

1 Tuesday, 2 February 2021
 2 (10.00 am)
 3 **SIR BRIAN LANGSTAFF:** Good morning, Ms Richards.
 4 **MS RICHARDS:** Good morning, sir.
 5 **SIR BRIAN LANGSTAFF:** Good morning, those who are watching
 6 around the country. We expect again to have somewhere
 7 around about 200 of you at home.
 8 Would you like to describe the circumstances in
 9 the room, Ms Richards.
 10 **MS RICHARDS:** Certainly, sir.
 11 I am here with one member of the counsel team,
 12 there's one member of the Inquiry solicitor team,
 13 there is Soumik, who will be displaying the rather
 14 large number of documents that we will be looking at
 15 today and tomorrow, and two members of the
 16 Inquiry team who are here to ensure the smooth running
 17 of the day.
 18 **SIR BRIAN LANGSTAFF:** Now, today, we hear about the
 19 presentation about first Cardiff AIDS patient. This
 20 is something which was promised I think during the
 21 evidence of Professor Ludlam, and in part was
 22 responsive to his own personal investigations of what
 23 he thought had been the situation, but we have
 24 uncovered, you think, the facts derived from the
 25 available medical records such as they are.

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1 We then, as currently timetabled, have
 2 three weeks for the trusts and schemes. We are
 3 extending that by a week to include the week of
 4 22 March. So there will be four weeks of evidence
 5 hearing from a number of key witnesses concerned with
 6 the Macfarlane Trust, Caxton, Eileen and Skipton, and
 7 we will publish a detailed timetable as soon as we can
 8 in that regard.
 9 We intend to have a week's hearing looking at
 10 the four current devolved financial assistance
 11 schemes. That will probably be in May. The evidence
 12 and presentation that had been provisionally
 13 timetabled for the week of 22 March that relates to
 14 Treloars and a presentation on other haemophilia
 15 centres, smaller haemophilia centres, will now be
 16 in May, and then we will conclude before Easter with
 17 evidence and presentation relating to Belfast as
 18 currently scheduled.
 19 **SIR BRIAN LANGSTAFF:** Thank you very much.
 20 I hope that suggests plainly the full precise
 21 details will be given in due course but I thought it
 22 important to let you know that we are proceeding next
 23 week with some evidence about the Haemophilia Society.
 24 It's not very neat because, in one sense, the
 25 Haemophilia Society evidence might, you will have

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1 That's followed today by a presentation, the
 2 start of a presentation, about the Newcastle
 3 Haemophilia Centre. As I told you last time we met,
 4 Dr Jones will not be giving evidence. Tomorrow, that
 5 will conclude, but we ought, perhaps, just to have
 6 a look forward to the timetable thereafter because it
 7 may suggest something which may be misunderstood.
 8 I think next week we have nothing but one
 9 witness for The Haemophilia Society scheduled and then
 10 we move on to something else, and that of course is
 11 not in any sense all the evidence we're going to hear
 12 about The Haemophilia Society.
 13 Do you want to fill us in with details,
 14 Ms Richards?
 15 **MS RICHARDS:** Certainly, sir. We're hearing from
 16 Mr Watters next week. We do intend to call other
 17 Haemophilia Society witnesses but for unavoidable
 18 reasons have been unable to timetable them for
 19 February, and so it's likely that those other
 20 Haemophilia Society witnesses will be called at some
 21 point after Easter and before the summer break. So
 22 the fact that we're calling Mr Watters next week is
 23 not an indication that we're not proposing to call
 24 other Haemophilia Society witnesses. We will do so in
 25 due course.

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1 thought, be heard in one batch, but it is important,
 2 as I said at the very beginning of this Inquiry, that
 3 we take the time we can as quickly as we can for
 4 obvious reasons, and it's convenient, as a matter of
 5 timing, to get this evidence heard and then we can
 6 move on rather than delay it until later.
 7 Thank you, Ms Richards.
 8 **MS RICHARDS:** So, sir, as you have outlined, I'm going to
 9 start today with looking at the position of the first
 10 Cardiff AIDS patient. We have seen repeated
 11 references in documents that we have looked at over
 12 the last few months of hearings to a patient in
 13 Cardiff who was understood to be the first
 14 haemophiliac in the United Kingdom identified as
 15 suffering from AIDS, and what was known and understood
 16 about others in relation to his case at the time may
 17 be relevant to decisions and judgments that you will
 18 have to make in due course, sir. And that's the
 19 reason for this presentation.
 20 As you have already referred to, you will
 21 recall Professor Ludlam, who himself had no direct
 22 knowledge of the patient at all, suggesting that it
 23 might have been a diagnosis made on a single clinical
 24 observation and perhaps casting some doubt on the
 25 diagnosis and I hope this presentation will dispel

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

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

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1 "Symptoms of reflux & dyspepsia related to food
 2 and bending over.
 3 "NOT awake at night."
 4 Then I think it says:
 5 "Some relief with [and it might be] antacid."
 6 It's not entirely clear.
 7 Then this:
 8 "Anorexia -- Lost 1 stone.
 9 "Loss of energy.
 10 "Sleeps all the time."
 11 **SIR BRIAN LANGSTAFF:** May I just ask, just beside the
 12 "14/3/83", before you get to the words "Treatment
 13 Centre", there is a number. Is that 51 kilograms?
 14 **MS RICHARDS:** That's what it looks like. Or it could
 15 possibly be 57, but that isn't --
 16 **SIR BRIAN LANGSTAFF:** Either way, that's really quite
 17 a low weight.
 18 **MS RICHARDS:** Yes.
 19 **SIR BRIAN LANGSTAFF:** Because 51 kilograms would probably
 20 be just over 7 stones.
 21 **MS RICHARDS:** Yes, for a young 20-year old man.
 22 **SIR BRIAN LANGSTAFF:** Yes.
 23 **MS RICHARDS:** Clearly the loss of weight, loss of energy,
 24 is a key feature of his presentation on that date.
 25 We then see under previous medical history,

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

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

8 Soumik, could we have on screen, please,
 9 CVHB0000157_482.

10 So we can see the first entry is a record from
 11 1 December 1982 which records Kevin being seen in the
 12 haemophilia centre. There's a reference to
 13 a discussion of his management -- he was bleeding from
 14 his upper gum -- with Professor Bloom, and him being
 15 given 1,500 units of Lister Factor VIII. But the key
 16 entry for the purposes of the presentation is the
 17 entry that starts halfway down the page.

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

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

24 "Treatment Centre.
 25 "Unwell since after [Christmas].

6

1 reference to:
 2 "Hepatitis -- Haemophilia -- has required a lot
 3 of treatment."
 4 And then I think next line, sir, reads:
 5 "Sinuses washed out."
 6 There's then a reference to various drugs,
 7 "some help".
 8 "Allergies -- none."
 9 If we turn over the page, we can see there's
 10 a reference to:
 11 "[Smoking] -- none.
 12 "Alcohol -- [half] a pint a night.
 13 "Works as precision tool engineer."
 14 Then, on an examination, this is recorded:
 15 "Thin.
 16 "Not ..."
 17 And that might say "anaemic", but it's not
 18 entirely clear to read.
 19 "Some inguinal nodes."
 20 And then:
 21 "Severe monilial infection of entire mouth &
 22 fauces."
 23 Which would reflect severe Candida infection.
 24 **SIR BRIAN LANGSTAFF:** Now the fauces is the back of the
 25 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.

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

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

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:

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

13

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

15

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

14

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 axillus/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

18

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

21

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

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

9 We can see it says:

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

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

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

33

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

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

8 Go to the next page, please.

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

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

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

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

23 I think that's the location.

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

35

1 that, Austrian-made Factor VIII.

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

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

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

19 Then if we look under "Medical Assessment":

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

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

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1 information and Professor Bloom would not comment.

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

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

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

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

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

36

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

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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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1 recorded by the Department of Health.
 2 If we skip on three months to the updated
 3 tables DHSC0002235_115, we can see it's from
 4 Mary Sibellas to Dr Field, again, it's an update to
 5 the epidemiological table, taking it up to
 6 12 October 1983. There are now more cases. The case
 7 numbers are 25. One case has been excluded, it would
 8 appear. If we go to the next page, we see the same
 9 entry in relation to Kevin's case, case number 8, the
 10 Cardiff case. If we go to the next page you'll see
 11 there is circled a case in Preston, reported
 12 20 June 1983, confirmed 23 June 1983, the diagnosis is
 13 there set out. That's recorded as being a case of
 14 blood transfusion during abdominal surgery in 1979,
 15 transfusion records being checked.

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

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

1 not quite clear.
 2 **SIR BRIAN LANGSTAFF:** Titre, is it, or titre?
 3 **MS RICHARDS:** Yes, it probably is.
 4 **SIR BRIAN LANGSTAFF:** So test to see whether he has
 5 pneumocystis.
 6 **MS RICHARDS:** Exactly, and then reference to also full
 7 blood count testing. Again, I don't need to go
 8 through all the records but there were records of oral
 9 thrush. If we go to admission sheet CVHB0000157_618,
 10 we can see in the second column along from the left,
 11 under the heading "Reason for admission/diagnosis:
 12 Haemophilic, AID". Top of the next column,
 13 "Additional health problems: haemophilia, AID
 14 Syndrome". He's also described as pale and
 15 underweight. So, again, clearly recorded in his
 16 notes.
 17 Again, there are a handful only of laboratory
 18 results which records the presence of the oral thrush.
 19 Then if we look, again, at what's being said by those
 20 in charge of UKHCDO in June, HCDO0000270_004. Again,
 21 this is a letter we've looked at on a number of
 22 occasions. It's from Professor Bloom and Dr Rizza to
 23 other Haemophilia Centre Directors, and it's only the
 24 first paragraph I need to look at for today's
 25 purposes. So this is 24 June 1983 and we've seen

1 if this is the same as the suspected Bristol case,
 2 it's a late diagnosis.
 3 **MS RICHARDS:** Yes. Yes, and then reported to -- I don't
 4 know whether that's reported to CDSC or Department of
 5 Health, 6 September.

6 **SIR BRIAN LANGSTAFF:** Yes.

7 **MS RICHARDS:** If we return to Kevin's own case and look at
 8 CBHB0000157_421 -- CVHB0000157_421. We can see on
 9 17 June Kevin being readmitted to hospital. He's
 10 recorded here as having a chest infection, nausea and
 11 vomiting. There's a reference to March 1983, him
 12 having been troubled with oral thrush and tonsillitis,
 13 "found to have leukopenia ?AIDS, also had T cell
 14 deficiency". There's then reference to the cough, and
 15 towards the bottom of the page to the nausea and
 16 vomiting.

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

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

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

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

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

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

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

21 We can see however in the British Medical
 22 Journal in August 1983 what was being said by CDSC.
 23 So if we go to DHSC0002231_019. This is the British
 24 Medical Journal, 6 August 1983. We can see under the
 25 heading "Communicable Diseases", it's:

1 "Surveillance of [AIDS] in the [UK],
2 January 1982-July 1983.
3 "Prepared by the Public Health Laboratory
4 Service [CDSC]."
5 There is a discussion of the definition
6 compiled by the Centers for Disease Control in the
7 States and so on.
8 If we go to the next page, there's
9 a description of the surveillance system being
10 utilised by CDSC and then if we go to bottom left-hand
11 column -- just a little bit further down, thank you --
12 so we can see there it's recorded:
13 "By 31 July 1983, 14 cases of [AIDS] had been
14 reported to [CDSC], mainly from clinicians."
15 Details of those are set out. Then if we skip
16 over a paragraph:
17 "Of the 14 patients, 12 were homosexual, one
18 was also a drug abuser; 10 were reported from London,
19 one from Bristol, and one from Oxford. The
20 haemophiliac patient was from Wales, and had received
21 Factor VIII imported from the US; a patient from
22 Lancashire [that may be the Preston case] did not come
23 within the known risk groups."
24 So Kevin's case there set out, as it would
25 appear from CDSC's perspective, consistent with what

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1 Then over the page -- not over the page,
2 right-hand column, towards the top of the page, we can
3 see then it's saying:
4 "At this time [that's May 1983] AIDS was
5 suspected ..."
6 It refers then to T cell studies supporting the
7 diagnosis, various immunological blood data there set
8 out, and then a further description of his symptoms in
9 August 1983.
10 So it would appear that from this, at least,
11 that AIDS was suspected in that patient from May 1983
12 but was not reported until early September 1983 to
13 CDSC and that may be an issue we will need to explore
14 further.
15 Returning to Kevin, this letter had suggested
16 that no definite case of AIDS in a haemophiliac had
17 yet been reported in Britain, which was obviously
18 incorrect, because we have Kevin's case. There was
19 a response to this from the Communicable Disease
20 Surveillance Centre, PRSE0004506.
21 **SIR BRIAN LANGSTAFF:** If we could stop there for a moment,
22 Ms Richards. If we go back to the left-hand column,
23 the top, where it says "No definite case of AIDS has
24 yet been reported although one patient may have early
25 features of the syndrome", there's a reference, it's

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1 we've seen as an accepted case of AIDS.
2 Just picking up communications in journals
3 about the classification of cases. In relation to the
4 Bristol case, that emerges in the medical literature
5 in November 1983. If we could just look at
6 PRSE0004509. This is a letter from Dr Daly and
7 Dr Scott of the Bristol Haemophilia Centre, so it
8 gives details of the Bristol case. If we look at the
9 first paragraph, it says, six lines down:
10 "No definite case of AIDS in a haemophiliac has
11 yet been reported in Britain although one patient may
12 have early features of the syndrome. We report here
13 a fatal case of AIDS in a haemophiliac who received
14 intensive treatment with Factor VIII concentrate of US
15 origin."
16 Then there is a description of his symptoms,
17 picking up from January 1982. If we go further down
18 that page please, Soumik, we can see under the table,
19 the Bristol patient's described in March 1982 as
20 having herpes zoster, symptoms of being unwell,
21 lethargic, listless, so "malaise" to use the
22 terminology of the AIDS/3 form. Then we can see,
23 again, reference to herpes and oral thrush in the last
24 paragraph and, indeed, to wider candida infections in
25 other parts of the body.

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1 reference 4. What footnote is that? What do the
2 notes refer to?
3 **MS RICHARDS:** It's to the article in the BMJ that we
4 looked at a few moments ago.
5 **SIR BRIAN LANGSTAFF:** Thank you.
6 **MS RICHARDS:** So the CDSC article in the BMJ.
7 **SIR BRIAN LANGSTAFF:** Right.
8 **MS RICHARDS:** Then if we then go to the response to
9 Dr Daly and Dr Scott's letter, PRSE0004506, and if we
10 zoom in on the letter in the left-hand column, which
11 is headed "Haemophilia and AIDS in the UK", please,
12 Soumik, it says:
13 "In their otherwise clear account of a fatal
14 case of [AIDS] in a haemophiliac in the UK, Dr Daly
15 and Dr Scott, referring to our account of AIDS
16 surveillance, state that 'No definite case of AIDS in
17 a haemophiliac has yet been reported in Britain
18 although one patient may have early features of the
19 syndrome'. The Communicable Disease Surveillance
20 Centre does indeed collect data on patients who may
21 have early features of AIDS, but our paper included
22 only those cases which met the definition of AIDS
23 compiled by the Centers for Disease Control, Atlanta,
24 on March 15, 1983. The information kindly provided to
25 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

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,

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

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

1 functions.

2 "3. He has bleeds, approximately one a

3 fortnight.

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

5 Then there's reference to a particular feature

6 of his haemophilia associated with his chronic

7 pneumonia, which may require prompt medical care.

8 Then this, the asterisk:

9 "Information to be withheld if report is sent

10 to Mr Slater --

11 "These clinical findings together with evidence

12 of depressed immunity mean that he has the syndrome of

13 acquired immune deficiency (AIDS)."

14 So, sir, one interpretation at least of that

15 document might be that those clinical findings and/or

16 the syndrome of AIDS, the diagnosis of AIDS, is to be

17 withheld from Kevin. We can't see anything in the

18 records which casts any further light, sir, on that

19 question on the basis of the material we've seen.

20 In terms of the wider picture in the autumn of

21 1984, if we look at CBLA0001884_007, this is

22 a document dated 10 September 1984. It's headed

23 "Current Situation Regarding AIDS":

24 "The attached table and histograms are based on

25 reports received from Haemophilia Centres on the

65

1 set out by the consultant physician in the chest

2 clinic who had been seeing Kevin because of his

3 symptoms of pneumonia.

4 There is then a pattern of repeat admissions to

5 the University Hospital Wales over the coming months.

6 His records record PCP having been diagnosed in

7 October 1983. There are records to suggest a degree

8 of barrier nursing and, again, we see a reference to

9 the diagnosis of AIDS really dating from March 1983 in

10 a letter from Dr Lucas. That's at WITN3408021.

11 If we go to the next page, this is at

12 4 December 1984, Dr Guy Lucas, who we know

13 subsequently took up a post in the Manchester

14 Haemophilia Centre but, at this stage, was working in

15 the University Hospital of Wales:

16 "This is the chap with severe haemophilia A who

17 was diagnosed as having AIDS in March 1983. Recently

18 his weight loss has accelerated and chest signs have

19 deteriorated."

20 Then there is a plan for a biopsy.

21 Then if we go to CVHB0000157_330, we see the

22 formal anti-HTLV-III positive test result. It would

23 look as though the sample was taken possibly at the

24 Royal Gwent Hospital in Newport on 22 November and the

25 test comes back, dated 12 December 1984, anti-HTLV-III

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1 patients who received the same batches of blood

2 products as the Cardiff and Bristol AIDS cases."

3 If we go over to the third page please, Soumik,

4 we see by way of example various tables, the top

5 histogram "Showing number of patients having received

6 commercial Factor VIII related to AIDS case A/1."

7 A/1 is the labelling used by Dr Craske to refer

8 to Kevin's case. A/4 is the Bristol case.

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

10 There are various other tables there set out but what

11 we see in terms of the wider picture is that by

12 10 September 1984 there is a public health

13 investigation underway to potentially identify what

14 batches of blood products may have been used to treat

15 patients other than the Cardiff and Bristol cases, and

16 yet within that same period of time, the autumn of

17 1984, there is evidence to suggest that Kevin himself

18 has still not been informed of his diagnosis.

19 We know also from CVHB0000157_307, this is

20 a letter from November 1984. It's from a physician in

21 the Newport Chest Clinic to a Dr Moffat in the

22 Haematology Department, the University Hospital of

23 Wales, it's copied to Professor Bloom and others. We

24 know from the last paragraph, last sentence, "the

25 prognosis is, obviously very poor", is what is there

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1 positive because, of course, by then testing is

2 available.

3 I should say that there is an extract from the

4 National Haemophilia Database, which gives a date of

5 a positive test or first positive test as

6 15 July 1984. Sir, it may be that another test was

7 carried out on a stored sample but, if so, we haven't

8 got any other records other than what's set out in

9 National Haemophilia Database.

10 Then Kevin was in and out of hospital on

11 various occasions in early 1985. The medical records,

12 and I won't go through them in detail, but they

13 document the continuing deterioration of his health.

14 He's described as weaker, as moving slowly, disturbed

15 sleep, thrush infections, and so on, are recorded. He

16 was an in-patient for several weeks February-March

17 1985, again with a range of problems recorded. He'd

18 been coughing up blood, pneumocystis again, and so on.

19 He was admitted again in April 1985 and the medical

20 records record him as deteriorating slowly physically.

21 Then in records relating to an admission at the

22 end of April and early May 1985, he is by that time

23 described as very thin, emaciated, he was unable to

24 move or stand up on his own. Poignantly, and

25 consistent with references in earlier records, he's

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1 described as remaining bright and cheerful with no
 2 other complaints.
 3 If we then just look briefly at a couple of
 4 other documents, CVHB0000157_035, we can see a letter
 5 from Professor Bloom to a Mr Lal, Medical Services
 6 Officer in the Pharmaceutical Division, Bayer House,
 7 and it's a request for assistance regarding Kevin and
 8 it's a request to use a particular drug Suramin,
 9 "since we are otherwise coming to the end of the
 10 line", is what Professor Bloom says. He asks if
 11 Mr Lal will consider letting him have it for
 12 a prescription on a named-patient basis.

13 There are then repeat admissions in the course
 14 of May and June. Kevin's described by now "as weak as
 15 a kitten". His final admission to hospital was on
 16 16 June and he remained in hospital until his death on
 17 23 June 1985.

18 There is just one further letter I will put on
 19 the screen, following his death, WITN3408024. If we
 20 go to the next page, it's a letter from a haematology
 21 registrar, Dr Lush, to what is probably the GP. It's
 22 9 July 1985 and it records Kevin's last admission and
 23 his death:

24 "Admitted: 6 June 1985. Died: 23 June 1985.
 25 "Cause of death: Acquired Immunodeficiency

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

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

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

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

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

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

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

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1 Syndrome."

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

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

12 "Over the next few days his condition gradually
 13 deteriorated. His speech became incoherent and he was
 14 experiencing some pain ... he required intravenous
 15 fluids ... he gradually became unconscious and died on
 16 23 June. In view of the nature of his disease, the
 17 death was reported to the coroner, but obviously no
 18 post-mortem was performed."

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

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

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1 **SIR BRIAN LANGSTAFF:** Or thereabouts.
 2 (11.58 am)

3 (A short break)

4 (12.15 pm)

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

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

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

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

22 I propose, in terms of the issues that will be
 23 explored, to look briefly at the history of and
 24 facilities at the centre, then to look at treatment
 25 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 TYWE000036_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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1 serve as centres of referral of particularly
 2 complicated cases, and also functioned as major
 3 centres for research.
 4 "In essence, therefore, a special subcommittee
 5 favoured the treating of all but the most complicated
 6 cases regionally rather than nationally."
 7 Then it's recorded that:
 8 "The principal difficulty arising from the
 9 treatment of haemophilia related to the assurance of
 10 an adequate supply of anti-haemophilia globulin [AHG],
 11 and the committee emphasised the recommendations of
 12 the earlier meeting that a full investigation ought to
 13 be undertaken into the factors relating to the supply
 14 [haemophiliac] AHG on a national basis."
 15 So the issue of supply and self-sufficiency
 16 there being identified. Then there is a discussion of
 17 centres for the region:
 18 "Three treatment centres might reasonably be
 19 provided in the Region - at Newcastle, Carlisle and
 20 Middlesbrough (the first two already being
 21 designated). Each of these would attract patients
 22 from a large enough area to ensure a special case load
 23 for the administration of an adequate standard of
 24 work, whilst at the same time provide a reasonably
 25 local service."

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1 linkage between the two hospitals."
 2 Then there is a discussion of certain problems
 3 relating to the Newcastle centre. So:
 4 "This sums up the Board's facts of the current
 5 situation, but further explanation reveals interesting
 6 information. Dr Bird plainly does not rate Dr Boon's
 7 interest (or indeed perhaps even expertise) for the
 8 very highly with reference to Haemophilia and plainly
 9 feels the alleged interest has only been stimulated by
 10 prospect of possible loss of designated stages.
 11 Although Dr Boon nominally maintains the Haemophilia
 12 Register this seems clearly to be in a poor state,
 13 being rarely referred to, and (according to Dr Bird)
 14 containing a good deal of erroneous information.
 15 Similarly, in the laboratory work on assay of
 16 anti-haemophilic globulin, Dr Bird and his staff are
 17 used for taking samples and making estimates.
 18 Possibly Dr Bird's feelings are coloured by his
 19 irritation of the fact that -- though he knows a good
 20 deal about haemophilia (in fact maybe more than
 21 most) -- he was not invited to attend this meeting of
 22 the Board's officers in July to discuss the care of
 23 persons suffering from coagulation disorders. But,
 24 looking behind his opinionously fair comments I do not
 25 think that he is ever impressed by the RVI's

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1 An approach was going to be suggested to the
 2 Ministry of Health setting forth proposals for the
 3 development of this regional service.
 4 Then we can see a little more about Newcastle
 5 at the bottom of the page:
 6 "Newcastle is designated by the Medical
 7 Research Council as a diagnostic and reference centre,
 8 this status be invested in Dr TH Boon, at the Royal
 9 Victoria Infirmary. The service provided links and
 10 Dr Boon as clinician with the Department of Pathology
 11 and Professor Heppleston, though it seems that ..."
 12 If we can zoom in on the top part of the page:
 13 "... routine work on coagulation studies is
 14 largely in the hands of Dr Muckle. Within the
 15 RVI empire are two other prominent figures in
 16 Haematology, viz Dr RB Thomson and Dr W Walker ... but
 17 each pursues specific interests and does not always
 18 deal in coagulation matters. The counterpart at
 19 Newcastle General Hospital is Dr T Bird who is
 20 a specialist in haematology, but not a clinical
 21 haematologist, it seems then as no clinician in this
 22 hospital with a particular bent for problems of
 23 coagulation. In ..."
 24 I'm not quite sure what the next word is, but:
 25 "... organisation of services there is no cross

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1 facilities."
 2 "There is no doubt that Dr Bird would be happy
 3 to provide a service in the management of coagulation
 4 disorders, but as he is not a clinical haematologist,
 5 he has no access to beds ..."
 6 And then it records that.
 7 "He [that's Dr Bird] believes a designated
 8 centre in Newcastle is important and is not impressed
 9 of the concept of concentration of three national
 10 supra-regional centres. In extending this theme he
 11 feels that facilities should be concentrated in one
 12 hospital, ideally under the control of a single
 13 clinical haematologist (he sights Dr EK Blackburn of
 14 Sheffield who has his own beds, out-patient clinics,
 15 et cetera). Short of this, a team of two comprising
 16 a clinician and a pathologist (haematologist) should
 17 supply the service. He accepts as logical the concept
 18 that this might be RVI based, but thinks it essential
 19 that there is an appropriate laboratory setup to back
 20 it; this may well imply the need for more trained
 21 staff."
 22 Then if we skip over a paragraph, there is
 23 reference to a confidential medical report issued to
 24 senior administrative medical officers of all regional
 25 hospital boards, and a letter asking if Mr Collins

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

11 And so on.

12 So we can see that -- this is undated but we
 13 can see that at some point in the second half of the
 14 1960s there is both a discussion of issues in relation
 15 to supply, a discussion of whether there should be
 16 a regional service centred around Newcastle, and
 17 concern expressed about the adequacy of provision
 18 under Dr Boon's directorship at Newcastle.

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

23 Soumik, it's TYWE0000036_005.

24 This is a letter from Dr Boon,
 25 27 November 1972, to the DHSS, and he is formally

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

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

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

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

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

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

15 Then he says this:

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

25 Then he goes on to set out his view that the

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

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

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

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

25 And he concludes:

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1 "For these reasons we feel that recognition as
 2 a Special Treatment Centre would be beneficial to our
 3 patients, our developing Regional services, and our
 4 staff, and would be grateful for the Department's
 5 approval."
 6 So that gives a snapshot of where matters stood
 7 in terms of Newcastle staffing early -- or certainly
 8 by end of 1972.
 9 We can see that in 1974, and it was in the
 10 course of 1974 that Dr Boon retired and Dr Jones took
 11 over his post as director, having been already in
 12 place as a consultant paediatric haematologist, or
 13 consultant paediatrician rather.
 14 In the course of 1974, the issue of the
 15 regional service was revisited. And if we go, first
 16 of all, to TYWE0000036_004, please, Soumik.
 17 We can see this is a document put together by
 18 Dr Jones for a regional haemophilia service:
 19 "In order to help patients with haemophilia and
 20 related disorders of haemostasis in the Newcastle
 21 Regional Hospital Board area it is proposed that
 22 a regional service be established. The provisional
 23 plan for the service is detailed in this memorandum,
 24 and the comments of Hospital Management Committee and
 25 individual doctors and dentists in the hospital

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1 Then the Royal Infirmary in Sunderland, and
 2 then if we go over the page, if we zoom in on the top
 3 half of the page, please, Middlesbrough General
 4 Hospital, Cumberland Infirmary and West Cumberland
 5 Hospital. Then what is said below that is:
 6 "It is suggested that all patients with the
 7 bleeding disorders requiring any form of hospital
 8 treatment should be referred in the first instance to
 9 the appropriate consultant for the area, or his
 10 deputy. Patients should not be sent to casualty
 11 departments or to surgical units on reception.
 12 "The Newcastle Centre will continue to be
 13 responsible for all major surgery and the treatment of
 14 complications. A new Haemophilia Centre and
 15 coagulation laboratory is scheduled to open in the RVI
 16 in late 1973. All patients will be registered and
 17 copies of their clinical and laboratory records filed
 18 at this Centre. An intensive survey of all patients
 19 in the Region is in progress to supply information
 20 needed for the initial data bank; to date 341 people
 21 are on the register and further 150 have to be
 22 tested."
 23 Then details are given of how the Royal
 24 Victoria Infirmary coagulation laboratory will
 25 undertake its work. Halfway through that paragraph

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1 service are invited."
 2 Then the current situation is described.
 3 "The DHSS now recognise 42 Haemophilia Centres
 4 in the [UK]."
 5 Then a few lines down:
 6 "However, the establishment of centres does not
 7 solve the major problems facing many patients. In
 8 order to enjoy normal education and employment they
 9 need treatment and advice without having to travel
 10 long distances from their home. Yet because of the
 11 rarity of the hereditary bleeding disorders it is
 12 obviously both uneconomic and impracticable to attempt
 13 to provide full laboratory and clinical services in
 14 all general hospitals."
 15 So the planned service is then set out:
 16 "It is proposed that one general hospital in
 17 each area of the region should be responsible for the
 18 care of patients with hereditary bleeding disorders,
 19 the majority of whom have haemophilia."
 20 We can see then listed the suggested hospitals
 21 and members of staff. I won't go into the details of
 22 the members of staff but we can see the Newcastle
 23 Centre, Royal Victoria Infirmary, the director Dr Boon
 24 until June 1974, various other members of staff set
 25 out.

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1 it's recorded that the centre, so that's the Newcastle
 2 centre:
 3 "... already works closely with the Regional
 4 Blood Transfusion Service and with other National and
 5 International Centres and specific blood factor
 6 fractions are either immediately available or can be
 7 rapidly obtained."
 8 So that was Dr Jones' plan for there to be
 9 a regional service with facilities at the other four
 10 regional hospitals there identified, as a first port
 11 of call for treatment, but with the Newcastle centre
 12 being responsible for all major surgery and
 13 complications.
 14 If we then look at TYWE0000036_003, we can see
 15 approval was given by the senior administrative
 16 medical officer to this proposal. This is a report
 17 dated 8 March 1974 by REN Stewart. It's the report of
 18 the senior administrative medical officer and it says
 19 this:
 20 "From time to time central advice is issued on
 21 'arrangements for the care of patients suffering from
 22 haemophilia and related diseases' ..."
 23 It refers to a Department of Health circular:
 24 "In my parallel fashion, and against the
 25 background of such guidance, intraregional discussion

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

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

14 So this support for Dr Jones' proposals, it
15 would appear, from a senior administrative medical
16 officer. Then finally on this issue, if we look at
17 TYWE0000036_002, we can see effectively approval from
18 the Newcastle Regional Hospital Board. This is
19 11 March 1974:

20 "Dear Secretary,

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

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

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

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

25 Then in 1980 a new dedicated haemophilia centre

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

6 And they are then set out, including now
7 Darlington:

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

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

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

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

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1 was opened.

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

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

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

24 "... in the Department of Haematology contains
25 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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1 onwards and from 1976 either he or Dr Hamilton were
2 attending the Reference Centre Director meetings. He
3 was also, for a number of years, chair of UKHCDO's
4 home therapy working group. We know also he served on
5 various other groups and committees. He was involved
6 with the Macfarlane Trust, he was a long-standing
7 member of The Haemophilia Society's Medical Advisory
8 Panel or committee and he was a secretary of the World
9 Federation of Haemophilia Paediatric Committee. He
10 continued in his post at the Newcastle centre until
11 2000, when he retired.

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

18 If we look at one document relating to
19 Dr Hamilton it's PJON0000053_001, please. This is
20 a letter from Dr Peter Hamilton to Dr Craske dated
21 21 June 1978. He says:

22 "Dear Dr Craske,

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

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

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

14 In terms of his role more broadly, I won't take
15 time going to Dr Hamilton's statement itself but he
16 describes in his statement his role as co-director as
17 being to provide clinical support and cover for
18 Dr Jones and the team. He ran a weekly out-patient
19 session for haemophiliacs, in particular reviewing
20 those -- this would have been from the 1980s and
21 1990s -- with HIV and hepatitis C at four monthly
22 intervals. He usually attended the weekly haemophilia
23 team review, which I take to be a reference to what we
24 saw described in that document by Dr Jones as their
25 weekly core team meeting.

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1 Peter Jones in the Haemophilia Department."

2 Then he says this:

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

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

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

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

7 Dr Jones retired, as I indicated, in 2000.

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

12 The other two staff members who I've referred
13 to, from whom we have witness statements, Sister
14 Maureen Fearn. She was appointed sister to the
15 haemophilia centre in either 1973 or 1974 and worked
16 there until her retirement in March 2003. She became
17 a clinical nurse specialist, in due course, in terms
18 of her title. She was also involved in the
19 establishment of the Haemophilia Nurses' Association.
20 Pat Latimer was a social worker at the centre between
21 1988 and 2002. There was a pre-existing social
22 worker, Jean Luvig. Pat Latimer was appointed as
23 a second social worker, specifically because,
24 according to her statement, of the overwhelming impact
25 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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1 patient figures had fallen and without the fear of
2 hospitalisation and the drip children were presenting
3 earlier and more often for quick out-patient therapy.
4 Cryoprecipitate is now the product of choice in major
5 surgery allowing the potent but antigenic animal
6 fractions and expensive human concentrate to be
7 reserved for major complications, the emergency
8 treatment of patients with Factor VIII inhibitors or,
9 in the case of concentrate, for prophylaxis."

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

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

25 "In this paper, the experience and conclusions

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1 with severe bleeds or following surgery."

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

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

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

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

22 So under the heading "Statistics":

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

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

8 "Present practice in Newcastle.

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

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

20 And then:

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

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1 moderate, 48 mild, 7 awaiting assay."

2 So a total of 170 with haemophilia A.

3 "52 von Willebrand's, 21 haemophilia B, 12 with
4 other factor deficiencies, 35 awaiting specific
5 diagnosis."

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

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

11 "Of these patients those with haemophilia A,
12 von Willebrand's disease and a minority of
13 haemophilia A carriers require cryoprecipitate or
14 concentrate. Those with haemophilia B require
15 Factor IX concentrate and those with other factor
16 deficiencies sometimes require FFP. Cryoprecipitate,
17 FFP or fibrinogen concentrate are required for
18 patients with acquired factor deficits and FFP is used
19 in occasional cases of angioneurotic oedema. Of the
20 170 known haemophiliacs A in the region, 43 regularly
21 attend Newcastle Centre with acute bleeds. All
22 haemophiliacs requiring surgery, dental extraction or
23 the management of complications attend Newcastle."

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

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1 described as being prepared and issued by the
2 Newcastle Regional Blood Transfusion Service annually,
3 of which 60 per cent go to the haemophilia centre,
4 40 per cent to other regional hospitals.

5 Hemofil, which is newly introduced by this
6 stage:

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

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

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

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

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

13 "Major disadvantage of cryoprecipitate is
14 therefore the empirical dosage that must be employed.
15 We purposely aim to give too much rather than too
16 little. There's no doubt that wastage occurs as
17 a result. However, far more wastage occurs when small
18 doses do not stop a bleed early in its development and
19 we believe that this is the major reason for
20 40 per cent of the available cryoprecipitate being
21 used in hospitals other than the centre. The second
22 disadvantage is the variability in supply,
23 particularly during holiday periods. There is never
24 enough cryoprecipitate to cover the needs of both
25 acutely ill patients and the requirements for surgery,

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

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

9 Then he says:

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

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

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

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

20 Sorry, sir.

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

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

24 **SIR BRIAN LANGSTAFF:** Next page.

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

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1 the gap being filled with either FFP or concentrate."

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

6 Then Hemofil:

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

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

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

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

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

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

23 Then he says this:

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

1 So you --
 2 **SIR BRIAN LANGSTAFF:** Just go to the top of page 4 again,
 3 the page we were looking at before this.
 4 **MS RICHARDS:** So that's electronic 3.
 5 **SIR BRIAN LANGSTAFF:** If we just look at what is the
 6 description of FFP there, this is a document which, on
 7 the whole, is talking up cryoprecipitate and talking
 8 down fresh frozen plasma. What it says about FFP is
 9 reactions are frequent -- third line down -- and acute
 10 allergic pulmonary oedema may complicate its use. So
 11 there's a reference there to reactions which shows
 12 plainly in the authors' mind that the authors don't
 13 mention any such reaction with cryoprecipitate as you
 14 pointed out.

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

25 So it may simply be that reactions are being

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

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

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

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

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

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

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

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

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

18 **SIR BRIAN LANGSTAFF:** No.

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

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

22 **MS RICHARDS:** Thank you.

23 **SIR BRIAN LANGSTAFF:** So 2.15.

24 (1.17 pm)

(Luncheon Adjournment)

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 PJON000099_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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1 require from follow up of these patients.
 2 "We at present have 45 haemophilia A patients
 3 on home therapy. Of course these 10 are participating
 4 in a survey being run by Lord Mayor Treloar College.
 5 They are therefore committed to being on the same
 6 product for another year."

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

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

13 PJON0000100_001, please, Soumik.

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

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

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

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

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

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

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

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

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

8 "Progress since December 1975.

9 "1. National.

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

19 "Progress has been slow and at this time supply
 20 remains very inadequate in every Region. In Newcastle
 21 150 vials each containing between 210 and 245
 22 Factor VIII units are delivered each month for the
 23 treatment of haemophiliacs in the Northern Region;
 24 this quantity fulfils approximately 20 per cent of the
 25 demand. Nationally, the estimated requirement for

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1 patients are now on or starting home therapy, and this
 2 is the total present number of Northern patients
 3 suitable or willing to participate in the programme.
 4 In 1975-76 the mean number of factor VIII units [per]
 5 patient [per] year for home therapy in this region was
 6 approximately 19,000 units. This compares with a
 7 National mean of approximately 25,000 units and with
 8 International means ranging from 35,000 units (USA) to
 9 129,000 units (Germany). The annual Northern
 10 requirement for home therapy is therefore
 11 approximately 1.25 to 1.5 million units out of a total
 12 annual requirement of 2.5 million units for all
 13 purposes ..."

14 Then if we go to the next page:

15 "In the past year prices of commercial
 16 concentrates have fallen from 12p [per] unit to 8p
 17 [per] unit. The cost [per] home therapy patient per
 18 year at Newcastle is now therefore approximately
 19 £1,520. This cost is offset by savings in ambulance
 20 and hospital charges.

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

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

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1 In the past year small quantities of other
 2 concentrates have also been used, chiefly for the
 3 treatment of complications in patients with
 4 Factor VIII antibodies."
 5 Then under the heading "Future demand":
 6 "With the maximum number of acceptable patients
 7 on home therapy demand should now be relatively
 8 stable. A small number of younger patients trained
 9 for 'on demand' home therapy are being prescribed
 10 limited prophylactic therapy in an attempt to prevent
 11 recurrent joint haemorrhages ... Present UK evidence
 12 suggests that prophylaxis increases Factor VIII
 13 requirements by about 14 per cent.
 14 "In the absence of an NHS alternative all home
 15 therapy patients are dependent on commercial
 16 concentrate. The alternatives available in the UK
 17 are ..."
 18 He then lists Hemofil, Koate, Factorate
 19 Kryobulin and Profilate. If we go over the page, if
 20 we zoom in on the top half of the page, again, thank
 21 you:
 22 "Hemofil and Koate are high potency products;
 23 the remainder are intermediate products (like the NHS
 24 product). With the exception of Koate all products
 25 are 8p/unit or more. Cutter (Koate) has recently

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1 Then if we go to the next page:
 2 "Before submitting this report we talked with
 3 Travenol Laboratories in order to try and achieve a
 4 comparable price reduction for the Northern Region.
 5 Although no such specific price reduction was
 6 forthcoming Travenol have expressed their willingness
 7 to meet officers of the AHA(T) to discuss their total
 8 service to the Area ... with a view to agreement of
 9 overall contract terms and cost
 10 effectiveness ... Hemofil could thus be viewed in the
 11 context of total expenditure/savings on Travenol
 12 products and services."
 13 That's a quote from Travenol. And then
 14 Peter Jones' comment is:
 15 "It is not within our competence to comment on
 16 this statement."
 17 "Conclusions" then:
 18 "1. The total Northern requirement for
 19 Factor VIII is approximately 2.5 million units per
 20 year. About 50 per cent of this requirement is at
 21 present met from commercial sources, most being used
 22 for home therapy with a small quantity for the
 23 treatment of Factor VIII antibody patients and
 24 complications.
 25 "2. There is no likelihood of total NHS supply

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1 introduced a price of 6.5p/unit to last until
 2 November 1977, when the new DHSS contract is issued.
 3 "In view of this price change we have given
 4 much thought to changing patients from Hemofil to
 5 Koate, with a possible maximum saving of £7,500 in the
 6 next five-month period. The two products are
 7 comparable. Hemofil having the relatively minor
 8 advantage of faster solubility. However, we would
 9 prefer to continue to prescribe Hemofil for the
 10 following reasons ..."
 11 Three reasons are given, the first is that:
 12 "It is now issued in a home care pack tailored
 13 to the needs of our patients ...
 14 "2. We are reluctant to start to change
 15 long-term home therapy patients to a new product to
 16 take advantage of a probable temporary advantage in
 17 price."
 18 Then, third:
 19 "We have no problems with supply,
 20 administration or patient acceptability with Hemofil
 21 and are reluctant to expose patients to another plasma
 22 pool from a different population of paid donors.
 23 Having weathered an outbreak of serum hepatitis with
 24 Hemofil we do not want to increase the theoretical
 25 chance of further infection."

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1 in the foreseeable future.
 2 "3. Permission of the Newcastle AHA(T) is
 3 requested in respect of continued prescription of
 4 Hemofil in preference to Koate (at least until
 5 November 1977)."
 6 Then if we go over the page we can see the
 7 table that is referred to in the body of the report.
 8 Again, if we zoom in on the top half of the
 9 page, so "1976-77 Anti-haemophilic Factor VIII", we
 10 can see the figures of Hemofil used per month.
 11 If we go down just a little further, please,
 12 Soumik, there's a total usage of 1,395,550 total units
 13 at a cost of £160,000-odd.
 14 Then we can see the purchase of Kryobulin, so
 15 some purchased in November, a small amount,
 16 2,592 units. Porcine globulin, 191,000 units
 17 purchased in April. And then Factorate purchased
 18 between June and September in relatively small
 19 magnitudes. Giving a total overall of 1,633,122 units
 20 of commercial concentrate purchased in the 1976-77
 21 period.
 22 So that gives us the information on what was
 23 being used and essentially why, in the Newcastle
 24 region in the period between 1974 and 1977.
 25 There's then a document that it may also be

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1 worth looking at from October 1977, PJON0000147_001.
 2 So this is authored by Dr Jones. It's entitled
 3 *Seminars in Haematology*, October 1977, and the
 4 specific article authored by Dr Jones is "Developments
 5 and Problems in the Management of Haemophilia". This
 6 tells us a little about Dr Jones' approach to the
 7 treatment of children but also clinical arrangements
 8 for home therapy, prophylaxis, and addresses issues of
 9 hepatitis.

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

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

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

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

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1 for the treatment of life-threatening bleeds and to
 2 cover major surgery -- there is still sufficient
 3 material from voluntary donation programmes to meet
 4 everyday requirements, and improved screening of paid
 5 donors has resulted in a fall in incidence of HB,
 6 antigen-positive plasmapheresis subjects to
 7 1.8/1000 -- it is our practice to restrict young
 8 children and mildly affected haemophiliacs to
 9 cryoprecipitate therapy."

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

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

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1 Factor VIII Blood Product Transfusion":

2 "Hepatitis. The introduction of commercial
 3 factor VIII lyophilised concentrates into the United
 4 Kingdom in 1973 was followed by at least three
 5 separate outbreaks of hepatitis among haemophiliac
 6 recipients, both hepatitis B and non-B varieties being
 7 implicated. The outbreaks were associated with
 8 batches derived from paid donor plasma pools of up to
 9 6,000 litres tested for HB antigen by countermigration
 10 electrophoresis. More sensitive testing using
 11 radioimmunoassay (RIA) of one of these batches, and of
 12 a further 13 batches from two manufacturers, revealed
 13 HB antigen positivity in 8 of the 14.

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

22 The basis for that view is unclear from this
 23 document:

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

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1 subclinical abnormality."

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

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

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

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

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

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

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

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

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

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

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1 medical record system was not designed for
2 haemophiliacs ...
3 "With the help of a number of
4 organisations ... we are at [if you go over to the top
5 of the next page] present attempting to design
6 a workable record-keeping system for haemophilia. As
7 a secondary objective ... this system is being
8 designed to allow for the long-term comparison of data
9 from individual treatment programmes."

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

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

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

5 Then he explains what that process will
6 involve:

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

12 Physiotherapy examination.

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

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

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

25 "... it became obvious that the usual hospital

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

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

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

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

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1 home treatment."
 2 If we go to the next page we'll see the
 3 suggested criteria for home treatment:
 4 "Patients should:
 5 "1. be over 6 years of age
 6 "2. have suitable veins
 7 "3. bleed frequently enough to warrant the
 8 training and expense involved
 9 "4. have a stable personality
 10 "5. have a capable relative or friend who will
 11 be present during injections.
 12 "6. have no history of chronic drug dependency.
 13 "In addition the home should contain
 14 a telephone and a reliable refrigerator."
 15 So the first of these, over six years of age,
 16 there is slightly different ages given in some of the
 17 papers, some suggest over four or being five but this,
 18 as a contemporaneous document, suggests the policy was
 19 to move to home treatment once a patient was either
 20 six or, as this says, over six years of age.
 21 It would follow from that, given what we've
 22 seen from Dr Jones' reports, that children certainly
 23 from the age of seven, if not younger, would have been
 24 receiving concentrates, commercial concentrates, on
 25 a regular basis, as part of their participation in the

1 regular -- regularly all the patients within Newcastle
 2 Centre, that would be the sensible thing to do."
 3 So, sir, you will see there three points:
 4 firstly, clear statement that home therapy was
 5 centralised from Newcastle, so under Dr Jones, rather
 6 than being administered in any of the associate
 7 centres of the Newcastle region; secondly, one of the
 8 reasons for that process was because of, as Dr Jones
 9 says, what they knew already about hepatitis, wanting
 10 to ensure very fundamental follow-up, as he put it;
 11 and the third is reference there to prophylaxis, and
 12 it is clear from the materials we've seen that there
 13 were elements of prophylaxis as part of the Newcastle
 14 home therapy programme in the 1970s and 1980s, in
 15 contrast to what we have heard in relation, at least,
 16 to some other centres, which suggested that there was
 17 not enough concentrate to structure home therapy on
 18 a prophylactic basis.
 19 If we can then, please, Soumik, have -- and
 20 this is still all under the heading of home therapy --
 21 TYWE0000029, please. This is a letter stamped as
 22 received on 16 August 1974 to a Dr Sackwood. It's
 23 from Dr Jones.
 24 It deals with a number of matters including, if
 25 we go over the page, the use of factor concentrates,

1 home treatment programme.
 2 The next document I wanted to look at, in terms
 3 of the general support for home treatment, from the
 4 Newcastle centre is Dr Jones' testimony to the
 5 Lindsay Tribunal. Soumik, that is, I think,
 6 LIND0000312. We'll come back to Dr Jones' evidence to
 7 Lindsay on a number of topics in the course of the
 8 afternoon or tomorrow but if we go to page 10, please,
 9 there's just a short passage. It's about 12 lines
 10 down or so, where the question is:
 11 "Q. And in terms of home therapy and
 12 prophylaxis, how was that organised?
 13 "A. Well, by consent, we decided to centralise
 14 home therapy and prophylaxis, and the reason was
 15 twofold: firstly, we were dealing with very expensive
 16 treatment, and we thought that by centralising the
 17 control of home therapy and prophylaxis, it would be
 18 far easier to audit that treatment. And the second
 19 main reason was, because of what we knew already about
 20 hepatitis, we wanted to ensure that we were doing no
 21 harm to patients, and that meant very fundamental
 22 follow-up which was regular and understood by
 23 everybody and properly audited.
 24 "So we thought that by centralising home
 25 therapy, keeping records properly and following

1 and we see reference to Kryobulin and Hemofil being
 2 licensed products and as being ideal for home therapy
 3 and also useful as a backup supply to cryoprecipitate
 4 and fresh frozen plasma. At that point in time, sir,
 5 August 1974, 23 patients on home therapy using
 6 Hemofil.
 7 If we then go on further three pages, please,
 8 we can see a document all about home therapy. So this
 9 appears to be some form of home therapy policy for the
 10 Newcastle regional haemophilia service. It's
 11 addressed to the patient. We can see that from the
 12 first paragraph:
 13 "You are about to start treating yourself at
 14 home ..."
 15 There's then a list of the kit that's provided.
 16 If we go further down the page:
 17 "Indications for home therapy.
 18 "Home therapy should be given in the event of:
 19 "1. Bleeds into joints.
 20 "2. Bleeds into muscles."
 21 Then the bottom of the page:
 22 "Home therapy by itself is suitable for
 23 uncomplicated joint and muscle bleeds and for bleeding
 24 from cuts which do not require stitches. In the event
 25 of any other bleed [and there's reference to the

1 bleeds listed at 3 to 6 above] you should contact the
 2 Centre as soon as possible."
 3 If we go over the page, there's a detailed
 4 description of the method for giving concentrate.
 5 Sir, you may recall that we saw during the
 6 presentation on the Birmingham haemophilia centres
 7 a document, a similar guide, given to patients for
 8 using cryoprecipitate by way of home therapy and it
 9 may be instructive to compare the two descriptions and
 10 processes, because -- well, you will see if you read
 11 through this, it's not necessarily a particularly
 12 simple and quick exercise that's being described.
 13 But, in any event, if we go to the next page
 14 please, Soumik, bottom half of the page, we can see
 15 what's said in relation to risks of infection is this:
 16 "There is a very real danger of infection from
 17 used syringes and needles and cases in which serum
 18 hepatitis has been caught by other members of the
 19 family are known. All equipment must be kept out of
 20 the reach of children and syringes must NEVER be
 21 washed out and given to children for use as water
 22 pistols. Even the most careful washing will not
 23 remove the virus responsible for the disease.
 24 "Allergic reactions.
 25 "These are rare with concentrate but if they

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1 "In this centre, it takes two days to train an
 2 experienced haemophiliac patient to treat himself at
 3 home ... With immediate treatment haemophilic bleeding
 4 stops. So does pain, loss of function, and long-term
 5 crippling. The expense of home therapy is
 6 considerable. However, like Dr Biggs, we think that
 7 to withhold such treatment is unethical, and we think
 8 that, in purely economic terms, the cost will be
 9 largely offset by savings in hospital and ambulance
 10 time.
 11 "For years the daily struggle to obtain enough
 12 Factor VIII containing material (usually
 13 cryoprecipitate) to meet the needs of haemophilic
 14 patients has been a therapeutic nightmare. Although
 15 in the Newcastle area we have received an excellent
 16 service from our Regional Transfusion Centre the needs
 17 of growing children and the increasing use of surgery
 18 have meant that demand has often outstripped supply.
 19 Like Lord Mayor Treloar College we have had to turn to
 20 other centres for help, but in spite of this we know
 21 that some patients, particularly in the periphery,
 22 still receive suboptimal treatment during acute
 23 bleeding episodes.
 24 "It is nowadays thankfully rare to read words
 25 like 'cruel' ... 'deprivation' and 'misery' ...

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1 occur an injection of Piriton should be given ...
 2 "Record-keeping.
 3 "Please keep a record of all treatment.
 4 Further supplies will only be issued on return of the
 5 record book to the Centre. If for any reason a dose
 6 is made up and not used this should be recorded."
 7 Then, over the page, we see the information
 8 that is supposed to be recorded by the home therapy
 9 patient: batch number, expiry date, date and time of
 10 treatment, dose given, reason for treatment,
 11 difficulties in treatment, side effects, measures
 12 taken to deal with side effects and effectiveness of
 13 treatment. Then there is advice in relation to
 14 storage in a fridge. The date of the document is
 15 November 1973.
 16 We see there a warning being given of the risks
 17 of infection from syringes and needles to others
 18 involved but not otherwise there described in terms of
 19 the potential risk to patients from the product
 20 itself.
 21 If we then go please to PJON0000142_001. We
 22 can see here the bottom left-hand column, there's
 23 a letter from Dr Jones. It's The Lancet, 20 July 1974
 24 talking about home therapy, and we can see from it
 25 Dr Jones' fervent support for home therapy:

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1 applied to the care of the physically handicapped in
 2 the United Kingdom. The majority of haemophilic
 3 patients only become physically handicapped because of
 4 inadequate treatment over the years. With adequate
 5 supplies of factor VIII concentrate there can be no
 6 excuse for this. The resources must be made
 7 available."
 8 It's not clear there whether he is talking
 9 about resources in terms of commercial concentrate,
 10 NHS concentrate or both but, in any event, that's
 11 Dr Jones' letter.
 12 If we then go to OXUH0003735. This is a letter
 13 of Haemophilia Centre Directors in 1975 and Dr Jones
 14 was present. He is listed on the second page, we
 15 needn't go to that. If we could go to page 11,
 16 please, I think that's it, we can see what is being
 17 said about a study of home therapy at the Haemophilia
 18 Centre Directors meeting. There's reference to
 19 Professor Ingram organising a study of home therapy at
 20 St Thomas' and Oxford. Then:
 21 "Dr Jones asked the meeting some questions
 22 which were answered by show of hands:- 25 Centres were
 23 now using home therapy, at 20 Centres commercial
 24 concentrate was used for some part of the home therapy
 25 programme, at 2 Centres British NHS concentrate was

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1 used and at 12 Centres some cryoprecipitate was used
 2 for home therapy. At 26 Centres commercial
 3 concentrate was used for some hospital treatment."
 4 So again, inevitably as with any document
 5 a snapshot, but an indication of two things, first of
 6 all commercial concentrate clearly in wide use for
 7 home therapy programmes in a number of centres by the
 8 mid-1970s, but also that cryoprecipitate, contrary to
 9 the evidence you heard, sir, from some clinicians,
 10 appears to have been regarded, certainly by 12
 11 centres, as on this show of hands at least, as
 12 suitable for home therapy to some extent at least.
 13 If we move then to PJON0000144_001, Soumik.
 14 So we can see a slightly more formalised
 15 survey, it would appear. This is a publication by
 16 Dr Jones in 1976. It's the proceedings of the World
 17 Federation of Haemophilia Congress in 1976 and
 18 Dr Jones' paper is entitled "Haemophilia A Home
 19 Therapy in the United Kingdom", and he refers to there
 20 having been a questionnaire by UKHCDO on the practice
 21 of home therapy. I just wanted to show you the
 22 right-hand column. Five lines down, we can see there,
 23 in response to the survey:
 24 "Thirteen of the Centres in the survey used
 25 cryoprecipitate in their home therapy programme; in

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1 of such a pack if you feel that it would be
 2 practicable to produce one."
 3 So it would seem an invitation to make NHS
 4 concentrates more user friendly and convenient for
 5 home therapy use.
 6 If we could now next then go to NHBT0000042
 7 please, Soumik. No? I wonder if I've got the wrong
 8 reference. Just give me a moment.
 9 "Minutes of the meeting of the home therapy
 10 working party, 11 October 1978", we can come back to
 11 it if need be. Whilst we see if there's
 12 an alternative reference, I can just read out,
 13 I think, in any event, the salient paragraphs. It's
 14 not a document we need to look at in detail. As I've
 15 indicated, Dr Jones was chair of the UKHCDO home
 16 therapy working party and this is a set of minutes of
 17 its meeting of 11 October 1978. There is reference to
 18 delayed development of a home therapy programme in
 19 Scotland. There's reference to having regard to
 20 figures for home therapy in the UK in 1977, returns
 21 suggesting increased use of cryoprecipitate and of
 22 commercial concentrate.
 23 Then, in relation to the letter that we just
 24 looked at to Sir William Maycock:
 25 "Dr Jones reported that he had not received any

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1 four Centres it was the sole product used."
 2 You see that, sir, right-hand column second
 3 line down from the top of the screen:
 4 "The remaining Centres relied on freeze-dried
 5 concentrates, mostly imported under Government licence
 6 by pharmaceutical companies, and prepared from large
 7 pools of plasma obtained from paid donors."
 8 Then we can see the table there set out: blood
 9 product used, number of centres as at February 1976,
 10 and we see 13 centres using cryoprecipitate.
 11 If we go now next then to CBLA0000798, this is
 12 a letter from July 1978 from Dr Jones to Dr Maycock,
 13 or now Sir William, and you will recall, sir, we
 14 looked earlier at that letter, a letter in which
 15 Dr Jones set out the disadvantages of the NHS product
 16 in practical terms. Here he says:
 17 "At the last meeting of the Haemophilia Therapy
 18 Centre Directors the question was raised as to whether
 19 the NHS would be prepared to produce a home therapy
 20 pack similar to that used by commercial companies.
 21 There was general support from the Directors for an
 22 NHS home therapy pack and as Chairman of the Home
 23 Therapy Working Party I am writing to ask if you have
 24 any views on the matter. We would be very prepared to
 25 discuss with you or your staff the contents and design

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1 reply from Sir William about the suggestion for an NHS
 2 home therapy pack. Sir William had now retired."
 3 Then the observation is:
 4 "There seemed little point in pursuing the
 5 matter unless there was a marked improvement in NHS
 6 concentrate supply and Dr Jones would contact the new
 7 director of Elstree for advice."
 8 I might come back to that, sir, then either
 9 after the break or tomorrow, because there is a list
 10 of long-term consequences of using concentrates in
 11 home therapy and prophylaxis, that I would want to put
 12 on screen, so I'll see if we can get a copy of that
 13 available for the hearing room after the break or, if
 14 not, I can come back to it tomorrow.
 15 Dr Jones produced a handbook in relation to
 16 home therapy in the course of 1978. I'm not proposing
 17 to go to that now but invite you to note that. Then,
 18 Soumik, could we try PRSE0001329. Yes, so we can see
 19 bottom of the page. It's June 1978, it's a report on
 20 "Haemophilia A home therapy in the United Kingdom",
 21 authored by Dr Jones, Sister Fearn, Dr Forbes and
 22 Dr Stuart, who were the members of UKHCDO's home
 23 therapy working party and we can just see, I think,
 24 the summary and conclusions will probably suffice:
 25 "Data on home treatment for patients with

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

7 Obviously this is the national picture.

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

13 Then it says:

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

17 "Despite the fact that numbers of patients on
18 home treatment have increased, so that about
19 60 per cent of the potential population were receiving
20 or being considered for home treatment in 1976,
21 inadequacies in the service still remain. In some
22 centres, follow-up is clearly inadequate; about
23 15 per cent of patients still rely on
24 cryoprecipitate ..."

25 So this is as at 1978 we can see

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

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

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

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

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

16 "Beneficial.

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

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

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

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

25 So an identification of an increase in

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1 cryoprecipitate still being used for home therapy.

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

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

8 Soumik, could we go to -- let us try this,
9 NTHT0000042. Thank you. My apologies, I've written
10 down the reference wrong.

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

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

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

25 "MF [that's Maureen Fearn] reported interim

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1 complications in terms of jaundice.

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

3 "Adverse.

4 "Long-term Sequelae of Infusion of
5 Concentrates.

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

8 Then various other sequelae identified.

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

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

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

24 "Although it is generally agreed that the
25 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.

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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1 of cryoprecipitate for home therapy.
 2 Returning then to the specific treatments and
 3 products used in the Newcastle centre, whether for
 4 home therapy or hospital treatment, we next have the
 5 1983 returns. Soumik, HCDO0000149_002, please. We
 6 can see these are the annual runs for 1983, for centre
 7 140, director Dr Jones, total number of haemophilia A
 8 patients treated in 1983, 117, zero carriers treated,
 9 10 von Willebrand's disease patients treated in 1983.
 10 Then we can see the figures. So for plasma there's
 11 a tiny amount used in hospital for a von Willebrand's
 12 patient. Then cryoprecipitate, and we can see here
 13 numbers have reduced drastically in terms of
 14 cryoprecipitate usage from the last return we looked
 15 at of 1976. Here the total cryoprecipitate usage for
 16 haemophilia A patients is, in hospital, 167,446 and
 17 then there's a small amount 18,000-odd for
 18 von Willebrand's disease patients in hospital.
 19 The amount of NHS Factor VIII concentrate
 20 represents a significant increase from the last
 21 available return that we looked at. So now the figure
 22 is 988,989 for NHS Factor VIII concentrate used in
 23 hospital but only a very small amount used for home
 24 treatment, 45,190.

25 Then we can see three or, in fact, four

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

11 The next document, just to complete the
 12 picture, shows us a record of Dr Jones' views on the
 13 use of porcine products. So it's IPSN0000036_012
 14 please, Soumik. This is a document we have looked at,
 15 individual components of it for different clinicians
 16 and centres on a number of occasions. So "Current
 17 approaches to the treatment of inhibitor patients in
 18 the UK". It's dated 2 November 1984. If we go to
 19 page 6, we see the authors description of the position
 20 in Newcastle:

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

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

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1 commercial concentrates being used in the course of
 2 1983, Profilate, Factorate, Koate and Hemofil.
 3 Previously, the predominant product was Hemofil. That
 4 now makes a relatively modest contribution, 7,500 in
 5 hospital, 127,372 units for home treatment. The next,
 6 in terms of proportion, is Factorate, next smallest,
 7 69,900 used in hospital, 151,980 used for home
 8 treatment, and then very substantial amounts of both
 9 Profilate and Koate used, predominantly for home
 10 treatment. So the figures for Profilate 251,550 used
 11 in hospital, 1.269 million used for home treatment and
 12 for Koate 176,724 units in hospital, 1.206 million
 13 units used for home treatment.

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

20 If we just go over the page, we can see the
 21 usage there for patients with antibodies, NHS
 22 Factor VIII used in hospital, 229,585 in the course of
 23 1983. So the predominant treatment for patients with
 24 antibodies is NHS Factor VIII and then NHS Factor IX
 25 278,514, and 606,475 for home therapy for patients

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

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

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

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

16 If we then, please, Soumik, go to
 17 BPLL0002848_001. This is a letter dated
 18 23 February 1988, so it's not, as it were, directly
 19 contemporaneous, it's looking back over a previous few
 20 years, but it's obviously closer in time to any
 21 current statement that we have and it's from Dr Jones
 22 to Dr Liam Donaldson, who was then the Regional
 23 Medical Officer at the Northern Regional Health
 24 Authority and he says this:

25 "I enclose a historical record of the use of

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1 Factor VIII preparations in the Northern Region since
 2 1969. I hope this will help answer many of the
 3 questions raised by the Regional Health Authority and
 4 Jim Cousins ... These figures, taken with my comments
 5 below, should allay any worries that the Northern
 6 Region's use of Factor VIII has been in any way
 7 untoward."

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

13 "... presented both in tabular and graphic form
 14 Table A lists the use of Factor VIII preparations from
 15 1969-1975. Between 1969-1974 the figures for Carlisle
 16 and Newcastle are incorporated. From 1975 the other
 17 Associate Centres in Sunderland, Middlesbrough and
 18 Whitehaven are included.

19 "Between 1969 and 1975 much of the service
 20 depended on the use of fresh frozen plasma.
 21 Commercial concentrates were introduced in 1973 and
 22 quickly made up the shortfall in local Blood
 23 Transfusion Service plasma and cryoprecipitate. The
 24 sudden rise in NHS Factor VIII concentrate usage in
 25 1971 was caused by the treatment of one patient who

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1 of the former."

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

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

9 I don't know precisely upon what data Dr Jones
 10 based these tables, and it may be that we need to do
 11 some further work in that regard, but we can see that
 12 this is product usage in the Newcastle supra region
 13 (so including the other centres that Dr Jones
 14 identified in the body of the letter) from 1969 to
 15 1975. I'm not going to read through the figures for
 16 plasma. You can see them set out there.

17 In terms of cryoprecipitate, we can see usage
 18 increasing overall from 270,000 in 1969 through to
 19 977,000 in 1975. In 1972, the usage seems rather low
 20 and it leaps then to 917,000 in 1973. But, in any
 21 event, that's the increase in use of cryoprecipitate
 22 over this period.

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

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1 suddenly developed high titre Factor VIII
 2 antibodies ..."

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

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

15 Then three paragraphs further down:

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

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

25 "I have already referred to the erratic supply

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1 Then we can see commercial concentrate introduced in
 2 1973 and rapidly increasing from 133,000 units in the
 3 first year of usage to 972,000 units in the third year
 4 of usage.

5 If we then go to table B, please Soumik -- so
 6 the next page -- I'm not for present purposes, sir,
 7 going to look at the comparison with the UK usage
 8 (although that may be an exercise that will need to be
 9 considered in due course) but just to look at what
 10 this tells us about Newcastle usage. So here we need
 11 to start from the bottom of the page. It starts with
 12 1976 and goes up to 1986. If we look at the box
 13 headed "Newcastle", we can see in 1976 the figure for
 14 cryoprecipitate is 676,050, and then that essentially
 15 reduces over the years: 1979, 452,000 units; 1980 only
 16 67,000 units; 1981 186,000 units; 1982 35,000 units;
 17 1982 167,00 units, and so on, with a slight increase
 18 in 1986 to 205 units, but overall a pattern of
 19 decrease in the use of cryoprecipitate over that
 20 period.

21 In terms of NHS concentrate, again working from
 22 the bottom, we see a relatively modest amount used in
 23 1976, 82,800, and then really quite disparate figures
 24 in different years. So an increase to 1.677 million
 25 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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1 the Pharmacy Department at the Royal Victoria
2 Infirmary. As far as I was aware, payment for
3 commercial blood products was arranged for by the
4 Regional Health Authority. At no point was the
5 financing of the purchase of commercial blood products
6 debited to the Blood Transfusion Service budget."

7 Then she says:

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

12 Then she talks about production of
13 cryoprecipitate. She says:

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

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

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

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

15 There is then just one other document with,
16 again, an external observation on Dr Jones' approach.
17 Soumik, it is TYWE0000352_001, please. This is
18 a rather later letter. This is 16 September 1986; so
19 we're now in the era of heat-treated products, which
20 I will be discussing tomorrow. It's a letter from the
21 District General Manager of the Newcastle Health
22 Authority to Dr Liam Donaldson as Regional Medical
23 Officer for the Northern Regional Health Authority and
24 it's about the budget for haemophilia treatment. He
25 refers to enclosing a point-by-point response but then

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

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

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

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

25 "(a) commercial Factor VIII was more easily

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1 says this:

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

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

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

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

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1 a capital allocation and revenue allocation by the
 2 DHSS to enhance production.
 3 Picking that up four years later or five years
 4 later in 1980, and just to see what the position was
 5 on a regional basis, if we go to DHSC0002201_002
 6 please, Soumik, we can see here a communication
 7 between the Northern Regional Health Authority and the
 8 Department of Health and Social Security. Again,
 9 I won't take you through the chain of correspondence
 10 but we can see in the second paragraph says:

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

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

21 That position is reiterated some 18 months or
 22 so later. If we go to DHSC0002215_023 so this is
 23 20 January 82 again a letter from the Northern
 24 Regional Health Authority to the DHSS and we can see
 25 it says:

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

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

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

25 So that's a view expressed by Dr Jones within

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

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

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

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

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

3 More publicly in journals, Dr Jones expressed
 4 firm views on issues relating to self-sufficiency. So
 5 if we start with DHSC0003722_064, please, this is an
 6 article in the British Medical Journal, 21 June 1980.
 7 It's entitled "Factor VIII supply and demand". If we
 8 could zoom in on the bottom half of the page please,
 9 Soumik, and I'll just -- it ranges over a range of
 10 topics, so I'm just going to dip into a couple of
 11 passages. Middle column, second paragraph:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14 Then he refers bottom of the page the last
 15 paragraph:

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

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)**
 22
 23
 24
 25

<p>MS RICHARDS: [69] 1/4 1/10 2/15 4/8 7/14 7/18 7/21 7/23 9/2 9/4 10/12 17/16 17/20 17/24 18/4 20/1 20/5 21/14 21/23 24/17 25/6 25/10 25/25 26/20 27/3 27/8 27/22 28/3 28/12 30/8 31/16 31/20 32/1 32/12 43/10 45/25 46/22 47/23 50/3 50/7 51/3 51/6 56/3 56/6 56/8 57/6 57/9 58/12 58/16 71/13 71/16 71/25 72/6 107/14 110/17 110/23 110/25 115/4 116/5 116/8 116/19 116/22 117/3 161/9 163/1 163/4 163/10 190/16 190/19</p> <p>SIR BRIAN LANGSTAFF: [72] 1/3 1/5 1/18 3/19 7/11 7/16 7/19 7/22 8/24 9/3 10/9 17/13 17/17 17/21 18/3 19/25 20/3 21/12 21/21 24/15 25/2 25/8 25/24 26/19 26/21 27/7 27/19 27/23 28/11 30/1 31/14 31/17 31/23 32/11 43/9 45/23 46/20 47/17 49/24 50/6 51/2 51/4 55/21 56/5 56/7 57/5 57/8 58/10 58/15 70/25 71/15 71/20 72/1 72/5 107/12 110/16 110/21 110/24 115/2 115/5 116/6 116/18 116/20 116/23 117/2 161/7 162/25 163/2 163/5 163/9 190/15 190/17</p> <p>'60s [1] 105/13 '70s [1] 188/16 '73 [1] 112/16 '81 [1] 33/25 '82 [1] 33/25 '83 [3] 33/25 36/23 43/25 '85 [1] 173/13 '86 [1] 173/13</p> <p>'arrangements [1] 88/21 'cruel' [1] 151/25 'deprivation' [1] 151/25</p>	<p>'Hemofil' [1] 119/24 'Hepatitis' [1] 98/15 'Kryobulin' [1] 119/25 'misery' [1] 151/25 'No [1] 56/16 'normal' [1] 144/24 'on [1] 133/9 'Profilate' [1] 119/25 'resistance' [1] 168/7 's [1] 79/22 'sale [1] 168/12 'subclinical' [1] 141/15 'The [2] 35/15 35/20 'willingness [1] 135/6</p> <p>... 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