MR. McCANN: Dr. Giangrande, please.

DR. PAUL GIANGRANDE WAS SWORN AND EXAMINED BY MR. McCANN AS FOLLOWS:
A. Paul Leo Francis Giangrande.

THE CHAIRPERSON: Morning.

Q. MR. McCANN: Morning. Morning, Dr. Giangrande. So, Dr. Giangrande, you hold a position of consultant haematologist at Oxford Radcliffe Hospital, isn't that so?
A. That's correct.

Q. You are the director of the haemophilia centre at Churchill Hospital in Oxford, isn't that so?
A. That's correct.

Q. And you also hold the position of honorary consultant haematologist at Nuffield Orthopaedic Centre in Oxford?
A. Yes.

Q. And you are also a doctor of medicine of the University of Manchester; you are a Fellow of the Royal Colleges of Physicians of London, Edinburgh and Ireland; you are a Fellow of the Royal College of Pathologists and Fellow of the Royal College of Paediatrics and Child Health.
A. Yes.

Q. I think also, Doctor, as the director of the Oxford Haemophilia Centre, you have responsibility, therefore, for one of the largest haemophilia centres in the United Kingdom, isn't that so?
A. Yes.

Q. Now, Doctor, just in relation to your curriculum vitae, might you just describe in general terms how -- in respect of your various positions you held throughout the 1980s, in general terms, how your interest in haematology developed over time at the beginning of the early 1980s, in general terms?
A. After originally training in general and internal medicine I moved into haematology in 1983, starting at Westminster Hospital and then I worked with an increasing interest in haemophilia and bleeding disorders in the UK in clinical and research appointments until I took up my consultant position in April, 1991. So in the 1980s, I was involved in haemophilia care as a training doctor.

Q. Yes. With increasing seniority as time went on?
A. That's correct.

Q. Though your particular expertise and standing in the profession comes your appointment as consultant?
A. In 1991.

Q. In 1991, yes. And I think also, Doctor, your -- the Oxford Haemophilia Centre is designated an international haemophilia training centre by the World Federation of

Haemophilia and, as a result of that, you do training for haemophilia centres throughout the world, isn't that so?
A. Yes.

Q. I think you have been twinned with a centre in Zagreb in Croatia --
A. We are twinned with Durban in South Africa and we have got some visitors from South Africa, and somebody arrives down this week from the Philippines to spend time with us.

Q. You are a member of the Medical Advisory Panel of the UK Haemophilia Society?
A. Yes.

Q. How many members are there of that panel?
A. I think about six. We never meet as a complete panel. We are invited to individual meetings and consulted about specific issues.

Q. Depending on topics?
A. Yes.

Q. I think, Doctor, the first -- the first issue I want to address with you this morning is the question of the national database and I think that the Oxford Haemophilia Centre has responsibility for the national database for haemophilia, isn't that so?
A. Yes, it was set up originally in 1969 and it's been computerised since 1977. It's a voluntary collaboration of haemophilia centres throughout the UK and the centres submit information to us on an annual basis and we draw up a report which we publish each year and submit.

Q. And what kind of information, Doctor, would be on that database?
A. The primary pieces of information we seek to collect are the number of patients in the UK with haemophilia and related disorders and the products they consume.

Q. Yes.
A. And then the other interesting -- the other piece of information we collect are the type of materials now that are used; whether the patients have got inhibitory antibodies; demographic data such as date of birth and HIV status and, in the event of death, the causes of death.

Q. Yes. And at this time the database wouldn't record HCV status?
A. That's correct.

Q. Right. But obviously if that is a cause of death, that would be noted in the database?
A. It would be noted. We certainly aim to collect information on hepatitis C status but that has not been done yet.

Q. Yes. And what was the purpose or usefulness of this database, Doctor?
A. The primary purpose in setting it up was to enable provision of treatment in the UK -- in the UK to be planned for. It's been very useful to know how many patients there are, to know what products are used, what quantity of products is used. And

you can actually plan for the future and see from the line on the graph, for instance, what the trend is. So you can make some financial provision for say five years down the line. So the primary purpose was really in planning for the care of patients through provision of blood products.

Q. Yes. And then, Doctor, are there any, at the moment, ethical -- medical ethical difficulties in maintaining this database and are there any anticipated difficulties?
A. In the past there was no legal obligation to request a patient's consent and so that was neither required by law -- well, it was not requested. Certainly the -- shall we say, the ethical climate has changed, so has the legal framework, and the introduction of the revised Data Protection Act now requires us, or will require us, to seek prospective consent from patients explicitly for data collected on an individual basis.

Q. Yes. And so how will the database deal with patients who decline to give consent?
A. If patients don't wish their -- don't give consent, then individual information will not be collected or analysed, but that shouldn't prevent us from collecting anonymised data. In other words, we will still be able to have information provided on the number of patients attending a centre and, say, global statement on how much blood products were used even though we won't be able to say that Mr. XY received such and such a product.

Q. So not only will you not be able believe to name the patient, you won't be able to identify the patients by giving them a number or initials?
A. That's correct.

Q. It will only be the global statistics for a particular centre, I see. And then I think -- yes. And how was the information about deaths and so forth communicated to the national database in the Oxford Centre, Doctor?
A. If a patient dies, then what happens is we receive a written piece of information from -- a special form that we receive from the individual centre director which will tell us that a patient died, the date of death and the cause of death.

Q. Yes.
A. But in addition, we can -- we have made arrangements to receive copies of the death certificate through the Office for National Statistics.

Q. Yes. And the last issue in this regard I want to address with you is the question of patients and a mobile information of patients moving from centre to centre and does that cause any difficulties tracking patients or keeping tabs on patients from the point of view of the database?
A. It can cause some logistical problems and we rely on colleagues around the country writing to us to let us know. What happens: Every year we send out a list of the patients to individual centres and we rely on our colleagues to say 'well, actually, patient X has moved to somewhere else,' so we do rely on that, yes.

Q. Yes. Now, I think then, Doctor, the Oxford Haemophilia Centre provides a 24-hour clinical and laboratory service to patients with congenital and acquired coagulation disorders?

A. Yes, that is the requirement for all comprehensive care centres in the United Kingdom as set out in document HSG (93)30.

Q. Yes. And the Oxford centre has responsibility for certain counties in England: Oxfordshire, Barkshire, Buckinghamshire, Gloucestershire and Northamptonshire?
A. That's correct.

Q. You produce annual reports and you also serve as a member of the Advisory Committee of the United Kingdom Haemophilia Centre Doctors' Organisation?
A. Yes.

Q. And you are a member of various working parties there?
A. Yes.

Q. And I think also you teach at the University of Oxford and you are honorary senior lecturer in haematology and a member of both Green College and Wolfson College, Oxford?
A. Yes.

Q. Now, moving to the question of Hepatitis C. I think, Doctor, at page 836 there is a study -- page 836 of the book you have in front of you, there is a study by Dr. Rizza and others?
A. Yes, I have it in front of me.

Q. Yes. Maybe you might just describe what the import and significance of that study is for the Tribunal, Doctor?
A. This was the final publication of the results of a clinical trial which sought to convince the medical community that dry heat-treated Factor VIII did not transmit Hepatitis C. It was a study, a collaborative study with colleagues around the United Kingdom in which people with haemophilia who had never been exposed to coagulation factor concentrates were given 8Y, which was a product at the time actually produced in Oxford.

Q. Yes.
A. And the patients were followed up to see if there was any evidence of hepatitis transmission.

Q. Yes. Of course, this study then was carried out at a time when there was HIV antibody testing --
A. Yes.

Q. -- to a sophisticated degree. Whereas its earlier studies, in particular Lancet 1988, had used a different --
A. There were two preliminary writtencommunications which examined -- which addressed this issue both for Factor VIII and 9A. The additional point of this study was it included HCV data, that's correct, yes.

Q. And, Doctor, are you aware has there been any study in relation to the safety of the Factor IX superheat-treated product from the --

A. Well, we mentioned the two previous studies that we referred to, the written Melbourne presentation which is in here on page 182, those were interim results which refer to both Factor VIII and Factor IX and of course there was a similar study that you have already referred to.

Q. The Lancet study?
A. Which --

Q. Certainly page 28, there is one version of it there?
A. So there was those two studies.

Q. Yes. But to date, there hasn't been, for whatever reason, it would appear, a study in relation to Factor IX. That is not to cast any doubt on the --
A. No, I think the reasons for that were very simple. The first is the purpose of the study was to show that it's the method that worked; in other words, what this study shows is that it's the dry heat treatment that was effective. And secondly, of course, people with Haemophilia B are far fewer in number than people with Haemophilia A and, therefore, logistically, it's quite difficult to get a sufficient number of patients together. So that's why this final study focussed for statistical reasons on Factor 8Y. But I don't think any one medical person reading that would be in any doubt that the same results would logistically apply, logically apply to the 9A as well.

Q. I see. And then, Doctor, at page 2 of your statement in the final paragraph you deal with that Lancet article in 1988 which you have just discussed. And then you also describe how superheat-treated factor concentrates, both VIII and IX, were introduced during 1985; that is, the super heat-treated product was introduced during 1985 throughout the United Kingdom?
A. What I'm saying -- yes, what I'm saying, they were introduced in 1985 in the United Kingdom. The plasma fractionation unit or centre was actually an integral part of the Oxford Haemophilia Centre and actually produced the material, and they were first introduced, shall we say, locally, because we used exclusively, at the time, these BPL products, but they then began to be introduced, that's correct.

Q. Yes, more generally?
A. More generally.

Q. I think you describe how all patients with Haemophilia A at the Oxford Centre had been switched to the National Health Service product 8Y, the BPL product, by October 1985, isn't that so?
A. Yes. I remember that I was not even in Oxford in 1985, so I think it's important that you recognise I was not there but I believe that to be a fact.

Q. To the case, yes. But I think also, Doctor, would you agree with me that whereas all patients at the Oxford centre may have been switched to the 8Y products, that that was not the case generally throughout the United Kingdom at that time?
A. I quite accept and there is evidence in the bundle we have that there was not even sufficient 8Y probably to cover the -- well not, probably there was not enough 8Y to cover the needs of the United Kingdom, but certainly in Oxford the policy was to use the plasma from UK volunteer donors.

Q. Yes. And then, Doctor, in relation to the BPL product 9A, are you aware, and it may well be you are not aware, when patients in the Oxford centre were switched to the 9A product?
A. I am afraid I can't tell you with precision when that was, but I accept it was a little bit later than the 8Y for reasons I believe Terry Snape has already addressed the Tribunal in some detail so I don't think it's necessary to continue that line.

Q. Yes. Thank you, Doctor.Now, then, Doctor, turning to matters of which you have direct involvement and that is beginning with the testing in relation to Hepatitis C at the Oxford Centre. Just in relation to this by way of background, Doctor, would the Oxford Haemophilia Centre have been treating patients who were suffering from AIDS at this time in 1990, '91, '92, '93, or would that have been -- or would those patients have been cared for elsewhere in the hospital?
A. No, there is no doubt about it, they were looked after very much in our centre, and still are.

Q. That was part of the backdrop, you are dealing with patients presenting with AIDS-related diseases at this time, and at the same time you are setting in train protocols and procedures for Hepatitis C testing?
A. Yes.

Q. Yes. I think in your statement you describe how between October 1990 and 1993, the task of testing for Hepatitis C antibodies was largely completed, and when you say testing, would that have included testing and informing patient of their HCV antibody status?
A. Yes. As I also made clear in my statement, we, in Oxford, had a liver clinic which had been established for some years. Dr. Joan Trowell - again her work appears in the bundle before you - ran a very regular -- weekly clinic in the Oxford Haemophilia Centre, so many patients were already under the care of a hepatologist. Many people with haemophilia in the UK, and I'm sure here were -- had followed the news of the introduction of Hepatitis C test, and we had previously talked about non-A non-B Hepatitis and so we moved to implement testing of our patients fairly swiftly. And that was obviously linked to informing that patients of the results because we certainly did not carry out testing and then not inform the patients of the results. Obviously the policy would have to be to inform them of the results.

Q. Yes. Just in relation to that, Doctor, just focusing on the words 'largely completed by 1993', just in broad percentage terms, could you describe for the Tribunal what numbers of patients in fact had been both tested and informed of the result of the test by the end of - well, by 1993?
A. Certainly by the 1990s - in the 1990s I should say that the Oxford Haemophilia Centre, I should start by saying was and still is a very large centre. We actually treated more patients with haemophilia than any other centre in the UK and of the order of similar to the Royal Free, of 250 severe patients with Haemophilia A, and most of these would be coming to us on a regular basis for treatment. The very minimum is to have a six-monthly follow up for all patients but obviously people used to come on a much more regular basis to be seen and to be treated. If I had to give an estimate, I would say that 80 percent of our patients with severe haemophilia would be very regular attenders, who don't default on appointments, and they would therefore have been tested as part of their six-monthly routine check-up. I think

another advantage of our centre is that we have got very good written records of treatments so that we know which patients have had precisely which products and, indeed, which batches and which dates. And this enabled us to follow up patients who had defaulted and identify those that needed to be tested and we would write to them and this would be -- this would account for another 15 percent. So we are up to about 95 percent that we had to sort of follow-up. And those would have been seen. And I think it's true to say there was then a number patients we would not have tested because we lost them to follow-up, who would have been tested after 1993. That would have been a very small minority, and that would have been despite efforts to chase these people up for testing.

Q. Right. So it's just then to recap on that, then, Doctor: You would think that by 1993, some 80 percent of the patients would have been tested and informed of their HCV status and then a further 15 percent?
A. I would have said actually by the -- even the 15 percent would be by the end of 1993.

Q. By 1993. Yes.
A. Because we started in late 1990, so by -- I'm saying that I would say 95 percent would have been tested by the end of '93.

Q. By the end of '93, and the further 5 percent?
A. I would accept that there are probably even one or two today we have not been able -- despite our very best efforts to have identified, but I would accept that most of those 5 percent would have been tested probably by about 1996, I would guess.

Q. Right. Tested and informed. Yes. And the mechanism for informing patients of their HCV status, were patients called specifically for a test or how was that carried out?
A. When the test became available, the test was offered as part of the routine tests done on the six monthly intervals or if a patient was attending the liver clinic it could have been done there.

Q. Yes. And at that time, Doctor, would pre-test counselling have been part of the -
A. There was no formal pre-test counselling, but obviously patients would have been told that we were testing for Hepatitis C. The haemophilia community was well aware that such a test existed and we don't do testing without consent; and obviously in the case of HIV, that's particularly important. So the patients, many of whom were already attending the liver clinic anyway because of known abnormal liver function test, it was not a shock to learn they were being tested for hepatitis, so we didn't offer specific counselling about it, but we certainly made sure that they were informed that we were carrying out the test.

Q. Yes. And then when the test was carried out, what arrangements were put in place for the next step for informing patients? Were patients told they could --
A. The patient would have been told the results and the policy was that only consultant staff which, in effect, was the two of us, both myself and Dr. Charles Rizza my predecessor really took the next opportunity, it's not there was a formal appointment made to come back to discuss the results, we would often note -- it's a small building, when people come in we would talk to them about the result. At the

next opportunity, whenever they came for treatment or follow-up and we would know that an individual patient had been spoken to because a record would be made in the notes so if Dr. Rizza had spoken to a patient, I would know about it and vice versa.

Q. Yes. I think the record in the notes is, we have -- you have kindly provided the Tribunal with a copy of that and it's at page 57 of your book and it's the 'Hepatitis C check-list'?
A. Yes, I have it in front of me.

Q. Yes. And it notes that you would obviously discuss the HCV result, current liver function test and as regards the follow-up arrangements, what was the position, having informed a patient of their -- let's say it was a HCV-positive result, what would have been the follow-up arrangements for that patient?
A. Well, in this connection, it would have been the option of referring a patient to the liver clinic which was held on a weekly basis and I think the majority of patients certainly wanted to see a liver specialist, it may be they only needed to see a liver specialist on one occasion for general discussion. Because obviously people liked to speak to an expert in that field for a discussion, so we were really talking about whether they wanted to see the liver specialist, that was the principal follow-up arrangement. But also to emphasise the need, particularly with some patients who were not keen to attend, that they really do need to attend to have, at the very least, their liver function test checked. So to emphasise the value of coming back for at least six-monthly check-ups.

Q. Yes. But there wasn't any arrangement put in place to come back shortly thereafter to see either yourself or Dr. Rizza at that time, at the Haemophilia Centre?
A. That would have been part of -- that was taken for granted anyway because the patients come on a fairly regular basis to be seen.

Q. Yes. At the next six-monthly --
A. Yes, as I emphasise, many of the patients don't come every six months. If they have severe haemophilia, they would be coming to pick up their own treatment or if there was a bleed. The six-monthly check-up is one of a formal check-up. I do not want to give the impression that patients only walk in the building every six months. That was not an accurate reflection.

Q. You would have also explained to patients the effect of alcohol consumption, the risk of transmission to sexual partners. You also offered testing for sexual partners of patients with haemophilia, isn't that so?
A. It's clear -- we recognise from work with HIV that there was a risk of transmission of HIV, and it was logical to think that there could be a risk of transmission of Hepatitis C and, indeed, Oxford was one of the first to produce published data - actually the second in the world. And an article, of which I was not a co-author, was published in May '93 looking at the incidence of Hepatitis C infection in -- and 3 of the 104 -- going from memory, 3 of the 104 sexual partners did test positive, and that was the basis of testing the sexual partners of our patients.

Q. Yes. Oh, yes, and, Doctor, was there any written material at the time of first diagnosis with HCV, was there any written material available or given to patients at that time?

A. We didn't have any at the time and I don't believe there was any. The UK Haemophilia Society has provided some material which we now issue to our patients. There is now a second issue of a book which I think first became available in about 1995. I think it's fair to say that many of the patients were already under a liver specialist, but we didn't have a lot of hard facts to tell patients, particularly about treatment, which is the final option, option six, about Interferon, so I think there was no written material in the very early days, no.

Q. I think you describe in your statement how the Oxford Centre was somewhat unique in that there was a hepatitis clinic devoted to liver problems at the centre since the 1970s, isn't that so?
A. We were unusual, I mean, not unique. I think you have already heard about the work from Sheffield. I think Sheffield was probably the premier centre in United Kingdom which had focused very much on this --

Q. I think we are agreed that the centre was, I think, somewhat unique, is how you put it in your statement, in relation to having a hepatitis clinic devoted to liver problems at the Oxford Haemophilia Centre in the early 1970s, isn't that so?
A. Yes.

Q. You were explaining how that was also shared with Sheffield?
A. And I would say Sheffield was the premier centre, yes, in the UK, in my view.

Q. And I imagine then it's the case that a number of patients would have already been diagnosed with non-A non-B Hepatitis before testing became available?
A. Undoubtedly, and again, such patients were the subject of research work, again which is referred to in the bundle.

Q. Yes. Now, Doctor, then in relation to say the protocol at PG 1, and the check-list, when that exercise is carried out or was carried out by yourself or Dr. Rizza, that might be described as medical counselling, and then to distinguish that and for the purposes of distinguishing that from counselling, psychotherapeutic counselling, social work counselling, could you describe what the position is at the Oxford Centre in relation to those resources and those kind of options for patients with haemophilia?
A. We don't have any clinical psychologists or social workers actually as part of our staff, although, obviously, we can use the generic social workers and psychologists of the hospital. We do have the benefit of six nurses, one of whom is actually a trained psychotherapist. And I think most patients actually prefer afterwards, having spoken to the doctors, to spend time talking to nurses. I have often found that they prefer, actually, afterwards, meeting the nurses. I think the nurses in our hospital and for our patient group met the need, and although we could refer people specifically to social workers or psychologists, it wasn't necessary. And I think it was a great help having the hepatology clinic established as long ago as the 1970s because it wasn't a shock to be told by many people that they were HCV positive. After all, they knew, many of them, that they were under the liver clinic with non-A non-B. It was just a change of name, I guess.

Q. Yes. And, Doctor, when you describe the six nurses, would these six be -- would the term 'haemophilia sister' be used -- six haemophilia sisters, in that sense, specialist nurses?

A. Various grades, but haemophilia nurses, yes.

Q. Yes. Would there be a number of other nurses maybe working at the centre?
A. No.

Q. I see. As you say, Doctor, one of the nurses was a trained psychotherapist. And would there be, if you are familiar with the term of intensive counselling, would that be undertaken - counselling session - would that be undertaken by that nurse or would it not take place at all?
A. Definitely not a task that is shared by all the staff, doctors and nurses.

Q. Yes. I see. Now then, Doctor, there is one document I want to refer you to, and I know I had difficulties finding it this morning. It's on page 64 of your book of documents. And this is a -- it's described as a 'Letter to Nature', which is an academic publication?
A. Yes.

Q. And I think you are one of the co-authors of this publication, this article, which is called 'Mortality before and after HIV Infection in the Completed UK Population of Haemophiliacs' and was published in Nature of the 7th of September, 1995, isn't that so?
A. Yes.

Q. And, Doctor, there is one curiosity in it which is at page 64 -- maybe if I might just read it and then you can comment on it. It says at page 64 of the book's pagination: "A reliable test for HIV antibodies became available to Haemophilia Centres early in 1985. Among those who were alive on the 1st of January 1985, 78 percent of potentially infected severe patients and 52 percent of moderate/mild patients had been tested by December 1985, rising to 90 and 74 percent respectively by January 1993." So just taking that proposition in isolation, Doctor, if I may, that would appear to suggest that by December 1985, that is, I guess, a little over a year since the test first became available, 78 percent of severe patients and 52 percent of moderate/mild patients had been tested for HIV. And that seems to be maybe unremarkable. But it just seems a little bit surprising if it's only 90 percent and 74 percent respectively by January, 1993, that some -- it does suggest on its face that 10 percent of severe haemophiliacs had, by that time, and 26 percent of moderate/mild haemophiliacs at that time, January 1993, had not been tested for HIV antibodies?
A. I don't think that is what it means. What it -- I don't believe that that doesn't mean the patients were tested locally. We got results from patients. We do have an index of HIV status but that has to be fed to us--

Q. Yes.
A. -- centrally. And what that means is that -- what I'm confident it means is I'm sure far more than 78 percent of people had been tested, of the severely affected patients, but it's not actually relevant to this study. And that's not -- we have not pushed -- for the purpose of this academic study, what actually mattered was mortality and the death certificates, and that's what we pushed to get for the study and I'm confident a greater proportion than --

Q. -- than those figures --

A. -- where they had been tested and that result was known locally, that's my clear understanding.

Q. Yes.
A. And equally when this is rising to 90 and 74 percent respectively by January, 1993, it doesn't mean to say they were all tested in say December, 1992.

Q. Oh, yes?
A. They could equally have been tested in early 1986. But I say in my fundamental reply to that, that I believe that means simply that the results were known locally but just hadn't been fed to UK CDO for one reason or another because it is a very sensitive issue, and I know that many doctors were reluctant to feed that information centrally.

Q. Yes. Just on a point of clarification, Doctor, as regards the HCV testing, patients were -- patients either came in or were seen at a next appointment and were told they were being tested and they were aware the background for HCV testing had become available and they were tested. As regards then telling patients, did that take place at the next outpatients clinic or at their next regular review date?
A. Often we were quite opportunistic because it's a small building, if I see people coming in, if I saw somebody coming in we would take that opportunity to speak to them or when they would next come for treatment. I mean, we had a list which we methodically worked through. We didn't set up special clinics merely to inform people of results.

Q. Yes. And then, I suppose it also follows that it's more likely, inevitably, that the severe patients with severe haemophilia were likely to be coming into the hospital or centre over that period of time and therefore the mild or moderates are more likely to be given their information at the regular check-up?
A. That's a very good point that you raise, and that's very true. And in the case of patients that we are not likely to see, obviously we have to take the service individually. What I would do in cases where patients were not scheduled to come back for some time would be to make some special arrangement. And with tests of this nature, what I always do is establish with the patient how they would like to be told and that is written in the notes as well: "Blood taken, the patient would like to be told by letter, by telephone call, they would like another appointment." In the case of those relatively few patients, that's what we would do and obviously fewer of the mildly affected patients would have tested HCV-positive anyway for the obvious reason that they received less treatment. So they were not quite the same focus for us as the severes --

Q. Yes.
A. -- in that regard.

Q. Yes, thank you very much, Doctor.

THE CHAIRPERSON: Thank you, Mr. McCann. Mr. McGovern?

MR. McGOVERN: No questions.

THE CHAIRPERSON: Mr. Christle?

MR. CHRISTLE: No questions.

THE CHAIRPERSON: Mr. McGrath?

MR. McGRATH: Just one --

THE CHAIRPERSON: I just forgot Ms. Murphy.

MS. MURPHY: No questions.

THE WITNESS WAS EXAMINED AS FOLLOWS BY MR. McGRATH:

Q. MR. McGRATH: Just one very brief question. I think that Mr. McCann has dealt with most of the issues which I wished to deal with. I think you have seen a book of documentation which was produced for you by the Tribunal, and on page 43 I just want to deal with this issue of the percentage of concentrate, 8Y concentrate that was used in the UK. Now, you have indicated to the Tribunal that in Oxford I think it's the case that 8Y was used and perhaps exclusively 8Y was used from 1985 on. Have you seen this graph before, Doctor?
A. I have seen the graph before, yes.

Q. Yes. And I think it's a graph, as I understand the evidence so far, it was prepared and presented by the -- Dr. Foster, as I understand it, to a Haemophilia Society conference or presentation, probably in 1991 or 1992 or thereabouts. You may not know that?
A. No.

Q. No.
A. When I say I have seen it, I have only seen it in the bundle that was provided to me and I was not previously -- I hadn't seen this particular slide but I not surprised by the content.

Q. I see. So we do see that in 1985, 13 percent of the Factor VIII concentrate used in the UK was the 8Y, and then it progresses to 28, 33 and 45. And then in 1988, dealing with 1988, 55 percent was "Other," which was described as the "predominantly 60 to 68 degrees treated" product. Would you have been aware of that at that time?
A. As I emphasised, I think this is really a little bit earlier than my remit because I was then a trainee rather than actually with responsibility for making choices of these nature, so all I can say is I have seen the data, they don't surprise me, and that's in line with what I thought. But what motivated people to choose between various products, I'm not -- I don't feel able or qualified to state here.

MR. McCANN: Thank you, Doctor.

THE CHAIRPERSON: Thanks. Mr. Aston?

MR. ASTON: Thank you, no questions.

THE CHAIRPERSON: Mr. Bredin?

MR. BREDIN: No questions.

THE CHAIRPERSON: Mr. Hayden?

MR. HAYDEN: Just briefly.

THE WITNESS WAS EXAMINED AS FOLLOWS BY MR. HAYDEN:

Q. MR. HAYDEN: Doctor, I think you initially stated, or you were asked by Mr. McCann in relation to the procedures you went through on the check-lists, so to speak, for notifying or identifying to patients their particular condition, and that was -- that was from the very outset when you set in train the question of testing and informing patients?
A. Yes, and we wanted to have a record, as much as anything else --

Q. Page 57.
A. The check-list was never signed by the patient or never seen by the patient but it is certainly a document which I produced and I wanted to be there in the record. I must be honest and say that it has always proved useful, sometimes there has been patients themselves didn't recall they had been told on a certain date. I think it was useful to have a written record in the notes.

Q. Yes. The Tribunal has heard before the position that many people, when hearing what sometimes might be bad news, sometimes the shutters come down slightly. This was in aid of yourselves as well as the patient in that it gave everybody an idea or a point in time recorded in the notes on a formal basis?
A. That's right. I mean, I am aware, for instance - and have been involved with litigation on HIV - the issue is not when was a person told, but what issues were discussed? But there was a medical /legal element to this as well for our protection.

Q. Self-preservation?
A. I would accept that, yes.

Q. But in essence, obviously from your point of view and anybody coming to the file or the records later on, it was of benefit in the context of being able to find out pretty quickly what the patient status was and when they had been told.
A. Yes, and if some of those options were not relevant, then we would cross them out. For instance, the question of sexual partners, if that hadn't been discussed, we would cross it out. It would be tailor-made for each consultation.

Q. I think you also indicated to Mr. McCann in the context of how people wished to be told, obviously the severe haemophiliacs would be more, by definition, more regular attenders but I think you indicated to Mr. McCann part and parcel of what you did at the time of taking the test and explaining what it was all about was you would get the wishes of the patient as to how they would wish to be informed?
A. That has always been our practice. I think it's very important to establish exactly how a patient wishes to be informed of potentially bad news.

Q. Yes. So mild, moderate or severe, part and parcel of the protocol you adopted would identify their own sentiments as to how they would like to find out?
A. Yes.

Q. And in that contest, obviously the question of six-monthly appointments may or may not fit into how the patient wished to be told?
A. Yes. I mean, the point is that the patients would not wait six months to be told the result of a test. That's clearly not the case.

Q. You also indicated, I think going through it, that you would make efforts if a patient had not either attended for a test or otherwise, efforts would be made to 'track them down' I think was the phrase?
A. Most definitely. We have individual records in our centre which record exactly what treatment a patient has had and when. And so we could identify from the database because much of this is computerised on our own database. We could identify patients who needed to be called back, because they had had concentrates or other high risk material at time when they could have been exposed prior to 1986 to HIV.

Q. Yes. That's where I was going, that, in essence, you have the information to identify who received what and when and could, from that, work out who was likely to be on - within the frame --
A. Within the frame -- yes, that is what we did and I know that other centres did that. And indeed we are often quite happy to provide information from the national database if people ask us for information.

Q. Yes.
A. We are happy to give them that information if that is of some help in tracing patients or identifying patients.

Q. But obviously that was all only possible because of the systems you had in place in relation to keeping records of what patients received?
A. Yes.

Q. You indicated that you had a list, I think in a direct answer to Mr. McCann you indicated you had a list we methodically worked through?
A. Yes, that was mainly the responsibility of one of the nurses; I will name her - Mary Fletcher - because she is the author of one of the papers you see in the Joan Trowell -- but she had a particular interest and she had the role of chasing the doctors up, actually, to make sure --

Q. That is where I was going.
A. She very effectively chased up to make sure that patients were chased up.

Q. Yes. That is where I was going. There was actually somebody designated as the official follower, so to speak, following the doctors to make sure --
A. I wouldn't wish to take the credit myself. I did it because we had someone who -

Q. Made sure?

A. Made sure.

Q. And obviously, or perhaps that is -- you felt that that was a useful way of making sure that their job was completed?
A. Yes.

Q. And the effects of that, I think you said to Mr. McCann earlier on, when albeit subsequently referred to in the context of page 64 on the statistics, I mean in your own centre on testing and notification, you felt that your own experience was 95 percent had been informed by 1993?
A. By the end of 1993 -- I would be confident of that.

Q. And that would not necessarily have been all in the latter end of 1993. That was just a point taken in time?
A. Yes.

Q. And given the page 64 and the statistics set out there, of the 78 percent and 52 percent and 90 and 74 percent, I think was, am I correct in understanding, indicated that the particular document in question was not based -- its emphasis was not these statistics, was mortality rate?
A. Exactly. The emphasise of this study was on hard data which was the death rates -- just looking at the -- not just HIV, the title of the paper was 'Mortality before and after HIV Infection'. In other words, to see what's happened to the death rate after the period known to be associated with HIV infection. So it was a statistical analysis showing that the death rate rose, for instance, from 8 per 1,000 in the late '70s, to 38 per 1,000 in 1992. So it was a purely statistical study using death as the hard data, I am sorry to put it in such blunt terms, and whether we had been told the HIV status was really of no consequence for the purpose of this academic study.

Q. Yes. But part of your feeling or part of your view in relation to the numbers as set out there on page 64 is that they are the national number -- the numbers reported, so to speak, to the National Centre?
A. Yes, and I would be confident that a large proportion had been tested and the results known locally, it's just we didn't have them to include in this paper but it was not really of importance for this particular paper.

Q. Yes. It wasn't an issue you were looking at in the context of the report.
A. Yes.

Q. Can I then ask you: in relation to the mortality for the future with the Hepatitis C, what is your own experience as -- at present and what way do you see things going?
A. Well, let's compare HIV and Hepatitis C. HIV, the maker -- has been the major cause of people with haemophilia since 1987 but the data is now encouraging and we will be publishing some results from the UK shortly to show the very positive effect that treatment has had in controlling HIV infection. By contrast, the number of deaths from liver disease has risen and will continue to rise, and to give a concrete example of that: Our Lancet Paper, which -- not this paper, but The Lancet Paper refers to a total of 51 deaths from liver disease. We will be publishing the latest figures shortly but I can tell you the number of deaths has risen to 212 in the UK.

THE CHAIRPERSON: What was the date of The Lancet article for 51, sorry?
A. It's page 175.

THE CHAIRPERSON: Thank you very much. Thank you, Doctor.
A. And in the -- page 176, the middle of the second column: "During 1969-92, 51 deaths were certified as caused by liver disease".

Q. MR. HAYDEN: We see on page 175 a shorter version, so to speak, interpretation, and it's there --
A. Yes, I think I would -- if we look at page 177, Madam Chairperson, the -- there are a series of figures. If we look at the top left figure, it shows the effect of the cumulative risk, that is the risk of dying from liver cancer -- of liver disease, I'm sorry, over a number of years, and the important message is that the figure was rising showing no evidence of a plateau, so in other words, when we completed this study, the death rate or the risk of dying was rising, it had not stabilised and we predicted at the time that the curve would continue to climb and that has been borne out and we will be updating that data. On the positive note, I would say that we now have treatment in the form of a combination of drugs which we hope will give as good an impact on life expectancy as we are seeing with the HIV treatment.

Q. But in relation -- when one looks at that article at page 175 to 177, on page 175 on the left-hand column: "There is an emerging risk of mortality from liver disease and liver cancer in the UK haemophilia population in individuals both infected and uninfected with HIV which probably results from infection with Hepatitis C."
A. That's correct. In other words, we did not-- when this study was carried out, know that the patient had, with certainty, been exposed to Hepatitis C but it's an obvious --

Q. Risk factor?
A. -- risk factor. The purpose of the paper was to focus on people who had been given blood products with a high risk of contamination with Hepatitis C as shown by previous studies.

Q. Again, it would appear from that -- and, as you say, the numbers that you have just indicated to Madam Chairperson which have yet -- are the new numbers about to be published, so to speak, shows that that assessment was accurate and that the death rate has escalated from liver disease and cancer. And is it correct or -- am I correct in saying that whilst one sees the HIV cohort having hit the blackest period in relation to mortality very early on from the dates of infection, the position with Hepatitis C is, in effect, the reverse of that; it seems to be much further out and now we are hitting into the period of time, it would appear, at least on the --
A. I would agree with that, that HIV had a more rapid impact and more severe and early impact. With Hepatitis C, things have been more drawn out, yes.

Q. Yes. But now with the numbers, it seems that we are getting into a very serious period of time. And in the context of treatment being made available for that eventuality as it's unfolding, what would you see would be a necessity or what would you see as being the main problems that are going to face the individuals?
A. Okay. I would also wish to clarify, with regard to HIV, another point that you raise: Of course, we are talking about larger numbers as well: In the UK, we know

that 1,229 people with haemophilia were exposed to HIV, we estimate; that probably around 3,000 were exposed to Hepatitis C. So I think in terms of impact, it's, therefore, quantitatively greater. It's certainly true that there is now treatment which is available for people with Hepatitis C, but the treatment with the combination of drugs known as Ribaviran and Interferon has ideally to be given at a fairly early stage in the treatment. And if people already have established scarring of the liver or cirrhosis, then it's going to be of relatively little value. And we know from data already published that a significant proportion will already have cirrhosis.

Q. Just, then, I think you'd indicated two articles in relation to the 8Y - it's just more a tidying up. I think there was also an article I think at page 142, am I correct in that? It's a UK haemophilia centre study?
A. Yes. This was a document, Madam Chairperson, that was just published internally within the UK haemophilia community. The other documents that I referred to were published data which would have been available to anyone, yes.

Q. Yes. Any person attending in the UK haemophilia centre would have access?
A. Would have had access to this document, yes.

Q. Is there any significance from the chart on page 145 - or what does it tell us?
A. The chart on page 145 is looking at patients and classifying patients according to whether they have Haemophilia A or B; in other words, whether they have received 8Y or 9A. It is helpful in that it gives us some idea of the previous exposure - whether the patients have had any blood products before. Perhaps the limitation of this paper, I would say, is that it is -- we obviously were not able to do Hepatitis C antibody testing, and it relies on looking at liver function tests to see if there is any evidence of inflammation of the liver associated with treatment with these products.

Q. Just, then, if I could ask you: In relation to your centre, obviously the clinic being linked from the early days made the appearance on the scene, so to speak, of Hepatitis C less of an out-of-the-blue situation - would that be a layman's summary of it - for the patients themselves?
A. Yes.

Q. As you say, it was a change of name; non-A non-B became Hepatitis C?
A. It was just a change of name, it was not something new like HIV.

Q. In the context of the assistants, you had six nurses, I think --
A. Yes.

Q. -- available to you for your level of patients?
A. Yes.

Q. And in that regard, I think you'd indicated that it was for a doctor to tell the patient and then into the system, so to speak, as to what supports that --
A. It was for a senior doctor, because we had two junior doctors that I hadn't mentioned, and, as well, two senior SHOs, and they were not involved in this process.

Q. And you could call upon the hospital if there was any assistance needed for the patients coming to terms with it, or their families?

A. Yes.

Q. And were there any protocols or procedures put in place to make that available, or was it a question of as you needed you asked or --
A. As we needed we asked, but I have to say not many patients needed support from outside the centre. I think they preferred to deal with people they already had long-standing relations with. And although our nurses are not trained social workers, many of those roles they could effectively take over.

Q. Was there any internal procedures put in place in the centre to assist the staff in dealing with the problems or was it a question of --
A. It's a very good question, and the answer to that is no. And that was also the case with the HIV, which I think would have been helpful, in retrospect.

Q. Yes. Yes. You would see it as a benefit or something that would be of benefit in the context of any future difficulty arising?
A. Yes. I mean, I think HIV certainly presented some problems. I know that many staff were obviously devastated by the death and illness of people that they had had a long relationship, professional relationship, with. And I know the effect that that had. And some nursing staff left, for instance, in some centres because of that sort of problem.

Q. Would it be correct to say that in relation to both the HIV and the Hepatitis C, the ethos in your centre would have been to test and inform them as quickly as possible?
A. It's always been my belief that patients should be told results, and I will give you another concrete example, although it's outside the remit of this Tribunal: You will know of the problem with variant CJD in the United Kingdom, and we were informed last December that some of our patients - actually a total of 85, as it turned out, a large number had received material back in 1996 from a donor who had subsequently died of variant CJD, and this presented an ethical dilemma - whether to tell the patient or not. And our view - and I have to say that was shared by most, if not all, of our colleagues in the UK - was certainly to make a free and frank discussion and revelation to the patients.

Q. Yes. In relation to -- if I can just go back to your statement for a moment on page two under "Hepatitis C," you identify "that the risk of transmission of Hepatitis C remained up to and including 1984, in factor concentrates prior to the introduction of heat-treated concentrates. I can state with confidence that no patient treated with blood products at the Oxford Haemophilia Centre after the introduction of heat-treated concentrates has ever been suspected or identified of developing Hepatitis C". So it seems that once the heat treatment became available to your centre, that's what everybody was put on to?
A. Yes.

Q. And I think you do say at the end of that page: "With regard to heat-treated Factor VIII and Factor IX concentrates, these concentrates first became available through BPL (UK manufacturers) in January 1985 and stocks were initially reserved for previously or minimally treated patients." So I take it that was in keeping with the

recommendations that had been handed down in previously unexposed or small exposure -- immediately or --
A. That's right.

MR. McGOVERN: Before the witness answers this, the witness has already said that this period he is being asked about is outside his -- it was earlier than his remit. This is when he was being asked by Mr. McGrath about the graph dealing with the years 1985 to 1988, so I don't see how he could know what he is being asked by Mr. Hayden.

THE CHAIRPERSON: Well, he did say he was training at the time. He did say that, at the outset, that his knowledge was gleaned from -- he didn't know about the actual treatment given, but he did know about certain other statistics.

MR. McGOVERN: I thought he wasn't in the Oxford centre at the time. If the witness feels he can answer it, fine. I had understood from an answer given earlier to Mr. McGrath that he felt this type of question --

THE CHAIRPERSON: I think that was in relation to the graph.
A. My observation would be that -- I would agree with the spirit that I was in training at the time, but equally, I do feel that I am able to answer some questions that relate to the period specifically in the Oxford centre and specifically anything that is in my report, because obviously those are points that I have tried to clarify. But I have avoided deliberately answering questions of a more global nature before 1991.

THE CHAIRPERSON: Right. Does that satisfy you Mr. McGovern?

MR. McGOVERN: Well, insofar as it goes. I don't know whether the witness is going to be asked to develop this any further, but I am content with the answer the witness has just given.

THE CHAIRPERSON: Right, Mr. Hayden?

MR. HAYDEN: Thank you, Madam Chairperson.

Q. Going on to the next page: "At our centre, all patients with Haemophilia A had switched to heat-treated 8Y by October 1985." When you say they had switched to heat-treated 8Y by October '85, before that they would have been on what?
A. It was introduced in the period -- over the period from January through to October. By October, it is a fact that I can confirm that, although I was not there, all our patients in Oxford -- all patients in Oxford were on 8Y by October 1995.

Q. And prior to that would they -- they would have been on -- their treatment would have been from what source?
A. I can again, as a matter of fact, state that the policy of the Oxford Haemophilia Centre had always been to use blood products derived exclusively from UK volunteer donors, and it was for that reason that, in fact, BPL had set up its own fractionation facility; an integral part of our building which actually supplied other centres as well.

Q. And then just finally -- two final things: I think in your CV, I think you indicated you are vice-president of medical -- Medical of the world haemophilia --
A. I was elected to the position of Vice-president Medical of the World Federation of Haemophilia in July last year.

Q. Yes. And then if I can just ask you to go to page 108 of the booklet. Could you just tell us how that arose or --
A. The background to this, Madam Chairperson, is that the Oxford Haemophilia Centre is a resource which people tap into from around the country, and indeed around the world. And we do receive periodic requests for information, which we always try to satisfy. I received a letter requesting some specific information from Dr. Lawlor, and I passed the letter on to Professor Sarah Darby, with whom I was collaborating on the HIV study - in fact, with whom I collaborate. I asked her to reply on my behalf, which she did, and that is why there is -- my name appears as a copied name in the correspondence.

Q. Yes. And that, I think, seemed to deal specifically with a request for information on Haemophilia B patients?
A. Yes.

Q. And I think it sets out there: "From table 3 of this paper there is no evidence that any patients with Haemophilia B became infected after the period January to June 1985." They were the statistics?
A. That is what it says, and that's what Professor Darby said.

Q. Yes.

MR. HAYDEN: Thank you.

THE CHAIRPERSON: Thank you, Mr. Hayden.

Mr. McCann?

MR. McCANN: I have no further questions for Dr. Giangrande.

THE CHAIRPERSON: Very well. Thank you very much, Doctor, and thank you for coming.

THE WITNESS THEN WITHDREW.

THE TRIBUNAL THEN ADJOURNED TO THURSDAY, 20TH OF SEPTEMBER, 2001, AT 10:30 A.M..