Thursday, 17 March 2011

(9.30 am)

MS DUNLOP: The first witness today, sir, is Professor Marc Turner.

PROFESSOR MARC TURNER (sworn)

Questions by MS DUNLOP

MS DUNLOP: Good morning, Professor Turner.

A. Good morning.

Q. We have a statement from you and we are going to look at that and ask you some questions about it but before doing so, I would like to look at your curriculum vitae. Which is PEN0100116. That should appear on the screen in front of you.

Professor, you are here in your capacity as, is it medical director of the SNBTS, Scottish National Blood Transfusion Service?

A. Yes, that's correct.

Q. I was just slightly thrown because I saw the words "associate medical director"?

A. I was only appointed as medical director in December and I started at the beginning of January this year.

Q. I think that possibly isn't recorded in your CV?

A. It isn't, I apologise.

Q. Not at all. It is just to clarify that that was the position. Can we look, please, at the first page in,

which is PEN0100117. It gives us a bit of basic biography and some outline of your education. Then if you go down the page, your qualifications. We see that you studied your undergraduate medical qualification in Manchester and then you came up to study in Edinburgh. Is that correct?

A. Yes. Between those two points I qualified in about 1983 and I did what were then junior house officer jobs and general medical training around Manchester and then in Derby Royal Infirmary. I came to Edinburgh in around 1987 to undertake higher specialist training in haematology.

Q. I notice from your list of qualifications that the fourth one is certificate in transfusion medicine. And that you have also completed specialist training as a haematologist?

A. Yes.

Q. I wonder if you could just give a bit of a description of the difference between haematology and transfusion medicine and where one stops and the other begins, if you like.

A. In the UK transfusion medicine is thought of and treated as a subspeciality of haematology. Haematology, as you know, is the study of blood overall. There are various subspecialities, for example, haematological

oncology, so the treatment of leukaemias and lymphomas, coagulation and haemophilia and transfusion medicine.

So it is those who have gone through higher specialism training in haematology will have spent some time, usually three to six months, also training in transfusion medicine.

THE CHAIRMAN: I think I'm again hearing the professor naturally rather than through the system.

A. I apologise.

THE CHAIRMAN: It won't be your doing, professor. It is just that this system is sensitive at both ends of the spectrum.

A. I'll sit closer.

MS DUNLOP: Taking it from the point where you were saying that transfusion medicine is a subset of haematology.

A. In this country now it is looked at as a subspeciality of haematology and during higher specialist training one would expect a haematologist to study in haematological oncology, coagulation medicine, some paediatric haematology and transfusion medicine.

In fact, during my training, because of the timing of my training and there was some changeover in the training structure, I spent two years from 1995 to 1997 as a senior registrar specialising in transfusion medicine. So specialising in that subset of

haematology.

Q. Right. What would be the day-to-day role of a specialist in transfusion medicine? Would you find specialists in transfusion medicine in the Royal Infirmary, for example?

A. We do have specialists in transfusion medicine in the Royal Infirmary but that is because the blood bank in the Royal Infirmary is managed directly by SNBTS, as it is in four of our other centres. In general hospitals, district general hospitals, the blood banks will normally be managed by somebody with a general qualification in haematology, who would have other duties obviously within the hospital.

Q. Right. But it is not the case that, for example, a surgeon with a patient thinks this patient may need a transfusion and summons a specialist in transfusion medicine?

A. No.

Q. The clinician makes the decision?

A. The clinician would make the decision on the ground and order the blood from the blood bank, and the role of the transfusion specialist or the haematologist with an interest in transfusion is more over a general professional management of the hospital blood bank and in haematology, giving advice on difficult cases, either

difficult serological cases -- difficult matching cases -- or difficult clinical cases.

Q. Just looking further on in your CV, can we turn to PEN0100118, please. You explain for us, both your general medical training and your higher specialist training. If we look towards the bottom of the page, we can see that you were a registrar in haematology in the Royal Infirmary and the Royal Hospital for Sick Children. Is that a rotation?

A. Yes, it was a rotation at the time, yes.

Q. Right. You progressed and became a senior registrar in transfusion medicine within Edinburgh and Southeast Scotland Blood Transfusion Service. From the next page, PEN0100119, you say that:

"Since April 1997 [you] have held or continue to hold the following positions."

Quite a number of positions, Professor Turner. You are professor of cellular therapy?

A. I am now, yes.

Q. Is that what lay people would think of as stem cell therapy or is it beyond that?

A. It would certainly encompass stem cell therapy but it goes a little beyond that, yes.

Q. What sort of things are encompassed within the term "cellular therapy"?

A. It would include hematopoietic stem cell, or what you would think of as a bone marrow transplantation. That's a cellular product. It includes among the newer therapies that we are developing, things like pancreatic islet transplantation, for example. The first pancreatic islet transplant in Scotland was carried out a few weeks ago here in Edinburgh.

Q. Is that for diabetes?

A. Yes, for specific groups of patients with diabetes and unstable diabetes and hypoglycaemic unawareness. It includes some therapies where we administer white cells, lymphocytes, to patients with certain kinds of infections. As you say, it includes the developing field of broader stem cell therapies and regenerative medicine, as an academic appointment. It's a forward-looking appointment.

Q. You have a number of managerial positions. You show that you are the clinical director of Edinburgh Blood Transfusion Centre and the clinical director of Aberdeen Blood Transfusion Centre. Is that out of date given the change of position in December?

A. It should be out of date and once I find a colleague to replace me, it will be out of date, yes.

Q. Right. It can't have been particularly easy to cover both Edinburgh and Aberdeen?

A. No, but on the other hand I have very good colleagues who work with me, who are perfectly capable of managing both units without my interference.

Q. Then to the next page, please, PEN0100120. We see at the bottom of that page, you detail clinical experience. As an honorary consultant haematologist at the Royal Infirmary until two to three years ago, you undertook a general outpatient clinic and you provided out-of-hours on-call coverage for the Royal Infirmary and the RHSC haematology service. You say you currently provide consultant cover for patients with primary immunodeficiency requiring home therapy with immunoglobulin. Firstly. Is that still the case?

A. That is still the case yes.

Q. Can you give us some examples of primary immunodeficiency?

A. Yes. These are a small group of patients who have usually deficiencies in antibody production of one form or another. There are various causes, some of them genetic, things like common variable immunodeficiency, for example. Some, not all of such patients experience recurrent infections, and require long-term immunoglobulin infusions. Nowadays quite a lot of those patients are able to give their own immunoglobulin at home, so we clearly need to provide support for them,

predominantly nursing support, although medical oversight is also required.

Q. I see. The point that's being made by the use of the word "primary" is in distinction to acquired immunodeficiency, or do you also get secondary immunodeficiency?

A. Yes, one does get secondary immunodeficiencies, of course, yes.

Q. As we realise, one also gets acquired immunodeficiency and that's a large part of the remit of our Inquiry.

A. Yes.

Q. You have clearly had a number of different roles and responsibilities, which you have detailed very carefully in your CV. You have also told us about your research experience on PEN0100125. You have led in the past three areas of research, quite complicated for lay people to follow, certainly 2 and 3. I think we can understand the risk of transmission of variant CJD by blood transfusion and the cell therapy group leader. Then the first one is perhaps slightly beyond us but basically it is to do with a form of antenatal screening.

A. Yes. More broadly immunological matching in regard to the blood; I would phrase it that way.

Q. Then if we look to the next page, [PEN010126], we see

that you have worked with Professor Sir Ian Wilmut?

A. Hm-mm.

Q. You mention, as the first challenge in that role -- that is working in the centre for regenerative medicine -- establishing a presence in the chancellor's building. Is that Little France?

A. Yes, it is the university medical school at Little France.

Q. Is there a goal to bring as much as possible on to that one site?

A. Yes, there is. Obviously there is the Royal Infirmary on site at present. The intent, as I understand it, is to bring the Royal Hospital for Sick Children up from Sciennes Road onto that site. There is the university medical school and the QMRI, the Queen's research institute, so the major research institutes.

We are just finishing the completion of the Scottish Centre for Regenerative Medicine, which is funded by the Scottish Government, which is a highly complex bespoke building. Around the back of that site in Little France Scottish Enterprise have prepared ground to bring in biotechnology and industry, I think the vision being that that will be a centre of excellence for Scotland, bringing together clinical, academic and biotechnology firms in new fields, particularly regenerative medicine.

Q. Thank you. Then you tell us some professional contributions. This is just edited highlights, professor. But on PEN0100127, you have plainly participated in a number of different groups and provided advice on different topics to the UK Government and indeed to other governments beyond Britain. Then you tell us on PEN0100128 about lectures and talks, even at the Science Festival which is trying to make what you do comprehensible to a wider audience. But plainly you must also give a lot of lectures and talk to specialist audiences. Then a very long list of research projects and publications, which goes indeed from 0129 to the final page, which is 0145.

So with that piece of background, can we now come to look at your statement that you have provided for the Inquiry today? That is [PEN0020452]. Before we look at the detail of this, professor, I want to clarify something - because I used a bad metaphor at the end of yesterday - that Scotland continues to operate a voluntary, non-remunerated donor system for blood. Is that correct?

A. That is correct.

Q. Our attempt today is to look at what happens both from the perspective of those who collect the blood from the donors and those who use the blood in a clinical or

therapeutic setting. So primarily I want to ask you about the first part of that: the people who collect the blood. How they do it and what they do with it.

In the first paragraph, which is on the next page of your statement, you give us a little bit of background on the current structure of SNBTS and I think we can see that in the first paragraph, that, like many organisations, seems to have had some administrative changes in the period with which we are more familiar. We are accustomed to seeing references to the five regional centres, with the headquarters, if you like, in Inverness, Aberdeen, Dundee, Edinburgh and Glasgow, the West at least. It looks, at least in the period which we are studying, as though these centres had a reasonable degree of autonomy. Is that perhaps slightly less so, now?

A. Oh, yes. I think it is a lot less so now. Probably around shortly after I joined SNBTS, around 1997/1998, the incoming new national director at the time, Mr Angus MacMillan Douglas, undertook quite a substantial restructuring of SNBTS on to national functional basis. So that, for example, a donor organisation, manufacturing -- that is red cell preparation, tissues and cells and clinical directorate -- are managed on a national basis rather

than on a regional basis. That's not to say, of course, that we don't still have regional centres in those cities that you have described.

Q. You tell us that the directors of the national services are accountable to the SNBTS national directorate and management board. The national director is not necessarily medically qualified. Is that right?

A. That's correct, not normally medically qualified.

Q. Is that position vacant as we speak?

A. No, no, Mr Keith Thompson is national director of SNBTS.

Q. Sorry. The position which is vacant, is it the director general health and chief executive of the NHS. Is that the one ...?

A. Yes, I believe that is the case. I think Mr Derek Feeley is acting in that position, although I don't know him personally.

Q. Obviously, I have been doing some web research and I did find that a Dr Kevin Woods had moved to New Zealand.

A. I believe that to be true.

Q. Just so that we are clear: there is the national director of SNBTS, there is a board for SNBTS; SNBTS is itself part of National Services Scotland and then National Services Scotland is obviously part of the NHS. The NHS now has, for Scotland, a person described as director general health and chief executive of the NHS

in Scotland?

A. I believe that to be correct, yes.

Q. In fact that is just one person, director general health and chief executive of the NHS. It sounds like a big role?

A. Yes, it does.

Q. No doubt it is. Some more general information is provided about the development of guidelines and we can see the sorts of issues on which guidelines are felt to be necessary: donor selection criteria, microbiological screening, components preparation, and there is obviously quite a lot of liaison with the other services in the UK?

A. Yes.

Q. The service, as we say, south of the border is organised for England and Wales, is it?

A. England and North Wales, yes. But the southern part of Wales has the Welsh Blood Service.

Q. What about Northern Ireland?

A. It has its own blood service. So there are four blood services within the United Kingdom.

Q. Then you tell us at the bottom of the page, towards the bottom of the page, about some advisory committees, standing committees, which provide advice on some of the general issues affecting blood transfusion?

A. Yes.
Q. Can we look at the next page, please? You are in the business of providing blood components as well as a number of tissue and cell products, such as bone, tendon, heart valves and haematopoietic stem cells. I was interested to see that you produce heart valves, I suppose because we had some discussions of heart valves last week. But what sort of heart valves are you producing?
A. They are recovered from deceased patients, quite obviously, and they are processed and stored. They can be stored frozen. It is not necessary to have viable cells for a heart valve. Then they are used during heart surgery, where a valve needs to be replaced. So they will be taken by the surgeons, obviously thawed and then used as replacement valves.
Q. You have helpfully listed for us in the same paragraph a number of EU directives and in fact it looked to me that there had been five directives in this area within four years, which is quite heavy activity from the European Union. Obviously, in the noughties the regulation of Blood and Safety and Quality has become pan-European, or the legislation with which you have to comply is pan-European.
A. I think that's correct. It probably looks more complex

than it is. There is obviously an overarching mother EU blood directive and then a number of subset amendments and directives that flow down from that, most of which are transposed into UK law, as I understand it, through the Blood safety and Quality regulations. Then similarly for tissues, there is the EU Tissue and Cells Directive and some daughter directives which have been transposed as the Human Tissue Quality and Safety Regulations.

Q. You then address, I think, an issue which was put to you by the Inquiry team: how and where blood is collected in Scotland, including the use of regular and one-off donors and sessions held within and without transfusion centres. You tell us about the active donor base. I suppose regular donors are particularly valuable, are they?

A. Yes, they are particularly valuable, because we depend on them for about 85 per cent of the blood that's donated. We can call them up because we know who they are, so we can put a base load of donors into a particular session, for example. And because they are regularly screened, there is a much lower deferral rate for them, both on donor selection and on screening.

Q. People's motivations for doing this are altruistic?

A. They are entirely altruistic. They get no reward. From

time to time we hold donor ceremonies and they get a small gift or something like that, small award, but that's the only reward they ever receive, the only material reward that they would ever receive.

Q. In blood donation circles we have noticed that very diplomatically no one is ever rejected, people are deferred. Is that right?

A. That's correct.

Q. If you are deferred, though, it is not really that you are going to be invited back, is it?

A. Not necessarily. Some people are deferred temporarily, for example, they might have a low-ish haemoglobin level or they might have had a head cold for example, something like that. So that would only be a temporary deferral. Clearly other people either disclose something in their donor history, in their personal history, which means that they have to be permanently deferred or if they test positive on a screening test, they would have to be permanently deferred.

Q. Because -- and this is common sense, professor -- as you explained to us, you have to have the health of the recipients of the blood in mind but you also pay attention to the health of the donors.

A. Absolutely.

Q. Yes. I noticed that you said at the bottom of the page

that blood and platelet donations are no longer accepted from donors who themselves might have received a blood transfusion since 1980. One or two aspects of that, I would like to pick up.

The first is the use of the word "might". Obviously it must be straightforward if someone knows they have had a blood transfusion and they say, "I have had a blood transfusion", but how do you detect the people who might have received a blood transfusion?

A. We can only do that by asking them. Most people do know whether or not they received a blood transfusion. But we also ask is it possible, because some people, for example, let's say, had a road traffic accident and they were unconscious, they might be uncertain. So they would be deferred as well on a precautionary basis.

Q. What about people who have just had surgery since 1980?

A. We don't routinely defer people who have just had surgery because only a minority of them would really have had a blood transfusion and many, many people would have had surgery of one form or another, often trivial.

Q. You say that that particular measure, that is deferral on a permanent basis, I suppose, to use the right language, of people who have received a blood transfusion since 1980, was introduced in 2004 and that was because of the perceived risk of variant CJD. One

of the cases we looked at last week concerned somebody who had a transfusion in 1990 and it transpired that that transfusion had transmitted Hepatitis C. When the donor was questioned about any possible risk factors that the donor had had, it turned out that the donor himself had had a blood transfusion. But obviously at that time there was no thinking about deferring people who had had a blood transfusion.

A. Hm-mm.

Q. I wonder if you could perhaps speak a little bit more about how and why the thinking changed?

A. The thinking in the UK changed because in the early part of 2004 the first documented clinical case of transmission of variant CJD by a red cell product was described. So at that point what had been considered to be a possibility clearly became a clinical reality.

That decision was taken, I think, probably on the advice of MSBTO at the time. I can't be certain about that. It was probably the route by which that opinion was reached.

Q. Could you remind us who that is?

A. That was the advisory committee on the Microbiological Safety of Blood, Tissue and Organs. The committee which preceded the current independent advisory committee, called SaBTO. That was a preceding committee. I wasn't

a member of it but I did attend to give professional advice from time to time. The rationale for that decision, to be clear, was to exclude the possibility of tertiary and higher order transmissions of variant CJD. So if I can explain that a little bit better.

Q. I think you had better.

A. Obviously a primary transmission would be from a BSE-infected cow to man. A secondary transmission would be, for example, transmission from somebody who is infected with variant CJD but not showing any clinical signs, through, let's say, a blood transfusion to a second person.

There is very little we can do at the present time to obviate that risk. However, what we didn't want to happen was then somebody who themselves had variant CJD through a blood transfusion to carry on donating and continue recycling the infection in the community, as it were. So we didn't want blood transfusion to become a route to continuation of the outbreak of variant CJD in the population. So that's why that decision was reached in the United Kingdom. That took out about 3.5 per cent of our donor population at that time; a little bit more of the blood because actually at that time, as you might expect, people who themselves had received blood transfusions in the past are often very

keen to contribute something back to the community.

So they often paradoxically make some of the most dedicated of our donors. So, as I say, that took around about 3.5 per cent of our donors out at that stage and probably we defer about 1 per cent of donors on that basis on an ongoing basis.

The only other country that I'm aware of that defers donors who have received previous transfusions on a permanent basis is France, and I believe they introduced that measure in around about 1997. I don't know the rationale for that but I think it was part of their reflection on the difficulties they had, particularly with HIV during that period. They really wanted to guard against other emergent infections being transmitted through that route.

My recollection is that the EU directives to which you just referred specify a six-month deferral for people who have received previous transfusions and also my understanding is, though I have less knowledge of this, that the US and Canada and some other countries, there is a 12-month deferral. So a temporary deferral for such individuals.

Q. Okay. You referred to the motivation of people who themselves have received a transfusion and it is not difficult to understand the thinking, that people are

very grateful and decide themselves to become blood donors. Dr Gillon referred yesterday also to the possibility of transfusion in a close family member and I imagine that that can be quite a powerful motivation as well. If, for example, one's child has been saved by a blood transfusion, then I think it is not difficult to understand that that might motivate somebody to go and become a donor themselves.

A. I think that's true, yes.

Q. Can we look at the next page, please? You tell us what we have covered already, that there can be problems with supply, you say particularly in maintaining supplies from the universal donor of O rhesus D negative blood group. That's in essence people whose blood could be given to anybody?

A. More or less, yes. They would comprise about 7 per cent of the general population.

Q. That's the blood which is presumably most in demand?

A. Most in demand because we use is for what we would term "flying squad blood". So we would put O rhesus D negative blood, for example, into an accident and emergency department or into the fridge in an obstetric unit. So if a patient comes in who is exsanguinating rapidly, they can use that blood which is to hand while sending samples to the laboratory for properly

crossmatched blood to be provided.

Q. Then you answer a question:

"What happens to a donation once collected?"

You tell us a bit about the donation pattern of most donors. You say:

"Haemoglobin levels which are tested by HaemoCue on a capillary sample."

Does that mean the pricking of a finger and taking of blood and putting it in a flask or breaker? Has that been superseded?

A. We still do a finger prick, as you say. We have tended to move on from the old-fashioned flasks but we use a small bench stop instrument, which is more accurate and slightly less messy.

Q. Then you say there is testing, plainly. You are looking for the ABO groups and rhesus D, and you say, sometimes more minor groups. I think we should just ask you for a general education about the ABO system. That is to do with people who have certain proteins on their red cells, or don't have proteins on their red cells, which means that they will produce antibodies to blood of a different type. Is that roughly correct?

A. Kind of.

Q. We had better let you explain it because you will do it far better than I can.

A. The ABO system is carbohydrate antigen system, so a sugar system rather than a protein system. Both kinds of systems are expressed on red cells. There are over 400 antigens expressed by red blood cells, classified into 12 systems.

Q. I knew it would be more complicated.

A. Which would make a very interesting lecture, which I will spare you. But the ABO system is a carbohydrate system. So that is expressed not just on red blood cells but on all the cells of our body. For those carbohydrates which we ourselves express, we do not develop naturally occurring antibodies to them but if we lack certain carbohydrate antigens, then we will develop antibodies to those carbohydrate antigens during our early development, usually when we are babies. That's probably because carbohydrates are also expressed, for example, on bacteria on our skin and in our gastrointestinal tract.

So to make that a little bit more concrete, if you are group O, for example, you will express naturally occurring antibodies to group A and group B because those are carbohydrate antigens you lack. If you are group A, you will express antibodies to group B and vice versa. And if you happen to be AB, then you will be a universal recipient, you will not express antibodies

to either of those two blood groups.

Q. Yes. Because if O is a universal donor, AB is a universal recipient. Is that right?

A. Yes.

Q. You test also for various pathogens, I suppose they are, a number of viruses. We recognise the abbreviations that we see there, Hepatitis C, Hepatitis B, HTLV. Is that really HTLV1 and 2?

A. It is, yes, sorry.

Q. Yes. I think we will come on to this at a later point in the Inquiry but HIV started life as HTLV3?

A. It did.

Q. And then was renamed "HIV"?

A. I believe that's the case, yes.

Q. Syphilis is a bacterial infection. Is that right?

A. It is.

Q. Yes. Then you say that you are also testing for HIV, Hepatitis B and Hepatitis C by nucleic acid testing. Perhaps you can explain the difference between the first batch, which you say is testing using serology and then the nucleic acid testing?

A. Yes. So syphilis, HIV, HCV and HTLV are all tested to look for patients with antibodies to those infections. Clearly, when one gets an infection, one develops an immune response, as you know, and one can detect

antibodies. In the case of HBV, I'm sorry, that's not exactly accurate because we test for the surface antigen for Hepatitis B rather than for the antibody.

Nucleic acid testing is based on a technique called polymerase chain reaction, which, in relatively simple terms, amplifies RNA or DNA and so, therefore, is very highly sensitive. So currently donations are tested by both techniques.

Q. I think the difference for us to understand as lay people is perhaps the difference between looking for antibodies, which is essentially a form of screening, and looking for active virus, which is the latter type of test. Is that correct?

A. Yes.

Q. Right. A finding of antibodies represents, as I understand it, a sort of clue that the virus has been here?

A. Yes, I think that's fair.

Q. And then you say that you test also for a variety of other infectious agents and then you develop a little further the notion of the different tests, so the hierarchy of tests, if you might put it like that, that you take samples which are initially reactive on screening and then subject them to a series of further tests. I suppose the most valuable screening tests are

ones which are very sensitive?

A. Yes, they have to be very sensitive, quite obviously, or we try to make them as sensitive as we possibly can because we don't want to miss people with infection. So we want a low false negative result.

Q. Yes.

A. But what that means, of course, is that you do then open yourself up to more false positives. So, typically, in modern screening -- because we are now on third or fourth generation tests, so there has been a lot of refinement of the technology, as you might expect, over the last ten or 20 years -- we find that about 0.2 per cent of the donations are initial reactives. You know, if you just screen the population, about 2 [sic - 0.2] per cent would come up with a positive for one or another marker.

Then what we typically do is we retest that sample twice using the same assay and we find that about 90 per cent of those are repeat reactive negatives, so it was just a glitch in the system at that stage. So perhaps only about 0.02 per cent are repeat reactive positive on that initial screening test.

But even then we don't necessarily assume that this means that the patient has that infection. At that stage we would quarantine the donation, we would take it

out of the system, to give ourselves time to look in much more detail, and we then would send the samples to a reference laboratory, where we do a whole series of different other kinds of tests, based on different kinds of platforms and technology, to try and establish whether it is a true positive or not. Again, in broad general terms, around 10 per cent of those repeat reactive samples turn out to be true infections and the other 90 per cent tend to be technical artefacts, as it were.

Q. So, just to assist our understanding with the first round of testing, it is the false negatives that would worry you because they would be infections that had slipped through the system. The false positives you cope with by doing further testing to find how many of them are true positives?

A. That's absolutely correct, yes. Clearly, we would not want to go back to a donor and tell them they were positive for a particular infection unless we were absolutely certain that that diagnosis was correct.

Q. And I suppose -- and we will come on to this much later in the Inquiry too -- before you introduce any new form of screening, you have to have a fairly accurate sense of how it performs?

A. Yes.

Q. Is that right?
A. Yes, I think that's true. You need a test which is obviously sensitive enough that it is going to work, it is going to be worth doing in the first place, but has a specificity level that is manageable without deferring large swathes of people. Normally, you would want to have at least one kind of confirmatory assay; otherwise, you have no way of sorting out the false positives and the true positives, as it were, and obviously when you are screening large numbers of healthy people, the false positive group far outweigh, as I have just described to you, the true positives, so the positive predictive value of the initial screening test is very poor from that point of view, and then, of course, legally we need a test which is CE marked.
Q. Which is, I'm sorry?
A. CE marked, under the In Vitro Diagnostics Directive, which means it can be marketed in the European Union and, therefore, in this country.
Q. I see. Just before we leave this page, the other word I want to pick up, just because it is not an everyday word for all of us, is that you are finding other viral -- or there are -- you are not necessarily finding them but there are other viral and bacteriological agents in the general population, many of which are of uncertain or

unknown pathogenicity. Does that mean their capacity to make people ill?

A. Yes, that's correct. Obviously, there are many, many bacteria and viruses all around us all of the time, some of which are known to cause disease, some of which can cause disease in certain kinds of patient in certain circumstances, such as CMV, for example, in patients who are immune-suppressed, others which are known of but are not known to have any disease-causing role, things like TT virus, for example.

Q. What sort of virus?

A. It is a virus which has been described, for example, called "TT virus", which is of uncertain significance in the general population. I think what I would try and get across is that, although we obviously focus on three or four viruses, there are many, many microbiological agents in our environment.

Q. Yes. Can we look at the next page, please? You were asked about the different components a donation is divided into and the time, place and methods of such division. You have got the two processing sites and they are covering blood donations from all five of the centres, are they?

A. Yes, that's correct. Broadly speaking, Gartnavel covers Glasgow and Inverness and the Lauriston Building covers

Aberdeen, Dundee and Edinburgh.

Q. And then you take us through the basics of what you do. We have seen this term on a number of occasions and I have again forgotten what it is and it sort of jumps out at me: what is a buffy coat?

A. If you centrifuge blood, what you find is that the red blood cells come down to the bottom of the tube or the pack, the plasma sits at the top and the white cells and platelets, depending on how hard you centrifuge, sit on a kind of thin white layer between the two, and that, for reasons that completely escape me is called the "buffy coat".

Q. Right, thank you.

THE CHAIRMAN: I have looked at "buffy coat" from the earliest days of opening papers and I have never yet, I think, seen any explanation as to the source of the name.

A. No, I am afraid I don't know the source of the name.

PROFESSOR JAMES: We don't think it is to do with vampire destroyers.

MS DUNLOP: As we read through the paragraph, professor, we see you describing the production of bespoke blood components. One example you give is red cells for intrauterine or neonatal exchange transfusion. So it is actually possible to transfuse an infant in the womb.

A. It is, yes.
Q. Presumably only beyond a certain stage of development?
A. Yes, with modern ultrasonography and technology from relatively early on -- 24 weeks, 25 weeks -- if required.
Q. What would be an example of a condition which would require that?
A. If, for example, you have severe anaemia in the foetus, so, for example, a woman who has anti-D and a D positive baby -- and that's rare now because of the prophylactic regimes we have in place -- typically that will cause haemolysis or breakdown of the baby's blood in utero. So that kind of patient, that kind of child, might require transfusion in utero, but it is quite rare and I think there is probably only one specialist centre now in Scotland that would carry out that kind of procedure.
Q. Then you say:
"All blood components except granulocytes are leukodepleted."
A. Yes.
Q. So you are taking the white cells out of everything apart from granulocytes. What are granulocytes?
A. They are white cells. So the leukodepletion filter would take them out, obviously. We very rarely use granulocytes in reality. Occasionally we use them for

patients, for examples, who are undergoing treatment for leukaemia or a bone marrow transplantation where their blood system is severely depressed, and if they have infections which are not responding with routine antibiotics, we might collect them and infuse them with granulocytes, but it is a very, very specific and bespoke indication.

Q. And the measure, leukodepletion, is thought to be a way of reducing the risk of variant CJD?

A. That was the rationale on which it was introduced, yes.

Q. For those of us who are not completely familiar with mathematical notation, at least in this form, reduction by 10 to the power 3 to 10 to the power 4 log 10, that's a lot of reduction, is it?

A. Yes, it is about a 1,000 to a 10,000-fold reduction. Actually, in reality now we achieve more than that, so most red cell components, platelet components, would contain less than about 1 million residual leukocytes in the whole component.

Q. Then you say there is some secondary processing -- it could be irradiation or washing -- and then you say some materials from commercial suppliers such as solvent detergent treated plasma, patients undergoing plasma exchange. That is really explained, is it, by the last sentence, that you do not make much use of UK plasma

because of CJD? Is that why you are sourcing some commercially, or is that the wrong thinking?

A. That's correct. Obviously, all plasma for plasma fractionation does not use UK plasma any more. That was demitted in about 1999. In terms of clinical plasma -- that is fresh frozen plasma -- there are two groups for whom we import plasma. One is children up to the age of 16 years and, as you can see, that has been in the past imported from the US but, going forward, will be imported from Austria, and that receives methylene blue treatment, which is a pathogen reduction treatment which can be applied to plasma. For patients undergoing plasma exchange, particularly for a condition called TTP, methylene blue treated plasma is thought not to be the best treatment. So pharmaceutically cooled plasma, called "octaplas", which is manufactured again from European plasma, is used. That again was advice given by MSBTO and then followed up by SaBTO.

Q. Possibly the biggest difference between the situation as it now is and the position in the 1980s, particularly the early 1980s, is that there isn't fractionation of UK plasma, indeed to the extent that PFC is closed. Is that right?

A. PFC is closed. BPL is the English fractionation centre, which is still open, but it imports plasma for

fractionation. So you are quite right, UK plasma is not used for fractionation.

Q. And Scotland doesn't fractionate any plasma?

A. No.

Q. What about albumin? I'm just interested in albumin. Are you still producing albumin?

A. No, albumin is again a fractionated plasma product, so it is commercially supplied.

Q. I thought I should ask you at this point also about immunoglobulins, just so that you could explain where they fit into the picture.

A. Yes. Similarly, immunoglobulins are prepared by plasma fractionation. So in the past they were supplied by the SNBTS Protein Fractionation Centre, as you know, but now they are supplied by commercial manufacturers.

THE CHAIRMAN: Does this mean that Scotland has lost its capacity for fractionation?

A. Yes, it does.

THE CHAIRMAN: Not only has PFC been dismantled in fact but the skill sets that were used there have gone?

A. Yes, those people have retired and left the organisation. So, yes, you are quite right, we have lost that capacity or capability altogether.

THE CHAIRMAN: And Scotland is therefore dependent on importation?

A. It is.
THE CHAIRMAN: It takes the preventative principle rather a long way, professor. Any comment on the current position you care to make?
A. Well, the decision to move away from UK plasma was driven by precautionary concerns at the time around variant CJD risk. It had been historically clear that sporadic CJD was not transmissible by blood components or plasma products, but at that time -- variant CJD was first described in about 1996 -- it was recognised that it was a different kind of disease and there was concern even at that stage that that might prove transmissible. I think the view was taken, certainly at UK Governmental level, so it was probably the committee of safety of medicines, that it would be preferable to move away from UK plasma, both because of the risk, because of the pooling effect one individual might contaminate a whole different series of batches of products, and also because of the view that if we ended up at that time having a lot of donors developing variant CJD -- you will probably recall people were talking about potentially very vast numbers of people developing this disease, which thankfully has never come to pass, but certainly that was thought to be within the realms of the plausible at the time -- we would end up continually

recalling batches all the time. So we would enter a shortage.

So that decision was made at that time for those reasons. I think with regard to PFC itself, it changed, if I could put it this way, the health economics of fractionation in Scotland. PFC had become one of the smallest fractionators in the world, particularly compared to big corporate commercial fractionators. And moving from a position where plasma was effectively free at supply, because it was provided from the whole blood collection programme, to one where it had to be purchased on the open plasma markets, changed the balance of economics as to whether it was worth continuing to try and supply products fractionated by ourselves from, in fact, US or German plasma, rather than just purchase them from the international community.

THE CHAIRMAN: There must have been an underlying assumption that the risk of transmission of variant CJD from blood collected in Britain was greater than the risk in source countries from which substitute supplies might be found.

A. Yes, I think there is substance to that assumption. The centre of outbreak of what really was a BSE epidemic was in this country and of the, in order of magnitude, about 220/230 cases of clinical variant CJD, probably about

180/190 have been in the United Kingdom. So BSE was predominantly a UK-centred outbreak, clearly with some cases in Ireland and western Europe. There had been two or three cases in the US of variant CJD but they are mainly in individuals who spent time in other countries, including our country. So I think that was probably a reasonable assumption at the time.

MS DUNLOP: PFC was in the business of fractionation. We will obviously be hearing a considerable amount of evidence about the processes that were undertaken at PFC. One chapter of that evidence we will look at is heat treatment of the different fractions from plasma, particularly in the manufacture of concentrated Factor VIII and Factor IX. One question I thought I should put to you, professor, is why there hasn't been a programme for the heat treatment of blood just as blood.

A. If you heat red blood cells, they will lyse. So they will not work. Also if you were to transfuse that into a patient, you would be transfusing cell free haemoglobin, which is highly toxic.

Q. By lyse do you mean break down?

A. Break down. I apologise, yes.

Q. Is that L-Y-S-E?

A. Yes, it is.

Q. Just so we have an accurate transcript.

Can we turn to the next page, please. You take us on in the journey of a donation by telling us firstly about storage:

"Blood components are normally ready for release within around 24 to 48 hours from collection on completion of testing and processing."

You say that the sort of IT systems you have in place now will not permit release of a component for use if testing is incomplete. And then you tell us about the various different storage requirements of the different components.

Platelets have to be continually agitated. Presumably that's done by machine, is it?

A. Yes, it is, yes.

Q. They just have to be shaken about?

A. Yes, correct.

Q. Then packs go to individual hospitals and you say there are 42 hospital blood banks throughout Scotland. Temperature controlled cold chain is maintained throughout. Five are directly managed by SNBTS and you list those. The remainder are managed by the territorial health boards. So is it the case that you send the components to the five and they then distribute to the more local blood banks? Is that how it works?

A. It varies a little. So in the central belt the blood will go direct from supply chain normally to the hospital blood banks. So, for example, St John's Hospital would receive blood direct from the Lauriston Building. They wouldn't bother to send to the Royal Infirmary first and then across to St John's for self-evident reasons.

In the north, particularly for example Aberdeen and Inverness, where we have a number of remote and rural hospitals, places like Orkney, for example, Shetland, the Western Isles, we keep a kind of secondary stock, as it were, in those centres and further supply from those. So it varies a little depending on the geography.

Q. So the logistics of it, particularly in the more remote parts of the country, are not necessarily straightforward, I imagine?

A. At times they can be very challenging.

Q. You say in this the last sentence in that paragraph:

"The SNBTS centres also carry out other specialised transfusion work."

That's the five, is it, the five centres?

A. Yes, that's correct.

Q. So they are looking at red cell reference serology, histocompatibility and immunogenetics. Can you give us a slightly more lay explanation of what's going on

there, please?

A. Sure. So the majority of patients are reasonably straightforward to transfuse but around 2 per cent of patients will have specific antibodies to some of the 400 or so red cell protein antigens which I described to you earlier. They will need blood which is specifically matched for that patient, so lacks those specific antigens. So that's what I mean by reference work.

That is additional work that requires to match the blood to the patient over and above routine pre-transfusion testing.

Histocompatibility and immunogenetics -- I'm sorry that's a little bit of a mouthful -- is around tissue typing. So these are antigens which are not expressed by red cells but are expressed by most other cells in the body and we match for bone marrow transplantation and for support of solid organ transplants. So, for example, if you have a kidney transplant, it is essential that the tissue type of the incoming donor kidney would be accepted by the recipient. It is not just a matter of the red blood group antigens. So we support those services as well.

Q. I see.

A. Those are clinical laboratory services, if I can frame them in that way.

Q. Thank you.

You were also asked about the retention, if any, of samples of individual donations and you explain that SNBTS strives to retain documentation and blood samples from donors in perpetuity. The current sample archive goes back to the mid 1980s. In what form are these samples stored? In tiny packs?

A. I'm not sure that I know the answer to that. But I would imagine that they would be stored as serum, which is -- serum or plasma. I imagine that's what's stored which would be stored frozen. They would have to be frozen obviously to store them for that kind of period. Obviously when we take the donation, we also take samples in parallel for the various testing that we discussed earlier. So there would be residual amounts of that sample left and I believe that that's what is stored, that's what is cryopreserved.

Q. I have seen reference to pigtails?

A. Yes.

Q. Where do the pigtails enter the process?

A. So when you have the pack of blood, what we normally do is there is a kind of long stringy bit that comes off it, which is connected to the pack of blood, and with a heat sealer it is sealed up into a number of segments. If you kind of envisage like a long thin sausage, okay?

That then the pack with that pigtail, as it is called -- I don't know why it is called a pigtail.

Q. Just because it hangs down from the pack. I don't imagine it is any more complex than that.

A. That goes to the hospital blood bank because then, when the hospital blood bank needs to -- there are three things in terms of pre-transfusion testing: we test the ABO group of the patient, screen the patient for antibodies and then finally do a crossmatch to ensure that the patient and donor blood are compatible with each other. That final step, that crossmatch, is done on one of those pigtail segments, to ensure that the blood that is being tested is the blood that's going into the patient.

Q. So the pigtails are not there to be retained after the event, they are there to be used in association with the transfusion?

A. They are used in association with the pre-transfusion testing in the hospital blood bank.

Q. Then you talk about the testing and release of blood by the blood banks and the problems that there can be. You have already described a bit of this -- the people who need more complex crossmatching. You say transfusion of incompatible blood can have very serious clinical consequences and is now the most serious hazard

associated with transfusion. Then in on page 7 in the second paragraph you explain how urgent it sometimes is to carry out a transfusion, giving some examples: Ruptured aneurysm or a placental abruption?

A. A woman with a placental abruption can exsanguinate in around 10 minutes.

Q. By "exsanguinate", I suppose in colloquial terms that would be bleed to death?

A. Yes.

Q. Yes. Then you explain a little bit about the indications for transfusion of the different components of blood. We are going to go into this a little more with our next witness, who is going to take over from you in the story of the journey of the donations.

Then finally, if we go to the last page, you talk about contra-indications for transfusion. Very few absolute contra-indications to transfusion except, of course, refusal of consent. There are still people who object on moral or religious grounds to transfusion. Is that correct?

A. Yes, for example, patients who are Jehovah's Witnesses won't accept blood.

Q. But one option for them might be what we have heard described as autologous transfusion. Is that correct or is that not something that they would accept?

A. There are a number of different techniques described under the umbrella autologous transfusion. One is autologous pre-donation, where the patient himself or herself donates three or four units prior to say, elective surgery, so that they can use their own blood. My understanding is that most Jehovah's Witnesses would not accept that form of autologous transfusion.

Much more commonly employed now is a technique called intra-operative cell salvage. There are certain surgical techniques within the theatre. There is a machine which recovers blood as it is lost and can wash it and recycle it straight back into the patient. I think some, though not all Jehovah's Witnesses, would accept that kind of technique.

Q. Then you talk about firstly the reporting of adverse events. There is obviously a system for that, a reporting mechanism through SNBTS and territorial health boards, clinical governing structures and then also to the blood service's Serious Hazards of Transfusions -- SHOT for short -- then the healthcare products regulatory agency?

A. Hm-mm.

Q. Then lastly the records kept of transfusions in patients' notes and elsewhere and these blood safety and quality regulations, which were the transposition of the

European Directive, obviously stipulate some requirements.

So you are maintaining records of all transfusions for 30 years, allowing full traceability of blood from donor to recipient. Most blood banks are approaching 100 per cent compliance and the patient's medical notes are also supposed to have a written record of the transfusion, including the reason for transfusion and the patient's consent.

I suppose, professor, thinking about it, if there is an adverse event that comes to light that is something to do with a transfusion and it comes to light because of illness in the recipient, you have to be able to trace who the donor was.

A. Yes.

Q. So you have to go, as it were, backwards to the donor.

A. Yes.

Q. But you then also have to be able to go forwards in a slightly different direction to other people who might have received components from the same donor?

A. Yes, that's absolutely correct.

Q. These must require really quite different record-keeping systems, a sort of backwards traceability and the forwards traceability.

A. It is probably the same system working obviously in

different directions. But it will be spread between the clinical environment, the hospital blood bank and SNBTS. So if there is an adverse event in the clinical environment, say if somebody has contracted a bacterial infection, for example, the clinicians should be notifying their hospital blood bank in the first instance and they will notify SNBTS.

So they will know who the patient is. They will notify SNBTS -- not of whom the patient is but what the donation numbers are because that's the key link. In that kind of context SNBTS would then identify obviously the donor but also any other donations from that individual. Because in that kind of context, some of those donations might still be in the system. As I have described any one donor may give two or three different components.

So often we would respond rapidly to that scenario and pull the other components on a precautionary basis. Also, if another component from that donor and that donation had been given, we would ask the hospital for clinical information on that recipient. We would ensure that those other recipients had been contacted and informed and investigated, as necessary.

Q. Yes. That system is going to work best if everybody sticks to the same numbering system, isn't it?

A. Yes.
Q. If somebody along the chain is renumbering with their own numbering system, that's a potential difficulty unless there is some sort of record kept of how one keys the one record-keeping system into the other?
A. We do not permit people to do that these days.
Q. Right. We have heard some reference to, I think, one instance of that, which seems to have happened in Glasgow Royal Infirmary in 1985.
A. Right.
Q. That for reasons related to IT difficulties, there was some renumbering going on and it is not now possible to access the key that would allow a read across from one numbering system to the other?
A. I see. A blood pack coming from SNBTS has the donation number, both in readable format and barcoded form, along with all the other details stuck on the plastic bag. So you can't remove it and put your own number on it today.
Q. I suppose all of this has been made much easier by the widespread use of computerisation.
A. Yes.
Q. If we went backwards from perhaps the early 1980s and before, all of this will have been done on paper?
A. I think that's true, yes, absolutely. And not just the computer but obviously everything that goes with it: the

barcoding systems, the fact that most of the testing is on automated equipment now, which is electronically linked to the IT systems. So the whole connectivity of the system is far better and takes out the human element, the written transcription elements out of the system.

Q. Then lastly, professor, where you allude to the patient's medical notes being supposed to have a written record of the transfusion including the reason and the patient's consent, I wondered if there had been any attempt made to study in a systematic way the actual compliance with those requirements on the ground?

A. I'm not aware of a systematic study. My own impression is that compliance is probably patchy. Both in Scotland and across the UK over the last five to ten years there has been an enormous amount of work invested in improving that end of the clinical transfusion process. So, for example, those people prescribing or administering blood have to go through a formal training and have competency assessments signed off. Obviously there are patient information sheets. Attached to the patient information sheets, certainly in Scotland, there is a sticky label which the attending clinician can take off and stick straight into the notes to sign, to say that he or she has spoken to the patient and they have

given informed consent. All of that is inspected through a national body such as Quality Improvement Scotland, for example. So there have been improvements but in a busy clinical environment, I suspect that compliance can be patchy at times.

Q. So if it is envisaged that a patient going for an operation is going to have a transfusion, that is something that should be discussed with the patient beforehand.

A. Yes, I think that probably does occur within the context of a surgeon who would be discussing the general procedure with that individual, yes.

Q. What about a situation where transfusion hasn't been anticipated but has had to be carried out in an emergency which has occurred in the theatre? Should it then be intimated to the patient afterwards that there has been a transfusion?

A. Yes, our guidance is that -- and obviously some people do come into, say accident and emergency, where they have had a road traffic accident, where it is not possible to give consent, and their lives need to be saved and the fact that they received a transfusion should then be discussed with them retrospectively.

Q. Thank you very much, professor.

A. Thank you.

THE CHAIRMAN: Can I ask two questions about compatibility? One relating to transfusion.

You have said that incompatibility is now the most serious hazard associated with transfusion. I have the impression that historically that was the most serious hazard recognised in the early part of the last century.

A. Yes, I think that's correct.

THE CHAIRMAN: And then what happened was that the transmission of pathogens of one kind or another came to be recognised.

A. Yes.

THE CHAIRMAN: And transplanted, as it were, that hazard into the system. Are we simply on a cycle, in which additional hazards might emerge again?

A. I hope that we are not on a cycle but, as I intimated in my statement, there are many other pathogens in the environment and of course some of them are genuinely new pathogens, such as variant CJD was ten years ago.

Some of them are pathogens which have spread from one part of the world to another, for example, West Nile Virus was unknown in the United States ten years ago but is now quite common in the United States and that's a reflection of the globalisation of trade and then, of course, our donor population being normal healthy people, travel much more than they perhaps did

20 or 30 years ago and go on exotic holidays. So I think for all those various reasons we are mindful of other infections that there are in the general environment, both those we know about and potentially new infections.

THE CHAIRMAN: I have seen a very long list that came from SNBTS -- and you may know something about it -- as an appendix to a document, that list a very large number of possible pathogens.

A. I haven't seen that list myself but I can imagine it, yes.

THE CHAIRMAN: So one must simply have in mind that despite your best efforts, other problems could arise?

A. That is absolutely true, I am afraid, yes.

THE CHAIRMAN: The other compatibility issue, I think, should be much shorter. How do you ensure compatibility of computer systems across the country, since I'm connected with an institution that can't ensure compatibility within itself?

A. That is a serious challenge for us also. Within SNBTS we have a single computing system -- perhaps it would be called "Progesa" -- with two components to it. One is the donation and blood processing part and the other is the blood bank part. So they speak to each other quite well. So communicating with our own blood banks is not

a problem. Hospital blood banks managed by other hospitals have different systems and building those interfaces can be difficult.

THE CHAIRMAN: I suppose the most you can do is be conscious of the problem, professor.

A. Yes, we are very conscious of that problem and are working on it.

THE CHAIRMAN: We will have break at that stage to assist the typist.

(11.00 am)

(Short break)

(11.33 am)

THE CHAIRMAN: Mr Di Rollo, do you have any questions?

Questions by MR DI ROLLO

MR DI ROLLO: I would like to ask in relation to two matters.

Professor, we see from your evidence this morning and from your report that a decision was taken from, I think you told us, 2004 to stop or to defer donors who had received a blood transfusions and you explained that was because of the risk of variant CJD. Was any consideration given at an earlier stage or at any stage in relation to deferring donors in order to prevent the transmission of Hepatitis C or any other virus, or HIV? Was any decision taken or any consideration given to

deferring at an earlier stage?
A. Not as far as I'm aware, during the period of time that I can speak to.
Q. Right. Are you able to give any explanation as to why that might be?
A. Well, I can only speak to the period of time in with which I'm personally familiar, which would have been about 1997 onwards, let us say, when I became a consultant. I think probably at that time it was felt that with regard to Hepatitis B, HIV and HCV, the testing was such that deferring, for example, previously transfused donors would not offer any particular advantage. I think that must have been the rationale for not considering that possibility.
Q. But in relation to the period before 1997, you are not in a position to tell us anything about that and any thought that might have been given in relation to that?
A. I'm not really in a position to do so, I'm sorry.
I joined the blood service in 1995 as a registrar, as you know, so in a junior position. I only really became a consultant in 1997. So I wasn't really party to those discussions or thinking.
Q. But your understanding is that, obviously, by the time you are in a position to give us any information, the testing was such that there wouldn't be any particular

advantage at that stage in deferring, for example, by Hepatitis C?

A. I think that was probably the general view. Probably, apart from the UK where there are special circumstances, and France, I think if one looks across the world, in terms of permanent deferral that still appears to be the view because most other countries would either not defer such individuals or only defer them for a limited period, say six to 12 months.

Q. The other matter I wanted to ask you about related to what's contained in page 6 of your report. This concerns the question of record-keeping.

The current sample archive, your statement says, goes back to the mid 1980s. Are you able to get any more specific than that? In other words, can you pin it down to a year or all you can tell us is it is the mid 1980s? Are you able to tell us which year in the mid 1980s it goes back to?

A. I can't tell you off the top of my head because I don't know. But I'm sure we have that information. So I can certainly provide that information to the Inquiry. I would caveat by probably saying that, given the advances in IT systems and record-keeping and so on, the earlier samples are less secure than more recent samples quite obviously. But I can find out that piece of

information and provide it to the Inquiry.
Q. I think it is obviously a matter for others but it would be helpful if that information was provided.
A. Sure.
Q. The other aspect of this that I just wanted to ask you is: is the archive Scottish-wide? It does contain all the regions? The information going back to the mid 1980s is Scottish-wide; it doesn't vary from region to region or anything of that kind?
A. As far as I'm aware. But I will clarify that for you as well. As far as I'm aware, that's correct. But I wouldn't wish to say that with absolute certainty.
Q. Thank you for that.
Thank you, sir.
THE CHAIRMAN: Mr Anderson?
MR ANDERSON: I have no questions, thank you, sir.
THE CHAIRMAN: Mr Sheldon?
MR SHELDON: I have no questions, thank you, sir.
THE CHAIRMAN: Professor, thank you very much.
MS DUNLOP: Sir, the next witness is Dr Derek Norfolk.
THE CHAIRMAN: Do we have a mechanism for picking up any additional information that the professor might give us? Have you worked it out?
MS DUNLOP: I think actually that information we can probably find from what we already have.

THE CHAIRMAN: Yes, I think I would expect that.
MS DUNLOP: If the professor is going to write in, I think we can perhaps deal with this after today's proceedings, but we will perhaps get a letter or something.
THE CHAIRMAN: I'm interested in the general question because there will be other situations in which witnesses offer to provide information and I would rather that there was some sort of arrangement in advance to ensure that the material is made available.
MS DUNLOP: Yes.

DR DEREK NORFOLK (affirmed)

Questions by MS DUNLOP

THE CHAIRMAN: I'm sorry that we were talking over you, as it were, but there was something to be cleared up.

Yes, Ms Dunlop.

MS DUNLOP: Good morning, Dr Norfolk.
A. Good morning.
Q. We like to ask witnesses to have a look at their own CVs. So could you please have in front of you, WIT0030274 which should pop up on the screen. This is your short curriculum vitae. So it is actually just a little over one side of A4, but it gives us, in summary form, your current positions since 2006.

You have been a consultant in haematology and transfusion medicine, which is a joint appointment

between NHS Blood and Transplant and Leeds Teaching Hospitals NHS Trust. You have also had an academic appointment in connection with the University of Leeds and you are the associate research and development director for the Leeds Teaching Hospitals Trust as well.

Until 2006, really for 20 years, you were a consultant haematologist at Leeds General Infirmary.

A. Hm-mm.

Q. So did your job change a lot in 2006?

A. Yes, I was a general haematologist. I started off in fact as a bone marrow transplanter but I had a major interest in blood transfusion, particularly clinical use of blood components and patient safety. When the opportunity came to change my role with the appointment to what was then the National Blood Transfusion Service, I was keen to do that.

So my present role, in fact I still am a clinical doctor -- I look after patients, I do outpatient clinics in Leeds, I run the clinical transfusion at the hospital -- but my blood service role is essentially a regional and national role, working with hospitals and clinical teams to promote best practice in blood transfusion and research and development in transfusion.

Q. Thank you. In that capacity, we can see that you hold a number of regional and national appointments, most in

connection with blood transfusion and the safety thereof.

Chief medical officer, National Blood Transfusion Committee. British Committee for Standards in Haematology, Blood Transfusion Task Force. We have heard of SHOT before. You are a member of the Serious Hazards of Transfusion executive working group and you are the co-author of their annual reports and have been since 1996.

You chair the standing advisory committee on clinical transfusion medicine, of the joint professional advisory committee for UK transfusion services. You are the editor of the fifth edition of the Handbook of Transfusion Medicine. Is that a publication for which Dr McClelland was responsible in its early days?

A. Indeed. Dr McClelland handed over the role to myself and we hope that the fifth edition is hopefully coming out later this year.

Q. You are also on a Department of Health CJD incidents panel. You are on the council of the British Blood Transfusion Society. At a more local level, you are the chair of the Yorkshire Regional Blood Transfusion Committee and the chair of Leeds West Research Ethics Committee. Or you were, sorry, between 1993 and 1995.

Then you tell us over the page that you have been

involved in clinical and laboratory research in haematology and transfusion medicine since the early 1980s and that you have more than 70 peer reviewed publications to your name. I expect almost all of them are on matters of haematology and blood transfusion?

A. Yes. The early publications relate to a whole range, mainly haematological oncology but in the last decade mainly in the field of transfusion medicine.

Q. Thank you. You have provided us with a statement at which I would like to look now. It is [PEN0100048].

You give us a little bit of the history of blood transfusion. The first well documented successes were those of an Edinburgh and London obstetrician. Who reported ten direct donor to patient transfusions. So basically what was happening then was that the donor had to be very close to the patient and there was just a pumping from one to the other?

A. It was usually the husband of the woman who was bleeding in child birth, and he sat next to the woman and a direct connection was made between them.

Q. In retrospect, the biggest flaw in that idea was that nobody really understood about blood groups. Not everyone's blood is compatible with everybody else's. Is it true it is someone called Landsteiner that we owe most of the thanks to for unearthing that?

A. Landsteiner was actually a microbiologist in Vienna. He was looking for something more related to bacteria than blood groups but did discover the blood groups and actually did have a great deal of interest in transfusion. So it took quite some time after Landsteiner's discovery before the knowledge of the groups started to influence clinical practice.

Q. It must have been, as they say, a bit of a step change that suddenly this information was understood. Presumably people were able to make use of it in transfusion. You say this at the end of the first paragraph: that war has always been a major promoter of advances in transfusion technology and medicine. Presumably because that's transfusion in extremis?

A. Absolutely, yes.

Q. It's in fact from the Second World War that the network of blood transfusion centres and panels of volunteer blood donors in the modern sense were established.

I don't want to digress too much but I think there is some quite interesting material on how there was a bit of a leak about the planned date for the allied invasion because it was apparent to journalists that the blood bank had opened and a journalist had been to see round the blood bank and he had been told that the blood would only keep for 21 days, so everybody knew that the

invasion was imminent because the blood bank had opened.

Anyway ...

THE CHAIRMAN: Did that include the Germans?

A. I think the Germans also had a blood transfusion system. They were very ingenious and of course Germany was the centre of medical science prior to the Second World War.

THE CHAIRMAN: There is almost a Dad's Army picture of people on both sides of the --

A. In fact there was a shortage of milk bottles during the war because they were commandeered by the transfusion services. So milk bottles with rubber bungs were the normal mode of transfusion.

MS DUNLOP: You tell us -- obviously it is not glass bottles -- that the transfusion service was able to introduce plastic transfusion packs from the mid 1970s. That was another leap forward, I imagine.

If we move to the next page, please, you refer to the altruism of volunteer donors and indeed Britain, the United Kingdom, has always had and continues to have a system of voluntary, non-remunerated donors. Is that right?

A. Yes, indeed.

Q. Yes. It is interesting to look at the figures that you give for 2008 to 2009, that the UK blood transfusion services -- so that's all four services added together,

is it?

A. It is, indeed.

Q. -- issued 2.2 million units of red cells, 250,000 units of platelets and more than 400,000 units of plasma. Compared with the era we are examining in the Inquiry, that's quite a shift, isn't it, from an era where finding enough plasma was a huge challenge?

A. Yes, I mean, the economy of blood usage has changed dramatically in the last two decades. We use very little whole blood, of course, in the UK now. So a good deal of the plasma which is collected with donations in fact is no longer used for clinical purposes and this has been especially the case in the last decade, when UK plasma is no longer used for the manufacture of blood products. So there is certainly no shortage of plasma but it is only used in very limited clinical indications now.

Q. So is a lot of plasma disposed of?

A. The majority of plasma collected in the United Kingdom, which is discarded as part of the process of producing red cells and platelets, is actually destroyed.

Q. Yes. We have had a little bit of information from Professor Turner already about the different storage requirements of the main constituents. That is red cells, platelets and plasma. That's your paragraph 2.1.

Then 2.2, you talk about the use of the centrifuge to produce the different layers. You say that there is spinning of the bag. So I mean, in a practical sense, how is the bag spun?

A. It is in a centrifuge.

Q. Just as the bag?

A. A machine, yes. It just simply spins the compound and separates the layers. You can't really do that in glass bottles, because you can't easily get the components out of the glass bottle. The plastic packs which have been in use for many years now are integral. So they are completely sealed. A sterile process.

Q. It is then possible to extract the different layers, and you say put it into multiple packs?

A. Indeed.

Q. Without contamination by human interference?

A. Absolutely. It is a completely closed process.

Q. You describe apheresis. Is that the correct pronunciation?

A. It is.

Q. Which is a process where the transfusion service can take what it wants from the donor and the donor gets the rest back, as it were. You say the rest of the blood is immediately returned to the donor. This is 2.3. It sounds a very specific form of technique. Is that any

different for donor? Is it a different kind of experience?

A. It takes a little longer than a traditional blood donation, but it is what is called a continuous flow process, so blood is taken out, split in the machine and usually the red cells and other components that aren't needed are returned to the patient in realtime. So in fact the incidence of adverse effects for the donor is actually rather less with this sort of donation than having a whole pint of blood taken quickly. So the blood volume of the patient remains pretty stable during the whole process.

Q. And you describe the different ways the body replaces what's taken out. The body replaces platelets and plasma much more quickly than red cells. I wanted to ask you whether platelets and plasma have to be typed in the way that the red cells are typed. We understand about looking at the ABO grouping, and that certainly happens with the red cells. Does it happen with the other bits?

A. Yes, ABO blood groups are present on platelets as well. You can transfuse platelets across ABO blood groups. You don't get severe transfusion reactions because it is the red cells that are the problem and the platelet transfusions don't contain any red cells, but there is

some evidence that it is better to receive platelets of your own blood group, that they are likely to survive a little longer in your circulation after transfusion. So, wherever possible, we try and transfuse patients with their own ABO group of platelets. But that's not always possible and it is perfectly safe to -- we have a hierarchy of transfusion depending on the availability of a particular component.

With plasma, of course, there are no red cells in the plasma, but all patients, for example who are blood group A, have anti-blood group B in their plasma and vice versa, patients with blood group O have both anti-A and anti-B. So, by giving plasma of the wrong group to a patient, so, for example, giving group O plasma to a group A patient, could, at least theoretically, produce a reaction in that patient by damaging the recipient's red cells. So again we try to give what we call ABO-compatible plasma to patients. So all platelet units, all plasma units, have an ABO blood group attached to them.

Q. Right. Now, you said about there are no red cells in the plasma, but the red cells, when they are produced as red cells to go to patient, they will still have some plasma in them, will they?

A. Yes, the red cells which are used in clinical practice

now, most of the plasma is removed from the donation and then what is called an additive solution, an anti-coagulant, which contains other chemicals which help to fortify the red cells, to maintain their metabolism -- but all red cell units will contain a very small amount of plasma, but a very small amount, and platelets are suspended in plasma, so that is the liquid part of the platelet component.

Q. So, when one looks, for instance, at the case of somebody who looks likely to have acquired Hepatitis C from a transfusion, say in the 1970s or the 1980s, and you discover that they were given red cells, you don't say to yourself, "Oh, well, you couldn't get hepatitis from that."

A. Absolutely. Even the relatively small amount of plasma would be capable of transmitting a viral infection.

Q. You go on to talk about red cells -- this is section 3 -- the most commonly transfused blood component, whereas it was the other way round perhaps in the early 1980s, that, if anything, it was sometimes red cells that were being discarded rather than, as today, plasma being discarded. Then you explain what their function is: they transport oxygen to vital organs and tissues carried by haemoglobin.

Then, 3.1.2, you say:

"The most clearcut indication for a red cell transfusion is in the patient who has dangerous bleeding after trauma, surgery or child birth, and prompt replacement of red cells can be life saving."

Dr Norfolk, there was an item, yesterday actually, on the radio about the industrial synthesis of red cells. Is that something that's on the horizon?

A. I think I covered that in a later section of the report. There is work going on and some of this work is going on actually in Scotland. There is a big collaborative project to try and grow red cells from haemapoietic stem cells taken from normal donor bone marrow and I guess this is what the item was about; I didn't hear it.

On a laboratory scale it is now possible to take stem cells and make them turn into red cells but there are major challenges still ahead in terms of scaling up that process, to make it possible to, you know, supply blood, and certainly I have been to a number of conferences in the last year where we have had an update on this work and I suspect we are still quite a few years away. But these are very encouraging developments, and there are other groups around the world who are already working on this as well.

Q. Yes. You do, you cover it in section 6 and you have said exactly that. So you are entirely consistent. You

say the technical problems are great and clinical use a probably many years away.

A. Predicting the future is ...

Q. Yes. I suppose the great advantage of that, though, is the enormous reduction in the possibility of transmission of pathogens?

A. Yes, although using stem cells introduces its own risks. But the cells that you would be giving to patients are end stage cells, so they don't contain DNA or nuclear material, so there are no genetic worries about giving that sort of material, and the cells will be taken from donors who have been very thoroughly screened for known infective transmissible causes. So I think the risk would be very, very small. The real challenges are around what blood group would be expressed on these red cells and whether you would have to develop lots of different cell lines for patients with different groups or could you develop a sort of universal red cell for transfusion. These are all issues at the moment.

Q. I see.

THE CHAIRMAN: Professor, there are some perhaps strange ideas there. Cells that have got no DNA and no nuclear material?

A. You see, red cells, of course, have lost their nucleus as they have developed in the bone marrow, so the

circulating red cells are a bag of haemoglobin and they don't contain any DNA or nuclear material at all. The bone marrow is very clever at doing that, and getting that to happen in a laboratory setting is actually extremely difficult.

THE CHAIRMAN: Professor James was anticipating your answer for me.

A. Right.

THE CHAIRMAN: Yes.

MS DUNLOP: Just in the rest of that section, Dr Norfolk, where you are talking about why people receive transfusion, you explain that the surgical requirement has, if anything, diminished, and you say:

"Improvements in surgical and obstetric techniques in western countries have reduced the use of blood for these purposes. In most modern hospitals more than half of all red cells are transfused to medical patients."

So that's patients with anaemia or other underlying conditions or diseases requiring transfusion?

A. Indeed.

Q. Platelets you describe in the next section, 3.2, if we can go to that. Thank you.

"Patients with very low platelet counts are at increased risk of bleeding."

It is the case, is it, doctor, that if somebody has

a particularly low platelet count, they might not, for example, be fit for surgery?

A. Absolutely, yes.

Q. So somebody who needs a particular operation but has a very low platelet count will need to have their platelets boosted?

A. By transfusion, yes.

Q. And then you instance other situations where people need platelet transfusion: diseases of the bone marrow such as leukaemia and also side effects of other forms of treatment for other conditions. Platelet transfusion is only from the late 1970s in fact. But the large majority -- and this is 3.2.2:

"The large majority of platelet transfusions are to try and prevent bleeding in patients."

Just at this point, when you have been describing the different components, I wanted to ask: where are the white cells? You don't really talk about the white cells.

A. I left white cells out of this. It is fair to say that there are very few white cell transfusions performed in modern practice. It is possible to harvest white cells from blood donations. When you spin the blood, they form a layer close to the platelets in the middle, between the plasma and the red cells. People have been

giving white cell transfusions on and off for many years. The problem is that the number of white cells you can collect from ordinary donations is actually very, very tiny in comparison to the body's own production of white cells.

The clinical evidence that you can give enough white cells to make a difference and improve patients -- the classic clinical scenario where patients might be considered for white cell transfusion would be a patient after cancer chemotherapy or bone marrow transplantation, who have a -- their bone marrow can't make normal cells. This is a patient who may have developed a very serious infection, which isn't responding to antibiotic therapy, and the possibility is that by giving white cells, which the patient doesn't have, you might be able to allow that patient to fight the infection or at least keep going until their own white cells can recover.

The evidence from clinical studies is that, as conventionally used, white cell transfusions are probably rather ineffective. They go in and out of fashion. There are no randomised clinical trials of white cell transfusions and it is an extremely difficult area in which to perform clinical trials. I think the state of the art at the moment is that, although we do

actually have technologies to produce white cells and we do issue a small number to hospitals, there is a wide divergence of clinical opinion about the value of these transfusions. Some clinicians use them quite often and many clinicians and haematologists don't use them at all.

To some degree, the development of white cell transfusions has been put on the backburner because of other developments, such as drugs that you can give to patients to stimulate their own white cell production as they recover from chemotherapy, things like granulocyte colony stimulating factor, which has been around now for about ten years. Once the patient is starting to recover, that can promote recovery of white cells. The sheer number that your bone marrow can produce is so vast compared to what you can transfuse. Also, white cells do carry certain risks. They very easily sensitise the patient to antigens present on the white cells and make the patient then more difficult to transfuse with other blood components.

So it is an unsatisfactory technology, which is unproven and actually is of very limited utility at present.

Q. But they are there as well; when we look at the different constituents of blood, white cells are there

and they are also in the bone marrow. Is that right?
A. Absolutely. They are produced in the bone marrow from the same stem cells as all blood cells.
Q. 3.1.1. You are talking here about plasma. I think we understand a little bit about the different fractions one can obtain from plasma. You talk about cryoprecipitate, a derivative of fresh frozen plasma. It contains a higher concentration of the clotting factors, fibrinogen, factor VIII and von Willebrand's factor. Fibrinogen is really factor I, isn't it?
A. It is indeed, and in fact, although cryoprecipitate was initially developed, I think in the 1950s, as a source of Factor VIII, a more concentrated way of treating patients with haemophilia, its primary use in the last two decades has been as a source of fibrinogen in patients with major haemorrhage.
Q. The clotting process is a chain, is it, doctor, involving the different factors in sequence?
A. Indeed.
Q. Perhaps you could say a little bit about it.
A. Well, it is very complicated. There are different components to the coagulation system. We have mentioned platelets already. You need to have normal platelets with normal function. We have lots of different clotting factors in the blood, which, when there is

a trigger, a stimulus, to produce a blood clot, such as damage to a blood vessel and trauma or surgery, a sort of chain reaction is initiated and the blood clotting factors start reacting with each other, and the end process is to produce an insoluble fibrous protein called fibrin, which is what we would recognise as a blood clot, and this forms around platelets which have been attracted to the site of the damaged blood vessel.

We also have a natural anticoagulant system and an anti-fibrinolytic system, which helps to break down a clot where you don't want it to be produced. If you make clots in the wrong place, that's what we call thrombosis, of course, and actually all of these systems in a normal individual work together in a beautifully co-ordinated fashion. There is a lot of what is often called inbuilt redundancy in the system as well.

Q. I didn't catch that. Redundancy?

A. Yes. You can actually drop individual components of the clotting system. Many of them can fall to quite low levels without a risk of bleeding because if other parts of the system are working well, then you have actually got a sort of safety net, but it is when you get below certain levels that the patient then has a great risk of bleeding and if they have damage to more than one component of their clotting system, they are more at

risk of bleeding. So if you have a deficiency of clotting factors and also a low platelet count or your platelets don't work properly, then you are more likely to bleed than if you have an individual deficiency.

Q. And, indeed, if you have levels of Factor VIII which are below adequate, then you will have haemophilia A to some extent, and if your levels of Factor IX are inadequate, you will have haemophilia B, and that represents in each case a missing link in the chain?

A. Absolutely, yes.

Q. And those are not deficiencies of the type you have just described that can be made up elsewhere?

A. No, certain clotting factors have a much more key role in the cascade than others, and so Factor VIII and Factor IX deficiency, if it is very severe, always leads to a severe bleeding syndrome, whereas there are other clotting factors in the cascade which you can have very low levels of and in fact you do not bleed at all.

A good example of that would be Factor XII deficiency. Patients with Factor XII deficiency actually have no bleeding tendency at all and paradoxically have an increased risk of getting blood clots. Our understanding of the clotting system is developing very quickly. I'm not a particular expert in that area but it is all much more complicated than

perhaps we thought it was 20 or even ten years ago.

THE CHAIRMAN: I think there is a certain consolation in that because I have to confess to having had some difficulty in finding a relatively simple way of describing the clotting process. You have mentioned cascade, and of course that's an expression I found early on, as people were trying to describe the process of the formation and effect of a mat on to which other elements in the process built up. But I had the impression that at a later stage the system was seen rather differently, as a particular factor escaping from the external wall of the vein and initiating a interaction or a reaction with other elements. What's the up-to-date position?

A. I think one of the problems has been that, of course, our knowledge of the coagulation system has evolved over time and most of our knowledge of the coagulation proteins like Factor VIII have come from laboratory in vitro tests in test tubes. What you can make happen in a test tube doesn't actually necessarily reflect what happens in nature. So this nice picture that we had when I was a medical student of Factor XII reacting with Factor XI -- XII, XI, IX, VIII, II, V -- to produce fibrin is in fact, we now know, just grossly wrong. The major stimulus to physiological coagulation, as you say,

is actually damage to the blood vessel and the release of substances which activate Factor VII. That triggers off an initial part of the coagulation pathway and if that isn't inhibited, you then get a sort of run away reaction.

The body is very clever at making sure that clots only form where you need them. So it quenches a reaction outside the immediate area where the blood clot is needed to be formed. It is a very clever system, which we still imperfectly understand.

THE CHAIRMAN: We can still talk about it being a cascade, can we?

A. It is a cascade.

THE CHAIRMAN: That's a comfort in itself, yes. Thank you.

MS DUNLOP: Maybe, doctor, if people had known then what they know now, the numbers might have been allocated in a different order. It all starts with Factor VII.

A. It was even worse before the numbers were allocated because all the coagulation factors were named after the patients in whom the original deficiency was reported. So Christmas Disease Factor IX in fact was Mr Christmas, who was a Canadian gentleman who died only recently.

Q. That's a distinction of a very particular sort.

A. Yes, indeed.

THE CHAIRMAN: Von Willebrand, was he a patient or

a physician?

A. He was a physician, and in fact he put his name to quite a number of different substances and diseases.

MS DUNLOP: Just because I can't resist the temptation of venturing on to more complicated territory -- which is always a mistake -- you can get genetic mutations which give you slightly different forms of the some of the factors as well, can you?

A. Indeed, and so, you know --

Q. Factor V?

A. Yes, indeed, and you can get what are called quantitative or qualitative abnormalities of certain clotting factors, so the mutation may cause you to have a very low level of a factor and then it is easy to understand why bleeding can occur, because you can't make the factor properly. Some mutations allow you to have normal levels of the clotting factor but it doesn't work properly, so you need to have a test which is based on the function of that factor, rather than just measuring how much of it there is in the blood, and again these technologies have developed over the years.

Q. Thank you. You talk about what is done with fresh frozen plasma, and that carries on to 3.3.2, 3.3.3, although we should note at the end of 3.3.2 that most clotting factors are made in the liver. We have already

learnt that for a person with haemophilia who has a liver transplant, that should in effect cure the haemophilia?

A. Yes.

Q. And then you explain in 3.3.4 about a precaution which has been taken in the United Kingdom in relation to CJD, that fresh frozen plasma for use in children below the age of 16 is now derived from imported donations from countries with a low instance of BSE, mainly the USA. So all the blood services, the four blood services, are importing such material as we speak?

A. Indeed.

Q. For that purpose?

A. Yes. The English National Blood Transfusion Service in fact, I think, owns a plasma collection facility in New England, which supplies the NHS.

Q. But the rest of us we would just get domestically sourced material?

A. Yes. I mean, the decision to source plasma for children from what I believe to be very low risk variant CJD areas was advice given to the government by the specialist advisory committee on the safety of blood tissues and organs, and the reason children were initially targeted to receive what one might call very, very CJD-safe plasma was because the majority of them

would not have been exposed to dietary CJD through eating beef. More recently, the advisory committee to the Department of Health has suggested that the Department of Health should consider whether it is feasible to import all plasma for all age groups. That recommendation was made about 19 months ago and the Department of Health are conducting a feasibility study. It is a question of feasibility, cost-effectiveness and so on; no decision has been made about that yet.

It would not be possible to import red cells and platelets from abroad. That was looked at very early on, when there was a considerable amount of anxiety about variant CJD, and it simply would not be possible to support the United Kingdom from importing all blood components.

Q. Right. So the prions are in the plasma?

A. No, about half of all the prions are actually present in the plasma component. The rest are associated with some of the red cells, for example, and white cells. My understanding -- and I'm not an expert on this -- is that pure platelets probably wouldn't carry prion but, of course, they are suspended in plasma, which does.

Q. In section 4 you deal with who gets blood transfusion and there are some graphs for us to look at. The first one is the red cell graph. You describe a number

of studies. The first is the EASTR study. Does that stand for Epidemiology and Survival of Transfusion Recipients? Is that correct?

A. It does indeed.

Q. And that's a study on all transfusions performed in 29 representative UK hospitals in 2001 and 2002, and we can see, in relation to red cells, the age and sex distribution of red cell recipients. You go on to explain that a little bit to us but, broadly speaking, we can see, if women are on the left, they dominate really from about 15 to about 55 and then men get their turn and then women come back in again over 75, presumably because there are more of us.

A. The men have all died by then and the women are outliving them.

Q. Steady on.

PROFESSOR JAMES: Some of them are still alive.

THE CHAIRMAN: That is not a comfort.

MS DUNLOP: Then you have also looked at transfusion data from 18 hospitals in the north of England.

A. Hm-mm.

Q. And looked at them four years apart. And then, if we go to the next page, you talk about the EASTR study. You explain, what is not difficult to follow, that red cell transfusions are more common in females in the 20 to

40-year age group, for obstetric and gynaecological reasons, and then at the end of the age distribution people are much more likely to need a transfusion over the age of 60. In fact the median age of patients receiving red cell transfusion is 69.

A. Indeed.

Q. And in the study of the 18 hospitals we get various statistics for the use of the red cells, what was wrong with the people who received them. You say:

"The most common surgical indications for transfusion were orthopaedic surgery such as hip or knee replacements."

Which is interesting because, I'm not sure, does that just reflect the fact that orthopaedic operations are very common or is there a lot of bleeding in an orthopaedic operation?

A. Well, both. They are very common operations and they are more commonly performed now. Knee replacements particularly are associated with quite a lot of bleeding. I think what these studies show, though, is that, although the number of operations carried out has increased quite significantly between those two time periods, 2000 to 2004, the actual amount and proportion of blood used for orthopaedic surgery hasn't increased. There are lots of studies showing that, with

improvements in orthopaedic surgical practice -- there are some very clever techniques you can use to collect the blood during the operation and give it back to the patient -- the average number of blood transfusions received by these patients has actually fallen quite significantly in most centres. It has been a very good development.

Q. I was trying to think in absolute terms of what must be the type of surgery that uses the most blood. One candidate might be, what, transplant surgery? Is that very heavy?

A. I think individual operations may use quite a lot of blood but they are not terribly common procedures. A good example of that would be liver transplantation. When liver transplantation first started, it wasn't uncommon for patients to need massive blood transfusions, sometimes 50, sometimes even 100 units of red cells, to support them during the procedure.

My colleagues now tell me that, you know, many of these patients receive only two or three units of blood during a liver transplant. Again, they have very clever technology to reinfuse blood during the operation, much more clever at supporting the coagulation of the patient. So you know, many of these procedures have shown a very significant reduction in blood usage.

I think cardiac surgery has and still is a quite a major user of red cells in the UK. Again, you know, there have been reductions in many centres now over time.

Q. As well as the surgical uses, you talk about the non-surgical uses. We can see the different possibilities listed there. The number of red cells used for medical indications has risen by 10 per cent since 2000.

A. These studies -- which are called "Where does blood go?" -- in fact, a further iteration of this study has just been collected and their data has been collected and hopefully it will be published later this year. So it will be very interesting to see what is happening now.

Q. There are entire periodicals on the subject of transfusion, are there not?

A. Indeed, yes.

Q. That's one of them, is it? Is it called "Transfusion"?

A. Transfusion is the journal of the American Association of Blood Banks and it is the premier transfusion journal.

Q. There is a British one, is there?

A. There is indeed. This is "Transfusion Medicine", which is produced by the British Blood Transfusion Society, and Vox Sanguinis, which is the journal of the

International Blood Transfusion Society; there are a number of smaller transfusion journals. Some transfusion medicine of course is published in more general haematological journals as well and in surgical and critical care journals, because a lot of the developments are actually occurring in particular clinical fields.

Q. I see. So you talk about various circulars from the chief medical officers. Then on the next page we can see another graph and this is the same exercise really but for platelets. This also comes from the EASTR study. Then we see again, certainly not the same pronounced difference between men and women in, kind of the middle years, but would do see a high usage in males in mid to late life, and you say that that may relate to cardiac surgery?

A. Yes. This is data from 2001, I think, it is a decade out of date now. Of course, I think the evidence is very strongly that what you are seeing there are male patients having cardiac bypass operations following heart attacks. And the epidemiology of heart attacks again has changed in the last decade. So this is historical data, I think.

Q. I see. Then the final graph is fresh frozen plasma, which we get on the next page and you say that's similar

to platelets.

A. Hm-mm.

Q. Large excess of older male recipients related to cardiac and vascular surgery. Can we move to the next page, please? You talk about current indications, contra-indications in specific risks of blood component transfusion. The figures you give at the end of the paragraph tell us what the estimated risk -- at least as at 2009 -- of acquiring particular viral infections from single donor blood components in the UK was. Really in relation to all of these, they are extremely low; almost entirely due to screening.

A. Screening and better donor selection.

Q. Yes.

A. Yes.

Q. You tell us a little more about SHOT. You say that the highest risks are now related to misidentification of patients at the time of blood sampling or transfusion. When I read that, it made me dig out my leaflet from the Newcastle Blood Centre that we visited. Are blood transfusions safe? The question is asked and it tells the patient the biggest risk from receiving a blood transfusion is being given the wrong blood. That's the message being communicated straight away.

A. Indeed.

Q. Perhaps in a rather blunt style that we wouldn't have found 20 or 30 years ago. Is that reasonable?

A. Yes, and identification of patients is crucial to so many aspects of medical and surgical care, not just transfusion, of course. Making sure you get the right drugs, the right surgery, the right imaging. So there is a big focus now on improving patient identification by training staff, new technologies and in many ways transfusion has led the field in this although the benefits will be much greater across other aspects of medical care.

Q. Right. You say:

"SHOT has also identified that bacterial transmission by certain components, especially platelets, remains a significant albeit rare risk."

In general, Dr Norfolk, you shouldn't really have bacteria in your blood. Is that right?

A. No, and under normal circumstances none of us would have bacteria in our blood. The way that bacteria get into blood donations is actually from the skin of the donor at the time of collection of the blood because of course we all have a normal bacterial flora on the skin. In fact, most of them carry out a healthy normal purpose but when the needle is inserted to collect blood, it is possible for a small number of bacteria from the skin to

get into the blood donation and into the pack and then under the right circumstances those bacteria could grow to sufficient quantities to produce harm to the recipient of the blood component.

Q. You explain how that could lead to transfusion-related acute lung injury and go on, though, to tell us that in context the absolute numbers reported are really very low. For 2009 there was only one death in the UK definitely attributable to transfusion.

A. Yes, although there were 14 ABO incompatible red cell transfusions reported to SHOT in that year but none of them were fatal.

Q. So my leaflet may be blunt but it is accurate?

A. It is absolutely accurate. I think what SHOT showed -- our perception was entirely focused on the risks of collecting blood and it being safe in the blood centre. SHOT immediately showed that the real risks for patients were actually hospital-centred and largely preventable by better techniques of patient identification, better systems in hospitals.

Q. Human error?

A. Human error. And human error will always occur but of course, you can develop systems to overcome human error. You can train people better. You can introduce technologies which eliminate human error from the

process and all of these things are now happening.

The other thing we are doing is trying to empower patients to ensure that they are identified properly. In the same way there was a campaign to reduce hospital-acquired infection by encouraging patients to say, "Have you washed your hands, doctor?" Or nurse. We are talking now about a campaign to empower patients to say, "Do you know who I am?" "Have you identified me correctly?" And there are proper ways of doing that.

Q. Goodness, doctor, we could spend a long time on the topic of how you encourage patients to challenge doctors or to try to obtain more information from doctors and that is already taking us into areas that we will perhaps be going to later in our Inquiry.

A. Absolutely.

Q. Just before section 5.2 you talk a little bit about prions. Prion, according to some web readings -- you will have to correct me if this is wrong, Dr Norfolk. A prion is a protein in misfolded form. Is that correct?

A. Indeed, like you, as a clinical doctor I wouldn't pretend to fully understand the basis of these prion diseases and I suspect nobody really does. They are not bacteria, they are not viruses. They are normal proteins that we all have that occur in a misfolded way

and if they enter another individual, they can encourage the patient's own normal prion proteins also to become misfolded. But there are many greater experts than me in this area.

Q. I think fortunately that's all we really need to know about prions, save perhaps that it seemed to be a made-up word from "protein" and "infection"?

A. I think that's right.

Q. Coined in relatively recent times.

Back to red blood cells. You say -- and this is no surprise -- that:

"The benefits of transfusion are most clear in patients who would otherwise quickly die from severe bleeding, whereas any harmful effects are more important in less acute situations or where alternative treatments are possible."

So this is just the risk/benefit analysis that presumably has to be considered in any transfusion situation?

A. Yes, one should always consider and discuss with the patient if there are alternatives to transfusion, which are equally effective and may be much safer. In many situations, which in the past blood would have been transfused, we would now treat the patient with medical therapy. So it should be very rare to transfuse

patients, for example, with iron deficiency anaemia, which would only be a temporary solution, whereas of course the treatment is replacement of the iron.

Q. Indeed, you go on to explain -- and this is going into the next page, the whole section headed "safety issues"-- nowadays the idea of the level of haemoglobin, for example, below which you need a transfusion, is lower than it used to be. You say:

"It used to be a haemoglobin level of 10."

THE CHAIRMAN: I don't think we have this page.

MS DUNLOP: Sorry, reading on to the next page. Yes. There it is:

"For many years it was traditional to use a trigger haemoglobin concentration of 10 for red cell transfusion after surgery. Custom and practice."

Then you say that it has been discovered that healthy individuals can safely tolerate much lower levels of haemoglobin. Presumably on the basis that it will come back up?

A. Absolutely, and you know, we all have good compensatory mechanism. Anaemia, especially if it comes on slowly, you speed up your heartrate, you breathe a little faster to get more oxygen into the blood and you can compensate to a very high level until you hit what is often called a critical point, below which major critical organ

functions start to deteriorate.

Q. There is much more of a focus on having, as you say, a individualised treatment plan rather than a sort of one size fits all approach, of saying all patients below a certain level need a transfusion?

A. I think this is going to be the next phase of therapy for anaemia and transfusion: to try and develop ways of individualising treatment to patients rather than having a sort of one size fits all approach.

Q. But there are some guidelines in relation to perhaps the more common situations.

Then platelets, where the safety issues are really quite different and you have covered that really already, talking about the risk of growth of bacteria. So they have a very short shelf life. This is three lines from the bottom:

"Although most of the bacteria are relatively harmless skin germs from the donor arm, much more dangerous bacteria occasionally grow."

You get some fatal reactions, and the main precaution therefore seems to be firstly not to keep your platelets for very long but also to improve the arm cleaning protocols for donors.

What happens to platelets if you don't keep agitating them?

A. They are metabolically active cells, they need a lot of energy to remain viable and so the packs that platelets are stored in is a special plastic which is actually breathable. Oxygen can pass into the pack and they are stored in relatively small volumes in quite flat packs and they are put on what are called flat bed activators which "shoogle" them about and that is optimal.

There is good evidence, though, recently, that you can take platelets off agitation for up to 24 hours without any significant reduction in function and that's quite important when platelets are being transported around, but that's a relatively recent bit of information.

The crucial problem with platelets is that they have to be stored at around 20 degrees centigrade, and that is a very nice medium for the growth of many bacteria and the short shelf life of platelets is almost entirely related to the risk of infection with older dated platelets, rather than any reduction in function on storage.

Q. You followed the statement structure for platelets as you did for red cells. You talk about the guidelines for the use of platelets and then you give us a summary of what the current consensus guidelines are. And then

lastly you deal with fresh frozen plasma. This is section 5.4. Again storage conditions. It's thawed and then you mention here the octaplas, which we have heard about already. That's a commercially available plasma product, which has been treated by solvent detergent as a means of viral inactivation. Then single donor plasma from American donors treated with methylene blue and light exposure has viral inactivation too. This is back to children under 16.

Safety issues. It turns out that actually it is female plasma that's more likely to cause the acute lung injury, so in fact there has been an effort to source all fresh frozen plasma from male donors and that has now been achieved?

A. Indeed. And the incidence of transfusion lung injury has fallen very significantly on successive SHOT reports since that was introduced in, I think, 2003.

Q. It is to do with having had children?

A. Indeed, these are what are called HLA antibodies. When you are pregnant, obviously the baby is half non-identical to you and you can produce antibodies against the tissue typing antigens in fact, the ones that are important in transplantation. These are the antibodies that cause this phenomenon of transfusion lung injury. Male donors very rarely have these

antibodies.

Q. Right. And then the same; you give indications for the use of fresh frozen plasma. This is on to the next page.

We see, for example, it could be factor 5 deficiency, wide variation in the clinical use of fresh frozen plasma. Much of the use being to do with abnormal clotting. 14 per cent was used to reverse the anti-coagulant drug, warfarin. So that must be for someone who is on warfarin but suddenly they need some procedure whereby their blood needs to clot?

A. Or more commonly, the patient has become oversensitive to the warfarin, so they have highly abnormal clotting and bleeding. Warfarin is a very difficult drug to handle. It interacts with many other medications and foodstuffs but for some years now the very specific antidote, which is a manufactured blood product, has been available and it is much more effective than FFP. FFP is no longer recommended for that indication.

Q. Section 6, you cover alternatives to blood component transfusion and you mention pre-deposit autologous transfusion. We have had some discussion of that already. It's really not something that's taking place in any sort of numbers nowadays.

Then this is the point at which you discuss some of

the newer technologies that are coming, the intraoperative cell salvage, which I take is already in place?

A. Absolutely, it has been around for a decade or more but its widespread introduction into hospitals is now only just occurring and this can be life saving technology. It is now more or less recommended at all hospitals who are treating women at risk of major obstetric haemorrhage -- going back to Blundell -- they should have such facilities available in the hospital.

Q. Could we move to a position where all those having surgery have their blood loss replaced by getting their own blood back again?

A. You could. For most surgery, the patients are not transfused at all anyway these days. So setting up the machine and collecting blood just in case you might need to give it back would be very expensive. But there are many intermediate operations where it probably would be sensible to collect the blood and then to give it back to the patient. Effectively you only need to save one unit of donor blood to pay for the disposables used in that operation, using these machines. So it can be highly cost-effective but it is very clinically effective in patients with massive bleeding. You can keep the patient alive by recirculating their own blood.

Q. Right.

THE CHAIRMAN: Could I understand a little bit what's happening. I think that one naturally envisages bleeding as the discharge of blood into the atmosphere in some way. Is the blood collected after it has come into the contact with the environment of the theatre?

A. The blood is actually collected usually from the abdominal or thoracic cavity of the patient. The nurse has a special type of sucker which doesn't damage the cells. As they are bleeding from the various organs, whichever organ is damaged, that blood is sucked into the machine. The machine is just like a cell separator that we use for collecting blood. It spins the blood, separates off the red cells, automatically washes them with saline and then pumps them into a little bag ready to transfuse back to the patient. It is an entirely automated process, which is technically relatively simple to perform.

THE CHAIRMAN: But there must be some exposure to the atmosphere.

A. Absolutely. That's why there is a washing process. If, for example, the patient had a bowel perforation -- so there were lots of bacteria present in the abdominal cavity -- then that would be a contra-indication to this process.

THE CHAIRMAN: It puts a high premium on the cleanliness of the atmosphere in the operating theatre.

A. Absolutely, although these machines really do clean the red cells very thoroughly. The other contentious area is in patients with cancer surgery, whether one might risk reinfusing cancer cells back into the patient and disseminating the cancer, but the evidence is that probably isn't a risk at all. You can actually filter the blood as it goes back into the patient. So the indications for this are increasing all the time.

THE CHAIRMAN: We have heard a little about nosocomial transmission of infection. To the inexpert observer this seems to be a high risk area.

A. In fact very, very few problems are reported and SHOT does collect data on autologous transfusion procedures.

THE CHAIRMAN: Thank you.

MS DUNLOP: This is the point, Dr Norfolk, where you mention the subject we alluded to earlier about artificial blood and that that's not really going to be with us any time soon and making platelets isn't very successful either. That's 6.2. As far as the future for plasma is concerned, you say many experts believe there will be a move away from using FFP to more targeted therapy with manufactured products, like prothrombin complex and fibrinogen concentrate, that contain predictable amounts

of specific clotting factors and have been treated to kill viruses. Of course, that was a problem historically in the treatment of haemophilia, that it was difficult sometimes giving products where the level of the required concentrate wasn't really known.

A. That's right. Ordinary, what we call clinical FFP collected from blood donors, there is an enormous range of normality between different human beings and the amount of clotting factors that they have. So these are very non-standardised units. Although there is an element of quality assurance, the clotting factors vary considerably and they are not of course a concentrate, and you have to give an awful lot of FFP to get a clinical effect.

Q. As far as modern treatment of haemophilia is concerned, you say some single blood clotting factors, such as Factor VIII, are now made by recombinant DNA technology rather than from donor blood. I don't want to use the wrong terminology, doctor; is it correct to say they are artificially synthesised?

A. Yes, these are not derived from human blood components.

Q. Therefore they don't carry a risk of transmission of viruses.

A. From blood donors?

Q. Yes.

A. Yes.
THE CHAIRMAN: What is the base material?
A. For these? It is way outside my area of expertise but my understanding is that the genetic material is grown in a variety of different types of animal cell, in tissue culture. But it is too far outside my area of expertise, I am afraid.
MS DUNLOP: In section 7 you tell us about the effect of the European Union in this area and we have actually heard from Professor Turner too about the different directives and amending directives which have led to a lot of activity in the early 2000s.

Then 7.1.1, you deal with the recording requirements. Again we have seen material to this effect before about records of transfusions in the patients' notes. Protect the patient. But of course originally, when the sort of recording requirements that you have highlighted were being written, as you say, what was in people's minds was Hepatitis B and then you chart different recommendations during the recent decades. The first edition of the UK Transfusion Service's Handbook of Transfusion Medicine. That's the publication we spoke about earlier, isn't it?
A. Yes.
Q. It is now into its fifth edition and you are the editor?

A. Yes. I haven't actually produced it yet but it will be produced later this year.
Q. It is in your in-tray?
A. It is in my in-tray.
Q. The first edition was edited by Dr Brian McClelland of Edinburgh and Southeast Scotland.
A. Dr McClelland edited the first four editions and I assisted him a little with the fourth edition.
Q. Right.
THE CHAIRMAN: Is this a good point at which to --
MS DUNLOP: Yes, I don't think I can finish before lunch and I think probably one shouldn't rush to try.
THE CHAIRMAN: After lunch.
(12.57 pm)
(The short adjournment)
(2.00 pm)
MS DUNLOP: Dr Norfolk, we need to go back to your statement, which was [PEN0100048], and I think this is where we were. Yes, that's exactly where we should be.
We are now going into a section or we are in a section headed "Recording blood transfusions and seeking patient consent". Then 7.1.3 and 7.1.4, you tell us about two sets of guidelines ten years apart. The first set from the British Committee On Standards and Haematology, which is a subcommittee of the British

Society for Haematology -- they are 1999 guidelines -- refer to:

"... a need for good documentation, key recommendations that the medical notes should contain a permanent record of the transfusion of blood and blood components."

So the prescription of blood and compatibility report, donation ID numbers, record of nursing observations, there should also be an entry describing the indication for the use of blood, date, number and type, effect, occurrence and management of any adverse effect.

Then, ten years later, guidelines giving much more detailed recommendations for documentation of the process. It looks to be the biggest single factor influencing the change is the European material which had been transposed by the Blood Safety and Quality Regulations. Was that really the biggest influence?

A. From the laboratory point of view there was much more stringent record-keeping and the requirement for traceability of all components.

Q. Yes. Even things like the clinical indication for transfusion. Presumably even where that might be thought to be self-evident, you are still supposed to document it.

A. It is regarded as good practice to do so, yes.
Q. So even for example, in a placental abruption, something where everybody would know why, you would still be expected to document.
A. That would be very manifest from the notes. So I can see what you are getting at. You probably wouldn't write that down specifically but that would be manifest in the notes in that situation. That isn't true of many transfusion episodes, though. Most indications are relative and an indication of the reason why a transfusion was regarded as necessary at that particular time is useful information.
Q. I see. I suppose particularly as you move towards a more individualised patient care plan, as it were, you are going to need that because it won't be sort of standard trigger points?
A. No, it documents a thought process which is very useful, of course, for future audit and investigation. There is a perception that the simple act of documenting the reason for the transfusion has an effect on the person prescribing the blood and may make them consider the merits of the decision to transfuse.
Q. I see. You say, however in 7.1.5 that there is continuing incomplete compliance, although this is primarily under reference to an English audit with no

reason for -- sorry, you were going to say something?
A. I was about to pre-empt your question. I think all audits in all parts of the United Kingdom show very similar levels of compliance.
Q. Right. No reason for transfusion in 28 per cent of case notes. No pre-transfusion clinical observations, 10 per cent of records. Post-transfusion observations missing in 35 per cent. The audit of red cell transfusion in neonates and children found clear records of the outcome in only 18 per cent of case notes, which is obviously quite a significant gap in that area.
THE CHAIRMAN: Is there any further information? Is there a geographical spread or is it uniform throughout?
A. It certainly varies between hospitals but there is no real geographical pattern. I think if you look at other forms of documentation in medical records outside transfusion, I suspect this is relatively typical. People don't necessarily record every action that they perform. So I don't find those surprising. There has been some improvement over time but in essence they are regarded as quality indicators, I think.
THE CHAIRMAN: Of course, the fact that it is not surprising might found quite a serious adverse comment.
A. Yes. I mean, if you are sitting in the position of clinician, of course, you are surrounded by guidelines

and things telling you to do this and to do that and I think that's one of the things that we need to take into account in making it easier for people to perform this sort of documentation. This is why the development of care plans and specific transfusion records have been developed; to make it as easy as possible to guide the clinician in the most effective way through the system, without unnecessary time and effort.

MS DUNLOP: You say in summary, and this is 7.1.6:

"The requirement for documentation has been well recognised and included in national recommendations since the 1970s. Basic information to be recorded has changed little."

Then the quality of record-keeping in the lab and the traceability of donations has improved to very high levels in recent years. But whilst clinical record-keeping has undoubtedly also improved, there is still evidence of variable compliance."

I suppose these are the people who are on the front line?

A. Absolutely.

Q. They have many tasks to attend to.

A. Precisely. And if people are not doing it, there are many different reasons and one may be that we are not, as I say, making it easy and practical for them to do

so.

Q. Yes. Looking at 7.2, this is your section on patient information and consent for transfusion. We have made some reference to this. Notes of transfusion. You refer to no mention of patient information or consent and these issues not specifically addressed in the first edition of the Blood Services Handbook, the 1989 one. Then in 7.2.2 you discuss the issue and you say:

"At present there is no legal requirement to seek separate consent for blood component transfusion in the UK, although the legal basis for this has recently been questioned."

Until now it has been seen as wrapped up in the general question of surgery. So for those people who are going for surgery, that's how it's seen as covered. But obviously that doesn't necessarily cover all the medical uses that you referred to earlier.

The 2009 guideline concludes that:

"Informed consent, whether verbal or written, should be obtained wherever possible and documented."

But you say that there is a wide variety of opinion, especially on the question of whether formal written consent for transfusion should be required, with obviously some fairly powerful people, fairly powerful bodies, arguing that separate written consent is

unnecessary.

Then patient information, in the last section. A 1997 survey showing what looks like quite an unsatisfactory situation, only 31 per cent of patients given any information. 20 per cent of those who were informed would have liked more information, especially about risks.

That has been addressed in the better blood transfusion initiatives. You refer to the circulars and there may be different circulars for Scotland but presumably to the same effect?

A. The better blood transfusion process was a pan-UK initiative, with all the chief medical officers taking part.

Q. So they would be joint circulars, would they?

A. I think they issued a separate circular in Scotland but it was the same circular.

Q. Transfusion practitioners, hospital transfusion teams and patient information leaflets. You have referred to that already.

Leaflets that are given to patients or leaflets that are left for patients to pick up and read if they want.

A. What normally happens is that leaflets are issued in pre-admission surgical clinics. Patients now commonly get a pack of information. Most hospitals will ensure

that all wards that carry out transfusions regularly have a supply of the leaflets and individual hospital policies may require that when consent is taken for transfusion, the patient is given a leaflet. In some hospitals that is policy and in some it is simply a guideline/recommendation.

Q. Of course, not everyone necessarily takes something in the first time they hear it and not everybody remembers what they have been told either. So I suppose a leaflet is a good thing because people can read it and re-read it.

A. When you talk to patients -- and there have been a number of studies -- patients do like a clinician to talk to them about this so they can answer questions. But, as you say, to be able to take away a leaflet, reflect on it and ask questions is what most people see as their preferred method.

Q. Yes. Then you give us your conclusion, that an informed consent wasn't a major issue for clinicians in the 1970s, increasing awareness following the emergence of HIV in the 1980s. This is possibly true of informed consent in a number of different areas of medicine really.

A. I think, if you step back and look at the transfusion agenda, it is mirroring the gradual shift away from

perhaps a more paternalistic approach to medicine to a more consensual approach.

Q. Yes. More general agreement, you say -- and this is about half way down the conclusion:

" ... more general agreement that patients should be provided with better information about transfusion, its risks, benefits and alternatives, ideally with access to objective quality-assured written material."

And obviously that you would document all of that and that there is still a way to go in actually achieving that desirable outcome?

A. Indeed.

Q. Dr Norfolk, there was one other matter I wanted to address with you and it's a question that we have mentioned several times in recent days at the Inquiry. It is whether steps should have been taken to defer -- although I think in practical terms I mean "exclude" -- as donors people who themselves had had a blood transfusion.

We know that that has been done in the United Kingdom as a measure to assist against variant CJD and that that dates from, I think, 2004 in the United Kingdom. But do you think it could be said that the steps should have been taken some years earlier in relation to the threat of non-A non-B hepatitis -- or

Hepatitis C, as it became?

A. Sure. I don't want to sidestep your question but what I would say: I suspect this is a much more complex question than it sounds at face value because variant CJD and Hepatitis C are very different entities. I suspect, to really make an informed judgment on this, you would need to go back to your statisticians and epidemiologists and look at the balance of risk and benefit because I don't know the answer. Certainly, the removal of transfused donors took 5 per cent of donors, approximately, out of the system and there were considerable concerns about possible blood shortages at that time. So again the true balance of risk and benefit to society as a whole from taking that step may be a difficult question.

The rationale for removing previously transfused donors because of the variant CJD issue was what the experts talked about recycling, which made those people a higher risk of infecting other people. I truly don't know whether the same considerations apply to a virus like Hepatitis C.

So I'm not trying to sidestep your question but I really don't think I'm the right person to ask that question and it is a more complex question than it sounds at face value.

Q. Thank you very much, Dr Norfolk.
A. Thank you.
THE CHAIRMAN: Doctor, does the expression the "Red Book" mean something to you?
A. Yes, the Red Book is the guidelines for the UK transfusion services produced by the J Pack(?).
THE CHAIRMAN: What form does it take now?
A. It takes the form of both a hard copy, which is reissued every few years, but also an online version, which is kept up-to-date regularly, because, obviously, things like donor deferral criteria vary quite a bit from time to time in the light of travel restrictions and new knowledge. So the two versions are available. As far as I understand, they will continue to be available in both a book and electronic version.
THE CHAIRMAN: So it is another source of guidance to the professional?
A. Yes, the Red Book in fact is primarily related to blood services. It is about the specification for blood components and guidelines for blood donation.
THE CHAIRMAN: Mr Di Rollo?
MR DI ROLLO: No, thank you, sir.
THE CHAIRMAN: No, thank you? I didn't consider that possibility open.
Mr Anderson?

MR ANDERSON: Thank you, no, sir.
THE CHAIRMAN: Mr Sheldon?
MR SHELDON: No, thank you, sir.
THE CHAIRMAN: Dr Norfolk, thank you very much indeed. You have been very helpful. Thank you very much.
MS DUNLOP: We have no other witnesses arranged to come today, so it is rather an early finish, I hope not entirely inconvenient.
THE CHAIRMAN: No, nor is it a finish. Thank you very much, ladies and gentlemen, tomorrow morning.
(2.37 pm)
(The Inquiry adjourned until 9.30 am the following day)

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