

Witness Name: Stirling Pugh
Statement No.: WITN4523001
Exhibits: WITN4523002-007
Dated: 21 July 2020

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR STIRLING PUGH

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 29 May 2020.

I, Stirling Pugh, will say as follows: -

Section 1: Introduction

1. My name is Stirling Pugh, and my work address is Department of Gastroenterology, Musgrove Park Hospital, Somerset Foundation Trust, Taunton TA1 5DA. My date of birth is GRO-C 1955. I qualified in 1979, and my current qualifications are PhD, FRCP, MSc (Medical Education), FHEA.
2. I am on the GMC specialist register for General (Internal) Medicine and for Gastroenterology. I have been a Consultant Gastroenterologist in Taunton since 1994 to date. I retired and returned part time in February 2015.
3. I am a general Gastroenterologist, latterly specialising in Hepatology until 2017, and I led the Viral Hepatology treatment at the Trust for many years. In 2010 my Hepatitis C service won Local and Regional NHS Acute Care awards, were National runners-up for the 'Taunton Model of Hepatitis C treatment evaluation (2010)'.
4. At the Trust I have been Gastroenterology Service Lead, Endoscopy Service Lead and Clinical Director of Medicine.
5. Regionally and Nationally, I was Chairman of an Expert Working Group for the Department of Health for Luminal Gastroenterology (HCG Chapter F) and a member of the Expert Working Group for Hepatology and Pancreatic diseases (HCG Chapter G) for over six

years. I was a member of the national Hepatology Commissioning Group and Somerset HA Blood Borne Virus Strategy Group (2009 to 2012), which developed Clinical Care pathways for Hepatitis C, direct referrals from and out-reach clinics in substance abuse units.

6. I have been asked to prepare this statement in respect of the Infected Blood Inquiry to specifically respond to concerns raised by witness W0072 in her statement dated 20.6.2016 at paragraphs 43 – 45 and elsewhere, and to assist the enquiry.
7. In order to prepare this statement, I have reviewed the relevant medical records of witness W0072 (having obtained witness W0072's written consent to do so) that relate to her care whilst I was her Consultant and the documents relevant to Hepatitis C and the treatments she received. I have reviewed the witness statements of witness W0072 dated 20 June 2016 and 25 July 2019. I also rely on my personal recollection of events from my involvement at that time, and my usual clinical practice at that time.
8. With regard to the medical records that I have reviewed for the purpose of preparing this statement, I confirm that I have reviewed witness W0072's paper records (5 volumes) and electronic records. The Specialist Nurse paper Hepatitis C treatment records were not found in the notes, but there are handwritten comments in clinic notes from the Hepatitis C Specialist Treatment Nurse.
9. I have been asked to provide this statement in order to respond to the following query: "At paragraphs 43-45 of her first statement, witness W0072 recalls that she undertook her first round of Interferon and Ribavirin treatment in around 2007, which she did not complete, and a second round of treatment in around 2009 or 2010, which successfully cleared the virus. She states that following the second round her physical condition was very poor, but that you appeared pleased because you could 'tick a box'. Please comment on this."
10. In order to provide a response to this, I first set out below a chronological account of my factual involvement with witness W0072 and then I will respond to the concerns that witness W0072 has raised.
11. In addition to responding to the concerns raised in paragraphs 43 and 45, I have added some additional factual responses to some of witness W0072's evidence where it is in my factual knowledge to provide a response in the event that may assist the Inquiry.

My Involvement:

12. I first met Witness W0072 on 13 March 2003 when I was asked to perform an upper GI (gastrointestinal) endoscopy for investigation of her symptoms of abdominal pain. At that

time, witness W0072 was a patient with the surgical team. Witness W0072 was then under the care of other gastroenterologists between 2003 and 2005 for further investigations and treatment of her gastrointestinal symptoms, but I was not involved in witness W0072's care during this period.

13. My first involvement with management of witness W0072's hepatitis C was on 4 September 2007 when I saw her in the Hepatology Clinic at the request of one of my colleagues to consider starting anti-Hepatitis C treatment. Her risk factors for hepatitis C were blood transfusions she told me she had in the 1970's. Witness W0072 told me that she never been an intravenous drug user. I also took over the care of her Crohn's disease and its treatment.
14. On 1 October 2007 I wrote to witness W0072, confirming infection with hepatitis C Genotype 2B with high viral load but no clinical evidence of advanced liver disease and I suggested combination treatment with interferon and ribavirin which was the standard treatment at that time. The plan was to wait for witness W0072's decision to commence treatment.
15. Following a response from witness W0072, I would have requested that she was seen in the Specialist Nurse Hepatitis C treatment clinic. According to the clinical records (WITN4523002), I note that she was seen in the treatment clinic on 4 January 2008 and advised about the risks and side effects. She was provided with an information sheet and prescription and the GP was sent a letter advising of the start of treatment with interferon and ribavirin. Witness W0072 attended the treatment clinic for blood tests on 18 January 2008 when she explained to the Specialist Nurse that she was feeling unwell with flu-like symptoms for which she had received treatment by her GP.
16. Witness W0072 contacted the Hepatitis C Treatment Nurses on 29 January 2008 (WITN4523002) to say that she had stopped the medication because she could not cope and was feeling anxious and not in the frame of mind to continue treatment. It was suggested by the Hepatitis C Treatment Nurses that she consider restarting treatment in a year's time.
17. From the records, I note that witness W0072 had approximately twenty-five days' treatment with dual interferon and ribavirin between 4 and 29 January 2008 (WITN4523002).
18. Witness W0072 was seen in the Gastroenterology Clinic by a Specialist Registrar on 3 February 2009 for follow up of Crohn's disease. The hand-written notes record, 'keen on trying interferon again, willing to go full length of treatment.' (WITN4523002).

19. Witness W0072 started her second course of pegylated interferon and combined ribavirin treatment in April 2010 (WITN4523003) and viral load fell to <15 iu/ml on 7 May 2010 indicating a rapid viral response which meant she could have a shorter 24-week course of treatment.
20. Unfortunately, in May 2010 witness W0072 developed tight jaw muscles, and this was thought, by the Gastroenterologist (who also treated patients with Hepatitis C) who saw her in my absence, to be a probable side effect of ribavirin. He advised that ribavirin treatment be reduced from three tablets twice daily to two tablets twice daily.
21. I saw witness W0072 on 4 June 2010 when she still had tight jaw muscles. I did not record any mouth ulcers, but if that had been a symptom, it would have been my usual practice to have examined the patient, documented the findings and suggested treatment. I suggested treatment with pentoxifylline (which was considered at that time to help with ribavirin side effects) and low dose diazepam for jaw muscle spasms.
22. Witness W0072 was seen by the Specialist Nurse in the Hepatitis C Treatment Clinic on 2 July 2010, it was noted in the records that she was feeling 'Much better. Slight discomfort in mouth – otherwise coping well with medication.' (WITN4523003).
23. On 30 July 2010 witness W0072 was seen by the Specialist Nurse in the treatment clinic who recorded 'No real problems, coping well, pleased with result.' (WITN4523003)
24. Witness W0072 was seen in the Gastroenterology Clinic for her Crohn's disease (also under my care) by the Gastroenterology Specialist Registrar on 3 August 2010. The clinic letter records that Witness W0072 was 'extremely pleased that her Hepatitis C is responding so well to treatment.' (WITN4523004).
25. Witness W0072 completed anti-hepatitis C treatment on 24 September 2010, having had twenty-four weeks of combined pegylated interferon and ribavirin (WITN4523003). I was asked to see her at that visit to the treatment clinic because she had symptoms of diarrhoea related to bacterial overgrowth, which was a complication of her Crohn's disease and previous gastrointestinal surgery, for which I had treated her for before. I advised a trial of antibiotic treatment with oxytetracycline.

Following Treatment:

26. Witness W0072 continued under my care in the Gastroenterology clinic and was seen 4 times in 2011; by the Gastroenterology Registrars 3 times, and by myself once on 6 December 2011. Our notes do not document any Hepatitis C treatment side effects. She did present at the appointment with me on 6 December 2011 (15 months post treatment) with mouth ulcers and sore eyes, and my clinical impression was that these were non-

gastrointestinal manifestations of active Crohn's disease (WITN4523006). I advised restarting Budesonide (a form of steroid) treatment, amongst other treatments, for her Crohn's disease.

27. I also wrote to witness W0072 about her investigations and treatments on several occasions in 2011. The main issues I was addressing were Crohn's disease symptoms of diarrhoea, which I investigated and I wrote to her with the results of blood tests, MRI small bowel scan, the results of a colonoscopy and biopsies (which confirmed active Crohn's disease), and a SeHCAT scan (which confirmed Bile Acid Malabsorption).
28. In addition to her clinical care, witness W0072 and I were in communication about the Skipton Fund. In total I have found from the records 14 clinical or Skipton Fund communications with her in the 9 months from March 2011 to December 2011.
29. The clinical notes that I have reviewed from 2011, following completion of treatment for Hepatitis C, do not mention hair loss or mouth ulceration.

Section 2: Response to Points Raised By WITNESS W0072

30. The Inquiry has asked me to address the following: *"At paragraphs 43-45 of her first statement, witness W0072 recalls that she undertook her first round of Interferon and Ribavirin treatment in around 2007, which she did not complete, and a second round of treatment in around 2009 or 2010, which successfully cleared the virus. She states that following the second round her physical condition was very poor, but that you appeared pleased because you could 'tick a box'. Please comment on this."*
31. Unfortunately, with the passage of time I do not remember the discussion that witness W0072 describes and I cannot find any reference to it in the handwritten records I have available to me at the time of preparing this statement, or in any letters that I have reviewed. I was always pleased for patients when treatment could be confirmed as successful by completion of the follow up blood test at 6 months post treatment and that we could report as such to the Regional Audit, upon which further funding for treatment of other patients was dependant. Based on my usual practice, I would have been concerned if witness W0072 had felt unwell at this point and would have assessed her symptoms and investigated as necessary. I would not have felt any pleasure if witness W0072 was unwell, and I am sorry if witness W0072 has interpreted any response at that time in that way.
32. I have checked in the notes and cannot find any reference to my seeing witness W0072 immediately after the result became available.

33. We could not have told witness W0072 that she was 'cured' until March 2011 after she had been off treatment for 6 months when a negative Hepatitis C virus PCR test at that stage would indicate Sustained Virologic Response (often rephrased as 'cure'). This news would have been conveyed by one of the Specialist Hepatology Treatment Nurses.
34. In the intervening 6 months she continued under the care of the Hepatitis C Treatment Specialist Nurses for follow-up post treatment including blood tests. She had follow-up appointment arranged in December 2010 which I note from the records that she could not attend, and she attended for follow up in January 2011 and March 2011.
35. In March 2011 a hand-written note by the Specialist Nurse at the time blood tests were taken records 'no problems.' (WITN4523003)
36. I wrote to witness W0072 on 4 April 2011 saying thank you to her for the kind 'Thank You' card and gift she had sent me. (WITN4523005)
37. The first documentation I can find of my seeing witness W0072 face to face following the Hepatitis treatment outcome in March 2011 is a clinic appointment for Crohn's disease follow up on 6 December 2011. (Please see above and WITN4523006). There were no discussions documented about the Hepatitis C treatment, which had been completed 15 months earlier in September 2010, or any effects.

Section 3: Other Issues

38. Although I have not been asked by the Inquiry to respond specifically to any other points in witness W0072's statement, there are a few points that I would like to address where it is in my factual knowledge to provide a response in the event that may assist the Inquiry. For ease of comment, I have put the paragraph reference in bold below and my comments follow from that in response.
39. At paragraph 44, witness W0072 states that at the end of Hepatitis C Treatment, '**After a few tests they said that I was clear of the virus. I felt like I was booted out with no care.**'
40. I am sorry that witness W0072 is of the understanding that she was not given further care. Following the end of treatment she had appointments to see the Specialist Nurse on three occasions (see WITN4523003 and paragraphs 33-35 above) and she continued under follow up with me for her Crohn's disease (see paragraphs 25-27 above). She was seen in the Gastroenterology Clinic, in which we also saw patients with Hepatitis C, 4 times in the year following the end of treatment.

41. In addition she also had access to the Hepatitis C Specialist Nurse Help telephone number and to me via telephone and letter. From the records I see I talked to her by telephone on 7 June 2011 about the Skipton Fund and Crohn's disease symptoms, I responded to letters from her on 5 August 2011, 7 September 2011 and 26 September 2011.
42. In the subsequent 2 years her follow up in the Gastroenterology department continued at the same intensity related to investigation and treatment of her Crohn's disease.
43. At paragraph 49, witness W0072 states: ***'I do not have liver function tests; I do not know how my liver is. No one tells you anything.'***
44. I am sorry that witness W0072 is of the understanding that she is not having liver function tests. The records that I have reviewed demonstrate to me that she has had recent liver function tests. Specifically, witness W0072 continues to be seen in the Gastroenterology Clinic for the follow up of Crohn's disease. Symptoms related to Crohn's disease continue to be an issue. The last letter (copied to witness W0072) I can find which specifically mentions liver function is in 2018 which lists 'previous hepatitis C with subsequent normal liver function.'
45. From the notes that I have seen, liver function tests have been performed many times since the end of Hepatitis C treatment, and 5-6 times a year over the last two years, during follow up of witness W0072's other health conditions. I note that witness W0072's latest blood tests from February 2020, requested by witness W0072's GP, show normal liver function tests.
46. At paragraph 54, witness W0072 expresses the concern that: ***'nobody ever warned me about the side effects of the drugs I took to clear hepatitis C'***.
47. Again, I am sorry if this is witness W0072's understanding, but I do not believe that this accords with the documents that I have seen nor my own recollection of my care. In 2008 and 2010, when Witness W0072 had treatment, dual therapy with interferon and ribavirin was the standard treatment available. I, and the Hepatitis C treatment specialist nurse, were always very frank with all our patients that the treatment could be onerous. The Specialist Nurse documented discussions about risks and possible side effects and provided an information leaflet at the start of witness W0072's first treatment in January 2008 (WITN4523002). The evidence I have found in the notes is that, at the conclusion of treatment and six-months afterwards, the issues witness W0072 presented to us were related to her Crohn's disease (WITN4523003).
48. I have not found any evidence that the conditions witness W0072 believes have been caused by Hepatitis C treatment (interferon and ribavirin) are related to that treatment.

49. The neurologists who investigated the peripheral neuropathy did not indicate any association. I wrote to witness W0072 on 4 January 2017 about the peripheral neuropathy and the Skipton fund application at the request of her current consultant gastroenterologist (WITN4523007). In that letter I explained that I did not think the hepatitis C treatment had caused the peripheral neuropathy.

50. A past medical history of back problems, and a history of back surgery were present when I took over witness W0072's care in 2007 and predate the interferon and ribavirin treatment.

51. The other conditions mentioned in witness W0072's statement (osteopenia and oral lichenoid keratosis) were not conditions that I can find evidence of whilst she was under my care, which concluded in 2013. I note that witness W0072's reference to these is from 2015 onward (5 years after the end of her Hepatitis C treatment) and therefore I am not in a position to comment on them as they are outside of my factual involvement in witness W0072's care.

Statement of Truth

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

Signed 

Dated 21 July 2020

Table of exhibits:

Date	Notes/ Description	Exhibit number
4 January 2008	Handwritten clinical records 1	WITN4523002
4 June 2010	Handwritten clinical records 2	WITN4523003
3 August 2010	Clinic letter	WITN4523004
4 April 2011	Thank You letter	WITN4523005
6 December 2011	Clinic letter	WITN4523006
4 January 2017	Correspondence	WITN4523007