Tuesday, 29 March 2011

(9.30 am)

MR MACKENZIE: Good morning, sir. We return to the topic C1 today and the witness today is Professor Leikola.

PROFESSOR ERKKI JUHANI LEIKOLA (sworn)

Questions by MR MACKENZIE

MR MACKENZIE: Good morning, professor.

A. Good morning.

Q. Professor, I would like to started by looking at your CV, please. That will come up on the screen in front of you, and the number is WIT0030004.

I think if we go to your qualifications, professor, we see you graduated from the University of Helsinki in 1966 with which degree?

A. Yes.

Q. Which degree did you graduate in 1966?

A. So-called licentiate of medicine. That means physicians licentiate.

Q. Is that similar to a bachelor of medicine?

A. That's right.

Q. I understand. And then a doctor of medicine in 1968?

A. That's right.

Q. We then see you went to the USA in 1969. We will come back to that. You then obtained a qualification in immunology in 1972. You became a professor in 1992 and

a fellow of the Royal College of Physicians in Edinburgh between 1994 and 2002.

Then when we look at your appointments. We see that between 1968 and 1969 you were an assistant physician in internal medicine and anaesthesiology at Helsinki and then between 1969 and 1972 you were an assistant surgeon. I think you then had a change of direction. Is that correct to say?

A. That's correct.

Q. And between 1972 and 1975 you were the head of the department of blood group serology in the National Public Health Institute, Helsinki. Can you briefly explain, please, what your duties were in that post?

A. Yes.

Q. What were your duties in that post?

A. The National Public Health Institute used to be called National Serum Institute and it was pure laboratory investigation concerning blood group serology, screening pregnant mothers for red cell antibodies and also some forensic serology.

Q. Thank you. Then between 1975 and 1988 you were the director of laboratory services for the Finnish Red Cross Blood Transfusion Service. Can you again, perhaps, tell us about your duties in that job between, say, 1975 and the early 1980s?

A. My duties were really concerned with the laboratory technology, the administration of the laboratory, which was the only laboratory within the National Blood Transfusion Service in Finland. We introduced more sensitive tests for Hepatitis B. We introduced different types of automation to the laboratory routine. There was a staff of about, I think, 90 people and I was in charge of all these laboratory aspects of the Finnish Red Cross Blood Transfusion Service.

Q. And in that post did you have any dealings with the clinicians? Did you actually have any responsibility for clinical matters?

A. I had no contacts with patients themselves. I had frequent contacts with different clinicians, surgeons, haematologists and so on concerning blood group compatibility, concerning blood transfusion safety and so on, but no direct contacts with the medical profession per se.

Q. Thank you, professor. Then we see that in 1988 until you retirement in 2001, you were the director of the Finnish Red Cross Blood Transfusion Service. Again could you perhaps briefly indicate, please, your main duties in that job.

A. Well, the Finnish Red Cross Blood Transfusion Service included both the transfusion service, the laboratory

service and also fractionation laboratory. They were all included in the same organisation and I was in charge of all these operations within the organisation. That means that I had the position of an executive director there. Therefore, I was not personally involved in any laboratory tests or, for that matter, I really was the administrative head of the organisation, having also the responsibility to be the main contact person with our international colleagues.

Q. Thank you. And we then see you had various posts abroad, in particular between 1969 and 1970 you were World Health Organisation research fellow at the University of California in San Francisco. What did you do there?

A. That was purely a research fellow position, post-doctoral position. I was interested in immunology, especially concerning red cell membranes and antibodies against red cells, and I was doing some research there. It had nothing to do with blood transfusion as such.

Q. Yes. Is it fair to say, doctor, that your first work in blood transfusion really was in 1972, when, as we saw, you became the head of the department of blood group serology?

A. And then only indirectly because the public health institute did not investigate blood donors or blood

recipients; there were only pregnant mothers and forensic medicine. I had informal contacts with my colleagues at the transfusion service because we were interested in the same matters but that was unofficial and indirect.

Q. So it's really in 1975 when you joined the Finnish Red Cross Blood Transfusion Service that your work became centred in the blood transfusion area?

A. Yes.

Q. Thank you. And then to complete your visits abroad, we also see that between 1977 and 1978 you returned to America, this time as a visiting scientist at the Irwin Memorial Blood Bank in San Francisco. In brief, professor, what did you do there?

A. When I came to the Blood Transfusion Service in Finland, the Finnish Red Cross, in February 1975, the whole organisation was in the middle of organising an international congress in Helsinki the following summer, and therefore I was very much involved in the practical arrangements within that congress. That happened to coincide with the European Security Conguess, or whatever it was mentioned. There were a number of problems. Therefore, I wanted to have some time to continue my research and therefore we made an arrangement that I could go to San Francisco, that

I knew beforehand, to spend one year there having nothing else to do than research, continue what I had been doing before.

Q. And in brief, professor, the research was on ...?

A. That was immunology. That was once again red cells, but other aspects of immunology also.

Q. I understand. We also see, professor, that between 1982 and 1986 you were the head of the blood programme department for the League of Red Cross and Red Crescent Societies in Geneva, and again, professor, what were your main duties and responsibilities in that post?

A. They were mostly giving advice and consulting the various Red Cross blood transfusion services around the world. Also some other transfusion services were involved. At that time we did not make a big difference between the state-run organisations and Red Cross-run organisations. Main emphasis was developing countries, where we felt that we could give some assistance and some teaching possibilities for those services that were emerging. One of the main tasks there was to promote the voluntary and non-remunerated blood donation as well as national self-sufficiency within blood products.

Q. Thank you. We then turn to various positions of trust in the scientific field you have held. You set out you have been a supervisor, assessor and opponent of MD and

PhD theses at four universities. You have been editor in chief of Transfusion International between 1982 and 1986. What is Transfusion International?

A. That was a newsletter by my small organisation in Geneva, by the League of Red Cross Societies, information leaflet, newsletter.

Q. I see. And then foundation of the journal Vox Sanguinis. Member of the board, 1992 to 1994, and president 1994 to 2003. What is that journal?

A. That is a scientific -- one of the leading research journals within blood transfusion science.

Q. When you say foundation of the journal, does that mean you were involved in founding the journal?

A. Well, I was the -- the journal was governed by a foundation and owned by a foundation and the foundation appointed the editor in chief and other editors but otherwise it had virtually nothing to do with the content of that journal. It was much more a governing position there; including finances and so on.

Q. I see. Also you were the editor of Current Studies in Haematology and Blood Transfusion, 1992 to 1998, a member of the editorial board of the journal Haematologia in 1992 to 2003, a member of the editorial board of the journal Transfusion Medicine, 1994 to 2006

and then member of the editorial board of the journal, ABO - Revista De Medicina Transfusional. 1999 to 2001. What journal is that, professor?

A. That is a Spanish journal for blood transfusion. It is a very small little journal and I think it stopped coming out a few years ago.

Q. I see.

A. These were more or less sort of honorary positions where I had very little in practice to do.

Q. Thank you. You then list domestic positions of trust. You explain you have been the chairman, secretary or member of numerous state, professional and Red Cross committees and working parties, societies, et cetera, and also were a member of the board of directors of Orion Corporation, Helsinki, in 1994 to 2004 and were also chairman of that company. What did that company do, professor?

A. Could you, please, repeat, please.

Q. Orion Corporation?

A. That is a pharmaceutical company.

Q. I see. Then you set out various international positions of trust. You were in the International Society of Blood Transfusion, you were a council member between 1980 to 1990. You were the chairman or member of numerous committees and working parties in the

Council of Europe. You were an observing member of the select committee of experts on quality control and automation, 1975 to 1984, and again, in the Council of Europe, you were a member of the committee of experts on blood transfusion and immuno-haematology between 1982 and 2001 and chairman, 1994 to 1996.

To pause there, professor. As lawyers, I think we are familiar with the Council of Europe from a legal perspective, in particular the Convention On Human Rights and the European Court of Human Rights. What role did the Council of Europe have in health matters and blood transfusion matters in the 1970s and 1980s?

A. At that time the EEC or EC did not have anything to do with health per se and the Council of Europe established a committee of specialists. I think originally after the dam disaster in the Netherlands, where much blood was needed and there was no international organisation that could somehow co-ordinate these different donations to that particular country, and that was in late 1950s, I believe. And then it grew sort of gradually to a forum of Western European representatives of various transfusion services and blood programmes, convened once a year in May, usually. It was able to give various recommendations -- nothing binding but recommendations -- but that was the only, let's say

official forum for these people within the fairly limited circle, to meet each other and discuss common problems that were in this particular area. And I think that within Europe in general this committee of experts or Council of Europe was a very important body in the general development of transfusion practice and transfusion safety.

Q. Thank you, professor.

Could we then go over the page, please? Now, professor on page 2 there is a long list of positions you have held. I'm not going to read out each one. I think instead I will ask that the complete list is inserted into the transcript of the evidence, but perhaps if I could pick out one or two, professor.

We see about number 6 down the International Group of Red Cross Blood Transfusion Experts. You were a member of that between 1982 and 2000. Then below that the advisory group of the blood programme of International Federation of Red Cross and Red Crescent Societies. Again, you were a member between 1982 and 1994. I think we can also see reference to you having acted as an expert witness, in particular in 1990 in a litigation in Australia. I take it that was to do with blood transfusion matters?

A. Yes, that was in the State of Victoria; where there was

a big trial going on concerning transmission of HIV.

Q. I see.

A. And the AIDS virus.

Q. Then I think similarly you were appointed as an assessor by the Supreme Court in Denmark. Was that again to do with blood transfusion matters?

A. That was once again the question of haemophilia patients infected by HIV.

Q. Yes. And then the second bottom in that list, I think you appeared as an expert witness for the Lindsay tribunal of enquiry into the Irish blood transfusion Inquiry. Is that correct?

A. Yes, that was mainly hepatitis then.

Q. Thank you. Then honorary memberships. We see various things listed, including prizes. Then under "Scientific Publications", you explain that you have approximately 100 articles and numerous congress abstracts on immunology, immuno-haematology and transfusion medicine. Various other textbook references are there, including editor along with three others on the management of blood transfusion services; World Health Organisation publication in 1990 and various other textbooks.
I think again, professor, I will ask for the whole of page 2 to be included in the transcript to save us having to go through it in detail now.

So putting your CV to one side, please, professor, if I may then look at briefly a list of your scientific publications. The reference is [WIT0030007]. I think you have provided this list, professor. Is that correct?

A. Yes.

Q. Again, I'm not going to go through it but in short we can see 105 publications, initially in the field of immunology and then later on in the field of blood transfusion medicine. Is that correct?

A. That is correct.

Q. Thank you. We can put that to one side.

The first statement I would like to look at, please, professor, is [WIT0030001]. By way of background, professor, I think the Inquiry had asked you to provide a statement explaining the Blood Transfusion Service in Finland. Is that correct?

A. Yes.

Q. And this is the statement you have produced and in paragraph 1 you explain:

"This statement refers mainly to the period 1975 to 2001."

We have already looked at your CV and then you explain in paragraph 2 that:

"The Finnish Red Cross Blood Transfusion Service was

established in 1948."

After the Second World War. You say in the final paragraph of paragraph 2 that:

"This is the background for a relatively centralised national organisation."

Can you explain briefly what you mean by "relatively centralised national organisation"?

A. This is the background for the fact that we in Finland did not establish separate blood centres around the country but the Red Cross established one organisation based in Helsinki, and having just one laboratory where all these samples would be sent from around the country. The idea of having centralised and national organisations included the idea of having just one national director, who would have an executive position, and in the various small collection centres that we had around the country there was no permanent, full-time medical head but these were mostly run by nurses and were then assisted in medical questions by local part-time consultants, that we called consultants. They were from various medical disciplines, helping in questions pertaining -- medical problems for the donors, whether they were eligible to donate and other things.

But this idea, that the Red Cross took this task after the war when there were very little resources

altogether, that led into the situation where the mainframe of the organisation having one big centre in Helsinki and a number of small little collection sites around the country then supplemented by different mobile collection teams, this is how it is running today.

Q. Thank you. And then we see in paragraph 3 that at the outset in 1948, the Finnish Red Cross appointed Dr Nevanlinna as the director of the new organisation. Professor Nevanlinna served in that position for 40 years until 1988 and you were then appointed his successor. We can see the director reported to the secretary general of the Red Cross. Is that the Finnish Red Cross?

A. That is the Finnish Red Cross.

Q. But was accountable to the health authorities. How was the director accountable to the health authorities if he wasn't employed by them?

A. If the health authorities required or were asking different questions concerning the medical aspects of blood transfusion, both transfusion and donation, they would always contact Professor Nevanlinna directly and not go through the official organisation, going to the secretary general of the Finnish Red Cross, and then further on to the director of transfusion service.

So it was understood in Finland that the transfusion

service is directly accountable for professional items to the National Board of Health, without involving really the structure of the Finnish Red Cross per se.

Q. I see. You explain there was no separate medical director and the Finnish Red Cross determined the duties of the director of the Blood Transfusion Service and the job description was admirably short and stated:

"The director is responsible for the operations of the Blood Transfusion Service".

You explain the operations were governed by the board of the Finnish Red Cross Blood Transfusion Service and they had to follow the law, rules and regulations established by the health authorities. Then in paragraph 4 you explain some of the legal and regulatory background and that in short, plasma products were considered as pharmaceuticals and were regulated, certainly in the 1960s. I think you explain that the Finnish National Board of Health gave guidelines concerning the administration of blood products and later concerning blood donation and testing. You also explain in the first sentence of that paragraph that up until 1967 there were no legal regulations concerning blood donation and transfusion of blood beyond those concerning the medical profession in general.

In paragraph 5 you explain:

"There has never been any legal provision for the Finnish Red Cross to carry out a sole national blood transfusion service."

You do say in the final sentence that:

"Hospitals have not established own blood centres, with a few exceptions in the past."

Is that correct?

Then over the page, please, in paragraph 7, you say that:

"From the beginning, the organisational philosophy was to combine centralisation and decentralisation."

I think this is as you explained earlier, the Finnish Red Cross BTS had the headquarters, the laboratory, the plasma fractionation centre and related functions in Helsinki. In addition there were 33 to 34 blood collection centres covering the whole country:

"[They] had no medical director but were managed by a local head nurse with guidance by a local part-time consultant doctor and under supervision of the medical staff in Helsinki."

You also explain there were fixed centres and mobile collections and that in 1980 there were a total of 335,000 collections; Finland having a population of about 5 million. I think that is well above the average rate of donation in industrial market countries. Is

that correct?

A. That is correct.

Q. I think by way of comparison we know that in Scotland in 1980 there were a total of 289,324 donations. I think Finland was a bit ahead of Scotland there.

I should pause and ask you, professor: in between 1975 until the early 1980s did you ever attend a donor session in Finland?

A. Personally?

Q. Yes.

A. Yes, I was giving blood myself.

Q. I see.

A. And that was a very -- especially later on, that was an extremely good way of exercising quality control of the whole procedures. I have given more than 100 times.

Q. Did you go under cover or did the staff know who you were?

A. Well, I think my people were actually quite happy that I was showing an example of giving blood and I very much enjoyed going to different places, sort of appearing all of a sudden and seeing how things were running but that was mostly -- yes, that was after 1975.

Q. In short, professor, I'm interested in the succeed half of the 1970s and the early 1980s, before the arrival of AIDS. I'm interested in how a donor session was

conducted in Finland and in particular what questions were asked of donors. Are you able to help us with that?

A. Well, first of all we had fixed sites and most of the donors would come there spontaneously, or they were called by telephone and so on. They were small local communities where these regular donors especially, they knew each other, and that was the social occasion to come to give blood. For mobile sessions, these were planned and budgeted about half a year before, and then we had vans that would be carrying the equipment for mobile sessions. These were not so-called "blood donation buses" but they were carrying the equipment, what they needed for blood donation, with them to schools, different institutions and so on, where sort of field beds were then organised and the donors would have had information about that already before and then they would come to these places.

We did not believe very much in rapid medical check by a doctor because in our mind we would say that it's extremely difficult for a doctor to say in five minutes' time that you are healthy. Therefore, we relied very much on the questionnaire that was given to the donors and because that was a voluntary and unpaid system, we were fairly confident that they would not have any

reason, against the best of their knowledge, to answer those questions, especially because they were constantly explained that this is for their own safety and that was for the safety of the recipients of their products.

I think that it worked quite well all together because when the nurses had more and more experience, I think that they were quite good in seeing the donor when there was something suspicious about him and were sort of immediately ready to go deeper into the questions and then referring that to the consultant doctor.

Q. You mentioned something suspicious. Can you give an example or examples of that?

A. I'm sorry?

Q. You mentioned that a nurse may see something suspicious with a donor. Can you give an example of what might be something suspicious?

A. Right now I can't, no. But they could well see the big bulk of donors were behaving sort of similarly and if there was somebody who would have been more aggressive or clearly had something to hide when he was filling the questionnaire, that I mean would have been suspicious.

Q. And what sort of matters were included in the questionnaire in the late 1970s/early 1980s?

A. They were pertaining to different diseases. The donors

were also asked whether they have had hepatitis or jaundice. Jaundice/hepatitis within parenthesis. And the list of questions at that time was fairly short and I don't remember all the questions that we were --

Q. Do you remember, professor, whether the list of questions included whether the donor had ever injected or used drugs?

A. No, I don't think so.

Q. I'm grateful. Could I then, please, professor, return to your statement. In paragraph 9 you explain that:

"The organisational background ..."

To the Finnish Red Cross Blood Transfusion Service:

"... explains why it was relatively easy to implement a national policy once a decision had been made centrally by either the BTS board or by the director and his staff in Helsinki."

You explain that there were weekly senior staff meetings about but the director carried the legal responsibility. These meetings were only advisory in nature and that:

"In major policy questions, the National Board of Health was consulted."

That would be the National Board of Health of the Finnish state?

A. That's right.

Q. And then paragraph 10, you explain the financing of the Finnish Red Cross Blood Transfusion Service. But in short it is a non-profit but self-supporting organisation. So it charges the customers, mostly hospitals, the costs of products and services. The pricing structure of production was decided by the board of the Finnish Red Cross Blood Transfusion Service but was subject to approval by the National Board of Health. The finances also included funds for research and development and also scientific research was supplemented by various grants from different foundations and other sources. Is that correct?

A. Yes.

Q. Paragraph 11 you explain:

"The flexible financial arrangement, ie there was no direct public or Red Cross subsidies or budget allocations to the Finnish Red Cross Blood Transfusion Service, has made it possible, in my opinion, to act rapidly with new safety measures if these were deemed necessary by the professionals. An example is Hepatitis C testing that was started in Finland at the beginning of February and fully implemented in April 1990 even though it was not an official requirement."

Could I then, please, go over the page. In

paragraph 13 you explain that:

"Being the only BTS organisation in Finland had also a drawback: it was not possible to discuss various BTS issues nationally with other colleagues. Therefore international contacts were vital for planning for new policies and updating previous ones."

In paragraph 14 you explain that:

"At the time now in question ..."

Which time period are you referring to there, professor?

A. From 1975 until 1984.

Q. Thank you. You explain:

"... there were several forums where blood transfusion directors could meet and exchange ideas and opinions."

In particular:

"The congresses and meetings organised by the International Society of Blood Transfusion.

"The Council of Europe expert committee's annual meetings."

And also the Red Cross meetings. And then in paragraph 5 finally you say that:

"The directors of the major services ..."

Is that a reference, professor, to the directors of the Red Cross in the various countries?

A. Not necessarily only the Red Cross. I think that within Europe those were mostly the members of the Council of Europe expert committees. That included also those countries where the Red Cross was not playing a role.

Q. I see. So you mean simply the directors of the major blood transfusion services --

A. That is correct.

Q. -- in various countries took part in many of these meetings and saw each other on these occasions. In short, I think there was much discussion. Both formal and informal?

A. Hm-mm.

Q. I'm grateful, professor. We can put that statement to one side, please, and the next document is [WIT0030027].

Professor, I think you were also asked by the Inquiry to prepare a statement on our topic C1, namely donations in prisons and from donors with a history of jaundice. Is that correct?

A. That's correct.

Q. Could I ask, professor, what did you have access to and take into account when preparing this statement?

A. Well, I was very much relying on my previous statements to the various court processes that you referred to earlier. I went also once to the archives of the

Finnish Red Cross Blood Transfusion Service. However, that was not very helpful because I must say that the order of documents was minimal in those archives. In addition, I telephoned to a few of my colleagues there that were active at the service during my time and even before my time, and combining these little bits of information, I then made this statement.

Q. Thank you. Who were the colleagues, your former colleagues, you telephoned and spoke to?

A. Well, that was Dr Helske, who made the study on the prevalence of Australia antigen, as it was called at that time, in 1973/1974. Dr Koistinen who was responsible for the blood donations during my first years at the service and also before my time. These were my main contacts relating to this particular time.

Q. Helske spelt H-E-L-S-K-E and Koistinen spelt K-O-I-S-T-I-N-E-N?

A. Yes.

Q. And I think, professor, in compiling this statement you were also sent various documents by the Inquiry. In particular I think you have been sent a copy of all of the C1 statements. Is that correct?

A. That is correct.

Q. And also various other documents, including a document called a C1 chronology. You have seen that?

A. Hm-mm, yes.
Q. And also I think you were sent a copy of the 1972 Wallace paper and the 1981 Barr paper, and also some hard copies, I think, just very recently, at the end of last week, perhaps, on the question of international guidance on donor selection?
A. That is true.
Q. Could I then, please, professor, turn to your statement. In paragraph 1 you explain that:

"Finland started testing blood donors for Australia antigen or HBsAg in 1970."

And you explain in paragraph 2 that:

"You commenced at the Finnish Red Cross Blood Transfusion Service in February 1975. The decision to stop blood collection in prison was made before that time ..."

So you have no personal recollections of the argumentation behind that decision but you explain:

"Something can be deduced from the documents available to [you] now and from interviews of some people working at the FRC BTS at that time."

Is that a reference to Dr Helske and Professor Koistinen?
A. Yes.
Q. You then explain in paragraph 3 that the then director

of the Finnish BTS, Professor Nevanlinna, wrote in 1955 a small textbook on blood transfusion intended for doctors, medical students and nurses.

In the fourth edition of the book, 1972, but the foreword signed in 1971, there are two pages on serum hepatitis. You quote a passage:

"In our country research is going on currently on the epidemiology of Australia antigen and serum hepatitis. The screening for Australia antigen must be regarded as a major step for the safety of blood transfusion therapy. On the other hand, only about one quarter or one third at the most of the carriers of the hepatitis virus can be identified."

Can you explain what is meant by that last sentence, please?

A. It is meant that when the screening started, it started with the so-called immunodiffusion method.

Q. Immunodiffusion method?

A. Yes. First we had the so-called immunodiffusion without this electroimmunodiffusion system, which already improved the sensitivity, but I think that he realises here that the sensitivity of this new test is far from being ideal and taking a precautionary stand that there are probably many other cases that are not found with this first insensitive test. And I think what he had in

mind which was not included in this little booklet, was that necessarily more sensitive tests were needed in order to get the better yield of positives.

Q. Thank you. Then in the next paragraph, paragraph 4, you explain that:

"In the early 1970s, the FRC BTS started a study on carriers of hepatitis virus."

Can you explain a little the background to that study, please?

A. I beg your pardon?

Q. I'm sorry. You explain that in the early 1970s the Finnish Red Cross Blood Transfusion Service started a study on carriers of hepatitis virus. Can you, please, explain a little the background to that study?

A. The background was the fact that at that time -- I think that the original background for this was the publication of Blumberg, who found this Australia antigen in the Australian population and his conclusion was that it must be a genetically determined property. And my predecessor, Professor Nevanlinna, was very interested in genetics and population genetics, so he read very carefully these new publications about the new genes and new population genetics and became very interested in this whole issue of Australia antigen. Then pretty soon Prince then was able to show that, no,

it was not genetical but it was related to hepatitis-associated virus. Therefore this opened up a totally new possibility to screen the blood donors to prevent some of the hepatitis that was quite well-known, that this is one of the complications of transfusion, which was not possible to totally avoid before. Therefore, he immediately became interested from the perspective of Blood Transfusion Service to see is this new marker really prevalent in Finnish population and how the general population would compare with our voluntary donors. How I see the reasons why this particular organisation started such a study.

Q. Thank you. You explain that the study resulted in a doctoral thesis in 1974 by Dr Helske entitled "Carriers of Hepatitis B antigen and transfusion hepatitis in Finland." which was published in the Scandinavian Journal of Haematology in 1974. At that time, professor, who was Dr Helske employed by?

A. He was employed by the Blood Transfusion Service. He had, as his routine task, to supervise and develop the test for hepatitis virus. So he was combining this rather small, routine task with this research that Professor Nevanlinna considered much more important than just sitting in the routine.

Q. And you explain in paragraph 4 that all together 315,000

blood donations were tested with an overall prevalence of 0.15 to 0.16 per cent Hepatitis B surface antigen positive, and the prevalence in prisoners was 0.721 per cent. So we can see about a five to six times higher prevalence in prison blood donors compared with non-prison donors. Is that correct?

A. That is correct.

Q. I think it may be helpful to now go to Dr Helske's work and that is [LIT0013562]. We can see on the first page the title and author of the study. Could we then, please, go to page 3568? This is original page 7 of the document and the title of this chapter is "An epidemiological study of Hepatitis B antigen in Finnish blood donors."

If we go to the right-hand column, please, about half way down the paragraph:

"There are some groups in which the HBAg carrier rate is many times higher than in normal populations. In countries with both paid and unpaid blood donors, the carrier rate among paid donors is 2 to 5 times high as among unpaid donors."

A reference to papers:

"The reason has been suggested to be that paid donors more commonly live in poor social and hygienic conditions. Which may be related to the prevalence of

HBAg carriers ..."

Again, a reference to certain international papers:

"... or come from certain groups in which the HBAg frequency is also high: drug addicts, 2 to 5 per cent ..."

A reference to papers:

"... prisoners, 0.7 to 1.7 per cent."

A reference to papers:

"... and prostitutes and patients attending venereal disease clinics, 1.4 to 3 per cent."

Again a reference to papers.

Really I think at this stage Dr Helske is looking at papers from around the world to identify groups in which there is reported to be a higher prevalence of Hepatitis B antigen compared to other parts of the population. Is that correct?

A. Yes.

Q. And if we could then, please, go to page 3571. There is a table, table 2. I think Dr Helske has now moved on to report the findings of his study among Finnish donors. Is that correct?

A. That is correct.

Q. This is originally page 10 of the document and one can see in the left-hand column the different donor populations and one can then see that two types of tests

were used. The next three columns relate to the findings based on the immunodiffusion testing, and then the final three columns relate to findings based on the CIEP method. Is that correct?

A. That is correct.

Q. One can see the last line of table 2, prisoners, and various findings set out there. So presumably, professor, is it clear from this that Finland was collecting blood from prisons at the time of Dr Helske's study?

A. I am not sure. I cannot reply to that.

Q. Yes. We may come back to that.

A. It is possible but it is also possible that they took separate samples.

Q. I understand. Then the next page, please, page 3572, originally page 11, in the left-hand column, half way down we can see the passage:

"Prisoners had the highest rate of prevalence, 1 per cent by ID and 0.7 per cent by CIEP. Compared to the rest of the donor population, the difference was statistically significant."

Then if we can, please, jump to page 53, which should be page 0.3614. In the summary at numbered paragraph 1, Dr Helske reports that:

"Screening tests of blood donors for HBAg were begun

in 1970 by the immunodiffusion method and continued since the spring of 1972 by the counterimmuno-electrophoresis method. The mean HBAg carrier prevalence was found to be 0.16 per cent. Slightly more carriers were encountered among young persons and the frequency was significantly above the mean in prisoners (0.9 per cent)."

I think, doctor, if one goes to the top of that page, it is stated:

"The study presented in this report was comprised of three parts:

"1. An epidemiological study of the occurrence of Hepatitis B antigen in blood donors in Finland.

"2. A study of the familial clustering of Hepatitis B infection in the families of HBAg carriers.

"3. A study of transfusion hepatitis and its relation to HBAg in Finland in light of the data available."

Does that suggest that prisoners fell within the first group, ie blood donors. Can one infer that?

A. That could be true.

Q. And if we could then, please, go to another page, page 3577, which is originally page 16 of the document, in the right-hand column, a few lines from the top, we see the subheading "Prevalence of HB antigen and

antibody and possible mechanisms of variation in different donor groups."

The author reports:

"The carrier rate of Hepatitis B antigen in this study among blood donors in Finland, ie 0.16 per cent, compares well with those in Scandinavian countries and the United States."

Then a few lines down, the author states:

"The high frequency of carriers among donors, (0.9 per cent) was consistent with the findings by other investigators. There is at present no satisfactory explanation for these differences between various population groups. Drug addiction has been suggested as one possibility since drug addicts are found most frequently among young adults. Illicit use of drugs no doubt accounts for a part of the acute cases of Hepatitis type B and consequently, for a few of chronic antigenemia with chronic hepatitis and together with tattooings, this might at least to some extent explain the high prevalence of carriers among prisoners."

THE CHAIRMAN: Before you leave that.

MR MACKENZIE: "The HBAg carrier state has been related to socio-economic and hygienic factors. A low socio-economic standard might favour the circulation and dissemination of Hepatitis B virus."

Can you explain, please, professor, how in 1974 it was thought that a low socio-economic standard might favour the circulation and dissemination of Hepatitis B virus?

A. The way of infection, whether Hepatitis B was really blood-borne or whether it would be more or less water-borne, like Hepatitis A, was, if I recall it correct, still unclear. Everybody would agree that at least blood could spread the disease, it needed blood contact, but people were uncertain about different other contacts, like physical contacts among family members, sweat and so on, whether that would be the cause of infection.

I think that because this was assumed earlier, before Hepatitis B really became known around 1969/1970, it was assumed that low socio-economic conditions, poor hygiene and so on, they were in general favouring different infectious diseases including hepatitis, and therefore I think that at that time many investigators took this assumption directly from older publications, without really going into the details of the spread itself.

Q. Thank you.

THE CHAIRMAN: Before you go on, Mr Mackenzie. At page 33, line 3, the transcript correctly shows that the word

read out was "donors". The word was "prisoners". I think that that might not be picked up in the ordinary correction routine, but it is the reference to the 0.9 per cent.

A. That is for prisons.

THE CHAIRMAN: Yes.

MR MACKENZIE: I'm grateful, sir, thank you.

Two final pages of this report, please, professor, page 3595, which is original page 34. This chapter is headed "Studies on transfusion hepatitis in Finland". I think this now forms part of the background knowledge of hepatitis. In the introduction Dr Helske states that:

"Hepatitis developing 16 to 180 days after transfusion of blood or a blood product is termed 'transfusion hepatitis'. The concept comprises mainly of viral hepatitis type B and hepatitis type A but included are also hepatitis produced by other viruses, cytomegalovirus, Epstein-Barr virus and possibly by other known or unknown viruses transmitted by means of transfusion."

If we can then go over the page, please, to page 3596, which is original page 35 of the document. In the left-hand column, about half way down Dr Helske stated that:

"According to the recommendation of WHO in 1973 the common forms of viral hepatitis are subdivided principally on epidemiological grounds, taking into consideration the presence of Hepatitis B antigen into viral hepatitis type A and viral hepatitis type B. Post transfusion mononucleosis due to cytomegalovirus may be encountered."

Et cetera. At the end of that paragraph:

"In some cases the Epstein-Barr virus may be the causative agent of post-transfusion mononucleosis."

Then:

"Quite often however, an aetiological diagnosis cannot be reached, although virus-like particles assumed to represent Hepatitis A virus have been demonstrated by immune electron microscopy (Feinstone et al, 1973) the method is still far from routine. Possibly there still are unrecognised viruses or other infectious agents that cause hepatitis."

We can put this paper to one side, thank you, professor. If we can then return to your statement, please. We can skip paragraph 5 because we have looked at the report already. Can we go to paragraph 6, please, professor. You state that:

"It is likely that it was decided in 1974 to stop the mobile collections in prisons as of beginning of

1975 based on the findings of Dr Helske. The main reason was to avoid transmission of Hepatitis B virus but it was considered that there might be other, unknown viruses as well."

To pause there, professor, you say that it is likely that it was decided in 1974 to stop the mobile collections in prisons. Does that suggest that Finland did collect blood from prisoners during this period?

A. I think that is correct. I don't know, but I could deduce it from this sentence, yes.

Q. And the second sentence in paragraph 6, where you state that:

"The main reason was to avoid transmission of Hepatitis B virus but it was considered that there might be other, unknown viruses as well."

What is the basis for that statement?

A. That is taken directly from the investigation of Dr Helske, where he listed the different possible viruses there that could possibly cause some jaundice and hepatitis. And there he lists also possible unknown viruses. This is my source of information.

Q. Yes. And as you explain, you have no first-hand knowledge of why Finland decided to stop collecting from prisons, assuming they had been collecting from prisons, but you did mention you had discussed matters with

Dr Helske, I think, as part of the preparation for this report. Did you discuss the question of collection in prisons and stopping collection in prisons with Dr Helske?

A. Yes, I discussed this matter with him and he said that he didn't remember when it was formally decided but he told me that when he showed his findings to Professor Nevanlinna, Professor Nevanlinna was, let's say, almost shocked, when he saw the difference between the prisoners and the donors in the general population. They had also thought that maybe also within army, where the conscripts would come voluntarily and in groups and so on, that was not a closed institution but not very far from that. They were a little bit afraid whether there would be a higher incidence of Hepatitis B also and they were quite relieved when they saw that it was 0.2 per cent, which was the same as from mobile units from the Helsinki larger area.

Dr Helske told me that after he had shown these results to Professor Nevanlinna, these were discussed by the senior staff and everybody agreed that, because of this high prevalence, it was probably much safer to stop the donations at prisons, especially because only a small proportion of the blood supply was coming from prisons.

If I may add here, I have the feeling that these results were discussed at the meeting of the Council of Europe expert committee in May 1974. I was not personally involved so I have been thinking of these connections, because in the same group there was Dr Maycock from the UK. He was representing the UK in that group. There were Dr Moore, Dr Freiesleben from Copenhagen, Dr Hogman from Stockholm who wrote this ISBT recommendation, including also avoidance of prisons as a source of blood.

So I think that this has been discussed at that time within a larger European group, especially because Dr Helske refers here to the finding being of similar magnitude as in other Scandinavian countries. And I'm quite sure that he refers to Sweden and Denmark and therefore these people were aware of the higher incidence of Hepatitis B antigen within prison inmates.

Q. Thank you, professor. We may come back to one or two points there shortly. But if I may simply continue with your statement at this stage, please, in paragraph 7 you explain:

"The head of the administration for Finnish penal institutions contacted the doctor responsible for blood directions (Dr, later Professor Jukka Koistinen) and demanded explanations for this policy change.

Professor Koistinen told me that the head understood it after having seen the prevalence figures."

Is that a reference, professor, to your discussion with Professor Koistinen when preparing this statement?

A. No, no. He discussed with Professor Koistinen in 1975 and then Professor Koistinen, if I recall it right, went to see this head of administration with all the data of Dr Helske and showed the difference between all other groups and then the prisoners, saying that these were really at risk of transmitting hepatitis. When I called Professor Koistinen, he said that he didn't remember whether that was over the telephone or whether he went there in person, but anyway, after these explanations he readily admitted that he was better to drop it out.

Q. Thank you. You explain that:

"However, afterwards, there were a few requests from the interior ministry to recommence blood donations."

You remember replying at least once during your tenure as director -- so that was some time after 1988 -- to the parliamentary commissioner when an inmate had complained about denial from blood donation and that your explanation was presumably satisfactory since you did not hear from the case since.

Professor, I would like to pause at this stage to look at two other documents from this period. The first

document is [SGH0046061]. Professor, this is a letter dated 6 January 1975 from Garrett Allen at Stanford University in California, sent to Dr Maycock of the blood products laboratory in England. Professor, had you seen this letter before being instructed by this Inquiry?

A. No.

Q. Were you in fact aware of Professor Garrett Allen before being instructed by this Inquiry?

A. No.

Q. I think you were then, though, sent a copy of the letter and you have had a chance to read it?

A. Yes.

Q. And can I, please, go down to the paragraph commencing about half way:

"The other imponderable ..."

What I will do, professor is read the paragraph and then ask you for any comment or view you have on this. So Professor Garrett Allen in 1975 says this:

"The other imponderable which has troubled most of us is the infectiveness in screening for the HB antigen. This failure, of course, dates back to at least 1971 and suggests that half, if not more, of the cases of post-transfusion hepatitis are caused by an agent other than Hepatitis A or B. Whatever this agent or agents

may be, it still seems to be more frequently encountered in the lower socio-economic groups of paid and prison donors. It is [the word might be] "normal" among volunteer donors. It seems that the most certain method we have for reducing the number of carrier donors at the present time is still to determine whether or not the donor has been paid in money or in reduction of his prison sentence."

Do you have any comments on that paragraph?

A. I think that it's very much in line with what we did in Finland. However, we were thinking at least at that time that these problems of prison conditions and drug addiction were quite different in America as compared to northern Europe and therefore we were not quite as anxious of these numbers as they were over there. However, I think that this statement here is very much in line with what was thought in our country.

THE CHAIRMAN: Can I interrupt just one moment. I'm a bit anxious that in the fifth last line the suggestion that it is "normal" among volunteer donors is something that ought to be checked, since the contrast would make more sense if it read "it is not normal". I don't know whether there is a hard copy available but I think that it could be potentially misleading if it reads "normal" rather than "not normal".

MR MACKENZIE: In short, sir, we have tried to obtain a complete copy but so far have been unsuccessful. I think what I'll do is read that sentence, or two sentences, again and put the word "blank" in where it is not entirely clear what the missing word is, simply for the record.

THE CHAIRMAN: I think the record is now probably clear enough that there is a problem, Mr Mackenzie, but I'm not personally inclined to read it as "normal" without verification of that.

MR MACKENZIE: Yes. I'm grateful, sir.

One point you mention, professor, was that the problem in the USA was considered to be quite different than that in northern Europe. Can you explain a little what you mean by that?

A. Well, there were a number of stories about the prison conditions in different parts of America. They were overcrowded and obviously there was -- at least we had the impression that drug use, illegal drug use, the use of intravenous drugs was much more common in those circumstances as compared to our countries, where most of the prisoners were simple thieves or that kind of people, who were not sentenced because of the same reasons as in a more violent atmosphere of America.

This is why we thought that, okay, the problem is

there, it might be also with us but certainly it would be much lower.

Q. Thank you. I propose then coming to another document from 1975, please, professor, and this is document [SGH0030187].

Professor, this is the letter dated 1 May 1975 by the chief medical officer for England and Wales, Dr Yellowlees, to all regional medical officers in England and Wales. The letter is headed "Blood donation and hepatitis". Professor, had you seen this letter before being instructed by the Inquiry?

A. Not before, no.

Q. I take it then, you weren't aware of its existence before being instructed by the Inquiry?

A. I received this letter with other documents from the Inquiry.

Q. I'm grateful.

A. But not seen that before.

Q. Thank you. But you have had a chance now to read it?

A. Yes.

Q. Under the heading "Blood donation and hepatitis," Dr Yellowlees explain that:

"The Department of Health and Social Security has recently received advice from a group of experts on the use of blood donations from certain categories of

donors."

If we look at the footnote at the bottom of the page, the group of experts comprised a subgroup of the advisory group on testing for Australia antigen. We know that that advisory group was led by Dr Maycock. The first page deals with geographical factors, the question of donors from certain areas. But then over the page, please, to page 2 under "Prisons", Dr Yellowlees states:

"There is a relatively high risk of Hepatitis B being transmitted by the blood of prisoners. But there is probably an equally high risk in other groups of the population, eg drug addicts, who are not so easily identified in advance as prisoners, if they can be identified at all. The advice we have received is that it is not necessary to discontinue the collection of blood at prisons and similar institutions provided all donations are subjected to one of the more sensitive tests referred to above."

Professor, part of the background to this letter, I should explain, is that in England and Wales, and in fact similarly in the West of Scotland, it had been found that prison donors had about a five times higher incidence of Hepatitis B antigen compared to non-prison male donors. Another part of the background, professor,

is that in the early 1970s in the UK Hepatitis B screening, like Finland, was commenced, using IEOP but then about 1975 the more sensitive RPHA and/or RIA were introduced. So that's all part of the background.

Reading, professor, the paragraph I have just read out, do you have any comment or views on that, based on what would have been known at the time? So the paragraph commencing:

"There was a relatively high risk of Hepatitis B ..."

A. To me, when I read this particular paragraph here on prisons, I agreed with the first sentence. I also agreed with the second sentence that there are various groups with high risks that are extremely difficult to identify. But somehow I don't see that this fact that we can't identify some risk groups would lead to the decision that one group that we can identify should not be excluded from the donor pool. This means that if there are a number of things that we can't do, that doesn't mean that if there is something that we can do, it should not be done. If that group can be clearly identified, as is stated here, the prisoners were a group with risk.

Q. That might be an appropriate time, sir, to take a short break.

THE CHAIRMAN: Yes, we will have a break.

(11.04 am)

(Short break)

(11.37 am)

MR MACKENZIE: Sir, before returning to Professor Leikola, reverting to Professor Garrett Allen's letter of 6 January 1975. We don't need to bring it up but the reference is [SGH0046061]. I'm grateful to Mr Di Rollo who advises that the word I speculated as "normal" is in fact "minimal" and I'll endeavour to provide the better source for that, sir.

THE CHAIRMAN: I'm not sure that we can improve on the source. If Mr Di Rollo tells us it is right, I'm perfectly content.

MR MACKENZIE: I'm grateful.

THE CHAIRMAN: I take it, Mr Di Rollo, that you do have a source and it is not just speculation.

MR DI ROLLO: I do have a source.

MR MACKENZIE: Professor, before the break we were looking at Dr Yellowlees's letter of 1 May 1975 and the question of the continued collection of blood in prisons and you offered certain comments on that. Professor, I think in short the justification for continuing with the practice at the time was that in England and Wales more sensitive tests to detect Hepatitis B, namely RPHA and/or RIA,

were either in use or were about to be introduced. Does that alter the views you expressed before the break at all?

A. If you would repeat your question.

Q. Yes, professor. Before the break you offered certain views on this letter and in short I think you said that, because it is not possible to identify all higher risk groups, it doesn't mean to say that you should avoid a known higher risk group which you can identify.

A. True.

Q. I think what Dr Yellowlees would say, if he were here, is that the important factor is that more sensitive screening tests for Hepatitis B were either in use or were about to be introduced. Does that factor alter the opinion you expressed before the break?

A. I think that the reasoning is more understandable but that doesn't change my opinion about the conclusion.

Q. So is your opinion that even with the introduction of more sensitive Hepatitis B screening tests around 1975, one should still have avoided a donor group which was known to carry a higher risk of Hepatitis B?

A. Yes, that is my opinion.

Q. Is this an area in which different experts could reasonably hold different views or do you consider that it simply would not be a reasonable view that collection

in prisons should continue?

A. I think that the meaning of introduction of a more sensitive test was interpreted differently by different experts and in some countries, notably in France, the donations in prisons continued and therefore I think that experts could interpret this differently. However, in the light, what was known at that time about Hepatitis B and possibly other viruses, I think this advice of, "Yes, go ahead with prison donations", was probably not correct.

THE CHAIRMAN: I wonder if I can be quite clear. It seems to me possibly there are two quite different issues that are in danger of running into one another. One is the reasoning in Dr Yellowlees's letter.

A. Yes.

THE CHAIRMAN: Which seems to run along the lines that in life we are constantly exposed to unknown risks, therefore there is little point in taking precautions against known risks.

A. Yes.

THE CHAIRMAN: There is a logical problem there.

A. Yes.

THE CHAIRMAN: The other issue is whether there was scope for differing professional opinion at the time as to the level and significance of risk associated with the

practice. Is it right to distinguish these two things?
A. These two things can be distinguished, yes.
THE CHAIRMAN: So far as the first is concerned, the purely logical point, have I rightly characterised your view?
A. Yes.
THE CHAIRMAN: So far as the second is concerned, I think what you have said is that in different countries, different views did prevail but you have got a particular view of your own as to the appropriateness of continuing to take from prisons? Or is that not the position?
A. I would refer to the practice in Finland, where we decided to stop that because the significance of prison donations as to the blood supply was not significant and therefore we decided to, so to say, play safe and therefore from our perspective this particular recommendation, "Yes, go ahead with prison donations", was not reasonable.
THE CHAIRMAN: Thank you.
MR MACKENZIE: Thank you, sir.
Professor, if I could leave that letter to one side now, please, and return to your statement to, paragraph 8, you state that:
"Information on international practice in 1970s and 1980s is difficult to obtain. To the best of my

knowledge, nothing was written on this aspect of donor selection in any international guidelines before 1983."

What do you mean, professor, by "this aspect of donor selection"?

A. This -- particularly donation in prisons.

Q. You go on:

"It may have been discussed unofficially outside the meetings but I do not remember having participated in any talks of that kind, save the French case."

To pause here, professor, I think, after writing your statement, you were subsequently sent by the Inquiry a 1976 document. Could we look at that, please? It is [DHF0012672].

This is the International Society of Blood Transfusion, "A guide to the criteria for the selection of blood donors", dated 1976. What is the significance, professor, of the word "Paris" on the front sheet of this document?

A. Headquarters of ISBT was situated in Paris at that time and I believe that refers to the printing place.

Q. Thank you. Professor, I think you did not have this document in mind when you prepared your statement for the Inquiry. Do you have any recollection of whether you saw this document at the time it was prepared or at any time in the late 1970s or early 1980s?

A. No, I have no recollection. I was not responsible for selection of donors and therefore even if I would have seen that in passing, I wouldn't have read it, probably.
Q. Thank you. If we can go on two pages, please, to 2674, we can see the publications committee B P L Moore from Canada, E Freiesleben from Denmark and C F Hogman from Sweden. I apologise for the pronunciation, professor. We also see that the original draft was submitted by B P L Moore in Canada. Do you have any knowledge of these individuals, professor?
A. Yes, I used to know all these people.
Q. How were they regarded in the transfusion community?
A. Especially, I would say, Dr Moore was very highly regarded because of his knowledge and common sense regarding approach to different problems. With Dr Freiesleben and Hogman, we did quite a bit of collaboration within the Scandinavian circles. So I knew personally these three people quite well.
Q. Thank you. If we go on four pages, please. Professor, I'm trying to work out the purpose for which this document was produced, who it was aimed at. We see on this page, original page 5, the heading "The non-remunerated blood donors: the essential element around which every blood transfusion service is shaped":
"None should join this select group whose blood may

transmit disease to his fellows or whose health may suffer as a result of his generosity. The necessary guidelines to ensure this state of affairs depend partly upon what infections are endemic and upon the average build and education of the population in the geographic area covered by the transfusion service and partly upon the resources available to interview and examine prospective donors."

So that's the introduction such as it is. Do you know, professor, or can you speculate in an informed way why this document was produced and who it was aimed at?

A. No, I don't.

Q. I see. Simply to complete this document, professor, if we can go, please, to page 2683, at paragraph 9 "Viral hepatitis", we have looked at at the Inquiry previously, professor, and there is a discussions of viral hepatitis and then the document continues:

"Prospective donors should be excluded if it is known that they ..."

Then over the page, page 2684:

"7. Are inmates of a correctional institution."

I think this is the only express international guidance the Inquiry is aware of, professor, on the question of collecting blood from prison donors. I take it you are not aware of any other international guidance

on this particular topic?
A. No.
Q. Separately, professor, there is the question of any guidance on collecting from donors with a higher prevalence of disease. Are you aware of any such guidance in the late 1970s or early 1980s, internationally?
A. I may have read them but, as I said, I was not directly involved in the selection of donors and then therefore I don't quite remember which ones I would have seen and which not.
Q. I'll take you to two documents shortly, professor, but what is the logic or reasoning for not collecting blood from donors with a higher prevalence of disease?
A. If these populations can be identified, it is, of course, one way of reducing the risk of transmission of the disease and there you have to consider the size of that particular group; how important that is as regards the total supply of blood and how high is the prevalence so that if this particular group is avoided, what would be the significance of that to the possibility to supply blood every time that is needed but the hospitals. So I can't say categorically that all groups that may have higher risk of infectious disease should immediately be precluded from giving blood but it is a consideration

between supply and the safety aspect of transfusion.

Q. Thank you. Sticking with the international guidance, could we look firstly, please, at [LIT0013272].

Professor, this is a report of a WHO meeting. The report is dated 1975 but if we go to page 3276, we can see in the top left-hand corner the actual meeting on viral hepatitis took place in Geneva in October 1974. If we can then, please, go to page 3298, the second last page of the document, original page 49, and if we look please at recommendation 7, the document states:

"There can be no categorical designation of high risk blood donor groups; the situation is likely to vary from country to country from time to time and within countries. Any subpopulation with specific characteristics shown to have a continuing carrier rate of HBsAg at least three times that of the total potential blood donor population may be considered for exclusion. However, such decisions should be made on a local basis with due regard to the needs and availability of blood."

So is that really consistent what you have just explained to us?

A. Yes, sir.

Q. If one were to apply that recommendation to Finland and the question of the collection of blood from prisoners,

then one would at least consider what is set out in recommendation 7, given that the prevalence of Hepatitis B among Finnish prison donors was a subpopulation shown to have a continuing carrier rate of HBsAg at least three times that of the total potential blood donor population.

A. Yes.

Q. Thank you. Finally on this point, please, professor, if I may then look at document [LIT0013627]. Professor, again, I take it you have no recollection of having seen this document at or around the time of its publication in 1978?

A. No, I have seen it only now.

Q. Yes, I see. For completeness, please, if we can then go to page 3632, and half way down, professor, the paragraph commencing "another important matter ..." we can see that:

"Another important matter was the requirements for the collection, processing and quality of human blood and blood products (see annex 1), and it was agreed that it would be most useful to have a single set of requirements applicable to all organisations and laboratories involved in the collection or fractionation of blood and blood products."

So that's the background to the guidelines. If one

then, please, goes to page 3651 -- we are now looking at the guidelines agreed at this WHO meeting -- under paragraph A5.3.2, "Infectious diseases", there is discussion of viral hepatitis. Over the page, please, professor, at page 3652, the very top paragraph. Professor, the guidelines distinguish between recommendations and a lesser category of guidance and what is said at the top of the page in indentation falls under guidance. What is stated is that:

"Donor populations showing a prevalence of acute or chronic hepatitis higher than that found in the general population should be avoided for collection. Both of single donor products, whole blood and its components and of plasma for pooling for the manufacture of plasma fractions known to be capable of transmitting hepatitis, such as clotting factor concentrates."

Applying that guidance to the situation in Finland, presumably Finnish prison blood donors would fall within the category: donor populations showing a prevalence of acute or chronic hepatitis higher than that found in the general population. Is that correct?

A. I think this is difficult to interpret because the prevalence of acute or chronic hepatitis is not necessarily synonymous with being a carrier of the virus. Therefore, I don't think that many people could

really define the populations showing high prevalence or just higher prevalence than general population of acute and chronic hepatitis.

Therefore, in my mind it should be related to those markers that can be shown and measured and not just saying that this population has higher prevalence of acute and chronic hepatitis. Beside, in this rather categorical recommendation it is not defined how much higher it should be.

For instance, if we go to the Finnish statistics, where Dr Helske was showing that in certain areas around Helsinki area, the prevalence was 0.2 whereas in the countryside it was only 0.1, if we would follow this categorically, all donors in the Helsinki area should be precluded, and therefore I don't think that this particular recommendation has been written by anybody who is, in practice, involved in blood collection or transfusion for that matter. The committee of biological standards was really comprising biologists and virologists and people involved in plasma fractionation. So I wouldn't pay very much attention to this particular recommendation.

Q. I understand, thank you.

Returning, please, professor, to your statement. In paragraph 9 you explain that Professor van Aken informed

you that blood collections by the Netherlands Red Cross Blood Transfusion Service never took place in prisons. Who is Professor van Aken?

A. Professor van Aken was the medical director of the CLB, which is the central laboratory of the netherlands Red Cross Blood Transfusion Service in Amsterdam. He was and he is a very prominent figure in the international circles of blood transfusion committees and different groups. He was the president of the International Society of Blood Transfusion and we have been working together with Professor van Aken for a number of years, and this is why I approached him in order to find out what was the situation in the Netherlands because before this Inquiry I had no idea whatsoever if they were collecting blood in prisons or not.

Q. And did Professor van Aken explain why the Netherlands Red Cross BTS didn't collect blood in prisons?

A. No explanations.

Q. Did you make any other investigations in respect of the practice in any other countries?

A. Well, I wrote to the Swiss Red Cross. I didn't get the answer before I filed my statement but their Professor Frey-Wettstein replied to me that in Switzerland, the Swiss Red Cross had never taken blood

from prisons. If they would have collected blood before his time -- I think he came to the service in the early 1970s -- at least during his tenure, no blood was collect from prisons in Switzerland.

Q. If we look, please, at document [WIT0030031], and is this, professor, a copy of an email from Dr Frey-Wettstein sent to you on 31 January this year. Is that correct?

A. That's correct.

Q. Which you then forwarded to the Inquiry and we can see Dr Frey-Wettstein states that:

"Dr Professor Leikola, your Inquiry about blood collection from prisons in the 1970s has been forwarded to me by the SRC ..."

Is that the Swiss Red Cross?

A. Yes.

Q. "... Blood Transfusion Service. I joined the Blood Transfusion Service in Zurich in 1969. My first task was to build up a mobile blood collections team in the greater Zurich area. We never collected blood from prisoners but in the early 1970s, we regularly visited a reform school for delinquent youngsters. This practice was soon dropped due to the new knowledge of the spread of TTD amongst this group of people."

TTD, is that a reference to transfusion-transmitted

diseases?

A. Yes.

Q. Although we are not told in this email when the practice was dropped.

A. No.

Q. So we don't know that. Then it goes on:

"I'm not sure if the ZLB ..."

Is that Zurich something blood?

A. ZLB was the Zentrallaboratorium. They had a similar system as in the Netherlands, where in Bern there was a large fractionation laboratory that had its own blood collection, mobile blood collection, in different parts of Switzerland; whereas the local centres, for instance in Zurich, they were confined to various cantons in Switzerland because it is a very federal state, and I had no contacts with the central laboratory. So this is all the information I have about them but I don't think that they went to prisons at that time but this is pure assumption.

Q. Yes. Did the ZLB collect blood both for transfusion of blood and its components and also for fractionation?

A. No, only for fractionation.

Q. Only for fractionation? I'm grateful.

Dr Frey-Wettstein states:

"I'm not sure if the ZLB collected blood in

penitentiaries. I only remember discussions about the risk of transfusing blood from prisoners at this time. If blood collection in penitentiaries had been practised at all, it certainly has been abandoned in the early 1970s."

So that is the recollection of Dr Frey-Wettstein. Can I take it, professor, that you have no first-hand knowledge of anything in this email; you rely entirely on what Dr Frey-Wettstein has told you?

A. Nothing more than this particular statement.

Q. I understand. If we could then, please, professor, return to your statement, paragraph 10, when you move on to France. In paragraph 10 you explain that in France:

"The tainted blood affair was much publicised in the media at the beginning of the 1990s."

You looked, I think, at the doctoral thesis by Caroline Bay, published in 1995, which contained a detailed description of what happened in France. I don't think we have to go into that in detail but is it correct, professor, that in France the transfusion service or services continued to collect blood in prisons at least the first half of the 1980s, up until perhaps 1985 and perhaps even beyond that?

A. Even beyond that. And what I was told and I have read was that there was tremendous pressure from the Ministry

of the Interior to continue that because it was included in their scheme for rehabilitation of the inmates when they were freed and entering society.

This is what I have been told and I just happen to have on my bookshelf this book, "Histoire de la Transfusion" because I have been interested in the history of blood transfusion. Sometime, maybe in 1999/2000, when I visited France I was given this thesis work saying that this describes most of the early history of transfusion, but then I found out that when it was published in 1995 these court proceedings were very actual and very much covered by the press and then therefore there is a very detailed description about the time schedule, what happened when and what kind of correspondence there was and so on.

Q. Yes. I think you explain, in paragraph 10, that in France prison collections accounted for a disproportionate number of HIV infections in transfusion recipients. That was what was found in France?

A. Yes, I think the whole proceeding was, of course, around HIV and not hepatitis.

Q. I understand. Then in paragraph 11 you explain that you:

"... remember having met Dr Michel Garretta, the

then director of the National Blood Transfusion Centre in Paris, several times in the late 1980s. The AIDS issue was much discussed."

You wondered why the French continued blood collections in prison when in Finland that had been stopped more than ten years earlier. And Dr Garretta said that he had turned to the Ministry of Health, urging the ministry to give guidelines precluding blood donations in prisons and according to Dr Garretta, the Minister of Interior had resisted such a change of policy and had let the Ministry of Health know his opinions. So again, that is perhaps second-hand knowledge which you received from Dr Garretta of the situation in France?

A. Yes.

Q. I'm grateful. In paragraph 12 you go on that:

"Until the Australia antigen or HBsAg was found to be associated with 'serumhepatitis', the main avoidable risks due to transfusion were thought to derive from blood group incompatibility, bacterial contamination of the blood vessel or transmission of syphilis. Transfusion hepatitis was seen as unavoidable albeit rare complication, mostly prevented by not using pooled, unheated blood and plasma products. After laboratory methods were developed to detect HBsAg it became soon

clear that part of the cases of transfusion hepatitis could be prevented by systematic screening of donors. After numerous epidemiological studies it was also clear that not all transfusion hepatitis transmissions could be avoided, either due to lack of sensitivity of HBsAg tests or existence of another virus or viruses. Examples of those studies have been discussed by Dr Helske (at pages 8 and 9)".

To pause there, professor, are you able to explain to us the developing knowledge of non-A non-B hepatitis in the 1970s or is that a question better asked of another witness, for example a hepatologist?

A. Well, as I explained here, before the Hepatitis B antigen was found, the main worries about transfusion safety were blood group compatibility and so on, and that was one of the reasons why I, who had been working with blood groups, was appointed as the head of the laboratory. So I had nothing to do with virology or transfusion safety matters.

I don't think we were, during the late 1970s, very much discussing the possibility of non-A non-B hepatitis. There was this category of other viruses, EBV, Epstein-Barr virus, cytomegalovirus and so on, but I don't think that before the publications, the two publications, Hogman TTD study from the United States

came where they clearly were speaking about non-A non-B hepatitis. I believe that was in 1981 but I'm not sure of the date -- we did not very much consider a category called non-A non-B hepatitis.

Q. During the 1970s, professor, I think there were a number of publications, in particular I think from North America, reporting on studies of post-transfusion hepatitis in patients. Perhaps I should just take you to some of these studies briefly, professor. If we could perhaps start with [LIT0010363], this is the 1974 Prince report. Is this paper familiar to you, professor?

A. I vaguely remember seeing that when I entered the transfusion service in 1975, but no clear picture.

Q. Yes. So this report by Dr Prince and colleagues published in the Lancet is the type of article that would have come to your attention when joining the transfusion service?

A. Probably if -- that would have appeared a year later. I don't know how much -- in the spring 1975, when I had so many other things to do with the congress that we were planning, I don't think that I would have read this very carefully through and I would have started thinking of its consequences as to our routine.

Q. Yes. Am I right in stating, professor, that this

article is an important article in looking at the developing knowledge of non-A non-B hepatitis?

A. Definitely, yes.

Q. Because we can see from the final sentence of the summary on page 1, that the authors concluded that:

"The data suggest that a large proportion of long incubation post-transfusion hepatitis is unrelated to Hepatitis B and control of post-transfusion hepatitis will require identification of a hepatitis virus or viruses, type C."

We can put that to one side, please. Could I then, professor, refer to [PEN0020836]. If we can scroll down the page, please, we can see in the bottom left-hand column this is a publication by Harvey Alter and colleagues from the National Institutes of Health in the Lancet in November 1975, entitled "Clinical and serological analysis of transfusion-associated hepatitis". Do you remember having seen this report before, professor?

A. I have probably seen this, yes.

Q. Is it really another example of another paper in the developing knowledge of non-A non-B hepatitis -- and again we can see this paper is from North America?

A. I think that all the papers by either Fred Prince or Harvey Alter were important when they appeared in

prestigious journals.

Q. I'm grateful. If we go to the right-hand column at the top, the final sentence of the summary, the authors report that:

"The existence of previously unrecognisable human hepatitis virus or viruses is probable."

I think we should then go to page 0839, where the authors expand upon that sentence a little. In the left-hand column, please, the bottom paragraph:

"Serological analysis of the eight cases of non-B hepatitis revealed no aetiological relationship to the cytomegalovirus or the Epstein-Barr virus. We had previously assumed that the major portion of transfusion-associated hepatitis unrelated to the Hepatitis B virus was due to the Hepatitis A virus but this was not substantiated in the present study. Application of both the IEM and immuno-adherence techniques demonstrated that none of these eight cases was serologically related to the Hepatitis A virus."

Four or five lines down:

"It thus appears that the Hepatitis A virus is rarely involved in the development of transfusion-associated hepatitis."

In the right-hand column towards the top, about six lines down:

"The strongest evidence that non-A non-B hepatitis is a transfusion related (and by reference virus related) event is the fact that it appears to occur with a defined incubation period and more important that, like type B hepatitis, it is considerably more common after the receipt of commercial blood than of voluntary donor blood. There is thus increasing suspicion that there exists one or more previously unrecognised human hepatitis viruses."

We can put that to one side. What I would like to do, professor, is refer you to two final American papers before then, asking you what was the view in Finland, for example, of these reports from America on this subject.

The second last paper, please, is [LIT0013657]. This is a report, professor, by Hoofnagle and others, "The transmission of non-A non-B hepatitis". It is published in July 1977 in the Annals of Internal Medicine. Do you recollect, professor, having seen this paper before?

A. I have definitely seen it.

Q. Yes. Did you see this at the time or as part of your assistance to the Inquiry?

A. I saw that at the time.

Q. I see. If one then goes, please, to page 3662. In the

left-hand column, about a third of the way from the bottom, the authors state:

"More and more evidence, however, indicates that non-A non-B hepatitis is due to a transmissible agent that is most likely a virus. Non-A non-B hepatitis is regularly associated with transfusion, accounting for at least half of post-transfusion hepatitis cases."

Then in the right-hand column, please, in the second paragraph:

"Several clinical and epidemiologic features of non-A non-B hepatitis have become clear from studies such as the present one."

I think four observations are then made, which I won't read, professor, because we have looked at them previously. Just to pause, professor, what do you consider was the status of the authors of this article and the authority of their research and conclusions?

A. That was a very convincing article. They were well-known investigators and I would say that most people working in this field would have seen this paper and also read it carefully through.

Q. Thank you. Finally, please, professor, document [LIT0010189]. This, professor, is an article by Berman, Harvey Alter and others, again from the National Institutes of Health in the USA. It was published

in July 1979 in the Annals of Internal Medicine and entitled "The chronic sequelae of non-A non-B hepatitis."

Do you recall having seen this article at the time, professor?

A. I have probably seen it. I don't remember it as clearly as the paper of Hoofnagle and others but I have probably seen this.

Q. Thank you. For completeness, please, page 0192, in the left-hand column at the bottom:

"Several interesting features of non-A non-B hepatitis and its relation to chronic liver disease derive from this study."

Then five observations are set out, which again I don't propose going through now, professor, because the Inquiry has looked at this before.

Thank you, professor, you can put that to one side as well. The question I would like to ask, if I may, professor, is: can you remember how these articles were received in Finland or in wider transfusion circles in the mid to late 1970s?

A. Well, I would say that after summer 1978, when I came back from my sabbatical year in America, when I was not involved in these cases at all -- but after that I think that it became clear in our minds that there is

definitely a virus, or maybe maximum two viruses, causing hepatitis that is like Hepatitis B and unlike Hepatitis A.

However, in those circumstances we also were feeling that, yes, it may cause a disease. It is mentioned in this article that in most cases the disease is mild and non-symptomatic and there were very little means to avoid that because we did not know any particular risk groups, even though it's clearly referred in this article that in most cases it is related to some parenteral contact with blood, either by tattooing, needle sharing or transfusion. But, yes, I would say that at that time, 1978, 1979, 1980, it became clear to us that such a disease exists.

Q. Thank you. Then returning to your statement, please. We are now at page 3, paragraph 13. You explain that:

"The blood donation sessions in prisons were advantageous in some respects."

You explain:

"For the donor organisers they were convenient since assistance was always found for various arrangements. The inmates came punctually when appointment times were given, and the wardens, like police force or military personnel, were known to be diligent blood donors. During holiday seasons these sessions could produce

a supplement to the blood supply. The moral side for the sentenced was that blood donation was one way of paying back to the society for their crimes or other misdeeds. The inmates were appreciated as human beings and voluntary, unpaid blood donations could be seen as a small step in the process of reintegration into the society outside prisons."

Again, presumably what is set out in that paragraph is not first-hand knowledge on your part because you weren't responsible for any prison sessions but rather it comes from what you have perhaps read on the subject?

A. These are just my philosophical considerations, yes.

Q. I understand. At paragraph 14 you say:

"On the other hand, it was conceivable that the donors might not be totally frank with their replies to the questions related to health matters or eg past use of intravenous drugs."

That of course depends on whether they were asked that question or not, "Have you ever used intravenous drugs?"

A. No, we did not.

Q. You didn't ask that question in Finland?

A. We took that question only in 1983, when AIDS came into the picture and we had the new recommendations.

Q. Yes. You go on to explain that:

"The peer pressure was and is known to be heavy under those circumstances. However, I believe many Europeans were thinking at the time that the drug problem is much smaller in European penal institutions as compared to the American ones."

When you state "at the time", what time period are you referring to?

A. I'm relating to the time between 1975 and 1983.

Q. Thank you:

"Most of the research on Hepatitis B was done in the United States. Therefore I think the investigators were readily willing to accept that the denial of using intravenous drugs was true. Secondly, in the 1970s it was well established that the occurrence of hepatitis virus was more common in prisoners as compared to the population at large. Wallace et al, 1972, assumed that the high incidence may be related to social habits and hygiene. This assumption was more or less copied to the later report by Barr and others in 1981. At the time when Wallace et al wrote their report, probably 1971, knowledge on the routes of infection was not as clear as it was later. Hepatitis A virus in contrast to Hepatitis B virus is water-borne and an infection could be related to poor hygiene. Other more realistic thoughts about the aetiology of Hepatitis B were

expressed by Dr Helske in 1973."

You refer to paragraph 5 of this statement. In that regard, if I could pause, professor, to look at the Wallace and Barr papers. The Wallace paper, please, is [SGH0029831]. I think, professor, you were sent a copy of this --

A. Yes.

Q. -- paper by the Inquiry?

A. That's true.

Q. Have you any recollection of having seen this paper before that?

A. No.

Q. In short, in this study in the West of Scotland it was found that prison donors had a higher prevalence of Hepatitis B antigen than non-prison male donors; the higher prevalence being approximately five times. Then if we go to the next page, please, the right-hand column, about half way down the page:

"The high incidence of Australia antigen of 1 in 153, 0.653 per cent in men prisoners has no obvious explanation. Viral hepatitis is not a serious clinical problem in the two institutions concerned and the positive donors are not drug addicts. What is not known is whether or not these men were Australia positive at the time of their first imprisonment. The high

incidence may be related to social habits and to hygiene."

Professor, if you had read that paragraph in 1972, what would have been your views on the postulated explanation for the higher prevalence of Hepatitis B in male prisoners?

A. Well, if the authors state here that the positive donors are not drug addicts, then I would have assumed that they have some way of controlling that and knowing that they are not drug addicts. We were a little bit concerned at that time that tattooing -- that was quite common in prisoners at that time. I was told already in the early 1960s that if you see a patient who has three blue spots here, that means that he is a real guy, he has spent some time in the prison.

Q. I think, professor, you referred to green and blue spots here?

A. Tattooing -- some little dots tattooed on the hand. So that these gangs should sort of recognise each other and therefore --

Q. Sorry, that was three blue spots on the hand?

A. On the hand, yes. But this is just a background for the fact that we were considering tattooing or needle piercing one of the risk factors within prisons and within prisoners and therefore, because Hepatitis B was

known to be transmitted by needle sharing and this type of poor hygiene for the tattooist, they were using the same needles, I would have thought that there was one way of confirming here that no drug addicts were indeed in the prisoners. Then I would have thought that, okay, it may well be so that it is related to social habits and to hygiene, whatever those social habits then are.

Q. What would you understand that last sentence to refer to:

"The high incidence may be related to social habits and to hygiene."

A. Social habits -- it is difficult for me to interpret that. Hygiene is, of course, means poor hygiene, whatever that means, I can't specify.

Q. Yes. And if you had read this article in 1972, would you have regarded the last sentence, that high incidence may be related to social habits and to hygiene, as a plausible explanation for the higher prevalence in male prisoners?

A. In 1972 I probably would have felt that it is a plausible explanation.

Q. Thank you. If I could then, please, look at the Barr article in 1981. The reference is [PEN0140068]. Again, I think, professor, you were sent a copy of this paper by the Inquiry but had not seen it before.

A. That is correct.
Q. I think fairly similar findings to the Wallace paper, that in male prison donors in the West of Scotland there was an approximately five times higher prevalence of Hepatitis B than compared with non-prison male donors. I think you have seen that from the paper?
A. Yes.
Q. And if we could then look at the second paragraph, please:

"The incidence of Hepatitis B surface antigen in our blood donors is shown in table 1. In over 10 years of total screening we have tested in excess of 1 million blood donations. Despite the high incidence of HBsAg in male prisoners, 1 in 145, viral hepatitis is not a serious clinical problem in the institutions surveyed, and the positive donors are not drug addicts. This high incidence is probably related to social habits and hygiene."

Professor, if you had read that paragraph in 1982, what reaction, if any, would that have caused in you?
A. Well, after seeing Dr Helske's article in 1975, and after having discussed this problem briefly, when the people from the prison administration approached Dr Koistinen, I think that these explanations brought forward by Dr Helske -- that was illegal use of

intravenous drugs, needle sharing and then tattooing -- were probably more plausible explanations than this one. And if I would have read this very carefully, I would have really questioned whether the explanation here is correct.

Q. You refer to Dr Helske's, I think, 1974 --

A. Yes, what I referred to -- 1975, when I came to the service and read that article.

Q. I see. That was my next question. So, yes, you read Dr Helske's 1974 report in 1975 when you came to the service?

A. Correct.

Q. The last sentence of this paragraph:

"This high incidence is probably related to social habits and hygiene."

If you had read that in 1982, do you think that was a possible explanation for the high incidence: social habits and hygiene?

A. I would have thought that it is possible but not probable.

Q. Why?

A. Because of our findings much earlier, that this is probably blood-borne and needs some piercing of skin, and therefore hygiene and social habits, which is a sort of very general statement, may not be all the

explanations for this high incidence.

Q. Thank you. Now, we can put that paper to one side again, professor, and return, please, to paragraph 16 of your statement, where you state:

"Taking into account the above considerations and the fact that the donations in Scottish prisons represented only a small fraction of the total blood supply, in my opinion it would have been reasonable to reconsider in Scotland in the latter part of the 1970s the policy of arranging blood donation sessions in penal institutions."

Professor, you say that it would have been reasonable to reconsider the policy of collecting blood in prisons. Do you consider that that policy ought to have been reconsidered at any point in the 1970s or early 1980s and, if so, when and why?

A. I think my feeling is that this matter should have been taken on the table and discussed in a logical way. Seeing what are the cons and pros of continuing this long practice goes long behind. However, the impression that I have received from reading these different documents that you sent me is that this matter was really not taken into serious consideration during the late 1970s up until 1981 and of course then 1983.

So my impression -- and this is just my impression

from reading these documents -- is that this tradition went on without really being seriously considered whether it should now be stopped because of various facts that had been published during the 1970s.

Q. If the matter had been considered, what do you consider ought to have been the conclusion at any time in the 1970s and the early 1980s?

A. In my opinion, that should have been stopped, not necessarily, you know, from one day on, but sort of faded away, so that it would not have caused very much publicity and the impression of not taking prisoners as human beings. But the conclusion would be that I think it would have been reasonable to stop this old practice.

Q. It would have been reasonable to stop it. Was it reasonable to continue the practice in the 1970s and early 1980s?

A. In these circumstances, where, if I'm not mistaken, it was not seriously discussed, then I think that it was reasonable to understand that it went on, even though in my opinion it should have been seriously discussed and then made the conclusion that, no, it's much better not to go to prisons.

Q. One final question, professor, before I leave this particular topic of prison collection. We know, professor, that studies, both in the UK and in Finland,

in the early 70s showed a higher prevalence of Hepatitis B among prisoners. We know that Hepatitis B was a blood-borne virus. We know in the later 1970s that we have seen the reports from America of the possible or likely existence of non-A non-B hepatitis and, while the agent or agents are unidentified, that also appears to be a blood-borne disease.

Does it follow, professor, given knowledge of the increased prevalence of Hepatitis B among prisoners, that one could reasonably have predicted in, say, the late 1970s that one might also expect an increased prevalence of non-A non-B hepatitis among prisoners?

A. At least in retrospect one would say that one could have seen this connection and drawn that kind of conclusion.

Q. Why?

A. Just because it appeared then, on the basis of the American studies, that the non-A non-B, at least in 1977/1978, is a blood-borne virus or viruses and very likely to be a virus. So if Hepatitis B is a blood-borne virus, then it is reasonable to think that the inmates would have also higher prevalence of this new, unknown virus.

Q. I don't --

A. Because the ways of acquiring the virus seemed to be quite similar.

Q. Yes. There is no suggestion of any studies in the late 1970s, I think/early 1980s of the prevalence of non-A non-B hepatitis among prisoners. Really, what we are talking about is a theoretical or paper exercise, and you said, I think, that in the late 1970s in retrospect one could, I think, have reasonably predicted that there might be an increased prevalence of non-A non-B hepatitis among prisoners. You said in retrospect, if one had asked oneself that question in the late 1970s, based on the available knowledge at the time, could one have reasonably predicted that there may well be an increased prevalence of non-A non-B hepatitis among prisoners?

A. Hm-mm, yes.

Q. Thank you, professor. That then, I think, deals with the question of prisons.

If we could then, please, revert to your statement to finish this off, in paragraph 17 you move on to a separate matter to do with accepting donors with a history of jaundice. You say in paragraph 17:

"Of the policy of acceptance of donors with a history of jaundice, I have no information except for Finland."

In paragraph 18 you explain that:

"In the third edition of Professor Nevanlinna's

textbook (1967) it is written: 'The incubation time (of serumhepatitis) is notably long, on average 70 days, from one month to even half a year, which of course makes the clarification of the aetiology more difficult.' Consequently, 'If the donor has been ill with infectious jaundice, his blood must not be given before at least three years have lapsed. The wording of the latter sentence remained unchanged in the 4th and 5th edition of the book (1972 and 1980) ... "

And you say:

"I do not know why the period of three years was selected as quarantine time. It might just reflect the prudent attitude of Professor Nevanlinna."

In paragraph 19:

"The donors were given a simple question: 'Have you or have you had jaundice (liver inflammation, hepatitis)?'"

You explain:

"[You] have not had access to documents of the time in question that would show the attitude towards other or unknown causes of past jaundice.

"[You] believe at least a history of having had jaundice as a baby did not preclude donation. [You] believe also that the donor would have been referred to a doctor if he had a history of jaundice of unknown

cause in adulthood. Depending on clinical evaluation, the donor may have been accepted or rejected for a period of three years or permanently."

In paragraph 20 you say that:

"On the basis of what was known at the time, in my opinion it was a reasonable policy to accept otherwise healthy individuals (after a quarantine time) but who gave a history of jaundice. In the past it was natural to think that the cause of jaundice would have been Hepatitis A since Hepatitis B would have been detected in the laboratory. However, once it became clear by the mid-1970s that after clinical Hepatitis B the patient may become a chronic carrier of the virus with HBsAg levels below detection limits and that there could be another hepatitis virus causing first jaundice and chronic carrier state without clinical symptoms, the policy could have been reconsidered. However, I think that precluding all donors giving a history of jaundice would not have had a major effect on the blood transfusion safety."

To pause there, professor, we know that in the UK, in both Scotland and England, from about 1975 donors with a history of jaundice were accepted as blood donors, provided the episode had occurred more than 12 months previously -- that's the one-year quarantine

period -- and also, of course, they had tested negative for Hepatitis B using an appropriately sensitive test.

Do you consider that was a reasonable policy?

A. We were asking only about so-called "infectious" jaundice, and I believe that our policy was similar to that, in Finland.

Q. I'm grateful. You also say, in the final paragraph of paragraph 20:

"Precluding all donors giving a history of jaundice would not have had a major effect on blood transfusion safety."

Can you explain why, please?

A. I think that the attitude towards transfusion safety is now quite different from what it was. Once again, these people with jaundice, some of them may have had subclinical disease and they could have been carriers of non-A non-B hepatitis and because the number of people who would state that they have had infectious jaundice would have been very small, I think that, taking into consideration what has happened since those times, it would have been reasonable to say that they are not entitled to give blood any more because that could have been an identified group with potential risk that would not have influenced too much the blood supply.

Q. Yes. Dealing with paragraph 20, the final sentence,

your conclusion that -- so this, professor, is with the benefit of hindsight. So in retrospect, even if a country had excluded all donors with a history of jaundice, I think your conclusion is that that would not have had a major effect on blood transfusion safety. Why is that? What are the reasons for that?

A. What we know about these diseases right now is that the vast majority of the carriers of either the Hepatitis B or Hepatitis C virus, they have not had any jaundiced phase in their disease. The vast majority is really subclinical and maybe not causing any symptoms at all. On the other hand, some people with acute infectious hepatitis, especially Hepatitis A, they recover completely from that jaundice and they are not hazardous to the blood transfusion matter. So in light of what we know now, I don't think that precluding people giving a history of jaundice would have very much influenced the final blood safety.

Q. I understand. Then, finally, in paragraph 21 you do say:

"On the basis of what we know now and after the much changed attitude toward blood transfusion safety and risks due to infectious agents, it would have been reasonable to decide that donors with a history of jaundice were not eligible for blood donation."

Why do you say that? What has changed?

A. Well, in my thinking I was thinking of a situation where a regular donor, who has given 60 times blood and so on, and this particular rule is introduced in the climate that was prevalent at that time, when transfusion safety was really not a big media issue and so on and if we would have introduced a total ban to all these people who had had jaundice in their childhood or whenever -- a regular donor, who would have given his blood 50 or 60 times, would have asked, "Have I done some harm before? I have given over a period of 15 years my blood and now all of a sudden you say that I'm dangerous and you have no proof of me being dangerous." Therefore, what I mean in this paragraph is that it could have produced quite a bit of resentment against the transfusion service, with the untoward effects then on donor recruitment.

Q. Professor, finally, my last question. In the first sentence of paragraph 21 you talk about the much changed attitude toward blood transfusion safety and risks due to infectious agents. Is that a change which happened gradually over time or is that a change as a result of a single event or issue or what?

A. It started with the shock in 1983 when it was recognised that AIDS, a new disease, could be transmitted by blood.

Then I think that it gradually grew over the years. We had mad cow disease and avian flu and so on and, because this came very much into the press and the media was full of the risks of transfusion, therefore I think that the attitude also within professionals changed quite a bit. It was not acceptable any more to have a certain very low degree of complications that was coming as a natural thing, like after major surgery you have to accept that sometimes there are complications. Now this was not acceptable as far as blood transfusion was concerned and therefore the attitude was quite different after, let's say, the 1980s.

Q. Thank you. Thank you, professor. I have no further questions, sir.

THE CHAIRMAN: After lunch, gentlemen.

(1.01 pm)

(The short adjournment)

(2.00 pm)

THE CHAIRMAN: Professor, I would like to get an impression of changing professional attitudes over three particular dates: 1977/78, when you were in San Francisco, 1981 when the MMWR announced the first five cases of what became known as AIDS and 1983, when the impact on the wider patient population began to be felt.

When you were in San Francisco in 1977/78, what was

the preoccupation? What were people in your field interested in?

A. Well, I was personally working in the cellar of the blood bank in San Francisco and there were very few news about the possible Acquired Immunodeficiency Syndrome going down to our little research room, and I don't think that I would have been really mentally aware of this kind of new disease coming into existence. There were many different diseases and from my personal recollection, I do not think that before summer 1978 when I came back to Finland, I would have been really aware of this kind of new disease.

As to your second question, in 1981, if I recall it right, we were quite interested in this now new disease because of its possible links to the haemophilia patient in California. And if I recall it right, there were three risk groups and one was Haitian --

THE CHAIRMAN: Immigrants from Haiti?

A. Yes, Haitian people moving to the United States. Secondly was promiscuous male homosexuals and thirdly were users of intravenous drugs. And then we thought in Finland at that time that, well, we don't have anybody that we would know who would come from Haiti. So that was sort of cleared. Secondly, these two other risk groups we were thinking that, okay, let's see what

happens in the United States. It is interesting to follow what is going on there but this is not really something that concerns our conditions in the north.

In 1983 I organised a meeting when I had moved to Geneva for the League of Red Cross Societies in 1982. In that capacity I arranged a meeting in Washington with Dr Barker, who had become the head of the American Red Cross blood programme and there he explained to us the situation in the United States and then it became quite clear to me that this is a new hazard for blood transfusion, and it cannot be confined to North America but it is certainly coming also to Europe.

In my international capacity, I felt that I have to give this message to my colleagues internationally also and since we had then in May this Council of Europe expert group meeting that I referred to already earlier, I took this matter up and said that we must do something about this before it really spreads over Europe, that it is certainly coming and therefore we made some recommendations how to possibly avoid this kind of disease, and thirdly, I then wrote to my little newsletter also a story about this and then repeated these recommendations that we had given at the Council of Europe.

So this recognition that it is not something that is

confined to the United States in certain -- I would call suspicious circles, but it was really something that was spreading and we had to do something about that also in Europe.

THE CHAIRMAN: Thank you very much. So even though you had been in San Francisco in 1977/1978, the 1981 announcement didn't really catch your attention at that stage as being relevant to Europe; it was 1983 --

A. Not relevant to European transfusion services.

THE CHAIRMAN: To transfusion services, yes.

Thank you very much.

Mr Di Rollo?

Questions by MR DI ROLLO

MR DI ROLLO: Professor, obviously from the evidence that you have given us this morning in relation to the decision in Finland as to whether or not to collect blood from prisoners, that decision you have told us was taken before 1975 and you, I think, have also described in the material in your statement and in your evidence that there was one director who had a clear responsibility for decision-making, and I think you have also indicated that the decision was taken apparently purely on medical grounds; it was for medical considerations. No other considerations came into play. Is that all correct?

A. That is all correct, yes.
Q. One thing I think is fairly obvious from your evidence also is that the decision seems to have been taken without any regard to the existence of non-A non-B hepatitis. Is that also correct? Is that too simplistic a view --
A. I think that's correct, yes.
Q. You do think that is correct?
A. Yes.
Q. One thing I would like you to comment on is that there is evidence that has been given from witnesses and material before the Inquiry, I think, which is to the effect that one possible reason for not doing anything about donations from prisons is the fact that it was felt that non-A non-B hepatitis was perhaps a benign condition, or a relatively benign condition. Obviously that consideration didn't come into play in the decision-making that took place in Finland. Is that correct?
A. Well, there were two factors behind the decision in Finland. First of all, it was realised that not all Hepatitis B cases were recognised by this test, that a good part of the people that were screened were negative with the new test but still were carrying the Hepatitis B virus and that was known that it was

a serious disease.

In addition to that, then was the possibility other viruses existing and probable existence of other viruses. So if we would avoid transfusing Hepatitis B, that was not detectable by those tests that were used at that time, then an additional factor was that we would also avoid those viruses that presumably were also within prisoners.

Q. And those other viruses were relatively benign or not didn't play a part in the decision-making process?

A. I think it took part in that we did consider that they were relatively benign and not always causing serious disease with jaundice and cirrhosis later on. Yes.

Q. So notwithstanding the fact that these other viruses were relatively benign, it was still felt inappropriate to take blood from prisoners?

A. Yes.

Q. I see. So does it follow from that that it would be not really reasonable to allow that consideration, ie the perception of the benignness or otherwise of non-A non-B hepatitis or other viruses, that that shouldn't really play a part in any decision-making that takes place? Do you understand my question?

A. I think I understand that. Well, it very much depends then on the relationship between its influence to the

blood supply and the relative risk, how it was seen at that time, whether it really is worth stopping going to those populations, to the penal institutions.

I think that at that time it was still mentally acceptable to have something that is a benign consequence of blood transfusion in the 1970s up until the era of AIDS. The aim was not to eliminate all risks of blood transfusion but the reasonable number of risks at that time.

Q. So --

A. I don't know if this answers your question.

Q. What I'm trying to understand is whether or not the understanding of the consequences as being benign or not is a material consideration in taking the decision at this time.

A. I think that it influenced, in the background, the decision. However, the main emphasis was really prevention of Hepatitis B at that time and therefore it is very difficult for me to say now, 35 years after that period, what was our impression of non-A non-B hepatitis at that time, whether or not that could possibly be prevented if that played a very crucial role in that type of decision or not.

Q. Right. So --

A. But once it became clear that it is a blood-borne virus

and so on, and as was shown in the late 1970s, that indeed it does cause disease and this disease is not necessarily mild, then I think that in a case where there is a possibility to prevent that, even if the measure is not very effective but still if that is possible, then I think it should have been done.

Q. Right. You are saying that would apply to the late 1970s?

A. That applies to the late 1970s, yes.

Q. I understand.

Thank you, sir, that's all I want to ask.

THE CHAIRMAN: Mr Anderson?

Questions by MR ANDERSON

MR ANDERSON: I'm obliged sir.

Good afternoon. Can we discuss the Council of Europe reports. I think you were the lead author in relation to one of those. Is that correct?

A. You mean how this group worked or -- I didn't quite understand your question. What this Council of Europe?

Q. Am I right in thinking that there were three reports, one in 1980 dealing with self-sufficiency, one in 1981 dealing with the care of haemophiliacs and one in 1983 dealing with AIDS. Is that correct?

A. Yes.

Q. I think we know from your third statement, which we

haven't in fact looked at today, that in relation to the third of those reports in 1983, you tell us that there was a small drafting group, including yourself, who made recommendations for the member states of the Council of Europe. Is that right?

A. Yes.

Q. Right. In relation to the first two reports -- that is to say 1980 and 1981 -- would I be right in thinking that they made reference to hepatitis and to high risk populations but did not make any reference to the question of donations from prisoners?

A. That is very difficult for me to remember, since I became a member of that group only in 1982 when I moved to Geneva and became an official observer to that group. So those reports that were given before 1982 I was not personally involved in, and I must say that I was not particularly interested in those thick reports and therefore it is very difficult for me to comment on that.

Q. All right. I can well understand that but perhaps if I simply suggested to you that my information is that those two reports in 1980 and 1981 did deal with hepatitis with high risk populations but made no mention of donations from prisoners, you wouldn't be in a position to deny that?

A. That sounds very reasonable to me.
Q. All right. Turning to 1983, which of course you are far more familiar with, that, we remind ourselves, really dealt with the question of AIDS. Is that correct?
A. Yes.
Q. Which, as you have just confirmed in answer to the chairman's question, was something that's becoming of very real concern in Europe in 1983. Is that right?
A. Yes.
Q. And am I right in thinking, with the caveat that we are dealing of course with AIDS in that paper, that that recommendation paper listed various high risk groups? Is that correct?
A. That is true.
Q. And am I right in thinking that that again didn't make any mention of prisoners?
A. No.
Q. Just to be clear, when you say "no", are you agreeing with me? Is that right?
A. That's right.
Q. I'm obliged to you, thank you.
THE CHAIRMAN: If the question was very clear, I'm sure the professor would have no difficulty.
MR ANDERSON: Oh well, I thought it was clear enough but there we are.

The ISBT Paris 1976 document that we looked at this morning -- do you remember that? -- can I just understand this: how should one weigh the significance and effect of the guidelines within the ISBT publication as opposed to recommendations that may or may not be within the Council of Europe documents?

A. Well, I think that the big difference was that ISBT was international and many of these recommendations were directed towards developing countries and trying to help, let's say, developing transfusion services with guidelines on how to establish a transfusion service and how to go ahead, whereas the Council of Europe group was clearly from industrialised western European countries with developed transfusion services, and it was understood within the groups that these recommendations are recommendations and they should be interpreted against the national circumstances where each and every member was active, and therefore the interpretation of those different recommendations would have been different in different countries and even in different transfusion services in western Europe.

Q. I'm obliged to you.

I mean, are you aware, professor, of any published guidance during the 1970s and 1980s in Europe from any governmental advisory committee, or statutory or

regulatory body, on the question of prison donations?
A. No.
Q. Would I be right in thinking that the first clear and unequivocal guidance from any regulatory body, anywhere in the world, was that which emanated from the FDA in 1995 on the question of prison donations?
A. That was probably the first binding regulation, yes. Of course, the Council of Europe recommendation came from the committee of ministers. So it carried some official weight but it was still a recommendation and not mandatory rule.
Q. I understand. Can we look together, professor, at your second statement. That's [WIT0030027]. In particular at paragraph 15. I would like to discuss this with you if I may. We should see that on the screen.
A. Yes, I have it here.
Q. You say there:

"Secondly in the 1970s it was well established that the occurrence of hepatitis virus was more common in prisoners as compared to the population at large."

You pray in aid the Wallace paper, the Barr paper. Now, as I understand it, professor, you yourself were unaware of the Wallace paper and the Barr paper until being invited to give evidence before this Inquiry. I think I'm right in saying you were unaware of the

minutes of the World Health Organisation in October 1974 we looked at this morning, and the World Health Organisation expert committee in 1978. You told us that you weren't aware of what the position was in relation to donations from prisoners in either Switzerland or the Netherlands. So I'm just wondering on what basis you say it was well established. Do you essentially depend on Dr Helske's paper for this view?

A. Pretty much so, yes. He refers to a number of studies.

Q. All right. That, I think, we see was published in the Scandinavian Journal of Haematology. Is that correct?

A. Hm-mm.

Q. I can understand that you may not but do you know if that is a journal that is well-known in the United Kingdom?

A. It should be within the haematologists.

Q. You say you weren't aware of the Wallace article which was published in the British Medical Journal, which, perhaps, because it is one that I'm familiar with, I thought would be one of quite high standing and well renowned in the world. Is that right?

A. Hm-mm.

Q. I just wonder why you think that those in Scotland in particular, and in Britain in general, should be aware of an article in a Scandinavian Journal of Haematology

if these other articles, for example, are unknown to you?

A. First of all it was a supplement to the Scandinavian Journal of Haematology. So it was not a regular issue, this thesis work, and it is very natural that these supplements would not be followed as keenly as the regular issues with the regular scientific articles.

As to the question why in Scotland that would have gone unnoticed as you referred to, I have no comments. But I believe that the British haematologists were following also that journal because in Scandinavia the level of haematology was considered to be rather high.

Q. All right. It is just that -- and I appreciate this is a matter that you are really unable to comment upon -- we haven't heard of this article previously in this Inquiry and we have had a number of those in the witness box, as it were, and this is the first reference to it.

All right. Can we go on then to paragraph 16, the next paragraph. You say:

"Taking into account the above considerations and the fact that the donations in Scottish prisons represented only a small fraction of the total blood supply, in my opinion it would have been reasonable to reconsider in Scotland in the latter part of the 1970s the policy of arranging blood donation sessions in penal

institutions."

Standing the state of knowledge in the 1970s, professor, about Hepatitis B, and if we remind ourselves that the Wallace paper, for example, talked of viral hepatitis not being a serious clinical problem in the two prisons concerned and the thought that it was mild and asymptomatic, I just wonder, professor, if, with the greatest of respect, this opinion you voice now is not one that is tainted with the benefit of hindsight. Is that not possible?

A. Well, what I'm trying to say here is that at the time when this Wallace paper was published, the question of donation in prisons was not generally discussed at all; you know, it went on and on since the 1950s and 1940s. However, it seems to me, especially now that I have had the opportunity to look at the papers from 1975, there was discussion in the 1970s -- especially in 1975 -- as to the avoidance of certain risk groups, including also prisons. And therefore I think, as I say here, that reconsideration of this matter in the late 1970s would have been -- the latter part of the 1970s -- would have been reasonable and if all the arguments and all the papers, including Dr Helske's, would have taken to the table and then discussed and on the basis of that then decided that, no, there is no danger in prisoners and so

on, I think that would have been different and I would have said that this decision is wrong.

However, I have the impression that this question of whether or not to go to prisons never was taken up as a serious matter to be discussed and to be judged according to the data available at that time.

Q. If you are right in the inference that you draw that it simply wasn't discussed, is it possible, do you think, professor, that the reason it was not discussed is because there was not any perceived problem because of the knowledge then current about Hepatitis B?

A. When you say "perceived problem", I would agree with you and this just shows that it didn't come up -- nobody really raised the question -- this is my impression -- as much as to put on the table and to discuss it very seriously. So I would agree with you that the problem of whether or not going to prisons was not perceived to be a very serious question.

Q. You referred at the beginning of your previous answer, I think, professor, to discussions in 1975. Were those the discussions you referred to this morning, which involved Dr Maycock?

A. Hm-mm.

Q. And I think you have been shown the letter from Dr Yellowlees, the chief medical officer. Do you

remember that? Which understandably I think you hadn't seen until you were invited to give evidence before this Inquiry. That letter we saw started by saying that the department has recently received advice from a group of experts. I think we know that that group of experts included Dr Maycock. Is that right?

A. Yes.

Q. So notwithstanding whatever the discussions were in 1975, the advice that appears to be being disseminated by the British Government in May 1975 was that it was not necessary to discontinue the collection of blood at prisons. Do you see that?

A. Yes.

Q. I understand your position is that you don't perhaps see the logic of it, but there we have it in any event. Is that right?

A. Well, I think that it shows that if somebody within the profession would have taken this matter up, the rest, who would prefer keeping the routine on, would then refer to that particular letter and saying that, "No, it is not a problem".

Q. There were reasons for and against, though, weren't there?

A. Hm-mm, that's right.

Q. I think what you are saying is it was a matter for

discussion?

A. Hm-mm.

Q. The way you put it is weighing the pros against the cons. Is that right?

Professor, thank you very much.

THE CHAIRMAN: Mr Sheldon?

Questions by MR SHELDON

MR SHELDON: Just to confirm one thing with you. Dr Maycock I think you said was present in the discussions prior to 1975 about Hepatitis B and hepatitis testing, is that right, and I think you refer to Council of Europe discussions?

A. He was representing the United Kingdom at that group and therefore I believe he was in those discussions.

Q. Yes, what was Dr Maycock's perceived status at that time in terms of his expertise?

A. I think he was very highly regarded, as was the whole UK system, Scotland, England and Wales. With the high degree of donation rate and also the all voluntary non-remunerated donor base, and I never met personally Dr Maycock but I understand that he was quite highly regarded, although some people have said that he was quite a stubborn person, but this is third or fourth hearing, but in general these people who were attending these meetings, especially those who were active in the

meetings -- there was a number of people who wouldn't say a word but then those who were active, they were quite aware of their position and they didn't hesitate to bring this forward and also many were saying that in my country the conditions are a little different so we interpret this differently.

Q. Thank you very much.

THE CHAIRMAN: Professor, thank you very much indeed. I hope you get your plane.

A. Thank you.

THE CHAIRMAN: I was tempted to ask how many stubborn people there were around the table at these meetings but I thought it was unwise to follow it.

MR MACKENZIE: Sir, there are no further witnesses today but if I could perhaps just spend two minutes tidying up one or two loose ends on this topic C1 before we leave it.

Sir, there are three witness statements which I should perhaps tender to you so they form part of the record, albeit it will be a matter for you, sir, of what weight to place, if any, on the content of the statements, given that the evidence will be untested.

Firstly Dr Brookes, who was the regional director in Dundee, is unable to attend but has provided a helpful statement, [WIT0030057]. Secondly, sir, Dr Ian MacDonald, who was a former deputy and then chief

medical officer in Scotland, has provided a statement, [WIT0030023]. But in short his evidence is not particularly relevant to this topic for reasons that are clear when one looks at the statement. It wasn't his responsibility, essentially, blood. So I have not called him to attend. Also Mr John Wastle was a senior executive officer in SSHD, I think, with some responsibility for blood matters for about one and a half years. His statement is [PEN0100316]. Again, I haven't called him, sir, given his evidence is very much by way of background.

In addition Dr Archibald McIntyre with SHHD has provided a helpful statement, [WIT0030013]. Investigations are ongoing as to whether Dr McIntyre is able to attend or not at a later date. So his statement is there if he is not able to attend. If he is able to attend, I think we will perhaps ask him to come along.

Dr Mitchell, who did come along, sir, I didn't go through his CV but I should refer to it. It is WIT0030413. Then Dr Dow, of course, is to return at a later block to complete his C1 evidence. I think the only two further matters, sir, under this topic are firstly, I have previously indicated I will produce a short note in conjunction with the SNBTS identifying the various different guidance documents on donor

selection, the manufacture of blood products and the use of blood and blood products; and I will do that, sir.

Then one final matter is a line of investigation which the Inquiry will seek to raise with the Scottish Government and that concerns, sir, the matter you had raised, namely who in the SHHD had responsibility for the health of prisoners, and hopefully we can obtain some information on the prison medical service and what might have been known by them at the relevant time.

That, sir, then completes the C1 topic and we are back tomorrow on the question of statistics with Professor Ludlum and Dr Tait.

THE CHAIRMAN: It did occur to me, thinking about things, that the prison inspectorate which we know has been very active in recent times might have existed for some considerable time and I don't know whether there is any material in the annual reports of the inspector that might help.

MR MACKENZIE: I will check that, sir.

THE CHAIRMAN: You will check that.

Mr Di Rollo, Mr Anderson, Mr Sheldon, the statements that have been tabled and not spoken to are statements that I would probably treat as valuable for what they contained unless you were to draw to my attention any

particular areas that were actually or potentially controversial. I have not read them. So I can't help you with that exercise at the moment. But I think it would be very helpful if you would let Mr Mackenzie know of any particular points on which you take issue so that they can be addressed as best possible.

MR DI ROLLO: Very good.

MR ANDERSON: I'm obliged.

MR MACKENZIE: That's it for today, sir.

THE CHAIRMAN: Thank you very much.

(2.42 pm)

(The Inquiry adjourned until 9.30 am the following day)