

Witness Name: Helen Caldwell

Statement No.: WITN3441001

Exhibits: None

Dated: 20.11.2019

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF HELEN CALDWELL

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 10 June 2019.

I, Helen Caldwell, will say as follows: -

Section 1: Introduction

1. My name is Helen Caldwell, my address is GRO-C
GRO-C and my date of birth is GRO-C 1967.
2. By way of professional qualification, I am a registered nurse, a non-medical prescriber, hold a Masters in Research and a Certificate of Education.
3. With respect to positions held as a medical professional I have been a Nurse Consultant in Hepatology at the Royal Liverpool University Hospital since 2008. My responsibilities include: Nurse Lead for hepatitis C in the Cheshire & Merseyside area; managing the hepatitis C treatment services in the Liverpool area; providing leadership and clinical support for the nurses in the team; dissemination of expertise to healthcare professionals engaged with patients with viral hepatitis in Primary and Secondary Care, Drug Dependency Units and local prisons; and managing patients with liver disease using advanced autonomous decision making and advanced clinical skills.

4. My other responsibilities as a nurse consultant include working alongside the medical hepatology team caring for patients with chronic liver disease in an out-patient environment. This is to ensure we deliver a high quality service to patients with liver disease using my advanced autonomous decision making and advanced clinical skills. I also manage a defined caseload of patients with links to joint clinics with existing medical consultants. My role also includes a nurse led paracentesis service for patients with end stage liver disease. I also continually try to establish effective, focused two way relationships with primary care to promote community care for patients with liver disease.
5. I am not or have never been involved in any committees or groups relevant to the Inquiry's Terms of Reference

Section 2:

At paragraph 34 of Ms Nevin's statement, she claims that all of Mr Nevin's appointments have been with you and that you told them that Mr Nevin would not experience any clearing treatment side effects (or virtually none). Ms Nevin claims that the tablets were given to them without the box and without a patient information sheet regarding the medication and its side effects. The physical and mental side effects of the treatment for Mr Nevin turned out to be 'horrendous' and included, amongst other things, rashes, flu-like symptoms, nausea and mood swings. Please comment on this.

6. The hepatitis C treatment clinics have been nurse led since 2000. There are a team of nurses across two specialities (Liver and Infectious Diseases) who deliver treatment in a designated hepatitis C clinic in the Royal Liverpool Hospital. From a hepatitis C clinical point of view, they are managed by myself, the Nurse Consultant in Hepatology and supported by a Consultant Hepatologist and a Consultant in Infectious Diseases. All the patients are seen in the clinic by a specialist nurse and then discussed at a weekly multi-disciplinary team (MDT) meeting which consists of the Consultant Hepatologist, Consultant in Infectious Diseases, Pharmacist and a Nurse Consultant or Specialist Nurse. During the MDT meeting, each case is discussed and a treatment plan is arranged. The treatment is then delivered in a nurse led clinic. Each patient who is on treatment is monitored in the clinic on a regular basis.

7. The patients are asked to attend the pharmacy department to pick up their medication and are to bring it back to the clinic where the nurse will, discuss potential side effects and discuss any concerns before being dispensed. All the medication is distributed with a summary of product characteristics (SPC). I did not see Sean on the day he commenced treatment, he was seen by one of my colleagues however she has stated in her letter to the GP that side effects had been discussed, which is standard practice. I have been reassured by the pharmacy department that all medication is dispensed with a SPC.
8. Sean was seen in the clinic by me, two weeks after starting treatment and I have documented that he was complaining of reflux of which I suggested over the counter remedies. He also complained of dry skin and I wrote to the GP asking him/her to prescribe Oilatum bath oil and diprobase cream. I then documented that he was coping well with no further issues. Routine bloods were obtained and he was given a further supply of medication by Pharmacy and a follow up appointment was arranged for 2 weeks later.
9. Two weeks later he was reviewed by a colleague and she commented in her letter that Sean's rash has improved with the creams however he was complaining of tiredness and was breathless on exertion. His bloods from 2 weeks previously did show a drop in haemoglobin (HB 151 down to 117) and my colleague did discuss a reduction in his ribavirin 'if it drops further' and then arranged repeat bloods. Anaemia can be a side effect of the ribavirin treatment and the guidelines as per SPC indicate reduce ribavirin if haemoglobin drops below 100 and discontinue if haemoglobin drops to 85.
10. Sean was reviewed at week 4, 8 and end of treatment, his haemoglobin remained stable (Hb 116) however he did comment about being 'snappy' at times and also feeling tired. He was reassured that side effects usually desist once treatment has been completed.
11. Sean was then reviewed 3 months post treatment, there was no mention of any long term side effects.

At paragraph 35 of Ms Nevin's statement, she alleges that the cost of the treatment seemed to be your paramount concern and that you made it clear that there was a

limited budget and that unless Mr Nevin accepted the offer of treatment straight away, he would miss out. Please comment on this. Please comment on this.

12. The new hepatitis C treatment (DAAs) were deemed expensive drugs and when they first became available patients were given treatment in order of priority i.e. patients with severe liver disease (in the context of hepatitis C, defined as a fibroscan >11.5kpa), patients who were co-infected and prison inmates. Patients with haemophilia were not deemed as priority. However, Sean's fibroscan was elevated at 12kpa therefore allowing him to be treated immediately. This was explained to him, but at no time did we ever consider not treating Sean because of a limited budget or lack of funding.

13. As said previously Sean had a high fibroscan which, in the context of hepatitis C, indicated he may have advanced fibrosis as a result of this, this is the reason why the MDT team, felt he should be treated as soon as possible, to prevent Sean progressing to cirrhosis or liver failure.

Section 3: Other Issues

14. There are no other issues I wish to comment on.

Statement of Truth

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

Signed

GRO-C

Dated

20-11-19