

Tuesday, 2 February 2021

(10.00 am)

**SIR BRIAN LANGSTAFF:** Good morning, Ms Richards.

**MS RICHARDS:** Good morning, sir.

**SIR BRIAN LANGSTAFF:** Good morning, those who are watching around the country. We expect again to have somewhere around about 200 of you at home.

Would you like to describe the circumstances in the room, Ms Richards.

**MS RICHARDS:** Certainly, sir.

I am here with one member of the counsel team, there's one member of the Inquiry solicitor team, there is Soumik, who will be displaying the rather large number of documents that we will be looking at today and tomorrow, and two members of the Inquiry team who are here to ensure the smooth running of the day.

**SIR BRIAN LANGSTAFF:** Now, today, we hear about the presentation about first Cardiff AIDS patient. This is something which was promised I think during the evidence of Professor Ludlam, and in part was responsive to his own personal investigations of what he thought had been the situation, but we have uncovered, you think, the facts derived from the available medical records such as they are.

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We then, as currently timetabled, have three weeks for the trusts and schemes. We are extending that by a week to include the week of 22 March. So there will be four weeks of evidence hearing from a number of key witnesses concerned with the Macfarlane Trust, Caxton, Eileen and Skipton, and we will publish a detailed timetable as soon as we can in that regard.

We intend to have a week's hearing looking at the four current devolved financial assistance schemes. That will probably be in May. The evidence and presentation that had been provisionally timetabled for the week of 22 March that relates to Treloars and a presentation on other haemophilia centres, smaller haemophilia centres, will now be in May, and then we will conclude before Easter with evidence and presentation relating to Belfast as currently scheduled.

**SIR BRIAN LANGSTAFF:** Thank you very much.

I hope that suggests plainly the full precise details will be given in due course but I thought it important to let you know that we are proceeding next week with some evidence about the Haemophilia Society. It's not very neat because, in one sense, the Haemophilia Society evidence might, you will have

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That's followed today by a presentation, the start of a presentation, about the Newcastle Haemophilia Centre. As I told you last time we met, Dr Jones will not be giving evidence. Tomorrow, that will conclude, but we ought, perhaps, just to have a look forward to the timetable thereafter because it may suggest something which may be misunderstood.

I think next week we have nothing but one witness for The Haemophilia Society scheduled and then we move on to something else, and that of course is not in any sense all the evidence we're going to hear about The Haemophilia Society.

Do you want to fill us in with details, Ms Richards?

**MS RICHARDS:** Certainly, sir. We're hearing from Mr Watters next week. We do intend to call other Haemophilia Society witnesses but for unavoidable reasons have been unable to timetable them for February, and so it's likely that those other Haemophilia Society witnesses will be called at some point after Easter and before the summer break. So the fact that we're calling Mr Watters next week is not an indication that we're not proposing to call other Haemophilia Society witnesses. We will do so in due course.

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thought, be heard in one batch, but it is important, as I said at the very beginning of this Inquiry, that we take the time we can as quickly as we can for obvious reasons, and it's convenient, as a matter of timing, to get this evidence heard and then we can move on rather than delay it until later.

Thank you, Ms Richards.

**MS RICHARDS:** So, sir, as you have outlined, I'm going to start today with looking at the position of the first Cardiff AIDS patient. We have seen repeated references in documents that we have looked at over the last few months of hearings to a patient in Cardiff who was understood to be the first haemophiliac in the United Kingdom identified as suffering from AIDS, and what was known and understood about others in relation to his case at the time may be relevant to decisions and judgments that you will have to make in due course, sir. And that's the reason for this presentation.

As you have already referred to, you will recall Professor Ludlam, who himself had no direct knowledge of the patient at all, suggesting that it might have been a diagnosis made on a single clinical observation and perhaps casting some doubt on the diagnosis and I hope this presentation will dispel

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those doubts.

First, however, it is important to give a name to the patient, he was Kevin Slater, and to recognise that for his family he was not and is not a case but a young man who had his whole life before him. He was just 20 when he first developed symptoms of AIDS and just 22 when he died. Kevin's older brother Paul was also tragically infected with HIV and died as a consequence of AIDS in 1991 at the age of just 30. Paul's partner, Lynda Maule, and his daughter Rachel Sharland, so Kevin's sister-in-law and niece, have provided statements to the Inquiry, and it is with their agreement that we identify Kevin and Paul by name.

Sir, because the purpose of this presentation is to cast further light on the state of knowledge of risk of AIDS to people with bleeding disorders, I'll be focusing upon the development and identification of Kevin's illness in 1983 and 1984, and how his condition was understood and presented by those who were aware of it. Thus, other than to note that Kevin was a severe haemophiliac who received a range of factor concentrates, we don't address today the source of his infection or cover other aspects of his life. But I wish to emphasise again for the benefit of his

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"Symptoms of reflux & dyspepsia related to food and bending over.

"NOT awake at night."

Then I think it says:

"Some relief with [and it might be] antacid."

It's not entirely clear.

Then this:

"Anorexia -- Lost 1 stone.

"Loss of energy.

"Sleeps all the time."

**SIR BRIAN LANGSTAFF:** May I just ask, just beside the "14/3/83", before you get to the words "Treatment Centre", there is a number. Is that 51 kilograms?

**MS RICHARDS:** That's what it looks like. Or it could possibly be 57, but that isn't --

**SIR BRIAN LANGSTAFF:** Either way, that's really quite a low weight.

**MS RICHARDS:** Yes.

**SIR BRIAN LANGSTAFF:** Because 51 kilograms would probably be just over 7 stones.

**MS RICHARDS:** Yes, for a young 20-year old man.

**SIR BRIAN LANGSTAFF:** Yes.

**MS RICHARDS:** Clearly the loss of weight, loss of energy, is a key feature of his presentation on that date.

We then see under previous medical history,

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family that we at the Inquiry have read everything that Linda and Rachel have been able to tell us about Kevin and Paul, about their lives and their deaths, and the impact of their illnesses and deaths on their families.

Sir, I'm going to start by looking at a medical record from March of 1983 relating to Kevin.

Soumik, could we have on screen, please, CVHB0000157\_482.

So we can see the first entry is a record from 1 December 1982 which records Kevin being seen in the haemophilia centre. There's a reference to a discussion of his management -- he was bleeding from his upper gum -- with Professor Bloom, and him being given 1,500 units of Lister Factor VIII. But the key entry for the purposes of the presentation is the entry that starts halfway down the page.

So Soumik, could we zoom in on the second half of the page, please.

It's the 14th March 1983. It's not always entirely easy to read the handwriting and, sir, I may call upon you for assistance in relation to some parts of the entry. We can see it says:

"Treatment Centre.

"Unwell since after [Christmas].

6

reference to:

"Hepatitis -- Haemophilia -- has required a lot of treatment."

And then I think next line, sir, reads:

"Sinuses washed out."

There's then a reference to various drugs, "some help".

"Allergies -- none."

If we turn over the page, we can see there's a reference to:

"[Smoking] -- none.

"Alcohol -- [half] a pint a night.

"Works as precision tool engineer."

Then, on an examination, this is recorded:

"Thin.

"Not ..."

And that might say "anaemic", but it's not entirely clear to read.

"Some inguinal nodes."

And then:

"Severe monilial infection of entire mouth & fauces."

Which would reflect severe Candida infection.

**SIR BRIAN LANGSTAFF:** Now the fauces is the back of the throat, isn't it, so if you open your mouth it's

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1 everything you can see right down the gullet.  
 2 **MS RICHARDS:** Yes.  
 3 **SIR BRIAN LANGSTAFF:** Yes, thank you.  
 4 **MS RICHARDS:** Then we can see there is then various  
 5 matters recorded. It looks like pulse, heart sounds,  
 6 "chest clear". There's then an abdominal examination  
 7 recorded:  
 8 "Some tenderness in [probably] epigastrium."  
 9 Then if we look further down we can see it  
 10 says:  
 11 "Probable -- (1) Reflex esophagitis."  
 12 And then:  
 13 "(2) ??"  
 14 And then that probably says "Immunologic".  
 15 I think I had originally read it as  
 16 "immunodeficient", but I think, sir, you've pointed out  
 17 it's more likely to say "immunologic" and I think  
 18 that's probably right.  
 19 Then there's a reference I think to  
 20 undertaking a:  
 21 "Throat Swab."  
 22 "LFT, U&E."  
 23 So that would be urea and electrolytes.  
 24 "[Full blood counts & film.  
 25 "[Barium] meal & limited follow through.

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1 diagnosis on 17 March, only three days after Kevin had  
 2 presented with symptoms that we have just seen.  
 3 Now, we know that it's in the course of March  
 4 of 1983 that UKHCDO, in conjunction with Dr Craske  
 5 from the Public Health Laboratory Service, was setting  
 6 up a system for the reporting of possible AIDS cases,  
 7 and although we've looked at these documents a number  
 8 of times, it's perhaps useful to revisit them in the  
 9 context of Kevin's particular case.  
 10 So if we could have, first of all, Soumik  
 11 HCDO0000517\_001, please.  
 12 This is the letter of 22 March 1983 sent to all  
 13 Haemophilia Centre Directors by Dr Craske, Dr Rizza  
 14 and Professor Bloom, in writing directors to report  
 15 possible cases of AIDS to the Public Health Laboratory  
 16 Service.  
 17 You'll see from the second paragraph, sir, that  
 18 the criteria for reporting cases are given in a paper  
 19 and they are said to be the same as those being used  
 20 in the USA.  
 21 If we turn to the paper that the letter refers  
 22 to, Soumik, it's HCDO0000273\_078. We can see this is  
 23 the AIDS/2 paper "Spectrum of disease presentation in  
 24 AIDS" and we can see diseases specific for AIDS and  
 25 a number of diseases are set out that may be specific

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1 "See in clinic this week."  
 2 So that's Kevin's presentation on 14 March, and  
 3 we see from that a number of matters there being  
 4 recorded of particular significance: the loss of  
 5 weight, the lack of energy and the severe Candida  
 6 infection of the mouth and throat.  
 7 We don't, I think, know with any certainty --  
 8 sorry, sir?  
 9 **SIR BRIAN LANGSTAFF:** Some reference to the inguinal  
 10 nodes. So there's something happening in the lymph  
 11 glands in the groin.  
 12 **MS RICHARDS:** Yes.  
 13 A query as to there being some immunological  
 14 problem. It's not entirely clear from the signature,  
 15 and obviously we can't see the signature on screen,  
 16 but the name looks like it might be Dr Liddell. It  
 17 doesn't look like, in any event, it's Professor Bloom  
 18 himself.  
 19 However, if we then look at CVHB0000157\_017, we  
 20 can see a laboratory form -- we don't have a complete  
 21 set, I think, of laboratory records, but this is dated  
 22 17 March 1983, and we can see there:  
 23 "Haemophilia.  
 24 "? AIDS."  
 25 So AIDS is first recorded as a potential

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1 manifestations of or associated with AIDS. They  
 2 include, obviously PCP and then we'll see references  
 3 further below to fungal infections, including thrush.  
 4 If we go over the page we can see, under the heading,  
 5 viral cytomegalovirus and herpes and herpes zoster  
 6 referred to, and then "AIDS-Related Diseases:  
 7 Non-specific diagnoses", pneumonia, central nervous  
 8 system dysfunction. Then "AIDS-Related Prodromal  
 9 Symptoms and Signs":  
 10 "The following symptoms and signs have been  
 11 common among AIDS cases prior to the diagnosis of the  
 12 specific diseases listed above. Report all patients  
 13 with any of these symptoms or signs:  
 14 "Throat pain and difficulty swallowing (lasting  
 15 more than a week)  
 16 "Shortness of breath  
 17 "Fever (lasting more than a week)  
 18 "Diarrhoea (lasting more than a week)  
 19 "Swollen lymph glands (lasting more than  
 20 a month)  
 21 "Cough (lasting more than two weeks)."  
 22 Then "Unexplained weight loss", which obviously  
 23 was one of the factors recorded in relation to Kevin.  
 24 Then "Haematologic/Immunologic Abnormalities",  
 25 and it then set out that various:

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1 "... test abnormalities are seen in a variable  
2 ... proportion of AIDS cases."

3 That includes there references to lymphopenia  
4 and, over the next page, we can see listed various  
5 abnormalities in relation to T-cells, and the  
6 significance of that we'll see shortly.

7 That was the material that all directors  
8 including, of course, Professor Bloom, as co-author of  
9 the 22 March letter, were working to.

10 Now, we know that in the course of April 1983  
11 Professor Bloom gave a talk followed by a Q and A  
12 session at the Haemophilia Society's Annual General  
13 Meeting. It's PRSE0000411, this is the Haemophilia  
14 Society's bulletin. Could we go to the second page  
15 please, Soumik. We see top left-hand corner "Talk  
16 given at the AGM: 23 April 1983". Our presentation  
17 notes says 22 April, sir, so that may need to be  
18 corrected, 23 April, Professor Bloom.

19 If we look at the bottom half of the page, we  
20 can see on the right-hand side "Acquired Immune  
21 Deficiency Syndrome". The text of the talk in  
22 relation to AIDS doesn't refer specifically to Kevin's  
23 case but, if we go please, Soumik, to page 5 and we  
24 look at the left-hand column, just over halfway down  
25 the page, if we go a little further down -- that's

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1 CVHB0000157\_437.

2 If we look at the top half of the page first,  
3 we can see it's a record from the University Hospital  
4 of Wales, the consultant is Bloom, the department is  
5 haematology. The date 25 April 1983:

6 "New Problem: self-referral.

7 "Pain and swelling [right] testis. Came on 2/7  
8 ago heralded by [right] loin pain in early hours of  
9 AM.

10 "[Right] testis became increasingly tender and  
11 sore and swollen over afternoon.

12 "Felt hot and flushed."

13 Then there's a reference to having seen the GP  
14 and having been prescribed antibiotics. Then it says:

15 "Continued pain in back and on [right] side."

16 Then:

17 "PMH [I think previous medical history] severe  
18 haemophiliac.

19 "Recent repeated tonsillitis -- oral thrush??"

20 Acquired Immunodeficiency Syndrome new."

21 Then the triangle symbol for diagnosis.

22 So there we see set out the particular symptoms  
23 that Kevin was reporting in relation to the pain and  
24 swelling and the oral thrush as part of the previous  
25 medical history, and the question mark AIDS being put

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1 fine, thank you, Soumik -- we can see there it says  
2 "Professor Bloom", this is on the left-hand side of  
3 the page and this is the Q and A session:

4 "It is unfortunate that haemophilia has been  
5 linked with AIDS. Apart from that we must not  
6 overlook the AIDS problem. One of my patients may  
7 have a mild form of it."

8 Then he goes on to say:

9 "Some patients show laboratory changes.  
10 Laboratory changes do not mean it is a serious  
11 disease. I do not know of any haemophiliac with AIDS  
12 in the UK, France or Germany. I do not think we need  
13 to get over-concerned about this. At the present time  
14 it would be absolutely wrong to curtail treatment."

15 That is, as far as we can identify, the first  
16 public reference by Professor Bloom to Kevin's case.  
17 There may be, sir, something of a tension between the  
18 suggestion "one of my patients may have a mild form of  
19 it" and "I do not know of any haemophiliac with AIDS  
20 in the UK, France or Germany" but, in any event, that  
21 is what Professor Bloom said.

22 It was a couple of days after that, on  
23 25 April, that Kevin was admitted as an in-patient to  
24 the University Hospital of Wales under the care of  
25 Professor Bloom. Soumik, could we please have

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1 forward as a suggested diagnosis.

2 We can then see references to the examination  
3 that's undertaken.

4 Sorry, I should just say in the left-hand  
5 column, just looking at the top of what we can see on  
6 the screen, in the margin we've got a reference,  
7 I think again, to full blood count, urea and  
8 electrolytes and LFTs, and then it looks like it says  
9 "2,000 units pre-post", but it's not entirely clear  
10 what that refers to.

11 So then continuing with the examination, he's  
12 described as flushed, temperature is set out. No  
13 significant nodes in axilla/cervical, no spleen but  
14 then it says "probably was palpable". No tenderness,  
15 no kidneys palpable, but "small node inguinal" is then  
16 recorded as part of the examination. So consistent  
17 with what we saw recorded for 14 March.

18 Then it records:

19 "Large swollen [right] testis. Tender and hot.  
20 Not able to distinguish epididymis from testis."

21 Then if we go over the page, it looks like it  
22 says "small prostate now tender, no masses". The  
23 diagnosis is not entirely easy to read:

24 "Epididymo orchitis [I think].

25 "Possible bleed.

16



1 "Possible bleed into a tumour/torsion."  
 2 Then there was a plan to admit him and to carry  
 3 out various tests including, again, liver function  
 4 tests and a full blood count. Then if we just look  
 5 further down the screen, please, Soumik, we can see  
 6 that the doctor there is Dr May, lecturer in  
 7 haematology.  
 8 So that's the first set of records for  
 9 25 April. There's then a second set of entries, if we  
 10 go on to the next page. In a different set of  
 11 handwriting, again, the consultant is ALB which we  
 12 would understand to refer to Professor Bloom.  
 13 **SIR BRIAN LANGSTAFF:** I think what may have happened here,  
 14 if you go back to the previous page, you see "Admit  
 15 A7".  
 16 **MS RICHARDS:** Yes.  
 17 **SIR BRIAN LANGSTAFF:** That's going to the ward A7. If you  
 18 go back to the page we were just on, this is now in  
 19 ward A7.  
 20 **MS RICHARDS:** Yes.  
 21 **SIR BRIAN LANGSTAFF:** So it looks as though there has been  
 22 a triage, he has been admitted. This is now the note  
 23 of examination on admission.  
 24 **MS RICHARDS:** That I think is right, sir. We don't know  
 25 who wrote this record. There is no name or signature

17

1 symptom because it says "No previous episodes" and  
 2 then there is a description of having treated himself  
 3 at home with Factor VIII.  
 4 If we go over the page, there's various matters  
 5 of family history set out, and then there are various  
 6 abbreviations used: SR, AS, RS, CVS, UGS, CNS, which  
 7 effectively records, for the most part, no symptoms.  
 8 Then on examination "fit young man", no cyanosis, no  
 9 clubbing, no LA -- I'm not sure what that refers to,  
 10 sir -- no anaemia, no jaundice. Mouth, now here it  
 11 says no candida, which isn't consistent what we see  
 12 elsewhere in the records but, in any event, that  
 13 appears to be what's there recorded. Chest, no signs  
 14 of infection, chest clear, and then we have pulse,  
 15 et cetera, heart sounds.  
 16 If we go on to the next page, we can see  
 17 an abdominal examination and, in particular, there is  
 18 recorded the findings on examination in relation to  
 19 the right testicle:  
 20 "Summary for urological opinion on cause of  
 21 testicular swelling."  
 22 Then there are various queries: bleeding to  
 23 testicle, I'm not sure I can read the next line, and  
 24 then torsion.  
 25 **SIR BRIAN LANGSTAFF:** Orchiditis.

19

1 at the end of the two and a half pages in this  
 2 particular set of handwriting.  
 3 **SIR BRIAN LANGSTAFF:** It begins with emergency admission.  
 4 **MS RICHARDS:** It does begin with emergency admission and  
 5 then if we pick it up in the third line, it says:  
 6 "Known case of severe haemophilia. Also in the  
 7 past has had recurrent attacks of tonsillitis. Factor  
 8 VIII level 0 per cent.  
 9 "March 1983 troubled with oral thrush and  
 10 tonsillitis found to have leukopenia, lymphopenia ..."  
 11 So that is presumably a record to the result of  
 12 the various laboratory investigations, which we know  
 13 were undertaken but we don't have the results  
 14 themselves:  
 15 "... ? AIDS.  
 16 "Also has T cell deficiency."  
 17 So, again, we can see being recorded here  
 18 a number of matters that resonate with what we saw  
 19 from Dr Craske's AIDS/2 document, in terms of  
 20 potential symptoms of AIDS that require to be  
 21 considered. In particular, we now see the blood count  
 22 results and the T cell deficiency.  
 23 There is then a description of the swelling in  
 24 the right testicle and further details given in  
 25 relation to that. We can see that this is a new

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1 **MS RICHARDS:** Oh, it is, thank you, sir. Then it looks  
 2 like --  
 3 **SIR BRIAN LANGSTAFF:** Query orchiditis, ;so he is thinking  
 4 it could be this.  
 5 **MS RICHARDS:** Then the notes continue with the next entry  
 6 being the following day, and a urological examination  
 7 which I don't need to go through, I think, any of the  
 8 details of.  
 9 But if we go to the last page of this document,  
 10 Kevin remained in hospital for a number of days. We  
 11 see the entry for 3 May at the top of the page, and  
 12 below the diagram we see clearly set out there the  
 13 words "oral thrush".  
 14 Those are some of the records from that  
 15 admission. There are two other sets of documents from  
 16 the admission that we should look at. The first is  
 17 CVHB0000157\_622. This is a form filled in on  
 18 admission. It looks as though it's filled in by  
 19 a nurse because we see in the bottom right-hand corner  
 20 "Name of Admitting Nurse". It gives a number of  
 21 details about the patient. But if we look in the  
 22 second column along we see "Occupation" and "Type of  
 23 Accommodation: Bungalow", and then if we look below  
 24 that, we can see:  
 25 "Reason for Admission/Diagnosis:

20

1 "Pain and swelling in right testis? Bleed?  
 2 Epididymo orchitis [I think]? Bleed into a tumour."  
 3 Then this:  
 4 "Haemophilic. AID Syndrome."  
 5 So it's clearly being recorded by the nurse  
 6 here and it doesn't look as though there is any  
 7 question mark there next to the phrase. It's clearly  
 8 been recorded there as a reason for admission or  
 9 a diagnosis "AID syndrome".  
 10 There is also one entry in the nursing records  
 11 we should look at.  
 12 **SIR BRIAN LANGSTAFF:** Just before you go from that, the  
 13 far right-hand column "Condition of mouth".  
 14 **MS RICHARDS:** Yes:  
 15 "Tongue -- coated. Thrush -- being treated at  
 16 present."  
 17 So, again, it's slightly unclear why there  
 18 appears to be that one reference that says no candida  
 19 when the other documentation suggests that there was,  
 20 indeed, oral thrush.  
 21 **SIR BRIAN LANGSTAFF:** "Nutrition" is "poor appetite" it  
 22 looks like, "last two days".  
 23 **MS RICHARDS:** Yes, that is what it says.  
 24 Then if we go to CVHB0000157\_624. We look at  
 25 the bottom of the page, this is an extract from the

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1 We can see set out there:  
 2 "Haemophilia Centre: Cardiff.  
 3 "Name of patient, Kevin Slater ...  
 4 "Coagulation defect: Factor VIII deficiency.  
 5 "Date disease (AIDS) first suspected:  
 6 17 March 1983."  
 7 That's the date we saw on the laboratory test,  
 8 sir, which also recorded AIDS. So we have  
 9 17 March 1983 identified by Professor Bloom as the  
 10 date upon which AIDS was first suspected.  
 11 "Date of onset of symptoms: early March 1983,  
 12 (oral thrush probably January 1983)."  
 13 Then a little further down there's the  
 14 question:  
 15 "... any specimens of serum and/or lymph node  
 16 or other organs from biopsy or post-mortem available  
 17 for study? Yes."  
 18 Then Professor Bloom writes "Stored serum or  
 19 plasma". So that would clearly indicate that Cardiff  
 20 had, certainly in relation to Kevin, stored samples of  
 21 his sera.  
 22 Then we have "Main clinical features", and  
 23 ticking boxes, yes or no: malaise, ticked yes; loss of  
 24 weight unexplained, ticked yes; enlarged lymph nodes  
 25 lasting more than one month, ticked yes; the other

23

1 nursing records and we can see for the entry for  
 2 25 April 1983 it refers to:  
 3 "Self-referral ... known haemophilic ... pain  
 4 and swelling in the [right] testis two days ago. Went  
 5 to GP ... patient has pain also in his back and  
 6 [right] side. Patient is being treated at present for  
 7 oral thrush following repeated tonsillitis recently."  
 8 So, again, there is that contemporaneous  
 9 reference from 25 April to oral thrush:  
 10 "Patient is ?? Acquired Immunodeficiency  
 11 Syndrome."  
 12 So again the nursing records recording,  
 13 although there with the question marks, AIDS as part  
 14 of the records.  
 15 Now, that was an admission on 25 April. We now  
 16 need to look at a key document completed by  
 17 Professor Bloom. It's at WITN3408009.  
 18 If we go to the second page, this is the AIDS/3  
 19 form. So this is the form that Dr Craske,  
 20 Professor Bloom and Dr Rizza circulated on 22 March  
 21 asking for directors to report any possible cases of  
 22 AIDS, as part of the surveillance and reporting  
 23 system. We'll look at this when we get to the last  
 24 page but this was signed by Professor Bloom and it's  
 25 dated 26 April 1983.

22

1 symptoms ticked no. So three clinical features  
 2 identified as significant there by Professor Bloom.  
 3 If we go to the next page, please, we can see  
 4 if we look at the -- zoom in on the top part of the  
 5 page, first of all, Soumik:  
 6 "Recurrent tonsillitis for five to six years,  
 7 1977."  
 8 Then:  
 9 "Other Symptoms and/or Signs: Dysphagia, oral  
 10 and oesophageal candidiasis."  
 11 Then:  
 12 "Epididymo-orchitis April 1983."  
 13 So that's the reference to the problem with the  
 14 testicle that we've seen recorded in the notes.  
 15 **SIR BRIAN LANGSTAFF:** Dysphagia is one of the items which  
 16 is identified on the checklist in AIDS/2, is it?  
 17 **MS RICHARDS:** I would need to double-check that, sir. I'm  
 18 not sure that it is but I will double-check. Shall we  
 19 go back to that. It is HCDO0000273\_078.  
 20 HCDO0000273\_078. On the first page, we've got the  
 21 various infections listed, including under fungal  
 22 infections, candidiasis thrush and then various other  
 23 fungal infections. If we go over the page we've got  
 24 the viral infections, bacterial infections, AIDS  
 25 related diseases, and then prodromal symptoms and

24

1 signs.

2 **SIR BRIAN LANGSTAFF:** Difficulty swallowing more than

3 a week, which is what I had in mind. I thought it had

4 actually used the word dysphagia, but it doesn't. It

5 just says swallowing, so that's my overinterpretation.

6 **MS RICHARDS:** Then, of course, the lymphopenia which we

7 have already seen set out in Kevin's records.

8 **SIR BRIAN LANGSTAFF:** I think we have them there on

9 Professor Bloom's letter, 3408009.

10 **MS RICHARDS:** If we can go back to that please, Soumik,

11 and go to the third page, WITN3408009. So we then

12 have a series of laboratory investigations. We can

13 see that the date was 17 March for a number of

14 investigations. The results are there set out and

15 then we have "BA swallow, March 1983, oesophageal

16 candidiasis". Then "Reduced killer and natural killer

17 cell activity April 1983".

18 We then have serological studies listed, just

19 draw attention to the fourth "herpes simplex", and

20 Professor Bloom has written in the right-hand margin

21 next to that "evidence of infection". Then under the

22 heading "Other", and I'm not sure I can read the first

23 entry.

24 **SIR BRIAN LANGSTAFF:** "Adenovirus" is the first one.

25 **MS RICHARDS:** Again, Professor Bloom has recorded

25

1 findings which gave rise to the comment that there was

2 lymphopenia.

3 **MS RICHARDS:** Presumably, sir, yes, exactly. So, as it

4 were, they have been interpreted for us through the

5 records. There's also reference to the reduced T cell

6 activity in the records themselves.

7 **SIR BRIAN LANGSTAFF:** Thank you.

8 **MS RICHARDS:** If we then go on to the fifth page, Soumik,

9 and we zoom in on the bottom half of the page, please,

10 various questions in terms of the patient's history

11 are answered in the negative, and then this:

12 "Final clinical diagnosis: Probable acquired

13 Immune Deficiency Syndrome."

14 Not possible, no question mark: the diagnosis

15 is probable AIDS on 26 April 1983 and although, sir,

16 you can't see on the screen see the signature, I can

17 tell you that the signature is that of

18 Professor Bloom.

19 **SIR BRIAN LANGSTAFF:** So if one is applying a legal test

20 of the balance of probability, if this were a legal

21 matter, he would have AIDS.

22 **MS RICHARDS:** Yes.

23 **SIR BRIAN LANGSTAFF:** If one was looking for proof beyond

24 a reasonable doubt, then one isn't. So it's the

25 difference between what is probable and what is proved

27

1 "evidence of infection" in the right-hand margin,

2 hepatitis B is negative.

3 Then if we go over the page we can see that the

4 various other factors that may give rise to a causal

5 connection with AIDS are effectively discounted. So

6 sexuality, drug addiction, visiting the US, contact

7 with patients known or suspected to have AIDS all

8 negative:

9 "Has the patient received any of the following

10 blood products?"

11 We can see Factorate is ticked, this is since

12 January 1980.

13 "Has the patient received any other blood

14 products since 1 January 1980?"

15 Cryoprecipitate is ticked.

16 Then if we go on to the next page we see

17 Elstree NHS Factor VIII concentrate is ticked and

18 Kryobulin is ticked.

19 **SIR BRIAN LANGSTAFF:** Can you go back to the blood count?

20 **MS RICHARDS:** That's the third page, Soumik.

21 **SIR BRIAN LANGSTAFF:** The results are shown there for the

22 T-cells, the absolute lymphocyte count and the

23 T helper suppressor ratio. They would require

24 interpretation, I think, if you are going to make

25 anything of what is said there but it was those

26

1 to a civil standard of proof and what is absolutely

2 certain.

3 **MS RICHARDS:** Yes, and of course it's entirely open to

4 a clinician to record something as being possible or

5 suspected, to include the question marks that one

6 conventionally sees in the medical records.

7 Professor Bloom has elected here, in a form he is

8 submitting in accordance with the surveillance and

9 reporting scheme set up by UKHCDO, to identify this as

10 a probable case of AIDS.

11 **SIR BRIAN LANGSTAFF:** Yes.

12 **MS RICHARDS:** Now, that's 26 April 1983. If we go to

13 DHSC001228, please DHSC0001228. We've looked at this

14 before. We note from a letter, which I won't put on

15 the screen, but there's a letter from Professor Bloom

16 to Mr Watters, 3 May 1983, which encloses his draft of

17 this which was then published on 4 May 1983 by The

18 Haemophilia Society.

19 So this is a week or so after Professor Bloom

20 has diagnosed Kevin as probably suffering from AIDS,

21 and we see the text, if we can zoom in on the main

22 paragraph please, Soumik. It refers to reports from

23 America of AIDS in persons with haemophilia causing

24 anxiety. It says "We are no strangers to infective

25 diseases, such as hepatitis", et cetera, et cetera.

28



1 It refers to investment in the blood products  
 2 laboratory at Elstree, and then says this:  
 3 "Bearing this in mind it is important to  
 4 consider the facts concerning AIDS and haemophilia.  
 5 The cause of AIDS is quite unknown and it has not been  
 6 proven to result from transmission of a specific  
 7 infective agent in blood products. The number of  
 8 cases reported in American haemophiliacs is small ..."  
 9 Then he says this:  
 10 "... and in spite of inaccurate statements in  
 11 the press we are unaware of any proven case in our own  
 12 haemophilic population."  
 13 Then he goes on to record the lack of cases  
 14 from Germany and to talk about the system of  
 15 monitoring set up by Haemophilia Centre Directors in  
 16 the Communicable Disease Surveillance Centre.  
 17 Sir, you will no doubt wish to consider, in  
 18 light of what we've seen was Professor Bloom's own  
 19 diagnosis of Kevin on 26 April 1983, the message here  
 20 set out by Professor Bloom, to the effect of "We are  
 21 unaware of any proven case in our own haemophilic  
 22 population". Much may turn on what he meant,  
 23 I suppose, by "proven" but whether that was  
 24 a misleading statement is no doubt something you will  
 25 wish to consider.

29

1 "Communicable Disease Report" for the week ending  
 2 6 May 1983, and under the heading:  
 3 "Acquired Immune Deficiency Syndrome: Cardiff.  
 4 "Acquired immune deficiency syndrome has been  
 5 reported in a 20-year old man with haemophilia in  
 6 Cardiff."  
 7 Then it goes on to summarise what we've seen  
 8 set at in the records, so the candida, the  
 9 epididymo-orchitis, the lymphopenia, low  
 10 T-helper/suppressor ratio.  
 11 "This is the first report of AIDS in a patient  
 12 with haemophilia in the [UK] known to CDSC."  
 13 So treated by CDSC as an AIDS case.  
 14 **SIR BRIAN LANGSTAFF:** What is quoted there is what  
 15 Professor Bloom had himself put in the report.  
 16 **MS RICHARDS:** Yes, certainly entirely consistent with it.  
 17 **SIR BRIAN LANGSTAFF:** And although Professor Ludlam  
 18 thought that it had been based entirely on the finding  
 19 of candidiasis, there's much more to it than that.  
 20 **MS RICHARDS:** There is. And of course there's also the  
 21 unexplained and significant weight loss, not recorded  
 22 here but clearly recorded from March onwards.  
 23 **SIR BRIAN LANGSTAFF:** And the lymphopenia and the  
 24 low T-cell/suppressor ratio and so on, the dysphagia,  
 25 yes.

31

1 **SIR BRIAN LANGSTAFF:** If he had been applying the usual  
 2 test of proof, then he has himself said it was proven.  
 3 If he is applying a rather stricter standard of  
 4 looking, perhaps at certainty, you can see an argument  
 5 that he wasn't, but it depends how it would be  
 6 understood and perhaps intended to be understood by  
 7 those who read it.

8 **MS RICHARDS:** Yes. And be that as it may, what it doesn't  
 9 say is, "We are aware of a probable case in our own  
 10 haemophilic population", which would have been on any  
 11 view correct and not misleading.

12 There are two -- actually, before I look at  
 13 those documents, there are two documents not referred  
 14 to in the presentation I want to go to in a moment,  
 15 but we know that Kevin's case was reported to CDSC, to  
 16 the Communicable Disease Surveillance Centre. We  
 17 don't know the precise mechanism or the date, so we  
 18 don't know whether Professor Bloom reported Kevin's  
 19 case directly or whether the mechanism was Dr Craske  
 20 passing on the AIDS/3 form or a summary of the  
 21 AIDS/3 form to CDSC, but we do know that they knew in  
 22 early May of the case, and we see that from, again  
 23 a document we've looked at before, PRSE0000353.

24 If we zoom in on just over the first half of  
 25 the page we can see the date there, this is the

30

1 **MS RICHARDS:** There are two additional documents I just  
 2 want to put up on screen from early May in which  
 3 Kevin's case is discussed.

4 The first is HSSG0010055\_001.

5 Sorry, sir, the system is running slowly today.  
 6 There are so many documents loaded on it, I think it's  
 7 slowing things down.

8 It's not currently on my screen, Soumik,  
 9 although I can see it is on other screens.

10 Sir, do you have the document on your screen?

11 **SIR BRIAN LANGSTAFF:** No, I don't.

12 **MS RICHARDS:** It's showing on some screens in the hearing  
 13 room and not others. Do you need the reference again?  
 14 Thank you.

15 So if we can just go to -- we're just missing  
 16 a heading on the top of the page. Thank you. So we  
 17 can see:

18 "Acquired Immune Deficiency Syndrome (AIDS)  
 19 "Note of a meeting convened by Welsh Office,  
 20 Medical Services Health Professional Group  
 21 4 May 1983."

22 So this is a Welsh Office meeting on 4 May of  
 23 1983, and it's a meeting convened to discuss, in  
 24 effect, Kevin's case.

25 In attendance are four from the Welsh

32

Office: Dr Crompton, Dr Lovett, Dr George, Dr Ferguson Lewis. There is Dr McEvoy from the Communicable Disease Surveillance Centre. There is Dr Skone, the Chief Administrative Medical Officer with South Glamorgan Health Authority. There is Dr Napier, the Welsh region Director of NBTS. And there is Professor Bloom. So they are all in attendance at this meeting.

We can see it says:

"The meeting was arranged to discuss the background circumstances of, and implications arising from, a publicly reported case of AIDS treated at the University Hospital of Wales."

The background history -- can we just zoom in on the paragraphs under the heading "Background History", Soumik, just to make it a little easier to see. Perfect, thank you.

So we can see a background history is set out, which, inferentially, would seem likely to have come from Professor Bloom. Of all the attendees at the meeting, he is the likeliest to have this information. Refers to a young man who has throughout his life had treatment with Factor VIII concentrates of various sources, and reference to having had only British Factor VIII concentrate in '81, '82, '83. Prior to

33

Under the heading "Public Statements", we see reference to The Haemophilia Society meeting:

"On 23 April, Professor Bloom addressed a meeting of a patients haemophilia society in London. He spoke from a typed manuscript in which reference was made to the fact that there was no definite case of AIDS amongst haemophiliacs in this country."

Go to the next page, please.

Zoom in on the top half of the page, first of all. Great.

"However in the discussion which followed he admitted that a case had been treated in Cardiff which showed some of the features of a mild possible AIDS.

"On Thursday 28 April, Susan Douglas, medical correspondent of 'The Mail' made contact stating that she knew that Professor Bloom was treating a patient with AIDS saying she had been so informed from a number of undisclosed sources. Professor Bloom neither confirmed nor denied the statement.

"Yesterday, Tuesday 3 May, 'The South Wales Argus' rang Professor Bloom to ask whether he was the patient reported in the press was a ..."

I think that's the location.

"... patient. There being so few haemophiliacs in any given location it was important not to give any

35

that, Austrian-made Factor VIII.

"Just before the Christmas of 1982 he developed oral thrush which progressed despite treatment initiated by the [GP] ... He eventually presented with a total leukopenia, a severe lymphopenia, a deficiency of T lymphocytes, a deficiency of T helper cells, a reduced helper:suppressor T cell ratio, and a history of recent weight loss of one stone which was thought mainly due to the difficulty in eating and swallowing occasioned by thrush ..."

So, sir, we effectively have there the interpretation of the blood results for us, presumably from Professor Bloom.

"Somewhat disturbingly 10 days ago the patient presented again with epididymal orchitis, the aetiology is unknown but he may have had a bleed into the right testes. ... protracted history of repeated attacks of tonsillitis."

Then if we look under "Medical Assessment":

"It is clear that this young man presents a clinical picture which fits within the case definition as set by the CDSC at Colindale."

So again the consensus view that appears to be recorded at the meeting is that this is a clear picture of AIDS.

34

information and Professor Bloom would not comment.

"Professor Bloom has provided all relevant information as a precautionary measure to the Medical Protection Society. Only one patient has telephoned in seeking information and advice."

Then there's a reference to reports in The Guardian newspaper on 4 May and the suggestion: "It is believed that the Haemophilia Society's London Liaison office is to take up with the Press Council the matter of enquiry through misrepresentation as a result of approaches they have received from the press."

Then, under the heading "Communicable Disease Surveillance Centre, Colindale":

"Colindale had received notification of the Cardiff case but has no information in respect of the second alleged case referred to in The Mail article of Sunday 1 May 1983. The Cardiff case fits the CDSC case definition with its depressed cellular activity and immunosuppression deficiency. Haemophilia directors and public health laboratory services have been circulated with a description of AIDS ..."

That's presumably the document from March '83: "... and a statistical office has been established in Oxford. Some 14 cases or so have been

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1 reported none of whom are haemophiliacs of greater  
2 severity than the Cardiff case. The CDSC has been  
3 similarly bombarded with telephone enquiries from  
4 the press."

5 Then there is a reference to "Systems of  
6 Reporting AIDS to CDSC", three mechanisms: death  
7 registrations, laboratory reports from microbiologists  
8 and clinical reports from various consultants.

9 "It is believed that the CDSC data  
10 underestimates the problem because patients may  
11 present to doctors in other specialties. Letters have  
12 been published in the Journals inviting wider  
13 reporting."

14 And that's a reference to BMJ publication of  
15 23 April 1983.

16 Then if we go over the next page, the meeting  
17 continues. And obviously these are important  
18 discussions that you'll want to consider in due  
19 course, but it continues with more general matters.  
20 Moving on from the specifics of Kevin's case, there's  
21 a discussion under heading "Impact of Publicity on  
22 [National Blood Transfusion Service] in Wales". There  
23 is then "American Experience of Blood  
24 Transfusion/[Blood] Products Association with AIDS",  
25 and it refers to two cases having been reported in

37

1 "The asserted greater risk arising from the use  
2 of purchased blood as opposed to voluntary donated  
3 blood is less than hitherto with the greater  
4 awareness of the AIDS problem."

5 Then it says:

6 "... no justification on the basis of facts so  
7 far established to ban the importation of Factor VIII  
8 though it was thought preferable in the case of  
9 children to restrict treatment to the BPL concentrate  
10 produced in Britain."

11 Then a reference to nursing and laboratory  
12 facilities and "Suggested Further Action":

13 "A letter in confidence from CMO to Chief  
14 Administrative Medical Officers and all consultant  
15 clinicians ..."

16 And:

17 "Agenda item for next CAMOs meeting."

18 Sir, we have not previously looked at that  
19 document in the hearings which is why I wanted to  
20 spend some time on it, but in terms of Kevin's own  
21 case, it is clear that the meeting regarded his  
22 condition as falling within the CDSC definition for  
23 AIDS, and that indeed was basis for the discussion  
24 that then followed.

25 There is one further document arising out of

39

1 patients receiving whole blood, one of which concerned  
2 a child, a dozen cases amongst haemophiliacs in the  
3 US, and it refers to public health measures in the US.

4 "Extent of Reliance upon USA Component?"

5 "We are still reliant to a very large extent  
6 upon the USA -- some 50 per cent of Factor VIII is  
7 still obtained from that source."

8 Then there is a discussion under the heading  
9 "What would be the effect of a ban of American  
10 Factor VIII?" It's described as being "it would be  
11 far-reaching."

12 "Blood product laboratories in the UK are  
13 presently working to capacity. If we were in Wales to  
14 attempt locally to make good our own deficit it would  
15 require a great deal of extra facility ... It follows  
16 that a ban on imported Factor VIII would necessitate:

17 "a. a reduction in patients treated.

18 "b. the modification of the home treatment  
19 facility ..."

20 There is then reference to the size of the  
21 haemophilia population and particular details given  
22 about the haemophilia population in Wales.

23 Then, over the page:

24 "Can we go on using Factor VIII?"

25 It's stated that:

38

1 the meeting that we should look at. HSSG0010055\_002.  
2 This is a note or minute dated 4 May 1983. It's from  
3 Dr Ferguson Lewis, who was Senior Medical Officer in  
4 the Welsh Office, and one of those attending the  
5 meeting. You will see it says:

6 "A meeting of the Chief Medical Officer  
7 together with others of his staff with the Director of  
8 the Cardiff Haemophilia Centre Professor Bloom (who is  
9 also professional adviser to The Haemophilia Society)  
10 and Dr Napier, Director of the Welsh region of the  
11 National Blood Transfusion Service took place this  
12 morning. Dr McEvoy of the Communicable Disease  
13 Surveillance Centre (CDSC) was in attendance.

14 "The Minister will wish to be advised that:-

15 "i. the patient of the Cardiff Haemophilia  
16 Centre does meet the CDSC case definition."

17 Then it continues:

18 "ii The patient is clinically well and  
19 certainly does not have a severe form of the disease;  
20 "iii. there are about 100 haemophiliac patients  
21 in the Wales and 2,200 in the UK as a whole there are  
22 no other reported cases;

23 "iv. there are many other types of patients who  
24 are recipients of blood or blood products;

25 "v. there is no proven connection between this

40



1 reported case and the use of imported Factor VIII."  
 2 That word "proven" again.  
 3 "vi. the level of risk if any were to exist to  
 4 the populace as a result of use of imported blood  
 5 products is very small;  
 6 "vii. there is therefore no cause for  
 7 precipitate action.  
 8 "The line advised continues to be that though  
 9 sensational reporting in the Press has caused concern  
 10 to very many people, no ..."  
 11 And then the word "established" has been  
 12 inserted:  
 13 "... no established link between AIDS and blood  
 14 transfusion has been proven.  
 15 "DHSS have informed me that the Minister is to  
 16 meet The Haemophilia Society on a date soon but not  
 17 yet fixed."  
 18 We can see, bottom of the page:  
 19 "Correction of above telephoned to ..."  
 20 And then it's not clear to me who that is  
 21 a reference to. But in any event we can see that the  
 22 minister -- I anticipate this is probably a minister,  
 23 junior minister, in the Welsh Office that they're  
 24 referring to -- being advised or an intention to  
 25 advise him that the patient at the Cardiff Haemophilia

41

1 American Factor VIII."  
 2 Next paragraph:  
 3 "Dr Galbraith asks that the Department should  
 4 consider the matter as a priority - and asks that any  
 5 top level meeting should include CDSC ..."  
 6 And of course, sir, we've looked at, on  
 7 a number of occasions, Dr Galbraith's own  
 8 communication to the DHSS a couple of days later.  
 9 **SIR BRIAN LANGSTAFF:** Yes.  
 10 **MS RICHARDS:** If we then go to WITN3408013 and we go to  
 11 the second page, we can see here that Dr Craske, at  
 12 the Public Health Laboratory Service, was seeking by  
 13 10 May to identify the likely source of Kevin's  
 14 infection. He is submitting records to Ms Spooner at  
 15 Oxford:  
 16 "Enclosed is the past transfusion records of  
 17 Kevin Slater since 1975. We are particularly  
 18 interested in Kryobulin of American origin transfused  
 19 since 1st January 1980, and also the batch of Armour  
 20 Factorate he received early in that year."  
 21 Then there are a number of pages of records  
 22 which I don't propose to go through.  
 23 We can then see a reference to Kevin at the  
 24 special meeting of Haemophilia Reference Centre  
 25 Directors on 13 May '83.

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1 Centre, i.e. Kevin, does meet the CDSC case  
 2 definition. And this is 4 May.  
 3 So those are records in relation to the Welsh  
 4 Office consideration of Kevin's case. We know that  
 5 the Department of Health and Social Security in London  
 6 was alerted to the development, and we can see that  
 7 from DHSC0002227\_021.  
 8 This is 6 May 1983. It's from Mary Sibellas to  
 9 Dr Oliver:  
 10 "AIDS American Factor VIII.  
 11 "Dr Spence Galbraith telephoned from CDSC this  
 12 morning with the following information:  
 13 "The male patient (aged 23 years) ..."  
 14 So the age is wrong.  
 15 "... in Cardiff who is a known haemophiliac now  
 16 appears to have the right symptoms and signs for  
 17 a diagnosis of AIDS."  
 18 Those are then set out, including opportunistic  
 19 infection, in the brackets:  
 20 "He has been ill for a month and has been  
 21 treated with American Factor VIII."  
 22 Then it continues in the next paragraph that:  
 23 "Dr Galbraith last night received information  
 24 from Spain that three haemophiliac patients there are  
 25 thought to have AIDS and also have been treated with

42

1 Soumik, that's HCDO0000003\_008, please.  
 2 We've looked at these minutes, obviously, on  
 3 a number of occasions over the last few months.  
 4 13 May 1983 "Special meeting, present Professor Bloom,  
 5 Dr Craske", various others there listed, and then the  
 6 purpose of the meeting was to consider the position in  
 7 relation to AIDS. If we pick it up six lines down in  
 8 the main text:  
 9 "There was clearly a need for Haemophilia  
 10 Centre Directors to discuss what should be done with  
 11 regard to the surveillance and reporting of suspected  
 12 cases and the management of patients."  
 13 Then this:  
 14 "To date in the United Kingdom one haemophiliac  
 15 is suspected of suffering from AIDS."  
 16 That's how it's recorded in these minutes, as  
 17 a "suspected case". Again, we don't see use of the  
 18 word "probable".  
 19 We can also see that, in addition to Kevin's  
 20 case being referred to by Reference Centre Directors,  
 21 there's a reference to it in a May 1983 meeting of the  
 22 Council of Europe's Committee on Blood Transfusion and  
 23 Immunohaematology. Soumik, that's CBLA0001710. This  
 24 is a note compiled by Dr Gunson. If we just look at  
 25 the heading:

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1 "Central Blood Laboratories Authority.  
 2 "Acquired Immune Deficiency Syndrome.  
 3 "Report on the discussion which took place at  
 4 the meeting of the expert committee on blood  
 5 transfusion and immunohaematology of the council of  
 6 Europe, Lisbon, 16-20 May 1983."  
 7 If we go to the second paragraph please,  
 8 Soumik:  
 9 "The committee was interested in the possible  
 10 association of this syndrome with a transfusion of  
 11 blood and blood products. Although some 12 patients  
 12 suffering from Haemophilia have contracted AIDS in the  
 13 USA the incidence in Europe, to date, has been much  
 14 less. There is one patient in the UK whose symptoms  
 15 fulfil the criteria defined for AIDS [that's Kevin]  
 16 and there is one further possible case ..."  
 17 It's not clear what that's referring to, sir.  
 18 Then there's a reference to:  
 19 "... two haemophiliacs in ... Germany ...  
 20 suspected of suffering from AIDS and ... a possible  
 21 case, retrospectively diagnosed after death in  
 22 Finland."  
 23 **SIR BRIAN LANGSTAFF:** It doesn't appear to have picked up  
 24 the Spanish cases.  
 25 **MS RICHARDS:** No, it doesn't. The Spanish cases are,

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1 "There is one suspected case in Cardiff.  
 2 Although CDSC states that this case meets the USA  
 3 criteria for AIDS, the clinician in charge does not  
 4 consider that it should be regarded as a confirmed  
 5 case. There is also a possible case at Bristol Royal  
 6 Infirmary but it may not meet the criteria. Further  
 7 details are being sought."  
 8 Of course, we know the Bristol case did indeed  
 9 meet the criteria. But that appears to suggest  
 10 a difference of approach between CDSC, confident that  
 11 the case meets the USA criteria, and Professor Bloom,  
 12 the clinician in charge, not considering it should be  
 13 regarded as a confirmed case which, sir, again, it may  
 14 be difficult to reconcile with his own completion of  
 15 the formal identification of this as a probable case  
 16 of AIDS.  
 17 **SIR BRIAN LANGSTAFF:** It's also difficult to reconcile  
 18 with the description given to the Welsh Office, that  
 19 immunodeficiency is present, so it was clear that the  
 20 picture was within the case definition. So you have  
 21 the two words, "probable" and "clear", on the one side  
 22 and "suspect" here.  
 23 **MS RICHARDS:** Yes, "suspect" and "not confirmed" here.  
 24 We know that Kevin's case was certainly  
 25 included by the Department of Health in tables which

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1 however, referred to in a further DHSS document  
 2 DHSC0002229\_019. So this is headed "Background paper  
 3 on Acquired Immune Deficiency Syndrome". It's not,  
 4 I think, dated but it appears to have been prepared,  
 5 we can see from other documents, for a meeting to take  
 6 place in early June 1983. If we look at the bottom of  
 7 the page:  
 8 "Is it transmitted in blood or blood products?  
 9 "As yet there is no conclusive proof that AIDS  
 10 is transmitted by blood as well as by homosexual  
 11 contact but the evidence is suggestive that this is  
 12 likely to be the case. The evidence relates to some  
 13 11 haemophiliacs in the USA and three in Spain in whom  
 14 the most likely explanation for the development of  
 15 AIDS was their exposure to American Factor VIII  
 16 concentrates. There is also some evidence that AIDS  
 17 has been transmitted to babies in blood transfusions."  
 18 So the Spanish cases are there picked up but  
 19 not the German ones.  
 20 **SIR BRIAN LANGSTAFF:** Not the German and not Finnish, so  
 21 very patchy.  
 22 **MS RICHARDS:** Over the page, second paragraph, there is  
 23 reference to Kevin's case:  
 24 "AIDS in haemophiliacs in the UK."  
 25 Then, somewhat curiously stated here:

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1 it was compiling to track cases. If we look at  
 2 DHSC0002229\_112, we can see this is dated 6 July 1983  
 3 Mary Sibellas to Dr Field:  
 4 "AIDS: Case Summaries Table.  
 5 "I have now updated the epidemiological  
 6 table -- there are now 14 cases in England and  
 7 Wales ...  
 8 "I am circulating the table to all those with  
 9 an interest so that Ministers can receive the most  
 10 up-to-date information we have."  
 11 Then if we go to the table itself which is  
 12 DHSC0002229\_113, we see "Acquired Immune Deficiency  
 13 Syndrome case summary England and Wales", and if we  
 14 look down to case 8, that is a reference to Kevin's  
 15 case, Cardiff is where reported; date reported  
 16 May 1983; date confirmed May 1983; nationality ethnic  
 17 group, British; male; 20; then the diagnosis "Candida;  
 18 AIDS epididymo-orchitis"; date of onset December 1982;  
 19 date of diagnosis May 1983; alive; heterosexual; the  
 20 next entry "Nil" is travel and US contacts, nil; blood  
 21 or blood products, haemophiliac, USA Factor VIII 1981,  
 22 NHS Factor VIII since 1981.  
 23 So there Kevin's case clearly being recorded by  
 24 the Department of Health in its epidemiological table  
 25 and at that stage the only bleeding disorder case so

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recorded by the Department of Health.  
If we skip on three months to the updated tables DHSC0002235\_115, we can see it's from Mary Sibellas to Dr Field, again, it's an update to the epidemiological table, taking it up to 12 October 1983. There are now more cases. The case numbers are 25. One case has been excluded, it would appear. If we go to the next page, we see the same entry in relation to Kevin's case, case number 8, the Cardiff case. If we go to the next page you'll see there is circled a case in Preston, reported 20 June 1983, confirmed 23 June 1983, the diagnosis is there set out. That's recorded as being a case of blood transfusion during abdominal surgery in 1979, transfusion records being checked.

But then we see the Bristol case recorded at number 17, date reported 6 September 1983, British, male, early 20s, PCP and haemophilic who received Factor VIII concentrate in December 1981 is there recorded. We haven't yet tracked through what we know of the Bristol case, sir, but that's the inclusion in these epidemiological tables being maintained by the DHSS.

**SIR BRIAN LANGSTAFF:** What is interesting about that one is on the date of diagnosis, third week of August. So

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not quite clear.

**SIR BRIAN LANGSTAFF:** Titre, is it, or titre?

**MS RICHARDS:** Yes, it probably is.

**SIR BRIAN LANGSTAFF:** So test to see whether he has pneumocystis.

**MS RICHARDS:** Exactly, and then reference to also full blood count testing. Again, I don't need to go through all the records but there were records of oral thrush. If we go to admission sheet CVHB0000157\_618, we can see in the second column along from the left, under the heading "Reason for admission/diagnosis: Haemophilic, AID". Top of the next column, "Additional health problems: haemophilia, AID Syndrome". He's also described as pale and underweight. So, again, clearly recorded in his notes.

Again, there are a handful only of laboratory results which records the presence of the oral thrush. Then if we look, again, at what's being said by those in charge of UKHCDO in June, HCDO0000270\_004. Again, this is a letter we've looked at on a number of occasions. It's from Professor Bloom and Dr Rizza to other Haemophilia Centre Directors, and it's only the first paragraph I need to look at for today's purposes. So this is 24 June 1983 and we've seen

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if this is the same as the suspected Bristol case, it's a late diagnosis.

**MS RICHARDS:** Yes. Yes, and then reported to -- I don't know whether that's reported to CDSC or Department of Health, 6 September.

**SIR BRIAN LANGSTAFF:** Yes.

**MS RICHARDS:** If we return to Kevin's own case and look at CBHB0000157\_421 -- CVHB0000157\_421. We can see on 17 June Kevin being readmitted to hospital. He's recorded here as having a chest infection, nausea and vomiting. There's a reference to March 1983, him having been troubled with oral thrush and tonsillitis, "found to have leukopenia ?AIDS, also had T cell deficiency". There's then reference to the cough, and towards the bottom of the page to the nausea and vomiting.

If we go over the page, bottom half of the page the O/E (on examination), we can see written on the right-hand side "oral thrush". If we go to the last page, we can see, bottom half: "

"Impression: chest infection, ?nausea and vomiting due to antibiotics."

Again, reference to there being various tests proposed, including a full blood count. Then what looks like a reference to pneumocystitis-like, maybe

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everything set out in Kevin's records to date. This says in the third line:

"So far one possible case has been reported to our organisation. This patient (A/1) [and we know from other documents that's Kevin] conforms to the definition published by the CDC in Atlanta, Georgia but cannot be described as a definite case. We are not aware of any other definable patients amongst the UK haemophilic population."

So the message being sent out to other directors by this communication appears to be a possible case rather than a probable case.

We know that in the following month -- and I'm not going to go to the documents which we looked at in the course of the presentation on the Cardiff Haemophilia Centre -- but the Haemophilia Society approached Professor Bloom again asking if he wanted to update his 4 May 1983 message, and he said that there hadn't been any major change and didn't see there to be the need to do so.

We can see however in the British Medical Journal in August 1983 what was being said by CDSC. So if we go to DHSC0002231\_019. This is the British Medical Journal, 6 August 1983. We can see under the heading "Communicable Diseases", it's:

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"Surveillance of [AIDS] in the [UK],  
January 1982-July 1983.

"Prepared by the Public Health Laboratory  
Service [CDSC]."

There is a discussion of the definition  
compiled by the Centers for Disease Control in the  
States and so on.

If we go to the next page, there's  
a description of the surveillance system being  
utilised by CDSC and then if we go to bottom left-hand  
column -- just a little bit further down, thank you --  
so we can see there it's recorded:

"By 31 July 1983, 14 cases of [AIDS] had been  
reported to [CDSC], mainly from clinicians."

Details of those are set out. Then if we skip  
over a paragraph:

"Of the 14 patients, 12 were homosexual, one  
was also a drug abuser; 10 were reported from London,  
one from Bristol, and one from Oxford. The  
haemophiliac patient was from Wales, and had received  
Factor VIII imported from the US; a patient from  
Lancashire [that may be the Preston case] did not come  
within the known risk groups."

So Kevin's case there set out, as it would  
appear from CDSC's perspective, consistent with what

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Then over the page -- not over the page,  
right-hand column, towards the top of the page, we can  
see then it's saying:

"At this time [that's May 1983] AIDS was  
suspected ..."

It refers then to T cell studies supporting the  
diagnosis, various immunological blood data there set  
out, and then a further description of his symptoms in  
August 1983.

So it would appear that from this, at least,  
that AIDS was suspected in that patient from May 1983  
but was not reported until early September 1983 to  
CDSC and that may be an issue we will need to explore  
further.

Returning to Kevin, this letter had suggested  
that no definite case of AIDS in a haemophiliac had  
yet been reported in Britain, which was obviously  
incorrect, because we have Kevin's case. There was  
a response to this from the Communicable Disease  
Surveillance Centre, PRSE0004506.

**SIR BRIAN LANGSTAFF:** If we could stop there for a moment,  
Ms Richards. If we go back to the left-hand column,  
the top, where it says "No definite case of AIDS has  
yet been reported although one patient may have early  
features of the syndrome", there's a reference, it's

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we've seen as an accepted case of AIDS.

Just picking up communications in journals  
about the classification of cases. In relation to the  
Bristol case, that emerges in the medical literature  
in November 1983. If we could just look at  
PRSE0004509. This is a letter from Dr Daly and  
Dr Scott of the Bristol Haemophilia Centre, so it  
gives details of the Bristol case. If we look at the  
first paragraph, it says, six lines down:

"No definite case of AIDS in a haemophiliac has  
yet been reported in Britain although one patient may  
have early features of the syndrome. We report here  
a fatal case of AIDS in a haemophiliac who received  
intensive treatment with Factor VIII concentrate of US  
origin."

Then there is a description of his symptoms,  
picking up from January 1982. If we go further down  
that page please, Soumik, we can see under the table,  
the Bristol patient's described in March 1982 as  
having herpes zoster, symptoms of being unwell,  
lethargic, listless, so "malaise" to use the  
terminology of the AIDS/3 form. Then we can see,  
again, reference to herpes and oral thrush in the last  
paragraph and, indeed, to wider candida infections in  
other parts of the body.

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reference 4. What footnote is that? What do the  
notes refer to?

**MS RICHARDS:** It's to the article in the BMJ that we  
looked at a few moments ago.

**SIR BRIAN LANGSTAFF:** Thank you.

**MS RICHARDS:** So the CDSC article in the BMJ.

**SIR BRIAN LANGSTAFF:** Right.

**MS RICHARDS:** Then if we then go to the response to  
Dr Daly and Dr Scott's letter, PRSE0004506, and if we  
zoom in on the letter in the left-hand column, which  
is headed "Haemophilia and AIDS in the UK", please,  
Soumik, it says:

"In their otherwise clear account of a fatal  
case of [AIDS] in a haemophiliac in the UK, Dr Daly  
and Dr Scott, referring to our account of AIDS  
surveillance, state that 'No definite case of AIDS in  
a haemophiliac has yet been reported in Britain  
although one patient may have early features of the  
syndrome'. The Communicable Disease Surveillance  
Centre does indeed collect data on patients who may  
have early features of AIDS, but our paper included  
only those cases which met the definition of AIDS  
compiled by the Centers for Disease Control, Atlanta,  
on March 15, 1983. The information kindly provided to  
us about the haemophiliac we mentioned led us to

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1 include him as a definite case of AIDS."  
 2 That is undoubtedly a reference to what they  
 3 described in their paper as "the Welsh case", but to  
 4 Kevin.  
 5 **SIR BRIAN LANGSTAFF:** Yes.  
 6 **MS RICHARDS:** So regarded by CDSC as a definite case of  
 7 AIDS.  
 8 **SIR BRIAN LANGSTAFF:** Thank you.  
 9 **MS RICHARDS:** Kevin's health continued to deteriorate and  
 10 we can see that from the medical records from October  
 11 1983, CVHB0000157\_394. So he's seen on  
 12 17 October 1983. Again, the consultant under whose  
 13 care he is identified as Professor Bloom, although  
 14 this is an entry that is made by Dr May:  
 15 "Seen in Haemophilia Centre.  
 16 "Known Acquired Immune Deficiency."  
 17 So identified by the doctor seeing him there on  
 18 17 October as a known AIDS case. Then there is  
 19 a description of his symptoms:  
 20 "Getting worse, vomiting, frontal headaches,  
 21 shivery, coughing -- sometimes productive."  
 22 The examination is carried out. If we go over  
 23 the page, we can see second line is "? opportunistic  
 24 pathogen", and then this underlined:  
 25 "He needs yellow stickers on bloods."

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1 Known Acquired Immune Deficiency Syndrome."  
 2 He's described as a pale-looking young man with  
 3 a chesty cough and head cold. So recorded there  
 4 clearly as a known case of AIDS.  
 5 Again, if we just look at CVHB0000157\_608, this  
 6 is a virology sheet. It's not the results that are  
 7 significant but we see "Date of collection,  
 8 17 October 1983; Clinical information, haemophilia,  
 9 pneumonia, AIDS". So again within the hospital  
 10 clearly regarded by this time as a definite AIDS case.  
 11 If we then look at HSOC0029476\_031, this is  
 12 a meeting of the Haemophilia Society's executive  
 13 committee on 6 December 1983. There are a number in  
 14 attendance. It doesn't include Professor Bloom but,  
 15 obviously, we know that there were communications  
 16 between the Haemophilia Society and Professor Bloom  
 17 throughout this period. If we go to the top of the  
 18 next page, please, Soumik, the first two lines:  
 19 "While there were no new suspected cases [it  
 20 would appear the Haemophilia Society have not picked  
 21 up on the Bristol case], it was noted that the Cardiff  
 22 case was now confirmed."  
 23 It's not quite clear why the Haemophilia  
 24 Society was identifying Kevin's case in December 1983  
 25 as now confirmed. It may have been on the basis of

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1 So that's how his bloods are going to be  
 2 treated and then bottom of the page, 18 October 1983,  
 3 "S/B [seen by] Professor Bloom", and there's  
 4 a reference over the next page to his current  
 5 lymphocyte count being better than it has been for  
 6 months. That's the [NB], the suggestion being that  
 7 the lymphocyte count has been worse earlier.  
 8 Then 19 October 1983, "weight loss and  
 9 repeated", I'm not sure what the next two words are.  
 10 **SIR BRIAN LANGSTAFF:** "... repeated infections certainly  
 11 suggest AIDS ..."  
 12 **MS RICHARDS:** "... certainly suggest ... regrettably."  
 13 There's a reference to something being quite in  
 14 keeping with PC infection, I think that must say.  
 15 **SIR BRIAN LANGSTAFF:** PC infection.  
 16 **MS RICHARDS:** Yes, exactly. There's a plan then set out,  
 17 and if we go to the top of the next page, we can see  
 18 the plan being discussed with Professor Bloom and  
 19 Professor Bloom agreeing to it there.  
 20 Again, if we look at the admission records,  
 21 CVHB0000157\_569, this is the form that we've now seen  
 22 on a number of occasions. This is for his admission  
 23 on 17 October:  
 24 "Reason for Admission/Diagnosis: pneumonia.  
 25 "Additional Health Problem: Haemophiliac."

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1 information from Professor Bloom but, if so, what the  
 2 basis for that was is also unclear in light of the  
 3 history. It may be that will be a matter we can  
 4 explore with Mr Watters next week.  
 5 We can see also in December a report in the BMJ  
 6 which refers to both the Bristol case and to Kevin.  
 7 It's PRSE0003773. This is, in fact, authored by  
 8 Dr Peter Jones. It's headed "AIDS, hepatitis and  
 9 haemophilia", and if we just look at the bottom  
 10 left-hand column, the last few lines on the page talks  
 11 about 17 cases of AIDS having been reported in the US  
 12 amongst people with haemophilia, "Ten patients have  
 13 died, all with [PCP]", and then it refers to the  
 14 position in Britain:  
 15 "... two cases of haemophilia and AIDS have  
 16 been reported to the Communicable Disease Surveillance  
 17 Centre at Colindale. One patient with [PCP] has died  
 18 (GL Scott, personal communications) [so that is the  
 19 Bristol case], and the other has had opportunistic  
 20 infections ([Professor Bloom], personal  
 21 communication)."  
 22 So that would suggest some form of dialogue or  
 23 discussion between Dr Jones and Professor Bloom, in  
 24 which Professor Bloom has informed Dr Jones that his  
 25 patient has opportunistic infections.

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1 There is then an overview of Kevin's situation  
2 in a letter at the end of 1983, 21 December 1983.  
3 Soumik, it's WITN3408015, go to the next page. So  
4 this is a letter, it's from Professor Bloom himself,  
5 21 December 1983, to a consultant ENT surgeon:

6 "You may remember seeing Kevin a couple of  
7 years ago. He is the 20-year old youth with severe  
8 haemophilia who had some sinus wash-outs two or three  
9 years ago. Unfortunately since then and during the  
10 last nine months, Kevin has had some rather more  
11 serious troubles. He presented in March with severe  
12 oropharyngeal and oesophageal candidiasis and had  
13 severe dysphagia and had lost a stone in weight. It  
14 became clear that his cell mediated immunity was quite  
15 severely impaired and he had a severe lymphopenia with  
16 a reduction of T4 lymphocytes. Although his  
17 candidiasis cleared up ... he subsequently developed  
18 other opportunist infections, including severe herpes  
19 which necessitated treatment ... and more recently  
20 an acute pneumonia which was clinically typical of  
21 [PCP] ...

22 "In summary therefore, Kevin is a severe  
23 haemophiliac who almost certainly has the Acquired  
24 Immune Deficiency Syndrome and has suffered from  
25 a number of opportunist infections over past nine

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1 have set out some of them in the note.

2 What is not possible to pick up from the  
3 documents, in terms of the medical records, is any  
4 discussion between the treating clinicians and Kevin  
5 about his condition. There is no record of any  
6 communication to him of an AIDS diagnosis.

7 There is material arising out of a Department  
8 of Health and Social Security request for information  
9 for the purposes of attendance allowance, which may  
10 suggest that Kevin was not told of his diagnosis, even  
11 as late as autumn of 1984. So if we look at  
12 CVHB0000157\_041, this is a DHSS letter. It's  
13 addressed to Dr Bloom. It's dated 19 October 1984.  
14 The context is Kevin having made an application for  
15 attendance allowance and in the second paragraph  
16 Dr Bloom is asked to supply a factual report based on  
17 your knowledge and records of the case. Then if we  
18 see the box which is the fourth paragraph down, but  
19 the text is in a box:

20 "A copy of your report may have to be sent to  
21 the claimant in the event of an application being made  
22 to the Board to review their decision or  
23 an application for leave to appeal against their  
24 decision. There is power to withhold any information  
25 which would be harmful to the claimant's health. If,

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1 months."

2 His current treatment is then described, and  
3 the bottom of the page Professor Bloom says this:

4 "Clearly with the added complication of the  
5 Acquired Immune Deficiency Syndrome, operative or  
6 invasive treatment would be most undesirable and of  
7 course his blood should be treated as infective ..."

8 Then over the page he goes on to ask for the  
9 ENT surgeon's views on whether anything could be done  
10 in relation to Kevin's sinuses, and we can see the  
11 letter is from Professor Bloom.

12 So there is a summary from Professor Bloom  
13 himself of Kevin's condition and the various  
14 manifestations of AIDS over that nine-month period  
15 from March 1983, sir.

16 In terms of the following year, there were  
17 repeated hospital admissions. Kevin was admitted as  
18 an emergency in January 1984. He was coughing up  
19 blood. He remained in hospital for a few days. We  
20 will perhaps just look at that CVHB0000157\_384. If we  
21 just look at the first few lines, we can see there is  
22 the triangle diagnosis "AIDS -- March 1983", and there  
23 are various references in Kevin's notes in the course  
24 of 1984 to the AIDS diagnosis and dating it back to  
25 March 1983. I won't go to all those references, we

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1 in your opinion, any of the information should be  
2 considered in this light, please note the relevant  
3 items of your report accordingly. There is no power  
4 to withhold information on any other grounds."

5 So that's the request that was made and then if  
6 we go to CVHB0000157\_042, the form's completed but  
7 it's not signed and so we don't know which clinician  
8 signed it. We know the letter was sent to Dr Bloom  
9 but we don't know whether it was Dr Bloom or someone  
10 else in his department who completed this. We can see  
11 handwritten out is the information that's requested by  
12 DHSS:

13 "Present condition.

14 "What attention does he require normally for  
15 body function.

16 "What is the frequency of bleeds.

17 "Are there any reasons why he can't give his  
18 own Factor VIII injections."

19 Then "Report from medical practitioner":

20 "Kevin Slater has severe haemophilia A. He  
21 also has chronic pneumocystis pneumonia and recurrent  
22 oral thrush."

23 There's an asterisk and we will come to that in  
24 a moment:

25 "2. He is able to care for normal bodily

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functions.

"3. He has bleeds, approximately one a fortnight.

"4. Hand bleeds will preclude self-treatment."

Then there's reference to a particular feature of his haemophilia associated with his chronic pneumonia, which may require prompt medical care.

Then this, the asterisk:

"Information to be withheld if report is sent to Mr Slater --

"These clinical findings together with evidence of depressed immunity mean that he has the syndrome of acquired immune deficiency (AIDS)."

So, sir, one interpretation at least of that document might be that those clinical findings and/or the syndrome of AIDS, the diagnosis of AIDS, is to be withheld from Kevin. We can't see anything in the records which casts any further light, sir, on that question on the basis of the material we've seen.

In terms of the wider picture in the autumn of 1984, if we look at CBLA0001884\_007, this is a document dated 10 September 1984. It's headed "Current Situation Regarding AIDS":

"The attached table and histograms are based on reports received from Haemophilia Centres on the

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set out by the consultant physician in the chest clinic who had been seeing Kevin because of his symptoms of pneumonia.

There is then a pattern of repeat admissions to the University Hospital Wales over the coming months. His records record PCP having been diagnosed in October 1983. There are records to suggest a degree of barrier nursing and, again, we see a reference to the diagnosis of AIDS really dating from March 1983 in a letter from Dr Lucas. That's at WITN3408021.

If we go to the next page, this is at 4 December 1984, Dr Guy Lucas, who we know subsequently took up a post in the Manchester Haemophilia Centre but, at this stage, was working in the University Hospital of Wales:

"This is the chap with severe haemophilia A who was diagnosed as having AIDS in March 1983. Recently his weight loss has accelerated and chest signs have deteriorated."

Then there is a plan for a biopsy.

Then if we go to CVHB0000157\_330, we see the formal anti-HTLV-III positive test result. It would look as though the sample was taken possibly at the Royal Gwent Hospital in Newport on 22 November and the test comes back, dated 12 December 1984, anti-HTLV-III

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patients who received the same batches of blood products as the Cardiff and Bristol AIDS cases."

If we go over to the third page please, Soumik, we see by way of example various tables, the top histogram "Showing number of patients having received commercial Factor VIII related to AIDS case A/1."

A/1 is the labelling used by Dr Craske to refer to Kevin's case. A/4 is the Bristol case.

We don't need to look at the detail of it.

There are various other tables there set out but what we see in terms of the wider picture is that by 10 September 1984 there is a public health investigation underway to potentially identify what batches of blood products may have been used to treat patients other than the Cardiff and Bristol cases, and yet within that same period of time, the autumn of 1984, there is evidence to suggest that Kevin himself has still not been informed of his diagnosis.

We know also from CVHB0000157\_307, this is a letter from November 1984. It's from a physician in the Newport Chest Clinic to a Dr Moffat in the Haematology Department, the University Hospital of Wales, it's copied to Professor Bloom and others. We know from the last paragraph, last sentence, "the prognosis is, obviously very poor", is what is there

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positive because, of course, by then testing is available.

I should say that there is an extract from the National Haemophilia Database, which gives a date of a positive test or first positive test as 15 July 1984. Sir, it may be that another test was carried out on a stored sample but, if so, we haven't got any other records other than what's set out in National Haemophilia Database.

Then Kevin was in and out of hospital on various occasions in early 1985. The medical records, and I won't go through them in detail, but they document the continuing deterioration of his health. He's described as weaker, as moving slowly, disturbed sleep, thrush infections, and so on, are recorded. He was an in-patient for several weeks February-March 1985, again with a range of problems recorded. He'd been coughing up blood, pneumocystis again, and so on. He was admitted again in April 1985 and the medical records record him as deteriorating slowly physically.

Then in records relating to an admission at the end of April and early May 1985, he is by that time described as very thin, emaciated, he was unable to move or stand up on his own. Poignantly, and consistent with references in earlier records, he's

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described as remaining bright and cheerful with no other complaints.

If we then just look briefly at a couple of other documents, CVHB0000157\_035, we can see a letter from Professor Bloom to a Mr Lal, Medical Services Officer in the Pharmaceutical Division, Bayer House, and it's a request for assistance regarding Kevin and it's a request to use a particular drug Suramin, "since we are otherwise coming to the end of the line", is what Professor Bloom says. He asks if Mr Lal will consider letting him have it for a prescription on a named-patient basis.

There are then repeat admissions in the course of May and June. Kevin's described by now "as weak as a kitten". His final admission to hospital was on 16 June and he remained in hospital until his death on 23 June 1985.

There is just one further letter I will put on the screen, following his death, WITN3408024. If we go to the next page, it's a letter from a haematology registrar, Dr Lush, to what is probably the GP. It's 9 July 1985 and it records Kevin's last admission and his death:

"Admitted: 6 June 1985. Died: 23 June 1985.

"Cause of death: Acquired Immunodeficiency

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Ms Moore and Ms Sharland that what they will have listened to, if they have been listening, cannot have been easy but I would like to thank them very much indeed for their agreement that it should be aired. It appears to me that, although it is hard to hear, it is important to hear it both and in particular for Kevin and what happened to him, but also to the reactions of those around him to what he was suffering from and what they made of it, which is quite illuminating. So thank you very much to them.

I think we're now due a break, are we, Ms Richards?

**MS RICHARDS:** Sir, yes, I'm sorry. I hadn't realised the time. I note it's nearly --

**SIR BRIAN LANGSTAFF:** No, it was important to finish it.

**MS RICHARDS:** I wanted to do that, sir, in one go. It is nearly 12.00, sir. I'm in your hands as to whether we take a break now or take the lunch break early or however you wish to proceed.

**SIR BRIAN LANGSTAFF:** Let us take a break for those who have been listening because, as I say, it can't have been easy listening for some, and come back, shall we, at 12.15. We will take a slightly later than usual lunch break at 1.15.

**MS RICHARDS:** Thank you, sir.

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Syndrome."

The history is then set out, it's the recent history that's set out there of the last admission. We can see in the second paragraph, last sentence, he was generally weak, had become unable to hold even a glass of milk for himself and his parents had to feed him. There is a description of the drugs he was receiving on admission for his condition, examination, and so on.

If we go to the second page, last paragraph, it's recorded that:

"Over the next few days his condition gradually deteriorated. His speech became incoherent and he was experiencing some pain ... he required intravenous fluids ... he gradually became unconscious and died on 23 June. In view of the nature of his disease, the death was reported to the coroner, but obviously no post-mortem was performed."

Kevin was just 22, sir, when he died. Sir, that is the information that we have identified relating both to Kevin's own medical records and to how his case was viewed by various significant agencies and bodies and individuals, in particular in the course of 1983.

**SIR BRIAN LANGSTAFF:** Yes. I'd just like to say to

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**SIR BRIAN LANGSTAFF:** Or thereabouts.  
(11.58 am)

(A short break)

(12.15 pm)

**SIR BRIAN LANGSTAFF:** Yes, Ms Richards.

**MS RICHARDS:** Sir, we turn now to Newcastle.

The material that we'll look at today and tomorrow is based largely on documents available to the Inquiry but I'll also be referring to -- contemporaneous documents, I should have said, but I'll also be referring as appropriate to the statements the Inquiry has received from those who worked at the centre in Newcastle in the 70s and 80s.

There are two statements from Dr Peter Jones, a statement from Dr Peter Hamilton, a statement from Maureen Fearn, the nursing sister, and a statement from Pat Latimer, a social worker. I understand these statements, which have already been disclosed to Core Participants, will be published on the Inquiry's website, I think following the conclusion of the presentation.

I propose, in terms of the issues that will be explored, to look briefly at the history of and facilities at the centre, then to look at treatment policies and blood product usage, and there's quite

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1 a lot of documentation that's relevant in that regard,  
2 then to look at what was known and understood by those  
3 working at the centre, principally Dr Jones, also  
4 Dr Hamilton, about the risks of hepatitis. And then  
5 what was known and understood about the risks of AIDS  
6 and what was done at the centre in response.

7 It may be that that set of topics is completed  
8 today but it may be that that runs into tomorrow.

9 I will then be looking at arrangements for the  
10 testing of patients and informing them of their  
11 diagnosis and more broadly at the patient experience.  
12 Then at the introduction of heat-treated concentrates  
13 in late 1984 and in 1985; then at the particular issue  
14 of AIDS transmission or suspected AIDS transmission  
15 from heat-treated products and Dr Jones' involvement  
16 in that issue; then HCV testing and diagnosis; and  
17 then interactions between Dr Jones and pharmaceutical  
18 companies; and then, more briefly, Dr Jones'  
19 involvement with The Haemophilia Society and with the  
20 Macfarlane Trust.

21 In addition to the two witness statements which  
22 Dr Jones has supplied to the Inquiry, we also have  
23 quite a lot of material which he's produced over the  
24 years. Those include: a fairly detailed personal  
25 record, a form of statement or report which he

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1 history of the centre in the first three paragraphs:  
2 "The Haemophilia Centre in the Royal Victoria  
3 Infirmary, Newcastle-upon-Tyne, was one of the  
4 original centres set up by the UK Medical Research  
5 Council in the 1950s. The prime purpose of these  
6 early centres was to accurately diagnose people with  
7 haemophilia and related bleeding disorders."

8 Second paragraph:

9 "At the outset the UK centres were little more  
10 than laboratory space for coagulation studies,  
11 performed by a pathologist with an interest in  
12 haematology. In Newcastle the first centre director  
13 was a physician who looked after the clinical needs of  
14 patients within the context of a busy practice in  
15 general medicine. The treatment of children with  
16 haemophilia was shared on an *ad hoc* basis between the  
17 paediatric consultants.

18 "The first clinic dedicated to these children  
19 [i.e. children with haemophilia] was started in the  
20 1960s when I was working with Dr William Walker,  
21 a consultant paediatric haematologist, and  
22 Professor Donald Court, a consultant paediatrician."

23 So that's the early emergence of the centre.  
24 We can then pick up some more of history in the second  
25 half of the 1960s from a paper at TYWE0000036\_001.

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1 produced I think in around 1990; his report to or  
2 reports to the Lindsay Tribunal and a transcript of  
3 his oral evidence to the Lindsay Tribunal; and  
4 a number of books and articles that he's authored over  
5 the years. I will be making reference to those in the  
6 course of the presentation today and tomorrow, as well  
7 as picking up, tomorrow, on themes emerging from the  
8 evidence the Inquiry's received from those who were  
9 infected and their families.

10 So, sir, that's the issues that I hope to  
11 address today and tomorrow. And of course, as with  
12 all of the presentations on haemophilia centres, these  
13 are not intended to be exhaustive. The range of  
14 material relating to Newcastle is vast. There will no  
15 doubt be other relevant documents. There will be no  
16 doubt be important submissions that Core Participants  
17 will wish to make in due course. This is intended  
18 only really to offer a summary of some of the key  
19 material to enable that further exploration in due  
20 course.

21 Sir, dealing first with the centre's history,  
22 Soumik, if we could have up on screen, please,  
23 PJON0000031\_001.

24 This is one of Dr Jones' reports to the Lindsay  
25 Tribunal, and there's just a little about the early

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1 This is a paper responding to an earlier 1965  
2 paper from the Ministry of Health. We don't need to  
3 look at all of it. If we go to the second page, and  
4 we look at the bottom half of the second page, we can  
5 see there reference is made to a special meeting which  
6 included Dr TH Boon, and then various other names are  
7 given. That's a special meeting of a committee of the  
8 Newcastle Regional Health Board, and Dr Boon was the  
9 centre director, to the extent that there was  
10 a director at that time, and this was looking at the  
11 organisation of a regional service within Newcastle  
12 and broader area. We pick it up five lines from the  
13 bottom, so the committee's recommendation was:

14 "... a number of regional treatment centres  
15 should be increased providing a more local service and  
16 that the facilities available should be such as to be  
17 capable of dealing with the great majority of elective  
18 clinical conditions arising in haemophilia patients.  
19 The establishment of comprehensive units within the  
20 Region enabled the staff concerned to become  
21 knowledgeable about the patients in their respective  
22 catchment areas, and conversely for the patients to  
23 gain confidence in staff who were familiar to them.  
24 Nonetheless, it was fully acknowledged that there was  
25 a need for one or two national centres which would

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serve as centres of referral of particularly complicated cases, and also functioned as major centres for research.

"In essence, therefore, a special subcommittee favoured the treating of all but the most complicated cases regionally rather than nationally."

Then it's recorded that:

"The principal difficulty arising from the treatment of haemophilia related to the assurance of an adequate supply of anti-haemophilia globulin [AHG], and the committee emphasised the recommendations of the earlier meeting that a full investigation ought to be undertaken into the factors relating to the supply [haemophiliac] AHG on a national basis."

So the issue of supply and self-sufficiency there being identified. Then there is a discussion of centres for the region:

"Three treatment centres might reasonably be provided in the Region - at Newcastle, Carlisle and Middlesbrough (the first two already being designated). Each of these would attract patients from a large enough area to ensure a special case load for the administration of an adequate standard of work, whilst at the same time provide a reasonably local service."

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linkage between the two hospitals."

Then there is a discussion of certain problems relating to the Newcastle centre. So:

"This sums up the Board's facts of the current situation, but further explanation reveals interesting information. Dr Bird plainly does not rate Dr Boon's interest (or indeed perhaps even expertise) for the very highly with reference to Haemophilia and plainly feels the alleged interest has only been stimulated by prospect of possible loss of designated stages. Although Dr Boon nominally maintains the Haemophilia Register this seems clearly to be in a poor state, being rarely referred to, and (according to Dr Bird) containing a good deal of erroneous information. Similarly, in the laboratory work on assay of anti-haemophilic globulin, Dr Bird and his staff are used for taking samples and making estimates. Possibly Dr Bird's feelings are coloured by his irritation of the fact that -- though he knows a good deal about haemophilia (in fact maybe more than most) -- he was not invited to attend this meeting of the Board's officers in July to discuss the care of persons suffering from coagulation disorders. But, looking behind his opinionously fair comments I do not think that he is ever impressed by the RVI's

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An approach was going to be suggested to the Ministry of Health setting forth proposals for the development of this regional service.

Then we can see a little more about Newcastle at the bottom of the page:

"Newcastle is designated by the Medical Research Council as a diagnostic and reference centre, this status be invested in Dr TH Boon, at the Royal Victoria Infirmary. The service provided links and Dr Boon as clinician with the Department of Pathology and Professor Heppleston, though it seems that ..."

If we can zoom in on the top part of the page:

"... routine work on coagulation studies is largely in the hands of Dr Muckle. Within the RVI empire are two other prominent figures in Haematology, viz Dr RB Thomson and Dr W Walker ... but each pursues specific interests and does not always deal in coagulation matters. The counterpart at Newcastle General Hospital is Dr T Bird who is a specialist in haematology, but not a clinical haematologist, it seems then as no clinician in this hospital with a particular bent for problems of coagulation. In ..."

I'm not quite sure what the next word is, but:

"... organisation of services there is no cross

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facilities."

"There is no doubt that Dr Bird would be happy to provide a service in the management of coagulation disorders, but as he is not a clinical haematologist, he has no access to beds ..."

And then it records that.

"He [that's Dr Bird] believes a designated centre in Newcastle is important and is not impressed of the concept of concentration of three national supra-regional centres. In extending this theme he feels that facilities should be concentrated in one hospital, ideally under the control of a single clinical haematologist (he sights Dr EK Blackburn of Sheffield who has his own beds, out-patient clinics, et cetera). Short of this, a team of two comprising a clinician and a pathologist (haematologist) should supply the service. He accepts as logical the concept that this might be RVI based, but thinks it essential that there is an appropriate laboratory setup to back it; this may well imply the need for more trained staff."

Then if we skip over a paragraph, there is reference to a confidential medical report issued to senior administrative medical officers of all regional hospital boards, and a letter asking if Mr Collins

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would formally concern from Dr Boon and Professor Heppleston ..."  
 It's not quite clear what that means:  
 "... that they wished the Teaching Hospital to continue to be designated as the diagnostic and registration centre in Newcastle. Mr Collins replied to the fact that he had discussed the matter with Dr Boon and Professor Heppleston who had prepared a report supporting the continuance of the Royal Victoria Hospital as a designated haemophilia centre."

And so on.

So we can see that -- this is undated but we can see that at some point in the second half of the 1960s there is both a discussion of issues in relation to supply, a discussion of whether there should be a regional service centred around Newcastle, and concern expressed about the adequacy of provision under Dr Boon's directorship at Newcastle.

We haven't been able to follow through the thread of this correspondence completely, and it may be it doesn't particularly matter, but we can pick it up in November of 1972 in a letter from Dr Boon.

Soumik, it's TYWE0000036\_005.

This is a letter from Dr Boon, 27 November 1972, to the DHSS, and he is formally

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centre in Newcastle fulfils all the requirements laid down in the Biggs and Rizza memorandum.  
 "As senior physician to the Infirmary all adult haemophilic patients are admitted directly to my care, and the recent appointment of Dr Peter Jones as consultant paediatrician with special Regional responsibility to patients with bleeding disorders has resulted in all children being similarly cared for by one physician. Both Dr Jones and I have direct access to the relevant laboratory facilities, and Dr Jones has responsibility for the developing coagulation laboratory in the new Department of Haematology under the direction of Dr Walker. We are able to perform the full range of investigations necessary for the diagnosis and management of patients with bleeding disorders at all times, and work closely with Regional Transfusion Centre."

If we go over to the top of the next page, zoom in a little closer:

"A new haemophilia unit is scheduled to open in April 1973, and it is hoped that this unit will act as the focal point of the Regional service. Dr Jones is at present engaged in the task of co-ordinating the medical, surgical, dental and social care of all haemophiliacs in the Region with the active

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asking for the department's recognition of Newcastle as a special treatment centre. He refers to a recent memorandum from Dr Biggs and Dr Rizza suggesting that Sheffield, Manchester and Oxford be the special treatment centres for England, and he sets out his understanding that Edinburgh, Glasgow and Belfast are similarly recognised.

He refers to a meeting of the Newcastle Regional Board, which I think is probably one of the meetings referred to in the document we looked at a few moments ago, a few years ago, in which:

"... it was the unanimous wish of those present that Newcastle should develop into a Special Treatment Centre."

Then he says this:

"The Newcastle Centre at the Royal Victoria Infirmary has, in spite of financial and staffing problems, a long record of service to haemophilic patients from the Region. Its position has recently been reaffirmed by the Regional Hospital Board and it is partly because of the developments that are now in progress and partly because of the large geographical area and population we serve that we would welcome special consideration by the Department."

Then he goes on to set out his view that the

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co-operation of our colleagues in outlying hospitals. The unit will also permit out-patient therapy for our local population and the provision of a home care programme. We hope to have the services of a full time Sister and auxiliary nursing staff, and have just appointed a full time secretary and a part time social worker to join the established team. This already includes an orthopaedic surgeon, a general surgeon, and dental and genetic advisory services.

"We are aware that the major requirement for a Special Treatment Centre must be its ability to treat major complications and undertake surgery. Our record in this field is, I believe, a good one."

He goes on to provide details of that. He says:

"We wish to continue to develop our experience and service in our own community, and believe that this approach is in the best interests of our patients. We know them and their relatives well. We think that it is often better to watch and observe clinical problems carefully than to act immediately, and we have experience in the detrimental effect of rapid emergency journeys to other parts of the country."

And he concludes:

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"For these reasons we feel that recognition as a Special Treatment Centre would be beneficial to our patients, our developing Regional services, and our staff, and would be grateful for the Department's approval."

So that gives a snapshot of where matters stood in terms of Newcastle staffing early -- or certainly by end of 1972.

We can see that in 1974, and it was in the course of 1974 that Dr Boon retired and Dr Jones took over his post as director, having been already in place as a consultant paediatric haematologist, or consultant paediatrician rather.

In the course of 1974, the issue of the regional service was revisited. And if we go, first of all, to TYWE0000036\_004, please, Soumik.

We can see this is a document put together by Dr Jones for a regional haemophilia service:

"In order to help patients with haemophilia and related disorders of haemostasis in the Newcastle Regional Hospital Board area it is proposed that a regional service be established. The provisional plan for the service is detailed in this memorandum, and the comments of Hospital Management Committee and individual doctors and dentists in the hospital

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Then the Royal Infirmary in Sunderland, and then if we go over the page, if we zoom in on the top half of the page, please, Middlesbrough General Hospital, Cumberland Infirmary and West Cumberland Hospital. Then what is said below that is:

"It is suggested that all patients with the bleeding disorders requiring any form of hospital treatment should be referred in the first instance to the appropriate consultant for the area, or his deputy. Patients should not be sent to casualty departments or to surgical units on reception.

"The Newcastle Centre will continue to be responsible for all major surgery and the treatment of complications. A new Haemophilia Centre and coagulation laboratory is scheduled to open in the RVI in late 1973. All patients will be registered and copies of their clinical and laboratory records filed at this Centre. An intensive survey of all patients in the Region is in progress to supply information needed for the initial data bank; to date 341 people are on the register and further 150 have to be tested."

Then details are given of how the Royal Victoria Infirmary coagulation laboratory will undertake its work. Halfway through that paragraph

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service are invited."

Then the current situation is described.

"The DHSS now recognise 42 Haemophilia Centres in the [UK]."

Then a few lines down:

"However, the establishment of centres does not solve the major problems facing many patients. In order to enjoy normal education and employment they need treatment and advice without having to travel long distances from their home. Yet because of the rarity of the hereditary bleeding disorders it is obviously both uneconomic and impracticable to attempt to provide full laboratory and clinical services in all general hospitals."

So the planned service is then set out:

"It is proposed that one general hospital in each area of the region should be responsible for the care of patients with hereditary bleeding disorders, the majority of whom have haemophilia."

We can see then listed the suggested hospitals and members of staff. I won't go into the details of the members of staff but we can see the Newcastle Centre, Royal Victoria Infirmary, the director Dr Boon until June 1974, various other members of staff set out.

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it's recorded that the centre, so that's the Newcastle centre:

"... already works closely with the Regional Blood Transfusion Service and with other National and International Centres and specific blood factor fractions are either immediately available or can be rapidly obtained."

So that was Dr Jones' plan for there to be a regional service with facilities at the other four regional hospitals there identified, as a first port of call for treatment, but with the Newcastle centre being responsible for all major surgery and complications.

If we then look at TYWE0000036\_003, we can see approval was given by the senior administrative medical officer to this proposal. This is a report dated 8 March 1974 by REN Stewart. It's the report of the senior administrative medical officer and it says this:

"From time to time central advice is issued on 'arrangements for the care of patients suffering from haemophilia and related diseases' ..."

It refers to a Department of Health circular:

"In my parallel fashion, and against the background of such guidance, intraregional discussion

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has been promoted on various occasions to define and clarify an organisational pattern which might be applicable in local circumstances. Renewed attention to the subject has now been prompted by Dr Peter Jones ... and a copy of a memorandum which he's prepared [which is what we just looked at] ... is attached for consideration.

"It is suggested that -- with the addition of Darlington as a centre to serve Darlington and its environs, and the inclusion of such amendments as the committee [that's the medical advisory committee] wishes to see incorporated -- the document in question be given appropriate distribution."

So this support for Dr Jones' proposals, it would appear, from a senior administrative medical officer. Then finally on this issue, if we look at TYWE0000036\_002, we can see effectively approval from the Newcastle Regional Hospital Board. This is 11 March 1974:

"Dear Secretary,

"The Board has given consideration to the introduction of a regional organisation for the treatment of patients with haemophilia and related disorders, and I enclose copy of a report of the Senior Administrative Medical Officer [that's what

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centre, comprising a consulting room, a waiting area, a coagulation laboratory, a treatment room and a room for the nurse and social worker and there are several contemporaneous documents which make reference to that.

The team working at the centre was supplemented by the arrival of Maureen Fearn as a nursing sister in 1974. A second nurse was appointed, Staff Nurse Jean Bough in 1976, and in the course of 1976, we can see -- I'm not going to take time going to it -- but we can see a series of papers being delivered by various staff members associated with the centre at the World Federation of Haemophilia conference. There were papers by chief technicians, social workers, the nursing sister, the physiotherapist, a psychiatrist, a dental surgeon and consultant surgeon. So, to some extent, a multidisciplinary service by the mid-or second half of the 1970s.

We know that in 1978 Dr Peter Hamilton joined the centre as consultant haematologist, and effectively as co-director of the centre, and over the following years key Reference Centre Director meetings were often attended either by Dr Jones or Dr Hamilton, usually one at least was present.

Then in 1980 a new dedicated haemophilia centre

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we've just looked at] which has been approved by the Board together with a memorandum prepared by Dr P Jones ... particularly concerning the topic. It will be seen that the proposals envisage the development of centres at certain hospitals viz ..."

And they are then set out, including now Darlington:

"The Board is prepared to see adopted in the Region the proposed pattern and organisation of the service as set out in the Report, and discussions will now take place with appropriate consultants in the above centres with a view to implementation."

Reference is made to Dr Jones having had preliminary discussions with consultants in the other centres and attention will be given to implementation of the scheme.

So that's the arrangement on a regional basis that was endorsed by the Newcastle Regional Hospital Board in March 1974.

It was in April 1974 that some, I think relatively limited, but some accommodation for the haemophilia centre was a centre became available in the Royal Victoria Infirmary. There was a new Department of Haematology and a suite of small rooms adjacent to that department were set aside for use of

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was opened.

Soumik, could we have HSOC0021607, please. If we go to -- I think it's probably page 9. Yes. So this is a pamphlet prepared at the time of the opening of the new centre on 22 May 1980, and if we pick it up in the middle column, second paragraph:

"Together with its associated Centres in Carlisle, Cleveland, Sunderland and Whitehaven, the Newcastle Centre serves a population of 3.3 million. Both acquired and hereditary disorders of homeostasis are investigated and monitored in its laboratory, the staff of which, under the supervision of Mr Oxley, perform some 26,000 tests a year in addition to those needed for out-patient anticoagulant control. Three hundred and three people with a hereditary coagulation disorder from 211 families are seen regularly in the Centre, and 78 of those more severely affected have been trained to treat themselves with intravenous injections of the relevant blood product at home."

I'll come back to the question of home treatment later. Then we see reference to the opening of a building by a member of the Royal family that day:

"... in the Department of Haematology contains a social work room for the counselling of families,

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1 a research and coagulation laboratory, a consulting  
2 room, a nurses' station and nursing Sister's room, and  
3 a preparation and treatment room which is used for the  
4 transfusion of people with a wide variety of disorders  
5 of the blood in addition to the treatment of  
6 haemophilia."

7 Then lastly on the topic of the centre, if we  
8 go to WITN0841010, please. This is a document  
9 authored by Dr Jones and published in a journal called  
10 Clot, it looks like, in 1982 "Guidelines for the  
11 Organisation of a Haemophilia Centre". If we go to  
12 the bottom of the second page we can see the last  
13 paragraph says:

14 "The figure [it's the figure on the next page,  
15 which we'll look at in a moment] shows the  
16 organisation in Newcastle in diagrammatic form. The  
17 Centre is staffed by a core team who work either  
18 full-time or part time with haemophilia and related  
19 disorders."

20 Then we have on the next page a diagram, zoom  
21 in on the diagram, which is said to show the staffing  
22 at the centre. It identifies a core team of  
23 haematologist, physician, paediatrician, nursing  
24 staff, technical staff, physiotherapist, social worker  
25 and secretary; an ancillary team which includes dental

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1 voice their opinions about individual patients and  
2 about the organisation of the Centre in an informal  
3 atmosphere. Support can be given to individual  
4 members of staff, and manipulation by particular  
5 patients discussed."

6 I'm not sure what that's a reference to.

7 Then home therapy outlined in the following  
8 paragraph:

9 "We make it a rule in our home therapy  
10 programme not to supply blood products unless a very  
11 careful record is kept of their use by individual  
12 patients. In this way we have detailed knowledge of  
13 all bleeds and their response to treatment when the  
14 patient comes in for follow-up. We have found it  
15 extremely useful to keep a calendar log of bleeds,  
16 rather than a written diary of episodes. Target  
17 joints can be spotted immediately and the effect of  
18 changes in treatment seen easily."

19 Then reference is made to the importance of  
20 24-hour cover.

21 That's, as it were, a whistle-stop tour through  
22 the development of the regional service with the  
23 Newcastle centre at its heart in the late 1960s and  
24 the course of the 1970s.

25 Just dealing briefly with the key personnel at

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1 services and surgical services, and so on; and then  
2 various services provided or said to be provided at  
3 the haemophilia centre set out there in the middle.  
4 Then we see a relationship with other hospitals and  
5 associated haemophilia centres, that's reference to  
6 the regional service that we've seen referred to, and  
7 home therapy programme, and that I will come back to.

8 If we go to the next page, this is what  
9 Dr Jones says in 1982 about the way in which the  
10 centre was operated. So picking it up in the first  
11 main paragraph:

12 "With the agreement of colleagues within our  
13 geographical region, which has a population of  
14 3.3 million, the home therapy programme is run from  
15 the Newcastle Centre and all patients are followed up  
16 there by members of the core team. Lines of  
17 communication between the Reference and Associate  
18 Centres and between the Reference Centre and District  
19 General Hospitals -- which one or two patients might  
20 be treated -- must be established clearly or  
21 complications could easily arise ..."

22 And then:

23 "It is particularly important to have regular  
24 meetings of the core team. We do this at weekly  
25 intervals. These meetings allow members of staff to

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1 the centre, Dr Peter Jones, trained as  
2 a paediatrician, initially in general paediatrics but  
3 became increasingly focused on the management of  
4 haemophilia and related disorders. Slightly different  
5 dates are given in different documents for when he  
6 took up his post as a consultant paediatrician at the  
7 Royal Victoria Infirmary. Some documents say 1970-71  
8 some say 1972, but clearly he was there by 1972, and  
9 became director of the centre. Again, it's not  
10 precisely clear on what date but it may have been when  
11 Dr Boon retired in June 1974 or it may be that he was  
12 co-director for a period of time, because I think at  
13 least some of the documents suggest he was director  
14 from 1972.

15 Dr Jones published a number of books, including  
16 a book called *Living with Haemophilia* and we'll look  
17 and the first edition of that at a later stage, or  
18 part of it. That was first published in 1974. He's  
19 published various other books and we will look at some  
20 extracts from some of them. He published numerous  
21 papers and articles and was particularly prominent in  
22 the media during AIDS crisis and, again, we'll look at  
23 some of the media reports in that regard.

24 He was a member of UKHCDO. There is reference  
25 in the minutes to him attending meetings from 1972

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onwards and from 1976 either he or Dr Hamilton were attending the Reference Centre Director meetings. He was also, for a number of years, chair of UKHCDO's home therapy working group. We know also he served on various other groups and committees. He was involved with the Macfarlane Trust, he was a long-standing member of The Haemophilia Society's Medical Advisory Panel or committee and he was a secretary of the World Federation of Haemophilia Paediatric Committee. He continued in his post at the Newcastle centre until 2000, when he retired.

Dr Peter Hamilton was appointed to the centre in 1978 as consultant haematologist and, we think, as co-director. It appears he was the first trained clinical and laboratory haematologist to be appointed to the centre and he spent the first few months of his appointment seconded to Cardiff and Oxford.

If we look at one document relating to Dr Hamilton it's PJON0000053\_001, please. This is a letter from Dr Peter Hamilton to Dr Craske dated 21 June 1978. He says:

"Dear Dr Craske,

"As I explained to you a short while ago, I am a recently appointed Consultant Haematologist here in Newcastle and I am working *inter alia* closely with

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Hepatitis B is, of course, important, but I do not want to concentrate just in this area - partly because of problems that must be involved in getting laboratories to co-operate in processing this blood. I aim to look at our Hepatitis B patients separately at some stage."

We see at the bottom of the page "[Enclosed] First batch of approximately 40 home therapy patients". So it looks as though he was sending off serum relating to a number of patients to Dr Craske and intending to do so on a regular basis. We can see, in any event, Dr Hamilton's particular interest in problems of liver disease in haemophiliacs.

In terms of his role more broadly, I won't take time going to Dr Hamilton's statement itself but he describes in his statement his role as co-director as being to provide clinical support and cover for Dr Jones and the team. He ran a weekly out-patient session for haemophiliacs, in particular reviewing those -- this would have been from the 1980s and 1990s -- with HIV and hepatitis C at four monthly intervals. He usually attended the weekly haemophilia team review, which I take to be a reference to what we saw described in that document by Dr Jones as their weekly core team meeting.

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Peter Jones in the Haemophilia Department."

Then he says this:

"One of my interests is in the haematology of liver disease. This obviously has relevance to haemophilia and I intend to make a special clinical study of the problems of liver disease in our haemophiliacs.

"I shall be observing them regularly for evidence of liver disease and checking biochemical parameters and auto-antibodies and immunoglobulins. I shall take off enough serum for sending to you once I have got everybody roped in, our routine follow-up clinics will generate repeat specimens every six months or a year. Obviously, the particular viral interest will be 'Hepatitis' associated viral titres, including I suppose EB, rubella and cytomegalo and others you think pertinent. But I suspect you will be interested in other viruses, and if you can think of anything you want done please ask! I think it is important to perform long-term studies on one population of haemophiliacs - the problem with multi-centre investigations is loss of enthusiasm after the first samples have been taken.

"You will note that I have written this far without mentioning specifically Australia antigen.

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Dr Hamilton says his first priority was to develop the coagulation laboratory and that he played no part in the administrative or budgetary running of the haemophilia service and he saw himself not so much as Dr Jones' partner but as a clinician supporting Dr Jones in the care of his patients and families.

Dr Jones retired, as I indicated, in 2000. Dr Hamilton, I think, may have been solely responsible as director for a short period but then Dr Hanley took up post and then in due course Dr Kate Talks and Dr Hamilton retired in 2002.

The other two staff members who I've referred to, from whom we have witness statements, Sister Maureen Fearn. She was appointed sister to the haemophilia centre in either 1973 or 1974 and worked there until her retirement in March 2003. She became a clinical nurse specialist, in due course, in terms of her title. She was also involved in the establishment of the Haemophilia Nurses' Association. Pat Latimer was a social worker at the centre between 1988 and 2002. There was a pre-existing social worker, Jean Luvig. Pat Latimer was appointed as a second social worker, specifically because, according to her statement, of the overwhelming impact HIV had on patients and families attending the centre.

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1 So, sir, that's an overview of staffing and  
2 centre facilities. I want to look next at what the  
3 documents show about product usage and treatment  
4 policies. I'm going to do that in largely  
5 chronological order, looking at contemporaneous or  
6 near contemporaneous documents and then, having done  
7 that, we'll look at what we learn or don't learn from  
8 Dr Jones' statement in that regard.

9 So to start with, could we have, just as  
10 an indication of Dr Jones' early views about  
11 cryoprecipitate usage, PJON0000136\_001 please, Soumik.  
12 This is a 1967 letter to The Lancet from Dr Jones.

13 If we can look at the bottom left-hand column,  
14 first of all, Soumik, it says here:

15 "In your leading article ... you rightly  
16 emphasise the value of small volume antihaemophilic  
17 facto cryoprecipitate infusion for the treatment of  
18 bleeding episodes in haemophilia. This advantage is  
19 especially important in children, and in my limited  
20 experience with five patients ..."

21 And he gives descriptions of the presenting  
22 problems in those five patients:

23 "... the results have been encouraging. We in  
24 this department have found it satisfactory to give  
25 cryoprecipitate directly, using a disposable plastic

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1 difficulty."

2 Then we see Dr Jones' name there set out.

3 So an early fan, if I can put it that way, of  
4 cryoprecipitate and contrasting its advantages to the  
5 treatment with fresh frozen plasma. We can see  
6 Dr Jones writing further in relation to  
7 cryoprecipitate in 1972, if we go to HSOC0022656,  
8 please.

9 This is a publication *Community Medicine*,  
10 28 July 1972. It's entitled "Answering the Needs of  
11 Haemophilic Children and Their Families", and we can  
12 see it's authored by Dr Jones. He deals with a number  
13 of matters relating to the organisation of care. I'm  
14 only going to focus on what he says about  
15 contemporaneous advances.

16 So picking it up under the heading  
17 "Contemporary advances", bottom left-hand corner:

18 "Thirty years ago, most haemophiliacs died of  
19 exsanguination in childhood. Today they can expect to  
20 live a normal lifespan."

21 So this is 1972 that this is being said:

22 "Two major developments have been responsible  
23 for this remarkable change. The first is a result of  
24 the work of Macfarlane and his colleagues in Oxford  
25 [and the identification of Factor VIII protein] ..."

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1 syringe ...

2 "A further advantage is that parents may seek  
3 medical advice earlier, knowing that one simple  
4 injection only may be required. In addition, nursing  
5 of small, often heavily sedated, children on  
6 long-continued intravenous-drip therapy will only  
7 rarely be needed.

8 "Until supplies of cryoprecipitate become  
9 readily available the use of fresh frozen plasma will  
10 continue to provide the basis of treatment in many  
11 hospitals. Continuous infusion therapy and [go to the  
12 top of the next page please] the use of large volumes  
13 of plasma ... may lead to circulatory over-load."

14 He provides further details of patients  
15 suffering in that regard, and then sets out in the  
16 next paragraph how the problem of circulatory overload  
17 can be largely prevented. Then he says this:

18 "Cryoprecipitate is now the method of choice in  
19 treating bleeding episodes in patients with  
20 haemophilia, but, when not available, adequate therapy  
21 with fresh frozen plasma is possible and can be made  
22 relatively safe ..."

23 Then he goes on to explain why.

24 "Concentrated human AHF should be reserved for  
25 patients in whom homeostasis presents particular

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1 Then he says:

2 "The second was organisation, shortly after the  
3 2nd World War, of the Blood Transfusion Services which  
4 today [if we go to the next column] supply all human  
5 fractions needed for treatment throughout the  
6 United Kingdom.

7 "For some years haemophilia therapy was  
8 dependent on fresh frozen plasma ... and this product,  
9 which should yield about 90 per cent of the  
10 Factor VIII activity of the fresh blood, served us  
11 well and in the treatment of haemarthroses and muscle  
12 haemorrhage. It had two great disadvantages:  
13 administration had to be by continuous infusion, which  
14 meant the admission of the child to a bed, and the  
15 level of Factor VIII that could be attained without  
16 circulatory overload was often inadequate in cases of  
17 overt haemorrhage."

18 Then he says this:

19 "The introduction of cryoprecipitate,  
20 a Factor VIII-rich fraction of fresh plasma discovered  
21 by Dr Judith Pool and her colleagues working in  
22 Stanford, provided the solution to these problems.  
23 Cryoprecipitate can be given by syringe, a full  
24 Factor VIII dose being contained in a small volume of  
25 residual plasma. Within weeks of its introduction in

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patient figures had fallen and without the fear of hospitalisation and the drip children were presenting earlier and more often for quick out-patient therapy. Cryoprecipitate is now the product of choice in major surgery allowing the potent but antigenic animal fractions and expensive human concentrate to be reserved for major complications, the emergency treatment of patients with Factor VIII inhibitors or, in the case of concentrate, for prophylaxis."

So again perhaps, sir, a contrast to the way in which cryoprecipitate has been compared by some witnesses to concentrates. We can see here that certainly in the late '60s and the early 1970s Dr Jones identified cryoprecipitate as a valuable, useful and relatively convenient form of treatment.

Now, in terms of the products in use, we can pick the picture up then in September of 1974 if we go to OXUH0000757. So this is a paper co-authored by Dr Jones and Sister Fearn in September of 1974 and it provides a fairly detailed account of what was said to be the practices in Newcastle at that time and, therefore, I propose to go through it relatively carefully. It's entitled "Optimum Use of Factor VIII Preparations at Present Available in the UK":

"In this paper, the experience and conclusions

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with severe bleeds or following surgery."

So we can see there from this that, with the exception of the home therapy programme for which Hemofil is used, cryoprecipitate is effectively the primary treatment of choice for mild, moderate and severe haemophilia according to this description of present practice in Newcastle.

Hemofil is then only used otherwise when insufficient cryoprecipitate is available or if there are some patients with antibodies or some who experience a severe reaction.

**SIR BRIAN LANGSTAFF:** Is there a mention in this document of NHS concentrate?

**MS RICHARDS:** No, there's a further description in more detail of what's used but it's clear that it was not at that time the present practice to use Elstree product, although we'll see how that develops over the years and Dr Jones' statement will say, or says, that there was insufficient Elstree concentrates. But we'll see also from the annual returns the extent to which Elstree product was used.

So under the heading "Statistics":

"Patients. Distribution of patients by diagnosis March 74 [so this gives us a snapshot of the number of patients] 80 severe haemophilia A, 35

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of the staff of the Newcastle Centre, where three Factor VIII preparations are used in the treatment of haemophilia, are presented. The preparations are cryoprecipitate (Newcastle Regional Blood Transfusion Service) [so that's where it's obtained from], Hemofil (Travenol Laboratories), fresh frozen plasma (Newcastle Regional Blood Transfusion Service).

"Present practice in Newcastle.

Cryoprecipitate is used for the treatment of outpatients attending the centre with bleeds, in-patients with bleeds, patients undergoing surgery or dental extraction, and patients receiving physiotherapy and mobilisation following bleeds.

"Hemofil is used in the home therapy programme, the management of severe bleeds when insufficient cryoprecipitate is available, the management of some patients with antibodies, and the management of those patients who experience severe reactions to cryoprecipitate or fresh frozen plasma."

And then:

"Fresh frozen plasma is used in adults with mild to moderately severe bleeds when no cryoprecipitate is available, and adults with mild to moderately severe bleeds when cryoprecipitate has to be reserved for use either in children or in adults

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moderate, 48 mild, 7 awaiting assay."

So a total of 170 with haemophilia A.

"52 von Willebrand's, 21 haemophilia B, 12 with other factor deficiencies, 35 awaiting specific diagnosis."

Then a reference to carriers, significant numbers: 234 potential, 100 known, giving a total of 624.

If we go over the page, we can see, if we start at the top of the page:

"Of these patients those with haemophilia A, von Willebrand's disease and a minority of haemophilia A carriers require cryoprecipitate or concentrate. Those with haemophilia B require Factor IX concentrate and those with other factor deficiencies sometimes require FFP. Cryoprecipitate, FFP or fibrinogen concentrate are required for patients with acquired factor deficits and FFP is used in occasional cases of angioneurotic oedema. Of the 170 known haemophiliacs A in the region, 43 regularly attend Newcastle Centre with acute bleeds. All haemophiliacs requiring surgery, dental extraction or the management of complications attend Newcastle."

Then we see more detail about the products. So in terms of cryoprecipitate 14,000 packs of cryo are

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described as being prepared and issued by the Newcastle Regional Blood Transfusion Service annually, of which 60 per cent go to the haemophilia centre, 40 per cent to other regional hospitals.

Hemofil, which is newly introduced by this stage:

"Expenditure on commercial concentrate will be approximately £20,000 in the first year of use in Newcastle. 23 patients with severe haemophilia A are now on the home therapy programme and account for the bulk of this supply. On average, each home treatment patient uses five vials of Hemofil a month. Within the region, Hemofil is only issued by the Newcastle centre, patients suitable for home therapy being trained there and having to visit the centre for renewal of stock on presentation of accurate records. Regional sub-centres may receive small stocks of commercial concentrate for emergency cover through Newcastle. A monthly audit of supplies is performed by the finance department and the sister responsible for the home therapy programme.

"FFP. Approximately 800 packs of FFP are prepared by the regional BTS per annum. 204 packs have been used in the management of haemophilia in Newcastle in the past year."

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pages are out of order on the electronic copy. That's the problem. There we are. Page numbered 3.

So we can see: children, infants two packs, two to five packs for those aged 1 to 5, five to eight packs for those aged 5 to 8, eight to ten packs for adolescents and adults. I think we have seen reference elsewhere in the evidence to a suggestion of needing 10 to 20 packs sometimes; so these figures appear a little different.

Then, in relation to major surgery, at least 20 packs of Newcastle product are required to raise the patient's Factor VIII level to 40 per cent initially.

"Major disadvantage of cryoprecipitate is therefore the empirical dosage that must be employed. We purposely aim to give too much rather than too little. There's no doubt that wastage occurs as a result. However, far more wastage occurs when small doses do not stop a bleed early in its development and we believe that this is the major reason for 40 per cent of the available cryoprecipitate being used in hospitals other than the centre. The second disadvantage is the variability in supply, particularly during holiday periods. There is never enough cryoprecipitate to cover the needs of both acutely ill patients and the requirements for surgery,

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Then there's a comparison of products. So cryoprecipitate, Dr Jones says this:

"Until this year, it's not been possible to perform regular assays on pooled cryoprecipitate in Newcastle. Assays on random packs have indicated a very variable yield ... dosage has been determined by clinical experience rather than either assays or formulae."

Then he says:

"The majority of severe bleeds cease with the following regime."

We see the normal arrangement would be two packs for an infant, two to five for children 1 to 5 years old, five to eight packs for 5- to 8-year olds, eight to ten packs --

**SIR BRIAN LANGSTAFF:** I think I'm on the wrong page here.

**MS RICHARDS:** I'm so sorry, page 3 it should be. Ah, I think the page numbers are reversed. Can you go to the next page. It's the page which has 3 at the top.

Sorry, sir.

**SIR BRIAN LANGSTAFF:** Do you want to start again? That's where --

**MS RICHARDS:** Go on to the next page.

**SIR BRIAN LANGSTAFF:** Next page.

**MS RICHARDS:** Go on to the next page. Don't worry, the

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the gap being filled with either FFP or concentrate."

So those are the disadvantages identified in relation to concentrate. The issue of allergic response which has been identified by others is not there set out by Dr Jones.

Then Hemofil:

"In comparison with other products, Hemofil was chosen for the home therapy programme for the following reasons: known dosage, small volume, ease of preparation, ease of injection, low incidence side effects, ease of storage, no deep freeze needed, small bulk, less chance of contamination, use for travel/work away from home, long life before expiring."

Then there is a discussion of how the batches supplied since November '73 have varied in potency, and there's a discussion about dosages and the effects of the home treatment programme.

If we go over the page -- oh, I'm so sorry, Soumik, it's page numbered 4. I think it will be page 3 electronically. That's it.

FFP is described as carrying no real advantage to haemophilic patients and may be dangerous.

"Conclusions. In preparing this paper, we have been asked to consider ways in which present resources

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available to UK haemophilia services may be used to the optimum advantage of patients. In attempting this, we must stress our conviction that the single most important factor in haemophilia management is the early recognition and immediate effective treatment of acute bleeding episodes. This means home therapy and the prescription to suitably trained patients of potent, small volume lyophilised concentrate with which to treat themselves under the supervision of the haemophilia centres. We do not think that cryoprecipitate is a suitable material for home therapy, not least because so much would have to be stored in patients' homes in large scale programmes that there would be insufficient for the needs of in-patients at present production rates. Any plan to conserve Factor VIII-containing blood products must take into account the fact that the majority of haemophiliacs are being under-treated. Therefore, schemes to rationalise management on a regional basis by improving the organisation of facilities will lead to increased rather than decreased or stabilised demand."

Then he says this:

"We do suggest the following measures may be of benefit in the present economic situation.

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So you --

**SIR BRIAN LANGSTAFF:** Just go to the top of page 4 again, the page we were looking at before this.

**MS RICHARDS:** So that's electronic 3.

**SIR BRIAN LANGSTAFF:** If we just look at what is the description of FFP there, this is a document which, on the whole, is talking up cryoprecipitate and talking down fresh frozen plasma. What it says about FFP is reactions are frequent -- third line down -- and acute allergic pulmonary oedema may complicate its use. So there's a reference there to reactions which shows plainly in the authors' mind that the authors don't mention any such reaction with cryoprecipitate as you pointed out.

It might be interesting to find out whether there is any significant difference between FFP on the one hand and cryoprecipitate on the other in causing such reactions because my understanding had been that cryoprecipitate is essentially the bit of plasma which, when it's precipitated after thawing, contains what is necessary to provide Factor VIII, and it would follow that FFP ought, if it has the same clinical effect, to have no more and no less, by and large, of what causes the reaction.

So it may simply be that reactions are being

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"A. A Government campaign to educate the medical profession in the recommended use of blood products, stressing the importance of using red cells rather than whole blood for most clinical problems. To be most effective, the campaign should be directed at surgeons and junior hospital doctors.

"B. A directive from the department to all hospitals that patients with haemophilia presenting with problems likely to require surgery, however minor, or dental extractions be referred to a haemophilia centre for treatment as early as practicable in the course of their illness."

And then over the page, C -- sorry, this will be the last page probably of the document, Soumik. That's it, great.

"The restriction of use of expensive commercial Factor VIII concentrates to recognised haemophilia centres. In our opinion, home therapy programmes should only be run from those centres where adequate supervision, including regular checks on VIII antibody and HAA status can be performed and the patients' use of concentrate carefully supervised. If the DHSS implement this proposal, additional financial support will be needed by the Regional Health Authorities concerned."

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referred to here because FFP is not particularly favoured and cryoprecipitate is not mentioned because cryoprecipitate is being favoured. That may be an interpretation too far.

**MS RICHARDS:** Yes. The other --

**SIR BRIAN LANGSTAFF:** It might be quite interesting to know what the answer is.

**MS RICHARDS:** Yes, we will see what we can find out in that regard.

The other point to note about this document is in relation to concentrate, if we go to -- it's numbered page 3; so electronic page 4, I think -- we see there nine listed advantages to concentrate in the form of Hemofil with five being low incidence side effects. No discussion in this document of issues relating to viral infection, hepatitis, or any identified disadvantages to concentrate at all.

**SIR BRIAN LANGSTAFF:** No.

**MS RICHARDS:** Sir, I note the time.

**SIR BRIAN LANGSTAFF:** Let us take a break until 2.15, shall we?

**MS RICHARDS:** Thank you.

**SIR BRIAN LANGSTAFF:** So 2.15.

(1.17 pm)

(Luncheon Adjournment)

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1 (2.15 pm)  
 2 **SIR BRIAN LANGSTAFF:** Yes, Ms Richards.  
 3 **MS RICHARDS:** Before the lunch break we looked at a paper  
 4 from September 1974. The next paper I want to look at  
 5 is from November 1975. Soumik, it's PJON0000099\_001,  
 6 please.  
 7 This is a report from Dr Peter Jones. It  
 8 appears to be a report to the regional area health  
 9 authority and we see a number of similar reports  
 10 possibly at approximately two yearly intervals,  
 11 although we don't have all of them, but we have this  
 12 and one from 1977 and then some later ones.  
 13 So this is November 1975 and we can see it's  
 14 a report to the Newcastle Area Health Authority on the  
 15 use of anti-haemophilic globulin within the northern  
 16 regional haemophilia service. Under the heading  
 17 "Available blood products" reference is made to the  
 18 need for treatment with AHG, and then it says:  
 19 "Human blood products containing AHG at present  
 20 available for treatment are:  
 21 "a. Fresh frozen plasma ...  
 22 "b. ... (Cryo)  
 23 "c. AHG Concentrate.  
 24 "FFP only provides a small dosage of AHG in an  
 25 unacceptably high volume of plasma and is only rarely

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1 three fractionation plants in the UK:  
 2 "AHG produced in Oxford is all used for Oxford  
 3 patients. That produced at Elstree is available to  
 4 any Haemophilia Centre but is in very short supply.  
 5 A new plant in Edinburgh will be commissioned in the  
 6 near future ...  
 7 "Production of the British AHG product is  
 8 directly linked to the volume of fresh plasma supplied  
 9 for fractionation. Until sufficient plasma is  
 10 forthcoming from Regional Centres the fractionation  
 11 plants cannot produce enough concentrate. On present  
 12 estimates only two thirds of the target figure for  
 13 concentrate needed to treat Britain's 3,000 severe  
 14 haemophiliacs will be met by 1977. A further  
 15 difficulty is that when plasma is used for AHG  
 16 concentrate production cryoprecipitate cannot be  
 17 produced; there is therefore likely to be a time lag  
 18 during the change over from [cryo] to concentrate  
 19 production. In this period demands for commercial AHG  
 20 may increase to cover treatment needs.  
 21 "Shortfall of supply to meet the clinical  
 22 demand is at present made up by importing commercial  
 23 AHG concentrate. Three firms have DHSS  
 24 import licences. The products are 'Hemofil',  
 25 'Kryobulin' and 'Profilate'."

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1 used for control of minor haemorrhage in adults.  
 2 "Although, with expert preparation, cryo is  
 3 a good vehicle for AHG, in comparison concentrate has  
 4 the following advantages ..."  
 5 Then there are a series of advantages set out:  
 6 "known dosage  
 7 "smaller volume  
 8 "easier preparation  
 9 "syringe injection  
 10 "lower incidence immediate side effects  
 11 "easier storage ...  
 12 "longer shelf life  
 13 "use for home therapy, travel and work away  
 14 from home."  
 15 But then this sentence:  
 16 "The major disadvantage of concentrate is  
 17 a higher incidence of hepatitis."  
 18 So that is recognised in this document in  
 19 contrast to the earlier document we looked at.  
 20 There is then a heading "Availability of blood  
 21 products" and the report tells us:  
 22 "Cryo is made by the Blood Transfusion Service  
 23 (BTS) from [locally collected blood] ..."  
 24 AHG concentrate, the report explains, has to be  
 25 made via fractionation and reference is made to the

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1 Then there is a description of "The position in  
 2 the Northern Region". Reference is made to the  
 3 reorganisation of the haemophilia centre network with  
 4 the RVI at Newcastle becoming a reference centre for  
 5 the northern region, with associate centres at  
 6 Sunderland, Middlesbrough, Darlington, Carlisle and  
 7 Whitehaven, so that refers back to the proposals that  
 8 we looked at this morning:  
 9 "Newcastle therefore has a prime responsibility  
 10 for the management of all patients with hereditary  
 11 bleeding disorders in the Region."  
 12 Then it refers to surgery, complications and  
 13 control of the home therapy programme being the  
 14 responsibility of the Newcastle Centre in the next  
 15 paragraph.  
 16 We then see reference to "Patients concerned  
 17 and where they live", and the figures here given are  
 18 91 severely affected patients known to the centre, and  
 19 we see the distribution as between the area health  
 20 authorities there set out:  
 21 "AHG use in the Region  
 22 "Figures for 1973 and 1974 are:  
 23 "1973 Cryoprecipitate Newcastle: 538,230 ...  
 24 Units."  
 25 In the Region, 351,610.

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1 FFP, 100,000 units.  
 2 Concentrate, 132,500 units.  
 3 So we can see there that in 1973  
 4 cryoprecipitate is, in terms of volume, the dominant  
 5 treatment.  
 6 If we go to the next page, we can see that  
 7 remains the position for 1974 but there is  
 8 a substantial increase nonetheless in the amount of  
 9 concentrate used.  
 10 So the figures: for Newcastle, 587,230 cryo  
 11 units -- or, factor VIII units; for the region,  
 12 379,260. Volume for FFP figures slightly unclear but  
 13 looks like it could be 90,000. Concentrate is  
 14 increased from the 132,000 we saw in 1973 to 432,240  
 15 units in the course of 1974.  
 16 It's said that the approximate number of  
 17 Factor VIII units per severe haemophiliac is 16,430.  
 18 There's then a comparison in the next paragraph more  
 19 generally, and the assertion is made that the northern  
 20 region figures are in keeping with expert estimates of  
 21 both the UK and USA.  
 22 The report then moves to a description of home  
 23 therapy:  
 24 "Because home therapy (HT) can only be run  
 25 successfully on concentrate the introduction of the

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1 amount of concentrate required for in-patient use.  
 2 However, the greatest short-term demand for  
 3 concentrate occurs when a haemophiliac with antibodies  
 4 to Factor VIII experiences a life-threatening bleed."  
 5 Dr Jones says:  
 6 "[We] prefer to manage our antibody patients,  
 7 at least initially, with massive doses of AHG. To  
 8 date this policy has been effective."  
 9 But he explains it accounts for two periods of  
 10 increased demand shown on the graph. Sub-paragraph ii  
 11 under that heading:  
 12 "All surgical procedures are at present  
 13 performed under cryoprecipitate cover in Newcastle.  
 14 To date 40 operations (including dental extractions)  
 15 have been performed in 1975. With the NHS changeover  
 16 from cryo to concentrate we may have to cover some  
 17 surgery with commercial concentrate for a period.  
 18 This is at present indeterminate."  
 19 Then there are "Conclusions" which really are  
 20 largely concerned with issues of finance. There's  
 21 a suggestion of expecting a financial commitment of  
 22 around £156,000 per year by 1977:  
 23 "... calculated on the present DHSS price of  
 24 12p/unit for commercial AHG concentrate ... It is  
 25 unlikely that that NHS concentrate will be available

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1 Newcastle HT programme in 1973 (when the commercial  
 2 concentrates were first licensed by the DHSS) is  
 3 responsible for the larger proportion of the extra  
 4 finance required to run the Centre."  
 5 Then we have some figures as at November 1975  
 6 for home therapy patients. Numbers of haemophilia B  
 7 patients on the home therapy 42 -- sorry haemophilia A  
 8 patients 42; haemophilia B patients 1. Then there are  
 9 various estimates, which I don't think I need to go  
 10 through in any detail, and if we look down the bottom  
 11 of the page we can see an estimated figure per Hemofil  
 12 unit per patient per year of £2,256.  
 13 We then go over the page, top half of the page,  
 14 first of all, please, Soumik, picking it up three  
 15 lines down:  
 16 "Approximately 180,000 of commercial  
 17 concentrate have been bought in the past year ... to  
 18 make up the deficit in BTS supplied VIII products for  
 19 in-patient use."  
 20 Then there are estimates of an expected rise in  
 21 patients on home therapy and concentrate use and then,  
 22 "Ways in which this total may be altered in practice",  
 23 it says:  
 24 "With all suitable severe haemophiliacs on  
 25 [home therapy] we might expect a decrease in the

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1 for home therapy by 1977."  
 2 Then there is a reference in terms of regional  
 3 allocation in paragraph B:  
 4 "... the financial commitment involved should  
 5 be sought either from the Northern Regional Health  
 6 Authority or from the various Area Health  
 7 Authorities ..."  
 8 Then a reference to potential savings in  
 9 ambulance and hospital time through the home therapy  
 10 programme.  
 11 So that gives an indication of product usage in  
 12 1973 and 1974 in particular. We still see the  
 13 dominance of cryoprecipitate but a significant  
 14 increase in the use of concentrate and concentrate  
 15 only being used for home therapy.  
 16 If we then move to the 1976 annual return,  
 17 Soumik, that should be HCDO0000052\_004. So there's  
 18 a covering letter from Ms Spooner to Dr Jones,  
 19 enclosing copies of the annual returns from 1976.  
 20 If we go over the page we can see -- if we go  
 21 into the top half of the page, first of all, Soumik --  
 22 "Annual Return for 1976", RVI, director Dr P Jones:  
 23 "Total number of haemophilic patients treated  
 24 during the year: 127.  
 25 "Number with Factor VIII antibodies: 9.

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1 "Total number of Christmas disease patients  
2 treated during the year: 6."

3 Then if we look at the materials used -- thank  
4 you -- so there's no final figure for plasma.  
5 Cryoprecipitate, the number of Factor VIII units is  
6 given as 689,990. We can see here some NHS  
7 Factor VIII concentrate being used. It looks like  
8 78,000, or certainly 70-something thousand for 1976.

9 We can see then in terms of the commercial  
10 concentrates, Factor VIII, the Armour product, 40,655,  
11 and then Hemofil, by far and away the largest volume  
12 of material used, just over 1.5 million units of  
13 Hemofil. Kryobulin, 10,000 or so. Other human  
14 Factor VIII concentrate, 7,800. Porcine Factor VIII  
15 concentrate, it looks like 170,000, on an inhibitor  
16 patient has been written in there, I think, and then  
17 NHS Factor IX concentrate it's either 56 or 86,400 --  
18 I think it's 86,400.

19 So we can see still a significant amount of  
20 cryoprecipitate, a small amount of NHS Factor VIII  
21 concentrate, small amounts of Factor VIII and  
22 Kryobulin, very large amounts of Hemofil being used in  
23 Newcastle in the course of that year.

24 The issue of use of Elstree NHS factor  
25 concentrates is further illuminated in two documents

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1 Then under the heading "Other difficulties":

2 "In comparison with Hemofil the Elstree product  
3 was more difficult to get into solution (taking  
4 a minimum of 15 minutes and usually 30 minutes or  
5 longer), more difficult to determine (for the above  
6 reason but also because of increased viscosity ? due  
7 to fibrinogen content) and more difficult to give  
8 rapidly because of volume. Piercing the stopper was  
9 sometimes difficult, the rubber being pressed into the  
10 bottle.

11 "Because of reactions and volume problems (it  
12 took up to three hours to administer a dose taking  
13 30 minutes with Hemofil), Hemofil therapy had to be  
14 restarted, and the patient's condition is now  
15 improving.

16 "I have checked with Dr Bird, the consultant in  
17 charge during my absence, and he confirms these  
18 difficulties, pointing out that the initial good  
19 response was due to the commercial product and not to  
20 Elstree AHG."

21 Go over the page. Look at the last paragraph:

22 "I hope that these observations will prove  
23 helpful to you, as we would be very anxious to use  
24 a British product if it became comparable with the  
25 fractions already on the market. At present however,

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1 CBLA0008631, please, Soumik.

2 This is a letter about an individual patient  
3 but it casts some light on Dr Jones' views of Elstree  
4 product versus Hemofil. So it's 3 February 1976.  
5 It's a letter addressed to Dr Maycock. The  
6 precipitating factor, in terms of the letter, appears  
7 to have been the treatment of a particular patient  
8 and, if we look under the heading "Experience with  
9 Elstree product", that's the second main paragraph, we  
10 can see Dr Jones explains:

11 "Difficulty in administration was experienced  
12 from the beginning of intermittent treatment with this  
13 product."

14 Then various problems are there set out, said  
15 to be associated with the Elstree product:

16 "... drip would slow and frequently stop. The  
17 skin area round the needle was red and the vein  
18 thought to be in spasm. Sometimes the drip could be  
19 restarted by flushing with saline but frequently  
20 another vein had to be used ... Following withdrawal  
21 of the needle it was difficult to secure local  
22 haemostasis even after pressure ..."

23 Et cetera, et cetera.

24 "Similar difficulties were reported by medical  
25 staff giving treatment in the evenings."

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1 size of bottle, volume of fluid required for  
2 reconstitution, time of reconstitution, viscosity, and  
3 difficulty in this particular patient with vein  
4 reactions rule out any possibility of either further  
5 treatment of antibody patients requiring high dose AHG  
6 or, and more important, using the present British  
7 product in our home therapy programme."

8 So those are the views of Dr Jones expressed to  
9 Dr Maycock in early 1976 indicating a clear -- a wish  
10 in principle to be able to use Elstree product but  
11 a clear preference for the Hemofil product.

12 There's a letter further that year, again to  
13 Dr Maycock, OXUH0000752, please, Soumik. This is  
14 appears to signal a possible change of mind on the  
15 part of Dr Jones, 1 July 1976:

16 "I am writing to ask if the time is right for  
17 me to put in a bid for regular supplies of the Lister  
18 concentrate? As you know, we are running a home  
19 therapy programme in the Newcastle region, and this is  
20 solely dependent on commercial AHG at enormous  
21 expense. I understand from speaking to  
22 Katharine Dormandy that you have been able to back her  
23 programme and I would of course be interested with  
24 even a few of our patients. We are of course very  
25 willing to supply you with any information you may

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require from follow up of these patients.  
 "We at present have 45 haemophilia A patients on home therapy. Of course these 10 are participating in a survey being run by Lord Mayor Treloar College. They are therefore committed to being on the same product for another year."

So a request there possibly to be able to have Lister concentrate. The reason given in this letter appears to be expense: "solely dependent on commercial AHG at enormous expense."

If we then move to 1977, we have Dr Jones' biannual report to the Regional Health Authority.

PJON0000100\_001, please, Soumik.

So this is headed "Report to the Newcastle Area Health Authority ... Factor VIII concentrate therapy: May 1977":

"In the last report to the AHA(T)(December 1975) the various therapeutic agents for the treatment of classical haemophilia A (factor VIII deficiency) were listed, and reasons given for the choice of freeze-dried concentrates rather than cryoprecipitate in the home care programme. At that time 42 severely affected haemophiliac patients from the Northern Region had been trained to treat themselves at home using an imported commercially

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Factor VIII has remained at a minimum of 40 million units per year since 1974. Although it has been shown that this requirement could be met by the voluntary donation programme of the BTS there is still insufficient fractionation capacity at both Elstree and Edinburgh. Maximum capacity at Elstree (including a proportion made in Oxford) is 15 million units per year. Thus, although the Northern BTS is at present able to supply sufficient fresh frozen plasma to meet approximately 75 per cent of the total Northern demand for Factor VIII, this target cannot be fulfilled in the absence of Government investment in fractionation facilities."

So that's the national picture. "Local":

"Whilst regular supplies of NHS concentrate, started towards end of 1976" --

So that's, as we understand it from the documents, the first time that NHS concentrate started to be used regularly at Newcastle, at the end of 1976:

"... and a continuing supply of locally produced high quality NHS cryoprecipitate have helped towards hospital treatment of haemophiliacs in Newcastle, there is still insufficient NHS material to reduce the financial burden imposed by the home therapy programme. Sixty five severely affected

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prepared concentrate. This product was also being employed in the hospital programme, both this and its use in home therapy being dictated by a shortfall in NHS supplies prepared from native blood."

So the suggestion there being it's lack of NHS concentrate rather than preference which is driving the decision-making:

"Progress since December 1975.

"1. National.

"Arrangements made for the collection of [FFP] by the Blood Transfusion Service (BTS) for the Elstree fractionation plant (England and Wales) and the Edinburgh fractionation plant (Scotland) have resulted in a modest increase of a good intermediate potency concentrate. This is distributed to Haemophilia Centres on the basis of figures submitted to the MRC working party relating to the numbers of patients treated in the previous year in the Region.

"Progress has been slow and at this time supply remains very inadequate in every Region. In Newcastle 150 vials each containing between 210 and 245 Factor VIII units are delivered each month for the treatment of haemophiliacs in the Northern Region; this quantity fulfils approximately 20 per cent of the demand. Nationally, the estimated requirement for

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patients are now on or starting home therapy, and this is the total present number of Northern patients suitable or willing to participate in the programme. In 1975-76 the mean number of factor VIII units [per] patient [per] year for home therapy in this region was approximately 19,000 units. This compares with a National mean of approximately 25,000 units and with International means ranging from 35,000 units (USA) to 129,000 units (Germany). The annual Northern requirement for home therapy is therefore approximately 1.25 to 1.5 million units out of a total annual requirement of 2.5 million units for all purposes ..."

Then if we go to the next page:

"In the past year prices of commercial concentrates have fallen from 12p [per] unit to 8p [per] unit. The cost [per] home therapy patient per year at Newcastle is now therefore approximately £1,520. This cost is offset by savings in ambulance and hospital charges.

"The attached table, prepared by MR WT Wing, shows in detail the purchases of commercial concentrates by the Northern Region in 1976-77.

"At present only one commercial concentrate, Hemofil (Travenol Laboratories), is used in Newcastle.

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In the past year small quantities of other concentrates have also been used, chiefly for the treatment of complications in patients with Factor VIII antibodies."

Then under the heading "Future demand":  
"With the maximum number of acceptable patients on home therapy demand should now be relatively stable. A small number of younger patients trained for 'on demand' home therapy are being prescribed limited prophylactic therapy in an attempt to prevent recurrent joint haemorrhages ... Present UK evidence suggests that prophylaxis increases Factor VIII requirements by about 14 per cent.

"In the absence of an NHS alternative all home therapy patients are dependent on commercial concentrate. The alternatives available in the UK are ..."

He then lists Hemofil, Koate, Factorate Kryobulin and Profilate. If we go over the page, if we zoom in on the top half of the page, again, thank you:

"Hemofil and Koate are high potency products; the remainder are intermediate products (like the NHS product). With the exception of Koate all products are 8p/unit or more. Cutter (Koate) has recently

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Then if we go to the next page:  
"Before submitting this report we talked with Travenol Laboratories in order to try and achieve a comparable price reduction for the Northern Region. Although no such specific price reduction was forthcoming Travenol have expressed their willingness to meet officers of the AHA(T) to discuss their total service to the Area ... with a view to agreement of overall contract terms and cost effectiveness ... Hemofil could thus be viewed in the context of total expenditure/savings on Travenol products and services."

That's a quote from Travenol. And then Peter Jones' comment is:

"It is not within our competence to comment on this statement."

"Conclusions" then:

"1. The total Northern requirement for Factor VIII is approximately 2.5 million units per year. About 50 per cent of this requirement is at present met from commercial sources, most being used for home therapy with a small quantity for the treatment of Factor VIII antibody patients and complications.

"2. There is no likelihood of total NHS supply

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introduced a price of 6.5p/unit to last until November 1977, when the new DHSS contract is issued.

"In view of this price change we have given much thought to changing patients from Hemofil to Koate, with a possible maximum saving of £7,500 in the next five-month period. The two products are comparable. Hemofil having the relatively minor advantage of faster solubility. However, we would prefer to continue to prescribe Hemofil for the following reasons ..."

Three reasons are given, the first is that:

"It is now issued in a home care pack tailored to the needs of our patients ..."

"2. We are reluctant to start to change long-term home therapy patients to a new product to take advantage of a probable temporary advantage in price."

Then, third:

"We have no problems with supply, administration or patient acceptability with Hemofil and are reluctant to expose patients to another plasma pool from a different population of paid donors. Having weathered an outbreak of serum hepatitis with Hemofil we do not want to increase the theoretical chance of further infection."

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in the foreseeable future.

"3. Permission of the Newcastle AHA(T) is requested in respect of continued prescription of Hemofil in preference to Koate (at least until November 1977)."

Then if we go over the page we can see the table that is referred to in the body of the report.

Again, if we zoom in on the top half of the page, so "1976-77 Anti-haemophilic Factor VIII", we can see the figures of Hemofil used per month.

If we go down just a little further, please, Soumik, there's a total usage of 1,395,550 total units at a cost of £160,000-odd.

Then we can see the purchase of Kryobulin, so some purchased in November, a small amount, 2,592 units. Porcine globulin, 191,000 units purchased in April. And then Factorate purchased between June and September in relatively small magnitudes. Giving a total overall of 1,633,122 units of commercial concentrate purchased in the 1976-77 period.

So that gives us the information on what was being used and essentially why, in the Newcastle region in the period between 1974 and 1977.

There's then a document that it may also be

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worth looking at from October 1977, PJON0000147\_001.  
So this is authored by Dr Jones. It's entitled  
*Seminars in Haematology*, October 1977, and the  
specific article authored by Dr Jones is "Developments  
and Problems in the Management of Haemophilia". This  
tells us a little about Dr Jones' approach to the  
treatment of children but also clinical arrangements  
for home therapy, prophylaxis, and addresses issues of  
hepatitis.

So if we pick it up on page 3, please, bottom  
of the page, I just ask you briefly to note in that  
last paragraph, at the bottom of the page:

"With advent of cryoprecipitate and lyophilised  
factor VIII concentrates, haemophilia management has  
moved into the field of preventative medicine. The  
recognition that by the age of 7 yr most severely  
affected haemophiliacs can tell that they are bleeding  
internally well in advance of the appearance of  
physical signs provides the rationale for rapid  
out-patient transfusion and home therapy."

So again discussing both concentrates and  
cryoprecipitate as having made significant differences  
to haemophilia management.

If you then go on, please, Soumik, to page 8,  
I think there is a discussion of "Side Effects of

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for the treatment of life-threatening bleeds and to  
cover major surgery -- there is still sufficient  
material from voluntary donation programmes to meet  
everyday requirements, and improved screening of paid  
donors has resulted in a fall in incidence of HB,  
antigen-positive plasmapheresis subjects to  
1.8/1000 -- it is our practice to restrict young  
children and mildly affected haemophiliacs to  
cryoprecipitate therapy."

So Dr Jones is saying in October 1977 that that  
is his practice to treat young children and mildly  
affected haemophiliacs with cryoprecipitate. Then it  
says:

"More worrying than these visible outbreaks of  
infection, which were expected because of the large  
donor pulls needed for source material, are the  
possible long-term effects of frequent transfusion  
therapy with lyophilised concentrates. Several  
viruses may be involved in post-transfusion hepatitis,  
among them cytomegalovirus, and probably other as yet  
unidentified hepatitis viruses. Whether or not  
repeated exposure to these or other agents will result  
in a rising incidence of chronic liver disease remains  
to be seen, but the haemophilic population at risk  
should be regularly screened for evidence of

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Factor VIII Blood Product Transfusion":

"Hepatitis. The introduction of commercial  
factor VIII lyophilised concentrates into the United  
Kingdom in 1973 was followed by at least three  
separate outbreaks of hepatitis among haemophiliac  
recipients, both hepatitis B and non-B varieties being  
implicated. The outbreaks were associated with  
batches derived from paid donor plasma pools of up to  
6,000 litres tested for HB antigen by counterimmigration  
electrophoresis. More sensitive testing using  
radioimmunoassay (RIA) of one of these batches, and of  
a further 13 batches from two manufacturers, revealed  
HB antigen positivity in 8 of the 14.

"Since these outbreaks, one of which involved  
15 haemophiliacs ... in Newcastle, the incidence of  
new cases of hepatitis has rapidly declined. The  
reasons for this decline are probably the increased  
sensitivity (RIA) in testing of individual donations  
by the manufacturers, who screen out positive donors,  
and the development of an increased resistance to  
infection in the haemophilic population."

The basis for that view is unclear from this  
document:

"While we disagree with the suggestion of  
Craske et al that commercial concentrates be reserved

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subclinical abnormality."

Then he refers to findings of Kasper in the US:  
"... patients without overt hepatitis but with  
an enlarged liver or spleen or both [and others with  
some] disturbance of hepatic function."

Then if we go to the next page, second  
paragraph:

"Other side effects. Although transitory  
allergic reactions ... are commonly experienced with  
cryoprecipitate therapy, they are easily controlled  
with antihistamines. It is our practice to give ...  
(Piriton) ... intravenously with each dose of  
cryoprecipitate.

"Also associated with plasma and  
cryoprecipitate therapy is acute, allergic pulmonary  
oedema, which, if not recognised and energetically  
treated, may be lethal. We have had experience of  
four cases, one in a girl with von Willebrand disease,  
all of whom rapidly responded to intravenous  
hydrocortisone and furosemide (Lasix). The key to the  
condition is provided by a chest radiograph",  
et cetera, et cetera.

So there a further discussion of side effects,  
sir, picking up on your observations this morning.  
Transitory allergic reactions in relation to cryo,

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common but easily controlled. A more acute reaction that can be associated, he says, with both plasma and cryoprecipitate but which can be recognised and energetically treated.

If we go over two further pages, we see then a discussion by Dr Jones of various matters relating to routine clinical practice in Newcastle:

"In the past, when the haemophiliac was an intermittent visitor to a casualty department or an acute medical ward, more attention was likely to be paid to the treatment of his haemorrhage and to his earliest possible discharge than to his general physical, psychological, and social health.

"With increasing awareness of the possible 'subclinical' effects of haemophilia (among them chronic liver disease secondary to multiple transfusions, renal damage and hypertension secondary to occult intracranial haemorrhage) and the knowledge that increasing longevity will be accompanied by the disorders associated with ageing ... it is clear that regular follow-up is essential."

He sets out his view that it's better for follow up to be the responsibility of the haemophilia centre. Then if we go to the next paragraph he says this:

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medical record system was not designed for haemophiliacs ...

"With the help of a number of organisations ... we are at [if you go over to the top of the next page] present attempting to design a workable record-keeping system for haemophilia. As a secondary objective ... this system is being designed to allow for the long-term comparison of data from individual treatment programmes."

So, sir, from this article, we learn, in terms of treatment policy, it's said to be the Newcastle centre's practice to restrict young children and mildly affected haemophiliacs to cryoprecipitate. We see, in part at least, Dr Jones' approach to hepatitis and we see the arrangements, in terms of clinical follow up, severely affected children twice a year and others and adults at least once a year.

The next set of annual returns that we currently have is for 1983, but before we look at them, I just want to examine in a little more detail some documents relating to the Newcastle centre's home therapy programme because it's clear that that accounted for the very significant usage or a large part of the very significant usage of commercial concentrates that we see in the Newcastle centre.

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"The routine in Newcastle is to try to see each severely affected child once every six months and moderately and mildly affected children and severely affected adults at least once a year."

Then he explains what that process will involve:

"... reviews of the haemostatic and general history, a social review covering environment, education or employment, and, when appropriate, enquiry into family planning. A general physical examination is performed ..."

Physiotherapy examination.

"... haematologic and biochemical profile, when this has not already been performed in association with the home therapy programme, includes a full blood count, serum, iron and transferrin estimations, blood urea, liver function tests, screening for hepatitis-associated antigen and antibody [et cetera].

"As far as possible [this is next paragraph] the follow-up clinics are kept as informal as possible, and every opportunity is given for a family to discuss their problems in private."

Then there's a discussion about record-keeping and it's said:

"... it became obvious that the usual hospital

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First of all, in terms of the general approach to home therapy, if we go to WITN0841011, please. So this is an extract of papers delivered at the World Federation of Haemophilia, Third European Regional Congress held in London April 1976, and it's the congress at which a number of members of staff associated with the Newcastle Haemophilia Centre gave papers.

If we go to, I think it's probably page 23, Soumik -- yes. So this is Sister Maureen Fearn. It says she joined the team in 1973 as full-time nursing sister. If we go over the page, we see her paper. So it's the next page. We can see she delivers a talk entitled "The role of the haemophilia centre sister", and she talks about her perception of the changing way in which treatment is provided over the years.

If we move on two pages, please, Soumik, we will see at the bottom of the page the enthusiasm that was expressed by Sister Fearn for the home treatment programme:

Job has been to run a home treatment programme. I say this because it is wonderful to see how it has changed the life of the haemophiliac and his family to that of relatively 'normal' people. There are at present 54 patients in the Newcastle region receiving

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home treatment."

If we go to the next page we'll see the suggested criteria for home treatment:

"Patients should:

"1. be over 6 years of age

"2. have suitable veins

"3. bleed frequently enough to warrant the training and expense involved

"4. have a stable personality

"5. have a capable relative or friend who will be present during injections.

"6. have no history of chronic drug dependency.

"In addition the home should contain a telephone and a reliable refrigerator."

So the first of these, over six years of age, there is slightly different ages given in some of the papers, some suggest over four or being five but this, as a contemporaneous document, suggests the policy was to move to home treatment once a patient was either six or, as this says, over six years of age.

It would follow from that, given what we've seen from Dr Jones' reports, that children certainly from the age of seven, if not younger, would have been receiving concentrates, commercial concentrates, on a regular basis, as part of their participation in the

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regular -- regularly all the patients within Newcastle Centre, that would be the sensible thing to do."

So, sir, you will see there three points:

firstly, clear statement that home therapy was centralised from Newcastle, so under Dr Jones, rather than being administered in any of the associate centres of the Newcastle region; secondly, one of the reasons for that process was because of, as Dr Jones says, what they knew already about hepatitis, wanting to ensure very fundamental follow-up, as he put it; and the third is reference there to prophylaxis, and it is clear from the materials we've seen that there were elements of prophylaxis as part of the Newcastle home therapy programme in the 1970s and 1980s, in contrast to what we have heard in relation, at least, to some other centres, which suggested that there was not enough concentrate to structure home therapy on a prophylactic basis.

If we can then, please, Soumik, have -- and this is still all under the heading of home therapy -- TYWE0000029, please. This is a letter stamped as received on 16 August 1974 to a Dr Sackwood. It's from Dr Jones.

It deals with a number of matters including, if we go over the page, the use of factor concentrates,

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home treatment programme.

The next document I wanted to look at, in terms of the general support for home treatment, from the Newcastle centre is Dr Jones' testimony to the Lindsay Tribunal. Soumik, that is, I think, LIND0000312. We'll come back to Dr Jones' evidence to Lindsay on a number of topics in the course of the afternoon or tomorrow but if we go to page 10, please, there's just a short passage. It's about 12 lines down or so, where the question is:

"Q. And in terms of home therapy and prophylaxis, how was that organised?

"A. Well, by consent, we decided to centralise home therapy and prophylaxis, and the reason was twofold: firstly, we were dealing with very expensive treatment, and we thought that by centralising the control of home therapy and prophylaxis, it would be far easier to audit that treatment. And the second main reason was, because of what we knew already about hepatitis, we wanted to ensure that we were doing no harm to patients, and that meant very fundamental follow-up which was regular and understood by everybody and properly audited.

"So we thought that by centralising home therapy, keeping records properly and following

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and we see reference to Kryobulin and Hemofil being licensed products and as being ideal for home therapy and also useful as a backup supply to cryoprecipitate and fresh frozen plasma. At that point in time, sir, August 1974, 23 patients on home therapy using Hemofil.

If we then go on further three pages, please, we can see a document all about home therapy. So this appears to be some form of home therapy policy for the Newcastle regional haemophilia service. It's addressed to the patient. We can see that from the first paragraph:

"You are about to start treating yourself at home ..."

There's then a list of the kit that's provided.

If we go further down the page:

"Indications for home therapy.

"Home therapy should be given in the event of:

"1. Bleeds into joints.

"2. Bleeds into muscles."

Then the bottom of the page:

"Home therapy by itself is suitable for uncomplicated joint and muscle bleeds and for bleeding from cuts which do not require stitches. In the event of any other bleed [and there's reference to the

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bleeds listed at 3 to 6 above] you should contact the Centre as soon as possible."

If we go over the page, there's a detailed description of the method for giving concentrate. Sir, you may recall that we saw during the presentation on the Birmingham haemophilia centres a document, a similar guide, given to patients for using cryoprecipitate by way of home therapy and it may be instructive to compare the two descriptions and processes, because -- well, you will see if you read through this, it's not necessarily a particularly simple and quick exercise that's being described.

But, in any event, if we go to the next page please, Soumik, bottom half of the page, we can see what's said in relation to risks of infection is this:

"There is a very real danger of infection from used syringes and needles and cases in which serum hepatitis has been caught by other members of the family are known. All equipment must be kept out of the reach of children and syringes must NEVER be washed out and given to children for use as water pistols. Even the most careful washing will not remove the virus responsible for the disease.

"Allergic reactions.

"These are rare with concentrate but if they

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"In this centre, it takes two days to train an experienced haemophiliac patient to treat himself at home ... With immediate treatment haemophilic bleeding stops. So does pain, loss of function, and long-term crippling. The expense of home therapy is considerable. However, like Dr Biggs, we think that to withhold such treatment is unethical, and we think that, in purely economic terms, the cost will be largely offset by savings in hospital and ambulance time.

"For years the daily struggle to obtain enough Factor VIII containing material (usually cryoprecipitate) to meet the needs of haemophilic patients has been a therapeutic nightmare. Although in the Newcastle area we have received an excellent service from our Regional Transfusion Centre the needs of growing children and the increasing use of surgery have meant that demand has often outstripped supply. Like Lord Mayor Treloar College we have had to turn to other centres for help, but in spite of this we know that some patients, particularly in the periphery, still receive suboptimal treatment during acute bleeding episodes.

"It is nowadays thankfully rare to read words like 'cruel' ... 'deprivation' and 'misery' ...

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occur an injection of Piriton should be given ...

"Record-keeping.

"Please keep a record of all treatment.

Further supplies will only be issued on return of the record book to the Centre. If for any reason a dose is made up and not used this should be recorded."

Then, over the page, we see the information that is supposed to be recorded by the home therapy patient: batch number, expiry date, date and time of treatment, dose given, reason for treatment, difficulties in treatment, side effects, measures taken to deal with side effects and effectiveness of treatment. Then there is advice in relation to storage in a fridge. The date of the document is November 1973.

We see there a warning being given of the risks of infection from syringes and needles to others involved but not otherwise there described in terms of the potential risk to patients from the product itself.

If we then go please to PJON0000142\_001. We can see here the bottom left-hand column, there's a letter from Dr Jones. It's The Lancet, 20 July 1974 talking about home therapy, and we can see from it Dr Jones' fervent support for home therapy:

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applied to the care of the physically handicapped in the United Kingdom. The majority of haemophilic patients only become physically handicapped because of inadequate treatment over the years. With adequate supplies of factor VIII concentrate there can be no excuse for this. The resources must be made available."

It's not clear there whether he is talking about resources in terms of commercial concentrate, NHS concentrate or both but, in any event, that's Dr Jones' letter.

If we then go to OXUH0003735. This is a letter of Haemophilia Centre Directors in 1975 and Dr Jones was present. He is listed on the second page, we needn't go to that. If we could go to page 11, please, I think that's it, we can see what is being said about a study of home therapy at the Haemophilia Centre Directors meeting. There's reference to Professor Ingram organising a study of home therapy at St Thomas' and Oxford. Then:

"Dr Jones asked the meeting some questions which were answered by show of hands:- 25 Centres were now using home therapy, at 20 Centres commercial concentrate was used for some part of the home therapy programme, at 2 Centres British NHS concentrate was

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used and at 12 Centres some cryoprecipitate was used for home therapy. At 26 Centres commercial concentrate was used for some hospital treatment."

So again, inevitably as with any document a snapshot, but an indication of two things, first of all commercial concentrate clearly in wide use for home therapy programmes in a number of centres by the mid-1970s, but also that cryoprecipitate, contrary to the evidence you heard, sir, from some clinicians, appears to have been regarded, certainly by 12 centres, as on this show of hands at least, as suitable for home therapy to some extent at least.

If we move then to PJON0000144\_001, Soumik.

So we can see a slightly more formalised survey, it would appear. This is a publication by Dr Jones in 1976. It's the proceedings of the World Federation of Haemophilia Congress in 1976 and Dr Jones' paper is entitled "Haemophilia A Home Therapy in the United Kingdom", and he refers to there having been a questionnaire by UKHCDO on the practice of home therapy. I just wanted to show you the right-hand column. Five lines down, we can see there, in response to the survey:

"Thirteen of the Centres in the survey used cryoprecipitate in their home therapy programme; in

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of such a pack if you feel that it would be practicable to produce one."

So it would seem an invitation to make NHS concentrates more user friendly and convenient for home therapy use.

If we could now next then go to NHBT0000042 please, Soumik. No? I wonder if I've got the wrong reference. Just give me a moment.

"Minutes of the meeting of the home therapy working party, 11 October 1978", we can come back to it if need be. Whilst we see if there's an alternative reference, I can just read out, I think, in any event, the salient paragraphs. It's not a document we need to look at in detail. As I've indicated, Dr Jones was chair of the UKHCDO home therapy working party and this is a set of minutes of its meeting of 11 October 1978. There is reference to delayed development of a home therapy programme in Scotland. There's reference to having regard to figures for home therapy in the UK in 1977, returns suggesting increased use of cryoprecipitate and of commercial concentrate.

Then, in relation to the letter that we just looked at to Sir William Maycock:

"Dr Jones reported that he had not received any

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four Centres it was the sole product used."

You see that, sir, right-hand column second line down from the top of the screen:

"The remaining Centres relied on freeze-dried concentrates, mostly imported under Government licence by pharmaceutical companies, and prepared from large pools of plasma obtained from paid donors."

Then we can see the table there set out: blood product used, number of centres as at February 1976, and we see 13 centres using cryoprecipitate.

If we go now next then to CBLA0000798, this is a letter from July 1978 from Dr Jones to Dr Maycock, or now Sir William, and you will recall, sir, we looked earlier at that letter, a letter in which Dr Jones set out the disadvantages of the NHS product in practical terms. Here he says:

"At the last meeting of the Haemophilia Therapy Centre Directors the question was raised as to whether the NHS would be prepared to produce a home therapy pack similar to that used by commercial companies. There was general support from the Directors for an NHS home therapy pack and as Chairman of the Home Therapy Working Party I am writing to ask if you have any views on the matter. We would be very prepared to discuss with you or your staff the contents and design

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reply from Sir William about the suggestion for an NHS home therapy pack. Sir William had now retired."

Then the observation is:

"There seemed little point in pursuing the matter unless there was a marked improvement in NHS concentrate supply and Dr Jones would contact the new director of Elstree for advice."

I might come back to that, sir, then either after the break or tomorrow, because there is a list of long-term consequences of using concentrates in home therapy and prophylaxis, that I would want to put on screen, so I'll see if we can get a copy of that available for the hearing room after the break or, if not, I can come back to it tomorrow.

Dr Jones produced a handbook in relation to home therapy in the course of 1978. I'm not proposing to go to that now but invite you to note that. Then, Soumik, could we try PRSE0001329. Yes, so we can see bottom of the page. It's June 1978, it's a report on "Haemophilia A home therapy in the United Kingdom", authored by Dr Jones, Sister Fearn, Dr Forbes and Dr Stuart, who were the members of UKHCDO's home therapy working party and we can just see, I think, the summary and conclusions will probably suffice:

"Data on home treatment for patients with

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haemophilia A ... were compiled for 1975 and 1976 from questionnaires answered by directors of haemophilia centres throughout the United Kingdom. There were 48 haemophilia centres in 1975 and 71 in 1976. The number of patients on or in training for home therapy increased from 267 to 488 in the two years ..."

Obviously this is the national picture.

"... and a further 241 haemophiliacs were considered suitable for home therapy by end of 1978. Apart from a small (but increasing) number of haemophiliacs on prophylactic treatment, most patients were on a low dose ... on-demand regimens ..."

Then it says:

"An estimated 55 per cent of the blood products used for home therapy in the UK in 1976 was imported from commercial sources.

"Despite the fact that numbers of patients on home treatment have increased, so that about 60 per cent of the potential population were receiving or being considered for home treatment in 1976, inadequacies in the service still remain. In some centres, follow-up is clearly inadequate; about 15 per cent of patients still rely on cryoprecipitate ..."

So this is as at 1978 we can see

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figures for prophylaxis; 3 Centre Directors were still to report. To date 24 Directors prescribed prophylaxis for 72 patients."

Then if we go to the next page, we can see, bottom half of the page, the heading "Long-term side effects":

"CF [that's Charles Forbes] reported the results of discussions in Glasgow on morbidity monitoring in haemophiliacs. He summarised the possible long-term sequelae of concentrate infusions as Beneficial or Adverse."

If we could go on two pages, please, we can see that appendix. So:

"Long-term Sequelae of Infusion of Concentrates in Home Therapy and Prophylaxis.

"Beneficial.

"Cost: Study of cost/benefit of home therapy."

We can see a number of factors set out: reduction of number or bleeds, number of admissions, number of days in hospital, et cetera.

Then, somewhat curiously under a heading which is "Beneficial":

"Increase in complications: carriers, jaundice, amyloid, isoimmunisation [and] renal complications."

So an identification of an increase in

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cryoprecipitate still being used for home therapy.

"... and too little money has been invested in making the NHS self-sufficient in Factor VIII production."

So that's again an overview of the national picture being provided by Dr Jones' home therapy working party.

Soumik, could we go to -- let us try this, NTH0000042. Thank you. My apologies, I've written down the reference wrong.

So these were the minutes I was referring to a few moments ago. And we see -- the bottom of the page, we see Dr Jones presented interim figures for home therapy in 1977:

"The returns suggested that, rather than the improvement expected in the use of British AHG concentrate for [home therapy], there had been further erosion with increased use of cryoprecipitate and commercial concentrate."

So, again, it would appear insufficient quantities of NHS concentrate available for usage in home therapy, leading to reliance on cryoprecipitate, but an increase in commercial. Then if we go over the page, under the heading "Prophylaxis", 3b, we see:

"MF [that's Maureen Fearn] reported interim

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complications in terms of jaundice.

And then, if we go over the page, we see:

"Adverse.

"Long-term Sequelae of Infusion of Concentrates.

"Liver: LFTs (bilirubin, alcohol, globulin, alkaline phosphates, Enzymes", et cetera.

Then various other sequelae identified.

So that's the product of Dr Jones' home therapy working party's minutes in 1978.

Sir, there's then just on the topic of home therapy, I think, one other document to look at. Soumik, it's PJON0000002.

This is a document authored by Dr Jones *Haemophilia Management, A physician's guide to the treatment of haemophilia*, and if we go to the third page, we will see the date, bottom of the page, 1979, and then if we go to, I think it should be page 84, Soumik, unfortunately it's not got consecutive numbering. Yes, so if we just zoom in a little closer, so we can see a broad description of what home therapy includes and if we look at the third paragraph, it says this:

"Although it is generally agreed that the lyophilised concentrates are the best products for

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1 home therapy, cryoprecipitate (or, in the case of  
2 factor V deficiency, for example, fresh frozen plasma)  
3 might be used."

4 So Dr Jones recognising the possibility of  
5 using cryoprecipitate there for home therapy. Whilst  
6 we're in this document --

7 **SIR BRIAN LANGSTAFF:** You may want to read the next  
8 paragraph.

9 **MS RICHARDS:** Yes:

10 "Many of the firms supplying lyophilised  
11 concentrate market home therapy kits which contain all  
12 the equipment required for self-infusion.  
13 Cryoprecipitate is usually pooled before use, the  
14 individual packs being flushed with sterile saline to  
15 increase the yield; several devices have been designed  
16 to make this task easier and the product therefore  
17 more likely to be aseptic."

18 There is also, to avoid the need to come back  
19 to this, a passage in this book or in this handbook in  
20 relation to hepatitis risks. If you will forgive me  
21 for a moment, I'm just trying to work out what page it  
22 is on because the page numbers are not consecutive.  
23 Try page 30, Soumik. If we go two pages further on --  
24 that's it. So if we zoom in on the section headed  
25 "Side effects", and I should say this is in the

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1 **MS RICHARDS:** We can take a break now or carry on.

2 **SIR BRIAN LANGSTAFF:** Shall we take a break and come back  
3 at, shall we say, 3.50?

4 **MS RICHARDS:** Certainly.

5 **SIR BRIAN LANGSTAFF:** 3.50, thank you.

6 (3.27 pm)

7 (A short break)

8 (3.50 pm)

9 **SIR BRIAN LANGSTAFF:** Yes, Ms Richards.

10 **MS RICHARDS:** Sir, there's one further document on the  
11 topic of home therapy, looking again at the national  
12 picture, that I propose to put on screen. Soumik,  
13 it's HCDO0000015\_092. This is the annual report for  
14 1979 of UKHCDO's home therapy working party, authored  
15 by Dr Jones November 1979, and if we pick it up in the  
16 third paragraph, we can see it says this:

17 "The working party has had the opportunity of  
18 studying the interim results for home therapy and  
19 prophylaxis in the [UK] in 1978. 821 haemophilia A  
20 patients and 101 haemophilia B patients are now on  
21 home therapy. If patients in training are identified  
22 as suitable for home therapy are taken into account at  
23 the end of 1978, 976 haemophilia A patients were on or  
24 awaiting home therapy. This is 82 per cent of the  
25 target predicted in 1975-76.

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1 context of a discussion of lyophilised concentrates:

2 "Side effects.

3 "Immediate side effects are extremely rare  
4 especially with the high purity products.

5 "Intermediate purity products occasionally  
6 produce allergic-type reactions.

7 "High dosage occasionally results in haemolytic  
8 reactions", et cetera.

9 Then this:

10 "Although most commercial plasmapheresis  
11 donations are now screened for Hb antigen by RIA or  
12 other sensitive methods, all concentrates prepared  
13 from large donor pools carry a greater risk of serum  
14 hepatitis and possibly other disease transmission than  
15 cryoprecipitate they should therefore be reserved for  
16 the treatment of severe haemophilia A in older  
17 children and adults. Cryoprecipitate is the material  
18 of choice for young children and patients with mild  
19 haemophilia A."

20 So that's to avoid coming back to this  
21 document. When we look in a little while at hepatitis  
22 risks in more detail you will see what's set out there  
23 in this guide from 1979.

24 Sir, I note the time.

25 **SIR BRIAN LANGSTAFF:** Yes.

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1 "In 1978, 18.4 million units of Factor VIII  
2 were used for home therapy and prophylaxis.  
3 (77 per cent of the predicted need of 23.8 million  
4 units).

5 "Mean use per patient per year in 1978 was  
6 24,241 VIII units. Although about half of blood  
7 product used still comes [it says for commercial,  
8 I think it should be from] commercial sources a very  
9 welcome change has been a rise in the use of Elstree  
10 Factor VIII from 1.02 million units in 1977 to  
11 6.6 million units in 1978. Surprisingly,  
12 cryoprecipitate is still being used by some centres."

13 So this is as at the end of 1979:

14 "98 haemophilia A patients were reported as  
15 receiving prophylactic treatment in 1978 (a rise from  
16 63 patients in 1977).

17 "101 haemophilia B patients were on home  
18 therapy or prophylaxis in 1978, mean Factor IX usage  
19 being 19,166 units. 25 B patients were on  
20 prophylaxis."

21 So that provides an overview of the national  
22 picture both in terms of numbers of patients on home  
23 therapy, the proportion receiving prophylactic  
24 treatment and the overall use of commercial  
25 concentrate, NHS concentrate and some continued usage

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of cryoprecipitate for home therapy.

Returning then to the specific treatments and products used in the Newcastle centre, whether for home therapy or hospital treatment, we next have the 1983 returns. Soumik, HCDO0000149\_002, please. We can see these are the annual runs for 1983, for centre 140, director Dr Jones, total number of haemophilia A patients treated in 1983, 117, zero carriers treated, 10 von Willebrand's disease patients treated in 1983. Then we can see the figures. So for plasma there's a tiny amount used in hospital for a von Willebrand's patient. Then cryoprecipitate, and we can see here numbers have reduced drastically in terms of cryoprecipitate usage from the last return we looked at of 1976. Here the total cryoprecipitate usage for haemophilia A patients is, in hospital, 167,446 and then there's a small amount 18,000-odd for von Willebrand's disease patients in hospital.

The amount of NHS Factor VIII concentrate represents a significant increase from the last available return that we looked at. So now the figure is 988,989 for NHS Factor VIII concentrate used in hospital but only a very small amount used for home treatment, 45,190.

Then we can see three or, in fact, four

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with antibodies.

Unsurprisingly, in terms of haemophilia B, if we go on two further pages, we see the usage is almost entirely NHS Factor IX. So there are 14 patients with haemophilia B treated in 1983, 104,438 units of NHS Factor VIII in hospital, 116,090 used for home treatment and then there is a patient with combined Factor VIII and IX deficiencies, for whom there has been some usage of cryoprecipitate and fresh frozen plasma.

The next document, just to complete the picture, shows us a record of Dr Jones' views on the use of porcine products. So it's IPSN0000036\_012 please, Soumik. This is a document we have looked at, individual components of it for different clinicians and centres on a number of occasions. So "Current approaches to the treatment of inhibitor patients in the UK". It's dated 2 November 1984. If we go to page 6, we see the authors description of the position in Newcastle:

"Royal Victoria Infirmary, Newcastle-upon-Tyne, Dr Peter Jones.

"Newcastle have 11 inhibitor patients, eight of whom are treated with human Factor VIII and three with NHS Factor IX, (two on prophylactic home treatment).

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commercial concentrates being used in the course of 1983, Profilate, Factorate, Koate and Hemofil. Previously, the predominant product was Hemofil. That now makes a relatively modest contribution, 7,500 in hospital, 127,372 units for home treatment. The next, in terms of proportion, is Factorate, next smallest, 69,900 used in hospital, 151,980 used for home treatment, and then very substantial amounts of both Profilate and Koate used, predominantly for home treatment. So the figures for Profilate 251,550 used in hospital, 1.269 million used for home treatment and for Koate 176,724 units in hospital, 1.206 million units used for home treatment.

We can see both more and different products being used that are commercial concentrates and so, whilst there is an increase in the use of NHS Factor VIII concentrate from what has been seen previously, clearly commercial concentrates are still the predominant treatment used.

If we just go over the page, we can see the usage there for patients with antibodies, NHS Factor VIII used in hospital, 229,585 in the course of 1983. So the predominant treatment for patients with antibodies is NHS Factor VIII and then NHS Factor IX 278,514, and 606,475 for home therapy for patients

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"Dr Jones considers porcine Factor VIII the first choice if either of the above forms of treatment fails and is relatively unconcerned about price, considering that in an emergency the cost can be justified. His greatest concern about using porcine Factor VIII for a prolonged period is the development of 'resistance' to the product."

Then there's a further discussion about that, and then this section concludes:

"Dr Jones currently holds a stock for clinical trial purposes, but in future would like to have a small stock on a 'sale or return' basis."

So it would seem that certainly the 1984 porcine Factor VIII is not a significant part of the product usage policy in Newcastle.

If we then, please, Soumik, go to BPLL0002848\_001. This is a letter dated 23 February 1988, so it's not, as it were, directly contemporaneous, it's looking back over a previous few years, but it's obviously closer in time to any current statement that we have and it's from Dr Jones to Dr Liam Donaldson, who was then the Regional Medical Officer at the Northern Regional Health Authority and he says this:

"I enclose a historical record of the use of

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Factor VIII preparations in the Northern Region since 1969. I hope this will help answer many of the questions raised by the Regional Health Authority and Jim Cousins ... These figures, taken with my comments below, should allay any worries that the Northern Region's use of Factor VIII has been in any way untoward."

Then, in the next paragraph, he says that he hopes that any questions relating to the management of haemophilia and incidence of HIV could be addressed directly to Dr Jones and to no-one else. Then figures:

"... presented both in tabular and graphic form Table A lists the use of Factor VIII preparations from 1969-1975. Between 1969-1974 the figures for Carlisle and Newcastle are incorporated. From 1975 the other Associate Centres in Sunderland, Middlesbrough and Whitehaven are included.

"Between 1969 and 1975 much of the service depended on the use of fresh frozen plasma. Commercial concentrates were introduced in 1973 and quickly made up the shortfall in local Blood Transfusion Service plasma and cryoprecipitate. The sudden rise in NHS Factor VIII concentrate usage in 1971 was caused by the treatment of one patient who

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of the former."

He then goes on to deal with heat-treated products, and I'm going to come back to that tomorrow when I look in more detail at the introduction of heat-treated products in Newcastle.

If we could go on please four pages, Soumik, of the tables -- sorry, could we go to the previous page to table A. My apologies.

I don't know precisely upon what data Dr Jones based these tables, and it may be that we need to do some further work in that regard, but we can see that this is product usage in the Newcastle supra region (so including the other centres that Dr Jones identified in the body of the letter) from 1969 to 1975. I'm not going to read through the figures for plasma. You can see them set out there.

In terms of cryoprecipitate, we can see usage increasing overall from 270,000 in 1969 through to 977,000 in 1975. In 1972, the usage seems rather low and it leaps then to 917,000 in 1973. But, in any event, that's the increase in use of cryoprecipitate over this period.

NHS concentrate we can see almost no usage at all with the exception of that one year 1971, when very large quantities of NHS concentrate were used.

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suddenly developed high titre Factor VIII antibodies ..."

Then table B shows the use of Factor VIII between 1976 and 1986. Most of the fresh frozen plasma in these years was used for people with Factor V deficiency.

"With the increasing use of home therapy and prophylaxis, cryoprecipitate usage declined over the years and, until recently, was only used for small children and mildly affected patients. The supply of NHS concentrate to the Northern Region has been, to say the least, erratic and the inevitable gross shortfall has been made up with commercial concentrate."

Then three paragraphs further down:

"Within the past six years, we [that's in the northern region, I think, rather than just Newcastle] have been responsible for treating between 5 per cent and 8 per cent of UK haemophilia A patients."

Then he asserts that the average per patient per year usage of Factor VIII has been in accord with the rest of the country. Skipping over the next paragraph, he refers to figure 2 and the discrepant usage of NHS and commercial concentrates:

"I have already referred to the erratic supply

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Then we can see commercial concentrate introduced in 1973 and rapidly increasing from 133,000 units in the first year of usage to 972,000 units in the third year of usage.

If we then go to table B, please Soumik -- so the next page -- I'm not for present purposes, sir, going to look at the comparison with the UK usage (although that may be an exercise that will need to be considered in due course) but just to look at what this tells us about Newcastle usage. So here we need to start from the bottom of the page. It starts with 1976 and goes up to 1986. If we look at the box headed "Newcastle", we can see in 1976 the figure for cryoprecipitate is 676,050, and then that essentially reduces over the years: 1979, 452,000 units; 1980 only 67,000 units; 1981 186,000 units; 1982 35,000 units; 1982 167,00 units, and so on, with a slight increase in 1986 to 205 units, but overall a pattern of decrease in the use of cryoprecipitate over that period.

In terms of NHS concentrate, again working from the bottom, we see a relatively modest amount used in 1976, 82,800, and then really quite disparate figures in different years. So an increase to 1.677 million in 1977; 959,000 in 1978; 926,000 in 1979; drops down

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1 to 623,000 in 1980; climbs up to 1.439 million in  
2 1981, drops down again to 980,000, and so on, and then  
3 a rapid reduction in the course of 1985 which no doubt  
4 reflects the introduction of heat-treated products.

5 Then we can see the figures for commercial  
6 concentrate which is, by a very significant margin,  
7 the main treatment recorded. So we can see 1976 the  
8 figure is 1.649 million. That increases the following  
9 year to 2,301,000; then 3,672,000 in 1978; 4,356,000  
10 in 1979; 3.5 million or thereabouts in 1980; 3,234,000  
11 1981; 3.6 million 1982; 3.26 million in 1983;  
12 4.391 million in 1984; and then 6.4 million and  
13 5.7 million '85 and '86. So the figures vary, but  
14 perhaps to a lesser extent, but clearly overall both  
15 a significant increase and the main product in use.

16 So that, in terms of the actual figures for  
17 units, and assuming the reliability of the data  
18 recorded in these tables, fills in as it were the gaps  
19 between the annual returns that we currently have and  
20 the other documentation we currently have to show the  
21 overall patterns of usage in the 1970s and in the  
22 1980s.

23 In terms of the mechanics of supply and the way  
24 in which decisions were taken, and who had a role in  
25 the decision-making in relation to treatment policies

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1 through the hospital pharmacy at the Royal Victoria  
2 Infirmary.

3 If we go to -- forgive me while I check  
4 a reference -- PJO90000056\_001, we can see from this  
5 an indication that price had a role to play  
6 potentially in terms of selection of commercial  
7 products. This is a memo dated 3 February 1981 from  
8 the Area Pharmaceutical Officer of the Newcastle Area  
9 Health Authority. He sets out the expenditure  
10 incurred by the Regional Haemophilia Centre during the  
11 current financial year and the figures are -- I'm not  
12 proposing to go through. The total is said to be  
13 inclusive of the following products: Hemofil,  
14 Factorate, Koate, Humanate, Profilate, and Autoplex --  
15 so all of those being using in that financial year --  
16 and then he observes:

17 "The ability to buy in bulk and to switch  
18 between brands has enabled a current price of around  
19 7.2 pence per unit to be achieved."

20 Sir, I should say that nothing in the material  
21 that we've seen so far suggests the kind of brand or  
22 batch dedication policies that we've seen from some  
23 other centres, although it's right to note clearly  
24 that for a number of years Hemofil was the chosen  
25 product before the centre started using a range of

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1 and product usage, there are just a few documents to  
2 look at and a few observations to make. We know both  
3 from what Dr Jones has said in the various materials  
4 we have looked at and in a letter from the Newcastle  
5 Regional Transfusion Centre that, whilst it would  
6 receive and supply BPL Factor VIII, commercial  
7 Factor VIII did not pass through the Regional  
8 Transfusion Centre. It was obtained directly from the  
9 commercial companies by the Haemophilia Centre at the  
10 Royal Victoria Infirmary. That's confirmed in  
11 a letter from the Regional Transfusion Centre in July  
12 of 1981.

13 In terms of how decisions then were taken by  
14 the Haemophilia Centre as to what products to use,  
15 Dr Jones' account in his statement is that there was  
16 an annual meeting which would involve him, a nursing  
17 staff member, a pharmacy staff member, and a patient  
18 representative who was usually the chair of the  
19 Northern Branch of the Haemophilia Society. Those  
20 meetings were not, he says, minuted. Dr Jones would  
21 present information about safety, efficacy,  
22 availability and price, and a decision would then be  
23 taken. Dr Jones doesn't recall, he says, any major  
24 disagreements about product choice or any need for  
25 a deciding vote. Then products would be purchased

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1 different commercial products.

2 It does not appear that the Regional  
3 Transfusion Centre had any significant role in  
4 decision-making. We can look at a draft statement  
5 from a consultant haematologist employed at the  
6 Regional Transfusion Centre. It is NHBT0019146. You  
7 will see, sir, this is an unsigned and undated  
8 statement. I'm not sure whether there is available  
9 a signed or dated statement but, in any event, it's  
10 from Ann Collins, Consultant Haematologist employed by  
11 the Northern Regional Health Authority at the Regional  
12 Blood Transfusion Centre, Newcastle-upon-Tyne, and it  
13 was, I think, clearly prepared in the context of  
14 litigation -- presumably the HIV haemophilia  
15 litigation.

16 She explains in the second paragraph that she  
17 succeeded Dr Murray as Medical Director at the  
18 Regional Blood Transfusion Service from  
19 September 1979. She sets out her belief that the  
20 general arrangements which were in force between the  
21 Haemophilia Centre and the Blood Transfusion Centre  
22 had been negotiated at some time in the past between  
23 Dr Jones and others.

24 "The practice in 1979 was for commercial blood  
25 products for haemophiliac patients to be ordered by

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the Pharmacy Department at the Royal Victoria Infirmary. As far as I was aware, payment for commercial blood products was arranged for by the Regional Health Authority. At no point was the financing of the purchase of commercial blood products debited to the Blood Transfusion Service budget."

Then she says:

"The treatment of haemophiliac patients themselves was entirely a matter for Dr Jones and his colleagues. Dr Jones was responsible for selection of a suitable commercial blood product."

Then she talks about production of cryoprecipitate. She says:

"In the 1970s, treatment of haemophiliacs was largely carried out with cryo and fresh frozen plasma. At this time, I was the senior registrar at the Blood Transfusion Service ... although it was sometimes a struggle because of the poor facilities we then had at Newcastle General Hospital, we usually managed to meet the demands of the Haemophilia Centre for cryoprecipitate and fresh frozen plasma. There was a gradual improvement in our facilities at Newcastle General Hospital prior to our transfer to the present purpose-built premises ... in September 1985. For example, whilst we were still at Newcastle General

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soluble.

"(b) some patients tended to have allergic reactions to NHS-produced Factor VIII. For example, some patients had shivering attacks presumably because NHS Factor VIII had more impurities ...

"(c) the presentation of commercial Factor VIII was more attractive to the Haemophilia Centre. At that time, commercial Factor VIII was sold with a bottle of water and a needle so that dried Factor VIII could be [infused]."

So that was Dr Collins' perspective as set out in this statement that there was in truth a preference for commercial over NHS products at the Newcastle centre.

There is then just one other document with, again, an external observation on Dr Jones' approach. Soumik, it is TYWE0000352\_001, please. This is a rather later letter. This is 16 September 1986; so we're now in the era of heat-treated products, which I will be discussing tomorrow. It's a letter from the District General Manager of the Newcastle Health Authority to Dr Liam Donaldson as Regional Medical Officer for the Northern Regional Health Authority and it's about the budget for haemophilia treatment. He refers to enclosing a point-by-point response but then

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Hospital a new laboratory was provided for the production of cryoprecipitate."

Then she talks about how Dr Jones became an advocate of home therapy for haemophiliacs at the bottom of the page. Then, if we go over to the fourth page please, Soumik, in last paragraph she says this:

"Although there was a shortfall in meeting the production targets for blood plasma by the Northern Regional Transfusion Centre, nevertheless this did not appear adversely to effect the operation of the haemophilia centre in Newcastle-upon-Tyne. In particular, I recall writing to Dr Jones as the Director of the Haemophilia Centre in August 1983 informing him that there was a large supply of Factor VIII from the Central Blood Products Laboratory, which was awaiting use at the Northern Regional Transfusion Centre. I recall I had previously spoken to nursing staff and to Dr Jones about the existence of this surplus, and because there was no reaction to my conversations, I eventually wrote to Dr Jones on 26 August 1983.

"It became apparent that there was a preference at the Haemophilia Centre for commercially produced Factor VIII blood product, for the following reasons:

"(a) commercial Factor VIII was more easily

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says this:

"You will, however, discern that one of our major difficulties lies in the exercise by Dr Jones of clinical freedom. This is clearly an issue with which we must come to grips. In the meantime, of course, the probability is that we're again heading for a substantial overspending on anti-haemophilia products and there is some urgency in clarifying our position with the RHA."

So, sir, just picking up there that observation to Dr Jones' exercise of clinical freedom.

More broadly on issues relating to self-sufficiency and supplies, without going to the underlying documents (because we'll no doubt pick this up when we consider the position of the blood services in more detail at subsequent hearings, sir), there are communications in the course of 1975 between the Northern Regional Health Authority and the Department of Health and Social Security considering the possibility of increased plasma production by the Regional Transfusion Service.

We have detailed in paragraph 69 of the presentation note that the references to the relevant correspondence -- I'm not going to go to it now -- but we can see that it resulted in course of 1975 in

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a capital allocation and revenue allocation by the DHSS to enhance production.

Picking that up four years later or five years later in 1980, and just to see what the position was on a regional basis, if we go to DHSC0002201\_002 please, Soumik, we can see here a communication between the Northern Regional Health Authority and the Department of Health and Social Security. Again, I won't take you through the chain of correspondence but we can see in the second paragraph says:

"In this region, we accept the introduction from 1 April 1981 of a policy of pro rata distribution from BPL."

Then it goes on to say:

"We don't see any possibility of increasing plasma supplies from 1981 to 1982. The department is aware of the congested state of our present Regional Transfusion Centre. A new centre is being planned and when we have it in five or six years' time, we should be able to consider increasing our plasma supplies."

That position is reiterated some 18 months or so later. If we go to DHSC0002215\_023 so this is 20 January 82 again a letter from the Northern Regional Health Authority to the DHSS and we can see it says:

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saying this:

"He felt strongly that the directors should set a new target for Factor VIII production for the Department of Health. 40 million units of Factor VIII was the target set in 1973, almost 50 million units of Factor VIII was used in 1977, and only 17 million units of this material was British-made concentrate. This meant that the Department of Health was not yet halfway towards the earlier target which had been set. In view of the high cost of commercial material, he felt sure it was better to spend the money on the British fractionation plants rather than to continue to spend large sums of money in purchasing foreign-made commercial concentrates."

Thank you. I hope we have a reference for that now. HSOC0010549. If that's right, it's page 14 of the document. Yes, thank you. So it's the bottom half of the page is the passage I read out and I'll just repeat the last sentence:

"In view of the high cost of commercial he [that's Dr Jones] felt sure it was better to spend the money on the British fractionation plants rather than to continue to spend large sums of money in purchasing the foreign-made commercial concentrates."

So that's a view expressed by Dr Jones within

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"We accept in principle [this is the second paragraph] the proposals for increasing the supply of fresh frozen plasma to BPL and the implications of this planning of the new laboratory we will be considering timescale for meeting our target but I think it unlikely we can achieve this before we have our new Regional Transfusion Centre in about three or four years time."

There is a later document to suggest that the new Regional Transfusion Centre opened in the course of 1985.

So we can see there on a regional level potential constraints upon the ability of the Regional Transfusion Service to up its sending of plasma to BPL. On a national level, Dr Jones voiced views on the issue of self-sufficiency on a number of occasions. I'm going to show three of them.

First of all, Soumik -- sorry, forgive me, I need to find the reference, first of all. It's a meeting. I don't have the reference recorded. It's a very short passage. I am going to read it and will supply the reference tomorrow. It's a UKHCDO Directors' meeting on 13 November 1978 attended by Dr Jones and, in the course of a discussion about supplies of concentrates, Dr Jones is recorded as

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the forum of the Haemophilia Centre Directors' meetings in 1978.

More publicly in journals, Dr Jones expressed firm views on issues relating to self-sufficiency. So if we start with DHSC0003722\_064, please, this is an article in the British Medical Journal, 21 June 1980. It's entitled "Factor VIII supply and demand". If we could zoom in on the bottom half of the page please, Soumik, and I'll just -- it ranges over a range of topics, so I'm just going to dip into a couple of passages. Middle column, second paragraph:

"At the end of 1978, because of a continuing shortfall in supply from the National Blood Transfusion Service, over 50 per cent of Factor VIII used in the UK for home therapy in haemophilia A was imported, a fact that should be of concern to all those who give blood regularly in the United Kingdom."

Then he goes on to discuss the position in relation to Germany.

Then over the page, if we go to the bottom half of the page please, Soumik, to the left-hand column:

"The second feature of the blood product market to cause concern is the use of plasma obtained from donors in developing countries. That this practice can be excused by arguing that the purchase of plasma

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increases the standard of living of the donors concerning is fallacious because it hinders the World Health Organisation's policy of encouraging the development of self-sufficiency in these countries. In addition to the widely publicised example of Nicaragua, I have told of recent plasmapheresis for export in and Belize, Brazil, Colombia, Haiti, Korea, Lesotho, Mexico, Panama, the Philippines, Puerto Rico, Thailand and Taiwan. In these countries, only the Travenol centre in Puerto Rico and that run by the Belize Pharmaceuticals Company Limited come under the US Food and Drug Administration Regulations. To my knowledge, no single manufacturer of commercial plasma products is yet self-sufficient in terms of source material, all companies being reliant on plasma brokers to some extent.

"Within the US, excellent facilities exist for the collection of [and if we can go to the top] plasma and what brokerage occurs is carefully monitored to comply with strict FDA rules. What happens outside the areas of FDA surveillance is anyone's guess. Many people in this country, including my own patients, have every reason to be grateful for the generosity of donors in other countries and for the skill of FDA supervised fractionators. However, I believe that it

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society. If members of the present Government concur with this view, they should be prepared to fund the changes and to support actively both voluntary blood collection and centralised and efficient management for plasma fractionation."

You can see the author there: by Dr Jones. So that's in mid-1980 those are the very trenchant views expressed by Dr Jones on the issue of self-sufficiency and Government funding.

Then there is one further article of 1985 on a similar topic. Soumik, it's HSOC0002441. This is a document authored by Dr Jones in September of 1985. I don't propose to go through all of it but just to a handful of passages. It starts:

"Blood is one of the most dangerous remedies in the clinician's armoury. Those who take it and process it regard it principally as a precious biological fluid and look to the conservation of its donors. Those in commerce because of it regard it as a commodity obeying the same laws of supply and demand as other commodities and look to conserve their products. Those who use it regard it principally as a medicament with which to conserve their patients."

Then, the very bottom of the page, Dr Jones refers to an exchange of correspondence published in

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would be wrong for the Department of Health to extend its present dependence on industry at the expense of more direct involvement with blood collection from unpaid voluntary donors. Higher prices for blood products would result.

"It's no coincidence that the price of Factor VIII is lower in the UK and higher in the West Germany than in most other European countries. The eventual destruction of one of the only totally voluntary blood donation services left in the world would follow.

"I think that my colleagues in the National Blood Transfusion Service would agree that our previous failure to become self-sufficient should be reversed. But it must be realised that nothing can be achieved without considerable changes in our organisation for the collection and processing of blood and in our attitudes to its optimum use. It will not be enough for Government to emulate the platitudes expressed by the Secretary of State at the DHSS in 1976 when we were told that self-sufficiency was expected in mid-1977. On that occasion, Dr David Owen said, according to the DHSS press release, blood voluntarily and freely given by the healthy to those in need is a manifestation of the values which we should all strive to maintain in

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the BMJ in August of 1985 and, if you go over the page, he says in the first paragraph referring to his response in the BMJ:

"I said that the United Kingdom had had the medical resources and technical expertise to create a modern and truly national Transfusion Service in the early 1970s, but that it had lacked leadership and honest financial backing instead of humbug from Government. The result was that the goal of self-sufficiency mouthed by politicians and senior doctors for over a decade had only been achieved recently for the fairly small population of 5 million people in Scotland."

Then he refers bottom of the page the last paragraph:

"In the early '70s I was privileged as a young consultant to sit in on discussions between members of the National Blood Transfusion Service, Haemophilia Centre Directors and members of the Department of Health and can well remember the frustration that we as clinicians had in trying to convince our colleagues of the need to supply us with sufficient Factor VIII from the volunteer sector to allow us to provide adequate treatment for the haemophilic families in our care. We met with resistance from almost everybody in

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1 authority, despite cogent arguments put forward by  
2 Dr Rosemary Biggs and her colleagues."  
3 He goes on to detail what he says clinicians  
4 were told.  
5 Then, bottom of the page:  
6 "As a measure of our failure to convince our  
7 colleagues that lyophilised Factor VIII and XI  
8 products were necessary for the alleviation of  
9 suffering in haemophilic families, Government allowed  
10 the importation of commercial products obtained from  
11 the blood of paid donors for the first time in 1973.  
12 The results of these imports were as dramatic as the  
13 introduction of cryoprecipitate had been in the mid-  
14 to late 60s. Home therapy programmes were started and  
15 the umbilical cord which until then bound haemophilic  
16 families to hospital for every facet of their  
17 treatment and care could at last be severed. The  
18 management of haemophilic within the United Kingdom  
19 started to equate with the management of the disorder  
20 in the USA and other European countries. It was at  
21 this stage that both the service and Government made  
22 the fatal mistake of relaxing their drive for  
23 self-sufficiency. It was far easier to pay £2 million  
24 or so revenue a year for these products than it was to  
25 put capital into the revamping of Elstree and the

1 provision of modern equipment and increased levels of  
2 staffing in the Regional Transfusion Centres."  
3 So the article -- I'm not sure whether it was  
4 published or not, but so the document continues.  
5 So a flavour there of Dr Jones' views in  
6 relation to failures of Government to achieve  
7 self-sufficiency which, sir, you will no doubt wish to  
8 consider as against the evidence showing the  
9 substantial use of commercial concentrates by Dr Jones  
10 at the Newcastle centre.

11 Sir, I note the time. I'm not going to finish  
12 the next part of what I want to look at speedily, so  
13 it may be wiser to pick it up in the morning, but I'm  
14 in your hands.

15 **SIR BRIAN LANGSTAFF:** Let's do that. So 10.00.

16 **MS RICHARDS:** Yes, sir.

17 **SIR BRIAN LANGSTAFF:** Ten o'clock tomorrow. Thank you  
18 very much.

19 **MS RICHARDS:** Thank you.

20 (4.34 pm)

21 (Adjourned until 10.00 am the following day)

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(55) certainly... - concur



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(58) donor... - epididymis



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