

Wednesday, 23 September 2020

(10.00 am)

SIR BRIAN LANGSTAFF: Ms Richards, you are going to deal with knowledge of the risk.

MS RICHARDS: Yes, sir.

SIR BRIAN LANGSTAFF: Today, just so that everyone knows where we will be in terms of timing, because we aren't subject to the witnesses giving his evidence, Ms Richards will have her timing under control, I understand.

MS RICHARDS: I hope.

SIR BRIAN LANGSTAFF: So what we will aim to do is we will aim to finish no later than 4.30. There will be, again, 45-minute breaks in both the morning and in the afternoon. The afternoon probably little bit earlier than it was yesterday to divide up the afternoon rather better. 45 minutes to enable you to have the time to go safely, at distance, to pre-allocated seats for refreshment.

So that's what we will do so you know where you are and what the timing will be.

Ms Richards.

Presentation by MS RICHARDS

MS RICHARDS: So, sir, if I can just start by explaining the purpose of today. Today is the provision of

I should say what today is not: it's not going to be examining in any kind of detail what was known by a particular individual or a particular organisation, or what should have been known by that individual or organisation, nor is it going to be looking in any kind of detail at what was done in response to those risks. Again, that will be material that's explored over the coming weeks and months with witnesses.

We're very grateful to core participants who have suggested additions to the material that's in the chronology. Some of that's been incorporated in today's presentation but we would welcome any continuing suggestions and the chronology can be updated with any additional material that core participants or indeed others think is relevant and can bring to our attention.

So, sir, broadly speaking the presentation falls into four categories chronologically. The first will be looking at the developing knowledge of risk of the transmission, through blood or blood products, of hepatitis from the 1940s through to the 1970s.

The second is to look more particularly at the developing knowledge about non-A non-B hepatitis in the course of the 1970s and knowledge of the

a chronological and historical overview of material relevant to the knowledge of risk of infection from blood and blood products. It will be undertaken by showing contemporaneous materials and those will be drawn from a range of different sources, Government, scientific journals, correspondence, meetings and so on as well as media, and we'll be showing a number of documentaries or documentary excerpts in the course of the day.

The purpose of the presentation is twofold: it's to place relevant material into the public domain. So core participants have already been provided with copies of all the material that will be referred to and with a detailed chronology relevant to this issue, but the purpose of today is to ensure that the material or some key parts of it is shared with those who have not had the opportunity to work through what will be thousands of pages of material, and to ensure that the wider public is enabled to understand what was or was not known at various relevant times.

The second purpose of today is to provide a backdrop to the evidence that's going to be heard from witnesses over the coming weeks and months, from clinicians in the first instance and, in due course, from politicians, civil servants and others.

seriousness of the condition.

The third is then to look at the developing picture in relation to HIV and AIDS in the first half of the 1980s.

The fourth then picks up the picture going up into 1991 in relation to developments, the discovery of hepatitis C and some key dates and documents in relation to that.

I don't propose, for the purposes of this presentation, to look beyond 1991, although clearly the years after 1991 contain much significant material, but those will be explored in later stages of the Inquiry's hearings and vCJD specifically will be the subject of a discrete hearing in due course next year. So I won't be touching on vCJD today.

The other point in relation to timing is I'm not quite sure how long today is going to take. If I don't get through the material that seems most important we'll continue tomorrow rather than sit late before moving on tomorrow to look at the actions of Professor Bloom and the Cardiff Haemophilia Centre.

Sir, there's no single right place to start but I'm going to start in the 1940s with observations of jaundice in army personnel and its relationship to the vaccination against yellow fever.

1 Henry, could we have, please, RLIT0000209.
 2 This is a document entitled "Jaundice in army
 3 personnel in the western region of the United States
 4 and its relation to the vaccination against yellow
 5 fever". It's the second of two papers published in
 6 the American Journal of Hygiene in 1944. The events
 7 to which the paper relates focus on the high
 8 prevalence of jaundice in troops in the spring and
 9 summer of 1942 in circumstances in which the troops
 10 had been vaccinated against yellow fever.
 11 It is a very long article, I am just going to go
 12 to a small number of points from it, but I am very
 13 grateful to core participants who have suggested some
 14 shorter precisés of this issue. I am going to give
 15 a couple of references that don't need to come up on
 16 the screen; it's for the benefit of others who may
 17 want to read about this issue.
 18 There are more recent analyses of this issue at
 19 RLIT0001238, RLIT0001234, and RLIT0001237. Those are
 20 all later documents that look back but I'm focusing,
 21 as I said, today on contemporaneous material.
 22 Henry, could we go, please, to what I think
 23 should be page 39 of the document. I'm sorry, my
 24 apologies, I am using the internal pagination. So it
 25 will probably be page 5 on the documentation you have,

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1 with the yellow fever virus and that it must have been
 2 introduced into tissue cultures in association with
 3 human serum ..."
 4 So that's the key issue here: human serum:
 5 "... presumably derived from a donor who was
 6 either in the incubation period or actually suffering
 7 from a mild subclinical attack of epidemic catarrhal
 8 jaundice."
 9 Then if we could go, please, Henry, to -- I will
 10 try to give you the right references -- page 58 of the
 11 article, which I think might be page 24 of 73. Yes,
 12 that's it.
 13 If we look down the bottom half of the page,
 14 please, so we can then, picking up on what had been
 15 observed in 1942:
 16 "Jaundice in the military forces in the
 17 United States and elsewhere following vaccination
 18 against yellow fever.
 19 "As stated in part 1 of this report, information
 20 was received in March, 1942, that in United States
 21 army personnel there was a considerable amount of
 22 jaundice which appeared to be associated with certain
 23 lots of yellow fever vaccine used for immunisation."
 24 Then, Henry, if you could skip on, please,
 25 because there's a very detailed account of the

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1 thank you.
 2 So we can just pick up here a report in 1937, in
 3 England.
 4 If we look halfway down the page, Henry, if we
 5 see the whole part. Thank you.
 6 "England Post Vaccination Jaundice. In 1937,
 7 Findlay and MacCallum reported that in the course of 4
 8 and a half years they vaccinated approximately
 9 2,200 persons against yellow fever and had observed 48
 10 cases of jaundice occurring from 2 to 7 months after
 11 vaccination."
 12 Then if we look at the right-hand column, Henry,
 13 could you highlight the first 10 or 12 lines of the
 14 second paragraph, beginning "Findlay and MacCallum".
 15 Is it possible to highlight that in yellow so it's
 16 easier for others to read.
 17 Anyway, those who are looking will be able to
 18 see what passage I'm referring to. So it refers to:
 19 "Findlay and MacCallum were firmly convinced
 20 that the jaundice was not caused by the yellow fever
 21 virus itself. In a later report, in 1939, they
 22 analysed in detail the various factors involved in
 23 this episode and came on the conclusion that the
 24 causal agent of the jaundice was a virus that had been
 25 cultivated serially in tissue cultures in symbiosis

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1 investigation, which I won't go to, to pages 54 to 55
 2 of 73 -- it's page 89 of the internal pagination.
 3 Next page.
 4 So if we pick it up under the heading
 5 "Conclusion", towards the bottom of that page:
 6 "It has not yet been possible to demonstrate
 7 conclusively which of the various materials used in
 8 the preparation of yellow fever vaccine actually
 9 contained the agent responsible for the outbreak of
 10 post-vaccination jaundice. However, in view of other
 11 investigations that outbreaks of hepatitis have
 12 followed the injection of human serum alone, and also
 13 that it has been possible to transmit a very similar
 14 disease by direct blood or serum transfer from
 15 patients suffering from infective hepatitis to healthy
 16 volunteers, human serum falls under suspicion much
 17 more definitely than any other substance in the
 18 vaccine."
 19 It's instructive to note, if we go to page 103
 20 if you are using the internal pagination, Henry, or
 21 it's pages 68 to 69, thank you, we see -- if we go
 22 down to the bottom of the page, please, Henry --
 23 "Recommendation", we see that in the course of this
 24 investigation the investigative team in April 1942
 25 made recommendations to the surgeon general of the

1 army to suspend the use of vaccinations in which human
2 serum had been implemented and to use, effectively,
3 different vaccinations and that had the desired effect
4 of stopping the particular attacks of jaundice that
5 had been observed.

6 Could we then turn from America to, still within
7 1942, in the war years, this country and go to
8 DHSC0100008_024, please.

9 We can see this is headed "Emergency Blood
10 Transfusion Services delayed jaundice". It's an
11 internal DHSS document and it's a note of a discussion
12 held in Dr Taylor's room on December 1st, 1942, with
13 a number of doctors in attendance:

14 "Dr Taylor said that recent investigations
15 suggested that blood transfusion might result in
16 delayed jaundice and the meeting had been called to
17 decide whether and how hospitals, maternity units and
18 general practitioners should be informed of the latest
19 developments on the subject and whether any
20 preventative administrative measures were possible."

21 Then Dr Bradley gave an account of the history
22 of the appearance of jaundice believed to be due to
23 the introduction of human serum.

24 We can see from this that going back to the 19th
25 century there had been issues of concern as to the

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1 occurred in England, but it had not been possible to
2 plan any follow up of transfused patients. Not
3 possible to rule out the possibility of natural causes
4 but certain information suggested there might be a
5 distinguishing clinical picture in the case of
6 jaundice caused by the introduction of human serum."

7 Then if we have over the page we can see
8 reference to certain measures having already been
9 taken, discussions with the Medical Research Council,
10 Dr Panton and Dr Proger and the Blood Transfusion
11 Officers:

12 "We are told that the MRC Transfusion Committee
13 had convened a small *ad hoc* subcommittee to enquire
14 into transfusion jaundice."

15 I emphasise this is in 1942.

16 "With the exception of the CMO's reports in '37
17 and '38 on the measles case, none of the known cases
18 had been published but Dr Bradley has now been asked
19 by the CMO [Chief Medical Officer] to publish in The
20 Lancet a memorandum which he had prepared on the
21 subject with a view to bringing it to the notice of
22 blood transfusion officers and general practitioners
23 and urging them to record the batch numbers of
24 transfusion materials used and any cases of jaundice
25 resulting."

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1 connection between human serum and jaundice, so we
2 have 1885 in Bremen 191 cases of jaundice follow the
3 use of humanised lymph. At (2) measles convalescent
4 serum, a batch of serum used on 109 children resulted
5 in 41 cases of jaundice and eight deaths. On another
6 occasion 57 c.c. injected and 14 children gave six
7 cases of jaundice and one death. That was picked up
8 by -- considered by the Chief Medical Officer of the
9 time in the late 1930s.

10 We then have the reference to yellow fever
11 vaccine, reports of jaundice in Brazil, in the
12 American forces -- that's the material we've just been
13 looking at -- reference to convalescent mumps plasma
14 with 87 cases of jaundice. All the above vaccines
15 et cetera contained human serum.

16 Then we have reference to blood transfusion.
17 The first case of jaundice following a transfusion was
18 notified from Wolverhampton; subsequently eight cases
19 of jaundice resulted from 35 transfusions of serum
20 given for peripheral vascular disease.

21 Then it says this --

22 **NEW SPEAKER:** 36 I think.

23 **MS RICHARDS:** I'm sorry, 36, yes apologies:

24 "In all 13 cases of jaundice apparently
25 resulting from transfusion were known so far to have

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1 Then if we just go down to the bottom of the
2 page:

3 "It was agreed that the following action should
4 be taken: (a) Dr Bradley agreed to word his memorandum
5 for The Lancet in such a way as to prevent unnecessary
6 alarm. He would stress the importance of recording
7 the batch number of materials used in transfusion and
8 of reporting cases of jaundice following blood
9 transfusion."

10 There's a reference to general practitioners
11 being asked to report matters to the hospital, and
12 then:

13 "(b) After the publication of this article the
14 Ministry would issue a DGL drawing attention to it and
15 asking hospitals and maternity units to maintain case
16 records, do all that was possible to follow up
17 patients who had been transfused and report any cases
18 of jaundice to the supply depot. The DGL would also
19 stress the importance of making a senior officer in
20 each hospital responsible for transfusions."

21 So it can be seen that at a senior level this
22 was regarded as a significant and important issue in
23 1942.

24 The memorandum that's referred to there that's
25 going to be published in The Lancet we have at

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1 NHBT0000091_011, please, Henry. We can see the date
2 of its publication is January 16, 1943. It's
3 published in The Lancet. The title is "Homologous
4 serum jaundice". It's a memorandum prepared by
5 medical officers of the Ministry of Health.

6 I won't go through the detail of it but if we
7 could turn, please, to -- it should be the fourth
8 page, Henry -- that's the one. We can see a heading
9 towards the bottom on the left-hand column,
10 "Transfusion hepatitis". Reference is made to various
11 incidents and then if we can pick it up on the
12 right-hand column, Henry, the paragraph beginning,
13 "The appearance of this phenomenon ..." I don't know
14 whether it's possible to highlight that. It's about
15 the fifth paragraph down, please:

16 "The appearance of this phenomenon [that's the
17 hepatitis jaundice appearing after some form of
18 receipt of human serum] was anticipated at the
19 Ministry of Health where information had previously
20 been received of another grave case of jaundice
21 following whole blood and plasma transfusion ... on
22 August 13, 1942, a meeting of the principal blood
23 transfusion officers was called to inquire, *inter*
24 *alia*, whether this was an isolated case or whether
25 transfusion was more frequently followed by hepatitis.

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1 now however, evident: any doubt as to the reality of
2 the association is removed by the frequency with which
3 hepatitis has followed the injection of human blood
4 products. The probability that further cases will
5 occur, particularly after transfusion, must be faced."

6 So that's The Lancet, Ministry of Health
7 publication, 1943.

8 Can we then please have up on screen, Henry,
9 DHSC0100008_051, please. It's not the easiest
10 document to read. I have a handy translation. It's
11 entitled, "Prevention of homologous serum jaundice
12 memorandum to MRC Jaundice Committee on administrative
13 and field aspects". It's authored by Dr Bradley. The
14 date is 20 June 1944. There are just a couple of
15 passages to read from this.

16 In the foreword, so this is the first paragraph:

17 "The observation that hepatitis may result from
18 injection of homologous serum after a long interval
19 has now been confirmed beyond doubt. At the present
20 time, transfusion with pooled dried serum appears to
21 be the source of greatest anxiety, although
22 comparatively small quantities of this product have
23 been used. With the greater use of transfusion in the
24 treatment of battle casualties [pause to observe,
25 obviously this is still during the Second World War]

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1 It transpired that not until August 12 did the cases
2 in the EMS hospital [that is the particular cases that
3 are being looked at in part of the memorandum] come to
4 the notice of the transfusion officers. Since then
5 the condition has been observed at three other
6 hospitals. The total of known cases following
7 transfusion is now 12. It must, however, be
8 remembered that no systematic follow up of transfused
9 patients has been attempted and that since an
10 association between transfusion and late jaundice is
11 unlikely to be recognised spontaneously, it is not to
12 be expected that such remote sequelae would be brought
13 to the notice of the blood transfusion officers."

14 Then this sentence:

15 "For this reason it cannot be assumed that whole
16 blood is innocent or that plasma is likely to be less
17 icterogenic than serum."

18 If we go two pages further on to the last page,
19 please, Henry, under the heading "Comment", this
20 Ministry of Health memorandum concludes as follows:

21 "The examples of homologous serum jaundice
22 collected in this paper make it clear that the subject
23 is one of major importance. Our understanding of the
24 mechanism has not advanced since 1937 when measles
25 serum jaundice was first described. One conclusion is

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1 a corresponding increase in jaundice may be expected.
2 The problem of serum jaundice is not only an immediate
3 one but may become of increasing importance as the use
4 of dried human serum in therapeutics is developed."

5 Then if we go down to paragraph (d) at the
6 bottom of the first page there's a discussion of the
7 relationship between homologous serum jaundice and
8 epidemic hepatitis and a reference to the yellow fever
9 vaccine jaundice investigations. Then it says this:

10 "By comparison with the estimated mortality of
11 epidemic hepatitis fatalities from homologous serum
12 jaundice have been disproportionately numerous."

13 Then if we go over the page, please, to
14 paragraph(f) on page 2:

15 "There is a strong suspicion that the severity
16 of hepatitis varies with different batches of serum.
17 Some kill and others produce relatively mild disease.
18 It is also probable that serum hepatitis occurs
19 without jaundice and that some patients may remain
20 ambulant and uncomplaining."

21 Then we see under the heading administrative
22 control, and again I emphasise this is in the 1940s:

23 "Although medical measures for the control of
24 serum jaundice must wait on further knowledge
25 concerning the nature of the jaundice producing agent

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1 and how to remove it, much can be done in the way of
 2 prevention, without this knowledge by (a) avoiding
 3 unnecessary transfusion. At the present time serum
 4 transfusion should be reserved for life-saving
 5 procedures only; (b) restricting the size of pools",
 6 then a number of other matters about records, sampling
 7 and so on.

8 Then top of the next page, this is still within
 9 the list of suggested administrative preventative
 10 measures:

11 "As far as possible transfusing any individual
 12 patient with serum from one pool only."

13 Then (g):

14 "Taking greater care to exclude blood from
 15 persons suffering from hepatitis on the assumption
 16 that serum jaundice is simply transmission by unusual
 17 routes of the agent of epidemic hepatitis."

18 If we go to the penultimate page, please, next
 19 page, next page, next page, last but one page, please,
 20 that's it, could we have the second paragraph
 21 highlighted, please:

22 "It is our duty to follow up and study serum
 23 jaundice just as we should follow-up any other
 24 communicable condition. Knowledge will come quickly
 25 only if the collection and collation of information is

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1 concerned for the future because blood products will
 2 continue to be used in civilian practice after the war
 3 and it would appear that the present experience
 4 amongst battle casualties provides an opportunity,
 5 which is unlikely to recur, for obtaining further
 6 information."

7 The documents to which he refers, the reports,
 8 I won't bring up, but they are all in the chronologies
 9 and the material that is disclosed to core
 10 participants.

11 Then we see -- if we have, please, Henry --
 12 DHSC0100008_105, we can see that there is then what
 13 would appear to be, from the participants, a fairly
 14 high level conference held at the Ministry of Health
 15 on 26 March 1945. The title of the meeting or the
 16 notice: "Jaundice Following Transfusion". We can see
 17 present the Chief Medical Officer, a number of senior
 18 officials within the armed services, representatives
 19 of the Blood Transfusion Services, including Dr
 20 Panton, to whom the previous letter was addressed, and
 21 representatives of the Ministry of Health, including
 22 Dr Bradley, who had been the author of one of the
 23 documents that we looked at earlier.

24 We can see here, on the first page:

25 "Sir William Jameson told the meeting that the

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1 deliberate and purposeful. We should evolve
 2 a carefully proposed plan, and provide adequate
 3 facilities for it to be carried out."

4 Then we see there Ministry of Justice (*sic*)
 5 20 June 1944.

6 **SIR BRIAN LANGSTAFF:** I think it is Minister of Health.

7 **MS RICHARDS:** Yes, Ministry of Health.

8 **SIR BRIAN LANGSTAFF:** Yes.

9 **MS RICHARDS:** Then, please, Henry, if we could have --

10 **SIR BRIAN LANGSTAFF:** Just pausing there for a moment so
 11 that most people will know I think that homologous
 12 means from human beings as opposed to from somewhere
 13 else.

14 **MS RICHARDS:** Yes. Yes, it's essentially the association
 15 between human serum and hepatitis that is the focus of
 16 all of these documents in the 1940s.

17 We then have, please, Henry, DHSC0100008_095.
 18 This is a letter dated 21 March 1945 -- April has been
 19 crossed out and March added. It's from -- could we
 20 have the whole document, sorry, Henry. It is from the
 21 Chief Medical Officer W Wilson Jameson and it says
 22 this:

23 "Dear Panton, homologous serum jaundice, I have
 24 received reports, attached, that hepatitis with a high
 25 fatality is frequently following transfusion. I am

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1 Ministry of Health proposed to attempt to carry over
 2 into peace-time something of the transfusion
 3 arrangements that had been in operation during the
 4 war. Unfortunately, it was beginning to appear that
 5 a large number of transfused persons subsequently
 6 developed jaundice and some died. He quoted
 7 Dr Stocks' figures culled from pensions records and
 8 death certificates. Although this serious
 9 complication might pass without comment in war-time,
 10 it would seriously handicap peace-time administration.
 11 Information concerning this puzzling condition was at
 12 present being collected independently by several
 13 persons and he was anxious to establish an orderly
 14 system of accumulating and using the information."

15 Then if we could go to the third page, please,
 16 Henry, we can see halfway down the page, if we just go
 17 down a bit further:

18 "The Chief Medical Officer, summing up, said
 19 that, although the accounts given were somewhat
 20 contradictory [and the accounts had been from various
 21 different military and other personnel attending the
 22 meeting], there was some reason for believing that
 23 hepatic jaundice may follow blood transfusion and that
 24 some transfused persons died of hepatic necrosis but
 25 the position was not clear. Nothing definite had so

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1 far been learnt from laboratory work and he hoped that
 2 epidemiological study might add something useful.
 3 This required a good system of recording and a free
 4 interchange [that should be interchange] of
 5 information."
 6 Then if we go to the fourth and final page
 7 please, Henry, just under the heading "Propaganda":
 8 "It was agreed that nothing which might cause
 9 public alarm or discourage transfusion in necessitous
 10 cases should be done. The Chief Medical Officer
 11 suggested that sometimes transfusions were performed
 12 unnecessarily and that it might be wise to send some
 13 publication to institutions. Dr Drury suggested, and
 14 it was agreed, that the opinions of regional
 15 transfusion officers on this matter should first be
 16 sought at a meeting to be held on 5 April 1945."
 17 Then, again still in the 1940s, if we could go
 18 to DHSC0100008_254, please, Henry, not going to go to
 19 the detail of these articles but just to note in terms
 20 of broadcasting to the wider medical profession what
 21 thus far has been to some extent conversations held
 22 internally within the Department of Health and with
 23 the armed forces, what we have here are three
 24 articles: Homologous Serum Jaundice; Homologous Serum
 25 Hepatitis; Two Cases of Homologous Serum Jaundice. We
 21

1 hepatic necrosis was greater than the risk incurred by
 2 withholding transfusion. Records of blood products
 3 issued from the northwest London area since 1940 being
 4 available, a follow-up of patients who had received
 5 transfusions in this area was, therefore, instituted
 6 in 1944 with a view to determining the incidence of
 7 homologous serum jaundice following transfusion, its
 8 incubation period and the symptomatology."
 9 The article then sets out the figures from that
 10 particular follow-up. We'll see, if we look at the
 11 third page, it's in relation to the findings of this
 12 report.
 13 Go -- right-hand column, Henry, just the
 14 paragraph above the heading "Summary", please.
 15 What this study found was that:
 16 "The character of the jaundice in the 77 cases
 17 here recorded was, with one exception, mild."
 18 It says:
 19 "This is in accord with the majority of other
 20 observers, but it must not be forgotten that a
 21 definite mortality after both transfusion jaundice and
 22 syringe jaundice has been noted."
 23 Also relevant to note, from the 1940s still, in
 24 1947, was the identification of higher risks
 25 associated with pooling of blood donations and we'll

1 can see they're printed from the proceedings of the
 2 Royal Society of Medicine in August 1946.
 3 Again, without going into the detail, if we can
 4 have up on the screen, Henry, RLIT0000052, we now have
 5 a publication in the British Medical Journal. This is
 6 September 1946. It's an article headed "The
 7 incidence, incubation period, and symptomatology of
 8 homologous serum jaundice", by Spurling, Shone and
 9 Vaughan and we can see here in the introduction it
 10 says:
 11 "Jaundice has been recognised with increasing
 12 frequency as a sequela of transfusion with whole
 13 blood, plasma or serum."
 14 Reference is made, amongst other things, to the
 15 Ministry of Health memorandum that we have looked at.
 16 "It's generally agreed that such jaundice is
 17 indistinguishable from, and of the same aetiology, as
 18 the jaundice following the use of convalescent serum,
 19 vaccines containing human serum and syringes
 20 contaminated with human blood. This jaundice is
 21 commonly called homologous serum jaundice.
 22 "Since certain of the cases reported after
 23 transfusion have proved fatal, it appeared important
 24 to determine if possible the incidence of this
 25 complication since it might well be that the risk of

1 go to just one document in that regard.
 2 Henry, it's RLIT0000054, please.
 3 We can see this is an American article,
 4 Homologous serum jaundice in recipients of pooled
 5 plasma". It's published in October 1947 by Brightman
 6 and Korns and I will just pick it up with the first
 7 paragraph:
 8 "The ready availability of pooled plasma,
 9 whether secured through commercial channels, state
 10 departments of health or local blood bank programs,
 11 has been a boon to medical practice. However, the
 12 fact that plasma may carry a virus capable of inducing
 13 hepatitis in the recipient has created a new public
 14 health problem of major importance."
 15 If we then go on, please, Henry, to the fourth
 16 page of this document, left-hand column under the
 17 heading "Comment" -- just scroll down -- so,
 18 "Comment":
 19 "A follow-up investigation of a large series of
 20 persons who received transfusions with pooled plasma
 21 has indicated that this form of therapy carries
 22 a significant risk of a serious and possibly fatal
 23 complication."
 24 Then figures in relation to upstate New York are
 25 provided.

1 Then if we go to the next page, please, Henry,
 2 under the heading "Summary", I will just read this:
 3 "1. Follow-up of 649 patients who received
 4 transfusions with dried pooled plasma revealed
 5 a subsequent incidence of homologous serum jaundice
 6 in 4.5 per cent.
 7 "2 the causative agent appears to be widely
 8 distributed but the attack rate is variable.
 9 "3. The attack rate was significantly higher
 10 among persons who were 50 years of age or more. No
 11 relation of the attack rate to the amount of plasma
 12 administered could be demonstrated.
 13 "4. Investigation of 51 deaths attributed to
 14 acute hepatitis revealed 15 cases in which the
 15 patients had received transfusion therapy during the
 16 six months prior to death. 12 of these had received
 17 plasma only.
 18 "5. 12 deaths attributable to homologous serum
 19 jaundice were reported in upstate New York during
 20 a seven-month period."
 21 Then this at 6:
 22 "Plasma as well as other forms of transfusion
 23 therapy, should be administered only when the clinical
 24 indications are absolute, so that the benefits to be
 25 derived clearly outweigh the risk of contracting

25

1 Yes, so we can see a World Health Organisation
 2 publication. This is in March 1953. The committee,
 3 the expert committee on hepatitis set up by the World
 4 Health Organisation had met in July 1952 and I'm not
 5 proposing to go to any particular part of this
 6 document but you'll see that by this time hepatitis,
 7 including serum hepatitis, is as it were on the agenda
 8 of the World Health Organisation on an international
 9 stage.
 10 Then if we could --
 11 **SIR BRIAN LANGSTAFF:** I think that was the document or at
 12 least part of the documentation which I referred to
 13 yesterday when I was asking questions of Dr David
 14 Owen.
 15 **MS RICHARDS:** Yes.
 16 **SIR BRIAN LANGSTAFF:** For those who are interested, the
 17 passage I was or the principles I derived from it are
 18 set out at part 10:
 19 "Prevention of the spread of hepatitis viruses A
 20 and B by human blood and by its products."
 21 **MS RICHARDS:** Yes. It's an important document and one
 22 that we will no doubt return to with some witnesses in
 23 due course.
 24 **SIR BRIAN LANGSTAFF:** Yes.
 25 **MS RICHARDS:** We've been in Wales with the Regional

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1 homologous serum jaundice."
 2 Now, turning back from America to the
 3 United Kingdom, and we've now reached the 1950s.
 4 Henry, could we have DHSC0100010_405.
 5 This is a letter dated 6 January 1950. It's
 6 from Dr Drummond of the Regional Transfusion Centre in
 7 Cardiff and it's to Dr Maycock at the Ministry of
 8 Health. It says this:
 9 "I have decided to abandon large pool plasma
 10 filtration. I do not feel I can justifiably continue
 11 to issue large pool plasma which has an incidence of
 12 homologous serum jaundice of 10 per cent, as opposed
 13 to 1 per cent for small pool plasma. Were a case of
 14 homologous serum jaundice to go to the law courts, and
 15 large pool plasma to be implicated, I don't think the
 16 court would be kindly disposed. It might argue we
 17 ought not to have issued large pool plasma since the
 18 incidence of homologous serum jaundice is ten times as
 19 great as after small pool plasma. It might be argued
 20 that the issue of large pool plasma is unjustifiable
 21 since it is practicable to make small pool plasma,
 22 either filtered or unfiltered. Such an argument would
 23 be unanswerable."
 24 Could we then, please, have, Henry, and I'm
 25 hoping I've got the right reference here, RLIT0000215.

26

1 Transfusion Centre. The next document takes us to
 2 Scotland, PRSE0000157, please. This is a memorandum
 3 from the Scottish Home and Health Department which
 4 I have a feeling I might have referred to yesterday as
 5 the Scottish Health and Home Department.
 6 16 December 1964 Scottish hospital memorandum number
 7 89, 1964, "Scottish National Blood Transfusion
 8 Association, hospital blood transfusion arrangements
 9 and the supply of blood products in clinical use".
 10 Then we'll see it's a memorandum describing the
 11 work of the Scottish Blood Transfusion Service and
 12 containing some suggestions as to the management of
 13 hospital blood banks, reminds medical officers of the
 14 risk of transfusion therapy and gives guidance on how
 15 the risks may be reduced. That's in paragraph 1.
 16 Then if we could go please to the first page,
 17 Henry, paragraph 11 the memorandum says this:
 18 "All blood for transfusion must be regarded as
 19 potentially contaminated, and care must be exercised
 20 to ensure correct conditions of storage. This applies
 21 not only during storage in the blood bank, but also
 22 during transportation."
 23 Then skipping over a sentence this:
 24 "The most important transmissible disease in
 25 this country is homologous serum jaundice or serum

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1 hepatitis, the incidence of which is 5 per 1,000
 2 recipients of blood or small pool plasma. No
 3 transfusion should be undertaken unless the benefits
 4 outweigh the risk of hepatitis."
 5 Then it says this in 12:
 6 "The avoidance of transfusion accidents is
 7 primarily the responsibility of those medical officers
 8 in charge of the patient ..."
 9 Pausing there, whether that is intended to
 10 encompass the risk of hepatitis referred to in the
 11 previous paragraph is unclear:
 12 "... and of those in charge of the blood bank
 13 and laboratory. The ramifications of the organisation
 14 of a blood transfusion service within a hospital are
 15 so widespread that it should be looked at from time to
 16 time by the medical staff committee ..."
 17 We are now in the 1960s and there are a number
 18 of reported materials in the course of the 1960s
 19 onwards showing the emergence of knowledge of the
 20 Australia antigen. I am not going to go to the
 21 majority of those documents but it's an important part
 22 of the chronological development of the knowledge of
 23 hepatitis B and for those who are interested, you
 24 don't need to put this up on screen, Henry, but there
 25 is an article in February 1965 which describes the

29

1 liver function tests has yet been devised which would
 2 reliably distinguish carriers of the virus from normal
 3 subjects."
 4 It then goes on to describe how recipients vary
 5 in their susceptibility. Then the next paragraph:
 6 "Some patients suffer no upset from the
 7 transmitted virus. Some may have only a transient
 8 liver dysfunction, with or without jaundice, and yet
 9 others may develop a rapidly fatal hepatic necrosis."
 10 Then reference is made to attempts thus far not
 11 particularly satisfactory of finding a means of
 12 killing the virus in the blood.
 13 If we go to the last page, please, of this
 14 document I think we can see from the way in which this
 15 last conclusion is expressed that this is intended to
 16 be advice from the Regional Transfusion Centre to
 17 practitioners in the field. Under the heading
 18 "Conclusion":
 19 "The practitioner should satisfy himself that it
 20 is really necessary to give blood and that no other
 21 treatment would be equally efficacious, even though it
 22 might take a little longer to achieve results. He
 23 might even benefit his patients by occasionally having
 24 the strength of mind to make the unfashionable
 25 decision not to transfuse. The hitherto healthy

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1 emerging knowledge of the Australia surface antigen at
 2 PRSE0001518.
 3 What I want to pick up however is a publication
 4 in August 1965, PRSE0003897. Again, we're drawing on
 5 a range of materials to show how knowledge may have
 6 been -- how risks may have been understood by
 7 different cohorts of practitioners. This is
 8 a publication called "The Practitioner" and it's, this
 9 particular part, complications of blood transfusion,
 10 is authored by Jean Grant, the then director of the
 11 Regional Transfusion Centre in Oxford. If we could go
 12 please to page 6 of this, Henry, under the heading
 13 "Transmission of disease", we can see there what is
 14 set out under the heading "Homologous serum
 15 hepatitis":
 16 "The development of homologous serum hepatitis
 17 is a hazard which besets rather less than 1 per cent
 18 of recipients of whole blood or small pool plasma."
 19 There is reference there to the MRC publication
 20 in 1954:
 21 "It is caused by the transmission of a virus
 22 from a carrier donor to a susceptible patient. The
 23 donor is probably not aware that he is a carrier. He
 24 gives no history of ever having had infective
 25 hepatitis himself ... and no single test or battery of

30

1 patient can well afford a one pint haemorrhage without
 2 replacement, after all as pointed out by Chassar Moir
 3 the blood donor himself lost a pint without anybody
 4 feeling that he ought, therefore, to receive
 5 a transfusion."
 6 Then, Henry, could we please have RLIT0000217.
 7 This is one of a number of documents authored by
 8 J Garrott Allen in the United States. This particular
 9 publication is I think 1 April 1966. It's headed,
 10 "Post transfusion hepatitis, a serious clinical
 11 problem", and it suffices I think only to look at the
 12 summary on this page in italics:
 13 "The risk of serum hepatitis from transfusions
 14 derived from prison and skid row populations is at
 15 least ten times that from the use of volunteer
 16 donors."
 17 This is being said in April 1966:
 18 "For every 100 patients receiving a single
 19 transfusion the attack rate is 0.3 per cent where the
 20 donor is of the family or volunteer type and
 21 3.2 per cent when the donor is from a prison or skid
 22 row population. The most practical method of reducing
 23 the hazard of serum hepatitis from blood are to limit
 24 the use of blood by giving one transfusion instead of
 25 2, 2 instead of 3, et cetera, and especially by

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1 excluding, if possible, all prison and skid row
2 donors. It is urged that the state and federal
3 control of the quality of blood used for blood
4 transfusions be studied with the possibility that
5 measures may be taken to increase its safety. If it
6 is necessary that blood from prison and skid row
7 donors be used to meet the demands such blood should
8 be labelled as carrying a significantly increased
9 hazard of transmitting serum hepatitis in order that
10 the physician prescribing blood may take the necessary
11 precautions."

12 Then from the US back to the UK with
13 RLIT0001219. This is the same year, August 1966, and
14 the relevance of this is just to show that the same
15 issue is raised in a leader in the British Medical
16 Journal in that year under the heading, "Transmission
17 of disease by blood transfusion", where it says this:

18 "Hepatitis, syphilis, malaria and brucellosis
19 have all been transmitted to patients who were given
20 whole blood or blood products. Hepatitis is by far
21 the most serious disorder transmitted in this way ..."

22 Then there is a reference to the different
23 incidence rates depending upon the size of the pool.
24 Then it says this:

25 "This important hazard of blood transfusion is

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1 to attempt to translate these results into national
2 figures. Estimates of the risk of hepatitis in blood
3 recipients in the USA vary from 0.3 to 4.13 per cent
4 and from a number of reports it was estimated that the
5 overall mortality from post transfusion hepatitis
6 could be as high as 27.5 per cent. Even more
7 significant is the fact that although infectious
8 hepatitis cannot be considered a major cause of death
9 it nevertheless ranked in 1959 in the USA second only
10 to influenza among the deaths attributed to acute
11 virus infections."

12 Then if we could go to the top of the next
13 column, please, Henry:

14 "In this country an estimate of the size of the
15 problem of hepatitis cannot be made since hepatitis is
16 not notifiable on a national basis. Nevertheless it
17 should be a matter for considerable anxiety that there
18 are indications that the number of deaths from
19 hepatitis after cardiac surgery in some centres
20 exceeds the mortality from surgery. Therefore, before
21 we can aspire to undertake any preventative measures
22 the first step should be the notification of hepatitis
23 and the establishment of a follow-up system for all
24 patients who have received blood transfusion. The
25 problem is surely of such importance as to preclude

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1 not as widely appreciated as it should be."

2 Then reference is made to one reason for that
3 possibly being the comparatively long incubation
4 period.

5 If we could then please have up on screen,
6 please, Henry PRSC0000821.

7 This is a letter dated -- or a publication again
8 in the British Medical Journal 5 November 1966 and
9 it's a letter from Professor Zuckerman from the London
10 School of Hygiene and Tropical Medicine. The
11 left-hand column please, Henry, the article headed,
12 "Blood transfusion and infectious hepatitis".
13 Professor Zuckerman who was based then at the London
14 School of Hygiene and Tropical Medicine was a leader
15 in the field of hepatitis at this time, as we will see
16 from later materials. He said this:

17 "There are at present no specific tests for
18 virus hepatitis but the serum transaminase levels have
19 proved a sensitive index of liver damage. These tests
20 have not been carried out in the small series of
21 patients reported by [he refers back to an earlier
22 publication] and it should be difficult to draw any
23 valid conclusions from their results on the absence of
24 anicteric post-transfusion hepatitis in 82 patient who
25 received 222 pints of blood. Hazardous and misleading

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1 any attempts to guess the actual figures for
2 hepatitis."

3 So that is Professor Zuckerman in the mid-1960s
4 recommending the establishment of a follow-up system
5 for all patients receiving blood transfusion.

6 There's a further document from
7 Professor Zuckerman, Henry, at RLIT0000220. You don't
8 have that? Don't worry. We can come back to that if
9 need be.

10 Can we then go to PRSE0003714. This is,
11 September 1969, an article in the British Medical
12 Journal or a letter in the British Medical Journal
13 from the Royal infirmary in Liverpool, headed "Serum
14 hepatitis in a haemophiliac". It says this:

15 "Serum hepatitis after the use of
16 cryoprecipitated antihemophilic globulin is unusual."

17 Refers to a reported case, and then says:

18 "We report a second case with a fatal outcome."

19 The letter then details the particular case,
20 which I won't take time going through, but if we go to
21 the concluding two paragraphs of the letter it says
22 this -- Henry, sorry, you can go back up. That's
23 great.

24 "The clinical and necropsy findings here are
25 fully compatible with a diagnosis of serum hepatitis.

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1 Cryo represents a considerable advance in the
2 management of the severe haemophiliac. This and other
3 centres have used many thousands of units without
4 mishap and we do not know of a similar case in
5 Britain. It is important to re-emphasise the
6 potential danger of cryo to ensure its use only when
7 strictly needed. A check should be kept of the source
8 of cryo to trace any serum hepatitis which may occur
9 in the future."

10 I'm not going to go to it but there is then in
11 the British Medical Journal two months later, in
12 November 1969, another case of serum hepatitis in
13 a haemophiliac patient reported in Belfast, and the
14 reference for those who are interested is PRSE0004488.

15 Sir, that brings me to the 1970s, and the next
16 document is one that might take a little longer to
17 look at, so is that a convenient moment to break?

18 **SIR BRIAN LANGSTAFF:** Yes, it is.

19 So we will take our break now for the next
20 45 minutes and be back at 20 to 12.

21 **(10.56 am)**

22 **(A short break)**

23 **(11.41 am)**

24 **MS RICHARDS:** Sir, we've reached the 1970s.

25 In July 1970 the Department of Health convened

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1 antibody in the hospital service;

2 "ii. the provision of reagents, choice of
3 methods and whether, and if so, what kind of, training
4 facilities are required;

5 "iii. the scale of accommodation, staffing,
6 equipment and other services necessary to implement
7 the group's proposals."

8 We can see that their members included
9 consultant virologists, directors of Regional
10 Transfusion Centres and a senior technical officer of
11 the Public Health Laboratory Service. They met first
12 on 5 October 1970, met on five subsequent occasions,
13 and then produced this particular report.

14 If we go, please, to page 4, paragraph 6, Paul,
15 we can see it's there said:

16 "Knowledge of all aspects of Australia
17 (hepatitis-associated) antigen is accumulating very
18 rapidly. Our recommendation should therefore be
19 regard as interim ones and they may have to be
20 modified in the light of new information."

21 So this was, as it says there, part of the
22 developing knowledge of what would soon be identified
23 and labelled as hepatitis B.

24 If we then go to the next paragraph, please,
25 next page, paragraph 7, we can see there:

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1 a meeting to discuss the problems of Australia antigen
2 in relation to blood transfusions and associated
3 matters.

4 In September of 1970, following that Department
5 of Health meeting, the Advisory Group on Testing for
6 the Presence of Australia (hepatitis-associated)
7 antigen and its antibody -- it's a rather lengthy name
8 of a group -- was formed under the chairmanship of
9 Dr Maycock. We have its first report at PRSE0000190.
10 It's, again, quite a long document and so I won't go
11 through all of it.

12 We can see if we go to the second page, please,
13 Paul, paragraph 2 we have the terms of reference, to
14 advise the health department -- sorry, I should pick
15 it up, in fact, before that because we can see its
16 geographical scope:

17 "... we were appointed in September 1970 as an
18 advisory group jointly by the Department of Health and
19 Social Security, the Scottish Home and Health
20 Department and the Welsh Office, with the following
21 terms of reference:

22 "To advise the Health Departments on:

23 "i. the organisation of and responsibility for
24 testing blood donations and other specimens of blood
25 for Australia (hepatitis-associated) antigen and its

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1 "Australia (hepatitis-associated) antigen is the
2 name used in WHO memorandum 1970 for the antigen
3 apparently associated with the infective agents
4 thought to be the cause of serum hepatitis."

5 Then various other names given for it are there
6 set out.

7 "The association between the antigen and serum
8 hepatitis commonly accepted as the most frequent form
9 of hepatitis observed following the injection of blood
10 and blood products is well-established and the antigen
11 can now be detected by a variety of laboratory tests."

12 Then if we go to the next paragraph, please,
13 paragraph 8, it says:

14 "Although the hepatitis agent maybe less widely
15 dispersed in the UK than in some other countries, the
16 institution of testing blood donations for Australia
17 antigen should reduce the incidence of serum
18 hepatitis, which is the most serious complication of
19 transfusion and so avoid suffering and disablement and
20 even death."

21 So the aspiration from the early '70s was that
22 the testing that was beginning to be available would
23 enable there to be a reduction in the incidence of
24 serum hepatitis. We will see as we go through the
25 1970s how that panned out.

40

1 If we go then please, Paul, to page 22. It's
2 headed chapter 10, "Summary of principal
3 recommendations". Thank you. So, "Summary of
4 principal recommendations":

5 "For the reasons already given we make the
6 following recommendations: (1) the Regional
7 Transfusion Centres should begin at the earliest
8 possible date, to test all blood donations for the
9 presence of Australia-hepatitis-associated antigen and
10 its antibody."

11 Then reference is made in the next paragraph to
12 the form of testing and recommendations in relation to
13 staffing, safety precautions, accommodation and
14 equipment. Then if we go to (iv):

15 "A donor found to be antigen or antibody
16 positive should not be allowed to continue as a donor
17 of blood intended for clinical use and he should be
18 told so and invited to give permission for his GP to
19 be informed."

20 Those were the recommendations at the beginning
21 of the 1970s. We then will move on to RLIT0000076,
22 please, Paul. This is April 1971.

23 It's a letter again from J Garrott Allen, the
24 professor of surgery at Stanford University School of
25 Medicine to a medical publication, California

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1 blood. The elimination of the use of these donors
2 would be of most help to reduce transfusion hepatitis
3 to a minimum, until a test of greater accuracy can be
4 developed to detect the infectious carrier. We cannot
5 develop a reliable national all-volunteer blood
6 programme [you see this is in the States] as long as
7 blood insurance programmes are permitted to exist or
8 as long as commercial blood is part of a blood bank
9 operation functioning under the euphemism of not for
10 profit. This is an important matter to the patient's
11 health."

12 Still in 1971, could we go to DHSC0002173_048,
13 please. This is a report that was prepared for an
14 April 1971 meeting of haemophilia centre directors.
15 We will be coming back, sir, to documentation relating
16 to haemophilia centre directors many times over the
17 coming weeks as we hear witness evidence from
18 clinicians. For present purposes I'll just look at
19 the first page. We'll see it's entitled:

20 "Jaundice and Factor VIII antibodies in treated
21 patients with haemophilia and Christmas disease. At
22 a meeting of the directors of the 36 haemophilia
23 centres of Great Britain held in 1967 it was decided
24 to make a study of the incidence of transfusion
25 hepatitis and inhibitors, two most alarming

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1 Medicine, in April of '71, "Post transfusion
2 hepatitis", and he says this:

3 "First, the numbers of patients who develop post
4 transfusion hepatitis will be about 1 in 33 transfused
5 when the blood from a volunteer population is
6 contaminated with as much as 44 per cent of blood from
7 prison donors. The numbers of patients with
8 transfusion hepatitis, under these circumstances, who
9 will be able to show disability or who will die of
10 this disease, will be approximately 0.9 per cent of
11 the total transfused. If one considers only volunteer
12 donors, we experience one case among every 278
13 patients and about one serious or fatal case among
14 every 1,000 patients transfused.

15 "Second, the use of commercial blood carries
16 a risk of causing transfusion hepatitis that is 10 to
17 70 times greater than when blood from volunteer donors
18 is used.

19 "Third, it is not possible in most instances for
20 the doctor to know if the blood his patient is about
21 to receive is from a high or low risk population."

22 Then if we can go to the next column please,
23 Paul, his sixth point:

24 "90 per cent of post transfusion hepatitis from
25 blood can be traced to the use of commercial or prison

42

1 complications of treatment of patient with coagulation
2 defects."

3 Reference is made to forms having been prepared
4 and which clinicians were invited to report the
5 incidence of jaundice. Then the next paragraph reads:

6 "Transfusion hepatitis is thought to be a virus
7 infection transmitted to the recipient by the donor
8 plasma. There is every reason to suppose that the
9 virus is contained in the various protein fractions
10 used to treat haemophilia and Christmas disease,
11 cryoprecipitate, human antihemophilic globulin or
12 HAHG and factor IX concentrate."

13 Then this:

14 "The danger of infection can be calculated and
15 will be related to the number of donors used to make
16 the material used for treatment or the number of donor
17 exposures. If large pools of plasma are used to make
18 therapeutic concentrates the theoretical danger of
19 infection will be increased."

20 As I say, it's a document we will come back to
21 at a later stage of the hearing so I will leave that
22 document there.

23 Move to 1972 back to the States. Could we have
24 please, Paul, DHSC0100024_079. In March of 1972 in
25 the States, President Nixon directed the Department of

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1 Health, Education and Welfare to study and recommend
2 a safe, fast and efficient nationwide blood collection
3 and distribution system. It's there recorded that:
4 "Authorities in the health field regarded the
5 present system as inadequate, pointing out that
6 hospitals in many cases are forced to buy blood from
7 commercial blood banks, which often accept blood from
8 such donors as derelicts and drug addicts who may be
9 the transmitters of such diseases as hepatitis,
10 syphilis and malaria."

11 There's another report, I don't ask you to put
12 it up, Paul, but in case anyone is interested in
13 reading further on this, Nixon's announcement is also
14 described in RLIT000223.

15 **SIR BRIAN LANGSTAFF:** Just before you leave that document,
16 this is not just an extract from an American
17 publication which stays, as it were, in American
18 readership, because it seems the original of this was
19 sent to the CMO.

20 **MS RICHARDS:** Yes.

21 **SIR BRIAN LANGSTAFF:** The CMO is now returning this for
22 the files.

23 **MS RICHARDS:** Yes.

24 **SIR BRIAN LANGSTAFF:** So some time very shortly after
25 President Nixon said what he said about the dangers of

1 commonly now refer to as hepatitis A and hepatitis B
2 being identified here:

3 "Serum hepatitis seems to occur more frequently
4 than infectious hepatitis as a result of the
5 administration of blood and blood products."

6 Then if we could go to the last page of this
7 document, please, Paul under the heading conclusions,
8 what Dr Maycock says there is:

9 "The incidence of serum hepatitis will diminish
10 as transfusion services adopt the practice of
11 excluding all donations of blood in which the
12 Australia antigen is detected."

13 Then the next paragraph says this:

14 "Following the demonstration of the association
15 between the presence of Australia antigen in
16 transfused blood and the occurrence of hepatitis in
17 a proportion of the recipients, terms such as 'safe
18 blood' and 'safe blood products' were applied to blood
19 and products derived from it in which the antigen had
20 not been detected. At the present time both terms are
21 misleading because treatment with blood and blood
22 products, except immunoglobulin and albumin which has
23 been heated [and gives the details there] continues to
24 carry the risk, admittedly a diminished one, of
25 transmitting hepatitis. Blood and blood products

1 blood, the CMO here saw it.

2 **MS RICHARDS:** Yes, absolutely, sir. This is a Department
3 of Health document and you are right we see from the
4 bottom original returned to CMO (Chief Medical
5 Officer) 29 March 1972.

6 Could we then have please, Paul, RLIT0000169.
7 This is an article by Dr Maycock whose name we've seen
8 now a number of times of the Blood Products Laboratory
9 in Elstree. It is headed "Hepatitis in transfusion
10 services". There are just two passages we'll look at.

11 The first is the first part of it:

12 "The transmission of viral hepatitis is the most
13 serious complication of the use of blood and blood
14 products. Two forms of hepatitis may be transmitted
15 in this way. One has a short incubation period of
16 some 15 to 40 days and is generally referred to as
17 infectious hepatitis, a disease usually transferred by
18 the oro-faecal route and assumed to be caused by an
19 agent known as virus A or IH virus. The other form is
20 serum hepatitis, one of the characteristics of which
21 is a prolonged incubation period of some 40 to 150
22 days, occasionally 180 days. It is assumed to be
23 caused by an agent known as virus B or SH virus."

24 So we see here the nomenclature or terminology
25 changes over the years but we see here what we

1 known to be potentially icterogenic should be used
2 with discrimination. They should be administered only
3 when the benefits they are likely to confer upon the
4 patient outweigh the risk to which their use exposes
5 him."

6 That's the view being expressed in 1972 by
7 Dr Maycock of the Blood Products Laboratory.

8 *(Brief pause)*

9 **MS RICHARDS:** From 1972 onwards we begin to see, in
10 various medical and scientific publications,
11 observations from clinicians that, even after the
12 exclusion of donors who had tested positive for
13 hepatitis B antigen, there were still residual cases
14 of post-transfusion hepatitis, and so it began to dawn
15 upon clinicians that there may be another form of
16 hepatitis transmitted by blood or blood products other
17 than hepatitis B.

18 There are a number of reports in relation to
19 that and we will just go, for present purposes, to one
20 of them.

21 Paul, it is PRSE0001431.

22 This is a publication in The Lancet in August
23 of 1974 by Prince and others. It is called
24 "Long-incubation post-transfusion hepatitis without
25 serological evidence of exposure to hepatitis B

1 virus", and we can get the message from the summary:
2 "An agent other than hepatitis B (HB) virus
3 seemed to be the cause of 36 (71 per cent) of 51 cases
4 of post-transfusion hepatitis identified during
5 prospective biweekly serological follow-up of
6 204 cardiovascular surgery patients. The sera of the
7 36 cases showed no evidence of the antigen or antibody
8 response expected to accompany infection by HB virus
9 and to be detectable by the sensitive assays used."

10 Then it refers to consideration of
11 cytomegalovirus, and then says this:
12 "The data suggests that a large proportion of
13 long-incubation post-transfusion hepatitis is
14 unrelated to hepatitis B and that control of
15 post-transfusion hepatitis will require identification
16 of a hepatitis virus(es) type C."

17 This is, I think, probably the first reference
18 in the medical literature to what was subsequently
19 identified as hepatitis C.

20 If we go to the last page of this document,
21 please, Paul, the first main paragraph on the
22 left-hand side:

23 "The fact that non-B hepatitis cases are less
24 frequently associated with serious acute illness does
25 not imply that such cases are of lesser importance.

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1 "Two strains of virus have been known for a long
2 time: hepatitis A (originally called infectious or
3 short-incubation hepatitis), and hepatitis B
4 (sometimes called post-transfusion hepatitis, because
5 it is spread through donated serum and other blood
6 products, and injections with contaminated needles).

7 "The existence of at least one other strain has
8 been apparent during the past six or seven years
9 because research has shown that a large number of
10 patients, particularly those infected from transfusion
11 or injection, were not carrying the hepatitis A or B
12 strains. In the United States up to 50 per cent of
13 transfusion-associated illness is caused by this third
14 'non-A non-B' agent."

15 So we see there the terminology that, over the
16 following years, became associated with this
17 particular virus: "non-A non-B hepatitis".

18 Could we then, Paul, move to CBLA0000249,
19 please.

20 This is an important letter from
21 Dr Garrott Allen, again, to Dr Maycock this time, at
22 the Blood Products Laboratory. It's dated
23 6 January 1975 and Professor Garrott Allen is raising
24 questions about the usage of Factors VIII and
25 Factors IX, and we pick it up in the third paragraph:

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1 Long-term complications of acute hepatitis B
2 infection, such as chronic hepatitis, cirrhosis and
3 hepatoma, have been reported to follow mild anicteric
4 infections more frequently than severe icteric cases;
5 consideration must thus also be given to the
6 possibility that non-B hepatitis may play a role in
7 the aetiology of some forms of chronic liver disease."

8 So there again in this report, identification of
9 the potential serious long-term consequences for the
10 liver of this newly recognised third form of
11 hepatitis.

12 **SIR BRIAN LANGSTAFF:** By the word "acute", we are to
13 understand something lasting for six months or less?

14 **MS RICHARDS:** Yes. So the distinction is between, as it
15 were, the short-term and the longer term.

16 **SIR BRIAN LANGSTAFF:** So every disease will have its acute
17 phase but once it goes past six months it becomes
18 known as chronic?

19 **MS RICHARDS:** Yes.
20 If we have, please, Paul, CGRA0000694, I think

21 we can see that this finds its way into national
22 publication. This is The Times for November 12, 1974:

23 "The Science Report: New Strain of Hepatitis
24 Isolated."

25 If we just pick it up in the third paragraph:

50

1 "Dr Pool ..."
2 That's a reference to Dr Judith Pool:
3 "... spent the past year at Oxford and tells me
4 that at least one of the sources for commercial
5 Factor VIII and IX is the Hyland Laboratories in the
6 Los Angeles area. Dr Biggs mentioned in her letter in
7 Lancet last June 29th that there was two other
8 commercial sources but Judy Pool did not know which
9 they were or whether they were from the United States.

10 "As you know, Cutter's product Konyne for
11 Factor IX deficiency has proved extraordinarily
12 hazardous, a 50-90 per cent rate of icteric hepatitis
13 developing from it. About half of these cases prove
14 fatal. Cutter's source of blood is 100 per cent from
15 skid row derelicts. The other imponderable which has
16 troubled most of us is the ineffectiveness in
17 screening for the HB antigen. This failure of course
18 dates back to at least 1971 and suggests that half if
19 not more of the cases of post-transfusion hepatitis
20 are caused by an agent other than hepatitis A or B.
21 Whatever this other agent may be, it still seems to be
22 more frequently encountered in the lower
23 socio-economic groups of paid and prison donors."

24 Then if we go to the next paragraph:
25 "A blood bank for these groups in the

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1 United States is a monetotropic establishment. The
 2 commercial blood banks attract these kinds of donors.
 3 Until we understand this problem better, I would hope
 4 that Great Britain would give some thought to what the
 5 purchase of Factors VIII and IX from the United States
 6 tends to do to our attempts to form a volunteer
 7 programme. Commercial blood banking perpetuates the
 8 high risk rates for hepatitis we encounter with their
 9 products and it also tempts those same commercial
 10 firms to sell the residual products of these high-risk
 11 donors to non-immunised patients who tend to be more
 12 susceptible to post-transfusion hepatitis than is so
 13 far the non-virgin haemophiliacs."

14 **SIR BRIAN LANGSTAFF:** When he uses the word
 15 "monetotropic", he is saying it attracts money, is he?

16 **MS RICHARDS:** Yes, I assume so, sir.

17 **SIR BRIAN LANGSTAFF:** It's an unusual word but I think
 18 that's what it means.

19 **MS RICHARDS:** It is. It's not one I've ever come across
 20 and I'm afraid it's not one I looked up, so I'm going
 21 to defer to your greater knowledge --

22 **SIR BRIAN LANGSTAFF:** Well, "tropic" I think means
 23 attracting, and "moneto" sounds like a money to me.
 24 If anyone has a better definition then they can let me
 25 know in due course.

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1 that for present purposes but if we could go to the
 2 second page under the heading "Prisons" the letter
 3 says this:

4 "There is a relatively high risk of hepatitis B
 5 being transmitted by the blood of prisoners. But
 6 there is probably an equally high risk in other groups
 7 of the population, eg drug addicts, who are not so
 8 easily identified in advance as prisoners, if they can
 9 be identified at all. The advice we have received is
 10 that it is not necessary to discontinue the collection
 11 of blood at prisons and similar institutions provided
 12 all donations are subjected to one of the more
 13 sensitive tests referred to above."

14 We will come back when we look at a document in
 15 the '80s to the question of continuing collection of
 16 blood from prisoners in the United Kingdom.

17 Without again going to too many documents, there
 18 are further articles reported in the course of the
 19 mid-1970s about this newly understood and recognised
 20 hepatic virus. One example again for the benefit of
 21 those who want to look at this in more detail is
 22 a report by Alter in The Lancet in November 1975.
 23 Paul, you don't need to put it up on screen but it is
 24 PRSE0001172.

25 That brings us to the end of 1975 and what

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1 **MS RICHARDS:** I am sure someone sitting alongside or
 2 beside me will be online on the Oxford English
 3 Dictionary as we speak. That's a hint!

4 Again, for reference, I am not going to take to
 5 it but we do have Dr Maycock's reply, and for those
 6 who are interested, it's at CBLA0000254.

7 Can I then, and we're still in 1975 here, go to
 8 PRSE000009. This is a document that Lord Owen
 9 referred to in his evidence yesterday, which we didn't
 10 look at during his evidence. I might have missed out
 11 a zero there, Paul, sorry.

12 Thank you.

13 So it's an example of what Lord Owen referred to
 14 as a "Dear Doctor" letter, so a means by which the
 15 Chief Medical Officer might communicate advice and
 16 information to medical practitioners. This is dated
 17 1 May 1975 to all regional medical officers. It is
 18 headed "Blood donation and hepatitis", and it is from
 19 Dr Yellowlees who was the then Chief Medical Officer.
 20 It says:

21 "The Department has recently received advice
 22 from a group of experts on the use of blood donations
 23 from certain categories of donors."

24 Various matters are then set out relating to
 25 geographical factors. I am not going to spend time on

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1 I propose to do now, sir, is to play the World in
 2 Action documentary that was broadcast in two parts on
 3 1 December 1975 and then a week later on
 4 8 December 1975.

5 Many of you will have seen this and be very
 6 familiar with it but not everyone, and the broader
 7 public may not know that in 1975 this documentary was
 8 made and broadcast. It's going to provide an
 9 important backdrop for the evidence we hear from
 10 clinicians and others over the coming months.

11 So, Paul, could we play, please, MDIA0000113.
 12 This is part 1 of "Blood Money", the World in Action
 13 documentary broadcast on 1 December 1975.

14 (*Blood Money, Part 1, World in Action, played*)

15 It will eat into lunch by probably 7 or
 16 8 minutes if we play the second half now, start lunch
 17 a little late, have the full lunch and then pick up
 18 the documents again after lunch, if that's all right?

19 **SIR BRIAN LANGSTAFF:** That would be a good idea.

20 **MS RICHARDS:** So if we could play the second part of this
 21 documentary, Paul, which is MDIA0000114.

22 (*Blood Money, Part 2, World in Action, played*)

23 Sir, it is 1.05. That would be a convenient
 24 point, I think, at which to break for lunch.

25 **SIR BRIAN LANGSTAFF:** We'll take a break until 2.05.

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1 2.05, please.
 2 (1.06 pm)
 3 (Luncheon Adjournment)
 4 (Luncheon Adjournment)
 5 (2.06 pm)
 6 **SIR BRIAN LANGSTAFF:** Ms Richards, can I just raise
 7 something with you which arose to me on reflection of
 8 the material you produced this morning. You produced
 9 quite a lot of material which evidences that there was
 10 a knowledge that voluntary/non-remunerated blood
 11 donors were less likely to produce an infected product
 12 than were paid donors, particularly those from the
 13 United States in the social groups from which they
 14 came.
 15 You have established that there was material
 16 which showed that as one increased the pool size so
 17 the risk of infection within that pool from one or two
 18 donations was increased.
 19 At the end of yesterday I asked Dr Owen what he
 20 could say about the relative pool sizes used to
 21 produce product in the NHS on the one hand and
 22 commercially on the other. In the documentary which
 23 we've just seen, there was a reference -- two
 24 references, one to the United States, where I think
 25 they quoted the figure of 2,000 to 6,000 litres of

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1 donors but that might give some idea of the relative
 2 size of pools.
 3 **MS RICHARDS:** Yes. Yes, it might, sir.
 4 **SIR BRIAN LANGSTAFF:** That's just what I wanted to raise,
 5 to see if those inferential figures bear that
 6 inference, and if anyone has any suggestion that they
 7 don't they can come back to you.
 8 **MS RICHARDS:** Yes, thank you, sir.
 9 Sir, the next document that we're going to look
 10 at is PRSE0004064, and it's a response from Dr Cash to
 11 the World in Action programme that we've just watched.
 12 It's BMJ, British Medical Journal,
 13 24 January 1976. If we could go down a bit further
 14 please, Paul, it's the letter headed "Commercial and
 15 NHS Factor VIII Concentrates". This was Dr Cash's
 16 reaction to the programme:
 17 "One of the inevitable dangers of a journalistic
 18 approach to medical problems is that limitations in
 19 time (radio or TV) or space (newspapers or
 20 periodicals) may give rise to a selection of comments
 21 made by experts which, when taken out of context and
 22 put together for a programme or article, are
 23 misleading. This probably arose during the ITN
 24 television series World in Action."
 25 Then he says in the second paragraph:

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1 plasma from which pools were made, and the other the
 2 NHS, 100 to 200 litres of plasma.
 3 This is the point I want to run past you. I am
 4 raising it with you really so that if anyone from
 5 their different perspectives who's listening, from the
 6 recognised legal representatives, would wish to
 7 comment and correct me if this is a wrong deduction,
 8 one inference would be that assuming, and the
 9 assumption may be wrong but assuming, that a litre is
 10 composed of two donations, each roughly half a litre
 11 of blood, or maybe four donations, probably more
 12 likely because a litre is a couple of pints, give or
 13 take, that would mean that in the States there would
 14 have been between 8,000 and 24,000 donations,
 15 individual donations, in a pool and in the
 16 UK somewhere between 400 and 600. If my arithmetic is
 17 right. Again, it may need to be checked.
 18 Of course, we don't know -- that's donations,
 19 it's not necessarily donors, because if the evidence
 20 produced by those who made the documentary is right,
 21 a number of those who went to give donations at the
 22 blood centres, plasma collection centres in the
 23 States, gave it repeatedly, twice a week, and may
 24 possibly have given it to more than one centre in
 25 addition. So there may have been a smaller number of

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1 "There's no doubt that the import into the
 2 United Kingdom of Factor VIII concentrates derived
 3 from external sources, however well-screened for
 4 hepatitis viruses, represents an unequivocal pathway
 5 by which ..."
 6 If we can have the top of the next column,
 7 please, Paul:
 8 "... the level of a potentially lethal virus
 9 into the whole community is being deliberately
 10 increased."
 11 Sir, I draw attention to that not least because
 12 of your question to Lord Owen yesterday about the
 13 concept in his evidence of deliberate decisions.
 14 "Although the absolute magnitude of this problem
 15 is exaggerated and over-dramatised by the television
 16 programmes, nobody with direct or indirect
 17 responsibilities for this phenomenon would wish to
 18 belittle the serious nature of the moral and practical
 19 dilemma which face us all."
 20 Then he goes on to comment specifically about
 21 the £500,000 and NHS targets, which is obviously an
 22 issue that we'll be revisiting in future hearings.
 23 The next document, please, Paul, is
 24 HSOC0016695 -- oh, I'm so sorry, yes, HSOC0016685.
 25 I have transcribed it incorrectly in my notes.

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1 This is an article published in July 1976 in the
2 Journal of Laboratory and Clinical Medicine. It's by
3 Hoofnagle and others, and the title:

4 "The prevalence of hepatitis B surface antigen
5 in commercially prepared plasma products."

6 I just want to go to the last paragraph of the
7 whole article, please, Paul, so the last page of the
8 document.

9 Sorry, the one before that, not the list of
10 references, the last text above that. Thank you.

11 So the last paragraph of the article, picking it
12 up in the second sentence:

13 "Recently it has been shown that not all
14 post-transfusion hepatitis can be classified as type B
15 hepatitis. More startling was the finding that the
16 non-B post-transfusion hepatitis could not be
17 classified as type A hepatitis. This has led
18 investigators to postulate the existence of a third
19 human hepatitis virus, a virus which also appears to
20 be harboured in blood. It's possible that this third
21 hepatitis virus can withstand the pooling and
22 fractionation procedure and that it's responsible for
23 some cases of hepatitis following the use of high-risk
24 plasma products. At present there are no markers and
25 no means of detecting this virus in blood. Until the

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1 risk commercial donors. This is the same error the
2 British made in 1974 when they augmented their supply
3 of haemophilic concentrates with commercially prepared
4 products from American pharmaceutical companies.
5 Craske reported a rise from 3 to 50 per cent in case
6 of hepatitis among his small group of patients with
7 haemophilia. As his studies have extended, the score
8 in late November was 58 cases, with two deaths. This
9 hazard was predicted before it was observed."

10 Then please, Paul, PRSE0000381. This is an
11 Article published in the Yale Journal of Biology and
12 Medicine in July 1976 by Purcell, Alter and Dienstag,
13 non-A, non-B hepatitis. If we could go to the second
14 page please, Paul, picking it up in the second
15 paragraph:

16 "The development of sensitive tests for
17 indicators of hepatitis A virus infection now makes it
18 possible to divide non-B hepatitis into type A
19 hepatitis and non-A, non-B hepatitis. Although the
20 term type C hepatitis has been suggested for the
21 latter disease, there is evidence that non-A, non-B
22 hepatitis may be caused by more than one agent and we
23 believe it is wiser, therefore, to use the less
24 mellifluous but more accurate designation non-A, non-B
25 type hepatitis. The term type C hepatitis should be

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1 nature of this virus and its disease is elucidated, it
2 is important to consider human blood and pooled plasma
3 products as potentially infectious. At the present
4 time, fibrinogen, AHF and Factor IX concentrates
5 remain high-risk plasma products which must be
6 considered likely to produce overt hepatitis in
7 susceptible recipients."

8 So, again, the clear recognition of non-A, non-B
9 hepatitis there.

10 Paul, if we could then have CGRA0000934. If we
11 just zoom in a little on that letter. This is another
12 letter by Professor Dr J Garrott Allen from
13 Stanford University. The date of this is May 1976 and
14 you'll see it's headed "The High Cost of Cheap Blood".
15 It's a communication to the New England Journal of
16 Medicine and it is essentially on the same theme as
17 we've seen from Dr Garrott Allen and indeed we saw in
18 the programme. Just picking it up in the last -- the
19 paragraph that's already highlighted on this copy.
20 He's referring to recommendations made in the States
21 from the Council on Wage and Price Stability, CWPS and
22 says:

23 "They reason that because patients with
24 haemophilia have been given transfusions they have had
25 their hepatitis and can receive products from high

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1 reserved until non-A, non-B hepatitis can be defined
2 serologically."

3 Hence we see non-A, non-B hepatitis as the
4 terminology used from pretty much this time on until
5 the late 1980s.

6 Then if we could go to the next page, please,
7 Paul, picking it up in the third paragraph:

8 "As with type B hepatitis, type non-A, non-B
9 hepatitis occurs significantly more frequently
10 following transfusion of commercially derived blood
11 than following receipt of blood derived from volunteer
12 sources. Thus type non-A, non-B disease has been
13 found to occur five to ten times more frequently
14 following transfusion of the former than following
15 transfusion of the latter."

16 Then the next paragraph begins:

17 "The epidemiology of non-A, non-B hepatitis
18 resembles more closely that of type B hepatitis than
19 that of type A disease."

20 Then if we can go to the next page, please,
21 picking it up about halfway down:

22 "Although type non-A, non-B hepatitis is
23 associated with less severe acute illness than type B
24 disease [and again the emphasis there is upon acute,
25 so the short-term, first six months] the long-term

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1 prognosis for the two diseases may be similar", and
2 then there's reference to elevated transaminase
3 values, reference to various studies on particular
4 patients. Then the last sentence of that paragraph:

5 "Thus, chronic non-A, non-B hepatitis is not
6 necessarily a benign infection and may be the cause of
7 a significant proportion of chronic hepatitis not
8 identifiable as type B disease."

9 Could we then please, Paul, still in July 1976
10 go to PRSE0001579. Now the context of this document,
11 sir, is a discussion triggered by the recommendation
12 of the advisory group on testing for the presence of
13 hepatitis B surface antigen, a particular
14 recommendation to discontinue the practice of
15 permanently excluding donors with a history of
16 jaundice.

17 If we could go to the fifth page please, Paul,
18 what we have there, the document is headed, "Comments
19 by the Royal College of Physicians", so the Royal
20 College of Physicians were commenting upon this
21 recommendation and suggesting that the recommendation
22 should not be implemented. About halfway down the
23 page, we have a passage which says this:

24 "Furthermore, transfusion hepatitis may be
25 caused by viruses other than hepatitis B for which at

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1 recognised in Britain [possibly not by the Department
2 of Health and Social Services if the previous document
3 is accurate] in Australia, Japan, Costa Rica and
4 possibly Germany. Not only does non-A, non-B
5 hepatitis occur worldwide but it's apparently spread
6 by modes other than transfusion."

7 Then we see a range of different routes
8 identified including haemodialysis, renal transplant:

9 "Several instances of chronic hepatitis have
10 followed acute non-A, non-B hepatitis. We feel there
11 are adequate data to support the existence of non-A,
12 non-B viruses."

13 So that's the medical and scientific
14 perspective. Then if we go please to RLIT0000226 we
15 see in this document that the existence of non-A,
16 non-B hepatitis now appearing to be essentially
17 a clinical consensus, consideration being given to the
18 nature and seriousness of the disease. This is an
19 article in May 1977 in Gastroenterology entitled,
20 "Development of chronic liver disease after acute
21 non-A, non-B post-transfusion hepatitis", by Knodell
22 and others. Paul, if we could go to page 7. It is
23 the penultimate page.

24 Under the heading "Discussion", that long
25 paragraph towards the end of the paragraph, please,

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1 present no tests are available. The existence of
2 hepatitis C was postulated recently."

3 That's a comment from the Royal College of
4 Physicians opposing the recommendation. If we look at
5 the previous page, Paul, this is the response of the
6 DHSS to the observations by the Royal College of
7 Physicians. They make a number of points. I just
8 wanted to pick up the point at paragraph 7:

9 "The DHSS response is no evidence has been
10 collected yet in UK to substantiate the presence of
11 a hepatitis C."

12 It may be thought there is a foreshadowing there
13 of the mantra of no conclusive proof that we will see
14 when we look at documentation relating to HIV.

15 Paul, if we could then please have PRSE0002602.
16 This is an article in The Lancet, we're now
17 12 March 1977, by Dienstag, Purcell, Alter and others.
18 If we could go to the third page please, Paul,
19 left-hand column towards the bottom of the page if you
20 could scroll down, we see a passage beginning:

21 "Besides these data other evidence for non-A,
22 non-B [and that's the data referred to earlier in the
23 Article. I won't go into the detail of that] other
24 evidence for non-A, non-B agents has been
25 accumulating. Non-A, non-B hepatitis has now been

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1 I'll just pick it up here:

2 "In this study, 44 cases of acute non-A, non-B
3 post hepatitis have been followed prospectively for
4 development of chronic liver disease. Ten patients,
5 23 per cent, had persistent liver enzyme elevations
6 from 12 to 36 months after acute transaminase
7 elevations were first recorded. Liver biopsy
8 specimens from these ten patients provide evidence
9 that acute non-A, non-B hepatitis (hepatitis C?), can
10 progress to chronic liver disease and cirrhosis."

11 Then if we go to the next page, top of the next
12 page:

13 "The frequency with which the acute hepatitis
14 cases caused by this non-A, non-B hepatitis-producing
15 agent progressed to chronic liver disease was high.
16 Histologically, eight of the ten cases of non-A, non-B
17 chronic hepatitis had progressed to chronic active
18 hepatitis and an additional patient already had
19 developed cirrhosis."

20 Then, on the same theme, I think two further
21 documents. RLIT0000228, please, Paul. This is in the
22 Annals of Internal Medicine, July 1977, an article by
23 Hoofnagle and others entitled "Transmission of non-A,
24 non-B hepatitis."

25 Again, Paul, if we can go to the penultimate

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1 page, so it is page 6 of 7. We see on the right-hand
2 column a paragraph beginning:

3 "Several clinical and epidemiologic features of
4 non-A, non-B hepatitis have become clear from studies
5 such as the present one. First, non-A, non-B
6 hepatitis closely resembles type B hepatitis. The
7 incubation period, clinical symptoms and signs, and
8 the potential for chronicity appear to be similar to
9 type B hepatitis. Undoubtedly what was once referred
10 to as 'serum hepatitis' included both type B and
11 non-A, non-B hepatitis."

12 Then it deals with the route of transmission,
13 spread predominantly by the parenteral route, and then
14 third:

15 "Non-A, non-B hepatitis appears to be associated
16 with a chronic carrier state and chronic liver
17 disease."

18 Then skipping a few lines:

19 "Finally, non-A, non-B hepatitis appears to be
20 common."

21 Then, Paul, if we can have PRSE0003622 this is
22 a report in The Lancet in September of 1978 by
23 Professor Preston, Dr Underwood, Dr Mitchell and
24 others based in Sheffield. It's looking at the
25 position of chronic liver disease in haemophiliacs,

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1 established cirrhosis. All our patients were
2 symptom-free at biopsy and it was impossible to
3 differentiate between the different forms of liver
4 disease on the grounds of biochemical abnormalities.
5 Since the patients undergoing biopsy had been
6 arbitrarily selected, it is reasonable to conclude
7 that a large proportion of haemophiliacs receiving
8 treatment with Factor VIII have important chronic
9 liver disease."

10 We will undoubtedly, sir, in the course of the
11 evidence over the coming weeks return to Professor
12 Preston's findings in 1978 and how others responded to
13 them.

14 If we could then, Paul, go to DHSC0002191_026.
15 This is a letter, January 1979, 8 January 1979. It's
16 from Dr Dane the School of Pathology at the Middlesex
17 Hospital Medical School, and it's addressed to
18 Dr Waiter at the DHSS. It is about non-A, non-B
19 hepatitis, and the plan was for there to be
20 consideration of that at a meeting. I just wanted to
21 pick up on the second paragraph:

22 "If one or more of these viruses is responsible
23 for the abnormal livers which are evidently common
24 among haemophiliacs, then chronic liver disease due to
25 these viruses might also be found among other

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1 and we can pick it up in the summary at the top:

2 "Systematic screening of 47 haemophiliacs in
3 Sheffield revealed abnormal liver function tests in 36
4 (77 per cent) with a tendency for these abnormalities
5 to persist. To assess the importance of these
6 abnormalities, percutaneous liver biopsy was carried
7 out on eight symptom-free patients under Factor VIII
8 cover. A wide spectrum of chronic liver disease was
9 demonstrated, including chronic aggressive hepatitis
10 and cirrhosis."

11 Then if we could go to the third, the last page
12 of this document, Paul, under the heading
13 "Discussion", the second paragraph:

14 "We confirmed earlier observations that
15 percutaneous liver biopsy can be carried out safely in
16 haemophiliacs given adequate Factor VIII cover and
17 appropriate laboratory control. As with any
18 non-haemophiliac patient, there is a risk of
19 haemorrhage with this procedure but experience
20 supports the statement of Lesesne, et al, that the
21 potential risks of complications from liver biopsy in
22 haemophiliacs are outweighed [et cetera].

23 "We also found a wide spectrum of chronic liver
24 disease, including benign self-limiting hepatitis,
25 potentially treatable chronic aggressive hepatitis and

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1 transfused individuals."

2 So an acceptance there apparently that abnormal
3 livers are evidently common among haemophiliacs. The
4 reference there to Dame Sheila is to
5 Dame Sheila Sherlock, who was then a leading expert on
6 liver disease.

7 Then if we go next, please, Paul, to
8 NHBT0000186_004. We see here a meeting invitation
9 from the Medical Research Council. It's dated
10 7 February 1979. It's addressed to Dr Craske. There
11 are similar invitations to others to attend the
12 meeting:

13 "Dear Dr Craske, *ad hoc* meeting on non-A, non-B
14 hepatitis."

15 It's an invitation to attend a meeting that took
16 place on 12 February. I just draw your attention to
17 this:

18 "The Chief Scientist of the Department of Health
19 and Social Security has informed the council that this
20 subject is being given high priority by the
21 Department. Some batches of a commercial product
22 containing Factor IX have been found to transmit this
23 form of hepatitis to chimpanzees and as a result the
24 product has not been given a licence. This is causing
25 considerable anxiety from the point of view of the

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1 treatment of patients. Also laboratory staff
 2 generally are beginning to enquire about laboratory
 3 safety, and trials of blood products are becoming
 4 difficult to stage because of concern over hepatitis
 5 transmission. Two aspects on which the Department
 6 sees a need for further work: research which will
 7 identify/characterise the agent carrying non-A, non-B
 8 hepatitis, and studies leading to the development of
 9 a test for the organism or its marker."

10 Sir, I am not going to go to the notes of the
 11 meeting itself. Again, undoubtedly it's a document
 12 that we will look at again over coming months. For
 13 those who are interested, I think it can be found at
 14 PRSE0001960.

15 Could we then, please, Paul, have BART0002487.
 16 This is a communication in April 1979. It's from
 17 Dr Kernoff at the Royal Free to Dr Colvin at the
 18 London Hospital.

19 If we just go to the last page for a moment,
 20 Paul, we can see it's written by Dr Kernoff in his
 21 capacity as Chairman of the Haemophilia Working Party
 22 of the NETR Association of Haematologists, and it's
 23 addressed, if we go back to the beginning of the
 24 letter -- sorry, Paul -- to Dr Colvin in his capacity
 25 as secretary of the NETR Association of

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1 therefore be introducing diseases which are not yet
 2 endemic in the UK. The moral reason for preferring
 3 NHS material is that it seems inappropriate to many
 4 that the maintenance of adequate standards of
 5 treatment to NHS patients should be dependent on blood
 6 obtained from paid donors from foreign countries."

7 But we can see there a recognition of the nature
 8 of non-A, non-B hepatitis as a serious disease with
 9 long-term consequences.

10 If we can then move from 1979 to 1980 and have,
 11 please, RLIT0000180. This is a study which looks at
 12 the position of children. It is from the archives of
 13 Disease in Childhood, 1980, "Liver disease,
 14 complicating severe haemophilia in childhood", by
 15 McGrath and others. Again, the research appears to be
 16 based at Sheffield Children's Hospital and Sheffield
 17 University Medical School. Summary:

18 "Liver biopsies were performed in 5 boys aged
 19 between 2 and 9 years with severe classical
 20 haemophilia who had persistently abnormal liver
 21 function tests. Abnormal histology was present in
 22 all; 4 had chronic persistent hepatitis and the fifth
 23 chronic aggressive hepatitis with early cirrhosis.
 24 Evidence of previous hepatitis B infection was present
 25 in one patient [et cetera, et cetera]. The

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1 Haematologists.

2 **SIR BRIAN LANGSTAFF:** That's North East Thames, is it?

3 **MS RICHARDS:** Yes, North East Thames Region, yes, it would
 4 be.

5 If we can go to the second page please, Paul,
 6 under the heading "Two types of therapeutic material
 7 available" -- sorry, I should add, of course, that
 8 both Dr Colvin and Dr Kernoff were closely involved
 9 with the treatment of patients with bleeding
 10 disorders. So, "Types of therapeutic material
 11 available". If we pick it up halfway down that
 12 paragraph, Dr Kernoff says this to Dr Colvin:

13 "Not only is commercial concentrate expensive
 14 but there are both clinical and moral reasons for
 15 preferring the NHS material. The clinical reason is
 16 the growing awareness of the probability that
 17 commercial concentrates have a higher risk of
 18 transmitting non-A, non-B hepatitis than NHS
 19 material."

20 Then Dr Kernoff says this:

21 "This is a serious disease with long-term
 22 consequences which, as far as is known, is at present
 23 much less common in the UK than in those parts of the
 24 world, particularly the USA, where donor blood for
 25 commercial concentrates is collected. We may

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1 significance of these findings in young boys is
 2 discussed, as is the role of exposure to Factor VIII
 3 containing blood products. It is concluded that
 4 cryoprecipitate should be used in preference to large
 5 pool Factor VIII concentrates in children with
 6 haemophilia."

7 If we could go to the last page, please, and I'm
 8 grateful this was a document flagged up by
 9 representatives from one group of core participants on
 10 the basis it does look specifically at the position of
 11 children, and if we go to the bottom of the left-hand
 12 column on the last page, Paul:

13 "This study suggests that only brief exposure to
 14 Factor VIII concentrates (13 to 45 batches) is
 15 necessary to produce chronic liver damage in at least
 16 25 per cent of haemophiliacs requiring regular
 17 treatment. As children usually receive treatment in
 18 hospital until considered suitable for treatment at
 19 home we recommend such patients should, if possible,
 20 be treated with cryoprecipitate in preference to large
 21 pool Factor VIII concentrates until the significance
 22 of the chronic liver damage is better understood or
 23 until such Factor VIII concentrates have been refined
 24 to exclude viral hepatitis agents."

25 Then there's a discussion about the use of

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1 biopsies.
 2 Two further documents from 1980. The first is
 3 WITN0282008 please, Paul. This is a memo, a minute,
 4 from Dr Diana Walford to Mr Harley within the
 5 Department of Health and Social Security and it's
 6 dated 15 September 1980. The context is, and we heard
 7 some allusion to this in Lord Owen's evidence
 8 yesterday, the possible commercial takeover by
 9 Beecham's of BPL. In the context of discussing that,
 10 Dr Walford said this, third paragraph:

11 "I must emphasise that 90 per cent of all
 12 post-transfusion and blood product infusion hepatitis
 13 in the USA and elsewhere is caused by non-A, non-B
 14 hepatitis viruses which, unlike hepatitis B, cannot at
 15 present be detected by testing donor blood. This form
 16 of hepatitis can be rapidly fatal, particularly when
 17 acquired by patients with pre-existing liver disease
 18 or can lead to progressive liver damage. It can also
 19 result in a chronic carrier state thus increasing the
 20 pool of these viruses in the community."

21 So an important recognition there, sir, in 1980
 22 by Dr Walford of the DHSS of the serious nature of
 23 non-A, non-B hepatitis.

24 Then finally from 1980, Paul, could we have
 25 PRSE0003209, please. This is a document authored by

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1 Then skipping down a sentence:
 2 "The only common factor was regular treatment
 3 with Factor VIII concentrate. Most of the patients in
 4 this group are children or young adults, though the
 5 age range at Oxford is 6 to 70 years. It seems likely
 6 that some patients will develop severe chronic liver
 7 disease over the next ten years."

8 The reason for drawing attention to that in
 9 particular, sir, obviously is Dr Craske's close
 10 association with the Haemophilia Centre Directors
 11 organisations, the meetings of which he attended on
 12 a regular basis and to whom he gave regular advice.

13 **SIR BRIAN LANGSTAFF:** Can you just give me one moment.

14 Yes, I have a note just to compare what you were
 15 saying in February 1979 with what he was saying there.
 16 My note of 1979, the reference is PRSE0001960, you
 17 mentioned it earlier, that reference, where he was
 18 quoting the views, not his views but the views of what
 19 he described as American and German workers, that up
 20 to 40 per cent of non-A, non-B infections progressed
 21 to chronic liver disease and so, so far as chronic
 22 liver disease and non-A, non-B infections are
 23 concerned, that's what he seemed to be saying then.

24 Is he saying anything different in this article?

25 **MS RICHARDS:** I'm not sure that he is, sir. It may be

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1 Dr Craske for a symposium of the Royal College of
 2 Physicians, I think. It's called, "The epidemiology
 3 of Factor VIII and IX associated hepatitis in the UK".
 4 If we could turn please to page 7, we see this being
 5 said. Under the heading, first of all,
 6 "complications", it said:

7 "Most cases of non-A, non-B hepatitis are mild
 8 illnesses. Six cases have been reported as severe.
 9 Two patients have died in the acute stage of the
 10 disease but there were complicating factors in both
 11 instances."

12 Then there's a discussion of acute fulminating
 13 hepatitis. Then discussion of chronic liver disease.
 14 There's reference to persistently elevated levels and
 15 then this:

16 "Most of these patients are symptomless, however
 17 a few have clinical features suggestive of chronic
 18 liver disease but the ethical problems associated with
 19 the indications for liver biopsy meant that few
 20 patients have so far undergone this procedure. About
 21 40 patients have undergone biopsy in the UK and
 22 approximately 50 per cent of these have histological
 23 evidence of chronic persistent hepatitis. Other
 24 patients showed evidence of chronic liver disease or
 25 cirrhosis."

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1 that under the heading "Complications" where he says
 2 most cases of non-A, non-B hepatitis are mild
 3 illnesses he's thinking there of the acute phase and
 4 the acute phase only, and that would make sense both
 5 of what he'd previously said and with what he then
 6 goes on to say under the heading "Chronic liver
 7 disease".

8 **SIR BRIAN LANGSTAFF:** So that might be a reconciliation of
 9 the two?

10 **MS RICHARDS:** It might be.

11 Paul, could we then have, please, HSOC0008581,
 12 please. This is a series of Hansard extracts from
 13 various dates. Could we go to the last page of the
 14 document, please. Here we have an extract from
 15 Hansard on 24 February 1981, so we're now in early
 16 1981. This is Lord Cullen who is responding on behalf
 17 of the Government, that's apparent from the previous
 18 page. Lord Cullen says this:

19 "My Lords, blood products are not purchased
 20 centrally. They are purchased by health authorities.
 21 I regret that up-to-date information on the
 22 expenditure on imported products is not available."

23 It is obviously pertinent to some of the
 24 observations from the witness yesterday.

25 "The country from which these products come is

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1 mainly the United States. Some also come from Austria
 2 and one or two other European countries. So far as
 3 concerns making sure that these products are free from
 4 infection, undoubtedly the careful checks which are
 5 made at all stages are extremely effective for all
 6 except a very few products, one of which is used in
 7 the case of haemophiliacs. There is a danger that
 8 Factor VIII which has to be injected into
 9 haemophiliacs can have in it a strain of hepatitis and
 10 at the moment there is no way of testing for these
 11 strains. That is the one product as to whose freedom
 12 from infection we cannot be absolutely certain.
 13 However, every effort is made to see that it is not
 14 infected and although, occasionally, something may
 15 happen, it is not of a serious nature."

16 That is obviously, it's fair to say, in fairly
 17 stark contrast to the material in the medical and
 18 scientific literature that we've been looking at in
 19 the second half of the '70s.

20 1981 of course is where we begin to pick up the
 21 first reports of what will become known as AIDS.

22 Paul, could we please have CGRA0000242. This is the
 23 June 1981 morbidity and mortality weekly report by the
 24 Centres for Disease Control in the States and we see
 25 here under the heading, "Pneumocystis pneumonia,

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1 active hepatitis and of cirrhosis."

2 Then this:
 3 "Indeed, in some cases early death from liver
 4 disease might prove to be the price paid by
 5 haemophiliacs for the improved quality of life
 6 afforded by the easy availability of clotting-factor
 7 concentrates."

8 So the issue there addressed in the British
 9 Medical Journal, obviously a very commonly read
 10 journal for medical practitioners, in those somewhat
 11 stark terms.

12 If we go then please, Paul, to CGRA0000424, we
 13 are now in the CDC's morbidity and mortality weekly
 14 report for the end of August of 1981 and a significant
 15 number of further cases of Kaposi's sarcoma and PCP
 16 are reported. Third line:

17 "Since July 3, CDC has received reports of an
 18 additional 70 cases of these two conditions in persons
 19 without underlying disease."

20 Again, I'm not going to go through all of them
 21 but we then pick in December of 1981 a number of
 22 articles in the New England Journal of Medicine which
 23 considered this condition about these previously
 24 healthy individuals contracting PCP and/or Kaposi's
 25 sarcoma.

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1 Los Angeles", identification in the period
 2 October 1980 to May 1981, five young men, all active
 3 homosexuals, treated for biopsy confirmed PCP at three
 4 different hospitals in Los Angeles, California.

5 I won't go through all the various different
 6 MMWR reports but what we see when we trace them
 7 through is that as they continue through 1981, more
 8 and more cases are reported. So a month later, for
 9 example, in July 1981 the report is of 26 cases of
 10 Kaposi's sarcoma and a number of further cases of PCP.
 11 That continues.

12 If we have, please, Paul, before I return to HIV
 13 and AIDS, one further reference from this time on
 14 hepatitis, PRSE0003110. This is an article in the
 15 British Medical Journal July 1981. It is worth
 16 reading the first paragraph:

17 "Despite advances in screening donors and in
 18 blood fractionation post transfusion hepatitis remains
 19 the major complication of the modern treatment of
 20 haemophilia. The diagnosis is usually inferred from
 21 abnormalities in the results of hepatic biochemical
 22 tests rather than from clinical evidence. Surveys in
 23 haemophiliacs have shown changes in the liver
 24 architecture consistent with previous viral assault,
 25 including those of chronic persistent and chronic

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1 If we could then go please Paul to PRSE0004476,
 2 the second page please, this is The Lancet
 3 December 1981. So we have the articles in the States
 4 in the New England Journal of Medicine and in The
 5 Lancet a letter which is referring to the recent
 6 reports from the United States and sets out what the
 7 authors understand to be the first report of the
 8 condition in a patient in the United Kingdom a patient
 9 who had been referred to the Brompton Hospital.

10 We then -- I don't ask this to be turned up,
 11 Paul, but in January of 1982, because it's a rapidly
 12 developing picture, the New England Journal of
 13 Medicine reports now 159 documented cases reported to
 14 CDC between June and November. It's described as
 15 a serious public health problem with a high mortality
 16 rate.

17 Then throughout 1982 the MMWR from CDC continues
 18 to report an ever-increasing number of cases of KS or
 19 serious opportunistic infections.

20 **SIR BRIAN LANGSTAFF:** These are all cases generally in the
 21 community. They are not restricted to those who
 22 receive blood or blood products in any way?

23 **MS RICHARDS:** At this stage, that's correct. At this
 24 stage they are predominantly being reported in gay men
 25 and then we pick up in July of 1982 from the MMWR for

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1 9 July reports of opportunistic infections in Kaposi's
 2 sarcoma amongst Haitians in the US, and that describes
 3 of 19 patients it says the clinical course has been
 4 severe. Ten patients have died. I will give the
 5 reference for those who want to look it up -- I won't
 6 put it up on screen -- but it's PRSE0003880.
 7 Then same date, 9 July 1982, if we could have up
 8 on screen please, Paul, CGRA0000288. Here we see the
 9 first cases being reported in those who have received
 10 blood products. So it's a notification or a report
 11 from The Department of Health and Human Services in
 12 America to manufacturers of plasma fractionation
 13 products concerning a meeting concerning opportunistic
 14 infections in haemophilia A patients:
 15 "Three cases of PCP in patients with haemophilia
 16 A receiving anti-haemophilic factor have recently been
 17 reported to the Centers for Disease Control. All
 18 three patients were heterosexual white men without
 19 a history of intravenous drug abuse."
 20 Then there is reference to over the previous
 21 year the hundreds of cases of reports, most of which
 22 had been at that stage in homosexual men and
 23 individuals who were IV drug abusers. Then the last
 24 sentence of that second paragraph:
 25 "Although the cause of this outbreak is unknown,

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1 of an agent through blood products."
 2 We see that this is immediately known to the
 3 Department of Health and Social Security, and we can
 4 see that from DHSC0002219_009. This is an internal
 5 DHSS minute. The date is 16 July 1982. It's not
 6 a 100 per cent accurate account but we see why when we
 7 look at the document. It's addressed to a Dr Holgate:
 8 "Dr Holgate.
 9 "American Factor VIII.
 10 "You will wish to know that Dr Harold Gunson,
 11 our consultant adviser in blood transfusion, has
 12 received information from the American Bureau of
 13 Biologics via Dr Joe Smith at NIBSC that there may be
 14 considerable publicity in the next couple of weeks
 15 concerning the safety of American Factor VIII. Please
 16 forgive the layman's explanation below ..."
 17 This is where it's not entirely accurate but the
 18 essential message is clear:
 19 "I hope it makes some sense. Apparently, some
 20 research is about to be published showing fairly
 21 conclusively that plasma taken from homosexual drug
 22 takers contains a sort of virus which goes undetected
 23 when the plasma is tested because it is suppressed by
 24 the drugs. However, when used for Factor VIII it
 25 becomes active again. It seems that 400 haemophiliacs

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1 the information suggests that a transmissible agent
 2 might be involved and concern about transmission
 3 through blood and blood products has been raised."
 4 So that's 9 July 1982, and we see there's
 5 a reference there to a meeting planned for the
 6 following week.
 7 If we could then please go to PRSE0000523, Paul.
 8 We see this also being formally reported by the
 9 Centre for Disease Control in MMWR for July 16, 1982:
 10 "CDC recently received reports of three cases of
 11 PCP among patients with haemophilia A and without
 12 other underlying disease. Two have died. One remains
 13 critically ill ...", et cetera.
 14 Details are given of those patients.
 15 Then if we go to the second page, please, under
 16 the heading "Editorial note", second paragraph:
 17 "The clinical and immunologic features these
 18 three patients share are strikingly similar to those
 19 recently observed among certain individuals from the
 20 following groups ..."
 21 Then the groups are there set out: homosexual
 22 males, IV drug users, et cetera.
 23 "Although the cause of the severe immune
 24 dysfunction is unknown, the occurrence among three
 25 haemophiliac cases suggests the possible transmission

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1 in the USA have exhibited signs of the virus."
 2 I don't think that is in fact accurate at that
 3 point in time.
 4 "The report is expected to be picked up by the
 5 lay press and may cause a furor. I do not know which
 6 brands of Factor VIII are involved. From the DHSS
 7 point of view, we can defend the National Blood
 8 Transfusion Services' own record. Someone taking
 9 drugs, gay or not, would not be bled provided that the
 10 injection marks showed. In any case, with our
 11 voluntary unpaid donor system we do not have the same
 12 problem as in the States where drug addicts are
 13 tempted to give blood simply for the money. However,
 14 about half of the Factor VIII bought from commercial
 15 companies is imported from the USA. Your division,
 16 when the published study is available (I understand
 17 that one of your sections scans the technical
 18 literature for such material) may have to consider
 19 revoking licences of certain manufacturers. Of course
 20 it may turn out that none of the Factor VIII involved
 21 is supplied to this country."
 22 Of course that was not the case. But we can see
 23 that at the same time as this information is being
 24 published in the States it's being shared with the
 25 Department of Health and Social Security in the way

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1 that we see there.
 2 If we then have, please, Paul, BAYP0004205.
 3 It's not the most legible of documents but we will see
 4 from the title it is "Summary report on open meeting
 5 of PHS committee on opportunistic infections in
 6 patients with haemophilia".
 7 So it is a report of a meeting in the States
 8 which took place on 27 July 1982 considering the
 9 significance of the occurrence of opportunistic
 10 infections in PCP in those three patients with
 11 haemophilia. Wide variety of organisations and
 12 participants.
 13 Then if we go to the second half of that page,
 14 under the heading "Aspects of discussion":
 15 "AIDS [it's one of the first examples of the
 16 term being used] and the sequelae of KS and OI [that's
 17 the Kaposi's sarcoma and opportunistic infections] are
 18 occurring in several populations [they are then
 19 identified]. The possibility exists that it is
 20 incurring in patients with haemophilia. If the PCP
 21 observed in three patients with haemophilia represents
 22 the same process as seen in other groups with AIDS,
 23 then a possible mode of transmission is via blood
 24 products, in this case Factor VIII concentrate. This
 25 finding would strengthen the existing hypothesis that

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1 a long-established journal. This article is dated
 2 13 August 1982, headed, "New disease baffles medical
 3 community".
 4 If we look in the first -- the left-hand column
 5 towards the bottom of the page it says this:
 6 "Although other explanations have not been ruled
 7 out, most investigators currently think that the
 8 disease is caused by an infectious agent, possibly
 9 a new virus or a new variant of an existing virus.
 10 The spread of AIDS resembles that of hepatitis B
 11 virus."
 12 Then if we could go to the next column, please,
 13 Paul, a bit further up, this is picking it up a couple
 14 of paragraphs in:
 15 "Hepatitis B is also transmitted through
 16 transfusion of whole blood or blood products.
 17 Recently three individuals with haemophilia have come
 18 down with AIDS, an occurrence which is particularly
 19 disturbing because of the possibility they acquired an
 20 infectious agent from the blood product they take to
 21 prevent bleeding. So far, however, there is no
 22 evidence linking ordinary blood transfusions to the
 23 immunodeficiency disease ..."
 24 Then the person cited there is a representative
 25 of the Centers for Disease Control.

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1 AIDS is caused by a transmissible agent."
 2 Then if we go next, please, to PRSE0003247 we
 3 move here from the States to an international congress
 4 in Budapest for the International Society of
 5 Haematology and the International Society of Blood
 6 Transfusion. It was attended by Dr Peter Foster of
 7 the PFC in Edinburgh in August 1982, and this is his
 8 report.
 9 If we go to the last page, please, Paul, the
 10 last page with any text on -- most of the paper is
 11 concerned with a very detailed technical discussion of
 12 issues relating to fractionation and other matters.
 13 But then he makes this reference:
 14 "In discussion future problems in the treatment
 15 of haemophilia, Aledort reported that the most recent
 16 problem to surface in the USA has been three deaths
 17 from pulmonary infections. This has been linked with
 18 the development of acquired immunodeficiency
 19 syndrome."
 20 So this information about the three
 21 haemophiliacs in the US is clearly by this stage being
 22 widely disseminated to knowledgeable individuals.
 23 Could we then have please, Paul, probably the
 24 last document before the break, RLIT0000200. This is
 25 an article in the publication Science,

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1 Sir, I note the time. I can probably just about
 2 fit in another document or we could break and resume
 3 after the break.
 4 **SIR BRIAN LANGSTAFF:** The only other thing just I note
 5 from a quick glance at what is said there in Science
 6 is if one looks at the third column across, about
 7 halfway down, it notes that the infections seen in
 8 AIDS patients which first began to be noticed in about
 9 mid-1979. Well, if that is correct, then it would
 10 look as though back in 1979, two years before the MMWR
 11 reported it in June of '81 there were developing
 12 infections and it might suggest, might it, a long
 13 incubation period?
 14 **MS RICHARDS:** Yes, absolutely.
 15 **SIR BRIAN LANGSTAFF:** For AIDS, from whatever was causing
 16 it.
 17 **MS RICHARDS:** Yes.
 18 **SIR BRIAN LANGSTAFF:** We will take a break until 3.45.
 19 (3.01 pm)
 20 (A short break)
 21 (3.43 pm)
 22 **MS RICHARDS:** We pick the picture up in September 1982
 23 now, HCDO0000410. This is a meeting of the
 24 Haemophilia Reference Centre directors on
 25 6 September 1982, and it's the first reference in any

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1 of their meetings to the question of AIDS.
 2 If we could go please, Paul, to page 11, we'll
 3 see the second paragraph and this is how it comes up:
 4 "Professor Bloom asked Dr Craske if he had any
 5 information about the acquired immune deficiency
 6 syndrome following reports from the United States and
 7 the possible relationship of the syndrome with blood
 8 products and hepatitis. Dr Craske said he would find
 9 out more about this and agreed to try and have some
 10 information available for the Haemophilia Centre
 11 directors at the Manchester meeting."

12 That Manchester meeting took place a week later.
 13 That's CBLA0001619. So we can see this is the bigger
 14 meeting, involving all of the Haemophilia Centre
 15 directors and not just the directors of the reference
 16 centres, 13 September 1982. If you could go please,
 17 Paul, to page 10, we will see Dr Craske's report back
 18 at the bottom of the page:

19 "The Acquired Immune Deficiency Syndrome.
 20 "The Reference Centre directors had asked
 21 Dr Craske to look into the report from the
 22 United States of this syndrome, mainly in homosexuals
 23 but including three haemophiliacs. It appeared that
 24 there was a remote possibility that commercial blood
 25 products had been involved. Dr Craske asked the

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1 MDIA0000010. So we're now in the mainstream
 2 media. Rather than scientific journals or medical
 3 journals, this is The Observer, 14 November 1982. "No
 4 defence against gay disease" is the heading. If we
 5 look -- it's quite small print -- in the fourth column
 6 please, Paul, top half of the page -- fourth column:

7 "AIDS is not infectious though as colds and
 8 measles might be. Close relatives and friends do not
 9 catch it. A major speculation is that the AIDS virus
 10 is carried in the blood and transmitted directly
 11 either sexually or through syringes, which is how
 12 hepatitis B, to which homosexuals are also prone,
 13 spreads. This link with hepatitis might also explain
 14 the presence of AIDS among heterosexuals who inject
 15 drugs [et cetera, et cetera]. This could also explain
 16 the presence of AIDS in a small group of heterosexual
 17 haemophiliacs who injected themselves frequently with
 18 a blood concentrate designed to encourage clotting."

19 So The Observer there reporting in November 1982
 20 the potential connection between -- or the potential
 21 blood transmission route of the AIDS virus.

22 Could we then, please, Paul, have
 23 BYAP0000018_119.

24 This is a new letter from the American National
 25 Hemophilia Foundation. The date is December 9, 1982.

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1 directors to let him know if they had any cases of the
 2 syndrome. The Working Party [that's the hepatitis
 3 working party of the Haemophilia Centre Directors
 4 Organisation] was considering the implications of the
 5 reports in the USA."

6 Sir, obviously one of the many issues that you
 7 will have to consider in due course about the response
 8 of haemophilia directors is whether this was, at this
 9 stage, a sufficiently urgent and accurate
 10 appreciation, this characterisation of a "remote
 11 possibility" of the involvement of commercial blood
 12 products.

13 Paul, could we have OXUH0002848, please. This
 14 is a further MMWR report from CDC, 24 September 1982.
 15 It includes now a case definition for AIDS. But for
 16 present purposes if we could just look at the third
 17 page, please, Paul, first main paragraph:

18 "Two points in this update deserve emphasis.
 19 First, the eventual case-mortality rate of AIDS a few
 20 years after diagnosis may be far greater than the
 21 41 per cent overall case-mortality rate noted above."

22 I just draw attention to that, sir, to indicate
 23 that at this stage one thing that was seemingly
 24 apparent was the very high mortality rate from AIDS.

25 Paul, could we next have, please, MDIA0000010.

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1 It's concerned with AIDS, "AIDS update":

2 "In July of 1982 the CDC reported three cases of
 3 AIDS identified among haemophilia A patients. Since
 4 then none of these have survived. The following is a
 5 summary of a December 10, 1982 CDC update on AIDS.
 6 The CDC has confirmed four additional and one highly
 7 suspect case among haemophilia A patients."

8 There's reference to there being no suggestion
 9 of the haemophiliacs acquiring the disease through
 10 contact with each other or other groups known to be at
 11 increased risk.

12 "The MMWR points out at all of these cases to be
 13 supposed to Factor VIII concentrates and all but one
 14 have also received other blood components."

15 Then, if we go to the next page, please, Paul:

16 "CDC recommends that patients should be advised
 17 of this risk."

18 Then the last two paragraphs:

19 "It is important to note that while there is
 20 insufficient data to directly link the spread of AIDS
 21 to concentrate, there is an increased concern that
 22 AIDS may be transmitted through blood products. It is
 23 the NHF's point of view that patients and parents
 24 should be aware of the potential risks."

25 Then it is suggested:

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1 "If you have any questions they should be
2 directed to the treating clinician."
3 So that's the advice emanating from the States
4 in December 1982.

5 If we then please, Paul, go to PRSE0003276 and
6 if we could go please to page 4, this is
7 10 December 1992 MMWR. This is the report of what's
8 referred to elsewhere as the San Francisco baby case,
9 sir. Possible transfusion associated acquired
10 immunodeficiency syndrome, California.

11 "CDC has received a report of a 20 month old
12 infant in the San Francisco area who developed
13 unexplained cellular immunodeficiency and
14 opportunistic infection. This occurred after multiple
15 transfusions including a transfusion of platelets
16 derived from the blood of a male subsequently found to
17 have AIDS."

18 If we go to the next page please, Paul,
19 editorial note, just over halfway down the page:

20 "The aetiology of AIDS remains unknown but it is
21 reported occurrence among homosexual men, intravenous
22 drug users and persons with haemophilia A suggests it
23 may be caused by an infectious agent transmitted
24 sexually or through exposure to blood or blood
25 products. If the infant's illness described in this

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1 should not withhold the use of clotting factor therapy
2 when needed."

3 If we then please, Paul, have CGRA0000434. This
4 is a Cutter memo, still in December 1982. This is
5 29 December 1982, so pharmaceutical company:

6 "It appears to me to be advisable to include an
7 AIDS warning in our literature for Factor IX and
8 Factor VIII. I realise that very little is known
9 about AIDS and the relationship that products we
10 manufacture have in causing the syndrome. However,
11 litigation is inevitable and we must demonstrate
12 diligence in passing along whatever we do know to the
13 physicians who prescribe the product", and then there
14 were steps set out for inclusion in package insert,
15 et cetera, once the wording is agreed.

16 So we've looked at -- sir, what Cutter was
17 saying. We've looked at what the National Haemophilia
18 Foundation in the States is saying. We're now going
19 to look at the domestic Haemophilia Society, the UK
20 Haemophilia Society. It's first bulletin of 1983. It
21 is PRSE --

22 **SIR BRIAN LANGSTAFF:** Before you go to 1983, you mentioned
23 a moment or two ago by reference to CBLA0001619,
24 I think suggesting that Craske had made a report and
25 the conclusion was that it was a remote possibility

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1 report is AIDS it's occurrence following receipt of
2 blood products from a known AIDS case adds support to
3 the infectious agent hypothesis."

4 We see there and if we go to PRSE0002436 this is
5 another newsletter from the National Haemophilia
6 Foundation in the States, the date now December 21,
7 1982. If we go further down we will see in the second
8 paragraph:

9 "There's an increased concern that AIDS may be
10 transmitted through blood products. Patients and
11 parents should be aware of the potential risks. There
12 is no conclusive evidence that cryoprecipitate or
13 fresh frozen plasma will reduce the risk of AIDS. We
14 feel however that this is no time to introduce
15 concentrates to patients who have never used them
16 before, except when there is an overriding medical
17 indication."

18 Then examples of patients who should not be
19 introduced to the concentrates at this time: new born
20 infants through age 4, newly diagnosed cases of
21 haemophilia, and those with mild disease.

22 Then it continues:

23 "At this time the NHF AIDS task force does not
24 recommend a change in treatment to those who have
25 received concentrates and therapy and by all means one

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1 that commercial blood products were involved and you
2 suggested I might have to resolve whether that was
3 a sufficient response. I don't know if we have
4 a copy, if Paul has a copy of BPLL0011645.

5 **MS RICHARDS:** I'm not sure that he will, sir.

6 **SIR BRIAN LANGSTAFF:** Let me tell you what my note says.
7 It will need to be checked, but I have a note that on
8 5 November 1982 Craske wrote a memo in respect of
9 AIDS, so this is only --

10 **MS RICHARDS:** We do have it, sir, with a different
11 reference, CBLA0001653_003 is Dr Craske on 5 November.

12 **SIR BRIAN LANGSTAFF:** I think he looks at the possible
13 cause. He puts forward three possible causes and he
14 discounts the first two causes. That is the use of
15 amyl nitrate as a sexual heightener during homosexual
16 intercourse and the immunosuppressive effects of CMV,
17 cytomegalovirus, which leaves only one.

18 **MS RICHARDS:** Yes, if we go to the next page, please,
19 Paul, we can see. Yes, it's put here by Dr Craske:

20 "The association with sexual promiscuity,
21 intravenous drug abuse and possibly [again, the word
22 is 'possibility'] the transfusion of commercial blood
23 concentrates, together with evidence of clustering and
24 a prodromal phase, suggest an infectious agent with
25 a similar epidemiology to that of hepatitis B."

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1 Then he says --

2 **SIR BRIAN LANGSTAFF:** So he discounts (2) and is left with

3 the infectious agent idea, doesn't he?

4 **MS RICHARDS:** Yes. Then he says:

5 "If (3) is the most likely cause ..."

6 Then he talks about the possibility of it being

7 present in plasma used to prepare hepatitis B

8 vaccines.

9 **SIR BRIAN LANGSTAFF:** I think, if you just scroll down to

10 the end -- I don't think there's anything else there.

11 But at least it may set the record straight so far as

12 he is concerned. Perhaps. Something I will have to

13 consider, in any event.

14 **MS RICHARDS:** Yes.

15 So, Paul, if we have, please, now -- we're in

16 early 1983 -- PRSE0004120, please.

17 This is a Haemophilia Society bulletin. We

18 don't have the precise dates, sir. It is the first

19 bulletin that was published in 1983 and so the

20 date that has been ascribed on our systems in the

21 chronology is effectively 1 January 1983. It almost

22 certainly was later than that but we don't know the

23 precise date.

24 If we could go to the penultimate page, please,

25 Paul.

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1 products. If AIDS is caused by an infectious agent

2 and if this agent is transmitted by blood product

3 infusion, and these are both big ifs, then it may be

4 that haemophiliacs could be at increased risk of

5 AIDS."

6 Then the question:

7 "Well, do haemophiliacs get AIDS?

8 "Amongst the group of patients with AIDS who

9 have been reported to the American authorities, there

10 have been 11 haemophiliacs. It's not entirely clear

11 how many of these haemophiliacs had risk factors which

12 were unrelated to their haemophilia."

13 Pausing there, the information in the MMWRs

14 doesn't suggest any association with any other risk

15 factors in its report of cases, and then the question:

16 "Could British haemophiliacs get AIDS?

17 "Of course it's possible, but I'd expect AIDS to

18 remain a rare disease. The idea that there's an

19 epidemic of AIDS amongst haemophiliacs is ludicrous."

20 Is his answer.

21 Paul, if we could then have CGRA0000301, please.

22 This is 4 January 1983. It's a report on a CDC

23 multi-agency meeting, so it's, again, an American

24 meeting.

25 If we go to the second page, the meeting that

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1 What we have towards the bottom human right

2 corner is, if we scroll down:

3 "AIDS and haemophilia; an interview with

4 Dr Peter Kernoff, director of the Haemophilia Centre

5 at the Royal Free Hospital in London."

6 Then if we go to the next page, please, it's

7 a written question and answer. I'll just refer to

8 three of the questions and answers:

9 "What's the cause of AIDS?

10 "That's not known, but because there are

11 similarities between the groups of people who seem to

12 be getting AIDS and those who are known to be at risk

13 of hepatitis B, it's been suggested that AIDS might be

14 caused by an infectious agent, perhaps a virus, which

15 is transmitted in the same way as hepatitis B. That

16 is, mainly by injected blood or blood products and

17 sexual contact. However, this is just a guess and

18 there are several other possibilities."

19 He doesn't set out what those possibilities are.

20 "Question: I begin to see links with

21 haemophilia.

22 "Answer: Yes, but they are very tenuous.

23 Certainly we know that haemophiliacs are at higher

24 than normal risk of getting hepatitis B because of

25 their frequent exposure to infusions of blood

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1 took place in Atlanta, and if we go down to the second

2 half of the page, "Aspects of discussion":

3 "AIDS continues to be a major public health

4 problem. In addition to the previously described

5 high-risk groups [and those are then listed] persons

6 with haemophilia are also at increased risk of

7 developing AIDS, presumably by introduction of

8 a transmissible agent in Factor VIII concentrate.

9 Five cases of AIDS have been reported in persons with

10 haemophilia since the three described in July and two

11 to three more are considered to be possible cases.

12 One case of AIDS has occurred in an infant who

13 received a platelet transfusion from a man who

14 subsequently was diagnosed as an AIDS patient."

15 That's probably a reference to the San Francisco

16 baby case.

17 "Several other AIDS cases under investigation

18 [5] have no risk factors but have received blood

19 products within the past two years. Some participants

20 were reluctant to accept the hypothesis that AIDS has

21 been transmitted by whole blood in the absence of

22 additional evidence."

23 So that's the CDC meeting in January 1983.

24 Then if we could, please, Paul, have

25 RLIT0000233.

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1 This is a publication in Science Journal,
 2 7 January 1983, "Spread of AIDS sparks new health
 3 concern". Picking it up in the left-hand column:
 4 "The relentless new disease called AIDS
 5 continues to spread."
 6 Reference to certain data, and then the second
 7 paragraph says this:
 8 "Moreover, blood products have come under
 9 increased suspicion as vehicles for spreading AIDS.
 10 An infant who received several infusions of whole
 11 blood in blood products developed the condition. One
 12 of the donors who had appeared well at the time he
 13 gave blood eventually died of the disease. The CDC
 14 also reports the diagnosis of AIDS in four
 15 haemophiliacs in addition to the three previously
 16 identified, confirming earlier suggestions that these
 17 individuals might be at high risk."
 18 We see here the comment from CDC, perhaps in
 19 contrast to Dr Kernoff's comment:
 20 "'The problem in haemophiliacs is real,' says
 21 the CDC's Harold Jaffe, 'It isn't going to go away.'
 22 Their latest reports support the hypothesis that AIDS
 23 is caused by an infectious agent, possibly a virus,
 24 that can be transmitted by close contact, including
 25 that between family members, or by blood products.

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1 the Observer, 16 January 1983, "Mystery disease
 2 threat":
 3 "A commercial blood product imported into
 4 Britain from the US may pose a grave threat to the
 5 health of haemophiliacs, who inject it to encourage
 6 clotting."
 7 Skip a paragraph:
 8 "Officials at the Government Centre for Disease
 9 Control in Atlanta, Georgia, have described the spread
 10 of the disease as an impending epidemic among
 11 haemophiliacs."
 12 Then the right-hand column, second paragraph,
 13 few lines down:
 14 "In the past ten months the disease has spread
 15 from the homosexual community to include haemophiliacs
 16 [and various others listed]. The cause remains
 17 baffling. One theory is that an infectious agent is
 18 transmitted directly, either sexually or through
 19 contaminated blood products, in a similar manner to
 20 hepatitis B, to which homosexuals and haemophiliacs
 21 are also prone."
 22 Then if we just scroll out, please, so we see
 23 the whole document, Paul, we can see from the
 24 handwritten notes at the top of the page that this is
 25 a document that came to the attention of the

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1 The latter possibility raises a serious health issue
 2 about the safety of the blood products used by
 3 haemophiliacs and perhaps by the general public."
 4 Then if we could, Paul, go to PRSE0002410, we
 5 are here in the New England Journal of Medicine,
 6 13 January 1983. The article is entitled "AIDS and
 7 preventive treatment in haemophilia". If we could go
 8 to the second page please, Paul, to the last
 9 paragraph:
 10 "The fact that haemophiliacs are at risk for
 11 AIDS is becoming clear. If the use of cryoprecipitate
 12 will minimise this risk, the current home infusion
 13 programme needs to be revised."
 14 Then there's reference to the studies there
 15 being small studies.
 16 "Unfortunately the data are consistent with
 17 a greater potential for AIDS in the population treated
 18 with concentrates. Physicians involved in the care of
 19 haemophiliacs must now be alert to this risk.
 20 Preventing the complications of the present treatment
 21 may have to take precedence over preventing the
 22 complications of haemophilia itself."
 23 Then, Paul, if we could have DHSC0002223_085.
 24 Do you have that? DHSC0002223_085. Thank you.
 25 So we're again back into the mainstream media,

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1 Department of Health and Social Security, because
 2 there's a note to Dr Walford, saying to her:
 3 "It would be useful to know the outcome of
 4 Haemophilia Centre directors meeting. Perhaps we can
 5 discuss at an opportune moment."
 6 She's says she's written to Professor Bloom for
 7 details of the meeting. We may look at that
 8 correspondence tomorrow when we look at
 9 Professor Bloom.
 10 So that's 16 January 1983. We then, please,
 11 Paul, could we have SBTS0000315_021.
 12 This is an article that doesn't really say
 13 anything different from what we have seen, but the
 14 point here is this is The Lancet, so the news is being
 15 broadcast now in The Lancet, 22 January 1983, under
 16 the heading, "Acquired immunodeficiency syndrome". At
 17 the very bottom of the page:
 18 "There are at least four major populations at
 19 risk in the USA, about 75 per cent of patients are
 20 homosexual males [if we scroll down please, Paul]
 21 13 per cent are intravenous drug abusers with no
 22 history of homosexuality, 6 per cent are Haitian
 23 immigrants who are not homosexual and do not abuse
 24 drugs, 0.7 per cent are haemophiliacs, about
 25 5 per cent of no apparent risk factors."

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1 Then if we look down in the left-hand column
 2 towards the end the second long paragraph, it says:
 3 "Finally, the syndrome may well be
 4 transmissible, women may acquire AIDS from their male
 5 partners and the disease is developed in haemophiliacs
 6 after Factor VIII administration, in a child after
 7 blood transfusion, and in four infants whose mothers
 8 either had or were at risk of AIDS."
 9 Next paragraph:
 10 "The overall mortality from AIDS is an alarming
 11 40 per cent and in reality it may be considerably
 12 greater since many patients who recover initially die
 13 subsequently from malignant disease or overwhelming
 14 infection. There are few reports of complete
 15 remission."
 16 That's picked up then in the New Scientist a few
 17 days later, PRSE000726. You may recall we looked at
 18 this article during the evidence of Andrew Evans last
 19 year when he had a recollection of his father seeing
 20 this, "AIDS transfusion patients may be at risk", so
 21 this is the New Scientist for 3 February 1983:
 22 "American scientists are scouring the country
 23 for the first case of the bizarre new disease AIDS in
 24 patients who have undergone major surgery."
 25 Then skipping over a couple of paragraphs it

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1 This is Mr Berry sending a summary of
 2 discussions at the meeting held at the Excelsior Hotel
 3 Heathrow Airport on Monday 24 January 1983. We have
 4 two accounts of this meeting. This is Mr Berry of
 5 Immuno's account and this is a document we're highly
 6 likely to come back to a number of times over the
 7 coming months, sir.
 8 We'll see at the top of the second page:
 9 "Summary of discussions of the meeting held at
 10 Excelsior Hotel, Heathrow Airport, Professor Bloom in
 11 the chair", and then there is a discussion, and I'm
 12 not going to go into the details of this part of the
 13 discussion about non-A, non-B hepatitis.
 14 If we could go to the last page of this note,
 15 paragraph 13, this is the only reference to AIDS in
 16 this note and it says this:
 17 "The possibility of reducing the risk of AIDS
 18 was not known at this stage. In any case, it is not
 19 known if AIDS is caused by a virus or an attacker
 20 inimical to T cells."
 21 For a more detailed understanding of what
 22 discussions took place at that hotel meeting we have
 23 to go to notes made we think by Dr Bolton and that is
 24 at PRSE0002647.
 25 Paul, could we go to the last page, first of

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1 refers to:
 2 "A task-force under Dr Harold Jaffe at the CDC
 3 in Atlanta has found seven cases of AIDS amongst
 4 haemophiliacs who do not fall into any of the other
 5 categories. Jaffe believes that the spread of the
 6 disease may be connected with new preparations of
 7 Factor VIII concentrate, the blood-clotting agent
 8 given to haemophiliacs which are made up from blood
 9 from large numbers of donors, rather than one
 10 individual. If this is correct, any patient in
 11 hospital who is given a blood transfusion could be at
 12 risk if one of the donors of the blood carries the
 13 virus. No cases of AIDS among British haemophiliacs
 14 have been reported so far, even though 50 per cent of
 15 the Factor VIII used in Britain comes from the US."
 16 Sir, shortly before that article, there was
 17 a meeting on 24 January 1983 at a London airport
 18 hotel. We're going to look at two documents that
 19 relate to that meeting. The first is at RFLT0000050,
 20 so you will see this is a letter being sent by
 21 Mr Berry the managing director of Immuno to
 22 Dr Kernoff, co-director of the Royal Free Hospital --
 23 the Haemophilia Centre at the Royal Free hospital and
 24 it was Dr Kernoff who some time after this gave the
 25 interview in the Haemophilia Society bulletin.

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1 all, so we can see the list of attendees. Those
 2 present included Dr Evans, Manchester; Dr Barrowcliff;
 3 Dr Rizza, Oxford; Dr Hamilton, Newcastle; Dr Ludlam,
 4 Edinburgh, Dr Colvin, London Hospital; Professor
 5 Hardisty we know from Great Ormond Street; Dr Preston,
 6 Sheffield, I think I'm sure I will get some of this
 7 wrong; Dr Mayne, Belfast; we have Dr Davidson;
 8 Dr Aronstam, who was Treloars; Dr Hill, we know
 9 Birmingham; Dr Edgecombe; Dr Prentice; Dr Savage, he
 10 was St Thomas'; Dr Kernoff, Royal Free; Dr Leslie;
 11 Dr Winfield; Dr Wensley, Dr Mibashan; Dr Craske; and
 12 then we have Professor Zuckermann, who we saw in the
 13 World in Action documentary, the hepatitis expert;
 14 Dr Bloom; Dr Shinton; the Immuno team are led by
 15 Dr Eibl.
 16 So it was a meeting involving a number of
 17 Haemophilia Reference Centre directors, others with
 18 a particular interest in hepatitis and representatives
 19 of Immuno.
 20 Again, I'm not going to deal with the discussion
 21 about non-A, non-B hepatitis. We'll come back to that
 22 at another time but if we go to the previous page
 23 please, Paul, we see a much more detailed account than
 24 we saw in Mr Berry's note of the discussion that took
 25 place about AIDS at that January '83 meeting:

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1 "Acquired immunodeficiency syndrome. This was
2 discussed in the after lunch period. Dr Craske
3 summarised the current position. He gave a clinical
4 description of the AIDS syndrome ..."

5 If we go down a couple of paragraphs:
6 "Up to 10 December 1982 some 800 people have
7 been reported as suffering from the AIDS and there was
8 a 45 per cent mortality. Ten haemophiliacs in the US
9 have been affected and five have died. The youngest
10 was aged 7. All cases have had prolonged treatment
11 with Factor VIII, but there is no specific implication
12 of one particular product or batch. Other cases
13 involving blood and blood product transmission have
14 included platelets transfused in three cases. In one
15 of these cases one of the donors was a young New York
16 man in his twenties. A second case was a 20-month old
17 child with rhesus HDN who had received several units,
18 including platelets known to have come from
19 a homosexual donor who was asymptomatic at the time
20 but who later died."

21 That again is no doubt a reference to the
22 San Francisco baby case:
23 "The child had developed autoimmune haemolytic
24 anaemia and a possible AIDS state."
25 Over the page:

1 So a much more detailed account there of
2 a discussion about current up-to-date information of
3 numbers affected in the US and again, sir, no doubt
4 we'll come back with individual witnesses to their
5 recollection and understanding of that meeting and its
6 significance in terms of what was done or not done
7 subsequently.

8 **SIR BRIAN LANGSTAFF:** Is there anything else in that
9 document which suggests anything other than some form
10 of infectious agent or agents?

11 **MS RICHARDS:** No, sir.
12 That was 24 January. The next Reference Centre
13 Director meeting, of haemophilia centre directors, was
14 on 14 February and we'll just briefly look at that
15 please. It is HCDO0000411. If we go to the second
16 page please, Paul, we can see these are draft minutes
17 but I don't think we have a final version. Minutes of
18 the 16th meeting of haemophilia reference centre
19 directors held at the Royal Free Hospital on Monday
20 14 February and we see the names of those attending
21 almost all of whom had been at the London airport
22 meeting approximately three weeks before.

23 If we look and see what was discussed about
24 AIDS, it's the fifth page of the document, Paul.
25 Thank you. Six lines down:

1 "The incubation period for the syndrome appears
2 to be six months to two years. In the UK so far only
3 one or two cases have been reported from the
4 Communicable Diseases Centre. The infectious
5 precautions including discouraging homosexuals from
6 donating blood or organs. Protocols from the US are
7 being considered by the hepatitis working party in the
8 UK. Apparently, the American fractionation companies
9 are very aware of the problem and are taking some
10 unspecified measures to screen out such donors. The
11 attention of the meeting was then drawn to the two
12 articles on the editorial in the New England Journal
13 of Medicine of 13 January, which in summary indicates
14 that the T4/T8 ratios among haemophiliacs receiving
15 Factor VIII is greater among those who have been
16 exposed to concentrates than those exposed to
17 cryoprecipitate only. However cryoprecipitate in the
18 US comes from volunteer unpaid donors and therefore
19 are presumably well motivated people. Final comments
20 on the possible nature of the transmissible agents
21 indicated that there may not be just one agent but a
22 mixture, i.e. a barrage of viruses, including
23 hepatitis B, non-A, non-B, CMV and many others
24 possibly transmitted from asymptomatic healthy blood
25 donors."

1 "The AIDS syndrome, Professor Bloom said that
2 the syndrome would be discussed at the Stockholm
3 meeting of the World Federation of Haemophilia.
4 Reports from the United States indicated that the
5 incidence of AIDS was higher than at first thought and
6 there was some concern that the haemophilic
7 population of the UK who had received American
8 concentrates might be at risk. Dr Craske summarised
9 the latest information from the United States, said
10 that approximately 10 cases of AIDS were thought to
11 have occurred in non-haemophiliacs in London, one in
12 Glasgow, and one in Manchester. Dr Craske had drawn
13 up a draft form for reporting of the cases. There was
14 a lengthy discussion regarding the report form and
15 which of the various documents which Dr Craske had
16 obtained from the United States should be circulated
17 to the haemophilia centre directors. It was agreed
18 that Dr Craske should draw up a new form for the
19 reporting of cases and to arrange for this to be
20 circulated to all haemophilias centre directors with
21 appropriate notes regarding the criteria on which the
22 diagnosis should be based. It was suggested that
23 Dr Craske should invite an immunologist to join the
24 hepatitis working party in view of the working party's
25 involvement with the AIDS syndrome."

1 That's the extent of the discussion on
2 14 February. You can see the action taken there is as
3 regards reporting and sharing of some information
4 about diagnosis.

5 There is no discussion recorded in the notes of
6 any steps to be taken to inform patients of the risk,
7 in contrast to what we see from the National
8 Haemophilia Foundation in the States, and no
9 discussion recorded in the notes about any changes or
10 possible changes to treatment policies or approaches.

11 Paul, if we could then please have PRSE0000546.
12 This is now the early March 1983, 4 March. It's
13 another MMWR report from the CDC in the States. If we
14 look at the third paragraph:

15 "The distribution of AIDS cases parallels that
16 of hepatitis B virus infection, which is transmitted
17 sexually and parenterally. Blood products or blood
18 appear responsible for AIDS amongst haemophilia
19 patients who require clotting factor replacement. The
20 likelihood of blood transmission is supported by the
21 occurrence of AIDS among IV drug abusers."

22 Then reference to:
23 "Sharing of contaminated needles, to an infant
24 developing severe immune deficiency and opportunistic
25 infection [that's the San Francisco baby case again]

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1 meeting of the Haemophilia and Blood Transfusion
2 Working Group. We can see there the attendees include
3 Dr McDonald, Dr Cash, Dr Forbes, Dr Foster, and
4 Dr Ludlam.

5 If we turn please to the second page, bottom of
6 the page:

7 "AIDS. Members were reminded of the recent
8 articles both at home and abroad about AIDS.
9 Dr Ludlam reported that in the UK a letter and
10 questionnaire had been sent out to haemophilia
11 directors."

12 That's no doubt a reference to Dr Craske's
13 proposals which had been discussed at the February
14 reference centre directors meeting.

15 "AIDS was an emotive issue in the USA and Canada
16 and was causing a move away from the Factor VIII
17 concentrates to the use of cryoprecipitate, with the
18 resultant supply problems. There was concern that
19 AIDS might appear in the UK and the Haemophilia
20 Society was attempting to reassure its members and put
21 fears of infection from blood products into
22 perspective."

23 Next page:
24 "The transfusion directors were loath to ask
25 questions to which exception could be taken by

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1 the possibility of acquiring AIDS through blood
2 components or blood is further suggested by several
3 cases in persons with no known risk factors who have
4 received blood products or blood within three years of
5 AIDS diagnosis. These cases are currently under
6 investigation."

7 So, sir, again picking up on one of your earlier
8 observations, no suggestion of any other cause and
9 here the term used is "likelihood" not "possibility"
10 of blood transmission.

11 If we could go to the second page, please, Paul,
12 picked it up six lines down:

13 "Furthermore, the California cluster
14 investigation and other epidemiologic findings suggest
15 a latent period of several months to two years between
16 exposure and recognisable clinical illness and imply
17 that transmissibility may precede recognisable
18 illness."

19 So we're there in early March. There's some
20 relevant communications in March between Bruce Evert
21 in the States and Professor Bloom, but I am going to
22 deal with that when we look at Professor Bloom and
23 Cardiff tomorrow.

24 Could we then please, Paul, have PRSE0000728.
25 This is a meeting on 22 March 1983 in Scotland,

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1 potential donors, but it was hoped that homosexuals
2 and others at risk might be discouraged from being
3 donors. In the meantime the transfusion directors
4 were considering how best to ensure the safety of the
5 plasma supply and Dr Forbes was conducting a sample
6 study of the immunological status of haemophilia
7 patients. The Chairman agreed to keep the matter in
8 view and bring it up for discussion at the next
9 meeting."

10 Sir, March 1983, there was an important decision
11 in the States.

12 Paul, could we have DHSC0001203.

13 This is 24 March 1983, a decision of the FDA,
14 the Food and Drug Administration.

15 This communication is from the director, Office
16 of Biologics, National Centre for Drugs and Biologics,
17 to all licensed manufacturers of plasma derivatives:

18 "Extensive discussions among licensed
19 manufacturers at the Office of biologics and concerned
20 groups such as the National Haemophilia Foundation
21 have led to a consensus concerning an appropriate
22 approach to decreasing the potential risk of
23 transmitting AIDS by certain plasma derivatives.
24 Plasma collected from donors suspected of being at
25 increased risk of transmitting AIDS [and then they are

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1 then defined] should not be fractionated into
 2 derivatives already known to have a risk of
 3 transmitting infectious diseases."
 4 Then if we skip down to the next paragraph:
 5 "We request that you immediately institute
 6 procedures with your plasma suppliers to assure that
 7 they have adopted appropriate donor screening
 8 practices and procedures."
 9 How that edict from the FDA was then responded
 10 to and played out in this country, in particular in
 11 decision-making by the Department of Health and Social
 12 Security will be something that we will explore in
 13 some detail with witnesses next year when we hear from
 14 Government witnesses.
 15 Then if we could then have, and this I think is
 16 probably the last reference for today, it's
 17 four minutes or so from a documentary. So we're now
 18 in April of 1983 and a documentary, Horizon
 19 documentary, called "Killer in the Village" was
 20 broadcast on the BBC on 25 April 1983. We only need
 21 a few minutes of it.
 22 Paul, it's BBCO0000002, and the clip we want is
 23 from 39 minutes and 20 seconds into the programme.
 24 *(Pause)*
 25 I'm sorry, I've given you the wrong reference.

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1 Completely my fault, Paul, sorry. There was an update
 2 a year later of this programme and I've given you the
 3 reference to that.
 4 It's BBCO0000004. Then from 39 minutes and
 5 20 seconds into that programme.
 6 *(Documentary, Killer in the Village, played)*
 7 So that, as I say, was broadcast on the BBC,
 8 I don't know whether it was BBC1 or BBC2, on
 9 25 April 1983.
 10 That is probably the right point at which to
 11 stop for the day.
 12 **SIR BRIAN LANGSTAFF:** Not bad timing. So thank you for
 13 that and we continue tomorrow. So we start at
 14 ten o'clock, do we?
 15 **MS RICHARDS:** Yes. We'll finish this presentation on
 16 knowledge of risk and then turn to look at certain
 17 materials relevant to Professor Bloom and the Cardiff
 18 Haemophilia Centre.
 19 There is a very long detailed note in relation
 20 to that which has been shared with core participants
 21 and their legal representatives and I won't be going
 22 through the detail of it. It will be a question of
 23 looking at some of the particularly key decisions and
 24 actions of Professor Bloom and the potential
 25 implications of those decisions and actions.

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1 **SIR BRIAN LANGSTAFF:** Yes, thank you very much.
 2 Until tomorrow then, and stay safe.
 3 **(4.33 pm)**
 4 **(Adjourned until 10.00 am the following day)**
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MS RICHARDS: [37] 1/4 1/10 1/23 10/22 18/6 18/8 18/13 27/14 27/20 27/24 37/23 45/19 45/22 46/1 48/8 50/13 50/18 53/15 53/18 53/25 56/19 59/2 59/7 74/2 79/24 80/9 84/22 92/13 92/16 92/21 100/4 100/9 100/17 101/3 101/13 115/10 122/14 NEW SPEAKER: [1] 10/21 SIR BRIAN LANGSTAFF: [37] 1/2 1/5 1/11 18/5 18/7 18/9 27/10 27/15 27/23 37/17 45/14 45/20 45/23 50/11 50/15 53/13 53/16 53/21 56/18 56/24 57/5 59/3 74/1 79/12 80/7 84/19 92/3 92/14 92/17 99/21 100/5 100/11 101/1 101/8 115/7 122/11 122/25	048 [1] 43/12 051 [1] 15/9 079 [1] 44/24 085 [2] 106/23 106/24 095 [1] 18/17 1 1 April [1] 32/9 1 December 1975 [2] 56/3 56/13 1 January 1983 [1] 101/21 1 May 1975 [1] 54/17 1 per cent [1] 26/13 1,000 [2] 29/1 42/14 1.05 [1] 56/23 1.06 pm [1] 57/2 10 [7] 6/13 27/18 41/2 42/16 93/17 96/5 116/10 10 December 1982 [1] 113/6 10 December 1992 [1] 97/7 10 per cent [1] 26/12 10.00 [2] 1/2 123/4 10.56 [1] 37/21 100 [2] 32/18 58/2 100 per cent [1] 52/14 103 [1] 8/19 105 [1] 19/12 109 [1] 10/4 11 [2] 28/17 93/2 11 haemophiliacs [1] 103/10 11.41 [1] 37/23 119 [1] 95/23 12 [8] 14/1 14/7 25/16 25/18 29/5 37/20 50/22 68/6 12 February [1] 72/16 12 lines [1] 6/13 12 March 1977 [1] 66/17 13 [4] 10/24 13/22 76/14 111/15 13 August 1982 [1] 91/2 13 January [1] 114/13 13 January 1983 [1] 106/6 13 per cent [1] 108/21 13 September 1982 [1] 93/16 14 [1] 10/6 14 February [3] 115/14 115/20 117/2 14 November 1982 [1] 95/3 15 [1] 46/16 15 cases [1] 25/14 15 September 1980 [1] 77/6	150 [1] 46/21 159 [1] 84/13 16 [2] 13/2 86/9 16 December 1964 [1] 28/6 16 January 1983 [2] 107/1 108/10 16 July 1982 [1] 87/5 16th [1] 115/18 180 [1] 46/22 1885 [1] 10/2 19 [1] 85/3 191 [1] 10/2 1930s [1] 10/9 1937 [3] 6/2 6/6 14/24 1939 [1] 6/21 1940 [1] 23/3 1940s [6] 3/22 4/23 16/22 18/16 21/17 23/23 1942 [9] 5/9 7/15 7/20 8/24 9/7 9/12 11/15 12/23 13/22 1943 [2] 13/2 15/7 1944 [4] 5/6 15/14 18/5 23/6 1945 [3] 18/18 19/15 21/16 1946 [2] 22/2 22/6 1947 [2] 23/24 24/5 1950 [1] 26/5 1950s [1] 26/3 1952 [1] 27/4 1953 [1] 27/2 1954 [1] 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