

Wednesday, 13 January 2021

(10.00 am)

SIR BRIAN LANGSTAFF: So this morning, Ms Richards, we have the presentation in respect of Manchester?

MS RICHARDS: That's right, sir.

SIR BRIAN LANGSTAFF: Yes. Let me just say a word or two to those who may be watching online. I was right to put the figures above 100 yesterday and I imagine it may be something very similar today. There is, of course, no live witness today. There is the remote presentation. Ms Richards.

Presentation on Manchester Royal Infirmary Haemophilia Centre by MS RICHARDS

MS RICHARDS: Sir, yes. Today's presentation focuses on the Manchester Royal Infirmary's haemophilia centre. It was a reference centre and one of the largest reference centres in the United Kingdom in the 1970s and 1980s. We've obviously heard from Professor Hay about Manchester from 1994 onwards, so the documents we're going to look at focus on periods prior to that.

We have prepared a written note which Core Participants have had access to which sets out what we've gleaned from documents that have been supplied to the Inquiry. Inevitably, the documents I'm going to refer to today are a selection from a much larger

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centres whose policies and practices haven't otherwise been explored through either through oral evidence or an earlier presentation.

In terms of directors, we know that Dr Israels was the director during the 1960s and then Dr Delamore took over. We don't know very much about Dr Irvine Delamore's early career. Documents suggest he worked in Edinburgh, then he went to Blackburn Royal Infirmary. By 1971 he had moved to Manchester Royal Infirmary and he took over from Dr Israels and remained director until 1989.

His co-director for a significant period of time was Dr Richard Wensley. We see Dr Wensley attending a UKHCDO meeting in 1971, at that stage on behalf of Bristol. He joined Manchester in 1974 and we can see a somewhat unusual arrangement in that he worked both as a consultant haematologist as part of the haemophilia centre and as part of the Northwest Blood Transfusion Service, and he had a particular interest in and expertise in the production of cryoprecipitate, which we'll come back to at a later stage.

We can look at one document which casts a little further light on the position in relation to Manchester. Soumik, it's NHBT0096549, please. If we

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number of documents. Inevitably also, the picture is an incomplete one. We do not have a statement from anyone who was in a position of responsibility at Manchester in the 1970s and 1980s, in terms of being a consultant or director. The earliest we have is a statement from Dr Guy Lucas who arrived in 1989 and became Haemophilia Centre Director for a short period of time prior to Professor Hay's appointment.

So it's an incomplete picture from which you, sir, will have to, in due course, draw inferences and you will no doubt be assisted in filling in the gaps from consideration of the fairly substantial number of witness statements from patients or patient relatives that the Inquiry has received.

Manchester Royal Infirmary was part of a bigger regional haemophilia service in the northwest of England, which included, in terms of the regional centres, Manchester Children's Hospital, the Lancaster Haemophilia Centre, and also Blackburn Royal Infirmary. Lancaster is sometimes described in the documents as a sub-centre, Blackburn Royal Infirmary as an associate centre of the Manchester centre. We will be looking further at the Children's Hospital, the Lancaster centre and the Blackburn centre in March, when we try and address all of the haemophilia

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go to the second page, first of all, we can see there's a letter from Dr Gunson, who was the regional transfusion director in Manchester for the Blood Transfusion Service, February 1986, and he refers in that letter to providing a short statement about the regional haemophilia service and to comment on Dr Wensley's role.

If we go to the next document, please, we can see if we look at the first half of the page some background information about the arrangements in Manchester. It says:

"The Regional Haemophilia Service is responsible for the treatment of adults suffering from haemophilia and is based at the Manchester Royal Infirmary, with a sub-centre at Lancaster. There are co-directors of the service -- Dr Delamore (Consultant Haematologist with Central Manchester District) and Dr Wensley (Consultant Haematologist Central Manchester District, 5 sessions and Regional Transfusion Centre, 6 sessions). Dr D Lee ..."

Who is not Dr Richard Lee who we heard about yesterday, who was based in the West Country by this time, but Dr D Lee:

"... is the consultant-in-charge of the Lancaster Transfusion Centre manages the sub-centre in

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1 Lancaster. Children suffering from haemophilia are
2 treated by Drs D Evans and R Stevens at the Manchester
3 Children's Hospital, although this also forms part of
4 the Regional Service.

5 "The Haemophilia Centre at Manchester Royal
6 Infirmary is also designated as one of the six
7 National Reference Centres."

8 Then there's a description of prior to 1975 the
9 principal method of treatment for haemophilia being
10 the use of cryoprecipitate, which was prepared from
11 human plasma at the Regional Transfusion Centre. Then
12 a reference to Factor VIII concentrate now being used
13 in increasing quantities.

14 There's then a discussion about
15 self-sufficiency and shortages, which we'll come back
16 to but if we go a little further down the page, just
17 below the paragraphs numbered 1 and 2, we can see the
18 arrangements in Manchester, little different from
19 elsewhere. It says this:

20 "In the middle 1970s when Factor VIII
21 concentrate was first purchased in this region, my
22 predecessor arranged with Dr Lane that these purchases
23 should be undertaken through the BTS [Blood
24 Transfusion Service] budget. Whilst the quantities
25 used were small and finance was more readily available

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1 in the use of cryoprecipitate in favour of the
2 Factor VIII concentrate and consequently the need in
3 the Regional Transfusion Centre for someone with his
4 specialised knowledge has also decreased."

5 Then it goes on to explain how his sessions had
6 been adjusted because of an increasing clinical
7 commitment, so with more sessions being devoted to the
8 haemophilia centre work than the regional transfusion
9 centre work.

10 It's not entirely clear the precise date on
11 which Dr Wensley became the co-director of the
12 haemophilia centre with Dr Delamore but we know that
13 he did. Upon Dr Delamore's retirement in March 1989,
14 Dr Wensley became the sole director. Dr Lucas then
15 took over from Dr Wensley as acting director in 1992
16 until September 1994 with the arrival of
17 Professor Hay.

18 Now, in terms of physical facilities and
19 staffing at the Manchester Royal Infirmary's
20 haemophilia centre, those appear to have been pretty
21 limited in the 1970s, and there are various references
22 in documentation to Dr Delamore seeking financial
23 assistance and grants from the Haemophilia Society to
24 assist with things such as the purchase of a deep
25 freeze.

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1 than it is now, there were few problems with this
2 arrangement."

3 Then he talks about there now being significant
4 different problems and asks for a change in the
5 arrangement. So, as we will see, purchases of
6 commercial concentrate, as well as the procurement of
7 Elstree BPL concentrate in Manchester, were all done
8 through the Blood Transfusion Service.

9 If we go to the next page, we can see a little
10 more information about Dr Wensley's dual role, which
11 again is a somewhat unusual feature:

12 "Dr Wensley was appointed as a Consultant
13 Haematologist to the Regional Transfusion Centre
14 (7 sessions) and the Manchester Area Health Authority
15 (Teaching) (4 sessions) in March 1974. His job was to
16 treat patients with haemophilia at the Manchester
17 Royal Infirmary and to be responsible for the
18 production of cryoprecipitate, which was at that time
19 the product of choice for the treatment of these
20 patients. He worked very hard and devised
21 a semi-automated method for producing high quality
22 cryoprecipitate [again, come on to that later] from
23 which the patients in the region derived considerable
24 benefit.

25 "However, since 1980, there has been a decline

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1 If we look at one document by way of example
2 it's HSOC0016116_029. We can see this is a record of
3 a meeting of the council of The Haemophilia Society,
4 17 March 1973, and Dr Delamore is recorded as being
5 one of those present. If we go on, please, to page 4,
6 Soumik, bottom half of the page, we can see under the
7 heading "Application for grants from Research Fund":

8 "Dr Delamore spoke about his application
9 outlined in the memorandum to council members. He
10 said that no major developments had taken place in
11 Manchester for about 20 years. In order to improve
12 facilities and expand the work of the Centre,
13 including a possible clinic for Home Treatment, a new
14 system of records was required and the present staff
15 could not cope with all this extra work. A request
16 has been made to the Hospital Management Committee but
17 this is slowly passing through the various committees
18 and will take a long time. Mr Tanner said he thought
19 the Society should help now to prevent delay in
20 Dr Delamore's plans and that the grant could be
21 considered as a 'bridging operation' and would help to
22 make the case for the Health Service to take over."

23 A grant for one year to cover the cost of
24 secretarial assistance to allow record-keeping and the
25 possible clinic for home treatment was agreed by the

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1 Haemophilia Society, extended for another year and
2 then in 1975 we know from other materials that the
3 Regional Health Authority took over funding.

4 If we look next, please, at PRSE0000421 we can
5 get a further insight into the staffing facilities at
6 Manchester in 1978. So this is documentation relating
7 to a seminar, organised, it would appear, by The
8 Haemophilia Society in 1978. If we go, please,
9 Soumik, to the third page, we can see on the
10 right-hand side, second paragraph, the speakers being
11 introduced:

12 "Dr Delamore is the Director of the Haemophilia
13 Centre at the Manchester Royal Infirmary. The centre
14 is a main Reference Centre and therefore acts in
15 a supervisory and advisory capacity and has links with
16 Centres in the surrounding area."

17 Then there's reference to other speakers.
18 We're told also that Dr Delamore's department deals
19 with the whole field of haematology and its many
20 specialisms. Then if we look on the right-hand side
21 we can see the text of what was being said by
22 Dr Delamore.

23 You may be interested to note, sir, in the
24 second paragraph, reference there to cerebral head
25 bleeds, which is something that's been picked up by

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1 dentistry education, and employment, and so on and
2 provide a counselling service through the Social
3 Services Department. Advice is offered also to GPs or
4 anybody else who might be concerned with the
5 management of haemophilia. Records of medical
6 patients to whom haemophilia cards have been issued
7 are made at the Haemophilia Centre and include all the
8 necessary personal details of patients."

9 Then there's reference here to the associate
10 centres:

11 "The new category allows for Associate Centres
12 who have been designated as suitable Haemophilia
13 Centres for the provision of an emergency service for
14 patients but are linked to Diagnostic Centres so that
15 together all the necessary facilities are provided."

16 We are hearing tomorrow, sir, from a witness
17 who was at an associate centre, so this may be some
18 useful background:

19 "The Special Treatment Centres were changed to
20 Reference Centres and were expanded to seven in
21 number. These are ..."

22 If we go over the page:

23 "... St Thomas' and the Royal Free Hospital in
24 London, Churchill Hospital Oxford, The Royal
25 Infirmarys of Sheffield and Manchester, The Royal

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1 other witnesses, and he says there:

2 "Fortunately ... they are rare, although it is
3 one of the major causes of death."

4 Then if we could have the bottom half of the
5 page please, Soumik, we have an explanation here from
6 Dr Delamore about the organisation of haemophilia
7 centres, which may be of assistance more widely as
8 well as in understanding the position in Manchester:

9 "Dr Delamore described how in 1968 Haemophilia
10 Centres were reorganised into Associate, Diagnostic
11 and Reference Centres. Before this, Oxford, Sheffield
12 and Manchester were three Special Treatment Centres.
13 In 1974 it was decided to make changes in the
14 arrangements of Centres. Centres should exist first
15 of all to provide a service to carry out all the
16 necessary investigations including the identification
17 of the specific coagulation factors concerned, monitor
18 coagulation factors and the effect of treatment, and
19 investigate the relatives of patients with haemophilia
20 and relative diseases. The second function is to
21 provide a clinical service which includes provision of
22 medical treatment at any time of the day or night and
23 at short notice for patients with haemophilia.
24 Thirdly, provision of an advisory service for patients
25 and their parents who might be concerned about

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1 Victoria Infirmary in Newcastle, and the University
2 Hospital of Wales at Cardiff. There are two main
3 Centres in Scotland; one in Edinburgh and one in
4 Glasgow. The advantage of the more numerous Associate
5 Centres is that patients do not have to travel so far
6 to get treatment."

7 Then you'll see there a diagram seeking to
8 explain the relationships.

9 "There are 44 Haemophilia Centres in England
10 and 58 Associate Centres. Associate Centres in
11 particular, are growing all the time. The Reference
12 Centres are expected to have special skills and
13 provide every facility that the patient with
14 haemophilia might need, for example, a 24-hour
15 telephone advisory service for both the patient and
16 Haemophilia Centre or Associate Centres in the region,
17 a special consultancy service for surgery, orthopaedic
18 surgery, dental care, paediatric and social care, and
19 to keep medical records and statistics. Together with
20 a wide range of ancillary services, they must advise
21 and organise such things as home therapy, prophylactic
22 therapy where necessary, and to provide a reference
23 laboratory service. Dr Delamore outlined how they are
24 expected to ensure close co-operation between all
25 working sectors in their particular region, and

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1 co-ordinate the availability of the necessary
2 outpatient therapy material. One great problem is the
3 shortage of Factor VIII replacement therapy with which
4 to treat patients.

5 "... Dr Delamore stressed how very important
6 the link must be with the blood transfusion service.
7 In Manchester, there is in fact a joint consultant
8 between blood transfusion and haematology."

9 That's Dr Wensley.

10 "Although he spends nearly all his time in the
11 haematology department on haemophilia, he has
12 a special responsibility to see that replacement
13 materials are present and supplied in regular
14 quantities and takes a special interest in the blood
15 transfusion service. Dr Delamore suggested that the
16 key organisation in solving the shortage of treatment
17 products must be the Blood Transfusion Service."

18 Then he goes on to talk about genetic
19 counselling and other matters.

20 **SIR BRIAN LANGSTAFF:** That description of the way in which
21 Dr Wensley spends his time doesn't fit.

22 **MS RICHARDS:** It doesn't.

23 **SIR BRIAN LANGSTAFF:** Because at this stage he was doing
24 seven sessions on blood transfusion and four on his
25 clinical commitments.

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1 to be completed in 1991.

2 You'll recall Professor Hay's oral evidence; he
3 described the facilities when he arrived in 1994 as
4 being a small haemophilia centre attached to
5 laboratories, which included a storeroom, an office,
6 two consulting rooms and a waiting area, and there
7 were, by the time Professor Hay arrived, a nurse
8 counsellor, two other haemophilia nurse specialists
9 and a clinical assistant.

10 So that's by way of introduction to the
11 arrangements at Manchester. The next topic I propose
12 to address deals with the arrangements for the supply
13 and distribution of products and issues relating to
14 shortages. Unsurprisingly, given what we've seen in
15 relation to other centres across the country,
16 Manchester also records difficulties in obtaining
17 adequate supplies of blood products really from the
18 late 60s, through the 70s and well into the 1980s.

19 There are a number of national meetings
20 attended for example by Dr Israels that look at the
21 national picture in relation to the need for
22 self-sufficiency, insufficient supplies and so on,
23 which we've looked at a number of those already. In
24 terms of Manchester's particular position, we can pick
25 up the picture by looking at a letter from March 1969

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1 **MS RICHARDS:** Yes, you are absolutely right, sir. It
2 doesn't quite fit. We can't, I think, shed any more
3 precise light on that other than we do see from other
4 documents that he certainly maintains that dual
5 responsibility for a number of years.

6 **SIR BRIAN LANGSTAFF:** Well, the whole rationale for him
7 asking to have five instead of four sessions for his
8 clinical commitments was that he felt that he could
9 not otherwise spend the five.

10 **MS RICHARDS:** Yes.

11 **SIR BRIAN LANGSTAFF:** Which again indicates that
12 Dr Delamore was seeing rather more of Dr Wensley's
13 services than they deserved.

14 **MS RICHARDS:** Possibly, sir, yes.

15 In terms of the physical layout of the
16 Manchester Royal Infirmary's facilities, there's
17 little by way of description from the 70s and 80, and
18 again it may be, sir, that you will derive greater
19 assistance from the statements of patients who
20 attended than from any of the documents.

21 We do see, and I won't go to the document in
22 relation to this, but we see in 1990 discussions about
23 the upgrading of treatment facilities, with six rooms
24 to be made available for a haemophilia-dedicated
25 treatment facility, and there's reference to works due

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1 from Dr Israels.

2 That's DHSC0100025_092.

3 If we could just zoom in on that. It's not the
4 best of copies.

5 It is dated 12 March 1969. It is from
6 Dr Israels to Dr Maycock at the Lister Institute,
7 Elstree, what became BPL, and Dr Israels is writing to
8 Dr Maycock in Maycock's "capacity as Adviser to the
9 Department of Health and as Chairman of the Blood
10 Transfusion Directors' Group".

11 He refers to their having had considerable
12 trouble in getting sufficient anti-haemophilic
13 material to deal with a difficult case, a surgical
14 case, and he refers to having received some material
15 from the Lister Institute but that giving out and
16 having to get material from Edinburgh, and he says
17 this:

18 "This, of course, was not sufficient. In the
19 ordinary way we would supplement this by
20 cryoprecipitate obtained from the Blood Transfusion
21 Service. But the Manchester Blood Transfusion Service
22 is quite unique and being unable to supply
23 cryoprecipitate on any scale ..."

24 This is as at 1969, the position changes in
25 later years.

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1 "... because the Regional Board have still not
2 provided the facilities for regular preparation of
3 this material. So we have had to prepare it ourselves
4 in our own laboratory and so far we have prepared 108
5 packs, equivalent to about 200 ml [of] plasma each.

6 "Dr Stratton, [who was the then director of the
7 Regional Transfusion Centre] has mobilised his
8 resources to a certain extent ..."

9 If we go on to the next page, again we zoom in,
10 he says:

11 "I am writing to you now because it is clear
12 that this sort of emergency arrangement must be
13 replaced by more permanent arrangements. We are,
14 after all, the second largest Haemophilia Centre in
15 the country and it is surely quite wrong that we
16 should be served by a Blood Transfusion Service which
17 is not fully equipped. Of course, this situation has
18 been appreciated for a long time and I drew
19 Dr Stratton's attention and the Regional Board's
20 attention to this matter at the time when it was
21 agreed to form major haemophilia centres. Originally
22 it was agreed that by September 1968 the Manchester
23 Regional Transfusion Service would be re-equipped and
24 staffed so as to be able to provide us with a proper
25 supply of cryoprecipitate. It is now March 1969 and

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1 "It is true to say that no region is yet in
2 a position to prepare as much cryoprecipitate as it
3 needs.

4 "Under the circumstances it is most unlikely
5 that arrangements could be made for Manchester to be
6 supplied from other regions in the way you suggest,
7 although I am sure other regions will, if they can,
8 help in an emergency."

9 That's the picture we get as at the end of the
10 1960s. It's clear from a range of materials that
11 throughout the 1970s obtaining sufficient supplies
12 continued to be a problem. There's a general
13 discussion of that in the Haemophilia Centre
14 Directors, the UKHCDO meeting of April 5 April 1971,
15 at which Dr Delamore represented Dr Israel. I don't
16 propose to go to that.

17 But then there is hope expressed in 1973
18 that -- with the appointment of Dr Wensley, who had
19 particular interest in and expertise, it was said, in
20 producing cryoprecipitate -- the position would
21 improve. There are Haemophilia Society records which
22 suggest that as at 1973 more cryoprecipitate was now
23 being produced.

24 However, we can see issues of supply continuing
25 to dominate discussions and, if we go to CBLA0000454,

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1 as you will see from the arrangements we have had to
2 make they are still hardly in a position even to cope
3 with emergency treatment."

4 Then he goes on to say in the next paragraph:

5 "... I am writing to ask you if in the interim,
6 while the Manchester RBTS gets properly organised, it
7 would be possible for you to arrange for the
8 Manchester Service to draw on other Services for
9 a supply of cryoprecipitate."

10 The response to that is at DHSC0100025_101. We
11 can see Dr Maycock's response 16 April 1969. He says:

12 "I have now had an opportunity to discuss, in
13 the Department, the proposal in your letter that the
14 major Haemophilia Centre at Manchester should be able
15 to obtain the necessary supplies of cryoprecipitate
16 from other regions, until such time as RTC Manchester
17 can undertake this task."

18 Then in the next paragraph:

19 "The development of facilities for preparing
20 cryoprecipitate in RTCs has been uneven and some
21 centres are no more advanced than RTC Manchester.
22 This arises mainly from two factors, the financial
23 priority accorded by the [Regional Health Boards] and
24 the regional assessment of the urgency and magnitude
25 of the haemophilia problem.

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1 we can see how, as at 1976, the arrangements were
2 being made for the supply of Elstree concentrate.
3 This is a letter from Dr Maycock to Dr Delamore, and
4 it says this:

5 "The *ad hoc* Expert Committee on the Treatment
6 of Haemophilia and the Regional Transfusion Directors
7 Meeting agreed earlier this year that concentrate
8 prepared at BPL should be distributed in proportion to
9 the number of haemophiliacs known to have been
10 treated.

11 "The latest figures of patients treated are
12 those for 1974 prepared by Dr ... Biggs from the
13 information submitted by Haemophilia Centre
14 Directors ..."

15 Then if we go to the next paragraph:

16 "The amount of concentrate being prepared at
17 BPL is about 50 per cent of the expected maximum
18 production of 50,000 bottles, each containing about
19 250 in Factor VIII. It is expected that production
20 should reach about 70-80 per cent of target by the end
21 of 1976 and 100 per cent by autumn 1977, assuming that
22 the necessary plasma is received and that no
23 unexpected difficulties occur."

24 Then he sets out the quantities of concentrate
25 to be allocated to Manchester and to Liverpool. And

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1 so what we can see here, it's said that these are
 2 based upon the number of haemophiliacs undergoing
 3 treatment. Of course we have seen elsewhere how this
 4 moved to the pro rata system, responding to the amount
 5 of plasma provided. But as at this date the amount
 6 distributed to Manchester is going to be 240 bottles
 7 monthly and to Liverpool 50 bottles.

8 It's then said if there needs to be any
 9 adjustments within the overall total available. We
 10 can see by correspondence in the following year, by
 11 the middle of 1977 --

12 **SIR BRIAN LANGSTAFF:** Just pausing there, you may be
 13 coming to this, but one of the difficulties of
 14 a system like this might be said to be that it is
 15 calculating supply not on the basis of what is needed
 16 but on the basis of what was used in the previous
 17 year, and what we have seen repeatedly from other
 18 centres has been the effects of one or two individuals
 19 who suffered particular bleeds whose demands meant
 20 that they used up a lot of whatever concentrate or
 21 other replacement therapy they were using.

22 So one would have expected that if the system
 23 was going to work properly it would need some sort of
 24 reserve or flexible bank from which to draw.

25 **MS RICHARDS:** Yes. We can see there being particular

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1 Directors and Haemophilia Reference Centre Directors
 2 ... in Sheffield ... 22nd October 1976 ..."

3 We can see it's a meeting that had been called
 4 by Professor Blackburn -- well -- or he was going to
 5 address that. For the agenda sets out the need for at
 6 least 40 million units of freeze-dried Factor VIII to
 7 treat the population.

8 "Is this estimate correct?

9 "... 4. Can the plasma needed to provide this
 10 amount of Factor VIII be supplied by the Transfusion
 11 Service?

12 "If not, what steps should be taken to provide
 13 the plasma needed to supply Factor VIII?

14 "a) Can a case be made to the Regional Health
 15 Authorities to increase financial support to the
 16 Regional Transfusion Centres to enable them to supply
 17 more plasma for fractionation?

18 "b) Should the Regional Health Authorities be
 19 encouraged to increase the purchase of commercial
 20 Factor VIII so that plasma now used to make
 21 cryoprecipitate could be sent for fractionation?

22 "5. If the plasma supply is increased do we
 23 have the ability in terms of laboratory space, staff
 24 and equipment to prepare 40 [million] units of
 25 Factor VIII and all of the other valuable plasma

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1 problems in this regard in relation to Manchester from
 2 some of the later documents.

3 **SIR BRIAN LANGSTAFF:** Was there any such -- have we come
 4 across any evidence of any such flexibility in the
 5 system?

6 **MS RICHARDS:** In terms of contemporaneous documentation,
 7 very little. I will show you Dr Gunson's statement,
 8 prepared in the 1980s, after the event, as it were,
 9 for the purposes of litigation, in which she addresses
 10 some of these matters. But there are various
 11 communications in which concern is expressed about
 12 available supplies being pegged to a particular year
 13 when the need was significantly in excess of that.

14 **SIR BRIAN LANGSTAFF:** Yes.

15 **MS RICHARDS:** So we do know that this initial figure of
 16 240 was -- the allocation was increased to 400 a month
 17 by June of 1977. Again, there are no single documents
 18 which really set out a whole picture. It's very much
 19 a question of looking at individual documents and
 20 trying to join the dots.

21 Sticking with 1976, there was a meeting in
 22 October of 1976 at CBLA0000473. We can see that this
 23 was a meeting that was intended to consider issues of
 24 supply and demand:

25 "Exploratory Meeting of Blood Transfusion

22

1 fractions in the [UK]?"

2 Then item 6 on the agenda:

3 "Methods of distributing preparations
 4 containing Factor VIII."

5 The minutes then appear on the next page. They
 6 are not actually a very useful guide to understanding
 7 what, if any, decisions were made at the meeting
 8 because they are actually a record of various
 9 contributions to the meeting rather than anything
 10 else. So you may wish in due course, sir, to read the
 11 whole document. For present purposes, I'm just going
 12 to look at what's said about Manchester, which is
 13 comparatively little.

14 If we go to the last page of this document, we
 15 can see Dr Wensley saying:

16 "In Manchester all Factor VIII containing
 17 materials are distributed by the Transfusion Centre,
 18 including the commercial material."

19 So that's a reference to the arrangement
 20 I referred to earlier whereby the transfusion centre
 21 effectively supplied both NHS cryoprecipitate, other
 22 materials and commercial.

23 Then there's the somewhat curious intervention
 24 by Dr Prentice:

25 "Objection. Manchester money comes from the

24

1 Region and not from the District."
 2 Quite what that's a reference to is unclear.
 3 So it would appear that this meeting was
 4 a means for people to express concerns rather than
 5 solve problems and at the end we see the meeting
 6 closed at 1.00 pm, no further meeting was arranged.
 7 There is then a local, as in to the northern
 8 region, meeting in 1979 that we have a record of.
 9 That's at DHSC0002195_037. So we can see this is
 10 described as "Meeting of the Northern Regional Group
 11 of Directors, 20 September 1979, "Representatives from
 12 Leeds, Sheffield, Manchester and Liverpool were
 13 present". It's said:
 14 "It was not possible to arrive at a consensus
 15 agreement with respect to the recommendations on
 16 page 5 of this document."
 17 We don't have that, so we don't know what that
 18 refers to, but then this is a note that sets out
 19 various areas of discussion. Just, again, picking up
 20 matters of particular relevance to Manchester,
 21 paragraph 2, it's said:
 22 "With respect to pro rata supply there was
 23 dissension by representatives from Manchester and
 24 Liverpool where the demand for cryoprecipitate was
 25 still great and indeed in the view of Dr Wensley was

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1 Then there's a reference to the position in
 2 Leeds and Sheffield, and then a reference to anomalies
 3 with respect to regional practices. So it said:
 4 "... it was felt that if certain anomalies with
 5 respect to Regional practices could be resolved, pro
 6 rata supply was indeed a logical development although
 7 it was conceded that if fresh plasma could be
 8 separated more economically in certain Regions then it
 9 would be advantageous for this Region to concentrate
 10 on that task."
 11 Then we see Manchester in paragraph 3:
 12 "Manchester and Liverpool considered that their
 13 demand and intended reduction of cryoprecipitate and
 14 other factors would not allow them to double the
 15 quantity of fresh plasma sent for fractionation."
 16 If we go over the page, a hope is expressed
 17 that:
 18 "... a dialogue could be set up with the Supra
 19 Regional Haemophilia Directors to determine realistic
 20 levels of Factor VIII production.
 21 "One region (Manchester) recommended central
 22 purchasing of Factor VIII from commercial sources
 23 within each Region."
 24 So we can see there the issue of pro rata
 25 supply being the basis for supply being discussed as

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1 advantageous for the treatment of certain patients."
 2 Somewhat tantalisingly, we don't learn from
 3 this, or I'm afraid from anything else we've yet
 4 unearthed, what particular categories of patients
 5 Dr Wensley, who was clearly from what we've seen
 6 an enthusiast for cryoprecipitate, but what particular
 7 categories he thought it was advantageous for, but we
 8 can see, at least, that as at the autumn of 1979 in
 9 Liverpool and Manchester cryoprecipitate was still
 10 very much in use.
 11 We see Dr Wagstaff, so that's from the Regional
 12 Transfusion Service, "confirmed that this was also
 13 a view being held by certain Haematologists in the
 14 Sheffield Region". There's then reference to
 15 particular issue in relation to Manchester and it says
 16 this:
 17 "... a large number of single donations of
 18 fresh frozen plasma were used in the Manchester Region
 19 for replacement therapy following intensive
 20 plasmapheresis. Also because of acidification the
 21 plasma following platelet separation was unsuitable
 22 for Factor VIII production. Thus although the
 23 Manchester Region separate plasma from 40 per cent of
 24 their intake within 18 hours only a proportion of this
 25 was available for fractionation."

26

1 at September 1979 but, again, this records various
 2 views being expressed rather than giving a clear
 3 picture of what, if any, decisions were taken.
 4 It may be instructive, therefore, to look at
 5 Dr Gunson's statement. That is at NHBT0020196_001.
 6 Now, of course, this was a statement prepared
 7 retrospectively for the purposes of litigation, not
 8 a contemporaneous document, and so you will wish to
 9 accord it such weight as you consider appropriate,
 10 sir. You will see, insofar as Manchester is
 11 concerned, that Dr Gunson sets out that from
 12 April 1980 to 30 April 1988 he was Director of the
 13 Northwest Regional Blood Transfusion Service and based
 14 in Manchester, and he gives a little insight into the
 15 arrangements in Manchester. So he says this:
 16 "As Regional Director [so he had previously
 17 been at Oxford for five years], I was responsible for
 18 the provision of the Blood Transfusion Services to the
 19 District Hospitals in the Oxford and Northwest
 20 regions. In both Oxford and in Manchester there was
 21 a Regional Haemophilia Service. While haemophiliacs
 22 are treated in hospitals, their management is under
 23 the auspices of the Regional Haemophilia Services.
 24 Another function in Manchester, but not in Oxford, was
 25 the purchase of commercial materials within the RTC

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1 budget for the treatment of haemophilia patients. It
 2 was my responsibility, in conjunction with the
 3 Directors of the Haemophilia Service, to negotiate the
 4 provision of the commercial Factor VIII concentrates
 5 to supplement supplies from within the NHS. The
 6 Regional Team of Officers who subsequently became the
 7 Regional Management Team, allocated a specific budget
 8 for this purpose to the Blood Transfusion Service,
 9 which was finally approved by the RHA [Regional Health
 10 Authority]. From this, we purchased supplies to
 11 fulfil the diverging gap between NHS supplies and
 12 demand."

13 He then makes the comment:

14 "In general, the Regional Health Authority
 15 allocated sufficient finance, and I am not aware of
 16 under treatment for the lack of Factor VIII supplies,
 17 although some non-urgent surgical procedures were
 18 deferred."

19 There are documents which suggest a different
 20 picture to that:

21 "Demand certainly increased over this period.
 22 However, the Northwest region, in general, used less
 23 Factor VIII per patient per year than other regions."

24 Again, there are some documents that suggest
 25 that's right. He then talks about the arrangements

29

1 paragraph numbers, sir, are references to paragraphs
 2 of the Statement of Claim in the HIV haemophilic
 3 litigation, so what follows are Dr Gunson's comments
 4 from his perspective. But if we pick it up at the
 5 very bottom of this page:

6 "I used to hold regular meetings with the
 7 physicians who treated the haemophilia patients
 8 concerning supplies -- how much, preferred products,
 9 et cetera. These meetings were *ad hoc* about twice
 10 a year from 1980/81 onwards. They continued until
 11 I resigned as Director of the Northwest Regional
 12 Transfusion Service in 1988. Some were attended by
 13 the Officers of the RHA, the RMO and the AGM Personnel
 14 ..."

15 Sir, we've not identified minutes or other
 16 records of those meetings at least thus far.

17 Then, in relation to Manchester, if we go on --
 18 sorry, Soumik, let me just check what page it is. If
 19 you go on another seven pages, please -- back one
 20 page, sorry. Yes, if we pick it up at the bottom of
 21 the page, he says:

22 "Within the Northwest Region, we worked on
 23 a year to year basis with the local knowledge of
 24 consultants in the Regional Haemophilia Service. This
 25 was based on the number of corrective surgical

31

1 for negotiating with companies. From 1982 to 1983 for
 2 contracts over £100,000 tenders had to be sought and
 3 he describes then the tendering process. Then, at
 4 bottom of the page, he says:

5 "A meeting was held with Dr Wensley and Dr Lee
 6 [that's from Manchester and Lancaster respectively]
 7 after the tenders were in and before the final order
 8 was placed. The ordering process occurred
 9 approximately once a year, normally February/March.
 10 However, in the last five years, because of increased
 11 usage, it was necessary to supplement supplies of
 12 commercial Factor VIII in December/January."

13 So they were running out by the end of the
 14 calendar year and having to purchase more commercial
 15 product.

16 "Dr Wensley was very much involved in the
 17 purchase of Factor VIII and was the person responsible
 18 for the distribution of both commercial and NHS
 19 products from the RTC. Dr Lee, then
 20 Consultant-in-Charge at the Lancaster Centre, managed
 21 the supplies of Factor VIII allocated to that Centre
 22 and Dr D Evans those supplied to the Manchester
 23 Children's Hospital."

24 If we then go over to the next page please,
 25 Soumik, the bottom of the next page, the references to

30

1 operations needed in the following year, together with
 2 the numbers of patients able to pursue a home
 3 treatment regime, with an added percentage added for
 4 emergencies. Home treatment involves extra supplies
 5 of Factor VIII in that a haemophilic would inject
 6 Factor VIII at the commencement of a bleed without
 7 waiting to see if the bleed was serious enough for him
 8 to attend hospital for treatment."

9 If we go on to the next page please, Soumik,
 10 and we look at the last paragraph, Dr Gunson says
 11 this:

12 "Although the use of cryoprecipitate declined
 13 nationally between 1975 and 1985, the usage in the
 14 northwest region remained high as a result of the
 15 policies adopted by the Regional Haemophilia Service.
 16 Cryoprecipitate competed with plasma sent for
 17 fractionation so that the latter targets were not
 18 achieved. However, Factor VIII from cryoprecipitates
 19 was used to treat haemophilia patients and this
 20 supplemented the supplies of NHS and commercial
 21 Factor VIII concentrates."

22 Then he says that details of the production of
 23 cryo and plasma are available at the RTC and at the
 24 Lancaster centre. Then in the next paragraph:

25 "Between 1982 and 1984, the Northwest Regional

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1 Health Authority financed the alterations to the
 2 former ICL computer factory to provide a new Regional
 3 Transfusion Centre. Coincidentally, they responded to
 4 my arguments to increase the plasma supply with
 5 additional financial allocations for this purpose. In
 6 1985/86, funding was provided for a plasmapheresis
 7 centre at Plymouth Grove and somewhat earlier,
 8 a similar, but smaller, plasmapheresis centre was
 9 established in Lancaster. In general, the production
 10 of plasma was divided in proportions of two-thirds
 11 from Manchester and one-third from Lancaster."

12 The majority of the rest of the document deals
 13 with more general matters and will obviously need to
 14 be read in full but -- rather than matters specific to
 15 arrangements in the northwest.

16 The perhaps somewhat rosy picture presented by
 17 Dr Gunson in that statement is not always borne out by
 18 contemporaneous documents, and so if we look at
 19 NHBT0089585 we can see here a letter dated
 20 18 August 1982. It's jointly from Dr Delamore and
 21 Dr Gunson to Dr Lane, Regional Medical Officer,
 22 Northwest Regional Health Authority, and we can see
 23 it's concerning Factor VIII supplies in the northwest
 24 region:

25 "We're writing to request a supplementary grant

33

1 level."

2 Then further details are then given, I won't
 3 read them all out but the figures stand for
 4 themselves. Then if we go over the page, it said
 5 this:

6 "Until recently it was anticipated that this
 7 level would be maintained in 1982/83 with 1.5 to
 8 1.6 million units coming from the BTS plasma
 9 fractionated by the BPL and an allowance of £100,000
 10 (a reduction of £60,000 from the previous year) for
 11 the purchase of commercial Factor VIII ...

12 "However, certain unavoidable factors have
 13 operated to our disadvantage, both with respect to the
 14 number of units of Factor VIII which will be received
 15 and the clinical problems encountered so far in the
 16 current year."

17 Then they set out a number of problems, I won't
 18 read them all out, but I will just refer to each of
 19 them in turn briefly. First was industrial action,
 20 which led to loss of blood collection sessions for
 21 a period of time.

22 (2) was significant increase in the use of
 23 other blood products in 1982 compared with 1981, which
 24 was said would make it more difficult to obtain the
 25 plasma targets for fractionation at the BTS, and there

35

1 of £38,500 to enable us to maintain our treatment for
 2 patients suffering from haemophilia in this region.
 3 A combination of factors has brought a situation in
 4 which the money available in the current financial
 5 year for the purchase of Factor VIII concentrates is
 6 insufficient for us to maintain both an adequate level
 7 of therapy for those patients already on home
 8 treatment and to enable us to expand our home
 9 treatment programme, although we already lag behind
 10 other regions in this respect.

11 "As you will be aware, the Factor VIII
 12 concentrate supplies for the region come from two
 13 sources:

14 "(a) The Blood Products Laboratory, from plasma
 15 supplied by the North Western Region Blood Transfusion
 16 Service.

17 "(b) Purchase of commercial concentrates from
 18 an allocation within the Blood Transfusion Service
 19 budget.

20 "Based on the 1980 to 1981 statistics, the RHA
 21 increased the revenue of the BTS to provide more
 22 plasma for fractionation. With respect to Factor VIII
 23 concentrates, it was anticipated that within two years
 24 the supply from BPL would equate with the total
 25 quantity of Factor VIII obtained at the 1980/81

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1 was going to be a reduced amount available for
 2 Factor VIII.

3 (3) refers to building works at BPL and
 4 an inability for BPL to fully process the plasma sent
 5 to them.

6 (4) a sharp increase in Factor VIII to cover
 7 emergency surgery and details are there provided.

8 Then over the page, (5) is about the use of
 9 Factor VIII therapy as maintenance therapy for
 10 patients with inhibitors which was a treatment policy
 11 pursued by Dr Wensley.

12 So the letter says:

13 "It can be seen therefore, that it has been
 14 possible to identify an additional expenditure of
 15 £38,500 for Factor VIII during the current year and
 16 this must be regarded as a minimum figure ...

17 "It is only the serious nature of the situation
 18 that has led us to write requesting a further grant
 19 and we would be grateful if you could give this matter
 20 your urgent and sympathetic attention ..."

21 The response from Dr Lane at the North West
 22 Regional Health Authority is at NHBT0089586, dated
 23 1 September 1982 and it said, in the second paragraph:

24 "The general answer to your question is that at
 25 this point in the year and in this year in particular

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1 it is quite impossible for the RHA to find additional
 2 money for any expansion or improvement of any service
 3 whatsoever. I know this will be disappointing
 4 particularly as the answer might have been different
 5 had you been able to foresee the need for expansion at
 6 the beginning of the year when resource allocations
 7 for regional specialty developments were made.
 8 However, that time is now passed and I think it would
 9 be very unwise to assume that in the next two years
 10 any improvement for regional specialties will be
 11 possible."

12 Then he says:

13 "Having said that in general the Authority's
 14 policy must be to maintain all services at their
 15 existing level since our resources are not being
 16 actually cut but only failing to grow."

17 Then the letter goes on to say:

18 "... [it is] quite wrong that the actions of
 19 clinicians should place you as supplier in reducing
 20 a service for haemophilia in order to improve
 21 a service for meeting platelet deficiencies ... We
 22 must ask you to maintain all blood supplies not only
 23 overall but detailed subdivision at the levels
 24 pertaining at the beginning of the year. This needs
 25 to be made clear to clinicians who use whole blood,

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1 aspirations from the plasmapheresis centre in
 2 Lancaster, which was due to begin operations in
 3 1983/84. Paragraph 2:

4 "Dr Delamore commented that the current levels
 5 of Factor VIII (concentrate and cryo) being pegged at
 6 the 1980/81 level was insufficient to meet, demand,
 7 but it was agreed that no action should be taken ...
 8 until it was known whether the Specialty Bid was to be
 9 approved or not."

10 That's presumably a bid for extra funding.

11 Then there is an agreement in relation to
 12 cryoprecipitate supplies in paragraph 4 and
 13 an agreement to maintain the monthly production rate
 14 of cryoprecipitate at 1,500 per month:

15 "... Manchester Royal Infirmary would endeavour
 16 to economise in its use so that as at 1 April they
 17 would have some stock in hand."

18 Then we see the bottom of the page, from
 19 1 April 1983 cryo production at Roby Street, which was
 20 Manchester, would be at the rate of 16,000 per year or
 21 1,330 per month, of which 1,000 would be allocated to
 22 the Manchester Royal Infirmary:

23 "(b) If the Specialty Bid is approved and when
 24 the additional material is available for expansion of
 25 home treatment, cryo production at Roby Street would

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1 those who use platelets and those who are using
 2 products for the treatment of haemophilia. The
 3 general rule must be supplies held at last year's
 4 levels, it being for clinicians to determine which
 5 cases should receive priority. In general, however,
 6 clinicians must not 'use up' the whole ration for the
 7 year at an early stage so that nothing is left for
 8 really serious cases towards the end of the year.
 9 I should be glad if you could arrange for some kind of
 10 monthly rationing process allowing reasonable
 11 flexibility for the irregular presentation of
 12 difficult cases."

13 Then he says:

14 "I don't believe that it is right to expect you
 15 to be the arbiter of life and death in terms of blood
 16 supplies ..."

17 Issues of supply and insufficiency of supply
 18 continued to be raised in the first half of the 1980s
 19 and so if we look, for example, at NHBT0089582, we can
 20 see, for example, there was a meeting on
 21 15 February 1983 to consider Factor VIII supplies in
 22 northwest region, attended by Dr Delamore and
 23 Dr Wensley from Manchester, Dr Gunson and then we have
 24 Dr Lee from Lancaster, Dr Stevens from the Children's
 25 Hospital. Reference is made in paragraph 1 to

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1 be reduced to 10,000 units per year, of which 500
 2 units per month would be allocated to the Manchester
 3 Royal Infirmary."

4 Then over the page, you'll see at paragraph 5
 5 the supply for 1984/85 was dependent on the
 6 plasmapheresis centre in Lancaster, as yet something
 7 of an unknown quality.

8 Then, sir, this is February 1983, you will see
 9 there:

10 "The problem of AIDS was discussed. It was
 11 agreed that no specific action should be taken at
 12 present, but the situation should be carefully
 13 monitored and a reappraisal of policy may be necessary
 14 if changes in treatment regimes have to be made."

15 I will come back to that but we've identified
 16 no documents that suggest that there were any changes
 17 in treatment policy in response to the risk of AIDS.

18 There are various other references in the
 19 course of 1983 to problems of funding and shortages
 20 and shortfalls. We can see that, perhaps, if we look
 21 at a letter from Dr Gunson, NHBT0096599_015. It's
 22 a letter dated 26 October 1983 to the senior assistant
 23 treasurer at the Northwest Regional Health Authority.
 24 As I say, it's from Dr Gunson. I won't read the
 25 letter in full but it is a letter which merits reading

40

1 in full. It's about Factor VIII supplies and you will
 2 see in the first paragraph Dr Gunson says:
 3 "... I decided to review the situation with
 4 respect to Factor VIII supplies from April 1980 in
 5 order that you might obtain a more complete picture of
 6 the problem.
 7 "The year 1980/81 is significant, because in
 8 March 1981 I presented a paper to the RHA giving
 9 details of the scheme to increase the supplies of
 10 Factor VIII and albumin products and demonstrated how
 11 these could be self-financing by 1983/84 from the
 12 savings made on purchase of commercial Factor VIII
 13 concentrates."
 14 Then he refers to figures actually of units
 15 actually received in 1980 to 1981:
 16 "Our expansion plans did not come to fruition
 17 until later in 1981/82 ..."
 18 He refers all of the increase in Factor VIII
 19 was used at the Manchester Royal Infirmary:
 20 "1982/83 was a difficult year, as you will
 21 recall, and I was allowed an additional £25,000 to
 22 purchase Factor VIII and this resulted in the total
 23 quantity received being comparable with 1981/82,
 24 although there was increased usage, particularly at
 25 Pendlebury."

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1 over 100,000 units of Factor VIII."
 2 Then there is a calculation of expected usage
 3 for the balance of the year set out. If we go to the
 4 next page, Dr Gunson says this:
 5 "It will be seen that the two quantities almost
 6 balance but no allowance has been made for:
 7 "(1) Elective surgery at the [Manchester Royal
 8 Infirmary] ..."
 9 And he refers to the waiting list for
 10 corrective orthopaedic surgery building up.
 11 "(2) Emergencies."
 12 And he says it's to be expected that some
 13 emergencies will arise during the latter half of the
 14 year. There are two problems associated with the
 15 supply of Factor VIII:
 16 "(1) A shortfall of material for use in the
 17 current year."
 18 And:
 19 "(2) A long-term problem with respect to
 20 provision of Factor VIII concentrate in 1984/85 and
 21 successive years.
 22 "Both of these have a common factor, which is
 23 the failure to open the Plasmapheresis Centre in
 24 Lancaster."
 25 You will have seen from the earlier documents

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1 That's the Children's Hospital.
 2 "During 1983/84 there is a significant increase
 3 in the Factor VIII supplies from BPL, as we have
 4 expected, and during the year we should receive
 5 2 [million] units."
 6 Then there is a reference to a grant made to
 7 purchase Factor VIII. That's presumably commercial
 8 Factor VIII:
 9 "Thus the total expected for 1983/84 will be
 10 3.62 [million] units which is approaching the quantity
 11 available for the previous two years."
 12 If we go over the page, he then sets out how
 13 the units have been used at the Manchester Royal
 14 Infirmary since 1 April 83, and we can see there home
 15 therapy, out-patients, elective surgery and
 16 emergencies, and the figures there.
 17 "The emergencies have been particularly heavy
 18 during this period, since four patients have been
 19 admitted with intracranial haemorrhage and have taken
 20 up large quantities of Factor VIII. It will be seen
 21 also that there has been increased use at
 22 Pendlebury ... and that at Lancaster, the usage for
 23 six months almost equals the whole of that issued for
 24 1982/83. Most of this increase is accounted for by
 25 one patient who fractured his femur and has received

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1 expectations were pinned upon the opening of that,
 2 that it would improve the situation in terms of supply
 3 but that didn't happen.
 4 He then sets out various options to correct
 5 matters:
 6 "(1) Reduce home therapy. This region has the
 7 lowest ratio for home therapy in the UK. At the
 8 Manchester Royal Infirmary, only 30 per cent of
 9 patients are receiving home therapy; the national
 10 average is 50 per cent and the target is 70 per cent.
 11 "(2) Prepare increasing quantities of
 12 cryoprecipitate at the RTC. This is a frozen product
 13 which has a high yield of Factor VIII can be used to
 14 treat patients but is difficult to use for home
 15 therapy. By preparing this product we would reduce
 16 the amount of plasma sent to BPL and consequently the
 17 quantity of Factor VIII concentrate received in
 18 return.
 19 "Before turning to either of these options,
 20 with their serious disadvantages, I would be grateful
 21 if you would consider the following proposals ..."
 22 The first proposal is essentially to ask for
 23 more money, to use to purchase commercial Factor VIII,
 24 using the allocation which the health authority would
 25 have expended on the unopened plasmapheresis centre in

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1 Lancaster, and he says:
 2 "This Factor VIII will be retaining at the RTC
 3 as an emergency reserve and I will try and obtain the
 4 agreement of my clinical colleagues to use it only for
 5 emergency purposes and for those elective surgical
 6 procedures that can no longer be postponed."
 7 Then (2):
 8 "Hold early discussions with respect to the
 9 policy for Factor VIII supplies for the future, since
 10 I can confidently predict that at current rates of
 11 usage we will not be self-sufficient in Factor VIII in
 12 1983/84. Also, there is good evidence that even with
 13 current usage the patients in this region are not
 14 faring as well as those in some other regions."
 15 Sir, we will look at such data as we have about
 16 usage but what we see is essentially the now familiar
 17 pattern of commercial concentrates being purchased to
 18 make up shortfalls because of insufficient supplies of
 19 NHS factor in Manchester, as in other parts of the
 20 country.
 21 **SIR BRIAN LANGSTAFF:** When he talks about self-sufficiency
 22 on the page which is currently on screen, what
 23 constituency does he have in mind? The whole of the
 24 country? He's not in that capacity, is he?
 25 **MS RICHARDS:** Not at that stage. Later he might have been

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1 arrangements as were made and when they were made in
 2 relation to the move to heat-treated products in the
 3 context of the response to the AIDS crisis, but I'm
 4 not proposing to take you, sir, at this stage, and
 5 more, indeed, those listening, to the materials
 6 relating to the second half of the 80s.
 7 We have set them out in some detail in our
 8 note. But they are less critical for the issues which
 9 you have to consider, sir, than the position in the
 10 70s and in the first half of the 1980s. But I invite
 11 you to note, and you will see it set out, there were
 12 continuing difficulties.
 13 And those are recorded not just in minutes of
 14 meetings but also they seem to be difficulties that
 15 are known to pharmaceutical companies. There are
 16 particular concerns expressed by The Haemophilia
 17 Society about supplies in the northwest region and the
 18 like.
 19 You may want to note, sir, one reference, which
 20 is to a letter from Dr Wensley in 1990. The reference
 21 is NHBTO018289.
 22 I don't need to put it up on screen, Soumik.
 23 But he there essentially sets out a concern
 24 that the region had been underfunded for years, and
 25 that his patients were receiving less therapy than at

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1 able to answer or the whole country --
 2 **SIR BRIAN LANGSTAFF:** So the "we will not be
 3 self-sufficient", it could be a comment on the
 4 national situation; it's more likely, perhaps, to be
 5 a comment on the regional situation, is it?
 6 **MS RICHARDS:** I think read in the context of the letter
 7 and the reference to current rates of usage, which
 8 he's there talking about the northwest region.
 9 I think it reads more likely to be a reference to the
 10 region rather than the national picture.
 11 **SIR BRIAN LANGSTAFF:** So again, at the risk of
 12 interpreting something to mean what it doesn't, it
 13 would look as if self-sufficiency being measured by
 14 the ability to (a) produce enough plasma to send off
 15 to BPL, to get back NHS concentrate, plus using enough
 16 plasma at the local RTC to produce cryoprecipitate to
 17 be used locally.
 18 Is that a fair reading?
 19 **MS RICHARDS:** I think so, yes, sir. Yes.
 20 **SIR BRIAN LANGSTAFF:** Probably the most likely.
 21 **MS RICHARDS:** Indeed.
 22 Sir, we've set out in our written note, by
 23 reference to the second half of the 1980s, continuing
 24 difficulties in relation to supply and shortages and
 25 decision-making. I will come on in due course to such

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1 other major UK haemophilia centres. But it is not
 2 clear from that letter whether he has in mind the
 3 years as in decades or the years immediately preceding
 4 the writing of his letter in 1990.
 5 There are also documents that we have referred
 6 to in the written note which show that cryoprecipitate
 7 was still being used as a treatment fairly regularly
 8 at least until 1990. There's reference to, however,
 9 the use having plummeted to a low level by 1994.
 10 Sir, I am going to move from issues of supply
 11 and the arrangements for purchase to looking at what
 12 information we have about the products that were as a
 13 matter of fact used. Again, it's a very piecemeal
 14 picture we have from the documents. We don't have,
 15 for example, the kind of document that we saw in
 16 relation to Cardiff where there appears to have been
 17 a contemporaneous treatment policy, although of course
 18 it raised in turn the question of whether that
 19 treatment policy was actually being applied, but we
 20 don't have anything of that kind in relation to
 21 Manchester and we don't, as I've said, have any
 22 statements or litigation reports authored by
 23 Dr Delamore or Dr Wensley that would help fill in the
 24 gaps. We have some returns to UKHCDO but only for the
 25 period with which we are really concerned, for the

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1 years 1976 and 1983, and then also we have a return
2 for 1986. So that provides us with some indication
3 but not, unfortunately, a complete picture of product
4 usage and, in particular, it doesn't tell us what
5 categories of patients particular products were used
6 for or what the reasons were for preferring particular
7 treatments or particular products over others.

8 I'll just pick up the picture with a reference
9 to cryoprecipitate however as at 1970. First I'm
10 going to take from an article in the Manchester
11 Evening News. It's a somewhat bleak article in its
12 tone and may reflect social policies of the time.
13 HSOC0006206.

14 It's a January 1970 article for the Manchester
15 Evening News.

16 If we could just see the whole of the text on
17 the bottom half of the page, please, Soumik. Thank
18 you.

19 So much of it is an article painting
20 haemophilia in a very bleak way, but the purpose for
21 referring to it is what it says about cryoprecipitate.
22 So if we look, first of all, at the bottom of the
23 second column, talking about children born with
24 haemophilia:

25 "In the past their future was bleak. Physical

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1 The reason for referring to this, sir, is, in
2 the context of Manchester, it is identifying
3 cryoprecipitate rather than, as we've later seen,
4 concentrates as being that which transforms the
5 treatment of haemophilia and, as already indicated
6 with Dr Wensley's work, we see cryoprecipitate
7 regarded as a significant part of the treatment of
8 haemophilia, certainly throughout the 1970s.

9 **SIR BRIAN LANGSTAFF:** It would fit with the life
10 expectancy documentation that we've seen earlier which
11 showed that the very substantial increase in the
12 expectation of life for all haemophiliacs came after
13 the development of cryoprecipitate.

14 **MS RICHARDS:** Yes. Yes, and we've heard a lot of
15 evidence, much of it no doubt understandable, about
16 the advantages of concentrate. It's perhaps important
17 not to lose sight of the fact that cryoprecipitate was
18 seen as a very major advance in treatment indeed and
19 carried with it, as we can see from this, many
20 perceived advantages.

21 **SIR BRIAN LANGSTAFF:** Yes.

22 **MS RICHARDS:** We can see Dr Delamore's preference for
23 treatments from a questionnaire he completed for
24 Dr Maycock in December of 1972. That's at
25 CBLA0000121. So the questionnaire is headed

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1 injuries led to serious internal bruising and
2 bleeding, and ultimately severe crippling of the
3 joints developed. Surgical operations frequently had
4 fatal results.

5 "But today ..."

6 So this is as at 1970.

7 "... with modern methods of treatment and
8 patient assessment, much of which has been pioneered
9 over the past 20 years at the Manchester Royal
10 Infirmary, haemophiliacs are for the most part able to
11 lead a near-normal, albeit hazardous, life.

12 "Their great salvation comes in small plastic
13 bags containing what is known as the
14 cryoprecipitate -- the anti-haemophilic serum (an
15 extract from the fluid non-cellular part of the blood)
16 which is given to them intravenously and which enables
17 their blood to clot."

18 Then the very bottom column on the right-hand
19 side -- sorry, the right-hand column, bottom of the
20 column, says:

21 "Haemophilia can now be contained. People
22 rarely die from the disease and are not often crippled
23 by it. Nonetheless it is seriously disabling ..."

24 Then there's again a reference to the context
25 of termination of pregnancies.

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1 "Factor VIII Concentrate for the treatment of
2 Haemophilia":

3 "Factor VIII concentrate is supplied as
4 a freeze-dried preparation in bottles containing from
5 400 to 600 units. At present the supply is
6 insufficient for all needs."

7 And then various questions and answers:

8 "How many patients with haemophilia do you
9 treat regularly? 200."

10 You can see Manchester was a very large centre.

11 "Would you prefer to use for the treatment of
12 your patients ..."

13 And then you'll see the answer given by
14 Dr Delamore is "Some cryoprecipitate and some
15 freeze-dried concentrate". So neither one nor the
16 other to the exclusion of each other but a combination
17 of both.

18 Then question 5 asks:

19 "How many single donations of cryoprecipitate
20 and bottles of concentrate do you need annually for
21 your present treatment policy?"

22 And 11,000 cryoprecipitate, 250 concentrate.
23 Then there's a request for how much -- "estimate you
24 would need annually", which is also filled in by
25 Dr Delamore. So that's his preference as of 1972.

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1 There's an accompanying letter from him at
2 CBLA0000104 from Dr Delamore to Dr Maycock, saying
3 he's completed the enclosed questionnaire:

4 "We prefer, in this department, to administer
5 cryoprecipitate since it makes up into a smaller
6 volume. If, however, freeze-dried concentrate were in
7 some way altered so that it could be dissolved more
8 easily and in a smaller volume, we would probably
9 choose that preparation in preference to
10 cryoprecipitate.

11 "The answer to question 6 ..."

12 Where he'd given estimates of what was
13 required:

14 "... is based on our present usage of
15 cryoprecipitate and freeze-dried concentrate, but if
16 freeze-dried concentrate were to become more readily
17 available, it may be that these figures would be
18 reversed.

19 "I do of course appreciate that the
20 freeze-dried preparations are much more suitable for
21 home treatment which we now hope to institute in
22 selected cases."

23 We can see, for example, from correspondence
24 between Dr Delamore and Dr Aronstam at Treloars, in
25 which Dr Delamore recorded treatment given to Treloars

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1 have three with Factor VIII antibodies,
2 14 haemophilia B patients treated during the year, and
3 one with Factor IX antibodies.

4 Then we can see the figures used: so in terms
5 of cryoprecipitate, and I'll take the figure from
6 units of activity, 850,560; NHS Factor VIII
7 concentrate, 450,295; and then we can see commercial
8 concentrates being used, a small amount, in relative
9 terms, of Profilate, 1,520; a larger amount, although
10 still small in relative terms, of Hemofil, 40,680, and
11 then a more significant amount of Kryobulin, 325,087.

12 We also see porcine Factor VIII being used
13 and -- sorry, Factor IX concentrate being used and
14 then FEIBA, 564,420 units of activity.

15 **SIR BRIAN LANGSTAFF:** In terms of Factor VIII, it looks
16 then as though, at this stage, there was marginally
17 more concentrate being used than cryoprecipitate.

18 **MS RICHARDS:** Yes. We put the figures in a table and
19 I think it gives us 36.8 per cent cryoprecipitate,
20 35.4 per cent Factor VIII. We then, to make up the
21 100 per cent, we've got FEIBA and porcine included,
22 but yes.

23 **SIR BRIAN LANGSTAFF:** That doesn't sound quite right, does
24 it?

25 **MS RICHARDS:** I'll check the figures later, sir.

55

1 students during the holidays when they were back in
2 the Manchester region, regular treatment with
3 cryoprecipitate, and we have correspondence in the
4 years 1973 and 1974 to that effect.

5 We see again from the contemporaneous documents
6 reference to the Royal Infirmary using Hemofil by
7 1975. But really the first -- a bigger picture that
8 we get about treatment and product usage is from the
9 1976 annual return.

10 So if we could go please, Soumik, to
11 HCDO0000080_003.

12 We can see it's completed by AM Burn, said to
13 be chief technician, and sent off to Ms Spooner at
14 Oxford.

15 If we go to the next page, we've got there the
16 figures for treatment of carriers of haemophilia, two,
17 treated with a mixture of cryoprecipitate and
18 Factor VIII concentrate.

19 The next page provides us with information
20 about the treatment of patients with von Willebrand's
21 disease in 1976, eight patients treated exclusively
22 there with cryoprecipitate.

23 Then if we go to the next page we see the bulk
24 of the treatment. So the total number of haemophilic
25 patients treated during the year, 139, and then we

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1 **SIR BRIAN LANGSTAFF:** Just --

2 **MS RICHARDS:** 850,560 units of cryoprecipitate --

3 **SIR BRIAN LANGSTAFF:** Then if you add up the others --

4 **MS RICHARDS:** Yes, 817,582 units of Factor VIII
5 concentrate. So slightly more cryo than Factor VIII.

6 **SIR BRIAN LANGSTAFF:** Yes. So this is probably about the
7 point at which you might expect in the following years
8 there would be a bit more concentrate used than cryo.

9 **MS RICHARDS:** Yes. Unfortunately, the next available
10 return we have, which I will come on to in a few
11 minutes, is for 1983 and we certainly see a change.

12 In terms of home treatment, you'll have seen
13 some references to a desire to start a home treatment
14 programme in the first half of the 1970s. The
15 documentation in relation to the introduction of home
16 treatment is pretty limited. We've got individual
17 patient statements which perhaps is going to be the
18 best source in that regard. We've got a patient, for
19 example, describing beginning home treatment in 1974.

20 There is one meeting which, before we break, it
21 might be worth looking at HCDO0000400 please, Soumik.
22 This is a Reference Centre Directors' meeting of
23 27 January 1978. We can see that from Manchester
24 Dr Delamore is there. If we go please, Soumik, to
25 page 8, there's a discussion on home treatment. So

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1 the heading for item 9 of the minutes is:
 2 "Use of cryoprecipitate or commercial
 3 Factor VIII for home treatment. Dr Dormandy had
 4 several patients on home treatment with
 5 cryoprecipitate and she wished to know if the
 6 Reference Centre Directors thought that such patients
 7 should now be treated with commercial freeze-dried
 8 concentrate."
 9 Then it says:
 10 "Dr Delamore also had a similar problem and was
 11 seeking guidance."
 12 That might tend to suggest that home treatment
 13 with cryoprecipitate, for some patients at least, was
 14 a feature at Manchester in the 1970s. The
 15 recommendation of the meeting is in fact that all
 16 patients on home treatment should have freeze-dried
 17 concentrate.
 18 Again, we have various exchanges of
 19 correspondence in relation to individual patients
 20 between Manchester and Treloars which show that in the
 21 latter part of the 1970s there's a mix of treatments
 22 being used, sometimes cryoprecipitate, sometimes
 23 Kryobulin, sometimes other commercial concentrates,
 24 sometimes NHS concentrate. There's no particular
 25 pattern discernible in relation to individual patients

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1 "We have a new batch of the current Speywood
 2 animal product going through at the moment ... I will
 3 send spend details, plus a sample, for testing ..."
 4 He refers to case notes on a French case, not
 5 quite clear what that's concerned with, and then he
 6 says he'll be seeing Dr Wensley "to talk about Koate
 7 in the hope that we can be restored to your list of
 8 suppliers".
 9 So it would appear that Manchester had
 10 previously purchased Koate and then had ceased to do
 11 so and this was an attempt to persuade Dr Wensley and
 12 Dr Delamore to start using Koate again.
 13 The records of the meeting themselves provide
 14 some further information. So if we start with
 15 IPSN0000338_014, this is Mr Williams' note of his
 16 meeting with Dr Delamore on 6 September 1978. It
 17 says:
 18 "Dr Wensley ... does all the Factor VIII
 19 buying, so this was very much a courtesy call.
 20 "The centre has used Armour material for the
 21 past year and is reluctant to change. They have just
 22 been notified of the price increase ... but even so,
 23 Delamore indicated that change was unlikely. I think
 24 if the incentive is made large enough this situation
 25 could be changed and I will be meeting with Wensley.

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1 that would suggest that at Manchester a single
 2 concentrate policy or batch dedication policy was
 3 introduced. The available evidence from individual
 4 patients and their records at UKHCDO suggest to the
 5 contrary, that patients would often be treated with
 6 different products at different times over the years.

7 Sir, is that a convenient time to break?

8 There's a little more to say about this.

9 **SIR BRIAN LANGSTAFF:** Yes. So 11.50.

10 **MS RICHARDS:** Thank you.

11 (11.20 am)

(A short break)

12 (11.52 am)

13 **SIR BRIAN LANGSTAFF:** Yes.

14 **MS RICHARDS:** Sir, still on the topic of product usage,
 15 some communications with and notes produced by
 16 Speywood from 1978 provides some further illumination.

17 If we start with IPSN0000338_013 --

18 IPSN0000338_013. We can see this is a letter written
 19 from Mr Williams of Speywood to Dr Delamore,
 20 September 1978. They have obviously had a meeting.
 21 He says:

22 "I enjoyed our meeting and look forward to
 23 keeping in touch with you ... I will send you a sample
 24 of our new product ...
 25

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1 Delamore stated cash for Factor VIII commercial
 2 purchase is tightly controlled ...
 3 "Commercial concentrates are only used for home
 4 treatment."
 5 So if that's a correct record, at this point in
 6 time, 1978, the home treatment programme was one that
 7 used commercial concentrates only. Then there's
 8 a discussion about animal products.
 9 Down towards the bottom of the page there's
 10 a discussion about von Willebrand's:
 11 "[Dr Delamore] felt a von Willebrand factor
 12 would be of considerable theoretical interest ... Cryo
 13 is used successfully at present, without problems."
 14 So it would appear, unsurprisingly,
 15 cryoprecipitate appears to be the treatment of choice
 16 for von Willebrand's patients at that time.
 17 Then if we go to IPSN0000338_011, we have the
 18 note of Mr Williams' meeting later that year with
 19 Dr Wensley on 22 November 1978:
 20 "Wensley is very interested in porcine,
 21 although his last clinical usage was a frightening
 22 experience. He believes FEIBA to be safer and
 23 possibly more effective, than our current product."
 24 Then "Human":
 25 "Our work on PE human was of great interest.

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1 In his view, a hepatitis free product would be of
2 enormous value.
3 "He buys commercial concentrate purely on price
4 and thinks the quality differences between
5 manufacturers are insignificant. He stated that
6 Lister material now compares well with commercial and
7 is gradually changing his home treatment patients to
8 this from Kryobulin and Hemofil. Commercial will then
9 be used only in operations."

10 Pausing there, it would appear there's
11 an intention on the part of Dr Wensley to shift the
12 home treatment programme from a commercial-based
13 programme to an NHS-based programme:

14 "He will ask us to quote next time round, but
15 currently has big stocks of Armour."

16 "A Regional contract of the style we are now
17 discussing, is of no interest, since he already buys
18 for all the Centres in his region. He has recently
19 been ordering in 250,000 unit lots and paying upfront,
20 calling off as required."

21 Then over the page, there's a discussion about
22 protein fractions containing immunoglobulins.

23 If we then look at NHBT0089538, this is
24 a letter dated 28 October 1981. It's from Dr Wensley
25 to Dr Smith at BPL, and if we look at the text of the

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1 That's the reference to desensitisation. It's not
2 clear from that whether what's been recorded as
3 Dr Wensley's practice is using several brands of
4 commercial concentrate for an individual patient, so
5 that a patient receives several different brands, or
6 whether, across the cohort of patients to whom this
7 practice applies, various different brands are used.
8 Again, we certainly don't seem to see here anything of
9 the only use one commercial product or batch
10 dedication that we've seen from some other centre
11 directors.

12 We then, in terms of documentation about
13 product usage, come to the 1983 annual return to
14 UKHCDO. If we start with HCDO000170_010, I'll
15 explain why some figures appear to be crossed out in a
16 moment. We can see this is the annual return for 1983
17 for Manchester Royal Infirmary, director Dr Delamore.
18 Total number of haemophilia A patients treated during
19 the year 140, carriers of haemophilia A 7,
20 von Willebrand's disease patients 24.

21 Then we can see the figures for
22 cryoprecipitate, 470,600 used at hospital for
23 haemophilia A patients, no record there of any being
24 used for home treatment. 13,860 for carriers. Then,
25 in relation to von Willebrand's patients,

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1 letter we can see from the second paragraph he says:

2 "In this region almost all Elstree Factor VIII
3 concentrate is used for home treatment of
4 haemophiliacs ..."

5 So it would appear that by 1981, that which had
6 been alluded to in the Speywood visit, the intention
7 of changing from commercial to Elstree product for
8 home treatment, had been implemented if what's said in
9 this letter is correct, at least at that point in
10 time.

11 If we then look at TREL0000248_104, we can see
12 here it's a letter from Dr Evans, at the Manchester
13 Children's Hospital, to Dr Aronstam at Treloars, and
14 it's really the first paragraph which tells us
15 a little about what's being done in the Royal
16 Infirmary:

17 "Dr Wensley tells me that they've used
18 500 units of several brands of commercial concentrate
19 intravenously, daily, to desensitise their patients."

20 Then there's a suggestion in the next paragraph
21 that that may not be ethical in relation to paediatric
22 patients.

23 Now, it would appear likely from what's said in
24 the first paragraph and from other materials that
25 we're talking there about patients with inhibitors.

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1 cryoprecipitate is there recorded as used both in
2 hospital and for home treatment, the figures given
3 74,760 and 27,300 respectively.

4 If we skip over the crossed out figures for
5 a moment and we see the next figure that's not crossed
6 out is the reference to Kryobulin, the Immuno
7 Factor VIII, and we can see a small amount there being
8 used for both hospital and home treatment. The reason
9 why figures have been crossed out is, I anticipate,
10 explained by a letter at HCDO000170_004. This is
11 a letter to Ms Spooner at Oxford from AM Burn, the
12 Chief MLSO at the Royal Infirmary, and he's recording
13 here alterations to the haemophilia returns for 1983.
14 So the inference may be that these are the correct and
15 up-to-date figures and that may be why we have seen
16 the crossed out figures on the other document.

17 We have NHS concentrate, hospital usage
18 283,844, home treatment usage 1,021,945. Then we see
19 Alpha Profilate, hospital usage 492,808, home
20 treatment 127,249. Hyland Hemofil 707,867 hospital,
21 560,786 home treatment. Porcine Factor VIII 52,910.
22 Factor IX 25,100, and Autoplex. Then Factor IX, this
23 is then for the treatment of haemophilia B, 540,185.

24 We can see here substantial quantities of NHS
25 product but also still substantial quantities of

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1 commercial products being used, and the home treatment
2 programme is neither exclusively commercial or
3 exclusively Elstree by now. In 1983 we can see those
4 receiving home treatment -- there's a mix of products
5 being used for home treatment.

6 There's then one further document from
7 November 1984 which provides some insight into
8 Dr Wensley's approach to the treatment of patients
9 with inhibitors. It is at IPSN0000036_012. This is
10 "Current Approaches to the Treatment of Inhibitor
11 Patients in the UK", third paragraph on that first
12 page says:

13 "The intention of this report is to summarise
14 the national trends in the treatment of haemophiliacs
15 with inhibitors and then to address more specifically
16 the current views and approaches of the directors of
17 the major haemophilia centres to the treatment of
18 their patients, with particular emphasis on their
19 attitudes towards Hyate:C."

20 It is dated 2 November 1984.

21 We've looked at this document for what it says
22 about individual directors on a number of occasions
23 and I'm going to show you in a moment what it says
24 about Manchester. It may be instructive at some point
25 to consider it as a whole, because what it shows is

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1 activated, or non-activated Factor IX 'almost
2 unethical' in view of its low degree of efficacy.
3 They have no fundamental objections to using porcine
4 Factor VIII but don't feel that they are likely to
5 have the need to use it very often. They are,
6 however, very interested in using it in 'virgin'
7 non-inhibitor patients, but see costs being the main
8 drawback in this area."

9 Pausing there, sir, two points to note about
10 this document. The first is the point just made in
11 the report, that Manchester expressed an interest in
12 using porcine Factor VIII for virgin non-inhibitor
13 patients. If we go back to the previous page, and
14 look at the second half of the page again, one can see
15 what appears to be set out here in 1984 -- indeed,
16 this a report dated the end of 1984 -- so at a point
17 in time at which the risk of AIDS may be thought to
18 have been fairly well known to centre directors,
19 a strategy which could perhaps be characterised as
20 somewhat a high-risk strategy of giving inhibitor
21 patients large amounts of Factor VIII, is here
22 recorded.

23 That brings us then to early 1985 and
24 introduction of heat-treated products. Again, we may
25 need to look at a handful of documents to try to get

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1 an absence of a consistent approach at least across
2 the major haemophilia centres to the treatment of
3 inhibitors and a very varied approach regionally.

4 If we go to the third page, we can see the
5 position in relation to Manchester, if we go down to
6 the bottom half, thank you. So:

7 "MRI have 16 inhibitor patients of whom 14 are
8 normally treated with either human Factor VIII or
9 human Factor VIII and plasma exchange."

10 Then further details given about the use of
11 plasma exchange.

12 "In other circumstances an immune tolerance
13 regimen is favoured whereby on presentation with
14 a bleed the patient is given a minimum of 20,000 units
15 of Factor VIII over the first five days ... and then
16 250 units given every other day, until the inhibitor
17 is suppressed. Manchester claim to have reduced the
18 inhibitor titre in 13 out of 14 of the patients using
19 this regimen."

20 Then there's a reference to two patients
21 treated in an Autoplex trial and Hyate having been
22 sent to Manchester for antibody assays.

23 Then if we look at the comments:

24 "MRI has a fairly idiosyncratic approach to the
25 treatment of inhibitors. They consider the use of

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1 a sense of the timing of the introduction of
2 heat-treated products. If we start with
3 BAYP0000024_070, we can see this is a Cutter report,
4 5 February 1985, so it's an internal memo, and it's
5 said:

6 "The activity seen in December '84 with regard
7 to AIDS and Factor VIII concentrate has slowed down
8 during January.

9 "All centres in this region have converted from
10 non-heat-treated commercial material to heat-treated
11 commercial Factor VIII concentrate. Opinion seems to
12 be divided, however, on the use of non-heat-treated
13 NHS material.

14 "The following centres are continuing to use
15 non-heat-treated NHS material ..."

16 You will see a number of centres there set out
17 but in the northwest region for present purposes
18 Manchester, and then Liverpool, Lancaster and
19 Blackburn.

20 So as at February 1985 this would suggest that
21 non-heat-treated Elstree product still being used in
22 Manchester.

23 If we go over the page and just see, bottom
24 half of the page, some insight into Dr Wensley's
25 thinking at this time. In the heading, "Development

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1 in major target accounts":
 2 "1. The Manchester connection.
 3 "Hopes of obtaining the Manchester contract
 4 during 1985 were dashed after learning that Dr Wensley
 5 had managed to raise finance for his research.
 6 "Dr Wensley has simply switched from Profilate
 7 to Profilate [heat-treated] ...
 8 "Dr Wensley appears to believe in the wet heat
 9 treatment process. However, he is reserving judgment
 10 until results of liver function studies on patients
 11 using Alpha HT are known.
 12 "Nevertheless, from further communication, he
 13 has told me that all being equal i.e. price and
 14 HTLV-III, non A, non B reduced risk, he will award the
 15 contract to Cutter. Tenders regarding this contract
 16 should be expected in late February or early March 85.
 17 "Dr Wensley has asked me if he could visit
 18 Cutter USA plants while in the States for the San
 19 Diego meeting in July. This request was passed on to
 20 Mr Pete Dehart who welcomed the idea and offered every
 21 help."
 22 So that's what we see being said there about
 23 Manchester.
 24 If we then go to NHBT0094577, what we've got
 25 here are a number of letters regarding the

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1 possibly contaminated concentrates, I would be obliged
 2 if you would reply to the following points.
 3 "1. Is this matter being given the urgent
 4 consideration and priority necessary to safeguard the
 5 lives of Haemophiliacs in the North West?
 6 "2. Why is Manchester Royal Infirmary the only
 7 Supra-Regional Centre in the UK not using heat-treated
 8 concentrates?"
 9 In 3 there's a reference to a meeting between
 10 The Haemophilia Society and Lord Glenarthur about
 11 funding.
 12 Over the page, just for the sake of
 13 completeness, it says:
 14 "Applications were made prior to Christmas for
 15 monies to be made immediately available for the
 16 purchase of heat treated concentrates; why has
 17 a decision not yet been reached, and how long is the
 18 Hospital to wait before they can expect an answer."
 19 If we then go, Soumik, to the third page
 20 there's a letter of the same date, 10 March 1985, from
 21 Mr Watters of The Haemophilia Society to Dr Gunson,
 22 saying:
 23 "We are more than a little alarmed to learn
 24 that, alone of all the Supra-Regional Haemophilia
 25 Centres, Manchester is without heat-treated Factor

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1 introduction of heat-treated products in the
 2 Manchester area.
 3 Soumik, could we go, first of all, because
 4 these are out of chronological order, to page 4.
 5 We can see here a letter from The Haemophilia
 6 Society. It's from the chair of the North West group
 7 of The Haemophilia Society to the chair of the North
 8 West Regional Health Authority:
 9 "Dear Sir John,
 10 "I write to you on a matter which is causing
 11 grave concern to all Haemophiliacs and their families
 12 in the North West area.
 13 "As you are no doubt aware, supplies of
 14 heat-treated concentrates have not yet been introduced
 15 for treatment of the patients at Manchester Royal
 16 Infirmary."
 17 So as at 10 January that is said to be the
 18 position as a matter of fact.
 19 "To be informed by the Hospital that this
 20 product, which is believed to be AIDS free, will be
 21 made available some time in 1985 is, quite frankly,
 22 not good enough.
 23 "Given the fact that Haemophiliacs are putting
 24 their lives at risk either by refusing essential
 25 treatment for bleeding episodes, or, by the use of

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1 VIII (or IX) for the treatment of patients with
 2 haemophilia. We take a most serious view of this and
 3 would be grateful if you could advise us of the
 4 reasons for the non-availability of such products in
 5 Manchester."
 6 He says he has written in the same terms to the
 7 health authority and copied it to Dr Wensley and
 8 Dr Delamore.
 9 Now if we then go to page 2 of this, we have
 10 Dr Gunson's response to Mr Watters, and he says this:
 11 "I can inform you that the decision to use
 12 heat-treated Factor VIII concentrate from commercial
 13 sources had been taken prior to my receipt of your
 14 letter. I can assure you that this matter was given
 15 careful consideration and that the serious nature of
 16 the problems which face patients suffering from
 17 haemophilia was not underestimated during discussions
 18 which have taken place between the Chairman and Chief
 19 Officers of the Regional Health Authority and myself.
 20 Allocation of the necessary finance has allowed the
 21 withdrawal of all untreated commercial Factor VIII and
 22 its replacement with heat-treated material and this
 23 process has now commenced. As you are aware,
 24 heat-treated Factor VIII concentrate from NHS plasma
 25 will not be available in any quantities until April,

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1 1985, and my colleague, Dr Wensley and I are urgently
2 considering means by which the use of untreated NHS
3 Factor VIII can be restricted without placing any
4 patients at risk."

5 Then he goes on to talk about the aspirations
6 for heat treatment, discouraging high-risk donors and
7 longer term hopes for a screening test.

8 So it would appear from Dr Gunson's response
9 that as at 15 January 1985, the decision has been
10 taken that heat-treated products will be used, the
11 finance has been allocated. What's less clear is
12 whether, as at this date, which is a month on, over
13 a month on, from the Reference Centre Directors'
14 meeting of 10 December 1984, whether the actual
15 process is substantially underway or not or whether in
16 the intervening weeks patients have continued to be
17 using unheated products for their home or hospital
18 treatment.

19 An inference may well be -- perhaps the most
20 likely inference -- that patients have continued in
21 the intervening weeks to be using unheated products.

22 If we can, on the same issue, go to a document
23 that I am very grateful for having been provided to
24 the Inquiry by Core Participants. It's COLL0000003.

25 These are the minutes of a special haemophilia

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1 Centre.

2 "She made reference to the last Haemophilia
3 Reference Centre Directors' meeting where it had been
4 decided to use heat-treated Factor VIII on all
5 haemophilia A patients as soon as possible ..."

6 That's must be the 10 December Elstree meeting.

7 "She said how pleased she was that the number
8 of patients who had attended the meeting."

9 There's then a lecture of viruses and
10 antibodies to viruses from Professor Longson and then
11 Dr Delamore is recorded as thanking Professor Longson
12 and then introducing the panel "who directly answered
13 questions from the audience as follows".

14 I won't go through all of them, sir -- you will
15 no doubt want to read the document in full -- but just
16 a couple of them, the first of which is relevant to
17 the issue we were just exploring:

18 "Q. Will all the haemophilia A patients go on
19 to heat-treated Factor VIII?"

20 Dr Wensley's answer:

21 "As home-treatment patients come in for more
22 Factor VIII supplies they will be changed onto
23 heat-treated clotting factor or be given more of the
24 same batch that they have been using. They will not
25 however, be treated by a new non heat-treated batch of

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1 meeting on AIDS held at the Manchester Royal Infirmary
2 on Sunday 3 February. And it's 1985; it is not dated
3 but it is clear from the context of the letter.

4 We can see that the meeting's chaired by
5 Dr Delamore. Speakers are Mrs Guy, chair of the North
6 West branch of The Haemophilia Society, and
7 Professor Longson, Professor of Virology, University
8 of Manchester. And then there's a panel
9 present: Dr Evans from the Children's Hospital,
10 Professor Longson, the virologist, Dr Wensley and
11 Dr Williamson, an immunologist consultant at the
12 Preston Royal Infirmary.

13 What one can see from this, this is, as it
14 were, a meeting to which patients were invited to
15 attend, and we can see the context of it from the
16 first paragraph:

17 "The meeting was declared open by the [chair],
18 Dr IW Delamore, who then introduced Mrs Guy ... as
19 first speaker. [She] said she had received many
20 telephone calls from haemophiliacs needing reassurance
21 and so she had asked the Haemophilia Department at MRI
22 to arrange a meeting as soon as possible."

23 So it would appear that the trigger for the
24 meeting is a request from The Haemophilia Society
25 representative rather than from the Haemophilia

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1 Factor VIII."

2 Again, sir, that answer would appear to
3 suggest, and we're now at 3 February, that there has
4 been no immediate request for -- or attempt at recall
5 of the unheated product that patients had, and that
6 products are going to be replaced as and when
7 patients' supplies for home treatment run out and they
8 come in, and then they'll given, even then, not
9 necessarily heat-treated clotting factor, they may be
10 given heat-treated clotting factor or more of the same
11 batch, and that's presumably dependent on supplies.

12 If we just then go over the page we can see
13 there's a question as to whether heat-treated
14 Factor IX is available, and Dr Wensley says:

15 "... not available from the NHS [at the moment]
16 ... [but] being ... explored ... hoped ... [it] will
17 become available by the summer of 1985."

18 Then there are various discussions about heat
19 treatment, about the symptoms of AIDS, about risks to
20 family members.

21 If we go to the third page, and we zoom in on
22 the top half of the page, we look at the third set of
23 questions and answers:

24 "[Question]: Should we assume that we have got
25 the HTLV-III virus and inform the dentist?"

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1 "[Answer]: All patients will shortly be tested
2 for the HTLV-III antibody but until the results of
3 those tests are available, it is best to assume that
4 you might [I think the word 'be' is omitted] positive
5 and to inform your dentist."

6 So I will come on in due course to the question
7 of testing but it would appear that as at 3 February
8 certainly not all patients had been tested, and an
9 inference from this answer may be that the process of
10 testing had not yet commenced.

11 In terms of the introduction of heat-treated
12 products, I'm not going to go to the following set of
13 documents I described, but I will just let you know
14 what they are, sir.

15 Dr Gunson addresses the issue in his HIV
16 litigation statement, but again, as I say, that's, as
17 it were, several years later after the event.

18 There is correspondence or memos in 1988,
19 I think in the context of responding to potential
20 legal claims, where Dr Lee and others provide a basic
21 chronology of decision-making in relation to
22 heat-treated product. But that's all about the
23 process of getting approval for funding rather than
24 the actual practical mechanics of when heat-treated
25 products and how heat-treated products were

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1 whether this heat-treated product was 8Y, which seems
2 unlikely in February '85, or was there the retro
3 heat-treated product which the NHS were producing as
4 an interim?

5 **MS RICHARDS:** I don't think we have any information
6 specific to Manchester but it would seem, from other
7 material that we've seen, unlikely to be 8Y, which
8 I don't think was anticipated to be available until
9 April of 1985.

10 **SIR BRIAN LANGSTAFF:** There was some, I think -- there's
11 some uncertainty, I think, we may see in later
12 evidence, about when the first batch was produced. It
13 certainly wasn't on general distribution but there was
14 some produced I think in December of '84, if one takes
15 on one view anyway, as expressed in the records. So
16 it's possible but it seems unlikely.

17 **MS RICHARDS:** It seems unlikely and obviously some at
18 least, as we can see from this, was not heat-treated
19 at all.

20 **SIR BRIAN LANGSTAFF:** Yes.

21 **MS RICHARDS:** If we go to BAYP0000024_149, we can see this
22 is an internal Cutter memo dated 29 March 1985 and,
23 actually, I think we've looked at this already but if
24 we look at the -- no, it's slightly later on from the
25 one we previously looked at. If we look at the bottom

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1 introduced.

2 There is, however, one later document that it
3 may be worth looking at.

4 Soumik, it's NHB0096599_012.

5 This is a later document. It's a memo from
6 Dr Wensley to Dr Lee dated 18 December 1988. But it
7 provides details of what supplies were received in the
8 first half of 1985:

9 "No heat-treated Factor VIII was received
10 before January 1985. The deliveries of heat-treated
11 Factor VIII to NBTS Manchester, are as shown below."

12 So just looking to start with in the right-hand
13 column, "Commercial", we can see that all the new
14 product received by way of commercial product in the
15 first six months of 1985 was heat-treated. It looks
16 like it was all Profilate, from that.

17 In terms of NHS product, we can see that in
18 both January and March of 1985, non-heat-treated
19 supplies were received, 135,000 units of
20 non-heat-treated (NHT) in January, 27,000 of
21 non-heat-treated material in March of 1985 and
22 presumably, given what we know about shortages, those
23 are products that were used for the treatment of
24 patients.

25 **SIR BRIAN LANGSTAFF:** Do we have any information about

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1 of the first page, we can see the reference to
2 Manchester:

3 "The signs are indicating that the Manchester
4 area will possibly start using Factor IX heat-treated
5 commercial material in April/May."

6 So those with haemophilia B would still have
7 been, I think on any view, being treated, if they were
8 being treated, with non-heat-treated material at this
9 point in time. Then:

10 "Regular NHS Factor VIII is being used."

11 The reference to "regular" appears to be
12 a reference to non-heat-treated Factor VIII.

13 Then not of direct relevance to the question of
14 the introduction of heat-treated product but possibly
15 of some interest, BAYP0000024_230. This is a later
16 Cutter memo, 20 May 1985, just the first paragraph.
17 It refers to a Profilate HT trial and results
18 presented by Dr Savidge:

19 "The results provide evidence to support
20 Alpha's claim that Profilate HT is free from non-A,
21 non-B hepatitis. Dr Savidge's results also support
22 those of Dr Kernoff and Dr Wensley. Both have
23 previously claimed the safety of Profilate HT in terms
24 of non-A, non-B hepatitis."

25 So drawing attention to that simply from what

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1 it tells us about Dr Wensley and his approach to
2 non-A, non-B hepatitis in 1985.
3 We do have the 1986 annual return to UKHCDO.
4 I think there's no reason for thinking that the
5 products used at that time were anything other than
6 heat-treated. I don't go to it but I will give you
7 the reference, sir. It's HCDO0000347_011, and what it
8 shows that in the course of 1986, 85 per cent or
9 thereabouts of Factor VIII use by MRI was commercial,
10 mostly Koate and Hemofil, and cryoprecipitate by 1986
11 was a very minor part of the materials that were being
12 used for haemophilia A patients.

13 Then, just finally on the question of porcine
14 Factor VIII, if we go to IPSN0000057_066, what we've
15 got here -- and if we have the first half of the page,
16 thank you -- is an abstract of a paper apparently
17 delivered at the World Federation of Haemophilia
18 meeting in 1986 by Burn, Cottrell, Maugham, Wensley,
19 Delamore, Manchester Royal Infirmary, on the use of
20 porcine Factor VIII to treat haemophilia A patients
21 without inhibitors. It records that:

22 "High purity porcine Factor VIII (Hyate C) was
23 used to cover essential surgery in four patients who
24 had received little or no previous blood products,
25 with the intention of avoiding any exposure to the

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1 a sense of, unfortunately, from the documents is what
2 the particular approach was, other than in relation to
3 the document we've just looked at, to treating
4 different categories of patients. It may be fair to
5 infer that patients with severe haemophilia A on home
6 treatment were clearly being treated by 1983 with
7 exclusively Factor VIII concentrates, both commercial
8 and NHS concentrates. I think it is fairly, probably
9 also, easy to infer that a reason for the substantial
10 uses of commercial concentrates was the absence of
11 sufficient quantities of NHS concentrates.

12 What the particular policies, if any, were
13 towards the treatment of patients with mild or
14 moderate haemophilia, or previously untreated or
15 minimally treated patients, isn't something that one
16 can pull together from the material that we've seen.
17 So it is unfortunately, at best, an incomplete picture
18 in that respect.

19 Moving then to the question of knowledge of
20 hepatitis, we can see through the very fact that
21 Manchester was one of the major reference centres and,
22 therefore, its directors from the very beginning
23 attended Reference Centre Director meetings, that the
24 clinicians in Manchester were aware of work being
25 undertaken in relation to hepatitis and hepatitis in

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1 AIDS-related virus and the hepatitis viruses. The
2 patients had no inhibitors to human or porcine
3 Factor VIII:C. Good levels of Factor VIII:C activity
4 were maintained during and for about seven days
5 following surgery, when progressive resistance was
6 noted in all patients."

7 Then there's further details there provided.

8 "We conclude that porcine Factor VIII:C is
9 a useful alternative to human Factor VIII:C
10 concentrate in mild haemophilia A patients who are
11 requiring essential surgery."

12 So a further insight into at least some aspect
13 of Manchester's treatment policies in response to the
14 risks of infection.

15 Sir, I'm going to move -- sorry, before I move
16 to the next topic -- we can take that down, thank
17 you -- just with some general observations about
18 product usage and treatment policy. We can see from
19 the documents that I've shown, broadly speaking, as a
20 matter of fact, what products were being used at the
21 Manchester Royal Infirmary to treat the patients with
22 bleeding disorders in the late 1970s and the first
23 half of the 1980s. We can see very substantial
24 quantities of Factor VIII concentrate being used, we
25 see the usage of cryoprecipitate. What we don't get

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1 blood products from an early stage, and simply by way
2 of example of that we look at OXUH0000831_001. This
3 is a meeting from October 1968 of the MRC
4 Cryoprecipitate Working Party, and a member of the
5 working party was Dr Israel's the then director at
6 Manchester. We can see from bottom of the page that
7 one of the issues there being discussed was the survey
8 of incidence of jaundice in haemophilia, and over the
9 page there is a more detailed discussion about how
10 that survey would be undertaken.

11 We can take that down, thank you.

12 Without going through all the minutes that
13 we've looked at on a number of occasions of both
14 Reference Centre Director meetings and Haemophilia
15 Centre Director meetings, we have seen from the
16 minutes that Dr Delamore and/or Dr Wensley were
17 regular attenders at these meetings, one or other,
18 sometimes both, was usually there, and thus they can
19 be taken to be aware of the information about both
20 hepatitis B and non-A, non-B hepatitis, and chronic
21 liver disease that was discussed during those
22 meetings.

23 You will recall yesterday, sir, Dr Bevan's
24 evidence of being particularly impressed as a junior
25 doctor as to what Dr Craske had said at a meeting in

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1 November 1979. There are various earlier meetings in
2 which reports from the Hepatitis Working Party is
3 shared with Reference Centre Directors, particularly
4 throughout the second half of the 1970s.

5 We can see also, if we look at
6 DHSC0002173_048 -- whilst we are getting that we will
7 be able to see from this document that, as Reference
8 Centre Directors, Dr Delamore and/or Dr Wensley in due
9 course were privy to the reports and studies that were
10 being undertaken. So this, by way of example, is
11 a written report that was prepared for a Haemophilia
12 Centre Directors meeting in April 1971, attended by
13 Dr Delamore, and it's a study of haemophilia A and
14 Christmas disease patients, and we can see -- I won't
15 go through the detail of it, but the first page --
16 reference to a study of the instance of transfusion
17 hepatitis and inhibitors, "two most alarming
18 complications of treatment".

19 Halfway down the page:
20 "Transfusion hepatitis is thought to be a virus
21 infection transmitted to the recipient by the donor
22 plasma. There is every reason to suppose that the
23 virus is contained in the various protein fractions
24 used to treat haemophilia and Christmas disease ..."

25 Then the next paragraph:

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1 is not so great as to overbalance the advantages of
2 the use of concentrates."

3 **SIR BRIAN LANGSTAFF:** The sentence perhaps deserves
4 highlighting, three lines down:

5 "The problem in recommending an increased
6 manufacture of these lies in the possible increase in
7 hepatitis and antibodies."

8 **MS RICHARDS:** Yes.

9 **SIR BRIAN LANGSTAFF:** So the link there appears to be,
10 theoretically at any rate, between the size of the
11 pool --

12 **MS RICHARDS:** Precisely.

13 **SIR BRIAN LANGSTAFF:** -- and the risk of hepatitis.

14 **MS RICHARDS:** Yes, exactly so. Actually, if we look at
15 the very bottom of that same page:

16 "The incidence of jaundice in treated patients
17 must increase with the number of donor exposures and
18 the number of donor exposures must increase using
19 concentrates derived from large pools. However, the
20 greater reliability, ease of administration, and
21 economy of manufacture are in favour of concentrated
22 materials."

23 Then there is an aspiration that a method will
24 be found to remove Australian antigen from
25 concentrated materials.

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1 "The danger of infection can be calculated and
2 will be related to the number of donors used to make
3 the material used for treatment or the number of
4 'donor exposures'. If large pools of plasma are used
5 to make therapeutic concentrated the theoretical
6 danger of infection will be increased."

7 Then there's a rather more detailed discussion.
8 If we go on to page 9, we can see, bottom of the page:

9 "The clinical value of free and early treatment
10 of haemophilic patients in the saving of life and
11 prevention of crippling is now well established. This
12 treatment is known to carry two main hazards:

13 "(1) The transmission of infective hepatitis."

14 We won't deal with antibodies. If we just go
15 further down the page, please, Soumik, there's
16 a suggestion of patients being very resistant to
17 clinical hepatitis:

18 "Hepatitis transmission must be related to the
19 number of 'donor exposures' of the patients. This
20 number will increase with the use of dried
21 concentrates made from large pools of donors."

22 Then it goes on to talk about the advantages of
23 concentrate treatment, and the view expressed at the
24 end of that first paragraph:

25 "We feel the increased risk of clinical illness

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1 So that's as early as 1971. If we then --

2 **SIR BRIAN LANGSTAFF:** Do you read in the last two
3 sentences there a call, or at least a view which may
4 be the same, that something ought to be done about
5 inactivating the virus?

6 **MS RICHARDS:** In the last sentence, yes, absolutely.

7 **SIR BRIAN LANGSTAFF:** This is in 1970 ...

8 **MS RICHARDS:** 1971.

9 **SIR BRIAN LANGSTAFF:** Thank you. So this is at a stage
10 when the NHS or the Lister Factor VIII is on-stream,
11 although it's generally not the product of use;
12 generally, cryoprecipitate is.

13 **MS RICHARDS:** Yes.

14 **SIR BRIAN LANGSTAFF:** It's before any commercial
15 concentrate made from even larger pools is licensed.

16 **MS RICHARDS:** Yes, that's a little later on.

17 **SIR BRIAN LANGSTAFF:** That comes in 1973, I think --

18 **MS RICHARDS:** Yes.

19 **SIR BRIAN LANGSTAFF:** -- but first used in 1972. Yes,
20 thank you.

21 **MS RICHARDS:** If we then look at OXUH0000499_002, we can
22 see a letter dated 9 March 1977. This is from
23 Dr Delamore to Dr Rizza at Oxford, and he's obviously
24 been asked to return a list of suggested topics for
25 study by working parties. He says:

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1 "I have ticked the three that I personally feel
2 are most worthy of study and have numbered them
3 according to priority."

4 If we go over the next page, we can see that
5 his number 1 priority for study by working parties of
6 the haemophilia centre directors is the incidence of
7 hepatitis in haemophilia.

8 If we go back to a document that we looked at
9 this morning, earlier this morning, and look at part
10 of it we didn't previously go to, it's PRSE0000421,
11 please, Soumik. This is the 1978 seminar that we
12 looked at for information about how Manchester
13 reference centre operated. If we go to page 5,
14 left-hand side, the second paragraph, this is still
15 part of Dr Delamore's talk:

16 "Hepatitis is carried in blood products and
17 Dr Delamore noted that very high percentage of
18 patients being treated for haemophilia and Christmas
19 disease are proving after all to be infected by one
20 type of hepatitis or another."

21 This is 1978, so non-A, non-B hepatitis is
22 known to be a distinct type of hepatitis from
23 hepatitis B:

24 "A great deal more work in assessing the
25 severity of hepatitis needs to be undertaken, possibly

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1 occasions for its early reference to AIDS, but if we
2 go to page 10, this is in the context of a discussion
3 of the work of the Hepatitis Working Party, we can see
4 there Dr Wensley is recorded as saying:

5 "... it was important to point out that
6 hepatitis B had not entirely disappeared; there had
7 been two new cases of hepatitis B in Manchester during
8 the current year."

9 Then, still in 1982, if we go to CBLA0001616,
10 we can see here, under the heading "Current topics in
11 Haemophilia", this is the programme for a scientific
12 symposium to be held in Manchester on
13 14 September 1982, to be chaired by Professor Bloom.

14 If we go to session II, so if we go a little
15 further down the page, "Hepatitis and Haemophilia", to
16 be chaired by Professor Longson. And then three
17 talks: The spectrum of Liver Disease in Haemophiliacs,
18 from Dr Stevens; Non-A, Non-B Hepatitis,
19 Professor Zuckerman; then The removal of Viral
20 Contaminants from Coagulation Factor Concentrates by
21 Dr Snape from BPL.

22 We have the text of Dr Stevens' paper -- well,
23 of the whole symposium -- at DHSC0002221_003. We can
24 see there:

25 "Department of Clinical Haematology, University

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1 to develop an immunisation against hepatitis or in
2 developing ways of making blood products safer.
3 Reference Centre Directors meet together two or three
4 times a year to discuss these problems and reassess
5 working parties ..."

6 Then it goes on to talk about the development
7 of antibodies. So, again, one can see Dr Delamore
8 clearly aware of and, it may be thought, concerned
9 about infection with hepatitis, and the phrase,
10 "a great deal more work in assessing the severity of
11 hepatitis needs to be undertaken", might be said to
12 reveal a view that it certainly could be serious.
13 He's not dismissing it as something benign or
14 harmless.

15 I'm not, sir, going to go to some of the papers
16 that we looked at on multiple occasions:
17 Professor Preston's 1978 paper, Dr Craske's 1979
18 working party reports. It can fairly be assumed that
19 Dr Wensley and Dr Delamore, as Reference Centre
20 Directors regularly attending these meetings, would
21 have been aware of publications and discussions such
22 as that.

23 If we go then to HCDO0000410, this is the
24 Reference Centre Directors' meeting from
25 6 September 1982. We've looked at it on multiple

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1 of Manchester.

2 "Current Topics in Haemophilia.

3 "Proceedings of the Symposium held in
4 Manchester, UK, on September 14th, 1982.

5 "Edited by Dr Wensley."

6 If we go to the next page we'll see this was
7 sponsored by Armour:

8 "We wish to thank Armour Pharmaceuticals for
9 making a generous financial contribution towards the
10 cost of the symposium and this publication."

11 If we go on two pages, this is just noteworthy
12 for the foreword by Professor Bloom. He says this:

13 "These are exciting times in the haemophilia
14 world."

15 Then he refers to:

16 "The Haemophilia Centre Directors of the UK
17 meet annually to discuss relevant problems."

18 And then he talks about the 1980 symposium. We
19 looked at that with Professor Lowe you, will recall,
20 sir.

21 So Manchester was following similar lines.

22 "In addition to reviewing current knowledge all
23 coagulation the Manchester Symposium concentrated on
24 the hepatitis problem and the pathogenesis and
25 treatment of inhibitors both of which constitute major

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1 problem areas for the haemophiliac. These are timely
2 presentations because hope has been engendered by the
3 development of hepatitis-reduced concentrates and for
4 the induction of immune tolerance to Factor VIII for
5 these therapeutic modalities still need very careful
6 assessment."

7 Then if we go to the last paragraph:

8 "The organisers of the Symposium are to be
9 congratulated [et cetera, et cetera] ... much remains
10 to be learned the knowledge imparted in this Symposium
11 sets us on a course that will at least alleviate, if
12 not yet cure the depressive component of our
13 psychiatric syndrome."

14 That's a reference to the first paragraph of
15 this form which talks about those who care for
16 haemophiliacs experiencing both highs and lows
17 effectively, and then this:

18 "Unfortunately, true to form, new hazards are
19 appearing on the horizon including the acquired immune
20 deficiency syndrome. The impact of these will no
21 doubt feature in our next Symposium."

22 So that's Professor Bloom's observations.

23 If we then go to -- try page 40, Soumik. Two
24 pages further on, thank you. Oh no, one page back, my
25 apologies.

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1 following headings.

2 "1. Clinical stigmata of liver disease in
3 haemophiliacs.

4 "2. Abnormal liver function tests ...

5 "3. Liver histology ...

6 "4. Therapeutic approach to liver dysfunction
7 in haemophiliacs."

8 If we go down the bottom of the page, there's
9 a discussion under this heading about jaundice.

10 Bottom of the page:

11 "... Non-A, non-B hepatitis is becoming
12 increasingly implicated, although the majority of
13 cases are non-icteric."

14 If we go over the page, just a bit further
15 down, thank you. So, picking it up in the paragraph:

16 "Direct questioning will not infrequently
17 reveal symptoms compatible with a viral hepatitis like
18 illness but such symptoms are not usually volunteered
19 by haemophiliacs and the suggestion that they may
20 possibly have some degree of liver dysfunction usually
21 comes as a surprise to the patient."

22 So, as it were, a problem of under-reporting:

23 "Although most clinicians have seen or have
24 heard about isolated haemophiliacs with severe liver
25 disease associated with other clinical features, such

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1 So, this is the text of the paper delivered by
2 Dr Stevens, which eventually translates to the
3 publication that we've seen referred to before in
4 1983, entitled "Liver Disease in Haemophiliacs: An
5 Overstated Problem?", and you will recall
6 Professor Hay then talked about the response to that
7 in his 1985 publication.

8 But instructive to see here what Dr Stevens was
9 saying:

10 "As a result of relatively recent developments
11 in plasma collection and fractionation, many
12 haemophiliacs now receive potent, easily
13 re-constituted convenient blood products which have
14 resulted in an improved lifestyle for the severe
15 haemophiliac. But at what price?"

16 "Over the past decade clinicians have become
17 increasingly aware of clinical, sub-clinical and
18 laboratory abnormalities in multi-transfused
19 haemophiliacs suggestive of hepatocellular damage, and
20 there is increasing evidence that such damage is the
21 result of viral infection, particularly non-A, non-B
22 hepatitis."

23 Then he says:

24 "The problems associated with liver dysfunction
25 in the haemophiliac can be considered under the

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1 cases are very infrequent, and in general terms the
2 symptoms and signs of significant liver disease are
3 found relatively infrequently in haemophiliacs."

4 So not found but he's saying there "relatively
5 infrequently":

6 "I am glad to say that the number of deaths due
7 to liver disease so far reported in the UK remains
8 very small."

9 There's then a discussion about abnormal liver
10 function tests.

11 If we go over two pages, please, Soumik. We
12 can see under the heading "Liver histology and
13 Haemophiliacs", he refers to:

14 "... various haemophilia centres undertaking
15 programmes of routine liver biopsy. The rationale for
16 such an invasive procedure in patients who were in the
17 main asymptomatic and have a haemostatic defect was
18 primarily the differentiation of chronic persistent
19 hepatitis from chronic active hepatitis and cirrhosis
20 which may benefit from specific treatment, and which
21 may also place a new prognosis on the life expectancy
22 of the haemophiliac.

23 "The following table reviews some of the
24 initial results."

25 If we go to the top of the next page, there's

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1 a review of various reports of liver biopsies and
 2 you'll see the first six cases, number with chronic
 3 active hepatitis/cirrhosis 3, so 50 per cent; the
 4 second, again an American study, 13 cases, five with
 5 chronic active hepatitis/cirrhosis, so 38 per cent;
 6 Mannucci (Milan), number of cases 11, number of
 7 chronic active hepatitis/cirrhosis 6, so 55 per cent;
 8 and then we have Professor Preston's Sheffield work;
 9 and then a reference to work by Professor Schimpf in
 10 Heidelberg, 32 cases, 10 with chronic active
 11 hepatitis/cirrhosis, 31 per cent.

12 It goes on to say:

13 "It can be seen that early reports suggested
 14 that up to 50 per cent of multi-transfused
 15 haemophiliacs have significant histological liver
 16 disease, either with chronic active hepatitis or
 17 cirrhosis, although histological interpretation may
 18 account for some variation in these exact figures."

19 He then refers to the Heidelberg survey,
 20 reporting the results of repeated liver biopsies and
 21 saying in those cases there proved to be no
 22 significant deterioration.

23 "We in Manchester have recently successfully
 24 carried out liver biopsies on twelve haemophiliacs,
 25 all of whom were multi-transfused and had persistently

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1 therapeutically useful information is obtained from
 2 liver histology in haemophiliacs is limited and may
 3 not justify the risk of this procedure."

4 So a significant part of Dr Stevens' message
 5 is: we don't get enough useful information to justify
 6 biopsies in haemophiliacs.

7 He then goes on under the heading "Therapeutic
 8 approach to liver disease in haemophiliacs" to say
 9 this:

10 "At this time we do not know how much of
 11 a problem liver disease represents itself in
 12 haemophilia. We do know that despite the exclusion of
 13 hepatitis B to a large degree, the dangers of viral
 14 disease transmission, presumably non-A, non-B,
 15 associated with intensive transfusion are far from
 16 over, and that even small donor pool cryoprecipitate
 17 may not be exempt from this problem. Although as yet,
 18 mortality and the advances clinical sequelae of liver
 19 disease in haemophiliacs are thankfully rare, the
 20 potential risks remain, and all multi-transfused
 21 haemophiliacs must be followed closely for any
 22 clinical or laboratory evidence of hepatic
 23 deterioration."

24 Then he goes on to suggest that it's debatable
 25 as to whether that should include liver biopsy.

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1 abnormal transaminase levels."

2 Then you will see there, of those twelve, one
 3 had chronic active hepatitis and cirrhosis, and four
 4 showing signs of very mild chronic active hepatitis,
 5 and then others, one with chronic lobular, one with
 6 chronic persistent hepatitis.

7 "In our survey [he says] ... only one patient
 8 had chronic active hepatitis and cirrhosis, although
 9 four other cases were considered to have very mild
 10 chronic active hepatitis."

11 If we then go over to the next page, we can
 12 see, if we just zoom in on the top half of the page,
 13 it says:

14 "On the basis of this Manchester trial and the
 15 results of this recent world-wide collaborative study,
 16 I would like to suggest the following conclusions ..."

17 The first is that:

18 "... long-term use of small donor pool products
 19 ... may carry as much risk of transmitting non A,
 20 non B hepatitis as that of large donor pool
 21 concentrates."

22 So I leave that to one side because we are
 23 really concerned here of the seriousness of non-A,
 24 non-B, and then:

25 "ii) ... the frequency with which

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1 Next page, last paragraph:

2 "The prospect of a new 'clean' replacement
 3 product either of human origin or from genetic
 4 engineering leave hope for the future but at the
 5 present time it appears that the clinical risks
 6 associated with replacement therapy may be overstated
 7 and are certainly outweighed by the need to treat the
 8 haemophiliac by the rapid replacement of his deficient
 9 clotting factor."

10 Sir, one question that you may wish to consider
 11 in due course is whether that suggestion that the
 12 clinical risks may be overstated and that leads then
 13 to the title of the published article, of which
 14 I think Dr Wensley was a co-author, is actually
 15 consistent with the text of what's set out in the body
 16 of the paper and the findings from other biopsy
 17 studies.

18 **SIR BRIAN LANGSTAFF:** Well, it's -- if taken out of
 19 context at any rate, it's difficult to understand how
 20 that fits with something in the region of 50 per cent
 21 of people who've been treated for ten years in an
 22 infection which, the assumption of the paper is, is
 23 associated with the replacement therapy, can be
 24 described as overstated, unless one knows what
 25 particular statements he's referring to.

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1 **MS RICHARDS:** Quite.
 2 **SIR BRIAN LANGSTAFF:** But if it's possibly a slow process,
 3 possibly ten years since -- one of the interesting
 4 things that goes through my mind as you were speaking
 5 is the earlier report showing that the cohorts of
 6 those treated by cryoprecipitate in 1971, presumably
 7 for a few years because cryoprecipitate wouldn't have
 8 been available until '65/66, showed no particular
 9 evidence of an incidence of hepatitis over and above
 10 that of the usual population.

11 Here, it's assumed that there certainly is an
 12 association, and so we start off with the basis that
 13 having concentrate can cause, and does cause,
 14 a hepatitis and the hepatitis in 50 per cent of the
 15 cases where there's been a biopsy (query, why the case
 16 is selected for study) are chronic active hepatitis as
 17 is understood at the time.

18 **MS RICHARDS:** Yes.

19 **SIR BRIAN LANGSTAFF:** And, in a few cases, cirrhosis.
 20 Yes, taken out of context, this is not an easy
 21 paragraph to understand.

22 **MS RICHARDS:** It's not and, of course, it then translates
 23 into the publication which we see at PRSE0002564. We
 24 just zoom in on the top half of the page:
 25 "Liver disease in haemophiliacs: an overstated

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1 Centre Director meeting. He was present at the
 2 14 February 1983 Reference Centre Director meeting
 3 when Dr Craske made a much more detailed presentation
 4 of the information he had gathered, and we've looked
 5 at versions of Dr Craske's reports. Dr Wensley
 6 attended 24 January 1983 meeting with Immuno at the
 7 London airport hotel. So he can be taken to have been
 8 aware of the reports from MMWR, the reports of the
 9 San Francisco baby and the other transfusion cases by
 10 that time, if not earlier.

11 In terms of local meetings, there's very
 12 little, as in local to the Manchester region, from
 13 1983 or 1984. We looked this morning at the
 14 February 1983 meeting, which was regarding supplies
 15 and shortages and distribution arrangements, where
 16 there was a passing reference, you will recall at the
 17 end of the meeting, to AIDS and no specific action to
 18 be taken at present.

19 There's no evidence to show any particular
 20 change in treatment policy in response to the risk of
 21 AIDS thereafter, until we get to heat treatment in
 22 1985, other than that reference in the abstract that
 23 we looked at before lunch to the use of Hyate:C for
 24 surgery in individual cases.

25 We know Dr Delamore attended the special

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1 problem?" co-authored by Dr Stevens, who was
 2 Manchester Children's Hospital, but then we will see
 3 a number of other names there, including Dr Wensley
 4 and Dr Delamore of the Haemophilia Centre at the Royal
 5 Infirmary. We've looked at the text of this
 6 previously. It's broadly consistent with the
 7 underlying paper that we've just looked at that was
 8 presented at the symposium.

9 **SIR BRIAN LANGSTAFF:** Yes.

10 **MS RICHARDS:** Sir, I'm just going to move on to the
 11 question of knowledge of HIV. I note the time. Shall
 12 we pick that up at 2.00?

13 **SIR BRIAN LANGSTAFF:** Yes, let's do that.
 14 (12.58 pm)

(Luncheon Adjournment)

(2.01 pm)

17 **SIR BRIAN LANGSTAFF:** Yes.

18 **MS RICHARDS:** Sir, turning to knowledge of risk of AIDS,
 19 there is little contemporaneous documentation, I think
 20 probably no contemporaneous documentation, to tell us
 21 about Dr Delamore's and Dr Wensley actual own views of
 22 the risks of AIDS transmission in the years prior to
 23 1985, but we know that they attended key meetings. So
 24 they attended the Reference Centre Director meetings,
 25 Dr Wensley was present at 6 September 1982 Reference

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1 Reference Centre Directors' meeting in May 1983, which
 2 resulted in the June 1983 letter sent out to
 3 Haemophilia Centre Directors. He also attended the
 4 October 1983 Haemophilia Centre Directors' meeting,
 5 that's the one in which Dr Chisholm made her
 6 suggestion about the reversion to cryoprecipitate.
 7 There's no record of him expressing any particular
 8 views at those meetings, and Dr Delamore and Dr Gunson
 9 attended the 10 December 1984 Elstree Reference Centre
 10 Directors' meeting.

11 So there's no doubt that between them,
 12 Dr Wensley and Dr Delamore were involved at the
 13 highest level of UKHCDO Reference Centre consideration
 14 and decision-making in the course of 1982 through to
 15 1984.

16 There is a letter at BAYP0000027_074 from
 17 November 1983, from a Cutter representative. The date
 18 is 23 November. It's addressed to Dr Wensley. It's
 19 from a sales manager, and he refers to a meeting:

20 "... I am writing to confirm the pricing
 21 details we discussed and to provide further
 22 information on the various Koate batches. I also
 23 enclose a copy of the May edition of ECHO magazine
 24 which was devoted entirely to AIDS. You will see that
 25 it contains a complete list of all the Plasma Donor

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1 Centres from which our plasma is sourced and you will
2 note that there are no centres in San Francisco or
3 New York."

4 So there in November 1983 is a pharmaceutical
5 representative, it would seem, trying to persuade
6 Dr Wensley that in terms of the risk of transmission
7 of AIDS, the Koate should be regarded as being safe.

8 We do have in Dr Gunson's litigation statement,
9 Dr Gunson's own account of his developing knowledge of
10 AIDS and, of course, he worked closely with Dr Wensley
11 at the Regional Transfusion Centre. If we go back to
12 his statement, it's NHBT0020196_001. It's -- forgive
13 me for a moment, Soumik. Try page 18. That's it.

14 So you'll see the way in which Dr Gunson puts
15 it at various points of his commentary on the
16 plaintiff's Statement of Claim in the litigation. So
17 here he says:

18 "During 1982 it was not, in my view, proven
19 conclusively that Factor VIII concentrates were the
20 cause of AIDS contracted by haemophiliacs."

21 Then he quotes a later presentation by
22 Dr Peter Jones. So the terminology there "proven
23 conclusively" obviously raises the question of whether
24 that was the right question to ask.

25 Just further down from that paragraph, he says:

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1 **MS RICHARDS:** We'll check what we have from Dr Jones in
2 terms of what Dr Jones was saying and where this quote
3 is taken from before we do the presentation on
4 Newcastle and Dr Jones in a couple of weeks' time,
5 sir.

6 **SIR BRIAN LANGSTAFF:** Please.

7 **MS RICHARDS:** If we go to the next page, Soumik, the
8 second half of the page, again we see the language of
9 proof:

10 "During 1982, the correlation between the
11 transfusion of blood and blood products was not
12 proven, nor was it known at that time that a virus
13 caused AIDS, although investigations were being
14 undertaken in this regard."

15 Then he says this:

16 "The first proven case of
17 transfusion-transmitted AIDS was reported in 1983 in
18 an infant given a transfusion of blood and blood
19 products in December 1982."

20 **SIR BRIAN LANGSTAFF:** It was actually reported on
21 10 December 1982.

22 **MS RICHARDS:** It was in the MMWR.

23 **SIR BRIAN LANGSTAFF:** But not until -- 1983 is obviously
24 a reference, I think, to The Lancet --

25 **MS RICHARDS:** Yes, in April of 1983. But of course it was

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1 "The first case of transfusion-associated AIDS
2 was reported in 1983 in an infant transfused in
3 December 1982 and this will be referred to later in
4 the statement."

5 So that is the San Francisco baby case.

6 **SIR BRIAN LANGSTAFF:** Just if you go back a moment to --
7 that's it -- the reference there to what Peter Jones
8 had to say refers to the MMWR, which is written by the
9 Center for Disease Control, reporting the infections
10 in three men with haemophilia. It says:

11 "... the possibility of a viral aetiology was
12 thought less likely than an immune response to the
13 constant barrage of extraneous denatured protein
14 involved in treatment."

15 That's not actually, is it -- or have I got
16 this wrong -- what the MMWR actually said?

17 **MS RICHARDS:** No. I'd read that as him saying that's what
18 Dr Jones was saying.

19 **SIR BRIAN LANGSTAFF:** But it appears to be a quote which
20 attributes it, or could be read as attributing it, to
21 the Center for Disease Control, because they seem to
22 be, my understanding, quite clear that they thought it
23 was more likely to be viral?

24 **MS RICHARDS:** Yes.

25 **SIR BRIAN LANGSTAFF:** Yes.

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1 discussed at a sequence of meetings in early 1983.
2 I can't recall without checking whether Dr Gunson was
3 present at those but, certainly, either Dr Wensley or
4 Dr Delamore was, including Dr Wensley at the Immuno
5 meeting on 24 January.

6 Then he refers to the leaflet, the regional
7 transfusion director leaflet. Now, of course, we've
8 looked at that at earlier stages of the Inquiry
9 hearings. That's the leaflet prepared in the middle
10 of 1983, which would advise donors, in answer to the
11 question about the transmission of AIDS, in terms of
12 the association does blood cause AIDS, blood
13 transfusion caused AIDS, or is it transmitted by
14 blood, almost certainly yes was the answer in that
15 leaflet in the middle of 1983. Given Dr Wensley's
16 close involvement with the Regional Blood Transfusion
17 Service, it may be that you may wish to infer that he
18 would have known about the production of that leaflet
19 and its contents.

20 **SIR BRIAN LANGSTAFF:** I know this may not be part of your
21 presentation at the moment, but Dr Gunson was
22 concerned with the blood service, so too, for most of
23 his time, certainly at that stage, was Dr Wensley.
24 One would have thought that the Blood Transfusion
25 Service in the UK would have kept a very close eye and

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1 contact with other organisations in significant
2 countries abroad, such as the United States and the
3 American Association of Blood Banks, for instance.

4 If that's right, then there was a source of
5 knowledge, or at least a view, opinion there because
6 I think it was in December 1982 that the American
7 Association of Blood Banks was actually advising its
8 members that it was most likely to be a virus.

9 **MS RICHARDS:** Yes, I'd have to check the dates, sir --

10 **SIR BRIAN LANGSTAFF:** I have a note of this. It's a note
11 which comes from the Krever report. It may be
12 a secondary source but he reported that the Chair of
13 the American Association of Blood Banks Committee on
14 transfusion-transmitted diseases wrote to its members
15 emphasising the threat of AIDS in the blood supply and
16 he wrote:

17 "My current best guess is that we are dealing
18 with an infectious agent able to be spread by blood
19 and blood products and individuals who receive large
20 quantities of factor concentrate are at an increased
21 risk."

22 So if that was a view expressed in a blood
23 transfusion organisation, not a voluntary donor in the
24 same sense as the UK position, but one might have
25 thought it would have crossed the Atlantic.

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1 "... reading scientific literature, by
2 attending meetings, by talking to experts and being a
3 member also of the DHSS Expert Advisory Group on AIDS
4 [although, of course, that wasn't set up until later].
5 We had staff meetings within the RTC. I held seminars
6 and teaching sessions for the scientific and other
7 non-medical staff, particularly those working on the
8 blood collection teams ..."

9 Then he says this:

10 "I first suspected the link between
11 haemophiliacs and AIDS during 1982 [we'll just go down
12 the page], when there were instances of haemophiliacs
13 contracting immune deficiency. However, it was not
14 known at that time that AIDS was caused by a virus and
15 when this was established, it was thought initially
16 that the AIDS virus was not so virulent in
17 haemophiliacs and only 1 per cent of those who had HIV
18 seroconverted would develop AIDS. This, of course,
19 has now been found to be entirely wrong. There were
20 times, until the proof that AIDS was a viral infection
21 and that it could be transmitted by blood products [go
22 to the next page], that I doubted the link with
23 haemophiliacs; other colleagues also had these
24 doubts."

25 He doesn't identify who those colleagues are:

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1 **MS RICHARDS:** Yes. We'll be looking, obviously, in more
2 detail at the role of the blood services and what was
3 and wasn't known and what was and wasn't done at
4 hearings later in the course of this year.

5 **SIR BRIAN LANGSTAFF:** Yes.

6 **MS RICHARDS:** Soumik, could we go, I think it's eight
7 pages further on. That's it, bottom half of the page.
8 So this is Dr Gunson continued. He says:

9 "I first became aware of the emergence of
10 HIV/AIDS from the information in the scientific
11 literature from the USA.

12 "The first reports were of the finding of
13 Kaposi's sarcoma in homosexuals. No-one knew what the
14 implications were at that time for the BTS. As the
15 reports began to accumulate, it was clear that the
16 immune deficiency related to this disease was a major
17 problem. The medical staff in the RTC discussed each
18 new development as any department would discuss such
19 major developments in another field. In 1983 [he
20 doesn't say when in 1983, but in 1983], as soon as we
21 knew that this virus was transmissible by blood
22 products, we were aware that the disease would have
23 a major impact on the work of the Blood Transfusion
24 Service."

25 Then he says he kept himself informed by:

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1 "Before the emergence of its cause by
2 a transmissible virus, other theories were put forward
3 for the origin of AIDS in homosexuals, eg pep pills,
4 nitrates, et cetera. Until proof was available that
5 [so that word again] that blood transfusion could be
6 a cause of AIDS, it was difficult to take specific
7 action within the BTS. From that time, I held no
8 doubts concerning the significance of blood
9 transfusion in relation to AIDS and acted accordingly.

10 "Any literature which I published on this
11 subject has been on the testing of blood donations and
12 safety of the blood supply.

13 "I am sure I was aware of the articles in the
14 Lancet on 15, 22 and 29 January 1983, since I made
15 a point of keeping up to date with the literature on
16 this subject."

17 That's what we have from Dr Gunson on his
18 knowledge and we know, of course, that there were
19 regular communications and interactions between him
20 and Dr Wensley, given that they were both working
21 within the same Regional Transfusion Service and,
22 indeed, were both jointly involved in arrangements for
23 the obtaining of and then the distribution of and use
24 of blood products.

25 Other than that, as I say, the question of what

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1 was known as a matter of fact and believed by
 2 Dr Wensley and Dr Delamore is going to be a matter of
 3 inference for you, sir, from the available material in
 4 both the literature and the various meetings which
 5 they both attended.

6 **SIR BRIAN LANGSTAFF:** Yes. Does Dr Gunson at any stage in
 7 that document, where he talks quite a bit about the
 8 knowledge that it was -- that is, a virus was the
 9 cause of AIDS, did he ever talk about the risk that it
 10 might be?

11 **MS RICHARDS:** No. Well, he talks about suspecting the
 12 link.

13 **SIR BRIAN LANGSTAFF:** Yes.

14 **MS RICHARDS:** But then elsewhere his language is couched
 15 in terms of what was known, in other words, known that
 16 things were as a matter of fact and what was proven.
 17 So the language that we see, for example, used by
 18 Dr Spence Galbraith in his May 1983 communication to
 19 the Department of Health, where he's talking about
 20 "likelihood" and "may" and then the need to act
 21 essentially on a precautionary basis, we don't see an
 22 echo of that here, no.

23 **SIR BRIAN LANGSTAFF:** What's made me ask that is by
 24 reference in particular to the views expressed by
 25 Dr Bevan yesterday, where he was critical, from his

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1 Atlanta meeting, talks about three groups of HTLV-III
 2 positive patients, and then asks to be informed if
 3 anyone falls into those categories or to notify
 4 Oxford, and counselling of patients is then discussed.

5 Also around the time of mid-1985 if we go to
 6 SHTM0000711, if we just zoom a little closer to that,
 7 so this is The Daily Telegraph, 31 July 1985, "AIDS
 8 alert as 400 get suspect blood":

9 "Four hundred haemophiliacs in North-West
 10 England are to be screened for AIDS after fears they
 11 could have contracted the disease by being given
 12 contaminated blood imported from America."

13 I will come on to the timing of the testing of
 14 the patients at the haemophilia centre in a few
 15 minutes:

16 "A North-West Regional Health Authority
 17 spokesman said that the tests have been ordered as a
 18 precaution. But Dr Richard Wensley, Director of
 19 Haemophilia at Manchester Royal Infirmary, believes
 20 that on statistical evidence two people may have
 21 contracted the disease."

22 The basis for that view being expressed by
 23 Dr Wensley, if this is an accurate newspaper report of
 24 his belief, is unclear, either from this or from any
 25 other contemporaneous material.

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1 perspective, of a view that looked for certainty and
 2 proof.

3 **MS RICHARDS:** Yes.

4 If we then look at NHBT0096599_043, and we go
 5 to the second page, we can see these are minutes of
 6 the North Western Supra-Regional haemophilia Meeting
 7 held on 7 May 1985 at the Regional Transfusion Centre
 8 in Manchester. We can see attendance, amongst others,
 9 from Dr Delamore, Dr Wensley, Dr Stevens. We've got
 10 Dr McVerry, for example, from Liverpool, we've got
 11 Dr Gunson, Dr Craske, Dr Lee from Lancaster, and so
 12 on.

13 You'll note, if we just go further down the
 14 page, please, Soumik, where it says "Minutes of last
 15 meeting":

16 "The last meeting had been held in 1980 and
 17 minutes for this were not available."

18 So it would appear that on a North Western
 19 Supra-Regional basis there had been no equivalent
 20 meeting for five years, notwithstanding, of course,
 21 all that was happening in that intervening five-year
 22 period.

23 There is a discussion -- if we look at the
 24 second page, under the heading "AIDS cases", there's
 25 a discussion there. Dr Craske reports from the

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1 **SIR BRIAN LANGSTAFF:** The date of that, you say, is
 2 31 July '85?

3 **MS RICHARDS:** Yes. So it's -- it may not be an accurate
 4 report, of course, but it's not clear what the basis
 5 for it is or what the reference to the statistical
 6 evidence.

7 **SIR BRIAN LANGSTAFF:** And why it was current at that date.

8 **MS RICHARDS:** Yes. Well, the issue was triggered by,
 9 I think, the arrival of the test kits. If we
 10 actually, sorry, just go back to the document we were
 11 looking at previously, NHBT0096599_043 --
 12 NHBT0096599_043 -- and if we go to the second page, so
 13 this is the 7 May minutes from '85 we were looking at
 14 a moment ago, the North West Supra-Regional
 15 Haemophilia meeting.

16 If we go to the third page, there was one
 17 paragraph I skated over. So, under the heading
 18 "AIDS cases", it's the last paragraph of that section:

19 "As one of the 6 Reference centres to have
 20 a kit for testing for HTLV-III antibody, tests in
 21 Manchester should be available by mid-June."

22 So it appears that there were going to be tests
 23 available actually to the haemophilia centre rather
 24 than necessarily having to send things off to
 25 Dr Tedder or elsewhere. It's not quite clear why --

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1 you'll see in a few minutes, when we get to the
 2 question of testing, the precise time-frame over which
 3 tests were undertaken on the patients most likely to
 4 be at risk remains unclear. But it may be that this
 5 is what triggers the newspaper article which is
 6 referring to tests having been ordered.

7 **SIR BRIAN LANGSTAFF:** It's particularly surprising because
 8 at this stage the big debate, I had thought, was about
 9 the testing -- the screening of blood supply for the
 10 presence of the virus and, at this stage, you showed
 11 us earlier in your presentation, in respect of
 12 Cardiff, how Professor Bloom was writing in mid-83 to
 13 say -- mid-85, I mean, to encourage the authorities to
 14 get a move on.

15 **MS RICHARDS:** Yes. It's puzzling because these minutes
 16 don't -- they don't seem to be referring to the
 17 availability of test kits for the Regional Transfusion
 18 Centres. They are talking about the availability of
 19 test kits for the reference centres, for the testing
 20 of haemophilia patients, and perhaps the intention is
 21 because -- this is pure speculation, I should add --
 22 Manchester obviously was a very large haemophilia
 23 centre, to enable testing of everybody or testing on
 24 a repeat and ongoing basis, initial tests having
 25 perhaps already been undertaken. But it's not clear

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1 He's writing to a firm of solicitors in
 2 Edinburgh on 15 July 1987 about a haemophiliac client
 3 who had contracted AIDS allegedly as a result of
 4 treatment at Edinburgh Royal Infirmary, and he says
 5 this:

6 "Perhaps I can reply in general terms about the
 7 current situation with regards to the AIDS virus and
 8 the haemophiliac ..."

9 Then he sets out general background:
 10 "... (AIDS) was first described ... in 1981 ...
 11 in US haemophiliacs in 1982; cases appearing in UK
 12 haemophiliacs since 1983."

13 Then he identifies the high-risk groups. Then
 14 he says this:

15 "In the UK, in 1983, in an attempt to reduce
 16 the risks to recipients of blood and blood products,
 17 donors who were in the above categories were requested
 18 to stop donating their blood."

19 So that's the leaflet from mid-1983 produced by
 20 the Transfusion Service.

21 "It had been realised that blood products ..."

22 So it "had been realised", past tense:
 23 "... that blood products such as Factor VIII
 24 freeze-dried concentrates probably carried more risk
 25 of containing the suspected infectious agent

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1 and it is slightly puzzling.

2 **SIR BRIAN LANGSTAFF:** Unless, I suppose, there was some
 3 system of checking to make sure that the heat-treated
 4 product actually worked.

5 **MS RICHARDS:** That's possible.

6 **SIR BRIAN LANGSTAFF:** But we have no other sign of that,
 7 have we?

8 **MS RICHARDS:** No. There is a reference somewhere in the
 9 documents, and in the documents relating to
 10 Manchester, to an -- where patients had tested
 11 negative, to undertake repeat testing.

12 **SIR BRIAN LANGSTAFF:** Yes.

13 **MS RICHARDS:** So it may be that these were tests that were
 14 intended to be utilised for that purpose or for the
 15 purpose of offering tests to relatives, partners and
 16 spouses. But it's not clear and the position is
 17 muddled rather than clarified by the report in the
 18 newspaper of what Dr Wensley is said to believe.

19 **SIR BRIAN LANGSTAFF:** And also by the fact that the report
 20 is very nearly three months after the meeting.

21 **MS RICHARDS:** Yes.

22 **SIR BRIAN LANGSTAFF:** But -- anyway.

23 **MS RICHARDS:** The only thing we have really authored by
 24 Dr Wensley directly is a slightly later letter, from
 25 1987, which is at MACK0000589.

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1 (especially if they were imported from the USA) than
 2 single donation products such as cryoprecipitate or
 3 frozen plasma. However, the latter products are more
 4 appropriate for the mildly affected haemophiliac and
 5 are, in general, unsuitable for self-administration by
 6 the severely affected haemophiliac."

7 It may be that -- couched as it is in those
 8 terms, it may suggest that Dr Wensley had not reverted
 9 to cryoprecipitate for severely infected
 10 haemophiliacs, although that's a matter of inference
 11 rather than what's set out in terms.

12 Then he goes on to talk about the further
 13 investigations that might be required in relation to
 14 the individual patient, but that's -- it would appear
 15 that he's saying there that it had been realised in
 16 1983 or by 1983 that blood products probably carried
 17 more risk than single donor products.

18 **SIR BRIAN LANGSTAFF:** Yes.

19 **MS RICHARDS:** There's then a document -- just excuse me
 20 a moment while I find the reference. WITN4715002. Go
 21 to the second page.

22 This is on a slightly different topic but it
 23 may assist in when you consider what response could or
 24 should have been made to the AIDS crisis.

25 So this is Dr Wensley writing in June of 1988,

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1 and if -- he's talking about a problem in which the
2 world supply of Factor VIII has "dried up", so there's
3 a shortage of Factor VIII.

4 If we go further down the page, please, Soumik,
5 he says this:

6 "How will we, in the North West, weather the
7 crisis?"

8 Then he talks about the hope that in the North
9 West they will be self-sufficient, and then he says
10 this:

11 "We hope that we will have enough freeze-dried
12 Factor VIII available to continue home treatment in
13 1988 for all patients who treat themselves, but
14 a temporary reversion to cryoprecipitate use for
15 certain home treatment patients has to be considered
16 a possibility. A handful of non-emergency operations
17 may have to be postponed and carried over to 1989."

18 So you'll see, sir, that in 1988, in response
19 to a worldwide shortage of Factor VIII, Dr Wensley's
20 contemplating a temporary reversion to cryoprecipitate
21 for home treatment and the deferral of non-emergency
22 operations. That may give rise to the question that,
23 if that's a step that can be taken in response to
24 shortage in 1988, are those steps that could have been
25 taken in response to a real risk of infection in the

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1 It's just interesting to note it said, under
2 the heading, "Provision of plasma", bottom part of the
3 page:

4 "The situation in certain RTCs was ..."

5 Then if we go to Manchester:

6 "Fewer requests received for 'Hemofil' since
7 'World in Action' TV programme."

8 It's the very last line of the page. It's one
9 of very few contemporaneous references in any of the
10 minutes or other documents that we've seen to the
11 World in Action programme. Whether that's fewer
12 requests from patients, who are concerned and worried
13 having seen it, or it represents views of clinicians
14 is unclear. It's being reported to this meeting by
15 the regional transfusion director.

16 There is -- if we move forward a number of
17 years to December of 1984, there is one document which
18 suggests information being provided to patients or to
19 a patient about the risk of hepatitis. That's at
20 WITN3543002. Go to the second page.

21 You can see the left-hand side of the letter is
22 slightly cut off so we don't get the complete sense of
23 it but it's 27 December 1984, and it's from the
24 haemophilia centre in Manchester to a patient:

25 "You are probably aware that treatment of your

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1 earlier part of the 1980s?

2 We should say we've seen no positive evidence
3 at least, and no evidence from patients or their
4 families who provided statements to the Inquiry, that
5 there were offers to revert to cryoprecipitate in the
6 first part of the 1980s in response to AIDS or the
7 developing risk of AIDS.

8 In terms of what information was or was not
9 provided to patients about the risks of hepatitis
10 and/or HIV/AIDS, the thrust of the evidence which the
11 Inquiry has received in both written and oral form
12 from patients and their families is to the effect that
13 they were not informed of risks of infection before
14 being treated. We've given a handful of examples in
15 the written note but you, sir, are, I know, reading
16 and considering each and every statement that the
17 Inquiry receives.

18 There is -- if we look at NHBT0016480, this is
19 "Regional Transfusion Directors' Meeting" of January
20 of 1976 and, insofar as Manchester is concerned,
21 I think it's Dr Stratton who was the regional
22 transfusion director at that time rather than
23 Dr Gunson, who was still at Oxford, and Dr Stratton
24 was in attendance.

25 If we go to page 7, please, Soumik.

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1 Haemophilia A Carrier state ... should you require
2 surgery or meet with an accident, can carry a risk of
3 giving you jaundice (technical name hepatitis).
4 Several different viruses can cause this complication
5 of treatment but hepatitis B and hepatitis non-A,
6 non-B are the main types in haemophiliacs.

7 "Hepatitis group of diseases usually takes the
8 form of a short or [I don't know what that word was
9 going to be] long-lasting, unpleasant, but very seldom
10 fatal, episode ..."

11 So that's the acute stage.

12 "These symptoms usually pass off completely in
13 a few weeks ... and normal health is regained."

14 Then it says:

15 "One important feature of hepatitis is that in
16 a proportion of cases it ..."

17 Probably the word "can" is missing --

18 **SIR BRIAN LANGSTAFF:** Or "may".

19 **MS RICHARDS:** -- or "may".

20 "... go on to a chronic disease of the liver
21 which may lead to symptoms in ..."

22 And perhaps the word that is missing is
23 "later". And then there's a reference to eradication
24 of hepatitis B and to immunisation with the
25 hepatitis B vaccine.

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1 Whether that was sent more generally or whether
 2 this was a one-off, we don't know but we haven't,
 3 currently at least, found any trace of any earlier
 4 equivalent letter identifying the risk of chronic
 5 disease of the liver of as a result of treatment.
 6 We've certainly found no written material until we get
 7 to 1985 and the letter we're about to turn to warning
 8 of the risks of AIDS.

9 So the letter that we have from 1985, from
 10 Dr Wensley, is at PMOS0000083, so this is a letter
 11 dated 4 January 1985, and the circulation is "All
 12 Adult Haemophiliacs". So it looks like it's
 13 a standard letter that was being sent to all patients
 14 at the centre:

15 "You will probably have learnt from television,
 16 radio and the newspapers, or from the Haemophilia
 17 Society, that cases of ... (AIDS) have occurred in
 18 Britain and that two haemophiliacs have died of the
 19 disease. In view of the anxiety that these reports
 20 can cause, may we bring some facts to your attention.

21 "Knowledge of the cause of AIDS has advanced
 22 rapidly. It is due to a virus called HTLV-III ...
 23 Recently it has been shown that many haemophiliacs
 24 have been exposed to the virus as a result of
 25 receiving large donor pool clotting concentrates. If

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1 at the top of the page and it's a letter from
 2 Dr Wensley.

3 So that's the first document that we found
 4 which is a document sent to patients dealing with the
 5 risks of AIDS and, of course, it's January 1985.

6 Then if we look at NHBT0085185_001, this is
 7 a further communication from Dr Wensley to a patient.
 8 This appears to be to one specific patient who has
 9 written to the Regional Health Authority, rather than
 10 a general letter for all patients. It says:

11 "... I have been asked to reply to a letter
 12 that you sent to the North West Regional Health
 13 Authority on 17 January 1985."

14 Then he says this, and the date of the letter
 15 is 6 March 1985:

16 "It is true that Haemophilia A patients in this
 17 Region will only receive Heat-Treated Factor VIII
 18 concentrates from this time onwards."

19 It's not entirely clear whether "this time" is
 20 17 January or the "this time" is 6 March:

21 "In replying to your second question, you can
 22 be sure that the Heat-Treated Factor VIII that you
 23 will be issued with for your home treatment will be
 24 free of the risk of conveying the HTLV-III (AIDS
 25 associated) virus."

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1 the virus behaves in the same way in haemophiliacs as
 2 in homosexuals or drug addicts, it is expected that
 3 most haemophiliacs exposed to the virus will remain
 4 well and will eventually become immune to it, a few
 5 may develop an illness with fever and gland swellings
 6 which will go away as they become immune, and a very
 7 few may develop AIDS. Until the right tests are
 8 available, it is probably best to assume that you
 9 could be carrying the HTLV-III virus."

10 Then there is a paragraph on the sexual
 11 transmission, and then if we go down the page, it
 12 said, rather over-optimistically this:

13 "The longer term outlook for haemophiliacs as
 14 far as AIDS is concerned is encouraging. The virus is
 15 quite sensitive to heat and plans are in hand to
 16 introduce heat-treated clotting factors in the near
 17 future in the North-West region."

18 There was then an aspiration for there to be
 19 an HTLV-III vaccine and synthetic factor concentrates.
 20 Then it said:

21 "If you ... have any queries ... do not
 22 hesitate to Mrs Redding or either of us requesting
 23 a further discussion."

24 The reference to "either of us", I anticipate,
 25 is to Dr Delamore or Dr Wensley whose names are given

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1 **SIR BRIAN LANGSTAFF:** Just in answer to your wondering
 2 whether it related to 17 January or 6 March, unless
 3 I'm persuaded otherwise, I think the natural inference
 4 is from 6 March, and the reason for that is that the
 5 second paragraph is expressed in the future tense --

6 **MS RICHARDS:** Yes.

7 **SIR BRIAN LANGSTAFF:** -- "will only receive ... from this
 8 time onwards", not have only received from the
 9 17 January. This is, after all, six weeks or so
 10 later.

11 **MS RICHARDS:** I agree, sir. It is the natural inference
 12 from the language used.

13 **SIR BRIAN LANGSTAFF:** So, unless there is some other
 14 reason to think that this is an early draft which is
 15 simply being rolled at again casually, something of
 16 that sort, that's how I will read it.

17 **MS RICHARDS:** If we look at the third paragraph, you can
 18 see an assurance being given that the heat-treated
 19 Factor VIII that you will be issued with will be free
 20 of the risk of conveying HTLV-III virus but, of
 21 course, we know that in both January and March of 1985
 22 the centre took delivery of non-heat-treated NHS
 23 factor, though it may be that wasn't being given out
 24 for home treatment, but, nonetheless, it was
 25 presumably received with the intention of being used,

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1 whether in hospital or at home. So there may be
 2 a question as to whether that was an assurance that
 3 could actually be given.

4 **SIR BRIAN LANGSTAFF:** Well, it also assumes that the none
 5 of the commercial heat-treated factor concentrate will
 6 carry even a small risk --

7 **MS RICHARDS:** Yes, it does.

8 **SIR BRIAN LANGSTAFF:** -- of carrying AIDS, something,
 9 which at least in the case of one manufacturer, prove
 10 illusory.

11 **MS RICHARDS:** Yes, sir, that is absolutely right. It is
 12 expressed in categorical terms: "will be free of the
 13 risk".

14 Then if we look then, and we're still in early
 15 1985, at a letter from Dr Wensley to the Department of
 16 Health, DHSC0003830_020, we can see it's dated
 17 1 February 1985 and Dr Wensley is saying this:
 18 "As a haemophilia Director with a large
 19 haemophilia practice at Manchester Royal Infirmary,
 20 I would like clarification of the measures required
 21 for dealing with the blood samples of patients with
 22 haemophilia.
 23 "My two questions, specifically are ..."
 24 It's the first that's of relevance for our
 25 purposes:

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1 there's words missing, and the concentrated clotting
 2 factor since 1980, and there's a recommendation that
 3 the patient call the Haematology Department to make an
 4 appointment.

5 There's a letter from September 1985 which is
 6 at DHSC --

7 **SIR BRIAN LANGSTAFF:** I think, just for the transcript,
 8 you said that was dated 22 May 1983, it is 1985.

9 **MS RICHARDS:** I'm sorry, yes, it is 1985. Then if we go
 10 to DHSC0013118, this is a letter dated
 11 2 September 1985:
 12 "We are now able to offer AIDS virus antibody
 13 testing (anti-HTLV-III) to all patients with bleeding
 14 disorders who have been treated with plasma,
 15 cryoprecipitate or concentrated clotting factor since
 16 1980."
 17 So this appears to be the full text but a later
 18 letter:
 19 "I would strongly recommend that we test your
 20 blood and suggest you call at the Clinical Haematology
 21 department any day Monday to Friday between 9 am and
 22 4.30 pm or by arrangement on a Saturday morning."
 23 That certainly shows that as late as
 24 September 1985 testing still appears to have been
 25 being offered for the first time to some patients. It

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1 "In the absence of results of anti-HTLV-III
 2 tests being available, should I assume that each of my
 3 haemophiliacs comes into the categories described ...
 4 [and it's referring there to a particular piece of
 5 guidance] 'patients in whom AIDS or PGL is suspected
 6 or has been diagnosed?'"

7 So that would suggest, and again it's
 8 consistent with other material, I think, that we've
 9 seen, that as of this point in time we don't know for
 10 certain whether some tests have been carried out but
 11 certainly it would suggest that the majority of
 12 patients in Manchester Royal Infirmary had not yet
 13 been tested for HTLV-III, which is obviously somewhat
 14 later than we've seen for some of the other centres.

15 The department's response is to say to assume
 16 that potential infectivity.

17 In terms then of trying to pin down when
 18 HTLV-III testing was undertaken, there are a couple of
 19 letters to individual patients. The first in time
 20 that we've identified so far is WITN3543003. Go to
 21 the second page. Again, unfortunately, the left-hand
 22 side of the letter's cut off. It's dated 22 May 1983
 23 but it appears to be making an offer of AIDS virus
 24 antibody testing to all patients with bleeding
 25 disorders who have been treated with plasma, and then

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1 may be that testing had already been undertaken for
 2 some of the patients earlier in the year but we've not
 3 been able to get to the bottom of that.

4 We have been sent, and I'm grateful for it,
 5 extracts from, for example, UKHCDO records relating to
 6 various patients at Manchester, which provide some
 7 earlier dates for samples, but whether that shows, for
 8 example, testing at the beginning of 1985, or whether
 9 it shows testing on stored samples later on is
 10 unclear. There's certainly at least one reference to
 11 a first positive date from much earlier on in the
 12 1980s, which would suggest that some testing on stored
 13 samples was undertaken. But it's not possible to be
 14 clear about that at this stage, nor do we know whether
 15 there was any form of pre-test counselling or whether
 16 there was testing undertaken without knowledge and
 17 consent. This obviously is an invitation to some
 18 patients to come and be tested with their knowledge
 19 but there is at least some evidence that the Inquiry
 20 has received from individuals who say that they were
 21 tested without their knowledge. So the picture is
 22 a mixed and somewhat confusing one at present.

23 **SIR BRIAN LANGSTAFF:** Who was the addressee of the letter,
 24 this letter, as far as we know? I'm not asking you to
 25 say anything about what is confidential on the copy

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1 but, in general terms, in terms of category, because
 2 I can understand perhaps why it may be that those who
 3 suffered from serious haemophilia A and attended
 4 regularly or were on home treatment and came in every
 5 one or two months to get a fresh supply, why they
 6 might have been tested, and if this letter had been
 7 intended to go to everyone there might have been
 8 others who may have had factor concentrate or plasma
 9 or cryoprecipitate at some stage in the previous
 10 five years. So it may be that this is designed to
 11 Hoover up the less seriously affected.

12 **MS RICHARDS:** It may well be, sir.

13 I have a version of this document which shows
 14 me the name but I don't know, without undertaking
 15 further research, what category of patient that person
 16 was.

17 **SIR BRIAN LANGSTAFF:** If it is a round robin letter there
 18 will be other examples.

19 **MS RICHARDS:** Yes.

20 **SIR BRIAN LANGSTAFF:** But, again, it's a pity that we
 21 don't have anybody here to give the explanation or any
 22 document that provides it.

23 **MS RICHARDS:** Yes, unfortunately we don't.

24 In terms of patients being given their results,
 25 again the evidence shows a mixed picture.

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1 rather than anything else.

2 We have examples of documents of patients being
 3 informed of negative HTLV-III results by letter rather
 4 than in person, and the Inquiry has received evidence
 5 from individuals saying that they were informed of
 6 a positive result by letter and without a direct
 7 follow-up consultation. So, again, the picture is
 8 a mixed one.

9 In terms of testing for hepatitis C, Dr Lucas,
 10 who has provided a statement to the Inquiry, says he
 11 doesn't have any specific recollection in relation to
 12 hepatitis C testing at the Royal Infirmary but
 13 believes it may have started in 1992 and that a staff
 14 grade doctor would communicate the results to and
 15 counsel patients.

16 You will recall yesterday's evidence from
 17 Dr Bevan that he regarded it as the responsibility of
 18 the consultant to undertake the exercise of informing
 19 both HTLV-III and hepatitis results to the patient.

20 Professor Hay's evidence to the Inquiry, and of
 21 course he was saying that for the most part this was
 22 something he thought had been undertaken before he
 23 arrived at Manchester, he said he thought hepatitis C
 24 testing in Manchester began in 1991, and that much of
 25 it was conducted in 1992.

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1 So if we go to WITN2117003, we can see this is
 2 a letter dated 1 July 1985. If we just see the whole
 3 letter. Just go slightly down. It's from Dr Wensley.

4 "This patient with haemophilia A who gives his
 5 own treatment ..."

6 So presumably on home treatment.

7 "... was reviewed recently in the clinic and he
 8 was given the result of his anti-HTLV-III antibody
 9 test, which was positive. This means that he is
 10 probably carrying the AIDS virus and has perhaps only
 11 a 1 or 2 per cent chance of contracting the disease
 12 himself. I hope shortly to arrange a meeting between
 13 the general practitioners who, like yourself, have an
 14 HTLV-III antibody positive patient and members of the
 15 department who treat haemophilia in the fairly near
 16 future."

17 So that's a test result for someone on home
 18 treatment who's most likely to be, one would have
 19 thought, somebody with more severe haemophilia --
 20 can't rule out there are other categories but that
 21 seems to be the likeliest -- and being given their
 22 result only in the middle of 1985, and at what looks
 23 like it might have been a regular appointment rather
 24 than any kind of specially arranged appointment.
 25 Although, again, that's perhaps a matter of inference

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1 Again, we have a few examples of letters that
 2 provide a little by way of dates, but your best
 3 evidence, sir, may well be, again, the evidence of
 4 individual patient witnesses or their family members.

5 If we look at WITN3289010, and we go to the
 6 next page, we can see that this is a letter,
 7 June 1983, and if we just zoom in on the passage
 8 relating to the hepatitis C result, this is a letter
 9 to a GP:

10 "Your patient is hepatitis C positive by
 11 a second generation test ... probably a chronic
 12 carrier of hepatitis C. There is a slight risk of
 13 [transmission] ... increased risk of long-term liver
 14 disease such as chronic active hepatitis, cirrhosis or
 15 hepatoma ..."

16 So we've got there evidence, clearly, that
 17 testing was still being undertaken in relation to
 18 hepatitis C in the middle of 1993 and you will recall,
 19 no doubt, from some of the oral evidence and the
 20 statements you have read that a number of individuals
 21 have given evidence to the Inquiry that they were
 22 tested for hepatitis C without their knowledge and
 23 only informed of the position afterwards.

24 We don't have either, I'm afraid, a perfect
 25 picture or a complete picture of how many patients

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1 were infected with HIV as a result of their treatment
2 at Manchester Royal Infirmary.

3 If we go to MRCO000388_188, we see this is
4 "Review of main UK cohorts of HIV seropositive cases
5 by NHS region/district and main clinical centres",
6 undertaken by Dr Philippa Easterbrook in July 1987.
7 And if we go to page -- I don't have numbered pages.
8 Try page 17. Yes, that's it.

9 So:
10 "[North] Western Region.
11 "District ... [North] Manchester ..."
12 If you look, sir, at the HIV positive, which is
13 the third column in the table along, and then go down
14 to where it says "Haemophilia Centre", you've got
15 "?100[positive]/180/200".

16 Professor Hay's evidence was that his
17 understanding was that 83 Manchester patients were
18 infected with HIV, of whom 10 were under the age of
19 18, and that 186 were exposed to hepatitis C at some
20 time.

21 So perhaps unsurprisingly, given that this was
22 a very large clinic, a very large number of patients
23 infected with both HIV and hepatitis C.

24 In terms of the treatment of patients with HIV,
25 again, sir, your best evidence is likely to be the

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1 don't have more detail as to what actually was being
2 said in particular about psychosocial and psychiatric
3 implications.

4 We've seen some evidence of the treatment of
5 HIV positive patients being shared between the
6 Manchester centre and other regional centres. There
7 are, for example, interactions between Dr Newsome at
8 Blackburn and Dr Wensley in relation to an HIV
9 positive patient, and their symptoms and their
10 treatment. The extent to which there was specialist
11 treatment rather than haematologists acting, as
12 Dr Bevan put it in his statement, as *ad hoc* HIV
13 specialists is unclear from the documentation, and we
14 certainly see when Dr Lucas took over, in 1992 and
15 1993, he is writing in relation to obtaining funding
16 for HIV drugs and talking in brief terms about the
17 treatment policy with respect to AZT in a way which
18 suggests that was certainly something in which the
19 haematologists had substantial involvement.

20 In relation to the treatment and care of
21 patients with hepatitis. From December '94 onwards,
22 we've got the evidence of Professor Hay, which I won't
23 repeat, and of course we have the evidence of the
24 multiple patients treated or diagnosed with
25 hepatitis C at Manchester.

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1 accounts of the patients who were themselves infected
2 as to how they were subsequently treated and what
3 medications and other treatments they received.

4 If we go to BPLL0002215 and go to the second
5 page, this is the programme for a course that was held
6 in January of 1988 at Manchester. We don't
7 unfortunately have any detail about the contents of
8 the course but we can see that information was being
9 provided as to the present UK situation. That's said
10 to be by Dr Peter Jones. There's said to have been
11 a presentation by Dr Gunson, "How safe are blood and
12 blood products?" Dr Pinching, on "New approaches to
13 therapy", and then, under the chairmanship of
14 Professor Bloom, in the afternoon, a session on
15 counselling the patient, their sexual partner, the
16 child and his parents by, respectively, Dr Kernoff,
17 Dr Morgan and Dr Evans (Dr Evans was the Manchester
18 Children's Hospital), and a discussion of "Insurance"
19 and "Psychosocial and psychiatric implications of HIV
20 infection" by Dr Catalan, who I think was based in
21 Oxford.

22 Then if we go to the next page, we can see
23 reference there to the AIDS treatment centre as
24 a topic, and then a closing session entitled, "An
25 uncertain future?" It's unfortunate, perhaps, that we

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1 There is -- I think perhaps we'll go to the
2 letter.

3 If we go to an October 1990 letter -- just give
4 me a moment while I get the reference. WITN1577008.
5 Go to the next page. We'll see there -- again, this
6 is in relation to an individual patient. This
7 October 1990. It is a letter from Dr Wensley,
8 although the signature for some reason appears at the
9 top rather than the bottom of the letter. It refers
10 to a referral to Dr Warnes in connection with the
11 chronic liver problem and the possible of
12 participating in a study of interferon that Dr Warnes
13 was carrying out, and there is a detailed letter --
14 I won't take you to it -- setting out the outcome of
15 the referral. So it would appear there is hepatology
16 involvement to some extent at least.

17 If we -- sorry, Dr Lucas' statement to
18 the Inquiry was to the effect that patients with
19 hepatitis C who showed a deterioration in liver
20 function or developed features of chronic liver
21 disease would be referred to a hepatologist.

22 It does appear that there may have been funding
23 issues in relation to the treatment of haemophiliacs
24 with hepatitis C in the Manchester area. So if we go
25 to DHSC0002545_070, we have a letter from Dr Lucas to

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1 the Chief Medical Officer of the North West Regional
 2 Health Authority in September 93:
 3 "Chronic Hepatitis C Infection in
 4 Haemophiliacs.
 5 "I thought I should write to you to flag out
 6 a health issue which relates to the past treatment of
 7 Haemophilia. This is a potential litigation issue and
 8 (almost inevitably) the treatment involved is
 9 expensive.
 10 "As a result of treatment with non-heat-treated
 11 blood products prior to 1985, many Haemophiliacs
 12 developed clinical jaundice or deranged liver function
 13 tests, not associated with serological evidence of
 14 hepatitis A or ... B ('non-A, non-B hepatitis').
 15 Recent technological advances have identified a new
 16 virus, hepatitis C, for which serological screening
 17 tests are available. We have been screening our
 18 Haemophilia population and I can give you a break-down
 19 of our results so far."
 20 You can see there set out 113 out of 162 of
 21 hepatitis C positive patients, and then it sets out
 22 the number who have deranged liver function tests, at
 23 the number who are also HIV positive is 48 as at that
 24 stage.
 25 If we go over the page, he says this:

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1 the long-term benefits of such treatment with Alpha
 2 interferon remains unproven."
 3 He refers to biopsies prior to treatment with
 4 interferon and the costs associated with that.
 5 And then at the bottom of the page says that:
 6 "From discrete sounding out of The Haemophilia
 7 Society, I think it is very likely that they will
 8 start to campaign in the relatively near future for
 9 compensation for hepatitis C infection and also for
 10 its active treatment."
 11 Over the page he says:
 12 "In view of this, I feel that it is vital that
 13 the problem is actively managed. I would find it
 14 extremely valuable if a Regional Policy or consensus
 15 statement could be formulated, enabling me, for
 16 example, to approach purchasers for the
 17 not-inconsiderable costs."
 18 Then in his statement Dr Lucas said the purpose
 19 of this letter was to make clear his feeling that
 20 there was a need for a national or at least regional
 21 policy for the management of hepatitis C infection
 22 caused by the use of infected blood products. He
 23 doesn't recall receiving a response to this, and then
 24 he ceased to be acting director the following year.
 25 **SIR BRIAN LANGSTAFF:** Just going back to the first page,

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1 "To summarise the problem, therefore,
 2 approximately 70 per cent of Haemophiliacs are
 3 hepatitis C positive C antibody positive, as a result
 4 of hepatitis C infection transmitted by blood products
 5 before 1985."
 6 Then he refers to a third having deranged liver
 7 function and he mentions one patient having received
 8 a liver transplant and two others both HIV positive
 9 dying of liver failure.
 10 "There is genuine uncertainty about the natural
 11 history of hepatitis C infection and its best
 12 management."
 13 Talks about long-term studies.
 14 "... the probability of developing clinical
 15 liver failure among those who survive for 15 years
 16 after hepatitis C infection is about 20 per cent. The
 17 experience of colleagues (and my own experience)
 18 suggests that this risk is considerably higher where
 19 there is concomitant HIV infection.
 20 "There is considerable uncertainty about the
 21 best management of patients with hepatitis C
 22 infection."
 23 And then he talks about an editorial advocating
 24 interferon and then says this:
 25 "This editorial, however, makes it clear that

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1 if we may. And the second page, please. Thank you.
 2 The third paragraph there:
 3 "Long-term studies appear to suggest that the
 4 probability of developing clinical liver failure among
 5 those who survive for 15 years ... is about
 6 20 per cent."
 7 So this is talking about a chronic hepatitis
 8 which after 15 years creates a 1 in 5 risk of clinical
 9 liver failure, which is very similar statistically,
 10 I think, to our own figures that our own expert group
 11 advised us was the case in hepatitis C infection,
 12 which would suggest that after 40 years there's
 13 60 per cent.
 14 **MS RICHARDS:** Yes.
 15 **SIR BRIAN LANGSTAFF:** It's the same -- if it's pretty much
 16 a straight progression after the first few years then
 17 you've got that sort of rate. What is interesting to
 18 me is that this is being said in September 1993.
 19 **MS RICHARDS:** Yes.
 20 **SIR BRIAN LANGSTAFF:** So anyone being advised about their
 21 infection in Manchester might have expected to be
 22 given to understand that if they'd passed the
 23 six-month period and were infected, so far as could be
 24 told, and tested positive, that there was this serious
 25 growing problem.

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1 **MS RICHARDS:** Yes.
 2 **SIR BRIAN LANGSTAFF:** Yes.
 3 **MS RICHARDS:** Yes, and you will wish no doubt to consider
 4 the evidence both in the form of written statements
 5 from individual patients, and from their records, as
 6 to the extent to which that was information and advice
 7 that was provided to them. More generally, on
 8 a national stage, you've heard lots of evidence of
 9 patients being told it wasn't very much to worry
 10 about.
 11 **SIR BRIAN LANGSTAFF:** That's why I draw attention to the
 12 particular date.
 13 **MS RICHARDS:** Yes.
 14 **SIR BRIAN LANGSTAFF:** Yes.
 15 **MS RICHARDS:** We also see, if we look at WITN0010007 and
 16 go to the third page of that, this is a letter,
 17 November 1993, from Dr Lucas and I'm just picking it
 18 up in the last five lines, he talks about what
 19 Dr Lucas' policy is:
 20 "... my current policy is to observe, checking
 21 liver function once or twice a year, and to consider
 22 a referral for some form of treatment such as
 23 Interferon therapy if there should be significant
 24 signs of deterioration."
 25 Then he says, in my relation to the individual

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1 it was reported in the local papers."
 2 So that's September 1991, and there's a brief
 3 reference to the same issue the following year,
 4 HCDO0000443. I will just look at the date, first of
 5 all. So 10 February 1992, the same committee meeting.
 6 If we go to page 6, and we zoom in on "AIDS in
 7 Haemophiliacs", halfway down that paragraph:
 8 "Dr Mayne asked if an agreed formula of working
 9 for death certificates should be considered. Dr Lucas
 10 said he would welcome the agreed policy; the Coroner
 11 always wanted an inquest in the Manchester area."
 12 Sir, I draw attention to that because we are
 13 seeing, as indeed we see from this, a variable
 14 practice across the country. By way of example, here
 15 in Newcastle it's said HIV [was] never put on the
 16 certificate but they made sure the coroner knew about
 17 it.
 18 Then, as I mentioned, this morning, Dr Wensley
 19 was known to have a particular interest in
 20 cryoprecipitate, and if we just look at -- we don't
 21 need to look at the document but, by way of example,
 22 in 1976 he was asked to join a working party to look
 23 at the quality of cryoprecipitate prepared at Regional
 24 Transfusion Centres, and he participated in that and
 25 various reports were produced by that working party.

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1 patient:
 2 "I would like to see him again in six months'
 3 time."
 4 So that is Dr Lucas's contemporaneous statement
 5 of his policy.
 6 Then, sir, moving to a slightly separate topic,
 7 the issue of what was recorded on death certificates.
 8 There are a couple of documents on the issue of
 9 inquests. If we go to HCDO0000441, please. So this
 10 is a meeting of UK Regional Haemophilia Centre
 11 Directors Committee, September 1991, and we can see
 12 that Dr Wensley was present. If we go to page 7,
 13 please, Soumik, and we go to the bottom of the page,
 14 there's an early discussion about what should be
 15 written on the death certificate, and then at the
 16 bottom of the page:
 17 "Dr Hay said that there had been some problems
 18 with the bereaved relatives who were keen that HIV
 19 should not be mentioned on the death certificate, even
 20 though the death was HIV-related and he would
 21 appreciate guidance about this. Dr Wensley said that
 22 the Manchester Coroner wished to know if a death was
 23 HIV-related. He was strict on this point and as
 24 a consequence all of the Manchester cases had
 25 autopsies. The press was usually at the inquest and

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1 If we go to one such report at CBLA0000880, if
 2 we go to the second page, we see "Report of a Working
 3 Party of the Regional Transfusion Directors
 4 Committee", and the members of that include Dr Gunson
 5 and Dr Wensley. Then if we go two pages further on,
 6 and we look at the first paragraph on the page:
 7 "Despite the increasing use of lyophilised
 8 Factor VIII concentrates for the treatment of
 9 haemophilia A, Factor VIII in cryoprecipitates
 10 prepared from single units of donor plasma still
 11 remains an important therapeutic substance."
 12 So that's the view being expressed by that
 13 committee as at the end of 1978.
 14 There is then, if we look at HSOC0010549 -- we
 15 have looked at this once before, but this is minutes
 16 of Haemophilia Centre Directors meeting,
 17 November 1978, and if we go to page 13, I think --
 18 yes, there's a discussion about the production of
 19 cryoprecipitate and in the second paragraph we see
 20 Professor Stewart saying:
 21 "... a lot of cryoprecipitate still was used in
 22 the UK and Directors would prefer to use the
 23 concentrates rather than the cryoprecipitate. He
 24 wondered what the relevant cost was ...
 25 "Dr Wensley said that it should be possible to

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1 make cryoprecipitate averaging 125 units per pack.
 2 There were technical problems in making the
 3 concentrates and he would suggest that the Department
 4 should wait at the moment before embarking on a policy
 5 of turning over entirely to concentrates."
 6 Then if we go over to the next page, second
 7 paragraph, I think we looked at this with
 8 Professor Tuddenham. Professor Tuddenham talked about
 9 the cost of cryoprecipitate being not dissimilar to
 10 the cost of commercial concentrate and Dr Wensley
 11 here, on the other hand, estimating that the cost of
 12 making cryoprecipitate was about one-third of the cost
 13 of making concentrates.
 14 Then his contribution to that meeting may
 15 reflect the fact that he was closely involved in the
 16 Regional Transfusion Centre's actual manufacture of
 17 cryoprecipitate, and he's described by Dr Gunson in
 18 a document we looked at earlier, I won't go back to
 19 it, as "having devised a semi-automated method for
 20 producing high-quality cryoprecipitate on which the
 21 patients in the region derived considerable benefit".
 22 This appears to be a product developed as
 23 between Dr Wensley and a commercial organisation
 24 called the Factor-Eightor. If we go to
 25 SBTS0000310_159, this is a letter from a company

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1 "The use of cryoprecipitate in the treatment of
 2 Haemophilia A ... is declining in England and Wales in
 3 favour of lyophilised Factor VIII concentrate.
 4 However, cryoprecipitate is the first stage raw
 5 material from which lyophilised Factor VIII is
 6 eventually prepared. Improvements in cryoprecipitate
 7 Factor VIII yield discovered during small-scale
 8 manufacture can sometimes be incorporated in practice
 9 into the large scale manufacturing process.
 10 "Cryoprecipitate is simple and economical to
 11 produce. What is it being used for at present?"
 12 Then there's a table with indications for cryo:
 13 von Willebrand's, mild haemophilia, haemophilia
 14 carriers, congenital afibrinogenaemia, et cetera,
 15 et cetera, then "Source for Freeze-drying":
 16 "Freeze dried cryoprecipitate is presently
 17 being produced at the Glasgow and Dublin Blood
 18 Transfusion Centres.
 19 "What conditions are necessary to obtain the
 20 best yield of Factor VIII clotting activity in
 21 cryoprecipitate?"
 22 Then a number of variables are listed on the
 23 next page.
 24 Then he says underneath that list:
 25 "In Manchester we find that the demand for

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1 Pritchard Laboratory Refrigeration, specialist in
 2 ultra-low temperature refrigeration, September 1980,
 3 "Increased Yields of Factor VIII". It's addressed to
 4 Dr Cash at SNBTS:
 5 "We take great pleasure introducing the PLR
 6 Factor-Eightor a unique British product developed in
 7 cooperation with Dr Wensley at the Manchester Blood
 8 Transfusion Centre.
 9 "The Factor Eightor will significantly increase
 10 the yield of Factor VIII as cryoprecipitate from human
 11 plasma, at the same time eliminating the hazardous and
 12 costly methods of production at present in use."
 13 That's the sales pitch for it but we have
 14 Dr Wensley's description at a 1981 symposium.
 15 NHBT0027395_008.
 16 So we can see the date there,
 17 26 September 1981, a symposium on "Aspects of Blood
 18 Component Production in the Regional Transfusion
 19 Centre". Then if we go to the next page, you can see
 20 it's said:
 21 "The following information has kindly been
 22 given to us by Dr Wensley from the Biotest Fifth
 23 Symposium [in] Edinburgh ..."
 24 Then we have an account of his paper, so
 25 halfway down the page it says this:

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1 cryoprecipitate is decreasing as more haemophiliacs
 2 are converted from hospital out-patient
 3 cryoprecipitate Factor VIII therapy and join our home
 4 treatment programme. This employs lyophilised
 5 Factor VIII concentrate for which the demand continues
 6 to rise and there is a reciprocal decline in
 7 cryoprecipitate usage.
 8 Then he talks about cryoprecipitate yields in
 9 Manchester cryoprecipitate. Then he goes over the
 10 page and says, top of the page:
 11 "Cryoprecipitate production employs four
 12 essential stages plasma separation, plasma freezing,
 13 thawing of the plasmas and final centrifugation to
 14 harvest the cryoprecipitate. We have automated the
 15 two middle stages of freezing and thawing of the
 16 plasma and have devised an automatic freeze-thaw
 17 cabinet, the Factor Eightor."
 18 Then he describes that and then in the fourth
 19 paragraph on this page, if we go down a little
 20 further:
 21 "In conclusion cryoprecipitate can be produced
 22 simply and cost effectively and in its freeze-dried
 23 form should be suitable for self-administration in
 24 home treatment programmes. The yield of
 25 cryoprecipitate Factor VIII from a given amount of

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1 starting plasma is about twice that of lyophilised
2 intermediate Factor VIII concentrate. I believe that
3 countries which are planning for complete
4 self-sufficiency in Factor VIII supplies should
5 consider the advantages of employing cryoprecipitate
6 manufactured by the automated system described above."

7 What happened to the Factor Eightor we've not
8 yet got to the bottom of. In terms, more generally of
9 the use of cryoprecipitate and, in particular,
10 Dr Wensley's views as to the benefit of
11 cryoprecipitate and the ability to produce
12 cryoprecipitate simply and economically, you may find
13 his observations instructive.

14 Sir, we have included in our note some
15 reference to Dr Wensley's involvement in
16 decision-making, in relation to the blood services and
17 screening tests but, bearing in mind that we're going
18 to be exploring that in significantly greater detail
19 when we look at the blood services later this year, in
20 hearings yet to be scheduled, I'm not proposing to
21 deal with that now.

22 We then come, as the penultimate topic --
23 I note the time, sir, but there's actually only
24 a short amount further to do, so, with your
25 indulgence, I will complete it rather than take

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1 happy to take part but he has already agreed to take
2 part in a study with Armour and he is not sure he will
3 have sufficient case material ...

4 "In order to conduct this study properly and
5 have proper co-ordination ... we should have some
6 further medical help ..." et cetera, and he encloses
7 a suggested protocol, which isn't ultimately
8 a protocol that's used.

9 We've identified in our notes further
10 communication and correspondence about this trial and
11 there are further iterations of a draft protocol for
12 the study. It's not entirely clear, however, on the
13 basis of what we've seen so far the extent to which
14 Manchester patients participated in the study and, if
15 they did, the extent to which that was on a fully
16 informed basis. There is also some evidence to
17 suggest that a trial of heat-treated Koate was
18 contemplated. So there's a draft protocol, for
19 example, in late 1984 provided by Dr Wensley to his
20 local Ethics Committee. So there's clearly some
21 knowledge of heat treatment and heat-treated product
22 in advance of its introduction in 1985.

23 The final topic is in relation to
24 pharmaceutical companies and interrelations with
25 pharmaceutical companies. We've looked at some

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1 a break.

2 Again, we've set out in our note -- under the
3 heading "Research" we've set at information gleaned
4 from documentation in relation to Dr Wensley's
5 involvement and the involvement of patients in
6 a number of trials and research studies.

7 I'm not going to go through most of it. It may
8 however be instructive to look at one document,
9 CBLA0001801. This is a letter, 3 February 1984, from
10 Dr Delamore to Dr Gunson, "Trial of NHS heat-treated
11 Factor VIII concentrate". So we've heard evidence,
12 obviously, from Dr Winter about his use of
13 heat-treated Factor VIII concentrate in advance of
14 1985. We know that that was undertaken at St Thomas'
15 and we have seen evidence for example in relation to
16 Sheffield about involvement in trials. We can see
17 this is a trial of an NHS heat-treated Factor VIII
18 concentrate. There's clearly been some discussion
19 between Dr Delamore and Dr Gunson. It says:

20 "... I have contacted the Haemophilia Reference
21 Centre Directors at Sheffield, Liverpool and Newcastle
22 and I have heard from Liverpool and Newcastle
23 indicating that they would be happy to participate in
24 such a trial. I have also heard from Dr Preston at
25 Sheffield saying that in principle he would be very

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1 interactions between Speywood and Cutter, in
2 particular, and Dr Wensley and Dr Delamore already.
3 If we go to BAYP0000025_062, we can see this is
4 a letter from Dr Wensley to Cutter dated
5 2 November 1984. This picks up on the issue of
6 a possible trial of heat-treated Koate but also shows
7 the broader interactions that Dr Wensley had with
8 pharmaceutical representatives:

9 "Thank you for your recent visit at which we
10 agreed I would put the provisional protocol for the
11 trial of heat-treated Koate [HT] to the Central
12 District Ethical Committee for their approval. This
13 is now underway. We also discussed my October 4
14 letter to you in which I outlined proposals for our
15 future experimental work on Factor VIII stability and
16 level in heparinised plasma and invited Cutter to give
17 us financial support as our local research fund grant
18 has not been renewed."

19 Then he clarifies some points in the letter:

20 "While I asked if financial support for
21 two years might be possible, I would be more than
22 happy to receive support for one year, possibly with
23 an option on Cutter's part to review it for a second
24 year depending upon the results. The direction of our
25 future work has not been settled but it could

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1 certainly be further slanted towards problems of
2 mutual relevance."

3 Then there is a subsequent meeting between the
4 Cutter representative and Dr Wensley and then, if we
5 go to BAYP0000024_086, we can see there reference to
6 a meeting taking place and then a telephone
7 conversation having taken place regarding:

8 "... the provision of maximum support to work
9 on heparin and Factor VIII yield. The outcome of the
10 conversation was that Mr Ted Betham has agreed to the
11 loan of the instrument and free software for 20
12 procedures and not 20 weeks."

13 So there's an offer of loan of equipment sought
14 by Dr Wensley to assist with his research.

15 We've already seen, I think, documentation
16 showing Armour sponsorship of that north-west
17 supra-regional haemophilia meeting. In one of the
18 earlier Cutter documents we've looked at, there's
19 Dr Wensley asking to visit Cutter whilst in the States
20 whilst in the country for a meeting, and there are
21 arrangements or suggestions of arrangements to arrange
22 the hotel and "look after you during your stay". We
23 can see a different type of benefit in another Cutter
24 report at BAYP0000008_189. We can see this is
25 May 1986. If you go to the third page, under the

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1 if testing facilities were available to the Children's
2 Hospital that weren't available to the Manchester
3 Royal Infirmary.

4 Sir, that, for present purposes, is the
5 material I was proposing to show you and those
6 listening in relation to Manchester. Clearly there
7 remain a lot of gaps. It may be that some of those
8 are filled by the discovery of further documents but
9 it is, I think, more likely that there are going to be
10 matters of inference for you, sir, and gaps that may
11 be filled by a thorough consideration of the evidence
12 of individual patients and their families.

13 **SIR BRIAN LANGSTAFF:** And just underscoring what you
14 picked up from the helpful contribution from a Core
15 Participant, what we've been dealing with has been
16 Manchester in the sense of the Manchester Royal
17 Infirmary, although I appreciate that much of your
18 presentation has also dealt with the north-west in
19 general terms because that's where Manchester is.

20 **MS RICHARDS:** Yes, absolutely. We are still to look at
21 the Children's Hospital and the other centres within
22 the north-west region. In particular, there was
23 material that refers to the centres under Dr Lee and
24 Dr Newsome and we'll be looking at those in some
25 detail at least when we do our presentation on all

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1 heading "Bayer Philharmonic Orchestra" those attending
2 at Manchester, Dr and Mrs Wensley, Dr and Mrs Evans,
3 Sister Alex Shaw apparently attending a concert
4 organised by or -- sorry, tickets provided by, it
5 would seem, Cutter. So those are some of the
6 interactions between pharmaceutical companies and
7 clinicians at the Manchester Royal Infirmary that
8 we've identified.

9 Sir, if you just give me a moment because we
10 have been sent, during the course of the afternoon, by
11 a CP a document for our attention. I'm just going to
12 read it, if that's okay. *(Pause)*

13 Yes, I'm grateful. I'm not going to refer to
14 the individual document or seek to put it up on screen
15 because it's not undergone a redaction process, but
16 I think I can refer to the broad trust of it and I'm
17 pretty sure we've seen similar documents in individual
18 evidence.

19 This is a letter, a standard form letter, from
20 the Royal Manchester Children's Hospital from May of
21 1985 which refers to having sent blood samples away
22 for testing, and it would indicate that by the end of
23 May 1985 those tests have come back. We'll obviously
24 look further at this when we look at the Manchester
25 Children's Hospital but it may be thought surprising

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1 other haemophilia centres that haven't hitherto been
2 covered.

3 **SIR BRIAN LANGSTAFF:** Yes. So Manchester Royal Infirmary,
4 that's as far as we go for now anyway.

5 **MS RICHARDS:** Yes.

6 **SIR BRIAN LANGSTAFF:** Tomorrow?

7 **MS RICHARDS:** Tomorrow we have evidence from Dr Shirley.

8 **SIR BRIAN LANGSTAFF:** Yes, and we start at 10.00?

9 **MS RICHARDS:** Yes.

10 **SIR BRIAN LANGSTAFF:** So 10.00 tomorrow and that's when we
11 meet again.

12 **(3.32 pm)**

13 **(Adjourned until 10.00 am the following day)**

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I N D E X

Presentation on Manchester Royal Infirmary 1
Haemophilia Centre by MS RICHARDS

<p>MS RICHARDS: [80] 1/5 1/14 13/22 14/1 14/10 14/14 21/25 22/6 22/15 45/25 46/6 46/19 46/21 51/14 51/22 55/18 55/25 56/2 56/4 56/9 58/10 58/15 79/5 79/17 79/21 87/8 87/12 87/14 88/6 88/8 88/13 88/16 88/18 88/21 101/1 101/18 101/22 102/10 102/18 106/17 106/24 107/1 107/7 107/22 107/25 109/9 110/1 110/6 113/11 113/14 114/3 116/3 116/8 117/15 118/5 118/8 118/13 118/21 118/23 120/19 124/19 128/6 128/11 128/17 129/7 129/11 131/9 133/12 133/19 133/23 144/14 144/19 145/1 145/3 145/13 145/15 159/20 160/5 160/7 160/9</p> <p>SIR BRIAN LANGSTAFF: [82] 1/3 1/6 13/20 13/23 14/6 14/11 21/12 22/3 22/14 45/21 46/2 46/11 46/20 51/9 51/21 55/15 55/23 56/1 56/3 56/6 58/9 58/14 78/25 79/10 79/20 87/3 87/9 87/13 88/2 88/7 88/9 88/14 88/17 88/19 100/18 101/2 101/19 102/9 102/13 102/17 106/6 106/19 106/25 107/6 107/20 107/23 108/20 109/10 110/5 113/6 113/13 113/23 116/1 116/7 117/7 118/2 118/6 118/12 118/19 118/22 120/18 124/18 128/1 128/7 128/13 129/4 129/8 131/7 132/23 133/17 133/20 143/25 144/15 144/20 145/2 145/11 145/14 159/13 160/3 160/6 160/8 160/10</p> <p>'65 [1] 101/8 '65/66 [1] 101/8 '84 [2] 68/6 79/14</p>	<p>'85 [3] 79/2 116/2 116/13 '94 [1] 139/21 'almost [1] 67/1 'be' [1] 77/4 'bridging [1] 8/21 'clean' [1] 100/2 'donor [2] 86/4 86/19 'Hemofil' [1] 123/6 'non [1] 141/14 'non-A [1] 141/14 'patients [1] 130/5 'use [1] 38/6 'virgin' [1] 67/6 'World [1] 123/7</p> <p>... [2] 42/22 66/15</p> <p>/</p> <p>/180/200 [1] 137/15</p> <p>0</p> <p>001 [4] 28/5 84/2 105/12 127/6 002 [1] 88/21 003 [2] 54/11 91/23 004 [1] 64/10 008 [1] 150/15 010 [1] 63/14 011 [2] 60/17 81/7 012 [2] 65/9 78/4 013 [2] 58/18 58/19 014 [1] 59/15 015 [1] 40/21 020 [1] 129/16 029 [1] 8/2 037 [1] 25/9 043 [3] 114/4 116/11 116/12 048 [1] 85/6 062 [1] 156/3 066 [1] 81/14 070 [2] 68/3 140/25 074 [1] 104/16 086 [1] 157/5 092 [1] 16/2</p> <p>1</p> <p>1 April [1] 39/16 1 April 1983 [1] 39/19 1 April 83 [1] 42/14 1 February 1985 [1] 129/17 1 July 1985 [1] 134/2 1 per cent [1] 111/17 1 September 1982 [1] 36/23 1,000 [1] 39/21 1,021,945 [1] 64/18 1,330 [1] 39/21 1,500 [1] 39/14</p>	<p>1,520 [1] 55/9 1.00 pm [1] 25/6 1.5 [1] 35/7 1.6 million [1] 35/8 10 [3] 91/2 97/10 137/18 10 December [1] 75/6 10 December 1982 [1] 107/21 10 December 1984 [2] 73/14 104/9 10 February 1992 [1] 147/5 10 January [1] 70/17 10 March 1985 [1] 71/20 10,000 [1] 40/1 10.00 [4] 1/2 160/8 160/10 160/13 100 [3] 1/8 55/21 137/15 100 per cent [1] 20/21 100,000 [3] 30/2 35/9 43/1 101 [1] 18/10 104 [1] 62/11 108 [1] 17/4 11 [1] 97/6 11,000 [1] 52/22 11.20 [1] 58/11 11.50 [1] 58/9 11.52 [1] 58/13 113 [1] 141/20 12 March 1969 [1] 16/5 12.58 pm [1] 102/14 125 [1] 149/1 127,249 [1] 64/20 13 [3] 66/18 97/4 148/17 13 January 2021 [1] 1/1 13,860 [1] 63/24 135,000 units [1] 78/19 139 [1] 54/25 14 [2] 66/7 66/18 14 February [1] 103/2 14 haemophilia B [1] 55/2 14 September 1982 [1] 91/13 140 [1] 63/19 149 [1] 79/21 14th [1] 92/4 15 [1] 112/14 15 February 1983 [1] 38/21 15 January 1985 [1] 73/9 15 July 1987 [1] 119/2</p>	<p>15 years [3] 142/15 144/5 144/8 159 [1] 149/25 16 [1] 66/7 16 April 1969 [1] 18/11 16,000 [1] 39/20 162 [1] 141/20 17 [1] 137/8 17 January [3] 127/20 128/2 128/9 17 January 1985 [1] 127/13 17 March 1973 [1] 8/4 18 [2] 105/13 137/19 18 August 1982 [1] 33/20 18 December 1988 [1] 78/6 18 hours [1] 26/24 186 [1] 137/19 188 [1] 137/3 189 [1] 157/24 1960s [2] 3/5 19/10 1968 [3] 10/9 17/22 84/3 1969 [5] 15/25 16/5 16/24 17/25 18/11 1970 [4] 49/9 49/14 50/6 88/7 1970s [11] 1/17 2/4 5/20 7/21 19/11 51/8 56/14 57/14 57/21 82/22 85/4 1971 [7] 3/9 3/14 19/14 85/12 88/1 88/8 101/6 1972 [3] 51/24 52/25 88/19 1973 [5] 8/4 19/17 19/22 54/4 88/17 1974 [6] 3/15 6/15 10/13 20/12 54/4 56/19 1975 [4] 5/8 9/2 32/13 54/7 1976 [10] 20/1 20/21 22/21 22/22 23/2 49/1 54/9 54/21 122/20 147/22 1977 [4] 20/21 21/11 22/17 88/22 1978 [13] 9/6 9/8 56/23 58/17 58/21 59/16 60/6 60/19 89/11 89/21 90/17 148/13 148/17 1979 [6] 25/8 25/11 26/8 28/1 85/1 90/17 1980 [10] 6/25 28/12 34/20 41/4 41/15 92/18 114/16 131/2</p>	<p>131/16 150/2 1980/81 [4] 31/10 34/25 39/6 41/7 1980s [11] 1/18 2/4 15/18 22/8 38/18 46/23 47/10 82/23 122/1 122/6 132/12 1981 [9] 34/20 35/23 41/8 41/15 61/24 62/5 119/10 150/14 150/17 1981/82 [2] 41/17 41/23 1982 [19] 30/1 32/25 33/20 35/23 36/23 90/25 91/9 91/13 92/4 102/25 104/14 105/18 106/3 107/10 107/19 107/21 109/6 111/11 119/11 1982/83 [3] 35/7 41/20 42/24 1983 [43] 30/1 38/21 39/19 40/8 40/19 40/22 49/1 56/11 63/13 63/16 64/13 65/3 83/6 94/4 103/2 103/6 103/13 103/14 104/1 104/2 104/4 104/17 105/4 106/2 107/17 107/23 107/25 108/1 108/10 108/15 110/19 110/20 110/20 112/14 113/18 119/12 119/15 119/19 120/16 120/16 130/22 131/8 136/7 1983/84 [5] 39/3 41/11 42/2 42/9 45/12 1984 [14] 32/25 65/7 65/20 67/15 67/16 73/14 103/13 104/9 104/15 123/17 123/23 154/9 155/19 156/5 1984/85 [2] 40/5 43/20 1985 [49] 32/13 67/23 68/4 68/20 69/4 70/21 71/20 73/1 73/9 74/2 76/17 78/8 78/10 78/15 78/18 78/21 79/9 79/22 80/16 81/2 94/7 102/23 103/22 114/7 115/5 115/7 125/7 125/9 125/11 127/5 127/13 127/15 128/21 129/15 129/17 131/5 131/8 131/9 131/11 131/24 132/8 134/2 134/22 141/11 142/5 154/14 155/22 158/21 158/23 1985/86 [1] 33/6 1986 [7] 4/4 49/2 81/3</p>	<p>81/8 81/10 81/18 157/25 1987 [3] 118/25 119/2 137/6 1988 [9] 28/12 31/12 77/18 78/6 120/25 121/13 121/18 121/24 138/6 1989 [4] 2/6 3/11 7/13 121/17 1990 [6] 14/22 47/20 48/4 48/8 140/3 140/7 1991 [4] 15/1 135/24 146/11 147/2 1992 [5] 7/15 135/13 135/25 139/14 147/5 1993 [4] 136/18 139/15 144/18 145/17 1994 [4] 1/19 7/16 15/3 48/9</p> <p>2</p> <p>2 November 1984 [2] 65/20 156/5 2 per cent [1] 134/11 2 September 1985 [1] 131/11 2.00 [1] 102/12 2.01 pm [1] 102/16 20 [3] 50/9 157/11 157/12 20 May 1985 [1] 80/16 20 per cent [2] 142/16 144/6 20 September 1979 [1] 25/11 20 years [1] 8/11 20,000 [1] 66/14 200 [2] 52/9 137/15 200 ml [1] 17/5 2021 [1] 1/1 22 [1] 112/14 22 May 1983 [2] 130/22 131/8 22 November 1978 [1] 60/19 22nd October 1976 [1] 23/2 23 November [1] 104/18 230 [1] 80/15 24 [1] 63/20 24 January [1] 108/5 24 January 1983 [1] 103/6 24-hour [1] 12/14 240 [1] 22/16 240 bottles [1] 21/6 25,000 [1] 41/21 25,100 [1] 64/22 250 [2] 20/19 52/22 250 units [1] 66/16</p>
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