Tuesday, 15 March 23011

(9.30 am)

THE CHAIRMAN: Good morning everybody. Ms Dunlop?

MS DUNLOP: Good morning, sir. I have prepared some very short remarks to make in relation to each of the four individuals, whose deaths the Inquiry requires to examine and in relation to whose deaths evidence was led last week.

I don't know whether you would prefer, sir that, I conclude all my remarks -- that is on all four -- before passing to other parties or whether you prefer me to speak on one and then allow other parties to speak.

THE CHAIRMAN: At this stage, I don't think it matters much but I think in the long-term, when I have to go back over matters, there might be an advantage in having each dealt with individually.

MS DUNLOP: Right.

THE CHAIRMAN: So if we do it that way, please.

MS DUNLOP: Right. Firstly then, in relation to Mr Victor Tamburrini, the evidence has shown that he was born on 27 April 1957 and he died on 17 November 2004 at Edinburgh Royal Infirmary. The cause of his death was the failure of a second liver transplant, that failure being due to recurrent Hepatitis C.

As far as the onset of his symptoms is concerned, he

had abnormal liver function tests by 1998 and he also had gynaecomastia, which we know from the evidence is a sign of advanced liver disease; both Dr Mutimer and Dr Alexander spoke about that.

The experts told us last week that it takes on average about 20 years to progress from infection to cirrhosis, it certainly then appears that he had cirrhosis by 1998 but for how long before that, it is hard to say.

Dr Mutimer's view was that Mr Tamburrini may have been infected with the virus in his teens or his 20s and that was based on his own experience of looking at individuals who, one assumes in a very broad sense, were like Mr Tamburrini. He said that in that group of people in Birmingham, the average age at which people come to transplant was 55.

It certainly appears that the course of his illness was fairly relentless. He had a positive test for the virus in September 2001; the first transplant on 26 October 2002. That transplant failed and he underwent a further transplant on 4 February 2004, dying around nine months later.

Dr Mutimer, the independent expert asked to comment on Mr Tamburrini's care by the Inquiry, said that he was not critical of any aspects of Mr Tamburrini's care.

How did he acquire Hepatitis C virus?

Well, the Inquiry has heard that he suffered burns and in the course of treatment for those burns, in 1984 at Glasgow Royal Infirmary, he was administered Stable Plasma Protein Solution. Research has resulted in the identification of the batch of SPPS by its number, and details of the treatment of that batch by a method accepted internationally as adequate, indeed ten times what would be adequate to inactivate the virus. The actual process on this particular batch was spoken to by Dr Cuthbertson and its efficacy by Professor van Aken.

We also know that there was a transfusion in 1998 at the time of further surgery, and that transfusion can be ruled out as a source of infection, both because of the extent of Mr Tamburrini's disease by then and also because of the evidence of Dr Peterkin, regarding each unit of red cells transfused at that time. In summary, all the donors were negative for Hepatitis C before the transfusion and have all been found to be negative since the transfusion, and she even researched a pack which was pierced in error and apparently discarded.

So my suggestion to you, sir, is that from the evidence led last week, there is not enough to allow you to conclude that Mr Tamburrini acquired Hepatitis C

virus as a result of National Health Service treatment. I would also suggest that the evidence has not revealed anything of the nature of a systemic issue that one would want to note and explore later in the Inquiry.

THE CHAIRMAN: The only question I would raise is whether, while there may be no systemic issues, there is material within the evidence given by the experts in relation to Mr Tamburrini's case that bears on a proper understanding of the natural history of Hepatitis C as it is developing, and that is the suggestion that I think is there, that drinking alcohol to any extent is in effect an accelerant in the progression. I don't know whether you would consider that that would fall under a systemic head or whether it is something that I ought to be interested in generally, not particularly related to Mr Tamburrini.

MS DUNLOP: Well, sir, it's certainly not something that the Inquiry team had planned to investigate in any detail. It may be something --

THE CHAIRMAN: I don't think you have, Ms Dunlop, but it is impossible to overlook the fact that in giving evidence, Dr Mutimer and Dr Bathgate each referred to this in slightly different ways, as something that affects -- not acquiring Hepatitis C but affects the rate at which Hepatitis C may damage the liver.

MS DUNLOP: It has been my understanding of the evidence, sir, that if one looks at Mr Tamburrini's death in November 2004, it is clear that that was because of the failure of a second liver transplant and that that failure was caused by very aggressive recurrent Hepatitis C.

THE CHAIRMAN: Yes, that's not the point that I'm interested in.

MS DUNLOP: I wonder if I could finish perhaps.

THE CHAIRMAN: Yes.

MS DUNLOP: If we look at the previous transplant, the 2002 transplant --

THE CHAIRMAN: Yes.

MS DUNLOP: -- it is also clear from the evidence that that transplant was carried out at a time when Mr Tamburrini had been told that he must become abstinent from alcohol and he had become abstinent from alcohol. So although for any individual with the Hepatitis C virus one might -- and liver surgeons, no doubt, are taking an interest in whether they consume any alcohol, therefore alcohol may feature for any patient as part of the very basic background circumstances that for this particular individual, given his abstinence in 2002 and the progress of his disease from then on, alcohol has faded from the picture as being in any real sense a cause of

his death in 2004.

THE CHAIRMAN: I think that that would be my impression at the moment. I can't say it's my view since matters are still open, but the evidence last week has brought out, I think, aspects of the natural history of Hepatitis C which are rather different, perhaps, from those I had anticipated.

Professor Alexander, for example, gave his description of the effect of the individuals' biological life as a significant factor in causing deterioration, the age of infection and the possibilities of things developing, are matters that have been growing in my mind. I don't really mind at the moment how you care to approach presenting that type of evidence, I have no doubt opportunities will come, but my concern at the moment is in the general.

I have raised it under this heading, because the evidence first emerged in that way. But I think all I can say is that I do have a significant interest in understanding better where we now stand in relation to the natural history of hepatitis.

MS DUNLOP: Perhaps I could draw to your attention, sir, that it is our plan to begin what we call the "C topics", that is a list of topics which relate fairly directly to Hepatitis C, to begin that section of the

Inquiry, with, as it were, a general question and answer session almost, on the Hepatitis C virus, and that's certainly a factor that we can address with one or more experts on the natural history of the disease.

THE CHAIRMAN: That's fine. Having left matters to you to develop, Ms Dunlop, I must sit back and await what you present. But I'm only anxious that you should be aware that last week did alert me to the need to develop my understanding of some of these matters.

MS DUNLOP: Thank you, sir.

THE CHAIRMAN: Mr Di Rollo, do you have any comments to make on what Ms Dunlop has said or on whether there are systemic issues that you have identified that arise from Mr Tamburrini's case?

MR DI ROLLO: As I understood it, sir, the purpose of today's discussion was to discuss whether systemic issues arose in relation to deaths. I didn't understand that now was the time to discuss anything in relation to findings in respect of the individuals' deaths themselves, and nothing which has been indicated in terms of what has been said already causes me any great concern, but dealing specifically with systemic issues, it does seem, respectfully, to me that Mr Tamburrini's case does shed light on the course of the disease, ie the course of the progression of Hepatitis C and our

investigation, or the evidence that we have heard last week, does highlight features of that which do raise a systemic issue for the rest of the Inquiry.

Difficulties --

THE CHAIRMAN: Sorry, what is that systemic issue?

MR DI ROLLO: The systemic issue, it seems to me, is the time that it takes for Hepatitis C to develop, how the disease progresses, if it might vary from person to person.

THE CHAIRMAN: May I interrupt? Is that the same issue that I was trying to describe?

MR DI ROLLO: Pretty much.

THE CHAIRMAN: Broadly the natural history of the disease as it affects individuals.

MR DI ROLLO: Yes, indeed.

THE CHAIRMAN: I think it is clear from what Ms Dunlop says that there will be plenty of opportunity to begin to study that in section C.

MR DI ROLLO: There are three other things that concern me in terms of the situation with Mr Tamburrini. It does appear that certain assumptions may be made about people who present with Hepatitis C by medical practitioners or by people working in the health service generally, in terms of their lifestyle.

It does, it seems to me, to highlight, at least in

a potential sense, the stigma that Hepatitis C presents for people with it and this case also, it seems to me, highlights the difficulties that individuals may have who use alcohol responsibly would have in abstaining from alcohol once they are given a diagnosis of Hepatitis C.

THE CHAIRMAN: I'm slightly concerned about the scope of the last point. I can understand the first: that there is material already in the public domain, before the Inquiry, that could cause one to look, perhaps more critically than otherwise, at the attitude of health service professionals that may be said to reflect a degree of suspicion, in some cases unjustified. For example, Mrs O'Hara that we will come to. So I see that.

I'm slightly concerned about what you mean about alcohol and hepatitis and how people should react, the difficulties that individuals may have who use alcohol responsibly in abstaining once their diagnosis is given. I'm not sure that my terms of reference actually deal with alcohol counselling and treatment to that extent, but bear that in mind. I'm not suggesting that you shouldn't look at the matter yet but bear in mind that the whole issue of alcohol counselling and treatment is a very wide one and I have not been asked to look at

that.

MR DI ROLLO: The other thing I did mention is the stigma of Hepatitis C and certain assumptions about lifestyle may be made, which is clearly an important matter, and arises in Mr Tamburrini's case in a particular way, potentially at least, and it arises in other cases too. But it is something which is, in my submission, a systemic point.

THE CHAIRMAN: I'm not so sure about that but it is good to have your comments on it at this stage.

MR DI ROLLO: Before we move on from Mr Tamburrini's case, there are certain issues which concern me in relation to certain features of the evidence, and I am unclear as to how the Inquiry is going to be asked or going to proceed in relation to making findings in relation to this matter.

Certain issues have not been explored in detail and my learned friend, counsel to the Inquiry, did indicate that the proposition was to be put forward that Mr Tamburrini was not infected as a result of treatments through the NHS. Evidence was given by Dr Mutimer that any hospital admission did have the potential, whether it was as a result of blood transfusion or a blood product or plasma or whatever else, did have the potential at least to cause an infection of Hepatitis C.

THE CHAIRMAN: If you look at the terms of reference, what I'm asked to do and what I think Ms Dunlop has been addressing, is the question of the cause by National Health Service treatment. Among other possible sources of infection, there has been reference to just general exposure to the hospital environment; that's there. There have been references to the sharing of needles as a possibility. If I start accumulating possibilities, Mr Di Rollo, I'm not sure where you expect me to end.

I just ask you to bear in mind that sometimes starting a hare is starting out on a course of total unpredictability. It may be that one answer here that one would end up with would be that it is not possible to say what the source of infection was. Once one has done that, listing the theoretical possibilities may not help anyone. But it is a matter for you. But I do urge you to think carefully about the end, not the telomeres, but the telemetry of your approach.

Still, it is a matter entirely for you on this batch but I take note of what you say. Any other possibilities?

MR DI ROLLO: I'm not sure what you want me to do now. I'm a little bit confused about what is expected of me in relation to this matter, I have to say. I don't know

what you want me to say or do at this stage.

THE CHAIRMAN: I'm looking for your help in working out where the Inquiry is going, Mr Di Rollo. It is a perfectly open and unqualified invitation to tell me what matters you think arise. If you have done that, I'm content. If there are other matters that you think arise from Mr Tamburrini's case, I'm happy to hear from you. I don't expect you to make final concluding submissions. As this Inquiry draws to its end, I would hope to get the help from all parties with submissions on matters of importance. And of course, the draft report will be circulated for comment and each individual with an interest will have an opportunity to make representations as to the accuracy of the draft report and as to omissions and additions that might be required. That all lies ahead.

I don't know what your difficulty is.

MR DI ROLLO: Well, I have indicated the systemic issue that arises from the discussion or the evidence that was provided last week. I have also indicated our difficulty, and I think you are well aware, sir, of the difficulties that we have with the evidence that was given last week and --

THE CHAIRMAN: I'm not. I have seen certain representations about alleged difficulties but I don't myself identify

them. It is entirely a matter for you, what you bring out, Mr Di Rollo. I did not ask for Mr Tamburrini to be brought here. I don't know the background to the invitation that he should have been listed as a cause for investigation. Matters have come out in evidence and they are there. And I will have to deal with them. But I don't see that as a particular difficulty.

MR DI ROLLO: Well, the problem that I have is that, in relation to Mr Tamburrini, Mr Tamburrini's relatives were told, in no uncertain terms at one-stage, that he was infected as a result of NHS treatment. That's what they were told.

THE CHAIRMAN: By whom?

MR DI ROLLO: There is a specific reference.

THE CHAIRMAN: Yes, I know, but this is an Inquiry into the facts. What someone else may have thought at some time in the past and on what evidential basis, I don't know and I cannot say what assumptions were made. I cannot say what analysis was made. I begin this Inquiry from the date I was appointed with the terms of reference I have got, and it is my obligation to investigate the facts, Mr Di Rollo.

Those facts, it seems to me, have been very thoroughly investigated to date and will no doubt receive further investigation. But any misconceptions

that led to the events or led to my terms of reference, are not a matter for me. I have to take them as they are.

I can assure you I will not go into the background. I'm not sure it would do anybody any good -- and I mean anybody -- but it doesn't seem to me to be relevant. I couldn't take anything you have asked me, for example, in effect, to revise the terms of a death certificate, to give effect to hepatitis in the case of Mrs O'Hara. That's what it amounts to.

MR DI ROLLO: I didn't ask anybody to do anything.

THE CHAIRMAN: You have challenged the completeness of the cause of death.

MR DI ROLLO: I have done no such thing.

THE CHAIRMAN: Oh, well --

MR DI ROLLO: I haven't challenged the completeness of any death certificate. I have simply asked a question.

THE CHAIRMAN: I'm trying to be helpful. I'm not trying to obstruct, but if you are incapable of accepting help, we will just get on. Do you have any other systemic issues to raise.

MR DI ROLLO: No.

THE CHAIRMAN: Mr Anderson?

MR ANDERSON: I'm obliged sir. Counsel to the Inquiry had two conclusions. The first was that the evidence did

not allow you, sir, to conclude that Mr Tamburrini was infected with Hepatitis C from NHS treatment, and clearly I have no quarrel with such a summation.

I suppose another way of putting it, however, is that we simply don't know how Mr Tamburrini came to be infected, and you, yourself, sir, have alluded to that already.

The second suggestion was that the investigation into Mr Tamburrini's death did not reveal any systemic issue, and with that I agree, and I have nothing further to say.

THE CHAIRMAN: Well, I think you can take it from what Mr Di Rollo said that there are differences of view on that, and you will no doubt take account of what he has indicated as potential systemic issues so far as they affect your clients' interest.

MR ANDERSON: Of course.

THE CHAIRMAN: Yes, Mr Sheldon?

MR SHELDON: Sir, there is very little that I can usefully add to the discussion that has already taken place. (inaudible) counsel to the Inquiry has already said. Sir, I think there is perhaps a limit to the proper extent of the minister's involvement, indeed in this particular chapter of the Inquiry or the extent to which submissions or suggestions can and should properly be made.

THE CHAIRMAN: Well, Mr Sheldon, I'll leave that to you. The mysterious ways of ministers are not always open to my understanding.

Ms Dunlop, has this been a helpful approach or is it merely causing muddying of waters?

MS DUNLOP: Perhaps I'm not the person to answer that, sir. I can certainly see the intention was to be helpful. The first perception was that we began our whole Inquiry with an examination of the circumstances of four people. By the end this will be a very long time in the past and some sort of taking stock issue at the end of that chapter of the evidence seemed like a good idea.

We have also been reminded by those who represent the families that there may well be systemic issues arising from the deaths of any one of those people and they have asked, entirely properly: how are those systemic issues to be examined? What we have said throughout is that we would endeavour to note them. We can't digress and have investigation of systemic issues along the way. We need to complete the examination of the evidence in relation to each of the four individuals, but we would note systemic issues which seemed to be revealed and return to them when we look at the general topics.

So the purpose of this was really twofold. Firstly

to do a kind of stocktaking, not as formal as submissions because it is probably better that all the submissions are heard together at the end, but a sort of stocktaking, reviewing where we have reached, and also noting if systemic issues have been revealed, which fall to be examined in the later stages, but if it is not helpful, I don't need to --

THE CHAIRMAN: I think it is helpful. I'm just concerned that others appear not to and don't appear to understand the purpose of the exercise at all.

But let's proceed. We have heard about Mr Tamburrini and I would like you now to go on with the other three.

MS DUNLOP: Sir, in relation to the Reverend David Black, we know that he was born on 1 May 1937 and that he died on 31 October 2003 at Strathcarron Hospice. The cause of his death was hepatocellular carcinoma in a transplanted liver.

Insofar as his treatment for haemophilia is concerned, the first record of any sort of detail that we have been able to discover of the administration of specific treatment is in 1965, when he received four flasks of AHG. It is probable that he also received cryoprecipitate in 1969. Both of these, 1965 and 1969, appear to have been dental extractions. It is also

probable that he received a large pool concentrate in 1975 and it appears to be definitely the case that he received a large pool concentrate in 1978.

There has also been reference to treatment by Dr Judith Pool, in Stanford in the United States, around 1970 and I should add, sir, to what was explored in evidence last week, by saying that there is on [BLA0012153]. We don't need to go to it. I can see people springing to attention ready to look at it. Just noting that 2153 is a better link between the episode Mrs Black describes in her statements of being ill on the way back from Korea and treatment in America. But that seems to be what she is describing in her statement, because 2153 refers to the Reverend Black being at that time returning from Korea and he is taken ill in California.

THE CHAIRMAN: There is a record of him being treated in Florida.

MS DUNLOP: Yes.

THE CHAIRMAN: I think you were uncertain when we looked at one document about it, but inevitably I have been looking around and there is a clear reference to Florida as a place he was treated.

MS DUNLOP: Yes, that's 1987, we saw a bit further on. But, yes, under the stress of the moment, I found it

impossible to identify Florida in relation to the Lawnwood Medical Centre but in fact Professor James pointed out that there is documentation around that time which shows him being recorded as living in Florida.

The first abnormal liver function test was 1979. He then appears to have had normal liver function tests in 1984 but then they were abnormal again in 1985 and he had a positive test for the virus in October 1991. We saw from the records that there was consideration of interferon treatment in the early 1990s, but he didn't undergo that.

He had his transplant in 1996 but unfortunately his liver function tests never returned entirely to normal. The sequence of events which I would suggest led to Mr Black's death is that he suffered from haemophilia, which led to the transfusion of blood products which caused Hepatitis C, which caused hepatocellular carcinoma in a transplanted liver. The fact that there had been extensive tumour in the explanted liver, in his own liver, was not known to his family until the investigations initiated by the Inquiry and that fact has been a shock to them.

But the evidence reveals that it's difficult to know, in fact it is impossible to know, whether the tumour from which Mr Black died in 2003, was

a recurrence of the previous carcinoma or the development of new tumour.

If it was a recurrence, then the evidence leads to the conclusion that there was no treatment available in the interval which would have altered the outcome. If it was a new tumour, then Dr Mutimer told the Inquiry that the only possible means of preventing its development would have been a prompt resort to antiviral medication after the transplant in 1996, to prevent such a development. But the evidence has also shown that interferon treatment at that time would have been extremely unpleasant and we also know from other evidence that there were very low chances of success in eradicating the virus at that time.

In relation to the shock which the family have experienced, learning that Mr Black's own liver was affected by carcinoma, that has caused the transplant unit at Edinburgh Royal Infirmary to conduct further investigations, and a report and a letter have been provided by the consultants at the unit offering to meet the family to discuss that aspect of matters.

Dr Colvin's evidence was that Mr Black's treatment was not unreasonable or inappropriate at any stage. The Hepatitis C virus was not identified until the late 1980s and there was no treatment of blood products until

the mid 1980s. So it hasn't emerged that there was any step which could have been taken, which could have prevented Mr Black's infection some decades before that. Insofar as his liver disease is concerned, Dr Mutimer said that his management was entirely appropriate.

I don't want to get into a debate about what is or isn't a systemic issue but perhaps I could simply say that the whole question of treatment of the blood products, and indeed the whole history of identification of the virus, will both be looked at as we move through the Inquiry, but as matters currently look, there isn't anything that has been identified by the investigation of Mr Black's death that looks to be a contender for a possible means of preventing Mr Black's death from Hepatitis C.

THE CHAIRMAN: Mr Di Rollo, I hope it is clear that you are not required to make final submissions at this stage on the facts but if you took serious issue with anything Ms Dunlop has said, I would wish to hear and I also wish to hear whether you have identified any systemic issues that you would like to flag up for investigation?

MR DI ROLLO: I don't wish to take any issue with anything that Ms Dunlop has said, sir. I think there are things in relation to history of the Reverend Black which highlighted matters which are systemic issues but those

systemic issues are being investigated, as I understand it, in any event. So I don't think there is anything specifically that arises as a result of this matter which can be linked specifically to it.

THE CHAIRMAN: It is not the end of the story. If it should turn out in the course of the wider examination that there are matters that can properly be referred back to any aspect of Mr Black's case, they can be raised but you don't identify anything in particular at this point that you would wish to flag up yourself?

MR DI ROLLO: Not specifically arising out of this death, no.

THE CHAIRMAN: Mr Anderson?

MR ANDERSON: Sir, I have nothing to add to the comments of counsel to the Inquiry, which I would respectfully adopt.

THE CHAIRMAN: Mr Sheldon?

MR SHELDON: I don't take issue with anything that Ms Dunlop has said.

THE CHAIRMAN: Ms Dunlop?

MS DUNLOP: Sir, I move to look at Mrs Eileen O'Hara, who was born on 9 October 1930 and who died on 7 May 2003 at Stobhill Hospital in Glasgow.

It is not a straightforward matter to summarise what the cause of Mrs O'Hara's death was. The evidence,

I would suggest, tends to lead to the conclusion that she died of sepsis in the form of pancreatitis and cellulitis, together with heart disease and liver failure caused by Hepatitis C. And the liver disease -- probably true also of the heart disease but since we are focusing on the liver disease -- the liver disease affected her potential to survive the infective illness.

For Mrs O'Hara, the onset of her symptoms seems to have been in the late 1980s. She did have abnormal liver function tests in 1984, although that could have been attributable to heart disease. There was, as we heard, a test for Hepatitis C at the end of 1990, which was negative but the clear weight of the evidence seems to be that that was probably a false negative result.

She was not in fact diagnosed as having Hepatitis C until 1995. After that there was some involvement of a gastroenterologist, Dr Forrest, but he does not appear ever to have seen the patient. His advice was that the chances of successful treatment with interferon were very low, and that advice Dr Mutimer found acceptable but you might take the view, sir, that the evidence discloses a gap in the information and advice which was given to Mrs O'Hara about having the virus.

THE CHAIRMAN: There is quite a difficult period between 1991 and 1994, when perhaps someone took their eye off

the ball.

MS DUNLOP: Well, sir, that certainly was the time when two very conscientious physicians who regularly saw Mrs O'Hara, one for her diabetes and one for her heart complaint, seemed to be trying to get to the bottom of what was wrong with her, and no one could suggest that that was an easy task, but once the positive test result had been received in 1995, it might be thought that she should at least have had one meeting with the gastroenterologist or somebody who was really in a position to explain what it meant to be told that you had Hepatitis C, instead of which, it was in fact her family, and her daughter, who was a qualified nurse, in particular who seemed to have done most of the research.

The evidence that we heard last week provides what you might think, sir, is a natural comparison with Mrs O'Hara's care in the form of the care given to Mr Laing, because we can see from that evidence that Mr Laing, who was diagnosed at roughly the same time, received counselling and indeed regular and conscientious follow-up at Aberdeen Royal Infirmary for the fact that he had Hepatitis C.

We understand that the difference was that Mr Laing was formally identified as part of a look-back procedure but that in practice there wasn't any difference between

the mechanism by which these two individuals had acquired their infection. There probably is a difference in the degree of certainty with which one can express the conclusions but it does appear that Mrs O'Hara is extremely likely to have acquired her infection through blood transfusion as well. We might consider, sir, that it is a bit of a pity that she doesn't appear to have received anything approaching the level of counselling and support which was offered to Mr Laing.

THE CHAIRMAN: Yes. I'm not sure that pity is the way one should necessarily put it. What occurs to me at the moment as being likely to give rise to systemic issues is the difference in treatment of patients that one can see in the case of the look-back exercise, where there were clearly defined protocols for dealing with patients. In the case of Mrs O'Hara, whose condition is the same but who does not fall within the particular scope of the look-back exercise, there is a question there, I think, as to the implications of the inconsistency, or apparent inconsistency, in treatment of the two groups of patients. I can see that as an issue requiring further investigation.

MS DUNLOP: It is intended, sir, when we come on to look at the Hepatitis C topics, that the look-back exercise, and

probably also that difference in treatment which emerges, will be looked at in more detail.

For Mrs O'Hara herself, the subsequent course of her illness -- that is after diagnosis in 1995 -- appears to have been a general deterioration in her health. The diabetes appears to have been under reasonable control but the heart disease perhaps less so, given quite severe heart failure in 1999.

As far as the transfusions were concerned, in chronological order there is evidence to show that there appears to have been a transfusion before 1971. One can speculate that that might have been in connection with the valvotomy because there isn't any obvious other surgery in the records.

There was transfusion of one unit of blood in 1972 in connection with a Caesarean section. Two units of blood in 1979 in connection with a hysterectomy, and then further transfusion of red cells in 1985 at the time of the heart valve replacement.

Dr Mutimer's view, although this is, I quite accept, simply conjecture to a degree, but the conjecture of a fairly highly informed witness, was that the most likely transfusions would be those in the 1970s. All three of those units have been identified in terms of when and where they were donated. They were donated at

Lockerbie, Coatbridge and East Kilbride which may provide some reassurance for the family who had an impression of how the infection may have come about.

There was no testing in the 1970s for the virus, which hadn't been identified at that time. So again, I would suggest that there doesn't appear to be a systemic issue raised in relation to prevention of the infection by the evidence led about Mrs O'Hara. I'm repeating myself now, but the only issue to which one might want to return perhaps is that concerning the information and support provided to people who had been diagnosed as having Hepatitis C, particularly if that infection is likely to have come about through blood transfusion.

THE CHAIRMAN: Mr Di Rollo?

MR DI ROLLO: In relation to Mrs O'Hara, I don't take any issue with anything that has been said. One matter which has been raised as a systemic issue is the recording or misrecording of Hepatitis C as a cause of death, and that, in my submission, is a matter which the Inquiry should consider as an important systemic issue, which was touched on by the evidence in this matter.

THE CHAIRMAN: I think that's so. But I would like it to be borne in mind that there are two quite distinct aspects to misrecording. There is that which is perhaps illustrated in Mrs O'Hara's case but there is also

information that suggests that, because of the stigma associated with Hepatitis C, there may have been pressures from families not to record Hepatitis C as part of the death. So I merely indicate that I would like this to be looked at generally and not particularly, Mr Di Rollo, but no doubt that will be borne in mind.

Mr Anderson?

MR ANDERSON: I'm obliged, sir. I agree with counsel to the Inquiry that the investigation into the death of Mrs O'Hara does not give rise to any systemic issue, save that of the general question of the dissemination of information, advice, support, which, of course, is going to be a discrete topic, which is going to be returned to and explored in some greater detail later.

THE CHAIRMAN: I have to report on it, particularly, Mr Anderson.

MR ANDERSON: Of course.

In relation to the course of the infection and treatment, it may be worth pointing out that, although, as counsel for the Inquiry says, it is likely that Mrs O'Hara was infected as a result of blood transfusions, given the number of blood transfusions that she had over the years and given the times of those transfusions, it is perhaps worth pointing out that we

don't know, of course, that Mrs O'Hara was infected by blood transfusion, if one compares that, for example, to the case that we are just coming on to, that is to say Mr Laing, where we have a positive identification, because a donor was identified. We don't have that in this case but I simply make that point for what it is worth. I accept that on the balance of probability, there is a very strong possibility and possibly a probability that she was so infected.

THE CHAIRMAN: Mr Anderson, the balance of probabilities may be enough for a public Inquiry of this kind and I think that could well prove to be the approach at the end of the day.

There is also, of course, with Mrs O'Hara's case, the opportunity to apply the general knowledge people develop about the natural history of the disease in the case of a lady, which might help us get closer on a balance of probabilities to the date that might be taken to be the date of infection but we will see how that develops.

MR ANDERSON: I accept all that, sir, it was just for what it was worth, sir, one should not simply assume that there had been infection because we heard from Dr Mutimer, of course, that there are still many ways in which people can be infected with Hepatitis C but

I entirely accept the generality and accept your comments.

THE CHAIRMAN: Mr Sheldon?

MR SHELDON: Once again, sir, I take no issue with what Ms Dunlop has said and I'm content that any systemic issue arising is likely to be investigated or dealt with at an appropriate later stage in the Inquiry.

MR DI ROLLO: I wonder, sir, just before we move on to the next case, the one matter that did arise -- I should have mentioned it earlier and I apologise for not doing so -- is that the issue of record-keeping, in terms of the evidence, did emerge. I appreciate it has absolutely nothing to do with the cause of death or anything like but it was something that was raised in the course of the evidence, and if that's the exercise in which we are engaged at the moment, ie identifying systemic issues, and from the evidence that was being led last week, then that is certainly one of them.

THE CHAIRMAN: I don't pretend to have remembered everything that has happened last week. What particular aspect of record-keeping is it you have in mind?

MR DI ROLLO: I think it was the inability to match up the Glasgow Royal Infirmary record of the batch that came from the Scottish National Blood Transfusion Service and once --

THE CHAIRMAN: Yes, thank for reminding me of that. I think that that is a matter that I drew to Mr Anderson's attention at the time, that would have to be looked at. It is the issue of accountability for what's happening, which is perhaps ancillary to the treatment of the patient but is quite important, yes, thank you.

MR ANDERSON: If I could respond to that, sir. It may be a matter of semantics. I'm not sure I would see that as a systemic issue. I noted your concern and I think I undertook to make an investigation into that and that is being done, but I'm not sure I would necessarily accept that it was a systemic issue but it may be --

THE CHAIRMAN: I might in due course, Mr Anderson, but at the moment we are dealing not with the end product of the exercise but with the identification of issues that have to be explored. I think it is something that has to be explored. What one would make of it at the end of the day is a different matter.

Ms Dunlop?

MS DUNLOP: In relation to Alexander Laing, we know that he was born on 7 December 1923 and that he died on 4 September 2003 at Aberdeen Royal Infirmary. Mr Laing was traced as part of the look-back exercise, which we hear was a UK exercise. He had had an operation for bowel cancer on 7 August 1990, during which he had had

a transfusion. A donor had subsequently been identified as positive for Hepatitis C. So those who had received blood from that particular donor were traced and one of those was Mr Laing.

He was seen -- through a process that we saw in his records involving his general practitioner and the local Blood Transfusion Service -- in June 1995 and he tested positive for Hepatitis C. He was referred to Aberdeen Royal Infirmary for specialist help in July 1995 and seen by Dr Sinclair. He had a liver biopsy in January 1996 which showed active hepatitis. There was some discussion with Dr Alexander as to whether it did or didn't show cirrhosis. On any view, at that time, prospects of successful drug treatment were very poor. It does seem that the matter was discussed between Mr Laing and Dr Sinclair and Mr Laing's view was that he didn't wish to accept the offer of treatment.

We saw also from the records just an incidental finding really but no doubt difficult for Mr Laing, that at one point, because of having Hepatitis C, he was refused treatment by his own dentist.

Evidence was also led about the deterioration of his health in 2003. By the summer of that year, when he underwent a CT scan, advanced liver disease was present and we know that he continued to deteriorate until his

death in September.

Dr Alexander described Mr Laing's care as "exemplary". As far as the possible screening of donated blood in 1990 is concerned, it appears, sir, that in this particular case any screening at that time would not have detected this particular donor's virus because it was genotype 3.

We heard some evidence from Dr Dow about the different genotypes and how well or otherwise they were recognised by the first generation tests. In general genotype 3 was not well recognised by the first generation tests. More than that, however, when this particular donor was tested as part of research in 1992, his sample did not react with the first generation test. So I would suggest, sir, that the evidence does show that even earlier introduction of screening of donated blood in Scotland would not have prevented Mr Laing's infection.

The research Dr Dow described to us, did, however, show that most of the donors whose virus was genotype 3 did have abnormally raised ALT, although the particular result for this individual was not known, and as Dr Dow pointed out, might not be especially valuable. On the statistical evidence then, looking at the group as a whole and noting that most genotype 3 donors were

picked up by ALT screening, it does appear that if surrogate testing, using ALT as the marker, had been in place in 1990, this particular donation would have been picked up and not used. So that does relate to a systemic issue, which is whether there should have been surrogate testing in place in the summer of 1990.

THE CHAIRMAN: Could I ask whether you are coming back again at any stage to look at the sensitivity and specificity of the tests in relation to genotypes? The reason I ask is that we do know from the pie charts that were produced that there were in some cases a reaction in the use of the first generation tests to general types other than genotype 1. Having looked at the material with Professor James, it seems possible that in looking at the spread across the column or table that is followed, there are different strengths of reaction reflected so that in some cases, what is acknowledged as a positive may in fact be a very weak reaction, which is not easily related to the identification of the genotype 3. It may just be a reaction to some similarity in genetic structure that doesn't identify it.

I just don't feel at the moment that I have got a complete grasp of that topic and if the opportunity arose, I think it might be helpful to go over it again.

MS DUNLOP: I note that, sir. I mean, save to say that it

is extremely complicated material, and I wouldn't necessarily want to take up the time of the Inquiry in going into the details of the structure of the various tests unless --

THE CHAIRMAN: I know that Professor Simmonds has attempted to assist your team and that a full understanding of the whole topic would take a very great deal of time and would be highly unlikely to add significantly to our understanding of it. But there is the one issue, I think: you have said that the probabilities of the infection being identified had the first generation test been applied, are simply not good, but if one looks at the pie chart there is about a 30 per cent response anyway, which --

MS DUNLOP: Sir, when I first saw those pie charts that struck me and I asked Dr Dow about that before he gave evidence last week -- and he did give some explanation of that, that some genotype 3 individuals were weakly reactive with the first generation tests. But in relation to this particular individual --

THE CHAIRMAN: I appreciate that.

MS DUNLOP: -- the cut-off was very far below the level at which that person could have been picked up. I was concerned that perhaps this was an individual who was just below the cut-off and on another day might have

been slightly higher and picked up, but that wasn't the case for this particular donor.

THE CHAIRMAN: Perhaps all you need to do is give me a reference to the evidence that shows that and that would satisfy my interest, but others might like to look at it.

Mr Di Rollo?

MR DI ROLLO: I agree that an important systemic issue arising from this death is the effectiveness or otherwise, obviously, of surrogate testing, and that is a significant point which clearly should be looked at.

Another possible systemic issue that occurs to me, which could potentially at least be looked into, is whether blood transfusions should have been accepted from donors who had themselves received blood transfusions. We know from the evidence in this case that as I understand it, although it wasn't possible to detect Hepatitis C in the blood that was given to Mr Laing, the history as narrated is that the donor had received a blood transfusion at an earlier stage. That might have been regarded, I would suggest, as a risk factor. It wasn't at that time but would be now. That is something that might be of interest as a systemic issue.

THE CHAIRMAN: I think the whole history of the selection

and deselection of blood donors is something that may well be covered. Clearly the rules changed from time to time and it would be of interest to follow that.

On your first point, where you talk about the effectiveness or otherwise of surrogate testing, there may be a supplementary issue, which is the judgment as to the introduction or non-introduction of testing in the light of contemporary understanding of effectiveness. It is not just the effective answer as an absolute which one could look at retrospectively, there is the issue of judgment at the time. That may have to be explored but subject to that, I have no comment on what you have said.

Mr Anderson?

MR ANDERSON: Yes, I'm obliged, sir. I have no comment upon the particular circumstances of Mr Laing's death but I am now becoming slightly confused about the whole efficacy of surrogate testing.

I heard Ms Dunlop say, I think on page 32, that in this particular case surrogate testing would have picked up the infection. But that is not as I had understood, I must say, Dr Dow's evidence. Indeed, if one goes to his report, which is [PEN0010016], the second of his conclusions stated:

"Had surrogate anti-HBc testing been performed on

donor T2103's previous donation in July 1990, it would also have resulted in a negative result and the donation would still have been cleared for use."

The confusion may simply be on my part but it does seem to me if there is any confusion, the matter does require some sort of ventilation. If that is right, the question is how that is best done. Dr Dow's, I think, scheduled to give evidence this Friday. That may be too soon and it may be appropriate to bring him back or it may be a matter we can deal with. It may be appropriate to discuss just how this is going to be further investigated.

THE CHAIRMAN: Well, this is an investigatory process. If there are differences between counsel in a matter of this kind, I would expect them to talk about it in the first place. Only if there is a real issue that cannot be resolved, need we go back to Dr Dow. If there is, no doubt Ms Dunlop can find a way of dealing with it when Dr Dow comes back.

MS DUNLOP: I'm not sure that's necessary, sir. If I could perhaps just explain -- I'm sure this is my fault -- that there are two different possible markers and the surrogate testing could have looked for antibody to Hepatitis B core antigen or it could have looked at the levels of ALT in the donor's blood.

In relation to the first, this particular donor was tested and didn't have that Hepatitis B antibody. So if surrogate testing had been in place and had been using that as the marker, the infection would not have been picked up. But in relation to raised levels of that liver enzyme, ALT, this particular donor was not tested as the research. So all one has is the general statistic but the general statistic is that most of the genotype 3 donors did have abnormally raised ALT. So just using the epidemiology, one could suggest that perhaps ALT screening would have picked up this donor's infection. I think that's how the confusion has arisen sir and I think it is perhaps better to clarify it at this point.

THE CHAIRMAN: Thank you. I just thought it would be better done quietly if there was an explanation, Ms Dunlop. But I think we now have it and Mr Anderson can no doubt take instructions on what you have said.

Mr Anderson, do you need further clarification?

MR ANDERSON: I think not, sir.

THE CHAIRMAN: Mr Sheldon?

MR SHELDON: Yes, again, sir, it seems to me that if any systemic issues arise, they are to be dealt with in future topics. I'm content with that.

THE CHAIRMAN: Thank you very much, all of you. It is

helpful to have a pause and to get a feel for where the Inquiry is at a particular point in time, and also to record it. This is going to be a long process and having, as it were, an aide-memoire as to where we stand at particular stages in the Inquiry is going to be very helpful to me in the long-term when I have to reduce all of this to a written report.

Ms Dunlop, where are we at the moment?

MS DUNLOP: That concludes my remarks for today, sir. It would be our intention to begin tomorrow with the evidence of Dr Jack Gillon. Tomorrow we are going to look at statistics with Dr Gillon and Professor Goldberg.

THE CHAIRMAN: When you say look at statistics, what are we going to look at in very general terms so that others have an idea as to where you are going?

MS DUNLOP: We are going to try to ascertain, as accurately as possible, the numbers for four different groups of people in Scotland. First would be those who acquired HIV from blood products, the second would be those who acquired HIV from blood transfusion, the third would be those who acquired Hepatitis C from blood products and the fourth would be those acquiring Hepatitis C from transfusion.

There are certain difficulties in relation to trying

to establish accurate figures for those groups of people.

THE CHAIRMAN: I suppose that might influence members of the public on whether they turn up at all for this phase of the Inquiry but it is clearly important.

Could I just raise one little point of terminology, and that is the use of the word "transfusion", because I'm conscious that it is not always used exclusively to relate to the transfusion in the course of surgery, using red cells or whole blood or whatever, but that sometimes it is used in relation to the infusion of blood products in the treatment of haemophilia.

I don't think that there is any way that you could resolve this ab ante, as it were, but it may be helpful from time to time, when we are looking at particular topics, to make clear if the word is used in a particular sense and in particular in a limited sense, rather than in the very broad sense of the use of the blood for therapeutic materials. It is just a request.

Very well, ladies and gentlemen, until tomorrow.

(10.46 am)

(The Inquiry adjourned until 9.30 am the following day)