Tuesday, 8 March 2011

(9.30 am)

THE CHAIRMAN: All of us on the Inquiry team, and I in particular, are all very conscious of the importance of this Inquiry to very many of you. It deals with matters that have affected lives. It also deals with matters that have resulted in death. And I think it would be appropriate that we acknowledged that fact by having a minute's silence at this stage to acknowledge the seriousness of the issues that we are beginning to explore. So if you can stand, we will stand now and have that one-minute silence.

Thank you very much, ladies and gentlemen.

Ladies and gentlemen, we are now about to begin this phase of the Inquiry, in which evidence will be led to enable me -- and I am afraid the responsibility is mine -- to make findings in fact on the issues that I have to resolve. This isn't the time for submission or argument. That will come, to the extent it is necessary, after all the evidence is out and we can see things in the round and take a reasonable view of what is contentious and what is not.

As you can see, we are surrounded by information technology and we may well be confronted with the odd problem. I would be very surprised if it all worked all

of the time to everyone's satisfaction. I think experience suggests it never does.

So we will take things easily at the beginning, so far as the IT is concerned, and if difficulties do arise, then please make sure that the Inquiry team finds out what's not working and they will try to assist participants to get the best out of the various forms of display and device that we have.

Ladies and gentlemen, this is a statutory inquiry. I'm bound by the terms of the Inquiries Act by the procedural regulations that are made under it and, what I referred to already, by my terms of reference. Within that framework I have particular responsibility to take such steps as I can to ensure that the proceedings are conducted in an efficient and cost-effective way.

Of course, everyone these days talks about economy but I would like to set it in a particular context for you and that is this: this Inquiry is funded from the National Health Service Scotland's budget. Every pound that is spent on the Inquiry is a pound that is not available for the care and treatment of National Health Service patients in Scotland. Every hour of clinicians' and other specialists' time that is spent at this Inquiry is an hour that is not available for scientific research or for the care and treatment of

patients in the wider health service.

So when I ask you, please, to bear that in mind and to understand that if I do try to keep control on matters, it is not for some quixotic reason or to support a government policy, it is to try to ensure that what we do here is worthwhile, that it is as comprehensive as it needs to be but that it avoids going into issues which are not my business.

However, I'm sure that we will work out a way of living with each other as we go along, even though there will be the odd hiccup, inevitably, on the way.

Ladies and gentlemen, the first stage in this Inquiry is, in effect, a fatal accident inquiry into the death of Mr Tamburrini and Ms Dunlop will open up that investigation immediately.

I have only got one bit of sort of practical advice to give you and that is that we will have a break. We will have a break somewhere round about 11 o'clock. I don't want to have a fixed time because I expect Ms Dunlop and counsel to tell me whether the timing is right and sometimes we will start a little early, sometimes we will start a little late, but so far as possible, the ideal will be to try to accommodate everyone to the best that we can.

Thank you very much.

Ms Dunlop?

Introduction by MS DUNLOP

MS DUNLOP: Thank you, sir. As you have explained, our first task is to look at the deaths of four individuals and this week we will endeavour to do that.

We are going to begin with the death of Victor Tamburrini, who died on 17 November 2004. An important part of the narrative of Mr Tamburrini's illness is his treatment in Glasgow Royal Infirmary in 1984 when he sustained burns. It would, sir, assist understanding of the rest of the evidence if we were to look at some material regarding that at the outset. So, before leading the evidence of any witnesses, I would like to look at some documents. The documents concerned are [TAM0012835] to TAM0012843. If we could have those on our screens.

If we could start with TAM0012835, please thank you. That's it.

You will see, sir, that this is a page from Glasgow Royal Infirmary. It is headed "Clinic and ward notes", dated 7 September 1984, emergency admission via the gate, and there is then a story from, presumably, Mr Tamburrini, of what had happened: that there had been a fire in his car, that he had sustained burns and also a little bit about personal circumstances.

If we look at the bottom where it says "Social" we see that he has a stall in a fruit market. He is married but has no family, no brothers and sisters and is a non-smoker.

TAM0012836. We see, on examination, what has been noted. The extent of the burns, and then, slightly further down, the doctor writes his impressions, towards the bottom of the page, about 20 per cent burns, probably no smoke inhalation and under, what is a management plan, we see "IV plasma running".

Then TAM0012837. TAM0012837 we note that the doctor taking the history is A Hendry. We can all see that in the box at the top of the page, and TAM0012838, that he has received plasma protein solution and we can see that, if we look, there is a box or a heading about a third of the way down the page, "Summary on discharge from shock room", and we can see that there are five possible codes for the IV colloid, and a number 5 has been entered in box 25 to show that he received plasma protein solution.

If we look at TAM0012840, we see from that that he was discharged from hospital on 6 October, 1984 and we see that that's at the foot of the page on the right-hand side, and TAM0012842, TAM0012843 refer to possible review in November to see what progress he had

made in recovering from the burns.

We also need to look at page [TAM0012462] and you can see, sir, that it is an intravenous therapy prescription sheet. I pointed out earlier that the doctor who took the history from Mr Tamburrini was Dr A Hendry, and we can see Dr Hendry's signature at least in relation to the first four infusions of PPS, plasma protein solution. We can also take from that page that the batch number of the PPS was 1194 and that almost all of the entries relating to the administration of the plasma protein solution are signed by two people, apart from the third entry. So one can see from that the regular administration of the solution which the doctor had prescribed for Mr Tamburrini on account of his burns.

The second matter I would refer to, simply by way of an introduction, is that Mr Tamburrini also received NHS treatment in 1998 when he underwent surgery. That will be covered in evidence tomorrow when Dr Peterkin is coming and will speak to that episode.

With that brief introduction, my Lord, my first witness is Mr Jean Tamburrini.

MRS JEAN TAMBURRINI (sworn)

THE CHAIRMAN: Do you prefer to sit or stand?

Mrs Tamburrini, Margaret, I think you know, is sitting here with you. Giving evidence can be quite

stressful so if you feel that you get into a wee bit of trouble from time to time, she is primed to respond. Just tell her what you would like and we will look after you.

Ms Dunlop.

Questions by MS DUNLOP

MS DUNLOP: Thank you, sir. Now, Mrs Tamburrini. I think Margaret took a statement from you; is that right?

A. Yes, she did.

Q. You have seen the statement since it has been typed up?

A. Yes.

Q. Do you have a copy of the statement in front of you? I think it will come up on the screen, in fact, if you wait. It is [PEN0010309]. Thank you.

I should explain, sir, that this version of the statement is not, in fact, Mrs Tamburrini's signed version. We do have another version, which is signed but we don't have a code number for that one yet. So we can work from this one. I think it is more or less the same as the version that you finally signed. Do you recognise that then?

A. Yes.

Q. Thank you. Mrs Tamburrini, I'm not going to ask you to read it out or ask you a whole lot of questions about it, but I thought perhaps we could cover one or two

points in the statement perhaps, where a bit of further clarification might assist us; just so you understand that that's what I'm seeking to do.

You tell us your personal details in the first paragraph and you tell us that you are the widow of Victor Tamburrini. You are from Glasgow; is that right?

A. Yes.

Q. Glasgow born and bred?

A. Yes.

Q. You say in your second paragraph that you met Mr Tamburrini, Victor. Did you call him "Victor" or "Vic".

A. Vic. His mum and dad called him "Victor".

Q. May I call him "Vic"?

A. Please.

Q. You met Victor in 1987 and you were married on 8 March 1991. I think, in fact, he had been married before. Is that right?

A. That's correct, yes.

Q. So when you got married, he must have been 30 and you were 27. I think -- is that --

A. We met when I was 27.

Q. All right, sorry.

A. We actually got married -- I would have been 30 when I got married.

Q. So when you met he was 30 and you were 27, and in fact you knew about his having had a car accident?
A. Yes, he had mentioned it, yes.
Q. But that was before you had known him?
A. That was before I had known him, yes.
Q. In your third paragraph you tell us about moving into a flat together in 1988 and that you would come home from work in the evenings and find that Vic was in bed?
A. Yes.
Q. What were you working as at the time?
A. I was working in retail, in the city centre.
Q. I'm sorry?
A. I was working in retail, Dorothy Perkins.
Q. You would get home from work, what, about tea time?
A. Maybe 6, after 6.
Q. Although you do go on to say that he was starting work at 4.30 am?
A. Yes, he did start work early.
Q. So he must have had to be up --
A. In fact, quite early.
Q. Before 4?
A. About half four I would say, I think he actually started -- maybe 5 o'clock, but he was up early.
Q. So you were certainly struck at that time by the fact that he was quite tired?

A. Yes.
Q. Is that fair? And then he was paid off from his job in 1991. That's the job at the fruit market?
A. Yes.
Q. And then he started working for his uncle in a factory. Was that another time when he had to be up early in the morning?
A. He was up early, not as early as the fruit market, maybe about seven-ish, if I can remember.
Q. And he was still a bit tired at that time; is that right? You say he found it difficult to keep his energy levels up?
A. Yes.
Q. And in fact he had to stop that and that's the point when he moved to work in a public house?
A. Yes.
Q. Then, 1998 he went to the doctor. He was feeling unwell and that really seems to have been the beginning of a period when he was increasingly seeing doctors, and in fact, if we look at paragraph 7, he went to Glasgow Royal Infirmary as well. And in fact, he had an operation in Glasgow Royal Infirmary in 1998 which we will go on to hear about from one of the doctors as well?
THE CHAIRMAN: The page has taken some time to catch up so

that, in fact, we have not been looking at paragraphs 5/6.

MS DUNLOP: Perhaps if we take a moment to do that. I will try to keep my eye on where the statement is.

Right, so we have covered paragraphs 5, 6 and 7 which is, I think, just narrative really, Mrs Tamburrini, of the 1990s?

A. Hm-mm.

Q. And if we could pause at the bottom of that page and look at something that happened in 1999, which is not actually covered in your statement, because I think there was some medical attention in 1999 in connection with gallstones. If we could, please, look at page [TAM0012572] in the medical records.

Do you see that letter now, Mrs Tamburrini?

A. Yes.

Q. That's a letter to Dr Jamieson at Bridgeton Health Centre from a consultant surgeon. That would be Vic's GP?

A. Yes.

Q. Is that your GP too?

A. Yes.

Q. And it tells us that he had been admitted as an emergency with severe epigastric pain and what had been wrong, and he had had a ultrasound which showed that he

had some large stones in his gall bladder. So he had had an episode of pain caused by gallstones, it seems; this is March 1999.

If we look at the next page, 2573, we can see that that's a letter relating to a further review in the pancreatic clinic and there have been some investigations carried out. Did you remember, or perhaps even just remember now when you see these letters, that there was a problem with gallstones?

A. He was actually told he had -- it was something wrong with gallstones, then they said something about food poisoning. That was mentioned as well. I don't know why.

Q. Right, fine.

Perhaps we could go back to your statement. If we go back to where we were, which was page 0310 in [PEN0010309]. In fact, we could go to 0311. You tell us some more about what happened in 2000 and 2001. In fact, I think, as we will see when we come to look at the hospital records, in 2001 he ended up at the Royal Infirmary by two different routes simultaneously. One through the GP and one through the dentist. I think you mentioned that in paragraph 9, that the dentist said he needed some medical attention, and then paragraph 11, that he was going to the outpatient clinic a few times,

and then in September 2001, he was told that he had Hepatitis C. Now, you say:

"I asked him what that was and he said he didn't know."

But I expect you knew that it was a liver illness, did you?

A. Being honest, no.

Q. No, right. Did you know that it was a virus?

A. We didn't really know anything about -- I knew a girl that had hepatitis one time years ago, through drinking out a dirty glass. I never thought anything -- it was to do with the liver.

Q. But I imagine that as the time wore you learned an awful lot more about it. Is that fair?

A. Yes.

Q. Right. If we look at the next page, 0312, and you tell us in paragraph 13 that, in fact, you yourself were tested and it was discovered that you didn't have Hepatitis C, but obviously some information was given about the need to be careful, especially with blood. So did you understand that the virus could be transmitted from getting blood from somebody else?

A. I was told I had to go and get tested, obviously, and then realised how serious it was.

Q. By February 2002, Vic was ill enough to be being

considered for a liver transplant. You tell us about that in paragraph 14, that he went to the liver transplant clinic at the old Edinburgh Royal Infirmary. That would be the old building in the centre of Edinburgh?

A. That's right.

Q. And you tell us that there was some discussion with the transplant coordinator about how serious his condition was. It must have been quite a shock to you to discover that he was going to need a liver transplant?

A. That was quite a big shock.

Q. You remember that quite clearly?

A. I remember that and sitting in the room with Roseanne. Vic was getting -- they were taking him away to get assessed.

Q. And then you actually tell us in paragraph 15 that you were having a difficult time yourself with your own health at that point:

"Vic stopped work in the summer of 2002."

You say:

"He continued to go to work when he felt up to it but he was unable to work a full day."

Is that still the bar job?

A. Yes.

Q. I think he became the manager of the bar, did he?

A. Yes, it was my brother-in-law's bar. So he was very good. He knew that Vic was ill and told him he didn't need to come in but he always sort of tried to get in.
Q. If we look at PEN0010313, please. It sounds as though the transplant actually going ahead was quite a sudden event. Is that right? I think he left the hospital one day and then there was a phone call to say that there was a liver available --
A. He got took in to hospital. No, he was feeling ill. I had to take him through Edinburgh, and they kept him in, and that's when he got -- he was on the waiting list. Because he had an infection and they said he would need a transplant, and he was supposed to -- I think he might have been in for about two weeks, and my brother-in-law and I were supposed to pick him up on 26 October to bring him home to wait, and I got a call that morning from one of the doctors to say that they had found a donor. So we had to go through -- my brother and I, we went through before he went into theatre that afternoon.
Q. So quite a sudden development, though, that the transplant was to happen?
A. Yes.
Q. Is that right? And then you say he made good recovery and he was in hospital for about a month. Actually that

period, between the transplant on 26 October and his leaving hospital on 15 November, would be one day less than three weeks, which doesn't seem very long for such a big operation. So I take it he did recover from that quite well?

A. He was in the high dependency only for one day and then he was back on the ward, and I think they were quite pleased because he was only 47, remember, he was a healthy guy before.

Q. Right. You tell us in the next paragraph about Vic going back and forward to Edinburgh Royal Infirmary for check-ups, and I suppose at some point the hospital moved out to Little France?

A. That's correct, yes.

Q. It must have been a bit of a trek for you?

A. Especially when you get lost.

Q. Did you get lost trying to find the new Royal?

A. Even when Vic came out and we had to go back for his appointments, we always took the wrong turning.

Q. I'm sure those of us who are actually local can sympathise with the difficulty of getting there. It is not always very easy.

By August -- and this is looking at paragraph 19 at the bottom of the page -- you say that Vic really wasn't so well again, and I think what you are describing is

that he was a bit jaundiced. He was a bit yellow in colour. You are nodding. Is that right?

A. Ah-huh.

Q. Now, Mrs Tamburrini, I don't want to take you through all the details of what happened from then on because we will be looking at the medical records with the doctors, but in short, he ended up having a second liver transplant in February 2004. Is that right?

A. That's correct.

Q. Yes. That operation, you say, didn't go so well. I'm now on 0314. Following the second transplant, paragraph 21, he was very unwell and you say he became a totally different person. One of the things that happened after the second transplant was that he was given antiviral medication?

A. Yes.

Q. Do you remember that?

A. Yes.

Q. Did you understand what the point of that was?

A. Yes, it was treating Hepatitis C. Well, hopefully going to treat the Hepatitis C.

Q. Was that partly because it was the Hepatitis C that had largely contributed to the failure of the first transplant?

A. Yes.

Q. So they were concerned to get in as quickly as they could and try and treat the Hepatitis C to give the second transplant a better chance of success. Is that your understanding?
A. That's my understanding, yes. I think the first time round they were just -- the drugs that Vic was getting, it was to stop the liver -- his body rejecting the first liver, and then obviously when it came back the second time, they decided to treat the Hepatitis C.
Q. And you say he had to inject himself. That was part of the antiviral medication?
A. Yes.
Q. I think some of it was injection and some of it was tablets. Is that your memory?
A. Yes.
Q. You remember the injections. And then paragraph 23. I think we all remember things better if there has been a family event around a time because it gives us a landmark, and you are telling us about a family wedding in April 2004 when Vic was really very unwell. Then by your own birthday on 6 October, you say he was getting confused and disorientated. Can we look at the next page, 315. He went in as an inpatient to Edinburgh Royal Infirmary and he passed away on 17 November 2004.
So in short, Mrs Tamburrini, unfortunately the

second transplant, despite everyone's efforts, was not a success?

A. No.

Q. Mrs Tamburrini, it is obvious to us all that Vic showed great courage throughout his illness and we do understand that it is not an easy thing for you to come here today and talk about it. I'm not going to ask you any more questions now but I do want to thank you for coming here today to assist us.

A. Thank you.

THE CHAIRMAN: Ms Dunlop, have you discussed with Mr Di Rollo and Mr Anderson whether they have other matters that may be raised.

MS DUNLOP: I haven't, sir, and I don't know whether they want to raise any matters with Mrs Tamburrini.

THE CHAIRMAN: Mr Di Rollo, Mr Anderson, of course, I have no notice of any questions you do wish to raise but I would be anxious not to impose the full strictures of the procedural regulations if I could avoid it, but it would be helpful if I knew whether there were issues that you wanted to ask about. Is there anything you want to raise with Mrs Tamburrini, Mr Di Rollo.

MR DI ROLLO: No, thank you, my Lord.

THE CHAIRMAN: Is there anything you wish to raise.

MR ANDERSON: No, sir.

THE CHAIRMAN: My hearing is not all that good sometimes, too.

Mrs Tamburrini, thank you very much for attending.

A. Thank you.

THE CHAIRMAN: Ms Dunlop?

MS DUNLOP: Sir, my next witness is Dr Andrew Bathgate, and I know that Dr Bathgate is in the vicinity but it may take a moment or two for him to be located because I think he may have gone for a brief walk. (Pause)

THE CHAIRMAN: Ms Dunlop, I think I'm getting indications again that there is difficulty in hearing.

I wonder, Mr Di Rollo, can you feedback what is happening.

MS DUNLOP: The difficulty may be, sir, when I move away from this microphone to look at the screen. There is a second microphone. It is possibly going to be trial and error on this. Can I adjust it so that it is pointing slightly more upright. I'm also being told that the difficulty is in hearing the witness.

(Discussion re microphone)

THE CHAIRMAN: Ladies and gentlemen, this has got to be a bit of trial and error. We have to get the systems properly calibrated so that everyone can hear but can I remind you that there is an alternative for a particular problem that is severe: we have got

something, not a loop, we couldn't put a loop in here, but there is an alternative that provides, in effect, a mini loop that would increase the sound volume for a particular person. We might try that when we have a break. Let's see if we can get things to work.

MS DUNLOP: Sir, I understand that actually I am audible. It is yourself and the witness who are difficult to hear.

THE CHAIRMAN: That's not unusual. I'll try and make good -- can you hear that?

MS MCCANN: I think you need to keep it closer to you.

THE CHAIRMAN: I think fortunately, ladies and gentlemen, I have said nothing that matters. So there was nothing lost but I will try to behave.

MS DUNLOP: Sir, Dr Andrew Bathgate is here and he is my next witness.

DR ANDREW BATHGATE (sworn)

Questions by MS DUNLOP

THE CHAIRMAN: Dr Bathgate, stand or sit according to what you find convenient.

MS DUNLOP: Dr Bathgate, you are a consultant hepatologist, I gather?

A. That's correct.

Q. And you are based in the Centre for Liver and Digestive Disorders, which is ward 205 at the Royal Infirmary in

Edinburgh. Is that right?

A. And the liver transparent unit, yes.

Q. That's the liver transplant unit.

I do have a copy of your curriculum vitae, which I don't know a number for but I gather is about to appear on the screen. Yes, it is already there.

From which we learn that -- and I'm now on the third page -- you are a graduate of Edinburgh University Medical School. Is that right?

A. That's correct, yes.

Q. And in your elective you spent some time in Zimbabwe and in Israel?

A. Yes.

Q. We see that you graduated -- this is at the bottom of the page -- from medical school in 1991. Then on the next page, page 4, we see you have an MD. What did you study for your MD?

A. It was liver transplant and acute cellular rejection within liver transplantation, prediction of that, 18 months' research.

Q. Thank you. Then if we turn to page 6, you tell us what your current job involves. You are currently working full time in the gastroenterology unit and the liver transplant unit. So you have a one week in four commitment to the unit. Is this still accurate?

A. We have an additional colleague, so it is one week in five.

Q. And you participate in the long-term follow-up of transplant patients. You do an ERCP list each week. Can you just give us a brief indication of what ERCP is?

A. It stands for "endoscopic retrograde cholangiopancreatography", so basically it is an endoscope camera going down through the stomach to the area where the bile duct comes into the small intestine, and depending on what the problem is, doing therapeutic manoeuvres within the bile duct. Usually it is a small gallstone that you aim to remove, or if there is a narrowing in the bile duct, a stricture, put a plastic stent through that to relieve obstruction.

Q. Right. You have a teaching commitment, which you set out on page 8 of your research, and then your teaching. On page 9, lectures that you have given over the period 2009 to 2010. You then list research awards you received, and moving on, we see publications. Then listed on pages 10, 11 and 12, chapters you have contributed to books and reviews and case reports, and then finally your membership of learned societies, professional and other. I think they are all professional really.

So equipped with that piece of background, I would

like, if I may, Dr Bathgate, to ask you about your involvement in the care of Mr Victor Tamburrini.

You have prepared a report about Mr Tamburrini and that is [TAM0012380]. I think it is TAM0012380. Yes. And it is up on the screen in front of us. I don't think you have actually got a date on it, Dr Bathgate, but we have noted that we received the report in September 2010. So, sir, if you could take this report as being dated September 2010.

Now, what I would like to do, Dr Bathgate, is to ask you some detailed questions about Mr Tamburrini, but I think it might help us all if we began by looking at the more general section of your report.

A. Okay.

Q. So can I ask you to look at TAM0012382, you give us a bit of background on Hepatitis C. Now, during the course of the Inquiry, we are obviously going to hear a lot more about Hepatitis C but for the moment, you tell us that Hepatitis C is an RNA virus. It infects humans, obviously, and is transmitted through contact with infected bodily fluids. Is that mainly blood to blood?

A. Mainly blood to blood.

Q. And you say that in Scotland, the most common route of transmission is sharing needles, although you also

mention blood product transfusion:

"Most infections, no acute illness. Infection is only discovered if a specific blood test is performed."

You then tell us that the virus has six major genotypes, of which three are commonly found in Scotland. We can see that the three that are commonly found in Scotland are 1, 2 and 3. There is, as I understand it, a kind of global distribution of different genotypes; is that reasonable?

A. That's correct, yes.

Q. I'm being reminded that actually there is a date on this, and you wrote it on 19 August 2008. So although we received it in 2010, we should take the date of it as being 19 August 2008. I'm sorry about that, sir.

Still on TAM0012382, you tell us that:

"The rate at which the liver is damaged by the virus is variable. The virus causes inflammation, hepatitis and scarring, fibrosis of the liver. The end stage of scarring is termed 'cirrhosis'."

Then you say:

"The rate at which cirrhosis occurs depends on the age of the individual at the time of infection and the route of transmission."

Then you have a graph, which is on TAM0012383. I have studied the graph to make sure I understand it.

I'm going to have a go, and please correct me if I am wrong, but in a nutshell, what this graph seems to tell us is that, to start with, of those who have post-transfusion hepatitis, which is the tallest column, the one on the left, 24 per cent will progress to cirrhosis over a period of 20 years and the mean age of that group of people at infection is 42. Is that right?

A. Absolutely correct.

Q. I'm relieved about that. Now, we can do the same exercise for the other three columns, so, when you say "liver clinics", is that just the run of patients at liver clinics?

A. These were patients who were referred on account of their Hepatitis C, and obviously that is all comers who have Hepatitis C, so anybody who would have additional risk factors would be included. So that probably explains the rate at which they progress slightly more quickly compared to the other two columns.

Q. Because, actually, there isn't much between the first two columns. 22 per cent of those seen at liver clinics will progress to cirrhosis over a period of 20 years and the mean age of that group at infection is 29, I think we can see from the bottom.

It is interesting also that blood donors are a column in their own right. So someone has looked at

a group of blood donors. Is that blood donors who are testing positive for Hepatitis C?

A. Yes, so they come to donate blood and everybody gets a Hepatitis C test. So people who are found to be Hepatitis C positive. So they are otherwise quite healthy individuals.

Q. Yes. And that is an exercise that has been possible in the UK since 1991, when screening of blood donations was introduced?

A. In the UK, yes.

Q. In the UK. And in fact, that was not possible until scientists had identified the virus or isolated the virus.

A. Correct.

Q. Which took place two or three years before that. Correct?

Now, you tell us, underneath the graph, that the main co-factor in hastening progression -- and that's progression of the cirrhosis --

A. Fibrosis to cirrhosis, yes.

Q. -- is alcohol, and that:

"The liver may continue to work well for a number of years with only 20 per cent, having a significant deterioration in ten years."

You then have a section -- and this is scrolling

down the page a little bit -- on treatment. Some people can get rid of it themselves. Young females apparently are doing quite well?

A. Yes.

Q. And there have different studies to try and ascertain what the rate of spontaneous clearance might be. There are also drug treatments available, and we have just heard, in fact, about Mr Tamburrini in 2004 having had drug treatment, and you explain on 2384 what the standard therapy at present is: pegylated interferon and ribavirin. So interferon is something people have to inject and ribavirin is tablets?

A. That's correct, yes.

Q. And again, this is something about which we will be hearing a great deal more, but these drugs cause significant side effects. Is that --

A. Absolutely, yes.

Q. You say:

"The duration of therapy depends on the genotype, with genotype 1 requiring 12 months of therapy, and 2 and 3 requiring six months."

Can we take anything from that to indicate that genotype 1 is, in some sense, the most serious, or is this purely about response to treatment?

A. It purely is about response to treatment. If you look

at outcomes, there is no difference between the different genotypes. It is purely a response to therapy.

Q. The last sentence on that page is:

"Treatment is less effective in individuals with cirrhosis and in the post-liver transplant setting."

I just wondered whether, briefly, you could explain to us why that is thought to be so?

A. Interferon stimulates your immune system and that's how it works. So in a sense, it is trying to help you clear the virus. So anything that will, in a sense, damp down your own immune system in any way will impair the effect of interferon, and people who have cirrhosis tend to have a dampened-down immune system. In the post-liver transplant setting they are given drugs to damp down the immune system and that is the reason that it doesn't work as well.

Q. I have noticed from some of the medical records that people have tacrolimus after they have had a transplant. Is that the principal antirejection?

A. Tacrolimus and azathioprine are the immunosuppressants, but tacrolimus is the principal one, yes.

Q. Thank you. If we look at the next page, you have a summary of Mr Tamburrini's notes. I would like, if I may, to cover this next part of your evidence by

making reference to medical records as well, just so that we can see entries in context.

A. Okay.

Q. So if we call up some pages and ask you to look at them. I would like to start in February 2002, which is the point at which Mr Tamburrini was referred by Dr Adrian Stanley from the Royal Infirmary in Glasgow to your unit. Dr Stanley is also a hepatologist. Is that correct?

A. That's correct, yes.

Q. So can I ask you to have a look at [TAM0012565]? And we can see that this is a letter dated 14 February 2002. This is Dr Stanley writing to Dr Simpson. Dr Simpson is a colleague of yours, I take it?

A. He is, yes.

Q. He is asking if you could -- "you" in the broad sense, meaning the liver transplant unit:

"... could review this 44-year old gentleman, having been found to be Hepatitis C positive."

PCR is just one form of testing for the virus. Is that correct?

A. Yes. The hepatitis C antibody, if that is positive, that means that you have met the virus at some point. PCR is actually looking for the virus, the RNA in the blood. So that determines if you are still infected.

Q. Right, thank you.

It says:

"With no obvious risk factors ..."

Dr Stanley moves on to mention his specific concern perhaps which is that his alphafetoprotein was 156 in October and then 366; 449 and then 535. Why is he so worried about that?

A. Alphafetoprotein is a marker of liver cell cancer. So Hepatitis C cirrhosis is a risk for liver cell cancer, and Alphafetoprotein becomes raised in cancer but it also can become raised in active hepatitis, particularly the viral hepatitis, either Hepatitis C or Hepatitis B, but at those sorts of levels, you would accept something up to about 200/300 usually for active viral hepatitis but once you get up to the levels mentioned here, you would be concerned that there is a liver cell cancer in the liver.

Q. Right. And we can see that that's obviously been in the mind of the doctors at the Royal Infirmary in Glasgow because they've carried out two ultrasound scans, an MRI and a contrast CT scan:

"Those investigations have revealed established liver cirrhosis with varices."

Can you explain "varices" to us, please?

A. The liver, when it becomes cirrhosed, is just like

nodules. So it is no longer smooth and the vein that drains from the gut and the spleen, called the portal vein, drains into the liver and it is like a bit of a dam if it is cirrhotic. So the liver no longer allows the blood to permeate freely through it, and under pressure it dams back and then dilates the venous channels in the stomach and the oesophagus, and that's what varices are. So it is like having varicose veins in your stomach and in your gullet because of the high pressure in the veins.

Q. Is it a bit like internal varicose veins?

A. Yes.

Q. Thank you. Now we see he doesn't have splenomegaly?

A. Correct, yes.

Q. So his spleen is all right?

A. His spleen isn't enlarged, yes.

Q. And he has two gallstones, but they haven't found any underlying tumour on these scans, mild ascites and poor synthetic function. The albumin is 24. What should it be?

A. About 40.

Q. And the prothrombin time?

A. At that time 9 would have been the normal.

Q. Right. So what is taking a lot longer than it should. Is that clotting?

A. Yes.
Q. And then the bilirubin, and I think is that meant to be ALT?
A. I think it will be, yes.
Q. So the bilirubin should be about what?
A. The upper limit normally is 17.
Q. And the ALT?
A. 40 or 50 depending on your lab.
Q. And he has been tested for Hepatitis B as well.

After that, the next piece of correspondence I would like to you look at is 0902, following the sequence of events. This is a report after Mr Tamburrini has been in the liver transplant unit in Edinburgh for assessment.

Can I just ask you to explain, Dr Bathgate, how the unit works? Those of us who have been to hospital, you know, you have your consultant, and you maybe don't always see your consultant, but that's the team looking after you; but the transplant unit isn't quite like that, is it?

A. As I have indicated, there are five physicians and there are a number of surgeons and intensivists or anaesthetists, and there is one team for a week which involves a physician, a surgeon, an intensivist, and we would take about one week in five. If you come in for

assessment, you are in for usually a period of five days, from Monday to Friday, where you would undergo investigations, heart, lungs, CT scans; you would speak to co-ordinators, social workers, psychologists, psychiatrists, if required, and then on Friday there was what's called an "assessment meeting", where not just the team for the week but the broader team -- everybody else associated with the transplant unit -- meet and they discuss the cases of the week for assessment and decide what the appropriate thing is to do at that point, whether it is to list for transplantation or we need more investigations or things are reasonable at the moment, we could put off for some time or you pick up something during the week which is unexpected or which would mean it would never be the right thing to do to transplant someone.

Q. I don't suppose the patient attends the meeting?

A. No.

Q. How are his or her views fed in?

A. Well, everybody is there. It kind of goes that the team of the week tends to be the patient's advocate and everybody else who haven't met them, obviously, see the facts and they would give their opinion as to their interpretation of the facts. The social worker and nurses, who have co-ordinators who have got to know the

patients as well, would give their opinion as well.

Q. And in relation to this particular period of assessment we can see -- and this letter runs to TAM0010904 -- if we look at [TAM0010902], a little bit of history at the beginning and then on TAM0010903, we can see that further testing has been carried out at ERI, more blood test results, more scans. There is also a reference -- and this is in what must be the fourth paragraph -- lipiodol?

A. Yes.

Q. That's a contrast medium, as I understand?

A. It is, yes.

Q. And another reference to the varicose veins, and there has really been a sort of all round package of investigation and support because he has also seen a psychiatrist. And the sort of results that we see there and that we saw in Dr Stanley's letter, is it possible for you to give us a indication of how ill he was at this point?

A. There are different markers that are used in the prothrombin time, the bilirubin, the albumin as they are there. You would say that they were moderately impaired, they were certainly not disastrous but far from normal. So you would say that was moderately impaired. Another marker was something called ascites,

which is usually mentioned if there is an ultrasound. So it doesn't mention that. That is not a good sign if there is ascites, and another marker of function is something called encephalopathy, which he didn't have. So I would say there was moderate impairment of liver function there.

Q. We can see from the second paragraph that there was a little ascites. Is that a collection of fluid?

A. Fluid in the abdominal cavity, yes. So a little ascites. You tend to score ascites on little moderate or severe. So if it is present but little, then that would be the best in terms of ascites. The prothrombin time would be moderate if you were scoring it. Bilirubin would be the highest level and albumin would be the lowest.

Q. We can see from the foot of the page that people are still thinking about the possibility of a tumour, hepatoma is mentioned. Elsewhere I have seen references to hepatocellular cancer?

A. Carcinoma.

Q. Carcinoma. Are these synonymous?

A. Yes.

Q. Now, can we turn to [TAM0010905], please? This is a letter dated 6 March 2002 and it is a referral from a liaison psychiatrist at Edinburgh Royal Infirmary to Dr Jauhar

at Parkhead Hospital and this is a reference, it appears, for some psychological support work in Glasgow. It looks as though around this time Mr Tamburrini is being told that he has to abstain from alcohol. Is that correct?

A. Yes.

Q. And for many people that's quite a difficult thing to do, particularly all of a sudden.

A. Yes.

Q. And a view has been taken that some support in that area might be a good thing. Is that right?

A. Yes.

Q. I think we should also note from that letter that Dr McCallum -- and this is at the end of the first paragraph -- is expressing a view that on a review of his medical case notes, it is most likely that he contracted it following a plasma transfusion in 1984 following 20 per cent burns.

Perhaps I should ask Dr Bathgate whether those of you who work in the transplant unit would have any detailed knowledge of what sort of product might have been administered in 1984 and what treatment it might have undergone, antiviral treatment.

A. No, as a hepatologist, we really wouldn't know a huge amount about that. Obviously, how people catch the

Hepatitis C isn't of a major interest to us. The interest is in how bad their liver is and what the appropriate form of management for that is. But I expected any possible route of transmission would have been explored on the initial clerking when Mr Tamburrini came in for assessment.

Q. We see also, in fact, from the sentence immediately before that, that:

"Mr Tamburrini did not give any history of drug misuse, either intravenous or otherwise."

Will he have been asked about that?

A. Yes.

Q. And are people asked only about intravenous use or are they asked about use generally?

A. Intravenous use is the risk factor for Hepatitis C, the main risk factor. So he would have been asked that specific question. Possibly not by the physicians involved would he have been asked about any other drug misuse, but certainly by the psychiatrist he would have been, yes.

Q. Following this particular trail, can we look now at [TAM0010898]. That is a letter dated 10 April 2002 from somebody called Audrey Ewing, who is a nurse who has visited Mr Tamburrini at home, we can see from that the end of the first paragraph, on 2 April 2002. If we can

just look at the line that's at the moment at the bottom of our screens, Audrey Ewing says in her letter that:

"Mr Tamburrini has admitted to some experimental drug use in his teens but denied any current use."

Now, just perhaps to avoid going back to this letter, if we can look at the following page, which is 899, we can see the signatory is Audrey Ewing, community psychiatric charge nurse, and there is some reference there to her support of Mrs Tamburrini and what is happening.

As far as the possibility of transplant is concerned, Mr Tamburrini is keen to accumulate as much information about this as possible and he is very motivated for continued abstinence. Just to follow that short trail a little bit further, can we have page [TAM0013092] from the records. This is from a different set of records, Dr Bathgate, and this form is, in fact, a 14-page form which has been completed by Audrey Ewing. We can see her signature on page 1. If we can look at 3097, you see there is a heading there, "History of substance abuse", and Audrey Ewing has written:

"Used speed when younger, tried cannabis."

So that gives us a little bit more information about what she's meaning in her letter when she writes to Dr McCallum.

To go back to the Royal Infirmary records, can we look at [TAM0010900].

This is a review. We can see that Mr Tamburrini was seen in the liver transplant follow-up clinic on 4 April. There has been another lipiodol CT scan. We can see -- and this is what I asked you about earlier -- hepatocellular carcinoma, but you have told us that that's synonymous with hepatoma. So they are still wondering if there might be a tumour. Is that right?

A. Yes.

Q. And the alphafetoprotein seems to have fallen a bit but that's actually a letter from Dr Simpson, who is one of your colleagues in the unit. Is that correct?

A. That's correct.

Q. And Dr Simpson is wanting really to keep an eye on the situation, keep monitoring the alphafetoprotein and do another CT scan in about another month's time as well. If we look at 0901, we can see that Dr Stanley from the Glasgow Royal Infirmary is still involved.

I'm not going to ask you to look at all the correspondence, Dr Bathgate, but to look at the ones that are slightly more significant. If we look at [TAM0012533], still monitoring the AFP. It is 640. So it has taken another turn and gone back up again, and then [TAM0012470].

So that was July. 2470 is the end of July and there is a reference to the AFP now being 732. Do you see that in the third paragraph?

Is that quite a concerning level, 732?

A. It is, yes.

Q. There is then a long letter at [TAM0010881]. This is to summarise the state of play as at August 2002. Mr Tamburrini has been an inpatient in the liver transplant unit in view of his progressively rising AFP. There has been a biopsy, but no evidence of tumour around the biopsy specimen. We can see that from the penultimate paragraph.

It looks as though the idea of transplantation is becoming a bit more urgent. Is that fair?

A. Yes.

Q. At this point. I think perhaps what we should take from this letter is firstly the top of page 2, so 883, in a short narrative of history there is, again, a reference to the plasma. Can you see about the middle of that paragraph it says:

"He was found to be Hepatitis C positive and the only source of infection was a plasma transfusion which he had when he sustained burns on his hands in the 1980s."

Do you see that?

A. Yes.
Q. So we can see that mentioned, and then at the bottom of that page, something that was interesting, at least to a layperson, was that the Hepatitis C PCR revealed copies more than 150 per millilitre. Perhaps you could explain that to us, doctor.
A. The level of virus that could be detected in the blood was set at 150, so you could only measure it in the blood if it was more than 150. So that simply means that it was positive. The tests are much better now, so you can go right down to 40 now, but the relevance of that simply means that there was active viral replication at the time. I don't think there was an absolute level given, whether the actual level of copies would likely have been in millions rather than 100s.
Q. Then if we look at the next page of that letter, again there is reference to virus. He has four grade 1 varices. Varices are graded then?
A. Yes.
Q. Is grade 1 the most serious or the least serious?
A. No, it is the smallest, it is the least serious.
Q. There is also reference to:

"Poor synthetic function of the liver."

Perhaps you could explain, at quite a basic level, to the rest of us about the liver's job and how that was

impaired.

A. Okay. Well, there are various markers, some of which I have mentioned already, which give you an idea of the severity of the liver disease, and some that are measured in the blood; and the three that are measured in the blood that tell you how well the liver works. There are things it has to make. That's why it is called synthetic functions. It has to make albumin, the major protein, it has to make clotting factors, and you measure that by the prothrombin time, and it has to get rid of bilirubin, which is the thing that makes you jaundiced.

So there are the three markers that you can measure in the blood which give you an idea of how well the liver works in the job that it needs to do. The other two things I mentioned previously, the ascites is a marker of how well the liver works as well as something called encephalopathy, which is a sleepiness or a confusion, where the liver fails to clear the toxic substances that your gut produces. So it usually clears them from the blood but if your liver isn't working well, then you get this kind of confusion, sleepiness and sometimes coma, related to poor synthetic liver function.

Q. Can we look next at [TAM0010878]. Dr Simpson saw

Mr Tamburrini in October 2002. We can see that his AFP has fallen markedly. This is slightly historic but it seems that the AFP had gone down at one point to 136, and then it says:

"The patient was feeling well even though his liver function tests would suggest he had poor liver function, but as at October, when Dr Simpson saw him, he was feeling more symptomatic, increasingly tired, having to sleep and not really sleeping at night."

There were two terms I wanted to ask you about from this letter. Where it says:

"Clinical examination revealed hepatic fetor but no flap."

What should we understand by that?

A. The encephalopathy that I just mentioned as an indicator of poor liver function does give something called a liver flap, which is where, if you ask someone to hold their hands out, they can't keep it steady, it begins to flap like that. (Indicates). So that's a marker of encephalopathy. A hepatic fetor is a sweet smelling acetone type breath that is associated with encephalopathy as well.

Q. Thank you.

We can then see two letters which are rather simultaneous. The first one is [TAM00010876]. The slightly

odd thing about this is that it is narrating what happened when Mr Tamburrini was admitted in October 2002. If we look at the following page, 877, it finishes with a plan for outpatient management.

If we flick back to 876, the letter is dated 13 December 2002, and it doesn't cover the fact that actually he has had his transplant by now. I'm sure, Dr Bathgate, this is not a matter of any significance but it may reflect something to do with a delay in typing up this letter or something of the sort?

A. I suspect so, yes.

Q. So this is half the story, as it were, he has been admitted on 17 October. The intention of putting him on the transplant list but he was markedly unwell. But in fact, if we look at the other letter, [TAM0010874], also dated 13 December, that tells us about the transplant on 26 October. It says here that he was admitted less than 24 hours post discharge, when a suitable liver became available, and he had undergone transplant on 26 October. It appears that there was a bit of a problem with infection. Is that right?

A. Yes, certainly the high temperature in the post-operative period would indicate that, yes.

Q. I can't remember if it is in this letter or in the other letter but there is a reference to paracentesis, which

had been required. Can you explain to us what paracentesis involved?

A. Yes. The term "ascites" that I used previously, the fluid in the abdominal cavity, if that accumulates to the point that it is very tense and swollen, then the drainage of that with a needle and catheter is called paracentesis. So drainage of ascitic fluid or peritoneal fluid.

Q. So if at October 2002, he was needing paracentesis, that means he must have had a very swollen and tender abdomen?

A. Yes, it is an indication that the liver isn't doing well.

Q. We can see from this that he went home on -- I think it must be on the next page, 875. "Discharged to home", it says, and yes, he was allowed to go home on 15 November 2002. So he is actually going home about three weeks after his transplant. Is that good, average...?

A. Average, probably two weeks. So slightly longer than average.

Q. But things didn't run entirely smoothly because he had to come back in and we can see that from [TAM0010872]. This is -- I think it is Dr Ng, is that right? -- saying:

"I reviewed him in the liver transplant clinic on

19 November ..."

So that's only days after his discharge:

"He went home about four days ago ... "

Can we perhaps scroll down a bit:

"... and started to feel unwell about one day ago. Right lower pain ... "

Can we move to the next page, please?

So he looked unwell and was obviously in pain. He was admitted for further investigations and management. Then the next letter is [TAM0010869], and we can see that what seems to have been causing the trouble was a bile leak. Is that right?

THE CHAIRMAN: Not in this period.

MS DUNLOP: If you see in the diagnosis it says:

"Bile leak one."

And he has had the transplant on 26 October. And if you then look at the second page, please, look at 70. Quite a bit of information there. I should give you a minute just to look at it. (Pause)

We can see a reference to ERCP, which, if we remember accurately when you told us earlier, someone has basically had a look. Is that right?

A. Yes.

Q. Put an endoscope down and had a look to see what the problem was?

A. Yes.
Q. And a stent was inserted at the anastomosis. Can you just explain that to us?
A. So liver transplant: you take the diseased liver out and put a new liver in, and you join up the three vessels -- one of which is a bile duct, one of which is an artery, one of which is a vein -- with your own bile duct, artery and vein, and the anastomosis is just the join of the bile duct, the new bile duct to your own bile duct.

An ERCP, you inject, contrast or dye into your own bile duct, so Mr Tamburrini's bile duct, and where that joins to the donated liver's bile duct, there is a leak at that join, the anastomosis, and to help that leak heal you put a plastic tube, which is the stent, across the junction of the anastomosis, so that bile would come down the plastic tube rather than leaking out at the anastomosis, allowing that to heal.
Q. And we can actually see that the surgeon -- and I'm looking at the penultimate paragraph -- continued to drain large amounts of fluid, presumably:

"He was reviewed by the surgeons who feel the stent may not be long enough."

But they did not want to have another go because it might cause further infection. Is that reasonable?
A. Pancreatitis is inflammation of the pancreas that can be

a consequence of the procedure of ERCP because the pancreatic duct lies in close proximity to the bile duct. So any intervention around that area can cause inflammation of the pancreas.

Q. So in short, they are not completely sure that this is going to work but they don't want to have another go at the moment?

A. It looks like it, yes.

Q. It is now ten past 11. I don't know, sir, if you would want to stop at this point and have a break and then we can go through to lunchtime?

THE CHAIRMAN: I think that would be appropriate.

(11.11 am)

(Short break)

(11.35 am)

MS DUNLOP: Dr Bathgate, when we stopped we were in December 2002 and really, just because it represents you coming on the scene, I wanted to look at a letter which is [TAM0010867].

THE CHAIRMAN: Now, Ms Dunlop, should we have it on screen, yet. Oh, it has just arrived.

MS DUNLOP: We do, yes. Your name jumped out at me there, consultant Andrew Bathgate. The screen is not on.

THE CHAIRMAN: It has come on.

MS DUNLOP: Thank you. Do you have it, Dr Bathgate?

A. Yes, I do.
MS DUNLOP: So the big screen isn't on, apparently.
THE CHAIRMAN: We are a bit short of runners at the moment.
It is on now. No.
MS DUNLOP: That's it? All screens on? No?
Right.
Actually, Dr Bathgate, this is an occasion when you are shown as the consultant but the letter is from a Dr Grace. Does she work in the unit?
A. She did then, yes.
Q. She did then, right. Okay? Right, does everyone have access to a screen?
So, this is Dr Grace saying that she has seen Mr Tamburrini on 17 December and he was generally well. Can we look at the second page, please, 868? So she is going to be discussing with the surgeons to see if -- and this is the point, really, that we established just before we rose -- the anastomosis needs to be redone:
Without going to all the material, I think it would be fair to say that over the next few months things seemed to have been reasonably stable, and in fact, we don't need to go to this, but at the end of January there is a letter, 859, which says that Mr Tamburrini was thinking about going back to work. But then if we look at [TAM0010857], we see that this is a letter dated

17 March 2003, and in fact what has happened is that there was a clinic visit on 27 February, and I think we are all learning a bit about these measurements, but some of them are abnormal; is that correct?

A. Yes.

Q. Right. The letter says that, because it says:

"Blood tests on admission had deteriorated."

And there was an ERCP which confirmed a stricture at the biliary anastomosis. So that is, I think you told us earlier, a stricture, a narrowing?

A. Yes.

Q. And another stent has gone in. Is that right?

A. Yes.

Q. Just check the next page, please, 858. All right, here we actually have the hospital moving to Little France. So the rest of us can remember that as well. Although you all went in stages, I think, didn't you?

A. Yes.

Q. So you went in May 2003?

A. 2003, yes.

Q. The next one to look at is [TAM0010832]. I suppose, doctor, that the best benchmark that you can have when you see a patient for review in a circumstance like this is to do all these liver function tests. Is that fair?

A. Yes.

Q. So that's what you are going to do when the patient comes for follow-up after a transplant operation; you are going to see how the liver is performing?
A. Yes.
Q. 832, we actually see this is you. I think, actually, this is your letter, which is revealed by the initials "AB" at the top, without looking at the signatory. You say that Mr and Mrs Tamburrini were both there and that Mr Tamburrini was feeling much better and able to carry out everything he wishes.

It sounds as though he is being very positive.

A. Yes.
Q. Yes. Do you remember him?
A. Oh, yes.
Q. Was he a positive sort of soul?
A. Yes.
Q. That's certainly what comes across. There is going to be a biopsy in October, and we can see that from the bottom of that page. You are thinking that will give you an idea whether there is any biliary obstruction as well as some information about his -- if we look over the page -- Hepatitis C, and then he is on tacrolimus. That's the anti-rejection medication; correct?
A. That's correct, yes.
Q. Now, if we look forward to November, [TAM0010824], we

see that as at November 2003, things are not looking so good and this is Dr Newsome saying that his symptoms of obstructive jaundice seem to have returned and he is obviously icteric and fatigued? Icteric?

A. Jaundiced.

PROFESSOR JAMES: Icteric.

MS DUNLOP: So he is icteric and fatigued. We have the usual liver function tests, and a conclusion after a discussion with Dr MacGilchrist, who is another physician; is that correct?

A. That's correct.

Q. And Mr Madhavan?

A. Is a surgeon.

Q. So there has been a discussion and:

"There have been longstanding problems with biliary strictures from about two months after his transplant. He will undergo angiography and MRCP to elucidate the state of his hepatic artery and the location of the stricture."

So that goes ahead and we can see that happened. [TAM0010814]. That seems to have been an overnight admission at the end of November, MR angiogram and MRCP, and then ultrasound-guided liver biopsy. I will just let you take a minute to look at this. It looks as though there is a bit of good news and bad news in that

letter. Is that reasonable?

A. I think so, absolutely.

Q. What's the good news?

A. The good news is that the biliary and anastomotic stricture doesn't seem to be causing a major problem but the bad news is the result of the liver biopsy.

Q. Yes. And if we look at page 2 of the letter, 815, we might get some more detail of that. And the biopsy is showing -- what I suppose we can call the "new liver" already has established cirrhosis, with evidence of recurrent and active Hepatitis C infection.

Dr Bathgate, Mrs Tamburrini says in her statement that she was under the impression that the transplant would cure the Hepatitis C but that doesn't happen. Is that correct?

A. That's correct, yes.

Q. So why does the Hepatitis C come back?

A. Because the Hepatitis C, although the liver is the main reservoir for the virus, exists in other cells throughout the body. So when you take the liver out, you take out the major source of the virus but unless you have responded to treatment or spontaneously cleared the virus yourself, it will always reinfect in your liver.

Q. And Dr Blair, who is writing this letter -- I think it

is Dr Carol Blair, is that right?

A. Yes.

Q. She is saying:

"This is obviously disappointing given the short period of time since the transplant."

In there is a plan to try again with the stenting, to try and improve the biliary drainage and see if this improves the liver function tests and look also at the level of viral activity. Would it be fair to say that, really, the history of matters since the transplant has been of two difficulties: one a sort of structural problem --

A. Yes.

Q. -- with the stricture --

A. The bile duct, yes.

Q. -- and the other one, obviously the infective problem with the fact that the virus is coming back. Is that a reasonable summary?

A. Yes, absolutely.

Q. We also see that it is being confirmed that his genotype 1A -- and Dr Blair says this in the letter -- there is a possibility of antiviral treatment, but if we cast our minds back to your report, from the point of view of how long treatment might have to continue, that's unfortunate because that's the one that takes the

longest to clear.

A. Well, it is the one that requires the longest period of treatment and is the least responsive to therapy.

Q. What, if anything, should we take from the "A"?

A. Not a great deal.

Q. Right. So, in terms of the one that is the least responsive or takes the longest to clear, there isn't a difference between, say, A and B?

A. 1A and 1B; not a huge amount. Genotype 1 is what everybody would regard as the hardest to treat.

Q. Now, go to [TAM0010812], we meet you again and you have seen Mr and Mrs Tamburrini, and this is on 4 December 2003, and again Mr Tamburrini may be trying to be positive in saying he is feeling slightly better. He has got a bit more energy but he knows that the biopsy has shown that the virus is still there and he may well require consideration for retransplant next year.

And then you say that:

"Because of his albumin and his bilirubin and his peripheral oedema, he is unlikely to tolerate any treatment."

I wonder if you could just flesh that out for us?

A. The treatment of pegylated interferon and ribavirin is toxic therapy, and for patients who have cirrhosis, there is even more toxic and can decompensate them from

a reasonably -- a reasonably compensated state to a very unwell state and even, in some cases, can lead to significant deterioration that may lead to their death.

Q. So he is really, you think, not well enough to start that sort of treatment at this point?

A. Yes, I mean, in all cases you would say: what is the potential benefit and what is the risk? And the chances of him responding to treatment are low and the chances of him being worse on treatment are relatively high. So in my mind that was a reasonably straightforward decision there.

Q. And we see you reflecting a bit in the next paragraph. You are asking what would we do differently next time. And this is presumably if it is decided to proceed to retransplant. You are asking yourself, "What could we do differently?" And you are answering your own question by suggesting that you would be fairly aggressive with the antiviral treatment. Is that right?

A. Yes.

Q. Accepting, of course, that that would have the sorts of drawbacks that you have identified.

A. It wouldn't be straightforward for the patient, no.

Q. We should look at the next page of that, please. So he is really a pretty regular visitor to your clinic over this period, isn't he?

A. Yes, transplant follow-up is fairly rigorous, in that, for the first three months we would see patients weekly or fortnightly and then every four weeks for the next three months and that's if it is going well. So if there are any potential problems, we would probably see them a minimum of once a month or once every six weeks.

Q. If we look at January, we find that [TAM0010799] is the letter that sets out the position as at 13 January. You can see there is a bit of a long list of problems and quite a long list of medication as well. If we look at the second page, where there is a bit of narrative, 800, I'll just let you have a look at that. He has been admitted from the clinic and we can see that he has actually had kidney problems at this point as well. What has caused the kidney problems?

A. Probably two things -- or possibly three. One, diuretic, which are water pills to try and clear any fluid. In the last letter it indicated he had peripheral oedema, which is fluid in the ankles. So he would be given diuretics to try and help that. The medication that is used to prevent rejection, tacrolimus, as we have discussed. One of the side effects of that is that it can impair kidney function, and the third thing is that his liver is deteriorating, which in itself can impair kidney function as well.

Q. And this is line 4. He says at that point he is suffering from itch and jaundice. What is it that causes the skin problem?
A. The bile flow through the liver becomes impaired in some liver conditions and something in bile, if it dams back into the circulation, causes the itch associated with what we call cholestasis, poor bile flow.
Q. Right. And in fact, we can see that what has happened is that another liver became available on 4 February and a further transplant has been carried out. And then it has been a complicated post-operative course with some peritonitis. So infection in the abdominal cavity?
A. Yes.
Q. There has again been a difficulty with a leak:
"The enteroenterostomy is the joining of?
A. Small bowel with small bowel. So, in a second transplant, when you join the bile duct, you do not join it to the patient's own bile duct for a second time because that leads to big problems. So what you do is you take a loop of small bowel and join that to the bottom of the new bile duct and then join that to the bowel again so that the biliary drainage is provided by a part of your own small bowel. And it was at the junction of the small bowel to the patient's own small bowel of this biliary drainage that there was a leak.

Q. We see that there was refashioning of that junction and after that he made a steady recovery and he was home on 28 February. Is that right?

Just have a look at the second page. There is a further letter, which deals with all of this sequence of events, which is [TAM0010804], if we could look at that. This is a letter to Dr Adrian Stanley of Glasgow Royal and this is actually from -- I don't want to get this wrong -- is Mr Akyol. He is the surgeon?

A. He is the surgeon, yes.

Q. Saying that it was worrying that the first transplant failed within 18 months, and if the graft failure is due to Hepatitis C recurrence, this is a poor prognostic factor. So he is really thinking along the same lines as you, is he, asking, "What can we do differently?" Is that reasonable?

A. Yes.

Q. So he is saying that, if it failed because of the recurrence of virus, that's worrying, but there were the structural problems as well, so they would hope to keep a close eye out for any structural problems on this occasion. Is that reasonable?

A. Yes.

Q. And then the operation, it says, was difficult -- this is the last paragraph on the page -- but was entirely

uncomplicated:

"At the time of writing he remains well. I hope he continues to make satisfactory progress."

I want to go forward to March, [TAM0010795]. Again, a long list of difficulties, a possibly even longer list of of medication, test results, some of these are really quite high as well, are they not?

A. Yes.

Q. Which ones jump out at you?

A. Well, the liver enzymes, which are the ALT, gamma GT and alkaline phosphatase, you see in the middle, between bilirubin and albumin are abnormal, yes.

Q. ALT, you told us earlier, should be 40 or 50?

A. Yes.

Q. What about the other two?

A. Gamma GT, men 55 and alk phos in our lab is about 135, 150.

Q. So these are seriously abnormal?

A. Yes.

Q. Yes. So although he seems to be feeling well -- or at least he is telling you he is feeling well -- these are concerns, and if we look over on the next page, 796, we see he is going to come in for an ultrasound and another biopsy.

Following that train of thought, [TAM0010793] is the

next letter. This tells us -- it is a bit of a challenge for us all in the first line of the narrative. I think the words seem to read "latered livier" actually should say "altered liver". It is not complex medical terminology; it is just typos, is it?

A. Yes.

Q. "Mr Tamburrini was admitted for investigation of his altered liver function tests."

And a biopsy was performed. The biopsy doesn't seem to have shown anything untoward but you felt, nonetheless, there was likely to be Hepatitis C recurring there. Is that correct?

A. Yes.

Q. And you were opting to start the anti-retrovirals at this point. This is coming back to trying to do things differently from the first time, is it?

A. Yes.

Q. When would you normally start treatment like this after a transplant?

A. Our usual practice is to do annual biopsies and if there was evidence of progression on a biopsy, then we would start treatment. The odd patient who has significant relapse within the first year is picked up on a biopsy earlier than that, and we would start on account of that biopsy. Certainly Mr Tamburrini would be the only

person that we would have started this early, six weeks.
Q. What's the downside to starting so early?
A. Well, the trials that were done -- as we have already discussed, everybody reinfects their liver. So trials have been done very early, ie within the first two weeks, to try and prevent that reinfection, and if you look at those trials, hardly anybody can tolerate the medication that early into the recovery period. Six weeks appears to be better tolerated but again it is still very early and patients tend not to, you know, respond in terms of their wellbeing and particularly in terms of the side effects which reduce the blood counts. Interferon, one of the things it does -- and ribavirin -- is to reduce, one, the white cell count -- for Interferon -- and, two, the haemoglobin with ribavirin, and they can occur to fairly large extents in the early post-operative period.
Q. So reducing your white cell count, making you more vulnerable to infections. Is that ...
A. I will say "probably" to that.
Q. Right. Well, correct me if it's wrong, please.
A. No, no. Well, I mean, in general, yes, but there is some literature that, in terms of the neutropenia or the reduced white count that you see in terms of Hepatitis C treatment, doesn't seem to pre-dispose you to infection,

but in general a lower white count does.

Q. And the haemoglobin, obviously making you a bit anaemic?

A. Absolutely, yes.

Q. Before we leave that page, I just wanted to ask you about another medication. I'm not going to pronounce this one because I could do the first half but not the second: erythro ...

A. Erythropoientin?

Q. Yes, what's the point of it?

A. You will have heard of "epo"? Erythropoientin is epo. So that stimulates the bone marrow to make more red cells. So it is counteracting for the anaemia that is induced by the Hepatitis C therapy.

Q. Then can we look at the next page, please? A long list of medication -- sorry, there was a reference which I have clearly missed. Can we go back to the previous page? There was a reference to Hepatitis C education. I wanted to ask you about that. Yes, can you see that in the paragraph of narrative four lines from the bottom. It says:

"He represented on Monday for his Hep C education."

A. We had three nurses who were very experienced in treating Hepatitis C, and the education simply relates to what to expect while being on the treatment for Hepatitis C.

Q. Right.
A. Because it is not pleasant treatment to take -- just to give them warning of what side effects they might feel and what to do in that setting.
Q. I see. Can we look [TAM0010789], which is just another snapshot along the way? This is end of April. He is saying that he is feeling tired and generally lacking in energy. He was saying he didn't feel depressed, although his wife was finding him a bit grumpy -- understandable with all this toing and froing from the hospital?
A. Yes, and the treatment, yes.
Q. Yes. Really a feeling of never getting out of the pit perhaps.

And his ribavirin is going up. I think we can see that in this letter:

"Following the clinic the ribavirin was increased to 400 milligrammes."

So it must have been felt that he was tolerating the treatment at this point?
A. Yes, to a certain degree. There is no doubt that the more interferon and ribavirin you get into the patient, the more chance of a response. So in patients who have had a liver transplant the tendency is to try and work up at a relatively quick rate, whereas patients who have never had a liver transplant, they just go straight in

at the top dose. But, because patients don't tolerate it as well in the post-transplant setting, you tend to work up from a kind of half dose to start with.

Q. [TAM0010783]. This is you, and you are seeing him in May, and again this issue of wanting to increase the ribavirin but his haemoglobin is a bit low. So the impression that we are getting, doctor, I think, from all these letters is that very many of these decisions are about balancing. Is that reasonable?

A. Yes.

Q. So what you are hoping to do is increase haemoglobin, make him a little bit less anaemic, as a result of this medication to stimulate the production of more red blood cells. Is that right?

A. Yes.

Q. And if that works, you will be able to increase the ribavirin?

A. To allow you to get as much therapy in as possible.

Q. [TAM0010781]. This is June 2004. There has been an ultrasound and a biopsy. Now, the ultrasound doesn't seem to have been concerning but the biopsy was. Perhaps you could explain what was so concerning about the biopsy?

A. The term "fibrosing cholestatic hepatitis" is indicative of severe recurrence of hepatitis C. It is relatively

unusual, probably only in about 5 per cent, maybe less than 5 per cent, of patients who are transplanted for hepatitis C, and it is thought to be due to very high levels of virus actually damaging liver cells themselves, as opposed to your own immune system causing the problem. So it is a marker of severe recurrence, yes.

Q. Right. We can all understand, obviously, what you mean by a grave prognosis but really the patient's chances of beating the virus are not really looking very high. Is that correct?

A. Yes.

Q. Now, without going to the records, we can simply see that Mr Tamburrini at this time begins to receive blood transfusions. Is that in an attempt to boost his haemoglobin?

A. Yes.

Q. And then if we look at [TAM0010774], we can see that he has had -- and this is the handwriting -- if we look at the lower section of handwriting, which is written at a slight angle:

"Two units RCC".

Is that red cells?

A. Red cell concentrate, yes.

Q. So that's being carried out at Glasgow Royal Infirmary

and in fact they have done some blood tests as well.

[TAM0010768], September, there is a reference here to the outreach clinic. So do we take from this that sometimes patients from Glasgow don't have to trek all the way to Little France, that the doctor comes to them, as it were?

A. Yes, we run outreach clinics in Glasgow, Dundee, Inverness, but they run only every three months. So if a patient's appointment would coincide with an outreach clinic, like Mr Tamburrini, who was coming regularly, then he would be seen on the outreach clinics that kind of were at the time that he was needing to be seen, yes.

Q. Right. Dr Simpson has seen him in Glasgow and again there is a liver biopsy organised, and I don't imagine a liver biopsy is a pleasant thing?

A. No.

Q. What does it require?

A. It requires local anaesthetic. The liver lies under your rib cage on the right-hand side, so it requires local anaesthetic to the skin and then a needle through the skin into the liver and a piece of liver tissue taken. It is not very pleasant but in a transplanted liver, because it has been cut out and put in, there is less sensation there anyway. So in my experience patients tend not to experience as much discomfort in

the post-transplant setting as in the pre-transplant.

Q. The next hospital attendance is September, [TAM0010762], and this is Dr Simpson, 20 September. We can, I think, take from this that he has been on, Dr Simpson says:

"Optimum doses of pegylated interferon and ribavirin."

So he is really, what, at about the maximum he can take -- yes? You are nodding, thank you -- with GCSF and epo. What's GCSF?

A. It is called "granularising colony-stimulating factor". And, as erythropoientin stimulates the marrow to make red blood cells, this product stimulates the marrow to make white blood cells or neutrophils. So there is an attempt to boost this white cell count.

Q. Now, the ultrasound, are there concerns revealed by the ultrasound?

A. Well, to me the inability to detect portal vein flow would be slightly concerning, yes.

Q. Is that likely to be a structural problem?

A. Well, because it is flow, it could be, or it could be that there is significant impedance to the flow of blood into the liver because of the disease, in which case the flow -- although there is flow, it appears stagnant at that point. So it could either be because there's thrombus or because there is damage to the liver and

there is just no flow at that point.

Q. Right. We should just have a look at the next page, please, and the biopsy results would be available and he will be reviewed at a further clinic appointment, and then, if we look at [TAM0010740], we find a long series of events summarised and, first of all, we see that he was actually taken in as an inpatient on 7 October. The reason he was taken in appears to have been, as the letter says:

"Significant deterioration in the last few weeks."

We can see for ourselves a number of things were wrong. He then became febrile. So he had a fever. Is that right?

A. Yes.

Q. And you tried a range of antibiotics, and we can also see from this letter that actually the interferon stopped. Now, increasing hepatic decompensation. Perhaps you could just explain to us that paragraph, what was happening here?

A. So, as we discussed earlier, the markers of severity of liver disease, the three blood tests, the bilirubin, albumin and prothrombin time and the two clinical factors of ascites fluid in the abdominal cavity and this usual neurological condition called encephalopathy, if the patient becomes more jaundiced or if they develop

ascites, or if they become encephalopathic, that is a sign the liver is decompensating, and in the second sentence -- well, in the first sentence it says he had increasing ascites and encephalopathy, which would both be markers of his liver deteriorating.

Q. And he would require the paracentesis; that's the drawing-off of the fluid?

A. Yes.

Q. And then, if we can look at page 2, really a very sad and difficult situation, doctor. It wasn't going to be possible to look at a third transplant because of what had happened so far and really, I suppose, what is being described here is palliative care, is it?

A. Yes.

Q. And that he passed away on 17 November.

Dr Bathgate, can I just ask to you look at the death certificate, [TAM0012946]. Cause of death has been noted as liver transplant graft failure, recurrent hepatitis C. Please correct me if this is wrong but my understanding is that one should really take from this that what the doctor is certifying is that the graft failure was the cause of death and that, in turn, was caused or contributed to by the recurrent hepatitis C. Is that correct?

A. That's correct, yes.

Q. Thank you. I take it you would have no issue with that.
A. No.
Q. Now, it is a long time since we looked at your report. Can we go back to it, please, at [TAM0012380]? Go to TAM0012387, where you have a section headed "opinion".

Now, I think, Dr Bathgate, much of this we have covered along the way but you do tell us about the problem of recurrent hepatitis C infection and that that is virtually universal. In the next paragraph you say he was:

"At the worst end of the spectrum of the disease."

Now, you have told us that the genotype that a patient has doesn't really allow you to say that their disease is worse. But what is it then? Is it the amount of virus?

A. Well, that's part of it. It's really the age at which their own liver deteriorates. It is a combination of the virus and the individual. If you infected ten people with the same virus, they would all develop significant liver disease at different times because your own body's response to the virus is quite important. There is evidence that would suggest that the younger a person develops a significant disease, with hepatitis C the worse their outcome is following liver transplantation, and that would be my take on

Mr Tamburrini.

The alphafetoprotein, which, as you will recall, was bouncing around in the high hundreds, is also a marker of the inflammatory activity of the virus and certainly in our experience it is not a good prognostic sign, no.

Q. So, in retrospect, that was actually something that was evident really from the beginning of his admission to your unit, that, as you say, the alphafetoprotein was bouncing around?

A. Yes, and that either reflected bad inflammatory disease or a cancer, and we obviously didn't know which until the liver came out, in which the original liver showed no cancer.

Q. After a transplant the explanted liver -- that is the liver that's removed -- is always sent for examination by a pathologist, is it?

A. Histology, yes.

Q. The next page of your report, TAM0012388, you say -- we have really already covered this, but you say in terms:

"There is no doubt that his death was related to Hepatitis C, causing failure of his liver transplant."

Then the second question, which is really what are the sources of the hepatitis C, you explain that:

"The only potential source of infection is the infected body fluid of another human being. Throughout

his notes it is indicated that the likely source of infection was infected plasma products following treatment for burns in 1984. This is certainly a potential source of infection but I'm unable to comment on the exact risk, as it is beyond my area of expertise as to the treatment of plasma products."

That's really something we have already covered too, that you are a hepatologist, not a chemical engineer or a transfusionist.

A. A transfusionist.

Q. A transfusionist, yes. And then you mention one or two other possibilities. Perhaps we could highlight them: transfusions in 1998, and from the evidence we are going to hear tomorrow it certainly looks that the blood transfusions in 1998 can be ruled out and you say you would expect that because of the fact that donated blood was by then being screened for Hepatitis C, but there is another independent factor, which is that you wouldn't have expected that infection in 1998 would lead to liver failure four years later.

It is rather difficult, Dr Bathgate, I think, to get a feel for what would be the length of time you would expect between infection and liver failure, but I think we can at least see that you're expressing the opinion here that four years is a bit short.

A. Far too short, yes.
Q. Far too short. Let's just take an average individual and say what would be the kind of expected period, or what are the parameters between infection and liver failure. What period of time are we anticipating?
A. Well, it really depends on the co-factors. If you are looking at just pure Hepatitis C, you certainly wouldn't anticipate liver failure before 30/40 years. That would be very unusual in pure Hepatitis C.
Q. But it does happen, I suppose?
A. Yes.
Q. But you do say that some things can presumably shorten that period?
A. Yes. I mean, we have looked at our own experience in southeast Scotland and, as indicated, alcohol is the major co-factor that we would see, and certainly in our experience at 25 years, if people drink less than 20 units, then only less than 10 per cent of them have even cirrhosis, which is ten years before you get liver failure, usually. If you are drinking between 20 and 50, then at 25 years that figure is over 10 per cent, and if you drink over 50 units, at 25 years this is still only cirrhosis. 40 per cent would have cirrhosis at 25 years. And that's our figure from southeast Scotland.

Q. Now, doctor, I'm also going to ask you to have a look at another medical report, just to see if you want to express any views. This is a report which has been obtained from an independent hepatologist for the Inquiry. It is a report from a Dr David Mutimer. The reference is [PEN0100310]. Sir, I was confusing the two reports earlier. It is this report that is undated and which should be regarded as having arrived in September 2010. Do you know Dr Mutimer?
A. Yes.
Q. How big a field is hepatology?
A. There are only seven transplant centres in the UK. So you would know all the transplant hepatologists. Hepatology itself probably only about 300 -- 200 to 300, so you would know most hepatologists.
Q. If there are only seven in the UK, is Edinburgh the only one for Scotland?
A. Yes.
Q. Where is the next nearest?
A. Newcastle.
Q. Now, you have Dr Mutimer's report. He is in fact based in Birmingham. Is that correct?
A. That's correct, yes.
Q. And that's one of the seven, is it?
A. Yes.

Q. He gives some narrative, with which we are now a little more familiar, but I wanted to ask you particularly to look at -- as well as being undated, I am afraid the report doesn't itself have pages on it so it will be 0313, where he says:

"I have been asked to consider four important questions."

Now, the first question he records is:

"What was the underlying cause of the original liver disease?"

And he gives his conclusion. Is there anything in that paragraph -- I'll give you a minute to read it, doctor, I'm sorry, but I'm going to ask you if there's anything in that paragraph with which you would take issue. (Pause)

A. No.

Q. I'm sorry?

A. No.

Q. The second question:

"What was his ultimate cause of death?"

The same exercise, please, Dr Bathgate, if you could have a read of that and if there is anything there with which you would take issue, perhaps you could let us know. (Pause)

A. Can we go down the next page?

Q. Yes, sorry, on to 14.
A. I suppose the only thing is ultimately the patient died as a consequence of liver disease, which was secondary to the Hepatitis C virus infection and alcohol.
I suppose that's true because if he didn't have that, he wouldn't require a liver transplantation but I wouldn't have said that that was the cause of his death; it was failure of his liver transplant that caused his death. But other than that, no.
Q. And that's really the last sentence you are referring to, is it?
A. Yes.
Q. Right. Then he has been asked whether Mr Tamburrini's treatment and management was appropriate, and again I'll allow you to moment just to read that, and that will involve going on to the next page as well, at the end.
(Pause).
I think I should say, Dr Bathgate, that it strikes me that "2003", where it occurs in the fourth last line on the page, should be "2004". It wouldn't really make any sense if it was 2003. I think the aggressive Hepatitis C recurrence that Dr Mutimer is referring to is June 2004?
A. Yes. That's fine. I wouldn't have any --
Q. You don't have any comment you want to make on that?

Thank you.

Then, lastly, he has looked at the likely source. But I think we should perhaps just leave it at the fact that you have told us that you yourself are not expert in the antiviral treatment of blood products, so it is perhaps better that we address those questions to someone who is. Is that reasonable?

A. Yes, that's fair.

MS DUNLOP: Thank you very much, Dr Bathgate. I don't have any further questions.

THE CHAIRMAN: Mr Di Rollo, is there any matter you would wish to raise with Dr Bathgate?

Questions by MR DI ROLLO

MR DI ROLLO: There is one point I would like to ask him about in relation to his report.

Dr Bathgate, I wonder if we could have the document [TAM0012380] on the screen, and I think it's on page 8. Just bear with me. It is in the opinion section just a bit further on, perhaps the next page, page 9 in fact.

There is a sentence there -- I take it you were familiar with Mr Tamburrini's notes, being his treating consultant.

A. His transplant notes, yes.

Q. And you have indicated there is absolutely no suggestion in the notes in relation to -- (inaudible) there was

a risk that he had been -- that the risk of intravenous drug use had any involvement in his Hepatitis C.

A. Yes.

MR DI ROLLO: Thank you. That was all.

THE CHAIRMAN: Mr Anderson, do you have any matters that you would like --

MR ANDERSON: I have no questions, thank you very much, sir.

THE CHAIRMAN: Dr Bathgate, thank you very much indeed for attending and for your help.

A. Thank you.

MS DUNLOP: Now, sir, it is a bit of an early finish because we are going to hear from Dr Mutimer but not until 2 o'clock.

THE CHAIRMAN: I think, ladies and gentlemen, if you can hear me at all, you should understand that Dr Mutimer will not be appearing in person but by electronic means and that has to be set up so that he can be dealt with continuously. So I think that we have to be flexible, we have to try and accommodate the time as best we can. So we will have an early lunch but we really must get back, I think, in, what, an hour, or what do you think?

MS DUNLOP: Yes, I think, sir, there are one or two loose ends that have emerged from the evidence so far, which I could usefully tie up before we speak to Dr Mutimer. So perhaps, yes, if we aim to start about quarter to and

I can do that.

THE CHAIRMAN: So, ladies and gentlemen, if you take that as a target, and I hope you can all hear me about when you have to come back. No. If I just put that out of the way and speak to you, can you hear me now?

Good, quarter to, please, for resumption.

(12.37 pm)

(The short adjournment)

(1.45 pm)

THE CHAIRMAN: Ladies and gentlemen, I understand that some people are wondering who we all are, and of course I'm remiss in not introducing all of the active player in this field, as it were.

If I start at the far corner here on the front door there is Mr Sheldon, who represents the Scottish Government at these proceedings. Then there is Mr Anderson who comes next. I think he has a portfolio of National Health Service interests, if I can put it that way.

Then Mr Di Rollo represents what I might call the patient interest group generally. So you understand why I go to him first. That seems to be the right way to get, as it were, a immediate answer to Ms Dunlop, if that's what's going to happen, and then Mr Anderson and Mr Sheldon have their own interests to follow on.

Beside me there is Professor James, and he is the chief medical adviser to the Inquiry. So when you see me turning and asking him questions, that's to make sure that I get an immediate bit of enlightenment on what's actually happening, which I naturally keep to myself so that I can write it up later as if I had had a tremendous insight of my own. But don't you worry about it if I speak to him, it is merely to ensure that I'm getting immediate feedback on the evidence, as it emerges.

Ms Dunlop, of course, you have heard as she has been introducing the case.

I hope that that at least enlightens you to some extent on who we are. I am afraid, as time goes on, you will become only too familiar with who we are but we will try to keep things going on a reasonably even footing so that you follow events.

Ms Dunlop?

MS DUNLOP: Thank you, sir. Before lunch, I indicated that there were a couple of loose ends which might usefully be tied up at this point before we, as it were, go to Birmingham. The first is to say that there was mention this morning of the nurse, Audrey Ewing, who I think became Audrey Russell, married and became Audrey Russell, and we did look briefly at a 14-page form which

she completed when she visited Mr Tamburrini at home.

We simultaneously tried to recover her records and tried to find her. We were successful, as is obvious, in recovering her records but we didn't manage to find her. She travelled to New Zealand and we made enquiries through nursing authorities in New Zealand to see if we could locate her but we couldn't, and perhaps if we could just look at the correspondence in relation to that, [PEN0010249], that's a letter, as you can see, sir, to the Nursing Council of New Zealand. We record that -- if we can get that back -- our understanding, which was gained from the place in which she used to work in Glasgow, that she moved to New Zealand several years ago. We tried to find her and the response is 0316, [PEN0010316]. The response is an email, sent very quickly, 2 December, from Clare Prendergast at the Nursing Authority in New Zealand saying that they had not been able to find Audrey Russell. So that's the first piece of information.

The other piece of information, which I should impart, is that it came to light that Mr Tamburrini's GP records had been destroyed and members of the Inquiry team also researched that to try to discover why and how that had happened. There is a synopsis of the relevant correspondence, which is [PEN0010305]. It is on the

screen now.

I don't propose to go to all these documents. I don't know, sir, if you would wish me to give -- I can give the reference numbers of each individual document, if that would assist for later study. I can do that now or I can do that at the close of business.

THE CHAIRMAN: Is there an immediate short answer to the --

MS DUNLOP: We are going to go to the last letter, which I think is the best summary of the position.

THE CHAIRMAN: Then I don't want you to go through the detail.

Ladies and gentlemen, I hope you understand what we are doing at the moment. The first point is dealing with something that is perhaps just a little technical. I will have to report, in due course, in some considerable detail on the history of matters and one question that can arise is, "Well, why didn't you get Audrey Ewing or Audrey Russell to come and tell you what was in there?" So I have to know and I have to be able to say efforts were made to trace her. They didn't happen and therefore we only have the 14-page form that she filled up and signed as an indication of what her evidence might have been.

The second point is slightly different, because we all know that what has happened to GP records is

a matter of interest to a number of interested parties at this Inquiry. In time, it may be necessary to look into some of these things in detail but if, in the case of Mr Tamburrini, we have an immediate answer, then it may be enough to take that and I can be confident that if there is more to it than that, it will be raised with me by Mr Di Rollo or by Mr Sheldon or by Mr Anderson.

So I don't want to take up time filling you with a lot of detail that may not prove to be required for any purpose of this Inquiry. Ms Dunlop, I think for the moment we needn't go into that but if anyone wants the information, Ms Dunlop clearly has it and there may be other things like that.

MS DUNLOP: Perhaps, sir, if we could just look quickly at the final item that's listed. Before we do that, I should say that Mr John Dunn, who is referred to in the second bullet point under the acronym COPFS, which is Crown Office and Procurator Fiscal Service, that he was actually the deputy crown agent. It is designated as "COPFS" but in short, members of the Inquiry team followed the records, where they went; they went from the Health Board to Crown Office and from Crown Office back to the Health Board practitioner services. That's where they were destroyed. They are destroyed in June 2009, and at that point the Scottish Government

legal directorate was considering whether or not to include Mr Tamburrini's death in this Inquiry.

You asked, sir, if there was a short answer and the short answer is really that the Crown Office didn't tell practitioner services not to destroy the records and the Scottish Government Health Directorate didn't tell anyone not to destroy the records. The destruction appears to have been entirely in accordance with normal policy. If one looks at the final item, which is the letter sent by email from Jill Lavelle to the Inquiry on 23 December 2010, that is [PEN0010299], in essence that is what is contained within that letter.

THE CHAIRMAN: Well, I would expect that if Mr Di Rollo wishes to raise any matters, he already has all the researches from you and he will do it. It is entirely up to Mr Di Rollo, ladies and gentlemen, whether this is a good example of the general point or not and we will hear from him in due course.

MS DUNLOP: I should say that we are not entirely devoid of information because there is a summary of what was in the GP records -- the beginning of this must be [TAM0011459]. 1459 and 1460. The sort of summary that one sees nowadays that appear at the front of people's general practitioner records.

So we do have that, which is a chronology of some

interest. If we just look at 1460, we can see that the record of treatment seems to go back to 1968, 31 December 1968, when Mr Tamburrini had an appendicectomy; although -- and perhaps this is just the sort of thing that happens -- we can see that the road traffic accident in which he sustained burns seems to have been noted as 1989 when in fact we already all know that it was 1984. However ...

That completes the brief examination of what I was describing as the loose ends, and with that in mind if we could now -- we hope -- connect up with Dr Mutimer in Birmingham and take his evidence.

DR DAVID MUTIMER (sworn)

Questions by MS DUNLOP

MS DUNLOP: Good afternoon, Dr Mutimer.

A. Good afternoon.

Q. Can you hear me?

A. Yes, I can.

Q. Good. The first thing I would like to do is just ask some basic details about yourself. You have provided your curriculum vitae and I don't actually have a number for that but I'm told we can produce that on the screen, so if you will bear with us for a moment while we call that up. We can all read for ourselves that you are a reader in hepatology within the department of medicine

in Birmingham University. Is that right?

A. Yes.

Q. As well as your academic position, you are a consultant hepatologist in the Queen Elizabeth Hospital in Birmingham?

A. Yes.

Q. Within that role, do you have responsibilities for liver transplant or in relation to liver transplant?

A. Yes, I do. I have been working in the Queen Elizabeth Hospital since 1989, and the reason to move to Birmingham was the liver transplant programme.

Q. Could I actually ask you one or two things about your curriculum vitae, can we look, firstly, at page 7, please. Are you able to get access to the pages within this? No?

Right, fine. I hadn't completely appreciated what was not possible.

All of this will be known to you so I'll just tell everyone here what's in the CV and if I say anything wrong, you can correct me. We can see from page 7 that you are an Australian. Is that right?

A. That's correct.

Q. And you trained in Melbourne?

A. Yes.

Q. Your undergraduate training was between 1975 and 1980

and then the biggest move, the move to the UK, was in 1986 when you came to Newcastle-upon-Tyne. Is that right?

A. That's right.

Q. Then if we -- those of us who can -- look at page 9 and see that you also studied for an MD, which you obtained in Melbourne. Your thesis was cytomegalovirus infection of liver transplant recipients. Then in 1988 you were awarded the Dame Sheila Sherlock prize. I think, for those of us who have been on something of a crash course in liver disease, the name "Dame Sheila Sherlock" has become very familiar, but she was a leading hepatologist; would that be fair to say?

A. Yes, that's true.

Q. And you also were awarded a travelling fellowship in transplantation in 1997, which you spent studying in Lille. Then if we turn to page 12, we can see that you have acted as an adviser to a number of societies, colleges, agencies and groups. One of the things we might note from that is -- and this is within paragraph 4, where there is a list of bullets -- you are a member of the Skipton Appeals panel, and you tell us that that relates to the compensation of patients who have acquired Hepatitis C as a consequence of contaminated blood transfusion. You began that role in

2006 and you have continued to be a member of the appeals panel. Is that right?

A. Yes, I am.

Q. In fact we can also see that our own proceedings are listed there. You have a number of editorial appointments. We can see that there are six journals mentioned there and in relation to all of them you appear still to be involved in an editorial capacity.

From page 15 you describe your clinical research. One of the things which is obvious, from what is a very lengthy narrative of different research projects, is that there is a lot of sponsorship from pharmaceutical companies, for example, SmithKline Beecham, Glaxo SmithKline, Wellcome, Pharmanet, Schering and so on. I take it that the funding from the pharmaceutical companies is essential to allow this research to be carried out?

A. Yes, I have had (inaudible) and I think a number of, (inaudible) pharmaceutical sponsored clinical trials (inaudible).

Q. You also have, from page 20 onwards, a list of lectures which you have been invited to give. Then you have British National Society meetings, Royal College presentations and a section -- and this may be more difficult for you if you don't have it in front of

you -- entitled "My four favourite publications". This is your own personal favourites from your back catalogue, is it?

A. A copy of it was prepared for technical promotion and I was asked to arrange my CV in that form.

Q. I see, thank you.

A. They are my favourite publications.

Q. They are, anyway, your favourite publications?

A. Yes.

Q. Right. Unsurprisingly they all relate to material with which we have become slightly familiar; liver transplantation and what may perhaps go wrong after liver transplantation seems to feature prominently.

You then have a list of publications by subject matter and then you have publications by date. If I can say this, doctor, a very impressive list, running to, I think, 121. Then a list of invited reviews, editorials and commentaries, book chapters and additional invited lectures, and lectures at UK national meetings and then regional UK and local meetings. It even looks as though you have been to Edinburgh a few times?

A. Yes, I have.

Q. You have been here to lecture a bit, have you?

A. (inaudible) college.

Q. So in your role as an expert hepatologist, you have been asked to look at the illness of Mr Victor Tamburrini, and indeed, you have prepared a report narrating your findings and your views. It would be helpful if you could have that report in front of you. It is code numbers [PEN0100310].

A. I have a hard copy.

Q. You have it?

A. My CV has come up.

Q. I'm sorry, I have finished with that now.

Your report was supplied to the Inquiry in September 2010 and that's the date we are using. We have already looked, this morning, at Mr Tamburrini's experience in Edinburgh Royal Infirmary from his referral there in 2002 and the two transplants he underwent in 2002 and 2004. We have also looked much earlier in the story at his experience in 1984, when he received treatment in Glasgow Royal Infirmary for 18 or 20 per cent burns.

The piece of the jigsaw that I would like to ask you about, Dr Mutimer, in the sense of assembling a factual history, is, therefore, his liver disease before 2002. Much of this is narrated by you in the report but I would like, really, to enable us to understand better what it is we are looking at, to take you to some of the

actual records themselves.

If we could begin by looking at [TAM0012570]. This is a letter from a general practitioner dated 8 June 2001?

A. Yes, I've got it in front of me. I'm struggling to get the font to a size which I can read easily. I'll do my best.

Q. This is really just to show that there were, in fact, virtually simultaneous referrals to hospital in June 2001 for Mr Tamburrini. This one is a referral by his general practitioner, who is referring Mr Tamburrini because he has developed swelling in his legs, and the GP narrates that he has a history of deranged liver function tests and that he has been in for acute pancreatitis in the past at which point it was also evident that he had gallstones.

He had also, by this point, had surgery which took place in 1998 and we are not going to go into that just now save to ask one thing. There is a reference there to gynaecomastia, which is something that this week, when we look at three gentlemen who all suffered from Hepatitis C, we can see from the records that at some point they all suffered from gynaecomastia. Could you give us a bit of explanation about that, please.

A. Yes, gynaecomastia (inaudible) observed in patients with advanced liver disease and cirrhosis. It is not

invariable (inaudible).

Q. I'm sorry, I think we are struggling slightly to hear you, doctor. I don't know whether you can go closer to a microphone or something.

A. Yes, (inaudible) because I can hear my voice at your end about two seconds after I speak. So I apologise if I have (inaudible). Can you hear me now?

Q. Yes.

A. Okay. So gynaecomastia can be observed in patients with cirrhosis. It is probably (inaudible) related with alcoholic (inaudible) but it can be observed in cirrhosis of any (inaudible). It is complicated by (inaudible) some of the medication used to treat patients with advanced liver disease can also cause gynaecomastia. I don't think he was taking advanced (inaudible) patients at that time.

THE CHAIRMAN: I didn't catch all of that, doctor, especially the last part. I think you said that it's found in patients with advanced liver disease and cirrhosis and probably classically was related to alcoholic liver disease but could be associated with any form of liver disease, but then you went on to comment on Mr Tamburrini and I didn't pick that up. Can you ...

A. Okay. I said that some medications are used in advanced liver disease which can cause gynaecomastia. I don't

believe that Mr Tamburrini was taking those medications at that time.

THE CHAIRMAN: Thank you. That makes it clear to me.

MS DUNLOP: Thank you. It can be a consequence of medication but in this case he wasn't on that sort of medication at that time.

A. That's correct, and it can be seen in patients with advanced liver disease as well.

Q. Essentially it is growth in the breast area. Is that correct?

A. Yes, it is.

Q. The other letter which shows his being referred to Glasgow Royal Infirmary is [TAM0012540]. Mrs Tamburrini told us this morning that Mr Tamburrini's dentist had told him that he needed to seek medical advice and this seems to be what transpired from that referral, because if we scroll down a little bit, we can see that this is a consultant in oral medicine. Do you have this page in front of you, doctor?

A. Yes, I do. I don't know whether Neil can increase the size of the page for me.

MS DUNLOP: It is being suggested that if you click on the document it may increase in size.

A. I'm not able to drag the margin of the page to enlarge it.

Q. I don't think there is anything particular that I need to take from this correspondence, save to show that Mr Tamburrini was referred to the Royal Infirmary by two different groups in June 2001, and at that point he had symptoms which, at least in retrospect, were consistent with the Hepatitis C, which was destined to be diagnosed.

If we look at [TAM0012542], do you have that?

A. I am (inaudible) from the dentist.

Q. Right.

THE CHAIRMAN: Ms Dunlop, are we getting a delay?

MS DUNLOP: I think it is just taking time for the documents to appear.

A. I can see it now.

Q. You can see it, and in fact this is investigation which is being carried out by a haematologist. So he has elevated MCV. Is that mean corpuscular volume?

A. Yes, it is.

Q. What is mean corpuscular volume?

A. It is the sizes of the red blood cell, and its most important relevance here is that a high MCV, that is large red blood cells, typically in patients with cirrhosis, particularly due to alcohol.

Q. Thrombocytosis, eosinophilia and reticulocytosis. Perhaps you could give us a brief explanation of those.

A. I think it is a typographical error. The patient has thrombocytopenia rather than thrombocytosis. I think the previous page had said (inaudible).

Q. So you think it should --

A. Thrombocytopenia.

Q. "Thrombocytopenia", it should be?

A. Yes, thrombocytosis means a higher platelet (inaudible). Thrombocytopenia, I think, this patient was suffering from, and that's typically seen in patients with cirrhosis.

Q. And the other two?

A. The eosinophilia and (inaudible) reticulocytosis usually means that the bone marrow is switched on to replace the red blood cells, and this can be seen in patients with advanced liver disease as well.

Q. Mr Tamburrini underwent further investigations on the instructions of the haematologist and if we look at [TAM0012553].

A. I'll tell you when it comes up. (Pause)

Yes, I see the page. Is it TAM0012553? Right-hand column?

Q. Yes. Yes, sorry, could we look at TAM0012554 as well. Stop at TAM0012553, please, yes. That was the letter I wanted to look at. There was a word in it that I did not understand and I thought I should ask you about his

haptaglobins. What are haptaglobins?

A. Haptaglobin is a protein that circulates in the blood, and if the red cells are being broken down, then the haptaglobin binds to the globin and disappears from the blood. So if the globin is undetectable in the blood, it tells you that the reds have been broken down.

Q. So it is a sign that red blood cells are being broken down?

A. Yes, if it disappears from the blood, it's (inaudible). Slightly low levels can be seen in patients with very advanced liver disease, just due to the liver disease itself.

Q. I don't know, sir, whether we should stop and try and improve the auditory quality. We are losing some of what Dr Mutimer says.

THE CHAIRMAN: If you look at 9711, for example, I think the answer there we can pick up, in part, from the document from which you are reading, but when Dr Mutimer comes to give his own explanation, we quite clearly are losing it in the transcript, and it might not be so easy later to make good the deficiency.

So I think, Dr Mutimer, if you would bear with us, we will try to improve the sound quality. There is very little point in taking your evidence if we don't get a reliable transcript of it.

A. That's okay.

THE CHAIRMAN: I think, Dr Mutimer, if you would bear with us, what we will have to do is a bit of repetition to make sure that we do capture the essence of what you are saying.

I can see the transcript as it is appearing and I know that it doesn't actually square with what I think I'm hearing you say, and some of the language is difficult.

Ms Dunlop, can we take it slowly and see. I think over the last page or two we do have quite a number of points at which the evidence will not reflect what Dr Mutimer is trying to tell us.

MS DUNLOP: We are also wondering here, sir, if Dr Mutimer's technical adviser is still with him.

Is your technical helper still there?

THE CHAIRMAN: He has gone, has he?

A. He has gone to London. Am I able to ring on a different telephone line?

THE CHAIRMAN: We think here that it's the reception at your end that is causing some of the difficulty at least, but I don't know at the moment how best to tackle that. Neil, is there a way of helping?

Dr Mutimer, we are going to try redialling and see if we get an improved connection.

A. Okay. I'll hang up then.

THE CHAIRMAN: Ladies and gentlemen, I'm going to adjourn briefly at this time. I think this is a matter for the technician to deal with and it won't help them for us to be party to it. One of the things that is going to be tried is to have a straightforward telephone link, which might let us hear the words while Dr Mutimer is looking at the documents. But we will have to let the technicians have a shot at it and see if they can solve the problem.

(2.38 pm)

(Short adjournment)

(2.47 pm)

MS DUNLOP: Dr Mutimer, let's have another go. We were looking at when Mr Tamburrini had undergone some investigations in September 2001 and I think, so as not to prolong the agony, we should just go straight to [TAM0012703]. Can you see that that's a test result? Do you have that?

A. No, I have still got 2553.

Q. We will give it a minute.

A. Yes, a result from Gartnavel General Hospital.

Q. From the regional virus laboratory, and we can see from the bottom that the date the specimen was collected was 5 September and then it was authorised -- I'm not quite

sure what that means -- on 12 September. Someone has also dated 19 September, but the important thing to take from this is that he had tested positively for Hepatitis C. Is that correct?

A. Yes, it says "HCV PCR positive". That's a way of detecting the presence of the virus.

Q. Yes. Can we go to [TAM00012559], please? Do you have that letter?

A. Yes.

Q. Mr Tamburrini is still being looked after in the haematology clinic and Dr McLintock, at the haematology clinic, has called Mr Tamburrini back to explain that he has Hepatitis C. There is a sentence which doesn't actually make sense:

"He does, in terms of the transmissions of Hepatitis C, he does not feel he has had any high risk behaviour."

I don't quite understand that. But there is a reference to a blood transfusion in 1998, which we will come back to.

He is not going to be followed up further in haematology, but if we look at [TAM00012552], this is the parallel track that we have seen was going on at the same time: that Mr Tamburrini was also being seen in the general medical clinic at Glasgow Royal Infirmary. 2552

relates to that and is a letter back to the general practitioner from a Dr Fisher who tells the GP that liver function tests at the time of the operation in 1998 had been abnormal, although further investigation had not been performed.

Perhaps we can skip forward to [TAM0012557]. Now Mr Tamburrini is being looked after in the liver clinic at Glasgow Royal Infirmary. There has been an ultrasound and we also are told that there is concern about the alphafetoprotein. Dr Mutimer, that's a story that we kind of started in the middle this morning with Dr Bathgate, but we now know, in fact, that the alphafetoprotein continued to rise. This is the beginning of concern about that and I think we also know too that the liver enzymes are raised.

At this point it was decided -- I think this is probably on the next page, if we could go to TAM0012558 -- to proceed. Yes, here is the reference to the abdominal ultrasound:

"No definite hepatoma ..."

And we know that's not liver cancer:

"... was seen. It was decided to proceed to an MRI of the liver."

Dr Gaya has discussed matters with Mr and Mrs Tamburrini and he know that it has been a great

shock for them.

Now, if we look at [TAM0012699].

A. It's an ultrasound report.

Q. Yes. I think you are ahead of us this time. 2699?

A. Yes, I have got that.

Q. Yes. And in fact the ultrasound report is saying that there is no focal lesion but he proceeded from ultrasound to an MRI, which is [TAM0012697]. Just to take this shortly, there seems to have been quite an important typographical error here:

"More importantly ..."

It says in the middle of the report:

"... there is ..."

And what has originally been typed is:

"... there is an underlying focal mass seen."

But there are two copies of this report in the records and on both that has been changed to no underlying "focal mass", and I think we are clear from having looked at all the other documentation, that that was the correct position; that there was no focal mass seen.

However, if we look at [TAM0012564], this is Dr Stanley from Dr Stanley's liver clinic, writing to Mr Tamburrini's GP and --

A. I don't have that letter, yet.

Q. Oh, sorry.
A. Yes, I have got it.
Q. There is a reference there, Dr Mutimer, to spider naevi. Could you explain what those are please?
A. Spider naevi are little vascular malformations which are seen in patients with advanced liver disease.
Q. Unfortunately this letter seems to proceed on the basis of the MRI scan report as uncorrected because it says:

"His recent MRI scan suggested fibrotic change, with an underlying focal mass."

But plainly Dr Stanley is still investigating the possibility of a tumour. There is then another visit in December, [TAM0012562], and still rising AFP, and Dr Stanley is planning to proceed to liver biopsy in four to six weeks.

A. I have still got TAM0012564.
Q. TAM0012562?
A. Yes.
Q. Right. So we know that there is continuing concern about the rising AFP, and if we then move to February 2002, more specifically 7 February, 2695.
A. Still on 2562. Yes.
THE CHAIRMAN: Ms Dunlop, I don't know if it is a solution but it occurs to me watching that every time we flick through a series of pages, there is an accumulation of

data going down that takes longer to come through. I don't know if there is a way of avoiding that.

MR PARKES: We are actually using two systems. Dr Mutimer is actually looking --

THE CHAIRMAN: So you can't look at a specific page.

MS DUNLOP: He has got it. [TAM0012695].

A. Yes, I'm looking at that.

Q. Right. He has had a CT scan of the abdomen and an abdominal ultrasound. I only wanted to ask you about portal hypotension?

A. I think that's a typographical error.

Q. Do you think that should be "hypertension"?

A. Yes, I do.

Q. So what would that be in layman's terms?

A. It means that with a damaged liver, the circulation of the blood through the liver is disturbed and the pressure in the blood vessels that are flowing to the liver will increase as a consequence of that.

Q. Then I think the last document in this sequence that we need to look at is [TAM0012566]. Do you have TAM0012566?

A. Not yet. 2695?

Q. TAM0012566.

A. Yes, I do.

Q. And this is Dr Stanley writing, on 11 February, to Mr Tamburrini's GP and saying:

"The recent scans have revealed cirrhosis with varices."

He has had some explanation already of what varices are. There is no evidence of an underlying hepatoma. So no evidence of liver cancer. The concern, however, is the rise in alphafetoprotein. Our understanding is that that can be associated with a carcinoma but it can also simply be an indicator of very active liver disease. Is that accurate?

A. Yes, this would be a pretty typical sequence of events for a patient with advanced liver disease. The magnitude of the alphafetoprotein is informative. If it is in the thousands, then almost always it means that there is liver cancer. When it is in the hundreds, as it was here, then that can be simply associated with an inflamed liver rather than with cancer. But the sequence of scans, the ultrasound, MR and CT would be done to exclude the possibility of liver cancer.

Q. I don't think we need to look at more of the correspondence because we know already that it was around that time that Dr Stanley referred Mr Tamburrini to the liver transplant unit in Edinburgh, and we can return to your report, [PEN0100310], where you pick up this narrative on page 2, which will be PEN0100311.

A. I have got my hard copy if you want to continue.

Q. That could be useful. I think we are at the last paragraph on the second page. You say:

"Dr Stanley referred the patient to Dr Ken Simpson, he was seen for assessment in February. There was concern that he had primary liver cancer but that was ruled out."

And so on. You make a reference to a report or communications from Nurse Audrey Ewing, and we have already heard about her and her input. You then tell us about the first transplant, which was 26 October 2002, and the post-operative complications and the ERCP, which we understand to be an investigation whereby, using an endoscope, it is possible to get a clearer idea of the nature of the difficulties. Is that correct?

A. That's correct.

Q. And there was a stricture, which required stenting. Further down in this paragraph you narrate the liver biopsy, towards the end of 2003. Do you see this:

"The liver biopsy that was performed at about that time showed established graft cirrhosis with evidence of recurrent and active Hepatitis C infection. Poor liver function persisted."

I should ask you, doctor: with the reoccurrence of Hepatitis C, are these factors related? That is, the problems there have been with the stricture and then the

recurrence of the virus? Does everything interrelate?

A. They are not necessarily causatively related but each of them will cause graft damage. So the development of cirrhosis during a period of approximately 12 months makes me think that, probably, the poor drainage via the bile duct and the inflammation from the recurrent Hepatitis C are both relevant.

Q. So both contributing to development of cirrhosis afresh?

A. I think so.

Q. Now, you say it is interesting -- and this is retransplant -- you say:

"It was decided that the patient should be regrafted."

In other words, another transplant should be carried out:

"This happened on 4 February 2004. It is interesting that the surgeon found a dilated and thickened donor bile duct."

Why is that interesting?

A. I think that during the first year post-transplant, the team were clearly having problems with the bile duct and it is my impression that they thought they had largely resolved that problem, but the finding of the dilated, thickened bile duct at the time of retransplantation I think suggests that perhaps that was a problem which

had not been completely resolved by them.

Q. And then we know that there were some difficulties immediately after the second transplant and indeed fairly early biopsy, and what Dr Bathgate described as a "grave prognosis" was given when the liver biopsy was carried out in June 2004. This is on the next page:

"The appearances were consistent with aggressive Hepatitis C recurrence, appearances were those of fibrosing cholestatic hepatitis."

We have already had an explanation from Dr Bathgate of the attempts that were made to improve matters by the use of medication but that ultimately these were unsuccessful.

You answered in your report four questions posed to you. What was the underlying cause of the original liver disease? If we could take blood products firstly, you say:

"I do not believe that blood products were the cause of his Hepatitis C infection."

Why do you say that?

A. I'm just looking for that. I'm sorry.

Q. Sorry. You have a question in bold:

"What was the underlying cause of the original liver disease?"

A. Yes.

Q. You say:

"I do not believe that blood products were the cause of his Hepatitis C infection."

A. I have found, it thank you.

Q. I just wondered on what you had based that view.

A. Well, the documented blood products that the patient had received included the plasma in 1984, I think it was, after the patient experienced the burns, and then the second occasion was the blood transfusion in 1998, after his mastectomies. And the documents that I saw and reviewed from Professor Allain and Professor Walker persuaded me that the plasma in 1984 was most unlikely to have been the source of Hepatitis C infection, and in addition, screening of blood products for Hepatitis C was introduced in England in 1991. I'm not sure about Scotland. I think it was about the same time. So that the chances of acquiring Hepatitis C from a blood transfusion in 1998 were extremely low indeed, and we know also that the patient already had abnormal liver function tests at the time of surgery in 1998. So the liver disease preceded that transfusion.

So that's the basis for me thinking that those two episodes, where the patient received blood products, are unlikely to be the cause of Hepatitis C infection.

Q. Can I just ask you, doctor, for your own view about the

likely time period between infection and liver failure? In other words, barring other factors, what would you expect would be the number of years between someone being infected with the virus and arriving at liver failure?

A. If you look at a large population of patients who were infected with Hepatitis C, then the median time from infection to cirrhosis is thought to be about 30 years; in other words, half of your patients will have developed cirrhosis at 30 years and the other half will have some lesser degree of liver damage.

What distinguishes the people who progress more quickly to cirrhosis are a number of factors, some of which we don't know. But we do know that men will progress more rapidly. We also know that alcohol will accelerate the progression to cirrhosis. But it is very rare to see cirrhosis within ten years of infection. It isn't common to see it within 20 years of infection, unless there are aggravating factors. Does that answer your question?

Q. Yes, thank you. What do you think would be the point from which we should count back? Should we be counting back from 2001 or should we be counting back from 1998?

A. Are you trying to guess the likely time of infection?

Q. Yes. If you were trying to do some sort of

retrospective assessment and work out around about when might he have become infected.

A. I think it is really difficult in this case because I think that alcohol made a significant contribution to the liver damage here and of course, people can develop cirrhosis from alcohol without Hepatitis C. So we don't have a very good estimate of the amount of alcohol that the patient consumed. There are a number of estimates by different professionals, at different times, in his file, and they range from really quite modest consumption to fairly heavy consumption.

Q. But if one took that --

A. To try to answer your question, if I think of the patients that we transplant in Birmingham who have Hepatitis C, who look a little bit like Mr Tamburrini, then the majority of those will have been infected in their early adult years, late teens, early 20s. There will be a history of significant alcohol consumption, not necessarily alcoholism, and the average age at which they come to transplantation is approaching 55.

Q. This is actually earlier in your report, doctor, but you do refer to the information that nurse Ewing obtained about Mr Tamburrini having mentioned some experimental drug use in his teens but denied any current use.

We have looked at her original entry, which reads:

"Used speed, tried cannabis."

That is not a reference to intravenous drug use, is it?

A. I missed what you said, I'm sorry.

Q. I was just saying that you make reference in your report to Nurse Ewing's interview?

A. Yes, I saw the letter from Nurse Ewing.

Q. Yes, and the actual entry in her records refers to having used speed and tried cannabis.

A. Yes.

Q. There isn't recorded there any intravenous drug use?

A. Yes, the greatest risk, of course, would be if the patient was injecting drugs and sharing needles. And from the records that I saw, Mr Tamburrini was asked on a number of occasions about intravenous drug use and the answer was always that he did not use intravenous drugs.

I think that the period in his teens where he was experimenting with drugs might identify a period in his life when he was at risk, however, and it is very likely that the people that he was mixing with and sharing drugs with -- it is quite possible and likely that some of them may have been Hepatitis C positive. So it may define a period in his life when he was more likely to come into contact with Hepatitis C.

Q. The other possibility, of course, would be if he had had

a blood transfusion in his earlier life, and the only other surgery, apart from the mastectomy, which we have mentioned -- and this is at a much earlier date -- is an appendicectomy. Is it conceivable that he could have had a transfusion in association with an appendicectomy?

A. That's very unlikely but I think that patients who have had hospital care at any stage in their life may be exposed to Hepatitis C infection.

We tend to forget that just being in hospital and having procedures done to us is associated with a risk of -- transmission of infection, and that includes Hepatitis C infection. So although the blood products that he has been given are unlikely to be a cause of Hepatitis C transmission, you can never exclude the possibility that he came into contact with Hepatitis C infection during his medical care, not necessarily those inpatient admissions even; it could have been dental or medical treatment that he had at any time in his early life.

Q. The second question, which you have answered, is: what was his ultimate cause of death? Perhaps the only part of your answer -- turn to the next page -- which Dr Bathgate might want to reword slightly, he told us, was the last sentence, where he was really of the view that it might be better to say that Mr Tamburrini died

as a result of the failure of the second transplant and that Hepatitis C contributed to the failure of the second transplant. I suppose you would want to say that the antiviral therapy did too. Is that right?

A. I think the decision to give antiviral therapy was absolutely correct, and perhaps what I haven't said is what a challenge it is to give those particular antivirals to patients who are as sick as Mr Tamburrini and who are receiving so many other medications, and it is recognised that the toxicity of the antiviral treatment is much greater in that setting than it is in giving the drugs to the average non-transplant patient with Hepatitis C, and I think he did have significant side effects from those antivirals.

I use them all the time in my post-transplant patients and they suffer many of the same problems. So I wouldn't want it to come across as suggesting that there is anything wrong in the way that it was given or in the decision to give it; I'm just saying, in fact, that the drugs are very toxic.

Q. Yes. In the round, Dr Mutimer, I don't think you are actually critical of any aspect of Mr Tamburrini's care. Is that right?

A. That's right.

Q. Before we leave your report, I should just correct what

may be a typographical error, which is on the bottom of that page. You narrate what happened after the second transplant and you say that there was the development of significant liver damage by June 2003. The second transplant was February 2004. So I think perhaps that should read, "Development of significant liver damage by June 2004".

A. Yes.

Q. Is that correct? Right. Thank you, Dr Mutimer, I don't have any further questions for you.

THE CHAIRMAN: Mr Di Rollo?

MR DI ROLLO: Yes, I have one or two questions if I may, sir.

Questions by MR DI ROLLO

MR DI ROLLO: Doctor, could we just have a look at a document which is a summary of the general practitioner records [TAM0011459]. It is TAM0011460.

A. I don't know whom I speaking to.

Q. My name is Simon Di Rollo. I'm representing Mr Tamburrini's family.

A. Thank you. I have got a document. 1460.

Q. Yes. If we look at that, as I understand it, we don't have Mr Tamburrini's general practitioner's records because they have been destroyed, but this is, as I understand it, a summary of the GP records, and you

will see that it says "repeat masters" and just above that we see, on the date 31 December 1968, appendicectomy. Is that right?

A. I can just see. Yes, I can see it. 31 December 1968. Appendicectomy.

Q. Yes. Go further up. We look first under 1999, 01/01/1995 says:

"Alcohol consumption in excess."

Do you see that?

A. Yes.

Q. If we go to TAM0011466. We will just have to wait until that comes up on the screen. And if we go down under "Alcohol", and we have there, 01/01/1995, "Current drinker; 18 units per week".

A. Yes.

Q. Would you describe 18 units per week as drinking alcohol to excess?

A. No. If you knew you had Hepatitis C, you would be advised to drink very little and preferably none.

Q. Yes. It might take someone a bit of time to adjust from using alcohol to stop using alcohol, even if they didn't drink to excess.

A. That's true.

Q. There is another point I just want to raise with you in relation to raised MCV, and perhaps you will forgive me

if I haven't fully grasped the science of this, but as I understand it, in your report you make a certain comment in relation to raised MCV level in Mr Tamburrini's case. It is [PEN0100310] and it is page 2. The document number is PEN0100310. I think it is in the third paragraph on the second page. The paragraph begins, "during the 2001 ..." and finishes, "October 2001". It is in the middle of that paragraph.

A. This is my report?

Q. Yes, it is.

A. Thank you.

Q. I think if we go further up to page 2, please. If we go to the first paragraph, it says:

"His MCV at that time was 100."

Do you see that?

A. Yes.

Q. I think, Dr Mutimer, you have prepared a report in a case that we are going to be looking at later on in the week, in relation to the Reverend Black?

A. Yes, I have.

Q. And I just want to ask you to comment in relation to a raised MCV level in that case, in which, as I understand it, there are raised MCV levels at a certain point in that case. If we can put the document in front of you, it is [BLA0010454]. Now,

I think --

A. It is not up yet.

Q. Sorry, running ahead.

Has it come up?

A. It is coming. Is it a haematology report that you are looking at?

Q. Yes, I think so. It is certainly headed up "Haematology department".

A. 454.

Q. Do you see there under "MCV", we have the level there up to 106?

A. Yes.

Q. Is that a raised MCV level there?

A. Yes, it is.

Q. And I don't think there is any suggestion in the case of the Reverend Black that alcohol consumption was to excess or anything of that kind. Are you aware of any suggestion of that nature?

A. I haven't revised his report for the sake of today's hearing but I agree, from what I recall, that there was not an issue about alcohol.

Q. So although a raised MCV level may be consistent with excess alcohol, is it consistent with other things as well?

A. Yes, it is.

Q. Thank you, sir, that's all I wish to ask.
THE CHAIRMAN: Thank you very much, Mr Di Rollo.
Anything from you, Mr Anderson?
MR ANDERSON: Nothing from me, sir.
THE CHAIRMAN: Mr Sheldon?
A. Nothing from me, my Lord.
THE CHAIRMAN: That's all for you, thank you very much, Dr Mutimer.
MS DUNLOP: We will obviously be seeing him again tomorrow.
The final witness for today, sir, is Dr Bruce Cuthbertson.

DR BRUCE CUTHBERTSON (sworn)

Questions by MS DUNLOP

MS DUNLOP: Dr Cuthbertson, good afternoon.
A. Good afternoon.
Q. I'm going on to start by asking you a few questions about your curriculum vitae and I'm hoping we can display that on the screen. The number I have noted for it is WIT0030196. As if by magic, there it is.
We can see from the third page of this -- so 0198 -- that your present role is as quality director for the Scottish National Blood Transfusion Service. Is that correct?
A. That is correct.
Q. And going back to the first page, you studied

microbiology at Edinburgh University. You did a PhD in Glasgow in the study of:

" ... immunological mechanisms responsible for high-titred antibody production in healthy blood donors."

You are a member of the Institute of Biology and a member of the Institute for Quality Assurance. And you have, in fact, been employed from 1974 until now by SNBTS.

A. Correct.

Q. In a number of different roles but you have also, for a large number of years, worked at PFC, which is the protein fractionation centre within the organisation known as SNBTS. Is that correct?

A. That's correct.

Q. You are also on a number of committees and you are in a number of learned societies, and you have contributed to a large number of publications. We have 27 listed here but you say you have also given many oral presentations and more than 15 poster presentations at various meetings.

Your role here today, Dr Cuthbertson, is in relation to the plasma protein solution which was received by a patient, Mr Victor Tamburrini, in Glasgow Royal Infirmary in 1984, and you have carried

out some investigation in relation to that, have you not?

A. Indeed.

Q. Yes. You and your colleague, Dr Perry, have prepared what's called a "Statement of clarification". That statement has in fact recently been augmented. It bears the number [PEN0110048], and perhaps we could all have it in front of us now.

Dr Cuthbertson, there is what perhaps could be characterised as a bit of a red herring here, in that the question with which you deal at the beginning of your paper is a question about a discrepancy between two different sources of material, which the Inquiry team had, about how exactly the material had been heated. Is that correct?

A. That's correct.

Q. And you took some trouble to explain what the discrepancy was and which version of events was correct, but since we are actually going to be hearing from Professor van Aken about the heat treatment and not from Professor Allain, I don't think we need to detain you by going into that at the moment. But more importantly, you then take us through information about the heat treatment process as applied to SPPS. So look at page 2, which is PEN0110049. I think we should start by

clarifying terminology. SPPS, stable plasma protein solution. Is that correct?

A. That's correct.

Q. Is also often referred to as "albumin"?

A. Stable plasma protein solution was a slightly less pure form of albumin. There were two forms of albumin allowed by the pharmacopeia: one which had more than 90 per cent of albumin and one which had greater than 95. One was called officially, in the monograph, "human albumin" and the other was called either "plasma protein fraction" or "stable plasma protein solution".

Q. I see. You explain to us there what the British Pharmacopeia is. In fact, we often see the letters "BP" after the description of a pharmaceutical product and that's what it stands for then, is it, British Pharmacopeia?

A. That's correct.

Q. So, as you say, that is:

" ... providing essential standards for the manufacture and release of medicinal products."

That:

"1194 was issued in 1983. The version of the BP in force at that time was published in 1980."

You have appended the monograph from the 1980 version as a PDF file. I'm not sure if I can

immediately take you to the correct reference for that single page but I think perhaps all that we need to do is look at the extract which you quoted. The extract from the pharmacopeia is [PEN0010259], and that's the page to which you are referring in your paper, is it?

A. That's correct.

Q. And actually, to avoid there being any doubt, you have quoted in your paper the key text, which we see there in italics; and for our purposes, the key sentence comes on page 3 of your paper. So if we could go back to that, please, back to [PEN0110048] and look at page 3, so 0050, a description of how the product is prepared, we see the sentence:

"It is then heated to and maintained for ten hours at 59.5 degrees to 60.5 degrees to prevent the transmission of hepatitis."

You have highlighted that in bold at the end of this section and you say -- although obviously the rest the paper is going to go on to develop this -- that:

"The SNBTS used manufacturing and test procedures which complied fully with this requirement."

Let's look at that in a little more detail, Dr Cuthbertson. Firstly, in section 4 we have the details of the heat treatment process:

"This albumin product was dispensed as

a 4.5 per cent protein solution stabilised with sodium caprylate."

Would it be correct to say that the function of the stabiliser is really to protect the product against the effects of heat?

A. That is correct.

Q. Because you don't want, in your pasteurisation process, to destroy the product which is intended for therapeutic use?

A. Without the stabiliser the albumin would coagulate much the same way as an egg does when you heat it.

Q. And then in section 5 you give us some details of the batch manufacture, and you say:

"The original batch record is available in microfiche format and a copy is appended as a PDF."

This it is, which is number [PEN0010260].

Some of this is not terribly easy to read, no doubt because it is a printout from a microfiche?

A. Correct.

Q. But I should have said, Dr Cuthbertson. I gather you have got your own copy of your statement there. Is that right?

A. That's correct.

Q. And the chairman has no objection to you being allowed to refer to that.

THE CHAIRMAN: No, none at all.
A. It might be easier for me to read that.
THE CHAIRMAN: Take it slowly so that the rest of us get it too.
MS DUNLOP: Yes. So we can see from the front page that this looks like -- this is still 0260 -- a comb-bound booklet. Is that the form in which --
A. Yes, it was a sheaf of papers that were assembled and bound.
Q. Right. And there are a total of 39 pages. I wanted you to look firstly at PEN0010268. So that would be page 9, I think, of your hard copy. Yes. It is a bit faint but if we peer at it, can we see that around about the middle of the page the word "pasteurisation" appears.
A. Yes, that's what that is.
Q. Where the operator, in his own handwriting, has written in a number of details. He has written in "1 to 60", "3.15 pm" and then "1.15 am" and the date, "10/5/83":
"Cabinet number 1 run satisfactory. C L Campbell."
Is that the line that we are looking at?
A. Yes.
Q. Above that, the boxes are headed, as I said "Crates", and there is a time, but above that, what does it say?
"pasteurisation ..."
What's the other word? If we can't work it out? We

can't work it out. I don't think it really matters.

A. I'm not sure what that says, to be honest. I think it just says:

"pasteurisation record" or "load."

Or something like that.

Q. It is perhaps also, in passing, worth noting that the column headed "Crates" is filled in 1 to 60 and we will come back to that.

A. Actually, I think it says "loaded":

"pasteurisation loaded."

It is slightly clearer on my copy than on your screen.

Q. Right. If we can go forward to 285 -- that's page 26, I think, for you -- you see it on the screen as well, which, if nothing else, will help you to find the right page in your hard copy, and it is a reference at the top, "P1194":

"Temperature check on number 5/11 probe of Honeywell."

Is that what that says at the top?

A. Yes.

Q. There is then a table with numbers in. Is that the 60 crates?

A. Yes.

Q. Right. I know you are going to explain all this later

in your paper but just so that we could have a look at some of this for ourselves at the moment, the operator, this C L Campbell -- do you remember his or her first name?

A. Rina, but I couldn't tell you what the C stands for. It's a lady, yes.

Q. Right. So this lady has filled in again:

"Run started: 3.15 pm. Run finished: 1.15 am. Temperature check during run and found to be 60 degrees centigrade."

Then PEN0010297, so the penultimate page in your hard copy, we can see on that there is a label. What's actually going on here with the inclusion of this label?

A. It is a sample of a label that was applied to the batch so that it could be inspected to confirm the details were accurate.

Q. Right. And the label, I think, we can see, has the batch number on it, "1194". Is that correct?

A. Yes.

Q. And the final page also seems to relate to Rina Campbell's contribution to the process because it seems to be some sort of time printout. Can you tell us what this is?

A. This is the chart recording from the actual pasteurisation run. As you mentioned earlier, there

were 60 crates of albumin, each crate held ten bottles and the pasteurisation chamber had six different levels or layers on it. In each one of those, a probe was placed in a representative bottle and then that recording -- the recording from each of those probes was recorded on this chart recording. And this is to confirm that the bottles were all behaving consistently.

It is in two parts because initially we did a quick wash of each bottle because there might be foreign bodies on the surface of the bottles. So that kind of washed it off. So that's the pre-rinse. Then it was cooled down, then it was allowed to start and then run continuously for ten hours at 60 degrees.

Q. So this is some sort of printout or readout from the machine?

A. It is before the sort of digital age, and it is simply a chart recording, with the six individual probes feeding on to this chart recording, which then is printed on the paper. It had a mechanical cog that moved it on while the recording took place throughout the ten hours of the incubation period. The actual scale, I should explain, is not in degrees, it is actually in percentage, and it is an arbitrary scale but it was calibrated so that 60 degrees equated on this particular scale to about 68 arbitrary units, which was

why the second sheet that you showed us earlier had a independent check that it was in fact reading at 60 degrees.

Q. I'm slightly chancing it here, but the calibration on the right-hand side we can see going up 6, 7, 8, 9, 10, then we take the 10 hours from the fact that the line seems to run from just before 8 to just past 18, if we look vertically?

A. Yes.

Q. Right, good.

THE CHAIRMAN: Dr Cuthbertson, I'm not sure I'm following precisely the two stages. Are all of the bottles full when the pre-wash is run?

A. Yes.

THE CHAIRMAN: So this is an external wash of the bottles as filled?

A. Yes.

THE CHAIRMAN: So that is aimed at what, removing any infection externally?

A. No. It is simply to remove any -- because at the recirculating system, it simply removed any protein so that the final product would have no contamination of protein that might have been left from the filling procedure.

THE CHAIRMAN: There might have been a spillage or something

like that?
A. Yes.
THE CHAIRMAN: That's fine.
A. If you imagine that like a whisky filling plant, small amounts of whisky might spill over the edge, this was the same thing. So this was simply to wash it off.
MS DUNLOP: Also, Dr Cuthbertson, I think you feature in the recording on PEN0010261, if we just glance back at PEN0010261, is that your signature, about the middle of the page?
A. Yes, it was. I was the microbiology manager at the time and I signed off the microbiology test results in fact.
Q. Having looked at the actual contents of the batch recording, we then have a section, which deals with the misunderstanding that there had been. I think, really, in short, the misunderstanding was in relation to which bit was the pasteurisation and which bit was the -- what is it? -- the calibration. What was the other part -- I think Professor Allain had looked at -- was it the autoclave steriliser validation test that he had misread as being the pasteurisation record?
A. That is correct.
Q. So you are confident that, in fact, the pasteurisation for ten hours at 60 degrees is vouched by these records?
A. I am indeed.

Q. I think you have been asked to consider in more detail whether something might have gone wrong in the processing of this batch, and if we look at page 6 of your statement of clarification, if we go back to [PEN0110048], which I think will be at 53. The first comment you have made, which is under the heading "Safety of pasteurised albumin products", you have said that the statement in the British Pharmacopeia that:

"The product is heated to and maintained for ten hours at that temperature so as to prevent the transmission of hepatitis."

You say:

"It is very rare for a regulatory document to make such a positive statement."

What is it you think is particularly positive? Is it the words "to prevent the transmission"?

A. Absolutely.

Q. Right. Can you perhaps explain that a little further for the rest of us?

A. Well, albumin has basically got an almost unblemished record of safety in clinical use. It has been in use since it was kind of invented in the 1940s by a US Army group who were looking to produce a stable product that they could use in the theatre of war basically.

To ensure that it was free from transmission of

hepatitis, it was, as we have said, heated at 60 degrees for ten hours and the efficacy of that was proven in a very nasty experiment, really, that was done on human volunteers in the 1940s, where those that received unpasteurised albumin became infected with Hepatitis B and those that received the pasteurised albumin didn't.

Since that time there has only been one recorded case of infection by albumin, and that was reported in the 1970s by a group led by Pattison. It is in Transfusion in 1976 and I think it is referred to by Professor van Aken in his paper.

Q. Yes, it is.

A. And basically that was a situation where the albumin was pasteurised in bulk, in a big tank, and it was found that in that tank there was a small pocket where the product wasn't heated and patients who received that particular product became infected with hepatitis B. And this contrast, all of the products that have been produced since that time by legislation within the pharmacopeia, are heated in the final bottle at 60 degrees.

So the final bottle is dispensed and then pasteurised, and the advantage of that is that there is no prospect of the product being recontaminated or of there being incomplete pasteurisation.

Since that time there has been no report in the world literature of hepatitis, of any sort, being transmitted by albumin and indeed, as far as I'm aware, there has never been in the world literature, a report of non-A non-B hepatitis, or as it later became, Hepatitis C, ever being transmitted by albumin.

So that is the basis on which the pharmacopeia is willing to sort of put its statement that this actually does effectively prevent the transmission of hepatitis.

Q. Now, your next section is entitled "Comments on security of SNBTS processing". You have been asked to address some further questions. In a nutshell, the questions are addressed to the possibility of something going wrong with the pasteurisation. I think the questions were really posed to you as two different hypotheses. First of all, what you record as 8.1, that this batch could have left the PFC without heat treatment having been carried out.

You answer that question, no.

A. I do.

Q. Yes.

A. Yes.

Q. I think you give us really quite a long narrative as to why the answer to that is, in your opinion, no. I don't really want to force you to go through all of this but

it might assist us, I suppose, if we could look at this with your flowchart beside us.

Can we endeavour to display two things simultaneously, please? The flowchart comes at the end -- it is rather difficult to work out because actually there isn't a page number on it, but it is going to be page 12, possibly, of this document. If you add on another 6 that would be 59, I think. I think we need to display the flowchart alongside 54, if he could, please. Dr Cuthbertson, I don't think it would do us any harm if you just talked us through the flowchart, please.

A. Okay.

Q. Are you able to do that?

A. Of course.

Q. Bearing in mind this is, for us, pretty unfamiliar territory.

A. In terms of the bits at the top, the purpose of the right-hand box, which is called "Albumin purification and filtration", that is simply to show that this is actually the end of a process rather than it in its entirety, and the product in question has gone through fairly extensive purification to come up with an albumin solution.

It is a bit like oil refining; the fractionation

process involves us in mining out various proteins, using a variety of biochemical techniques, and the principal one is called cold ethanol fractionation. So at the end of that we have a product, which is, as I said earlier, more than 90 per cent albumin and that is then sterile filtered to remove bacteria and is then dispensed into bottles in an aseptic filling suite, which is manned by people who are trained in sterile processing.

Q. Just to interrupt you. We can take it from the left-hand side of the flowchart that the bottles and the stoppers themselves have been separately sterilised?

A. They have been separately sterilised and they are sterilised at 121 degrees for 15 minutes, and as you can see there, the bottles were sterilised on 9 May 1983 and were held in a sterile environment overnight and the stoppers themselves were sterilised on the day of the filling.

So on the day of the filling, 596 bottles were filled in this particular batch. The process involved placing 400 millimetres into each bottle, then putting a stopper into the neck of each bottle and then an overcap was put over that, which had an aluminium neck, skirt, with a flip-top cap.

Once the bottles had been filled, they were passed

out of the sterile room to an independent sealing machine which sealed the seal on the overcap on each bottle so that there was no risk of the stoppers coming off, kind of like -- sounds like a drink metaphor again, but the wine bottle with a cork in has an overcap put on that; the same sort of idea here.

Q. I think at one point in your paper you refer to it as a "crimped top". I see that as more like a Schweppes bottle?

A. The neck was slightly proud of the rest of the bottle and it was sealed round that.

Q. Sorry, I interrupted you.

A. That's okay. So they were then put into crates of ten and each of the crates was individually labelled with the lot number, and apart from two unpasteurised bottles which were transferred directly to the QC laboratory, the remaining 594 bottles were transferred round to the pasteurisation baths and were loaded into pasteurisation bath one, where they were stacked into the shelves on this great chamber. And the pasteurisation chamber was actually developed by PFC and it was commissioned in 1979. And the way it worked was that there were a number of spray heads that sprayed water over the surface of the bottles.

Q. Like shower spray heads?

A. Exactly the same. And above each crate of ten there were three of these spray heads which sprayed water so that the bottles -- I actually looked for a picture but I am afraid I couldn't find one -- were rolled on to a sort of runner under these spray heads, and as I said earlier, there were six of the crates had probe bottles placed in them.

The doors were then shut and then water that was heated at 60 degrees was recirculated over the surface of the bottles and that very rapidly heated the bottles up to 60 degrees. They were then left that way, as we have seen earlier, for ten hours, and then at the end of that the doors of the pasteurisation baths were opened and the bottles were allowed to cool.

And that takes us up to -- yes -- and then the next stage was the bottles were then -- the crates were then taken out of the pasteurisation bath and were loaded on to cages, but before that was completed, 12 bottles representative of the load were taken and passed to the QC lab for testing.

Q. Sorry, if I can just interrupt. By this point -- and I'm comparing the text with the flowchart -- there are the six dummy bottles, which makes the 594 up to 600, and the dummy bottles simply have temperature probes in them?

A. Well, they had water in them.
Q. Sorry, but that's to check that the water is reaching 60 degrees. Is that correct?
A. That's right, and they were just distributed throughout the load.
Q. At the beginning you have also kept back two unpasteurised bottles which have gone to the quality control laboratory at the start?
A. That's correct.
Q. Yes, right. Sorry, carry on.
A. That's fine. At the end of the run the bottles were put into a cage and then they were sealed with a tag, a security seal, and again the cage was labelled with the individual lot number, which then went into an incubation room, because part of the pharmacopeia requirement is that each bottle is incubated at around 30 degrees for two weeks for any bacterial contamination to grow and be evident. Because albumin is a very good growth medium for bacterial contamination.

After that, they remained within the cage in a holding area until they were inspected, and they weren't inspected until the QC had been performed, and part of the QC, as we will come back to, actually demonstrated that the product had been pasteurised effectively. Once all the batch testing had been

completed and the manufacturing records had been reviewed, then the batch was released for labeling and packaging and inspection.

And that was actually done in this record by a QC manager on 30 June 1983.

Q. I think just to interrupt you again, the sentence which you have, if you look at the text -- I struggled slightly with the sentence beginning "although":

"Although it is virtually inconceivable that non-pasteurised SPPS could have been included in a batch intended for clinical use, a further safeguard ..."

I think something is missing there. I think perhaps we need the words:

"There was a further safeguard."

Or something like that:

"There was a further safeguard which would have prevented the inclusion of one or more non-pasteurised bottles."

A. Yes.

Q. Maybe not actually, sorry. I think it is my fault:

"A further safeguard, which would have prevented the inclusion of one or more non-pasteurised bottles, resulted from the inspection."

I think we just maybe need a comma after "bottles".

A. Yes.

Q. You will take a comma after "bottles", Dr Cuthbertson.
A. I certainly will.
It was actually quite a complex sentence and my legal counsel advised that at the time.
Q. Yes, it's getting a bit late in the day.
A. The purpose of the inspection which was carried out before the bottles were labelled was multiple. Firstly, it was to demonstrate that the actual seal on the neck of the bottle that I have described was integral, because it was a tamper-proof seal that we put on and clearly it needed to be integral when it left the plant. But, secondly, each bottle was examined under two forms of light, direct light and polarised light, to look for the presence of any sort of contamination, be it bacterial, or in some cases there were things like fibres that had got into the bottle.
Q. This is visually examined?
A. And then it was visually examined.
Q. Naked eye?
A. Yes, each bottle was visually examined. So we carried out an inspection in an inspection room. The batch record doesn't actually have a statement in it that the labeling area had been inspected and was clear. So only one batch was in there at that one time.
They were inspected for any defects, and the point

of the very complicated sentence is that, one, albumin is pasteurised, its characteristics change. As it is filled, before it is heated, it is a sort of light, fairly clear, slightly browny solution. And the pasteurisation does actually change it. It becomes slightly more opalescent and it goes from that light browny colour to a sort of greeny browny colour, and they are quite clearly visually distinct, and the point of the complex sentence was to say that if, by any chance, there had been any confusion about the pasteurisation of all or part of the batch, then that would have been detected at this inspection, when every individual bottle was inspected for quality. In all my experience at PFC we never had such an event, but if that had occurred, then it would have been easily picked up.

So the inspection was multifold but one of the by-products of it would have been to detect whether or not an individual bottle had not been pasteurised.

Q. Right, and every bottle is looked at?

A. And every bottle is examined.

Q. Yes.

A. I'm not really proud of this, but in actual fact in this particular batch there was something like 110 reject bottles, which I think is evidence that they had all

been individually examined.

Q. We are on to page 8 now, I think, really, where you have described the visual change, which is effected in albumin by pasteurisation. But just again to reconcile what's in your text with what's in the batch processing record, I think we find what you say, page 38 of the batch record, at PEN0010297 in the actual batch records. So we need to replace one of the things we are looking at with the batch processing record.

Look at PEN0010297.

A. Yes.

Q. That's your reconciliation sheet, is it?

A. Yes. But that's, if you like, the summary of all of the inspection activities that were carried out on this particular batch, which initially confirms that the labels in the batch information was correct. There is a statement there that says there was a card check on the cages and then it says in brackets "SPPS only" and that's because only SPPS was actually in cages; all other bottles were in a different form of container -- just to demonstrate that it was the correct batch that had been removed.

Q. And there is the 110 rejects, someone has written in.

A. Yes, that's right. So originally 594 bottles went into the pasteurisation cabinets. 12 of those were taken as

standard QC samples, one was submitted for rabbit pyrogen testing, one was submitted for abnormal toxicity testing. 110 were rejected. It doesn't say why but, as I said, most of those will have been because of the presence of perhaps fibres in the bottle. And that left 470 good bottles that went on to be labelled and packaged.

Q. Right. I think actually we already looked at what you say in your text:

"Secondly, the run sheets shows 60 crates were loaded into the pasteurisation bath and the position of the probes was recorded correctly."

Then:

"Thirdly, only two bottles of albumin remained unpasteurised."

This is reading from page 8 of your statement, if we go back to that. Thirdly, you have explained that there were the unpasteurised bottles -- I think, because it is late in the day, we won't necessarily look at this for ourselves, but it is within the record that there is a column for A bottles and a column for the B bottles. The B bottles were the 12 that were not subjected to the pasteurisation process, as you told us earlier.

A. No, it was the other way round.

Q. I'm sorry.

A. The 12 were the ones that were pasteurised.
Q. Sorry, 12 that were, and you told us earlier in the flowchart that they went to the quality control laboratory.
A. Yes.
Q. The unpasteurised bottles and the pasteurised bottles are compared. Maybe we should have this in front of us. PEN0010275 in the batch record. That's your reference, page 16. That's what happened on 10 May. You tell us that the two bottles were delivered to the quality control laboratory on 10 May. The other bottles were delivered on 11 May and -- this is the denouement -- it is actually PEN0010265 that shows the results of the comparison.

We see the A bottles compared with the B bottles. So the A bottles are the bottles that have not been pasteurised and the B bottles are the pasteurised bottles. You give us, on page 9 of your paper, some of the changes that could be observed by that comparison exercise. For example: elimination of alkaline phosphatase, increase of high molecular weight and detection of albumin polyacrylamide gel electrophoresis testing.

THE CHAIRMAN: Ms Dunlop, how are we getting on?
MS DUNLOP: We are nearly finished. I'm hopeful that we can

finish in about five or ten minutes.

THE CHAIRMAN: Right. That includes making due provision for Mr Di Rollo and the others?

MS DUNLOP: Well, I mean, I can take this very quickly. I'll try for five minutes.

THE CHAIRMAN: Perhaps I can ask a couple of questions just to perhaps inhibit you somewhat.

Dr Cuthbertson, you told us that the albumin was the end of a process. You didn't tell us where it began, and it might be helpful to know what the raw material coming into PFC was.

A. The raw material was plasma, which was the liquid part of each blood donation, which was collected by, in 1983, six centres, the five Scottish centres, and we also took in plasma from Northern Ireland. Each plasma donation holds about 250 millilitres, and in those days we were processing in batches of about 500 litres. So that's about 2,000 donations.

The plasma was crushed and then, as I said earlier, it was fractionated through a number of different processes.

THE CHAIRMAN: I don't think that we should get the full fractionation process today.

A. No, I'm not going to give you that, but into a number of different process that led to the albumin being

purified. A typical yield was about one bottle of albumin per litre of plasma and a typical batch would have come from about 3,000 donors in those days. So it is a pooled plasma product which has been fractionated into the various components.

THE CHAIRMAN: I'm sure everyone will become familiar with fractionisation. The other question is the reference to fibres or fibre-type material that's seen on inspection of this now opalescent product. What do you mean by "fibres"? Is that cat's hairs and things like that?

A. No, we did actually do a very full investigation and the principal source actually, forensically -- we went to the police with it -- was actually from the gowns of the operating staff, and subsequent to 1983 we actually put in a very expensive piece of cleaning equipment which substantially reduced the number of these so-called "fibre rejects".

MS DUNLOP: In short, Dr Cuthbertson, that section, 8.1 of your paper, is designed to show that all the requisite processes were carried out on batch 1194 and that the quality control process was completed and the record is there to show that.

A. That's correct.

Q. The other question you were asked was whether it was possible that the batch could have been contaminated in

some way after treatment, which could have caused it to transmit HCV. This is the foot of page 9, and you have answered that, I think. The clearest answer for us to follow is that the pasteurisation was conducted on bottles which were already sealed. And they were not opened again.

A. No, not until they were required by the patient.

Q. Yes.

A. And as I mentioned earlier, there is a tamper-proof seal so if that had come off, then the bottle would automatically be rejected.

Q. And in fact, for good measure, you have added in, on page 10, that Hepatitis C was never used in any virucidal efficiency trials, so you were not, in fact, working with Hepatitis C for good reason in 1983. In 1983 no one had Hepatitis C virus anyway. In fact, my understanding is even today it hasn't been properly isolated.

A. It has not been formally cultured, no.

Q. So it is not as though anyone was working with Hepatitis C. Then finally you have conducted, or caused to be conducted, some enquiries within SNBTS to see if there were any records of anyone else acquiring Hepatitis C from this particular batch. We can, I hope, call up the right documentation in relation to that.

[PEN0110004].

You were asked whether there is any record of anyone else and you say, just reading it short, that you do not have records of the patients to whom the products were infused -- that would be an individual patient's records -- but you say it could be assumed that over 100 patients will have received this batch in the rest of Scotland and Northern Ireland, and you have no record of any patient being infected through the use of SPPS, in fact, at all, whether batch 1194 or any other.

A. That's correct.

Q. And there is also a statement by Dr Jacqueline Barry, who is the pharmacal vigilance manager from SNBTS, which is PEN0010060, which is at the very back of your statement of clarification. Perhaps we can go to the last passage and scroll back from the last page. It is one of the final pages. I don't think it has actually got a number on it. Yes, it is not that one obviously, the one before maybe?

A. Yes, I think it is.

Q. Yes, there we are, Dr Jacqueline Barry?

A. Yes.

Q. Dr Jacqueline Barry, right. She says:

"There has been a formal review of the pharmacal vigilance files ... 42 reports of adverse reactions but

none of them related to infectious episodes, nor reports of a transmission of infectious disease associated with albumin arrest, PPS."

Thank you, Dr Cuthbertson.

THE CHAIRMAN: Mr Di Rollo?

MR DI ROLLO: I think, sir, I would just ask if I could reserve my position in relation to this matter. There are some systemic issues which may arise out of PFC and the position is that this statement we got yesterday, or the final version of it, and there may be other matters that we wish to ask questions about in due course but I wonder if I could just reserve my position at the moment.

THE CHAIRMAN: Well, I'm content at the moment, Mr Di Rollo, but do remember that your purpose in being here is to help me get to answers, and I expect you to let Ms Dunlop and the others know, as we go, what issues are arising so that counsel and the witness can be given a proper opportunity to consider matters. But certainly you may reserve your position at the moment.

MR DI ROLLO: Thank you.

THE CHAIRMAN: I rather think that that was another way of suggesting it is time we went home.

Dr Cuthbertson, you realise that those of us who sit here all day eventually reach the point of saturation

and we therefore have to have a break. Ms Dunlop, is it appropriate to break at this stage?

MS DUNLOP: Yes, I was just confirming, I don't think either of the other legal teams wants to put any question to Dr Cuthbertson at this stage. There is every likelihood we will be seeing Dr Cuthbertson again anyway.

THE CHAIRMAN: I was assuming it was inevitable we would see Dr Cuthbertson again, but if that is sufficient for the moment, then we can release Dr Cuthbertson.

Thank you for your attendance so far.

A. Thank you, sir.

(4.27 pm)

(The court adjourned until 9.30 am the following day)

I N D E X

Introduction by MS DUNLOP 4
MRS JEAN TAMBURRINI (sworn) 6
Questions by MS DUNLOP 7
DR ANDREW BATHGATE (sworn) 21
Questions by MS DUNLOP 21
Questions by MR DI ROLLO 79
DR DAVID MUTIMER (sworn) 87
Questions by MS DUNLOP 87
Questions by MR DI ROLLO 116

DR BRUCE CUTHBERTSON (sworn) 120
Questions by MS DUNLOP 120