Tuesday, 9 November 2021

(10.00 am)

SIR BRIAN LANGSTAFF: Yes, Ms Scott.

MS SCOTT: Today is the start of the blood services hearings and this morning I'm going to be giving a presentation about the structure and history of the blood services in England, Wales, Northern Ireland and Scotland and then this afternoon we're going to hear from Ms Fraser Butlin who is going to give a presentation on early look-back.

We will be having presentations for the remainder of this week. Ms Richards will be starting a presentation on Professor Cash tomorrow and we will finish the week with a presentation on Dr Gunson, and next week we will have some oral witnesses.

Presentation by Counsel to the Inquiry on the Structure and History of the Blood Services

MS SCOTT: I'm going to start this presentation looking at the case, looking at the history and structure of the English blood services but much of what I say in this part of the talk applies also to Wales and that will become clear, I hope, as I go through this part of the presentation. Then I will give a separate part of the presentation on specifically Welsh parts, the Welsh history and structure.

So the early days of blood transfusion, I'm going to start in 1921 with a gentleman called Percy Lane Oliver who established a civilian voluntary blood donation panel and by 1926 the Red Cross Society had become fully responsible for that service.

The panel arranged blood donors to a number of London hospitals to meet emergencies requiring blood transfusion and all the donations on that panel were voluntary and unpaid. There were other panels operating outside London on a similar basis but the information that the Inquiry has seen relates that there was more information in relation to the London panel and so, primarily, that's what I'm going to speak about.

Transfusions at this stage were person to person so, in other words, the donor was called up by the panel, having been notified by the clinician in hospital that they required blood, and they went off to the hospital and stood by the patient and the blood went from one to the other.

So this -- as a result of some bad experiences that some of the donors had, Mr Oliver drew up some regulations to protect the donor and these regulations address both the physical process of blood donation -- so, for example, to safeguard the donor to make sure

that there was proper procedures for taking of the blood, the equipment was clean, and so on -- and for the psychological effects of giving blood to a sick person in hospital. So, for example, the regulations suggested or stated that the donor shouldn't be taken to a ward full of sick patients in order to give blood.

Moving on, then, to the outset of the Second World War, Dr Janet Vaughan, who was a haematologist at the Hammersmith Hospital in London, drawing on experiences in the Spanish Civil War, advanced a plan to supply blood for transfusion to civilians in London. This involved the creation of blood depots and in 1939 the Ministry of Health approved the establishment of four blood depots to treat London civilians. These blood depots were managed by the Medical Research Council on behalf of the Ministry of Health. So this is the first involvement of Government in blood services.

It's also the beginning of blood banking on a large scale, which was possible because of the use of sodium citrate solution, which is an anticoagulant that allowed blood to be stored outside the body without clotting.

In 1940, in response to a lack of provision

outside London, regional blood depots were established throughout the country and they were established close to large district hospitals in major cities. These depots were set up in Newcastle, Leeds, Nottingham, Cambridge, Birmingham, Oxford, Manchester, Liverpool, Cardiff and, later, Belfast. So initially there were nine and then with Belfast there were ten.

These depots, along with some others, and we'll come on to in due course later, became known as Regional Transfusion Centres. These Regional Transfusion Centres outside London were managed by the emergency medical service, as opposed to the Medical Research Council who was managing the depots in London.

In 1943, it was agreed between the managers of the London depots, the Ministry of Health and the Medical Research Council that the blood supply had reached such a scale that national management was required and in 1946, September 1946, the National Blood Transfusion Service for England and Wales was created by the Ministry of Health.

That encompassed the London depots, the four depots were reduced to two. The Regional Transfusion Centres, by now there were 12 of those and they were joined in 1955 by Brentwood and in 1969 by Wessex,

which was based in Southampton, making 14, and that's the number we usually see referred to in documentation.

The Regional Transfusion Centres, sometimes referred to as RTCs, were managed and run by Regional Transfusion Officers who then became known as Regional Transfusion Directors. They were medically qualified. These Regional Transfusion Directors -- I'm going to refer to them as that throughout this presentation -- the Regional Transfusion Directors met regularly with the Ministry of Health who was responsible for managing the service.

The meetings were chaired by Dr William Maycock who later became Sir William Maycock, who had been appointed as Consultant Adviser on Blood Transfusion to the Chief Medical Officer of the Ministry of Health.

The purpose of the Regional Transfusion Director meetings was to advise the Consultant Adviser, Dr Maycock, so that he in turn could advise the Ministry of Health.

The next event is the creation of the National Health Service in 1948 and that led to the formation of 12 regional hospital boards in England and Wales and they became responsible for administering

hospitals and specialist services in their areas, and the management of Regional Transfusion Centres was transferred from the Ministry of Health to the Regional Health Boards. So there is a period between 1946 and 1948 where there is management by Central Government of the Blood Transfusion Service in England and Wales but by 1948 that has been devolved out to the regions to the regional hospital boards.

By 1953 the UK had more than 500,000 donors on its national panel and, in addition to this, it's important to remember that many hospitals had their own donor panels, and that remains the case during the 1970s and 1980s in the period that the Inquiry is primarily concerned with. That will be something that -- an issue that will come up in the hearings that are in the next weeks and months.

SIR BRIAN LANGSTAFF: Can you help, was there a national panel as such and, if so, how did that fit with the system whereby the Regional Health Boards administered specialist services in each of the regions separately?

MS SCOTT: My understanding is that there was no national panel, as such.

SIR BRIAN LANGSTAFF: There was no national panel.

MS SCOTT: So each of the Regional Transfusion Centres had their own panels.

SIR BRIAN LANGSTAFF: So when you said a moment or two ago that there were 500,000 people on the national panel what you meant was if you added together all the regions --

MS SCOTT: Indeed.

SIR BRIAN LANGSTAFF: -- and the nation we are talking about is England --

MS SCOTT: England and Wales.

SIR BRIAN LANGSTAFF: -- and Wales, so two nations?

MS SCOTT: Yes.

Regional Transfusion Centres were responsible for a range of services, including and most obviously, the collection of blood from voluntary donors, the processing of that blood and the testing of blood donations, the supply of blood to hospitals within their area and, on some occasions, they also supplied blood to other hospitals and bodies outside their area, and the supply of some blood products to hospitals in their area (so, for example, cryoprecipitate).

SIR BRIAN LANGSTAFF: Cryoprecipitate you would define, for purposes of this presentation, as a blood product?

MS SCOTT: Yes.

SIR BRIAN LANGSTAFF: Even though, in a sense, it is just part of blood, nothing has been done to it except

getting rid of what else isn't cryoprecipitate?

MS SCOTT: Yes. I do define it as a blood product in this presentation, sir, yes.

SIR BRIAN LANGSTAFF: So when we talk about blood, we're not talking about cryoprecipitate, we're talking about red blood or --

MS SCOTT: Exactly.

SIR BRIAN LANGSTAFF: Where does plasma fit?

MS SCOTT: Yes, and red cell concentrate. There is a continuum between what sometimes is referred to as whole blood and getting on for blood products but I was differentiating -- in the early days the Regional Transfusion Centres were really only providing, pretty much, whole blood and then, as we go through the history, the product, if you like, from the Regional Transfusion Centre changes.

There are procedures that are carried out to the whole blood to turn them into what I am referring to as products, although, as you say, it is simply removing plasma, for example, to concentrate red cells or making cryoprecipitate or products of that nature.

SIR BRIAN LANGSTAFF: Thank you.

MS SCOTT: The Regional Transfusion Director -- I think I have already mentioned this -- was medically qualified and, importantly, was appointed by and

accountable to the Regional Health Board. Each Regional Transfusion Centre was autonomous and this led to a divergence in practice between them, and that's a theme that we will develop as we go through the presentation.

In 1949, Dr Maycock was appointed the Superintendent of the Lister Institute Laboratories at BPL and, in 1954, BPL was established at Elstree, although its history goes back to 1943. Plasma supplied by the Regional Transfusion Centres was fractionated at BPL to produce blood products as the Regional Transfusion Centres did not have their own fractionation facilities. So they were able to make some blood products or some products, like cryoprecipitate, red cell concentrates, but they weren't able to fractionate blood into blood products such as Factor VIII, Factor IX, and so on, and so they provided plasma to BPL.

I'm going to move on now then to 1970, where there were efforts to restructure the NHS generally and, of course, the Blood Transfusion Service was affected by those proposed changes. Can we go, Soumik, please to NHBT0017065. This is a minute of a special meeting held on 16 April 1970 at the Regional Transfusion Centre in Cambridge of Regional

Transfusion Directors, to discuss the Green Paper on the future structure of the National Health Service.

We can see the attendees. We have Dr Maycock, who is the chair. We've got attendees from the Department of Health and Social Security, we've got all of the Regional Transfusion Directors and we've got an attendee from the Blood Group Reference Laboratory.

We can see on that first page:

"Green Paper on the Future Structure of the National Health Service.

"The Chairman recalled that, following an informal discussion of the Green Paper with a few Directors, he had written to all directors on 6 March, setting out what seemed to be the alternative ways of administering and organising NBTS and that at RTD meeting [Regional Transfusion Directors meeting] 11 March it had been decided to hold a special meeting to discuss the Green Paper."

If we could turn over the page to the bottom of the second page, what the Regional Transfusion Directors then do is set out the potential organisational -- the potential options for organisational change for the Blood Transfusion Service. They consider regional health councils and

they then consider area health boards and central administrations.

I'm just going to read from those two parts of the minute:

"Area health boards.

"Likewise the meeting agreed unanimously that administration of a regional transfusion centre by an Area Health Board was unlikely to be satisfactory. There would inevitably be difficulties, particularly financial difficulties, if a regional centre were administered by an Area Health Board because the latter was designed to provide services to its own area and not to a group of Area Health Boards. The Area Health Board concerned would have to adopt a regional outlook, with regard to the regional transfusion centre and it was to be expected that, while some Boards would succeed in doing this, others would not. The position of a transfusion director in such an administrative scheme would be difficult."

SIR BRIAN LANGSTAFF: Implicit in this is that the term "area" is describing a smaller area of land than a region.

MS SCOTT: Yes, I think that must be right.

SIR BRIAN LANGSTAFF: Otherwise this wouldn't make sense.

MS SCOTT: Yes.

SIR BRIAN LANGSTAFF: So area health boards, and there might be a number in a region and, indeed, their boundaries might not be exactly with -- coincident with what had been the region.

MS SCOTT: Indeed.

SIR BRIAN LANGSTAFF: So you'd end up with a system of Regional Transfusion Centres to serve a region getting its money from a number of different area health boards within the region.

MS SCOTT: Yes.

SIR BRIAN LANGSTAFF: Yes, I see.

MS SCOTT: Then they go on to discuss central administration:

"The meeting agreed unanimously that the opportunity presented by the proposed reorganisation of NHS could be seized to reintroduce a National Blood Transfusion Service in the true sense of that name and unanimously proposed that the Regional Transfusion Centres should be centrally administered and financed. Since the administration of the service had been decentralised in 1948, it had become clear that development of the regional centres had been uneven and that many difficulties had arisen from the fact that administration and financing of the service were the responsibility of 13 different

authorities.

"A centrally administered and financed service could be planned nationally" --

SIR BRIAN LANGSTAFF: So at this stage there were just the 13.

MS SCOTT: 13, yes.

SIR BRIAN LANGSTAFF: Wessex came later, did it?

MS SCOTT: I think that's right, yes:

"A centrally administered and financed service could be planned nationally in an effective manner and run more efficiently than a service with decentralised administration and financing. For example it would be simpler to provide for the performance of certain functions which need to be done in only one or a few centres ..."

And then a number of different examples are given of those functions.

The meeting then goes on to discuss what the centralised service might look like. If we could just go down the page then to 5, "Advisory committees", there's another unanimous agreement at the meeting that:

"... whatever the form of administration finally adopted, the Regional Transfusion Directors' Meeting should be retained. It was suggested that

consideration should be given to making this a statutory committee."

You can take that down, Soumik.

So that was the unanimous agreement of the Regional Transfusion Directors and, it seems, from the minute of that meeting, the other attendees, so from the Department of Health and Social Security, that there should be central administration of blood services.

SIR BRIAN LANGSTAFF: Just looking at that last recommendation for a moment, the supposition is that although the Blood Transfusion Service had been organised on a regional basis -- sorry, could we have it back up, Soumik?

MS SCOTT: It's page 5 if you go down.

SIR BRIAN LANGSTAFF: If you are going to retain the regional transfusion directors' meeting, if it makes any sense, there still has to be a job for Regional Transfusion Directors to do, which means the regions must still exist as such so far as the Blood Service is concerned.

MS SCOTT: Yes.

SIR BRIAN LANGSTAFF: So although the rest of the Health Service was moving away from regions into areas, perhaps smaller groups, smaller areas, smaller

volume -- whatever the right word is -- smaller, the regions remain for the purposes of blood transfusion.

MS SCOTT: Yes, and equally, looking at it from the other way, if it's to go to a centralised administration, so to be centrally administered and financed, the proposal then is, even in those circumstances, the Regional Transfusion Director meetings would still remain. They must have been thinking, well, even with a centrally financed and administered service, you would still need transfusion centres in the region responding to local demand and so you would require meetings of the Regional Transfusion Directors.

SIR BRIAN LANGSTAFF: Yes. So either it was going to stay as it was or it's going to go big.

MS SCOTT: Yes.

The Department of Health and Social Services rejected -- sorry, Social Security rejected the proposals of the Regional Transfusion Directors, and we can see that at NHBT0016117.

This is another Regional Transfusion Directors meeting on 25 October 1972, so two and a half years later, and we can see again similar attendees: Dr Maycock in the chair, Regional Transfusion Directors, we've got an attendee from the Scottish Home and Health Department and from the

Scottish National Blood Transfusion Association, we've got an attendee from the Northern Ireland Blood Transfusion Service, and we've got attendees from the Department of Health and Social Security.

If we can turn to page 4, please, of that minute we can see, under paragraph 3:

"The NBTS in the revised National Health Service

"The Chairman referred to the report, Organisation of National Blood Transfusion Service, prepared by a Working Group and approved unanimously by the RTD meeting, which had been given to the [Chief Medical Officer] on 1 September 1971. Subsequently two meetings had been held in the Department [that's the Department of Health and Social Security]. Mr Gidden [from the Department of Health and Social Security, we can see from the attendee list] had come to inform the meeting of the present position.

"Mr Gidden said that as Directors knew, the Government's White Paper on NHS reorganisation left the responsibility for the provision of a blood transfusion service with the Regional Health Authority."

So, just pausing there, we've moved from Regional Hospital Boards to Regional Health Authorities.

"In general it had been decided that the functions of the RHAs, although extended to include present local health authority functions, should remain the same as those of Regional Hospital Boards now. Nevertheless, the Department recognised that the BTS [Blood Transfusion Service], although a vital component of the hospital service, was unlike any other component, and that a degree of central co-ordination in its operation was highly desirable if not essential. This existed in an important measure already through the meetings of the RTDs, which, however, had an informal and not a formal basis.

"In the reorganisation of the Health Service it was envisaged that a much more thorough going planning procedure would be adopted, which would allow the Department to monitor the plans of health authorities on a continuing basis. This should help to ensure that important requirements of the BTS were not neglected. This was a deliberately new feature of the administrative arrangements, and the staff of the Department is to be very substantially increased to deal with individual regions."

So that's the case put forward by the Department of Health and Social Security as to why there isn't a centralised service.

If we go over to the next page, we can see the reaction to that from the Regional Transfusion Directors:

"The meeting expressed the greatest disappointment at the Department's rejection of its proposals for a centrally controlled service and criticised the delay of more than a year between the presentation of the proposals and this meeting. In the discussion the following points were raised:

"a. Regional Transfusion Directors (i) Would this become a statutory advisory committee? Mr Gidden said that it would not; the only statutory committees were those of the Central Health Services Council; it would not be possible to form such a committee which could replace the RTD meeting."

So that's no to the other unanimous agreement from that minute we looked at in 1970.

"(ii) The RTD meeting was the only body that could give informed professional and technical advice to the Secretary of State about the running of NBTS. Did the Department propose to take measures to ensure that the advice given by the RTD meeting and accepted by the Department was applied uniformly and effectively in the regions? Hitherto advice, although apparently accepted by the Department might be

disregarded regionally. Was the Department in future likely to try to ensure that all RHAs carried out centrally accepted advice?"

Sir, pausing there that's a theme that we see repeated again and again over the years that arises with this regional structure:

"Mr Gidden pointed out that the Department alone could decide what weight should be given to advice tendered by the RTD meeting."

Sir, you may wonder whether that is an answer to the rather tricky question posed there by the Regional Transfusion Directors.

"b. Implementation of policy by RHAs. Mr Gidden explained that the proposed planning cycle described in 'Management Arrangements for the Reorganised NHS' would enable the Department to exercise much closer scrutiny of the work of RHAs. For example, it was unlikely that failure by an RHA to provide for capital developments in an RTC would go unnoticed."

Again, sir, it's not clear precisely what that means but that is something that we will be considering as we go through the hearings.

SIR BRIAN LANGSTAFF: On the face of it there may be a difference between the idea that the regions have control of their regions and the idea that

the Government has control of the regions.

MS SCOTT: Yes.

SIR BRIAN LANGSTAFF: It's difficult to see how both can co-exist easily.

MS SCOTT: Indeed.

Soumik, you can take that down.

So the plan as of 1974 is the management of Regional Transfusion Centres moves from Regional Hospital Boards to Regional Health Authorities but with greater departmental scrutiny, as set out in that document.

It was recognised that the NBTS required some form of central co-ordination, as we have seen in the minute of that meeting, and so the Central Committee for the National Blood Transfusion Service was formed in 1975 to co-ordinate the work of the Regional Transfusion Centres. It was charged with keeping under review the operation of the National Blood Transfusion Service, including BPL and the Blood Group Reference Laboratory in England and Wales and advising the Government on the development of the Service.

SIR BRIAN LANGSTAFF: Where exactly did that leave the meetings of the Regional Transfusion Directors because that's, what you told me earlier, was what they were doing?

MS SCOTT: So those continued and one of the criticisms of the central committee was that there was no formal liaison or relationship between the meetings of the Regional Transfusion Directors and the central committee and, ultimately, the central committee was abandoned and was replaced by a different kind of committee.

SIR BRIAN LANGSTAFF: Yes.

MS SCOTT: So it might be helpful to look at the first meeting minute of the central committee. We can see that at MRCO0000060_023. We can see that that's the minutes of the meeting held on 19 June 1975, and the members of the committee included two Regional Transfusion Directors, the Consultant Adviser to the Chief Medical Officer, Dr Maycock, representatives nominated by the Royal Colleges, and other members in various specialties of medicine, the Department of Health and Social Security, and it was chaired by Dr Beddard who was a Deputy Chief Medical Officer.

You can take that down. In fact -- hang on, sorry, can we turn to page 2 of that document. Yes, if you just enlarge that so we can actually see it. If we go four lines down:

"Referring to paragraph 14 of the Report, [it] stressed that the Committee should concern itself with

aspects of the NBTS which had national rather than regional significance and not with details which were purely of local interest.

"Turning to paragraph 21 of the Report the Chairman said that central financing could be contemplated in only very exceptional circumstances since to do otherwise would be to detract from the prerogative of Regional Health Authorities to determine, within the financial allocations made to them by the Department, their own priorities according to regional needs."

Then missing out the next paragraph -- next sentence:

"Development of the NBTS would be largely dependent on efficient operation by redeployment of, rather than addition to, resources; what was chiefly wanted from the Committee were recommendations, advice and ideas to this end."

Then the next paragraph:

"Professor Scott said that the Regions suffered from [I can't read that word] to finance developments in the policy formulation of which they had no say; he agreed that the committee would have to be circumspect in any advice it offered" --

SIR BRIAN LANGSTAFF: I think it's "having", "having to

finance developments in the policy formation of which they had had no say ..."

MS SCOTT: Yes:

"... he agreed that the Committee would have to be circumspect in any advice it offered to the Department which had financial implications. In answer to Professor Stewart the Chairman said that the Department would, of course, consider carefully any advice tended by the Committee; if the advice was accepted it would be conveyed to RHAs in the same way as guidance was given on other aspects of the NHS. Mr Brooking said that Regions would welcome this."

So you can all already see the difficulties. You have got a central committee, which is considering issues of national importance not regional ones but with no budget, that is advising a Regional Transfusion Centre funded regionally.

We can see by 1974 concerns being raised about the structure of the blood service from outside organisations and, in particular, raising concerns about the impact on the drive for self-sufficiency. We can look at an example of that. So DHSC0100024_126.

This is an editorial in the BMJ. We can see at the bottom of that page it is 27 July 1974. If we go

to the second -- it's called "Blood Donors and the transfusion service", and if we go over to the second column of that, there is, in the top paragraph, about halfway down that paragraph, in the middle, it starts "Finally":

"Finally, there is no evidence to" --

The editorial has been discussing the fact that self-sufficiency has not been met and says:

"Finally, there is no evidence to support the conclusion that the failure of the Blood Transfusion Service to meet the increasing demands rests at the feet of the voluntary blood donor. Indeed the evidence suggests that there is no shortage of voluntary donors in Britain prepared to come forward and contribute to local and national needs. The problem rests on the quality of management (or lack of it) which has led to a steady decline in the British Blood Transfusion Service since the late 1950s. There has been no effective national planning; the regional and protein fractionation centres now lack sufficient staff, accommodation, equipment and the basic organisational units to do the job. Moreover, the medical staff in the centres are often geographically and administratively isolated from the care of patients. The remedy, then, is not for a topping-up

exercise with donors offered theatre tickets or nylon stockings but for an urgent appraisal (for the first time) of a national policy for the procurement and eventual distribution of a natural resource which, unlike oil, will be still readily available in 100 years' time."

Can we also look at PRSE0000598, which is also the British Medical Journal, and we can see if we turn over to page 3 of that that this article, "The blood transfusion service and the National Health", is written/authored by John Cash, National Medical Director of the SNBTS. If we go back to the first page, he says, in the second paragraph down:

"The sustained failure of the transfusion services in England and Wales, known as the National Blood Transfusion Service, over the past two decades to meet the needs of the National Health Service extends far beyond the provision of factor VIII concentrates. In London and the home counties there are chronic and occasionally serious shortages of blood, which have an appreciable impact on both the NHS and a large uncontrolled private sector."

If we go to the bottom of that column:

"Many general managers of regional health authorities must view their regional blood transfusion

centres with some concern. These centres continue to produce the therapeutic products against no nationally agreed specifications, yet are within nine months of new legislation on product liability. They are aware of severe shortages in adjacent regions but have no mechanism to give or receive help."

Then if we go down that column to what went wrong and, halfway down that paragraph there -- sorry, "What went wrong?" Yes, so halfway down the paragraph, we start:

"The National Blood Transfusion Service is a fragmented and disorganised shambles. Thus it has been possible, and on many occasions, for severe shortages of blood to arise in one part of the country while less than 10 miles away (in another region) the regional health authority is dismantling part of its blood collection programme because of sustained excesses."

Then going down to the last whole sentence in that paragraph:

"Somehow the concept of the 'gift relationship' of the voluntary donor and the needs of the patient have been lost by a service which in truth is a series of tight compartments with little or no facility to work together. This system of management is wholly

inappropriate for modern blood transfusion practice; it is both wasteful and dangerous."

Then if we go over to the right-hand column to the bottom of that section called "A foundation for change", we see a third of the way through that last paragraph:

"The only option that will provide the quality of service the health services in England and Wales need, and the one that will give the blood donors an assurance that their gifts are appropriately used, is the creation of an integrated National Blood Transfusion Service, which is removed from direct regional health authority funding and managed by a new and separate health authority which includes the Blood Products Laboratory."

So that's the rather strongly expressed view of Professor Cash about the English service.

SIR BRIAN LANGSTAFF: Now, he was expressing that from a Scottish perspective.

MS SCOTT: Indeed.

SIR BRIAN LANGSTAFF: When he talks about "the creation of an integrated National Blood Transfusion Service" is he talking about a service for England and Wales or England, Wales, Scotland and Northern Ireland.

MS SCOTT: My understanding is that it's for England and

Wales, rather than for a truly national service and if we turn to the very end of that article it may give us some insight into that:

"Many good friends and colleagues in England and Wales may take exception to criticisms of the [NBTS] by the national medical director of its wee sister in Scotland. Undoubtedly my critique is partly based on 'self' interest: the continued decline of the [NBTS] is now having a destabilising effect on the Scottish service. Nevertheless, the overriding reason for this cri de coeur is my belief that unless the vital importance of the blood transfusion services to the well being of the health services in the UK is better understood, and the decline in performance arrested, then within the next decade the consequences will be grave."

I am not sure that does give us any more insight but he is referring throughout to the National Blood Transfusion Service and has made it clear that that is the England and Wales service. So I had read it as referring to the England and Wales service, rather than a cry for a fully-integrated UK service.

SIR BRIAN LANGSTAFF: Yes. Well, he appears to be saying that the Scottish service is doing rather better than he sees the NBTS is doing.

MS SCOTT: Yes. In May 1977, the NBTS, together with the director of BPL, submitted the National Blood Transfusion Service -- submitted a document, which we should, I think, look at. It's CBLA0000612. If we go over to the second page, we can see it's a document called:

"The National Blood Transfusion Service

"Its present Status and Proposals for Reorganisation

"A submission prepared for consideration by the Royal Commission on the National Health Service."

SIR BRIAN LANGSTAFF: So this is ten years before the article you have just shown me?

MS SCOTT: Indeed.

If we go back to the first page we can see in the letter from Dr Gunson to the Royal Commission enclosing the document it's said that:

"This document represents the consensus of opinion of the Directors of Regional Transfusion Centres in England and Wales and the Director and Director designate of the Blood Products Laboratory, Elstree."

That's the basis upon which the document's been authored. Then if we go over the page to page 3, we can see the summary of the report. I'm going to pick

it up at (c):

"During recent years, the Transfusion Service has assumed an increasing national role, which has served from constraints arising from regional development *[sic]*, inadequate central co-ordination and financing and a poor integration of the activities of the Regional Transfusion Centres."

Then at (d):

"Proposals are put forward for improving the national commitment of the Transfusion Service by allocation of central finance and management through the a statutorily constituted executive committee and the appointment of a National Medical Co-ordinator. Proposals are made ... for the retention of flexibility of Regional Transfusion Centre functions within Regions."

Then (e):

"It is essential that the Regional Transfusion Centres are provided with adequate resources ... accommodation", et cetera.

Then if we go over the page to page 10, they set out there the different functions that the Regional Transfusion Centres perform and we can see it has been split into national functions and regional functions. National functions are said to be:

"Blood Products -- Factor VIII and ... IX concentrates, dried plasma, plasma protein fraction, normal and specific immunoglobulins."

Then:

"Reagents for use in blood group serology and for quality control."

Then regional functions are the:

"Supply of whole blood an concentrated red cells.

"Supply of blood components ... platelets and leucocytes. The short life of such components, ie less than 72 hours, limits their supply to within a Region", and tissue-typing and specialist regional services.

Then it goes on to say:

"The present organisation which exists in the Transfusion Service limits the development of the national aspects of the service."

At the bottom of that paragraph:

"The Central Committee is only advisory to the DHSS and, on national or any other aspects of the Transfusion Service, the DHSS is not in a position to instruct regions on the allocation of finance to RTCs. Finally, the RHAs are not involved in national policy-making for the NBTS, although ..."

SIR BRIAN LANGSTAFF: "... these policies ..."

MS SCOTT: Thank you.

"... these policies may commit RHAs to the allocation of extra funds from the regional budgets to finance development at RTCs."

So pointing out there that the structural problems arising -- the problems arising from the structure.

The next event that happens is that Dr Geoffrey Tovey succeeds Dr Maycock as the Consultant Adviser in Blood Transfusion to the Chief Medical Officer. That happens in 1978, and Dr Tovey establishes three divisions of the Regional Transfusion Centres, the Eastern Division, the Western division and the Northern Division, and they have area -- divisional meetings, so groupings of Regional Transfusion Centres getting together to create supra regions and discussing issues that apply to their regions, and they were tasked -- those regional meetings were tasked by Dr Tovey with discussing National Blood Transfusion Service policy ahead of Regional Transfusion Director meetings were encouraged to advance policy proposals.

So we now have -- the Regional Transfusion Directors are meeting in two different forums: all

together in Regional Transfusion Director meetings and then in these divisional meetings.

We understand that by March 1979 the Department of Health and Social Security had not been convinced by the proposal we have just looked at to centralise the Blood Transfusion Service and so Dr Tovey drafted a report in February 1980 entitled "Proposed Plan for Reorganisation of the NBTS", which I don't think we need to go to, but for those who want to look at it it's DHSC0002197_089. In that report, he stated that there was a general appreciation within the service that the major defects within the service were unlikely to be overcome in the absence of a national managed authority with statutory powers, but he noted that such a policy was not going to be implemented immediately, and so he made a number of interim suggestions to try to improve the co-ordination amongst Regional Transfusion Centres and for closer links with the Scottish National Blood Transfusion Service.

One of the suggestions he made was the introduction of a central co-ordinating committee for the National Blood Transfusion Service, due to the perceived failure of the central committee to carry out that co-ordinating role. That was adopted by the

Department of Health and Social Security in 1980 by replacing the central committee with a new advisory committee on the National Blood Transfusion Service. That committee was chaired by the Department of Health and Social Security and it was made up of: a Regional Health Authority representative -- so understanding where the finances for the Regional Transfusion Centres come from, there is now Regional Health Authority representative on that national -- on that advisory committee -- Regional Transfusion Directors representatives; a director of BPL; the Consultant Adviser to the DHSS, at that time Dr Tovey; and observers from the Department of Health and Social Security; from the Scottish National Blood Transfusion Service, usually Dr or Professor Cash; Dr Doyle from the Welsh Office; and Dr Acton from the DHSS in Northern Ireland.

The terms of reference for that committee were to advise the DHSS and the Welsh Office on the co-ordination and work of Regional Transfusion Centres and the Central Blood Laboratories in England and Wales and to advise on the co-ordination of the Regional Transfusion Centres and Central Blood Laboratories with that of Scotland and Northern Ireland.

So, as I understand it, that's the first time there was a formal brief, if you like, for looking at co-ordinating the blood services in England and Wales with those in -- with that in Scotland, albeit it was through an English and Welsh committee.

I'm going to move now to February 1985 to a document DHSC --

SIR BRIAN LANGSTAFF: When you tell me it's to advise, it is to advise who: the Minister?

MS SCOTT: To advise, yes.

SIR BRIAN LANGSTAFF: So the power to do something about what the advice suggests is left with the minister?

MS SCOTT: Yes, the Welsh Office and the Department of Health and Social Security.

So moving on now to February 1985, DHSC0002259_037.

By now we have -- Dr Gunson is now the consultant adviser in blood transfusion to the Chief Medical Officer. He has replaced Dr Tovey.

Here we have a document being sent by Dr Fraser on behalf of Dr Gunson to the Deputy Chief Medical Officer, Dr Harris, at the DHSS:

"... requesting that the DHSS consider the options available to achieve a nationally co-ordinated transfusion service in England and Wales."

So here we have Dr Gunson making similar representations to those that had been made by others before him.

If we turn over the page, we can see the title "Regional Transfusion Directors' Committee Organisation of the Blood Transfusion Service", and the document sets out -- if we go over to page 2 -- so we have there the title, "Regional Transfusion Directors' Committee Organisation of the Blood Transfusion Service", and the document sets out the background and the functions of the regional transfusion centres.

Then if we go on to the next page, page 3, I'm going to look at paragraph 5. This part of the document they are concerned with the problems of the current structure and setting out some of the problems. I just draw your attention to the part on plasma supply:

"Plasma supply for the preparation of fractionated products has highlighted the difficulties of co-ordinating the activities of regional centres. Whilst certain RHAs have agreed to increase plasma collection in line with national targets others have only agreed in principle without specifying a time scale and may not exceed the plasma required to attain

regional self-sufficiency. One RHA has not responded to the request for additional plasma.

"There are, again, RTCs who will find it difficult, or impossible, to achieve a level of plasma connection for regional self-sufficiency whilst others have the potential to supply in excess of their regional needs."

Then over the page Dr Gunson sets out the particular advantages of a nationally co-ordinated committee, co-ordination with the work of the regional blood transfusion centres. At paragraph 7:

"7.1. A coordinated national blood collection programme making the maximum use of the donor base throughout the country.

"7.2. A more effective co-ordination of the activities of the Central Blood Laboratories with the Regional Transfusion Centres.

"7.3. Planned activities at certain RTCs for special services and plasma connection for certain products could be based on a national programme and need not be reduplicated at each RTC ...

"7.5. Rationalisation of blood collection and labile product production could lead to significant revenue savings ...

"7.6. A nationally co-ordinated Service would

avoid the anomalies which exist at present in a number of regions where a District Hospital is more appropriately served by a Regional Transfusion Centre outside its own region."

The paper finishes at paragraph 9 with a request from the Regional Transfusion Directors:

"... that the DHSS consider the options available to achieve a nationally co-ordinated Transfusion Service for England and Wales."

And requested that a working party is established in order to do just that.

In 1986 it was agreed that the Department of Health and Social Security Central Management Services would carry out an investigation into the organisation of the National Blood Transfusion Service, and they carry out -- their report is dated October 1987.

It's CBLA0002392. We can see there, "An organisational study", and at the bottom we can see it is "NHS Management Consultancy Services", and that's October 1987.

It's a lengthy piece of work which involved visiting a number of Regional Transfusion Centres and considering in detail the work undertaken by the centres and differences in practice that they came across during their investigations.

If we go to page 6, at paragraph 5 they say:

"On the question of organisation we suggest that there are 3 options available for the future of the BTS. The implementation of the recommended information system is crucial to each."

So they had identified that there was not sufficient reliable management information to allow effective management of the Regional Transfusion Centres. And so, briefly, the three options are -- and the first one is, effectively, leave the organisational structure as it is but introduce reliable management information and continuing financial constraints to allow for more co-ordinated and effective management.

The second option is that -- to tackle the question of the relationship between the Central Blood Laboratories Authority and the Blood Transfusion Centre and the problems with lack of co-ordination between regions. So the second option is said to tackle that:

"... by raising the profile of the existing Regional Transfusion Directors Committee and the Advisory Committee on the Blood Transfusion Service and by introducing a new co-ordinating committee for CBLA and the BTS. Under this option the committees

would have no executive power as this option envisages that the BTS would remain a regionally managed and funded service. However by formalising the role of the committees it is suggested that greater cognisance may be taken of their views and decisions."

So effectively sort of power up the existing committees and structures.

Then the third option they identify is the creation of a special health authority to centrally manage and fund the Blood Transfusion Service. It "could also be responsible for CBLA" if that were considered to be appropriate.

In 1988 the Department decided to adopt the second recommendation made, it's set out in this report, i.e. to continue regional executive management but with further central co-ordination. And they did this by forming the national directorate on 28 July 1988.

We can see what they say about that in the press release issued, and that is DHSC0004764_060.

"National management structure for Blood Transfusion Service.

"Edwina Currie, Parliamentary Secretary for Health, today announced that new management arrangements would be made to provide a formal

national management structure for the National Blood Transfusion Service (NBTS). Replying to a Parliamentary questions ... Mrs Currie said:

"'We have decided that new management arrangements are needed for the supra regional and national dimension of the National Blood Transfusion Service (NBTS).

"'We therefore intend that operational responsibility at the national level for the NBTS and the Central Blood Laboratories Authority (CBLA) will be exercised on behalf of the Health Ministers for England and Wales by the NHS Management Board and undertaken by its Director of Operations, in consultation in respect of Wales with the Director, NHS Wales. Day to day implementation of the national strategy will be delegated to a new National Director of the NBTS and a small supporting staff.

"'The key objective will be:

"'a) to implement a cost effective strategy for ensuring an adequate supply of blood throughout England and Wales;

"'b) to implement a cost effective strategy for the supply of plasma to the blood products laboratory of the CBLA;

"'c) to co-ordinate the activities of the NBTS

and the CBLA;

"'d) to promote the efficiency of the NBTS.'"

So this body, the national directorate, was directly funded by the Department. Dr Gunson was appointed as the national director and reported to the director of operations of the NHS management board.

Mr Roger Moore, a civil servant at the Department, was appointed the deputy director, but management of the individual Regional Transfusion Centres remained with the Regional Health Authorities, and Dr Gunson, in his statement for the hepatitis litigation, described the National Directorate as operating via persuasion rather than executive power.

Where National Directorate policy required the use of additional resources by regional transfusion centres, this created difficulties because there was no national budget to effect any those policies. Regional Transfusion Centres' budgets remained controlled by regional health authorities, and we'll explore in the coming weeks and months whether there are any exceptions to that in terms of particular policies for testing blood donations and so on.

The first meeting of the National Directorate of the National Blood Transfusion Service National

Management Committee took place on 1 December 1988. The committee was attended by the director and deputy director of the National Directorate and a number of Regional Transfusion Directors, including the heads of the three divisions that Dr Tovey created.

The terms of reference were: to consider matters of importance in relation to the work of the NBTS and to advise the national director; to bring forward to the committee matters of national importance to the work of the NBTS; to receive reports from the NBTS and the CBLA liaison committee; meetings of the head laboratory scientists, nurse, donor service managers and administrators and managers, *ad hoc* working parties and the national publicity subcommittee, so in order to receive the reports from all the various different working groups and committees; and to report to the divisions the decisions reached by the National Directorate -- so information coming both ways.

Also at that time a month later, in January 1989, the National Blood Transfusion Service and Central Blood Laboratory Authority Liaison Committee was established. That was a formal committee, a committee in which there was formal liaison between the two.

Also in January 1989, the Regional Transfusion

Director meetings came to end. So that's the full meetings of all the Regional Transfusion Directors.

The meetings of the divisional directors continued, so the three divisions continued to meet, but there was no longer the regular meetings between all of the Regional Transfusion Directors.

SIR BRIAN LANGSTAFF: Which of the divisions dealt with London?

MS SCOTT: The Eastern, I believe. Let me just check. Yes, Eastern: north London, Brentwood, South London and Cambridge.

The Western division was Oxford, Bristol, Southampton, Birmingham and Cardiff.

And Northern was Newcastle, Manchester, Sheffield and Leeds.

The minute of that last Regional Transfusion Director meeting in January 1989 records that the only formal contact now remaining between Scotland and England was between Dr Gunson and Dr Cash. The reason for that was that the Scottish directors would attend those meetings and that may have been the driver for the creation of the Liaison Committee between the two blood services which was formed in June 1990.

So, following the cessation of the Regional Transfusion Director meetings, which of course were

also attended by the Department, the remaining channels of communication between the Department of Health, as it now was, and the NBTS were direct contact between Dr Gunson and Department officials and doctors, via the Management Board Co-ordinating Committee and by the annual report submitted by the National Blood Transfusion Service.

Despite the creation of the National Directorate, there were continuing calls for centralisation of the English and Welsh Blood Transfusion Service. Dr Gunson continued to make proposals for a move towards a national service and, in 1991, Department of Health went out to consultation on the future of the Blood Transfusion Service and, in particular, on plans to combine the Central Blood Laboratory Authority and the National Blood Transfusion Service.

Ultimately, the final structure of what became the National Blood Authority was determined by the technical working group, the National Blood Authority technical working group, who met over a period of time, finally reporting in July 1992.

Can we turn to that. It's SBTS0000466_008.

We can see there the:

"Report of the technical working group on

operational aspects of the National Blood Authority."

If we turn to page 16, we can see there "Terms of reference" and "Membership".

"... Terms of reference ...

"In light of the general support for the principle of establishing an influential National Blood Authority for England ..."

Note, just England.

"... and Ministers' acceptance of that principle, the Technical Working Group is asked to reconsider the operational mechanisms for the NBA and make recommendations. In particular the Group should examine:

"- the proposed role of the NBA as the central [co-ordinator *(sic)*] for blood supplies to hospitals;

"- its proposed role in the allocation of capital to the Regional Transfusion Centres;

"- the composition required for the NBA to provide a satisfactory balance of interests between users, the RTCs and the BPL and which could take proper account of donor interests."

In framing its recommendations, the Working Group should take full account of the established policy in relation to self-sufficiency and the need for the NBA to and respond to developments within the

EC."

Then we can see the list of members of the working group, who include Dr Gunson, Dr Wagstaff, who was a Regional Transfusion Centre director, representatives from regional health authorities, and from the Welsh Office and from the Department of Health.

We can see the summary of recommendations at page 4:

"Summary of Recommendations.

"... Role of the NBA.

"The NBA should be given the authority and means to achieve the national objectives for the blood supply ..."

The second issue is something that they had gone out on consultation as to whether or not it should be a central contractor, and that was rejected.

"The NBA should operate as a strategic authority to plan and implement a national strategy for the blood services.

"The NBA should approve key aspects of the RTCs' business plans and monitor their output ...

"The NBA should control the transfer of plasma to BPL for contract fractionation at agreed quantities, quality and handling charges ..."

So you can see there, sir, that the RTC structure is to remain but with the NBA sitting above it controlling certain aspects and approving business plans.

Then if we go to page 10, at paragraph 2.5:

"Control of blood services.

"2.5. The Group concluded that the NBA should therefore be set up as the strategic authority for the blood services. It would plan and implement through the RTCs and BPL a National Strategy designed to ensure that the required volume and range of blood and blood products were obtained as economically and efficiently as possible consistent with quality, safety and efficacy.

"2.6. The NBA would co-ordinate the activities of the thirteen RTCs and of BPL in support of the National Strategy, promote good practices in relation to quality and efficiency and influence sensible development of the RTC network and of BPL in accordance with the National Strategy.

"2.7. The NBA should be given the right to approve key aspects of the business plans of the RTCs and to agree target production quantities for each, as well as to agree the level of handling charges. They would monitor out-turn and have the right to intervene

if have quantity or quality were not as agreed. There would be a managed market rather than a 'free for all' and NBA would develop a protocol, in conjunction with RTCs, to guide hospitals who wished to change the RTC from which they purchased their services."

If we go over the page, we see how the RHA, the Regional Health Authority, fits into this structure at paragraph 3.3:

"The RHAs are the line managers of the RTCs the introduction of the NBA as the strategic body, or Special Health Authority for the blood supply would limit the scope for RHAs managing their RTCs from a purely local perspective. However, the Group envisaged that the RHAs would be represented on the National Blood Authority ... and so contribute to the formulation of the National Strategy. The Regions would be brought in should disputes arise between the NBA and individual RTCs."

So a slightly complicated arrangement where the RHAs and RTCs retain a relationship but the NBA also has some say. It's clearly an attempt to deal with the problems of self-sufficiency, and so on, by giving the NBA power to control quantities and quantity and quality of, presumably, blood collection and plasma production to BPL.

Sir, I note the time. I've got probably another, sort of, five or ten minutes on England before I turn to the other blood services.

SIR BRIAN LANGSTAFF: I think we'll come to that, shall we then, at 11.45. So 11.45.

(11.16 am)

(A short break)

(11.45 am)

MS SCOTT: Sir, we have arrived at 1 April 1993 with the Department of Health establishing the National Blood Authority. It established a Special Health Authority, called the National Blood Authority. We've looked at the recommendations of the working group and the NBA's role was to monitor the operation of the Regional Transfusion Centres and to provide advice as to the co-ordination of their respective activities.

Shortly after the National Blood Authority was established, the order establishing it was significantly amended. So from 1 April 1994 -- so a year into its existence -- the NBA took over direct responsibility for the collection, screening and processing of blood and its constituents and supply of blood and blood products for the NHS. So there was a hybrid position, if you like, of a year between 1 April '93 and 1 April '94 where you had the NBA in

existence with the Regional Transfusion Centres operating through the Regional Health Authorities. That came to an end on 1 April 1994.

Probably the easiest place to understand how that looks is to look at the presentation, which is INQY0000307 at page 28. What we have done there is set out the functions of the NBA at paragraph 87. So the initial functions -- if we can go down to the bullet points, the initial functions that were contained within the 1993 -- that were exercised by the NBA in 1993 were:

"the provision of laboratories for the manufacture of blood products ...

"... for therapeutic, diagnostic and other purposes;

"research and development in plasma protein fractionation for other purposes;

"the manufacture of blood grouping re-agents and other related re-agents;

"the supply of blood products prepared or manufactured under sub-paragraph (b) [which is actually preparation of plasma fractions] for the purposes of the health service ..."

Then if we go down to the footnote, we can see that, in addition, it had paragraph (f):

"... 'the monitoring of the operation by Regional Health Authorities of the transfusion service, and the provision of the advice to the Secretary of State in connection with that service' and '(g) the provision of advice to Regional Health Authorities as to the co-ordination of their respective activities in connection with the transfusion service, with a view to securing and maintaining an adequate supply of blood and plasma for the purposes of the health service'."

SIR BRIAN LANGSTAFF: What has been set out in 87 is the 1994 position, not the 1993 position.

MS SCOTT: Indeed.

SIR BRIAN LANGSTAFF: So the footnote, no doubt, is accurate. What I think you said was "in addition".

MS SCOTT: So the position in 1993 was that those provisions in bullet points and the two provisions in the footnote were in place. The provision in 1994, the two bullet points -- sorry, the two footnotes (f) and (g) came out and, if we go back to paragraph 87 (aa) was inserted, so the bullet points remaining in '93 and '94. In '94, (aa) was added, which makes the NBA responsible directly for:

"... collection, screening and processing blood and its constituents and supplying blood plasma

[et cetera] for the purposes of the health service ..."

So that was added in in 1994.

SIR BRIAN LANGSTAFF: I see, so the black bullet points on the screen were there from the beginning --

MS SCOTT: Indeed, and remained there.

SIR BRIAN LANGSTAFF: -- and (aa) was added --

MS SCOTT: It was, and --

SIR BRIAN LANGSTAFF: -- and, in order to make way for (aa), the provision of advice and the monitoring of the operation were removed.

MS SCOTT: Indeed, and if we go over the page, also added in '94 was (h), which is:

"... the promotion, by advertisement and otherwise, of the giving of blood and its constituents for the purposes of the health service, with a view in particular to maintaining an adequate number of persons who are willing to give blood or its constituents for these purposes ..."

SIR BRIAN LANGSTAFF: So previously was it a matter for the individual regions how they advertised whether you should come and give blood?

MS SCOTT: Indeed, it was, yes.

SIR BRIAN LANGSTAFF: And it would follow what you are told about the process of donation and how it was

organised?

MS SCOTT: Yes.

SIR BRIAN LANGSTAFF: Soumik, can we go to WITN672006 -- WITN0672006.

MS SCOTT: This is a statement of Dr Gail Miflin on behalf of the NBTS. If we could go to page 92 of that statement, she sets out what she understands that 1994 order actually meant. She says this, at paragraph 272:

"On 1 April 1993, the National Blood Authority ... the predecessor to NHSBT, was established as an SHA [a Special Health Authority]. At that time the NBA was responsible for BPL and the International Blood Group Reference Laboratory."

So that's the 1993 position:

"On 1 April 1994, the NBA then became responsible for the RTCs. I understand that from that date the regional health authorities no longer managed the RTCs. The name of the RTCs was changed to blood centres (BCs)."

It goes on to say in paragraph 273:

"Referring to the documents I have been provided, it would appear that the [blood centres] and their functions became assimilated into the [National Blood Authority] as a single national service. The

centres increasingly were treated parts of the whole institution, rather than distinct institutions operating around the country."

Now, Dr Gunson was initially appointed as the first national director of the National Blood Authority when it was formed in April '93, but he retired in May '94 and was replaced by Dr Angela Robinson. In September '94, the NBA issued a document called "Proposals for the Future Blood Service", which was a consultation document, which was a synopsis of a 777-page review called the Bain Report, and that consultation proposed centralising management into a single small unit, consolidating testing facilities and putting cost-saving proposals into effect, whilst securing the future blood supply in terms of quantity and safety.

The NBA received a large number of responses to that consultation, primarily from those areas -- regions rather -- where their Regional Transfusion Centre was being considered for amalgamation with other centres.

Following that consultation, the NBA created three administrative zones in London and the South East, in the Midlands and the South West, and the Northern Zone, with an administrative centre in each.

It is administrative centre was in London and the South East was North London, Midlands and the South West was Bristol, and the Northern Zone was in Leeds. They amalgamated now the Lancaster Regional Transfusion Centre with the Manchester one, Bristol with Plymouth and Oxford with Birmingham.

The National Blood Authority was abolished on 1 October 2005 and replaced by the establishment of the NHS Blood and Transplant NHSBT, a Special Health Authority in England and Wales.

So the current position is that NHSBT is the health authority with responsibility for managing blood services in England -- and I will come on to explain why that doesn't include Wales in a moment -- and it has responsibility for managing services including transplantation services in relation to stem cells, human tissue and human organs in the UK.

I'm now going to move on to Wales. Before I start I hope it will have been clear that much of what I said in the previous part of the presentation applied to Wales, so this is just the Welsh-specific issues that I'm dealing with here, and I should also say that there is currently less detailed information available to the Inquiry about the history of Wales -- of the Welsh Blood Service, but that's something that

we will continue to investigate and it may be that more information comes as a result of oral evidence.

So NBTS (Wales) was made up of a single Regional Transfusion Centre in Cardiff, which served the hospitals in south and mid-Wales. The Regional Transfusion Centre in Cardiff was established in 1940 and following the establishment of the NHS in 1948 it was managed by the Welsh Regional Health Board. In 1974, NBTS (Wales), effectively the Cardiff Regional Transfusion Centre, became the responsibility of the Welsh Office.

In 1982, responsibility was delegated by the Welsh Office to the South Glamorgan District Health Authority and in 1991 responsibility for NBTS (Wales) was delegated to the Welsh Health Common Services Authority. NBTS (Wales) did not become part of the National Blood Authority when it was formed in 1993. That was just for the Regional Transfusion Centres in England. This change prompted consideration as to the future management of the Welsh blood transfusion services.

If we can look please at SCGV0000053_013. So we can see from this page here that this is a letter -- a covering letter, dated 14 November 1994, to R Ponton in NHS Scotland and it is from a P Davenport of the

Health Services Division of the Welsh Office, and it says:

"Future Management Arrangements for the National Blood Transfusion Service (Wales) ...

"I promised to let you have a copy of the recommendations for future management arrangements for [NBTS (Wales)]."

Then if we turn over we can see the document itself, "Recommendations for Future Management Arrangements for the National Blood Transfusion Service (Wales)", and then the date is October 1994.

Then if we turn over to page 4, we can see the contents of that report, and page 6 we can see the objective of the report:

"The objective of this report is to recommend the chosen option for future management arrangements for the National Blood Transfusion Service (Wales) ... following receipt of a direction from the Secretary of State for Wales indicating that Welsh Health Common Services Authority ... should cease to maintain managerial control of [NBTS (Wales)]."

It sets out what happened in 1991, that managerial control was transferred to them from South Glamorgan Health Authority.

It's then probably worth looking at the vision

and mission of NBTS (Wales), which appears below. The vision is:

"'To be the acknowledged Centre of Excellence for blood transfusion and transplant immunology services in Wales'.

"... Mission

"'Through the generosity of donors and the valued contribution of staff, to provide quality blood transfusion and transplant immunology services for the treatment of patients in Wales'."

If we then go on to page 8, paragraph 4.3, we can see what prompted the report:

"The establishment of the [NBA] to take over direct managerial control of the Transfusion service in England from April 1994, and the outcome of the Bain review into transfusion services, has resulted in amalgamation of the former regional services within England into three zones. Managerial and support services will be centralised within each zone and certain laboratory functions will be reorganised on a supra-regional basis, thus allowing a small number of English Regional Centres to be closed (this includes the Mersey Centre)."

I will come onto why that is significant in a moment.

"The ethos behind these changes is to achieve greater efficiency and a higher quality service. The situation in Wales should therefore seek to mirror and support these initiatives, and particularly move towards a largely cohesive United Kingdom Transfusion Service."

If we go over the page to -- sorry, if we go over to page 11, we can see that there are a number of shortlisted options that the report recommends, at paragraph 8, section 8:

"The following are therefore the shortlisted options worthy of further consideration ...

"A. Do minimum ([NBTS (Wales) becomes a] Special Health Authority).

"B. Incorporation into the NBA as a fifth Transfusion Centre within the South West Zone.

"C. [NBTS (Wales)] as a fourth zone within NBA.

Then if we go back to page 9, we can see what "do minimum" means. That's paragraph 7.1, if we go down to 7.1:

"This is taken to assume that formation of a Special Health Authority for [NBTS (Wales)] alone as opposed to, at present, being within the managerial control of a Special Health Authority. This option would be robust against all external influences and

would maintain the unique identity of the Welsh Transfusion Service."

Then missing out the next sentence:

"It is recognised that this option will probably best serve the need for accountability to the Secretary of State for Wales and potentially could also lead to a co-operative co-existence with the National Blood Authority and also the Scottish and Irish Transfusion Services."

Then if we go over the page to page 10, we can see a bit more detail at 7.4 about the option of incorporating it as the fifth transfusion centre within the South West Zone:

"This option would embrace entirely the ideals of the NBA although further evaluation is necessary to examine the ability to retain overall accountability to the Secretary of State for Wales. It must be recognised that all strategic planning within the [NBA] has already taken place and the zonal planning is now well advanced. The timescale for incorporation of Wales as a potential fifth Centre within the South West Zone, therefore, could mean that professionals within the Welsh service would have little influence regarding already decided strategy and policy. However, because this option provides the support and

guidance of a large organisation with the same overall service objectives, it is retained for further evaluation."

Then over the page we see a bit more detail about the third proposal, which is "[NBTS (Wales)] as a fourth zone within NBA":

"This option, whilst embracing the ideals of the NBA, would offer an initial consideration greater opportunity for maintaining accountability to the Secretary of State for Wales and deserves further evaluation. However, the difficulties regarding strategic planning are also to be recognised and there could be some difficulty in engrafting Wales as a fourth zone subsequent to any formation of the NBA. It is assumed that this option, despite that fact that [NBTS (Wales)] has substantially lower annual collection volume than the equivalent English zones, would enable Wales to have similar status to an equivalent English zone. This would be reflected in the Managing Director of [NBTS (Wales)] being a member of the NBA Management Executive, and there being a Welsh member on the NBA Board. This option is therefore retained for future *[sic]* evaluation."

SIR BRIAN LANGSTAFF: "... for further evaluation."

MS SCOTT: I'm sorry. Then if we go lastly on this

document to page 38, we can see what the ultimate recommendation of this report was:

"In making a recommendation, it is recognised that Option B: Incorporation into the NBA as a fifth Transfusion Centre within the South West Zone should be discarded, on the basis of poor satisfaction of quality financial evaluations.

"In examining the remaining two options, Option A: Do minimum (NBTS(W) Special Health Authority) and Option C: NBTS(W) as four zone within the NBA, it has been clearly shown that Option A far outweighs Option C as far as satisfaction of quality criteria, there being little difference in the financial evaluations.

"It is therefore recommended that the option of choice, based on quality criteria, is ...

"... Do minimum ...

"This would best serve the needs of the people of Wales in offering good stewardship of capital assets, effective service delivery and maintenance of accountability to the Secretary of State for Wales."

So that was the proposal. In fact, it appears that that was not taken up because the service continued to be managed within the Welsh Health Common Services Authority, so a Special Health Authority was

not, in fact, at that stage established.

Now, initially, the Blood Transfusion Service in Wales reported to the Ministry of Health and then the Department of Health and Social Security, and then from 1965 it reported to the Welsh Office. The Welsh Blood Service was formed in 1999 and reported to the Senedd. Also, in 1999 responsibility for NBTS, for the Welsh Blood Service transferred over to the Valindre NHS Trust, pursuant to the Valindre National Health Service Trust Establishment Amendment Order 1999.

Now, the director of the Cardiff Regional Transfusion Centre was Dr Napier from 1978 to 1998 and he also held the position of as part-time medical director of the Welsh Blood Service from 1999 to 2002, and we'll be hearing oral evidence from him next week.

So that, sir, is the position of the Welsh Blood Service, insofar as it -- and, sir, you will have noticed that I've only made mention of South and Mid-Wales.

The position in relation to North Wales was different. So hospitals in North Wales were served by the Regional Transfusion Centre in Liverpool, hence why it was significant that that Regional Transfusion Centre was being merged by the NBA.

That position continued to be the case after the formation of the NBA in 2003. So when there was a split between England and Wales on 1 April 2003 with the establishment of the National Blood Authority, the hospitals in North Wales continued to be serviced by the Liverpool Regional Transfusion Centre. So they effectively went over to the NBA and formed part of the National Blood Authority.

In 2005 when NHSBT was formed as a Special Health Authority it was a Special Health Authority for England and Wales because it incorporated the hospitals in North Wales, or the services for the hospitals in North Wales, I should say.

So the NHSBT took responsibility for those county boroughs in North Wales that had historically been served by the Liverpool Regional Transfusion Centre and had formed part of the English service. It was not until 2016 that management of the provision of hospitals in North Wales transferred to NHSBT to the Welsh Blood Service. So it was not until 2016 that there was a unified Welsh Blood Service.

It's perhaps unsurprising in those circumstances, ie one Regional Transfusion Centre in Wales and the fact that North Wales was serviced by an English Regional Transfusion Centre, that the Welsh

Regional Transfusion Director -- and for the period of time the Inquiry is concerned with that was Dr Napier -- was part of the same committees, groups and decision-making forums as the English Regional Transfusion Directors.

So we see Dr Napier attending Regional Transfusion Director meetings in England, we see Cardiff as being part of the western, south western zone of Regional Transfusion Centres, as created by Dr Tovey, and we see Dr Napier attending or at least being invited to attend those meetings, and we see, occasionally on minutes of meetings for advisory committee and central committee, and so on, Welsh representatives, but the question as to how -- as to the extent to which Wales was represented on decision-making bodies and advisory forums is an issue to be explored at the hearings.

Sir, I'm now going to move on to Northern Ireland and in common with the position in Wales, there is at present not much information available to the Inquiry about the history of the Northern Irish Blood Transfusion Service and, again, that is something that we continue to investigate and it may be that more evidence comes to light during the oral hearings.

In 1948, the Northern Irish service became the responsibility of the Northern Ireland Hospitals Authority and in 1953 a new headquarters was established in Belfast which later became the Belfast Regional Transfusion Centre.

Also in 1953, the Service started to use a mobile donation unit, which was the first of its kind in the United Kingdom.

At this stage, the blood transfusion laboratories were at the Royal Victoria Hospital in Belfast. In 1961 they moved to Belfast City Hospital, but in 1970 the laboratories and the blood donor organisation were brought together in one building and amalgamated into a single organisation.

In Northern Ireland, the NHS was merged with the broader social care system in 1973 and called the Health and Personal Social Services and later the Health and Social Care system.

Between 1972 and 1999, the health system of Northern Ireland was managed by the UK Government via the Northern Ireland office.

So until 1999, public and social policy decisions appear to have been taken at Westminster and communicated through the Secretary of State within the Northern Ireland office, who answered directly to the

UK Government.

During this period of direct rule, 1972 to 1999, it appears that the default position in terms of reform and the development of policy and strategy in health and social services was to mirror English policy decisions.

During this time, the service came under the remit of the Eastern Health and Social Services board.

On 1 June 1994, a special agency came into -- it was established. A special -- sorry, a special health and social care agency was established. The Personal Social Services (Special Agencies)(Northern Ireland) Order enabled the establishment -- sorry, sir, I've got that rather muddled. Let me start that again.

On 1 June 1994, an order came into operation which enabled the establishment of a special health and social care agency to which the Department of Health and Social Services could delegate its functions.

Also on 1 June 1994, the Northern Ireland Blood Transfusion Service special agency was established, established as a special health and social care agency pursuant to the order that allowed such agencies to be established.

On the same date, directions came into force which set out what the functions of the Northern Ireland Blood Transfusion Service were, and those directions required it to ensure that all hospitals and other clinical units in Northern Ireland are provided with adequate supplies of blood and blood products.

In 1995, the Northern Ireland Blood Transfusion Service moved to a purpose-built facility on the City Hospital site in Belfast, and this remains their headquarters.

The service had one Regional Transfusion Centre in Belfast. The first director of the service, between 1969 and 1980, was Colonel TE Field, followed, from June 1980 to May 1994, by Dr Morris McClelland, who was also the Regional Transfusion Director of the Belfast Regional Transfusion Centre.

From June '94 and the creation of the Northern Ireland Blood Transfusion Service, Dr Morris McClelland's title became that of chief executive and medical director, and he stepped down in 2009.

SIR BRIAN LANGSTAFF: So he served for 29 years, from 1980?

MS SCOTT: Yes.

We can see from the minutes of the meetings that we have that a representative of the Northern Ireland Blood Transfusion Service attended English and Welsh Regional Transfusion Director meetings from the 1960s through to 1989, when the meetings were abolished.

We can also see that Dr Morris McClelland was invited to attend the Scottish National Blood Transfusion Directors' meetings and the co-ordinating group meetings from the end of 1982, and we can also see that the Northern Ireland Office, via a representative of the Department of Health and Social Services, Northern Ireland, attended meetings of the advisory committee of the National Blood Transfusion Service.

Again, the extent to which there was representation in decision-making forums for the Northern Ireland Blood Transfusion Service is something we will explore in the forthcoming hearings.

It's just worth noting before leaving Northern Ireland that the service had had its plasma fractionated by BPL, but in the early 1980s it appears that it began sending its plasma to Scotland for fractionation at PFC.

SIR BRIAN LANGSTAFF: The "early 1980s" can cover a wide variety of years.

MS SCOTT: It can.

SIR BRIAN LANGSTAFF: Some of which are of great significance in this Inquiry. When?

MS SCOTT: My recollection is it was 1982 to -- about 1982, 1983. Let me just check that that is correct, that my recollection is correct.

Perhaps, sir, I can get back to you on the specific date.

SIR BRIAN LANGSTAFF: It may be a slowly developing process over a period of time, I appreciate, but it would be useful to know when it started and when effectively it became the complete picture.

MS SCOTT: Yes.

Sir, then I come last but not least, of course, to Scotland. So Scotland originally had a walking blood donor panel established in Edinburgh by a Mr Jack Copland at the Edinburgh Royal Infirmary.

There were initially 12 volunteers on the panel and they would be collected and taken to the patient when blood was required.

SIR BRIAN LANGSTAFF: So when they are described as a "walking", they are collected?

MS SCOTT: That's what I understand.

Once it looked like there was going to be an outbreak of war, the Second World War, the Department

of Health set up a transfusion subcommittee and this recommended that stores of blood should be made available in various centres. So by the beginning of World War II there were blood banks at the Royal Infirmary in Edinburgh and at Stobhill Hospital in Glasgow.

In 1940 the Scottish National Blood Transfusion Association, a charitable body, was formed to run the Blood Transfusion Service. At this stage, the Scottish Blood Transfusion Service consisted of five regional blood transfusion centres: the Edinburgh Regional Transfusion Centre served Edinburgh and the south east of Scotland; there was a centre in Glasgow that served Glasgow and the west of Scotland; a centre in Dundee that served Dundee and the east of Scotland; in Aberdeen, served Aberdeen and the north-east of Scotland; and in Inverness serving Inverness and north Scotland.

Each transfusion centre had a transfusion director and, in addition, there was from the beginning a national organiser. Initially this was Mr Copland.

By 1944, the centres combined had 57,000 donors, and in 1948, of course, we know that the National Health Service was created, and at that stage the

blood service became the responsibility of the Secretary of State for Scotland. So whereas the position in England was that, on the establishment of the National Health Service, that was devolved to the regions, in Scotland it remained with Central Government, the responsibility.

The Scottish National Blood Transfusion Association continued as a charitable body which managed the blood service through its Executive Committee, but the Secretary of State for Scotland took over all its premises, equipment and staff.

SIR BRIAN LANGSTAFF: Can I just understand that.

Was did taking over its premises, equipment and staff consist of and where were the lines drawn between that and management, which you say remained with the charity?

MS SCOTT: Sir, I don't have --

SIR BRIAN LANGSTAFF: Or isn't it clear?

MS SCOTT: It's not clear to me and it may be something that we can explore as we go through the hearings. But when one looks at the meeting minutes, it's clear that Regional Transfusion Centre directors are having to make bids for improvements to accommodation for equipment and so on to Central Government, and so it seems that the funding was centrally -- was with

Central Government, but quite what the role of the SNBTA was in terms of management is not clear to me at the moment.

SIR BRIAN LANGSTAFF: So in addition to premises, equipment and staff, one could add financing or funding, could one?

MS SCOTT: Yes, that's my current understanding but I suspect that more will come clear as we progress through the hearings.

SIR BRIAN LANGSTAFF: It might. I mean, if it's a charity then it may well have drawn its money from other sources.

MS SCOTT: Yes. And we see as well that it survives various -- it effectively ends up as a donor organisation, the SNBTA, surviving changes to the structure of the service.

Can we look at PRSE0001217. This is a circular dated 3 November 1972 entitled "Health Service Reorganisation Scotland", and it was a circular issued by the Scottish Home and Health Department. We can see that on page 5 at the bottom there, Scottish Home and Health Department.

Then if we go back, please, to the first page we can see it's entitled:

"Sir

"COMMON SERVICES AGENCY

"INTRODUCTION

"1. This circular indicates the likely form and functions of the Common Services Agency and describes the intended initial steps towards setting it up."

Sir, this was issued by the Scottish Home and Health Department, and we can see what the purpose of the CSA was if we go to page 2, paragraph 5:

"The CSA's prime role will be to act as an agent for the health boards in providing them with important supporting services of a kind likely to be best organised centrally. The broad policies and questions of broad resource allocation in respect of these services will be decided by the Secretary of State on the advice of the Planning Council, as appropriate, in the light of the needs of the health boards and of the Department for the services being [funded *(sic)*] for them."

Then if we go to annex A, which we find at page 6, we see "Proposed functions of the common service agency", and if we go down to "A. Services", we can see at (iii) that -- sorry, (iv), rather, it includes Blood Transfusion Services.

So the proposal is for the creation of this common service agency to which the functions of the

blood service would be transferred. And we can see that the central organisation -- if we go back to page 2, the central organisation, the structure of the CSA, at paragraph 6:

"The CSA will be operating a range of disparate services and this fact will determine its basic organisation. The main responsibility for the day to day running of each service within the allocated expenditure and in accordance with the broad policies will fall to the chief officer or director of that division of the CSA; and he will in most cases be directed responsible to the Management Committee or to any sub-committee which may be set up for the particular service."

Then if we go over the page to paragraph 11 under "Policies", page 3, paragraph 11:

"It is envisaged that the broad policies within which most divisions of the CSA will work will have been laid down by the Secretary of State having regard to the needs and priorities of those for whom the service is provided and to any advice from the Planning Council. Each division will operate within its predetermined budget expressed as an earmarked allocation by the Department to the CSA in the light of budget estimates submitted annually through the

Management Committee."

So the proposal is for a very much centralised structure, centrally funded, centrally managed, of the blood services within this common service agency.

On issue of this circular, there was some significant concern on the part of the Regional Transfusion Directors about the plan. Their concerns were not only that there was no detail about precisely how the transfer was going to work but also that it would be an overly bureaucratic structure. And so they set out their views in a number of documents, but I'm just going to look at one of those. It's an PRSE0004463.

It's a letter written to NA Milne, Hon Secretary, in Edinburgh, and if we go to the second page of the document we can see it's signed by a number of Regional Transfusion Centre Directors, including director Dr John Cash, who was the director of Edinburgh at the time, and Mr John Watt, who was the first scientific director of PFC.

If we go back to the first page, we can see that the subject of the letter is "Health Service Reorganisation, Scotland - The Blood Transfusion Service", and it starts:

"1. Following a meeting of the Regional

Directors and the Scientific Director of the Protein Fractionation Centre, held in the Regional Blood Transfusion Centre at Edinburgh ... on 9 January 1974, I have been requested to convey to you their unanimous opinion and constructive suggestions regarding the future arrangements for the management of the Blood Transfusion Service in Scotland.

"2. They desire to express their alarm and deep concern that the Scottish National Blood Transfusion Association has indicated its intention to transfer its responsibilities to the Common Services Agency on April 1st 1974, solely, as it appears to the Directors, on the basis of Circular HSR(73)C40."

Which is the circular we just looked at.

"They wish to convey in the strongest possible terms that they consider the proposals for the transfer of these responsibilities as set out in [the] circular to be totally inadequate as a basis on which to judge whether the immediate and future commitments to the Health Service can be effectively discharged.

"3. In view of the imminent changes in the scope and function of the Blood Transfusion Service, it is their considered opinion that the lack of detail not only renders the document unacceptable as a formula for their transfer to the Common Services

Agency, but also calls into question the choice of this Agency as the organisation best suited to undertake the management of the Blood Transfusion Service in Scotland. In particular it is stressed that far reaching changes in the Clinical, Scientific, Technical and Organisational spheres of blood transfusion practice have emerged since the present proposals were first considered. They appreciate that detailed information about the intentions of the Common Services Agency may not be available to either the Scottish National Blood Transfusion Association or the Scottish Home and Health Department representatives. If this is so, it reinforces the need to delay implementation of [the circular].

"4. As the professional group directly responsible for the operation of the Blood Transfusion Services in Scotland, they therefore consider it their duty to make the following proposals:-

"(i) That arrangements for the transfer responsibility for the Blood Transfusion Service to the Common Services Agency be held in abeyance, in order to allow full and urgent discussions to take place between the Medical and Scientific Directors, the Scottish National Blood Transfusion Association, the Central Consultative Committee and Senior

Representatives of the Scottish Home and Health Department.

"(ii) That the Scottish National Blood Transfusion Association be asked to continue in office in its present form, with the addition of the National Medical Director and the Administrative Officer with supporting staff, until such time as an acceptable solution for the effective management of that Blood Transfusion Service in Scotland has been agreed."

So despite this request from the transfusion directors, in April 1974 the Blood Service was reorganised and placed administratively within the newly formed Common Service Agency of the Scottish Health Service, in a division of the CSA called Scottish National Blood -- the Scottish National Blood Transfusion Service.

The CSA was overseen by the Scottish Home and Health Department and its successors, namely the Scottish Executive Health Department and the Scottish Government Health Department.

The Scottish Home and Health Department and its successors were administered prior to devolution by the Scottish Office, Department of the Secretary of State for Scotland. And since devolution in 1999, the Common Services Agency has been administered through

the relevant minister, currently called the Minister of Health and Social Care, who is answerable to the Scottish Parliament.

The functions of the CSA were initially set out in the National Health Service (Functions of the Common Services Agency) (Scotland) Order 1974, and required the CSA to supply human blood for the purposes of carrying out blood transfusion and related services including the production of blood fractions. Its functions also included the donor services previously administered by the SNBTA which continued as a charitable body to represent blood donors.

So I think, sir, in answer to your question, I think that may be the answer to the question: the SNBTA was concerned with donor services and the transfer of the equipment, personnel and accommodation was in relation to the other services of the Blood Service.

In October 1976, the Transfusion Directors sent the Scottish Home and Health Department a paper setting out their views on the future of the Blood Transfusion Service, and we can see that at PRSE0001535.

We can see the covering letter is to the Scottish Home and Health Department, Dr McIntyre, and

it says:

"You will remember the discussion at the BTS Directors' meeting on 1 July at which it was agreed that a paper concerning medical staffing and the future of blood transfusion should be submitted to you."

Then the middle of the next paragraph:

"I am accordingly enclosing a draft discussion paper on future management of BTS which has been agreed all by BTS Directors."

Then we get to the paper itself on page 2, and it's called "Future management of the Blood Transfusion Service in Scotland". Paragraph 1:

"This paper sets out, as a basis for discussion, the consensus views of Scottish Transfusion Directors on the future management of the Blood Transfusion Service in Scotland."

Paragraph 4:

"The position in 1976

"The anxiety expressed during these meetings has been realised."

It's referring to the anxiety expressed by the directors as it's gone over the history of the development of the CSA:

"The Management Committee does not have within,

or available to, it, such independent specialist and other advice as was available within its predecessor, the Executive Committee of SNBTA. This lack of professional expertise and clinical user involvement is considered by the Transfusion Directors to be a retrograde step in the management of the service.

"5. For some years before 1974 it had been planned that a small BTS Headquarters should take over the duties of the part-time officers of SNBTA and the medical secretary and administrative officer provided by SHHD. In the event the headquarters was not established until nearly 1974 at the time of transfer to CSA, when a CSA headquarters office was also established, apparently to undertake on behalf of CSA Divisions duties hitherto carried out within the Divisions themselves. The resultant duplication of effort, made worse by the recruitment of inexperienced staff to CSA headquarters, has been expensive, unrewarding to all concerned and detrimental to effective management. The Transfusion Directors are now in no doubt that the appropriate place for BTS central administration is in its own headquarters aided by financial and management containing and internal audit. This arrangement would be cost effective. Interposing CSA headquarters as a tier

between the Directors of CSA Divisions and the Management Committee to which they are accountable has been most unfortunate."

Then it goes on at paragraph 6, over the page, after the quote there:

"After [two and a half] years' experience and following careful consideration it is the view of the Transfusion Directors that BTS should be administered as a National Service and that its nature renders it unsuited to management by a committee composed entirely of Health Board members and officers and officials of SHHD within the framework of CSA."

Then the proposal that's made for the future is set out at paragraph 7:

"It is suggested that the service should transfer to a Management Committee responsible to the Secretary of State and having the following membership:

"Chairman, appointed by Secretary of State ...

"Transfusion Service National Medical Director ...

"Transfusion Directors ...

"Donor interest ...

"User interest ...

"Health Board interest ..."

And:

"... Observers [from the Home and Health Department] (Medical, Executive and Finance) ...

"[And] The secretary to the Committee should be the National Administrator of the [Blood Transfusion Service].

"The Committee would assume the executive authority presently exercised by the CSA Management Committee and there would be no further need for the present Co-ordinating Group of Transfusion Directors; the Directors' professional meetings are however essential and should continue. It is hoped that the Secretary of State would continue to receive advice from the Blood Transfusion/Advisory Group to the Planning Council."

The response to this we can see at PRSE0002319, and it's dated 2 December 1976, to Ms Corrie, who sent the paper we've just looked at. It's the second paragraph:

"The paper [which is the paper we have just looked at] is being circulated within the Department and I am not yet in a position to sent you any formal reply. It is only fair to say however that the SNBTS is now formally a part of the NHS and can therefore only be administered in the existing health service

framework."

It goes on to say that that has been made clear to the directors on a number of occasions.

Undeterred by this, the directors continue to press their point that the current structure is expensive and, frankly, in their view, doesn't work. And an agreement is reached in June 1977.

We can see that recorded in a document at PRSE0000108.

This is a minute of a special meeting of the management committee of the Common Services Agency held on 26 April 1978. If we go down to the bottom of this page, at 681, "Matters arising from these minutes":

"(i) Minute 648(i) - Management Arrangements in the Blood Transfusion Service.

"There was submitted the report of the *ad hoc* Committee on management arrangements in the Blood Transfusion Service. Presenting the report, the Chairman recalled that in 1977, the Blood Transfusion Service Regional Directors had asked to meet the Secretary of State to express their concern at management arrangements in the Blood Transfusion Service. The Management Committee, at their meeting on 15 June 1977, had agreed to establish an *ad hoc*

Committee with the remit 'to examine and report to the Management Committee on the management arrangements for the Blood Transfusion Service within the Common Services Agency'. It was now urgent that the management arrangements for the Blood Transfusion Service be resolved, and he had therefore called a special meeting of the Management Committee to consider the report of the *ad hoc* Committee. A letter had been received from Dr JD Cash on behalf of all the Regional Directors of the Blood Transfusion Service confirming that they accepted the recommendations of the *ad hoc* Committee. The Chairman expressed his appreciation."

We can see over the page what that looks like.

"After a full and frank discussion, the Management Committee accepted the recommendations of the *ad hoc* Committee on management arrangements in the Blood Transfusion Service and agreed:

"(i) to establish a Sub-Committee of the Management Committee specifically to deal with matters relating to the Blood Transfusion Service to be known as the Blood Transfusion Service Sub-Committee;

"(ii) that the Blood Transfusion Service Sub-Committee should have the terms of reference set other ion Appendix 1 ..."

We can see that at page 5 of this document:

"There shall stand referred to the Blood Transfusion Service Sub-Committee:

"(1) The review of the operational activity of the Blood Transfusion Service to ensure that the services provided are efficient and economic and within approved financial allocations.

"(2) The formulation of proposals for the development and improvement of the services ...

"(3) Liaison with other authorities on developments in the [Service].

"(4) The review of complaints ...

"(5) The control of the establishment of staff within the [Service] and the appointment and dismissal of staff ...

"(6) The application to staff ... of nationally approved terms and conditions of service ...

"(8) The provision of medical and operational equipment required ...

"(9) The preparation of capital programme ...

"(10) The appointment of such *ad hoc* advisory committees and working parties as may be necessary to advise on specific matters relating to the service provided by the Blood Transfusion Service."

So those are the terms of reference of the

subcommittee. Then if we go back to page 2, it sets out the constituents -- the constitution, rather, of the Blood Service Subcommittee at subparagraph (iii) there:

"Six members of the Management Committee (one of whom would be Convener) -- including the Chairman and Vice-Chairman as ex-officio members in terms of the Standing Orders of the Agency, Two specialists in clinical medicine, Two specialists in laboratory medicine, One medical officer from the Scottish Home and Health Department, One representative of Donor Interests."

Then we see at (v):

"... that the National Medical Director should, as a matter of course, receive the agenda and supporting papers for each meeting of the Blood Transfusion Service Subcommittee and attend or be represented and [over the page] that the other Directors within the Blood Transfusion Service should also receive copies of the agenda and supporting papers of each meeting and, subject to the agreement of the Convener, attend if they so wished ..."

So that was the agreement that was reached in June 1977, and so what then happened was that that subcommittee, in turn, set up a working party in which

representatives of the -- in which the transfusion directors participated.

There were further legislative changes in 1978, which had the effect of reconstituting the CSA, and so members of the management committee of the CSA were appointed by the Secretary of State and that structure remained largely unchanged, following the appointment of Professor Cash in 1978 as the National Medical Director. Again, the extent to which the regional services retained autonomy through the period will be an issue that we will -- sorry, the extent to which the individual Blood Transfusion Centres retained autonomy through this period will be explored within the hearings.

We can see from the minutes that are available to us that, through the late 1970s and 1980s the Scottish National Blood Transfusion Service Co-ordinating Group met on a regular basis, as did the SNBTS directors. I've already mentioned, when I was doing the presentation on England, that the first formal liaison, if you like, between Scotland and England and Wales came when the advisory committee to the National Blood Transfusion Service in England was formed in December 1980, and there was -- part of the remit was to advise the Department of Health and

Social Security on co-ordination of the English and Welsh and Scottish Blood Transfusion Services.

The first joint committee between the Scottish and the English services was the formation of the SNBTS/NBTS liaison committee in June 1990.

We can also see from the minutes that there was regular attendance by Professor Cash at Regional Transfusion Director meetings in England, that Dr Cash attended the Advisory Committee on the NBTS formed in December 1980, although that Committee was dealing only with matters concerning England and Wales, and there was often an English director or a representative of the National Directorate, once that had been formed, at Scottish Regional Transfusion Director meetings.

In 1990, the Scottish National Blood Transfusion Service created a General Manager position and that position was then renamed National Director in 1996, and the National Medical Director, who was Professor Cash, became the National Medical and Scientific Director.

So the regional directors and the PFC director became managerially accountable to the General Manager, who then became known as the National Director, and professionally accountable to the

National Medical and Scientific Director.

The SNBTS management board at that stage compromised *(sic)* the General Manager, the National Medical and Scientific Director, the five Transfusion Centre Directors the Director of PFC, a National Donor Services Manager, Director of Human Resources, a Director of Finance, and a Director of Quality.

Following a strategic review in 1998-1999, SNBTS was restructured to move away from regional structure towards a national structure and, since that time, all blood donor services have been managed nationally. A directorate for operations was created to manage donor services, manufacturing and logistics and the number of blood processing and testing units was reduced to two.

A national quality directorate was formed along with other national support services and hospital blood banking and related clinical and laboratory functions remained distributed within the Regional Transfusion Centres. The Regional Transfusion Directors became clinical directors.

In 2002 to 2003, the Common Services Agency underwent a strategic review and, once again, the clinical directors of Scottish National Blood Transfusion Service expressed their dissatisfaction

with the CSA, as being not qualified to manage the performance of the SNBTS, and a report authored at that time concluded that there was some justification for those concerns because of the lack of a developed system of clinical governance in the CSA and a lack of clarity about the role and purpose of the board and a lack of clarity about how the CSA and its divisions add value to each other's activities.

Following that review, the governance arrangements were strengthened. The SNBTS national director became an executive director of the CSA board and the CSA board adopted the governance structure of other health boards, including a clinical governance committee and a centralisation of some of its support services.

On 1 October 2008, the National Health Service Functions of the Common Services Agency Scotland Order removed the production of blood fractions from the functions of the CSA. The CSA remained responsible for the provision of supplies of human blood for transfusion and related services, and there was a period of wider organisational structural change in 2012-2013 resulting in consolidation of a number of CSA divisions, often called strategic business units, and the centralisation of support services, but the

SNBTS was considered of sufficient size and specialty to retain its own identity.

In 2013, there were changes to the name. The SNBTS Board was renamed Senior Management Group and was chaired by the SNBTS national director. The medical and Scientific Committee was renamed the Clinical Governance and Safety Group and the posts of clinical directors were removed and SNBTS was organised into a number of national directorates led by associate directors. Those were donor and transport *(sic)* services, blood manufacturing, patient services and strategy planning and performance.

There's been no significant further change to structure since that time.

It appears from the documentation that the Inquiry has that the SNBTS was funded centrally from the Scottish Government's central budget rather than from region health budgets as was the case in my England and Wales, that until 2002/2003 the Scottish Home and Health Department provided the CSA with a ring-fenced budget for the blood service but, after this time, there was no ring-fenced budget so it was left to the CSA to allocate a budget to the SNBTS as part of its internal business planning.

So, sir, that brings me to the end of the

presentation on the history and structure of the Blood Transfusion Services. The presentation is accompanied -- supported by a written presentation, which has been disclosed to Core Participant through their legal representatives and will be made available on the website, and that has more detail and references to other documents that, for reasons of time, I haven't been able to go to.

SIR BRIAN LANGSTAFF: Yes. Well, thank you very much. So that concludes, just before 1.00, the first part of today's business. So we will meet again at 2.00. Then it's Ms Fraser Butlin, is it, we will hear from at that stage?

MS SCOTT: Yes.

SIR BRIAN LANGSTAFF: Yes, thank you very much.

(12.59 pm)

(Luncheon Adjournment)

(2.00 pm)

SIR BRIAN LANGSTAFF: Yes.

MS FRASER BUTLIN: Thank you.

Sir, before I start the second presentation for today, looking at early look-back processes, one question which arose earlier in Ms Scott's presentation was about plasma from Northern Ireland and when that was processed by PFC in Scotland. That

was something that was picked up in the Belfast haemophilia centre presentation, the official request for it to be dealt with by PFC rather than BPL was in May 1981 and it was expected at that point that the first plasma would reach PFC in October 1981. All the referencing for that point can be found on the website in the Belfast presentation.

SIR BRIAN LANGSTAFF: Thank you.

Presentation by Counsel to the Inquiry relating to early look-back processes

MS FRASER BUTLIN: Sir, the second presentation for today, as I've said, is looking at early look-back processes. Perhaps it's worth starting by explaining that the purpose of this presentation is twofold. Firstly, it's to put a selection of the documents that the Inquiry has identified into the public domain for those who have not had access to the full set of documents that has been provided to the Core Participants.

Secondly, it's to set the scene and to provide the backdrop for subsequent witness evidence. This presentation seeks to set out what had been done previously in relation to look-back processes, albeit often informally, so that we can then explore in much more detail with the relevant witnesses what happened

with the hepatitis C look-back process.

Before I start the substance of the presentation, it's worth just dealing with one point of terminology. In the presentation, I will be talking about both look-back and reverse look-back. Look-back, or sometimes called targeted look-back, is where a donor is identified as being positive for, say, hepatitis B or HTLV-III and the recipients of any transfusions are then traced. Reverse look-back is where a recipient of a blood transfusion or -- tests positive or was identified as suffering from jaundice in the early days, and the donor is then traced.

Both of those processes form part of this presentation. I am going to address three parts, three points, in the presentation. The first thing we will look at through the documentation is matters we've identified dealing with early jaundice enquiries, the investigations that were undertaken and the extent of the tracing of donors that took place when jaundice was suffered by a recipient of a blood transfusion; secondly, we will look at hepatitis B look-back processes; and, thirdly, we will look at the HTLV-III look-back process.

So starting off then with early jaundice enquiries, we've been unable to identify a precise

date when there was a requirement on regional transfusion offices to report cases of post transfusion jaundice to the Ministry of Health but, as we will see, reports were certainly being made from 1947, so from a very early stage.

The documentation we have identified suggests that notification of post-transfusion jaundice was not always straightforward or complete, and if we could go to DHSC0100009_103, please, we have a letter from a regional transfusion officer to Dr Maycock in the Ministry of Health, dated 1 December 1947, reporting a case of jaundice after a transfusion of plasma.

Then if we go to the second page, the officer notes:

"I have been making enquiries around the hospitals and talking to RSO, but in spite of the fact that I have told them many times that we wish to have cases of jaundice reported to us I fear that quite a number in this area have not been reported ..."

We then have a set of minutes of a meeting of Dr Maycock and the Regional Blood Transfusion Officers at DHSC0100054, please.

The meeting took place on 14 January 1948, and if we go to the bottom of the page we can see minuted that:

"Dr Maycock reported that during the last 18 months or so, 78 cases of haematogenous hepatitis had been reported to the Ministry, of which some 25 per cent had died, but there was no record of the outcome of about half of the remaining cases. In view of the importance of collecting as much accurate information as possible of cases of haematogenous hepatitis, he [Dr Maycock] had prepared a report form for completion in such cases, which was submitted and approved by the meeting with the exception of a particular paragraph ..."

So we see Dr Maycock seeking to establish a clearer reporting system.

We have a copy of a report form. It's not exactly the same as what was discussed at the January 1948 meeting but it appears to be the form that was in use by October 1949.

That is at DHSC0100011_006.

On that form, we can see, at points 5 and 6, a note of the primary disease or injury, in this case post partum haemorrhage and shock, and, 6, the reason for the transfusion: haemorrhage and obstetric shock.

We then see notes at the bottom of this page. Under point 8, records dealing with the subsequent development of jaundice and what exactly happened for

the patient.

If we go back up to point 7 on the same page, we see a note which explains that two pints of plasma had been given:

"Transfusion was given in the middle of the night at the patient's home. Unfortunately numbers of bottles were not kept, in the excitement of the moment."

SIR BRIAN LANGSTAFF: Just the reference to the plasma there, my eyes noticed, when you went to the very first document you showed us, from 1 December 1947, that's DHSC0100009_103 --

MS FRASER BUTLIN: Yes.

SIR BRIAN LANGSTAFF: If we just go back there.

MS FRASER BUTLIN: DHSC0100009_103.

SIR BRIAN LANGSTAFF: And if we go over:

"... the general impression I have gained ..."

It's the last five lines:

"... is that the officers who have been in the hospitals for sometime consider the Canadian plasma has been the cause of the [problem]."

Do we know anything about the use of plasma from Canada?

MS FRASER BUTLIN: Sir, no. That's something that we also noted as we were preparing for this presentation, and

it's something that the team is looking at further.
SIR BRIAN LANGSTAFF: It may have been something which originated during wartime.
MS FRASER BUTLIN: Indeed.
SIR BRIAN LANGSTAFF: But it would be just interesting to know a bit more about it.
MS FRASER BUTLIN: Indeed, sir. I'm afraid it's not something I can assist with today but it is certainly something that's on our radar.
SIR BRIAN LANGSTAFF: Very well. Thank you.
MS FRASER BUTLIN: So we don't need to go back to it, Soumik, but looking at the report form from 1949 we can see that there is a note that on this occasion batch numbers weren't recorded, and we have a similar note of the failure to record batch numbers in a separate report from Wales.

If we could turn to -- sorry, just one moment.

Yes, if we could have DHSC0100008_054. My apologies, sir, I've just noticed we're taking this out of chronological order. We're going back to 1944. We should have looked at it earlier. Apologies.

But this a letter that also flags up issues around batch numbers. It's a letter from the regional blood transfusion officer to Dr Panton of the Ministry of Health, highlighting that they were "asked to see

a case of delayed transfusion Jaundice" that day. There's then a description of the clinical details of the patient and a note that she was given both plasma and whole blood.

The point I want to note from this document is on the second page, and that is the regional transfusion officer recording that:

"Unfortunately the surgeon did not record the batch number of [the] bottle of plasma. We have the identity of the donors. Do you want any blood from the patient. Also is it worth while our trying to contact the donors? They are apt to be a bit touchy when questioned."

Which is something else that we will pick up during the presentation, the issues being raised about how to approach donors when jaundice has been identified.
SIR BRIAN LANGSTAFF: It's obviously not the first time then that donors have been asked to help where it is thought that the blood which they gave may well be the source of a subsequent infection.
MS FRASER BUTLIN: Indeed. So, even in 1944, we can see that this appears to be a relatively well-established process, although we've been unable to give a more definitive date for you.

SIR BRIAN LANGSTAFF: Yes, thank you.
MS FRASER BUTLIN: Staying with the reporting system and, apologies, returning to the forms that were used, we have another example of a form which is helpful to see which is from Wales, dated 15 August 1950, DHSC0100011_011. You'll see it's very similar to the form we looked at just a moment ago. We can see again at point 6 -- 5 and 6, the primary disease or injury and the reason for the transfusion, in this case haemorrhage and shock following a prostatectomy.

We then see at point 7, the date of the transfusion and we can see that, on this form, there is a record of the number for the bottle whole blood and batch numbers for the plasma and, again, sir, you'll notice that, against the plasma, it says "CAN", which is something else, again, in relation to Canada that we've noted and will explore.

We can also see here the notes in brackets after the batch numbers and the whole blood numbers. "Donor has not had jaundice", so that donor appears to have been identified and communicated with but, in relation to the second bottle of whole blood, on 23 March 1950, they have recorded "Donor did not reply to letter".
SIR BRIAN LANGSTAFF: But they obviously haven't been able to make any enquiries about the Canadian plasma if it

was the Canadian plasma which was responsible.
MS FRASER BUTLIN: Indeed. There's no note at all of what happened in relation to those products.

The issue of donors not necessarily responding when they are followed up by the Regional Blood Service is a theme that we see throughout the time-frame.
SIR BRIAN LANGSTAFF: Just as a matter of interest, this is 1950, is it?
MS FRASER BUTLIN: It is, sir, yes.
SIR BRIAN LANGSTAFF: If the Canadian -- just go back to where we were please, Soumik. Thank you. The date there is 28 February 1945. So, presumably, that was the date when the plasma was first taken?
MS FRASER BUTLIN: It's very unclear at this point, sir, and again it's something that we've highlighted that we need to consider further.
SIR BRIAN LANGSTAFF: So it would suggest, as I think there has been some reference in one of the other documents you have just been showing me, that the plasma might have been dried and reconstituted --
MS FRASER BUTLIN: Indeed.
SIR BRIAN LANGSTAFF: -- but it plainly had a long shelf life.
MS FRASER BUTLIN: Indeed, yes. I think that's not

something we've seen particularly before.
SIR BRIAN LANGSTAFF: This is -- we're told the plasma had a much longer shelf life than red blood, it lasts for two or three years. This is an example of it being used five years after -- if this date is the date of taking -- five years after it has been taken and, presumably, if it's been dried, dried pretty quickly --
MS FRASER BUTLIN: Indeed.
SIR BRIAN LANGSTAFF: -- and it would suggest that it was wartime.
MS FRASER BUTLIN: Indeed, 1945. Yes, indeed. It's something, sir, that we are aware we need to look further at.
If we then continue into the 1960s we have a number of examples where reverse look-back and look-back had been mostly successful. One of those examples is from Wales in December 1964. We have a letter of December 1964, we don't need to put it up. Dr Bevan informed Dr Maycock that there had been a homologous serum jaundice case and the usual follow-up of donors had been undertaken.
That was then followed up by a letter, which is dated 4 January 1965, DHSC0100017_002, please, Soumik. So the letter refers to the earlier letter, which had

simply said the usual follow up of donors had been undertaken and it was addressing "three recent donations from the implicated donor have been traced back":
"One, as you know, went into post-vaccinial pool no 50 which has now been destroyed. The second was transfused in Orpington in 1962. A recent follow-up of the recipient shows no evidence of any trouble whatsoever and certainly no jaundice. The third was transfused at Cuckfield Hospital in July, 1963.
A report has now been received to the effect that the recipient was followed up for 12 months after transfusion and there's no record of any jaundice resulting.
"Although the donor involved has re-affirmed his freedom from jaundice at any time, he has now been [query] implicated on three occasions and he has, therefore, been withdrawn from the panel."
So here we have an example of a donor being identified as being problematic and the previous donations being followed through.
A very similar example can be found in a report from May 1965, DHSC0100017_027, please.
This is a report, if we just look at the bottom please, Soumik, we can see it's from the North East

Metropolitan region and then we can see in section 7 a record of the bottle numbers that had been transfused with the plasma batch number, which was not recorded. So we have the bottle numbers of the whole blood but no record of the plasma batch that was used.
We have the usual clinical notes, as well as some liver function tests, and then, at the bottom of the page, we have a note that's been added by the Regional Transfusion Director, at the very bottom:
"Eight donors have been contacted deny a history of jaundice or contact with a case."
There are eight different bottle numbers of blood that were used so it appears that, at least in relation to the blood, they had been able to contact the eight donors in relation to the blood but, of course, there was no record of the batch number of the plasma. So it's simply another example of what was being done during this period by way or both reporting homologous serum jaundice and also the tracing work that was being attempted.
The Inquiry -- we have also identified evidence of ongoing difficulties in the 1960s with these exercises. Firstly, there were issues around the resource implications of following these processes.
If we could have DHSC0100015, please -- sorry _241,

apologies. This is a letter from Dr Drummond to Dr Maycock, so from the Welsh region, dated 22 May 1962 and in that letter he says this:
"We discussed briefly at the recent MRC meeting the matter of tracking down cases of HSJ [homologous serum jaundice]. It is, I hope, a fair statement of fact that our methods have produced, and are producing, results in the way of cases of post-transfusion serum hepatitis. More cases could be traced, but the work has now become too great to be adequately coped with, as I hinted in a previous letter.
"It is worth considering what is involved in a hypothetical case which has had, for example, 7 bottles of blood and 3 of SP Dried Plasma (of different batches). Suppose the donors of the 7 bottles of blood have, between them, donated on 30 occasions. The fate of each donation has to be accounted for -- that may mean going back 10 years, or more, in some donors. For each donation transfused, the recipients must be contacted. We have to ascertain via the hospital, then GP, whether patient still survives. If alive, we must ascertain from the patient whether he, or she, had jaundice in the six months following transfusion; several cases have come

to light in this way. In the case of donations used for plasma, the fate of the plasma must be ascertained and recipients traced, as above. Finally, in case of SP plasma, all the donors (if this region) contributing to the pools must be accounted for and all donations they have given back-traced as above.

"If this work is worthwhile, particularly as the machinery for a continuing survey in one region, we must have more hands for the job. As things are, this work must be cut down rather than increased."

He goes on to ask for authorisation to use what he describes as a bleeding session doctor for the work one day a week.

Another issue that is raised in the documentation about these processes and challenges of them relates to the issue of reports of jaundice not being made to the Regional Transfusion Services.

If we can have DHSC0100017_034, please.

Again, this is a letter from Dr Drummond to Dr Maycock, in July 1965, where he records:

"We have felt for some years that the Cardiff RI does not notify us as many cases as it ought. I give below figures on usage of blood and plasma and cases of serum hepatitis notified to the BTS."

There's then data provided in letter whereby

Dr Drummond compares the case incidence of serum hepatitis at Cardiff RI with that of the rest of the region or the apparent incidence in light of their reports. He says at the end that using the case incidence of the rest of the region:

"... the expected number of cases for the Cardiff RI would be 13.6 cases (which is 0.034 per cent) and not 9 (which is 0.023 per cent) as notified to the BTS."

So the case incidence that's reported appears to be lower than that he would expect given the reporting across the region.

He goes on, just over the page, please:

"I am not sufficient of a statistician to say precisely what interpretation should be placed on these figures, but it appears to me that 9 cases of serum hepatitis is rather too few for Cardiff RI. I would be interested to have the views of the [Ministry statisticians] ..."

We then also have Dr Maycock's response. DHSC0100017_047, please.

Dr Maycock responds indicating that he hadn't been able to show the letter to a statistician, but halfway through the first paragraph he notes:

"It certainly looks on the face of it that

a number of cases of serum hepatitis are not being detected at the Cardiff Royal Infirmary, although I am not sure whether the figures are large enough to make this difference significant."

SIR BRIAN LANGSTAFF: By "significant", he would be meaning, presumably, "statistically significant", in the sense that it is used in statistics.

MS FRASER BUTLIN: That would be my understanding of what he saying, sir.

Dr Maycock then refers to a journal paper relating to the incidence of jaundice in Philadelphia, and that showed an incidence of 0.05 per cent. It's just in the midst of the second paragraph:

"... i.e. slightly higher than that found in the Welsh Region excluding the Cardiff Royal Infirmary. However, he found an attack rate of anicteric hepatitis equivalent to 870 per 10,000 units transfused, i.e. an incidence of 8.7 per cent, and concludes that in Philadelphia General Hospital there may have been over 100 cases of anicteric hepatitis for each icteric case diagnosed. His figures are statistically significant."

Sir, the point of highlighting these two letters is really the issue being raised by the Cardiff Centre with Dr Maycock that perhaps reporting from the

hospital was too low and reporting was not happening in the way they expected.

SIR BRIAN LANGSTAFF: So the difference is between transfusions and units transfused?

MS FRASER BUTLIN: Yes.

SIR BRIAN LANGSTAFF: So -- otherwise it just looks, on the face of it, which is why I was puzzling over the wording, that exactly the same hospital, in exactly the same study, has produced two completely different results.

MS FRASER BUTLIN: Yes, indeed.

SIR BRIAN LANGSTAFF: The explanation appears to be to me at the moment, but you can tell me if I'm right or wrong as far as you can understand it -- or, so the difference may be that the first, that's the incidence of 0.05 per cent, is per transfusion, and the next is per units transfused. But I don't quite understand why that should produce the results that way round if that's right. So I'm still a bit puzzled by this.

MS FRASER BUTLIN: I'm still somewhat puzzled by the Philadelphia paper. But the point that is being raised from my understanding is that, on the basis of the number of units transfused, there is at that time a broad understanding of the likely incidence of jaundice, which is what Dr Drummond had raised in our

previous letter as well, to say: that's what we would expect across the region, but Cardiff's reporting appears rather low. And my reading of Dr Maycock's letter is that he is agreeing in light of also the work done in Philadelphia. The precise figures from the Philadelphia paper are not wholly clear.

SIR BRIAN LANGSTAFF: I'm just rowing back on what I said a moment or two ago, it just doesn't make -- I'm not very clear what sense it makes. I need to go to the original article to see.

MS FRASER BUTLIN: I think we would. The point --

SIR BRIAN LANGSTAFF: It is not worth our while doing that, it's not making that point.

MS FRASER BUTLIN: Exactly.

SIR BRIAN LANGSTAFF: It's a "Have you seen this article by the way?" type of remark.

MS FRASER BUTLIN: That's exactly, sir, what I would say that the Philadelphia paper is a little peripheral to what we are drawing together for today and the point of today is that Dr Maycock appears to be largely agreeing with Dr Drummond that one would have expected a greater reporting of homologous serum -- sorry serum hepatitis from the Cardiff RI.

SIR BRIAN LANGSTAFF: Where he says "slightly higher than the Welsh region", it is actually half as much again.

MS FRASER BUTLIN: Indeed and one must then remember that Cardiff is lower again than the Welsh region excluding Cardiff.

SIR BRIAN LANGSTAFF: Yes.

MS FRASER BUTLIN: So there does appear to be an understanding in 1965 that that reporting of hepatitis from the hospital to the Regional Transfusion Centre is not wholly accurate.

SIR BRIAN LANGSTAFF: This is in respect, is it, of anicteric hepatitis reports or is it in respect of jaundice?

MS FRASER BUTLIN: The letter from Dr Drummond -- if it is helpful we can have it back up -- is in relation to cases of serum hepatitis.

SIR BRIAN LANGSTAFF: So it's both icteric and anicteric, because one of the documents which you were showing me earlier was talking cases of jaundice and within six months. So it was looking at acute cases and not at the sort of slow-burn anicteric case, which may be a more typical case of what we now know as hepatitis C.

MS FRASER BUTLIN: Indeed. Unfortunately, this is something of a generalisation, sir, but the documents are not as cleanly defined as one might have wanted, especially when one is looking at the look-back and

the reverse look-back processes. There are some that look at serum hepatitis and some that look at jaundice, and others that are a mixture.

SIR BRIAN LANGSTAFF: They are creatures of their time.

MS FRASER BUTLIN: Precisely, sir.

Then if we can move on to just highlight a couple of documents from the 1960s that deal with problems arising because of record-keeping, if we could have DHSC0100017_044, please. This is a letter from 1965 from the director of the -- sorry, the director of the NBTS region 1, to Oxford's Regional Transfusion Centre, noting that:

"Further to your letter of 9th June [and they give the reference], we have now been able to contact the above donor. The delay was due to her having changed her name on marriage -- it is now Mrs [X] and it was just by coincidence that we found this out. This donor is a nurse and she has answered our questions in the following way ..."

So there appears to have been a delay and a difficulty in tracing a donor because they had changed their name upon marriage, which one might consider to be something which happens relatively frequently.

Other difficulties of record-keeping are also

present in the documentation we have. If we could have DHSC0100113_017, please. It is a letter from June 1969 from the North East Metropolitan Regional Blood Transfusion Centre to Dr Maycock. There is a report enclosed of post transfusion jaundice but I would just draw your attention to the last paragraph:

"With reference to out other donor ... I am afraid she has returned to her native Scotland -- address unknown -- the search continues!"

So an example -- and we've drawn out examples of things that we've seen across a number of documents, but an example of a donor having moved location and therefore not being able to be traced.

If we move on into the 1970s, again we have evidence of both look-back and reverse look-back being carried out. One example is DHSC0100018_172, please. It's from the South London region, dated 21 March 1975, so a very similar form to what we were looking at in the 1960s and here we have at paragraph 8, point 8 on the form, the brief clinical notes of what had happened to the patient and, above it, we have a note of the bottle numbers for the blood that had been transfused, at point 7.

Then at point 11, there's a space for remarks.

We see there:

"All the donors have been re-sampled and tested and one of them, whose donation was given to the patient on 21st June, 1974, has been found to be very weakly positive by radioimmunoassay by Dr Dane. I think it is a fair assumption that this is indeed a case of post transfusion jaundice."

So this is simply one example of many of the process working and a report being provided, even in 1975, to the Department of Health.

A moment ago we noted the difficulties of resourcing being raised by -- in one case, in Wales. That issue reappears in 1978, February 1978. Although the minutes don't deal specifically with look-back and reverse look-back as being a difficulty for staffing, it's perhaps worth just noting that there appear to have been significant staffing issues. If we could go to NHBT0018353, these are the minutes of the Regional Transfusion Directors meeting of 22 February 1978 and if we turn to internal page 7, there's a heading "Medical Staffing":

"Directors discussed staff shortages in Regions and the number of times they'd advertised without result. Altogether they were 10 vacancies, including one Deputy Directorship. There were 2 vacancies in

Newcastle, Liverpool, South London and Bristol had one vacancy. Brentwood and Cambridge each had a vacancy, but had not received any applications. There was one vacancy at Cardiff."

So although this is not specific to look-back, it's an issue that has been raised in relation to look-back and reverse look-back and we see a broader context for that in 1978.

So drawing the threads together in relation to early jaundice investigations, we've identified a reporting system was in place but there are four themes that arise from the documents that I wanted to highlight today and I hope I've done so through the documents. There were difficulties arising from clinicians not reporting all cases of post-transfusion jaundice, or serum hepatitis; there were difficulties with record-keeping, in particular the noting of donor numbers and batch numbers; there were problems surrounding whether donors responded to the blood services contact and with keeping up-to-date with the contact details of donors; and there were resourcing problems and staff shortages.

So that then takes us on to hepatitis B look-back processes. Addressing that now, because it straddles the early jaundice enquiries but it also

goes to a point beyond the hepatitis C look-back, and we'll see what I mean by that, but it's convenient to deal with it now because it ties into the early jaundice enquiries. But I expect it is something we will come back to at a later point as well. It is simply to set some of the basic position in place.

Once hepatitis B was identified then investigations into post-transfusion hepatitis B was taking place much as they did with post-transfusion jaundice. It really merges in the documents to exactly what was just being dealt with as post-transfusion jaundice and then what was specifically being dealt with as hepatitis B, in and of itself. Very similar issues arose in relation to those processes as we've already identified.

First of all, if I can pick up some of the documents that deal with difficulties around batch numbers, record-keeping and tracing of donors. If we could have DHSC0100018_056, please. Here we have a report from Dr Maycock to a Dr Cuthbert dated 19 September 1974, attaching four reports of hepatitis in patients associated with transfusion. In the first example he notes:

"There seems little doubt that this is a case of hepatitis B and a donor was found on retest to be

positive for [hepatitis B antigen]."

So an example of a successful reverse look-back. Then we have the fourth case:

"This patient clearly had hepatitis B for which the fibrinogen may have been responsible. Unfortunately no record of the batch number was kept."

We then come into 1985 at NHBT0115650_303. We have a letter from -- sorry, we have a letter from Dr Hewitt to a Charing Cross Hospital senior lecturer in haematology, dated 26 November 1985, which records that:

"In May 1984 you reported to us a case of probable post transfusion hepatitis B in this patient."

She explains what had happened, and then says:

"In view of the high probability of post transfusion hepatitis B in this case, we attempted to contact and resample all the involved donors. A total of 28 donors have given repeat samples and none has any marker of past hepatitis B infection. Unfortunately, we have been unable to contact the remaining 4 donors, all of whom are young males and who have not responded to letters or attended any blood donor clinics in the interim, despite requests to contact us. We are making one final effort to

contact these four in an attempt to close this enquiry. I apologise for the long delay in sending this report to you, but unfortunately we have been unable to reach a definite conclusion."

So again, once it was a more specific matter of hepatitis B rather than the general jaundice enquiries, we see ongoing difficulties of contacting donors and difficulties around batch numbers.

We then come to a series of letters from 1990. In June 1989 a patient had died, and at that point the North London Regional Transfusion Centre were notified that the patient was suffering from hepatitis B. There was then a delay of a year before BPL were notified of the infectivity of the plasma that the patient had received.

For the purposes of today, we don't need to go into the detail of how that one-year delay arose, but out of that incident Dr Hewitt undertook a review of post-transfusion hepatitis B reports across the period of 1986 to 1989, and it's that report that I want to go to.

The document is NHBT0003770, please. It's a report she made to Dr Gunson, and if we pick up at the second paragraph, please:

"Between 1986-1989 there are a total of 14

reports of hepatitis B to us which we felt were likely to be associated with blood transfusion. As you will see, we investigate 3-4 cases of possible/probable post-transfusion hepatitis B each year. Two of these ... were felt to be due to transfusion abroad and no recall of NLBTC donors followed. In a further two cases ... there was no donor follow-up because the reports involved an incidental finding of HBsAg positivity in a multi-transfused recipient, without any indication of date of seroconversion (or indeed, proof of a previous HBsAg negative status).

"In 8 of the remaining 10 cases, an attempt was made to contact all involved donors. The response rate was high, although not complete. In 3 cases, all resampled donors were negative for HBV markers ... and in other 3 one resampled donor was anti-HBc positive ... and withdrawn as 'possibly implicated'. One case ... was predicted by us, when a donor was detected HBsAg positive at the next donation, the previous donation was subsequently confirmed HBsAg negative. This donor was obviously in the early infectious stage of hepatitis B infection, but below the level of detection in [surface antigen] screening tests, at the time of the implicated donation. The final case ... has been fully documented.

"This leaves 2 cases ... where the numbers of donors involved were huge, and recall of all donors thought to be logistically impossible. Examination of records revealed a common donor, found to be anti-HBc positive on recall."

Anti-HBc positive on recall.

"Thus out of 14 documented cases in 1986-1989;

"4 - not investigated for reasons given

"5 - 'implicated' donor anti-HBc positive, HBsAg negative

"3 - no HBV markers identified in resampled donors and no donor implicated

"1 - donor in early stage of HBV infection, but HBsAg negative.

"1 - donor had low level of HBsAg.

"This summary indicates that the checking of original HBsAg results on donors involved in PTHB enquiries is unlikely to be of help to BPL in deciding the fate of 'held' products. Our latest report to BPL involving 183 donors and 120 plasma donations forwarded to BPL required 15 hours of Senior Scientific Officer time to check original HBsAg results. If the checking of previous HBsAg test results is now to be part of BPL's requirements, we shall obviously require additional resources!"

So again what we see in this report, which was the survey of a period of 1985 to 1989, are issues arising in relation to tracing donors and, at the end, concerns about resources and the work required to be able to do this sort of work.

There are other examples of investigations into hepatitis B being delayed.

If I can turn up NHBT0023823, please, Soumik. It is a letter from February 1995 which addresses in the first paragraph that:

"This [was] a jaundice enquiry that has been going on for almost three years now."

It's explained that in this case it related to bone marrow that was stored in a liquid nitrogen tank while infectious and it was then transmitted to other patients. So it is slightly different but the purpose of showing this document, sir, is paragraph 2:

"We thought we had solved the problem on two occasions, but both donors have proved to be negative of subsequent retesting. I am writing to you now because Richard Tedder asked me to go through with a fine-tooth comb all our non attending donors, and I am ashamed to see that I now see what I should have seen before - that four of those donors live in South London."

And so contact was being made.

If we just go over the page -- sorry, one further page -- we can see just an apology at the end:

"... I am really sorry that these donor addresses hadn't 'clicked' with me earlier - my only excuse is that we have closed (and reopened) this enquiry on at least three occasions, as new evidence has come to light - not to mention new lists of donation numbers from UCH. However I have now written it into my procedure that I must check the addresses of lapsed donors in case they are attending you or Colindale."

Sir, the point, really, of picking up this document is simply the fact that some enquiries took a number of years to complete and there were, again, difficulties of identifying donors and donor addresses in order to be able to complete those processes.

A further example of that, even into 1993, NHBT0010671, it's a letter from a Dr Herborn, a consultant haematologist, to Dr Gunson, about a "Donor who has probably caused post-transfusion Hepatitis B":

"Thank you for your advice concerning this donor. As I mentioned on the telephone, he is now linked with two cases of post-transfusion Hepatitis B.

His tests for [hepatitis B surface antigen] have always been negative but he has anti-HBc. Unfortunately, we ran out of serum and could not test him for anti-HBs.

"I wrote to him three times and the third letter has been returned by the Post Office marked 'Not at this Address'. He is not registered with a GP and there does not seem to be any way we can contact him. I wrote to a Doctor in each of the UK Transfusion Centres."

So, again, a further example in 1993 of difficulties of contacting donors and identifying where they were.

In 1995, a study into the incidence of hepatitis B in the donor population was undertaken. The purpose of the study was said to be to assess the transmissibility of hepatitis B in blood donations negative for hepatitis B surface antigen but positive for antibody to hepatitis B core. The study was planned so that it took place after the hepatitis C look-back. So we are a little further on in time.

The study went ahead after the hepatitis C look-back but it's clear that the look-back exercise that then followed wasn't straightforward, partly because of difficulties with accessing medical

records. I just want to go through a few documents dealing with this particular study.

If we could turn to NHBT0012414, please, and if we can go to page 3 to start with, please. We have a letter from August 1996 from a consultant haematologist to Dr Hewitt about the hepatitis B look-back study and it records this:

"A small start! These are the four unit number proformas for those blood components sent to the Atkinson Morley's Hospital. The blood bank at AMH was closed down 2 [and a half] years ago. We can trace three of the units, but one has sunk without trace; no records exist of its fate either in AMH records or our own at St George's (blood was transferred down here after two weeks at AMH, and you resupplied AMH with newer units).

"I am returning all four report forms. The St George's reports will take some time to come through. There are 82 of them, and all the old record books have to be gone through to pick them up -- it's laborious!"

To which Dr Hewitt replied, it's the second page of this document, please:

"Thank you very much for the forms ...

"Please could you bear in mind that we can offer

help going through old record books, if your laboratory staff would feel that an additional person would indeed be a help and not a hindrance! The majority of hospitals are able to complete this task quite easily, because the records are on computer. If this is not the case at St George's, then we would do everything possible to lighten the load on your staff", and they were expecting to employ a student who might be used for it.

So, again, we see in 1996, in the hepatitis B look-back study, difficulties being raised in relation to medical records at the hospital level for exactly what had happened to blood components.

We then continue to NHBT0030267_002, please. We have a report form around red cells that had been issued to Lewisham, and we can see handwritten on this very first page "untraceable". If we turn the page, we can see at the top that there are records available to identify receipt of the component and the fate of the component, that it was transfused to a patient. But if we go to point 5, we can see that, in relation to the patient's surname and forename, it's simply written "Unknown male" and then a note on the side, "[Patient] transferred to another hospital from [A&E]".

So again another example of the limited information that was being identified in relation to some recipients and it's perhaps helpful to look at a draft report of the study from October 1996, NHBT0007899, please. It's an update that was given to the MSBT 10th meeting. So it's an update on the study as at 14 October 1996, and the key part of it, for our purposes today, is part 2, "Recipient tracing" where we can see the number of components, in relation -- the first column is in relation to South Thames, the second column is in relation to East Anglia.

We can work our way through identifying the number of components in South Thames was 1,122 and, at that stage, information was awaited on the fate of 576 components. Information that was awaited on patients was 403 in South Thames, whereas in East Anglia there was just 204 components, of which 4 the fate of the component was awaited and nothing was awaited in relation to particular patients. But the other figure to note, of course, is also the "no notes available", there were three components in East Anglia where no notes were available, and it simply gives an indicator of some of the successes and difficulties of the recipient tracing.

The final document in relation to hepatitis B

that I want to go to today is NHBT0016619, please. It's a letter from 2009 from Dr Hewitt dealing with a notification that had been given about a patient with acute hepatitis B, diagnosed in December 2008.

The second paragraph records that:

"We forwarded to you a notification form on 9th February 2009, requesting details about the infected patient, the test results, and a copy of the transfusion laboratory record for the patient in question. To date, I have not received any of this information."

According to the email, the patient had undergone cardiac surgery and an orthopaedic procedure. They had received two units of blood products on each occasion and the donation numbers were quoted.

"Whilst awaiting the further information, we identified the 4 donations listed in [the] email and established that all 4 donors had re-attended at least once since the donation transfused to patient [X] in the summer of 2008. The archived samples from all 4 subsequent donations were retrieved and tested for the presence of anti-HBc. All 4 examples were anti-HBc negative. These results exclude any of the donors as having been infected with hepatitis B. The

4 blood donations listed in [the doctor's] email cannot therefore be implicated as a source of hepatitis B infection in patient [X].

"I would stress that we have not received the minimum information necessary in order to document the details of this case. In particular, donation numbers have been provided in an email and not from a computer laboratory print-out. We therefore cannot vouch for the accuracy of the donation numbers provided to us.

"If you could now provide the information requested, we can include it in the file and confirm that the correct donations have been investigated. Otherwise, I am now closing our investigation with the conclusion that patient [X's] hepatitis B infection was not due to the transfusion of the 4 units of 'blood products' notified to us in [the doctor's] email. We have assumed that the blood products in question were red cells."

As a final document in 2009, it's simply to note again the difficulties of that communication between the hospital and the blood services.

Sir, I am about to move on to HTLV-III look-back but I note the time. I am happy to start and then break or whatever you would prefer.

SIR BRIAN LANGSTAFF: Let's take a break now and have it

all in one go. So we'll come back, shall we, at 3.35. 3.35.

(3.05 pm)

(A short break)

(3.36 pm)

SIR BRIAN LANGSTAFF: Yes.

MS FRASER BUTLIN: Thank you. In this third and final part of the presentation, we're going to just be looking at the HTLV-III look-back. We are, of course, going back in time from where we were in relation to hepatitis B.

Initially, we can see that HTLV-III look-back work was undertaken much the same way as for post-transfusion jaundice. If we can have DHSC0006923_071, please, Soumik, we have a -- sorry, we have a letter from -- a draft letter from Dr Gunson to Dr Galbraith, dated 3 April 1984, which says:

"The Regional Transfusion Centres already have systems available for the follow-up of donors who are implicated in patients who develop Transfusion Associated Hepatitis. I do not see that fundamentally the proposal to follow-up donors implicated in patients who develop AIDS or the follow-up of donations given by persons who subsequently develop AIDS is significantly different. From this point of

view, therefore, I am sure that you would have full co-operation of the Regional Transfusion Directors in this matter."

The next day from that draft letter, there appears to have been a meeting between Dr Galbraith, Dr Gunson and Dr McEvoy. That's on 4 April 1984. If we could have CBLA0001833, please.

Here we have a note of the meeting setting out a process that was to be followed. Point 1:

"CDSC will inform the appropriate RTD when a patient is diagnosed with AIDS; if the patient admits to donating blood, contact will be by telephone.

"Investigation will be undertaken to find out whether the person is registered as a donor.

"If the answer is NO, CDSC will be informed.

"If the answer is YES, further action will be:

"Trace the fate of blood donations, with respect to all products, given during the previous FIVE years.

"If plasma has been sent to BPL for fractionation Dr RS Lane will be informed as soon as possible.

"The appropriate hospitals should be asked to identify the patients who received the blood products, provide any information they have on the subsequent

progress of the patients and the name of the patients' family doctors.

"Subsequent to consultation with the Defence Organisations a communication will be sent to the family doctor informing him of the circumstances and a copy of the letter sent to CDSC who will carry out any further follow-up."

We're going to pick up that point in a moment, sir. So if we just hold that in our minds, the process then continues:

"CDSC should be kept informed of progress."

Then a reverse look-back situation is addressed in part 2:

"CDSC will inform the appropriate RTD when a patient is diagnosed with AIDS who has stated that he/she has received a transfusion of blood and/or blood products.

"If the patient has received blood products derived from pooled plasma which may involve a large number of donors, Dr McEvoy will discuss with the RTD the practicalities of follow-up within the resources available. If the patient is a haemophiliac, Dr Craske, Consultant Virologist, PHLS, Manchester will also be involved. If the patient has received NHS products derived from pooled plasma, Dr Lane will

be informed.

"If the patient has received blood products which have been prepared and issued from the RTC the following action will be taken.

"Identification of the donors from whose blood the products were prepared.

"Again, after consideration of the practicalities of the situation with respect to the particular case in discussion with Dr McEvoy, it may be necessary to recall the donors for:

"(a) Interview and medical examination.

"(b) Collection of blood sample to carry out non-specific tests.

"Where this is done and by whom will be at the discretion of the RTD.

"If none of the donors involved fall into high-risk groups for AIDS, CDSC will be informed.

"If any donor is suspected of having AIDS then referral should be made for further medical examination and an investigation carried out with respect to previous donations as detailed in paragraph 1.3 above."

The point I flagged just a moment ago at 1.3.4, "Subsequent to consultation with the Defence Organisations a communication will be sent to the

family doctor", that issue was raised again at a meeting of the Regional Transfusion Directors on 11 July --

SIR BRIAN LANGSTAFF: Just before we leave that last page, can we just go back to the second page. It's little (b) at the top of the page, 2.2(b), "Collection of blood samples", so this is from a suspected donor?

MS FRASER BUTLIN: Yes.

SIR BRIAN LANGSTAFF: The suggestion is there may be a collection of blood samples to carry out non-specific tests. So one wonders whether the implication of that might be that the donor isn't told what the tests are for.

MS FRASER BUTLIN: It's not something I can address.

SIR BRIAN LANGSTAFF: No, it's without there being specific evidence on it, it's -- if what people are looking for here is HTLV-III or indicators -- this being, what, April '84 -- indicators that there may be T cell abnormalities, difficult to know why it should be non-specific.

MS FRASER BUTLIN: Well, sir, it might be non-specific in the sense that the donor isn't told or it might be non-specific in that it is general tests that there isn't a specific test that they are recommending.

SIR BRIAN LANGSTAFF: It is not anyone speculating that

that means that there was a recommendation to carry out tests, pulling the wool over the eyes of the donor is actually reading too much into it.

MS FRASER BUTLIN: One simply doesn't know, sir.

SIR BRIAN LANGSTAFF: Yes, thank you.

MS FRASER BUTLIN: In terms of the reference to the defence organisations and a letter going to the family doctor, we pick that up at the Regional Transfusion Directors meeting of 11 July 1984, DHSC0002245_002. It's the second page of these minutes, under the heading "AIDS":

"Dr Gunson had approached the Medical Defence Union. Their reply was that an adequate precaution if a patient had been given 'at risk' blood was that the General Practitioner should be informed in confidence. Previous experience with cases of venereal disease in donors led some members to doubt this procedure.

"It is possible that a DHSS working group will be set up and legal implications could be considered."

We can then turn to the first meeting of the advisory committee of the NSBT working group on AIDS, and we're going to look at a memo recording what happened at that meeting. The memo is dated 27 November 1984.

It's DHSC0002251_011, please.

The memo is written by an ME Abrams from Med SEB to a Dr Harris, simply noting what the committee had discussed, and under (vi) it was noted that:

"Donors should be told that HTLV-III testing will be added to the other tests done."

We're now in November 1984:

"Donors with positive tests should be told the answer -- although no unanimity on who should do it or how. Follow up of such donors and patients, and counselling, and contact tracing arrangements etc are being considered by IMCD. There are very difficult and complex issues to be taken on board: one suggestion was a regional immunology service to deal with all this at special centres."

We then see much more formalised processes becoming a part of the discussions within the meetings about screening of blood donations.

So if we go on to a meeting of the Regional Transfusion Directors dated 10 July 1985, at CBLA0002212, we can see at the top of the document the date, and then if we go over to the third page, under the heading of "AIDS" there was a report on a number of meetings:

"It was felt not essential to have the GP's name in all instances but that all donors must be informed

that testing will be carried out."

And there's discussion of a leaflet.

"Obviously HTLV-III positive donations would be destroyed. The initial approach to such a donor would be from the NBTS and afterwards counselling would be essential. We look to the Expert Advisory Group for guidelines but GPs should be involved, with the donor's consent."

If we go over the page:

"It was agreed that follow up of previous donations of plasma should be for 3-5 years.

"The Chairman requested the approval of the Meeting to let the Group draft a flow diagram for AIDS testing and following up of donations. The meeting tomorrow will, if given approval, pass on recommendations to the Expert Advisory Committee and save considerable time."

So at this July 1985 meeting is the point at which a much more structured discussion is starting in relation to following up of donations.

And we see then the meeting of the working party the next day, there was discussion about look-back.

DHSC0000406. It's internal page 4, please. Under point 7, headed "Follow-up of recipients of previous donations given by donors found to be

HTLV-III positive":

"7.1. Efforts will be made to determine the names of any patients who received blood and components from the donations taken during the past five years and the information regarding the known or possible seropositivity of the donation given to the Consultant in charge of the patient.

"7.2. If plasma from any of the donations was sent for fractionation, full follow-up of all patients receiving coagulation factor concentrates may be difficult or impossible. Since patients suffering from haemophilia A and B are being investigated for anti-HTLV-III at present, it is recommended that no additional follow-up be carried out."

That position was modified slightly by the expert advisory group on AIDS on 30 July 1985.

PRSE0002628, please. It's internal page 5 please. I'm sorry, before we go there, we can see that the meeting was 30 July 1985.

And then internal page 5, under the heading 7.4.3, "Follow up of blood donations previously given by donors who are identified as positive for HTLV-III":

"[X] said that the Screening Sub-Committee had recommended that the haematologist in charge of the

hospital blood bank should be informed if it was believed that an earlier donation could have transmitted HTLV-III infection. The haematologist would be asked to identify the recipient of the suspect donation and to inform the clinician in charge of the case when the blood had been transfused. The BTS was aware of the importance of good record keeping to enable the follow up of donations. It was suggested that these follow up investigations would provide a good opportunity to check on the transmission of the virus between spouses and from female to male, and a national registry would be useful. Members agreed with the Sub-Committee's recommendations and considered that it would be up to the clinician in charge of the patient to decide on what subsequent investigations should be made. It was also agreed that, although there might be practical difficulties, the follow up for donations, should go back a minimum of five years from the date of the donation."

From the evidence that was given to the Penrose Inquiry, it appears that the five-year rule was also used in Scotland, and we have seen nothing that suggests that that's not the position. We have had statements from the Northern Ireland Blood

Transfusion Service, the Welsh Service and the Scottish Service. All of those indicate that the four nations operated the HTLV-III look-back procedure together, and it was a more centralise and structured process than the earlier hepatitis look-backs, and so it was a four nations process.

SIR BRIAN LANGSTAFF: This is a five-year from the date of clinician.

MS FRASER BUTLIN: Yes.

SIR BRIAN LANGSTAFF: So if one is looking at a blood product, it may be as much as seven years ago?

MS FRASER BUTLIN: It could be, indeed. Although you will note the difficulties highlighted in the earlier document in relation to blood products, and whether that was, in fact, feasible or not.

SIR BRIAN LANGSTAFF: So probably this is related to transfusion as such?

MS FRASER BUTLIN: I think that would be a fair reading of the document, sir. It's certainly a conclusion you could reach.

It is clear, however, that there was an issue about donors who self-excluded from donating and wouldn't then become known to the blood services subsequently. Dr Hewitt has raised this point in her witness statement and I'm sure we will explain that at

a later point, but I raise it now simply so that I can take you, sir, to the minute of a meeting of the expert advisory group on AIDS of 26 November 1985.

The document is DHSC0001736. So it's 26 November 1985. And if we turn to the final page, page 12, under the "Agenda item 16 Any Other Business" we see:

"Dr Tedder, on behalf of Dr Contreras asked clinical members whether they would consider asking sero-positive patients as a matter of routine if they had donated blood since 1978 and where blood had been donated, if they would refer their patients to the Regional Transfusion Centre in order that recipients of donations could be followed up."

So we see him asking, and it appears at that stage unresolved, whether those who were identified as being HTLV-III positive should be asked about having given blood so that a look-back process could be followed in relation to them as well.

We have identified a number of examples of the notification process and the look-back process operating as expected from those meeting minutes, but I want to just look at one particular example now.

CBLA0000010_209, please.

It's a letter from October '84 from the deputy

medical director of the Wessex Regional Transfusion Centre to Dr Snape:

"To confirm Dr Smith's and my own telephone calls to you within the last day or two. We have been informed that one of our male donors has been admitted into a Bournemouth hospital; the clinical diagnosis is, almost certainly, AIDS."

Then he gives the details of his previous known donations, and we can see that the first one:

"Donation not used. Time expired plasma pooled and sent to BPL ..."

The second:

"Whole blood donation sent to one of our Portsmouth hospitals not returned ..."

Third:

"FFP sent to BPL [giving the batch and pack number]. Plasma reduced blood sent to one of our Portsmouth hospitals and not returned ..."

Then fourth:

"Plasma separated and frozen."

This was a very recent donation.

It indicates at the end of the letter:

"Regarding Donations 2 and 3. We are not getting in touch with the clinicians involved until the diagnosis is confirmed."

But the indication is that they have -- or one might read the letter as suggesting they have identified who the clinicians for those patients are and once -- if the diagnosis is confirmed, then they would be getting in touch with the clinician.

This is then picked up in a further subsequent report.

Apologies, sir, if I can just take a moment.

Yes, a fuller report of the incident was prepared in October -- later, in October 1984.

DHSC0001111. If we can start at page 2, please. Yes.

We see on this page a note of the "Donor condition and products affected", but if we then go on to the second page, the next page, the third page of this document, we see under the heading "2. Actions to secure/recall implicated products", and we see that:

"Dr Smith (Wessex) was informed of [the] implication of [the batch] ... and was asked to recall all vials including any held by patients for home therapy.

"Dr Napier ... was unavailable but Mr Booth ... was informed ... and was asked to recall all vials ... including home therapy issues.

"Both telephone conversations were confirmed in writing ..."

It goes on to explain that various batches were then held pending investigation. Then on the next page, we have a record of the results of the Factor VIII recall and we can see that 400 vials were despatched to Cardiff, broken down in that way: 150 were held at the RTC; in relation to Heath Park 101 out of 150 were recovered; Morriston 51 out of 60 were recovered; Carmarthen, 36 out of 40. So:

"A total of 338 vials was recovered; 9 patients received the batch."

And we get similar information in relation to Wessex.

We then have a note under "Follow-up actions":

"Dr Smith ... was asked to report any plasma from this donor despatched to BPL (or PFL) within the last 5 years. Dr Smith was also asked to determine whether the donor had a history of attendance at local special clinics more venereal disease."

Then, finally, there are, on the last page, observations on the incident and there's just one paragraph that I think is worth highlighting here, and that's paragraph 5.3:

"The appearance of this donor at three different

Centres within two years clearly underlines a fundamental problem when carrying out follow-up of donor incidents of this sort. Surely central co-ordination of donor records is unavoidable."

That's the view of Dr Snape.

Before we leave that document, I just want to highlight the second page, with the heading of the report, so that the next document makes sense. It's noted that it's a summary report on the recall of the batch HL3186, and we see this picked up again in the document CBLA0000010_202.

This is a letter in 1988 from Dr Craske to Dr Lane dealing with batch HL3186, and the second paragraph:

"The follow-up we were doing eighteen months ago of this incident was bedevilled at that time by the reluctance of Haemophilia Centre Directors to cause, what they considered to be, an unnecessary worry to their patients, so that a follow-up of the recipients who received this product has not been carried out in the formal sense."

There then was reference to a paper that had been published and Dr Lane's letter had prompted Dr Craske to reopen the enquiry. Unfortunately, at this point, we have not been able to trace that letter

from Dr Lane. Efforts are ongoing but, in the fourth paragraph of this letter, Dr Craske says:

"Your letter prompts me to re-open this enquiry, as we [don't] know the outcome of patients who received this and other batches which may have been contaminated with HIV. I will consult my files and let you have a report as to what is known at the present time."

The point raised by Dr Craske in relation to the Haemophilia Centre Directors is a point that's raised also by Dr Rejman in 1992. He had prepared a memo to Mr Canavan. It's a memo dated 6 February 1992, DHSC0002585_004.

We can see on the second page of the memo that the context of it is about financial assistance and we can see that in paragraph 7. But the paragraph I want to draw your attention is paragraph 4 on the first page, which notes that:

"... I think it is important to remember what happened to the original 'look-back' pilot suggested by EAGA. There was considerable resistance from some Consultants to inform recipients who might be at risk of HIV, and various reasons were put forward for this including (i) not being of any benefit to a patient who was likely to die from his primary disease in the

near future and (ii) the distress that could be caused to a patient or his family of knowing that he was infected with HIV, when he was actually dying of another disease. There was also opposition from some local ethical committees on similar grounds. It is possible that the prospect of financial gain may make 'look-back' easier on this occasion."

So it's noting, in this context in relation to blood transfusion in tissue recipients that Dr Rejman's understanding at that time was there had been resistance in relation to informing recipients of their risk of HIV.

The question of the reluctance of clinicians is also highlighted in two further documents, one of which is more contemporaneous. It's December 1985 from a consultant -- between -- sorry, let me start again.

It's a document, a letter, from 1985 between two consultant haematologists, which gives us some indication of at least what one person's view was in addition to what we have already noted. It is NHBT0011051_010, where it's noted that the screening process had started and it was agreed that if any positive donor was found their previous donations would be traced. One such donation had been

highlighted to them and, in the middle of the second paragraph, this haematologist indicates:

"I personally am not quite sure what the Transfusion Service hopes to achieve by this type of follow-up but I am told that it would be helpful if you could find out who received the donation and inform the Consultant in charge of the patient of this finding. I have to ask you to ensure that the recipient is not told because the worry inflicted on the poor recipient would be out of all proportion to the possible risk."

We then have an epidemiological study that was being run from 1986 from Bristol and there are a number of documents from that epidemiological study that I want to go to now.

The first is DHSC0002480_047. This is a letter from Dr Wallington, who was running the study, to his colleague, setting out the nature of the study that was being proposed. It's a letter that went to the Regional Transfusion Centre Directors and it explained the need for further research. If we look at the end of the first page, we can see that he notes the following:

"Some patients will have been infected by transfusion in this country, but as yet they have not

been identified. Most of these will not belong to the high risk groups and will therefore provide an opportunity to study how this virus spreads, if at all, outside of the high risk groups. It can also be argued that these people and their close contacts should be identified and counselled for their own sakes. As you know it has been agreed that an attempt be made to identify and study these patients and their household contacts."

He then notes that:

"The project will be co-ordinated from Bristol but is totally dependent on considerable work on the part of each Regional Transfusion Service and other health service staff who will have to be contacted at the regional level."

He goes on towards the end of the letter to say:

"[He looks] forward to receiving details of both donors and patients whose permission we have to contact. Perhaps we could start with enquiries based on the donors picked up by screening since last October 14th, there are also instances in which patients infected by blood transfusion have brought the problem to light and a donor can be found by back tracing."

The focus of the study is set out rather more

clearly in a letter to Dr Gunson in May 1987. The document is NHBT0004202. It is the first paragraph where you see him set out the point of the study:

"As you knowit has been agreed within the NBTS that an attempt be made to identify, help and investigate patients who have received transfusions which might have infected them with HIV, also where necessary their household contacts."

If we turn the page, he sets out, in the second paragraph, what he terms "Task Two", the "Yellow sheets", which are the recipient tracing and study, and he says:

"... I have been questioned much more vigorously on the ethics of this part of the study than on Donor tracing, people have been very worried about the idea of approaching blood recipients a proportion of whom will be well and unsuspecting with such a dread diagnosis and even more in doubt about investigation of household contacts. Opinion has been changing rapidly and most people now believe that infected persons should be identified whenever possible for public health reasons. As this part of the study will undoubtedly prove controversial I think colleagues in Haematology should be fully informed before being presented with notification of a donation thought to

be infectious."

So what I would suggest this document highlights is that there clearly was an ongoing controversy about whether recipients should be informed of the risks, as we saw in earlier documents.

Then what we have -- sorry, sir. The next piece of correspondence that we should go to is a response from Dr Wallington to Dr Gunson in 1991.

What appears to have happened is that concerns were raised in January 1991 by Dr Contreras that nothing had been heard about the study despite her sending a lot of data, and what we then have is the response from Dr Wallington in relation to that.

The document is NHBT0004810.

What Dr Wallington says in the second paragraph is:

"I think that Marcela's [Dr Contreras'] letter expresses a reasonable concern. I have so far received data on 84 donors on the comprehensive questionnaire that she mentions. North London and one or two other Regional Transfusion Centres including the Manchester Centre have continued to send in completed forms. Certain Transfusion Centres have never sent them. Scotland has never participated apart from a few forms from Edinburgh."

Then there is some discussion of other data gathering exercises that had taken place, and towards the end of the letter he says:

"I think at this stage we should abandon the study as I do not think that we will learn more from it that is not being learnt from other data gathering efforts."

Then the final page:

"As you are well aware the look back element of this study never got off the ground, people were simply unwilling ..."

Exactly what they were unwilling to do, whether it was the participation in the study or undertaking some element of the look-back process is unclear from the letters, and that is something we will need to explore further.

But it perhaps suggests that there were difficulties in the -- both -- there was controversy in relation to informing recipients and there was difficulties in obtaining data from transfusion centres of exactly what was being done and who had been traced.

The difficulties with look-back exercises are also exemplified in a study by Dr Hewitt, Dr Moore and Dr Barbara which was discussed at the IV International

AIDS conference in June 1988 in Stockholm. The reference is NHBT0057880.

We see here the "Objective", which was:

"To trace past recipients who might have received blood components infectious for HIV.

"... Donations were traced for 3 categories of donors: (i) current donors found positive for anti-HIV, (ii) ex-donors reported positive, (iii) donors implicated in cases of transfusion-transmitted HIV. Hospitals were notified of involved blood components, traced their fate and blood samples were obtained from living recipients wherever possible.

"Results. Previous donations had been given by 9 of 17 current donors, 4 ex-donors and 2 identified as anti-HIV positive through infected recipients. Of 44 blood components made, 6 were unused, 9 not traced by the hospital and 4 incorporated in plasma pools for Factor VIII. Of recipients who could be traced; 11 were deceased, 8 were not infected, 3 were anti-HIV positive and 4 were not tested. Seven recipients were notified as infected. In 2 cases donors were implicated, 2 cases could not be solved despite contact of all available donors, 1 could not be pursued due to inadequate hospital records and 2 are incomplete.

"Conclusions. These investigations are time-consuming. Hospital records are often deficient. The benefit produced by these enquiries has been little, but 3 blood recipients have been identified as seropositive and spread to their sexual partners possibly averted."

That's obviously an extract of a conference paper that was given, but it gives us some indication of the conclusions of the work in relation to that material.

We have a further report by Dr Hewitt from 1993, DHSC0006351_032 in tab 107.

At DHSC0006351_32, if we start on page 1.

So we can see there the date it was received by CDSC, in July 1993, and then if we go over the page we have the "Abstract", which indicates the "Objective", which was:

"To study the transmission of HIV by blood donated from individuals subsequently identified to be infected with HIV."

And the "Design" of the study, it was a:

"Retrospective study of previous donations from individuals subsequently identified as infected with HIV. Investigation of donations from individuals believed to have transmitted HIV infection by

transfusion. Investigation of donations transfused to recipients later found to be infected with HIV. In whom the only identified risk for infection was blood transfusion."

Then if we go down to the "Results":

"Five HIV infected recipients were identified, who had not previously been known to be infected. In addition, the RTC became aware of 2 recipients known to be anti-HIV positive but previously unreported. All infected in the recipients were transfused before 1985 with unscreened blood or components. Of the possible transfusion-transmitted HIV infections, one third were considered not due to transfusion, one third thought likely (without the identification of a culprit donor) and 5 donors were identified as likely to have been responsible for 6 reported cases. One case could not be investigated through lack of records and one is still under investigation."

What we note in the "Conclusions" are that:

"Investigations failed to reveal any infection arising after screening of blood donations commenced in 1985 [in this study]. Overall, 42% of identifiable recipients died within 6 months of transfusion. Eight of 32 ... living recipients were infected with HIV and 5 of these were newly detected through the

investigation. Laboratory record keeping was generally deficient prior to 1985; accurate recording of transfusion details in patient medical records remains a conspicuous problem up to the date of the report. The investigation confirms the exceedingly small chance of transmission of HIV by transfusion of screened blood and blood components ..."

So, again, something that was highlighted in relation to early jaundice enquiries: the difficulties in relation to both laboratory record keeping and patient medical records and the challenges that that gives rise to in a look-back process.

It's perhaps instructive to go into the detail of this study in relation to one element and that's internal page 11.

Under the heading "Discussion":

"The investigation of possible transfusion-transmitted infection is extremely laborious and time-consuming. Investigation must be both thorough and methodical. This involves work for the RTC, hospitals, General Practitioners and FHSAs. Meticulous checking of the records at the RTC and hospital laboratory is necessary to ensure that the relevant donation is traced to the correct recipients and recorded in the patients' medical notes. It is

not uncommon to find that a hospital laboratory has records of issuing a donation for a particular recipient, but the medical notes contain no information about the donations transfused. Such an omission obviously leaves room for doubt when investigating possible cases of transfusion transmitted infection. Hospital laboratory record keeping has generally much improved since the Health Circular relating to Record Keeping and Stock Control ... On the other hand, audits of blood transfusion practice continue to show gross deficits in the recording of information in medical notes.

"The majority of cases of transfusion transmitted HIV infection arise from blood transfusions given in 1982-1984. As record keeping was not satisfactory at that time, and usually related to non-computerised systems, it can often be difficult and time-consuming to retrieve information within the RTC, in the hospital laboratory and in the medical records department. Furthermore, recipients can be difficult to trace if no longer under hospital care. In many instances, recipients have moved home and are no longer registered with the General Practitioner caring for them at the time of transfusion. As

contact is made first through a doctor a significant amount of time is spent in correspondence with FHSAs, to trace the appropriate GP. Sometimes the RTC has written to five or six doctors in an individual case (haematologist, surgeon, physician, referring physician GP) without any of them wishing to take responsibility for notifying the recipient. Not only does this cause extra work, but it considerably delays the investigation. On occasion several reminder letters have been necessary before the RTC has been supplied with relevant information. The period between initiation and completion of an investigation can be as long as one year. The more distant the transfusion, the longer the investigation will take."

If we go to the next paragraph and just pick it up halfway through:

"It is of continuing concern to the BTS that there is no mechanism for checking whether a lapsed donor has subsequently been reported as HIV positive through the confidential reporting system operated by the Communicable Disease Surveillance Centre. The failure of professionals to ask individuals diagnosed as infected with HIV about prior blood donation and then to notify the RTC also leads to missed opportunities to identify all recipients infected with

HIV by transfusion."

So that was the discussion of Dr Hewitt in the study -- sorry, Dr Hewitt in 1993.

The final point I want to picked up in relation to the HTLV-III look-back is the issue of donors who didn't subsequently return to give blood and the difficulties that that appears to have raised and the documents in relation to that that have been identified.

If we could start with NHBT0099107, please it's a letter from 9 August 1991 from Dr Hewitt to a consultant paediatrician and if we pick up the third paragraph:

"Our usual practice in reports of possible transfusion transmitted HIV infection is to institute a search for the records of the relevant donors. This we have done. As you will know, routine screening of blood donations for evidence of HIV infection did not start until 1985. It was in September 1983 that the Department of Health issued advice about the exclusion of certain individuals from blood donation who might be at risk of HIV infection. It is likely that once we have traced the donors involved in [X]'s case, we will find that a proportion have donated since 1985 and will therefore have been tested for anti-HIV. Our

problem is what to do about the rest. It is possible that one or more of the donors ceased donating before 1985 in response to requests from the Blood Transfusion Service to self-exclude from blood donation. In these cases, especially if we have no recent record of an address, attempts at contact with these ex-donors have been singularly successful. We will, however, examine our records then determine what action is necessary."

SIR BRIAN LANGSTAFF: Do you think it should be "unsuccessful"?

MS FRASER BUTLIN: Yes, I read it twice, sir, and wondered if what was being said was that it "singularly successful", as in it was only successful on one occasion or occasional moments. It doesn't quite scan.

SIR BRIAN LANGSTAFF: I mean, that's the context, isn't it?

MS FRASER BUTLIN: It is.

SIR BRIAN LANGSTAFF: Otherwise, the context it to put "un" in front of "successful".

MS FRASER BUTLIN: Indeed.

SIR BRIAN LANGSTAFF: It's the use of the word "singularly".

MS FRASER BUTLIN: The letter goes on:

"Even if we decide to investigate no further, we strongly believe that all cases of possible transfusion transmitted infection should be notified to the National Blood Transfusion Service so that we may at least document the case."

Two final documents on this point, NHBT001 -- apologies, just give me one moment, sir.

Yes, only one further document, DHSC0014978_092, a letter from a clinical director of the South Thames Blood Transfusion Service to Dr Rejman in relation to a particular case:

"I fear that we're not going to satisfactorily resolve this case. Of the 23 donors implicated, there are 11 who are lost to follow-up. Attempts were made to contact these donors in 1986, but they failed to attend for further sampling when requested and have not donated subsequently. As it happens, a significant number were from a local college and had moved on."

So a further example of the difficulty if donors didn't re-attend.

Sir, will go to the final document, NHBT0015135_002, please. It's a letter from August 1998 from Dr Gorman to Dr McGovern, dealing with an application by a patient to the financial

assistance schemes and trying to track whether they traced the transfusions that they had received:

"Because (as you will appreciate) Ms [X] has received a very large number of transfusions, we have confined ourselves to identifying donors from two groups of donations ..."

They are then set out, and then we go to the last paragraph of the letter, where Dr Gorman says:

"However I feel that it is unlikely that all of Mrs [X]'s donors will either be contactable now or will have donated again since the index donation. This is not for any sinister reasons, but simply because a significant percentage of donors cease to donate every year."

Therefore, she suggests it should be going to the adjudication board in relation to the financial assistance scheme. So, again, a recognition from another consultant haematologist, Dr Gorman, that even without the self-exclusion of donors, there's a significant proportion of donors who simply don't return on a regular basis.

So that brings me to an end of the presentation on HTLV-III look-back, both in terms of its process and some of the difficulties that were identified by those undertaking it. There is, of course, a full

written presentation with a large number of other references and other examples of the things I have highlighted today on Relativity for Core Participants, and I understand it will be on the website, the Inquiry website, at a later point.

SIR BRIAN LANGSTAFF: Yes, well, thank you very much. So that's the end of your presentation today.

MS FRASER BUTLIN: That's the end of the presentations for today, sir.

SIR BRIAN LANGSTAFF: Tomorrow?

MS FRASER BUTLIN: There will be a presentation tomorrow in relation to Professor Cash.

SIR BRIAN LANGSTAFF: Yes. So that's a 10.00 start, Professor Cash, tomorrow.

(4.30 pm)

(Adjourned until 10.00 am the following day)

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