Tuesday, 7 December 2021

(10.00 am)

SIR BRIAN LANGSTAFF: Good morning, Dr Galea.

THE WITNESS: Good morning.

SIR BRIAN LANGSTAFF: You can see me, can you?

THE WITNESS: I can, yes.

SIR BRIAN LANGSTAFF: And you can hear me obviously. You are, I think, an hour ahead of us where you are, are you?

THE WITNESS: That is correct.

SIR BRIAN LANGSTAFF: So when we take breaks, which we will do during the day, I'm afraid they will correspond with our coffee breaks and our lunch breaks and I hope you are happy to put up with that?

THE WITNESS: No problem.

SIR BRIAN LANGSTAFF: In a moment or two I'm going to ask Oliver to administer the oath. You are affirming I think. You are talking to an audience here in Aldwych House in central London, you are talking to a small audience in the auditorium, a number of lawyers, a number of participants. Beyond this room, however, you are talking to roughly 100 or so people, is what I expect the audience will be today, who will be watching online as your evidence is streamed. So that is who you are talking to.

Now are you there on your own?

THE WITNESS: Yes.

SIR BRIAN LANGSTAFF: Very well.

Well, Ms Scott will ask you questions in a moment or two once you have been sworn.

Oliver, please.

DR GEORGE GALEA (affirmed)

Questions from MS SCOTT

MS SCOTT: Dr Galea, can you see and hear me?

A. I can, yes.

Q. I'm going to start with a brief overview of your career and then go on to look at some of the committees and groups that you participated in.

So, you were, between 1980 and 1984, a lecturer in haematology in the Aberdeen University, is that right?

A. Yes.

Q. And then in 1984 you took up a post as a senior registrar at the Aberdeen and North East Scotland Blood Transfusion Service, a post you held until 1989?

A. Correct.

Q. The director at that time was Dr Urbaniak, is that correct?

A. Yes.

Q. And we are going to be hearing from him in January.

Then from 1989 to 1993 you remained at the Aberdeen Blood Transfusion Service but you were at that time a consultant, is that correct?

A. Yes.

Q. Between 1993 and 1996 you were the director of the Inverness and North Scotland Blood Transfusion Service?

A. Yes.

Q. And between 1996 and 1999 you were the director of the Dundee and East Scotland Blood Transfusion Service?

A. Yes.

Q. Then in 1999 you took up a national post as the national Tissue and Cells Director, based in Edinburgh, which was a post you held until 2013?

A. That is right.

Q. And then from 2014 you have been acting as a consultant to the Maltese government, which is a post you continue in today?

A. That is right.

Q. And your statement tells us that you have never given evidence in any previous inquiry or any previous litigation concerned with the issues that this Inquiry is looking into, is that correct?

A. No, that's right, I haven't.

Q. Turning then to the working groups and committees. Is

it right to understand that you had a post as the medical adviser to the Blood Collection Programme, which is a post within the SNBTS?

A. That is right.

Q. And you describe in your witness statement that that role was to recommend changes and to update donor medical issues and harmonise donor matters throughout the SNBTS?

A. That was the main aim, yes.

Q. And we will look at some of the work that you did in that role as we go through the morning.

And in that role you provided regular reports to the Medical and Scientific Committee of the SNBTS, of which you were not at that stage a member, but you did attend parts of their meetings when those reports were discussed so that you could report upon them, is that right?

A. That is right, yes.

Q. You were also -- and you tell us this was an extension of your role as the medical adviser to the Blood Collection Programme -- you were also the chair and member of the Scottish Donor Consultants Group, is that right?

A. Yes.

Q. And in that role you made recommendations to the

Medical and Scientific Committee of the SNBTS for approval and you ensured that there was consensus approval for any recommendations from the other donor consultants who you met with within that group?

A. That is right.

Q. And so that was really -- is this right, to understand that that was a forum in which consultants around Scotland could meet and share best practice and then report on to the Medical and Scientific Committee?

A. In the context of donor matters, yes.

Q. Then from 1993, when you became a director of the Inverness centre and, equally, when you were a director from 1996 of the Dundee centre, you became a member of the Medical and Scientific Committee of the SNBTS?

A. Yes.

Q. And if we can just look at a document, just to have a look at how that worked. It is SNBTS0000456_027.

So on the first page of this we have a structure, and so there we have there -- the Chairman Is the national medical and scientific director. And the secretary is product services manager.

Then the members of the committee are: the five directors of the Regional Transfusion Centres, the

director of PFC, the director of NSL, and then also the director of the Belfast Regional Transfusion Centre.

Then in attendance as an observer from the English NBTS representative, who is non-voting, and then product services assistant and assistant secretary, also non-voting. Is that how you recall the Committee to have operated in your time?

A. I think it did change a bit. I think the secretary was the national operations manager, Martin Bruce, for a long time as part of the Medical and Scientific Committee.

In my time I wasn't aware that the national director of Belfast was a full member of the group. I knew that he used to attend quite often.

I have occasionally, but fairly rarely, seen an NBTS representative from the English Blood Service. And the product services assistant, I'm not quite sure that that -- I cannot recall who that person was actually.

Q. Then if we turn over to page 4 of this document we can see the remit of the committee:

"The MSC was set up by the SNBTS Board with the remit to advise the Board on members of medical and scientific policy.

"This is achieved by:

"- making recommendations on issues which affect donor safety ...

"... which affect patient safety.

"- overseeing donor education activities.

"- implementing and maintaining an effective programme of medical audit.

"- implementing and maintaining an effective Quality Assurance Programme within the SNBTS.

"- ensuring that Scientific work performed within and on behalf of the SNBTS is of an appropriate professional standard and is appropriately monitored to ensure validity.

"- ensuring the Board is kept up to date with scientific developments ...

"- ensuring the maintenance of supply of appropriate diagnostic reagents to the NHS in Scotland.

"- ensuring that microbiological screening of SNBTS donations conforms to UK standards.

"- ensuring that SNBTS products conform to appropriate modern standards."

Then it says:

"To assist in the performance of the above, the MSC will receive regular reports from ..."

And we can see there you are there noted as the medical adviser to the Blood Collection Programme.

So can we date this document sometime between 1989 and 1993? So between the time when you became a consultant in Aberdeen and before you took up your post as director in Inverness?

A. That's probably fair, yes. I think so.

Q. And then we can see other members -- other people there set out and that also provide regular reports to the MSC, the Medical and Scientific Committee.

If we go over the page, that list continues, including director of PFC, IT managers, quality assurance coordinators, et cetera.

Turning then to -- you were also, is this right, by dint of your directorship of -- both in Inverness and Dundee, you were also a member of the board of the Scottish National Blood Transfusion Service, and the function of the board was to discuss management and financial matters and to make decisions about those matters for the SNBTS?

A. Yes, that is correct.

Q. You were, between 1991 and 2000, a member of the UK Blood Transfusion Service Standing Advisory Committee on Donor Care and Selection?

A. Yes.

Q. The purpose of that committee was to maintain appropriate specifications on the care and selection of donors was it?
A. Yes, make recommendations --
Q. Were you going to say something, to make recommendations?
A. On donor selection criteria, on deferral processes, and so on.
Q. The body, is it right, that the recommendations were made to was to the JPAC, is that correct --
A. Yes, that is right.
Q. -- and to the Joint United Kingdom -- UK Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee known as JPAC?
A. Yes, that is right.
Q. Can we look at a document, just to help us understand how this committee worked. NHBT0000190_063.

This is a letter dated 14 December 1990 to Dr Calman the Chief Medical Officer in the Scottish Home and Health Department. If we turn over to the second page we can see it is a letter from Dr Cash, National Medical and Scientific Director, and it is actually page 2 of this that I want to draw your attention to. It says there:

"Harold Gunson has most positively responded to

my suggestion that there should be established a UK BTS Standing Committee which is responsible to the two 'Directorates' for maintaining appropriate specifications on the care and selection of donors. This Committee is chaired by Dr Bill Wagstaff ... and Dr Galea and myself are the SNBTS representatives. Dr Galea heads up a small SNBTS group which seeks to ensure that a collective SNBTS input is put into the UK BTS Standing Committee. This development should ensure harmonisation of content but it cannot address the issue of the operational differences -- Scotland will continue to be several months ahead in the implementation of change."

That relates to an issue he raises in the beginning of that letter. So, is it right to understand then that there the reference to the small SNBTS group, which you head up, is a reference to the donor consultant group and that, as well as feeding information from that group into the MSC, you were also feeding information from that group into the Standing Advisory Committee on donor care and selection?
A. That is right, yes --
Q. Just a point on the dates, here. We can see that this letter is dated December 1990. So clearly by

December 1990 this -- the decision had been made for the Standing Advisory Committee to exist. But we know from the documentation that we have that the first meeting of that committee didn't take place until almost a year later. Do you know -- the first meeting was in October 1991.

Do you know why there was that delay?
A. No, I really don't know. Maybe it was trying to find the appropriate numbers. I'm not sure. It also was the beginning, I suspect, because there were a number of Standing Advisory Committees that formed later, which all fed into JPAC, whether that took some time for the English blood services to appoint people, and so on, I'm not sure why there was a delay.
Q. That Standing Advisory Committee, I'm going to refer to it as the Standing Advisory Committee but, as you rightly point out, there were a number of standing advisory committees but, as I understand it, it is this Standing Advisory Committee that I'm going to be asking you questions about primarily today.

The Standing Advisory Committee was also concerned with -- was concerned with the production of donor exclusion material and revisions to donor material, such as the AIDS leaflet, is that right?
A. Yes, in some ways. It wasn't fully responsible for

it. I mean, the group made recommendations, clearly. The implementation of the leaflets, and so on, weren't part of the remit of the group, you know, how they looked, whether they were field tested or not, and that was an operational matter. When it came to the principles, yes, the SAC was the group that discussed these items and then it depended very much on what the condition was. Some things like the AIDS exclusion criteria went up to the highest levels to be agreed, like the EAGA, and so on, the Scottish Government and -- sorry, the UK governments to approve.

Whilst other issues, which were, you know, whether somebody can be deferred, if they have been to a malaria country say, then they could be agreed at that group. It depended on the scale of the matter and how serious the issue being discussed was.
Q. So some decisions, some recommendations, could be made purely by the Standing Advisory Committee to JPAC and if JPAC accepted that recommendation, is it right that that would then be promulgated to the National Blood Transfusion Services, so in your case to the SNBTS, for the SNBTS to implement?
A. Yes, we formed guidelines, what we called the A to Z, you know, the alphabetical index of all the foundations, and that was updated on an annual basis

and, therefore, we could use that criteria in our routine deferral and acceptance of donors.

Q. I will be asking you some questions about the A to Z guidelines later on this morning.

Equally, as you tell us, there are some decisions or some recommendations that required the Standing Advisory Committee to consult with other organisations, such as the Expert Advisory Group on AIDS, for example, and then once their input had been received, or even perhaps a decision made by EAGA, then a recommendation for the Standing Advisory Committee would go to JPAC, having carried out that exercise.

A. Even sometimes, you know, over the years have changed. You know; many of these serious decisions were taken to SaBTO or MSBT, as well, for agreement. Also, for example, if there was a recommendation regarding testing, we used to consult with the SAC on Transfusion Transmitted Infections. So it was a pretty, kind of, flexible way of taking the expertise from the most appropriate body.

Q. The Standing Advisory Committee was also concerned with drawing up what's colloquially called, as I understand it, the Red Book or the Guidelines for the Blood Transfusion Service in the UK, or at least

a chapter on that.

A. Yes, the chapters which relate to donor care.

Q. Exactly. Again, we will look at that document in due course.

Then you were a member of a number of other advisory committees and working groups. So you were a member and later chair of the UK NIBSC BTS Standing Advisory Committee on Tissue and Stem Cells between 2001 and 2010. You were president of the British Association of Tissue Banking between 2003 and 2005, is that right?

A. Yes.

Q. You were Chair of the British Association of Tissue Banking Medical Special Interest Group and Vice President of that group?

A. Yes.

Q. You were a member of SaBTO between 2007 and 2014, bringing your expertise as a tissue banker to that group, and you were a member of the SACTTI -- so the Standing Advisory Committee on Transfusion Transmitted Infections, SACTTI -- Working Group on vCJD and on the vCJD test subgroup but you were not a member yourself of SACTTI itself, is that right?

A. That is right.

Q. I think, lastly, although you were also a member of

the MSBT subgroup on bone, as the Chair?

A. Yes. That was a subgroup of MSBT or SaBTO, as it became known afterwards, in the early years, when I began to input into the group when it came to bone and tissues.

Q. Turning then to your time as a lecturer in haematology at Aberdeen University. Was that a purely academic post or did it involve clinical or laboratory work?

A. It involved both. It involved lecturing, research and also some clinical work in the wards.

Q. What clinical work were you undertaking at that stage?

A. In haematology, haematology.

Q. Were you working with people with haemophilia?

A. Not really, most of the time in the ward it used to be with leukaemic patients, in the oncology wards.

Q. Were you, at that time, or towards the end of your time as a lecturer on haematology, teaching anything about AIDS and the risks of AIDS being transmitted by blood and blood products?

A. When I was in haematology, as far as I can recall, probably not. I had a set number of lectures to give and they were agreed a year in advance, kind of thing. I don't recall giving lectures on AIDS at that stage, no, I don't think so.

Q. Can you recall when you first knew that HIV or AIDS

was -- or HTLV-III -- was a virus transmitted by blood?

A. It was big news in the early '80s, '82/'83, something like that, so clearly I was aware of it. It was a topic of conversation in many conferences I attended and clearly when I joined the blood service in Aberdeen it was clearly a very hot topic then, it was very well known, it was discussed, and so on. It was around that time.

Q. Is this right, that you knew about it in -- by the time you took up your post as senior registrar in Aberdeen in 1984, did you know by then that it was -- that HTLV-III was a virus transmissible by blood and blood products?

A. Probably yes, I cannot swear but probably yes. I would have thought I would have known about it.

Q. Then in your -- can you recall what you were teaching -- when you were a lecturer in haematology, can you recall what you were teaching about hepatitis and, in particular, what you were teaching about non-A, non-B hepatitis or whether you were teaching about non-A, non-B hepatitis?

A. No, my teaching was very much in the leukaemic field because that's what I was doing and also things like basic haematology, like iron deficiency anaemia or

megaloblastic anaemia, infectious complications of transfusions, I wasn't part of the transfusion field then, so I'm pretty sure I was not teaching that at the time.

Q. Were you aware at that time, can you recall, that hepatitis was transmissible by blood or blood products, or at least some forms of hepatitis, and could be serious?

A. In the case of hepatitis, it was a well known fact that hepatitis was transmitted by blood and that, you know, blood was tested for hepatitis B, I think for syphilis as well at the time, it was already being tested then. So, clearly, it was well known that hepatitis -- that blood can be a vehicle for transmission of hepatitis B.

Hepatitis C was a different story. It wasn't part of the scene then, as far as I can recall. I'm pretty sure it wasn't. It was a condition known as non-A, non-B hepatitis, which you know, where jaundice was transmitted by blood and the hepatitis B antigen was negative. So it was known that there was this transmission taking place. Nobody knew what it was, as such, and that it was happening, yeah sure.

Q. Are you able to tell us when it was or when about it was that you knew that non-A, non-B could use serious

liver disease?

A. As I recall, probably when I was in the blood service as a senior registrar, '89/'90, something like that, probably. And it was -- I know that sometimes it used to be discussed in the labs. Not so much about hepatitis C but about this non-A, non-B hepatitis that was taking place. So it was a known condition, it wasn't like a mystery.

At the time, it was part of the 1001 things that you learn about transfusion medicine, I was still in training then. So yes, of course, you learn about the complications, so learning about antigens, blood groups and it can transmit disease, sure, and like hepatitis B, non-A, non-B hepatitis, syphilis, malaria, and so on.

Q. I'm going to ask you some questions about your time at Aberdeen, so 1984 and 1993. We have Dr Urbaniak coming to give evidence in January, so the questions I'm going to ask you are necessarily focused on what you were doing at the transfusion centre, rather than more generally what was happening.

First of all, can you tell us what your responsibilities were in your senior registrar post, so between 1984 and 1989?

A. When you are in training within the blood service, at

least in Aberdeen, I had no specific responsibilities as such. It is a very hierarchical situation within the Blood Service, at least where I worked. So the director was in charge of the centre. I was in training. I was doing -- I was revolving around different parts within the Blood Service and outside.

So I think in the first two or three years, two years of my training, two or three, I was spending four months in haematology, four months in infectious disease units and four months at the blood centre, doing rotation to expose myself to transfusion matters. Then I did my MB, which was a postgraduate course, like a PhD, which took me about 18 months, I believe.

And then I was -- my responsibilities as such when I was in the Blood Service was to check all the blood groups of all new donors and of patients, because we used to do antenatal work as well for pregnant women, advising on anti-D, for example, who gets anti-D or not.

We used to share an on-call rota. So because we were attached -- we were part of Aberdeen Royal Infirmary, so we also ran the blood bank for the hospital, and therefore if people required any advice on what components to give, if somebody required

platelets or somebody required FFP or a massive bleed or a postpartum haemorrhage, there always used to be a medical officer on call. I used to be one of those. I think we were three or four, so it was a one in three rota -- a 24/7 rota. I believe it was a week on, two weeks off basis because, although we used to be called at night, you know, many of the on-call discussions could take place over the phone, so you didn't have to come in very often.

Sometimes we had to come in because we also used to do plasma exchanges on patients who were very ill, like hemolytic uremic syndrome or macroglobulinemia, and so on, so we have to do it with the current plasma exchanges, and those you had to come in and do them. You know, it used to be a procedure which could last, say, three or four hours on a machine in the wards with a patient.

So rotations, on-call, learning about -- and without any specific responsibilities for any part of the blood centre itself. It --

Q. And were you -- sorry, I interrupted you?

A. It is okay, sorry. It is fine.

Q. And were you attending donor sessions during that period of your career?

A. A few, because initially, you know, it was something

which you do as part of your rotation. You learn how it is done. And then you are -- you know, you are an extra because, you know, the donor sessions were all staffed appropriately. They did not depend on people in training. Because clearly if I went away for four months in a ward, I wasn't available to be at sessions. So I went, I saw them, I learnt about them, but I wasn't part of them as a routine.

Q. So you wouldn't have performed the role of a medical officer in a donor session while you were a senior registrar?

A. No, or very, very rarely. However, I used to be available -- when I used to be on call, I used to be available for any queries. If sometimes a doctor or a nurse has a question in a forest or in a village somewhere and they are not sure, there was always somebody in the centre who could answer the question or tried to answer the question or support the nurse or doctor and say, "Do not take" or "Accept" or "Defer", whatever.

So that was my limit of involvement there.

Q. And when you became a consultant in 1989, how did your role change?

A. It changed quite a bit because then I do not think I remained on call as I used to be so frequently

because there were people in training who were doing it, although I still participated I think. But then I had more of donor interests areas. So I was in charge. Although the director was always in charge, if you like, but my section was the donor section where I was responsible for. So I would advise Stan Urbaniak about things like donors, like are we collecting enough or should we go to a different halls, or should we organise things in a different way, and so on and so forth.

Q. Can you recall whether, during that period in Aberdeen, it was considered to be part of the duties either of yourself or of any of your other colleagues at the centre to educate clinical colleagues in other hospitals about transfusion medicine and in particular about the risks of blood and blood products?

A. Absolutely. We had the advantage because we were part of the hospital, the blood centre was based in the hospital itself. I mean just outside Aberdeen Royal Infirmary was the blood centre. So we were very close. And we also ran the blood bank for Aberdeen Royal Infirmary. We also did cross-matching. So we had very close relationships with the consultants and with the medical staff in the hospital itself.

So, for example, we -- I remember I was always

interested in audits and we ran a number of audits on the use of blood, for example, on obstetrics. We used to identify that for a particular situation, for a caesarean section for example, some consultants would order two pints of blood, some would order six. And we would say, you know: What is this? Why is this happening? So we would audit them. Then over the years, in Aberdeen, we established what are known as MSBOSes, Maximum Surgical Blood Ordering Schedules, so that, with the consent of the clinicians and surgeons, we used to go and discuss with them and we would say, "Look, for example, a vasectomy only need two pints of blood and not more, unless there are complications". So we used to set these schedules which, very often, they agreed with, and these became the norm.

So any operation that came in, any request of blood that came in for a particular operation, the people in the blood bank would know how many units to cross-match, and this brought down the use of blood quite a lot. Because, as I say, there were surgeons who were much more liberal in their usage and, with these kind of discussions and with these schedules, we reduced the use of blood quite a bit.

And we published all this actually because they were very useful -- because you then show people that

nobody died because you only gave them two pints of blood, nobody came into harm because you reduced blood usage. And then, with time, all the consultants became much more confident and they became the norm.

Q. Did you implement that system that you've just described, with the schedules of amounts of blood, in the centres you then became director of in Inverness and Dundee?

A. Yes. In actual fact, I think these became quite national within Scotland. So when I went to Inverness they were already in place. And what we did was I tweaked them, for example. And it is very difficult sometimes because different surgeons from different hospitals have different needs. And therefore if, for example, in Aberdeen for a hip replacement you require two pints of blood and in Inverness it was three, well, that wasn't too much of a problem. So generally we used to tweak them but not be so exact as to have for Scotland two pints of blood for every operation.

Q. What about education in terms of the risks and, in particular, the risk of transfusion-transmitted infection from blood and blood products; did that form part of the conversation with your clinical colleagues?

A. Yes. And I think many of the clinical colleagues knew

about the risks. I mean, they knew that blood could be infectious. I mean, HIV was very much -- you know, high on the agenda at the time, and hepatitis. So they didn't need much persuasion kind of thing. They knew about the risks. Most of the teaching was to medical students.

So, medical students -- I used to teach quite a lot at the time, and obviously the risks of transfusion-transmitted infections was -- I used to hammer it down, you know. Very important. I say it till today: the safest blood is the blood that's not given. So, you know, be conscious and give little -- give as much as the patient requires but don't go overboard. And so on. So that kind of -- yeah, I mean, it used to be part of my agenda to teach the medical students about that.

Q. And were there any formal mechanisms for sharing this kind of information with the clinical colleagues rather than students? Were there any meetings or a programme of lectures or anything of that nature?

A. Yes. We -- I used to attend the various committees. So, for example, the ethics committee used to meet once a quarter or something like that, and probably once every alternate time or maybe once -- maybe once every six months or once every nine months I used to

go back and show them their blood usage, show them how much they have cut down. And they used to like it because it used to be done in a non-threatening way. So it used to be like -- when I used to go, if there were four obstetricians, I used to name them A, B, C, D, so that even they don't know who they were when they were in the room, so that nobody felt threatened. And it wasn't like, "Why did you do this?" But, "Here is what you have used. Is there any way that we can cut this any more?"

So it was done in a non-threatening way, in a collaborative way. And, yes, I mean, I think they were a big success in terms of required.

Having said that, at the same time, there was the Better Blood Transfusion Initiative which was taking place. So medical students were being taught about this: how to give blood, how to cross-match people, much better to give components then whole blood.

In actual fact, the use of whole blood, I can remember very few instances, for example, when whole blood was used, because the clinicians knew and the young doctors in training all knew that component therapy was much better for patients than the blood that was whole blood. So, yes -- with orthopaedic

surgeons we did the same. So there were thick groups who used to attend the committees and let them know about blood usage and so on.

Q. You have mentioned that in Aberdeen you were the -- the transfusion centre was also the blood bank for the Aberdeen Royal Infirmary.

A. Yes.

Q. That was the case, was it, as well in Inverness and Dundee?

A. Yes, I was very lucky in that respect because wherever I worked it was the blood bank as well. So we used to do all the cross-matchings. We worked on site, in the main hospital, and therefore you could build up liaisons with clinicians much more easily than if you were five miles away, you know, in a transfusion centre.

Q. And so the role of the transfusion centre was twofold really. It was to, on the one hand, get the donations in, separate them into components where necessary, and store those components and supply those components to all of the hospitals in its area as well as acting as -- and, of course, supply plasma for fractionation, as well as acting as a blood bank?

A. Yes. That changed around '97, I think, when the processing and testing sites changed within the SNBTS

and they became located in Edinburgh and in Glasgow, so the peripheral, if you like, blood blanks lost their processing ability, so then all the blood that was collected went to the processing sites, and in our case it used to be in Edinburgh. All the blood was processed there and then we got back the components, you know, the platelets, the plasma and the red cells.

Q. And that was when you were in Dundee?

A. Yes, correct.

Q. I will ask you a few more questions about that in due course.

So is it right to understand then, in terms of the records that you had access to, for those hospitals that where you blood banked, whether it was Aberdeen, Inverness or Dundee, that you had access to patient records in those hospitals but not in the other hospitals?

A. Patient transfusion records, yes, not the full hospital records. But yes, we had access to their transfusion records, yes.

Q. So when it comes to look-back, trying to identify what's happened to particular components of blood or particular packs of blood, was it very much easier for those patients?

A. I suspect it was and because we had records -- within

SNBTS I don't think we ever threw paper out. You know, we keep everything. Everything was kept. Even though we became computerised, I think even paper records were kept. So it was, I think, relatively easier to trace patients, I mean, because we had all the records ourselves.

And if I recall correctly, when we did the look-back, those hospitals, those centres which were also in the blood banks, like I was, we -- our finding of patients was much easier than if you were, for example, in Glasgow, where -- in Glasgow, they weren't part of the hospital, they didn't keep patient records, and therefore it was much more difficult. Because you were dependent, then, on the blood bank, on a different consultant, different people. You know, different blood banks. So I think it was relatively easier for us to be more -- and probably, although I'm not sure, maybe a bit more comprehensive as well, because we kept records forever.

Q. Although that's the case only for the hospitals that you were the blood bank for. There were other hospitals on your patch in Aberdeen that wouldn't have -- that wasn't the case?

A. There were hospitals like, you know, in the islands, in Shetland and in Orkney, where, you know -- we used

to supply them with blood but they kept all the records themselves.

Similarly, with Dundee and Inverness, there were other hospitals which we didn't judge their blood bank. We were attached to the main teaching hospital, if you like, but other general hospitals, we supplied them with their blood and with the platelets but nothing else.

Q. You say in your statement that efforts were made to improve the flow of information from hospital blood banks back to the transfusion centre --

A. Yes --

Q. Can you recall what efforts were made and what was effective and what wasn't?

A. We used to insist, for example, if I can remember correctly now because it is a long time ago, that if a bag of blood was sent out for a patient, we used to send out sheets with the patient's name on and then we used to insist -- or try to insist -- that that sheet comes back to us with the patient's name, so that we know that that unit has been transfused.

Now, initially I remember it used to be quite patchy, like we used to get something like -- I'm guessing here, but around 70 per cent, say, of the paperwork used to come back.

So we used to have -- like when I used to go to speak with the consultants, I used to tell them, "Please, in your wards, make sure that you encourage all the nurses and all the junior doctors to give you all the papers back."

And -- because also there were times -- and this I don't think you can change -- where you sent out a unit of blood, it doesn't come back, and then you assume it has been transfused. Now sometimes it could have been discarded in the ward. You know, maybe the patient didn't need it, it was out of spec, it was out of the fridge and so on, so then it was discarded in the ward. So we didn't get -- we could never get all the paperwork back. But it definitely improved in my time.

And the last time I was involved in this was before I became a tissue services director. So I think more efforts have been made since then to make sure that all the paperwork or as many come back so that one can reconcile exactly that the patient has got the blood or otherwise.

Q. Just looking at the donor sessions held while you were in Aberdeen. Is it right to understand that they took place all over the Aberdeen area, including in Shetland and Orkney?

A. Shetland and Orkney, I don't think so. I don't think, Shetland and Orkney, we ever had a blood session there. But throughout the region, yes, in village halls, sometimes in the workplaces. Sometimes if it was a small village, for example, and there was an appropriate hall, we used to send what is called the "blood mobile", so it is a big truck with its back -- in the back of it, there were -- it was compartmentalised into two or three different sections. So a donor would go in, he has his haemoglobin tested, has his medical screening done, and then bled in the van itself. So yes, in many places, workplaces, village halls, and sometimes in this blood mobile.

Plus also we obviously had sessions in the blood centre itself, in Aberdeen. We had a static donation centre.

Q. Was there plasmapheresis in Aberdeen while you were there?

A. Yes, yes. It was (unclear) machine for plasmapheresis. I can't recall exactly whether it was in Aberdeen or Dundee but we also collected platelets by apheresis machines. Yes, that we did.

Q. Do you recall whether or not there were any sessions held in prisons during your time in Aberdeen, in

particular during your early years in Aberdeen?
A. I can't recall, I don't think so sometimes. It might be better if Stan Urbaniak can give you an answer on that one but I do not think we did. Nor did we take blood in prisons in Inverness or in Dundee, as I recall, I don't think so.
Q. Do you recall whether you took -- had any blood -- had any donation sessions with members of the military?
A. Good question. Maybe in Inverness there was a big centre in Kinloss. I suspect we did, although I'm not a 100 per cent sure but I suspect we did. Partly because my predecessor was a military man, as well, Billy Whitrow, and maybe had links with them. So I think we probably did, from military personnel, from Kinloss, RAF Kinloss it used to be, it maybe still is.
Q. Do you know whether there was any conversation or any discussion about whether or not those donors may pose a higher risk of transfusion-transmitted infections or whether that was something you thought you should consider or look into?
A. I'm not aware we had any discussion specific about it. I know that in some forum, whether it was MSC or -- there was a discussion about prisoners. There was a good about prisons somewhere, I can't remember the exact forum where it was, and whether people should go

and keep on collecting from prisoners or not. I think there was a mixed review.

Some people said that prisons are high-risk areas, if you like, others said the risk is of drug use and, therefore, if you exclude people who are drug users then you can still go to prisons, but because in Dundee and Inverness prisons wasn't an issue for me, then I didn't give it much attention because it wasn't an issue for me. Military, I'm not aware of.
Q. I am just going to ask you a handful of questions about HIV while you were at Aberdeen. So you arrived there just prior to HIV testing being introduced. Did you have any role in the decision as to when HIV testing should be introduced in Aberdeen?
A. No, absolutely no.
Q. Did you have any role in the decision-making as to what needed to be in place before it was introduced in Aberdeen?
A. I had no role in decision-making when I was in training at all. It was a very hierarchical situation. I'm not saying it is bad, it is how it was. And, therefore, particularly because I was so new, it was just I'm learning and I was being told that, you know, we are going to start testing, and so on and so forth.

So, at the time, I just took everything at face value. I know that at some point -- I'm trying to think when, whether it was when I was a consultant or before, I was sent to a course on counselling donors who were HIV positive and to learn about how HIV is transmitted amongst particularly gay men, and so on.

And I did do some counselling in Aberdeen for HIV positive donors, yes, I did. You know, when it was introduced and what issues have to be done before, in Aberdeen, no, I had no say.
Q. So those questions would be best directed to Dr Urbaniak next year?
A. They would be much better, yes --
Q. You anticipated my next question, which was about the HIV counselling or the HIV course. Was that the counselling training that was delivered at St Mary's Hospital in Paddington, London?
A. Yes, yes, yes, yes.
Q. Were you the only attendee from the Aberdeen centre?
A. Yes. As far as I know, yes, I'm pretty sure.
Q. Did that mean that you effectively took the lead on HIV donor counselling when you returned back to Aberdeen?
A. It was probably a shared responsibility between me and Dr Urbaniak but probably I did most of them, yes.

I mean, in Aberdeen -- I'm trying it to think -- we didn't have many HIV positives but, maybe I'm guessing here, but I don't know, five, six, people perhaps, something like that, of that order. And I would have done quite a few of those, yes.
Q. I'm just going to turn just to -- turn up and have a brief look at the AIDS leaflets that were in use during your time. So the first one, I believe, is PRSE0003003. So we can see here a document here called, "AIDS: New Information for All Blood Donors", and we can see at the top:

"Our primary concern is for your safety ..."

Second paragraph:

"We want you to know that we are about to introduce an important new addition to our donor health screening programme -- all donations will be tested to see whether you have been in contact with the HTLV-III virus which may cause AIDS."

Is it right to understand that this was the leaflet that came into use just before HTLV-III screening was introduced?
A. It must be. I think, however, there were also leaflets sent out before, when there was no test being done. There were leaflets which specified the high-risk people so that, you know, like gay men or

intravenous drug users, and so on, not to come and give blood because we were very scared that people would come and give blood because they wanted to find out whether they were positive or not. So I think, even before the test came out, these things were issued.

Q. Yes, I think my question was a little bit unclear. I wasn't suggesting that this was the first HTLV-III -- or first AIDS leaflet sent out by SNBTS but, just in terms of the chronology, you arriving in 1984 and this then being the first revision during your time there?

A. I can't remember any details but it must be.

Q. Then it says at the bottom of that:

"Please remember it is essential, although we are introducing the HTLV-III testing, you must not volunteer to give a blood donation if you are or have been a practising homosexual or bisexual man; a drug user, either man or woman, who injects drugs; resident in or a visitor to Central African countries; a sexual partner of people in these groups."

Then there is reference there to being asked to sign a health-check form, which will include the statement that you have read and understood the importance of this message and then making the point

that, if you don't wish your blood to be tested, don't give blood.

Then if we turn then in -- can you recall how this leaflet was provided to donors? Was it sent with call-up cards? Was it given during sessions?

A. Yes, I can. It was definitely freely available at sessions, at every session. If I remember correctly, it was even sent to all blood donors beforehand, when they were called up and maybe, although I'm not sure, maybe even to all GPs.

It was definitely very widespread. We wanted to make sure for the safety of the blood that -- because, one, there was always a risk of a window period of transmission because, at the time, we were only testing for the antibody and we wanted to make sure, therefore, that the deferral criteria as listed were very well known to everybody because didn't want them to come and be tested just to find out.

Q. Then --

A. I believe there was a very wide exposure for this leaflet.

Q. Then if we move to this document, PRSE0002158, "AIDS -- An Important Message for Blood Donors". If we look at the bottom of that document we see "Revision 5, May 1987" and we can see that the --

"AIDS -- People Who Must Not Give Blood", the criteria there, halfway down the page:

"Anyone who has AIDS or the AIDS ANTIBODY.

"Any man who has had sex with another man since 1977."

So that has changed from "practising homosexuals" to "any man who has had sex with another man since 1977":

"Anyone who has ever injected themselves with drugs.

"Anyone who has lived in or visited Africa south of the Sahara at any time since 1977 and has had sex with men or women living there.

"Anyone who has had regular treatment with blood products since 1977.

"Any man or woman who has been a prostitute at any time since 1977.

"Anyone who has ever had sex with a person in the above groups even on a single occasion."

Did you have any role -- recalling that this is from May 1987, did you have any role in drafting that leaflet?

A. No, it is before my time, for sure. Having said that, the exclusion criteria over time have changed quite a bit. Every revision changed to look at the current

epidemiology at the time, the risk factors at the time. So although the main groups remain the same, but there were quite a few changes over the years. But I think there were two or three major revisions but, otherwise, there were also other changes, for example the 1977 date was dropped. So like, for example, have you ever been a homosexual or practised -- because we wanted to move away from just being a homosexual to the actual risky practice.

Some countries were included in some of the leaflets initially, like Haiti and Chad and Zaire, I think, were dropped because the epidemiology didn't substantiate them to be in the categories. So we stuck with sub-Saharan Africa throughout the whole time, practically, because the epidemiologists take it there was fairly endemic in those regions.

There was a question, where, for example, it was changed to anybody who has had sex in Africa of any race because, initially, people had thought that they were earmarking blacks, that we were being in some way racial, whilst we were not. So there were these tweaks to look at the current epidemiology at the time.

Some of the temporary exclusions changed from two years to one year because obviously the tests

became better, became more sensitive, so it was felt one year was a very good safety margin for picking up the antibody.

So two or three big revisions but, in the meantime there were also these kind of tweaks, if you like, always, as far as I know, approved at the highest levels.

Q. Can we look now then, please, at MACK0001160. So we can see this is a letter dated 16 November 1990 to Professor Cash and it is from you. You say, at the bottom of that page:

"Mairi Thornton has passed onto me the English AIDS leaflet telling me that you would like ours to be the same."

Can you recall then that there was a drive in -- certainly from Professor Cash, that there should be parity in leaflets between England and Scotland in 1990?

A. Definitely and I would say, you know, there was a drive between as much commonality as possible and this drive became bigger, if you like, so it wasn't just in the leaflet but, in this case, definitely there was a push. But from my working life within SNBTS, I have always worked to make sure that, as far as possible, there was harmonisation and commonality

between the UK blood services, not just -- UK blood services.

Q. So you then say:

"I have gone over our current Scottish Leaflet and the English ones to look for major differences and I have taken the opportunity, now that I do have quite a number of AIDS deferral leaflets from other countries, to look at what other countries have. I shall try and discuss them step by step, itemising them as per Scottish Leaflet."

It is the Scottish leaflet that we have just been looking at that you were comparing with the English leaflet. Just for the transcript, I do not think we need to go to it, but the English leaflet that you were looking at is at PRSE0002158.

Then you go over and you go through the various different categories. So:

"Anyone who has AIDS or the AIDS antibody", is the first category.

Then over the page:

"Any man who has had" --

Sorry, back to page 2:

"Any man who has had sex with another man since 1977."

You note you are in agreement there with

England:

"Anyone who has ever injected themselves with drugs."

You note there is a departure there between England and Scotland:

"Anyone who has lived in or visited Africa south of the Sahara at any time since 1977 and has had sex with men or women living there."

You say -- note that that's practically identical, with the exception of changing the sub-Saharan Africa to African countries, except those on the Mediterranean.

Then, over the page:

"Anyone who has had regular treatments with blood products since 1977."

You note that the English AIDS leaflet doesn't mention that at all. Then:

"Any man or woman who has been a prostitute at any time since 1977."

You note, again, that there is a difference between Scotland and England in relation to that criteria.

Then number 7, commonality in the criteria about having had sex with a person in that group.

Then you conclude by saying, at the last

paragraph there:

"I find that our guidelines are better when it comes to excluding donors who are regularly on blood products. The English version only excludes sexual partners of haemophiliacs. What about patients with von Willebrand's disease who receive Factor VIII."

We don't need to go to it but you include a table of the summary of your findings on the difference.

Is it right to understand that the work you did here -- and remembering that this is in November 1990 and we looked at that letter from Professor Cash in December 1990, in which he sets out that the Standing Advisory Committee on Donor Care and Selection had been agreed at that stage, is it right to understand that this work that you started here, in terms of commonality between England and Scotland, was in fact picked up by that Standing Advisory Committee and dealt with in that forum?

A. I suspect that's exactly what happened, although I can't recall the specifics but it would be the kind of work -- which I would have done and then given it to the SAC and said these are the main differences, and probably there would have been a discussion as to whether things needed changing or whether the

interpretation was all right. So, yes, that would be the exact forum that I would have taken it to.

Q. Perhaps I can put it another way, do you recall, whether between November 1990 when you wrote this letter and that first meeting in October 1991 of the Standing Advisory Committee, you doing any work on the Scottish AIDS leaflet to bring it in line with the English leaflet, and the issuing --

A. I wouldn't have, no. I don't think I would have, having noticed the differences and having done, if you like, an international survey, looking at what other countries were doing, I would have sent it to John Cash and then I think it would have been discussed at the SAC. I don't think I would have done anything myself to modify it or change it. I didn't feel I had the authority to do that in any case.

Q. Now, I'm going to ask you some questions about -- again, bearing in mind that you have told us you weren't involved in any real decision-making in Aberdeen, I'm just going to run through a list of questions with you just to check the position with you. Were you involved while at Aberdeen, even as a consultant, with decisions made about targets for blood collection and the amounts of plasma to be sent to PFC for fractionation?

A. Not really, no. Clearly, there would have been discussions, you know, like if the targets were increased, it would have been asked, for example, can we achieve these extra targets or these extra kilos of plasma and probably I would have given my input, but the decision whether to accept those targets or not would have been the director's one.

Q. Were you involved with the decision about whether or not to introduce surrogate testing for non-A, non-B while you were in Aberdeen?

A. No.

Q. Do you recall discussions taking place about whether or not that should be introduced?

A. There was discussion. I can't remember the year whether it was in Aberdeen or a bit later. Yes, there was discussion about whether surrogate testing, anti-core or ALT testing should be done and I think, you know, there were people who had very different views. It was discussed in a number of forums, definitely in Aberdeen or in Inverness.

I do remember having these discussions with colleagues, I can't remember the exact place but, yes, I was very aware that one could do surrogate testing if one wanted, yeah.

Q. Was surrogate testing introduced in Aberdeen during

your tenure there?

A. From my knowledge no.

Q. Were you involved in any of the decision-making around when to introduce hepatitis C testing while you were in Aberdeen?

A. No. My understanding is that that was a national decision. So I don't think -- maybe I'm talking out of turn but I do not think it was even Urbaniak's decision. It was a national decision when to go, a start date, probably even it was a UK-wide decision.

Q. So those questions are best directed to Dr Urbaniak next year?

A. I think he will be able to give you more of a background to that, yes.

Q. I have just got one question I think to ask you about hepatitis C screening in Aberdeen. You were asked a question in the Rule 9 about whether or not -- about screening and you say that -- you said that you believed that all stock was screened at the start of testing. I just wanted to explore that with you a little.

One of the matters the Inquiry is interested in is whether blood collected prior to screening being implemented, and being collected and split into its various components and perhaps frozen red cell

concentrate or fresh frozen plasma, or a product with a long shelf life, whether that -- those products would have been issued from the centre post-screening unscreened? Are you able to help us with that?

A. I think that all this stock would have been screened. So if there is plasma, remember we always kept archive samples, small archive samples and, therefore, if it is something that has been stored for a long time, it could probably be even easier to issue it screened, because you have time. So I think that all the stock or the vast majority of it would have been tested on the day when testing was started, in mid-October or September 1991. I would be very surprised if it wasn't. I can't be a 100 per cent sure but I'm 99 per cent sure, I would have thought, that all the stock would have been screened and tested.

And even bloods that have been stored for a long time, you know, like red blood cells, for example frozen blood, that wasn't going to be issued in a hurry and then you have even more time to screen it, so definitely would be screened.

Q. Do you recall what happened to the components, products, blood that was already in circulation in blood banks in other hospitals? Do you recall whether or not untested product was recalled and replaced or

do you think that that would have been used and -- so untested product could have been used after screening was introduced?

A. I cannot remember specifically but, knowing how SNBTS works, I would be very surprised if it wasn't because, you know, when it came to blood safety, I think we were careful and thorough to make sure that they were as tight as possible when it comes to blood safety. So although I can't remember I would be very surprised if it wasn't. I would have thought all the blood and products would have been tested on the day.

MS SCOTT: Sir, going to move on to look at some of the work that Dr Galea did in his role as medical adviser to the Blood Collection Programme and I note that it is 11.15 am in our time. I wonder if now is an appropriate time for a break?

SIR BRIAN LANGSTAFF: Yes. We will take a break until 11.45 am our time. I think it may be 12.45 pm your time.

A. Okay.

SIR BRIAN LANGSTAFF: I am right, am I, about your time?

A. That's all right, no problem at all. That's fine. You are right. It is now 12.15 pm.

SIR BRIAN LANGSTAFF: During the break, what I say to all witnesses at this stage, is they must not discuss the

evidence they have given or any evidence they think they are yet likely to be asked to give with anyone, whoever that person is, but you can talk about anything else you like.

A. Okay, I will surely do that.

SIR BRIAN LANGSTAFF: Thank you.

A. Thank you very much.

(11.15 am)

(A short break)

(11.45 am)

SIR BRIAN LANGSTAFF: Yes.

MS SCOTT: So Dr Galea, I'm going to ask you some questions now about the National Medical Register. Can you just tell us what that was?

A. Yes. Before around, I don't know, 1990 or thereabouts, every region in Scotland had its own system of maintaining their donor records. So a donor that gave blood in Aberdeen wouldn't be known in Inverness or anywhere else. And therefore it became clear that some people could, for example, donate in one place, trying to get their HIV status, for example, and then come and give somewhere else without being known that they are positive in a different region.

So the National Medical Register was a way of

putting people on this register who were either high-risk people or because we wanted to make sure that confidentiality was maintained, and therefore if a name cropped up on this register it did not necessarily mean that you were in a high-risk group. We also put other donors, a few donors that were also permanent deferrals.

So these were a group of donors who were permanently deferred. Some that were partaking in high-risk behaviour and others would have been permanently deferred from other reasons like myocardial infarction, for example.

So this was a way of ensuring that if your name was put in the National Medical Register, wherever you gave in Scotland your name would come up. And therefore if you gave in Aberdeen and you were found positive and you tried to give blood in Glasgow, then you were identified.

The way that this was managed was -- it was not an automatic process, so every week a named consultant could know -- because obviously he'd be reviewing the medical records of donors -- and those that would fall into this category would update -- would update the National Medical Register of his region. So if I was in Inverness, I would put one or two donors, for

example, on the NMR, the National Medical Register. From that point on those donors who gave anywhere in Scotland would be identified.

And we had codes, which I can't remember, so -- some -- it would be code 1 was high-risk behaviour and code 2 wasn't. So if somebody would be in Glasgow, they had identified this donor, they would immediately know that this person was high risk or not.

So this was a way of ensuring that whilst all the records were still regionalised, people who were in high-risk behaviour could not give blood anywhere in Scotland.

Q. If we look at a paper to get a bit of detail on it, it is SBTS0000449_008.

So at the top it says "National Medical Register". We don't need to turn to page 3, but at page 3 your name and Mairi Thornton's name appear as the authors of the paper, and it is dated 17 February 1992.

Can you just tell us who Mairi Thornton is?

A. Mairi Thornton was the National Donor Services manager.

Q. And you set out there what the purpose of the register is. Primary purpose is:

"To prevent transfusion of blood or blood

products from people in the following categories:

"1.1.1 Those donors who have themselves declared they are in the high risk (HIV) categories (whether or not the blood has been tested).

"1.1.2 Those donors who have been confirmed positive for syphilis, HBsAg, HIV and HCV.

"1.1.3 Those donors with a proven history of cancer."

Then:

"Secondary.

"1.2.1 To prevent such persons from donating.

"1.2.2 To prevent donors who may place themselves at risk by donating, to donate."

Then it says this:

"It is acknowledged that 1.2.1 [ie to prevent such persons from donating] should not be pursued until such time as microcomputers are in use at all sessions through the SNBTS and 1.1 above is known to be working effectively."

So is it right that in fact it was rolled out in two stages? The first was to -- because there wasn't the facility at the donations session to stop them from actually donating, the first priority was to make sure that, once they'd donated, that the donation wouldn't be transfused, and then only later, once you

had the hardware, the computers, at the sessions, could you actually stop them from donating?

A. Correct. Because obviously if you stop a transfusion from being given, then you have achieved your goal: that blood has not been given. As a secondary point, then yes, if you have computers at sessions, you can actually prevent a donor from actually donating blood. So you would then be preventing your secondary risk, if you like, of potentially exposing staff who are handling that blood.

Q. We know from other documents, which we don't need to go to -- I can give the reference for the transcript, SBTS0000479_005 -- we know from that document that this National Medical Register had been introduced by 28 April 1993.

Can you recall how soon after it was introduced, and presumably that primary function came into play, the secondary function with the computers started to operate?

A. Good question. I cannot remember when the computers were taken out at sessions. I cannot recall.

Q. Do you think it was when -- can you remember whether it was during your time at all? Was that when you were in Inverness perhaps or in Dundee?

A. Yes, I think it was. I think it was. I suspect it

might have been when I was in Dundee. I cannot be 100 per cent sure, but I guess it would have been 1996/1997, something like that. I can't really remember.

Q. And then the rest of that page sets out some of the detail you have already told us. But if we could go over the page, please, just to pick up on a couple of points.

"3.6. It is mandatory that there is written evidence to support placing someone on the National Medical Register. In the case of hearsay evidence it is incumbent on the named officer in charge to pursue evidence from the donor concerned before placing him/her on the register. If all reasonable attempts fail, then the donor's name should be put on the Register."

"3.7. It is recommended that an appropriate comment is put on the donor record which will alert the session staff should the donor attempt to give blood again, but will maintain confidentiality eg 'Donor is Permanently Off Service and has been advised not to donate'."

That is the point you were raising earlier. Then just at 3.11:

"All donors placed on the register must be given

a simple and brief letter explaining why they, and if applicable their partners, must not donate again."

Do you recall those provisions working in practice?

A. Yes. And we were very careful. Before you put somebody on this register, you had to have clear evidence that they were high risk. We could not rely on simple hearsay evidence. Somebody might not like a person and come and say, "Joe Bloggs, you know, is a drug user", and he is not. So we had to have reasonable evidence, either from the GP, for example, or by asking the donor himself sometimes. So definitely people that were put on the National Medical Register, we were pretty certain that they were in a high-risk category or they had a permanent condition which would debar them from donating. I cannot recall instances where we put somebody on the NMR without having such evidence.

Q. And was it, in your view, a successful system? Did it work well?

A. It did. It did function a couple of times. I am sure that there were people where, you know, I got a notification that somebody, say, from Inverness tried to give blood in Edinburgh or vice versa. So it definitely worked in practice.

Q. And is there any reason why this system couldn't have been implemented earlier than it was?
A. I cannot think of a specific reason as such, no. I think, you know, having been, really, alerted to the fact that, you know, first there was HIV, then there was hepatitis C in 1991 and so on, then you begin to think about how to make the system more and more secure. And the realisation that the donor records were regionalised, then we thought of the idea of saying: look, you know, we must make sure that we prevent these people from donating anywhere in Scotland.

So I presume if we had thought about it before we could have done it earlier. It is one of those things where we talked about it, we did it, and it was implemented.
Q. I'm going to ask you some questions now about the Standing Advisory Committee's work on the Red Book guidelines, and indeed guidelines in -- the Scottish A-Z guidelines.

Starting, first of all, with the Red Book, can we have, please, NHBT0054484_003.

In fact, can we turn to page 40 of that document, please.

So here we've got "Guidelines for the Blood

Transfusion Service". If we turn over the page, we can see 1993, second edition, at the top there.

Then, if we turn over to the next page, we can see:

"Preface to second edition."

We can see that is signed by W Wagstaff, chairman of the UKBTS/NIBSC Liaison Group, and his forward is dated October 1992, if we go down the page there.

Then if we carry on over the page to page 43, we can see the contents. And if we go over to page 44, there are various different chapters there. And if we go over to page -- sorry, I beg your pardon. The page before. You were on the right page there.

You have got there "Chapter1 Selection of Donors", and then various different subheadings.

Then if we turn, please, to page 62. In fact we better go to 61. Annex 1 sets out current membership of the various different liaison groups and groups contributing to the guidelines.

And if we go over the page to page 62, we can see there the working party on donor sessions, and we can see your name down there as from Aberdeen.

Is that the Standing Advisory Committee or was that a separate working party?

A. No, I think that working group became the Standing Advisory Committee.
Q. So that rather long-winded introduction was to orientate us in this document and to understand the part that you played in drafting, as I understand it, those parts of the guidelines that were concerned with donor selection. Is that right?
A. Yes. I mean, there was -- in the Red Book itself, which is this document that we have in front of us, that was made up of a number of chapters of course. And each SAC was responsible for drafting their chapter. And in that chapter, you know, there were broad guidelines, general introductions, principles, how a donor is treated, you know, he gets his haemoglobin checked, then a medical assessment and whatever. Then there was also the alphabetical index, if you like, of -- the comment: medical deferral conditions, the definite -- the donor exclusion criteria.

So there was this chapter in the Red Book itself which discussed the principles of how a donor is bled. And then there was a separate document, which is the medical selection criteria for -- and actually there are -- now there are four or five. There is one for whole blood donations, one for bone donors, one for

stem cell donors, et cetera.

And they go into the specific detail of conditions, common medical conditions on which a decision needs to be made, whether a donor can be accepted or not with blood.
Q. So we can see -- if we turn then to page 69, we can see at 1.5:

"Conditions necessitating temporary deferral or qualified acceptance."

We can see there the beginning of the A-Z guidelines. Is that what you were referring to there?
A. Yes --
Q. And if we go over the page -- sorry, you were about to say something?
A. I was just going to say, in future editions then these conditions became a separate document.
Q. And then if we go over the page, we can see what it says about hepatitis. Halfway down the page there:

"Hepatitis (confirmed) -- review 12 months ..."

No, I have lost it:

"... review 12 months from recovery."

Then if we go over the page, to 72, we can see the detail of what's said about hepatitis under the "Infectious diseases" category. And so this section

of the guidelines was to be used by the medical officer to work out what should happen when somebody declares hepatitis, is that right?

A. Yes, correct.

Q. And we have got there:

"Individuals with a history of jaundice or hepatitis should only be considered as blood donors 12 months after recovery from the illness. At this stage, approved test for HBsAg and anti-HCV should be negative. The presence of anti-HBs does not debar."

And goes on to talk about risk groups being those who have received transfusions, acupuncture and so on.

Can you recall the discussion about hepatitis and why it was the decision was made to allow those that had suffered from hepatitis B at this stage to -- and had hepatitis C potentially, although I don't think they would then be negative, but hepatitis B -- if they had recovered, to donate?

A. At this stage we are talking about hepatitis B. And the criteria are very tight, in that, one, you have to have a complete recovery. Which means that sometimes you can have a chronic hepatitis, where you either have a low level of HBsAg. And in particular, if you have been in contact with hepatitis B, you develop

what is called anti-core antibody, which means either you have been in contact with the virus or, more importantly, that the virus is still replicating within you. So the only time that we could accept (audio distortion) hepatitis to donate blood again was that the HBsAg, the antigen itself, had to be negative. And the tests for hepatitis B are now extremely sensitive, so they can pick up very, very low level antigenemia. You have to have anti-core that is negative, to make sure you have no chance of having virus replication. And most importantly, you have to have very high level of antibody, anti-HBs, because anti-HBs is a neutralising antibody. And therefore if you've got -- I think the level is 100 international units per litre. If you have that high level of antibody then you are immune, then there is no chance of you getting hepatitis B again. And therefore, in that case, it would be quite safe to give blood again.

Q. And --

A. -- (overspeaking) -- it has been over a year, at least, minimum of a year, before you can give blood.

Q. Can you recall whether consideration was given just to simply debarring anyone that had had hepatitis from being a blood donor?

A. Oh, yes, you can debar him for many reasons. For example, he is still seeing a doctor about his condition. Whatever the markers are, we would not even accept him. There are conditions, for example when you know that you've got hepatitis A. In that case you could. But even in the health check questionnaire, it does say if you have been in contact with jaundice recently, if you are still seeing your doctor about any condition, you would be debarred.

So this is not, "Please come back and give us blood", but if somebody had hepatitis B, is fully recovered and wants to keep on donating, then he or she would be allowed.

Q. But why not just say, "Well, actually, if you have had an infectious disease like hepatitis B, even if all of your tests come back saying that it is safe" -- why not debar them from donating?

A. Because in this condition we can be really certain that the patient is not infectious. If you have got a very high level of anti-HBs, which I think even till now is compulsory to have -- you have to have very high level of anti-HBs, which is a neutralising antibody, so there is minimal chance or no chance of the virus being there. Because if there is any virus, it is neutralised. And therefore they can donate.

Plus the fact, of course, that some of these donors can donate anti-HBs plasma because they have very high level of anti-bodies which can be used then to treat patients.

Q. Presumably that plasma would go into a special section, wouldn't it? It wouldn't be going into the general pool. Is that --

A. No, no, no. Anti-plasma will go for fractionation and produce high level anti-HBs.

Q. Could it not be said though that somebody that had contracted hepatitis B, for example, although the hepatitis B itself may not pose a risk to the blood supply because -- for all the reasons that you have outlined, that it may be indicative of risks, that they are a high-risk donor with respect to other infections that the Blood Services don't actually know about or screen for?

A. As I said, we did not encourage these people to give blood. It was not, "Please come back". Plus, it was only if they either insisted or we wanted -- because some people are very committed and for them giving blood is a very important ethical, social thing to do -- and sometimes it was important that we get the anti-HBs plasma if they were hyperimmune.

Having said that, clearly every time a donor

came they had to go through the medical questioning. If they were a drug user they could not give blood. So any continuing risk clearly would debar that donor.

So, as I say, it wasn't a free-for-all "Please come back", it was if somebody insisted, then -- and that's why it -- I think we had stated: history of anti-HBs -- a presence of anti-HBs does not debar because we can actually get them for hyperimmune plasma, but if they belong to a high-risk group or there was any reason that they might have chronic hepatitis, they would definitely be debarred.

And if they had chronic hepatitis even once, then they will be debarred for good. There will be a permanent deferral. But if you had, for example, anti-core antibody, then that would be a permanent deferral.

Q. Can I look now at the SNBTS donor medical selection guidelines, which I think you were involved in revising in 1992, which is WITN3530083.

I don't know whether you are going to be able to help us with the chronology of the document we have just looked at and this document. So the document we have just looked at, you will recall was published in 1993 but the forward, written by Dr Wagstaff, was dated October 1992. And here we have "Donor Medical

Selection Guidelines" with a date stamp on it of 13 October 1992.

Can you recall the chronology of these two different documents, which came first, or were they effectively produced at the same time?

A. I suspect they were. My aim always was to have, as much as possible, identical guidelines in the UK. So very often if the guidelines on a UK-wide basis on the Red Book committee, on the SAC, were agreed, then my role was to transpose those into SNBTS documentation.

So there will be, you know, the proper (audio distortion), the proper SOPs, the proper training and so on and so forth, but very often they would be as close or similar as possible. So I suspect that these would be very similar to what UK guidelines were.

SIR BRIAN LANGSTAFF: Just by way of observation, the document which you showed me which you have taken me to the dates of 1992 and 1993, 1992 for the foreward, 1993 for the revision, the first page of it, I think, said 1994 on it. That particular publication.

So can we go back to NHBT0054484_003.

MS SCOTT: Yes, sir, the first page we turned up before we turned on.

SIR BRIAN LANGSTAFF: Yes. I think you see at the bottom

of the page, if I'm right, if my memory is correct, it says 1994. Can we just have a look?

MS SCOTT: It does, yes.

SIR BRIAN LANGSTAFF: It does?

MS SCOTT: It does. But, sir, that is because it is the first amendment to the second edition. So one has the second edition, which is 1993, with the first amendment to the second edition being in 1994.

SIR BRIAN LANGSTAFF: I see.

So we were looking at the 1994, having been amended from what was in existence in 1993?

MS SCOTT: The document I was looking at -- the detail -- where we looked at the hepatitis, that detail was in the 1993 non-amended second edition. We have not looked at the first amendment to the second addition. It's just it -- that happens to be the first page of that document, which is why it came up.

SIR BRIAN LANGSTAFF: So we have one document for the first page being an amendment to a revision which contains the unamended following pages -- or are they, stitched together, two documents?

MS SCOTT: They're stitched together, two documents.

SIR BRIAN LANGSTAFF: I see.

MS SCOTT: You've got the first amendment at the beginning of the document, with the -- you've got the first

amendment to the second edition at the beginning of the document, and the second edition halfway through the document.

SIR BRIAN LANGSTAFF: Yes. It would be helpful, I think, to understand -- and for accuracy -- for me to know if I'm looking at pages in the same document, which appear to be the same document and under the same reference, or not. And obviously in this case I'm not, but thank you.

I'm sorry about that exchange, Dr Galea.

MS SCOTT: Turning to the SNBTS donor medical selection guidelines, if we can just look at page 2, please. We can see there it says:

"These guidelines are based on the Guidelines for the Blood Transfusion Service in the United Kingdom, Volume 1, chapter 5 ..."

So that, I think, refers to the 1989 version, because we -- we just looked at -- we looked at volume 1 and it was chapter 1 that we were looking at for the donor selection chapter:

"... and they should be read in conjunction with them. They represent the collective opinion of the SNBTS having been discussed in detail by all Donor Consultants and approved by the Medical and Scientific Committee of the SNBTS.

"These guidelines are under constant review to ensure that blood obtained from our voluntary non-remunerated donors is of the safest and highest quality. There is a formal annual update. Queries and problems should be discussed locally and where appropriate, referred to Dr Galea and the Donor Consultants Group for clarification or amendment to the next edition."

Now, we do have an earlier version of this from 1990 of this document, but is it right to understand that it was this 1992 version which was the first one that you were concerned with reviewing, involved in reviewing?

A. I could not be 100 per cent sure but I think so. I really can't remember whether I was involved in the first one. I suspect not but I can't be 100 per cent sure.

Q. Certainly your name doesn't appear on the 1990 version.

A. But this one is definitely -- I was involved in this one, that's for sure.

Q. Then it says this, the general responsibility -- "the decision", sorry:

"The decision to accept or defer a donor rests with the Medical Officer or Nurse at the session. The

guidelines may therefore be varied at their professional discretion, having due regard to the welfare of donors and the safety of recipients. It is expected however that the concepts of these guidelines are adhered."

These were, were they -- they were guidelines, could be departed from, but your expectation was that people would stick to them?

A. That's correct. That's correct. In general, I think, both doctors and nurses who were involved in the deferral process would rather defer if they had any doubts than not. And that's why it was like -- so they were more precautionary in their approach. So if they had any doubt -- I mean, sometimes I used to have discussions with the nurses -- like they would have used some terms, some slang term which, for example, is used in drug addicts, and they would pick it up and they would say we would rather not take that donor.

So when -- they were precautionary -- but yes, the guidelines were there as benchmarks. So they had to adhere to them. But if they had any reason to doubt the donor or any -- some medical condition which they haven't heard of or which wasn't on the guidelines, then they would defer. And that was the general approach, being precautionary rather than

accepting donors when they had doubts.

Q. Then if we go back to the document to donor selection procedures, it sets out what actually happens in a donor session:

"All donors are asked to read the health and associated literature.

"They are then asked verbally a set of questions to establish that nothing in the guidelines applies to them. These minimum verbal questions are set out in Appendix 6."

Appendix 6 is at page 59 of the document:

"1. Have you read and understood the health check and is there anything that applies to you?

"2. When was your last donation ...

"3. Have you been keeping well? Are you attending your doctor or hospital or taking any medication?

"4. Since your last donation have you travelled or lived outwith Western Europe?"

Now, I don't think we have a copy of the health check. Could you remember what that had in it?

A. The health check proper was -- I can't remember the exact detail, it was a sheet of paper and had the details of the donor, his address, his date of birth, and so on and so forth, when he last donated blood.

And then there were a series of questions which were in chronological order.

So, for example, in the last -- have you ever been told not to donate blood, have you ever suffered from cancer, for example, and then in the last year have you been to your GP? Have you been inoculated with any vaccines, and then in the last month and in the last few weeks or in the last week.

It used to pick up the common questions like have you been feeling unwell, are you on any medications, and so on and so forth.

Then, there used to be a section on the high-risk questions, or the behavioural questions, and then they signed that they consent to their blood being -- if you were a first time -- if you were a regular donor -- initially, very early on, as I can remember, they used to just sign on a common sheet that they have read that and that's it. Then every -- as time went by, in the 1990s, every donor had to sign his own particular donor health check.

And then, if you were a first-time donor or a lapsed donor, you had a personal interview. Your health check questions would be reviewed by a clinical staff, either a doctor or a nurse, and he or she would go all the way through it with you, specifically ask

the high-risk questions. You know are you sure you haven't been in active sex with a gay man, have you ever been a drug user, have you been with a prostitute, et cetera, then do you have any other questions that you want to discuss, are you at risk of being in high risk -- do you want to have a test for HIV, and so on.

If everything of that was clear, then they signed and they consented that their blood was tested for infectious diseases. I think initially it was just for HIV and then it became for all the viruses that we test for and they also consented that they will be contacted if there was a positive result, a confirmed positive result but they would be contacted and they would be asked to be interviewed by us so we can refer them for appropriate care.

But that was the procedure that was followed, whether it was a first-time donor or a returning donor.

Q. You have just described there the interaction between the donor and staff at the session, in terms of asking questions. The 1992 document suggests that the verbal questions that are asked are those ones we just looked at in appendix 6, minimum verbal questions. I know that later on in 1996, or thereabouts, the personal

donor interview came into being and I'm going to ask you about that a little bit later on.

Is it right to understand that, in 1992, there was limited verbal questioning of donors but rather later on a more detailed interview was introduced?

A. Correct. That is correct.

Q. So if we then turn, if we can, please, to the section on hepatitis, just to get your view on how that fits in with the document we saw, the Red Book document from 1993.

If we turn to page 23, please. Halfway down that page we have "Hepatitis":

"Childhood ([less than] 12 years) jaundice/hepatitis, with full recovery -- accept.

"Jaundice/hepatitis/hepatitis B -- consult nurse or doctor.

"Note for nurse or doctor

"Defer and obtain more information from GP May be acceptable 1 year after full recovery provided all mandatory tests are negative. Refer to Centre. History of Hepatitis B or C usually debars."

So is it right to read that as somewhat more precautionary than the Red Book guidelines we looked at earlier?

A. Probably a bit more precautionary in its approach. As

I said before, we weren't looking to get these donors back, it was only when people insisted, that you know they necessarily have to be debarred. Within Scotland we took the position that, you know, hepatitis B or C generally debars. However, we will refer to the centre, we will do all the tests, and then if the donor wants to come back -- so, for example, as far as I recall, we did not call them back to give blood. We did not deliberately call them back to give blood, like ordinary blood donors would.

We wouldn't send them any call-up letters but if, however, somebody came back we could accept them after we would have done all the tests in the centre. And that's why it says for a nurse or doctor at session, refer to us. Then we can go and look into the history, do the blood tests. If they are negative, if there was no high-risk behaviour of any sort, then we would debar the donor. That's why it says history of hepatitis B or C usually debars, not always.

Q. So, in a sense, in the Scottish guidelines, the starting position is rather different, isn't it? It is history of hepatitis B or C usually debars, whereas in the UK guidelines it is saying, well, actually if all the tests come back, then and are acceptable then

you can let them on. Would that be fair?

A. Yes, like -- not quite, I mean, in the English one it says the presence of anti-HBs does not debar. Here we are saying history of hepatitis B usually debars. So both were precautionary but I suspect that within SNBTS we were even more precautionary.

Q. We don't need to go to these but there were various references over the years, up until, certainly, 1999, to there being differences between the English -- or the UK and the Scottish guidelines and that being raised and consideration given to what should be done about it. What can you recall about that?

A. I think yes. My role, I used to bring information from the SAC, for example, for this particular condition we were accepting on a UK-wide basis. But I had to get those deferral criteria, if you like, approved by the MSC and, in general, you know, most of the directors on the MSC were pretty precautionary. And if they had any doubt or some of them raised any doubt as to the advisability of such an acceptance then I think, in general, they would err on the side of caution. That's why sometimes our guidelines appeared to be a bit more tight than the UK ones.

I don't know what the English did but, in my case, I had to go through MSC and we had to go through

them and give their blessing to whatever was approved.
Q. I just want to get your view on an entry in this document, JPAC0000002_013. It is a minute of a meeting of the UKBTS NIBSC Standing Committee on the Selection of Donors, so the Standing Advisory Committee, 22 September 1994, and it is at point 4 at the bottom of the page there:

"Report from UKBTS/NIBSC Executive meeting in Birmingham ...

"Main item discussed was the standing of [the] guidelines ..."

The UK guidelines we looked at earlier:

"Approval has been given by NBA [National Blood Authority], but concerns have been raised by Scotland in relation to lack of managerial involvement in the process. It was decided that the structure should include wide professional representation. The central committee includes National Directors who would naturally consider wider political and financial issues."

Can you recall, does that perhaps give us an insight into one of the concerns that the SNBTS had about those guidelines?
A. I think it just reflects what I just said. Because within the SAC were a group of professional

consultants dealing with donor care and, therefore, you know, most of the decisions that were made I fully subscribed to. I had the extra step, if you like, of taking the guidelines to the MSC and because, obviously, the majority of MSC members were the medical directors of each region, they had input into them and that's why you will see that some of the criteria were slightly more precautionary in Scotland.

And I think that is what was being reflected in this minute, that if -- and I'm not sure what happened in England. If in England, once they went to JPAC, then they were approved, then I think my concern was, or the concern was: but are you sure that you involved all the right people that have to give their input? Maybe they did, I'm not sure.
Q. I'm now going to ask you some questions about your involvement in devising procedure for donor counselling for those donors who tested positive for hepatitis C.

So you were asked to form part of -- or sit on a working party with Dr Gillon and others, to consider donor counselling for those infected with hepatitis C, weren't you?
A. Yes.
Q. If we look at PRSE0000515. We will come back to this

part of the document, which is the recommended procedures, if we could start off please on page 3, which is the title, "Report of the National Medical Director [on] Donor Counselling", and it is prepared by the Working Party, Dr Gillon, Dr Crawford, Dr Galea and Dr Davidson.

If we turn over the page we can see what you were asked to do:

"[Dr Gillon] was requested by the NMD to constitute this small working party to discuss the donor counselling requirements of SNBTS in the light of imminent introduction of HCV testing. The remit was:

"1. To produce operational guidelines for BTS doctors (or other doctors engaged by the BTS), in context of counselling anti-HCV confirmed positive donors.

"2. To liaise as appropriate with Dr Harold Gunson.

"3. To produce a first draft guideline for consideration by the Directors on 14th August."

Then it sets out there you met on 3 July in Edinburgh.

Then, if we turn back to page 1, we can see the recommended procedure that you drew up and you made

reference to this already in your oral evidence but it sets out what happens at 2:

"Donors with prove screening tests and positive [confirmatory tests]."

It sets out the steps that need to be taken there:

"As soon as positive confirmation results are received, the donor must be placed on 'permanently off-service' status."

We are talking about the National Medical Register, is that --
A. Not just, yes, but also, even when we modified our computer system to the new system (unclear), and so on, you know, you can still put patients -- donors as permanently off-service, which means they can never donate again, and somebody like that, some of these donors would definitely be on the NMR, yes.
Q. So then:

"The standard letter is sent [out], informing the donor that the test is positive and requesting attendance for further samples", and it says that must arrive at the beginning of the week.

"An appointment for initial counselling and assessment has been offered at the earliest opportunity", and that must be for at least an hour.

The initial counselling must be carried out by medical officer experienced in donor counselling or familiar with the information package.

"The donor is informed that he or she must not give blood or carry an organ donor card. Permission to inform the ... GP is requested.

"The donor is given written advice (provided by each centre individually) on the implications of a positive test", and that's included in this document. We will turn to that in a minute.

"The donor should be given a contact telephone number for further advice.

"The donor is offered a second counselling interview within 1 week."

If we turn over the page. We see that:

"Samples are taken for repeat HCV antibody tests ... and any other tests considered to be indicated ..."

Then it sets out what should be done in relation to donors where, once the second tests have come back, including consultation with the GP, if permission is given for that, and referral for follow-up outside the blood transfusion service.

If we turn on through the document, we can see at page 7 a document called "Background Information

for SNBTS Medical Officers, Counselling Anti-HCV Positive Donors".

We don't need to look at the detail of this but this document sets out some background on non-A, non-B and on the testing, and so on. Is it right to understand that this was a document that was provided to all medical officers who would be engaging with positive donors and giving them information, so that they had a full understanding of the background to HCV testing?

A. Yes, correct. And, actually, the number of doctors who were doing counselling was quite limited, there were people who understood how to counsel donors, how to handle donors by giving them bad news and they were all consultants who were in charge of donor care.

So it was a limited group of people, who I believe were very experienced in this kind of work.

Q. Then, if we turn over to page 10, this part of the document runs from page 10 to 13, but we can see a detailed document which sets out the provisions for informing the donor and we have got there the letter, the initial contact would usually be by a standard letter. So was a standard letter provided for dissemination to donors?

A. Yes.

Q. And --

A. -- (Overspeaking) --

Q. Sorry?

A. I was just going to say it was sent by registered post, so it doesn't get lost, and so on, and there were instructions on every step.

Q. Yes, even down to the tone:

"[It] should be reassuring in tone and specifically mention that the reactive test result has nothing to do with AIDS. The donor will be invited to come in for further testing", et cetera.

Then it gives detailed provisions on the interview, the first counselling session, setting out what should happen when the news has been broken, under "Breaking the news":

"The initial news-breaking should be direct and simple, with the minimum of preliminary. The essential information is that one of the tests done on every donation has shown a positive reaction. Explain that this is a new test", et cetera.

SIR BRIAN LANGSTAFF: I think we are dropping off the screen.

MS SCOTT: Sorry. Thank you, sir. So "Breaking the news", if we go down:

"Explain that this is a new test for ...

hepatitis C. This can be passed on by blood transfusion ..."

Then it says:

"At this point it will generally be appropriate to allow the donor to ask questions, but it is recommended that the following information must be conveyed to the donor at the initial consultation, and preferably reinforced at a subsequent interview ..."

Then three points are set out that must be covered initially:

"That chronic liver damage can occur, and that their liver function therefore should be assessed ...

"That even where abnormal liver function is detected, the prognosis is good in the majority of cases, and treatment is available ...

"That there is little known about the routes of spread of the virus in the population, and that sexual transmission does not readily occur. Detailed instructions about protecting others ..."

Then the balance of the document sets out in a question and answer form, if we can just have a look at the next page, some of the questions that the group anticipated might be asked by the infected donor, "What does a positive test mean?" "Does it mean I've got hepatitis?" Then at the bottom "Will I die of

this?" and so on.

That goes on for another couple of pages and then suggested answers. So this was a document, was it, that was given to all of those who were involved in the counselling of HCV donors?

A. I have used it myself for sure.

Q. Then if we turn back, please, to page 5. We can see at paragraph 4 there what it says:

"It is important to redefine the SNBTS policy on our responsibility ..."

This is paragraph 4 of the draft report produced by the Working Group to the SNBTS. The group says -- the Working Party says this:

"It is important to redefine the SNBTS policy on our responsibility to the donor regarding the way in which we convey information about positive tests. The Group noted a letter from Dr Whitrow to Dr Gillon in which he outlined some of the practical difficulties encountered in donor counselling in the North Region. The Group therefore agreed that the extent of counselling and investigation undertaken must be at the discretion of any RTD, depending on local circumstances. It is our view that our duty is to inform the donor personally, ie at an interview with a member of the SNBTS medical staff or another doctor

recruited for that purpose."

Just on that issue, can you recall the difficulties that Dr Whitrow raised about counselling in the North Region?

A. Actually, I can on this one. I think the case was that, as you know, Inverness covers the whole of the Highland region, which is a massive area, and I think his concern was that he had a donor who lived up in the north of Scotland, something like 150 miles away. And his concern was that, you know, why am I calling this donor down 150 miles to give him bad news? Why can't I do it over the phone? But it was the difficulty that he had.

It was the fact that the donor was very far away, had to come back all the way and then travel back up with bad news, if he was driving, he could be not concentrating on driving enough, and so on and so forth. So his question was: could he give this information, say, by phone?

I think we still felt that, ideally, because this was a one-off, you know, it was a rare occurrence, wherever possible there should be a meeting between the donor and the SNBTS consultant to do it face to face and allow time, and so on, to discuss it and to digest the information. But it was

left at the discretion of the RTD, of the Regional Transfusion Director, that if some locum comes and says don't allow this, then the RTD could decide, look, I'm going to do it by phone or by fax or whatever it means he wanted to progress along. That was the reason, I think, why that specific issue was mentioned.

Q. You had experience, presumably, of implementation of these guidelines, of this policy in three different centres, so in Aberdeen, Inverness and Dundee?

A. Yes.

Q. What was your experience in those three centres, as to how this was implemented?

A. Luckily, I didn't have problems like with distancing, and so on and so forth. So either in Inverness, any counselling I did myself, because I was the only medical doctor at the time; in Dundee I shared the responsibility, that was myself and Dr Sam Robinson; and in Aberdeen it was either me or Dr Urbaniak that did the counselling. So I think there were very thorough documents, they told us how to proceed, what to do, how to handle the donor, how to defer, and so I found them very useful.

Q. You were able to provide interviews on a one-to-one basis in person, in all of those three centres?

A. Yes, in my case, every time, yes.

Q. Was there any audit done of how this was implemented in other centres that you know about?

A. To my knowledge, no. Luckily these were relatively rare events, so it wouldn't have been easy to audit because the numbers are small but, to my knowledge, there wasn't a formal audit, no.

Q. Are you aware of there being occasions in other centres in which the first counselling appointment was carried out by the GP or by another non-blood service clinician?

A. It wasn't raised. If these things happened then they were handled by the local director. They weren't raised at MSC, for example, or at any other forum that I'm aware of.

Q. Did you have, at any time, either in Aberdeen or Inverness or Dundee, did you have any psychological support services available that you could refer the infected donors to?

A. We did. Luckily, I never had to use them but part of the preparation of donor counselling, for every -- like, you know, when we introduce it for, like, the hepatitis C, which was the one I know quite a bit about, then, yes, we asked the psychology department of the university whether there was somebody that

could support us, so we always had back up.

I always had back up knowing somebody was in need of psychological support and you would notice that, either by frequent phone calls, for example, or things like that. Then I had somebody that I could help but I never had the need to do it myself.

Q. We saw in the document that one of the remit of the group was to consult with Dr Gunson. Do you recall whether that liaison -- in fact, the word is "to liaise as appropriate with Dr Gunson", do you recall whether there was liaison and what the outcome of that was?

A. I believe that Jack Gillon sent him a copy of the guidelines. What he did himself personally afterwards, whether he spoke with him, I don't know -- or whether he went down to Manchester, I don't know.

Q. Perhaps that's something we can --

A. I do recollect the letter was sent, the documents were sent.

Q. I'm going to leave --

SIR BRIAN LANGSTAFF: Before we leave that document. May I just ask one question and have the document back up. The document does begin, in part, by saying, I noticed, that nobody knows -- and this, of course, was before HCV testing was done across the board -- no

one knows quite how many people will suffer from the condition in the donor population, and the estimates were between 0.1 and 2 per cent. So that's 1 in 1,000 or 2 in 100.

When it comes to answering donors' questions, the suggested answer is that a donor will be told it is 1 in 200. Now, why hit on 1 in 200, rather than saying, "We don't really know, but it is somewhere around", and then you can give a figure centrally in the range between 0.1 and 2 per cent? Can you help with the thinking behind being very precise with the donor, rather than telling them what the actual position was so far as medics knew it?

A. I'll try my best. The document was primarily written by Dr Gillon. We had the advantage, if you like, that Dr Gillon's prior training was in hepatology and gastroenterology, so rightly or wrongly we assumed that whatever he said, you know, was correct. So I didn't -- I personally didn't question that, that's for sure and, to my knowledge, we did not question that figure.

I suppose he derived it from the best knowledge he had at the time, and that's as far as I can go.

SIR BRIAN LANGSTAFF: Thank you.

MS SCOTT: While you were in Aberdeen you carried out

a comparison of donor deferrals between the Edinburgh and the Aberdeen centre, is that right?

A. Yes.

Q. A study which you published which we can turn to. We don't need to turn to it but, for the transcript, it is WITN6931002.

Can you just tell us what the overall finding of that study was?

A. Yes. It was a ten-month retrospective study looking at donor deferrals. We were collecting data on donor deferrals all the time as part of our routine. And this was an audit which was commissioned by the clinical research and audit group, as part of the audit programme of SNBTS, which was chaired by Brian McClelland. We noticed that the deferral rates between the two regions were quite different.

So I wanted to find out how come? We are using the same guidelines, what are the issues here? What's going on?

So we did a retrospective study. We tried to compare the data, so we took random samples of these deferrals. So, for example, I took 50 deferrals from Aberdeen, gave them to Jack Gillon in Edinburgh and see whether he would interpret them correctly -- as I did, or vice versa, and we found that the

comparability was quite good.

What we noticed was that there were different management systems in the centres, in the two centres. So when the study was done, in Edinburgh, Jack Gillon was, there was already a single donor health check questionnaire per donor being asked, which each donor had to sign, compared to the one sheet which everybody signed in Aberdeen.

Secondly, I'm pretty sure that first-time donors in Aberdeen were -- sorry, in Edinburgh, were undergoing a limited (audio distortion) interview. So we thought, well, that is something which is obviously important and clearly a more direct contact with the donor is more beneficial. The donor will be able to tell you more than otherwise by just signing a paper, which it would have signed X number of times before, if he was a regular donor. So that was one important finding.

The other important finding was that the decision -- we only looked at deferrals. So the study had quite a limited scope. We were not looking at how good the acceptances were. We were only looking at the deferrals, so it was quite limited. But having looked at the deferrals we found that, whether the deferral was done by a doctor, or a nurse, or a clerk,

the deferral was generally a correct one. The difference was that -- in the management of the donor himself.

For example, in one region, like in Aberdeen, if a donor is seen by a clerk first and she looks at his questionnaire, if she sees anything she would refer to a doctor immediately, if she sees something of any doubt she would refer to a doctor or a nurse. Whereas in Edinburgh, for example, she would take (audio distortion) like if somebody says "I have a current cold", she would say, "Sorry, if you have got a current cold, you can't give now". Whilst in Aberdeen that didn't happen.

So we notice that, although the deferrals were generally correct, the people who were doing the deferrals were different. There was no difference when it came to medical or surgical deferrals between the clinical teams, whether you are a doctor or whether you are a nurse and, importantly, the different documentation between Edinburgh and Aberdeen, particularly the tick box questionnaire and the personal interview that was taking place in a limited way in Edinburgh, was bearing fruit, in terms they were picking up more deferrals in the context, particularly, of high risk.

I mean, clearly, there are limitations, also, in the fact that maybe the populations were different. Maybe the Edinburgh people were more open about their behaviour or their drug addiction or whatever, compared to the more reserved people in the northeast perhaps. Also one needs to remember that, at the time, you know, 1985, and so on, Edinburgh was the HIV capital of the world, at least that's how it used to be known. So there was a lot of drug addiction taking place and therefore maybe the prevalence was higher and therefore the deferrals had nothing to do with the person interviewed himself but more with the background prevalence of the behaviours.

So although there were limitations, I think it bore some fruit, and within those limitations I think this audit was the seminal study which then allowed personal donor interviews to be rolled out in all the Scottish regions.

Q. Was it another consequence of your study that donor sessions became nurse-led rather than having to have doctors present?

A. Yes. Having seen that there was no difference in the decision-making process, if you like, between when it came to medical and surgical deferrals between doctors and nurses, then it helped support the fact that we

could go to led nurse sessions. It wasn't the only study. There were other reasons which helped us go down that route. One was the fact that we couldn't get medical staff that were -- that could be rostered on a regular basis.

Some of the -- many of the medical staff were there as part-timers, who were -- for example, the GPs used to do sessions with us, so you couldn't roster them properly. And therefore it made life very difficult for somebody like myself who wanted to train all the doctors and nurses about their availability.

So we had some concerns, because if you don't attend the training sessions and you are still being rostered, then how good is your decision-making process? Whereas a nurse employed by the Blood Service was always there, and we know that nurses are very good at following guidelines. So when you give them good training and you give them -- and you offer them the guidelines -- and we also showed in the study that the guidelines were pretty good. There were very few conditions that could not be found in the guidelines or that a nurse couldn't interpret from the guidelines.

So even though you had good guidelines, the nurses had to be trained, the doctors had to be

trained, and you had to be doing the job on a regular basis.

And we had difficulties in recruiting good doctors on a regular basis, and we felt that, with this study, it helped us in the support of saying we can do nurse-led sessions throughout Scotland, which we ultimately did.

Q. I'm going to leave your time in Aberdeen now and move on to your time in Inverness and then Dundee.

Before we break for lunch, could you just give us a sort of pen picture of what the facilities were like in Inverness, what the role of the centre was, the challenges and so on?

A. Personally it was a big challenge, it was a big move for me, from being a consultant in a centre to becoming a director -- it was my first role as a director -- learning how to manage people for the first time.

It was a move to a smaller centre. Inverness was smaller than Aberdeen. It was still a very useful centre in the context of all the functions that Aberdeen did and Inverness also did. It was a smaller group of people, which had its own challenges because we were covering an enormously large area, and therefore, you know, we had difficulty in getting the

resources to make sure that every nurse -- every session was properly staffed and so on and so forth.

It was also a time of a big challenge for me because a new centre was being built at the time. So I spent -- my first or two was spent learning how to manage people. I restructured the department because the predecessor, once he knew he was leaving, he wanted to retire, he just left the restructuring to myself as the new incoming director. So I restructured the department with a proper management team around me, a laboratory manager, a finance manager, a donor services manager. I appointed a new quality manager. Plus, having to get to know all the new haematologists, all the new surgeons, and building a new centre. So -- plus making sure that we don't run short of blood at the same time, and making sure that the requisite functions were still functioning adequately. So I was pretty busy in the first few years in Inverness.

Q. Your statement tells us that -- and we know from other documents -- that the centre was funded -- funding came from the SNBTS and that budgets had to be approved by the SNBTS. So you had your own budget but it was all approved by the SNBTS, is that correct?

A. That happened in every centre I went. That's how

SNBTS functioned. And CSA gave the funds to SNBTS and then the money was allocated to us. Within that money allocation, okay, that was my responsibility, but any new service, any new appointment that I had to make, I had to get the blessing of the national finance director and so on and so forth.

So although we had the budget, the allocations were all set. So they all knew what the money is going for -- what the money is being spent on. And the majority of it was on staffing of course. But any new initiative, any new appointment, had to be approved centrally.

Q. You have already told us it was the smallest centre in Scotland, and you estimated that you took about 20,000 donations a year, is that right?

A. I guess so, yes, about that much. Yes.

Q. And that number stayed pretty stable over the three years that you were there?

A. Yes.

Q. I will just ask you a couple of questions about the targets. You have mentioned previously that the targets were provided to you for donor collections by the SNBTS. So those were centrally, were they, but you were consulted about them, were you?

A. I mean, when it came to donation targets, those were

mostly historical, how much we collected. I think we were -- in Inverness, we were probably a bit above average in terms of percentage of people that donated per 100 population. Normally it is around the 5 per cent mark. So we were pretty comfortable with that. When it came to plasma targets, those were set by SNBTS. And I'm pretty sure we achieved them all every year.

Q. Your statement tells us that you had -- a plasmapheresis programme was in place when you arrived at Inverness, and that's the same for Dundee as well?

A. Yes. Yes, it was all machine apheresis. It wasn't a cheap option. It was much more expensive than getting plasma from whole blood. But if we were then short of plasma to reach our targets, then that was a very useful source of plasma collection.

And also then, once you have got the machines, you can use them also to collect platelets. Because the staff were trained, the nurses were all trained, and therefore it was a relatively simple move then to get platelets if you had to.

Q. Your statement also tells us that the centres, so relevant for both Inverness and Dundee, were licensed by the Medicines Health Care Regulatory Authority,

(sic) which was a biannual process, a biannual process of inspection, is that right?

A. Yes, every two years they used to come along and spend two or three days, they used to go around, you know, and ask people whatever they wanted to ask and then they would give you a report with either particular deficiencies, or major deficiencies, or minor deficiencies, and then, depending on those and depending on the time lag -- so if they tell you that you have a major deficiency which must be rectified in two months, for example, then once you showed proof of that, then they would give you a licence for the next two years.

MS SCOTT: Sir, would now be an appropriate time to take a lunch break?

SIR BRIAN LANGSTAFF: Yes, it would. We will take a break now for an hour. It will allow you what may be a latish lunch for you but it is our lunch time here. I'm sorry you have to fit in with English time.

A. No problem.

SIR BRIAN LANGSTAFF: So 2 o'clock for us, 3 o'clock for you.

A. Okay, thank you very much.

(1.00 pm)

(The short adjournment)

(2.00 pm)
SIR BRIAN LANGSTAFF: Yes.
MS SCOTT: Dr Galea, I'm just going to ask you a few general questions about Dundee and then turn to some of the work that you did in Inverness and Dundee and donor counselling and look-back and so on, which will bring us to the end of my questions.

So the same question that I asked you in respect of Inverness: can you give us a sort of pen picture of the centre at Dundee and what you met when you went there and the challenges that you faced?

A. Yes. Dundee was a bigger centre, about the same size as Aberdeen. The big challenge for me in Dundee was that it was a time when the -- when SNBTS was changing from having five fully independent, if you like (audio distortion) transfusion centres, where each centre did its own processing and testing, to shifting the processing and testing to Edinburgh and Glasgow. So the Dundee, Aberdeen and Inverness blood centres lost that capability.

This was a time of great insecurity for the staff. Some people had to loose their jobs. Some had to change their functions completely. So, I mean, my role there really was to manage that change.

There was also a new blood centre -- sorry,

a new donation centre being refurbished. And similarly, you know, although by now I had learnt a few management skills, I had to learn all about the new management team, keep the show on the road, make sure that the blood came in, and so on and so forth. So that was my main challenge in Dundee.

Q. I'm just going to ask you a little bit of detail about the centralisation of the processing of blood.

Once that had moved to the central belt, to Edinburgh and Glasgow, is it right to understand that all donations that were taken -- that were collected by any of the Regional Transfusion Centres were sent for testing for viral infections to Edinburgh or Glasgow before being released; is that correct?

A. They were all sent as whole blood, as they were collected, and then they were processed in Edinburgh or Glasgow, tested in Edinburgh or Glasgow, and then sent back our pro rata share, if you like, of what we needed.

Q. So no more making your own fresh frozen plasma, no more making your own cryoprecipitate, all of that was done centrally?

A. Yes.

Q. So effectively your laboratories were decommissioned, were they, and staff made redundant?

A. They changed the rules completely, yes, yes, yes.

Q. Do you think that hospitals would have noticed a difference to the arrangements? They were presumably still getting components from you, the product from you. Would they have noticed a difference, do you think?

A. We had many, many discussions with them, because they required a lot of reassurance that they felt that you know they had been getting such a good service from -- before. Whenever they phoned for platelets, you know, at 2 in the morning, they got them, because they were there. They wanted that same reassurance that if the processing and testing was going to be transferred and -- they were still going to get the same level of service from us as before. And therefore that required a lot of discussions, with a lot of reassurance, with a lot of meetings with them. Once the transition happened, I think it was generally very smooth.

Q. And what did you understand to be the aims of centralisation?

A. I think it was partly cost-saving, I suppose. Two, improving the standardisation. So you only have two centres doing processing and testing rather than five. In fact, I think PCR testing of all donations was done

only in one centre in Glasgow. So I think, you know, rationalisation of services, cost-saving and harmonisation.

Q. Now, I understand that in about -- well, we will look at the article where this information comes from, but in July 1997 all centres in Scotland introduced the tick box questionnaire for use in donor sessions. Is that right?

A. I mean, I can't remember the exact date but if you have got the date then that's what it was, yes.

Q. Can we just look at that. It is at NHBT000044271_003.

So, is it right to understand that this is a document that would be provided to the donor to fill in themselves? Because we have got there they need to sign it in various -- they need to sign a declaration that they have read the blood safety leaflet and they declare to the best of their knowledge they are not at risk of infection. That's on the left-hand side, "Declaration by donors", and that their blood can be tested and they understand the nature of the procedure and the associated risks involved, as explained in the blood donation leaflet, and so on. And they also are asked to consent to their general practitioner being able to give information to the Blood Transfusion Service.

A. I suspect -- I'm not 100 per cent sure but I suspect this might be an English version. I am not 100 per cent sure that we actually asked for the GP's name in our version. But I think that is the only difference. Otherwise, as I indicated before, the questions are in sequential order. You know, "ever in the past year", "in the past six months", and so on. So I do recognise this being a tick box questionnaire which had to be ticked every time by every donor.

Q. And it had to be ticked by -- so we can see in the tick box questionnaire part, there is "Yes", "No" and "Staff use". Is it right to understand that the donor would be given this and they would be expected to do the ticking and the "Yes" and "No", and then --

A. That is right.

Q. -- once they had signed it, it would be given to a staff member who then had the ability to write something, if necessary, in the "Staff use" column?

A. Yes. And if they were first-time donors, then that would be the basis for their personal interview.

Q. So I'm just going to come on to personal interviews, but this tick box questionnaire would be given to all donors, would it, repeat donors and first-time donors?

A. Yes.

Q. We can see in the tick box questionnaire, section 7,

a mention of CJD. Can you recall whether or not that came into the questions that were put to donors at the time the tick box questionnaire came out or whether that formed part of the questioning of donors prior to that?

A. No, I mean, I can't -- I mean, '97 appears about right. Clearly here we are talking about CJD and not the variant form, which came later. There was --

SIR BRIAN LANGSTAFF: This is a revision dated 19 January 1998. So it may follow on from an earlier version. So 1997 may not be quite right.

MS SCOTT: Yes.

A. I cannot remember when that questioning was introduced and -- I was trying to explain that that had to do with the classical CJD variant -- sorry, with a classical CJD, not the variant, because in the classical type there are some people who have a family history of CJD, unfortunately, and they would know about it. And there was a lot of debate in the donor and SAC as to whether to ask this question to everybody, and ultimately it was decided that if people had a family history of CJD, they would know about it, because it is something that, you know, that happens by chance, and therefore it was a question which we felt they could answer.

Q. Then we can see all donors are asked to answer some questions and first-time donors or donors who haven't given for two years are asked to answer other questions. Then there is the warnings on the right-hand side, "For all donors", the groups of people that shouldn't give blood. And that echoes the material that we have looked at before, but it includes not only those who are HIV but also those with hepatitis B or hepatitis C -- if they carry the hepatitis B or hepatitis C virus. And then --

A. Yes.

Q. -- the other categories set out there.

Then they are asked to say:

"Is it possible that any of the above might apply to you?"

And asked to say yes or no there.

And then, at the bottom of that part, there is an opportunity, if we come out of that box, right at the bottom there, to -- do you wish to speak to a nurse in confidence:

"Do you wish to speak in confidence to a doctor or a nurse?"

So there was an opportunity, was there, by the time this revision came out, which is correctly identified as January 1998, for there to be private

confidential discussions between donors and staff?

A. Yes, we were very aware that, you know, we were dealing with very sensitive topics here, you know, about personal behaviours and so on. So although people -- many people felt comfortable ticking a box, some people might feel that, you know, somebody might see them or a friend might see them ticking a box, and in that case we wanted to make sure that in every session there was an area that was completely private. And I remember, you know, having radio background noise so nobody could listen to the discussion, so that if somebody wanted to speak in confidence to us, they had the opportunity to do so in private.

Q. Did that have an impact on the places that you could go to to hold donor sessions?

A. I can't remember specifically whether it was -- whether there was -- some specific places couldn't be used anymore, but we did make sure that wherever we went, in halls and so on, there were a number of measures that had to be looked at in terms of health and safety, in terms of availability of water, availability of a private area, and so on and so forth.

So, yes, I mean, they had to have a place where a donor could speak confidentially with one of our

staff, otherwise it would not be a good place to have a blood donation session.

Q. I'm going to come on to look at the audit you did of the use of this questionnaire, but I'm going to turn, first of all, to the introduction of the donor interview, the personal donor interview process, and look at that, and then -- because you audited those two things together.

So can we turn, first of all, please, to STHB000677 -- sorry, STHB0000677.

This is the meeting of the Medical and Scientific Committee from March 1993, and we can see that you were present.

If we turn over to page 7, please. We can see at the top there:

"Donor Selection Procedures: Intensive Interviewing

"The members noted that data from the USA suggest that face to face interviews with donors significantly enhances high risk donor exclusion. The benefits of computer interviewing were mentioned and it was agreed that careful consideration of cost would be required. Dr Galea reported that a meeting of the Donor Consultants with representatives of the Microbiology Reference Unit is to be held in summer

1993 to assess the results of the evaluation exercise which had been underway in SEBTS. Dr Galea will report back to MSC thereafter."

Are you there -- the evaluation exercise underway in SEBTS, is that what eventually you wrote up with --

A. Yes.

Q. We will come to that in due course.

So this is 1993, so it is clearly an early MSC meeting for you, because you have just been appointed at Inverness. But as far as you are aware, is this when this idea about intensive interviewing was first discussed by the directors or had that been an issue previously?

A. I can't remember the exact dates because I used to attend before just as a medical adviser, but I suspect it is about the right time, 1993, because I had conducted -- we had conducted the audit in Edinburgh and Aberdeen. Edinburgh and the southeast had been piloting personal donor interviews in some of the sessions, which actually was -- the data of which reflected in my study, which showed that personal donor interviews were pretty effective, particularly in eliciting high-risk behaviour. So I suspect that it must have been one of the very first times that it

was discussed.

Q. You say you were piloting the donor interview. Were you doing that in Aberdeen?

A. No, the piloting was -- when we did the audit, Edinburgh were piloting it and in Aberdeen we weren't.

Then I think after the results were widely disseminated, it was accepted that, you know -- and for the other reasons that I mentioned earlier today, availability of doctors, et cetera -- I think a move by SNBTS was that yes personal donor interviews are a good idea to try to implement throughout Scotland.

Q. Then we don't need to turn up these documents but the documents that we have show that following this there is a decision made in May 1994 to accept personal interviews should be introduced, and thereafter there is discussion about when that could be introduced, and at one stage it is suggested that it should be introduced in different centres at different times. And then in October 1995 funding was released which would allow the same start date in all of the centres, and that start date was set in September 1996. Does that accord with your recollection?

A. Probably. I think when I went in Dundee, which was in 1996, it was just about, or -- or just about to be introduced. So, yes, 1996 will be a correct date.

Q. And it was agreed that some prevalence data would be collected to effectively audit the use of this interview?

A. I did that in my region. When I went to Dundee and we introduced personal donor interviews, I followed it up, I put a year's study, because we had just introduced the tick box questionnaire for all donors and personal donor interviews for first-time donors, and you could see, if you do -- if you look at the data before and after, it confirmed that, yet again, the personal donor intake were very effective in eliciting information about high-risk behaviour or data about the blood safety leaflet. And I think that confirmed all of the previous work that was done which showed that they are really effective in this context.

Q. Shall we look then at the article you published in *Transfusion Medicine*. It is WITN6931003.

So this is:

"The impact of the new tick-box questionnaire, and the personal donor interview, on donor deferrals in the East of Scotland."

If we read the summary:

"The impact of a new tick-box questionnaire (TBQ) and personal donor interview (PDI) on donor and recipient safety was assessed over an 18-month and

a 13-month period, respectively, by prospectively studying individual donors prior to and after the introduction of the new methodology. A 'hit' was defined as an instance where the TBQ or PDI prompted a donor to divulge information which they would not otherwise have divulged, with the new information having an impact on donor eligibility. There was a 'hit' rate of 0-19% for TBQ and 0-65% for PDI. Of these donors, 33% in the TBQ category and 14% of PDIs were reinstated, 24% and 32%, respectively, were deferred because of a malaria/chagas risk, and 16% of the 'hits' related to donor safety issues. When assessing recipient safety, particularly risk of a window period viral transmission, PDI is very significantly superior at identifying such donors (14 times better). Such information establishes the important safety aspects of these interventions and requires that further work be done to see whether PDIs, in particular, may be better targeted to specific groups of donors."

Then, just to get the dates of this, if we look down the right-hand column, "Materials and methods", it says there that:

"The tick-box questionnaire (TBQ) which is printed on the back of the Donor Session Record was

introduced for all donors in July 1997."

If we go over the page, to the left-hand column, you can see at 2 there, at the top:

"During the late 1990s, SNBTS also decided to phase in the introduction of the Personal Donor Interview (PDI) on a region by region basis. The PDI, for first-time and two-year lapsed donors, was introduced in the East of Scotland region in January 1998. This interview, undertaken by a nurse or doctor, allows careful review of the responses to the TBQ, followed by direct oral questions regarding possible risk behaviour."

Is that right? It started in Edinburgh first and then other centres followed suit?

A. Yes. And when I went to Dundee, as I say -- I'm not quite sure exactly why but the previous director did not implement it at the time. So, having done it before in Inverness, I felt, well, it is something I have good experience of, I know SNBTS want to do it, so within a few months of me arriving in Dundee I began to implement the changes, to introduce the tick box questionnaire for everybody and the personal donor interviews for first-time and lapsed donors.

Q. In terms of donor response to being asked questions, sometimes quite personal questions, about their risk

behaviour, were donors surprised, upset, angry, any of the above, at questions being directed to them in respect of those matters?

A. No. In general, the response was very positive. I think the trick is to train the staff really well how to handle these issues. Because, as you say, they are very personal issues. You don't know the donor very well, you are meeting them for a very short period of time, so you have to handle these things very sensitively. But, in general, most donors felt that these questions were being asked to improve, let's say. So it was more of a positive response rather than, "Why are you inquiring about my personal life?"

Q. So key is training the staff but key is also to have very strong messaging to the donors that this is not a personal attack to them, these questions are being asked for blood safety reasons?

A. Yes, yes.

Q. I'm going to move on now from donor selection issues and ask you some questions about look-back, and that's my final topic for today.

So can I ask you -- can we look first, please, at PRSE0000796. This is a letter, 15 October 1993 to all of the centre directors. So you are then in post

in Inverness.

It says:

"Look Back ...

"One of the outcomes of the recent HCV Symposium at the RCPE was that there was a need to refer patients who have recently acquired HCV infection to specialists for consideration as to whether they should have early interferon therapy.

"I do believe this places an obligation on the BTS to use its best endeavours to advise clinical colleagues accordingly when we have evidence that a recipient may have acquired HCV.

"It is my intention to raise this matter at our next MSC and I would be most grateful if you would discuss it with your medical team so that our MSC discussion reflects all professional views throughout the service."

Can you remember whether there was a practice, when you first arrived in Inverness and at the time that you received this letter, of carrying out any kind of *ad hoc* look-back. So, for example, if you did find a donor that had tested positive for HCV, whether there was a practice of trying to identify what had happened to any previous donations?

A. I think -- in the context of HCV, I think that was the

case but only on an *ad hoc* basis. So if we find one, then, you know, you would look back and see, yes, whether the blood that was taken was still in stock, whether it was transfused, whether it was sent to PFC. You would notify accordingly. So if it went for fractionation you would notify the fractionation centre. If the blood was still in the unit, in the RTC, it would be destroyed, and if unfortunately it was transfused, they would notify the clinician. So on an *ad hoc* basis, yes, we looked back.

Q. Can we look next then at a document -- at PRSE0003344. So this is a document relating to the national look-back programme. So this is some eight months after the letter from Professor Cash that we have just looked at, again to all of the centre directors:

"HCV-Look Back Programme.

"I thought it might be helpful to clarify the position -- at 20 June 1994 -- after the unusual events following our last MSC meeting."

Just pausing there. Maybe too much to ask you this but can you recall what the unusual events were around that time?

A. Sorry, I can't. I'm trying to think but, no, I can't remember, unfortunately.

Q. Then he says this:

"There are likely to be three evolving approaches designed to provide the now necessary SOHHD approval for the SNBTS to commence a formal 'nation-wide' HCV Look Back programme."

It looks like, by this stage, the Home and Health Department approval is required for the national look-back programme, is that what you understood to be the case?

A. Yes, absolutely. Yes.

Q. Then he says:

"These approaches can be summarised as follows ..."

So first of all he sets out that the Advisory Committee on Transfusion Transmitted Diseases will need to make a recommendation to the NBA and an extraordinary meeting is going to be called to consider the topic as soon as possible.

Then, if we go over the page, he looks -- next page. The other two strands there are the donor consultant group, the group that you chaired, and it says that:

"[You have] kindly agreed that this Group will act as the focus for an emerging draft SNBTS operation plan which, in due course, will be submitted to the MSC for approval and thence via David McIntosh

hopefully to [the Home and Health Department]. It would be my intention to attend these meetings in order to provide the best possible communication between the Service and ACTTI.

Then lastly, he believes:

"... it is operationally important, and in patients' interests, that we (SNBTS) consult with senior ... hepatologists on this topic. I'm certain that even across Scotland this will enhance our ability to achieve an orderly and optimal approach. The plan will be to acquire as much advice as possible with regard to the practical consequences of an HCV look back programme."

So we will pick up in a moment, by looking at a document, what's set out in paragraph 2. Can you recall what the -- whether or not you did indeed consult with hepatology colleagues and what their response was to the HCV look-back programme?

A. I say what I did. I definitely consulted with the local hepatologist because the issue, of course, was there's no point identifying these recipients if there was nobody to see them urgently. Because you have just given them a bit of bad news, clearly, and they had to be seen pretty urgently.

So I met with I think it was one or two

haematologists in Dundee and they agree that, you know, if it was a recipient that was notified of being infected and if the consultant who was in charge of their care notified them and they would know that they were part of the look-back programme, that they would see them pretty urgently. So that was my buffer, if you like, my fallback position.

Once we began the look-back, I'm not quite sure what happened afterwards because that was not my remit anymore but I wanted to make sure that there was somebody available to see these recipients of blood pretty urgently.

Q. Then if we pick up what's said in paragraph 2 there, the operational plan. Can we look, please, at SBTS0000462_011.

We have got there a document entitled "SNBTS Guidelines for HCV lookback, Dr G Galea". Then there is some handwritten notes on there to Jack. I don't know whether you know what those are or who wrote them?

A. That is for Jack Gillon because he was part of the group. I don't know who wrote it, maybe it is Brian, I'm not sure.

Q. If we go over the page then, please, to page 2, we can see the HCV look-back programme. Is it right to

understand that this -- these are effectively the operational guidelines that Professor Cash mentioned in that article we just looked at?

A. Yes, yes, yes.

Q. So you say:

"On February 1st and 2nd, the Donor Consultants Group met and discussed in detail the HCV Lookback Programme."

At (a):

"It was agreed that the UK BTS proposals were a targeted lookback."

(b):

"Reasonable efforts should be made to trace all recipients. Where appropriate and possible this may include the use of archive donor samples to assist with their targeting of the individuals involved."

Was that when you found a positive donor, you would go back and test the archive samples to see when the infection arose and which donations were infected, effectively?

A. Yes, because we kept all the archives and, therefore, we could trace exactly at what point the donors seroconverted, clearly if he was a previous donor, if he had given previous donations. So we could trace back until we got a negative donation and, therefore,

we could then know which recipients to go and find out.

Q. Then you set out what the NBA are doing, which is that they are not using archive samples and the reasons why they are not. (c):

"It is essential to establish that the recipient is alive before any attempt is made to contact them.

"(d) The original prescribing physician should be informed in the first instance, followed soon after by the recipient's GP, if the patient is still under the original prescriber's care. If the recipient is not under the original prescriber's care any longer, the GP will be contacted first.

"(e) A BTS Consultant for each region will be responsible for the lookback programme.

(f) All activities concerning lookback programmes should be carefully documented.

(G) Since Dr Gillon is updating the HCV counselling document on a UK wide basis, it was felt that the same document should be used throughout Scotland."

Just pausing there. Is that referring to the HCV counselling document that we looked at to be used for donors or is this a different counselling document, specifically for look-back?

A. It is a combination. So you have the counselling document for donors but we also had very detailed procedures as to how we go about tracing the recipients of blood as part of this look-back programme. So it is -- you know, it was a combined document, if you like, or two combined documents. One was how to counsel a donor and the other one was how to actually do the look-back programme to identify the recipients and what to do with them.

Q. If we go over the page, we can see the action by RTCs. Is this the detail that you were just --

A. Yes.

Q. -- mentioning. So:

"All reference laboratory confirmed HCV antibody positive donors to be identified and their donor record examined."

Next paragraph:

"All donations given prior to the index HCV antibody positive donations to be identified by donation number, together with all the unfractionated blood components prepared for these previous donations."

Then you have to establish:

"The fate of all these previously donated units and their associated unfractionated components ..."

You have to:

"... list [out] all the components issued to each hospital", which has got to provide the donation number, the type of component, the date of issue, et cetera.

Then it says:

"The ... Donor Consultants Group do not believe that patients exposed to IVIgG need to be contacted and tested. This is not part of a targeted lookback."

Again, just pausing there. Was that a decision made by the Donor Consultants Group or was that a decision made by the SNBTS or indeed by the Home and Health Department, that the targeted look-back didn't include IVIgG recipients?

A. Remember, this paper is part of a document that is going to MSC. So these were recommendations by the Donor Consultants Group. This was discussed at MSC. I don't believe, although I may be wrong, but I do not believe it went to the Scottish Office because of the well-known safety issues that were concerned.

IVIgG, when it is processed and fractionated, is a very safe product. To my knowledge there has been no transmissions ever of hepatitis C through it and therefore because it was a very safe product, there would have been no need to actually trace those

recipients. So I am pretty sure that this was approved by MSC. I wouldn't have thought it would have gone to the Scottish Health Department.

Q. Then the document goes on to set out that the hospital, where the infected product component was provided to the patient must contact the patient. Then at that bottom large paragraph halfway through -- down it says:

"A letter is sent for the haematologist to send to the hospital clinician and a letter for the clinician to send to the patient."

It looks like part of the process was to have standard letters, for hospitals to provide to the patients, is that right?

A. I think so. Actually, I believe, if my memory serves me well, this was a UK-wide initiative. It wasn't just for SNBTS. Standard templates were produced, standard letters were produced. I think it was a big attempt, I think, to have a unified approach on this and I'm pretty sure that even the templates and the letters were UK wide.

Obviously, they had to adapt them to your personal circumstances, so you would have the SNBTS logo on top, and so on, but the content and the letter itself were drafted, I think, on a UK-wide basis.

Q. Then if we go over the page. We get to the section "Other Notes", if we look at 2, we can see there it says:

"The Donor Consultants Group felt that counselling of donors", and it says "? Recipients", which I think must be right?

A. Recipients, yes.

Q. "... should be done by the physician under whose care they are either in hospital or their GP. As a last resort, however, following consultation with either, it was felt by the SNBTS consultants that adequate care was not being given to particular recipients, then they may be involved in counselling such recipients either pre or post testing."

Do you recall whether or not that occurred in either of the centres that you were the director of?

A. No, no. It didn't happen. The haematologists that were involved -- I mean, clearly it wasn't 100 per cent proof programme. Some donations we could not trace fully but those that we did and it was the majority of them, and a significant majority, the haematologists or the clinician in charge of the patient, who still knew the patient, agreed to give them the news, which made a lot of sense because the clinician in charge of the patient knew the patient.

They wouldn't have known us at all and, therefore, they had built a much better rapport with the clinician in charge and therefore it would have been much better and it made complete sense that they tell them the news.

And this was agreed beforehand, they didn't receive this letter just out of the blue. Everybody knew that the look-back programme was going to take place and sometimes if I got a recipient or I knew of a recipient, before sending the letter, I would phone up the clinician and I would say we have found a person who has probably been transfused with HCV infected blood, do you know him, are you happy to talk to him, and so on. I would make contact, I would liaise with the clinician himself.

Q. Can you recall how easy or difficult the centres found it to do everything that they were expected to do in terms of going back and finding the right archive samples to test and then, from there, working out where the donations were and where they went, and so on?

A. It wasn't an easy task. It was very laborious. Many of the records were manual, as well, because they were pre-computerisation. So it wasn't an easy process to go through all the notes and try to identify the

recipients. In my case, where I was in Dundee and in Inverness, numbers were small.

I suspect if you were working in a big centre, it would have been a pretty -- it couldn't have been an easy task to do this work. Very labour intensive, very detailed, you have to go through the notes, and so on and so forth, trace the patients, look at the numbers, look at the donations, get the archive samples tested. It was a significant piece of work.

Q. If we can turn to SBTS0000463_005. So we can see this is a meeting of the Medical and Science Committee of 17 May 1995. Again, we can see that you are present.

If we can turn please to page 5. There is a section entitled "HCV Lookback". The first paragraph there, I just want to get your recollection of this:

"There was agreement that the implementation process had been problematic with delays/misunderstandings in receipt of documentation from SHHD and typographical/factual errors in the content of standard letters eg in [North East] region, letters had gone from SHHD to GPs but not hospital MOs which resulted in numerous phone calls to the RTC.

"Nevertheless, good progress was being made across the SNBTS."

They go on to review the position, which I will come to in a moment. Can you remember whether you experienced any of these what looked like being articulated as teething problems?

A. I would say maybe some teething problems, yes, but in general nothing sticks out in my mind which says it was very difficult to do or to achieve. I think, you know, you have these teething problems, maybe wrong letters or maybe wrong phones, or something like that but, in general, I don't think, personally, we found it very difficult --

Q. Then if we -- sorry, I interrupted you.

A. I was going to say where I worked in Dundee because that's where I was at the time when this was happening.

Q. Then if we go -- it says, "Review of Current Position", and it starts with Belfast but, if we go over the page, this document is actually dated 17 May 1995, so I think you must have been in Inverness at that stage.

A. Sorry, okay.

Q. We can see the:

"North -- all donations had been traced back as far as records would allow (1979). All available archive samples had been tested and this demonstrated

two seroconversions. The lookback process was restricted to positives and the last 'true' negative."

Just pausing there. Is it right to understand then that rather than this being a look-back that arises as new donors are being screened, you are actually going back through all the archive samples? It is not a question of a donor walking through the door, having an HCV test for their donation as part of their normal practice and realising they've got HCV so then going to the archive samples, are you searching through the archive samples?

A. No, no -- we looked for all the HCV positives that were ever found, and looked back at all their archive samples and see how many of them were positive. And we kept on testing it, in this case up to 1979, which is a long time back, to identify which was the first negative donation. And then we could say all the previous donations prior to that -- after that, sorry, we need to find where they went.

Q. But the trigger for looking through the archive samples was a donor walking through the door, having a donation taken, and being found to be HCV positive?

A. That was -- yes, but -- yes, absolutely. So anybody who was positive, we then looked back at all the previous donations before.

Q. Understood. Then you say:

"Of 11 patients still alive ..."

Can you just help me to understand that. You have demonstrated two seroconversions but then you talk of 11 patients still being alive. So are we to understand that that is 11 patient recipients from the two seroconversions?

A. Can you repeat that, please, about the seroconversions.

Q. So you say there:

"All available archive samples had been tested and this demonstrated two seroconversions."

A. I was going to say if someone gave, for example, ten previous donations, so there was one seroconversion between donation 1 and 2 and there were nine more, those nine we then traced back.

Some -- obviously some blood would not have been given, some blood would have been discarded, some blood would have been given to patients. And we then traced all the recipients that got the blood.

As I said, there is one caveat to that, and that sometimes if we gave out blood and the blood didn't come back, then we assume it was transfused. But we felt, you know, better tell somebody he might be infected and then be negative rather than miss him.

Because if the -- if we had no proof that the blood was not transfused then you either say, "Well, I don't know where it's gone", or you try -- and trace that patient. So that blood went out for patient X, we don't have proof, we still tell patient X that he might have been infected, because then, as soon as the result comes back that he's negative, then his mind is put at rest. If we don't tell him, he might be positive and he would never know. So we felt better be precautionary and test everybody.

Q. So, just looking back at this document then, so of the two seroconversions you had managed to trace from the infected donations that they had given, 11 alive patients, five of whom had been contacted, and then another ten components that had been sent to other centres and they had been contacted?

A. Yes.

Q. Can you then help me with this, STHB0000687.

We are moving on now from this document we just looked at, which was May 1995, and we are moving on now to a document, again, meeting of the Medical and Scientific Committee in October 1995. Again, you are present.

If we turn to page 4. If you can help me to understand what's said there under 4, "HCV lookback".

Then if we could go down please to (iv):

"With respect to recipients of blood components pre HCV testing, the MSC agreed:

"- that testing of available donor archive samples would be neither cost effective nor appropriate."

So here is it right that we are talking about whether or not there should be testing of archive samples, not triggered by a current donor coming in and being found to be HCV positive, but simply -- well, not simply, but the transfusion centre going back through its archives to see if they can find any donations that might be positive?

A. Exactly, yes. That's why we called it a targeted look-back, rather than do a general look-back where you go and test -- I mean, remember, we were collecting about 300,000 donations per year. So to test all that would have been monumental and probably not cost effective at all because the numbers you are going to find were very, very small.

Q. So what's said there is that an offer to test anyone who had received blood components or products prior to HCV screening was likely to be the most effective option, that this latter option should not be pursued until the present HCV look-back exercise was

substantively complete and that the sample collection and testing process should be provided by the blood transfusion services.

Can you recall whether or not this subsequent look-back or offer, sorry, to test anyone who had received blood components or products prior to HCV screening, was that offered during your time in the Blood Transfusion Service, so before 1999?

A. To my recollection it wasn't offered as a service by SNBTS.

It may have been offered by the clinicians but, to my knowledge, it wasn't something that we, as a Blood Transfusion Service, offered. I don't think so.

Q. Can you recall whether there was any subsequent discussion about this, about what's said here, once you had got to the end of the look-back, whether that was brought back to the table?

A. I don't recollect any more discussion after then, no, particularly after 1999, then I moved into tissue, and so on. So it could have been discussed in the context of blood but I can't recall it being discussed, no.

MS SCOTT: Sir, those are the questions that I wish to ask Dr Galea. Core Participants and their legal representatives will no doubt need some time to

consider whether they want to ask me to put further questions to Dr Galea. I wonder whether we could have a break now?

SIR BRIAN LANGSTAFF: Yes. How long do you think you might need?

MS SCOTT: I don't know. Shall we try for 20 minutes and --

SIR BRIAN LANGSTAFF: Let's make it 30 minutes, shall we, and come back at 3.20 pm; 4.20 pm your time, doctor.

The purpose of this is to allow Core Participants through their lawyers to ask Ms Scott to ask some further questions of you on various topics which -- to which they want answers, and to allow her to field those questions, we just take some time. I can't tell you how long we shall be when we come back, it may be very short but it may not be.

But, in any event, I look forward to seeing you back at 4.20 pm your time, 3.20 pm us.

(2.55 pm)

(A short break)

(3.20 pm)

SIR BRIAN LANGSTAFF: Yes.

Questions from CORE PARTICIPANTS

MS SCOTT: Dr Galea, I have got questions on various different topics so we will have to dot about a bit.

The first lot of questions relates to the schedules that you were telling us about that were brought in, I think you were describing, when you were working in the Aberdeen centre, to work with clinical colleagues about the amount of blood that they were using.

I have been asked to ask you whether it was your idea to introduce those schedules and, if not, whose idea it was?

SIR BRIAN LANGSTAFF: We have lost sound.

MS SCOTT: We can't hear you, Dr Galea.

SIR BRIAN LANGSTAFF: Shall we just see if we can get the sound back. Right.

A. Sorry about that.

SIR BRIAN LANGSTAFF: Do you want to start again? Did you hear the question? Do you want it repeated?

A. Thank you, it is all right, I have got it.

I think it was probably an SNBTS idea in general. The demands for blood were increasing, the number of donors were obviously about the same or getting harder to get the same number of donors, so any initiative to reduce blood wastage was considered to be a very useful one. Plus the context, of course, that we were beginning to think about the Better Blood Transfusion project and how to reduce blood wastage in

general.

So when I was in Aberdeen we discussed it, a number of colleagues in the blood centre, me, Dr Urbaniak, other doctors, and we began to establish these schedules. We did a lot of research, found out what the normal usage of blood was, when these were being used, began to set up our own local schedules, discussed them with the clinicians, and then implemented them.

Q. These schedules, were they in the form of written documents that were provided as guidelines to clinicians in different disciplines?

A. They were very simple and -- they were a simple table. And they were matched with a speciality. So, for example, it was with orthopaedic surgeons, we gave them a square, a chart, and we said: "Total hip replacement: 4 units"; "Total knee replacement: 2 units"; "Revision hip" -- whatever -- "5 units".

And they would adhere to it. And once they agreed with the schedule, whatever request they made on the cross-matching form, we would stick with the schedule. If the request was -- for example, if you're asking -- if the normal amount of blood used was two units and they asked for six, we would phone up and say, "Is there a particular reason why you want

more blood than average?" And so on and so forth.

So there was this dialogue taking place and a review every six to eight months. I used to go -- as I said before, I used to go to their committees and present the data.

Q. Was the purpose of those schedules to try to limit the amount of blood which was being used?

A. Yes, because, you know -- not to limit it, but to use the appropriate amount.

At the time many surgeons had very different views and -- I mean, I will never forget, things like open heart surgery, some surgeons, some -- particularly younger surgeons who, you know, had come from abroad, for example, were using four units of blood for open heart surgery. Others were using ten. And clearly one of them is wrong. So it was that kind of dialogue.

And normally the blood ordering schedules ended up being on the conservative side. So we would put out four units of blood, say, for open heart surgery. If they required more, either before, because they knew that the patient was a difficult one, or afterwards, we could always provide them with extra blood as they required, but the routine was fixed and that was really helpful.

Q. And do you know whether or not those schedules were used in Scotland before your time as a consultant in 1989?

A. All I know is that I established them in Aberdeen. Whether they were used before in Edinburgh, Glasgow or anywhere else, I'm not sure.

Q. Did you ever discuss the benefits of using schedules and sharing information with clinical colleagues with anyone south of the border, so in England?

A. Not so much, because remember in England the blood services did not have the blood bank facilities that we have. So we were also the blood bank of the hospitals. This was more of, if you like, a blood bank oriented issue. This was more to do with blood usage and discussion with the clinicians.

My understanding was that, in England, blood services were wholesale and they sent blood to the hospitals to do blood bank hospitals. So it wasn't a topic that particularly was discussed with the blood services but, you know, I presented the data in various conferences, discussed at MSC, and so on, and so it was a well known fact and I would have thought -- I would be surprised if similar schedules weren't also used in England.

Q. When did the system come in whereby the local

hospital, which transfused blood or a blood component, reported back to the blood bank the details of the patient to whom the blood had been transfused?

A. Ever since I joined. They always had the requirement, so since 1987 -- '84.

The problem more is that, in the early days, they weren't very good at it. So the hospitals, you know, weren't very good at returning the information and it took a lot of time and effort to convince them that it was something which was important, it was essential for traceability, for audit purposes, for quality purposes for licensing purposes, and I know, for example, that in Scotland we had teams of nurses in hospitals going round, explaining how to keep blood, how to make sure that these forms were returned, how to store blood, and so on and so forth, with questions to ask the patients before they got the blood to make sure they got the right blood.

So it was part of a big concerted effort that the numbers of returns -- of information return, but it was always a requirement. We always knew that some patients got blood. That is how we were able to do the look-backs, for example, because we had all the information.

Q. What types of blood or blood components did you keep

samples of? Was it everything collected at the centre, including plasma sent to PFC?

A. We kept samples of every donor, every donor that came. So it was one sample per donor, if you are talking about the archive. Obviously, we had samples for grouping, for testing, but if you are talking about archives, we always kept one archive -- one sample per donor --

Q. So if, for example, you --

A. On each time, on each time. On each time they came. Sorry, on each donation, rather. On each donation we kept a sample.

Q. So if you were producing any pooled components would you keep a sample of a batch of pooled components?

A. As far as I know, no, because we knew that a pool, say a pool of platelets, would be made up of six or five donations. So we knew where the donations were coming from because we had a sample per donor. So if a platelet pool got contaminated we could exactly trace which one it was because we had a sample from each donor.

Q. I'm going to ask you some questions about donors now. What medical information, if any, were you able to compile about repeat donors, as their involvement with your service went on?

A. Well, the information we kept on donors were their basic demographic information. Their date, their sex, their name, their address, very often, their blood group, clearly each time, and we knew their blood group, and then we kept the records, their health check questionnaire, for example, they were all kept and we would then, if there was any deferral code that had to go in the computer, that was kept.

But everything was done confidentially and on a need-to-know basis. So sometimes if I wasn't on blood donor sessions I wouldn't have access to particular donors who were -- whose blood was collected on that day for example.

Q. Would it have been useful to have had access to more medical information on donors?

A. Can you repeat the question, please?

Q. Would it have been useful to have access to more medical information on donors? So we saw in the tick box questionnaire the consent form for the GP, and you thought that was an English form. Would it have been helpful, for example, to have had the ability to seek information from the GP?

A. If there was a reason. We did contact the GPs quite a lot if we had doubts. Sometimes there were donors who would say, "I have been to hospital", and they

would not quite know why. You know, "I've got a pain in my hip."

"What is the cause?"

"I'm not sure."

Then we had the ability to contact the hospital or to contact the GP via the donor and get who the GP is and the information. It was on a *ad hoc* basis. If there was no need to contact the GP or the hospital, there would have been no need. If, however, there was any queries, then yes, we did.

Q. When you were telling us about the National Medical Register, one of the questions I asked you was what was the trigger for this coming into existence, and you spoke about high-risk donors donating in one area, donating or trying to donate in several areas.

A. Yes.

Q. Could you tell us a bit more about that. What evidence was there of high-risk donors doing that, going from one to the other? Was that a common occurrence?

A. Not a common occurrence but it was a risk. Because if somebody was absolutely determined to find out whether she was HIV positive, for example, or has been exposed to hepatitis and she wanted to find out, then if you went to Aberdeen, say, and she was refused -- if she

was determined she might go to Dundee and say, "I want to be a blood donor", and try to find out. So to make sure that that didn't happen -- because obviously having a unit of blood escaping through the net like that would not have been a very good thing at all, so we wanted to block that option, and therefore these patients, as I say, diluted with a few others, were put on this register so that they couldn't do that.

Q. So is it right to understand that the National Medical Register was brought in to guard against a risk of something happening rather than because there had, in fact, been incidences where donors, high-risk donors, had moved from one area to another?

A. To my knowledge yes, it was a precautionary step.

Q. If a donor refused to do a hepatitis C test or, indeed, a HIV test, would the transfusion centre refuse to accept a donation and any further donations from that donor?

A. If somebody was found positive for a test, absolutely.

Q. No, if somebody wouldn't consent to the testing of their blood for viral infections, what would happen?

A. We just wouldn't take the blood at all. That was a complete no-no.

Q. And they would be deferred indefinitely, would they?

A. Permanently, yes.

And, I mean, obviously there would be a question with the nurse or the doctor and say, you know, "Why are you not consenting to this? Is there a reason?" But if the donor refused or didn't consent, then there is no way we would take a blood sample anywhere, no. Ever.

Q. Given that having unprotected sex is a risk for viral infection, was any consideration given -- in any of the many meetings and so on that you attended to consider material for exclusion of donors -- to including in the high-risk categories any donor who had unprotected sex?

A. We discussed a number of issues around that. One was, for example, even in the -- in some of the high-risk categories, we said, "Even if you have had sex male-to-male once, even with a condom", for example -- because we feared that, you know, the type of sex that they might have, the condom might burst and so on and so forth, so we were very careful to -- even though you -- some people do use safe sex and so on and so forth, we were very careful and fearful of risky activity.

So if the activity was considered risky, then it didn't matter whether you used any protection or not. At the time we felt you cannot give blood.

Q. I should have been clearer, I don't mean male-with-male sex, I mean heterosexual, male/female sex?

A. I think male/female sex, as far as I know, I'm not an epidemiologist, but the risk there was very much if you had sex with an intravenous drug user or if you had sex with somebody from sub-Saharan Africa where the background prevalence was high. Then, yes, whether it was unprotected or not, we wouldn't take you.

Q. So is it right then to understand that there wasn't consideration given to including in the high-risk donor list heterosexuals who had unprotected sex?

A. No, except in the fact that we -- at one point we discussed promiscuous activity because I know that some countries have it as an exclusion criteria, you know, if somebody has X number of contacts in a year or something. But I remember the discussion said something like how -- you know, whatever is called promiscuous is a very personal thing. Some people think X number is all right and other people don't.

So we felt that is going to be very, very difficult for a nurse or a doctor to exclude or make a judgment on and, therefore, heterosexual sex in the context of high-risk activity was restricted to those

activities listed in the leaflet.

Q. Can we look back at a document we looked at earlier, MACK00001160. This is the letter that we looked at earlier from you to Professor Cash, dated 16 November, where you carry out the analysis of the differences between the English and the Scottish AIDS leaflet.

I have been asked to ask you a question that arises out of what's said on page 3., and it is the last paragraph. I think it is probably -- we can probably just pick it up. You are talking about the difference in the guidelines and we can probably just pick it up towards the end of that paragraph:

"Although the risk from FFP and Cryo is obviously much less in terms of donor exposure, FFP and Cryo are untreated in contrast to Factor VIII concentrates. Although epidemiologically the risks of exposure to FFP and Cryo are less than Factor VIII, I think that from a medico-legal point of view one should not accept such a risk, knowing that it exists."

I have been asked to ask you what you were referring to there when you referred to medico-legal risks -- or risks in a medico-legal context. What did you understand the risks were in that context -- and in what legal context?

A. From memory, I think the discussion was around whether we should include haemophiliacs in the list, were they high risk or not? And there was a discussion around the fact that you know by the time these leaflets were out, many of the haemophiliacs would have been given heat-treated products and therefore they were considered safer, much safer, than the ones before and, therefore, we stuck on, as far as I know, saying that we should only exclude sexual partners of haemophiliacs, rather than including the haemophiliacs as well.

And I know at one point -- I'm not sure whether there was a disparity for a long time between the English and the SNBTS version but I know that in some versions haemophiliacs were included and then in others they were excluded because of what I have just said.

So in some instances we just had the sexual partners, in others there were also the haemophiliacs included as well, purely because the risk of a haemophiliac, of getting HIV after he was exposed to heat-treated products and other virally inactivated products, was very, very small.

All right, you have some haemophiliacs who would have been exposed to FFP, which is very small donor

exposure compared to a pool product, but a pool product is inactivated, whilst the FFP or cryo is non-inactivated. So the risk -- it is a balance of risk isn't it -- between lower donor exposure but non-treated, compared to a much higher donor exposure but treated.

Q. We looked, at the beginning of your evidence, at the make up of the Medical and Scientific Committee, and we had a discussion about who was and wasn't part of that committee. And you may remember that there was on there the director of NSL.

Can you recall what part the director of NSL played in the Medical and Scientific Committee?

A. He was an equal member of the MSC. National Science Laboratory was a laboratory that did research for SNBTS, and it was considered an equal partner in MSC. What kind of research they could conduct on which reagents, for example, or on blood groups, on genomics, whatever the direction that he was given by MSC. So although he wasn't directing a regional centre or anything, but he played a very important part and he was an equal partner.

Q. Lastly, you mentioned in your statement that you -- well, you say in your statement that you were not a transfusion infection expert, and I have been asked

A. I looked outside the centre in the context of -- for example, I looked -- it is called the NMRU, the National Microbiology Reference Unit of the SNBTS. There was Dr Brian Dow, before him there was Eddie Follett, these were the people I used to go to if I had a query about a test result and they would help me out and explain to me what the issues were so within SNBTS there was expertise but not within the RTCs.

Then on a UK-wide basis then obviously there were some very, very well-renowned experts who I could go to if I wanted to for advice, as well.

MS SCOTT: Sir, may I turn behind me to see if Mr Ross has any questions. No, he has confirmed that he doesn't have any questions, so I have no more questions to ask.

SIR BRIAN LANGSTAFF: I have no questions.

MS SCOTT: Dr Galea, is there anything you would like to add to your evidence?

A. No, I just hope that I've been helpful in the evidence I have given. It is not an easy task to remember things that happened 35 years ago or thereabouts but I hope, in a small way, I contributed and I hope that the outcome of the Inquiry is fair and equitable and as you want it to be.

to ask you what would qualify a doctor to hold such an expertise? Is there such an expertise?

A. Well, if you look at the composition of SACTTI, for example, which is the SAC on transfusion-transmitted infections, at least in my time there was a mixture of virologists, epidemiologists, so they understood a lot about prevalence data and incidence data.

Some people understood very well how kits -- how the various test kits worked, what was the meaning of a repeat reactive and how to avoid it and so on, how do you -- which tests you would use for confirmatory assays, compared to screening assays, which tests were appropriate for blood donor screening purposes compared to diagnostic purposes, because obviously they are very different, they have to be extremely sensitive. And also being able to have very high throughput numbers.

So that kind of expertise, which clearly I don't have, there were people within the UK Blood Services that had it. And, you know, if you look at the composition of SACTTI, you will get two, three, four people there who obviously had those credentials.

Q. Was there anybody in the blood transfusion centres that you worked in that held that expertise or did you need to look outside the centres for that expertise?

So that is all I have to add.

SIR BRIAN LANGSTAFF: Well, it -- I would like to thank you for the way in which you have given us such a wealth of information, in particular about ways and means of ensuring that, as you put it earlier, that the safest blood is the blood that's not given. It may be a well-used phrase by you but it may well be used by us again. I wait to see. But you have certainly given us information about that and a lot about the care and selection of donors.

You might just like to know that in the short break before this part of the hearing, one of the Core Participants who had been listening to you give evidence mentioned to me in passing "What a great witness", he said. There you are. And what a wealth of information you have given him.

So, you can understand why I'm thanking you.

A. Nice to know. Thank you very much.

MS SCOTT: Sir, tomorrow we have Dr Williamson giving evidence.

SIR BRIAN LANGSTAFF: Yes, 10 o'clock tomorrow.

(3.50 pm)

(The hearing was adjourned until 10.00 am on Wednesday, 8 December 2021)

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