Thursday, 12 January 2012

(9.30 am)

(Proceedings delayed)

(10.05 am)

PROFESSOR PHILIP CACHIA (sworn)

Questions by MR GARDINER

THE CHAIRMAN: Yes.

MR GARDINER: Thank you, sir. Good morning, Professor Cachia.

A. Good morning.

Q. We usually start off with a new witness by having a look at the CV. So could we just have a look at [PEN0172820]? I think you told us that this was a reduced curriculum vitae but it's actually 24 pages long, I see. We will just go through it.

So we see on the first page that your current position is Postgraduate Dean, East of Scotland. Could you just tell us about that?

A. Yes. Between graduating from medical school and taking up a career post as a consultant or principal in general practice, doctors undergo postgraduate training which, in the United Kingdom, is regulated by the General Medical Council and Postgraduate Deans are responsible for the quality management of those training programmes and for assessing the progress of individual doctors in

training through that, and then signing them off as having completed their training.

Q. Thank you. If we go to page 3, please.

THE CHAIRMAN: It indicates you are Postgraduate Dean for the East of Scotland. What universities and hospitals does that cover?

A. It's Dundee University. There are four Postgraduate Deans in Scotland, each linked to the four graduating medical schools of Aberdeen, Dundee, Edinburgh and Glasgow.

THE CHAIRMAN: So East of Scotland doesn't include St Andrews.

A. St Andrews isn't a graduating medical school because they do a pre-clinical course and then send their students elsewhere to graduate.

THE CHAIRMAN: Oh, they send them away. Thank you.

MR GARDINER: On page 3, the second part, we see your formal qualifications. Can you just tell us what they are, starting in 1977?

A. Yes, so at the time that I was at Edinburgh medical school, you, after three years, completed a BSc in medical sciences, and it was a six-year course. So I completed my MBCHB in 1980. I then undertook training in hospital medicine, completed my membership of the Royal College of Physicians of the UK in 1983. I took

time out of clinical practice from 1985 to 1988 when I undertook a laboratory-based MD thesis in the department of pathology in Edinburgh. That was after having been a registrar in haematology at the Western General in Edinburgh. I then returned to haematology training in Cardiff, where I completed the required exams for haematology, the MRC (Path), and then later on as a Consultant was made a fellow of the College of Physicians of Edinburgh and then a fellow of the College of Pathologists.

Q. Thank you. If we go over the page to page 4, we see a list of your notable achievements, a very impressive list, starting in 1985, down at the bottom, with the Colin and Ethel Gordon scholarship and going through the years. I noticed in 1997 you were the Scottish national haemophilia database coordinator. Could you tell us about that a little bit?

A. Yes, that was around the time that the haemophilia directors of Scotland were introducing recombinant Factor VIII and Factor IX therapy for all patients and we had set up a consortium to oversee and manage that on a national basis, and I originally set up the database that provided the information about usage for that, and I think subsequently was taken over by a proper database manager.

Q. In 2000 I see "chairman of oncology and haematology clinical governance sub-committee"; what did that involve?

A. That was at the time that clinical governance was introduced in the health service. There had to be a formal proactive process for looking at the quality and standards of clinical care and learning from adverse events and introducing new ways of improving the quality of service. So at that time we had a combined directorate that included the oncology and haematology clinical services, and I set up and chaired that group.

Q. I see 2001, director of general professional training at the Royal College of Physicians of Edinburgh. What did that involve exactly?

A. General professional training in those days, prior to the modernising medical career reforms, covered senior house officer training. So after qualification and doing a house officer year, before becoming a registrar in a speciality, you undertook a number of senior house officer jobs. That was called "general professional training".

As the college director, I was responsible for developing standards and educational opportunities for Senior House Officers and also we -- within Scotland, in conjunction with the college in Glasgow, we ran an

inspection process, whereby we went round different hospitals in Scotland looking at the quality of SHO training, with a view to suggesting improvements and spreading best practice.

Q. Yes, thank you.

THE CHAIRMAN: When did that service begin, Professor? This is when you joined?

A. No, it was established at the time I joined it. It was called "IMSPEC" and it must have been, I would have thought, probably the late 1990s.

MR GARDINER: Just because you have mentioned it, I know we are looking at your CV at the moment but you talk there about "best practice". We have heard that phrase used before. Could you tell us what you understand by that term, "best practice".

A. Yes, so a lot of the regulatory processes for medicine run by the General Medical Council are focused on setting minimum standards that have to be achieved in order to ensure standards of practice, and clearly, if you set a minimum bar, then everybody who sort of creeps over that bar is then deemed to have met those standards.

I think it was increasingly recognised by a number of regulators, not just in medicine, that that was a bit of a minimalist approach and in doing any regulatory

visit, if you go and visit a department, with a fundamental purpose of ensuring that they are meeting minimum standards, you quite often come across outstanding examples of innovative practice and really good ideas. So part of the regulatory process now is not just to ensure minute standards but to identify exemplary practice and attempt to disseminate and spread it amongst other units.

Q. So how does best practice compare to a standard that's, as you put it, just over the bar?

A. Yes. That's a challenging question. I guess there is no ceiling. If you are going to encourage innovation and new ideas, then inevitably some of them are not going to work, so some of them will fail but there will be others that make genuine improvements, the particular example we are talking about, the training of SHOs. So there could be very substantial differences but there would often be an evolution and ultimately, sort of innovation becomes established practice or it can be recognised as best practice and will ultimately be incorporated into standards and become the normal or routine practice.

Q. So would it be fair to say that best practice is what doctors should aspire to?

A. Yes.

Q. Thank you. Just going down the years, we can see 2002, you were the chairman of Tayside area medical committee; 2003, lead clinician, Tayside community anticoagulant service; 2004, NAS representative on Scottish modernising medical careers delivery group; 2005, chairman of New Deal review. 2008 caught the eye. This is NES patient safety lead. Could you tell us a little bit about that?

A. So the Institute of Medicine in the United States identifies six domains that define the quality of healthcare delivery. So they will include clinical excellence, person centredness, timeliness, equity and patient safety is one of those domains. It's probably not a particularly good name. What it really refers to is the unintended harm that happens to patients because of the complexities of healthcare delivery, and a patient safety programme is an explicit, planned, managed attempt to eliminate unintended harm by improving the reliability of systems, the culture of supporting staff, the learning from errors, identifying human factors or using human factor science to try and just improve reliability.

So it's distinct from clinical excellence and medical practice. We know from evidence based medicine what is the right thing to do. Patient safety is

a co-ordinated approach to make sure that the systems of delivery from the hospital portering system right through to pharmacy and computer systems are all designed to eliminate unintended harm.

Q. Right. Okay. Thank you very much. Could we just pass over to page 5 next, please? What we see there, in working from the bottom in chronological order, are the appointments throughout your career. Is that correct?

A. That's correct, yes.

Q. We notice that in June 1988 to January 1991 you were Senior Registrar at the University Hospital of Wales, Cardiff under Professor Jacobs and Professor Bloom?

A. That's correct.

Q. I would like to ask you a little bit about that. The Inquiry has heard about Professor Bloom and his practice and it has been suggested that he was a fairly academic doctor, if you like. Was that your experience of him?

A. Professor Bloom was certainly a leading academic in the world of haemophilia but he was also a very hands-on and person-centred clinician, who knew all of his patients and was certainly extremely approachable and very supportive of Senior Registrars when we needed advice about contemporary treatment of patients.

Q. Yes. How much experience did he have of clinical practice and dealing with patients and so on?

A. Yes, the Cardiff centre looked after the patients from childhood onwards, so he had looked after and been involved in the care of the patients there ever since they had been children.

Q. Yes, and did Cardiff cover quite a large area?

A. The haemophilia centre specifically? Yes, it was a big regional haemophilia centre that took patients from all of South Wales and Bristol and I think some parts of Cornwall as well.

Q. Yes. Would you say that Professor Bloom was -- how shall I put it? -- a modern doctor? Did he have forward thinking?

A. Yes, Professor Bloom came from a generation where, I guess, his approach to patients might be considered sort of fatherly, yes, that was the way he was.

Q. Yes. Would that make him more of a directive clinician than maybe a modern one maybe?

A. Yes, he didn't have so much to do with the day-to-day sort of management of patients and counselling. He would see the patients on ward rounds and so on, but it was his staff. There was an associate specialist in the haemophilia centre, three haemophilia nurses and a Senior Registrar at all times. So that would be the staff group that on a day-to-day basis talked to and counselled patients.

Q. Yes. What was your exposure to haemophilia care during that period, when you were at Cardiff?
A. Yes. At that time the Cardiff rota involved four months' attachments in the different elements of the service. So that would include an attachment at the district general hospitals of Llandough and Cardiff Royal Infirmary, the ward, which was primarily the treatment of leukaemia and lymphomas, the day unit, the laboratory and the haemophilia centre. So for a four-month period, I think, twice or maybe three times in the time that I was there, I would have my entire daytime job in the haemophilia centre, learning about haemophilia care and working with the associate specialist, the haemophilia nurses and Professor Bloom when he did his ward rounds. In addition to that, out-of-hours, we obviously would see haemophilia patients when they presented, if we were the on-call Senior Registrar.
Q. That was irrespective of whether you were on a haemophilia block or not --
A. Correct, yes. If you were on-call, you covered the whole service.
Q. Yes. The associate specialist, was that a doctor?
A. Yes, that's correct. It was a non-consultant-grade doctor but with a lot of experience in haemophilia care.

Q. Do you remember what their name was?
A. It's Dr Has Dasani.
Q. Yes. During that period, who did you receive your training in haemophilia care from?
A. So on a day-to-day basis, it would be Dr Dasani and the haemophilia nurses and on a regular basis, when Professor Bloom did his ward rounds, or indeed if you needed out-of-hours advice, even if Professor Bloom wasn't on call, he was usually the person that you would get hold of to discuss a particular problem with a haemophilia patient.
Q. Yes. What were you taught about the approach to giving information to patients and counselling them and so on?
A. Yes, I think within the haemophilia centre in Cardiff there was a fairly modern and patient-orientated approach that involved a partnership between the staff and the patients there and every attempt was made to keep patients fully up to date with the issues of the day and the changing evidence base.
Q. Yes. What would that involve as far as investigations on patients and what patients would be told about investigations that were being done?
A. Yes, there would be a regular screening programme that would include the sort of recommendations of the UKHCDO and that would include sort of regular viral testing,

and patients would be verbally informed of the nature and reason for that and any trends that were obvious in terms of their own personal results.

Q. Yes. And when you say "trends", are you referring to the development of medical knowledge about their condition and treatment?

A. Yes, well, trends in their personal sets of results; for instance if liver function tests were deteriorating or going up and down or stable, they would be informed about that, as well as contemporary information about the evolving knowledge of hepatitis and HIV.

Q. Yes. And then after you spent that time at the University Hospital of Wales, I see from your CV that between 1991 and January 1992, you were a Medical Research Council training fellow. What did that involve?

A. So I had applied for and obtained the MRC fellowship, which was for a year of post-doctoral studies, it was based in Professor Jacobs' research laboratory. So most of that time was spent in a laboratory, undertaking -- the unit's principal interests were the group of disorders that are known as "pre-leukaemia disorders". So they are abnormalities in the blood which we know are likely to lead on to full-blown leukaemia, and the unit was studying them with an attempt to understand how

leukaemia happens and potential therapeutic interventions to stop it happening.

I would have had some clinical exposure because I was seeing patients in clinics, collecting samples from them, getting informed consent for participation in the research work of the unit but most of it was laboratory based.

Q. Perhaps you could explain to us what you understand by "obtaining informed consent" in that context?

A. Yes, so really the crucial issue is that the patient has a clear understanding, in language and terms that he or she can understand, of, in this case, the reason for undertaking research, the potential benefits to them and to future generations of doing that research, any potentially negative consequences of participating in the research and that they have control of that agenda and can get the information that they require and can then make a decision on a personal basis as to whether or not they wish to participate in that research.

Q. Yes. Thank you.

THE CHAIRMAN: Can I ask one question arising out of that? You refer there to ensuring that the patient has a clear understanding in language and terms that he or she can understand. And so on. How much variation was necessary in practice in dealing with individual

patients to ensure that the message was communicated?
A. Yes, a great deal of variation, and I think to really be able to obtain informed consent in that way, you need to firstly get to know and understand the patient. You need to develop trust as a mutual basis for the relationship, and once you have developed trust and know what their personal value systems are, what their intellectual capacity is, what their belief systems are, you can then have a real discussion that allows them to understand and, as I say, have control of the decisions that need to be made.
THE CHAIRMAN: So a superficially simple statement such as "ensuring that they have got a proper understanding" really comes to be part of a very wide spectrum of possibilities when you deal with the individual in question.
A. That's correct, yes.
MR GARDINER: Thank you. Could we just pass over to page 6 of the CV? We see there that you have given us some more detail about your current appointment as Postgraduate Dean. Just go to page 7. At the bottom of the page. "Postgraduate education activities". I think over the succeeding pages, you list in more detail the work that you have done, and then on page 8 you list your activities as a PG tutor. What's that?

A. It's a postgraduate tutor. So before or as part of my development as an educationalist in medicine in 1997, I became a postgraduate tutor within Tayside. So I had two sessions a week, a day a week basically, in which I worked for the Postgraduate Dean, whom I ultimately succeeded as a sessional commitment to the deanery.

Q. Yes.

A. So that meant I reduced my haematology commitment by two sessions a week but that was also the opportunity to use that funding to employ a clinical assistant in the haemophilia centre.

Q. I think when we come to your statement, we will see that in more detail.

If we go over the page, please, you give us the summary of your contributions to postgraduate education committees in the UK and Scottish ones, and just passing to page 10, a list of more appointments and, over the page, page 11, we have a summary of your management experience. In fact the CV is very full and gives us all of the details about you and your career, so I'm not going to go through it in detail. Perhaps if we could just go to page 24, to have a look at your publications. Just tell us what these are, please.

A. So at that stage of my career my intention was to specialise in malignant haematological conditions. So

my MD thesis and most of my publications were looking at a group of disorders known as "chronic lymphoproliferative disorders". They are malignancies of the immune system and both my time in Edinburgh, doing my doctorate thesis, and in Cardiff as an MRC fellow were all fundamentally looking at understanding the nature and causation factors of haematological malignancies and new opportunities to try and treat them.

Q. Yes. And what we see here is a chronological list of the publications that you have been involved in.

A. Yes.

Q. Which are mainly in that area.

A. Correct, yes.

Q. Thank you. I would like to turn to your statement now, please, which is [PEN0180853].

This is a statement that you have provided at the Inquiry's request in connection with this topic, which is what we call "C5", which is really about information to patients and relations between doctors and patients.

Your statement is very full and deals with matters which are not specifically about this topic. So I will be passing over some of it. But we see there at paragraph 1.1 a repeat of information about your current position, current post, and I just noted at the bottom

of that first paragraph that this statement has been based on your memory and you have not had access to records. Is that right?

A. Yes, just in terms of the timescales for producing the statement, it really is based on my memory and also just to note that having been out of clinical practice or out of haematological clinical practice for seven years, it was a bit of a rusty memory at the beginning.

Q. Yes, thank you. Paragraph 2.1 you say that in 1992 you were appointed as a consultant haematologist in Tayside. Perhaps you could just tell us in your own words about that, professor?

A. Yes. Having completed training and now being eligible to become a consultant, my wife and I were keen to return to Scotland, where we were both born, and this was the first opportunity that came up. For reasons that are unclear to me, Tayside, even in the 1980s, did not have a modern haematology service. The haematology training and service delivery in the UK is based on a combined and integrated clinical and laboratory service and the training involves learning both about laboratory haematology and clinical practice. But for reasons unknown to me, in Tayside in the 1980s the laboratory haematology service was provided by the pathology department. There were two consultants who

were pathologists rather than haematologists but had, over the years, developed an interest in blood pathology and they ran the laboratory service, and there were clinicians, who were not haematology trained, with an interest in lymphoma and haemophilia, who provided the clinical service.

That changed with the appointment of Professor Pippard to the first chair of haematology, I think around 1987, and Martin Pippard was really charged with creating a modern haematology service in Tayside and I was his first appointment in 1992, when one of the laboratory consultants retired. So I was a replacement for his post.

Q. Yes. But it wasn't intended that you would just remain in the laboratory. Is that right?

A. No, no, absolutely. I was appointed as a fully trained clinical and laboratory haematologist to participate in all the general duties of the department. When I was appointed, the job was advertised as a job for a consultant with an interest in malignant haematology but, as I say in my statement, because I had replaced a Laboratory Consultant and had the sort of, probably, unique pleasure of a very quiet clinical practice when I started -- on day one I had a tidy desk and no patients to look after, which didn't last for long --

Martin Pippard, because I had come from Cardiff, as a preeminent haemophilia centre, asked me if I could at least undertake a needs assessment of the haemophilia service in Tayside, because that was one of his priorities -- one of his many priorities for developing a sort of modern, competent haematology service in Tayside.

Q. Yes. If we go to paragraph 3.1, which is on page 2, you talk about that initial assessment. Could you just tell us what that involved, the initial assessment?

A. Yes, so the initial assessment involved talking to predominantly the staff who had been involved in providing some of the haemophilia care.

So Dr Heppleston at that time was the named clinician. There was a regional SNBTS service in Ninewells. There were laboratory staff who knew quite a lot about the patients, and certainly had a lot of data around factor levels, inhibitors and so on, and George Urquart was the Consultant Virologist at the time.

Obviously at that stage I didn't know any of the patients, so, you know, my initial trawl for information was around the professional staff who had been involved in providing the service that was available at that time.

Q. Yes. What documentation did you have available to you?

I think in the next paragraph --

A. So very little. Dr Heppleston gave me a little box with a set of file cards in it, a series of names, many of which proved to be out of date, and probably the principal source of reliable information was the SNBTS records of factor concentrates use for home delivery and the coagulation laboratory's data on factor levels.

Q. Yes. I see that you say that the box of file cards had approximately 200 names in it?

A. From memory, yes.

Q. How was the prescription of factor concentrates being carried out at that point?

A. So at that time the patients phoned up staff in the regional transfusion service and were issued with a factor concentrate. So their prescriptions weren't really scrutinised and their regular use of factor concentrates was not monitored by clinical staff in haematology.

Q. Yes. Was that surprising to you?

A. Yes.

Q. Yes. If we go over the page, we see at paragraph 3.3 that there was no haemophilia centre or dedicated location. Could you explain to us what the position was in that case?

A. Yes, so from memory we had a haematology ward and we had

a small sort of day unit, where patients could come up for either a procedure or ongoing treatment, and if a haemophilia patient phoned up because of a bleeding problem or requesting help, they would be seen in that day unit --

Q. Yes.

A. -- by the on-call staff for the day.

Q. Yes. And I see in the next paragraph you talk about the haematology service predominantly consisting of a crisis intervention service. So were they effectively operating as a safety net for the care of these patients?

A. That should actually read "the haemophilia service".

Q. Sorry.

A. It's a typo on my -- I think other parts of the haematology clinical service were fairly well structured and supported but, yes, from what I could see at the time, there was no regular, routine arrangement for a patient with haemophilia to be seen, whether or not they had particular problems, for the sort of monitoring, review, joint assessment and so on that are a core part of comprehensive care, and that any elements of comprehensive care that were delivered were on an opportunistic basis. If a patient happened to come up for advice, then a member of staff might or might not

provide that element of comprehensive care but it was certainly not in a co-ordinated, managed, planned manner.

Q. Yes. How did the picture in Dundee compare to what you had seen in Cardiff?

A. Yes, clearly a marked contrast, in which in Dundee we were clearly not meeting the standards that had been set and were agreed nationally by the UKHCDO.

Q. Yes. I mean, broadly, could you summarise what those standards were?

A. Yes, I guess the requirements for a group of patients with a lifelong, chronic illness that has many personal, social, psychological and physical consequences, are for planned, managed treatment of all of those and that cannot happen without a process of regular review, contemporary knowledge of the changing evidence about treatment, about management of inhibitors, management of the complications, interventions to improve joint disease and so on, and none of those things were happening in a planned manner.

Q. Yes. Thank you. And I see paragraph 3.6, you say that there were no formal liaisons between the haematology department and key specialist services, including dentists, HIV specialists, hepatologists, orthopaedic surgeons, physiotherapists, social workers. Would you

have expected to see that at that time?
A. Yes, again, a part of comprehensive care is having a multidisciplinary team to deal with the many complications that I just described, and while a patient with haemophilia, if they needed, for instance, physiotherapy, they would get it in Tayside, it would be on, again, the opportunistic basis of they came up with a problem, a physiotherapist was phoned, but not a named physiotherapist, just a duty physiotherapist. So in trying to set up and establish comprehensive care for our group of patients in Tayside, I had to set out in a planned way to approach each of these departments and try and get a named individual who we could start to work with, to prospectively agree how to best provide different sets of services there for patients with haemophilia, and wherever possible to have named people so that the patients knew who they were seeing and could develop the trust, confidence and so on in a practitioner they were seeing on a regular basis.
Q. I noticed at the end of that paragraph that one of the key specialist services that was absent was trained counsellors. Could you tell us, what would you expect a trained counsellor to do for that service?
A. So that was specifically in relation to HIV, not that I had any HIV positive patients at that particular time,

and hepatitis.

Q. So a trained counsellor, would that be a nurse or a doctor or ...?

A. Yes, so certainly at that time the -- for instance, the Tayside HIV service had trained counsellors, who were nurses, who were always available when a new diagnosis was made, to spend a lot of time with the newly diagnosed patient and his or her family, to get over the emotional shock of the diagnosis and support them over those early years.

I think at that time the hepatologists didn't have specifically trained counsellors for Hepatitis B and C but I think they may have now.

Q. I mean, these counsellors, they would be based maybe at a genitourinary clinic and you would have access to them?

A. They were based in the infectious diseases department, which at that time was off site, it wasn't in Ninewells Hospital. So again, what I wanted to do was make sure I had established a network of contacts and people that I could involve in creating the quality of service that we wanted to deliver in Tayside.

Q. Yes. Thank you. If we could go over the page now to page 4, paragraph 3.8. Here you tell us that from your discussions with Dr Heppleston, the two major areas of

clinical need that required urgent addressing were first of all the 15 to 20 knee and hip joint replacements that were needed as a clinical priority on the basis of severe arthritic pain, and then the second major area was about HCV testing. Could you just tell us about that, please?

A. Yes, so when I was doing the sort of needs assessment and speaking to Dr Heppleston, he had a list of patient names from the virology department, who had tested, stored sera, when the HCV antigen test was introduced, and identified some who was positive and handed that list on to Dr Heppleston.

Q. Yes. What documents, if any, existed about this testing?

A. There were no documents. It was simply a sheet of paper that had a list of stored sera unique identifiers, a patient's name, and the result of the test.

Q. Yes. Were you able to tell who had taken the blood that had been tested?

A. No, I had no sort of governance or knowledge to be certain that the serum that had been stored was taken from that patient; it was simply taken out of the deep freeze in virology.

Q. Okay, right. How did you know that it had just been taken out of the deep freeze? Was this what

Dr Heppleston told you?

A. Yes, I went to see Dr Urquhart, who was a Consultant Virologist, to discuss the genesis of this list and why the tests were done, and he explained that they had stored serum from times that the patients had presented with clinical problems and that more or less out of interest he had undertaken the testing.

Q. And were these all patients with haemophilia?

A. The list that I was given, yes. I have no idea what other samples the virology department might or might not have tested with the new assay.

Q. Yes. Was Dr Urquhart able to tell you what patients had been told about why the blood had been taken in the first place?

A. No.

Q. Was he able to tell you whether patients had agreed to their sera being tested?

A. Not really. He was quite clear that this was an action that the department had taken because they had the new assay.

Q. Right. Okay. So he was quite clear that consent had not been obtained?

A. To do this test. That's correct.

Q. Yes. What was your reaction to that information, Professor?

A. Well, I guess -- I have to say my initial reaction was to be a bit horrified because I don't think I would have sanctioned that action personally and also, thinking about meeting these patients for the first time, it didn't seem like a particularly good news story or way of creating a relationship based on trust.

Q. Is that because practically the first thing you would have to say is, "We have done -- or someone has done -- testing on your blood without asking you first"?

A. Not necessarily the first thing but clearly it would be a vital piece of information that I wouldn't withhold from them.

Q. Yes. I mean, is there any way at all that something like this could have happened in Cardiff?

A. Obviously, I can't speak for what the virology department in Cardiff might or might not have done, certainly from the perspective of the haemophilia service, then, no, I don't think so.

Q. Yes. You wouldn't have been at Cardiff at the time that the first antigen test became available. Is that right?

A. That's correct, yes.

Q. Are you able to tell us what procedure was followed in Cardiff when that test became available?

A. Not really from memory, no.

Q. What would you expect to have happened when that test

first became available, in terms of information to patients?

A. Yes, I think there would have been an open sharing of information that, you know, there is a new test that possibly identifies the causative agent of non-A non-B Hepatitis, that clearly at that stage there are concerns about the test, there are going to be some -- it's not comprehensive, there will be some false positive and some false negative results, but it is a significant step forward in trying to understand the aetiology of non-A non-B Hepatitis.

Q. Yes.

THE CHAIRMAN: It might not be too safe to speculate about what might have happened in Cardiff, Professor, since we have a record of Professor Bloom expressing the opinion on 12 February 1990 that consent wouldn't have been required.

A. Would have?

THE CHAIRMAN: Would not have. So sometimes these things are best just left as not known.

MR GARDINER: Thank you, sir.

Just while we are on that topic, these particular patients' results, how did you resolve that situation that you found yourself in with those patients?

A. So to confirm the Hepatitis C result, I always took

a fresh sample. I would not have acted on the result of a stored serum alone. And clearly in starting to meet these patients for the first time, there was a lot of information that I had to give them. I had to introduce myself as a new Consultant, I had to get across the aspirations of what we were trying to do in terms of establishing a haemophilia service. Then there were all the issues around regular review, joint review, viral disease and so on.

I would guess in retrospect, with the benefit of another 20 years' experience, I probably gave them too much of an information overload on the first meeting and if I were to do it again, I would probably have gone about it in a slower manner, introducing some of these issues over a series of meetings.

Q. Yes. So you obtained a fresh sample of blood; did you tell the patients that their stored sera had been tested? Is that something that came out?

A. Yes.

Q. I'm going to come back to the actual information that you gave patients in those contexts but perhaps if we could just follow your statement through and I think --

THE CHAIRMAN: If you are starting on a new topic, it might be better to continue after the break.

Can I ask, Professor, so far as the virologists were

concerned, when the assay came along, it was perhaps something that would be very tempting for those who had stored sera, simply because of the novelty of the situation and general interest. Do you have any feeling whether that might have led to a general practice of testing stored material?

A. I certainly didn't ask Dr Urquhart at the time, simply because I had tunnel vision for the issue around talking to patients with haemophilia in Tayside, so I don't know. I guess there would be relatively few groups of patients for whom they would have stored sera and for whom there would be such an obvious question.

THE CHAIRMAN: Yes. Yes, I suppose it's unlikely that there would be much stored material for people who had had transfusions in the course of surgery, for example.

A. Yes, correct.

THE CHAIRMAN: Yes, I think we will have a break at that point.

MR GARDINER: Thank you.

(10.59 am)

(Short break)

(11.32 am)

THE CHAIRMAN: Yes, Mr Gardiner?

MR GARDINER: Thank you, sir.

Before the break, Professor, the chairman referred

to a document and it would be helpful to have a look at that. It's [LOT0034450].

We see that these are the minutes of the 19th meeting of the AIDS group of haemophilia centre directors, held at the Royal Free Hospital on 12 February 1990, and we see that present were Dr Bloom and many other notable and eminent physicians.

Could we just go to page 4453? We see that the context is a discussion about Hepatitis C tests, and we see at the bottom of the big paragraph the sentence that starts:

"At the moment the tests were quite reliable but it would soon be possible to do confirmatory tests ..."

Then the next sentence is the one that I think the chairman referred to:

"Professor Bloom didn't see why permission needed to be asked for Hepatitis C tests as it was just another LFT."

Before the break I asked you to speculate about what you thought would happen in Cardiff on the basis of your knowledge, when the test came in, and if I can just find it, what you said was:

"I think there would have been an open sharing of information that, you know, there is a new test that possibly identifies the causative agent of non-A non-B

Hepatitis ..."

And so on. Just to give you an opportunity to comment further, having seen these minutes.

A. Yes, thanks. Yes, I think the context is important, in comparing my position in Tayside with what Professor Bloom has said there. Clearly his patients were in a managed process, in which they had been counselled about non-A non-B and may well have given implied consent for ongoing monitoring of that condition, whereas I was faced with a group of patients I hadn't even met yet. I didn't know what information they had been given and just felt intuitively that it was not right that they had been tested without their -- without knowing -- without their permission, without knowing more about what they had been told in the past.

So Professor Bloom -- my speculation may well have been wrong, although I do think that the haemophilia centre staff in Cardiff, they would have explained to patients on a contemporaneous nature that, "There is a new test and we are going to test your blood for it".

Q. Yes.

A. I don't think they would have simply done the test and then come to the patient with the result.

Q. Yes. But as the chairman says, we are speculating to

a certain extent about that.

A. Yes.

Q. Thank you.

THE CHAIRMAN: Your position on your own practice is quite clear, Professor, and that's perhaps the most important thing at the moment.

MR GARDINER: Yes. Thank you, sir.

Could we just return to the professor's statement, please? Could we go back to page 4? Thank you.

You have just been telling us in the statement about the two major areas that need to be addressed, and I think over the next two or three pages you talk about what you did in reaction to the situation that you found yourself in at Dundee. Perhaps you could just broadly explain what you did.

A. Yes. So we obtained funding for an additional Consultant Haematologist posts. It was around 1993/1994 from my memory, and Professor Pippard and myself had to decide whether to try and recruit a specialist in coagulation disorders and haemophilia or not, as that was one of the key priorities for the department.

Another priority for us, however, was to recruit an academic because the department did not have a very high academic profile in the UK. It was a disadvantage in attracting high quality registrars to our training

scheme because there was no sort of research opportunities for them.

Given the size of our centre, with only about 30 severe patients with haemophilia, we eventually decided that the chances of getting an academic with an interest in haemophilia were just too remote. So that was when we made the decision that I would change my job plan from the treatment of malignant haematological disorders to take on the haemophilia doctor role and we would then try and recruit an academic with an interest in leukaemia research, which we did indeed do and made a very effective appointment that way.

Certainly at that stage, when a doctor finishes training to the level of a CCT or certificate of completion of training in the UK, although my previous interests had been in malignant haematology, you are pretty pluripotent at that time. So I had had all the training necessary to develop an interest in haemophilia, although clearly I lacked -- you know, I had limited experience.

So that was why it was extremely important for me to establish a relationship with the directors in the comprehensive care centres in Scotland. So it was primarily Professor Ludlam in Edinburgh, to whom I would go for help and advice, although in his absence I would

also contact Professor Lowe. And we set about trying to develop the infrastructure in terms of space in the haemophilia centre clinic and the staffing that would be required to deliver comprehensive care in collaboration with the comprehensive care centre in Edinburgh.

Q. Yes. What staff did you have at your disposal in the early years?

A. So to start off with, nobody really. There was myself, there would be the nurses in haematology, none of whom had any specialist training in haemophilia, and there would be the registrars, so the registrar who would be on the ward or day unit would assist in the first assessment of a patient with haemophilia.

Q. Yes. What proportion of your time was spent solely on haemophilia care during these first few years?

A. So it would be variable. Obviously, I had general haematology duties. The consultants on a weekly basis received all the new admissions to the unit. I had ongoing -- I was developing a clinical practice of patients with leukaemia and lymphoma and we would always have inpatients who were under my care. We shared the laboratory duties in terms of routine reporting, communication with general practitioners, specialist investigations and so on, clinical consultations within the hospital, teaching commitments and so on.

So my actual commitment to haemophilia would vary from time to time. There were clearly times when it was higher and times when it was lower. I would think in the early years, as I say, from 1993/1994 for the next two or three years, it may have taken up to 40 per cent of my time; probably over the duration of 12 years as a haematologist in Tayside perhaps about 20 per cent would be an average.

Q. Yes. I think, if we look at paragraph 4.4, you talk about employing a part-time specialist haemophilia nurse, June Ward. Could you tell us a little bit about that, please?

A. Clearly that was a key priority for me to be able to have the expertise and commitment of a specialist haemophilia nurse and I had to submit a business plan to get the funding for a salary, which I successfully did in about 1994, and June Ward was appointed in early 1995.

At that time she had experience of haematology nursing but no particular experience of haemophilia care and, as part of her sort of induction, she spent time in the comprehensive care centres in both Edinburgh and Glasgow. And at the beginning of her job we would see patients together all the time, so that June and I could develop a relationship and understand each other and so

that she could acquire fairly rapidly the knowledge about haemophilia care that would be necessary for her to deliver her role as a specialist nurse.

Q. Yes. Was she subsequently involved in counselling patients and helping with testing and so on?

A. Yes, yes.

Q. And what training did she receive as to how to go about that particular task?

A. So that would be training on a one-to-one basis with myself.

Q. Right. Okay. Perhaps you could outline very broadly, Professor, what you told her were the essentials of carrying out that task?

A. Yes. So it wasn't difficult. June and I had similar value systems. We both believed in patient-centred care, and from example in the first instance and then discussion about how a consultation had gone afterwards. We had similar views about how we wanted to develop the service and deliver it to our patient group.

Q. Yes. Okay. I mean specifically what did you tell her about how to carry out pre-test counselling?

A. For a new patient or an existing patient?

Q. Could you tell us about both situations?

A. So obviously for the patients with haemophilia who were in the region but who hadn't necessarily had regular

treatment, then the first thing to do is to try and establish a relationship with the patient, to try and firstly understand what their existing knowledge of non-A non-B Hepatitis, Hepatitis C was, and on the basis of their existing understanding to then try and build on that.

If it was somebody who did not have any understanding, then you would really have to start from the beginning about the likelihood of viral hepatitis as a consequence of blood product treatment prior to viral inactivation procedures and go through the reasons for wanting to test, the benefits of so doing, the potential for treatment, which obviously wasn't that established in those days, and then gain their agreement to do the test.

Q. Yes. When you say "build on their knowledge", is that to make sure they understood the contemporary knowledge about the disease?

A. Yes, some patients would be pretty well informed through the Haemophilia Society, through other patients that they had spoken to, through the informal contact with the medical and nursing staff in the unit. So for some patients they were already fairly well informed, others were less so.

Q. Yes, thank you. If we have a look at page 6 of your

statement, at the top we see paragraph 4.6, and you explain:

"From 1995, June Ward and I set about establishing the haemophilia centre and the delivery of comprehensive care in Tayside."

And you list the priority areas for action, which are listed there, one to seven on that page. Then over the page. These are all the kinds of things that you mentioned as being lacking when you arrived in Dundee first of all. Is that right?

A. That's correct.

Q. I propose to pass on to your practice in relation to testing and consent. Is there anything in those two pages which you considered are priority areas for action that you think are particularly relevant to the next question, the consent. No?

A. No, I don't think so.

Q. Okay.

THE CHAIRMAN: Can I ask you just about one? In fact it's the very first:

"Establishing the centre management, documentation and local protocols."

What sort of areas would be covered by the local protocols you thought necessary?

A. So one of the important issues for us was that June and

I were not going to be in the unit 24 hours a day. While she and I were perfectly clear about the standards of practice that we were developing, we needed to have protocols that covered the other haematology medical and nursing staff, should a patient present with problems out-of-hours, so that we had consistent management across the whole staff group.

The other early priority for me was in fact protocols for managing surgery. I had prioritised the orthopaedic surgery because I felt that was an early win that might establish the trust of the patient group, that something was going to be different --

THE CHAIRMAN: You had this backlog of people.

A. -- and was going to be better. And because we hadn't had any elective orthopaedic surgery in Tayside for a patient with haemophilia -- and it's a major procedure -- I did spend a lot of time writing extensive protocols for the surgeons, for the anaesthetists, for the ward staff who would be looking after the patients post-operatively. That was one of the key early areas.

THE CHAIRMAN: I think you might have answered my next question, which is how formally these protocols were presented and to whom they were presented. We are talking about formal written --

A. Yes, these were formally written protocols, which

I think the centre has been unable to find, and clearly from the service's perspective as a protocol is developed and a new version is put in place, then you would actually want to delete the original protocol. The last thing you want is two protocols in a clinical area that might be saying slightly different things. So they have got contemporary protocols in the centre but not the ones that relate back to this period.

So for the out-of-hours service, you know, for the out-of-hours protocols, we had regular haematology educational meetings at which consultants, nursing staff and registrars would all be present, and we would present the haemophilia protocols in that context and we would have a written set of protocols that were kept at the nurses' desk in the general ward and in the haemophilia centre, once we had it established.

For the surgical protocols, they were very widely distributed to the anaesthetics department, the orthopaedic department and again amongst all of the staff who might be providing 24-hour cover for the patients.

PROFESSOR JAMES: Could I clarify two brief points please? Once things had settled down, how many patients did you find that you actually had on your books that you were seeing relatively frequently?

A. There was in the region of 25 patients with severe haemophilia, who would require regular treatment and home therapy and so on, and about 100 with milder coagulation disorders, including mild haemophilia, von Willebrand's disease and some rarer factor deficiencies.

PROFESSOR JAMES: Thank you. And second, had it been the practice that more severe patients had gone to the comprehensive centres, particularly, obviously, Edinburgh, until you arrived? Is that how perhaps some of the "worst" patients were being looked after or was that incorrect?

A. I'm sure that some of the patients would have been seen in the Edinburgh centre. Over the specific issue of chronic joint disease, for various reasons, no patient had ended up having surgery in Edinburgh or Glasgow, even though that offer was available to them. And I guess that may be for family reasons and, you know, travelling such a long way for major surgery and so on. So I'm sure patients would have been seen but again, it wasn't in a planned manner; it would be on an ad hoc basis.

PROFESSOR JAMES: Thank you. Thank you, sir.

THE CHAIRMAN: Thank you very much.

MR GARDINER: Thank you, sir. Yes, we do have an example of

a protocol which I think we could have a quick look at. It's [PEN0180930]. Is that an example of --

A. Yes, clearly that's -- I wouldn't describe that as a protocol, which would have to be a more detailed document, but that may be a working guideline that might be laminated and put on the ward for -- put in the haemophilia centre for regular use. A protocol would have to be more detailed and have a rationale and references and --

Q. There is another document perhaps we could have a look at, which is [PEN0180932].

These are documents that have been provided to the Inquiry by June Ward, I should say, sir.

Could we go over the page -- is this more --

A. Yes, this is not a protocol that we have written; this was an NHS Tayside regional approach to providing care for Hepatitis C, up until the production of this protocol, which was particularly, I think, focused on the treatment options. If we wanted to offer interferon therapy to any patient, we had to make an individual case to the medical director through a hepatologist, and this was an attempt to standardise the care of Hepatitis C treatment across all patient groups in Tayside on the basis of a protocol.

Q. So the protocols that you are talking about at the

moment are really, would you say, training aids for members of staff working in the hospital?

A. Yes, in having a protocol, I would expect a reference document, to which anybody can go, and it would give the background information, it would have an educational purpose, it would give the rationale and reasons, but obviously -- and we would have protocols for the treatment of leukaemia, lymphoma, myeloma, all the other conditions -- on a day-to-day basis, staff are not going to have the time to consult such a detailed document but it is there for reference if they need it. And the first document you showed is a helpful aide-memoire so that if you are seeing patients in a busy clinic environment and you just need to refresh your memory about whether they should have a particular test done as part of that protocol or guideline, they would be able to access that.

Q. Yes. Did you produce a protocol that was specifically directed to HCV testing and the correct procedure to follow with a patient?

A. Not a specific haemophilia patient protocol. I worked with Dr John Dillon, who was the principal source of expert advice around Hepatitis B and C, and basically used his protocols. We may well have adapted them for the particular context of haemophilia but it was not

original work by ourselves.

Q. Yes, right, okay, thank you. I would like to pass on now to the practice in relation to testing, and that's back to the statement, please, at page 0861.

Which page is that?

THE CHAIRMAN: It starts on 60.

MR GARDINER: Yes, I have got that, thank you.

Yes, so this is question 5, and you explain here that there were three separate phases, historical periods, if you like. Could you just tell us about that?

A. So before my appointment, as I have indicated earlier, there was not a planned, managed process for seeing and delivering ongoing care to our patients with haemophilia. What counselling may have taken place was on an opportunistic basis when they were attending the hospital for other reasons.

Then the second phase was once I had agreed to take on the role of the lead clinician for haemophilia care and I was beginning to see patients and attempting to establish both a relationship with them and deliver the standards of regular care that we have discussed, but again it was slightly opportunistic, and then from 1995 onwards, once June was appointed, she was much more organised than I had been around starting to get

a formal appointment process. We had a dedicated space in creating a haemophilia centre, where we could see the patients. We didn't need to look for a spare room in the day unit. And obviously it developed from there.

Q. Yes. Thank you.

If we go on down to paragraph 5.2.1, the question is:

"When did they start testing their patients for HCV?"

We have already dealt with the first bit there, the cohort of 30 patients. Could you just tell us what happened from 1992 onwards, please?

A. So from the time I started to see patients, I would, as I have indicated previously, introduce myself, explain what we were trying to do in the department and go through the gamut of issues in relation to their haemophilia, allied conditions, you know, joint conditions, dental work, and on to Hepatitis C, B and HIV. And I would, at first meeting, want to ascertain what knowledge they had about HCV and try and build on that knowledge and obtain their informed consent for participation in ongoing review and assessment of their liver function and Hepatitis C status.

Q. What would that involve, obtaining their consent? How would that be done?

A. So it would have to be individualised and based on what they already knew. I would then take the conversation forwards and explain the latest information we had about Hepatitis C, about the Hepatitis C test, if they had or hadn't been tested for it, and explain the potential benefits of that test.

Q. Yes. Would you give the patient the opportunity to decide not to have the test, for example?

A. Yes, that would certainly have been my intention. As I indicated earlier, I think, you know, in retrospect I probably tried to do too much at the first visit, when I saw the patients, given the sort of unique situation we had in Tayside. Perhaps, if I were doing it all over again, I might spread the load of information over two or three visits.

Q. Yes. Do you know what happens if you give a patient too much information like that?

A. Yes, clearly -- we are all humans, there are limits to the amount that we can assimilate, remember and truly understand. So if you give too much information all at once, it will be inevitable that a patient is not going to remember everything that you have said.

Q. Yes. So what is a preferable practice in that situation? How would you make sure that a patient got the information that they required?

A. You would explain to them. You have to start off by getting a feel for the patient, where they are, what their sort of cognitive skills are. Then you explain to them, in language that you think they will understand, and ask them what they have understood, assuming that you have time in the consultation to do that.

Q. Yes. Understood about the disease?

A. Understood about -- yes, so if you have just counselled them, say, about Hepatitis C and the test and so on, you can then ask them a question, you know, "What have you understood about that?" and if they play back to you a fairly accurate record of what you have said, then that's good. If they haven't, then you know that you have not succeeded in getting across the concepts that you attempted to do.

Q. Yes. During this period, 1992 to 1995, would you have explained the implications of a positive diagnosis to the patient before the test was taken?

A. Yes, I would. As these were mostly patients who had not had the benefit of ongoing follow-up and discussion, I generally sort of started from the beginning.

Q. Yes. We know that knowledge of Hepatitis C changed over time. Between 1992 and 1995, can you remember what you were telling patients about the implications of a diagnosis for their health?

A. Not with absolute certainty in terms of, you know, I wouldn't have said it before 1992 or after 1995. But, yes, at that time it was clear that more evidence was arising around the fact that Hepatitis C was not necessarily the benign condition that we had assumed in the previous decade, and I would explain that to patients. Looking at their sort of individual profile in terms of did they have evidence of chronic liver disease, how badly affected were their liver function tests and trying to look at other potential complicating issues such as their alcohol intake or other prescribed drugs that they were on.

Q. We know that for certain patients the disease developed to cirrhosis and for another proportion to liver cancer. Was that possibility discussed with your patients during this time?

A. Yes. So cirrhosis certainly. I'm not sure from memory about hepatocellular cancer. I'm not sure when that was identified. It may be mid 1990s. I'm not sure about that but once we were clear about the link, it would be something that June and I would discuss with the patients because for hepatocellular carcinoma, we would be monitoring their alphafetoprotein test.

Q. So would you have passed on your knowledge of the development of the disease to June Ward to make sure

that she would pass that on to the patients? Is that how it worked?

A. Yes.

Q. Thank you. Can we just go on to the next page, please, page 9, the second paragraph:

"Did they tell their patients that HCV tests were being carried out? What did they tell their patients about HCV testing? Did they obtain consent ..."

I think we have just dealt with that:

"Were there any written guidelines or policies on HCV testing produced by the unit at this time?"

I think you say that there weren't protocols that specifically dealt with testing?

A. Yes, in terms of Hepatitis C, we didn't set about writing a separate set of protocols. We took the protocols from John Dillon as the liver specialist and adapted them for haemophilia.

Q. Yes. Is that what to do once a diagnosis has been made?

A. Yes, so certainly once we had a diagnosis, and particularly if there was evidence of chronic liver disease or progression, then we would aim to have the patients jointly seen by John Dillon and myself, or John Dillon and June.

Q. Yes. But you understand that no such guidelines have been found --

A. That's correct, yes.
Q. -- despite the search by June Ward. Thank you. The next question is 5.3.1:

"What was their practice in relation to telling their patients the results of an anti HCV-positive test? Did they inform their patients immediately upon receiving their results? If not, why not?"

Can I just ask you to answer that question in your own words, Professor?

A. Thank you, yes. So for all of the patients, including those in whom we had been given the results from virology, we took a first test -- we took a fresh blood sample to confirm the test, and our aim was, in seeing a lot of these patients for the first time, to give them a follow-up appointment fairly rapidly, within a month or so, to discuss again the gamut of tests that we had undertaken. And if their HCV status was positive, we would take a second blood sample for a confirmatory test.

So our aim was to see everybody within a month of first meeting them. Prior to June's appointment, I may not have achieved that objective, largely because I was just working on my own and June was far more organised than I was around making follow-up appointments.

Q. Yes. So you would take blood for a first test and then

if that test was positive, the patient would come back and have more blood taken. At that point would the patient be told that they had tested positive the first --

A. Yes, and that it was a screening test, that it was fairly reliable but to be absolutely certain, we would do a second test.

Q. Yes, and at that point, before you had done the confirmatory test, would you go into the detail of the implications of the diagnosis and so on?

A. Yes, I would, particularly if, you know, if there was other supporting evidence. If it was a patient who had had extensive treatment, then they almost certainly were HCV-positive. If they had evidence of abnormal liver function tests or clinical evidence of chronic liver disease, then I wouldn't necessarily wait for the confirmatory test.

Q. Yes. What would you tell patients at that time about the implications of the diagnosis?

A. So part of what you would say to a patient would depend on the clinical context. So if they very clearly had evidence of chronic liver disease, you would have to be honest and say that, you know, "There is evidence of progressive liver disease, so you may be in the group of patients who are going to go on and develop cirrhosis".

If somebody had no evidence and over a period had relatively normal liver function tests, you would tell them that they might be in the better prognosis group but that there was no guarantee of this.

Q. Yes.

A. So you would try and stratify the risk according to all of the evidence in front of you and give them an idea of progression over time. So over successive clinic visits you would either try to reassure them or to be honest with them about the risk of progression.

Q. Yes. So you are not giving us a picture of one visit, "Here is the news about your situation," and then it's not mentioned again. You continued to mention and discuss with the patient. Is that right?

A. Yes.

Q. Was there anything else that you told patients when they received the positive result? You mention, I think, at some point, the possibility of transmission to third parties and so on?

A. Yes, we would and offer to test partners if so wanted.

Q. Yes. Would you have any advice about sexual transmission during this period?

A. Yes, I mean, obviously, you know, there was advice from UKHCDO independent of viral testing because of viruses that we might not know about and the fact that none of

the tests were 100 per cent reliable, but if somebody did come up as Hepatitis C-positive, then we would go over that and the potential issue of sexual transmission.

Q. Yes. So would you be encouraging preventative --

A. Barrier contraception, yes.

Q. Thank you. Okay. If we go over the page to page 10, the question is:

"What did they tell their patients about the implications of HCV?"

I think we have covered some of that but perhaps you could just talk to us a bit more about what you did.

A. So knowledge was constantly evolving over the course of that decade. We would try to keep patients up-to-date with that evolving knowledge and as I indicated earlier, also important to try and individualise the advice, depending on the evidence of liver disease and progression in each patient.

Interferon therapy was available from, I think, 1994/1995-ish. In the early stages it was a case that had to be made by a referring clinician to the medical director for approval, but then from 1998 that NHS Tayside policy for treatment that you showed earlier came out and patients could be offered treatment on that basis.

June or I would never initiate treatment without involving John Dillon as the Consultant Hepatologist. He had the specialist knowledge of that and we would discuss and did undertake some liver biopsies on selected patients, if John felt that would be of benefit in terms of deciding about treatment.

Q. Yes. Thank you. Sorry. Can we just go back, Professor? I asked you earlier about whether, during these meetings with patients when they had received a positive result, you would discuss the possibility of sexual transmission and whether you would be encouraging a particular approach, and I don't think we caught your reply. What was it? What would you be advising patients?

A. We would advise barrier contraception because of the risk of transmission.

Q. Right, thank you very much. Just in case we missed it, would there be any other lifestyle advice that you would give patients?

A. Obviously alcohol intake is something that can have an adverse impact on liver disease. We would review any prescription medications that they might be on for potentially hepatotoxic effects and discuss over the counter medications.

Q. Yes. How strong would your advice be about alcohol use

at that time?

A. So I think at that time UKHCDO recommendations were not the total abstinence of alcohol but to use it moderately and I think, you know, the advice would be that any amount of alcohol is potentially toxic to the liver but clearly, in determining the risks and benefit, then, you know, the individual's lifestyle and enjoying a bit of social alcohol was a decision for them to make.

Q. Yes. Just bear with me. (Pause)

Could we have a look at [PEN0180649]. This is the Collective Response of haemophilia centre staff. I would like to ask you a couple of questions about it, Professor.

Could you tell us what your involvement was in the production of this document?

A. Yes. So my involvement was fairly minimal. I was sent a copy of the Collective Response at an advanced draft stage, asked to comment on it. I made a number of minor changes in relation to the different context of Dundee and the haemophilia centre and the lack of comprehensive care at an earlier stage.

Q. Yes. Thank you. So you didn't help draft it?

A. No.

Q. No. Thank you.

Sir, I propose to move on to the witness' comments

on Dr Hay's report, unless you have any questions?
THE CHAIRMAN: Just one. Did you have any contact with the SNBTS locally over this period?
A. Yes.
THE CHAIRMAN: They clearly had an interest in respect of donor screening in Hepatitis C testing, as you did. Did you discuss with them what they were doing in the way of counselling and information they were giving?
A. Good question. Not explicitly around donor counselling, no. We have a slightly unusual set-up in Dundee, in that there is a regional transfusion service that also provides the hospital blood banking. So we had a lot of contact with them over the hospital blood banking side of things and in relation to factor concentrate storage and prescription, but not so much around the donor side.
THE CHAIRMAN: Yes. Yes, thank you.
MR GARDINER: Thank you. Yes. Could we have a look at [PEN0181186] now, please? This is a report to the Inquiry from Dr Charles Hay. We are about to hear evidence from him, Professor.
You have had an opportunity to read this. Is that right?
A. I have, yes.
Q. Thank you. It's a very long report but the bit that I would particularly like to refer to is on page 27 of

[PEN0181186].

Yes, thank you.

Just to put this in context, Dr Hay has been asked by the Inquiry to look at the developing knowledge about the disease and to think about what doctors would have been and should have been telling their patients at various time periods, and at this section of the report he is talking about his own practice. If we look at paragraph 63 -- I'm just going to read it out -- he says:

"It was my practice in Liverpool and Manchester to inform patients that I was testing them for Hepatitis C and to go over (again) an outline of Hepatitis C. Consent and counselling was, and is, not the norm prior to Hepatitis C testing and hepatologists would, and do, routinely test for Hepatitis C as part of an investigation for abnormal liver function test without discussing the test specifically with the patient. They may tell them they are testing for hepatitis viruses."

Next paragraph:

"Some patients have complained, many years after the event, that they were tested 'without their permission'. In some they may, indeed, have been tested without being specifically informed and in other cases it is documented that they were informed both that they were

being tested and of the result. The idea that a Hepatitis C test should engender prolonged pre-test counselling derives from the practice adopted after 1985 by most centres of counselling prior to HIV testing. The implications of a positive HIV test could be perceived as a death sentence, led to loss of insurance, marriage breakdown, and even in some cases suicide. There is no comparison between this and Hepatitis C testing. For that reason, there has never been a specific consent process attached to Hepatitis C testing even though it would be normal practice to inform the patient that they were being tested and to inform them of the result."

Paragraph 65:

"In our centre, we informed them we were testing them for Hepatitis C, discussed the result with them when available and wrote to the GP and documented the discussion."

I'm going to refer you to a report by Professor Nathanson and ask you to comment on both reports, but just before we leave this one, do you have any comment about those paragraphs there?

A. Yes. Clinical context is obviously really important. So a patient referred to a hepatologist with hepatitis of unknown origin -- that could be viral or drug induced

or an autoimmune disorder -- clearly has to be investigated for that cause, and the process of obtaining consent for a battery of tests which identify the cause of hepatitis might be different from a patient with haemophilia.

So I think clinical context is important and one would expect a practitioner to modify their practice in the light of the context that is in front of them.

Again, with haemophilia care of patients in a proper managed process, there will be ongoing consent or there will be ongoing information about non-A non-B Hepatitis, and the addition of a Hepatitis C test is not necessarily starting with a new problem; it's part of an ongoing follow-up and review process. So depending on the consent that they have already given for sort of monitoring of liver function tests and their knowledge of non-A non-B, I think the context may well be different.

Q. Yes. Thank you. Can we have a look at Professor Nathanson's supplementary statement? Sorry, that's [PEN0180419]. Again, you have had a opportunity to read that?

A. I have indeed, yes.

Q. Thank you. If we look at the first question that Professor Nathanson was asked, which is in the bottom

half of the page:

"What is the current approach to testing for HCV? In particular what information should a clinician provide to his/her patients about the disease and the implications of a positive diagnosis? What is the current GMC/BMA guidance on this point?"

Professor Nathanson starts by referring to the GMC's booklet on Good Medical Practice, and she refers to an quotation which talks about:

"... a doctor using specialist knowledge and experience in clinical judgment and the patient's views and understanding of their condition to identify which investigations or treatments are likely to result in overall benefit for the patient. The doctor explains the options to the patient setting out the benefits. The doctor recommends a particular option."

And so on. If we just go over the page, the paragraph at the top, Professor Nathanson says:

"Today doctors are expect to offer the patient all the elements of information identified in this guidance. It is essential that it is understood that the information is offered; no patient can or should be forced to listen to the full set of information."

In the fourth paragraph she stresses again:

"What matters is the offering being made, and the

doctor being sensitive to what the patient wants to know."

The second last paragraph on the page, she stresses:

"When seeking agreement to tests, one element of the information offered will be to explain what the tests might show, why it is being performed, and what decisions will be made in respect of the results."

And so on. So this is an answer to the current approach to testing. What would your reaction be to what Professor Nathanson has written there?

A. Thanks. So her statement defines the sort of generic best practice for the ethical clinical practice in terms of obtaining informed consent, and that is something that all doctors should aspire to but probably none of us deliver every time, every patient, firstly because of the clinical context that we have already discussed and, secondly, because, you know, the clinical environment is sometimes a chaotic and messy one and there are multiple other pressures on a doctor's time.

So in the particular instance of haemophilia care, then obviously it's a long-term, ongoing process and it's not something to be done on one clinic visit and then parked; it will be part of the ongoing dialogue that you have with patients at regular review meetings.

Q. Yes. Thank you. If we could go over the page and look

at the second question, and the question, which is put to Professor Nathanson, is:

"What was the correct approach to testing for HCV between 1991 and 2000? In particular what information should a clinician have provided to his/her patients about the disease and the implications of a positive diagnosis? What was the current GMC/BMA guidance on this point and how did it evolve? Were there any circumstances in which testing could be done without obtaining a patient's consent?"

She starts off her answer by referring to the BMA publication "Philosophy and practice of medical ethics". It's stated that:

"The basis for any discussion about consent is that a patient gives consent before any investigation or treatment proposed by the doctor. The doctors offer advice and the patient decides whether to accept ..."

A little bit further down the page she refers to a GMC advice from 1988, entitled "HIV infection and AIDS: The ethical considerations", particularly a paragraph which says:

"It has long been accepted and is well understood within the profession that a doctor should treat a patient only on the basis of the patient's informed consent."

She then refers to a 1997 GMC advice and draws attention to paragraph 4, which says:

"Some conditions, such as HIV, have serious social and financial, as well as medical, implications. In such cases you must make sure that the patient is given appropriate information about the implications of the test, and appropriate time to consider and discuss them."

If we could just go over the page, she goes on to say:

"It is clear and explicit that in 1997 the GMC required doctors seeking consent to have regard to the implications of the test result. This is more explicit than the earlier advice on testing for HIV, but is in accord with it. While the advice relates to HIV, it is important to note that it identifies 'some conditions such as HIV' and is not, therefore, limited only to testing for HIV."

She says:

"Given that in the nine years from the production of the advice on testing for HIV to this advice on serious communicable diseases, more and more doctors have had to test for HIV, and therefore had to consider how to advise on testing for conditions with serious non-medical consequences, the GMC was almost certainly

reflecting best practice and a recognition that not all practitioners were as yet practising at this level."

Would you agree with me, Professor, that Professor Nathanson seems to be suggesting there that for HCV testing, a doctor should adopt the same procedure that was adopted for HIV testing; in other words, a more prolonged form of counselling and discussion of the implications with thinking time and so on?

A. Thanks. Yes. So again these are principles for best practice that come in the form of guidance or advice that a good clinician will interpret in the light of the clinical context. So the example you quoted earlier of, say, a patient presenting to a hepatologist with unexplained severe hepatitis, where the correct care of that patient would be absolutely dependent on identifying the cause of the hepatitis, I would expect a clinician to take a different approach around getting informed consent because there is a matter of urgency and need, for the benefit of that patient's management and their health, to complete these tests.

If you took a completely different clinical context, say, a member of staff who had had a needle stick injury from a Hepatitis C-positive patient, then I think that is fundamentally different and I would expect the

process that Dr Nathanson outlines there to be gone through in some detail. You have got a completely healthy patient who might be infected. If he or she is found to be Hepatitis C positive, it would have implications for life insurance and so on, then they are entitled to hear the detailed risks and benefits of undergoing testing and to decide for themselves whether or not they want to undergo the testing.

It's clearly their decision and the responsibility of the doctor, should they decide not to be tested, to make sure they are clear that HCV is a potentially curable condition and there are implications if they decide not to.

I think context is really important.

Q. Yes. I'm grateful to you for your full answer on that. I was specifically just asking you to acknowledge that she does seem to be suggesting this extended HIV-type counselling. Would you agree with that --

A. She is, that is generic advice. It cannot possibly cover the multiple clinical conditions that, as I said, in the sometimes chaotic clinical environment clinicians have to deal with and will have to assess the risks and benefits of every action that they take and then take appropriate action.

Q. Yes. But if we could have a quick look at [PEN0181239],

this is a document that you have kindly provided the Inquiry in connection with Dr Hay's report and Professor Nathanson's supplementary report. Before I ask you about this, would you agree that there does appear to be a conflict between what Dr Hay is saying in his report about the requirement for that extended type of counselling and what Professor Nathanson is talking about?

A. I wouldn't say a "conflict" because I think they are different documents. If Dr Nathanson is trying to identify, using GMC Good Medical Practice, the principles of obtaining informed consent, to which we should all work towards and aspire, then the appropriate interpretation of those principles will be dependent on clinical context.

Q. Yes. So we see here in your response you say you agree with the report from Dr Nathanson and have no additional comments. We shouldn't interpret that as you preferring what Professor Nathanson is saying over what Dr Hay is saying, if indeed there is a difference.

A. It's not a preference because I think the individual reports are for different purposes.

Q. Yes. You have told us that you think that Dr Nathanson is trying to identify the GMC Good Medical Practice and the principles of obtaining informed consent. How

should we be looking at Dr Hay's report then?

A. Dr Hay is explaining, in the context of his clinical practice, how he, as a haemophilia doctor, delivered his clinical care, taking into account Good Medical Practice and all the principles of good clinical care.

Q. Yes. I don't want to put words in your mouth, so tell me if I'm wrong about this, but are you suggesting that what Professor Nathanson is describing is an aspiration or an ideal or ...?

A. Yes, it's certainly an aspiration and an ideal but it is advice and guidance and every doctor in their clinical practice needs to take cognisance of standard practice, good principles and advice, but recognise that the multitude of different clinical contexts and situations means that he or she needs to conduct their practice and deal with the issues that they are dealing with that day in the knowledge of that advice but tailoring it to the particular circumstance. So the two examples of somebody with a needle stick injury and somebody who has got severe unexplained liver disease, the principles are the same but the actual practice will be very different.

Q. Hm-mm. One of our witnesses has referred to the implications of a test as being the difference between being well and then, after the result of the test, being unwell, being a patient. I mean, is that what you mean?

A. Well, certainly, for somebody who has had a needle stick injury, that might well be the case. There is no compelling medical illness that they have at that time and they may make an informed decision that even though they have had a needle stick injury from an HCV-positive patient, that it is their personal decision not to proceed with testing. That's a position that a patient may want to take and a doctor's responsibility is only to provide them with the risks and benefits and information that they need to make that decision.

Q. And what's the difference between that and a patient who attends a liver specialist, having been referred by his clinician?

A. The principle is the same but the advice is different. The advice is, "If you do not have these tests, then we will be unable to manage the acute illness that you have to best possible practice and you may be limiting our ability to make an accurate diagnosis and therefore give you the best treatment. It may have an immediate adverse impact on your health."

So it is a more compelling situation, in which the risk/benefit of having the test is significantly different.

Q. I suppose it's an easier decision for the patient, is it, in that situation?

A. Yes, in the situation where, if you have got severe unexplained liver disease and you want to get better from it, then absolutely, it is a less contentious ethical issue, whereas Dr Nathanson's guidance has to cover the entire spectrum. You know, the principles of ethical practice, but it has to be generic enough that it covers the entirety of medical practice.

Q. Yes.

PROFESSOR JAMES: Could I just add one small thing? I'm Professor James, medical adviser, and I happen to be a liver specialist.

So I would add that in the very good example that you chose of somebody coming in with unexplained serious liver disease, it strikes me at least that Professor Nathanson's aspirational advice is even more aspirational in nature because there might be four or five or more different conditions which would result from the battery of tests which were undertaken by the doctor, and it would really be very difficult for somebody to give information about the implications of a positive diagnosis. What it might mean in terms of treatment, prognosis, et cetera, for all of those four or five conditions before undertaking the battery of tests. Indeed, one would certainly think that the problems with information overload that you and counsel

have already alluded to this morning really would become quite reductio ad absurdum. I think you chose a very good example, if I may say so.

Thank you very much, sir.

MR GARDINER: Just to maybe pursue this a little bit further, there are extremes. I mean, Dr Hay in his report referred to situations where patients simply hadn't been told that they were being tested for Hepatitis C. Clearly that's not appropriate; you were horrified when you found out about that in Dundee. So you would agree that that was not appropriate, I take it?

A. Yes, I agree that patients have a right to know all the pertinent and relevant information about their health and the investigations that a doctor has undertaken. Clearly, it's the responsibility of the doctor to provide them with that information in an appropriate, empathetic, understanding and controlled manner. So, you know, it may be that you don't necessarily deal with all of the issues in a single sitting, it may be that you need to park a particular issue until another consultation, but it would be inappropriate for a doctor to withhold relevant information about somebody's health.

Q. Yes. I suppose it is a question of degree as well

because you could have a situation where a doctor might say to a patient, "I'm going to test you for Hepatitis C," and then just get on with it, not really giving the patient the opportunity to say yes or no to the offer of a test. That's maybe not as reprehensible but it wouldn't be a good approach. Is that fair?

A. Yes, I would intuitively feel that was the wrong approach. If the basis of a successful doctor/patient relationship is trust, then I think you need to build up that trust on, you know, the grounds of explanation and agreement for the actions that you are going to undertake.

Q. Yes. Thank you. Would you just bear with me, Professor? (Pause)

Professor, there is just one final thing I would like to ask you about and it's really a comment that you made to us earlier before we came in, about the experience of patients with haemophilia over the last years and decades. These patients, what do you feel their experience has been?

A. Obviously haemophilia is a horrible, lifelong condition and over the last 30 years or so I think -- you know, for patients in this group there have been these waves of huge optimism around fantastic advances in treatment, such as factor concentrates and home therapy, which

revolutionised the life of patients, prophylactic treatment that now prevents joint disease in boys who are born today, interspersed with the horrors of HIV and hepatitis and new variant CJD. So every time there seems to be a substantial advance, there is some sort of nasty surprise waiting, and I think it has been very difficult for this group of people to cope with that.

Q. I think you told us that there had been waves of optimism and waves of despair. Is that right?

A. Yes.

Q. Thank you very much, Professor.

I have no more questions, sir.

THE CHAIRMAN: Mr Di Rollo?

MR DI ROLLO: Sir, I don't require to ask any questions.

THE CHAIRMAN: Mr Anderson?

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

MR JOHNSTON: I have no questions either, sir.

THE CHAIRMAN: Professor, thank you very much indeed.

A. Thank you.

MR GARDINER: Sir, we have Dr Hay next. I think it might be better to start him after lunch actually.

THE CHAIRMAN: Yes, then can we start early? Do you know whether he is here?

MR GARDINER: He is here, so if we could maybe start a quarter of an hour early.

THE CHAIRMAN: Is that acceptable to everybody? Right, we will adjourn now.

(12.48 pm)

(The short adjournment)

(1.45 pm)

DR CHARLES HAY (continued)

Questions by MR GARDINER

THE CHAIRMAN: Good afternoon.

Yes, Mr Gardiner?

MR GARDINER: Good afternoon, Dr Hay. You have previously given evidence to the Inquiry during the specific deaths section on 18 March 2011 and we looked at your CV at that point.

THE CHAIRMAN: Is it as long ago as that?

MR GARDINER: Statistics, I'm sorry. But there is a helpful summary at page 2 of the report that you have prepared for this topic. Could we have a look at that? It's at page 2 of [PEN0181186].

I take it that you are still director of the haemophilia centre in Manchester?

A. Yes.

Q. And still chairman of the UKHCDO?

A. I relinquished the chair of UKHCDO in the autumn of last year.

Q. Right. I wonder if you could try to speak into the

microphone that's just in front of you there. Thank you very much.

We see on page 2 of your report your qualifications and your present post, consultant haematologist, director Manchester Haemophilia Comprehensive Care Centre, honorary senior lecturer in medicine, Manchester University and that you were appointed in 1994, and there is a brief summary at the bottom of your career and experience. Could you just tell us about it very quickly?

A. Well, I did my house jobs in Sheffield, where I qualified, and my first house job was six months of general surgery with the Professor of Surgery. I then became, in fact, the first haematology houseman. It was partly haematology, partly general medicine, partly gastroenterology, for six months, and in fact that was the point at which I was really exposed to coagulation for the first time and that drew me into haematology.

I then went on to do general medical training posts in Sheffield and in London, before becoming a registrar in haematology back in Sheffield, then subsequently became senior registrar in the same department I had done my house job in and continued to develop my interest in thrombosis and haemostasis, and it was at that point that I started to look after patients with

haemophilia more full-time and made one or two clinical observations that led ultimately to the liver biopsy series which we published in The Lancet in 1985 and in Blood in 1983.

Q. Yes, thank you. We will look at your early work a little bit later but could we go to page 3 of our report, we see under the heading "Introduction" (a) to (h), the questions that you have been asked to address by the Inquiry, the risk of non-A non-B Hepatitis, each of the landmark years, state of knowledge about the severity of the illness, information given to patients about the risk of non-A non-B Hepatitis, your personal practice in relation to telling patients the results of anti-HCV-positive tests, what clinicians reasonably have been expected to tell their patients about the implications of Hepatitis C in the early days and from 1995 onwards, whether the information and practice would differ between patients who have been treated before or not, tracing and testing of patients who might have been exposed and when HCV testing of patients with bleeding disorders started.

So these are the questions that we are hoping that you are going to be able to help us with today.

I should mention that your report is very comprehensive, very helpful and very lengthy and deals

with areas which the Inquiry has looked at before and so I will be skipping over some parts and focusing on this specific topic, which is about information to patients.

At the bottom of page 3 there is a reference to what you just told us about working as a haematology houseman at Sheffield Royal Infirmary and the results published in the Preston et al paper, and if we just go over the page, on page 4 you describe to us your early years of practice. Could you just talk us through what you describe on this page, please?

A. Okay. Well, about the time I was the haematology houseman, Mannucci published the first report of the use of DDAVP in the letter to The Lancet. Partly because of the department's interest in this relatively newly described non-A non-B Hepatitis, they took this up very early and I actually was involved in some of these very early treatments with DDAVP, although it was unlicensed for that indication at the time.

I returned to the department as a Senior Registrar in 1983 and had to do a regular follow-up clinic on our patients with haemophilia, and what got the ball rolling was the clinical observation that one of our patients who had been biopsied back in the late 70s had developed clinical signs of cirrhosis. What was particularly remarkable at that time was that the biopsy result had

shown chronic persistent hepatitis.

Now at that time chronic persistent hepatitis, which is a histological appearance of the liver, was associated with a benign, non-progressive outcome. So it was very surprising to see somebody whose previous biopsy, only about three or four years before, had shown chronic persistent hepatitis, who now had full-blown cirrhosis and who actually had had an episode of encephalopathy. So I went to Professor Preston and I pointed that out to him and I suggested that it might be of some interest to do further biopsies, particularly in the patients who had previously had a biopsy, to see if their liver disease had progressed and to see whether the natural history of non-A non-B Hepatitis was actually more progressive than had been supposed.

We convened a group, which was made up of the previous authors, plus myself, worked out a protocol and arranged a series of biopsies. I mean, these biopsies, I think it was felt, would have been required clinically in any case because liver biopsies are a classical way in which liver disease is monitored.

The natural history of chronic persistent hepatitis at that time was largely based on a paper by Chadwick et al, which looked at chronic persistent hepatitis in patients with Hepatitis B. And with hindsight perhaps

we shouldn't have expected that it would pursue the same natural history with a different virus.

Q. Yes. Could I ask you, doctor, why it was that you proposed this change in the progression? You say in the middle of the paragraph:

"I proposed that the natural history of non-A non-B Hepatitis might differ from chronic Hepatitis B."

What made you propose that?

A. Because what we were observing in that patient was out of keeping with what we would have expected to see according to the paper of Chadwick et al.

Q. So it was that one patient --

A. It was that one patient, who was a particularly extreme example. Because, you know, if he had had chronic active hepatitis, which is characterised by bridging necrosis, so you have bits of the liver actually, obviously, dying, it wouldn't have been so surprising because that's a frequent appearance before you develop full-blown cirrhosis.

Q. Yes.

THE CHAIRMAN: Mr Gardiner can I just fill in one date, to get the timespan here? Paragraph 2, you refer to Mannucci and I see from the list of authorities at the back, that was 1977 that was published.

A. Yes.

THE CHAIRMAN: How soon after that do you think it was that you administered that first dose of DDAVP?
A. I can't remember exactly but probably within two or three months.
THE CHAIRMAN: So that really gives us the timespan for this interest.
A. Absolutely, yes.
THE CHAIRMAN: Yes. Thank you.
MR GARDINER: Thank you, sir. If we look to paragraph 4, we see that you became the senior lecturer in Liverpool in May 1987. Could you tell us what research interests you pursued at that time?
A. Well, I continued to pursue research in haemophilia but not liver disease. I was interested in the immunological effects of Factor VIII concentrate. I did some of the early clinical trials with antiretroviral drugs, I increasingly published papers on Factor VIII inhibitors, that sort of thing.
Q. Yes. You say that you have been continuously involved in the management of patients with bleeding disorders since 1983 and as a haemophilia centre director, since 1987, and that you have been the custodian of the national UK haemophilia database since 2002?
A. Yes.
Q. Thank you. Can we just move over the page, please, to

page 5? So we see the heading, "Hepatitis C testing and the risk from blood products and blood components prior to 1 September 1991". This is an area where I'm going to move fairly quickly but we see the first reference, paragraph 5:

"In the 1970s ..."

Just to read this short:

"... non-A non-B hepatitis was considered to be a benign and non-progressive condition."

A. Yes.

Q. Yes. Then paragraph 6 and 7 deal with what was known at that point and I would like to just turn over to page 6, please. Under the heading of "Donor self-exclusion and HIV testing", you refer to a pilot scheme for donor exclusion in North London in 1984, and if we just move on to paragraph 10, you talk about:

"HIV testing reinforced the effect of donor self-exclusion and taken together, these steps reduced the number of high risk donors giving blood."

And I'm just going to read that short. If we go over the page to page 7, at paragraph 11 you have referred to various papers and calculations and you end up with a conclusion towards the end of paragraph 11, which is that there was approximately a tenfold reduction in the risk of post-transfusion Hepatitis C in

the UK, during the course of the 1980s, following the introduction of donor self-exclusion and HIV testing.

Could you just say something about that very briefly, why that happened?

A. Well, the risk group for Hepatitis C and for HIV are similar; they share a lot of the same risk factors. Therefore steps to exclude one virus will have an effect on the other --

Q. Yes.

A. -- to reduce post-transfusion hepatitis. Now, one thing one should say, however, is that, although there is a tenfold reduction in risk per unit, it wouldn't make much difference to the risk from the concentrate that's derived from that plasma because the donor pools were so large. But in terms of the risk from single donor units of the cryoprecipitate or red cells, it would reduce the risk considerably.

Q. Yes, and I think you deal with that specifically later on in your report. Thank you. So the next heading is "Surrogate testing", and again, this is an area that the Inquiry has looked at in some detail, so I'm going to pass over the next few pages, and if we could take it up again at page 14, which is 1199, so paragraph 27 of your report. Just to put it in context, in the previous pages you have been setting out the different tests that

were available at different times and at paragraph 27 you say:

"The second generation test was validated and widely introduced in late 1991 and early 1992 and the first Hepatitis C test for most patients generally dates from 1992 or 1993 for that reason."

In the next paragraph you explain a bit more about that. Could you just talk us through what you are mentioning in this next paragraph, please?

A. Sure. I mean, many patients -- if you ask them to cast their mind back -- have got the false impression that perhaps they contracted Hepatitis C the first time, around then, because that would have been the first time they had a test, but in fact since we had been aware of non-A non-B Hepatitis for some years, it was by that stage normal to regularly check the liver function tests of patients with bleeding disorders. Those with intermittent or persistently abnormal liver function tests would usually expect to have had that discussed with them and should already have known that they had non-A non-B Hepatitis.

They may have forgotten that, particularly during the HIV era, where HIV, quite rightly, adopted a much higher profile.

But against that context, for most of those patients

actually having Hepatitis C test was to some extent by way of being a confirmatory test because Hepatitis C, having finally been isolated and a test developed, the assumption would have been that most of the abnormal liver function tests that we were seeing in that group would be attributable to Hepatitis C.

Q. Yes.

A. Some is obviously attributable to alcohol and obesity, as in the general population, but the assumption would be that most of it was attributable to Hepatitis C.

Q. Yes.

A. Because some of the patients that tested positively had normal liver function tests too.

Q. I suppose in the context of tests like this that were being taken, the liver function tests, patients would have been told why they were having these tests done?

A. Yes.

Q. And you say in that paragraph that patients that had been treated infrequently and who didn't follow up may have been tested later but there would have been no harm because of the rate of progression of Hepatitis C, and you mention the treatment with Alpha interferon. When did that first become possible, the treatment with Alpha interferon?

A. Well, originally Alpha interferon was introduced -- it's

actually in my report -- in, I think, the mid-90s and Alpha interferon on its own for six months is not very effective.

Q. Yes. So that wouldn't be available until the mid-90s?

A. I think that's right.

Q. Yes. Just moving on to the next heading, which is "Calculation of risk of Hepatitis C", you explain in the first sentence:

"Patients treated with pooled blood products prior to the introduction of viral attenuation in 1985-87, will have been infected with Hepatitis C."

So that was certain, was it Dr Hay?

A. They would have been exposed to it. It relates to the maths really. When you have donor pools for manufacturing concentrates of 20 to 50,000 donations, even with a very low incidence in the donor population, inevitably you would end up with a number of infected donations in each plasma pool. It wasn't recognised at the time but that meant that all the concentrates prior to viral attenuation would transmit Hepatitis C.

Q. Yes. If we go over the page to page 15, at the top of the page:

"... transmission, therefore, recognised to have been inevitable."

And you make the point:

"There was no difference ... in the infectivity for Hepatitis C of different brands sourced from the UK, mainland Europe or the USA."

Can you just explain that briefly?

A. It comes back to the same thing. Even though it has been shown that there are geographical differences in the background incidence of Hepatitis C, because of the large number of donor units in each donor pool for fractionation, regardless of the origin of the concentrate, they would all have been infected and there is no evidence to suggest that British products were less likely to transmit Hepatitis C. That contrasts, of course, with HIV, where there were some advantages to using British products because HIV spread later into the British donor population.

Q. Yes.

A. I think that there was a supposition that American concentrate was more likely to transmit hepatitis because people were aware of the skid row blood banks that existed in the 1960s and I don't think fully understood the system of payment for blood donation in the United States.

Q. Yes. But what you are saying there is that it wouldn't really make much difference from a non-A non-B point of view?

A. No, from a non-A non-B point of view, it didn't make any difference.

Q. Yes. And the next --

A. Sorry to keep interrupting you. You have to remember that I think although there are so many horror stories about the United States, we were still taking blood donations from prisons in this country until the early 80s.

Q. Yes. Paragraph 30 you explain that:

"The risk of transmission of Hepatitis C from the administration of single-donor blood products depends on the number of units transfused ..."

I think over the next few pages of your report you look at the risk of transmission, and I don't want to spend time on that. It's very, very helpful and very detailed but if we could just go to your conclusion, which is at page 19.

THE CHAIRMAN: Which paragraph?

MR GARDINER: I'm sorry, it's paragraph 42.

THE CHAIRMAN: We don't have page references.

MR GARDINER: I'm sorry. At paragraph 42 you are assessing the risk of contracting Hepatitis C and you say at the bottom of paragraph 42 that this would place:

"... the risk during 1983-4 at between 0.6 per cent and 1 per cent per unit of single-donor blood product

transfused, say 0.75 per cent."

This is a figure that you have arrived at by looking at the papers in the previous pages of your report. Is that right?

A. Yes, and assessing the methodology employed.

Q. Yes.

A. Because it's a soft estimate.

Q. A soft estimate? Thank you. You then explain how to estimate the cumulative risk and you have produced a table on the following page, which is the second half of paragraph 44, and without spending too much time, Dr Hay -- I know it's a complicated subject -- could you just briefly explain what that table shows there?

A. Well, across the top you have the percentage risk per unit and I have given a range of risks because, obviously, that's disputed to some extent, and the methodology that was employed before the introduction of Hepatitis C testing was relatively soft and some of the studies that looked at it didn't test frequently enough and that may have minimised their ascertainment and introduced ascertainment bias into the study.

So across the top you have a range of the percentage risk per unit. Down the left-hand side you have the number of units and then you can read off what the percentage risk is. Above that I explain the

mathematical basis for working out that risk, because it isn't just simply multiplying, say, 0.75 by the number of units.

Q. Yes.

A. We probably don't need to go into the maths.

Q. Right. I think so.

THE CHAIRMAN: I'm sure that I will remain immune from that but what about the methodology? Is it well established in your view?

A. Yes, yes. The methodology for working out a table like this is relatively easy. I did it originally with a scientific calculator. The principles adopted are in the previous paragraphs. The point is really that a lot of patients will actually have been infected with Hepatitis C before they were ever given concentrate, especially patients with severe haemophilia who were very regularly treated with cryoprecipitate from the mid 60s.

THE CHAIRMAN: So you will understand that if I have to avoid going into the book on A level statistics I keep through there, I really need your evidence that this is an appropriate methodology. So that's why I'm asking.

MR GARDINER: If we look at the bottom line, we have 440 units and if we read along and apply your 0.75 per cent, we get the figure of 96 per cent. So do I understand

that if a patient has had infused 440 units of cryoprecipitate, then there is, by your calculations, an 96 per cent chance of risk of infection?

A. Yes, if you accept that the risk per unit is about 0.75 per cent.

Q. Yes. How many units would a typical person with severe haemophilia use in the course of one year?

A. Well, back then the standard dose for a haemarthrosis would be 6 to 12 bags. A bag of cryoprecipitate contained about 80 units of Factor VIII. The first bottles that were produced of concentrate had about 250 units in them. So even so, that's quite a conservative dose. The current dose would be 1500 to 2,000 units. That would be a lot of bags of cryo.

The patients bleed between twice and week and once a fortnight on average. Some patients bleed less than that. So you can work it out from there, but that would be between 600 bags plus a year. To be honest, I think back then they probably sat on a lot more of their bleeds than they do now. Ie they would only come into hospital if they were in pain because this was very much hospital-based treatment. You store cryo at minus 40. It doesn't lend itself to home treatment. So, you know, they would get a bleed, they would come into hospital and have treatment.

But you can see a couple of years you would be way over these figures.

Q. So within a couple of years you would be well past 440 units. You are nodding?

A. Yes.

Q. Yes, thank you. So if we move on to the next heading, which is "The state of knowledge of non-A non-B Hepatitis amongst haematologists during this period," and this is something that the Inquiry is familiar with, first reported by Mannucci in the Journal of Clinical Pathology, and then the second half of the 1970s, it was suggested that between 35 and 85 per cent of patients with haemophilia were infected with non-A non-B Hepatitis. That's right, is it?

A. That was based on abnormal liver function tests. So what they are actually reporting are the percentage of patients with abnormal liver function tests because they wouldn't have been able to know about those patients who may have been infected with Hepatitis C but whose liver function tests were normal. So that was almost certainly an underestimate but it was the best estimate that could be made at that time.

Q. Yes. Then if we go over the page to page 21, paragraph 46, you refer to the early liver biopsy series and so the references, which are at the back of your

paper, 44 to 48, these are Mannucci, Preston, White, Mannucci and Stevens. These are the --

A. Yes, and there were others.

Q. Yes. All found evidence of only very mild liver disease and you say that you discovered something with the wisdom of hindsight. Perhaps you could explain that?

A. Okay. Why did they only find mild liver disease? I think, with the wisdom of hindsight, now that we know more about the natural history of Hepatitis C, one would say that we found very little evidence of serious liver disease at that time because the patients had not been infected with Hepatitis C for very long and the natural history is one of either non-progression or very slow progression in most patients, and they just hadn't had the Hepatitis C long enough for us to begin to see the more serious manifestations.

Q. Yes. So you didn't have the whole picture?

A. That's right.

Q. Or even very much of the picture?

A. That's right, we were looking at a group of patients at a relatively early stage in their natural history.

THE CHAIRMAN: Can I ask you about one thing that has interested me from time to time? Until concentrates became available in the mid 70s and later, the impression I have is that the life expectancy of

a severe haemophilia patient was very much less than it became thereafter.

A. Hm-mm.

THE CHAIRMAN: Does that have a bearing on this matter?

A. Yes, I think it does. The life expectancy of untreated haemophilia, if you go back to the beginning of the 20th century, is only 10 to 15 years. With the introduction of blood transfusion, that increased to 29 years. But as late as the early 60s, the life expectancy of US patients with severe haemophilia was still averaging out at only 40 years. Treatment was always relatively delayed because it was based in hospitals. Patients didn't have the opportunity to treat themselves early. They also suffered far more morbidity because all of their joint bleeds were treated late and by current standards with inadequate doses of product.

So the introduction of home therapy in the early 1970s was expected to improve the quality of life and life expectancy, and before all these viruses became apparent, actually real methods suggested that the life expectancy would be near normalised. In fact a more recent estimate from Darby et al, which we published in Blood in 2007, showed that even now patients with severe haemophilia have a life expectancy about two or three

years shorter than the general population.

THE CHAIRMAN: We have seen Dr Biggs' early study supported by the actuarial material, which seemed to me fairly narrowly based, I have to say.

A. I agree with you.

THE CHAIRMAN: Anyway for present purposes, of course, it's a factor that we have to take into account that very many of those who might potentially have developed severe liver disease unfortunately didn't survive to a point at which that became apparent?

A. Yes.

THE CHAIRMAN: Thank you.

MR GARDINER: Thank you.

This early liver biopsy series, you say, was very influential. You stressed that the condition was non-progressive and benign. Could you tell us about when you had an interaction with a London Professor of haematology.

A. Once we had started to do liver biopsies more regularly, and began to present our results, I was approached by a certain Professor of haematology, who looked askance and asked me why I was bothering to do all these liver biopsies because, as he said, it's only a biochemical curiosity. We had already begun to suspect it was a good deal more than that but I mentioned that anecdote

really just because his view was not so far from the consensus at the time.

Q. Yes. What percentage of specialists at that point doubted that this was a non-progressive and benign condition?

A. I think most haemophilia doctors felt that it was benign and non-progressive until we published, to be honest. There were a lot of liver biopsy studies in the late 70s and very early 80s showing benign liver disease. I think the Stevens paper came out in 1981 and the Mannucci one, 1982. But it's a long time.

Q. Yes.

A. But at the time we were doing our liver biopsy, I don't think anyone in the UK was looking at this. Aledort was looking at it in the United States.

PROFESSOR JAMES: Can I make just two brief comments, sorry? One is that actually the view of the benignness of it may have been reinforced by the fact, I think, that from the very wonderful UKHCDO patient database that you are now the guardian of, as a matter of fact there was a sort of four- or five-year period towards the end of the 70s in which there were no deaths from liver disease among haemophiliacs recorded. I think that's correct, isn't it?

A. Yes, I think it is.

PROFESSOR JAMES: So that perhaps reinforced people's view that whatever it was, it wasn't causing anything very serious. The other thing perhaps to just mention is that although the view was taken in the Stevens and others studies that you referred to, that it was "benign", as a matter of fact, when you and others examined these papers carefully, there was already a 10 per cent incidence of cirrhosis in those. So they actually came out with conclusions that were sometimes perhaps a little too reassuring.

A. Yes, I agree with that. Mannucci's paper -- I think they had one patient with cirrhosis already out of 11 patients.

PROFESSOR JAMES: Yes.

A. But, you know, they very much pushed this line that it was benign. In fact the title of our paper was actually a parody of Stevens' title.

PROFESSOR JAMES: Yes.

A. Quite deliberately we were poking fun at it.

PROFESSOR JAMES: Thank you.

MR GARDINER: Were you poking fun at it because you were so confident that it was wrong?

A. Yes, we were pretty sure it was wrong. We were publishing the largest series of liver biopsies and there is strength in numbers scientifically. A lot of

the previous studies were, apart from anything else, very small and it seemed logical that, because we were looking later, we might well see more serious liver disease because the patients had had longer for the disease to progress.

Q. And in the next paragraph, paragraph 47, you say that when you presented your findings, the results were greeted with alarm and incredulity?

A. Up to a point, yes.

Q. Was that actually at the time that you presented them? You got that reaction?

A. Yes, I had an oral presentation at the British Society for Haematology and I think it was a surprise to people and people, you know -- there was then an active correspondence in The Lancet following my publication in which Mannucci tried to explain to me that we had got it all wrong.

Q. Then Aledort et al published their two papers, 85 and 86?

A. Yes.

Q. Which supported your conclusions. So is that why you say that there was gradually acceptance that the condition was much less benign than had previously been supposed?

A. Yes.

Q. Right, thank you. Well, that section of your report is sort of general history, leading up to the specific questions that we have asked you to address, and if we could go to paragraph 48, page 22, these are the answers that you have provided us with. At paragraph 48 you say:

"The risk of contracting Hepatitis C from clotting factor concentrate approached 100 per cent at all times prior to the introduction of viral attenuation."

And in the next paragraph you refer back to your estimate of risk calculation and also that donor exclusion had reduced the risk of transmission, and it's at paragraph 50 that you start to deal with the state of knowledge in the landmark years and, doctor, could I just ask you to talk us through this paragraph, please?

A. Paragraph 50?

Q. Paragraph 50, yes.

A. Thank you. Well, Mannucci published his paper in J Clin Path in 1975. That's not a huge wide circulation journal to be honest but awareness started after that point and I think there was very widespread awareness that there was some form of liver disease in a lot of our patients by the late 70s, though nobody really knew what the clinical significance was. And very varied

prevalences were reported.

In Australia at that time they were still using cryoprecipitate mainly. In fact there is a paper I haven't quoted you from there, where they, despite using a lot of cryoprecipitate, nevertheless have quite a high incidence.

I think we have dealt with most of the rest of that paragraph already to be honest.

Q. I think the next date you mention is 1985. You say that that view held sway until 1985?

A. Yes.

Q. What was the attitude after 1985? How did it develop?

A. I think there was a gradual acceptance that our observations were correct and that a significant minority of patients with non-A non-B Hepatitis would develop serious liver disease.

Q. Yes. And then over the page, at paragraph 51, you mention the next significant date, which is 91/92. Why was that significant in this history?

A. That's significant because this is the point at which Hepatitis C testing is widely introduced. And a lot of the patients are tested. Some of those whose liver function tests had been normal will have been identified as chronic carriers. Of course, it was an antibody test. So it didn't necessarily tell you whether you had

active Hepatitis C or not and it wasn't known. It would just tell you whether you had been exposed or not.

It wasn't known how many patients remitted spontaneously.

Q. Yes.

A. The other thing which is very significant about that is that once Hepatitis C testing became available, we rapidly realised that a condition that's not talked about any more very much, cryptogenic cirrhosis of the liver, was largely attributable to Hepatitis C. I mean, what cryptogenic cirrhosis means is they have got cirrhosis and you do not know why.

Q. Where it came from?

A. And the fact that you then discover that most of those patients have got Hepatitis C and no other cause is alarming because it tells you a bad story about the natural history of the condition.

Q. Yes. Did you get this extra information about cirrhosis as a result of the testing? People tested positive for the virus and therefore were sent for biopsies? Is that how it went?

A. No, I mean, the patients with cryptogenic cirrhosis that I'm talking about are not necessarily bleeders. I'm talking about this coming out in the literature, hepatologists testing the patients that they may well

have already been following up to manage their cirrhosis.

Q. What I'm getting at is you say:

"A further step in our understanding came with the advent of testing. We realised that most patients with cryptogenic cirrhosis did have chronic Hepatitis C."

What was the link between the testing and the discovery of that? How did that --

A. Well, when you have got a condition and you do not know what the cause is and a new test comes along, you are going to use it, and studies appeared where people had tested patients with cryptogenic cirrhosis and found a high incidence of Hepatitis C.

PROFESSOR JAMES: Sort of the other way round from what had happened before. Loads of liver clinics hastened to test all their patients with "cryptogenic liver disease" not due to drinking too much et cetera et cetera and found that a very significant proportion of those cirrhotic patients turned out to be Hepatitis C-positive.

A. Yes.

MR GARDINER: So you had the diagnosis of cirrhosis before and --

A. Now you find out why they have got it.

Q. I see, thank you.

A. Because, as far as anybody knew at that point, they had no risk factors for cirrhosis. So why did they develop it?

Q. You also mention in that paragraph the link with hepatocellular carcinoma. How did that link come to be known?

A. Well, hepatocellular carcinoma almost invariably presents in the context of cirrhosis. So there is an incidence of hepatocellular carcinoma with all causes of cirrhosis, although the risk varies depending on the cause, the risk of hepatocellular carcinoma is less in people with alcoholic cirrhosis and primary biliary cirrhosis than it is with post viral cirrhosis. And I think it had already been recognised that Hepatitis B was a cause of hepatocellular carcinoma.

Patients with cirrhosis and hepatocellular carcinoma of unknown cause would have also been tested in the way that Professor James has just described and the link would have been discovered, this isn't something that immediately came to light through observation of patients with bleeding disorders. The first report of hepatocellular carcinoma in one of our haemophilia patients in the UK was as recent as 1995 and I think looking at our statistics, it's quite interesting, the long lag period that must have occurred before we

started to regularly observe hepatocellular carcinoma in our cohort of patients.

Q. So that comes about by comparing the cause of the cirrhosis and seeing --

A. Yes.

Q. -- what the prognosis was?

A. Yes.

Q. I see and what year was that link first recognised?

A. I'm not sure exactly what year.

Q. Right, okay.

PROFESSOR JAMES: It would be the early 90s, 92, something like that.

MR GARDINER: We can check that.

PROFESSOR JAMES: Dr Hay said, as far as, you know, haemophilia is concerned, the first UK reported one, he says, from their unparalleled database was in 95.

MR GARDINER: Yes, that's helpful. The reason I'm asking is because obviously that's something that one might mention to a patient --

A. Absolutely and we do. But in the very early 90s I don't think that we would have done. By the mid-90s we certainly would have done. It was becoming clearer by then what the risk was and we currently quote a 5 per cent risk.

Q. Yes, thank you. The next paragraph deals with the

information that was given to patients about what you have just been telling us and could you talk a little bit about that?

A. Okay. Well, in the late 70s and the early 80s they wouldn't have been told a great deal, partly because there wasn't very much known. In the centres I worked in there was a background interest in this area, so we were checking liver function tests from the mid 70s on. My experience in other haemophilia centres leads me to believe that it became more widespread about 1980. The two haemophilia centres of which I have been director started to check liver function tests regularly about 1980. So it will have varied. Bear in mind there wasn't any treatment.

I would expect that if the liver function tests were persistently or intermittently abnormal, that the patient would have been told this and would have been told that they probably had non-A non-B Hepatitis. But in the late 70s and early 80s, they would have been told it was nothing to worry about, because that was the consensus of opinion, and they would have been told that the cause wasn't certain. All sorts of things were considered, not all viruses.

Q. Yes. So I think --

A. In the early days it wasn't even clear that it was

caused by a virus. People wondered whether there were contaminants in the concentrates, toxins, who knows? But they would have been told there was no test. It was thought not to be readily transmissible and they should have been told to minimise their alcohol intake because that's general advice for anybody with a chronic abnormal liver function, whatever the cause.

Q. Yes. Sorry, just to go back, you said that if a patient was persistently having abnormal liver function test results "persistently", would that be, what, several months in a row?

A. What I mean by that -- you may have noticed I have talked about persistent or intermittent abnormalities. With Hepatitis C it is not uncommon to see a pattern whereby the liver function tests are not always abnormal. So you might check them every six months and perhaps half of them are completely normal. The condition seems to wax and wane and, you know, with a series of liver biopsies, we actually saw patients going from chronic persistent hepatitis to chronic active hepatitis and back again. So, you know, their condition went through more active and less active phases. So you have to check the liver function tests regularly or you could miss that.

Q. Yes.

A. But some of the patients, their liver function tests are invariably abnormal.
Q. And at what stage at this time would you expect a clinician to be saying to his patient, "I think you might have non-A non-B Hepatitis"? How persistent would the abnormal findings have to be?
A. At least two abnormal liver function tests over at least six months. There is a definition of chronic hepatitis, which relates to that.
Q. Yes.
A. If your liver function tests are abnormal for more than six months, then it's chronic.
Q. And if this was chronic you would expect the clinician to tell the patient, "I think you have got non-A non-B Hepatitis"?
A. Yes.
Q. Thank you. So at that time -- and you have gone through the list of things that you would expect a patient to be told -- the general message to the patient would be reassuring?
A. Yes.
Q. And the minimising alcohol, is that just common sense because if you have got a liver condition, then ...?
A. Yes, I mean, it's general advice that would be given to anybody with a chronic liver condition because it's

generally recognised that alcohol can be a co-factor for liver disease progression. If you have got some other reason for your liver to be inflamed, then the safe limit doesn't apply to you.

Q. Yes. So even as early as this, the possibility of alcohol being a co-factor is in clinicians' minds?

A. It's just general advice to people with chronic hepatitis. I don't think there was any evidence that it was a co-factor.

Q. That's later?

A. Evidence did emerge later.

PROFESSOR JAMES: Would it be fair to say also that these were young men and as a matter of fact alcohol was a pretty recognised, not that uncommon, cause of morbidity and ill-health among this group already, wasn't it?

A. I'm not sure that patients with haemophilia drink more than the general population.

PROFESSOR JAMES: I wouldn't for a moment suggest that they did but --

A. Young men drink generally more than the general population.

PROFESSOR JAMES: Yes, and particularly men in their 20s, who are afflicted by pain and not very happy with their lives and so on. From my memory from your database,

there were a number of deaths associated with alcohol over the years, as it were.

A. Yes, absolutely and some of the accidents that happened that normal people might have survived were certainly associated with alcohol, and you are also right in saying that they are a relatively young cohort, probably reflecting the high mortality in earlier years, the average age of the patients that we biopsied was 32.

MR GARDINER: Just to be clear about terms, when you use the word "co-factor" for alcohol, are you referring to the synergism between alcohol and the virus, which is discovered, I think, quite a lot later on.

A. Yes, I mean, there is no direct evidence of it at that point but if you developed acute hepatitis, you would be advised to not drink any alcohol at all, probably.

Q. Yes. And in the last sentence in paragraph 53, you say:

"Many of these conversations will have been forgotten ..."

Why do you say that?

A. I know it to be true. Some of these conversations have been documented and yet the patients deny that took place.

Q. Yes.

A. And this is a well recognised phenomenon in medicine and it's particularly likely to happen if the conversation

is in the context of, you know, bad news. That's particularly relevant to the HIV era. It reminds me of an advert that I read a few years ago for Macmillan nurses. The caption was "a common side effect of cancer is deafness", and the point that they were getting at is that, you know, you tell people bad news, you might even tell them in detail, and then they will deny it later and that denial may be entirely sincere but, you know, they don't take it in.

So doctors know that it's important often to go over things on several separate occasions because they may not be remembered and particularly, you know, if you tell them, "You have got a bit of a biochemical curiosity and it's nothing to worry about," well, they might go away and not worry about it and quietly forget about it and then they read about AIDS and this is considerably more worrying because here is a condition that's actually presenting with death.

Q. But we have heard about this phenomenon before from various witnesses in the context of bad news. The reason I was asking you is because this would seem to be not necessarily that bad news, you would be saying to the patient, "I think you have got a condition but don't worry, it's not a serious one." So it's not really bad news, is it?

A. Well, no, it's not particularly bad news. But it's not particularly bad news 35/40 years ago. So with the best will in the world, it's a long time in which to forget about it and then the next time you hear about it, it possibly is more significant and, you know, whilst there was no treatment and it was thought not to be a progressive condition, I doubt that the doctors brought it up every single time they saw their patients, whereas these days, you know, every time I see the patients, I tell them what their liver function tests are, we talk about when they are going to have their next ultrasound. There are still some that after years and many discussions, I'm trying to persuade to accept treatment.

MR GARDINER: Yes.

Sir, I'm about to move on to another topic. Perhaps that would be a good time for a break.

THE CHAIRMAN: Yes.

(3.09 pm)

(Short break)

(3.25 pm)

THE CHAIRMAN: Yes, Mr Gardiner?

MR GARDINER: Thank you, sir.

Professor, before the break we were at paragraph 54 of your report. I think over the next few paragraphs

you talk about AIDS and how the principal concern of haemophilia treaters and of patients was AIDS in the early 1980s and how that overshadowed the question of hepatitis. Could you just talk to us a little bit about that?

A. Well, AIDS became apparent in about 1980 and of course it presented with an outbreak of homosexuals dying from PCP. So, you know, the presentation itself was fairly dramatic and so it was associated with death from the very beginning, and for several years nobody knew the cause.

Quite early on some patients with haemophilia died. There were a few patients that had very rapid progressive disease. It's now recognised that they had a certain immune genotype that was associated with very rapid progression but there was one patient, I think, in Bristol who was documented to die within three months of infection, and there were one or two deaths from acute HIV and so, you know, even before the test came along, when we didn't know how many patients were infected, the whole thing was invested with considerable dread.

Then, of course, in the mid 80s we got a test. So all the patients were tested, 50 per cent of the UK cohort of patients with severe haemophilia turned out to be infected, and there was considerable doubt about the

natural history of the disease.

So patients were hungry for information and in fact, in those centres where the managing clinicians were very conscientious about keeping them up-to-date, they were told a whole lot of stuff that was fervently believed at the time but which turned out to be probably incorrect.

I can remember patients being told that if they hadn't developed full-blown AIDS within two years, they wouldn't, and the following year it was three years and the year after that it was four years, and it gradually dawned on people that, you know, you could have this for quite a long time before you developed a clinical problem and you couldn't reassure anybody with HIV that they wouldn't die from the disease, and of course there was no treatment.

THE CHAIRMAN: Dr Hay, can I just be clear, when you say "50 per cent of the UK cohort", in this context is it the UK cohort as a whole?

A. I was talking about the UK cohort. I think the percentage in Scotland is lower.

THE CHAIRMAN: So if one takes account of regional variations, there are patchy areas where the concentration is much higher?

A. Absolutely right, yes.

THE CHAIRMAN: Sorry for doing that but I think, as you

know, "UK" is a flexible term.

A. Absolutely and even within England, there were big variations from one centre to another.

I mean, that's its background. So on the one hand you might be talking to a patient about this non-A non-B thing that is really nothing to worry about and on the other hand talking to them about HIV, which is potentially life-threatening and might kill them all, and in fact did result in the death of two thirds of them before effective treatment emerged.

MR GARDINER: Yes.

A. And the point I was making in these paragraphs is that some of these conversations were going on concomitantly and will have contributed to people not really remembering a great deal about what was said about the Hepatitis C, because frankly it was a very subsidiary part of the conversation.

Q. Is that because the patient's focus was so clearly --

A. Both the patient's and the doctor's.

Q. Yes. So clearly on AIDS?

A. Yes.

Q. Thank you. And I see that you say in paragraph 54 that you have experience of patients who commonly deny that they have been counselled about Hepatitis C even when such counselling has been documented in the notes?

A. Yes.
Q. Is that counselling that went on at this time?
A. Yes.
Q. Yes. Thank you. At paragraph 55 and 57 you refer to guidance from the UKHCDO reference centres, which also shows, you say, the focus on AIDS at that point?
A. Very much so, because following that guidance would have had no impact on Hepatitis C.
Q. Yes. If we could just go to paragraph 59 now. I think in this paragraph you are also again stressing how HIV/AIDS overshadowed the question of hepatitis and you make the point that clinical consultations in clinic visits increased fivefold during this period?
A. Yes.
Q. Which period are you talking about here, Dr Hay?
A. I'm talking about the period, I would guess, 80 through to 86/87. A lot of additional staff were employed in haemophilia centres, the frequency of consultations increased enormously.
Q. So this phenomenon of patients not remembering because AIDS is overshadowing things, that's different from patients not remembering because they are being given bad news. It's a different phenomenon. Is that right?
A. Not entirely because, you know, in the course of a consultation you would discuss a number of things.

You would discuss their haemophilia, how often they were bleeding, where they were bleeding, all that sort of thing. You might talk about their hepatitis and their HIV, all in the same consultation.

Q. Yes.

A. You know, if they were infected with HIV, that would be the main focus of their interest because this would be the issue of most immediate importance. Hepatitis C, for most of these patients, was not going to kill them at that point.

Q. Of course.

A. Whereas they would feel that there was an imminent danger of death with HIV.

Q. Of course. So at paragraph 60, if we could just go over the page, you list what most affected patients will have been told, and am I right in thinking that this is essentially the same as what they would have been told in the period that we looked at before, late 70s to early 1980s?

A. No, it isn't.

Q. Except, I was going to say, there is the mention of 20 per cent perhaps developing cirrhosis. Is that the main difference?

A. That's the main difference. But also that the condition could be slowly progressive.

Q. Yes.

PROFESSOR JAMES: Can I just add: do you think that the fact that the disease changed its name -- very inconsiderately for the patients. So you were talking to them about non-A non-B and then in 1992 suddenly there is a discussion, particularly in view of the fact that you now had a test, of this Hep C, and one's impression is that some of the patients actually thought of them as two different illnesses.

A. I think that may be the case for some patients, certainly. Hepatitis C is a far more definite entity.

PROFESSOR JAMES: Despite the best efforts of the clinicians looking after them, but that might have contributed to the sort of "denying" that they had ever been told about this illness before.

A. Yes.

MR GARDINER: Thank you. Yes, so the difference is that cirrhosis is mentioned and that this is a disease that's slowly progressive.

A. Yes, or could be slowly progressive.

Q. Or could be. The previous period, you characterised the advice as "reassuring"?

A. Yes.

Q. How would you characterise this?

A. Relatively reassuring.

Q. Right.
A. Because at that time we had evidence that a minority had progressive disease but, you know, we found 15 per cent in our liver biopsy series, but obviously, if you find 15 per cent at that stage, clearly the percentage could climb with the passage of time. So there would be some uncertainty surrounding that figure. So, you know, we might have quoted a 20 per cent risk. I think by that stage it was clear that if it did progress, it would usually do so slowly.
Q. Yes.
A. So I think patients would find that relatively reassuring. And hepatologists would probably characterise it as a condition with a good prognosis.
Q. Yes. Okay. And you say:

"These conversations would have been short and not very memorable. The condition was usually asymptomatic and that if progressive, it was likely to be only slowly so."

Why do you say that they were not very memorable?
A. I'm just basing that on the number of patients that can't remember it, plus, you know, it's not as reassuring a message as they might have got earlier but I think patients would have taken it as relatively reassuring. They would have been made aware that there

was a risk of serious liver disease, which they might not have been aware of before, but probably left with the impression that chances were they would not get it. If you play the statistics.

Q. Yes. And h:

"... minimise alcohol intake."

So there is no change there in the advice. What about the possibility of sexual transmission? Is that something that's discussed at this point?

A. We still didn't have a test. Very few of the wives had been tested. I don't think very much was known about sexual transmission. This becomes more obvious later, when you have the test.

Q. Yes. But I see that you say in the second half of paragraph 60:

"... condoms were not required."

So you wouldn't be advising patients to use barrier --

A. Unless they had HIV.

Q. Thank you.

A. In which case we actually gave them condoms.

Q. Yes.

A. Something I never thought I would do when I went into thrombosis and haemostasis.

Q. After this period, the mid 1980s, was there a period or

did there come a time when the advice to patients changed?

A. Until we had a test, I don't think it changed very much.

Q. Yes. What was the advice at that point?

A. When we had a test, it became apparent that there was a small risk of spouses being affected and we would offer to test the spouse.

Q. Yes.

A. And by that stage, I think by the early 1990s, we would probably have increased our estimate of the risk of serious liver disease.

Q. Right.

A. Because certainly by the mid-90s, we were seeing more patients with serious liver disease presenting.

Q. Yes.

A. And by that stage it was also clear that co-infection with HIV was a major co-factor for liver disease progression. So in the mid-90s three quarters of the patients who died from liver disease were co-infected with HIV.

Q. Yes.

A. Most of those patients had full-blown AIDS at the time of death. So paradoxically, the statistics suggest that the liver disease didn't worsen their prognosis, but that's just a mathematical thing. It's like saying, if

they hadn't died from liver disease, they would have died from HIV soon after, and in fact there was a peak of liver deaths around that time because once we had an effective treatment for HIV, the immune system improved and progression of Hepatitis C was less of a problem.

Q. Yes.

A. Plus we were treating them with interferon.

Q. I think if we jump forward to paragraph 68, which is at page 28, you see that's 68f, those are the things you have just told us from the early 1990s, and by this stage you are also mentioning the small risk of liver cancer as well because that link has been established?

A. Established, yes.

Q. Thank you. If we just look at the paragraph before that, in 1995/1996 interferon started to be used to treat chronic Hepatitis C and you had started to discuss that with the patients as well. So there is a treatment option at that point as well?

A. Okay.

Q. Okay. I would like to have a look at the section of your report which deals with your practice as far as testing and information was concerned, and that starts at paragraph 63.

Just to let you know, Dr Hay, I will be taking you to Professor Nathanson's report and then after that your

commentary on her report, but this is the bit of your first report that deals with your practice, I think. So that's paragraph 63, 64 and 65. Can I just ask you to explain to us what your practice was?

A. Well, if I was testing for Hepatitis C, I would tell the patient that I was going to conduct the test. I would take the opportunity to talk to them again about Hepatitis C. I would have expected that conversation would already have taken place about liver disease. I would not take written consent for the test. Of course, when you tell a patient that you are going to do a test, they have the opportunity to refuse and although I can't remember anybody ever refusing a Hepatitis C test, certainly I have come across relatives refusing and people refusing to have HIV tests. Anyway the opportunity is there.

I would discuss the implications of the result, were it to be positive. If the patient had chronic liver function tests that were abnormal, I would lead them to expect a positive result, you know, based on their treatment history, you would have an idea of what the result was likely to be when patients were tested for the first time. We still have patients who have been lost to follow-up for a very long time, who are coming out of the woodwork, who are being tested for the very

first time, even now.

Q. Yes.

A. Some of them have only been exposed to a few units of plasma but nevertheless, given the risk, they need to be tested.

Q. Yes.

A. Back then I would tell them I was doing the test and then they would have the test and then I would see them face-to-face to talk about the result.

Q. Yes. I assume that you have, with other patients, provided HIV-style pre-test counselling?

A. Yes.

Q. And so what you have just described for Hepatitis C pre-test discussions, how would that differ from HIV-type counselling?

A. Well, the implications are quite different and so the conversation would have been very different. There are and have, from a very early stage, after the test became available, been national guidelines. This is the current one from 2008.

That is a much longer and involved conversation and they may wish to go away and think about it before coming to have a test.

You would give them lengthy counselling back at that time because, you know, a positive HIV test in the early

80s and 90s would have been regarded as potentially a death sentence. There were implications that you had to describe to them, to do with employment and insurance. They became virtually uninsurable. They found great difficulty getting a mortgage and you had to describe and consider all of those things. And there was no effective treatment until really, effectively, the mid-1990s when highly active antiretroviral therapy came along.

So HIV is almost unique in having such a formal lengthy counselling process before you actually do a test.

Q. How long would you take typically to counsel a patient in those circumstances?

A. Well, in those days extremely variable. Maybe as little as 20 minutes, perhaps as long as an hour.

Q. Yes.

A. To be honest with you, what I have just described to you in terms of what I would have done for Hepatitis C goes way beyond what a hepatologist would have done both then and now.

Q. Yes. Before we get on to that, would you be able to estimate how long it would take to discuss the HCV test with a patient?

A. In a patient who is thought to have non-A non-B

Hepatitis, it would not take very long at all, five minutes perhaps, unless they had lots of questions.

Q. Yes.

A. Even now, most of the discussion is often about the side effects of treatment, the relative merits of treatment, that sort of thing, which you wouldn't have been discussing before we were using interferon in the mid 90s.

Q. Yes.

A. I actually think that in general, when it came to Hepatitis C testing, haemophilia doctors probably talked more about the test than hepatologists, partly because of their prior experience with HIV.

Q. Yes.

A. And I think also that may have been an expectation in the patient group, which was higher than that in the general population for the same reason.

Q. Yes.

A. And when patients are critical of the extent of the discussion surrounding Hepatitis C, they are seeking to draw a parallel with HIV counselling, which I don't think exists because there was never any national guidance on taking consent for Hepatitis C testing.

Q. Yes. Could I just ask you, Dr Hay, just to try to understand the process for a Hepatitis C test, I mean,

I appreciate that every patient is different and I don't want to, you know, try to reduce what the doctor is doing but is the question "I am going to test you for Hepatitis C" or is the question "I would like to test you for Hepatitis C"?

A. I think it would depend on the doctor. I think hepatologists would be thinking, "I'm going to test you for Hepatitis C," and they may actually just say, "I'm going to test you for hepatitis viruses and various other things, to find out why your liver function test is abnormal".

Q. And a haemophilia clinician?

A. Because of our experience with HIV, I think we would normally say "I think we should do a test for Hepatitis C", and in the case of someone already known to have liver disease, to tell them that that is probably the cause.

Q. The way you put it there was, "I think we should do a test". So that sounds like asking the patient for their agreement. Is that right?

A. I suppose so.

Q. I'm trying to draw the distinction between that and a doctor saying, "I am going to test you for this". Do you see the distinction, Dr Hay?

A. I do. I think some doctors would have said one thing

and some the other. I don't think I can generalise.

Q. What do you think would have been appropriate at that time?

A. I think we were obliged to test everyone for Hepatitis C. I think that if we had not tested patients, then we would have been subjected to criticism. I think it's nice to ask the patient but, to be honest, if they had said "no", then there would have had to have been a conversation around that and my experience was that this was never a difficulty, to be honest.

Q. Yes.

A. But, you know, some of my colleagues may well have tested, you know, without actually mentioning what the test was.

Q. Yes, but you wouldn't consider that appropriate?

A. Well, it wasn't my practice.

Q. Yes.

In paragraph 64 -- I think you have touched on this already -- you say:

"The idea that a Hepatitis C test should engender prolonged pre-test counselling derives from the practice adopted after 1985 by most centres of counselling prior to HIV testing."

You say:

"There is no comparison between this and Hepatitis C testing."

I think your conclusion there is that HIV-style counselling is not appropriate. Is that right?

A. Yes.

Q. Before I pass to Professor Nathanson's reports, is there anything else you would like to say about your practice and your opinions about this point?

A. I think there would have been a range of practice, and you have to bear in mind that, you know, I have had an interest in hepatitis for a long time. I think that in many places the patients would have been tested without it being specifically discussed. You showed me a minute from UKHCDO earlier in the day, in which this very point was discussed and opinion was expressed that it was just another liver function test.

Q. Yes.

A. And there was obviously a dichotomy of opinion then about whether you needed to discuss it or to take consent.

Q. Yes.

A. You know, in my practice I was approaching it from a background of already having discussed the patient's liver function tests with them in advance and this is a confirmatory test. That doesn't require a prolonged

discussion but, you know, it is a matter of interest. So at the very least it should be mentioned, but I think some other people would have just done the test and that is universal clinical practice amongst hepatologists even today.

Q. Yes. Just for our records, I think you are referring there to minutes of the 19th meeting of the AIDS group of haemophilia centre directors on 12 February 1990, when it's recorded that Professor Bloom made a comment that he didn't see why permission was needed to be asked for Hepatitis C tests, as this was just another LFT. In our database that is [LOT0034450] but that's what you are referring to, is it?

A. Yes, it is.

Q. Okay. Let's have a look at Professor Nathanson's supplementary statement. Which is [PEN0180419].

You have seen this supplementary statement, haven't you, Dr Hay?

A. I have.

Q. The question that I would like to have a look at is the one half way down the first page:

"What is the current approach to testing for HCV? In particular what information should a clinician provide to his/her patients about the disease and the implications of a positive diagnosis? What is the

current GMC/BMA guidance on this point?"

You will remember that Professor Nathanson refers to the GMC's booklet on Good Medical Practice and she has highlighted a paragraph that states:

"A doctor uses specialist knowledge, experience and clinical judgment, and the patient's views and understanding of their condition, to identify which investigations or treatments are likely to result in overall benefit for the patient. The doctor explains the options to the patient, setting out the potential intention, risks ..."

I'm reading this short because we have already looked at this today and you have looked at it. If we could go over the page, Professor Nathanson, at the top of the page, writes:

"Today doctors are expected to offer the patient all of the elements of information identified in this guidance. It is essential that it is understood that the information is offered; no patient can or should be forced to listen to the full set of information."

Then just jumping down to the fourth paragraph:

"What matters is the offering being made, and the doctor being sensitive to what the patient wants to know."

And so on. I don't want to take up more time with

that because you have read it and we have seen it recently, but broadly speaking, you wouldn't disagree with those sentiments?

A. Roughly speaking, no.

Q. No. We will come to your commentary on Professor Nathanson's report but if we could move to page 0421, question 2:

"What was the correct approach to testing for HCV between 1991 and 2000?"

Professor Nathanson starts by referring to the BMA publication "Philosophy and practice ..." which says:

"The basis for any discussion about consent is that the patient gives consent before any investigation and treatment proposed by the doctor."

She then refers to "HIV infection and AIDS: the ethical considerations", where, again, there is a reference to consent, and then the third publication that she relies on is the GMC advice "Serious communicable diseases", dated October 1997. You have had a chance to look at all of these. Is that right?

A. Yes.

Q. She refers to paragraph 4, which says:

"Some conditions, such as HIV, have serious social and financial, as well as medical, implications. In such cases you must make sure that the patient is given

appropriate information about the implications of the test, and appropriate time to consider and discuss them."

If we could just go over the page, this is at the top, Professor Nathanson's opinion, where she says:

"It is clear and explicit that in 1997 the GMC required doctors seeking consent to have regard to the implications of the test result. This is more explicit than the earlier advice on testing for HIV, but is in accordance with it. While the advice relates to HIV, it is important to note that it identifies 'some conditions such as HIV' and is not, therefore, limited only to testing for HIV."

She talks about the nine years of testing on HIV and that the GMC was reflecting best practice here.

Before asking for your specific comment on Professor Nathanson's opinion, would you agree with me, Dr Hay, that Professor Nathanson does seem to be advocating there an HIV-style of counselling before a Hepatitis C test?

A. I agree.

Q. Yes. So I think we should now go to your revised commentary on her report, which is [PEN0181360].

THE CHAIRMAN: It doesn't have a reference on our prints of it.

MR GARDINER: Yes. It had one when it was put out to you, sir. It has got one now.

Sorry, it's 1349.

THE CHAIRMAN: And before that?

MR GARDINER: [PEN0181349].

Dr Hay, you kindly prepared a report in response to Professor Nathanson's supplementary statement and then you revised it and so I think this version is almost exactly the same --

A. Well, in fact let me be clear here. You say I have revised it. I haven't actually amended any of the bit that you got before. What I have done is to add some further comments at the end which relate to her first report, which I did not have. So my reports on her supplementary comments haven't changed at all.

Q. Yes. That's very helpful.

So if we look at paragraph 2, you say:

"When preparing in report, I had access to photocopies of the following documents."

At (a) you say but not her original statement but actually, I think by this stage you had seen her original.

A. Yes.

Q. Thank you. You also mention at paragraph (c) that you discussed these issues with the head of your hospital's

...?

A. Yes, our hospital's sexual health department with whom I do a joint clinic.

Q. I think what I'll do, Dr Hay, is I'll just let you answer in your own way your comments to Professor Nathanson's reports.

A. Okay. I mean, Professor Nathanson has approached the questions put to her from a general medical ethics perspective, and she has supported her conclusions in this supplementary commentary, which I presume she was asked because her first report makes no reference to Hepatitis C.

Q. Yes.

A. And seems exclusively concerned with HIV. But she has supported her comments with full references and Hepatitis C is mentioned in only one of these and in that reference only once in seven pages, and I would suggest that those references really are far more relevant to HIV and by virtue of not really providing any specific guidance to Hepatitis C, I think it's doubtful that they can be taken to support her suggestion that counselling for Hepatitis C should be provided in exactly the same way as for HIV.

Q. Yes.

A. And in fact, since that time, even counselling for HIV

has been downgraded somewhat.

She acknowledges that her report to consent for testing would be tempered by knowledge of the condition at the time and I have tried in my report to point out that the sort of things that you would say to the patient will vary as knowledge developed and as one's perception of the disease changed, because, you know, as it becomes apparent that Hepatitis C is not infrequently progressive, it would adopt a higher profile in one's conversations with one's patients.

But she doesn't offer any specific opinion on the way in which the changing state of knowledge would have affected consent at specific times.

She acknowledges that the GMC 1997 guidance reflects best practice but doesn't offer any evidence of the extent to which this guidance has ever been applied to consent for Hepatitis C testing, a point which I make, because I would suggest to you that it has never been adopted in relation to Hepatitis C testing.

Q. Yes. Could I just stop you there? What do you understand by "best practice" when that term is used in this context?

A. I think it's the practice to which one should aspire.

Q. Thank you.

A. The GMC serious communicable diseases guidance mentions

a range of diseases that they would recognise as serious communicable diseases. They include TB, Hepatitis B, HIV and Hepatitis C but, to be frank, I think their inclusion of Hepatitis C is rather dubious. I discussed this specific point with my hepatological colleagues and they looked askance at this because we recognise that the infectivity of Hepatitis C is at least an order of magnitude less than either HIV or Hepatitis B. It's not a very infectious virus. So to talk about it as a communicable disease in the same breath as these other things, you know, both sexually and in other ways -- it's not so readily transmitted.

Although we are all aware that patients can and have died from Hepatitis C, in general terms the prognosis is relatively good. Patients can live with Hepatitis C for many decades, without it causing them problems and when it does cause problems, it's usually slowly progressive.

And it's treatable, depending on the genotype. Some genotypes have between 80 and 100 per cent response to peg interferon and ribavirin and with new developments in the treatment of genotype 1a and 1b, the response rate for that genotype is also improving considerably. I don't think it's fair to compare the two and to lump them all together, and in fact if you look and read through the GMC serious communicable diseases guidance,

all the specific advice offered in that document is specific to HIV.

Okay, then we come to the issue of you must obtain consent from patients before testing for serious communicable diseases, except in the rare circumstances described in various paragraphs, which relate to vulnerable adults, children and unconscious patients. I think that guidance reflects normal rather than good practice for HIV.

Q. I have asked you about best practice and here you are mentioning "normal practice" and "good practice"?

A. Yes.

Q. Is there a difference between "good practice" and "best practice"?

A. What I would describe as "normal practice" is what happens invariably rather than practice to which one would aspire.

Q. Yes. So good practice is the same as best practice there?

A. Almost uniquely for HIV. I mean, there are so many guidelines about testing and counselling that some form of counselling, albeit relatively perfunctory, now always takes place. I have been HIV-tested twice. The damned insurance companies insisted on it. My GP tells me that 50 per cent of people that live in my area have

had an HIV test, just because it's an area where houses cost a lot of money. I can tell you from personal experience that the counselling can be fairly perfunctory.

Q. But it's true to say that with the change in prognosis with HIV, the need for counselling has reduced. Is that not right?

A. Yes, absolutely, absolutely. And I think it's now common practice that you are given a leaflet, given some time to read it, asked if you have any questions and asked if you consent to the test.

Q. Yes.

A. Rather than a prolonged conversation. That reflects the fact that the vast majority of people with HIV now live normal healthy lives and respond well to treatment.

Q. Yes.

A. Which is a very different story from before 1995.

Q. Yes.

A. So, you know, I don't have very much problem with what she says about HIV but the situation with Hepatitis C is very different and she says in her report at one point -- an almost throwaway line, where she says "and of course it would be the same for Hepatitis C" full stop. That's about it. And frankly I would disagree with that, violently.

Q. And I think at paragraph 9 you explain why you say that the situation for Hepatitis C was different in a number of respects.
A. Well, for a lot of the patients the test was in effect a confirmatory test, and at the time it was done, I think the prognosis was considered -- and still is considered -- relatively good.
Q. Yes.
A. That is not to say that patients with Hepatitis C don't develop serious liver disease because they obviously do. I'm making a relative statement and it should be recognised as such.
Q. Yes.
A. At that time, of course, you had patients dying from HIV also. So there is no comparison between the two.
Q. Yes.
A. The year before HAART came out, 15 per cent of the entire cohort died within 12 months. So to compare the two conditions is, to be honest, a bit fatuous.
Q. I think at paragraph 12 you tell us about the practice of liver specialists and perhaps you could talk a little bit about that.
A. Well, if faced with somebody with abnormal liver function tests, I think the majority of them would just test for it. They would discuss the tests very briefly.

The way my own hepatologist explained it to me was as he explained it to one of the nephrologists, who had raised the same question with him. He said to the nephrologist, "Well, do you take consent to do someone's electrolytes," and of course you don't. But the prognosis of somebody with an elevated creatinine and renal failure is considerably worse than the prognosis of somebody with Hepatitis C.

Similarly, you could say: should you take consent to do a full blood count, and what would you tell the patient? Because the full blood count could be normal, it could show iron deficiency, it could show acute myeloid leukaemia. When one of our patients comes for a consultation, that consultation generally generates in excess of 20 tests. If we took specific consent for all of them, we would spend all afternoon doing that.

Q. Yes. I wonder if there might be a difference between a general test and a specific test for a particular -- well, in this case, virus?

A. That's a good question. But I think it's a grey area because a general test can show up a life-threatening illness, just as a specific test can. And actually, when you are testing for Hepatitis C, you are testing for something that has generally a good prognosis, a much better prognosis than ischaemic heart disease or

cancer or renal failure, so why pick out Hepatitis C?

Q. I'm suggesting this to you: I wonder if the answer to that is that, depending on the result of the test, in some situations you go from being a well person to being an unwell person. You become a patient if you have a positive diagnosis, whereas in the case of being referred to a liver specialist, you are probably being referred because you are already unwell?

A. Not necessarily. A large proportion of the population have liver function tests done regularly. If you are on statins, which half the population are, and a whole range of other drugs, you have your liver function tests done regularly and then if it shows something up, you may get referred.

So you may be perfectly well and you may feel well, most patients with Hepatitis C are asymptomatic. You know? They will not necessarily know that they are infected. Liver function tests are being done a lot.

Q. The point that you are referred to your liver specialist, though, is the point at which it is suspected at least that you are ill?

A. Well, it's suspected -- well, it's shown that you have abnormal liver function tests. The significance of which is uncertain. One of the commonest causes of abnormal liver function tests is obesity. Would you

describe that person as ill?

Q. Ill or may be ill?

A. Ill or may be ill. That's right.

Q. I'm suggesting a distinction.

A. You see, the problem is you have the same problem with every test, every test you do, if it's abnormal.

Q. Yes. With haemophilia clinicians I would suggest to you that the situation is different because the patient isn't necessarily unwell before the test, if you follow me?

A. They are not any iller after the test.

Q. If they get a positive diagnosis, then they become a patient, don't they?

A. Well, you have identified a potentially treatable condition, which is the reason for doing the test.

Q. Would you accept, Dr Hay, that obtaining informed consent from a patient that, for a liver specialist, is maybe something that does not require as extended discussion as with a haemophilia clinician?

A. I can't see the distinction. Both clinicians are testing for the same condition. The implications of the test are the same.

Q. Perhaps we could just have a look at paragraph 13 of your commentary. Again, you are talking about your invariable practice, which was to discuss the condition

prior to testing. I think that you yourself are drawing a distinction between your own practice and the practice that you have noticed in --

A. Yes.

Q. What's your explanation for that?

A. Well, to be honest, I think I have been influenced by my experience with HIV, which is an experience that hepatologists have generally not had, although our hepatologist also does a joint clinic with the STD doctors and sees patients who are co-infected.

Q. Yes. Are you doing it the right way or is he doing it the right way?

A. I think that I'm doing it the better way. But I find the difference interesting and I don't think that there is any guidance as to what one should do out there.

Q. You are doing it a better way because it's closer to best practice?

A. Yes, I think so. And to be honest with you, I think that patients with haemophilia also have higher expectations, as a very broad generalisation, of the health service than many other patient groups. This is a recurring problem because they are often disappointed by their experiences of other sectors; because we have to offer them a drop-in service, we see them very regularly. You know, by the nature of their condition

we have to provide them with that service.

Q. Yes.

A. And unfortunately you do not get that sort of level of service from other parts of the NHS.

Q. Yes. Just reading on in your report, the commentary, rather, paragraph 16, you say that you would generally agree with most of Professor Nathanson's first report, as far as it goes:

"Her history of the development of consent for HIV testing appears accurate to me."

If we could just go over the page. You talk about the guidelines issued over the years to cover HIV testing. I think you have already mentioned that. In paragraph 17 --

THE CHAIRMAN: Before you ask that, can I ask how we are getting on in time because I understand you have to catch a plane.

A. Fairly soon, yes.

THE CHAIRMAN: And there may be questions from others. I'm not quite sure how we are going to manage it, Mr Gardiner.

MR GARDINER: I'm aiming for 4.30 and I understand that Mr Anderson has a couple of questions but apart from that ...

MR DI ROLLO: I may have one or two.

MR GARDINER: Right, okay.
THE CHAIRMAN: And we also have to have regard to the stenographer's capacity for --
MR GARDINER: I'm nearly finished.
THE CHAIRMAN: Perhaps you might just bear in mind what the problems are. Is half past all right for you, doctor?
A. Yes.
MR GARDINER: Paragraph 17. You tell us about your experience of haemophilia patients. Could you just describe that very briefly?
A. Well, very few of my patients have refused to have either a Hepatitis C or an HIV test. The situation with spouses is a little bit more complex, particularly with HIV. We would strongly recommend that spouses be tested on a regular basis, quite apart from safe sex practice, and we like to see the spouse come with the patient to clinic.

We found that we got a far more reliable account of the extent to which they were following safe sexual practice from the wife than from the husband. And sometimes we wondered whether the husband was transmitting the advice to his wife that they should be tested. As times has gone by, we are increasingly persistent about that.

But some spouses refuse to be tested and I think

that that was tied up with the complex dynamics of their relationship and the potential for the husband to feel very guilty if he had transmitted the condition to his wife.

Some of those wives subsequently were tested when either their relationship broke down our their husband died. That suggests to me that it was all tied up in that way.

Q. Yes.

A. There are also issues around confidentiality. You know, like other conditions, we would encourage patients to discuss it with their relatives but we have to respect their confidentiality. Very occasionally we had problems with the patient not wishing us to inform the GP. That is more unusual but it's normal practice always to ask, and that's documented in the notes.

One example I could give you is a situation where the patient lived next door to the doctor's receptionist and even though his relationship with his neighbour was perfectly good, he was understandably concerned about confidentiality, and we were eventually able to negotiate a compromise, whereby we sent the clinic letters to the GP's home address and he kept the patient's medical records at his home. Because we prefer to tell the GP, because if the GP doesn't know,

the GP may think the patient has just got a cough, when they have got pneumocystis pneumonia, or the GP may needle stick himself and not realise that he has potentially placed himself at risk. So if they refuse to let the GP know, then we have to adopt their general practice needs.

Q. Yes. Just moving quickly to paragraph 19, and you are commenting again on Professor Nathanson's report, you say that there are practical limitations to informed consent and you list them over the page on page 8. You say there is not enough time to consent for every test. To get full consent would take two to three hours.

A. My suspicion is that Professor Nathanson isn't actually suggesting that we take consent for every single test. But that's not actually what she says.

Q. Yes.

A. But she doesn't really explore, okay, if you are not going to take consent for every single thing that you do, how are you going to choose which tests you take consent for and which not?

You know, it seems obvious that if you are going to do some surgery or you are going to do a test that is unpleasant or hazardous in some way, that you would take detailed consent for that. But when it comes to blood tests, whilst not disputing anything about HIV, where do

you draw the line? Because every single blood test that you do could potentially throw up a life changing result. And it isn't normal to consent for every single test.

Q. Yes.

A. You know? The arguments that you have raised for Hepatitis C could be applied equally to an abnormal blood count or abnormal biochemistry. So whilst it's my practice always to ask about Hepatitis C, there is a range of opinion and a very wide range of clinical practice.

Q. Yes.

A. And consent may be implied. At the end of the day, you can't force the patient to go and have a blood test.

Q. Yes.

A. And they have all the request forms in their hand.

Q. Yes. Thank you.

I think the next few paragraphs of your report relate to the question of obtaining permission to carry out research and we are not going to look at that today. So I'm going to pass over to your last page, page 10, where you list the differences between HIV and HCV relevant to counselling. I think we have discussed these already but you would say that these differences suggest that where it was appropriate to have extended

counselling for HIV, it was not appropriate to do so for HCV. Am I right in saying that?

A. Yes.

Q. Okay. Would you just bear with me a sec? (Pause)

Thank you very much, Dr Hay.

A. Thank you.

THE CHAIRMAN: Mr Di Rollo?

Questions by MR DI ROLLO

MR DI ROLLO: Can I ask you about the use of the word "benign" in the mid 1980s? What would a doctor understand by the use of the word "benign" in relation to a disease?

A. One that was usually either non-progressive or slowly progressive and which resulted in serious disease in the minority of patients.

Q. Right. So it wouldn't be saying that it would never result in a serious disease nor would it mean for a doctor that it wouldn't be progressive in all cases as well?

A. It would be applied, for example, to a range of haematological malignancies, for example, like chronic lymphatic leukaemia.

Q. What a layperson might understand by "benign" might be different from that. He might have a different understanding. But when you are using the word "benign"

in your report, you are using it as a doctor would understand it?

A. Yes, I mean, it's a very relative statement and it does not imply that it would never cause a problem.

Q. Of course, a patient hearing the word "benign" might not understand it in that way.

A. I'm not sure I would use the word "benign" to a patient.

Q. Right. What word would you use to a patient?

A. I wouldn't use a word. I would describe the fact that -- you know, I would have said what I said before. That is that, you know, it may not progress at all, it's only in the minority in whom it does and if it does progress, it progresses slowly.

Q. All right. Can we just very, very briefly deal with this apparent difference between you and Dr Nathanson in relation to the distinction between HIV and HCV. If I can just try and tease out something about that. I think you refer to the classification of HIV and HCV as "serious communicable diseases", and they are both classified as such, is that right, by the GMC?

A. By the GMC.

Q. As I understand it, a serious communicable disease is one which may be transmitted from human to human and may result in death or serious illness. That is what is described as a serious communicable disease?

A. Yes.
Q. It's fair to say under that definition, Hepatitis C does qualify. It may be transferred from human to human and it may result in serious illness and it may result in death. That's correct, isn't it?
A. It is, but there is an order of magnitude difference between the two.
Q. Obviously, the order of magnitude may vary from time to time, depending on what treatment is available and what's understood about the progression of the disease --
A. No, I'm talking about an order of magnitude difference in infectivity, which will not vary from time to time.
Q. It's fair to say also that with Hepatitis C there is a stigma attached to it. If someone has Hepatitis C, that disease carries with it a stigma, which perhaps other diseases do not have. One of the reasons for that perhaps is that Hepatitis C is something that drug abusers frequently have. So Hepatitis C in society has a stigma attached to it.
A. I'm not sure I entirely accept that. I think there is far less understanding or awareness of Hepatitis C in the general population than there is of HIV, about which, of course, there have been major public health advertising campaigns. I think there is unquestionably

a huge stigma associated with HIV, to the extent that many patients started to keep their haemophilia secret because people started to associate haemophilia and HIV together and they were worried that they would lose their jobs and things like that.

Q. This Inquiry has heard from a number of patients who have Hepatitis C and they have given evidence, I think, that they have felt, and continue to feel, stigmatised by having Hepatitis C and are extremely anxious to keep it very quiet that they have Hepatitis C. That would tend to suggest that Hepatitis C does have a stigma attached to it. Is that not right?

A. Well, if it does, it's not to the same degree.

Q. Is it your position that Hepatitis C does not have a stigma attached to it? Is that your evidence?

A. If there is a stigma attached to it, it's less than HIV.

Q. It's also fair to say that Hepatitis C, if treatment is provided, can be extremely unpleasant?

A. No question.

Q. And Hepatitis C may -- it doesn't always -- but it may have significant consequences in terms of a person's lifestyle and choices in the future.

A. If they develop serious liver disease, then certainly. But if they don't have serious liver disease, most of them are asymptomatic and have a normal quality of life.

Q. It may affect a patient's decision-making in terms of how they go about forming relationships with members of the opposite sex and the course of those relationships?
A. I have to say that whilst that is my experience with HIV, it is not my experience with Hepatitis C. In particular, the evidence is that sexual transmission is less of a problem. But in fact, even with HIV, sexual transmission, if you are on treatment, is much less of a problem to the extent that the guidance on safe sex is currently under review.
Q. If you are in a relationship with somebody and you have Hepatitis C, you are going to have to tell them you have got Hepatitis C and you are also going to have to tell them that it is, potentially at least, a sexually transmissible disease?
A. It is historically not as readily --
Q. You have to tell them that it's sexually transmissible, never mind that the likelihood may be less but the potential is there.
A. Well, yes, sure, the potential is there but they will be told that -- you know, about 3 per cent of spouses become infected. It's a relatively low proportion.
Q. Do you not think that a patient then with all of this kind of information available to them, would want to know whether or not they are going to be tested for

Hepatitis C; in other words, it is not unreasonable for a patient to desire to know whether or not such a test is being carried out upon them?

A. I think it's perfectly reasonable that they should know it's being carried out. But bear in mind that when most of these patients were first tested, way back in the very early 90s, there was very little known about sexual transmission. This was not anything we could offer them any information on at that particular time. It's something I would certainly discuss with them now. But, you know, I have to say to you that most of the patients who have got asymptomatic Hepatitis C, it does not make a huge influence to their relationships and their plans for life.

MR DI ROLLO: Sir, I don't have any other question, thank you.

THE CHAIRMAN: Mr Anderson?

Questions by MR ANDERSON

MR ANDERSON: Two matters very quickly.

Dr Hay, good afternoon. The 1997 GMC advice on serious communicable disease that Professor Nathanson relies upon to some extent, my information was that that was actually withdrawn by the GMC in November 2006. Is that correct?

A. That's correct.

Q. Yes. The second matter is this: can you look with me, please, at your original report, at page 5 of [PEN0181186]? Look with me, please, at paragraph 6. This may seem very pernickety but there is a reason for this. You see in the last sentence there you say:

"All types of blood and blood products have subsequently been shown to transmit Hepatitis C."

Do you see that?

A. Yes.

Q. Am I right in thinking that that's not perhaps quite strictly accurate there, that albumin stable plasma protein solution and immunoglobulin have not been shown to transmit Hep C?

A. That's true.

Q. Are we to understand "blood products" in that sentence as meaning Factor VIII and Factor IX concentrates?

A. Well, clotting factor concentrates.

Q. I'm obliged to you. Thank you, doctor.

A. Yes, and blood components.

THE CHAIRMAN: Do you feel you can sort of amend it on the hoof or would you rather let us know what the amendment ought to be?

A. No, I should change that to make it a little more specific, so that it refers to clotting factor concentrates and blood components.

THE CHAIRMAN: Is that clear enough for you?
MR ANDERSON: Yes, I think so. Doctor, thank you very much.
THE CHAIRMAN: Mr Johnston?
MR JOHNSTON: I have no questions, thank you.
THE CHAIRMAN: Dr Hay, thank you very much indeed.
A. Thank you.
MR GARDINER: That's it for today, sir.
THE CHAIRMAN: That's it for today.
(4.43 pm)
(The Inquiry adjourned until 9.30 am the following day)

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