplant and were receiving post-transplant care. Because W0491's late spouse had comorbidities and poor mobility it was agreed that she should be treated at the Queen Alexandra Hospital in Portsmouth which was closer. She could then be seen there by Royal Free London NHS Foundation Trust hepatology clinicians.

25. In this regard, the Royal Free London NHS Foundation Trust had a service level agreement whereby hepatologists from the Royal Free Hospital would treat patients such as W0491's late spouse in joint clinics at Queen Alexandra Hospital, which would run 3 or 4 times a year. I was one of the Consultants who went down to Queen Alexandra Hospital to see patients at these clinics, and I had been doing this since I

had joined the Trust as in 2013. In these clinics, I would see patients in conjunction with the local Consultants, in this case usually Dr Fowell Consultant Hepatologist at Queen Alexandra Hospital.

26. Reference to W0491's late spouse's medical records, which have been obtained by my solicitors Bevan Brittan LLP, disclose that W0491's late spouse was a patient who was receiving post-transplant care from the Consultant's at the Royal Free Hospital following a liver transplant performed on the 23 March 2014. She had undergone the transplant for decompensated cirrhosis secondary to genotype 1 chronic Hepatitis C. She had suffered complications as a result of the surgery including major bleeding secondary to a hepatic artery aneurysm and localised wound infections. This necessitated an extensive inpatient stay and this is referenced in W0491's supplemental statement dated 14 December 2020 at paragraph 8 where he makes reference to the liver transplant and the fact that his wife was not finally discharged following the surgery until August 2015.

27. I refer to a letter dated 29 October 2013 from Professor Ala at Frimley Park Hospital who notes that W0491's late spouse had had failed interferon and combined therapy in the past twice. A copy of this letter is attached to this statement as **Exhibit WITN7660007**. For this reason W0491's late spouse was not treatment naïve.

28. I note that I saw W0491's late spouse together with Dr Fowell at a clinic at the Queen Alexandra Hospital on the 9 September 2015. In a letter dated 21 September 2015, it was noted as follows:

"With respect to Hepatitis C treatment, there was no evidence of significant liver fibrosis on liver biopsy performed in December 2014 and as such there is no urgency to clear Hepatitis C. Moreover, current National guidelines do not allow the use of new directly acting interferon – free regimens in post-transplant patients without a significant liver injury due to Hepatitis C. This may of course change in the fullness of time and if the new drugs become available for patients such as Mrs -- then we would be pleased to prescribe them. The only high efficacy Hepatitis C drug regimen that might be funded at present would be one including Sofosbuvir Interferon and Ribavirin
but given her various ongoing medical problems we are keen to avoid Interferon."

29. This letter is appended to this witness statement at **WITN7660007**. I should point out that unfortunately we are missing the final page of this letter from the records provided to me.

30. The letter references the fact that W0491's late spouse asked us whether she would be eligible for treatment with Hepatitis C. As referred to in the letter, it would have been explained to W0491's late spouse that unfortunately she was not eligible for treatment with the new drug Sofusbuvir at the time because as referenced in **Exhibit WITN7660002,** NICE TA330 did not approve the use of Sofosbuvir in combination with Peginterferon alfa and Ribavirin in adults with genotype 1. This was because in patients such as W0491's late spouse who had undergone a liver transplant there was a risk of inducing a rejection in a post-transplant patient treated with interferon. It is therefore normal practice only to use interferon containing treatment regimens if there was evidence of post-transplant liver fibrosis. The reason for this is because in patients without fibrosis, the risk of using interferon, and triggering rejection outweighed the benefits of using the treatment regime. W0491's late spouse did not suffer from fibrosis and so was not eligible for treatment regimes including Sofosbuvir at that time.

31. I note that there is also a letter dated 23 March 2016 relating to a clinic on the 9 December 2015, a copy of which is exhibited to this statement at **Exhibit WITN7660007** which references a discussion with W0491's late spouse regarding her eligibility for antiviral Hepatitis C treatment.

32. At paragraph 2 of that letter it states as follows:

"I have not made any changes to her management today. It is important now we get a Sirolimus trough level performed and I have given her form [sic] to have this done at the surgery (it would of course require sending away and needs a EDTA tube). The team from the Royal Free have provided her with a 3 month supply of Sirolimus today in clinic, which they brought from London and they will do the same at the next appointment in 3 months time. We undertook transient elastography today which gave a normal liver stiffness of 5.9 kPa. This effectively rules out significant fibrosis or cirrhosis and reassures that she is not developing rapid fibrosis progression associated with Hepatitis C post transplantation. We are hopeful that Interferon – free Hepatitis C treatment will be available for non-cirrhotic patient such as Mrs -- during the course of 2016, but this is subject to NHS England approval on funding, which to date is yet to be received".

33. There is no reference in the letter to whether I was present at this clinic, but the letter refers to a team from the Royal Free being present that day, so I would have seen W0491's late spouse that day. I can see from the letter that Dr Fowell appears to have had a further discussion with W0491's late spouse about her eligibility for Hepatitis C

treatment with Sofosbuvir. The letter confirms that at that stage W0491's late spouse had no significant fibrosis or cirrhosis, and also that she was therefore still not eligible for treatment with Sofosbuvir.

34. I note that I next saw W0491's late spouse at Queen Alexandra Hospital on the 18 May 2016 in the company of Dr Fowell and the clinic letter dated 20 May 2016 is appended to this statement at **WITN7660007.** At this clinic it was noted that W0491's late spouse's health had improved somewhat which is indicated by the fact that at paragraph 1 of the letter we noted that we were impressed that she had managed to walk the short distance from the waiting room with 2 sticks, indicating improved mobility.

35. At the time W0491's late spouse was exhibiting new symptoms including tachycardia and peripheral oedema. We considered that her symptoms were likely to be related to her anti-rejection treatment, which was required in relation to her liver transplant. This was likely to be a reaction to her medication Sirolimus and for that reason we had decided to stop this medication and switch her back to her previous immunosuppressant drug regime with Tacrolimus and Mycophenolate Mofetil. In the clinic letter of the 20 May 2016 there is a reference to a further discussion which we had with W0491's late spouse regarding anti-viral Hepatitis C treatment which states as follows:

"The other issue we discussed was her Hepatitis C. Interferon free treatment is now funded for patients such as -- who have chronic Hepatitis C and are post liver transplantation. We have advised waiting until she is established on her new immunosuppressant regimen, but then our Hepatology Nurse Specialists will be in touch with a view to us offering her Harvoni. The NHS England recommended first choice therapy would be the Abbvie regimen, (based on her prior treatment status and genotype 1 infection), but this can be problematic from the point of view of drug interactions especially with Tacrolimus dosing and the Harvoni regimen would be preferred".

36. It's clear from this letter that the plan was therefore for us to proceed with antiviral Hepatitis C treatment with Harvoni (which includes Sofosbuvir). It is therefore notable that we had planned to start antiviral treatment including Sofosbuvir only some 2½ months after NHS England had confirmed that a patient such as W0491's late spouse was eligible for treatment with this drug. However, we could not commence the treatment immediately, because she was starting a new immunosuppressant

treatment regime. Starting a patient on antiviral drugs at the same time as starting a new immunosuppressant treatment regime is contraindicated. In the circumstances the plan was to wait for 4 – 6 weeks for W0491's late spouse to settle into the new treatment regime before offering her the Harvoni antiviral treatment.

37. It should be noted that W0491's late spouse was not eligible for treatment using the Daclatasvir regime, which included Sofusbuvir, (which was approved by NHS England on 1st March 2016). As referenced at paragraph 32 above the letter of 23 March 2016 states that transient elastography performed on 9 December 2015 found no evidence of fibrosis. As referenced at paragraph 23 above, this treatment was only approved for genotype 1 patients without cirrhosis, treated or untreated, if the person had significant fibrosis.

38. I note from the Queen Alexandra Hospital correspondence that I saw W0491's late spouse again together with Dr Fowell at a clinic on the 31 August 2016. I append the clinic letter dated 5th September 2016 referencing what was discussed at that meeting at **Exhibit WITN7660007**. Unfortunately when I saw her on the 31 August 2016 she had had significant health problems since I had last seen her. This had led to her hospitalisation at St Richard's Hospital with problems with peripheral oedema and heart failure which we noted was in part due to proteinuria and hypoalbuminaemia. She had been discharged from St Richard's Hospital in August 2016, but had been immediately readmitted via accident and emergency to Queen Alexandra Hospital with similar problems and aching muscles.

    The letter of 5 September 2016 references a discussion which we had regarding potential treatment for Hepatitis C at paragraph 2 page 2 which states as follows:

    "We touched on the issue about Hepatitis C. Her current renal impairment would make treatment difficult and we suggested that she needs to be more clinically stable for us to consider treatment. If her renal function improves then we would use currently licensed antiviral therapy, but if the renal function remains at her current level (eGFR<30) then we would need to wait for newer agents that are better renally tolerated and are yet to be fully approved and funded by NHS England."

39. As noted in the letter of the 5 September 2016, at the time W0491's late spouse was suffering from renal impairment. As referenced at paragraph 22 above, the Harvoni treatment was contra-indicated in patients with renal impairment, and therefore unfortunately it was not possible to proceed with anti-viral treatment incorporating

Sofosbuvir at the time. In addition, at that time there were no anti-viral treatments available for patients such as W0491's late spouse with renal impairment which were approved by NHS England. I should point out that the third page of this letter is missing from the records which have been provided to me.

40. The final reference in the correspondence to a discussion with W0491's late spouse and her husband regarding potential Hepatitis C treatment is in a letter of the 25 November 2016 sent following a clinic on the 23 November 2016. A copy of that letter is included at **Exhibit WITN7660007**. I note that there is reference to this discussion in the final paragraph of that letter which states as follows:

"I will see her again in Satellite Clinic in 3 months' time and may see her again on the ward as an Inpatient as necessary. Finally, her husband asked again about Hepatitis C treatment. Drugs are now available to treat her genotype 1 infection, but not in the context of her degree of renal impairment. There are newer drugs coming on line that can be used in patients with low eGFRs, but we stressed that the priority at the moment is to get the other medical problems under control and then to treat the Hepatitis C once things are more stable. By this stage, the drugs may be routinely available to NHS England, but if not may require an individual funding request."

At the time W0491's late spouse was an inpatient under the care of the renal team at Queen Alexandra Hospital, after being transferred from St Richard's Hospital the previous week, where she had been an inpatient for around 5 weeks. Unfortunately her degree of renal impairment continued to preclude W0491's late spouse from being started on the Harvoni regime.

41. I can see from W0491's late spouse's records for the Royal Free London NHS Foundation Trust, the Portsmouth Hospitals NHS Trust and the St Richards Hospital records, copies of which have been obtained by Bevan Brittan, that thereafter W0491's late spouse remained a patient at Queen Alexandra Hospital until at some point she was transferred to St Richard's Hospital. I have access to a discharge summary for the Royal Free London NHS Foundation Trust which confirms that W0491's late spouse had been transferred from St Richard's Hospital on the 23 February 2017 with a diagnosis of an Ecoli abscess in the liver and hepatic artery conduit. I note she remained an inpatient at the Royal Free Hospital until the 28 April 2017 when she was transferred back to St Richard's Hospital. I note that during her time at the Royal Free Hospital she had undergone a PTC drain insertion for biliary drainage. She had

undergone an ultrasound of the liver which had showed the hepatic artery conduit to be occluded with an abscess present in segment 8. Unfortunately she suffered a fall on the ward on the 5 March 2017 when attempting to get to the commode, sustaining head trauma. W0491's late spouse was transferred back to St Richard's Hospital on 21 April 2017. I note that very sadly her condition did not improve and she died on the 25 May 2017.

42. Very sadly, the state of W0491's late spouse's health following the limited period in May 2016 when her health improved enough to consider antiviral Hepatitis C treatment, was never again good enough to consider treatment with Harvoni.

Response to criticisms by Witness W0491001

43. With regard to my comments regarding Witness W0491001's comments at paragraphs 9 to 12 and 15 of his supplemental statement dated 14 December 2020, I agree that I would see W0491's late spouse together with Dr Fowell approximately every 3 months at the Queen Alexandra Hospital. I also agree that there would have been discussion about the effectiveness of the new drug Sofusbuvir for Hepatitis C genotype 1 patients. Reference to the correspondence exhibited to this statement does show we had regular discussions with W0491's late spouse and her husband regarding her eligibility for treatment with Sofusbuvir. It is correct to say that on the 9 December 2015 there were discussions about the fact that she was not yet eligible for treatment with Sofusbuvir. As referenced above treatment with Harvoni was planned at the clinic on the 18 May 2016 but subsequently W0491's late spouse was too unwell to undergo treatment.

44. At paragraph 34 I note that it is stated as follows:

"I cannot stop wondering whether the consultants I have mentioned above wilfully withheld details of a beneficial treatment or were simply negligent in failing to prescribe it. In my more cynical moments I tend towards the former."

45. For the reasons set out above, W0491's late spouse was not eligible for treatment with a treatment regime including Sofusbuvir until the Harvoni regime was approved for

treatment by NHS England on the 1 March 2016. At the clinic on 18 May 2016, when W0491's late spouse's health had improved, we planned to treat her with Harvoni as soon as she had settled on her new immunosuppressant treatment regime. Thereafter W0491's late spouse's renal impairment and state of health was never sufficiently good for her to undergo treatment with Sofusbuvir.

46. In the circumstances I submit that it is clear that there was no decision to wilfully withhold anti-viral treatment with Sofusbuvir and no negligent failure to provide treatment. The decision not to commence the Harvoni regime was based on clinical grounds, because commencing this treatment was contraindicated because W0491's late spouse was renally impaired.

47. At paragraph 35 it is stated as follows:

"In general, I believe that Sandra encountered resistance to being prescribed a potentially life saving drug due to financial considerations and austerity measures. Although it is possible that medical considerations informed the decision, I feel the medical establishment and Sandra's treating clinicians missed an opportunity to save her during her window of wellbeing in late 2015/early 2016. I believe that at this time she would have been well enough to endure the course of treatment".

48. I do not agree with the suggestion that financial considerations and austerity measures prevented W0491's late spouse's treatment with antiviral medication including Sofusbuvir. Until 1st March 2016 there was no treatment regime including Sofusbuvir which was available to genotype 1 patients who were not cirrhotic, were not treatment naïve, where treatments including Interferon were contraindicated. These treatments were not available based on NICE guidance regarding which treatment regimes were efficacious and safe.

49. As I have explained above, funding for new antiviral drugs to treat Hepatitis C were not funded by individual Trusts but funded centrally by NHS England. Clinicians were keen to treat patients for their benefit and to ensure they utilised the full allocation of funding available to each ODN. As I have explained above, the reason treatment did not go ahead was because W0491's late spouse needed to settle on her new immunosuppressant drug treatment regime. Thereafter her health deteriorated and the extent of her renal impairment precluded treatment with Harvoni.

50. Finally I note that W0491 references a missed opportunity to prescribe antiviral medication which might have saved his wife's life. In fact W0491's late spouse did not die of complications connected with Hepatitis C infection, but from a range of medical problems, including complications associated with the transplant surgery she underwent in March in 2014, including an hepatic artery bleed and damage to the biliary tree. There was no evidence of significant liver fibrosis developing post-transplant. For these reasons, even if she had undergone treatment with Harvoni, sadly this would not have prevented her death.

51. Finally I note the contents of paragraph 42 of W0491's supplemental statement dated 14 December 2020. It is not within the remit of this statement to consider all the queries raised in that paragraph. However I hope that this statement has answered his queries regarding when NICE approved Sofosbuvir and when in 2016 W0491's late spouse was eligible to receive a treatment regime including this drug.

52. In conclusion, I should add that I was very sad when W0491's late spouse died in May 2017, particularly because she was a patient I had treated for some time and got to know well. I extend my sympathies to W0491.

Statement of Truth

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

Signed GRO-C

Dated 28 February 2023

Table of exhibits:

Date	Notes/ Description	Exhibit number
25th February 2015	NICE TA 330	Exhibit WITN7660002
June 2015	NHS England Clinical Commissioning Policy Statement	Exhibit WITN7660003
25 November 2015	NICE TA 363	Exhibit WITN7660004
1st March 2016	NHS England Specialised Services Circular	Exhibit WITN7660005
25 March 2015	Paper from Journal of Hepatology EASL Recommendations on Treatment of Hepatitis C 2015	Exhibit WITN7660006
Various	Extracts comprising correspondence from patient W0491's late spouse's medical records	Exhibit WITN7660007