1	Wednesday, 31 March 2021	1	want to refer to Dr Mayne's most recent statement, and
2	(10.00 am)	2	what she says about the information she says was
3	MS RICHARDS: Sir, just two matters I'm going to pick up	3	provided to patients. Soumik could we have
4	from yesterday. Firstly, you asked the question when	4	WITN0736009. Could we go to page 46, please.
5	we looked at the annual returns as to whether there	5	This part of the statement is in relation to
6	was any apparent correlation between the severity of	6	a series of questions posed by the Inquiry about the
7	haemophilia, mild, moderate or severe, and the receipt	7	process of consent. If we pick it up at
8	of more than one type of concentrate or treatment.	8	paragraph 69.1, Dr Mayne says this:
9	The answer is, Ms Fraser Butlin having analysed the	9	"The customary practice of the [Northern
10	return data for 1978, 1979, 1980 and 1984, that	10	Ireland] Haemophilia Centre was to check patients'
11	there's no apparent correlation.	11	blood at every visit. I must stress that many
12	The second point arises out of the documents	12	patients attended at widely spaced intervals, at times
13	I referred to yesterday in relation to the proposed	13	six months to a year apart for those that were mildly
14	exchange in around 1988/1989 between Northern Ireland	14	or moderately affected. Those that were severely
15	and Scotland at the time of Z8 usage. The later	15	affected or were involved in the programme of home
16	evidence I'm not going to put the documents up on	16	treatment were seen and checked more frequently."
17	screen suggests that that exchange did take place	17	And then she refers to forms which those on
18	and that there was an exchange of Z8 allocated to	18	home treatment completed.
19	Northern Ireland with commercial products supplied by	19	Then at 69.2 she says:
20	Scotland.	20	"Thereafter, they" I take it those are the
21	We looked yesterday afternoon at documents	21	home treatment patients "were seen at monthly
22	relevant to what was or should have been known and	22	intervals. It was in my view imperative that their
23	understood by those working in clinical roles at the	23	bloods were checked to ensure that they had not
24	centre about risks of hepatitis. Before I move to do	24	developed any haematological problems such as anaemia,
25	a similar exercise in relation to HIV and AIDS, I just	25	unduly excessive bleeding or the development of
	1		2
1	inhibitor that would negate the efficacy of their	1	MS RICHARDS: Yes.
2	concentrate and finally, to check on their liver	2	We'll see similar expression when we look at
3	function tests and hepatitis status."	3	the question of consent to treatment on the next page.
4	So part of the monthly testing for those on	4	So those questions concerned consent in relation to
5	home treatment appears to have been according to	5	blood testing. These questions concern consent in
6	Dr Mayne not just to look at liver function tests but	6	relation to treatment. At 70.1 she says this:
7	to expressly consider the question of hepatitis.	7	"All patients attending the Centre were happy
8	Then in 69.3 she says:	8	to receive treatment with factor concentrates.
9	"Patients were well versed in this practice	9	"70.2 In the early days of treatment with
10	and accepted the information given to them about the	10	concentrates, it was not the practice at the time to
11	blood testing and the purposes for which they were	11	obtain written informed consent. Patients, to put it
12	being taken. They seemed happy to consent to these	12	mildly, were overjoyed at receiving concentrate
13	arrangements."	13	treatment. As the [home treatment] programme
14	What that paragraph doesn't do is spell out	14	progressed, some severally affected patients felt left
15	what information it is Dr Mayne says was routinely	15	out and contacted the Centre to request the
16	given to patients about blood testing and the purposes	16	opportunity of participating in the [home treatment]
17	for which tests were being undertaken.	17	programme."
18	If we then go to the	18	And then this:
19	SIR BRIAN LANGSTAFF: It would imply that what they were	19	"Everyone was told of the risk of viral
20	told was the checks were for their hepatitis status.	20	infections associated with all blood and blood
21	MS RICHARDS: It might well imply that.	21	products."
22	SIR BRIAN LANGSTAFF: And the expression "they seemed	22	Again, what that doesn't identify is what
23	happy to consent" suggests that there was no active	23	actual information was provided to patients about the
24	consent. It was an assumption by her that they were	24	risk of viral infections. I should add, sir, having
25	happy.	25	reread every statement received by the Inquiry by or
	3		4 (1) Pages 1 - 4

1	about a patient treated at the Belfast Haemophilia	1	any other member of staff in respect of their
2	Centre, that does not accord what Dr Mayne says	2	treatment."
3	here does not accord with any of the evidence that	3	Again, just picking up on some of the evidence
4	the Inquiry has received from patients or their family	4	from patients and relatives that the Inquiry's
5	members.	5	received, there are patients who recall, indeed,
6	If we then just go down the page, just to	6	recall being delighted about factor concentrates.
7	complete what Dr Mayne says, she says at 71.1:	7	There are patients who describe being left with the
8	"For the purpose of clarification, at the	8	impression that these were pioneering treatments is
9	instigation of concentrate therapy, all matters	9	a phrase used in one statement, miracle treatments,
10	pertaining at that time in respect of risk were	10	wonder drug, although I should say in relation to the
11	conveyed to patients before they commenced on [home	11	latter Dr Mayne has said that's not a phrase she would
12	treatment]. Discussions included comparison of	12	have used. But those are the recollections of
13	treatment with cryoprecipitate and treatment with	13	patients. None recount a recollection of being
14	concentrates. No figures were mentioned but patients	14	advised of risks of significant health consequences as
15	understood that concentrates came from a large number	15	a potential result of receipt of factor concentrates.
16	of donors in comparison to cryoprecipitate."	16	Sorry, I should just complete the series of
17	Of course, if that's right, it doesn't follow	17	answers by going over the page to the top of the next
18	that they understood and were informed about the	18	page. This is in relation to testing and whether
19	relative risks or potential consequences as a result	19	patients were tested without their express consent.
20	of those risks:	20	I'll come on to that later on this morning also but
21	"However, the prospect of their lives being	21	whilst we're in this statement Dr Mayne's answer is:
22	revolutionised, the ease of injection, and the ability	22	"Absolutely not."
23	to undertake reliable dose calculations precluded any	23	That's to the question of were patients tested
24	obvious reservations about the treatment. No patient	24	for HIV or hepatitis or for any other purpose without
25	favour expressed any reservation to myself or	25	their express consent. She says she obtained verbal
	5		6
1	consent from the patient in all cases and, again,	1	particular in relation to the question of providing
2	there is evidence that the Inquiry holds from patients	2	information about HIV and AIDS.
3	which is to the opposite affected and I will refer to	3	I don't think we have any form of narrative
4	that a little later.	4	about as things became clearer this is what
5	SIR BRIAN LANGSTAFF: If we just go back a page, and 71.1	5	I explained. We do when we get to the mid-1990s, 1995
6	she is speaking in the first sentence of when	6	specifically, of course by which time infections will
7	concentrate therapy on home treatment was begun. It	7	already have occurred. We do have a more detailed
8	may but probably isn't talking about treatment not at	8	account of the weekend that was organised in around
9	home but in hospital because it refers to "HT".	9	1995 to provide information, it was said, about
10	MS RICHARDS: Yes.	10	hepatitis C. But I can't recall any account which
11	SIR BRIAN LANGSTAFF: But it doesn't say that there was	11	picks up upon the point that you have just made, but
12	any further discussion in respect of the risks as they	12	I will check that both so that I can be confident I've
13	became better known in the case of hepatitis non-A,	13	given you an accurate answer and, of course, out of
14	non-B or as they were becoming known in respect of the	14	fairness to Dr Mayne.
15	risks of whatever it was that caused AIDS later	15	Sir, I'm going to move next to documentation
16	identified.	16	and evidence relevant to what was as a matter of fact
17	Is there anything in her witness statement	17	known in Belfast or what should have been known in
18	which deals with what she says about the continued	18	Belfast by the clinicians I hasten to add, not
19	conversations that might have been expected in the	19	patients, about the risk of AIDS and HTLV-III.
20	light of the changed and developing perception of	20	So if we start if we go back to that same
21	risks?	21	document please, Soumik, WITN0736009 we start with
22	MS RICHARDS: I don't think so, sir. I am going to show	22	Dr Mayne's witness statement and go to page 25,
23	you in the course of the morning some other parts of	23	please. We can see at the top of the page, Dr Mayne
24	her statement where she talks about the provision of	24	says this:

1	became known as HIV/AIDS first came to my notice	1	Compromise Syndrome", and it refers to:
2	during an informal lunchtime discussion with three	2	"A remarkable outbreak of opportunistic lung
3	colleagues. They were the late Arthur Bloom,	3	infections and/or Kaposi's sarcoma in homosexual men
4	Virologist John Craske and the late Peter Kernoff.	4	has been reported this year in the United States."
5	"30.2. John Craske was describing the content	5	And if so, that's an article in The Lancet,
6	of a paper just published, to the best of my	6	12 December 1981. So that might fit the bill in terms
7	recollection in the Lancet, but with the passage of	7	of it helping us to date the discussion to which
8	time I cannot be more specific. It described an	8	Dr Mayne refers.
9	account of an immune condition which had occurred in	9	If we go next to Dr Mayne's HIV litigation
10	homosexual males in San Francisco. I enquired as to	10	report CBLA000072_024. If we turn to page 32,
11	the relevance to haemophilia. He reminded us that the	11	Soumik.
12	individuals cited in the paper were known to maintain	12	So under the heading "The Development of the
13	their lifestyle by being paid blood donors, as was	13	AIDS Epidemic", if we go to the bottom of the page,
14	documented in the World in Action (1975) programme.	14	Dr Mayne says this:
15	Whilst the revelations of that were horrific, I was	15	"Early publications during 1981 (62) and 1982
16	unprepared for the shock of the news of a possible	16	(63)"
17	future infection which could affect those in receipt	17	And the footnoted publications there are
18	of plasma derived concentrates, namely, the	18	footnote 62 is a publication in the New England
19	Haemophiliac population."	19	Journal of Medicine by Gottlieb, Schroff, Schanker and
20	Dr Mayne, perhaps unsurprisingly can't recall	20	others about PCP pneumonia, evidence of a new acquired
21	when this conversation took place. There is The	21	cellular immunodeficiency. It's a 1981 New England
22	Lancet article that might be the article that's	22	Journal of Medicine. I don't have the precise date
23	described at PRSE0004476. I'm not going to go through	23	but we can check that.
24	the detail of it. You'll see it's a letter to the	24	The 1982 publication to which she is referring
25	editor about something then referred to as "Gay	25	is in the Annals of Internal Medicine 1982, an article
20	9		10
	· ·		10
1	by Friedman-Kien and others, "Disseminated Kaposi's	1	HIV litigation report to suggest that these
2	sarcoma in homosexual men".	2	developments were unknown to her or unknown to the
3	In any event, she says:	3	Haemophilia Centre Directors members, organisation
4	"Early publications during 1981 (62) and 1982	4	members. On the contrary, the implication might be
5	(63), describing the unexpected outbreaks of the rare	5	thought to be she's setting this out precisely because
6	disorders [PCP] and Kaposi's sarcoma in homosexuals	6	they were known and were a subject of discussion.
7	provoked discussion amongst Haemophilia Centre	7	So that's what she says in the litigation
8	Directors as early as September 1982."	8	report about the knowledge in 1982. I should just
9	We'll look at that in a moment.	9	remind you, sir, although we've looked at it on
10	"At that time particular relevance to	10	a number of occasions, of the UKHCDO records of
11	haemophilia care was not yet evident. In July 1982	11	discussions in 1982.
12	MMWR reported that three haemophiliacs had	12	We start with HCDO0000410. You will recall
13	developed AIDS, but little evidence had accumulated to	13	this is the Reference Centre Directors' meeting on
14	suggest that haemophiliacs of themselves constituted	14	6 September 1982 attended by Dr Mayne and by Dr Craske
15	a special risk group for AIDS."	15	as well and by a number of others.
16	And then she says at the top of the next page:	16	If we go to page 8 we see towards the bottom of
17	"The situation changed with increasing	17	the page the beginning of a verbal report from
18	haemophiliac involvement and towards the end of the	18	Dr Craske about the work of the Hepatitis Working
19	year"	19	Party.
20	So that's towards the end of 1982.	20	Then if we go on to page 11, in the paragraph
21	" they were categorised as a separate	21	halfway down the page beginning, "Professor Bloom
22	'at risk' population."	22	asked":
23	And then she goes on to refer to some UKHCDO	23	"Professor Bloom asked Dr Craske if he had any
24	interactions which I'll deal with separately.	24	information about the acquired immune-deficiency
25	So, again, there's nothing in Dr Mayne's	25	syndrome following reports from the United States and
	- · · · · · · · · · · · · · · · · · · ·		
	11		12 (3) Pages 9 - 12

1	the possible relationship of the syndrome with blood	1	party was considering the implications of the reports
2	products and hepatitis. Dr Craske said that he would	2	from the USA. So those are the minutes of the
3	find out more about this and agreed to try to have	3	September 1982 meetings. Obviously, we don't have
4	some information available for the Haemophilia Centre	4	a more detailed account of the underlying discussions
5	Directors at the Manchester meeting."	5	because the minutes are only, on any view, a summary.
6	Then if we go to the Haemophilia Centre	6	What we do know is that in November 1982
7	Directors' meeting the following week at CBLA0001619,	7	Dr Craske produced the first version of a report
8	so this is the Manchester meeting of the bigger group	8	about AIDS.
9	of Haemophilia Centre Directors, 13 September 1982.	9	If we go to HCDO0000557, we see a letter from
10	The list of attendees on the second page tells us that	10	Dr Craske dated 11 November 1982. This letter is
11	Dr Mayne was present and there is a short discussion	11	addressed to Ms Spooner. We do have copies of this
12	about AIDS on page 10. Bottom of the page:	12	letter addressed to others, including I think
13	"The acquired immune deficiency syndrome. The	13	Dr Kernoff and at least one other Reference Centre
14	Reference Centre Directors had asked Dr Craske to look	14	Director.
15	into the report from the United States of this	15	What's not clear from what we have been able to
16	syndrome mainly in homosexuals but including three	16	analyse is whether this letter was being sent solely
17	haemophiliacs. It appeared that there was a remote	17	to members of the Hepatitis Working Party, which would
18	possibility that commercial blood products had been	18	not have included Dr Mayne, or whether it was being
19	involved."	19	sent, at this point in time, to the Reference Centre
20	And we considered in earlier hearings the	20	Directors as well, which would have included Dr Mayne.
21	question which will ultimately be for you to resolve,	21	So I'm afraid at the moment we simply don't know the
22	sir, of whether that was a fair or accurate statement	22	answer to that question.
23	given the state of knowledge already by that time.	23	But, in any event, we have over the page the
24	Dr Craske asked the directors to let him know	23 24	first version of a report prepared by Dr Craske. It's
25	if they had any cases of the syndrome. The working	2 4 25	dated 5 November 1982 on its third page, and if we
20		25	
	13		14
1	look at the second page sorry, the next page, my	1	occasions. It's one of the records of the meeting
2	apologies, Soumik. Bottom half of the page, we see	2	with Immuno at London Airport or at a London airport
3	the passage we've explored before under the heading,	3	hotel on 24 January 1983.
4	"Aetiology":	4	If we go to the last page, please, we see in
5	"Several theories have been advanced. It seems	5	the bottom half of the page the list of attendees and
6	likely that this is a 'new' syndrome."	6	we'll see that they include Dr Mayne.
7	And then he sets out the three theories.	7	If we go to the page before that, we can see
8	"Effect of drugs", and says this is not a factor.	8	the heading almost halfway down the page, "Acquired
9	A second theory is "the immuno-suppressive effect of	9	immunodeficiency Syndrome", and we see there set out
10	cytomegalovirus infection", and he says this seems	10	the discussion about AIDS, Dr Craske summarising the
11	unlikely.	11	current position, giving a clinical description of the
12	Then over the page the third possible cause,	12	AIDS syndrome, and then picking it up towards the
13	"the association with sexual promiscuity, intravenous	13	bottom of the page reference to the mortality rate,
14	drug use and possibly the transfusion of commercial	14	45 per cent mortality, and then in the last paragraph
15	blood concentrates", and then he says just below that:	15	a description of haemophiliacs in the United States
16	"If (3) is the most likely cause, then it seems	16	affected:
17	possible that such an agent might be present in the	17	"Ten affected five have died. The
18	plasma of hepatitis B carriers used to prepare	18	youngest was aged 7. All cases have had prolonged
19	hepatitis B vaccines."	19	treatment with factor VIII but there is no specific
20	The relevance of that was this was a paper	20	implication of one particular product or batch. Other
21	Dr Craske had prepared at that stage for the Medical	21	cases involving blood and blood product transmission
22	Research Council's hepatitis vaccine working group.	22	have included platelets transfused in three cases. In
23	So that's November 1982.	23	one of these cases, one of the donors was a young
23 24	If we then go to PRSE0002647, this again is	23 24	New York man in his twenties. A second case was
25	a document that we have looked at on a number of	2 4 25	a 20 month old child with rhesus HDN who had received
20		20	40
	15		16 (4) Pages 13 - 16

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1	several units, including platelets known to have come	1	to later. So continuing with the chronology, there's
2	from a homosexual donor who was asymptomatic at the	2	then a Reference Centre Directors' meeting in
3	time, but who later died."	3	February 1983. That's at HCDO0000411.
4	That's the San Francisco baby case.	4	It's right I should note the covering letter
5	If we go over the page, the discussion	5	which sends out the draft minutes is 9 May 1983, so
6	continues with reference to the incubation period:	6	it's several months after the meeting on
7	"In the UK, so far only one or two cases have	7	14 February 1983.
8	been reported from the communicable diseases centre."	8	I mention that because if we look at the next
9	There's then reference to, "protocols from the	9	page, we can see that Dr Mayne did not attend this
10	United States [that] are being considered by the	10	particular Reference Centre Directors' meeting on
11	Hepatitis Working Party", and a reference to American	11	14 February 1983. We see apologies for absence were
12	fractionation companies being "very aware of the	12	received from her.
13	problem".	13	If we go to page 5, Soumik, we can see the
14	Then in the next paragraph a discussion of the	14	discussion about the AIDS syndrome. Professor Bloom
15	editorial, that's the Desforges editorial, in the	15	reporting it:
16	New England Journal of Medicine, 13 January 1983.	16	" would be discussed at the Stockholm
17	So that, it's a matter for you, sir, but may be	17	meeting at the World Federation of Haemophilia.
18	taken as a guide to what by 24 January 1983 would have	18	Reports from the United States indicated that the
19	been known to Dr Mayne about the latest developments	19	incidence of AIDS was higher than at first thought and
20	in the state of knowledge in relation to AIDS risk for	20	there was some concern that the haemophilic population
21	haemophiliacs.	21	of the UK who had received American concentrates might
22	There was then, again in terms of the	22	be at risk."
23	chronology in early 1983, which is of some particular	23	Then there is a discussion of a form being
24	significance for Belfast patients because of the dates	24	prepared for the reporting of cases and Dr Craske was
25	of seroconversion for most of them, which I'll come on	25	going to draw that up and it would be circulated to
	17		18
1	all Haemophilia Centre Directors with appropriate	1	Then the letter continues, this is the second
2	notes regarding the criteria on which a diagnosis	2	paragraph:
3	should be based.	3	"The criteria for reporting cases are given in
4	I should note although Dr Mayne wasn't present	4	the accompanying paper AIDS/2."
5	at that meeting, her HIV litigation report does refer	5	And a request is made to use the form AIDS/3.
6	to that meeting, so it may be something that she was	6	If we look at the enclosed documents
7	aware of, and aware of the discussion, but we can't	7	themselves, they are, first of all, we start with the
8	say that for certain.	8	AIDS/1 report. That is HCDO0000517_002.
9	We do know however that as agreed at that	9	So this is an updated version of Dr Craske's
10	meeting Drs Craske, Rizza and Bloom did write to all	10	November 1982 report. It's dated at the end of the
11	centre directors, so that would have included	11	paper, 1 March 1983. Again, it sets out the growing
12	Dr Mayne, in March of 1983. And we can see the letter	12	knowledge at the Communicable Disease Centre in
13	at HCDO0000517_001. This is the letter	13	Atlanta of infections.
14	of 22 March 1983. Again, we've looked at it before	14	Then if we go towards the bottom of the page we
15	but not, as it were, through the prism of the Belfast	15	see reference in the last paragraph to delay between
16	Haemophilia Centre:	16	initial symptoms and diagnosis.
17	"Dear Director,	17	If we go over the page, we see reference, just
18	"Re: Acquired Immune Deficiency Syndrome"	18	towards the middle of the page, to mortality rate.
19	And then there's reference to:	19	And then if we go to the next page, the bottom half of
20	"Recent discussions in both the Hepatitis	20	the page sorry, I should start with the top half of
21	Working Party and a recent meeting of the Reference	21	the page, my apologies. There's reference in the
22	Centre Directors"	22	third line:
23	And the system being set up:	23	"Since then reported cases of a similar
23 24	" for the reporting of possible cases of	23 24	syndrome have been noted in"
2 4 25	for the reporting of possible cases of [AIDS]"	2 4 25	-
20		20	And then there are various now very familiar
	19		20 (5) Pages 17 - 20

1	categories, including the following:	1	further down the page, to three patients having,
2	" recently in 7 haemophiliacs, 6 of whom	2	acquired the disease where the most likely mode of
3	also have no association with drugs or sexual	3	transmission was blood or platelet transfusions.
4	promiscuity. Three cases have been described in the	4	He refers then to the incubation period. He says:
5	UK and one in Spain. All probably acquired their	5	"The most recent information suggests that
6	disease in the USA. However, 4 cases were recently	6	at least ten haemophilia A patients have been reported
7	observed in Denmark"	7	with clinical features of the syndrome."
8	Then if we go further down the page we have the	8	And at the end of that paragraph that five of
9	discussion of aetiology, again in similar terms to the	9	those have since died.
10	discussion in the November 1982-version of Dr Craske's	10	There's reference to possibility of sexual
11	paper. So he discounts effect of drugs in	11	transmission at the bottom of the page.
12	paragraph 1. He suggests that cytomegalovirus as	12	Then if we go to the next page and we look at
13	a cause is unlikely in paragraph 2. And then if we go	13	the last the first paragraph, the last two
14	over the page he alights upon (3) as the most likely	14	sentences, where he says:
15	cause, so "sexual promiscuity, intravenous blood abuse	15	"All the epidemiological evidence is consistent
16	and possibly the transfusion of commercial blood	16	with the existence of a transmissible agent whose mode
17	concentrates". This time, below paragraph 3, rather	17	of spread is remarkably similar to that of
18	than referring to the issue of hepatitis vaccines he	18	hepatitis B."
19	says this:	19	Then he refers to precautions against
20	"If (3) is the most likely cause, then it is	20	cross-infection and then says:
21	possible that such an agent might be present in the	21	"It is thought likely that batches of
22	plasma pools used to prepare commercial factor VIII	22	factor VIII concentrate which might contain the AIDS
23	and IX concentrate manufactured from donor plasma	23	agent came into use since January 1st 1980 in the USA.
24	collected in the USA."	23 24	The Communicable Disease Centre of the US Public
25		24 25	
20	He refers in the next paragraph, if we go	20	Health Service at Atlanta, Georgia, therefore has
	21		22
1	requested the UK Haemophilia Centre Directors to	1	the December MMWR.
1 2	requested the UK Haemophilia Centre Directors to	1 2	the December MMWR. SIR BRIAN LANGSTAFF: I think December was more than
2	co-operate with them in a survey by reporting cases of	2	SIR BRIAN LANGSTAFF: I think December was more than
2 3	co-operate with them in a survey by reporting cases of AIDS possibly associated with transfusion of	2	SIR BRIAN LANGSTAFF : I think December was more than seven.
2 3 4	co-operate with them in a survey by reporting cases of AIDS possibly associated with transfusion of US commercial factor VIII concentrate."	2 3 4	SIR BRIAN LANGSTAFF: I think December was more than seven. MS RICHARDS: I think it may well have been an earlier
2 3 4 5	co-operate with them in a survey by reporting cases of AIDS possibly associated with transfusion of US commercial factor VIII concentrate." He says:	2 3 4 5	SIR BRIAN LANGSTAFF: I think December was more than seven. MS RICHARDS: I think it may well have been an earlier MMWR. The ten patients so Dr Craske goes:
2 3 4 5 6	co-operate with them in a survey by reporting cases of AIDS possibly associated with transfusion of US commercial factor VIII concentrate." He says: "Cases will also be notified to the	2 3 4 5 6	SIR BRIAN LANGSTAFF: I think December was more than seven. MS RICHARDS: I think it may well have been an earlier MMWR. The ten patients so Dr Craske goes: "The most recent information suggests at
2 3 4 5 6 7	co-operate with them in a survey by reporting cases of AIDS possibly associated with transfusion of US commercial factor VIII concentrate." He says: "Cases will also be notified to the Communicable Disease Surveillance Centre in the UK at	2 3 4 5 6 7	SIR BRIAN LANGSTAFF: I think December was more than seven. MS RICHARDS: I think it may well have been an earlier MMWR. The ten patients so Dr Craske goes: "The most recent information suggests at least ten"
2 3 4 5 6 7 8	co-operate with them in a survey by reporting cases of AIDS possibly associated with transfusion of US commercial factor VIII concentrate." He says: "Cases will also be notified to the Communicable Disease Surveillance Centre in the UK at the Central Public Health Laboratory, Colindale,	2 3 4 5 6 7 8	SIR BRIAN LANGSTAFF: I think December was more than seven. MS RICHARDS: I think it may well have been an earlier MMWR. The ten patients so Dr Craske goes: "The most recent information suggests at least ten" That's footnote 8, and he says it's a personal
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1	the States.	1	not in attendance at that meeting. It was, however,
2	So we know Dr Mayne is present at that meeting	2	obviously a very significant meeting. How the
3	at the Excelsior Hotel, Heathrow Airport, 24 January,	3	discussion was communicated to Dr Mayne and when it
4	and we know that this letter and its attachments were	4	was communicated to Dr Mayne, we don't know.
5	sent to all Haemophilia Centre Directors.	5	Again, we've looked at this on a number of
6	For the sake of completeness I'll just as	6	occasions. If we just go briefly down the page we'll
7	well as looking at the form, we'll just look at the	7	see Professor Bloom outlined the background to the
8	other two documents.	8	meeting and its purpose:
9	So if we go to the other two documents that	9	"The recent publicity had caused
10	accompanied the letter. If we go to HCDO0000273_078,	10	considerable anxiety to haemophiliacs and their
11	that's, as it were, a note for directors as to	11	medical attendants as well as to the Department of
12	conditions, symptoms and findings to look out for and	12	Health."
13	report, and we can see from the third page that's also	13	If we go over the page sorry, it was the
14	dated 1 March 1983.	14	previous page. My apologies. Yes, if we go down. It
15	Then if we go to HCDO0000517_004, that's the	15	says this is halfway down this long paragraph:
16	form that directors were asked to complete in relation	16	"To date in the [UK] one haemophiliac is
17	to possible cases and, of course, we've looked by way	17	suspected of suffering from AIDS."
18	of example at the actual form completed by	18	So that is again, we anticipate, the Cardiff
19	Professor Bloom in relation to the Cardiff case.	19	case that Professor Bloom is there referring to. And
20	Those are the communications from Haemophilia	20	again, Dr Mayne in her litigation report refers to
21	Centre Directors sorry, to Haemophilia Centre	21	a knowledge of there being that case.
22	Directors in March of 1983.	22	Following that meeting, recommendations were
23	If we then go to HCDO0000003_008, this is the	23	sent to all centre directors, so that would have
24	special meeting of Reference Centre Directors held on	24	included Dr Mayne, in June of 1983 and the reference
25	13 May 1983, and it's right to note that Dr Mayne was	25	for that is HCDO0000270_004. It's the letter of
	25		26
1	24 June 1983. It refers to the special meeting of the	1	accorded with her own view. She talks on multiple
2	reference centre directors in the opening paragraph	2	occasions throughout her various statements of what
3	and then says this:	3	she regarded as the immense benefits of treatment with
4	"At the above mentioned meeting on May 13th the	4	factor concentrates.
5	following general recommendations were agreed.	5	In relation to this letter, Dr Mayne's evidence
6	"1. For mildly affected patients with	6	is this essentially reflected existing practice at the
7	haemophilia A or von Willebrand's disease and minor	7	Belfast Haemophilia Centre. We've looked already at
8	lesions, treatment with DDAVP should be considered.	8	the position of children and seen that those who were
9	Because of the increased risk of transmitting	9	being treated at the Royal Belfast Hospital for Sick
10	hepatitis by means of large pool concentrates in such	10	Children were treated with cryoprecipitates but that
11	patients, this is in any case the usual practice of	11	there were two severely affected children treated with
12	many Directors.	12	factor concentrate, so I think not entirely correct to
13	"2. For treatment of children and mildly	13	say that it was the policy across the board for all
14	affected patients or patients unexposed to imported	14	children.
15	concentrates many Directors already reserve supplies	15	In terms of paragraph 1, suggestion there of
16	of NHS concentrates (cryoprecipitate or freeze-dried)	16	treatment with DDAVP, we've seen from the annual
17	and it would be circumspect to continue this policy."	17	returns comparatively infrequent reference to DDAVP,
18			
	And then it goes on to say that:	18	albeit it's right that I note we don't have every
19 20	"It was agreed [at the 13 May meeting] that	19	return for the early part of the 1980s.
20	there [was] as yet insufficient evidence to warrant	20	We do see von Willebrand's patients,
21	restriction of the use of imported concentrates in	21	apparently, being treated largely with
22	other patients in view of the immense benefits of	22	cryoprecipitate.
23	therapy"	23	In terms of mildly affected patients or
24	Although Dr Mayne was not present at that	24	patients previously unexposed to imported
25	meeting it's clear from her evidence that that	25	concentrates, the position is less clear in relation
	27		28 (7) Pages 25 - 28

1	to Belfast. I don't think we have any specific	1	moderate bleeding disorder she deals with that in the
2	evidence about a particular treatment policy in	2	bottom half of this page and says this in 20.1:
3	relation to previously untreated patients.	3	" effective treatment of bleeding disorders
4	In relation to those who were mildly affected	4	is patient specific and needs to take account of
5	haemophiliacs or those whose haemophilia was of	5	individual circumstances. Occasionally, it was
6	moderate severity, Dr Mayne addresses this in her	6	necessary to use concentrates for patients whose
7	witness statement at WITN0736009. We pick it up at	7	bleeding disorders were classified as mild or
8	the bottom of page 17, bottom half of the page.	8	moderate. I can best illustrate circumstances in
9	You'll see reference in the bold print to the	9	which this situation arose by reference to specific
10	question posed by the Inquiry which refers to the	10	examples."
11	June 1983 UKHCDO recommendations and she's asked what	11	Then she sets out in her next paragraph an
12	the Belfast Centre's policy is, and her answer is as	12	example of two brothers who had what might be
13	follows:	13	described as a typical level for a mildly affected
14	"As described above, the policy of using	14	patient but asserts that clinically they were much
15	cryoprecipitate for treating mildly affected patients	15	more severely affected and that appropriate doses of
16	and children was adhered to but, at times, proved in	16	cryoprecipitate proved totally ineffective.
17	practice to be much more complex than expected."	17	If we go over the page, paragraph 20.4 suggests
18	She then says that:	18	that in relation to those patients they resorted to
19	"Cryoprecipitate, DDAVP and antifibrinolytic	19	concentrates, and then she gives another example in
20	agents were, and are, used for the management	20	20.5 and 20.6 of other patients, and in paragraph 20.6
21	of von Willebrand's syndrome."	21	talks about then the use of concentrate and says this:
22	Then over the page she sets out in	22	"Theoretically, I would have advocated the use
23	paragraph 19.1, and we looked at this or a similar	23	of much larger doses of cryoprecipitate, but by the
24	passage yesterday, at the position in relation to	24	time these results were available"
25	children, but then in relation to people with mild or	25	She gives a description of the tests that were
	29		30
4	and a station in the above were such	4	as a second on the assent ways of attendance and if we
1	undertaken in the above paragraph.	1	as present on the second page of attendees, and if we
2	" the patients had become used to	2	go to page 10 under the heading "Any Other Business",
3	concentrate and rejected cryoprecipitate."	3	this is the meeting at which Dr Chisholm raised the
4 5	She doesn't say what information was given to the patients to enable them to make an informed	4	question of reversion to cryoprecipitate for home
6	·	5 6	therapy and Professor Bloom is reported as expressing the view that there was no need for patients to stop
7	decision as between concentrates and cryoprecipitate. And then says:		the view that there was no need for patients to stop
8	•	/	·
O		7	using commercial concentrates because at present there
٥	"I have gone into these cases in some detail to	8	using commercial concentrates because at present there was no proof that the commercial concentrates were the
9 10	explain that classification of bleeding disorders as	8	using commercial concentrates because at present there was no proof that the commercial concentrates were the cause of AIDS. We've again canvassed in a number of
10	explain that classification of bleeding disorders as 'mild' or 'moderate' in vivo activity is not always	8 9 10	using commercial concentrates because at present there was no proof that the commercial concentrates were the cause of AIDS. We've again canvassed in a number of previous hearings the significance or otherwise of the
10 11	explain that classification of bleeding disorders as 'mild' or 'moderate' in vivo activity is not always straightforward nor is it a reliable indication of	8 9 10 11	using commercial concentrates because at present there was no proof that the commercial concentrates were the cause of AIDS. We've again canvassed in a number of previous hearings the significance or otherwise of the phrase "no proof".
10 11 12	explain that classification of bleeding disorders as 'mild' or 'moderate' in vivo activity is not always straightforward nor is it a reliable indication of patients' clotting Factor VIII. Limiting treatment	8 9 10 11 12	using commercial concentrates because at present there was no proof that the commercial concentrates were the cause of AIDS. We've again canvassed in a number of previous hearings the significance or otherwise of the phrase "no proof". You will recall, sir, that the discussion goes
10 11 12 13	explain that classification of bleeding disorders as 'mild' or 'moderate' in vivo activity is not always straightforward nor is it a reliable indication of patients' clotting Factor VIII. Limiting treatment to, for example, cryoprecipitate is in practice not	8 9 10 11 12 13	using commercial concentrates because at present there was no proof that the commercial concentrates were the cause of AIDS. We've again canvassed in a number of previous hearings the significance or otherwise of the phrase "no proof". You will recall, sir, that the discussion goes on to talk about ease of access to cryoprecipitate as
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10 11 12 13 14 15 16 17 18 19 20 21 22	explain that classification of bleeding disorders as 'mild' or 'moderate' in vivo activity is not always straightforward nor is it a reliable indication of patients' clotting Factor VIII. Limiting treatment to, for example, cryoprecipitate is in practice not always its easy as it might seem in theory." So it would appear that whilst Dr Mayne is saying that her general policy in relation to those who were mildly affected was to treat with cryoprecipitate and not concentrate. There were cases of those who were not severely affected who were treated with factor concentrates. So that's the position as at June 1983. We then in terms of Haemophilia Centre Directors'	8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	using commercial concentrates because at present there was no proof that the commercial concentrates were the cause of AIDS. We've again canvassed in a number of previous hearings the significance or otherwise of the phrase "no proof". You will recall, sir, that the discussion goes on to talk about ease of access to cryoprecipitate as opposed to difficulty in getting large amounts of commercial concentrates. In relation to the Belfast Centre, it doesn't appear there was any lack of access to commercial concentrates and we've seen them being used in large measure during the early 1980s, but it also doesn't appear that there was any lack of access to cryoprecipitate. You will recall yesterday Dr Mayne saying that there was a sufficient supply of cryoprecipitate from the Regional

(8) Pages 29 - 32

1	situation regarding AIDS", and that sets out the work	1	to treat haemophilia."
2	he's proposing to do. Then we'll see halfway down the	2	So that's Dr Mayne's articulation of what her
3	page halfway down that paragraph, sorry:	3	understanding was of the views of haemophilia
4	"There was some discussion regarding the two	4	centre Reference Centre Directors, which was the
5	cases of AIDS in haemophiliacs in the [UK]"	5	small cohort of which she was a number at that time.
6	So that by this time is the Cardiff case and	6	SIR BRIAN LANGSTAFF: So what she's describing is that
7	the Bristol case.	7	giving people who suffer from haemophilia commercial
8	" and Dr Scott gave details about his case."	8	concentrate was recognised before the end of 1982 as
9	And that's a reference, we understand, to the	9	being making them an at-risk group, that the risk
10	Bristol case.	10	was one which was recognised by her colleagues as
11	So that's the position as at 17 October 1983.	11	Reference Centre Directors and was known as
12	If we go back to Dr Mayne's litigation report at	12	a realistic possibility in very early 1983.
13	CBLA000072_024 and we pick it up at page 33 sorry,	13	MS RICHARDS: Yes, precisely. If we pick it up in the
14	I have already referred to that's it, if we go to	14	next paragraph, we see Dr Mayne saying this:
15	the top half of the page I've already referred to	15	"Throughout 1983 publications occurred with
16	the first sentence which was looking at 1982, and then	16	increasing frequency confirming the presence of some,
17	we can see Dr Mayne referring to the March 1983 paper.	17	if not all, the preceding immune abnormalities to be
18	That's Dr Craske's paper that we looked at a few	18	present in homosexuals, in multi-transfused adults,
19	minutes ago. You are right, sir, she refers to the	19	children and in some haemophiliac patients."
20	seven haemophiliacs there, rather than the figure of	20	Then we see she refers to some publications, so
21	ten, and if we look towards the bottom of this	21	a January 1983 publication by Jones.
22	paragraph she says:	22	Then if we go over the page and that's
23	"The Directors considered it possible that an	23	Dr Peter Jones' publication in The Lancet, "Altered
24	infectious agent could be present in blood and	23 24	immunity in haemophilia". If we go over the page, we
25	present, in particular in the Factor concentrates used	25	see at the top of the page she's referring to the
20		2.0	
	33		34
1	Desforges article in the New England Journal of	1	And she records that:
2	Medicine in January 1983. The White article is a 1983	2	"Further reports of immunological abnormalities
3	editorial in the Annals of Internal Medicine. I don't	3	in Haemophilia were presented. Patients attending the
4	have the precise date in 1983 but it sounds like it's	4	meeting expressed worry regarding the possible
5	early 1983 because she then goes on to say this, after	5	curtailment of their treatment."
6	referring to the White Article:	6	A theme which, sir, you might wish to consider
7	"Such publications, plus the media coverage of	7	whether it arises from this part of her litigation
8	the syndrome in the press, on radio and television,	8	report appears to be a theme of saying this was or may
9	caused great anxiety to patients and their haemophilia	9	have been known to patients because of what was being
10	centre physicians. Therefore, in February 1983	10	reported in the media and/or through attendance at the
11	a special meeting of the Reference Centres was	11	World Haemophilia Federation Congress.
12	convened to plan measures which might be undertaken	12	There's no narrative in the litigation report
13	regarding surveillance of patients and their	13	of discussions with patients specifically. I'll come
14	treatment."	14	on to what Dr Mayne says on that subject in her
15	I've already referred to that meeting. She	15	witness statements in a little while.
16	describes it in further detail further down. It may	16	Then if we go to the bottom of this page she
17	be that she's conflating the February and May 1983	17	refers to:
18	meetings to some extent in her narrative here but she	18	"By September 1983 two haemophiliacs in the
19	then talks, bottom of the page, about the	19	[UK] were suspected of contracting AIDS following
20	recommendation sent to centre directors in June 1983.	20	treatment with commercial concentrates."
21	If we go to the top of the next page she refers	21	She suggests that:
	2		" Haemophilia Centres were circularised
	to a discussion about AIDS at the World Haemonhilia	//	
22	to a discussion about AIDS at the World Haemophilia Federation Congress in Stockholm and says this:	22 23	•
22 23	Federation Congress in Stockholm and says this:	23	informing them of the batch numbers of the suspected
22 23 24	Federation Congress in Stockholm and says this: "There was great awareness of the AIDS problem	23 24	informing them of the batch numbers of the suspected infected Factor VIII concentrates."
22 23	Federation Congress in Stockholm and says this:	23	informing them of the batch numbers of the suspected

			• •
1	a reference to at that point in time. But we do know	1	which talks it's Cheingsong-Popov, I think it is.
2	that investigative work was being undertaken by	2	MS RICHARDS: The Popovic article that she refers to is
3	Dr Craske looking at batches, so it may be that's what	3	a publication in Science in 1984 and without checking
4	she's referring to.	4	I can't recall, I'm afraid, the month, and then the
5	"Surveillance and collation of data was	5	editorial in the BMJ that she says accepted that AIDS
6	undertaken by the Hepatitis Working Party."	6	was transmitted by blood products is an editorial
7	Then she refers to the report by Dr Daly and	7	entitled, "Infection, immunity and blood transfusion",
8	Dr Scott which was in The Lancet in late 1983,	8	the author being given as Bruce-Chwatt, which again
9	November 1983, the first death of a UK haemophiliac	9	I will need to check the month.
10	from PCP, and she records that:	10	SIR BRIAN LANGSTAFF: Yes.
11	"At that time the world statistics indicated	11	MS RICHARDS: And then reference to the Danish study that
12	that some 26 Haemophilia A patients and two	12	was in The Lancet. Again, without checking I can't
13	Haemophilia B patients had been reported to CDC as	13	recall off the top of my head which month it was.
14	having AIDS."	14	Well, in fact, so that I needn't go back to it
15	She then goes on over the page I'm not going	15	if we go to the next page and look at the bottom half
16	to go through this part in detail to talk about the	16	of the page she says this this is obviously looking
17	identification of HTLV-III and various publications in	17	generally in the United Kingdom and not specifically
18	that regard in the course of 1984.	18	at Belfast because this was a report for the HIV
19	At the bottom of the page she reports she	19	litigation to the Department of Health, but she says
20	refers to an article about patients having antibodies	20	this:
21	to HTLV-III and then says:	21	"The results of antibody testing of the UK
22	"During the same month" I need to check	22	haemophiliacs accumulated during 1985, it was found
23	which month that is, sir, because I don't think	23	that 44 per cent were positive. 1983 was found to be
24	SIR BRIAN LANGSTAFF: Well, that's the article in I think	24	the major year of infection, established from the
25	September in The Lancet, isn't it, Popovic et al,	25	availability of retrospective testing for some but not
	37		38
	31		30
1	all patients."	1	Members of the medical profession and laymen are
2	And then she says this:	2	entitled to express public opinions regarding the
3	"Thus, the recommendations to revert to	3	state of the art at any time. Media reporters are
4	cryoprecipitate unfortunately would have been too late	4	particularly adept in this respect. However, in the
5	to prevent infection."	5	light of subsequent scientific knowledge the expressed
6	Given that those recommendations appeared in	6	opinions may require revision."
7	amongst other things the New England Journal of	7	Then she says:
8	Medicine in January of 1983, how logically it could be	8	"Such opinions are documented in paragraph 63."
9	said that that recommendation would have been too late	9	To understand that we need to look at which
10	to prevent infection if 1983 is the major year of	10	version of HIV litigation Statement of Claim she's
11	infection, well it simply doesn't follow	11	referring to. But she says this:
12	chronologically.	12	"Their expression was based on the then
13	Then it's perhaps worth reading Dr Mayne's	13	available evidence and reflected the element of doubt
14	observations in the following paragraph. She says	14	which existed regarding the magnitude of the AIDS
15	this:	15	problem in haemophilia and its causation. They did
16		16	not unduly underestimate or understate the position
	"The foregoing paragraphs indicate that the		
17	growing awareness of the grave threat of infection to	17	during the year 1983, a feeling which now might be
18	haemophiliac patients through AIDS."	18	construed by the aid of the retrospectoscope."
19	I think there must be a verb missing there.	19	So it's not entirely clear what is being said
20	She refers to:	20	in that. It appears to be suggesting that there
21	" during these years 1982-85 dramatic	21	should be the avoidance of retrospective reflection or
22	developments in medicine received worldwide publicity.	22	any application of hindsight possibly.
23	Medicine is both a science and an art. Scientific	23	SIR BRIAN LANGSTAFF: At the moment what I'm inclined to
24	research forms the basis for advances in treatment.	24	do, but obviously it's subject to any submissions
25	The art is the appropriate application of the science.	25	I may later receive at the end of the Inquiry, that
	39		40 (10) Pages 37 - 40

1	what she appears to be saying is that the position	1	Again, we've looked at this on a number of
2	during the year 1983 was indeed understated and	2	occasions but not for the purpose of highlighting
3	underestimated. However, that is what appears now	3	Dr Mayne's attendance. So it was the haemophilia
4	looking back. At the time, the science had not	4	Reference Centre Directors' meeting held at BPL
5	advanced sufficiently to allow for those conclusions	5	10 December 1984 to discuss what should by now be
6	properly to be drawn.	6	done, and we can see from the list of attendees
7	MS RICHARDS: That may be what she is saying and, of	7	Dr Mayne there along with a range of other
8	course, you have the benefit of being able to look	8	representatives.
9	yourself at the contemporaneous materials from 1982	9	I'm not going to go through the detail of the
10	and 1983 to assess that claim.	10	meeting. There is no particular contribution to the
11	SIR BRIAN LANGSTAFF: It's not a question of what was the	11	meeting from Dr Mayne that's identified in the
12	cause, what was the problem, was it understated. It's	12	minutes. You will recall, sir, it records the
13	a question of whether it should have been stated in	13	Reference Centre Directors' discussion about what
14	a different way is the question I think she's	14	should now be done both in terms of testing patients
15	addressing.	15	and in terms of ceasing to use commercial
16	MS RICHARDS: Yes, what was understood as a risk, what	16	concentrates.
17	action could and should have been taken, what	17	We can see Dr Mayne writing about the meeting
18	information could and should have been provided to	18	in brief terms at BPLL0010480. She writes to Dr Lane
19	patients to enable informed judgments to be made by	19	at BPL on 12 December 1984 thanking him and his staff
20	those whose health and lives were potentially being	20	for the hospitality at the meeting and says this:
21	placed at risk.	21	"The meeting was certainly beneficial if indeed
22	Going to then, just in terms of UKHCDO	22	somewhat depressing."
23	meetings, refer to one further meeting on this topic.	23	Just perhaps picking up on the issue of
24	It's the December 1984 meeting at Elstree, at	24	reflection as set out at the end of that section of
25	HCDO0000394_117.	25	Dr Mayne's litigation report, if we go to
	41		42
1	LOTH0000080_007. This is a rather later letter. It's	1	because of Dr Mayne's views in relation to the fate of
2	August 1993, so it's three years on from the	2	Professor Allain but because of what she suggests as
3	production of the litigation report and obviously	3	a more general point, "the doctors concerned", which
4	a decade on from the key events in 1983 but it's	4	would encompass presumably not only those in the
5	a letter Dr Mayne wrote to the editor of The Lancet	5	position of Professor Allain but all those involved
6	about what had happened in relation to	6	with treating haemophiliac patients with blood
7	Professor Allain in France, and she says this in	7	products, so all Haemophilia Centre Directors,
8	the picking it up in the second sentence:	8	including herself, guilty only of ignorance she says.
9	"This action [that's the imprisonment of	9	No doubt for you to decide whether that is an accurate
10	Professor Allain] instilled a feeling of dismay and	10	characterisation of the position.
11	grave concern over the fate of such a respected	11	If we turn next, on the issue of the extent of
12	colleague; one who I know personally and for whom	12	HIV infection in the Northern Ireland haemophilia
13	I have the highest regard for his scientific	13	community, to one of Dr Mayne's witness statements.
14	contributions to the field of Haemophilia and for his	14	It's at WITN0736006, so it's one of her statements
15	humanitarian attitude to the entire problem of HIV	15	from last year. If we pick it up at the bottom of the
16	infection contracted by Haemophiliac patients through	16	page, "Statistics", she says this:
17	the receipt of blood products."	17	" it is not difficult to recall the data for
18	Then she says this:	18	the overall UK percentage of treated Haemophilia
19	"The evolvement of the HIV problem within the	19	patients who became infected with HIV. I believe it
20	haemophilia population has caused immeasurable	20	to be 44.5 per cent. Some regions in England and
21	distress to patients and to all physicians treating	21	Wales attained figures greater than 70 per cent. The
22	them. The doctors concerned were guilty of one fault,	22	comparable figure for Northern Ireland (NI) was
23	namely that of ignorance. The imposition of a prison	23	14.5 per cent, clearly anomalous. I well recall
24	sentence in these circumstances seems illogical."	24	presenting the [Northern Ireland] data to a meeting of
25	Now I draw attention to that not particularly	25	the [UK] Haemophilia Directors Organisation (UKHCDO)
	43		44 (11) Pages 41 - 44

verb politely scoplical about the veracity of the content of the politic scope of the content of the politic scope	1	in Autumn 1985. Some colleagues, not unsurprisingly,	1	patients, largely, it's just over a third.
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47		•		-
47 48 (12) Pages 45 - 48	25	•	25	·
		47		48 (12) Pages 45 - 48

1	into pools from which our [Factor VIII] was produced,	1	in documents authored by Dr Mayne relevant to issues
2	has developed [AIDS]."	2	relating to what action was or was not taken in
3	And then in the third paragraph:	3	response to the risk of AIDS reflection or absence of
4	"Only one batch in the [UK] is implicated.	4	reflection and what information was or wasn't provided
5	Fortunately this is a heat-treated batch"	5	to patients.
6	And he gives the batch number.	6	If we can start with the litigation report at
7	"This small heat-treated batch was distributed	7	CBLA0000072_024 and if we go to page 40, this is the
8	in December 1984 in January 1985 to a few centres	8	last substantive page of the report. What follows is
9	only, of which yours is one, and we anticipate the	9	simply the footnoted or end note references. This is
10	product has already been used."	10	under a heading "The duties of care and breaches of
11	And then a suggestion that if it hasn't been,	11	the duties of care", and then there are some
12	it should be returned and there will be reimbursement	12	observations from Dr Mayne in relation to hepatitis
13	or replacement. So that's, I think, the communication	13	risk and then AIDS risk and she says this:
14	to which Dr Mayne was referring in her statement.	14	"The earlier sections of the report affirm that
15	Sir, there's some more to say in relation to	15	haemophiliacs were at risk from hepatitis through the
16	HIV and AIDS, so perhaps we could pick that up after	16	medium of their treatment"
17	the break.	17	She then refers again to what must be matters
18	SIR BRIAN LANGSTAFF: Yes. Let's take a break now until	18	set out in one of the versions of the HIV litigation
19	11.45.	19	Statement of Claim about alternative measures and she
20	MS RICHARDS: Thank you.	20	says:
21	(11.15 am)	21	"In general, they are impractical but in
22	(A short break)	22	particular [she refers to one of them] denies the goal
23	(11.45 am)	23	of haemophilia treatment, namely to minimise pain and
24	SIR BRIAN LANGSTAFF: Yes.	24	disability and to prolong life. Its conjectural
25	MS RICHARDS: Sir, I'm going to refer now to various parts	25	implementation would have restricted the choice of
	49		50
	to a few and a second to the second second in the second s	4	and the first of the control of the
1	treatment available to the physicians in charge of the	1	essentially being the person in charge.
2	patient: the personal in possession of all the	2	SIR BRIAN LANGSTAFF: This is a justification of
3	information regarding the patient's needs."	3	paternalism I think.
4	Now, I emphasise those sentences because they	4	MS RICHARDS: Yes. Then she continues:
5	may be relevant to any assessment you make, sir, about	5	"The alternative treatments; cryoprecipitate,
6	Dr Mayne's views as to the patient-physician	6	Desmopressin and animal concentrates have already been
7	relationship.	7	discussed and found wanting for the universal
8	SIR BRIAN LANGSTAFF: It is not, as I read it, consistent	8	treatment of severe haemophilia."
9	with the view which was clearly expressed to us by the	9	Again pausing there, it may be that those are
10	expert ethicists who emphasised, I think, the person	10	treatments that would not suffice for universal
11	in possession of all the information regarding the	11	treatment. It doesn't necessarily follow they
12	patient's needs, in the broad sense, is usually the	12	couldn't be used for treatment for some at least
13	patient.	13	severe haemophiliacs. Then she says this:
14	MS RICHARDS: Precisely.	14	"The risk/benefit ratio of non-treatment versus
15	SIR BRIAN LANGSTAFF: Although how best medically to	15	treatment could not be upheld" and I guess that
16	resolve the needs is a matter upon which the doctor	16	begs the question of by whom "in the light of the
17	has very valuable information to give in the light of	17	plight of haemophiliacs in the era before infusion
18	what he understands the individual patient's needs to	18	treatment became available. A return to bed rest,
19	be.	19	immobilisation and analgesia for joint bleeds would
20	MS RICHARDS: Precisely.	20	have been untenable."
21	SIR BRIAN LANGSTAFF: Have I summarised their view	21	So strong terms there used by Dr Mayne to
22	properly?	22	characterise what she says was the option, treatment
23	MS RICHARDS: Absolutely, and this appears to show	23	versus non-treatment, and her identification and
24	a different concept of characterisation of the	24	characterisation of the risk benefit ratio predicated,
25	patient-physician relationship, with the physician	25	it would seem, upon at least on one reading of this
	51		52 (13) Pages 49 - 52

1 document an assumption that that's ultimately may cause alteration of decisions or changed actions. 2 a balancing exercise for the physician rather than the 2 Like everyone else, I wish that none of my patients 3 3 had been infected as a result of blood products. patient. In relation to AIDS she then deals with it 4 4 However, after careful appraisal I remain convinced 5 5 that the course of action pursued by both myself and shortly by saying: 6 "Comments of a similar nature apply to the 6 my colleagues was measured and appropriate for that 7 paragraphs ... relating to AIDS." 7 time in light of the information and the state of 8 8 So that's the HIV report. knowledge at the time." 9 9 If we then go to Dr Mayne's main witness So that is Dr Mayne's response. Then in answer 10 10 statement, at WITN0736009, and if we turn, please, to to the next question, "What decisions or actions by 11 page 30, we look at the question at the bottom of the 11 you and/or by the Centre could and/or should have 12 page, and it's a question that the Inquiry has posed 12 avoided, or brought to an end earlier, the use of 13 to most of the clinicians from whom it's requested 13 infected blood products?", she refers to that answer. 14 statements, who were haemophilia clinicians practising 14 In terms of the question of whether it patients 15 15 at the relevant time: were warned or provided with information or advice 16 "Do you consider that your decisions and 16 about the risks of HIV so that the patients could make 17 17 actions, and those of the Centre in response to any an informed decision, that's obviously a matter for 18 18 known or suspected risks of infection were adequate you to determine. You will recall the evidence that 19 and appropriate? If so, why? If not, please explain 19 the Inquiry has already received and heard from 20 what you accept could or should have been done 20 patients themselves or from their relatives, which is, 21 differently." 21 I think I'm right in saying, universally to the effect 22 22 Then Dr Mayne's response at the top of the that they were not provided with specific advice, 23 23 warnings or information about risks of AIDS from page: 24 24 factor concentrates prior to the group meetings that "The two words 'could' and 'should' often 25 suggest that today, with the benefit of hindsight, it 25 took place probably in January 1985 and which I'll 53 54 1 come on to. 1 MS RICHARDS: It is possible and I'm going to go through 2 2 So that's the evidence for you to assess from where I can find reference in her statements to this 3 patients -- from people who were infected or from 3 issue. I can't guarantee that I necessarily refer to 4 4 their family members. every single statement that she refers to it and no 5 In terms of Dr Mayne's witness statement, if we 5 doubt you will be reading them all again in due 6 stick with the document on screen but go first of all, 6 course, sir. But it is absolutely possible that she 7 7 please, to page 28, bottom of the page is the may be referring to earlier statements. 8 8 question: In relation to this statement, if we go to 9 9 "Did you take steps to ensure that patients paragraph 43.1, I'm looking here for passages which 10 were informed and educated about the risks of 10 deal with information provided to or discussions held 11 hepatitis and HIV? If so, what steps? 11 with patients, so it's page 31. She was asked about 12 "[Answer] I do not think I can expand usefully 12 reversion to treatment with cryoprecipitate and her 13 to answer this question other than as already answered 13 answer is this: previously." 14 14 "Theoretically a return to using 15 15 cryoprecipitate would have been appropriate for some In terms of what is previously set out it's not 16 16 clear what Dr Mayne is there referring to in the patients. However, it was neither a practical nor 17 statement. There's little that I can see which talks 17 realistic option. Following lengthy explanatory 18 about the provision of information to patients in the 18 discussions, during which the possibility of reverting 19 earlier part of her statement. There is a discussion 19 to cryo was raised, I was greeted by an emphatic 20 which I'm going to come on to about what was done in 20 refusal from the patients concerned. Patients had 21 response to the risk of AIDS, but that all appears to 21 become used to carrying their concentrate/pack with 22 22 be at a later stage but be that as it may that's them to school, to college or their workplace. The 23 23 Dr Mayne's answer to that question? presence of that pack had become life changing. 24 SIR BRIAN LANGSTAFF: Is she possible referring to other 24 A return to being dependent on the availability of 25 witness statements which she gave earlier? 25 a fridge freezer and to the lengthy process of thawing

55

(14) Pages 53 - 56

4		4	ible Cash matient was annotated with information
1 2	and preparing cryoprecipitate was just not acceptable to them."	1 2	possible. Each patient was provided with information
		3	provided by the national Haemophilic Society. There
3	Unfortunately, what that paragraph doesn't tell		were few occasions when concentrate was given to
4	us is when it is said such conversations took place or	4	patients other than those with haemophilia or allied
5	what information was provided about risks to enable	5	disorders. I recall rare incidents when concentrates
6	a judgment to be made by the patient.	6	were given to counteract the excessive effects of
7	I should say I don't think we've seen anything	7	Warfarin anti-coagulation. It was also used for
8	in individual statements from people who were infected	8	patients with advanced liver disease."
9	or their relatives which reports any such	9	She refers, top of the next page, to instances
10	conversations but assuming for the purposes of debate	10	where concentrates were used erroneously on an
11	in Dr Mayne's favour she had them, it doesn't tell us	11	emergency basis within the ICU.
12	when she had them and whether it was at any stage	12	So, again, that doesn't actually tell us what
13	prior to the group meetings in January 1985.	13	information was provided. It merely says leaflets or
14	If we then turn over the page and go to the	14	information from The Haemophilia Society was provided
15	bottom half of the page, so this is under a series of	15	and discussions were held with patients, but the
16	questions relating to the provision of information to	16	content of that information remains unclear.
17	patients, she's asked the general question:	17	If we go to the next page sorry, stick where
18	"What information did you provide or cause to	18	we are, Soumik. Paragraph 47.1, you'll see the
19	be provided to patients with a bleeding disorder	19	question that's been posed of her, and by reference to
20	about the risks of infection in consequence of	20	the HIV litigation expert report, was picking up on
21	treatment with blood products prior to such	21	her assertion that patients became aware of the risks
22	treatment commencing?"	22	of hepatitis during the mid-1970s.
23	The answer is:	23	She's asked what the factual basis for that is
24	"No local leaflets/printouts were available.	24	and what discussions she had with patients in the
25	Discussions with patients were held if and when	25	mid-'70s.
	57		58
1	What she cays by you of reproposis:	4	information. I don't agu this in naigrative terms
1	What she says by way of response is:	1	information I don't say this in pejorative terms,
2	"An annual meeting for patients, relatives and	2	just as a matter of fact it doesn't provide us with
3	members of staff was held as part and parcel of the	3	information about what the content of any such articles might be.
4	activities of the Northern Ireland Group of the National Haemophilia Society. Over time,	4 5	•
5			If we go over the page we then see the assertion at 47.4:
6 7	a multiplicity of experts was invited to be speakers.	6	
	Each gave an opening talk on aspects of haemophilia	7	"Therefore, the patients in the 1970s onwards
8	and then the afternoon was open to patients and their	8	would have been aware of all aspects of haemophilia
9	relatives to ask questions of the experts - questions	9	treatment and research, if they attended their local
10	about treatments, about the risks, about advances in	10	society and read its magazine."
11	therapy, changes in scientific research etc."	11	That's, well, sir, a matter for you as to
12	And then she gives a list of some of those who	12	whether that's an adequate substitute for information
	spoke over the years.	13	
13	· ·	13	being provided directly to patients by their
14	So, again, that doesn't answer the question,	14	physician.
14 15	So, again, that doesn't answer the question, the actual question asked, which is what the	14 15	physician. If we go further down the page there's then
14 15 16	So, again, that doesn't answer the question, the actual question asked, which is what the discussions were, what's the basis for saying that	14 15 16	physician. If we go further down the page there's then a question about what information was provided before
14 15 16 17	So, again, that doesn't answer the question, the actual question asked, which is what the discussions were, what's the basis for saying that patients were aware of risks of hepatitis. That	14 15 16 17	physician. If we go further down the page there's then a question about what information was provided before the commencement of home therapy and there's a more
14 15 16 17 18	So, again, that doesn't answer the question, the actual question asked, which is what the discussions were, what's the basis for saying that patients were aware of risks of hepatitis. That doesn't address the content of any communications at	14 15 16 17 18	physician. If we go further down the page there's then a question about what information was provided before the commencement of home therapy and there's a more detailed answer about the process of training families
14 15 16 17 18 19	So, again, that doesn't answer the question, the actual question asked, which is what the discussions were, what's the basis for saying that patients were aware of risks of hepatitis. That doesn't address the content of any communications at these what was said to be annual meetings rather than	14 15 16 17 18 19	physician. If we go further down the page there's then a question about what information was provided before the commencement of home therapy and there's a more detailed answer about the process of training families in relation to home therapy.
14 15 16 17 18 19	So, again, that doesn't answer the question, the actual question asked, which is what the discussions were, what's the basis for saying that patients were aware of risks of hepatitis. That doesn't address the content of any communications at these what was said to be annual meetings rather than the fact of them.	14 15 16 17 18 19 20	physician. If we go further down the page there's then a question about what information was provided before the commencement of home therapy and there's a more detailed answer about the process of training families in relation to home therapy. In terms of risks of infection, what we see is
14 15 16 17 18 19 20 21	So, again, that doesn't answer the question, the actual question asked, which is what the discussions were, what's the basis for saying that patients were aware of risks of hepatitis. That doesn't address the content of any communications at these what was said to be annual meetings rather than the fact of them. If we go to the next paragraph, Dr Mayne says:	14 15 16 17 18 19 20 21	physician. If we go further down the page there's then a question about what information was provided before the commencement of home therapy and there's a more detailed answer about the process of training families in relation to home therapy. In terms of risks of infection, what we see is at the bottom of the page, it's just said in last
14 15 16 17 18 19 20 21	So, again, that doesn't answer the question, the actual question asked, which is what the discussions were, what's the basis for saying that patients were aware of risks of hepatitis. That doesn't address the content of any communications at these what was said to be annual meetings rather than the fact of them. If we go to the next paragraph, Dr Mayne says: "Patients also had their own magazine/journal	14 15 16 17 18 19 20 21	physician. If we go further down the page there's then a question about what information was provided before the commencement of home therapy and there's a more detailed answer about the process of training families in relation to home therapy. In terms of risks of infection, what we see is at the bottom of the page, it's just said in last sentence on the page:
14 15 16 17 18 19 20 21 22 23	So, again, that doesn't answer the question, the actual question asked, which is what the discussions were, what's the basis for saying that patients were aware of risks of hepatitis. That doesn't address the content of any communications at these what was said to be annual meetings rather than the fact of them. If we go to the next paragraph, Dr Mayne says: "Patients also had their own magazine/journal originally started by me but then passed on to the	14 15 16 17 18 19 20 21 22 23	physician. If we go further down the page there's then a question about what information was provided before the commencement of home therapy and there's a more detailed answer about the process of training families in relation to home therapy. In terms of risks of infection, what we see is at the bottom of the page, it's just said in last sentence on the page: "At all times patients were advised regarding
14 15 16 17 18 19 20 21 22 23 24	So, again, that doesn't answer the question, the actual question asked, which is what the discussions were, what's the basis for saying that patients were aware of risks of hepatitis. That doesn't address the content of any communications at these what was said to be annual meetings rather than the fact of them. If we go to the next paragraph, Dr Mayne says: "Patients also had their own magazine/journal originally started by me but then passed on to the patients entitled 'CLOTT'."	14 15 16 17 18 19 20 21 22 23 24	physician. If we go further down the page there's then a question about what information was provided before the commencement of home therapy and there's a more detailed answer about the process of training families in relation to home therapy. In terms of risks of infection, what we see is at the bottom of the page, it's just said in last sentence on the page: "At all times patients were advised regarding the risks of disease, any then-known risk of using
14 15 16 17 18 19 20 21 22 23	So, again, that doesn't answer the question, the actual question asked, which is what the discussions were, what's the basis for saying that patients were aware of risks of hepatitis. That doesn't address the content of any communications at these what was said to be annual meetings rather than the fact of them. If we go to the next paragraph, Dr Mayne says: "Patients also had their own magazine/journal originally started by me but then passed on to the	14 15 16 17 18 19 20 21 22 23	physician. If we go further down the page there's then a question about what information was provided before the commencement of home therapy and there's a more detailed answer about the process of training families in relation to home therapy. In terms of risks of infection, what we see is at the bottom of the page, it's just said in last sentence on the page: "At all times patients were advised regarding

The Infected Blood Inquiry

			• •
1	any time they had a problem."	1	terms of providing information in advance of treatment
2	Again, there's a sharp contrast between what	2	or in the course of treatment programmes, and then we
3	Dr Mayne says and what those who have provided	3	have the general statement that she has no doubt she
4	statements to the Inquiry say in relation to being	4	had informal discussions with patients at clinical
5	warned of risks.	5	appointments but we're not told what the content of
6	Then we have the question at 50.1:	6	those discussions were. And, again, the evidence from
7	"When did you first discuss AIDS or HIV	7	individual patients or their family members is to the
8	with any of your patients?	8	effect that information about the risks was not
9	"50.1 At this distance in time, I cannot	9	communicated to them.
10	recall the details but I have no doubt I had informal	10	So that's what she says in her statement about
11	discussions with the patients at clinical	11	information provided to in that statement about
12	appointments. The minutes of the UKHCDO meeting in	12	information provided to patients.
13	December 1984 have been brought to my attention.	13	If we go back in this statement then to
14	I note that I attended; however, I cannot recall	14	page 28, she's asked the question, so this is now
15	attending or the meeting itself. I assume that the	15	"What actions did you take in response to the risk of
16	decision to hold the 1985 meetings"	16	AIDS", she's asked the question in 35:
17	So those are the group meetings held for	17	"What, if any, actions did you take to reduce
18	patients in January or thereabouts.	18	the risk to your patients of being infected with HIV?"
19	" was influenced by this meeting. It was	19	She says:
20	then decided to have formal meetings. I arranged for	20	"[She] followed the recommendations issued by
21	three meetings to take place in early 1985."	21	UKHCDO in June 1983 which reflected my existing
22	And she refers to those being described in her	22	practice in any event."
23	earlier witness statement.	23	We've already explored that. That's the
24	So in terms of any dates, we have the	24	June '83 letter and the UKHCDO recommendations in
25	January 1985 meetings, which obviously is too late in	25	relation to children, mildly affected patients and
20		23	
	61		62
1	previously untreated patients.	1	of 1983.
2	Then she's asked the question:	2	I should draw your attention to a previous set
3	"Did you continue to use blood products to	3	of answers on page 26, where Dr Mayne is asked the
4	treat patients, after becoming aware of the possible	4	question:
5	risks of infected with HIV? Why?"	5	"What, if any, enquiries and/or investigations
6	And she says this:	6	did you carry out or cause to be carried out in
7	"Within my response to [question] 33 I have	7	respect of the risks of transmission of HIV or AIDS?
8	indicated that I continued to use concentrates. Even	8	What information was obtained as a result?"
9	with the benefit of hindsight, I cannot envisage	9	The way in which Dr Mayne has answered that is
10	otherwise. In reality, the choice was stark stop	10	to look at the process of testing patients for
11	treatment with concentrates with all the risks and	11	HTLV-III and what happened thereafter, so there's not
12	disruption that would entail for patients or continue	12	a suggestion in her answer of enquiries or
13	with treatment in light of the information then	13	investigations prior to the actual point of testing
14	available."	14	which seems to have commenced at the beginning of
15	In common with some others who have provided	15	1985. We can see that because she that talks in
16	evidence to the Inquiry from a clinical perspective or	16	paragraph 33.3 about what her expectation was as to
17	from some of the material we've seen in		
		17	how many patients would be HTLV-III positive. She
18	contemporaneous documentation, the choice is posed as	18	poses a rhetorical question about immunity in
19	this stark choice between essentially no treatment or	19	paragraph 33.4.
20	continuation of treatment rather than a potential	20	If we go down the page, she says that this
21	spectrum of choices.	21	may be in relation to an earlier period in fairness
22	She refers in the next paragraph to the special	22	she says:
23	meeting of Reference Centre Directors, and that's	23	"The treatment policy was kept under review.
24	I think an accurate reflection of what the outcome	24	Discussions and many conversations took place with the
25	of the Reference Centre Directors' meeting in May	25	patients."
	63		64 (16) Pages 61 - 64

Again, that doesn't reflect the evidence that individuals who were infected or their family members has provided to the Inquiry so those are factual issues that will be for you, sir, to consider.

She says a return to cryoprecipitate was offered and was turned down. Again, there's no information as to when she says that offer was made or to whom and she says patients were asked to reduce

their usage if possible.

There's certainly a later letter, from the late 1980s when there's a request for reasons of financial constraint, for patients to reduce their usage.

There's no documentary evidence of patients being asked to reduce usage that the Inquiry has found in the first half of the 1980s; so relevant to the risk of AIDS.

She then refers to offering testing to staff. That again puts this into the either very end of 1984 or 1985 period. She refers then in the next paragraph to regular patient testing continuing and where appropriate testing of partners being carried out. Again, that puts what she's talking about squarely into 1985 or thereafter.

If we go to the next page, the measures she then sets out I think on a fair reading of the

the anti-HTLV-III seroconversions from negative to positive are as follows."

Sir, I should say what flows from this and is acknowledged by Dr Mayne in her statements is that, in common with some other haemophilia centres, samples of sera were stored I think in the Regional Virus Laboratory primarily, possibly exclusively. To what extent that was with the knowledge or informed consent of patients I think is probably unclear on the state of the evidence but, as a matter of fact, there were stored sera samples and that enabled this exercise to be undertaken for a number of those who had been found to be positive for HIV and the dates are significant.

First one, last negative result January '84, first positive result July '84, so seroconversion within the first half of 1984. Second one is last negative result October '84, first positive result April '85, so seroconversion in the last months of '84 or the first months of 1985. The third suggests seroconversion in the period between February and October of 1983; the next August 1983 and January 1984; then January '83 and January '84; then November '83 and June '84; September '83 and February '84; February '83 and November '83; September '83 and March '84; September '84 and July '85; August '83 and

statement all relate to the period from 1985 onwards, at least that seems the likeliest reading. So she talks out paragraph 33.8 about needing to disseminate information because of misconceptions relating to stigma. She talks in paragraph 33.9 about speaking on the radio/TV, attending a range of meetings to offset and counteract incorrect rumours regarding infection with HIV.

She then talks about increasing staffing levels in 33.10, and in 33.11 liaising with colleagues from other disciplines. So that's looking I think then at how to treat and care for those infected with HTLV-III HIV rather than the prior question of what steps were taken to consider and the best response to the risks in advance of those risks actually being fulfilled.

Sir, that's I think the most relevant part of Dr Mayne's main witness statement. If we then look again at information about the circumstances of infection and dates of seroconversion, we pick it up at BHCT0000484. This is a letter dated 15 October 1985. It's from the Regional Virus Laboratory at the Royal Victoria Hospital to Dr Mayne and it says:

"We have completed the retrospective study on our stored sera from your patients. The results of

March 1984.

Then there are four patients listed for whom we have a first positive result, the earliest of those dates being February 1983 and one being February 1984, but no earlier stored serum samples. So what we can see from that list is no apparent seroconversions prior to 1983. The earliest date of a last negative result is January 1983 and the majority of the last negative results are later than that. That obviously raises the question of whether, given what was known in late 1982 and by the beginning of 1983, these were avoidable seroconversions.

So that's information about the patients who were found to be HIV positive. As Dr Mayne's statement says there is also one spouse or partner who was infected with HTLV-III.

You will recall Dr Mayne's statement saying that there were no children who seroconverted. However, that might depend upon one's definition of a child. If we go to BHCT0000846_004, if we go to the next page, so this is a letter from Dr Mayne to Dr Machin in the Haematology Department of the Middlesex Hospital, 18 October 1985. Obviously, the patient details are redacted but you can see -- sorry, if we go up the page -- the date of birth is 1971.

(17) Pages 65 - 68

1	This is a letter written in 1985 so it refers to	1	If we go to BHCT0000860 and go to the next
2	a 14-year old. For the avoidance of doubt I confirm	2	page. Again, this is picking up upon the suggestion
3	it does refer to one of the patients listed in that	3	in Dr Mayne's statement that no child was infected.
4	letter we looked at a few moments ago.	4	This says "Surveillance of paediatric HIV infection
5	We can see from this it refers to a "moderately	5	and AIDS follow-up", and if we look further down the
6	severe haemophiliac", so not severe, moderate	6	page we can see:
7	severity, and if we go to the bottom of the page we	7	"Has the child received treatment for HIV?
8	can see this paragraph:	8	"Yes", and we can see that the child has
9	"The most significant problem with [him] is the	9	received AZT. If we go over the page sorry, we're
10	fact that the human material given in January [so it	10	back to the first page, I should say. We see there
11	would seem that's January 1985, given what's set out	11	reference to this patient having HIV-related symptoms
12	in the rest of the letter] produced seroconversion on	12	and details are there given.
13	10 July 1985 with a positive HTLV-III	13	Sir, again, obviously patient identifying
14	result confirmed. I have not told the patient this	14	details are redacted by the Inquiry but it appears
15	result, nor his family, at the present time"	15	from the information we have that relates to the same
16	Again, the letter is October 1985, so three	16	person, that same patient as we looked at in relation
17	months further on:	17	to the previous letter.
18	" the reasons are due to the precarious	18	If we then go to one of the other documents
19	family base of the patient."	19	authored by Dr Mayne, again looking at seroconversion
20	The letter continues over the page but there's	20	rates, it's RHSC0000067_002. We've looked at this
21	nothing material for present purposes in that letter.	21	previously. It's Dr Mayne's March 1988 report. If we
22	So that would suggest that a 14-year old was	22	just pick up on something she says on page 4, under
23	infected, and infected at a late stage, and the fact	23	the heading "HIV Positivity", at the bottom of the
24	of his infection with withheld from him and his family	24	page, she says:
25	for a period of time.	25	"The HIV antibody positive rate for severely
20		25	
	69		70
1	affected patients in the UK is 54 per cent, with some	1	If we just go to page 4, we can see at the
1 2	affected patients in the UK is 54 per cent, with some centres having ratings of 75 to 80 per cent."		If we just go to page 4, we can see at the bottom of the page Dr Mayne making the same point
2	centres having ratings of 75 to 80 per cent."	2	bottom of the page Dr Mayne making the same point
2 3	centres having ratings of 75 to 80 per cent." I think we have seen 44 per cent cited	2 3	bottom of the page Dr Mayne making the same point suggesting that the incidence of positivity in her
2	centres having ratings of 75 to 80 per cent." I think we have seen 44 per cent cited elsewhere, but in any event.	2	bottom of the page Dr Mayne making the same point suggesting that the incidence of positivity in her patients was low probably because all her home therapy
2 3 4 5	centres having ratings of 75 to 80 per cent." I think we have seen 44 per cent cited elsewhere, but in any event. "In Northern Ireland only 16 patients have been	2 3 4 5	bottom of the page Dr Mayne making the same point suggesting that the incidence of positivity in her patients was low probably because all her home therapy patients were kept on one product and, as I say, that
2 3 4 5 6	centres having ratings of 75 to 80 per cent." I think we have seen 44 per cent cited elsewhere, but in any event. "In Northern Ireland only 16 patients have been shown to be antibody positive. This is equivalent to	2 3 4 5 6	bottom of the page Dr Mayne making the same point suggesting that the incidence of positivity in her patients was low probably because all her home therapy patients were kept on one product and, as I say, that doesn't appear to be correct, although the individual
2 3 4 5 6 7	centres having ratings of 75 to 80 per cent." I think we have seen 44 per cent cited elsewhere, but in any event. "In Northern Ireland only 16 patients have been shown to be antibody positive. This is equivalent to 25 per cent of the most severely affected patients and	2 3 4 5 6 7	bottom of the page Dr Mayne making the same point suggesting that the incidence of positivity in her patients was low probably because all her home therapy patients were kept on one product and, as I say, that doesn't appear to be correct, although the individual patient data we have doesn't clearly distinguish home
2 3 4 5 6 7 8	centres having ratings of 75 to 80 per cent." I think we have seen 44 per cent cited elsewhere, but in any event. "In Northern Ireland only 16 patients have been shown to be antibody positive. This is equivalent to 25 per cent of the most severely affected patients and 16.5 per cent of all treated patients in the	2 3 4 5 6 7 8	bottom of the page Dr Mayne making the same point suggesting that the incidence of positivity in her patients was low probably because all her home therapy patients were kept on one product and, as I say, that doesn't appear to be correct, although the individual patient data we have doesn't clearly distinguish home therapy and hospital therapy. Some had only received
2 3 4 5 6 7 8 9	centres having ratings of 75 to 80 per cent." I think we have seen 44 per cent cited elsewhere, but in any event. "In Northern Ireland only 16 patients have been shown to be antibody positive. This is equivalent to 25 per cent of the most severely affected patients and 16.5 per cent of all treated patients in the Province."	2 3 4 5 6 7 8 9	bottom of the page Dr Mayne making the same point suggesting that the incidence of positivity in her patients was low probably because all her home therapy patients were kept on one product and, as I say, that doesn't appear to be correct, although the individual patient data we have doesn't clearly distinguish home therapy and hospital therapy. Some had only received one product for ten years and then there's
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(18) Pages 69 - 72

1	Dr Elizabeth Mayne found out that he had been given	1	which were not full haemophilia centres or doctors who
2	two bottles of Edinburgh Factor IX on the day his	2	were not knowledgeable about risks providing treatment
3	niece was born. It was never written down by the kind	3	where it wasn't required.
4	Doctor who administered the dose and it led to much	4	If we then look at the question of the meetings
5	consternation for the patient, his family and myself.	5	that were held in January 1985 and we can take that
6	The sad and ironic aspect of the whole performance was	6	down, Soumik I'm sure you will recall, sir, from
7	that the patient did not need the Factor IX. He has	7	the Belfast hearings some very vivid testimony about
8	mild Christmas Disease and does not suffer from	8	those meetings at the hospital. I'll have to dart
9	Haemarthrosis. The Doctor who saw him either forgot	9	between different statements I think in order to see
10	or did not realise these facts and [he] now sadly has	10	what's said about those meetings by Dr Mayne.
11	full-blown AIDS."	11	So if we start with WITN0736001 and we go to
12	Again, the patient cross-referencing between	12	page 7, so this is Dr Mayne's statement in response to
13	the documents available to the Inquiry identified	13	a number of individual statements from people who were
14	there is, it would appear, one of the patients listed	14	infected, a number of whom were giving evidence at the
15	in that letter, that list of seroconversions. So	15	oral hearings in Belfast, and in paragraph 2.6 she
16	there we have an account of a patient with mild	16	says:
17	haemophilia B, even on Dr Mayne's account, having been	17	" categorically, there was no HIV testing
18	given Factor IX, not I should say according to this	18	carried out before the meetings that were convened in
19	letter by Dr Mayne but elsewhere, completely	19	January to March 1985 at the Royal Victoria Hospital."
20	unnecessarily. It's not clear from this or from the	20	So that assists, if that's correct, in telling
21	other material the Inquiry has I think which hospital	21	us that there was no HIV testing in the course of
22	that treatment was administered at.	22	1984. We know of course that there were HIV tests or
23	That obviously raises an issue that we've seen	23	HTLV-III tests carried out in relation to samples from
24	explored elsewhere in relation to other centres within	24	1983 and 1984 and possibly earlier, but she says there
25	the United Kingdom of systemic problems with hospitals	25	was no HIV testing and she gives that window of
	73		74
1	January to March 1984 as the dates	1	several months to complete, as patients were requested
2	SIR BRIAN LANGSTAFF: 1985.	1 2	several months to complete, as patients were requested to come to the Centre in small groups to allow
	SIR BRIAN LANGSTAFF: 1985. MS RICHARDS: 1985, sorry when these meetings occurred.		to come to the Centre in small groups to allow sufficient time for discussion and debate. Actual
2	SIR BRIAN LANGSTAFF: 1985. MS RICHARDS: 1985, sorry when these meetings occurred. If we then go to WITN2658002, go to the second	2	to come to the Centre in small groups to allow sufficient time for discussion and debate. Actual testing of samples commenced on 2 January 1985. Each
2 3	SIR BRIAN LANGSTAFF: 1985. MS RICHARDS: 1985, sorry when these meetings occurred. If we then go to WITN2658002, go to the second page, we see that this is the report entitled	2 3	to come to the Centre in small groups to allow sufficient time for discussion and debate. Actual testing of samples commenced on 2 January 1985. Each sample was coded. The prefix was BV (Belfast virus)
2 3 4 5 6	SIR BRIAN LANGSTAFF: 1985. MS RICHARDS: 1985, sorry when these meetings occurred. If we then go to WITN2658002, go to the second page, we see that this is the report entitled "A synopsis of haemophilia re Mr Malachy Devlin", and	2 3 4 5 6	to come to the Centre in small groups to allow sufficient time for discussion and debate. Actual testing of samples commenced on 2 January 1985. Each sample was coded. The prefix was BV (Belfast virus) and each patient's sample was allocated a sequential
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(19) Pages 73 - 76

8 RICHARDS. Sir, whose there was a meeting		AIR DRIVE AND THE D. 7	4	
8 SIR RRANA LANGSTAFF: It may just be relating to 8 my Richardos. Yes. 9 meeting where the relating about 9 sepressed - 9 surpressed - 9 surp	1	SIR BRIAN LANGSTAFF: Page 7.	1	that's given for the open meeting is 1983, which
Mr. Kijabatick, but it seemed to be more generally suggested - 5 suppressed - 5 s				•
6 MSRCHARDS: Yes 6 Sheart MARDS and the Harmonthillies present the choice 7 SIR BRIAN LANGSTAFF: - because it's talking about 7 of whether they wanted to know the result of their HIV 8 neetings, so it look as shough it's wider, no HIV 8 test." 10 medings, so it look as shough it's wider, no HIV 8 test." 10 march '85, i.e. none before March '1985 meeting. 10 "Lound that bizare." 11 MS RICHARDS: Yes. Well, that's obviously not consistent. 11 If you had a bizare." 12 with saying that the actual testing commenced on 12 WITMO7/38005, and if we go to - this is in response at with saying that the actual testing commenced on 13 the Marsden statements. If we go to page 10 hink 15 15 this statement. She says: 16 "Three open meetings were held regarding the will state the mark of the meeting		**		-
8 MS RICHARDS: Yes. 9 Itelang carried out before the meetings in January to 9 Heart of the whether they wanted to know the result of their HIV 8 meetings, so it blocks as though it's wider no HIV 8 testing carried out before the meetings in January to 9 And she says: 10 Macri 85, i.e. none before Macri 1985 meeting, 10 "Tound that bizarre." 11 MS RICHARDS: Yes. Well, that's obviously not consistent 11 If we look at one of Dri Mayne's responses at with Tour 3000,5, and five go to —this is in response to 2 with Tour 3000,5, and five go to —this is in response to 3 2 January 1985. 13 January 1985. 13 the Marsden statements. If we go to page 10 I think is in response to 3 2 January 1985. 15 Str BRIAN LANGSTAFF: Tipust wanted to confirm that was 15 str.				
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79 80 (20) Pages 77 - 80		79		80 (20) Pages 77 - 80

previously as it seemed irrelevant. However, in view of Louise Marsden's apposite description I thought I should enlarge on the detail to the Inquiry."

Then if we go to WITN0736001, again this is another of Dr Mayne's statements and if we look at page 11, please, bottom half of the page, this is in response to a recollection of the meeting described by

Mr Hamilton, and Dr Mayne says this:

"... when the possibilities of viral infection became known, in 1984, towards the end of that year, meetings were planned to meet with all patients who had received treatment. They began in January 1985. Routinely, they were scheduled to take place in Ward 37, block A, [Royal Victoria Hospital]. Initially, Mr Hamilton's description of a hexagonal room caused bewilderment. After two weeks consideration, I remembered that Ward 37 was not available for one of the scheduled meetings due to an influx of emergency admissions the previous evening. The only hospital venue available, therefore, was the Sir Ian Fraser Lecture Theatre which was located off the main hospital corridor. It was a historical venue as it was the old anatomy and surgical theatre for teaching medical students. It was in the form of a rotunda, with a glass ceiling and tiered seats which

individual taking of samples rather than the group meeting; I don't know:

"All samples were tested and labelled anonymously by a code."

And then -- well, I might as well read this so I don't have to come back to it. I'm going to look at the process for giving patients their diagnosis in a moment. She says:

"Patients plus relatives were invited to come back to receive their results. If negative, at first, it was thought a letter might be a good idea but this was rapidly rejected. All but two families returned for results and both received a home visit. The situation was dire and all members of the Centre's staff did the best they possibly could. Only 16 adults tested positive but for each and every one of them it was then a disaster. All patients accepted the invitation to be tested, but some deferred the appointment to a more convenient time."

So that's the further description we have from Dr Mayne of the group meetings and the arrangements for testing. I should say that in the evidence the Inquiry has received from individuals, whilst it's absolutely right that there is evidence of patients being informed of their diagnosis in person, there is

were very uncomfortable. It had old fashioned heavy wooden doors which clanged shut when closed. It had been refurbished and was used for weekly physicians meetings and post graduate seminars. Sadly there was no facility for tea and coffee."

I refer to that because this meeting was obviously a very significant event in the memory of a lot of individuals and it seemed important to draw out what information we have from Dr Mayne about it. She then continues:

"I cannot recall how the subsequent blood testing was [arranged]."

So it sounds as though there was testing undertaken on this account immediately following the meeting:

"It may have been necessary for the attendees to walk to a nearby ward. I do not remember. I can certainly remember that the room was not locked. There was absolutely no justification or reason to take such a step."

Then perhaps in contrast to the other accounts she says here:

"As much time and space was given for discussion as was necessary."

That may, of course, be a reference to

also evidence of patients being informed of their diagnosis, both negative and positive in some cases, by letter. So that again may be an area where there is a factual conflict that you, sir, may wish to consider in due course.

One of the themes that has emerged from the statements of those who were infected or from their family members is as to the adequacy of the information that was provided when patients were told their HIV diagnosis and again you'll recall, sir, it's a theme that the Inquiry has heard both in relation to evidence relating to Belfast and in relation to evidence relating to a number of other centres, criticisms or concerns expressed about the adequacy of the information that was provided. It has been to some extent, perhaps, a fairly typical clinician response to say much was uncertain and the information that was provided was the information that was known at the time.

There is some evidence from individuals suggesting that their impression was that they were given no choice about whether to be tested for HIV, only as to whether they wished to know the results.

If we look at WITN2658009, these are the terms of a letter written to one patient, Mr Devlin, and

84 (21) Pages 81 - 84

4		4	
1	again we looked at a lot of the material relating to	1	a shortage, I do not know, but yes, as to the
2	his tragic case in the oral hearings in Belfast, but	2	question of were people did think they were obliged
3	this is a letter 25 March 1985. It helps gives some	3	to have a test or not, does she ever deal with the
4	context as well and a chronology to the period of time	4	question of why would you give people a choice as to
5	over which testing was being undertaken. This is late	5	whether they wanted to know the results if they had
6	March and Dr Mayne is writing saying:	6	had a choice as to whether they should be tested in
7	" we have serum for the antibody to the	7	the first place?
8	virus. A positive test does not mean that the person	8	MS RICHARDS: I'm going to check that because I'm
9	will be developing AIDS but it is important to carry	9	confident Dr Mayne does deal with it somewhere.
10	out this test"	10	This might be one of the places, WITN0736005.
11	And she says:	11	If we go to page 5 and we look at the bottom of the
12	" I want to know the antibody status of all	12	page, you'll see this is in response to an individual
13	patients before receiving heat-treated material."	13	witness statement, and reference is made to the
14	So that would suggest that as at 25 March 1985	14	witness W1371's statement describing the meeting and
15	patients were still receiving unheated concentrates	15	the witness saying that Dr Mayne said all
16	and the change had not taken place or at least not	16	haemophiliacs in the room would be tested for HIV
17	taken place for all patients. Then it's a "please	17	because she was erring on the side of caution, and so
18	come for a simple straightforward blood test". So it	18	Dr Mayne is invited to comment on the patients only
19	could I think in fairness to Dr Mayne be said there's	19	being given the option to choose whether or not they
20	no compulsion there, but equally it could be said in	20	wanted to know the results of the testing. This is
21	fairness to some of the criticisms that have been	21	Dr Mayne's response:
22	expressed that there's no statement there that it's	22	"HIV testing was offered to all those who had
23	a choice for the patient to make.	23	been in receipt of blood factor concentrates. The
24	SIR BRIAN LANGSTAFF: It sounds a bit like rationing the	24	witness is correct, because in carrying out such
25	heat-treated material, presumably because of	25	a widespread testing it probably was 'erring on the
	85		86
4	side of actions library at the time of actually.	4	airean alasudassa kut thatta Da Marinala sasan assa in this
1	side of caution'. However at the time of actually	1	given elsewhere but that's Dr Mayne's response in this
2	testing, the patient was invited to give consent and	2	statement to the question that you raised, sir.
3	if they had any difficulty in doing it the test was	3	SIR BRIAN LANGSTAFF: Yes, it doesn't really deal with the
4	easily postponed until a future date or not carried	4	point at all, which is really a question of argument,
5	out at all in accordance with the patient's wishes.	5	I suspect, and it may simply be she was offering
6	Several patients postponed testing but none refused.	6	people not only a test but if they didn't want to know
7	It seemed only right and proper that they should be	7	the result, they didn't want to know the result, but it seems rather curious that you would expect people
8	given the opportunity to know or not know the results.	8	it seems rather curious that you would expect beoble
9			
40	One of the secretaries took a note of the names of	9	to go for a test without wanting to know the result
10	patients who did not wish to know the result."	9 10	to go for a test without wanting to know the result one way or the other.
11	patients who did not wish to know the result." And then she deals with the individual patients	9 10 11	to go for a test without wanting to know the result one way or the other. MS RICHARDS: Yes. I can't
11 12	patients who did not wish to know the result." And then she deals with the individual patients in question, or the individual patient and his spouse	9 10 11 12	to go for a test without wanting to know the result one way or the other. MS RICHARDS: Yes. I can't SIR BRIAN LANGSTAFF: It's just an observation and it may
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1 received Factor treatment whether in the form of 2 cryoprecipitate or freeze-dried concentrate should be 3 offered testing for HIV. Patients and their relatives 4 were invited to a succession of meetings to update 5 them on all known risks and information about the 6 virus." 7 Again, that still doesn't tell us what the 8 information was that was provided. 9 "The meetings took place between January and 10 March of 1985 at the Royal Victoria Hospital. Patients were invited to be tested; it was a matter of 11 12 choice whether they wished to do so. No-one was 13 compelled to participate." 14 Then she says -- I'll just find the reference 15 WITN0736009, page 35, paragraph, 51.1, so bottom half 16 of the page: 17 "I have set out previously that I arranged 18 a number of special meetings in 1985 with the 19 patients. At that meeting they were invited to be 20 tested. Their express consent was invited for that 21 testing and prior to such testing had no knowledge of 22 whether a patient was infected with HIV. I only 23 became aware after the test results were received." 24 What's not clear, and we saw the date of the letter inviting Mr Devlin to come and be tested, which 25 89 1

undertaken then. That may of course be a reflection that remains unclear.

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In terms of the process then for telling

If we look at WITN0736005, and we go to page 10, please, if we look at the bottom half of the page, paragraph 3.10.1, now this is in relation to

"There was no intention to" -- so the question is -- the criticism that Dr Mayne is being asked to respond to is the appropriateness of informing a witness of their test result by letter. Dr Mayne's response is:

"There was no intention to relay this information but the secretarial staff had a difficult job to complete and they would have assumed despite the clipboard entry [I think that's a reference to where they've taken information about how people wanted to be told their results, but that may be

was late March 1985, what's not clear is why it took a period of time for the testing to be undertaken. There may be plenty of explanations as to why but obviously every day, week or month that goes past potentially puts patients or their relatives at risk and so we've seen example in another case of a patient being tested for example in July 1985, so the testing process seems to have taken a period of months. That may simply be a reflection of what the facilities were that were available and the numbers that had to be tested

It's not clear whether there was any particular sequence chosen in terms of testing first particular cohorts of patients and then testing other cohorts of patients at later stage. We don't know one way or another those kind of details.

SIR BRIAN LANGSTAFF: I thought you made a suggestion a few minutes ago that at at least one of the meetings those who were there understood they were to go down the corridor and have a test, unless they wanted to defer it.

MS RICHARDS: That's certainly what Dr Mayne says about one of the meetings. I don't think we have the same detail about the other two meetings and we know from other references that certainly not all testing was

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wrong] that you would be pleased to know the negativity of the result. It was the policy of the Centre not to send positive information via a letter. Either patients were told when they came to the Department or else I myself visited them to discuss the positive results."

You will recall again we looked at this during the Belfast hearing but I think it's probably worth referring to again in the context of the issues we are currently exploring. It was a letter BHCT0000896. This is October 1985 and I'm sure you will recall this letter, sir, because of the evidence you heard about the relative's concern about the language in which it was expressed. So this is not a communication of the outcome of the first test. It's a communication of the outcome of the investigations into dates of seroconversion:

"You will be glad to know that you became positive some time between February 1983 and October 1983. We have no sample between those two dates but I imagine that you became positive some time during the summer of 1983. Therefore you have more than passed the two-year point."

I should then show you what Dr Mayne said in response, because she accepted that the use of the

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(23) Pages 89 - 92

of not all patients attending the meetings. Again,

patients their results, I've indicated that there's some evidence of patients saying in their statements or their relative's statements to the Inquiry that

they were told the results by letter. There isn't evidence to suggest that that was a universal practice I should make clear.

relaying a negative test result:

word "glad" would seem to be appalling. If we look at
WITN0736001 and we go to page 10, paragraph 4.2, this
was Dr Mayne's account of telling this particular
patient how she communicated the result to him and
that she did so in person by visiting his house and
then she explains towards the end of the paragraph the
context of the letter and what she says the seemingly
appalling use of the word "glad", because she says it
was in response to him asking if she could find out
exactly when he was infected and him saying he would
be glad if she could find and let him know.
So that's communication by letter of

So that's communication by letter of seroconversion dates. It's obviously not the same as communication by letter of the positive result itself but, as I say, there is some evidence the Inquiry has received which suggests that that was the position.

We've already looked at a letter in relation to one patient, the patient who was 14 or thereabouts, and the fact that that patient and the patient's family had not yet been told the positive HTLV-III result.

If we look at BHCT0000846_003, you'll see this is a letter of 18 October 1985 to a school. Before we look at what's there set out it's a letter of the same date of the letter that was being written to a doctor

Then it refers in the next paragraph to retrospective samples being sent off and then a suggestion that other family contacts come in to be tested. Now, again, it's unclear I think from the information we have as to whether the communication of that information by letter to family members was done with the patient's consent or not.

Then in terms of just a further example on the issue of communication of test results, go to WITN0265001. This is -- if we go to page 14, I think, and pick it up in paragraph 50, it says this:

"In 1985, prior to telling me that I was HIV positive, Dr Mayne had come to the house when I wasn't there and told my parents that me and my two brothers had HIV. When I went to see her, I told her that I had not wanted my parents to be informed but she said it was better for them to know."

So obviously highly material evidence there in relation to HIV diagnosis.

SIR BRIAN LANGSTAFF: How old was that patient?

MS RICHARDS: They were an adult -- in 1985 would have been in their 20s. I'm afraid I don't know the brothers' ages.

Then if we go to WITN2658008, again, I think we probably looked at this when we heard the testimony

in London, so a doctor in London is being told the positive result for a particular patient in October '85 in circumstances where the patient and their family has not been told. What we see here appears to be, or hints at, Dr Mayne wanting to let the school know. That's an inference that you could draw from the letter. It's not clear. She asks for a personal conversation with the person to whom the letter's addressed at the school by telephone in the second letter. So it raises the possibility that others were being told of diagnosis but not the patients themselves or their record. We can take that down.

Again, there are a number of different accounts the Inquiry's received. There are patients who have no recollection. There's a patient who has no recollection of being tested or being told of the test result, which was negative, only discovering being tested on receipt of their medical records. Again, to try and get some understanding of the dates when testing was being undertaken, if we look at WITN2607004, this is a letter 12 February 1985 and it says:

"I'm sure that, by now, you have heard that [X]'s blood sample was positive for the AIDS related virus."

relating to Mr Devlin at the oral hearings in Belfast but, again, it just provides a little further light on the process of telling patients their results. So this is August 1985 to a GP:

"The problem of testing for response to the AIDS virus is well-known throughout the media and my policy has been to ask each patient when they are being tested if each individual wishes to know the result or not. At the meeting, Malachy himself declared that he did not wish to know the result, therefore I have respected his wishes and have not informed him."

But then Dr Mayne says that she's written to the patient's spouse and, of course, that in itself may ultimately give rise to the inference of the patient themselves being infected.

Again, these are bits and pieces of jigsaw information relating to individual patients which may assist you in forming an overall view, sir.

Dr Mayne has responded to that in her statement. I'm sorry, I don't have the reference noted down but I note the time and I can pick that up perhaps at 2 o'clock. There are a handful of further references and documents to look at on this issue but they will take longer than minute or so, so perhaps we

(24) Pages 93 - 96

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1	could adjourn for lunch now.	1	that the Inquiry has examined that Dr Mayne was alive
2	SIR BRIAN LANGSTAFF: Very well. 2 o'clock.	2	to the issues relating to confidentiality and stigma,
3	MS RICHARDS: Thank you, sir.	3	and we can see that, for example, from BHCT0000981.
4	SIR BRIAN LANGSTAFF: 2 o'clock.	4	This is a letter from January 1986 to a GP
5	(1.01 pm)	5	about an individual infected with HTLV-III, but if we
6	(Luncheon Adjournment)	6	just look at the bottom of the page and what she's
7	(2.00 pm)	7	written in handwriting at the very bottom:
8	MS RICHARDS: Sir, if I can just go back to the documents	8	"Phone call to GP re extreme need [of]
9	we were looking at before lunch, Soumik, WITN2658008,	9	confidentiality."
10	I had been about to say before lunch that there was	10	We can see that also in RHSC0000040_050. This
11	a response from Dr Mayne to this letter. That's	11	is the meeting of something called the HIV Advisory
12	incorrect. What I had in mind was Dr Mayne's	12	Group of the Eastern Health and Social Services Board.
13	explanation within the letter.	13	It's their second meeting, in October 1986, and we can
14	She describes her policy about asking patients	14	see that Dr Mayne is one of the attendees.
15	if they want to know the result, and then a reference	15	If we go to page 3, picking it up in the fourth
16	to her practice in relation to spouses being tested.	16	and fifth paragraphs, we can see the discussion refers
17	Then she says in the last paragraph:	17	to:
18	"I have been trying to keep the panic situation	18	"The confidentiality of information on AIDS
19	at the minimal level throughout the Province's	19	patients is an important matter the media are only
20	haemophilic population, hence this practice."	20	entitled to historic information, eg at six-monthly
21	Quite how that's an explanation of the policy	21	intervals about the number of cases and the number of
22	or practice is unclear but I just wanted to make clear	22	deaths"
23	that's what Dr Mayne says in the letter itself as	23	And then in the next paragraph Dr Mayne is
24	opposed to any particular statement.	24	recorded as:
25	More generally, it is apparent from materials	25	" [raising] the possibility of telephonists
	97		98
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1	being able to listen to conversations and that we	1	friends were bewildered and frightened. I gave much
2	should be careful about what we say over the	2	thought to the planning of how to achieve the
3	telephone"	3	essential HIV testing. Finally, I agreed to have
4	And a suggestion of staff education also being	4	group meetings, three in total. All patients who had
5	directed toward telephonists so they are aware of the	5	been treated were invited to attend with the exception
6	importance of confidentiality.	6	of the paediatric patients who were looked after by
7	More generally in her witness statement, at	7	their haematologist.
8	WITN0736009, at paragraph sorry, page 36 she talks	8	"The prime aim of the meetings was to provide
9	at the bottom of the page, last paragraph:	9	information about the global situation, and secondly,
10	"Lack of knowledge within the general	10	to inform patients of the local situation. In
11	population and the limited experience of many	11	particular, the mode of transmission from person to
12	individuals led me to suggest that patients should not	12	person and its effect on the day-to-day living of
13	publicise their results unnecessarily."	13	those concerned, information about care about was
14	Again, that chimes with some of the oral and	14	given to friends and relations. It was suggested to
15	written testimony the Inquiry has received. I should	15	be careful as the general public was not well informed
16	also note, if we look at the next page, I omitted to	16	about modes of transmission and infectivity."
17	take you earlier to a rather more detailed explanation	17	So, again, that's the suggestion of keeping
18	or account of the January 1985 onwards meetings from	18	these matters confidential. And then she says in
19	Dr Mayne in this statement. So I will, if I may, just	19	terms:
20	invite you to look at the bottom half of this page and	20	"Finally, there was a need to address
21		21	confidentiality, lack of which gave great concern to
22	then over the page. She says this at paragraph 54.1:	22	
23	"When the HIV/AIDS tragedy was evolving in the 1980s, to be told of a positive HIV test was in	23	patients.
23 24	essence a death sentence. There was no treatment.	23 24	"The format of the meetings was that I gave an introduction. Thereafter, there was time for an
24 25	Patients were terrified. Likewise, relatives and	24 25	introduction. Thereafter, there was time for an informal chat over a cup of tea"
20		20	400
	99		100 (25) Pages 97 - 100

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1	Again, that's not consistent, I think, with	1	information gained through combined monthly meetings
2	some of the accounts we have of at least including	2	with colleagues in Scotland and, thirdly, in an
3	Dr Mayne's own account, of at least one of the	3	informal manner through conversations with my
4	meetings.	4	colleagues with whom I had worked in the USA,
5	SIR BRIAN LANGSTAFF: That was the third meeting in the	5	Australia and Europe. In a different context, I also
6	old lecture theatre.	6	had regular discussions with my STD colleagues."
7	MS RICHARDS: Precisely:	7	She then refers in the next paragraph to going
8	" and finally the testing would take place."	8	from time to time to London for meetings. Again,
9	So that again suggests that the expectation was	9	I think that's potentially looking forward in time.
10	that those who were present at the meeting would	10	Then in paragraph 54.5 she returns to the
11	immediately be tested:	11	format of the group meetings at the hospital. She
12	"My sources of information regarding HIV	12	says:
13	infection were multiple; the UKHCDO AIDS working	13	" I presented and explained to patients and
14	party, chaired by Dr Rizza, provided copies of all	14	relatives the characteristics of the HIV virus.
15	publications as and when they appeared. This	15	Inside the body cavity in the blood stream, it was
16	information was invaluable."	16	lethal. However, outside the body the virus was
17	Now, I will need to double-check, sir, but my	17	extremely vulnerable. It could be destroyed by
18	recollection is that the UKHCDO's AIDS group was set	18	a simple wipe of bleach and certainly, heat treatment
19	up for the first time or met for the first time in	19	removed its activity Therefore, apart from IV,
20	January 1985, so it's unlikely that there had been	20	i.e. through treatment, blood transfusion, dirty
21	much produced by that stage. Of course, as the months	21	needles between drug users, there was no way that it
22	went on, the AIDS group did meet on several occasions	22	could be transmitted except by sexual intercourse. It
23	during 1985 so more might have been produced. She	23	was easier to transmit it by what could be described
24	says:	24	as vigorous sexual intercourse.
25	"This information was invaluable. Secondly,	25	"After my introduction, the patients were
20	101	20	102
	101		102
1	offered testing. At this point in time, testing was	1	aware of the difficulty of imparting unpleasant news
2	not mandatory. Patients could say yes or no. I had	2	to patients. I had been much involved in telling
3	anticipated that most people would accept the	3	individuals that either they, or their close relative
4	opportunity to be tested. They all did. The reason	4	was suffering from acute leukaemia and all the
5	for couching the invitation for testing in this manner		problems associated with chemotherapy. I well knew
6	was to permit patients to be in full control of their	5 6	from experience that the audience for this type of
7		7	
	lives - circumstances which, sadly, would change		introductory session would perhaps remember as much as
8	radically if the tests proved to be positive. They	8	25 per cent of what they were told and it was unlikely
9	were told that no names would be used, that a coding	9	that they would remember more than 50 per cent.
10	system would be applied and that for confidentiality	10	Therefore, it seemed important to me to reiterate to
11	purposes the results would be logged into	11	them exactly how their lifestyle might change in the
12	a confidential notebook. They were asked if they	12	future if they had experienced transmission of the
13	wished to know their result. Contrary to my	13	virus. I also asked them to refrain from sexual
14	expectations one patient declined to hear the result.	14	activity before they came back for their results.
15	His response posed a problem. Rapidly, I had to	15	They were aghast, and there was some laughter at this,
16	consider the action I would take if this particular	16	but the purpose was to protect spouses and
17	patient tested positive. It was recognised that all	17	partners and the general public."
18	patients who tested positive would require	18	So that's Dr Mayne's more detailed account of
19	a confirmatory test. Apart from taking his routine	19	her recollection in her most recent witness statement
20	treatment, sexual transmission was the only other	20	and then over the page so questions were asked
21	means of transmission. Therefore, a short delay	21	about why she about her decision to tell patients
22	before his confirmatory test would not constitute a	22	their test results only if they wished to be told, and
23	public health issue.	23	she refers back to the answer above.
24	"After the testing was completed, I then had	24	She's then asked in question 56 about the
25	a concluding address with the patients. I was acutely	25	policy in relation to testing partners and family
	103		104 (26) Pages 101 - 104

1	members and she says there:	1	anti-HTLV-III in your patients are as follows"
2	"Following the confirmation of a positive	2	And then there are two identified as positive
3	result spouses/partners were tested by mutual	3	and then a series identified as not positive and then
4	agreement."	4	down the bottom of the page is:
5	Then she's asked about what, if any,	5	"We have no sera in store from"
6	information or advice was provided to partners or	6	And then there are two patients there
7	family members and the response is to say that all	7	identified. So it would appear that the testing
8	relevant information was relayed, either in the centre	8	process was ongoing for a period of time.
9	or at home during home visits but it doesn't tell us	9	If we look over the page sorry, not over the
10	what information or advice was, as a matter of fact,	10	page. If we look at BHCT0000161, there's a later
11	relayed. That's, as I say, to complete the picture in	11	letter, 12 September 1985. Again, it provides results
12	terms of Dr Mayne's evidence on that issue.	12	of anti-HTLV-III tests in the centre's haemophiliac
13	I've referred to Dr Mayne's statement that	13	patients. The first three, who are listed as
14	15 patients were infected with HIV as a result of	14	positive, two of those are identified as having
15	treatment. In fact, if we go back to BHCT0000484,	15	already been tested, one by the regional virology lab,
16	there are 16 patients listed, and then of course there	16	which is where this letter emanates from, one by
17	is the one additional case of a partner who became	17	Dr Tedder, but the second of the three is what appears
18	infected, so 16 cases of direct infection and one of	18	to be a new result. So again, it would appear that
19	infection via sexual transmission presumably, or	19	the testing process was still ongoing as at
20	indirect infection, however one wants to term it. So	20	September 1985. And then there's a whole list of
21	a total of 17 cases in that regard.	21	patients who are anti-HTLV-III negative.
22	Just then two further documents in relation to	22	If we can then just turning to the question
23	the testing process. If we look at BHCT0000158, this	23	of how those patients with HIV were treated, it would
24	is a communication, 21 August 1985:	24	appear as though the process for treatment for
25	"The results of our latest test for	25	their HIV was that they were treated by Dr Mayne.
	105	20	106
	100		100
1	There is reference in later statements to arrangements	1	reference to a test, for example, by Dr Tedder. So it
2	being made for some form of joint clinic or joint	2	may be that sera were sent off to be tested elsewhere.
3	arrangement with an infectious diseases specialist,	3	It's not clear. But, in any event, in terms of the
4	but that looks to be from around 1999 onwards or	4	Regional Virus Laboratory there's no reason to doubt
5	indeed a little later than that during Dr Anderson's	5	what's said here, that their process began in May of
6	tenure.	6	1985.
7	If we go to WITN3082020, we can see an article	7	We can also see from the next paragraph that it
8	in the Ulster Medical Journal. We looked at one	8	says that:
9	yesterday which was about hepatitis B infection in	9	"Retrospective testing of haemophiliacs was
10	Northern Ireland. This is "[HIV] infection in	10	done on available sera which had been stored at
11	Northern Ireland 1980-1989", and it's published in the	11	minus 20 degrees centigrade in the Regional Virus
12	Ulster Medical Journal in April 1991.	12	Laboratory and fresh sera were obtained from the
13	If we go to the second page I should say,	13	Department of Haematology, Royal Victoria Hospital."
14	Dr Mayne is identified as one of the authors under	14	Then if we go to the next page, and we look at
15	the heading "Methods", the second paragraph tells us	15	the third paragraph it says:
16	that:	16	"The 16 haemophiliacs identified as
17	"The Regional Virus Laboratory began anti-HIV	17	infected with the virus in 1985"
18	testing in May 1983 (sic) and the Northern Ireland"	18	So that doesn't include the one partner.
19	SIR BRIAN LANGSTAFF: '85.	19	" when HIV antibody testing became available
20	MS RICHARDS: I'm so sorry:	20	have been cared for by the Northern Ireland
21	" 1985 and the Northern Ireland Blood	21	Haemophilia Service. Of the 55 remaining persons 49
22	Transfusion Service in October 1985."	22	have been cared for by the genito-urinary
23	So there is evidence of some test results	23	services. The remaining six have been cared for
24	earlier in 1985 and it may be that those were tests	24	by other agencies."
25	that were undertaken elsewhere. We've seen one	25	So that would appear to confirm that the
	107		108 (27) Pages 105 - 108
			(21) rayes 103 - 100

The Infected Blood Inquiry

1	responsibility for the consequences of their HIV	1	who subsequently developed AIDS and the comment made
2	infection was retained within the haemophilia centre.	2	by I think Dr Mayne was that thankfully there had been
3	If we go two pages further on under the heading	3	no seroconversion?
4	"Testing", the second paragraph refers to testing of	4	MS RICHARDS: The comment made by Dr Mayne, as
5	patients with coagulation defects, so it says:	5	I understand the position, relates to a patient whose
6	"One hundred and twenty-three patients with	6	identity I think is known to the Inquiry who was not
		7	
7	coagulation defects who had received treatment with		as the matter of fact infected with HIV. I think
8	blood products were tested and 16 were positive	8	that's right.
9	(13.8 per cent). If only severely affected patients	9	SIR BRIAN LANGSTAFF: So this is another episode where
10	are included this rises to 25 per cent."	10	MS RICHARDS: It may be the same batch
11	It's not entirely clear why you would include	11	SIR BRIAN LANGSTAFF: (unclear: multiple speakers)
12	only severely affected patients in one sense because	12	product might have been well, was in this case
13	we have seen two examples of patients who were not	13	implicated?
14	severely affected who were infected with HIV.	14	MS RICHARDS: Yes, I don't think we've seen anything other
15	"Stored sera were available on 11 of the 16	15	than that single letter from Armour so it may be that
16	positive patients and when tested showed that	16	it was a batch used for more than one patient.
17	seroconversion occurred between 1983 and 1985. The	17	I don't know. But there is some evidence
18	source of seroconversion in one patient in 1985 was	18	Dr Mayne's evidence, as I recall, relates to
19	traced to a batch of heat-treated factor VIII which	19	a particular patient who was not infected with HIV.
20	was found retrospectively to be contaminated with	20	This is I think no reason to doubt what is said here
21	HIV."	21	in a journal co-authored article co-authored by
22	SIR BRIAN LANGSTAFF: Do we know if that's the same as we	22	Dr Mayne in 1991, so only a few years after the event,
23	looked at earlier on today, where there had	23	which tells us that there was one heat-treated
24	been heat-treated Factor VIII, it had been reported as	24	seroconversion.
25	a batch from Armour where there had been a contributor	25	Who that was, we don't know. We have looked as
	109		110
1	you will recall in the course of today at a letter	1	Some are recorded as attending clinics
1	you will recall in the course of today at a letter	1	Some are recorded as attending clinics
2	which refers to an identification of a patient	2	elsewhere:
2	which refers to an identification of a patient seroconverting in 1985. Whether it's that patient or	2	elsewhere: "These patients have open access to the clinics
2 3 4	which refers to an identification of a patient seroconverting in 1985. Whether it's that patient or a different patient, given that we also know there	2 3 4	elsewhere: "These patients have open access to the clinics and the counselling and social services provided at
2 3 4 5	which refers to an identification of a patient seroconverting in 1985. Whether it's that patient or a different patient, given that we also know there wasn't an immediate switchover, it would appear, to	2 3 4 5	elsewhere: "These patients have open access to the clinics and the counselling and social services provided at these centres. A designated HIV clinic is in
2 3 4 5 6	which refers to an identification of a patient seroconverting in 1985. Whether it's that patient or a different patient, given that we also know there wasn't an immediate switchover, it would appear, to heat-treated products, is unclear.	2 3 4 5 6	elsewhere: "These patients have open access to the clinics and the counselling and social services provided at these centres. A designated HIV clinic is in operation at the Royal Victoria Hospital. In-patient
2 3 4 5 6 7	which refers to an identification of a patient seroconverting in 1985. Whether it's that patient or a different patient, given that we also know there wasn't an immediate switchover, it would appear, to heat-treated products, is unclear. SIR BRIAN LANGSTAFF: Yes.	2 3 4 5 6 7	elsewhere: "These patients have open access to the clinics and the counselling and social services provided at these centres. A designated HIV clinic is in operation at the Royal Victoria Hospital. In-patient management has mostly been handled by the
2 3 4 5 6 7 8	which refers to an identification of a patient seroconverting in 1985. Whether it's that patient or a different patient, given that we also know there wasn't an immediate switchover, it would appear, to heat-treated products, is unclear. SIR BRIAN LANGSTAFF: Yes. MS RICHARDS: But in any event, as we see there, evidence	2 3 4 5 6 7 8	elsewhere: "These patients have open access to the clinics and the counselling and social services provided at these centres. A designated HIV clinic is in operation at the Royal Victoria Hospital. In-patient management has mostly been handled by the genitourinary medicine physicians, with close
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	1110 1111	coloa Diooa ii	or maion Loui
1	positive patients for counselling by the director of	1	fourth paragraphs she says:
2	the Centre averages ten visits per month and many of	2	"The staffing levels in the Centre were
3	these visits last up to two hours in duration."	3	augmented by an E grade nurse, a full-time secretary
4	So a description there of Dr Mayne undertaking	4	and a scientific officer. The letter was to help with
5	counselling, but what she means by "counselling" and	5	the laboratory side of the situation and possible
6	what might be meant more generally by "counselling"	6	future research."
7	may be different matters.	7	It's not entirely clear how that assisted with
8	"Initially there were 16 HIV positive	8	HIV care but this her answer in response to a series
9	Haemophilic patients in Northern Ireland. They were	9	of questions a question about what enquiries or
10	all adults."	10	investigations were undertaken in respect of the risks
11	I have already drawn attention to the fact that	11	of transmission of HIV.
12	one at least seems to have been 14 at the date of	12	Then paragraph 33.11:
13	testing.	13	"Measures were taken to liaise with colleagues
14	"By 1991 three had already died."	14	from other disciplines as and when necessary.
15	We have seen that picked up in the Ulster	15	A Dermatologist, a Neurologist, and an Infectious
16	Medical Journal. Go to the top the next page:	16	Disease expert were all briefed, and were willing to
17	"During that year [so 1991] a fourth patient	17	and did attend patients in the Centre. In respect of
18	died of salmonella septicaemia directly related to his	18	general assistance, a liaison was also formed with the
19	HIV condition."	19	Sexually Transmitted Disease Department. They had
20	That is an update as at 1991 that four of the	20	many more HIV patients."
21	16 had already died.	21	Then if we turn to BHCT0000609, go to the next
22	In terms of what Dr Mayne says about the	22	page. This is a letter in relation to one patient.
23	arrangements for the care of those with HIV, if we	23	It's from June of 1994. I'm not proposing to go
24	turn to WITN0736009, this is her main statement again,	24	through the detail of it.
25	and we go to page 27, if we look at the third and	25	We can see in the first paragraph, just over
20		20	
	113		114
1	halfway down, she talks about sorry, Dr Mayne talks	1	I have never utilised the maximum recommended dose.
2	about her next visit to London hoping to:	2	Most patients in this Centre have been treated
3	" have some further consultations with	3	intermittently, rather than with permanent
4	experts there in the dermatological manifestations of	4	prophylaxis.
5	HIV infection."	5	"I think patients can be reassured that the
6	And then there's a discussion about what	6	drug has a well established role in treating certain
7	treatment the patient should receive. We see that	7	aspects of HIV and AIDS."
8	continuing in the next paragraph, discussion about	8	And she carries on.
9	what treatment the patient should be on.	9	So again it would appear decisions relating to
10	•		.,,
	So, again, it's one example. There are other	10	use of AZT from a clinical perspective were taken by
11	examples in the bundle of Dr Mayne essentially being	11	Dr Mayne. There is a description by Dr Anderson
12	the primary clinician in relation to the haemophiliac	12	picking up the picture a little later on in her
13	HIV patients.	13	witness statement, as I indicated a few minutes ago,
14	If we go to HSOC0010892 and we go to the third	14	of care being shared with an infectious diseases
15	page, there's a letter from Dr Mayne dated March 2,	15	consultant and, again, Dr Benson I think will be able
16	1994, which contains her comments on AZT. She says:	16	to assist tomorrow in relation to the position as at
17	"The advent of AZT was a therapeutic advance in	17	2008 and since in that regard.
18	the management of HIV. At the time of granting of its	18	Turn then to the information that the Inquiry
19	licence, I remember being particularly concerned about	19	has about the process of testing for hepatitis C and
20	its side effects."	20	informing patients of their diagnosis. The themes
21	She sets out what she thought those would be,	21	which emerge from the evidence which the Inquiry have
22	and then says:	22	received from people who were infected with
23	"Despite these reservations, I have found it to	23	hepatitis C or their relatives has a number of common
24	be effective in treating HIV positive patients whose	24	themes. Some, not all but some, describe being
25	CD4 counts were falling. I would admit, however, that	25	unaware of being tested for hepatitis C. A number of
	115		116 (29) Pages 113 - 116
			· · -

1	them draw attention to there being an apparently	1	statement I should have drawn attention to it. So
2	significant delay between date of testing, whether	2	I referred earlier to the individual statements giving
3	with the first test or a second generation test, and	3	a near-universal account of not being told about the
4	the patient themselves being informed of their	4	risks of viral infection from their treatment, and to
5	diagnosis. Some recount an experience of only being	5	some recalling receiving the impression of it being
6	told effectively when there's a significant event	6	a wonder drug or pioneering or a miracle treatment.
7	going on and they are attending the Haemophilia Centre	7	You will see here Dr Mayne responds to one
8	and then, as it were, are told almost as an	8	individual witness statement. She says this:
9	afterthought about the hepatitis C diagnosis.	9	" no warnings, apart from vein care and
10	A further theme that emerges from this	10	aseptic techniques, were given because at that
11	statement is of insufficient information being	11	time"
12	provided in terms of the nature of the virus, its	12	And we will have to look back at
13	likely consequences, treatment options and the like,	13	Mr Kirkpatrick's statement to check the particular
14	and a final theme which emerges from the witness	14	time.
15	statements, some of the witness statements, is of	15	" I believed the treatment was both
16	a degree of false reassurance or perhaps I should say	16	effective and safe. I certainly do not recall being
17	over-optimistic reassurance about the nature of the	17	asked about risks. The words 'wonder drug' may have
18	condition.	18	emanated from others but not me. I doubt if I would
19	I want to start then, if I may, with looking at	19	have dared to utter such words."
20	Dr Mayne's various accounts of the position in	20	So I should have referred to that. Then
21	relation to hepatitis C testing. So if we go, first	21	returning then to the issue of hepatitis C testing, if
22	of all, to WITN0736001 and if we go, first of all,	22	we go on two pages, Soumik, we look at paragraph 3.2,
23	to in fact, if we go first of all to page 6, if we	23	I should refer probably back to 3.1. This is in
24	look at paragraph 2.2, this is in fact on a slightly	24	response to an account of a patient being having
25	different point but whilst we are looking at this	25	their hepatitis C diagnosis communicated to them in
	117		118
1	a corridor. She says she doesn't recall:	1	in relation to the testing process.
2	"It would not be my clinical practice to	2	I should also draw attention to paragraph 3.4.
3	discuss patients' health in a corridor."	3	Dr Mayne says in the first sentence:
4	Then more generally in relation to hepatitis C	4	" there was no specific test for Hepatitis C
5	testing she says this:	5	available in 1987."
6	"Precise laboratory testing for Hepatitis C	6	That obviously is correct, and then she
7	became the norm in 1992-1993, the virus having been	7	describes hepatitis C as not a prevalent concept in
8	identified in 1991."	8	'87:
9	That latter date, obviously, is not correct.	9	"It merely referred to the existence of
10	SIR BRIAN LANGSTAFF: No, it was 1988 but not published	10	abnormal liver function tests designated by the UKHCDO
11	I think in detail until 1989.	11	Hepatitis Working Party as non-A, non-B hepatitis."
12	MS RICHARDS: Yes. And there is evidence of testing	12	Well, I think the term "non-A, non-B hepatitis"
13	having been undertaken at the Centre in 1991 as well	13	is not attributable to UKHCDO's hepatitis C working
14	as 1992 to '93.	14	party but had been in common usage since at least the
15	SIR BRIAN LANGSTAFF: Yes. This talks about the norm, but	15	mid-1970s. But in any event, we see then she says
16	it was introduced across the board apparently from	16	in response to the patient saying she was not advised
17	1 September 1991.	17	until 1993 of her hepatitis C diagnosis, Dr Mayne
18	MS RICHARDS: Yes. She says:	18	says:
19	"It was not my clinical practice to test	19	"Precise laboratory testing for Hepatitis C
20	patients for Hepatitis C without their consent. All	20	[only became available] in 1992-1993."
21	patients attending the centre, after receiving blood	21	If we then turn on four pages, I think, Soumik,
22	products, were checked physically and had laboratory	22	to paragraph 5.4, this is part of Dr Mayne's response
23	investigations."	23	here to an individual witness, here to the statement
24	Then she goes on to talk about liver function	24	of Mr Nigel Hamilton. Dr Mayne says:
25	tests but, in any event, that's the general statement	25	" the diagnosis of hepatitis C was difficult
	119		120 (30) Pages 117 - 120

1	as nearly all patients had evidence of abnormal liver	1	re-tested in 1991. In 1991 a further sample was taken
2	function tests"	2	and tested and a further sample was taken and tested
3	She refers again to it being given the title	3	in 1993, making three tests in all. The customary
4	non-A, non-B hepatitis, and then says:	4	length of time elapsed between testing and results
5	"Definitive tests for Hepatitis C were not	5	becoming available. Patients were seen as soon as
6	available until 1992-1993"	6	possible after their results were received for
7	It may of course turn on the use of the word	7	consultation and discussion.
8 9	"definitive", but obviously there were tests available prior to that.	8 9	"Present day practice would require oral or written permission to carry out viral blood tests. At
10	So that's that witness statement. If we then	10	the time in question, locally, nationally and
11	go to WITN0736005, if we go to the bottom of the	11	internationally, expediency seemed paramount and
	•		
12	second page we can see in paragraph 2.1.1 there's	12 13	specific consent was often not obtained. Quite unlike
13	a description in the second half of that paragraph to		the situation relating to HIV testing, when no test
14	what was said to be the practice of the virology	14	was ever carried out without consent of the patient.
15	laboratory to keep a sample of serum to be retested in	15 16	Refusal to have any test was acceptable at all times."
16	the future.	16	Again, there may potentially be much to unpick
17	She then, in paragraph 2.1.2, says:	17	in that paragraph. Specific consent often not
18	"The Hepatitis C virus became isolated in	18	obtained, but it's then said refusal to have any test
19	1991."	19	was acceptable at all times. Of course, if a patient
20	We've already dealt with the incorrectness of	20	doesn't know what they are being tested for it may be
21	that date.	21	a little difficult for them to exercise a right of
22	"Tests became available to detect HCV antibody	22	refusal to the test.
23	around that time but tests for active HCV infection	23	Picking up upon the dates given at the top of
24	were not available until 1993. As far as I can	24	the page, you will no doubt recall, sir, from the
25	recall, I believe the original 1976 sample was	25	hearing in Belfast and from the oral and written
	121		122
1	testimony overall from patients treated at this	1	It was now felt important that he should know the
1 2	testimony overall from patients treated at this	1	It was now felt important that he should know the findings hence the invitation to come and meet with
2	centre, there is evidence in medical records of tests	2	findings hence the invitation to come and meet with
2 3	centre, there is evidence in medical records of tests being undertaken in 1991 but of patients not learning	2 3	findings hence the invitation to come and meet with the staff."
2 3 4	centre, there is evidence in medical records of tests being undertaken in 1991 but of patients not learning the results until some considerable time later,	2 3 4	findings hence the invitation to come and meet with the staff." So there is an example, but a fairly striking
2 3 4 5	centre, there is evidence in medical records of tests being undertaken in 1991 but of patients not learning the results until some considerable time later, sometimes in 1992 or 1993 but sometimes much later.	2 3 4 5	findings hence the invitation to come and meet with the staff." So there is an example, but a fairly striking example in terms of the dates, of a patient tested
2 3 4 5 6	centre, there is evidence in medical records of tests being undertaken in 1991 but of patients not learning the results until some considerable time later, sometimes in 1992 or 1993 but sometimes much later. We've given a number of examples in the written note	2 3 4 5 6	findings hence the invitation to come and meet with the staff." So there is an example, but a fairly striking example in terms of the dates, of a patient tested in 1991, using the tests then available, a positive
2 3 4 5 6 7	centre, there is evidence in medical records of tests being undertaken in 1991 but of patients not learning the results until some considerable time later, sometimes in 1992 or 1993 but sometimes much later. We've given a number of examples in the written note and I'll refer to a handful of them.	2 3 4 5 6 7	findings hence the invitation to come and meet with the staff." So there is an example, but a fairly striking example in terms of the dates, of a patient tested in 1991, using the tests then available, a positive result, but the patient learning for the first time
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17 "I do not remember the witnesses being present 18 at the residential weekend, at least I do not remember 19 seeing or speaking with them on that occasion. If 19 Then this: 20 they were not present it was sad as they might have 20 "The patient's final diagnosis of active HCV 21 received much help and advice." 21 was not made until after the 1993 test was in routine 22 There's no evidence that we've thus far 23 uncovered of any for those potentially majority of 24 patients who didn't attend this particular conference, 25 and there may of course be multiple reasons why 26 describes as being available from 1993 was not	15	individuals.	15	future management to a significant degree. As
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25 and there may of course be multiple reasons why 25 describes as being available from 1993 was not	24		24	
127 128 (32) Pages 125 - 128	25	and there may of course be multiple reasons why	25	describes as being available from 1993 was not
		127		128 (32) Pages 125 - 128

1	seemingly in routine use, to use her phrase, in the	1	testing was in use it would be when the patient
2	Belfast Centre until 1996.	2	attended for a routine appointment that they might be
3	Then if we go no, we've looked at the next	3	tested. Again, there is some evidence from
4	passage I was going to refer to already today. If we	4	individuals of them being occasional evidence of
5	then turn to WITN0736007 this is a further statement	5	being called in when there was special in some
6	from Dr Mayne in response to individual witness	6	individual special circumstances, but more generally
7	statements. If we go to the second page, paragraph 5,	7	that appears to have been the case and then not being
8	so again Dr Mayne repeats the error about when HCV was	8	told the result for some considerable period of time,
9	identified. Then she says:	9	and I think Dr Mayne suggested it would have been at
10	"Tests for antibody were available in 1993	10	the next routine appointment, but certainly there were
11	[again, that doesn't appear to be right], but not	11	no special arrangements made for communicating the
12	indicative of active clinical infection. Tests for	12	diagnosis prior to the patient's next general
13	RNA viral load were available in 1994/95. The patient	13	attendance, at least as a matter of general practice.
14	visited in 1995 and therefore was not involved in any	14	There may of course have been individual symptoms.
15	particular delay. He was seen as soon as possible in	15	If we look at the bottom of this page, we can
16	rotation with his fellow patients."	16	see a response from Dr Mayne to the observation by
17	She says he was informed that the source of	17	a witness that she did not offer any support or
18	infection was his treatment. The evidence more	18	counselling after informing him of the HCV diagnosis.
19	generally suggests that there was no programme for	19	She says:
20	calling patients in to be tested specifically for	20	"Neither support nor counselling were
21	hepatitis C or calling them back in to be informed of	21	available. At that time it was significantly
22	their test results as soon as those test results were	22	problematic trying to establish a good clinic for
23	available or as soon as practicable after those test	23	hepatitis patients to attend. Additionally, as the
24	results became available.	24	witness' wife mentioned in her statement 'we,
25	The evidence suggests that once hepatitis C	25	rather naively, thought that Hepatitis C was not so
	129		130
	120		100
1	dire'."	1	If we go over to the top of the next page she
2	Top of the next page Dr Mayne says this:	2	says:
3	"Many of the clinicians, myself included, could	3	"It had been suspected for many years that
4	not in 1995 foresee how complex, disastrous symptoms	4	regularly treated patients were likely to have the
5	and complications of the virus would develop, sadly."	5	virus previously known as Non-A Non-B hepatitis,
6	Again, you will need to assess that by	6	subsequently known as hepatitis C. Patients had been
7	reference to what you, sir, conclude a clinician could	7	attending the Centre regularly for many years and
8	or should have understood in or by 1995.	8	receiving advice before the confirmation of their
	•		-
9	If we then go to WITN0736009 and we go to	9	diagnosis. They were informed that they had a chronic
10	page 41, we pick it up at the bottom of the page, at	10	viral infection of the liver that was causing
11	62.1 Dr Mayne asserts that:	11	inflammation."
12	" patients infected with [non-A, non-B]	12	Again, there is evidence to contrary effect
13	hepatitis were informed of the existence of their	13	from some of the patients in their written statements
14	abnormal liver function tests. At the time the	14	to the Inquiry, and then she refers to advice about
15	condition was termed Non-A Non-B. At that time	15	alcohol consumption and diet.
16	although patients had raised liver function tests they	16	If we then go further down the page, she says,
17	were otherwise well."	17	to the date given here in paragraph 63.1, that:
18	It doesn't say that they were told that they	18	"The Centre began testing patients for
19	had non-A, non-B hepatitis. It doesn't say that they	18 19	"The Centre began testing patients for Hepatitis C in 1993 when the test became available."
		18	"The Centre began testing patients for Hepatitis C in 1993 when the test became available." So we do have a range of different tests
19	had non-A, non-B hepatitis. It doesn't say that they	18 19	"The Centre began testing patients for Hepatitis C in 1993 when the test became available."
19 20	had non-A, non-B hepatitis. It doesn't say that they weren't, but what it says that they were informed of	18 19 20	"The Centre began testing patients for Hepatitis C in 1993 when the test became available." So we do have a range of different tests
19 20 21	had non-A, non-B hepatitis. It doesn't say that they weren't, but what it says that they were informed of the existence of the abnormal liver function tests.	18 19 20 21	"The Centre began testing patients for Hepatitis C in 1993 when the test became available." So we do have a range of different tests a range of different dates, of course, there were
19 20 21 22	had non-A, non-B hepatitis. It doesn't say that they weren't, but what it says that they were informed of the existence of the abnormal liver function tests. Then next paragraph she says:	18 19 20 21 22	"The Centre began testing patients for Hepatitis C in 1993 when the test became available." So we do have a range of different tests a range of different dates, of course, there were different tests being developed. She says in the next
19 20 21 22 23	had non-A, non-B hepatitis. It doesn't say that they weren't, but what it says that they were informed of the existence of the abnormal liver function tests. Then next paragraph she says: "It was not possible to inform patients of	18 19 20 21 22 23	"The Centre began testing patients for Hepatitis C in 1993 when the test became available." So we do have a range of different tests a range of different dates, of course, there were different tests being developed. She says in the next paragraph:
19 20 21 22 23 24	had non-A, non-B hepatitis. It doesn't say that they weren't, but what it says that they were informed of the existence of the abnormal liver function tests. Then next paragraph she says: "It was not possible to inform patients of active hepatitis C infection until the specific blood	18 19 20 21 22 23 24	"The Centre began testing patients for Hepatitis C in 1993 when the test became available." So we do have a range of different tests a range of different dates, of course, there were different tests being developed. She says in the next paragraph: "All patients were routinely assessed for liver

			• •
1	definitive test for active Hepatitis C became	1	tested, would show the presence of anti-measles
2	available in 1993."	2	antibody although of course they had no clinical
3	Then towards the bottom of the page, picking it	3	evidence of the condition. During discussion with
4	up well, perhaps halfway down that paragraph it	4	patients they found it difficult to understand the
5	says:	5	explanation of having HCV antibody. Some were worried
6	"Patients were surprised at the clinical	6	that I was keeping secrets from them."
7	examination but the abnormal test results were	7	Just pausing there, again a common theme from
8	explained, they were told they did not have	8	the witness statements is that they were not given
9	Hepatitis B, a condition of which patients were well	9	this information about the results of early tests.
10	aware."	10	Dr Mayne continues:
11	Just pausing there, some statements relate	11	"When the specific tests became available in
12	patients not being aware that they had had	12	1993, the results indicated in many cases active
13	hepatitis B:	13	disease. Even in 1993 it was difficult, even
14	"Likewise, they knew they did not have any	14	impossible, to give any precise prognosis or details
15	symptoms of Hepatitis A, therefore they were not	15	of how the diagnosis may play out in time. As
16	surprised when they were told that they probably had	16	developments progressed viral load testing became
17	a condition called Non-A Non-B hepatitis."	17	capable of the estimation of infection. Likewise,
18	Then if we go over the page she continues in	18	different subtypes of the virus were accurately
19	that paragraph her views about the seriousness or	19	diagnosable. At this time a special liver clinic was
20	otherwise of non-A, non-B hepatitis and then 63.3 says	20	established."
21	this:	21	And she gives a little more information about
22	"Some 3-4 years prior to 1993 tests for	22	that.
23	Hepatitis C antibody became available. That test, if	23	If we go over the page, in response to the
24	positive, only indicated that the individual had met	24	question how many patients were infected with
25	the virus at some time. In a similar way, adults, if	25	hepatitis C her answer is in excess of 100. Then if
	133		134
	100		101
1	we look at the third paragraph, 65.3 sorry, the	1	3-6 months. The very mildly affected were seen
2	third paragraph under the question in 65 she says	2	annually."
3	this:	3	So the Inquiry has evidence of patients who
4	"With regard to HCV, the tests were done in	4	were not seen even annually. Now, that may have been
5	batches to facilitate the effective management of the	5	a matter of patient choice, of course, but there
6	laboratory. The patients were informed at their next	6	doesn't appear to have been any arrangement for
7	routine clinic visit. That may have been some time	7	bringing those patients in for a period of testing,
8	later."	8	and we see some examples of testing a number of years
9	And the evidence certainly suggests also in	9	later.
10	many cases a very significant gap of time in that	10	Top of the next page what Dr Mayne says is
11	regard. She says in 65.4:	11	that:
12	"It is important to state that a positive	12	"At a later date from late 1993 onwards, if
13	antibody test required no action at this time.	13	their definitive test showed active disease the
14			
15	Positivity merely showed that, at some time in the	14 15	patient was contacted and seen as soon as possible.
16	past, the patient had been exposed to the virus"	15 16	Then management would proceed, after discussion, to
17	And she develops that theme.	16 17	the Liver Clinic and possible treatment with alpha
	Then the last paragraph on this page:	17	interferon."
18	"The antibody tests were explained to patients	18	It's not clear what's meant by "their
19	at the next routine visit. The timing of routine	19	definitive test [showing] active disease", because
20	reviews depended on the severity of the patient's	20	there are individual accounts and I think not disputed
21	condition. Those on Home Treatment or severely	21	in Dr Mayne's responses to them of patients, for
22	affected were seen on a monthly basis. The moderately	22	example, not being told their hepatitis C results
23	severe were seen theoretically on a six-monthly	23	until 1996 in some instances.
24	basis I say theoretically because if they had no	24	So that's the account, the main account in
25	problems they would cancel for perhaps a further	25	Dr Mayne's most recent and most detailed statement.
	135		136 (34) Pages 133 - 136

1 We've looked at the example referred to in one of her tomorrow. 2 earlier statements of testing in 1991 patient being 2 If we go to WITN1382001 and, again, these are 3 3 informed on 1996. We've given further examples in the just examples of some of the broader themes that 4 4 written note and of course, sir, you have all the emerge, and we go to the fourth page, I've referred 5 individual statements available to you to consider. 5 already to a theme about patients not being given what 6 6 Perhaps one or two further examples may be worth they regard as sufficient or adequate information or 7 looking at for present general purposes. 7 being given overoptimistic reassurance. We see in 8 8 If we go to WITN257001, this is an example, if paragraph 18 -- I should say this is an example of 9 9 we go to the third page -- WITN2570001, sorry. a patient asking to be tested and being tested and 10 10 being told their diagnosis in 1992, so tests clearly If we go to the second page of that, first of 11 all. So if we pick it up at paragraph 5, towards the 11 were available earlier than the dates that Dr Mayne's 12 bottom of the page, this is an example of a patient 12 other statements might suggest. 13 13 account, of them being invited to go in for screening Then in paragraph 18: 14 because of a brother's diagnosis of hepatitis C. And 14 "I was told by Dr Mayne that despite my 15 then if we go to the next page we can see in 15 Hepatitis C, I would probably have a long and normal 16 paragraph 4.1 patient saying that they were given 16 life and that it was just a risk of having 17 their diagnosis in 2003, after, I think it was, the 17 Factor VIII. Dr Mayne did not discuss any of the 18 18 brother's death in 2002. So that's one example. potential health issues; she just brushed over it very 19 There are then accounts that we have and. 19 quickly. She did not discuss any treatment, although 20 again, we've sought to summarise them in our written 20 there wasn't any available then, or provide any advice 21 note, of some witnesses only becoming aware of 21 on how to manage and understand the infection. She 22 22 relatives' hepatitis C infections after the patient simply told me that I had it and it would do me no 23 had died or some only becoming aware in recent years 23 harm." 24 of hepatitis C infections and we may hear some 24 So that's one example. Then if we go to 25 relevant evidence from Dr Benson in relation to that 25 WITN2569001 and we go over the page. So this is 137 138 1 another account of -- and it may, I think, be 1 April 1992, about a particular patient, 2 2 a sibling potentially of one of the statements we have Richard Lowry -- and you will no doubt, sir, I'm sure 3 already looked at but I'm not sure of that, but we see 3 remember the evidence of his widow in Belfast --4 again an invitation in paragraph 4, at the bottom half 4 mildly affected haemophiliac. 5 of the page to being screened following a brother's 5 If we look at the bottom of the page, we can 6 death from hepatitis C. 6 see Dr Mayne saying in the last four lines: 7 7 "... he has had elevation of his liver enzymes If we go to the next page, at paragraph 4.1 the 8 8 witness says in the second line: for a number of years. This is related most likely to 9 9 "There was a time when I didn't attend hospital infections with Hepatitis C virus. His results vary 10 for a number of years and that was because I wasn't 10 between two and three times the normal range of sent for. I think this was between 1997 and 2003. 11 11 values." 12 Hepatitis C was only mentioned to me after my 12 So, April '92, Dr Mayne feeling able in this 13 [brother's] death." 13 case to articulate a diagnosis or likely diagnosis of 14 hepatitis C. 14 Then if we go over two pages, top of the next 15 15 page: Over the page she says in the second line: 16 16 "I wasn't offered any support or counselling at "Hepatitis C is an unknown quantity to some 17 the time of being diagnosed. I think if I had been 17 degree, between 80 and 90 per cent of treated 18 offered counselling in how to manage this infection, 18 Haemophiliacs are known to be positive, all are 19 I doubt I would be suffering with depression now. The 19 clinically well. From liver biopsy specimens obtained 20 only information offered was not to share my razor. 20 in some centres it would appear that a small 21 I was informed of my diagnosis in a clinical manner 21 percentage of patients may ultimately develop 22 22 and felt there was little empathy for me." cirrhosis or chronic active hepatitis." 23 23 Then if we just look at a couple of letters Perhaps a particularly difficult letter to read 24 from Dr Mayne on the issue of hepatitis C, so first of 24 now in light of what we know happened to this 25 all WITN2655002, this is a letter from Dr Mayne, 25 gentleman.

139

(35) Pages 137 - 140

1	SIR BRIAN LANGSTAFF: Yes.	1	doesn't quite fit with what she wrote on
2	MS RICHARDS: But there's Dr Mayne setting out her	2	15 April '92
3	apparent understanding of the condition in April 1992.	3	MS RICHARDS: No.
4	If we then turn to WITN1382003, second page, this is	4	SIR BRIAN LANGSTAFF: in that last letter about
5	a letter at the end of 1992, 21 December 1992. It's	5	Richard Lowry.
6	in relation to one of the witnesses whose statements	6	MS RICHARDS: Yes, and it doesn't quite fit with what we
7	we looked at who said she was led to believe that the	7	have heard more generally about the position.
8	hepatitis C wasn't a problem and this, I think, would	8	SIR BRIAN LANGSTAFF: No, it doesn't easily reconcile with
9	appear to confirm the accuracy of her recollection	9	that.
10	because, if we look at the bottom paragraph, it says:	10	MS RICHARDS: Then just picking up on the point in
11	"I have explained to Anne that there are	11	relation to interferon, we can see from this that that
12	several viruses which cause positivity to Hepatitis C.	12	was again, just as we've seen HIV infection being
13	Generally it is thought that it is very unlike	13	treated by Dr Mayne, we see in the early years at
14	Hepatitis B infection and it may not have any serious	14	least in the 1990s Dr Mayne taking responsibility for
15	sequelae for liver function in the future. Presently	15	the treatment of those of her patients who had by that
16	Professor Eric Preston and other Colleagues in the	16	time been diagnosed with hepatitis C.
17	Haemophilia Centre Directors Organisation are carrying	17	We see the letter in relation to Richard Lowry
18	out an assessment of the benefit received by a 6-month	18	that we looked at also refers to her offering
19	course of Alpha Interferon. The results to date are	19	interferon treatment as at April 1992. So she was
20	quite promising and if Anne's tests suggest that she	20	taking it upon herself at that stage as, indeed, we've
21	should fit into this category I will discuss it	21	heard other haemophilia clinicians were doing,
22	further with the patient and with yourself."	22	I should make that clear, to be the treating clinician
23	So that is apparently Dr Mayne's understanding	23	in relation to this virus.
24	in December 1992 of the nature of hepatitis C.	23 24	We saw the reference in one of Dr Mayne's
25	SIR BRIAN LANGSTAFF: Well, it's what she wrote but it	2 4 25	earlier statements to seeking a degree of specialist
20		25	
	141		142
1	input and if we go to this is in relation to	1	in the last sentence:
2			
	nepatitis C ii we go to wi i No/ 3000 i and we go to	2	"There were many discussions between me and
	hepatitis C if we go to WITN0736001 and we go to paragraph 6.2, which is page 13 I think, and we pick	2	"There were many discussions between me and Dr Jones" and he took over as acting director when
3	paragraph 6.2, which is page 13 I think, and we pick	3	Dr Jones" and he took over as acting director when
3 4	paragraph 6.2, which is page 13 I think, and we pick it up in paragraph 6.2 so this is a response to Simon	3 4	Dr Jones" and he took over as acting director when Dr Mayne retired "at that time as we were trying to
3 4 5	paragraph 6.2, which is page 13 I think, and we pick it up in paragraph 6.2 so this is a response to Simon Hamilton's witness statement, she says in 6.2:	3 4 5	Dr Jones" and he took over as acting director when Dr Mayne retired "at that time as we were trying to set up a regular joint hepatology/haemophilia clinic
3 4	paragraph 6.2, which is page 13 I think, and we pick it up in paragraph 6.2 so this is a response to Simon Hamilton's witness statement, she says in 6.2: " up until the Hepatitis C virus was	3 4	Dr Jones" and he took over as acting director when Dr Mayne retired "at that time as we were trying to set up a regular joint hepatology/haemophilia clinic and were in regular contact with the hepatologists to
3 4 5 6 7	paragraph 6.2, which is page 13 I think, and we pick it up in paragraph 6.2 so this is a response to Simon Hamilton's witness statement, she says in 6.2: " up until the Hepatitis C virus was identified in 1991 no-one really knew what to expect."	3 4 5 6 7	Dr Jones" and he took over as acting director when Dr Mayne retired "at that time as we were trying to set up a regular joint hepatology/haemophilia clinic and were in regular contact with the hepatologists to press our case."
3 4 5 6 7 8	paragraph 6.2, which is page 13 I think, and we pick it up in paragraph 6.2 so this is a response to Simon Hamilton's witness statement, she says in 6.2: " up until the Hepatitis C virus was identified in 1991 no-one really knew what to expect." Et cetera.	3 4 5 6 7 8	Dr Jones" and he took over as acting director when Dr Mayne retired "at that time as we were trying to set up a regular joint hepatology/haemophilia clinic and were in regular contact with the hepatologists to press our case." So the position in relation to when such
3 4 5 6 7 8 9	paragraph 6.2, which is page 13 I think, and we pick it up in paragraph 6.2 so this is a response to Simon Hamilton's witness statement, she says in 6.2: " up until the Hepatitis C virus was identified in 1991 no-one really knew what to expect." Et cetera. "Always I had an ominous feeling about the	3 4 5 6 7 8 9	Dr Jones" and he took over as acting director when Dr Mayne retired "at that time as we were trying to set up a regular joint hepatology/haemophilia clinic and were in regular contact with the hepatologists to press our case." So the position in relation to when such a clinic was established is not entirely clear.
3 4 5 6 7 8 9	paragraph 6.2, which is page 13 I think, and we pick it up in paragraph 6.2 so this is a response to Simon Hamilton's witness statement, she says in 6.2: " up until the Hepatitis C virus was identified in 1991 no-one really knew what to expect." Et cetera. "Always I had an ominous feeling about the virus"	3 4 5 6 7 8 9	Dr Jones" and he took over as acting director when Dr Mayne retired "at that time as we were trying to set up a regular joint hepatology/haemophilia clinic and were in regular contact with the hepatologists to press our case." So the position in relation to when such a clinic was established is not entirely clear. Dr Anderson in her statement describes when she
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3 4 5 6 7 8 9 10 11 12	paragraph 6.2, which is page 13 I think, and we pick it up in paragraph 6.2 so this is a response to Simon Hamilton's witness statement, she says in 6.2: " up until the Hepatitis C virus was identified in 1991 no-one really knew what to expect." Et cetera. "Always I had an ominous feeling about the virus" She says, and then she refers to the weekend meeting in 1995 and exhibits a programme for that.	3 4 5 6 7 8 9 10 11	Dr Jones" and he took over as acting director when Dr Mayne retired "at that time as we were trying to set up a regular joint hepatology/haemophilia clinic and were in regular contact with the hepatologists to press our case." So the position in relation to when such a clinic was established is not entirely clear. Dr Anderson in her statement describes when she arrived there being limited hepatology input only and that being a particular concern of hers and she's
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1 right. But we've suggested in our note that the medical records being kept within the day ward records 2 general processes in relation to record-keeping are 2 department in a separate section to other records 3 3 presently unknown. In fact, we do have some belonging to other haematology patients, and then 4 4 describes the transfer because the centre relocated. information about record-keeping which I should have 5 5 So she describes the transfer of records, which she referred to 6 6 First of all, Dr Anderson in her statement, says she personally oversaw at the time of the 7 perhaps -- I think you have this, Soumik. It's 7 centre's relocation, and then, bottom of the page, she 8 8 WITN4027001. If we go to page 60 -- it's a very long described introducing a typed record of all patients 9 9 statement. I should say Dr Anderson joined Belfast attending for day case assessment. Of course, that 10 10 centre in November 2000 and we'll see -- sorry, it's would have only been from November 2000 or whatever 11 page 16, not 60. My apologies. 11 date she introduced it onwards and wouldn't relate to 12 We'll see her description of the state of 12 the quality of the notes at an earlier stage. That's 13 13 Dr Anderson describing the notes as she found them. medical records at 6.8.23 of her statement. She says: 14 "Medical records were handwritten and kept 14 Then we do have the more general statement 15 meticulously. There was excellent administrative and 15 about record-keeping within the Trust. Soumik, this 16 secretarial support and it followed that the filing 16 is the document you should have received today. It's 17 was good with the medical records kept within dividers 17 WITN3449007. This is a statement of Caroline Leonard 18 in the case notes and any written results filed in 18 for the Belfast Health and Social Care Trust, and if 19 separate sections." 19 we go to -- if we go perhaps just to the last page, 20 She says in the last sentence of that 20 there's a description of what archives the Trust hold 21 paragraph: 21 and a history given of the Trust's archiving system. 22 22 "These case records were of a superior quality Then we see an account -- I'm sorry, can we go 23 to those I had seen at many other institutions I'd 23 to the page prior to that. Thank you. We see 24 worked at previously." 24 a description there of retention and destruction 25 Then she describes in the next paragraph the 25 policies and processes from 1948 to date. I'm not 145 146 1 going to go through the detail of what are, I think, 1 processes in relation to record-keeping are presently 2 2 a number of exhibits but I just draw your attention to unknown, that wasn't a fair characterisation of the 3 the fact that there's said to be or there is 3 fact that we have also got this material. 4 4 a retention and disposal schedule. It's said to be How any of this then explains individual 5 based upon the principles contained within 5 missing records is an exercise that we'll have to 6 a Department of Health guidance -- that's 6 undertake to the extent that we are able to do so and 7 7 paragraph 5.2 -- and she refers to policy being it may be is that Dr Benson may be able to assist us 8 8 adopted by the Trust. Then she says at 5.3: again tomorrow with what at least the position's been 9 9 "Prior to this, records were retained and/or since he has been director of the service. 10 disposed of in accordance with the Trust and legacy 10 Then in terms of the provision of information organisations' retention and destruction policy that 11 11 more generally to third parties -- oh, I note the 12 was in place at the relevant time." 12 time. I've still got a handful of matters I need to 13 Then there are a range of Northern Irish 13 dealt with; so it would be more than a few minutes, so perhaps we could take a break at this point. 14 14 circulars that are referred to relevant to the 15 question of document retention and document 15 SIR BRIAN LANGSTAFF: Yes, certainly. Roughly how long do 16 16 destruction. you think you have left? 17 Then we look in paragraph 5.4, so if we just go 17 MS RICHARDS: Half an hour. 18 further down the page, we see reference to 18 SIR BRIAN LANGSTAFF: Yes. Well, we will take a break now 19 a suspension of the destruction of any records in 19 until 3.45. 20 August 2015. That was in response to the Historical 20 MS RICHARDS: Thank you, sir. 21 Institutional Abuse Inquiry and we are told that 21 (3.18 pm) 22 22 suspension of destruction or records continues to (A short break) 23 23 remain in place. Now, there's a lot more detail there (3.46 pm) 24 that will need to be unpicked at an appropriate stage 24 MS RICHARDS: Sir, I'm just then going to refer on the 25 but, having said in the written note that the general 25 topic of data and records to examples of information 147 148

(37) Pages 145 - 148

	The f	illieotea biooa	inquity 51 materi 2021
1	being provided to third parties, most commonly Oxford	1	we have redacted the details of the individual patient
2	and the Oxford returns.	2	but it's headed:
3	We've already looked at some examples of the	3	"Confidential
4	annual returns in relation to Belfast which are not	4	"UK Haemophilia Centre Directors' Survey of
5	just the generic annual returns but also contain	5	Patients with AIDS or AIDS-related illness"
6	detailed patient data with named patients, information	6	And then we can see information, if we go
7	about dates of birth and so on, the nature of their	7	further down the page, about the patient's clinical
8	bleeding disorder and the treatment they've received.	8	condition and about their treatment being provided.
9	If we then look at BHCT0000850, this is	9	And then further down the page we can see under
10	a letter from the Oxford Haemophilia Centre from	10	the heading "Additional comments", a number of matters
11	Ms Spooner dated 21 October 1992 to Dr Mayne,	11	set out about the individual patient.
12	Professor Bridges and Dr Dempsey and it says:	12	As I say, although we've redacted the patient's
13	"On reviewing the cases of AIDS or AIDS Related	13	name, the name and date of birth are there in the
14	illness reported to us on FORM AIDS/3, CDSC's FORM	14	material that's sent to Oxford. That's one example
15	AIDS 1 or the Paediatric Surveillance Forms, we find	15	where information relating to HIV or AIDS diagnosis is
16	it is several months since we last had news of some of	16	being communicated.
17	the patients. I should be most grateful if you could	17	If we go back a number of years and look at an
18	complete and return to me as soon as possible the	18	example of another kind of data, HCDO0000054_005, we
19	enclosed form(s) for your patient(s) to give	19	can see here in a letter from Ms Spooner to Dr Mayne
20	up-to-date information. The information will be	20	dated April 1977 an expectation that Oxford will be
21	treated in strictest confidence; the completed forms	21	sent a form giving names and details of patients.
22	will not be passed to anyone outside Oxford	22	That was by reference to a particular cohort: five
23	Haemophilia Centre."	23	von Willebrand's disease patients treated in Belfast
24	Then if we go over the page we can see an	24	during the year 1978.
25	example of a completed form from Dr Mayne. So again	25	Then if we look at HCDO0000153_008 again
	149		150
1	these are by way of example we can see here we've	1	named patient.
2	moved forward to May of 1984, and it's Dr Mayne	2	If we then go to BHCT0000831_001, again we can
3	sending Ms Spooner information about the treatment	3	see Dr Rizza asking for information, this is now
4	received by identified named patients.	4	January 1989, about a particular patient, trying to
5	Then if we go to BHCT0000861_003, we can see	5	locate a death certificate, and information is
6	a request here coming from Dr Rizza to Dr Mayne,	6	requested. If we go to the bottom of the page, to the
7	Dr Bridges and Dr Dempsey in December of 1986. It	7	handwritten note it says:
8	refers to a recent survey of anti-HIV in haemophiliacs	8	"I am surveying all death certificates of
9	and says:	9	anti-HIV positive haemophiliacs to see how many"
10	" the patient(s) listed below attending your	10	I'm not sure
11	Centre have reported as being anti-HIV positive in the	11	SIR BRIAN LANGSTAFF: " might have died"
12	1986 survey, having been anti-HIV negative in the 1985	12	MS RICHARDS: " might have died of HIV-related illness
13	survey. In order to find out how this seroconversion	13	but not certified as AIDS."
14	relates to use of heated or unheated factor	14	So, again, an understandable reason, and this
15	concentrate I should be grateful if you could let us	15	is in relation to a deceased patient, but raises the
16	have some more details"	16	question of what patients or their families
17	We can see the reason is for the monitoring of	17	understood.
18	safety of heated blood products. So the requests may	18	If we go to BHCT0000831_003, I think we've only
19	be entirely understandable requests; the issue that	19	got the first page of this letter but we can see it's
20	they give rise to, as we've seen with a number of	20	a fairly detailed response from Dr Mayne to Dr Rizza
21	other centres and clinicians, is the extent to which	21	giving information about the patient and their
22	patients were aware of or asked to consent to or did	22	circumstances.
23	consent to the dissemination of information about	23	Then if we look at what Dr Mayne has to say
24	them. And if we look down the bottom of the page, we	24	about the provision of information
25	see again this is a request relating to a specific	25	SIR BRIAN LANGSTAFF: Just what's the date of that?
	151		152 (38) Pages 149 - 152

The Infected Blood Inquiry

1	MS RICHARDS: The date of the letter? If you go to the	1	"All patients attending the Centre were aware
2	top of the page, it's February 1989.	2	of the existence of UKHCDO."
3	SIR BRIAN LANGSTAFF: Yes. And the cause of death there	3	Top of the next page:
4	was liver failure related to a non-A, non-B hepatitis.	4	"They were aware that the secretariat collected
5	MS RICHARDS: Yes.	5	and compiled stats on an annual basis relating to
6	SIR BRIAN LANGSTAFF: Yes.	6	their treatment and they realised the procedures were
7	MS RICHARDS: And of course that may cast into an	7	necessary in order to estimate changes in treatment
8	interesting light some of what we've seen Dr Mayne	8	product availability year by year. In those
9	saying in her statement about her understanding	9	circumstances it was a matter of implied, rather than
10	and, indeed, in her correspondence in the 1990s	10	express, consent."
11	about the nature of hepatitis C.	11	Now, it may be right that patients had
12	If we go to Dr Mayne's statement at	12	knowledge of UKHCDO. It may be right, I know not one
13	WITN0736009, and we go to page 51, please, Soumik,	13	way or another, that patients were aware of UKHCDO's
14	Dr Mayne is asked a series of questions about	14	secretariat collecting and compiling statistics.
15	involvement of patients in research studies. She says	15	It doesn't, I think, follow as a matter of
16	they weren't involved in research studies without	16	logic or inference that patients must be taken to have
17	their express consent. Then she's asked at	17	been aware that named data, in particular sensitive
18	paragraph 76 about patient data:	18	data about matters such as HIV status or the
19	"Was [that] used for the purpose of research or	19	progression of medical conditions, was also being
20	any other purpose without express consent?"	20	provided to UKHCDO.
21	She answers "no".	21	Again, we've seen this is not an issue unique
22		22	to Belfast. It's an issue that's arisen in relation
23	Then in relation to the sharing of patient data (anonymised or otherwise) with third parties such as		
		23	to many centres, probably all of them, and one which
24	UKHCDO or the Oxford Haemophilia Centre, she says	24	UKHCDO itself was attempting to wrestle with at some
25	this:	25	stage.
	153		154
1	SIR BRIAN LANGSTAFF: What I think it appears to be saving	1	noted that 25 years ago there was a lot of ignorance
1 2	SIR BRIAN LANGSTAFF: What I think it appears to be saying is that no-one was actually asked to agree that this	1	noted that 25 years ago there was a lot of ignorance
2	is that no-one was actually asked to agree that this	2	and fear associated with HIV and hepatitis and it was
2 3	is that no-one was actually asked to agree that this is how the information should be shared.	2	and fear associated with HIV and hepatitis and it was felt to be an act of humanity not to use those terms
2 3 4	is that no-one was actually asked to agree that this is how the information should be shared. MS RICHARDS: Yes.	2 3 4	and fear associated with HIV and hepatitis and it was felt to be an act of humanity not to use those terms on the death certificate in order to protect the
2 3 4 5	is that no-one was actually asked to agree that this is how the information should be shared. MS RICHARDS: Yes. SIR BRIAN LANGSTAFF: Or shouldn't be shared.	2 3 4 5	and fear associated with HIV and hepatitis and it was felt to be an act of humanity not to use those terms on the death certificate in order to protect the deceased and their relatives. Very often"
2 3 4 5 6	is that no-one was actually asked to agree that this is how the information should be shared. MS RICHARDS: Yes. SIR BRIAN LANGSTAFF: Or shouldn't be shared. MS RICHARDS: Then I just want to pick up next on the	2 3 4 5 6	and fear associated with HIV and hepatitis and it was felt to be an act of humanity not to use those terms on the death certificate in order to protect the deceased and their relatives. Very often" She doesn't say "always", but:
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1	to porcine products. Dr Mayne and I think Dr McNulty	1	evidence of involvement in a clinical trial, so this
2	had some involvement in a study in relation to the	2	is the Concorde trial, and there's a request there by
3	purity of NHS Scottish concentrates or at least some	3	the Medical Research Council for information relating
4	anticipated involvement in that issue.	4	to the patient's death. That's a request in
5	If we have a look at MACK0001300_002, we can	5	September 1992. Dr Mayne's response, we should
6	see Dr Mayne being sent a copy of a protocol for a PUP	6	perhaps go to this for what it may indicate more
7	study in December 1988 and that appears to be from	7	generally about her knowledge, is at BHCT0000948.
8	other documents in relation to a further Scottish	8	If we go to the second page, we can see in the
9	product said to be purer than Z8. It's not clear what	9	first paragraph so it's a letter 30 November 1992.
10	happened in relation to that study, I should say.	10	She refers to or she says apologises for the delay
11	Some other handful of examples of Dr Mayne's	11	in responding to the letter regarding the patient
12	involvement OXUH0000451, if we go to the second page	12	involved in the Concorde trial. She then gives
13	we can see this is a reference to UKHCDO's Factor VIII	13	a detailed description of his admission to the
14	inhibitor working party and there is a trial of	14	haematology unit.
15	Factor VIII versus Autoplex and it says a meeting of	15	If we go over the page or rather back a page,
16	the participants in this trial was held in	16	these letters are in the wrong order, again she gives
17	February 1982 in London and then a number of	17	further details leading up to the patient's death. If
18	participants are listed including Dr Mayne.	18	we just look at the third paragraph it says this:
19	If we look further down the page there's	19	"In summary; severe haemophiliac who was
20	reference to a discussion about a draft clinical	20	a carrier for Hepatitis B and Hepatitis C who
21	protocol and then the trial comprising a double-blind	21	developed HIV illness"
22	random allocation assessment of Factor VIII versus	22	And then gives details of that illness.
23	Autoplex. So that's again one example at least of	23	So again we can see in relation to this patient
24	anticipated involvement in a trial.	24	at least a diagnosis of hepatitis C having apparently
25	If we then look at BHCT0000951, there's some	25	formally been made by it's not clear I think
	157		158
1	whether it's I think it is made in life actually.	1	been some arrangement whereby some products were
2	If we look further up the page, first paragraph on	2	provided free of charge to clinicians in return for
3	that page, the last four lines, it says:	3	the provision of clinical data.
4	" he had liver failure related to his	4	Then if we go two pages further on, there's
5	carrier status for Hepatitis B and Hepatitis C"	5	a list of some 52 clinicians, but bottom of the page
6	So again, that may be an indication which casts	6	we see there listed Dr Mayne as one of them.
7	some further light upon what Dr Mayne is elsewhere		we see there listed by Mayne as one of them.
	Some farther light apon what by Mayne is elsewhere	7	I want to move next to a separate tonic which
×	saving about the serious or otherwise nature of	7 8	I want to move next to a separate topic which
8 a	saying about the serious or otherwise nature of	8	now postdates Dr Mayne's retirement which is in
9	hepatitis C at this time.	8	now postdates Dr Mayne's retirement which is in relation to the vCJD notification exercises. There is
9 10	hepatitis C at this time. There's a reference we can take that down,	8 9 10	now postdates Dr Mayne's retirement which is in relation to the vCJD notification exercises. There is a very detailed account from Dr Anderson in her recent
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1	Then in the next paragraph she deals with the	1	Sheffield:
2	issue of patient notification and says this:	2	"On the other hand, in the adult population
3	"With regards to the action being taken to	3	only a minority wanted to know."
4	inform or not inform patients, as you know there was	4	And there's reference there to information that
5	considerable controversy over whether or not patients	5	Dr Anderson had received from Dr Makris. She then
6	should be informed, and if they were to be informed in	6	says:
7	what manner. As you are aware, a letter was sent from	7	"I do know that two hospitals in London, the
8	the Haemophilia Society to its members and was	8	Oxford Haemophilia Centre and the Canterbury
9	received in Northern Ireland on Friday, 19th January."	9	Haemophilia Centre are directly informing their
10	She encloses a copy of that, and then says:	10	patients.
11	"I have tried to gauge how different	11	"After several lengthy discussions with
12	haemophilia centres have approached the problem around	12	Dr Dempsey, who has the majority of affected Factor IX
13	the [UK]. The Scottish Centres are minimally involved	13	patients, it was felt appropriate to take the
14	as they do not use BPL products. The Welsh Centre in	14	situation forward in Belfast by directly writing to
15	Cardiff have informed all their patients (17 last	15	affected patients, all of which now parents of
16	week) by phoning them and asking them to come up to	16	children involved, outlining the situation and asking
17	the haemophilia centre, and thereafter informing them	17	them to ring Dr Dempsey urgently. The mother will
18	with appropriate counselling. In Sheffield,	18	also be informed by Dr Dempsey. It is hoped that this
19	a different approach was taken, following along the	19	counselling will take place later this week."
20	lines of Dr Frank Hill, the Chairman of [UKHCDO].	20	Then there's a reference to another adult
21	A letter was sent from the Sheffield Children's	21	patient described as being a prominent member of The
22		22	Haemophilia Society, and then Dr Anderson says this:
23	Hospital on Wednesday and it would appear that the majority of parents want to know if their children	23	•
			" it was felt both by myself and also by
24 25	have received the implicated batch."	24 25	Dr Mayne, with whom I discussed the situation on
20	Over the page, again this is in relation to	25	Saturday morning, that it was essential he was
	161		162
1	informed. The patient was counselled by myself and	1	And the raises concern theut whether that is
	miorinoa. The patient was esamested by myssin and	1	And she raises concern about whether that is
2	took the information relatively quietly, with the	2	professional misconduct, and then says:
2 3	took the information relatively quietly, with the		professional misconduct, and then says:
	took the information relatively quietly, with the comment that this was probably inevitable for any	2	professional misconduct, and then says: "At the end of the day I think this is an
3	took the information relatively quietly, with the comment that this was probably inevitable for any patient receiving plasma derived blood products."	2	professional misconduct, and then says: "At the end of the day I think this is an extremely complex situation. Dr Dempsey and I have
3 4	took the information relatively quietly, with the comment that this was probably inevitable for any patient receiving plasma derived blood products." Then there is discussion about the problem	2 3 4	professional misconduct, and then says: "At the end of the day I think this is an extremely complex situation. Dr Dempsey and I have chosen to approach the situation by considering our
3 4 5	took the information relatively quietly, with the comment that this was probably inevitable for any patient receiving plasma derived blood products."	2 3 4 5	professional misconduct, and then says: "At the end of the day I think this is an extremely complex situation. Dr Dempsey and I have chosen to approach the situation by considering our centre on a particularly individual basis."
3 4 5 6	took the information relatively quietly, with the comment that this was probably inevitable for any patient receiving plasma derived blood products." Then there is discussion about the problem about whether or not to inform patients with	2 3 4 5 6	professional misconduct, and then says: "At the end of the day I think this is an extremely complex situation. Dr Dempsey and I have chosen to approach the situation by considering our centre on a particularly individual basis." So that's an account of Dr Anderson's thinking
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1	in relation to patients and their care and treatment.	1	received at a national level in relation to that.
2	Then she deals with the position at both a national	2	Then in paragraph 84.1.7 she refers to
3	and a local level. Her statement also covers	3	a further notification process in September 2004
4	Edinburgh because she moved from Belfast elsewhere and	4	which, in fact, was completed after she'd left her
5	then on to Edinburgh.	5	position as the director of the centre and refers
6	So if we go over the page there is then	6	there to the national discussion in relation to that.
7	a useful summary on this page and the next of the	7	Then she goes on to talk about, if we go
8	notification exercise, so we can see at the top of the	8	further down the page, discussions at a local level,
9	page, paragraph 84.1.1 she refers to the first	9	and we've seen one example of that in the letter we
10	notification involving BPL products in January 2001,	10	looked at. So she gives an account in relation to the
11	refers to the proposed approach from UKHCDO, and then	11	first notification exercise of local discussions in
12	the next paragraph she talks about there being	12	January 2001.
13	a consensus view that patients had the right to be	13	If we go over the page she gives information
14	informed of receipt of an implicated batch of product.	14	about an urgent meeting convened to discuss it. She
15	If we go further down the page she refers then	15	then gives similar information in paragraph 84.2.2
16	in paragraph 84.1.3 to The Haemophilia Society letter,	16	about the second notification exercise and, again, I'm
17	and we saw that referenced in Dr Anderson's own letter	17	not going to read through it but we can see that's
18	a few minutes ago.	18	where it's located within her witness statement and if
19	We see reference in 84.1.4 to a draft letter	19	we continue down the page she refers to there being
20	being circulated by UKHCDO and then if we go so	20	ongoing discussions in relation to Scottish and
21	that's the 2001 notification in a nutshell in terms of	21	Northern Ireland haemophilia doctors group and so on.
22	what was considered on a national level.	22	If we go over the page, we can see in
23	If we go over the page, she then refers to the	23	paragraph 84.2.5 she says:
24	second notification involving SNBTS products in	24	"As the second notification involved SNBTS
25	November 2002 and gives details of what advice was	25	product and affected patients in Scotland and
	165	20	166
	100		100
1	Northern Ireland, it was felt appropriate to inform	1	refers to:
	Northern Ireland, it was felt appropriate to inform patients through a notification process in the same		
1 2 3	patients through a notification process in the same	1 2 3	" [recalling] very few telephone calls to
2	patients through a notification process in the same manner in both regions and at exactly the same time,	2	" [recalling] very few telephone calls to the Centre, and I can recall that no patients
2 3	patients through a notification process in the same manner in both regions and at exactly the same time, with the same letter albeit with minor local	2 3	" [recalling] very few telephone calls to the Centre, and I can recall that no patients requested counselling following the letter
2 3 4 5	patients through a notification process in the same manner in both regions and at exactly the same time,	2 3 4	" [recalling] very few telephone calls to the Centre, and I can recall that no patients requested counselling following the letter However, at clinic visits, patients did seek more
2 3 4	patients through a notification process in the same manner in both regions and at exactly the same time, with the same letter albeit with minor local modifications to reflect the prior notification exercise in Belfast."	2 3 4 5	" [recalling] very few telephone calls to the Centre, and I can recall that no patients requested counselling following the letter However, at clinic visits, patients did seek more information about the situation in general, and this
2 3 4 5 6	patients through a notification process in the same manner in both regions and at exactly the same time, with the same letter albeit with minor local modifications to reflect the prior notification exercise in Belfast." Then she gives further information following	2 3 4 5	" [recalling] very few telephone calls to the Centre, and I can recall that no patients requested counselling following the letter However, at clinic visits, patients did seek more information about the situation in general, and this enabled a general discussion to take place and any
2 3 4 5 6 7 8	patients through a notification process in the same manner in both regions and at exactly the same time, with the same letter albeit with minor local modifications to reflect the prior notification exercise in Belfast." Then she gives further information following that about the 2004 notification exercise and	2 3 4 5 6 7	" [recalling] very few telephone calls to the Centre, and I can recall that no patients requested counselling following the letter However, at clinic visits, patients did seek more information about the situation in general, and this enabled a general discussion to take place and any queries to be answered."
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167

(42) Pages 165 - 168

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1 If we go on to page 158, there's then also 2 a detailed account of how and when patients were 3 provided with information and, as I say, that 4 continues again over a number of pages, and I'm not 5 going to go through the detail of that. 6 If we pick matters up on page 163 she then, in 7 response to question 88, sets out what information was 8 providing to patients about risks of vCJD at the 9 Belfast Centre and she summarises that on page 163 and 10 over the page on to page 164. 11 Then if we turn to page 165 she's asked about 12 counselling support and advice and says in 13 paragraph 89.1.1 -- thank you, Soumik -- in relation 14 to the 2001 and 2002 notification exercises she refers 15 to help-lines, counselling being available through 16 face-to-face sessions with herself and the associate 17 specialist should patients wish it. Patients were 18 also giving counselling and support and updates at 19 review clinics and then she also refers to the 20 availability in 2001 of face-to-face sessions of the 21 paediatric centre if required. 22 Then finally, if we go to page 166, the 23 question is asked at the bottom of the page about 24 measures put in place regarding vCJD at the Belfast 25 Centre from a public health perspective and she begins 169 1

She then refers to further revised guidance in

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"With such practical difficulties for the multidisciplinary team in terms of knowing which patients had wished to be informed, and those who wished not to be informed, to the best of my recollection around 2003 I think we took a pragmatic approach at the Belfast Centre to apply the same infection control measures to all the patients. As this involved quarantine of only some surgical instruments this was relatively straightforward. Operating theatre staff would be informed of the need for disposable instruments, and it seemed that these were becoming more commonplace in use."

position in 2004 and then explains again that she wasn't involved in the execution of the 2004 vCJD

So there is then some further evidence in the pages that follow from Dr Anderson about some specific issues relating to the antithrombin III product

to answer, the bottom of the page:

"In January 2001, to the best of my recollection, there was no advice available regarding the public health measures required in relation to the care and treatment of patients who had received factor concentrate ..."

She explains she raised this issue with the Director of Public Health and in the next paragraph she explains it was problematic. She recalls an instance when the dental school at the Royal Hospital site was required to shut for decontamination of surgical instruments.

She refers then to all surgical instruments and ventilators being quarantined for patients who had received implicated batches of product, many of whom had not wished to be informed of their exposure:

"Patients were not able to undergo endoscopy and colonoscopy as the public health risk had not been clearly defined, leading to waiting lists for procedures and delays to diagnosis. From discussion with other Centre Directors at the time, this was a common situation around the UK and not unique to the Belfast Centre."

Again, that accords with the evidence the Inquiry has heard.

170

notification exercise and various communications that Dr Anderson had at the time but, as I say, it's a very detailed 30-plus page account from her perspective of what happened in Belfast in relation to vCJD.

Sir, in our written note we have sought to summarise Dr Mayne's involvement with UKHCDO as chair in 1990 to 1993. We've referred to her membership of The Haemophilia Society's Medical Advisory Panel, which she seems to have been on from 1982 to 1994, although there's little documentation revealing the substantive content of her involvement, and we've referred to her appointment as trustee of the Macfarlane Trust between 1991 and 1996 and then her appointment to the Eileen Trust from 1993 to 1996.

I'm not proposing to deal with any of those matters now because the focus yesterday and today is upon Belfast rather than some of Dr Mayne's later and more national activities.

We've also in the written note highlighted some documents describing interactions that Dr Mayne had with pharmaceutical companies. We've looked yesterday at some of her exchanges with Speywood.

There are bits and pieces of correspondence, for example, Dr Mayne providing an account of a named patient requiring Hemofil to a pharmaceutical company,

172

(43) Pages 169 - 172

2003 regarding decontamination of surgical instruments and again refers to endoscopy being viewed as a high-risk procedure, so endoscopes were quarantined and reused for single patients. Then says in paragraph 91.1.6:

Then she refers to her recollection about the notification exercise.

1 2 3	discussions about patients' adverse reaction to Hyate:C, again with Speywood. There is some evidence of sponsorship by
4 5	pharmaceutical companies of attendances at
	conferences. So, for example, there is documentation
6	to suggest that Speywood sponsored Dr Mayne to attend
7	a conference to present a paper on porcine factor, and
8	there is also some evidence of Dr Mayne having a role,
9	perhaps in her capacity as chair of UKHCDO, with an
10	inspection of the Octapharma plant in Vienna in 1992
11	and attending with Dr Lee, Dr Jones, Professor Peake
12	and Professor Preston to obtain detailed information
13	about the fractionation procedures. That was at the
14	time of an outbreak of hepatitis A.
15	Those are, in broad terms, the interactions
16	that the documents reveal in relation to
17	pharmaceutical companies.
18	If we go to Dr Mayne's own statement
19	WITN0736009 and it's first of all, if we turn to
20	page 13, paragraph 11.1, bottom half of the page she
21	suggests that the relationship which existed between
22	the centre and the pharmaceutical companies was
23	business-like and professional.
24	Then if we turn if I can find the page
25	reference to page 70 she says, bottom of the page,
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1	active member, in September 1994 the minutes of the
2	UKHCDO meeting record Dr Mayne introducing a paper
3	setting out a process for Haemophilia Centre Directors
4	to make declarations of interest, which was agreed and
5	it doesn't appear that there had been any such
6	requirement prior to that in relation to UKHCDO rather
7	than local Trusts.
8	So that's the documentary evidence and the
9	thrust of the witness statement evidence received in
10	relation to policies and practices at the Belfast
11	Haemophilia Centre.
12	SIR BRIAN LANGSTAFF: Yes. Well, thank you very much. So
13	tomorrow we have Dr Benson.
14	MS RICHARDS: Tomorrow Dr Benson at 10 am.
15	SIR BRIAN LANGSTAFF: Ten o'clock. Ten o'clock it is.
16	MS RICHARDS: Thank you, sir.
17	(4.28 pm)
18	(Adjourned until 10.00 am the following day)
19	(tajvatitou aliai 10.00 alii alio lollomiilg day)
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she's "never provided advice or consultancy services to [a] pharmaceutical company".

Top of the next page:

"... never received ... pecuniary gain ..."

Then if we look at paragraph 117:

"... never received any financial incentives from pharmaceutical companies to use certain blood products."

And then she says at 118.1:

"I believe it became known throughout the pharmaceutical industry that I was unreceptive to gifts. If a company product was in use or if a pharmaceutical company so desired, educational gifts at the centre or extra accessories for the patients were acceptable, i.e. slides, pamphlets and books."

She refers then to getting sponsorship for the meeting on hepatitis C (that's the hotel conference she describes elsewhere in her statement) in 1995 and she says funding was accepted for travel to scientific meetings, either to present a paper or take part in discussion groups.

So that is again an outline of the position in relation to involvement with pharmaceutical companies. It's perhaps relevant to note that, following her stepping down as chair of UKHCDO but whilst sill an

'92 [2] 140/12 142/2 81/6 109/15 **17 [3]** 29/8 105/21 **1985 [58]** 38/22 45/1 **1997 [1]** 139/11 '93 [1] 119/14 **11 November 1982 [1]** 161/15 48/23 49/8 54/25 **1999 [2]** 107/4 143/21 MS RICHARDS: [68] 17 October [1] 33/11 57/13 61/16 61/21 'at [1] 11/22 14/10 19th January [1] 1/3 3/21 4/1 7/10 7/22 'at risk' [1] 11/22 61/25 64/15 65/19 **11.1 [1]** 173/20 17 October 1983 [1] 161/9 23/17 23/20 24/4 'CLOTT' [1] 59/24 **11.15 [1]** 49/21 31/23 65/23 66/1 66/21 1st [1] 22/23 24/13 24/17 24/22 'could' [1] 53/24 **11.45 [2]** 49/19 49/23 **18 [2]** 138/8 138/13 67/19 68/23 69/1 24/25 34/13 38/2 'erring [1] 86/25 **110 [1]** 45/12 18 October 1985 [2] 69/11 69/13 69/16 38/11 41/7 41/16 46/2 2 January [1] 76/22 'met' [1] 123/13 117 [2] 41/25 174/5 68/23 93/23 71/23 71/24 74/5 49/20 49/25 51/14 **118.1 [1]** 174/9 19 April 1991 [1] 74/19 75/2 75/3 76/4 2 January 1985 [2] 'mild' [1] 31/10 51/20 51/23 52/4 56/1 76/4 77/13 'moderate' [1] 31/10 159/20 77/10 77/13 80/2 **12 [1]** 75/9 71/20 75/3 76/21 'new' [1] 15/6 12 December 1981 [1] 19.1 [1] 29/23 81/12 85/3 85/14 2 o'clock [3] 96/23 76/25 77/2 77/6 77/11 97/2 97/4 's [1] 94/24 10/6 **1948 [1]** 146/25 89/10 89/18 90/1 90/7 77/16 77/18 86/8 2.00 pm [1] 97/7 'should' [1] 53/24 **12 December 1984 [1] 1960s [1]** 156/16 92/11 93/23 94/21 88/11 88/17 90/22 1970s [4] 58/22 60/7 **2.1.1 [1]** 121/12 42/19 95/12 95/21 96/4 'treaters' [1] 35/25 95/21 97/3 97/8 101/7 **2.1.2 [1]** 121/17 'users' [1] 35/25 12 February 1985 [1] 120/15 128/17 99/18 101/20 101/23 107/20 110/4 110/10 'we [1] 130/24 94/21 **1971** [1] 68/25 105/24 106/11 106/20 **2.10.1 [1]** 87/17 110/14 111/8 119/12 'wonder [1] 118/17 12 September 1985 **1974 [1]** 72/23 107/21 107/22 107/24 | 2.2 [1] 117/24 119/18 125/12 125/23 [1] 106/11 **1975 [1]** 9/14 108/6 108/17 109/17 |**2.4.1 [1]** 124/13 126/1 126/5 141/2 **125,000 [1]** 47/15 **1976 [1]** 121/25 109/18 111/3 151/12 **2.6 [2]** 74/15 126/9 142/3 142/6 142/10 ... **[8]** 47/1 98/19 101/8 **13 [3]** 88/22 143/3 **1977 [1]** 150/20 **1986 [4]** 98/4 98/13 **2.61 [1]** 126/9 148/17 148/20 148/24 107/21 108/19 152/11 1978 [2] 1/10 150/24 **20.1 [1]** 30/2 173/20 151/7 151/12 152/12 153/1 153/5 1979 [1] 1/10 152/12 160/24 20.4 [1] 30/17 13 January 1983 [1] **1987 [1]** 120/5 153/7 155/4 155/6 **1988 [3]** 70/21 119/10 | **20.5 [1]** 30/20 ... **1985 [1]** 107/21 17/16 **1980 [2]** 1/10 22/23 175/14 175/16 ... and [2] 47/1 101/8 20.6 [2] 30/20 30/20 13 May [1] 27/19 1980-1989 [1] 107/11 157/7 SIR BRIAN ... might [2] 152/11 **13 May 1983 [1]** 25/25 **1980s [6]** 28/19 32/19 1988/1989 [1] 1/14 2000 [2] 145/10 LANGSTAFF: [66] 152/12 13 September [1] 48/4 65/11 65/15 **1989 [5]** 1/14 107/11 146/10 3/19 3/22 7/5 7/11 ... when [1] 108/19 2001 [9] 160/15 13/9 99/23 119/11 152/4 153/2 23/10 23/18 24/2 **1981 [4]** 10/6 10/15 160/19 164/8 165/10 13.8 per cent [1] 1990 [1] 172/7 24/11 24/16 24/20 0 165/21 166/12 169/14 1990s [4] 8/5 127/3 109/9 10/21 11/4 24/23 34/6 37/24 001 [2] 19/13 152/2 169/20 170/2 **1371's [1]** 126/6 1982 [23] 10/15 10/24 142/14 153/10 38/10 40/23 41/11 002 [3] 20/8 70/20 2002 [4] 137/18 10/25 11/4 11/8 11/11 **1991 [20]** 107/12 13th [1] 27/4 45/23 49/18 49/24 157/5 165/25 168/19 169/14 **14 [3]** 93/18 95/10 11/20 12/8 12/11 110/22 112/20 113/14 51/8 51/15 51/21 52/2 003 [3] 93/22 151/5 113/12 12/14 13/9 14/3 14/6 113/17 113/20 119/8 **2003 [4]** 137/17 55/24 71/16 75/2 152/18 139/11 171/2 171/11 14 February 1983 [2] 14/10 14/25 15/23 119/13 119/17 121/19 76/15 76/23 77/1 77/3 004 [3] 25/15 26/25 18/7 18/11 20/10 33/16 34/8 41/9 122/1 122/1 123/3 **2004** [5] 166/3 167/8 77/7 77/14 77/17 68/20 14.5 per cent [1] 68/11 157/17 172/9 123/10 123/12 124/6 167/12 171/20 171/21 85/24 88/3 88/12 **005 [1]** 150/18 **1982-85 [1]** 39/21 44/23 137/2 143/7 159/20 **2008 [2]** 116/17 90/17 95/20 97/2 97/4 **007 [1]** 43/1 **140 [1]** 164/15 **1983 [58]** 16/3 17/16 144/17 172/13 101/5 107/19 109/22 **008 [2]** 25/23 150/25 2015 [1] 147/20 **144 [2]** 164/17 164/21 17/18 17/23 18/3 18/5 **1992 [13]** 119/14 110/9 110/11 111/7 2021 [1] 1/1 **024 [3]** 10/10 33/13 **15 [1]** 45/13 18/7 18/11 19/12 123/5 138/10 140/1 119/10 119/15 125/7 50/7 20s [1] 95/22 15 April '92 [1] 142/2 19/14 20/11 25/14 141/3 141/5 141/5 125/19 125/24 126/3 036 [1] 160/14 15 October 1985 [1] 25/22 25/25 26/24 141/24 142/19 149/11 21 August 1985 [1] 141/1 141/25 142/4 **050 [1]** 98/10 27/1 29/11 31/21 158/5 158/9 173/10 105/24 66/21 142/8 148/15 148/18 078 [1] 25/10 31/23 31/25 33/11 21 December 1992 [1] 15 patients [1] 105/14 1992-1993 [3] 119/7 152/11 152/25 153/3 **150 [1]** 167/13 33/17 34/12 34/15 141/5 120/20 121/6 153/6 155/1 155/5 34/21 35/2 35/2 35/4 **1993 [20]** 43/2 119/7 21 October 1992 [1] **153 [1]** 167/24 175/12 175/15 1 March 1983 [2] **155 [1]** 168/18 35/5 35/10 35/17 120/17 120/20 121/6 149/11 20/11 25/14 **156 [1]** 168/23 **22 January [1]** 160/15 35/20 36/18 37/8 37/9 121/24 122/3 123/5 1 September 1991 [1] 23 August 1994 [1] 123/21 128/21 128/25 **| 158 [1]** 169/1 38/23 39/8 39/10 '70s [2] 58/25 156/17 119/17 72/19 **16 [9]** 45/19 71/5 40/17 41/2 41/10 43/4 129/10 132/19 133/2 **'83 [8]** 62/24 67/22 **1.01 pm [1]** 97/5 **24 January [1]** 25/3 108/16 109/8 109/15 48/10 62/21 64/1 133/22 134/12 134/13 67/23 67/23 67/24 **10 [8]** 13/12 32/2 111/15 113/8 113/21 67/21 67/21 68/4 68/7 136/12 172/7 172/14 24 January 1983 [2] 67/24 67/24 67/25 47/21 78/13 91/12 145/11 68/8 68/11 74/24 78/1 **1994 [5]** 72/19 114/23 16/3 17/18 **'84 [9]** 67/14 67/15 93/2 155/9 175/14 **16 adults [1]** 83/16 92/19 92/20 92/22 115/16 172/9 175/1 24 June 1983 [1] 27/1 67/17 67/18 67/22 10 December 1984 [1] 16 cases [1] 105/18 107/18 109/17 **1994/95 [1]** 129/13 **25 [1]** 8/22 67/23 67/24 67/25 42/5 **1995 [9]** 8/5 8/9 127/7 25 March 1985 [2] **16 patients [1]** 105/16 **1984 [21]** 1/10 37/18 67/25 10 July 1985 [1] 85/3 85/14 **16.5 per cent [1]** 71/8 38/3 41/24 42/5 42/19 129/14 131/4 131/8 **'85 [6]** 67/18 67/25 69/13 143/12 143/15 174/18 | **25 per cent [3]** 71/7 **163 [2]** 169/6 169/9 48/12 49/8 61/13 76/19 77/10 94/3 10 May 1985 [1] 48/23 104/8 109/10 **164 [1]** 169/10 65/18 67/16 67/22 1996 [9] 123/25 107/19 **10.00 [2]** 1/2 175/18 **165 [1]** 169/11 68/1 68/4 74/22 74/24 123/25 124/9 128/22 **25 years [1]** 156/1 **'87 [1]** 120/8 **100 [1]** 134/25 **166 [1]** 169/22 75/1 75/11 75/12 129/2 136/23 137/3 **25,000 [1]** 47/10 '90s [2] 125/25 126/4 **11 [4]** 12/20 24/24 26 [2] 37/12 64/3 **16th [1]** 45/16 81/10 151/2 172/13 172/14

(45) MS RICHARDS: - 26

2	50 [1] 95/11	9	164/9 166/10 167/23	adequacy [2] 84/8	47/24 49/16 54/4 63/4
27 [1] 113/25	50 per cent [1] 104/9	9 May 1983 [1] 18/5	168/20 169/2 172/3	84/14	81/16 89/23 100/6
28 [2] 55/7 62/14	50.1 [2] 61/6 61/9	90 per cent [1] 140/17	172/24	adequate [3] 53/18	102/25 103/24 110/22
20 [2] 33/1 02/14	500 [1] 159/13	90s [1] 126/2	accounts [7] 77/22	60/12 138/6	119/21 122/6 128/21
3	51 [1] 153/13	91.1.6 [1] 171/6	82/21 94/13 101/2	adhered [2] 29/16	129/23 130/18 136/15
3-4 years [1] 133/22	51.1 [1] 89/15	95 [1] 129/13	117/20 136/20 137/19	71/14	137/17 137/22 139/12
3-6 months [1] 136/1	52 clinicians [1]		accumulated [2]	adjourn [1] 97/1	143/14 162/11 166/4
3.1 [1] 118/23	160/5	A	11/13 38/22	Adjourned [1] 175/18	afternoon [2] 1/21
3.10.1 [1] 91/13	54 per cent [1] 71/1	ability [1] 5/22	accuracy [1] 141/9	Adjournment [1] 97/6	59/8
3.16 [1] 143/24	54.1 [1] 99/21	able [11] 14/15 41/8	accurate [8] 8/13	administered [2] 73/4	
3.18 pm [1] 148/21	54.5 [1] 102/10	99/1 116/15 128/1	13/22 44/9 45/20	73/22	again [105] 4/22 6/3
3.19 [1] 155/18	55 [1] 108/21	140/12 144/15 148/6	46/22 47/6 63/24	administrative [1]	7/1 11/25 15/24 17/22
3.2 [1] 118/22	56 [1] 104/24	148/7 168/23 170/17	72/12	145/15	19/14 20/11 21/9
3.4 [1] 120/2	6	abnormal [5] 120/10	accurately [1] 134/18	admission [1] 158/13	23/16 26/5 26/18
3.45 [1] 148/19		121/1 131/14 131/21	accused [1] 163/22	admissions [1] 81/19	26/20 32/9 38/8 38/12
3.46 pm [1] 148/23	6 different [1] 47/14	133/7	achieve [1] 100/2	admit [1] 115/25	42/1 47/2 50/17 52/9
30 [2] 53/11 164/10	6 September 1982 [1]	abnormalities [2]	acknowledged [1]	adopted [3] 147/8	56/5 58/12 59/14
30 November 1992 [1]	12/14	34/17 36/2	67/4	167/21 168/21	59/25 61/2 62/6 65/1
158/9	6.2 [3] 143/3 143/4 143/5	about [176]	acquired [7] 10/20	adopting [1] 125/11	65/6 65/18 65/22
30-plus [1] 172/3	6.8.23 [1] 145/13	about AIDS [1] 14/8	12/24 13/13 16/8 19/18 21/5 22/2	adult [3] 95/21 162/2 162/20	66/18 69/16 70/2
30.2 [1] 9/5	60 [2] 145/8 145/11	above [4] 27/4 29/14		adults [5] 34/18 83/16	70/13 70/19 73/12
31 [1] 56/11	62 [3] 10/15 10/18	31/1 104/23	across [2] 28/13 119/16	113/10 133/25 160/25	87/23 88/22 89/7 91/2
31 March 2021 [1] 1/1	11/4	absence [3] 18/11	act [1] 156/3	advance [3] 62/1	92/7 92/9 94/13 94/18
32 [1] 10/10	62.1 [1] 131/11	50/3 126/23	acting [1] 144/3	66/15 115/17	95/4 95/24 96/2 96/17
33 [2] 33/13 63/7	63 [3] 10/16 11/5 40/8	absolutely [8] 6/22	action [8] 9/14 41/17	advanced [3] 15/5	99/14 100/17 101/1
33.10 [1] 66/10	63.1 [1] 132/17	46/4 51/23 56/6 82/19	43/9 50/2 54/5 103/16	41/5 58/8	101/9 102/8 106/11
33.11 [2] 66/10 114/12	63.3 [1] 133/20	83/24 125/23 144/25	135/13 161/3	advances [2] 39/24	106/18 112/18 113/24
33.3 [1] 64/16	65 [1] 135/2	abuse [2] 21/15	actions [5] 53/17 54/1	59/10	115/10 116/9 116/15
33.4 [1] 64/19	65.3 [1] 135/1	147/21	54/10 62/15 62/17	advent [2] 47/5	121/3 122/16 123/10
33.8 [1] 66/3	65.4 [1] 135/11	Academic [1] 79/10	active [14] 3/23	115/17	124/13 126/18 126/22
33.9 [1] 66/5 35 [2] 62/16 89/15	69.1 [1] 2/8	accept [2] 53/20 103/3	121/23 123/14 123/22	adverse [1] 173/1	129/8 129/11 130/3
36 [1] 99/8	69.2 [1] 2/19	acceptable [4] 57/1	123/24 128/20 129/12	advice [12] 54/15	131/6 132/12 134/7
37 [3] 78/18 81/14	69.3 [1] 3/8	122/15 122/19 174/15	131/24 133/1 134/12	54/22 105/6 105/10	137/20 138/2 139/4
81/17	7	accepted [5] 3/10	136/13 136/19 140/22	127/21 132/8 132/14	142/12 144/14 148/8
		38/5 83/17 92/25	175/1	138/20 165/25 169/12	149/25 150/25 151/25
4	7 October 1983 [1]	174/19	activities [2] 59/4	170/3 174/1	152/2 152/14 154/21
4 cases [1] 21/6	31/25	access [5] 32/13	172/18	advised [3] 6/14	157/23 158/16 158/23
4.1 [2] 137/16 139/7	70 [1] 173/25	32/17 32/20 76/11	activity [4] 31/10	60/23 120/16	159/6 159/11 159/24
4.2 [1] 93/2	70 per cent [1] 44/21	112/3	102/19 104/14 112/20	Advisory [2] 98/11	161/25 166/16 167/19
4.28 pm [1] 175/17	70.1 [1] 4/6	accessories [1]	actual [8] 4/23 25/18	172/8	168/15 168/20 169/4
40 [1] 50/7	70.2 [1] 4/9	174/14	59/15 64/13 75/22	advocated [1] 30/22	170/24 171/3 171/20
41 [1] 131/10	71.1 [2] 5/7 7/5 75 [1] 71/2	accompanied [1]	76/3 76/21 77/12	aetiology [2] 15/4 21/9	173/2 174/22
43 [2] 45/12 45/21	76 [1] 153/18	25/10	actually [5] 58/12 66/15 87/1 155/2	affect [2] 9/17 124/21	against [1] 22/19
43.1 [1] 56/9		accompanying [1]	159/1	affected [33] 2/14	Agatha [1] 72/25 aged [1] 16/18
44 per cent [2] 38/23	8	20/4	acute [1] 104/4	2/15 4/14 7/3 16/16	agencies [1] 108/24
71/3	80 [1] 140/17	accord [2] 5/2 5/3	acutely [1] 103/25	16/17 27/6 27/14	agent [5] 15/17 21/21
44.5 per cent [1]	80 per cent [1] 71/2	accordance [2] 87/5	add [2] 4/24 8/18	28/11 28/23 29/4	22/16 22/23 33/24
44/20	83 [1] 164/16	147/10	addition [1] 78/19	29/15 30/13 30/15	agents [1] 29/20
45 per cent [1] 16/14	84.1.1 [1] 165/9	accorded [1] 28/1	additional [3] 88/20	31/17 31/19 47/22	ages [1] 95/23
46 [1] 2/4	84.1.3 [1] 165/16	according [2] 3/5	105/17 150/10	62/25 71/1 71/7 72/15	aghast [1] 104/15
47 [1] 45/21	84.1.4 [1] 165/19	73/18	Additionally [1]	79/5 109/9 109/12	ago [6] 33/19 69/4
47.1 [1] 58/18 47.4 [1] 60/6	84.1.7 [1] 166/2	accords [1] 170/24	130/23	109/14 135/22 136/1	90/18 116/13 156/1
49 [1] 108/21	84.2.2 [1] 166/15	account [31] 8/8 8/10 9/9 14/4 30/4 73/16	address [4] 59/18	140/4 160/24 162/12	165/18
	84.2.5 [1] 166/23	73/17 79/18 82/14	100/20 103/25 127/13	162/15 163/20 166/25	agree [2] 80/3 155/2
5	84.2.8 [1] 167/10	93/3 99/18 101/3	addressed [5] 14/11	affirm [1] 50/14	agreed [6] 13/3 19/9
5 November 1982 [1]	85 [2] 39/21 167/14	104/18 118/3 118/24	14/12 79/16 88/15	afforded [1] 75/15	27/5 27/19 100/3
14/25	85.1.8.5 [1] 167/25	123/11 125/19 136/24	94/9	afield [1] 80/21	175/4
5.2 [1] 147/7	88 [1] 169/7	136/24 137/13 139/1	addresses [1] 29/6	afraid [5] 14/21 38/4	agreement [1] 105/4
5.3 [1] 147/8	89.1.1 [1] 169/13	146/22 160/10 164/7	addressing [1] 41/15	48/2 48/13 95/22	aid [1] 40/18
5.4 [2] 120/22 147/17			adept [1] 40/4	after [24] 18/6 35/5	AIDS [67] 1/25 7/15
<u> </u>	<u> </u>	L			(46) 27 - A

	1100 1500 1511	15/15	40.4/0.40.4/5.40.5/40	44714 440140 444100	0010 0010 00104 00140
Α	146/8 152/8 154/1 154/23 155/13 161/15	45/15	134/2 134/5 135/13 135/18	117/1 119/16 141/23 158/24	68/2 68/9 68/24 69/18 70/12 70/14 71/20
AIDS [65] 8/2 8/19	162/15 164/11 170/13	anaemia [1] 2/24 analgesia [1] 52/19	anticipate [2] 26/18	appear [18] 31/15	84/24 92/9 94/13
9/1 10/13 11/13 11/15	171/13 173/19	analyse [1] 14/16	49/9	32/16 32/19 72/6	94/14 96/7 96/17
13/12 14/8 16/10	Allain [4] 43/7 43/10	analysed [1] 1/9	anticipated [3] 103/3	73/14 106/7 106/18	96/23 98/19 99/5
16/12 17/20 18/14	44/2 44/5	anatomy [1] 81/23	157/4 157/24	106/24 108/25 111/5	105/16 106/1 106/2
18/19 19/25 20/4 20/5 20/8 22/22 23/3 24/10	allied [1] 58/4	Anderson [15] 116/11	anticipating [1]	112/12 116/9 129/11	106/6 106/13 106/14
26/17 32/9 33/1 33/5	allocated [2] 1/18	144/10 145/6 145/9	163/13	136/6 140/20 141/9	106/21 109/10 112/1
35/22 35/24 36/19	76/6	146/13 160/10 160/15	antifibrinolytic [1]	161/22 175/5	115/10 117/7 117/8
37/14 38/5 39/18	allocation [1] 157/22	160/18 162/5 162/22	29/19	appeared [3] 13/17	117/25 122/20 136/20
40/14 49/2 49/16 50/3	allow [2] 41/5 76/2	164/9 168/16 168/21	antigen [1] 75/23	39/6 101/15	137/19 138/2 140/18
50/13 53/4 53/7 54/23	alluded [1] 168/15 almost [2] 16/8 117/8	171/24 172/2 Anderson's [3] 107/5	antithrombin [5] 163/7 163/7 163/16	appears [16] 3/5 36/8 40/20 41/1 41/3 51/23	140/18 141/11 141/17 141/19 145/2 147/1
55/21 61/7 62/16 64/7	along [2] 42/7 161/19	164/7 165/17	168/14 171/25	55/21 70/14 78/2 94/4	147/13 147/14 147/21
65/16 70/5 71/21	alpha [2] 136/16	animal [1] 52/6	antithrombin III [5]	106/17 112/13 130/7	148/1 148/6 149/4
73/11 75/17 85/9	141/19	Annals [2] 10/25 35/3	163/7 163/7 163/16	155/1 157/7 159/25	150/13 151/1 156/21
94/24 96/6 98/18 99/22 101/13 101/18	already [24] 8/7 13/23		168/14 171/25	application [2] 39/25	156/22 157/18 158/16
101/22 110/1 116/7	27/15 28/7 33/14	Anne's [1] 141/20	anxiety [3] 26/10 35/9	40/22	161/7 161/13 162/9
149/13 149/13 149/14	33/15 35/15 49/10	announced [1] 78/5	123/19	applied [1] 103/10	163/8 163/15 163/17
149/15 150/5 150/5	52/6 54/19 55/13	annual [7] 1/5 28/16	any [82] 1/6 2/24 5/3	apply [2] 53/6 171/12	164/13 172/23 173/15
150/15 152/13	62/23 72/16 75/17 93/17 106/15 113/11	59/2 59/19 149/4 149/5 154/5	5/23 5/25 6/1 6/24	appointment [5] 83/19 130/2 130/10	area [1] 84/3 areas [1] 155/23
AIDS-related [1]	113/14 113/21 121/20	annually [3] 45/12	7/12 8/3 8/10 11/3 12/23 13/25 14/5	172/12 172/14	argument [1] 88/4
150/5	129/4 138/5 139/3	136/2 136/4	14/23 13/23 14/3	appointments [3]	arisen [1] 154/22
AIDS/1 [1] 20/8	149/3	anomalous [1] 44/23	32/16 32/19 40/3	61/12 62/5 87/21	arises [3] 1/12 36/7
AIDS/2 [1] 20/4	also [37] 6/20 21/3	anonymised [1]	40/22 40/24 47/12	apposite [1] 81/2	163/9
AIDS/3 [2] 20/5 149/14	23/6 23/13 25/13	153/23	51/5 53/17 57/9 57/12	appraisal [1] 54/4	ARMO0000382 [1]
aim [1] 100/8	32/19 58/7 59/22	anonymously [1] 83/4	59/18 59/25 60/3	approach [5] 156/11	48/22
aired [1] 78/23	68/15 84/1 98/10 99/4	another [14] 30/19	60/24 61/1 61/8 61/24	161/19 164/5 165/11	Armour [4] 47/24
airport [4] 16/2 16/2	99/16 102/5 104/13	79/23 81/5 90/6 90/16	1	171/12	48/23 109/25 110/15
24/15 25/3	108/7 111/4 114/18	110/9 123/10 128/5	75/18 80/13 87/3	approached [1]	arose [1] 30/9
al [1] 37/25	120/2 124/23 135/9 142/18 143/19 148/3	139/1 150/18 154/13 159/25 162/20 163/24	87/21 87/25 88/20 90/12 97/24 105/5	161/12 approaches [1]	around [7] 1/14 8/8 107/4 121/23 161/12
albeit [2] 28/18 167/4	149/5 154/19 155/25	answer [21] 1/9 6/21	108/3 111/8 119/25	125/18	170/22 171/11
albumin [1] 163/19	162/18 162/23 163/17	8/13 14/22 29/12 54/9	120/15 122/15 122/18	appropriate [15] 19/1	arranged [5] 61/20
alcohol [1] 132/15	165/3 167/15 169/1	54/13 55/12 55/13	125/24 127/23 129/14	30/15 39/25 46/11	80/20 82/12 89/17
alights [1] 21/14	169/18 169/19 172/19	55/23 56/13 57/23	130/17 133/14 134/14	53/19 54/6 56/15	127/9
alive [1] 98/1 all [92] 4/7 4/20 5/9	173/8	59/14 60/18 64/12	136/6 138/17 138/19	65/21 79/6 147/24	arrangement [3]
7/1 16/18 19/1 19/10	alter [1] 128/14	87/15 104/23 114/8	138/20 138/20 139/16	155/14 161/18 162/13	107/3 136/6 160/1
20/7 21/5 22/15 24/25	alteration [2] 46/14	125/1 134/25 170/1	141/14 145/18 147/19	163/14 167/1	arrangements [6]
25/5 26/23 28/13	54/1	answered [3] 55/13	148/4 153/20 155/12	appropriateness [2]	3/13 75/25 83/21
34/17 39/1 43/21 44/5	Altered [1] 34/23 alternative [5] 47/8	64/9 168/8 answers [4] 6/17 64/3	156/8 156/19 159/19 160/18 163/3 164/25	79/20 91/17 approximately [1]	107/1 113/23 130/11 arrived [1] 144/11
44/7 45/3 45/4 51/2	50/19 52/5 79/1 79/4	124/17 153/21	168/7 172/15 174/6	47/10	art [3] 39/23 39/25
51/11 55/6 55/21 56/5	although [12] 6/10	anti [11] 58/7 67/1	175/5	April [9] 67/18 107/12	40/3
60/8 60/23 63/11 66/1	12/9 19/4 27/24 51/15	106/1 106/12 106/21	any other [1] 6/1	140/1 140/12 141/3	Arthur [1] 9/3
71/8 72/4 72/14 75/13 75/15 78/21 78/23	72/6 76/14 131/16	107/17 134/1 151/8	anyone [1] 149/22	142/2 142/19 150/20	Arthur Bloom [1] 9/3
79/3 79/12 79/21 80/4	134/2 138/19 150/12	151/11 151/12 152/9	anything [3] 7/17 57/7		article [12] 9/22 9/22
81/11 83/3 83/12	172/10	anti-coagulation [1]	110/14	April 1977 [1] 150/20	10/5 10/25 35/1 35/2
83/14 83/17 85/12	always [7] 31/10	58/7	anyway [1] 24/21	April 1991 [1] 107/12	35/6 37/20 37/24 38/2
85/17 86/15 86/22	31/14 46/2 125/1	anti-HIV [5] 107/17 151/8 151/11 151/12	apart [4] 2/13 102/19	April 1992 [3] 140/1 141/3 142/19	107/7 110/21
87/5 88/4 88/25 89/5	143/9 155/25 156/6 am [10] 1/2 7/22	152/9	103/19 118/9 apologies [5] 15/2	archives [1] 146/20	articles [1] 60/4 articulate [1] 140/13
90/25 91/2 100/4	49/21 49/23 152/8	anti-HTLV-III [4] 67/1	18/11 20/21 26/14	archiving [1] 146/21	articulation [1] 34/2
101/14 103/4 103/17	160/21 163/22 164/10	106/1 106/12 106/21	145/11	are [90] 2/20 6/5 6/7	as [218]
104/4 105/7 113/10	175/14 175/18	anti-measles [1]	apologises [1] 158/10		ascertain [1] 167/21
114/16 116/24 117/22 117/22 117/23 119/20	American [2] 17/11	134/1	appalling [2] 93/1	17/10 20/3 20/7 20/25	aseptic [1] 118/10
121/1 122/3 122/15	18/21	antibodies [1] 37/20	93/8	24/18 24/25 25/20	ask [2] 59/9 96/7
122/19 127/8 128/12	amongst [4] 11/7	antibody [15] 38/21	apparent [6] 1/6 1/11	29/20 33/19 40/1 40/3	asked [31] 1/4 12/22
132/24 137/4 137/11	35/25 39/7 72/10	70/25 71/6 75/21 85/7	23/21 68/6 97/25	40/8 46/3 46/3 50/11	12/23 13/14 13/24
139/25 140/18 145/6	amount [1] 87/20 amounts [2] 32/14	85/12 108/19 121/22 123/14 129/10 133/23	141/3	50/21 52/9 58/18 61/17 65/3 67/2 67/13	25/16 29/11 56/11 57/17 58/23 59/15
	amounts [2] 32/14	120/14 120/10 100/20	apparently [J] 20/21	01/11 05/5 01/2 01/15	01111 00120 00110
h	·	·	·		(47) AIDS - asker

(47) AIDS... - asked

Α	16/5 32/1 42/6 82/16	avoided [1] 54/12	72/23 77/7 79/1 82/6	71/23	141/18
asked [20] 62/14	98/14 128/4	aware [22] 17/12 19/7		begins [1] 169/25	benefits [2] 27/22
62/16 63/2 64/3 65/8	attending [15] 4/7	19/7 58/21 59/17 60/8	86/24 88/13 92/12	begs [1] 52/16	28/3
65/14 91/16 103/12	36/3 61/15 66/6 75/13	63/4 89/23 99/5 104/1	92/25 93/8 109/12	begun [1] 7/7	Benson [6] 116/15
104/13 104/20 104/24	78/19 91/2 112/1	124/22 133/10 133/12	118/10 123/10 126/2	being [113] 3/12 3/17	137/25 144/14 148/7
105/5 118/17 151/22	117/7 119/21 132/7	137/21 137/23 151/22	135/24 136/19 137/14	5/21 6/6 6/7 6/13 9/13	175/13 175/14
153/14 153/17 155/2	146/9 151/10 154/1	154/1 154/4 154/13	139/10 141/10 146/4	14/16 14/18 17/10	best [7] 9/6 30/8
164/22 169/11 169/23	173/11	154/17 161/7 164/18	165/4 172/16	17/12 18/23 19/23	51/15 66/14 83/15
asking [6] 93/9 97/14	attention [8] 43/25	awareness [2] 35/24	become [3] 31/2	26/21 28/9 28/21	170/2 171/10
138/9 152/3 161/16	61/13 64/2 113/11	39/17	56/21 56/23	32/18 34/9 36/9 37/2	better [5] 7/13 47/19
162/16	117/1 118/1 120/2	AZT [4] 70/9 115/16	becomes [1] 23/21	38/8 40/19 41/8 41/20	95/17 125/2 125/7
asks [1] 94/7	147/2	115/17 116/10	becoming [7] 7/14	52/1 56/24 60/13 61/4	between [26] 1/6 1/14
aspect [2] 73/6 80/25	attitude [1] 43/15	В	63/4 75/16 122/5 137/21 137/23 171/18	61/22 62/18 65/13 65/21 66/15 68/4 68/4	20/15 24/23 31/6 61/2 63/19 67/20 72/11
aspects [3] 59/7 60/8	attributable [1] 120/13	baby [1] 17/4	bed [3] 52/18 79/3	75/17 83/25 84/1 85/5	73/12 74/9 89/9 92/19
116/7	audience [1] 104/6	back [23] 7/5 8/20	80/9	86/19 90/7 91/16	92/20 102/21 109/17
assertion [2] 58/21	augmented [1] 114/3	23/10 23/15 33/12	been [98] 1/22 3/5	93/25 94/1 94/11	112/12 117/2 122/4
60/6	August [8] 43/2 67/21	38/14 41/4 62/13	7/19 8/17 10/4 13/18	94/16 94/16 94/17	126/18 139/11 140/10
asserts [2] 30/14	67/25 72/19 96/4	70/10 71/17 83/6	14/15 15/5 17/8 17/19	94/20 95/2 96/8 96/16	140/17 144/2 172/13
131/11	105/24 123/25 147/20	83/10 97/8 104/14	20/24 21/4 22/6 24/4	97/16 99/1 99/4 107/2	173/21
assess [3] 41/10 55/2	August 1983 [1]	104/23 105/15 118/12	36/9 37/13 39/4 39/9	115/11 115/19 116/14	bewildered [1] 100/1
131/6	67/21	118/23 124/25 128/6	41/13 41/17 41/18	116/24 116/25 117/1	bewilderment [1]
assessed [1] 132/24	August 1985 [1] 96/4	129/21 150/17 158/15	46/20 47/25 49/10	117/4 117/5 117/11	81/16
assessment [4] 51/5	August 1993 [1] 43/2	back at [1] 118/12	49/11 52/6 52/20	118/3 118/5 118/16	BHCT0000158 [1]
141/18 146/9 157/22 assist [4] 96/19	August 1996 [1]	background [2] 26/7	53/20 54/3 56/15	118/24 121/3 122/20	105/23
116/16 144/15 148/7	123/25	164/20	58/19 60/8 61/13	123/3 123/9 126/9	BHCT0000161 [1]
assistance [1] 114/18	August 2015 [1]	balancing [1] 53/2	67/12 71/5 72/22 73/1	127/17 128/3 128/9	106/10
assisted [1] 114/7	147/20	base [1] 69/19	73/17 79/12 80/4 80/8	128/25 130/4 130/5	BHCT0000484 [2]
assists [1] 74/20	Australia [1] 102/5	based [3] 19/3 40/12	80/20 82/3 82/16	130/7 132/22 133/12	66/20 105/15
associate [1] 169/16	author [1] 38/8	147/5	84/15 85/21 86/23	136/22 137/2 137/13	BHCT0000609 [1]
associated [4] 4/20	authored [5] 50/1	basis [12] 39/24 47/9	93/20 94/4 95/22 96/7	138/5 138/7 138/9	114/21
23/3 104/5 156/2	70/19 110/21 110/21	58/11 58/23 59/16	97/10 97/18 100/5	138/10 139/5 139/17	BHCT0000612 [1]
association [3] 15/13	112/22	71/12 79/15 124/23	101/20 101/23 104/2	142/12 144/11 144/12	72/18
21/3 23/13	authors [1] 107/14	135/22 135/24 154/5 164/6	106/15 108/10 108/20	146/1 147/7 149/1	BHCT0000831 [2]
assume [1] 61/15	Autoplex [2] 157/15 157/23	batch [17] 16/20	108/22 108/23 109/24 109/24 109/25 110/2	150/8 150/16 151/11 154/19 157/6 161/3	152/2 152/18 BHCT0000846 [2]
assumed [1] 91/22	Autumn [1] 45/1	36/23 47/23 48/22	110/12 111/23 112/7	162/21 163/10 165/12	68/20 93/22
assuming [1] 57/10	availability [5] 38/25	49/4 49/5 49/6 49/7	112/13 113/12 116/2	165/20 166/19 168/16	BHCT0000850 [1]
assumption [2] 3/24	47/12 56/24 154/8	109/19 109/25 110/10	119/7 119/13 120/14	169/15 170/14 171/3	149/9
53/1	169/20	110/16 160/24 161/24	1	Belfast [39] 5/1 8/17	BHCT0000860 [1]
asymptomatic [1]	available [50] 13/4	165/14 168/12 168/25		8/18 17/24 19/15 28/7	70/1
17/2	30/24 40/13 46/21	batch this [1]	135/7 135/15 136/4	28/9 29/1 29/12 32/16	
Atlanta [2] 20/13	48/14 51/1 52/18	160/24	136/6 139/17 142/16	38/18 45/6 74/7 74/15	151/5
22/25 attach [1] 159/21	57/24 63/14 73/13	batches [4] 22/21	146/10 148/8 148/9	75/8 76/5 84/12 85/2	BHCT0000896 [1]
attachments [1] 25/4	75/20 75/22 75/23	37/3 135/5 170/15	151/12 154/17 158/25		92/10
attained [1] 44/21	76/8 80/14 81/18	be [209]	160/1 160/24 170/18	129/2 140/3 145/9	BHCT0000948 [1]
attempting [1] 154/24	81/20 87/20 90/10	be present [1] 15/17	172/9 175/5	146/18 149/4 150/23	158/7
attend [8] 18/9 78/21	108/10 108/19 109/15	became [28] 7/13 8/4	been an [1] 24/4	154/22 162/14 165/4	BHCT0000951 [1]
100/5 114/17 127/24	112/14 120/5 120/20	9/1 44/19 45/13 46/5	been heat-treated [1]	167/6 167/15 169/9	157/25
130/23 139/9 173/6	121/6 121/8 121/22	52/18 58/21 81/10	109/24	169/24 170/23 171/12	BHCT0000981 [1]
attendance [5] 26/1	121/24 122/5 123/21	89/23 92/18 92/21	before [21] 1/24 5/11	172/4 172/17 175/10	98/3
36/10 42/3 79/22	124/6 127/14 128/25 129/10 129/13 129/23	105/17 108/19 119/7 120/20 121/18 121/22	15/3 16/7 19/14 34/8 52/17 60/16 71/16	Belfast Centre [1]	bigger [1] 13/8
130/13	129/10 129/13 129/23	123/21 129/24 131/25	1	believe [4] 44/19	bill [1] 10/6
attendances [1] 173/4	132/19 133/2 133/23	132/19 133/1 133/23	77/10 85/13 93/23	121/25 141/7 174/10	biopsy [1] 140/19 birth [3] 68/25 149/7
attendants [1] 26/11	134/11 137/5 138/11	134/11 134/16 164/17		believed [1] 118/15	150/13
attended [8] 2/12	138/20 163/15 169/15	174/10	104/14 123/23 132/8	belonging [1] 146/3	bit [1] 85/24
12/14 60/9 61/14	170/3		began [5] 76/21 81/12		bits [2] 96/17 172/23
78/25 79/12 80/23	averages [1] 113/2	14/5 17/24 18/8 27/9	107/17 108/5 132/18	151/10	bizarre [2] 78/10 80/2
130/2	avoidable [1] 68/12	32/7 35/5 36/9 37/23	begin [1] 76/19	beneficial [1] 42/21	bleach [1] 102/18
attendee [1] 77/23	avoidance [2] 40/21	38/18 44/1 44/2 48/7	beginning [5] 12/17	benefit [6] 41/8 52/14	bleeding [7] 2/25 30/
attendees [7] 13/10	69/2	51/4 64/15 66/4 72/4	12/21 64/14 68/11	52/24 53/25 63/9	30/3 30/7 31/9 57/19
					(48) asked bleeding

(48) asked... - bleeding

В	
	eding [1] 149/8
ble	eds [1] 52/19
blir	nd [1] 157/21
	ck [1] 81/14
	od [41] 2/11 3/11
	16 4/5 4/20 4/20
	13 13/1 13/18 15/15 /21 16/21 21/15
	/21 16/21 21/15 /16 22/3 33/24 38/6
	/10 22/3 33/24 36/6 /7 43/17 44/6 54/3
	/13 57/21 63/3 80/5
82	/11 85/18 86/23
94	/24 102/15 102/20
	7/21 109/8 119/21
	2/9 128/9 128/11
	1/24 151/18 163/4
	4/7 ods [1] 2/23
	oom [9] 9/3 12/21
	/23 18/14 19/10
25	/19 26/7 26/19 32/5
	wn [1] 73/11
BM	J [1] 38/5
	ard [3] 28/13 98/12
	9/16 d y [2] 102/15
	2/16
	d [1] 29/9
bod	oks [1] 174/15
	rn [1] 73/3
	th [16] 8/12 19/20 /25 39/23 42/14
	/5 72/24 79/20
	/13 84/2 84/11
	8/15 162/23 164/23
16	5/2 167/3
bot	tles [1] 73/2
bot	ttom [59] 10/13
	/16 13/12 15/2 16/5 /13 20/14 20/19
	/11 29/8 29/8 30/2
33	/21 35/19 36/16
37.	/19 38/15 44/15
	/11 55/7 57/15
	/21 69/7 70/23 72/2
	/10 75/10 77/25
	/6 86/11 89/15 /12 98/6 98/7 99/9
	/20 106/4 112/23
	1/11 123/8 128/6
	0/15 131/10 133/3
	7/12 139/4 140/5
	1/10 146/7 151/24
	2/6 155/9 155/18
	0/5 164/21 169/23 0/1 173/20 173/25
	unds [1] 127/5
	L [6] 42/4 42/19
	9/20 161/14 165/10
16	8/14

BPLL0005964 [1] 159/17 BPLL0010480 [1] 42/18 breaches [1] 50/10 break [6] 49/17 49/18 49/22 148/14 148/18 148/22 breakdown [1] 48/10 Bridges [4] 79/10 80/23 149/12 151/7 brief [1] 42/18 briefed [1] 114/16 briefly [3] 26/6 77/22 156/13 bring [1] 124/25 bringing [1] 136/7 Bristol [2] 33/7 33/10 broad [2] 51/12 173/15 broader [1] 138/3 brother's [4] 137/14 137/18 139/5 139/13 brothers [2] 30/12 95/14 brothers' [1] 95/23 **brought [2]** 54/12 61/13 Bruce [1] 38/8 Bruce-Chwatt [1] 38/8 brushed [1] 138/18 **Bull [1]** 48/9 bundle [1] 115/11 business [3] 32/2 79/13 173/23 business-like [1] 173/23 but [143] 3/6 5/14 6/12 6/20 7/8 7/9 7/11 8/10 8/11 9/7 10/23 11/13 13/16 14/23 16/19 17/3 17/17 19/7 19/15 28/10 29/16 29/25 30/14 30/23 32/19 35/4 35/18 37/1 38/19 38/25 40/11 40/24 42/2 43/4 44/2 44/5 46/4 48/10 50/21 55/6 55/21 55/22 56/6 57/10 58/15 59/23 61/10 62/5 67/10 68/5 68/24 69/20 70/14 71/4 73/19 74/24 77/4 78/2 79/15 80/13 83/11 83/12 83/16 83/18 85/2 85/9 85/20 86/1 87/6 88/1 88/6 88/7 88/14 88/21 90/3 91/21 91/25 92/8 92/21 93/15 94/11 95/16 96/2 96/13

96/22 96/24 97/22

98/5 101/17 104/16 105/9 106/17 107/4 108/3 110/17 111/8 113/5 114/8 116/24 117/25 118/18 119/10 119/15 119/25 120/14 120/15 121/8 121/23 122/18 123/3 123/5 123/14 124/4 124/7 126/15 129/11 130/6 130/10 131/20 133/7 136/5 139/3 139/3 141/2 141/25 145/1 147/2 147/25 149/5 150/2 152/13 152/15 152/19 156/6 156/17 159/19 160/5 164/11 164/19 166/17 167/16 172/2 174/25 **Butlin** [1] 1/9 **BV [1]** 76/5 BV1 [1] 76/7 BV396 [1] 76/7 by [140] 1/19 1/23 2/6 3/24 4/25 4/25 6/17 8/6 8/18 9/13 10/19 11/1 12/14 12/14 12/15 13/23 14/24 17/10 17/18 23/2 24/23 25/17 25/18 27/10 29/10 30/9 30/23 33/6 34/10 34/21 36/18 37/2 37/6 37/7 38/6 40/18 41/19 42/5 43/16 45/3 46/18 47/24 50/1 51/9 52/16 52/21 53/5 54/5 54/10 54/11 56/19 57/6 58/2 58/19 59/1 59/23 60/13 61/19 62/20 67/4 68/11 70/14 70/19 73/3 73/19 74/10 75/17 76/9 81/7 83/4 84/3 91/8 91/18 93/5 93/12 93/14 94/9 94/23 95/6 100/6 101/14 101/21 102/17 102/22 102/23 105/3 106/15 106/16 106/25 108/1 108/20 108/22 108/24 110/2 110/4 110/21 111/16 111/23 112/7 112/23 113/1 113/5 113/6 113/14 114/3 116/10 116/11 120/10 123/9 123/21 124/20 125/11 125/18 127/5 127/11 130/16 131/6 131/8 136/18 138/14 141/18 142/13 142/15 147/8 150/22 151/1 151/4 154/8

158/2 158/25 161/16 162/14 162/18 162/23 162/23 163/1 164/5 164/22 165/20 173/3 cabinet [1] 76/10 calculations [1] 5/23 call [1] 98/8 called [3] 98/11 130/5 133/17 Callender [1] 143/17 calling [2] 129/20 129/21 calls [1] 168/2 came [6] 5/15 9/1 22/23 92/4 104/14 123/23 can [74] 8/12 8/23 10/23 16/7 18/9 18/13 19/12 25/13 30/8 33/17 42/6 42/17 50/6 55/12 55/17 56/2 64/15 68/5 68/24 69/5 69/8 70/6 70/8 71/17 72/1 74/5 75/10 82/17 87/25 88/14 94/12 96/22 97/8 98/3 98/10 98/13 98/16 106/22 107/7 108/7 114/25 116/5 121/12 121/24 123/8 130/15 137/15 140/5 142/11 143/25 144/21 146/22 149/24 150/6 150/9 150/19 151/1 151/5 151/17 152/2 152/19 156/13 157/5 157/13 158/8 158/23 159/10 159/19 165/8 166/17 166/22 168/3 168/18 173/24 can't [8] 8/10 9/20 19/7 38/4 38/12 48/13 56/3 88/11 cancel [2] 80/19 135/25 cannot [5] 9/8 61/9 61/14 63/9 82/11 Canterbury [1] 162/8 canvassed [1] 32/9 capable [1] 134/17 capacity [3] 80/7 80/9 173/9 Cardiff [4] 25/19 26/18 33/6 161/15 care [18] 11/11 50/10 50/11 66/12 80/6 100/13 111/21 112/13

112/16 113/23 114/8

116/14 118/9 144/16

146/18 160/22 165/1

170/5

cared [3] 108/20 108/22 108/23 careful [3] 54/4 99/2 100/15 Caroline [1] 146/17 carried [10] 45/3 64/6 65/21 74/18 74/23 76/18 77/9 79/17 87/4 122/14 carrier [2] 158/20 159/5 carriers [1] 15/18 carries [1] 116/8 carry [5] 64/6 79/14 85/9 122/9 156/20 carrying [3] 56/21 86/24 141/17 Carson [1] 160/16 case [22] 7/13 16/24 17/4 25/19 26/19 26/21 27/11 33/6 33/7 33/8 33/10 85/2 90/6 105/17 110/12 130/7 140/13 144/7 145/18 145/22 146/9 168/13 cases [28] 7/1 13/25 16/18 16/21 16/22 16/23 17/7 18/24 19/24 20/3 20/23 21/4 21/6 23/2 23/6 24/21 24/25 25/17 31/8 31/18 33/5 84/2 98/21 105/18 105/21 134/12 135/10 149/13 cast [2] 88/20 153/7 casts [1] 159/6 categorically [1] 74/17 categories [1] 21/1 categorised [1] 11/21 category [1] 141/21 catering [2] 78/20 79/21 causation [1] 40/15 cause [13] 15/12 15/16 21/13 21/15 21/20 32/9 41/12 54/1 57/18 64/6 123/18 141/12 153/3 caused [6] 7/15 26/9 35/9 43/20 81/16 124/20 causing [1] 132/10 caution [1] 86/17 caution' [1] 87/1 cavity [1] 102/15 CBLA0000072 [3] 10/10 33/13 50/7 CBLA0001619 [1] 13/7 CD4 [1] 115/25 CDC [2] 24/9 37/13

CDSC's [1] 149/14 ceasing [1] 42/15 ceiling [1] 81/25 cellular [1] 10/21 cent [15] 16/14 38/23 44/20 44/21 44/23 71/1 71/2 71/3 71/7 71/8 104/8 104/9 109/9 109/10 140/17 centigrade [1] 108/11 Central [1] 23/8 centre [100] 1/24 2/10 4/7 4/15 5/2 11/7 12/3 12/13 13/4 13/6 13/9 13/14 14/13 14/19 17/8 18/2 18/10 19/1 19/11 19/16 19/22 20/12 22/24 23/1 23/7 25/5 25/21 25/21 25/24 26/23 27/2 28/7 31/22 31/24 32/16 32/23 34/4 34/4 34/11 35/10 35/20 42/4 42/13 44/7 53/17 54/11 63/23 63/25 71/22 75/14 76/2 92/3 105/8 109/2 112/17 112/21 113/2 114/2 114/17 116/2 117/7 119/13 119/21 123/2 127/8 128/12 129/2 132/7 132/18 141/17 143/16 145/10 146/4 149/10 149/23 150/4 151/11 153/24 154/1 155/24 156/19 160/23 161/14 161/17 162/8 162/9 163/10 164/6 166/5 168/3 169/9 169/21 169/25 170/21 170/23 171/12 173/22 174/14 175/3 175/11 centre if [1] 169/21 centre's [4] 29/12 83/14 106/12 146/7 centres [17] 35/11 36/22 45/4 49/8 67/5 71/2 72/11 73/24 74/1 84/13 112/5 140/20 151/21 154/23 161/12 161/13 163/9 certain [3] 19/8 116/6 174/7 certainly [10] 42/21 65/10 82/18 90/22 90/25 102/18 118/16 130/10 135/9 148/15 certificate [3] 152/5 155/12 156/4 certificates [4] 152/8 155/8 155/20 156/12

(49) bleeding... - certified

certified [1] 152/13

C 112/3 169/19 chronic [3] 125/21 common [7] 63/15 3/2 4/12 5/9 7/7 21/23 confines [1] 78/18 132/9 140/22 clipboard [1] 91/23 67/5 116/23 120/14 22/22 23/4 28/12 confirm [4] 69/2 77/14 cetera [2] 125/10 chronologically [1] close [2] 104/3 112/8 127/6 134/7 170/22 30/21 31/3 31/18 34/8 108/25 141/9 143/8 closed [1] 82/2 45/15 46/17 47/5 confirmation [3] 39/12 commonly [1] 149/1 chair [3] 172/6 173/9 commonplace [1] chronology [3] 17/23 clotting [2] 31/12 47/23 56/21 58/3 105/2 123/9 132/8 174/25 18/1 85/4 128/14 171/18 60/25 71/12 89/2 confirmatory [2] chaired [1] 101/14 Chwatt [1] 38/8 co [4] 23/2 110/21 communicable [4] 151/15 163/8 163/17 103/19 103/22 Chairman [1] 161/20 circularised [1] 36/22 110/21 112/9 17/8 20/12 22/24 23/7 170/6 confirmed [3] 24/20 change [3] 85/16 69/14 123/25 circulars [1] 147/14 co-authored [2] communicated [6] concentrate/pack [1] 103/7 104/11 26/3 26/4 62/9 93/4 circulated [2] 18/25 110/21 110/21 56/21 **confirming** [1] 34/16 changed [3] 7/20 co-operate [1] 23/2 118/25 150/16 conflating [1] 35/17 165/20 concentrates [37] 4/8 11/17 54/1 circumspect [1] 27/17 co-operation [1] communicating [1] 4/10 5/14 5/15 6/6 conflict [1] 84/4 changes [2] 59/11 circumstances [10] 112/9 130/11 6/15 9/18 15/15 18/21 confusion [1] 124/19 154/7 30/5 30/8 43/24 66/18 | coagulation [3] 58/7 21/17 27/10 27/15 Congress [2] 35/23 communication [10] changing [1] 56/23 94/3 103/7 130/6 109/5 109/7 24/9 48/21 49/13 27/16 27/21 28/4 36/11 characterisation [5] 152/22 154/9 164/17 code [1] 83/4 92/14 92/15 93/12 28/25 30/6 30/19 31/6 conjectural [2] 46/11 44/10 51/24 52/24 cirrhosis [1] 140/22 coded [1] 76/5 93/14 95/5 95/9 31/20 32/7 32/8 32/15 50/24 78/3 148/2 cited [2] 9/12 71/3 coding [1] 103/9 105/24 32/17 33/25 36/20 conjecture [2] 46/9 characterise [2] 47/2 claim [3] 40/10 41/10 coffee [1] 82/5 communications [3] 36/24 42/16 52/6 48/16 52/22 50/19 **cohort [2]** 34/5 150/22 25/20 59/18 172/1 54/24 58/5 58/10 63/8 consensus [1] 165/13 characterises [1] 46/9 community [1] 44/13 63/11 85/15 86/23 consent [24] 2/7 3/12 clanged [1] 82/2 cohorts [2] 90/14 characteristics [1] 90/14 3/23 3/24 4/3 4/4 4/5 clarification [1] 5/8 companies [8] 17/12 157/3 102/14 clarified [1] 78/24 **Colindale [1]** 23/8 127/12 172/21 173/4 concept [2] 51/24 4/11 6/19 6/25 7/1 charge [4] 51/1 52/1 classification [1] 31/9 collation [1] 37/5 173/17 173/22 174/7 120/7 67/8 87/2 89/20 95/7 159/22 160/2 classified [1] 30/7 colleague [1] 43/12 174/23 concern [9] 4/5 18/20 119/20 122/12 122/14 chat [1] 100/25 cleaning [2] 78/20 colleagues [10] 9/3 company [5] 47/9 43/11 92/13 100/21 122/17 151/22 151/23 check [11] 2/10 3/2 34/10 45/1 54/6 66/10 172/25 174/2 174/12 126/22 144/12 163/25 153/17 153/20 154/10 79/21 8/12 10/23 24/17 102/2 102/4 102/6 clear [24] 14/15 27/25 174/13 164/1 consequence [1] 37/22 38/9 86/8 87/25 28/25 36/25 40/19 114/13 141/16 concerned [9] 4/4 comparable [2] 44/22 57/20 101/17 118/13 46/18 55/16 72/12 collected [2] 21/24 43/22 44/3 56/20 45/14 consequences [5] checked [3] 2/16 2/23 73/20 89/24 90/1 80/24 100/13 115/19 5/19 6/14 75/24 109/1 154/4 comparatively [1] 119/22 90/12 91/10 94/7 collecting [1] 154/14 28/17 155/13 163/22 117/13 checking [4] 23/25 97/22 108/3 109/11 college [1] 56/22 comparison [2] 5/12 concerns [3] 84/14 consider [8] 3/7 36/6 38/3 38/12 126/5 114/7 128/24 136/18 colonoscopy [1] 5/16 127/4 160/17 53/16 65/4 66/14 84/5 checks [1] 3/20 142/22 144/9 157/9 170/18 compelled [1] 89/13 conclude [1] 131/7 103/16 137/5 Cheingsong [1] 38/1 158/25 combined [2] 102/1 compiled [1] 154/5 concluding [1] 103/25 considerable [6] Cheingsong-Popov conclusion [1] 46/11 compiling [1] 154/14 clearer [1] 8/4 143/15 26/10 123/4 124/19 **[1]** 38/1 clearly [5] 44/23 51/9 come [16] 6/20 17/1 130/8 144/13 161/5 complaint [1] 127/6 conclusions [1] 41/5 chemotherapy [1] 72/7 138/10 170/19 17/25 36/13 55/1 Complement [1] Concorde [2] 158/2 consideration [1] 104/5 clinic [11] 107/2 55/20 76/2 83/6 83/9 46/15 158/12 81/17 Chief [1] 76/12 112/5 130/22 134/19 85/18 89/25 95/3 complete [8] 5/7 6/16 Concorde trial [2] considered [5] 13/20 child [5] 16/25 68/20 135/7 136/16 143/16 95/13 124/2 160/11 25/16 76/1 91/22 158/2 158/12 17/10 27/8 33/23 70/3 70/7 70/8 143/23 144/5 144/9 105/11 144/25 149/18 161/16 condition [10] 9/9 165/22 children [14] 27/13 113/19 117/18 131/15 168/5 coming [3] 80/21 completed [7] 2/18 considering [2] 14/1 28/8 28/10 28/11 clinical [21] 1/23 25/18 66/24 103/24 133/9 133/17 134/3 127/13 151/6 164/5 28/14 29/16 29/25 149/21 149/25 166/4 135/21 141/3 150/8 16/11 22/7 61/11 62/4 commandeered [1] **consistent** [5] 22/15 34/19 45/19 62/25 63/16 79/11 116/10 80/8 completely [3] 71/17 **conditions [2]** 25/12 51/8 76/16 77/11 68/18 160/25 161/23 119/2 119/19 127/5 commenced [4] 5/11 73/19 80/3 154/19 101/1 162/16 129/12 133/6 134/2 64/14 76/4 77/12 completeness [2] conference [5] 127/14 consternation [1] Children's [1] 161/21 139/21 150/7 157/20 commencement [1] 25/6 88/21 127/24 128/3 173/7 73/5 chimes [1] 99/14 158/1 159/18 159/23 60/17 completion [1] 156/11 174/17 constitute [1] 103/22 Chisholm [1] 32/3 160/3 complex [3] 29/17 conferences [1] 173/5 constituted [1] 11/14 commencing [2] choice [11] 50/25 clinically [3] 30/14 57/22 76/7 131/4 164/4 confidence [1] 149/21 constraint [1] 65/12 63/10 63/18 63/19 123/15 140/19 comment [4] 86/18 complications [1] confident [2] 8/12 constraints [1] 47/11 78/6 84/22 85/23 86/4 clinician [5] 84/16 110/1 110/4 163/3 131/5 86/9 construed [1] 40/18 86/6 89/12 136/5 115/12 131/7 142/22 confidential [5] 76/9 comments [3] 53/6 Comprehensive [1] consultancy [1] 174/1 choices [1] 63/21 160/22 76/13 100/18 103/12 159/25 115/16 150/10 consultant [3] 79/11 choose [1] 86/19 clinicians [10] 8/18 commercial [13] 1/19 comprising [1] 150/3 116/15 143/17 chosen [2] 90/13 53/13 53/14 125/18 13/18 15/14 21/16 157/21 confidentiality [6] consultation [2] 164/5 131/3 142/21 151/21 21/22 23/4 32/7 32/8 98/2 98/9 98/18 99/6 122/7 126/7 Compromise [1] 10/1 Christie [1] 72/25 consultations [2] 156/11 160/2 160/5 32/15 32/17 34/7 100/21 103/10 compulsion [1] 85/20 **Christmas** [1] 73/8 clinics [3] 112/1 36/20 42/15 concentrate [26] 1/8 confined [1] 80/17 79/15 115/3

(50) cetera - consultations

C	Cornwall [1] 163/10	criteria [2] 19/2 20/3	68/4 75/1 92/16 92/21	deferred [1] 83/18	83/20 113/4 116/11
<u>C</u>	correct [10] 28/12	criticism [1] 91/16	93/13 94/19 122/23	deficiency [4] 8/25	121/13 145/12 146/20
consumption [1]	47/2 72/6 74/20 78/2	criticisms [2] 84/14	124/5 132/21 138/11	12/24 13/13 19/18	146/24 158/13
132/15	80/3 86/24 119/9	85/21	149/7	defined [1] 170/19	Desforges [2] 17/15
contact [1] 144/6	120/6 126/15	cross [2] 22/20 73/12	day [9] 73/2 90/4	definite [1] 47/18	35/1
contacted [2] 4/15	correctness [1] 48/15		100/12 100/12 122/8	definition [1] 68/19	designated [3] 112/5
136/14	correlation [2] 1/6	22/20	146/1 146/9 164/3	definitive [6] 121/5	120/10 128/23
contacts [1] 95/3	1/11	cross-referencing [1]	175/18	121/8 123/24 133/1	desired [1] 174/13
contain [2] 22/22 149/5	correspondence [2]	73/12	day-to-day [1] 100/12	136/13 136/19	Desmopressin [1]
contained [1] 147/5	153/10 172/23	cryo [1] 56/19	days [1] 4/9	degree [6] 46/13	52/6
contains [1] 115/16	corridor [4] 81/22	cryoprecipitate [26]	DDAVP [4] 27/8 28/16	117/16 124/19 128/15	despite [3] 91/22
contaminated [3]	90/20 119/1 119/3	5/13 5/16 27/16 28/22	28/17 29/19	140/17 142/25	115/23 138/14
47/24 48/22 109/20	couching [1] 103/5	29/15 29/19 30/16	deal [7] 11/24 56/10	degrees [1] 108/11	destroyed [1] 102/17
contemporaneous [3]	could [34] 2/3 2/4	30/23 31/3 31/6 31/13	86/3 86/9 88/3 88/19	delay [5] 20/15	destruction [5]
41/9 63/18 160/12	9/17 23/10 33/24 39/8	31/18 32/4 32/13	172/15	103/21 117/2 129/15	146/24 147/11 147/16
content [6] 9/5 58/16	41/17 41/18 47/13	32/20 32/22 39/4	dealing [3] 80/5 87/15		147/19 147/22
59/18 60/3 62/5	47/14 49/16 52/15 53/20 54/11 54/16	46/16 46/20 46/24	155/19	delays [1] 170/20	detail [15] 9/24 31/8
172/11		52/5 56/12 56/15 57/1 65/5 89/2	deals [7] 7/18 30/1	delighted [1] 6/6	35/16 37/16 42/9 81/3
context [4] 85/4 92/9	83/15 85/19 85/20 93/9 93/11 94/6 97/1	cryoprecipitates [1]	53/4 87/11 161/1 164/15 165/2	demonstrated [1] 123/12	87/25 90/24 114/24 119/11 144/13 147/1
93/7 102/5	102/17 102/22 102/23	28/10	dealt [2] 121/20	Dempsey [6] 149/12	147/23 167/19 169/5
continuation [1]	103/2 123/22 125/12	cumbersome [1]	148/13	151/7 162/12 162/17	detailed [17] 8/7 14/4
63/20	131/3 131/7 148/14	46/22	Dear [1] 19/17	162/18 164/4	48/10 60/18 99/17
continue [4] 27/17	149/17 151/15 155/15	cup [1] 100/25	death [15] 37/9 99/24	denies [1] 50/22	104/18 136/25 149/6
63/3 63/12 166/19	couldn't [1] 52/12	curious [1] 88/8	137/18 139/6 139/13	Denmark [1] 21/7	152/20 158/13 160/10
continued [2] 7/18	Council [1] 158/3	current [3] 16/11	152/5 152/8 153/3	dental [1] 170/10	164/8 167/23 168/20
63/8	Council's [1] 15/22	32/25 160/21	155/7 155/12 155/19	department [9] 26/11	169/2 172/3 173/12
continues [11] 17/6 20/1 52/4 69/20 82/10	counselled [1] 163/1	currently [3] 36/25	156/4 156/12 158/4	38/19 68/22 92/5	details [16] 33/8
133/18 134/10 147/22	counselling [15]	48/14 92/10	158/17	108/13 114/19 146/2	61/10 68/24 70/12
167/23 168/22 169/4	112/4 113/1 113/5	curtailment [1] 36/5	deaths [1] 98/22	147/6 163/13	70/14 90/16 127/10
continuing [3] 18/1	113/5 113/6 130/18	customary [3] 2/9	debate [2] 57/10 76/3	depend [1] 68/19	134/14 150/1 150/21
65/20 115/8	130/20 139/16 139/18	122/3 128/17	decade [1] 43/4	depended [1] 135/20	151/16 158/17 158/22
contracted [1] 43/16	161/18 162/19 168/4	cytomegalovirus [2]	deceased [2] 152/15	dependent [1] 56/24	165/25 168/16 168/23
contracting [1] 36/19	169/12 169/15 169/18	15/10 21/12	156/5	depends [1] 46/3	detect [2] 121/22
contrary [3] 12/4	counteract [2] 58/6 66/7	D	December [15] 10/6 24/1 24/2 24/17 41/24	deposition [1] 80/1 depressing [1] 42/22	123/22 determine [1] 54/18
103/13 132/12	counts [1] 115/25	Dale [1] 24/9	42/5 42/19 49/8 61/13	depression [1] 139/19	
contrast [4] 61/2	couple [4] 23/10	Daly [1] 37/7	75/11 75/12 141/5	derived [4] 9/18 125/9	
82/21 112/12 112/15	23/15 139/23 164/13	Danish [1] 38/11	141/24 151/7 157/7	163/4 163/19	developed [7] 2/24
contribution [1] 42/10	course [33] 5/17 7/23	dared [1] 118/19	December 1984 [4]	derives [1] 45/11	11/13 49/2 110/1
contributions [1]	8/6 8/13 25/17 37/18	dart [1] 74/8	41/24 49/8 75/11	dermatological [1]	128/13 132/22 158/21
43/14	41/8 54/5 56/6 62/2	data [17] 1/10 37/5	75/12	115/4	developing [3] 7/20
contributor [1] 109/25 contributory [1]	74/21 74/22 82/25	44/17 44/24 48/3 48/8	December 1988 [1]	Dermatologist [1]	85/9 127/6
111/18	84/5 88/15 91/1 96/14	72/7 148/25 149/6	157/7	114/15	development [2] 2/25
control [2] 103/6	101/21 105/16 111/1	150/18 153/18 153/22	December 1992 [1]	describe [2] 6/7	10/12
171/13	121/7 122/19 126/1	154/17 154/18 159/18	141/24	116/24	developments [4]
controversy [1] 161/5	127/25 130/14 132/21	159/23 160/3	decide [1] 44/9	described [13] 9/8	12/2 17/19 39/22
convened [3] 35/12	134/2 136/5 137/4	date [26] 10/7 10/22	decided [2] 61/20	9/23 21/4 29/14 30/13	134/16
74/18 166/14	141/19 146/9 153/7	26/16 35/4 68/7 68/25	88/25	61/22 72/16 81/7	develops [1] 135/16
convenient [1] 83/19	156/16	77/25 87/4 89/24 93/25 111/13 113/12	decision [4] 31/6	102/23 124/16 144/13 146/8 162/21	Devlin [5] 75/6 75/7 84/25 89/25 96/1
conversation [3] 9/21	coverage [1] 35/7 covering [1] 18/4	117/2 119/9 121/21	54/17 61/16 104/21	describes [12] 35/16	DHNI0000049 [1]
94/8 126/14	covers [3] 126/4	126/6 132/17 136/12	decisions [6] 53/16 54/1 54/10 116/9	97/14 120/7 127/12	160/14
conversations [6]	164/10 165/3	141/19 146/11 146/25	164/23 167/11	128/25 144/10 145/25	diagnosable [1]
7/19 57/4 57/10 64/24	Craske [18] 9/4 9/5	149/20 150/13 152/25	declarations [1] 175/4		134/19
99/1 102/3	12/14 12/18 12/23	153/1 159/21	declared [1] 96/10	163/8 174/18	diagnosed [2] 139/17
conversion [1] 47/16	13/2 13/14 13/24 14/7	dated [10] 14/10	declined [1] 103/14	describing [8] 9/5	142/16
conveyed [1] 5/11	14/10 14/24 15/21	14/25 20/10 25/14	decontamination [2]	11/5 34/6 86/14 125/8	diagnoses [1] 124/15
convinced [1] 54/4	16/10 18/24 19/10	66/20 72/19 115/15	170/11 171/2	125/10 146/13 172/20	diagnosis [29] 19/2
copies [2] 14/11	24/5 32/25 37/3	149/11 150/20 160/15	defects [2] 109/5	description [15]	20/16 83/7 83/25 84/2
101/14 copy [2] 157/6 161/10	Craske's [3] 20/9	dates [15] 17/24	109/7	16/11 16/15 30/25	84/10 94/11 95/19
COPY [2] 10/10 101/10	21/10 33/18	61/24 66/19 67/13	defer [1] 90/21	78/14 80/3 81/2 81/15	116/20 117/5 117/9
				(51)	consumption - diagnosis

D 27/2 27/12 27/15 disposal [1] 147/4 10/22 14/3 14/21 16/10 18/24 24/5 159/12 160/6 162/24 33/23 34/4 34/11 disposed [1] 147/10 23/25 26/4 28/18 29/1 32/25 37/3 172/20 172/24 173/6 diagnosis... [18] 35/20 44/7 44/25 disputed [1] 136/20 35/3 37/23 48/2 48/7 Dr Craske's [3] 20/9 173/8 175/2 118/25 120/17 120/25 63/23 71/22 72/10 disruption [1] 63/12 57/7 60/1 83/2 83/6 21/10 33/18 Dr Mayne's [63] 2/1 128/20 130/12 130/18 6/21 8/22 10/9 11/25 141/17 170/21 175/3 disseminate [1] 66/3 88/19 90/15 90/23 Dr Dale Lawrence [1] 132/9 134/15 137/14 Directors' [10] 12/13 disseminated [2] 11/1 95/22 96/21 110/14 24/9 28/5 33/12 34/2 39/13 137/17 138/10 139/21 110/17 110/25 125/12 13/7 18/2 18/10 31/22 128/3 Dr Daly [1] 37/7 42/3 42/25 44/1 44/13 140/13 140/13 144/19 Dr Dempsey [6] 31/25 42/4 42/13 dissemination [1] 48/16 51/6 53/9 53/22 126/2 126/5 150/15 158/24 170/20 63/25 150/4 done [8] 42/6 42/14 149/12 151/7 162/12 54/9 55/5 55/23 57/11 151/23 did [33] 1/17 18/9 distance [1] 61/9 53/20 55/20 95/6 162/17 162/18 164/4 66/17 68/14 68/17 dirty [1] 102/20 19/10 40/15 48/1 55/9 disabilities [1] 79/7 distinguish [1] 72/7 108/10 135/4 156/8 Dr Elizabeth Mayne 70/3 70/21 73/17 57/18 61/7 62/15 disability [1] 50/24 distress [1] 43/21 donor [4] 17/2 21/23 74/12 76/13 78/11 **[1]** 73/1 62/17 63/3 64/6 73/7 **Dr Jones [2]** 144/3 disabled [2] 80/17 distributed [1] 49/7 48/25 163/20 79/18 79/24 81/5 73/10 76/19 83/15 80/20 dividers [1] 145/17 **donors [5]** 5/16 9/13 173/11 86/21 87/18 88/1 86/2 87/10 93/5 96/10 disaster [1] 83/17 do [31] 1/24 3/14 8/5 16/23 47/10 47/15 **Dr Kernoff [1]** 14/13 88/18 91/18 93/3 101/22 103/4 114/17 disastrous [1] 131/4 8/7 14/6 14/11 19/9 doors [1] 82/2 **Dr Lane [1]** 42/18 97/12 101/3 104/18 126/16 130/17 133/8 disciplines [2] 66/11 28/20 33/2 37/1 40/24 dosage [2] 46/22 47/6 Dr Lee [1] 173/11 105/12 105/13 110/18 133/14 138/17 138/19 114/14 47/18 53/16 55/12 dose [3] 5/23 73/4 **Dr Machin [1]** 68/22 117/20 120/22 124/14 151/22 155/24 168/5 discounts [1] 21/11 82/17 86/1 89/12 116/1 **Dr Makris [1]** 162/5 126/13 126/25 136/21 168/11 discovering [1] 94/17 doses [2] 30/15 30/23 109/22 118/16 125/19 Dr Mayne [146] 2/8 136/25 138/11 141/23 didn't [4] 88/6 88/7 discretion [1] 155/24 126/14 127/17 127/18 3/6 3/15 5/2 5/7 6/11 double [2] 101/17 142/24 153/12 156/14 127/24 139/9 discuss [9] 42/5 61/7 132/20 138/22 145/3 157/21 8/14 8/23 10/8 10/14 157/11 158/5 160/8 died [10] 16/17 17/3 87/21 92/5 119/3 146/14 148/6 148/15 double-check [1] 12/14 13/11 14/18 172/6 172/17 173/18 22/9 111/16 113/14 138/17 138/19 141/21 161/14 162/7 14/20 16/6 17/19 18/9 Dr McNulty [2] 143/20 101/17 113/18 113/21 137/23 166/14 doctor [5] 51/16 73/4 doubt [13] 40/13 44/9 19/4 19/12 24/11 25/2 157/1 152/11 152/12 discussed [6] 18/16 73/9 93/25 94/1 56/5 61/10 62/3 69/2 25/25 26/3 26/4 26/20 Dr McNulty's [2] diet [1] 132/15 24/14 52/7 80/25 doctors [5] 43/22 44/3 108/4 110/20 118/18 26/24 29/6 31/15 143/24 155/16 difference [2] 23/20 122/24 139/19 140/2 Dr ME Callender [1] 127/2 162/24 74/1 155/13 166/21 31/25 32/21 33/17 126/18 144/14 34/14 36/14 42/7 discussion [36] 7/12 document [10] 8/21 143/17 different [20] 41/14 42/11 42/17 43/5 46/8 9/2 10/7 11/7 12/6 15/25 48/19 53/1 55/6 down [40] 5/6 12/21 Dr Peter Jones' [1] 47/14 51/24 71/18 75/19 146/16 147/15 16/8 21/8 22/1 23/11 48/23 49/14 50/1 13/11 16/10 17/5 34/23 74/9 80/12 94/13 26/6 26/14 26/15 33/2 17/14 18/14 18/23 147/15 160/12 50/12 52/21 55/16 Dr Rizza [4] 101/14 102/5 111/4 112/19 19/7 21/9 21/10 26/3 documentary [2] 33/3 35/16 60/15 59/21 61/3 64/3 64/9 151/6 152/3 152/20 113/7 117/25 125/17 32/12 33/4 35/22 65/13 175/8 64/20 65/6 70/5 73/3 66/22 67/4 68/21 Dr Scott [2] 33/8 37/8 132/20 132/21 132/22 42/13 55/19 72/10 documentation [5] 74/6 90/19 94/12 70/19 71/24 72/2 Dr Tedder [2] 106/17 134/18 144/21 161/11 76/3 82/24 98/16 8/15 63/18 72/22 96/22 106/4 115/1 72/13 72/19 73/19 108/1 161/19 draft [3] 18/5 157/20 115/6 115/8 122/7 172/10 173/5 124/12 126/8 132/16 74/10 75/10 76/9 78/4 differently [1] 53/21 134/3 136/15 157/20 documented [2] 9/14 133/4 147/18 150/7 78/14 79/25 81/8 82/9 165/19 difficult [8] 44/17 163/5 166/6 168/7 150/9 151/24 155/25 83/21 85/6 85/19 86/9 dramatic [1] 39/21 91/21 120/25 122/21 168/15 170/20 174/21 documents [16] 1/12 157/19 159/10 165/15 86/15 86/18 90/22 draw [8] 18/25 43/25 134/4 134/13 140/23 discussions [24] 5/12 1/16 1/21 20/6 25/8 166/8 166/19 167/9 91/16 92/24 94/5 64/2 82/8 94/6 117/1 155/21 12/11 14/4 19/20 25/9 50/1 70/18 73/13 167/25 174/25 95/13 96/20 97/11 120/2 147/2 difficulties [2] 88/14 36/13 56/10 56/18 97/23 98/1 98/14 96/24 97/8 105/22 Dr [288] drawer [1] 76/10 171/7 57/25 58/15 58/24 157/8 159/12 172/20 98/23 99/19 106/25 Dr Anderson [14] drawn [3] 41/6 113/11 difficulty [4] 32/14 59/16 60/25 61/11 116/11 144/10 145/6 107/14 110/2 110/4 173/16 118/1 87/3 104/1 144/24 62/4 62/6 64/24 75/16 does [10] 5/2 5/3 19/5 110/22 112/23 112/24 dried [2] 27/16 89/2 145/9 146/13 160/10 dire [1] 83/14 102/6 144/2 162/11 46/15 69/3 73/8 76/23 160/18 162/5 162/22 113/4 113/22 115/1 **Drs [1]** 19/10 dire' [1] 131/1 166/8 166/11 166/20 85/8 86/3 86/9 164/9 168/16 168/21 115/11 115/15 116/11 drug [5] 6/10 15/14 direct [1] 105/18 173/1 doesn't [36] 3/14 4/22 171/24 172/2 118/7 120/3 120/17 102/21 116/6 118/6 directed [1] 99/5 disease [15] 20/12 5/17 7/11 31/4 32/16 Dr Anderson to [1] 120/24 123/9 126/11 drug' [1] 118/17 directly [4] 60/13 21/6 22/2 22/24 23/7 32/19 39/11 52/11 160/15 128/10 128/24 129/6 drugs [4] 15/8 21/3 113/18 162/9 162/14 27/7 58/8 60/24 73/8 57/3 57/11 58/12 Dr Anderson's [3] 129/8 130/9 130/16 21/11 23/13 director [8] 14/14 114/16 114/19 134/13 59/14 59/18 59/25 107/5 164/7 165/17 131/2 131/11 134/10 due [6] 47/10 56/5 19/17 113/1 144/3 136/13 136/19 150/23 60/2 65/1 72/6 72/7 Dr Benson [6] 116/15 136/10 138/14 138/17 69/18 81/18 84/5 148/9 160/16 166/5 diseases [3] 17/8 87/23 88/3 89/7 105/9 137/25 144/14 148/7 139/24 139/25 140/6 88/15 170/8 107/3 116/14 108/18 119/1 122/20 175/13 175/14 140/12 141/2 142/13 duplicate [1] 45/5 directors [33] 11/8 dismay [1] 43/10 129/11 131/18 131/19 Dr Bridges [1] 151/7 142/14 143/21 144/4 duration [1] 113/3 12/3 13/5 13/9 13/14 disorder [3] 30/1 136/6 142/1 142/6 **Dr Chisholm [1]** 32/3 149/11 149/25 150/19 during [23] 9/2 10/15 13/24 14/20 19/1 57/19 149/8 142/8 154/15 156/6 Dr Craske [15] 12/14 151/2 151/6 152/20 11/4 32/18 37/22 19/11 19/22 23/1 25/5 12/18 12/23 13/2 175/5 152/23 153/8 153/14 38/22 39/21 40/17 disorders [5] 11/6 25/11 25/16 25/21 13/14 13/24 14/7 30/3 30/7 31/9 58/5 doing [2] 87/3 142/21 155/9 156/21 157/1 41/2 56/18 58/22 25/22 25/24 26/23 disposable [1] 171/17 don't [28] 7/22 8/3 14/10 14/24 15/21 157/6 157/18 159/7 75/12 92/7 92/22

(52) diagnosis... - during

D	92/5	22/15	130/4 132/12 134/3	expand [1] 55/12	F
	elsewhere [10] 71/4	episode [2] 79/2	135/9 136/3 137/25	expect [3] 45/25 88/8	
during [9] 101/23	73/19 73/24 88/1	110/9	140/3 156/10 156/13	143/7	face [4] 169/16
105/9 107/5 113/17	107/25 108/2 112/2	equally [1] 85/20	156/15 158/1 164/14	expectation [3] 64/16	169/16 169/20 169/20
126/10 126/12 127/3	159/7 165/4 174/18	equivalent [1] 71/6	170/24 171/23 173/3	101/9 150/20	face-to-face [2]
134/3 150/24	Elstree [1] 41/24	era [1] 52/17	173/8 175/8 175/9	expectations [1]	169/16 169/20
duties [2] 50/10 50/11	eludes [1] 45/22	Eric [1] 141/16	evidence that [1]	103/14	facilitate [1] 135/5
E	emanated [1] 118/18	erring [1] 86/17	54/18	expected [2] 7/19	facilities [1] 90/9
	emanates [1] 106/16	erroneously [1] 58/10	evident [1] 11/11	29/17	facility [1] 82/5
each [9] 47/9 58/1 59/7 76/4 76/6 83/16	emerge [2] 116/21	error [1] 129/8	evolvement [1] 43/19	expediency [1]	facing [1] 88/14
87/19 96/7 96/8	138/4	essence [1] 99/24	evolving [1] 99/22	122/11	fact [20] 8/16 38/14
earlier [22] 13/20 24/4	emerged [1] 84/6	essential [2] 100/3	exact [1] 167/11	experience [3] 99/11	47/18 59/20 60/2
	emergency [4] 58/11	162/25	exactly [3] 93/10	104/6 117/5	67/10 69/10 69/23
24/19 50/14 54/12 55/19 55/25 56/7	79/13 80/9 81/19	essentially [4] 28/6	104/11 167/3	experienced [1]	71/13 93/19 105/10
61/23 64/21 68/5	emerges [2] 117/10	52/1 63/19 115/11	examination [1] 133/7	104/12	105/15 110/7 113/11
1	117/14	establish [1] 130/22	examined [1] 98/1	expert [3] 51/10 58/20	117/23 117/24 145/3
74/24 75/18 99/17 107/24 109/23 118/2	empathy [1] 139/22	established [6] 38/24	example [31] 25/18	114/16	147/3 148/3 166/4
	emphasise [1] 51/4	71/22 116/6 134/20	30/12 30/19 31/13	experts [5] 59/6 59/9	factor [35] 4/8 6/6
128/16 137/2 138/11	emphasised [1] 51/10	143/16 144/9	48/10 48/11 72/16	115/4 127/3 127/13	6/15 15/8 16/19 21/22
142/25 146/12 earliest [2] 68/3 68/7	emphatic [1] 56/19	estimate [1] 154/7	90/6 90/7 95/8 98/3	explain [2] 31/9 53/19	22/22 23/4 28/4 28/12
early [14] 4/9 10/15	enable [3] 31/5 41/19	estimation [1] 134/17	108/1 115/10 124/4	explained [5] 8/5	31/12 31/20 33/25
11/4 11/8 17/23 28/19	57/5	et [3] 37/25 125/10	124/5 136/22 137/1	102/13 133/8 135/18	36/24 45/15 47/5 49/1 54/24 73/2 73/7 73/18
32/18 34/12 35/5	enabled [2] 67/11	143/8	137/8 137/12 137/18	141/11	54/24 73/2 73/7 73/18 86/23 89/1 109/19
61/21 127/3 134/9	168/7	et cetera [2] 125/10	138/8 138/24 149/25	explains [6] 93/6	
142/13 156/17	enclosed [2] 20/6	143/8	150/14 150/18 151/1	148/4 167/9 170/7	109/24 111/10 128/14 138/17 151/14 157/13
ease [2] 5/22 32/13	149/19	etc [1] 59/11	157/23 159/24 166/9	170/9 171/20	
easier [1] 102/23	encloses [1] 161/10	ethicists [1] 51/10	172/24 173/5	explanation [6] 47/8	157/15 157/22 162/12 170/5 173/7
easily [2] 87/4 142/8	encompass [1] 44/4	Europe [5] 46/17	examples [14] 30/10	80/4 97/13 97/21	Factor IX [3] 73/7
Eastern [1] 98/12	encountered [1]	102/5 124/24 125/10	80/22 109/13 115/11	99/17 134/5	73/18 162/12
easy [2] 31/14 125/1	125/16	125/15	123/6 124/10 136/8	explanations [1] 90/3	factor VIII [14] 16/19
Edinburgh [4] 73/2	encouraged [1] 60/25	even [7] 47/13 47/15	137/3 137/6 138/3	explanatory [1] 56/17	21/22 22/22 23/4
165/4 165/5 167/16	end [14] 11/18 11/20	63/8 73/17 134/13	148/25 149/3 156/21	explicable [1] 71/11	31/12 47/5 49/1
editor [2] 9/25 43/5	20/10 22/8 34/8 40/25	134/13 136/4	157/11	explored [5] 15/3	109/19 109/24 111/10
editorial [5] 17/15	42/24 50/9 54/12	evening [1] 81/19	excellent [1] 145/15	62/23 71/13 73/24	138/17 157/13 157/15
17/15 35/3 38/5 38/6	65/18 81/10 93/6	event [12] 11/3 14/23	Excelsior [1] 25/3	75/7	157/22
educated [1] 55/10	141/5 164/3	62/22 71/4 80/13 82/7	except [1] 102/22	exploring [1] 92/10	facts [1] 73/10
education [1] 99/4	endoscopes [1] 171/4		exception [1] 100/5	exposed [1] 135/15	factual [3] 58/23 65/3
educational [1]	endoscopy [2] 170/17		excess [1] 134/25	exposure [3] 47/14	84/4
174/13	171/3	event in [1] 82/7	excessive [2] 2/25	167/18 170/16	failure [3] 111/17
effect [7] 15/8 15/9	England [6] 10/18	events [1] 43/4	58/6	express [8] 6/19 6/25	153/4 159/4
21/11 54/21 62/8	10/21 17/16 35/1 39/7		exchange [3] 1/14	40/2 78/21 89/20	fair [3] 13/22 65/25
100/12 132/12	44/20	every [8] 2/11 4/25	1/17 1/18	153/17 153/20 154/10	148/2
effective [4] 30/3	enlarge [1] 81/3	28/18 48/3 56/4 80/16	exchanges [1] 172/22		fairly [3] 84/16 124/4
115/24 118/16 135/5	enquired [1] 9/10	83/16 90/4	exclusively [1] 67/7	36/4 40/5 51/9 77/5	152/20
effectively [1] 117/6	enquiries [3] 64/5	everyone [3] 4/19	execution [1] 171/21	78/22 84/14 85/22	fairness [5] 8/14 46/8
effects [2] 58/6	64/12 114/9	54/2 78/5	exercise [14] 1/25	92/14	64/21 85/19 85/21
115/20	ensure [3] 2/23 55/9	evidence [69] 1/16	53/2 67/11 122/21	expressing [2] 32/5	falling [1] 115/25
efficacy [1] 3/1	128/12	5/3 6/3 7/2 8/16 10/20	148/5 160/18 165/8	126/22	false [1] 117/16
eg [1] 98/20	entail [1] 63/12	11/13 22/15 27/20	166/11 166/16 167/6	expression [3] 3/22	familiar [1] 20/25
egis [1] 143/16	entailed [1] 159/16	27/25 28/5 29/2 40/13 54/18 55/2 62/6 63/16	167/8 167/12 171/22 172/1	4/2 40/12	families [3] 60/18
eight [2] 24/20 24/21	entered [1] 76/8 entire [1] 43/15	65/1 65/13 67/10	exercises [2] 160/9	expressly [1] 3/7	83/12 152/16
Eileen [1] 172/14	entire[1] 43/13 entirely [7] 28/12	74/14 75/7 77/19	169/14	extent [7] 35/18 44/11 67/8 71/13 84/16	family [16] 5/4 55/4
either [9] 65/18 73/9	40/19 46/18 109/11	83/22 83/24 84/1	exhibits [2] 143/12	148/6 151/21	62/7 65/2 69/15 69/19
92/4 104/3 105/8	114/7 144/9 151/19	84/12 84/13 84/20	147/2	Extern [1] 80/15	69/24 73/5 84/8 93/20
125/12 128/1 164/23	entitled [5] 38/7 40/2	91/6 91/9 92/12 93/15	existed [2] 40/14	extra [1] 174/14	94/4 95/3 95/6 104/25
174/20	59/24 75/5 98/20	95/18 105/12 107/23	173/21	extreme [2] 98/8	105/7 156/8
elapsed [1] 122/4	entry [1] 91/23	110/17 110/18 111/8	existence [5] 22/16	127/7	far [6] 17/7 79/16
element [1] 40/13	envisage [1] 63/9	116/21 119/12 121/1	120/9 131/13 131/21	extremely [2] 102/17	80/21 121/24 127/22
elevation [1] 140/7	enzymes [1] 140/7	123/2 124/14 125/13	154/2	164/4	159/19
Elizabeth [1] 73/1	Epidemic [1] 10/13	125/17 127/22 128/2	existing [2] 28/6		fashioned [1] 82/1
else [3] 46/23 54/2	epidemiological [1]	129/18 129/25 130/3	62/21		fate [2] 43/11 44/1
	-1				
·	·	·		·	(52) during fot

(53) during... - fate

-	00/40 00/7 00/40	f	40014 405145 40010	427/40 420/5 420/7	474/04
<u>F</u>	83/10 86/7 90/13 92/15 101/19 101/19	found [14] 38/22 38/23 52/7 65/14	160/4 165/15 166/3 166/8 167/7 167/9	137/16 138/5 138/7 146/21	174/21 growing [2] 20/11
fatigue [1] 80/24	106/13 114/25 117/3	67/12 68/14 73/1	171/1 171/23	gives [17] 30/19	39/17
fault [2] 43/22 128/6	117/21 117/22 117/23	78/10 109/20 115/23	Furthermore [1] 47/8	30/25 49/6 59/12	guarantee [1] 56/3
favour [2] 5/25 57/11	120/3 124/7 137/10	125/4 134/4 146/13	future [10] 9/17 87/4	74/25 80/22 85/3	guess [1] 52/15
fear [1] 156/2	139/24 145/6 152/19	168/10	104/12 114/6 121/16	134/21 158/12 158/16	guidance [2] 147/6
features [1] 22/7	158/9 159/2 160/17	four [6] 68/2 113/20	123/20 125/4 128/15	158/22 165/25 166/10	171/1
February [14] 18/3	165/9 166/11 173/19	120/21 140/6 159/3	141/15 168/12	166/13 166/15 167/7	guide [1] 17/18
18/7 18/11 35/10	Firstly [1] 1/4	160/25		168/23	guidelines [2] 163/13
35/17 67/20 67/23	fit [5] 10/6 76/23	fourth [4] 98/15	G	giving [9] 16/11 34/7	163/15
67/24 68/4 68/4 92/19	141/21 142/1 142/6	113/17 114/1 138/4	gain [1] 174/4	74/14 78/14 83/7	guilty [2] 43/22 44/8
94/21 153/2 157/17	five [5] 16/17 22/8	fractionation [2]	gained [1] 102/1	118/2 150/21 152/21	
February 1982 [1]	124/9 128/9 150/22	17/12 173/13	gap [1] 135/10	169/18	<u>H</u>
157/17	five years [1] 124/9	France [1] 43/7	gastroenterology [1]	glad [4] 92/18 93/1	had [118] 2/23 9/9
February 1983 [3]	flag [1] 164/12	Francisco [2] 9/10	112/10	93/8 93/11	11/12 11/13 12/23
18/3 35/10 68/4	flows [1] 67/3	17/4	gathered [1] 128/3	glass [1] 81/25	13/14 13/18 13/25
February 1984 [1] 68/4	focus [1] 172/16	frank [2] 75/15 161/20	gauge [1] 161/11	global [1] 100/9	15/21 16/18 16/25
February 1989 [1]	follow [7] 5/17 39/11	Fraser [2] 1/9 81/21	gave [7] 33/8 55/25	go [188]	18/21 26/9 30/12 31/2
153/2	52/11 70/5 154/15	free [1] 160/2	59/7 78/6 100/1	goal [1] 50/22	37/13 41/4 43/6 45/14
Federation [3] 18/17	167/20 171/24	freeze [2] 27/16 89/2	100/21 100/23	goes [11] 11/23 24/5	47/25 54/3 56/20
35/23 36/11	follow-up [1] 70/5	freeze-dried [2] 27/16		27/18 32/12 35/5	56/23 57/11 57/12
feel [1] 126/16	followed [3] 62/20	89/2	general [24] 27/5	37/15 71/10 90/4	58/24 59/22 61/1
feeling [4] 40/17	145/16 168/17	freezer [1] 56/25	31/16 44/3 50/21	119/24 166/7 167/19	61/10 62/4 67/12 72/8
43/10 140/12 143/9	following [20] 12/25	frequency [1] 34/16	57/17 62/3 80/18	going [25] 1/3 1/16	73/1 78/25 79/2 79/12
fellow [1] 129/16	13/7 21/1 26/22 27/5	frequently [1] 2/16	87/15 99/10 100/15	6/17 7/22 8/15 9/23	80/4 80/8 80/20 81/12
felt [10] 4/14 75/14	36/19 39/14 46/9	fresh [1] 108/12	104/17 114/18 119/25	18/25 37/15 41/22	82/1 82/2 85/16 86/5
124/1 125/2 125/7	56/17 82/14 105/2	Friday [1] 161/9	125/9 130/12 130/13	42/9 49/25 55/20 56/1	86/6 86/22 87/3 88/25
139/22 156/3 162/13	124/8 139/5 161/19	fridge [1] 56/25	137/7 144/16 145/2	83/6 86/8 102/7 117/7	89/21 90/10 91/21
162/23 167/1	167/7 168/4 168/22	Friedman [1] 11/1	146/14 147/25 168/6	129/4 147/1 148/24	93/20 95/13 95/15
few [11] 33/18 49/8		Friedman-Kien [1]	168/7 168/10	160/13 164/11 164/19	95/16 97/10 97/12
58/3 69/4 90/18		11/1	generally [14] 38/17	166/17 169/5	100/4 101/20 102/4
110/22 116/13 148/13	67/2 80/4 106/1	friends [2] 100/1	77/4 97/25 99/7 113/6	gone [1] 31/8	102/6 103/2 103/15 103/24 104/2 104/12
163/9 165/18 168/2	footnote [3] 10/18	100/14	119/4 125/13 125/20 129/19 130/6 141/13	good [3] 83/11 130/22	108/10 109/7 109/23
field [1] 43/14	23/23 24/8	frightened [1] 100/1	142/7 148/11 158/7	145/17	109/24 109/25 110/2
fifth [2] 77/25 98/16	footnoted [2] 10/17 50/9	from [178] fulfilled [1] 66/15	generation [1] 117/3	got [4] 48/9 148/3 148/12 152/19	113/14 113/21 114/19
figure [7] 24/12 24/13	footnotes [1] 23/22	full [7] 73/11 74/1	generic [1] 149/5	Gottlieb [1] 10/19	119/22 120/14 121/1
24/14 24/18 24/19	force [2] 24/9 78/25		genito [1] 108/22	GP [3] 96/4 98/4 98/8	123/13 123/14 125/21
33/20 44/22	foregoing [1] 39/16	156/16	genito-urinary [1]	grade [1] 114/3	128/13 131/16 131/19
figures [4] 5/14 44/21	foresee [1] 131/4	full-blown [1] 73/11	108/22	graduate [1] 82/4	132/3 132/6 132/9
45/11 46/19	foreshortened [1]	full-time [1] 156/16	genitourinary [2]	Grammatically [1]	133/12 133/12 133/16
filed [1] 145/18	70/8	fully [2] 124/21	111/24 112/8	125/12	133/24 134/2 135/15
filing [2] 76/10 145/16	forget [2] 71/18 71/19		gentleman [1] 140/25	granting [1] 115/18	135/24 137/23 138/22
filter [1] 155/25	forgot [1] 73/9	function [10] 3/3 3/6	Georgia [1] 22/25	grateful [2] 149/17	139/17 140/7 142/15
final [5] 45/20 117/14	form [14] 8/3 18/23	119/24 120/10 121/2	get [2] 8/5 94/19	151/15	143/9 145/23 149/16
128/20 167/10 168/9	20/5 25/7 25/16 25/18	131/14 131/16 131/21	getting [2] 32/14	gratitude [1] 78/23	154/11 156/19 157/2
finally [5] 3/2 100/3	81/24 89/1 107/2	132/25 141/15	174/16	grave [2] 39/17 43/11	159/4 160/18 162/5
100/20 101/8 169/22	149/14 149/14 149/19	funding [2] 159/12	gifts [2] 174/12	great [3] 35/9 35/24	163/7 165/13 170/5
financial [3] 47/11 65/11 174/6	149/25 150/21	174/19	174/13	100/21	170/14 170/16 170/18
1	formal [1] 61/20	further [48] 7/12 21/8	give [7] 51/17 86/4	greater [1] 44/21	171/9 172/2 172/20
find [8] 13/3 56/2 89/14 93/9 93/11	formally [1] 158/25	22/1 35/16 35/16 36/2	87/2 96/15 134/14	greeted [1] 56/19	175/5
149/15 151/13 173/24	format [2] 100/23	41/23 45/3 60/15	149/19 151/20	grew [2] 24/24 127/5	Haemarthrosis [1]
finding [1] 75/25	102/11	69/17 70/5 72/21	given [37] 3/10 3/16	group [26] 11/15 13/8	73/9
findings [2] 25/12	formed [1] 114/18	83/20 88/20 95/8 96/2		15/22 34/9 45/13	haematological [1]
124/2	former [1] 125/14	96/23 105/22 109/3	38/8 39/6 46/23 48/18	45/17 45/18 45/21	2/24
first [44] 7/6 9/1 14/7	formerly [1] 159/22	115/3 117/10 122/1	58/3 58/6 68/10 69/10	46/4 48/1 54/24 57/13	haematologist [2]
14/24 18/19 20/7	forming [1] 96/19	122/2 124/8 124/12	69/11 70/12 73/1	59/4 61/17 71/21	79/11 100/7
22/13 33/16 37/9 48/4	forms [4] 2/17 39/24	126/8 129/5 132/16	73/18 78/1 82/23	71/22 71/25 83/1	haematology [5]
55/6 61/7 65/15 67/14	149/15 149/21	135/25 137/3 137/6	84/22 86/19 87/8 88/1	83/21 98/12 100/4	68/22 79/11 108/13
67/15 67/16 67/17	Fortunately [1] 49/5	141/22 147/18 150/7	100/14 111/4 118/10	101/18 101/22 102/11	146/3 158/14
67/19 68/3 70/10	forward [3] 102/9	150/9 157/8 157/19	121/3 122/23 123/6	160/16 166/21	haemophilia [84] 1/7
	151/2 162/14	158/17 159/2 159/7	132/17 134/8 137/3	groups [2] 76/2	2/10 5/1 9/11 11/7
	<u> </u>				/54) fatique - haemonhilia

(54) fatigue - haemophilia

Н Hamilton [3] 81/8 18/3 held [12] 25/24 42/4 88/23 120/24 HCDO0000517 [3] 56/10 57/25 58/15 haemophilia... [79] Hamilton's [2] 81/15 19/13 20/8 25/15 59/3 61/17 74/5 78/16 11/11 12/3 13/4 13/6 HCDO0000524 [1] 143/5 78/17 79/1 157/16 13/9 18/17 19/1 19/16 hand [1] 162/2 71/20 help [3] 114/4 127/21 22/6 23/1 25/5 25/20 handful [4] 96/23 HCDO0000557 [1] 169/15 25/21 27/7 28/7 29/5 123/7 148/12 157/11 14/9 help-lines [1] 169/15 31/22 31/24 34/1 34/3 HCV [13] 121/22 handled [1] 112/7 helping [1] 10/7 34/7 34/24 35/9 35/22 handwriting [1] 98/7 121/23 124/21 126/10 helps [1] 85/3 36/3 36/11 36/22 126/12 126/16 127/4 Hemofil [1] 172/25 handwritten [2] 37/12 37/13 40/15 128/8 128/20 129/8 hence [2] 97/20 124/2 hepatology [3] 144/5 145/14 152/7 42/3 43/14 43/20 44/7 happen [1] 125/3 130/18 134/5 135/4 hepatitis [102] 1/24 44/12 44/18 44/25 3/3 3/7 3/20 6/24 7/13 happened [5] 43/6 **HDN [1]** 16/25 45/25 50/23 52/8 64/11 140/24 157/10 he [38] 9/11 12/23 8/10 12/18 13/2 14/17 53/14 58/4 58/14 59/5 13/2 15/7 15/10 15/15 172/4 15/18 15/19 15/22 59/7 60/8 67/5 71/21 happened in [1] 43/6 21/11 21/12 21/14 17/11 19/20 21/18 73/17 74/1 75/6 75/14 happy [4] 3/12 3/23 21/18 21/25 22/4 22/4 22/18 27/10 37/6 76/12 108/21 109/2 3/25 4/7 22/14 22/19 23/5 24/8 50/12 50/15 55/11 112/17 117/7 141/17 harm [1] 138/23 49/6 51/18 73/1 73/7 58/22 59/17 107/9 142/21 143/15 144/5 has [43] 5/4 6/11 10/4 73/10 80/24 93/10 116/19 116/23 116/25 149/10 149/23 150/4 22/25 24/11 43/20 93/10 96/10 123/14 117/9 117/21 118/21 153/24 156/19 159/14 118/25 119/4 119/6 49/2 49/10 51/17 123/15 123/17 124/1 159/15 161/8 161/12 53/12 54/19 62/3 64/9 128/22 129/15 129/17 119/20 120/4 120/7 161/17 162/8 162/9 65/3 65/14 70/7 70/8 140/7 144/3 148/9 120/11 120/11 120/12 162/22 165/16 166/21 72/22 73/7 73/10 159/4 162/25 120/13 120/17 120/19 172/8 175/3 175/11 73/21 83/23 84/6 He refers [1] 22/4 120/25 121/4 121/5 haemophilia A [3] 84/11 84/15 93/15 121/18 123/13 123/22 he's [1] 33/2 27/7 37/12 45/25 head [2] 38/13 79/10 126/24 128/23 129/21 94/4 94/15 96/7 96/20 haemophilia B [2] 129/25 130/23 130/25 98/1 99/15 112/7 headed [1] 150/2 37/13 73/17 116/6 116/19 116/23 heading [12] 10/12 131/13 131/19 131/24 Haemophilia/Hepatitis 15/3 16/8 32/2 32/25 132/5 132/6 132/19 124/14 136/3 140/7 **[1]** 143/15 148/9 152/23 162/12 50/10 70/23 75/11 133/1 133/9 133/13 haemophiliac [14] 170/25 107/15 109/3 111/20 133/15 133/17 133/20 9/19 11/18 26/16 has provided [1] 65/3 150/10 133/23 134/25 136/22 34/19 37/9 39/18 hasn't [1] 49/11 health [17] 6/14 22/25 137/14 137/22 137/24 43/16 44/6 69/6 hasten [1] 8/18 23/8 26/12 38/19 138/15 139/6 139/12 106/12 111/15 115/12 have [187] 41/20 98/12 103/23 139/24 140/9 140/14 140/4 158/19 having [25] 1/9 4/24 119/3 138/18 146/18 140/16 140/22 141/8 haemophiliacs [27] 22/1 37/14 37/20 147/6 163/13 169/25 141/12 141/14 141/24 11/12 11/14 13/17 70/11 71/2 73/17 170/4 170/8 170/18 142/16 143/2 143/6 16/15 17/21 21/2 78/23 79/17 79/20 hear [2] 103/14 143/15 144/20 153/4 23/12 23/23 26/10 106/14 118/24 119/7 137/24 153/11 156/2 156/24 29/5 33/5 33/20 36/18 119/13 127/4 128/23 158/20 158/20 158/24 heard [10] 54/19 38/22 50/15 52/13 134/5 138/16 144/25 77/23 84/11 92/12 159/5 159/5 159/9 52/17 78/6 86/16 147/25 151/12 156/15 94/23 95/25 125/13 173/14 174/17 108/9 108/16 111/21 142/7 142/21 170/25 Hepatitis A [1] 133/15 172/12 172/13 172/22 158/24 173/8 112/14 112/16 140/18 HCDO0000 [1] 71/15 hearing [2] 92/8 hepatitis B [10] 15/18 | 173/9 174/18 174/24 151/8 152/9 HCDO0000003 [1] 122/25 15/19 22/18 107/9 haemophiliacs with 25/23 hearings [7] 13/20 133/9 133/13 141/14 **[1]** 112/14 HCDO0000054 [1] 32/10 74/7 74/15 75/8 156/24 158/20 159/5 haemophilic [5] 18/20 150/18 85/2 96/1 hepatitis C [50] 8/10 47/7 58/2 97/20 113/9 HCDO0000153 [1] heat [10] 49/5 49/7 116/19 116/23 116/25 half [21] 15/2 16/5 150/25 85/13 85/25 102/18 117/9 117/21 118/21 20/19 20/20 29/8 30/2 HCDO0000270 [1] 109/19 109/24 110/23 118/25 119/4 119/6 33/15 38/15 57/15 26/25 111/6 111/9 120/4 120/7 120/13 65/15 67/16 75/10 120/17 120/19 120/25 HCDO0000273 [1] heat-treated [7] 49/7 81/6 89/15 91/12 85/13 85/25 109/19 25/10 121/5 121/18 123/13 99/20 121/13 139/4 HCDO0000394 [1] 110/23 111/6 111/9 123/22 126/24 129/21 148/17 155/18 173/20 heated [2] 151/14 129/25 130/25 132/6 41/25 halfway [7] 12/21 16/8 HCDO0000410 [1] 132/19 133/1 133/23 151/18 26/15 33/2 33/3 115/1 12/12 Heathrow [1] 25/3 134/25 136/22 137/14 133/4 HCDO0000411 [1] heavy [1] 82/1 137/22 137/24 138/15

highlighting [1] 42/2 highly [1] 95/18 141/12 141/24 142/16 Hill [1] 161/20 him [11] 13/24 42/19 69/9 69/24 73/9 93/4 93/9 93/10 93/11 96/12 130/18 himself [1] 96/9 hindsight [3] 40/22 53/25 63/9 hints [1] 94/5 his [28] 16/24 33/8 |hepatology/haemophi| 42/19 43/13 43/14 69/15 69/24 69/24 72/22 72/23 73/2 73/5 78/25 85/2 87/12 93/5 96/11 103/15 103/19 103/22 113/18 129/16 129/18 140/3 140/7 140/9 158/13 159/4 historic [2] 80/15 98/20 historical [2] 81/22 147/20 history [1] 146/21 HIV [106] 1/25 6/24 8/2 9/1 10/9 12/1 19/5 38/18 40/10 43/15 43/19 44/12 44/19 104/19 104/21 113/24 45/13 45/16 46/6 47/24 48/5 49/16 116/12 120/17 124/16 50/18 53/8 54/16 55/11 58/20 61/7 62/18 63/5 64/7 66/8 66/13 67/13 68/14 70/4 70/7 70/11 70/23 143/22 144/10 144/13 70/25 74/17 74/21 74/22 74/25 75/21 77/8 78/5 78/7 78/17 156/15 156/17 156/18 78/22 80/2 84/10 84/22 86/16 86/22 164/10 164/14 164/16 87/17 87/22 89/3 89/22 95/12 95/15 166/18 167/12 171/19 95/19 98/11 99/22 99/23 100/3 101/12 102/14 105/14 106/23 106/25 107/10 107/17 108/19 109/1 109/14 56/9 72/24 76/19 78/3 109/21 110/7 110/19 111/17 111/18 111/21 112/5 112/15 112/25 120/23 124/15 132/17 113/8 113/19 113/23 114/8 114/11 114/20 115/5 115/13 115/18 115/24 116/7 122/13 142/12 150/15 151/8 151/11 151/12 152/9 152/12 154/18 155/12 156/2 156/25 158/21 HIV litigation [1] 12/1 HIV-related [2] 70/11 152/12

139/6 139/24 140/9

140/14 140/16 141/8

143/2 144/20 153/11

158/20 159/5 159/9

Hepatologist [1]

hepatologists [1]

144/11 144/16

her [101] 3/24 7/17

24/12 26/20 27/25

30/11 31/16 34/2

34/10 35/18 36/7

36/14 44/14 45/11

48/17 48/20 49/14

52/23 55/19 56/2

56/12 58/19 58/21

61/22 62/10 64/12

76/10 80/3 95/15

95/15 96/20 97/14

97/16 99/7 104/19

114/8 115/2 115/16

125/8 125/10 127/2

129/1 130/24 133/19

134/25 137/1 141/2

141/9 142/15 142/18

145/6 145/12 145/13

153/9 153/9 153/10

158/7 160/10 164/9

164/20 165/3 166/4

172/3 172/7 172/11

here [18] 5/3 35/18

82/22 94/4 108/5

110/20 118/7 120/23

150/19 151/1 151/6

hexagonal [1] 81/15

high [2] 46/23 171/4

higher [1] 18/19

highest [1] 43/13

highlighted [1]

172/19

hers [1] 144/12

herself [3] 44/8

142/20 169/16

64/16 67/4 72/3 72/4

7/24 12/2 18/12 19/5

28/1 28/2 29/6 29/12

lia [1] 144/5

174/17

143/17

144/6

(55) haemophilia... - HIV-related

37/21 48/21 64/11 I had [11] 61/10 80/4 23/16 24/12 24/14 35/15 71/13 91/5 Н 64/17 66/12 67/1 97/10 97/12 102/4 24/17 24/24 28/12 105/13 138/4 148/12 HIV/AIDS [2] 9/1 68/16 69/13 74/23 103/2 103/15 104/2 37/24 39/19 41/14 i.e [5] 75/23 77/10 99/22 93/20 98/5 106/1 138/22 139/17 145/23 45/9 48/2 49/13 51/10 102/20 128/22 174/15 hold [3] 61/16 123/20 106/12 106/21 I hasten [1] 8/18 52/3 54/21 63/24 lan [1] 81/21 146/20 HTLV-III [12] 8/19 I have [14] 31/8 33/14 65/25 66/11 66/16 ICU [1] 58/11 holds [1] 7/2 37/17 37/21 48/21 43/13 61/10 63/7 67/6 67/9 71/3 71/23 idea [1] 83/11 home [26] 2/15 2/18 64/11 64/17 66/12 69/14 80/25 96/11 72/12 73/21 74/9 identification [3] 2/21 3/5 4/13 4/16 68/16 69/13 74/23 113/11 116/1 125/19 78/13 80/9 85/19 37/17 52/23 111/2 5/11 7/7 7/9 32/4 87/14 91/23 92/8 95/4 93/20 98/5 141/11 161/11 164/4 identified [15] 7/16 45/13 45/17 45/18 human [1] 69/10 I indicated [1] 116/13 95/10 95/24 101/1 42/11 73/13 106/2 45/21 45/24 46/5 47/1 I just [6] 1/25 77/14 humanitarian [1] 102/9 110/2 110/6 106/3 106/7 106/14 47/25 60/17 60/19 110/7 110/20 116/5 43/15 80/13 97/22 147/2 107/14 108/16 119/8 72/4 72/7 83/13 105/9 humanity [1] 156/3 119/11 120/12 120/21 129/9 143/7 151/4 155/6 105/9 135/21 I know [1] 154/12 130/9 136/20 139/1 hundred [1] 109/6 160/23 163/10 homosexual [4] 9/10 husband [1] 127/2 I may [2] 40/25 139/11 139/17 141/8 identify [2] 4/22 10/3 11/2 17/2 Hyate:C [1] 173/2 163/22 143/3 145/7 152/18 167/21 homosexuals [3] 11/6 I mention [1] 18/8 154/15 155/1 157/1 identifying [1] 70/13 13/16 34/18 I might [1] 83/5 158/25 159/1 159/24 identity [1] 110/6 hoped [1] 162/18 l agree [1] 80/3 I move [1] 1/24 164/3 171/11 if [279] hoping [1] 115/2 l agreed [1] 100/3 I thought [2] 81/2 ignorance [3] 43/23 I must [1] 2/11 horrific [1] 9/15 l also [2] 102/5 90/17 44/8 156/1 I myself [1] 92/5 hospital [29] 7/9 28/9 104/13 III [21] 8/19 37/17 I necessarily [1] 56/3 I told [1] 95/15 45/7 66/22 68/23 72/8 I am [4] 7/22 152/8 I need [2] 37/22 I travelled [1] 124/22 37/21 48/21 64/11 72/24 72/25 73/21 163/22 164/10 148/12 I tried [1] 124/24 64/17 66/12 67/1 74/8 74/19 78/18 79/3 I arranged [1] 89/17 I needn't [2] 38/14 I understand [1] 68/16 69/13 74/23 79/13 80/6 81/14 l assume [1] 61/15 93/20 98/5 106/1 167/16 110/5 81/20 81/22 89/10 l attach [1] 159/21 I note [4] 28/18 61/14 I want [3] 85/12 106/12 106/21 163/7 102/11 108/13 111/25 I attended [1] 61/14 163/7 163/16 168/14 96/22 148/11 117/19 160/7 112/6 128/10 139/9 I can [13] 8/12 30/8 I was [9] 9/15 56/19 I omitted [1] 99/16 171/25 143/18 161/22 163/11 55/12 55/17 56/2 I only [1] 89/22 95/12 103/25 124/21 illness [5] 149/14 170/10 82/17 87/25 96/22 I read [1] 51/8 129/4 134/6 138/14 150/5 152/12 158/21 hospitality [1] 42/20 97/8 121/24 144/21 I recall [2] 58/5 75/19 139/21 158/22 hospitals [3] 73/25 159/19 173/24 I refer [1] 82/6 I wasn't [3] 95/13 illogical [1] 43/24 160/17 162/7 I can't [5] 8/10 38/4 I referred [2] 1/13 139/10 139/16 illustrate [1] 30/8 hotel [3] 16/3 25/3 38/12 56/3 88/11 imagine [1] 92/21 118/2 I well [2] 44/23 104/5 174/17 I remain [1] 54/4 I cannot [4] 9/8 61/9 I will [7] 7/3 8/12 38/9 immeasurable [1] hour [1] 148/17 63/9 82/11 99/19 101/17 141/21 I remember [1] 43/20 hours [1] 113/3 I confirm [1] 69/2 115/19 164/12 immediate [1] 111/5 house [2] 93/5 95/13 I continued [1] 63/8 I remembered [1] I wish [1] 54/2 immediately [2] 82/14 how [32] 26/2 39/8 I did [1] 126/16 81/17 I would [5] 30/22 101/11 51/15 64/17 66/12 I didn't [1] 139/9 I say [8] 72/5 93/15 103/16 115/25 118/18 | immense [2] 27/22 76/23 82/11 91/24 I discussed [1] 105/11 124/9 135/24 139/19 28/3 93/4 95/20 97/21 162/24 150/12 169/3 172/2 I'd [1] 145/23 immobilisation [1] 100/2 104/11 106/23 I do [2] 55/12 82/17 I'II [12] 6/20 11/24 I seem [1] 79/9 52/19 111/20 111/21 114/7 I don't [18] 7/22 8/3 17/25 25/6 36/13 immune [8] 8/25 9/9 I should [32] 4/24 124/21 131/4 134/15 10/22 23/25 29/1 35/3 6/10 6/16 12/8 18/4 48/19 54/25 74/8 12/24 13/13 19/18 134/24 138/21 139/18 57/7 60/1 83/2 83/6 19/4 20/20 32/24 57/7 77/21 89/14 123/7 34/17 46/14 159/13 148/4 148/15 151/13 88/19 90/23 95/22 64/2 67/3 70/10 73/18 160/11 immune-deficiency 152/9 155/3 161/11 96/21 110/14 110/17 81/3 83/22 87/14 I'm [38] 1/3 1/16 8/15 **[1]** 12/24 163/8 164/22 169/2 125/12 126/5 88/17 91/10 92/24 9/23 14/21 37/15 38/4 immunity [3] 34/24 however [20] 5/21 I doubt [2] 118/18 99/15 107/13 117/16 40/23 42/9 48/2 48/13 38/7 64/18 19/9 21/6 26/1 40/4 139/19 118/1 118/20 118/23 49/25 54/21 55/20 immuno [3] 15/9 16/2 41/3 45/20 46/21 54/4 I draw [1] 43/25 120/2 138/8 142/22 56/1 56/9 74/6 77/21 24/14 56/16 61/14 68/19 I emphasise [1] 51/4 145/4 145/9 149/17 83/6 86/8 86/8 92/11 immuno-suppressive 80/14 81/1 87/1 I enquired [1] 9/10 94/23 95/22 96/21 157/10 **[1]** 15/9 102/16 105/20 115/25 I explained [1] 8/5 I speculate [1] 46/12 107/20 114/23 139/3 immunodeficiency [2] 155/12 168/5 I found [2] 78/10 I summarised [1] 140/2 146/22 146/25 10/21 16/9 HSOC0010892 [1] 168/10 51/21 148/24 152/10 160/12 immunoglobulin [1] 115/14 I suspect [1] 88/5 I gave [2] 100/1 164/18 166/16 169/4 163/19 **HT [1]** 7/9 100/23 I take [1] 2/20 172/15 immunological [1] HTLV [16] 8/19 37/17 I guess [1] 52/15 I think [63] 14/12 I've [8] 8/12 33/15 36/2

112/10 imparting [1] 104/1 imperative [1] 2/22 implementation [1] 50/25 implicated [8] 49/4 110/13 160/24 161/24 165/14 168/11 168/25 170/15 implication [2] 12/4 16/20 implications [3] 14/1 127/4 163/17 implied [1] 154/9 imply [2] 3/19 3/21 importance [1] 99/6 important [10] 82/8 85/9 87/21 88/16 98/19 104/10 124/1 135/12 155/10 155/13 imported [3] 27/14 27/21 28/24 **imposition [1]** 43/23 impossible [2] 46/22 134/14 impracticable [2] 47/1 47/3 impractical [1] 50/21 impression [4] 6/8 80/18 84/21 118/5 imprisonment [1] 43/9 incentives [1] 174/6 incidence [4] 18/19 72/3 72/11 80/10 incidents [1] 58/5 inclined [1] 40/23 include [3] 16/6 108/18 109/11 included [9] 5/12 14/18 14/20 16/22 19/11 26/24 45/20 109/10 131/3 includes [1] 160/25 including [9] 13/16 14/12 17/1 21/1 44/8 76/7 101/2 127/13 157/18 incorporated [1] 48/25 incorrect [2] 66/7 97/12 incorrectness [1] 121/20 increased [4] 27/9 47/15 47/16 80/10 increasing [3] 11/17 34/16 66/9 incubation [2] 17/6 22/4 indeed [6] 6/5 41/2

immunology [1]

(56) HIV/AIDS - indeed

78/17 137/22 137/24 127/11 76/19 91/8 162/18 163/1 165/14 17/16 17/18 22/23 140/9 168/11 170/16 171/9 internationally [1] isolated [1] 121/18 24/14 24/24 25/3 indeed... [4] 42/21 infectious [4] 33/24 171/10 171/16 122/11 issue [21] 21/18 34/21 35/2 39/8 49/8 107/5 142/20 153/10 107/3 114/15 116/14 informing [10] 36/23 intervals [3] 2/12 2/22 42/23 44/11 56/3 54/25 57/13 61/18 indicate [3] 39/16 infectivity [1] 100/16 91/17 116/20 130/18 98/21 73/23 88/19 95/9 61/25 67/14 67/22 46/19 158/6 inference [3] 94/6 161/17 162/9 163/15 interview [1] 75/13 96/24 103/23 105/12 67/22 67/22 68/8 indicated [7] 18/18 96/15 154/16 163/18 163/24 167/17 into [13] 13/15 22/23 118/21 126/9 139/24 69/10 69/11 74/5 37/11 63/8 91/5 inflammation [1] infrequent [1] 28/17 31/8 49/1 65/18 65/23 151/19 154/21 154/22 74/19 75/1 76/4 76/18 116/13 133/24 134/12 76/9 92/16 103/11 155/7 155/19 157/4 76/22 77/9 77/13 132/11 infusion [1] 52/17 indication [2] 31/11 influenced [1] 61/19 inhibitor [3] 3/1 123/23 125/19 141/21 161/2 170/7 81/12 89/9 98/4 99/18 159/6 influenza [1] 80/10 128/13 157/14 153/7 issued [2] 62/20 101/20 152/4 160/15 indicative [1] 129/12 influx [1] 81/19 inhibitory [1] 80/18 intravenous [2] 15/13 | 159/22 161/9 164/8 165/10 indirect [1] 105/20 issues [7] 50/1 65/4 inform [7] 100/10 initial [1] 20/16 21/15 166/12 170/2 individual [29] 30/5 131/23 155/14 161/4 Initially [2] 81/15 introduced [2] 119/16 87/21 92/9 98/2 January 1983 [2] 35/2 48/11 51/18 57/8 62/7 113/8 161/4 163/6 167/1 146/11 138/18 171/25 68/8 72/6 74/13 79/15 83/1 informal [5] 9/2 61/10 injection [1] 5/22 introducing [2] 146/8 it's [100] 9/24 10/21 January 1984 [1] 86/12 87/11 87/12 62/4 100/25 102/3 injections [1] 46/12 175/2 14/24 16/1 17/17 18/4 67/22 96/8 96/18 98/5 118/2 information [111] 2/2 input [2] 143/1 144/11 introduction [2] 18/6 20/10 23/18 24/8 January 1985 [8] 49/8 118/8 120/23 123/10 3/10 3/15 4/23 7/25 Inquiry [29] 2/6 4/25 100/24 102/25 25/25 26/25 27/25 54/25 61/25 69/11 129/6 130/6 130/14 8/2 8/9 12/24 13/4 5/4 7/2 29/10 40/25 introductory [1] 104/7 28/18 35/4 36/25 38/1 74/5 81/12 99/18 133/24 136/20 137/5 invaluable [2] 101/16 22/5 24/6 31/4 41/18 53/12 54/19 61/4 39/13 40/19 40/24 101/20 148/4 150/1 150/11 48/14 50/4 51/3 51/11 63/16 65/3 65/14 January 1986 [1] 98/4 101/25 41/11 41/12 41/24 164/6 51/17 54/7 54/15 70/14 73/13 73/21 investigations [5] 43/1 43/2 43/4 44/14 January 1989 [1] individuals [10] 9/12 54/23 55/18 56/10 81/3 83/23 84/11 91/7 64/5 64/13 92/16 44/14 45/9 46/1 47/2 152/4 48/4 65/2 82/8 83/23 57/5 57/16 57/18 58/1 93/15 98/1 99/15 114/10 119/23 48/22 53/12 53/13 January 1st [1] 22/23 84/20 99/12 104/3 58/13 58/14 58/16 110/6 116/18 116/21 investigative [1] 37/2 55/15 56/11 60/21 January 2001 [4] 127/15 130/4 132/14 136/3 147/21 invitation [4] 83/18 66/21 70/20 70/21 164/8 165/10 166/12 60/1 60/3 60/12 60/16 induce [1] 46/13 62/1 62/8 62/11 62/12 170/25 103/5 124/2 139/4 72/12 72/12 73/20 170/2 industry [1] 174/11 Inquiry's [2] 6/4 94/14 invite [2] 99/20 63/13 64/8 65/7 66/4 76/19 77/7 77/8 78/2 jigsaw [1] 96/17 ineffective [1] 30/16 66/18 68/13 70/15 Inside [1] 102/15 160/13 83/23 84/10 85/17 job [1] 91/22 inevitable [1] 163/3 79/8 82/9 84/9 84/15 invited [11] 59/6 85/22 88/12 88/15 John [4] 9/4 9/5 79/10 inspection [1] 173/10 infected [33] 36/24 84/17 84/18 87/17 instance [1] 170/10 78/21 83/9 86/18 87/2 90/12 92/8 92/15 80/23 44/19 48/5 54/3 54/13 87/24 89/5 89/8 91/21 instances [2] 58/9 89/4 89/11 89/19 93/13 93/24 94/7 95/4 John Craske [1] 9/4 55/3 57/8 62/18 63/5 91/24 92/3 95/5 95/6 136/23 89/20 100/5 137/13 98/13 101/20 107/11 joined [1] 145/9 65/2 66/12 68/16 96/18 98/18 98/20 instigation [1] 5/9 inviting [1] 89/25 108/3 109/11 111/3 joint [6] 52/19 79/6 69/23 69/23 70/3 107/2 107/2 143/23 100/9 100/13 101/12 instilled [1] 43/10 involved [13] 2/15 112/19 114/7 114/23 74/14 75/17 75/17 101/16 101/25 102/1 Institutional [1] 13/19 44/5 104/2 115/10 122/18 126/19 144/5 84/7 89/22 93/10 Jones [3] 34/21 144/3 105/6 105/8 105/10 129/14 153/16 158/12 128/24 136/18 141/5 147/21 96/16 98/5 105/14 161/13 162/16 166/24 141/25 145/7 145/8 116/18 117/11 124/15 institutions [1] 173/11 105/18 108/17 109/14 124/17 125/5 126/24 145/23 167/10 171/14 171/21 145/10 146/16 147/4 Jones' [1] 34/23 110/7 110/19 111/15 134/9 134/21 138/6 instruments [5] involvement [12] 150/2 151/2 152/19 journal [11] 10/19 116/22 131/12 134/24 139/20 144/19 145/4 170/12 170/13 171/2 11/18 153/15 156/14 153/2 154/22 155/21 10/22 17/16 35/1 39/7 infection [52] 9/17 148/10 148/25 149/6 171/15 171/17 157/2 157/4 157/12 157/9 158/9 158/25 59/22 107/8 107/12 15/10 22/20 38/7 149/20 149/20 150/6 157/24 158/1 160/18 159/1 159/15 159/19 110/21 113/16 156/24 insufficient [2] 27/20 38/24 39/5 39/10 150/15 151/3 151/23 172/6 172/11 174/23 160/14 160/15 164/14 judgment [2] 46/25 117/11 39/11 39/17 43/16 152/3 152/5 152/21 involves [1] 163/20 166/18 172/2 173/19 Intensive [1] 80/6 44/12 46/6 48/18 152/24 155/3 158/3 intention [2] 91/15 involving [3] 16/21 174/24 judgments [1] 41/19 53/18 57/20 60/20 162/4 163/2 163/23 91/20 165/10 165/24 It's one [1] 16/1 **July [5]** 11/11 67/15 66/7 66/19 69/24 70/4 164/24 166/13 166/15 Ireland [27] 1/14 1/19 interactions [3] 11/24 its [13] 14/25 25/4 67/25 69/13 90/7 78/22 81/9 101/13 167/7 167/22 168/6 172/20 173/15 2/10 32/23 44/12 26/8 31/14 40/15 July 1982 [1] 11/11 105/18 105/19 105/20 169/3 169/7 173/12 intercourse [5] 44/22 44/24 45/4 45/7 50/24 60/10 100/12 July 1985 [1] 90/7 107/9 107/10 109/2 information was [1] 102/22 102/24 126/10 59/4 71/5 75/14 102/19 115/18 115/20 June [9] 26/24 27/1 111/17 111/18 111/21 169/7 126/13 126/17 107/10 107/11 107/18 117/12 161/8 29/11 31/21 35/20 112/15 115/5 118/4 informed [34] 4/11 interest [1] 175/4 107/21 108/20 112/20 itself [6] 32/23 61/15 62/21 62/24 67/23 121/23 123/14 123/22 5/18 31/5 41/19 47/24 interesting [1] 153/8 113/9 124/25 128/18 93/14 96/14 97/23 114/23 123/24 125/22 127/5 interferon [4] 136/17 155/20 156/18 160/22 June '83 [1] 62/24 54/17 55/10 67/8 154/24 128/8 129/12 129/18 141/19 142/11 142/19 June 1983 [4] 29/11 83/25 84/1 95/16 161/9 166/21 167/1 IV [1] 102/19 131/24 132/10 134/17 96/12 100/15 117/4 intermittently [1] Ireland with [1] 1/19 IX [5] 21/23 73/2 73/7 31/21 35/20 62/21 138/21 139/18 141/14 123/17 129/17 129/21 116/3 Irish [1] 147/13 73/18 162/12 just [71] 1/3 1/25 3/6 142/12 171/13 131/13 131/20 132/9 internal [3] 10/25 35/3 ironic [1] 73/6 5/6 5/6 6/3 6/16 7/5 infections [9] 4/20 135/6 137/3 139/21 159/20 irrelevant [1] 81/1 8/11 9/6 12/8 15/15 4/24 8/6 10/3 20/13 January [42] 16/3 161/6 161/6 161/15 international [1] isn't [4] 7/8 37/25 20/17 23/10 25/6 25/7

(57) indeed... - just

J	13/23 17/20 20/12	105/25	140/23 141/5 142/4	107/5 116/12 122/21	12/9 15/25 19/14
	26/21 40/5 54/8 67/8	latter [2] 6/11 119/9	142/17 149/10 150/19	124/12 126/8 134/21	25/17 26/5 28/7 29/23
just [55] 26/6 41/22	87/20 89/21 99/10	laughter [1] 104/15	152/19 153/1 158/9	139/22 156/19 167/9	33/18 42/1 69/4 70/16
42/23 45/23 46/1	124/20 124/25 154/12	Lawrence [1] 24/9	158/11 160/14 160/20	172/10	70/20 71/10 72/15
47/20 48/19 48/20	158/7 164/20	laymen [1] 40/1	161/7 161/21 165/16	liver [19] 3/2 3/6 58/8	85/1 92/7 93/17 95/25
57/1 60/2 60/21 70/22	knowledgeable [1]	leading [3] 47/15	165/17 165/19 166/9	111/16 119/24 120/10	100/6 107/8 109/23
71/16 71/17 72/1	74/2	158/17 170/19	167/4 168/4 168/15	121/1 131/14 131/16	110/25 112/19 129/3
76/15 76/16 77/3	known [27] 1/22 7/13	leaflets [2] 57/24	letter and [1] 25/4	131/21 132/10 132/24	137/1 139/3 141/7
77/14 77/21 80/13	7/14 8/17 8/17 9/1	58/13	letter's [1] 94/8	134/19 136/16 140/7	142/18 149/3 156/23
88/12 88/17 89/14	9/12 12/6 17/1 17/19	leaflets/printouts [1]	letters [2] 139/23	140/19 141/15 153/4	166/10 172/21
95/8 96/2 97/8 97/22	34/11 36/9 53/18	57/24	158/16	159/4	looking [16] 25/7
98/6 99/19 105/22	60/24 68/10 72/25	leaps [1] 127/5	leukaemia [1] 104/4	lives [3] 5/21 41/20	33/16 37/3 38/16 41/4
106/22 114/25 126/9	81/10 84/18 89/5 96/6	learning [2] 123/3	level [6] 30/13 97/19	103/7	46/4 56/9 66/11 70/19
133/11 134/7 138/3	110/6 125/21 132/5	124/7	165/3 165/22 166/1	living [1] 100/12	97/9 102/9 117/19
138/16 138/18 139/23	132/6 140/18 159/15	least [21] 14/13 22/6	166/8	load [2] 129/13	117/25 124/11 125/20
142/10 142/12 146/19	174/10	24/7 48/13 52/12	levels [2] 66/9 114/2	134/16	137/7
147/2 147/17 148/24		52/25 66/2 85/16	liaise [1] 114/13	local [8] 57/24 60/9	looks [2] 77/8 107/4
149/5 152/25 155/6	L	90/18 101/2 101/3	liaising [1] 66/10	100/10 165/3 166/8	lot [4] 82/8 85/1
158/18 160/12 164/12	lab [1] 106/15		liaison [1] 114/18	166/11 167/4 175/7	147/23 156/1
164/13 167/9 167/24	labelled [1] 83/3	130/13 142/14 144/16	licence [1] 115/19	local discussions [1]	LOTH0000080 [1]
justification [2] 52/2	laboratory [15] 23/8	148/8 157/3 157/23	life [5] 47/6 50/24	166/11	43/1
82/19	45/6 66/22 67/7 76/12	158/24	56/23 138/16 159/1	locally [2] 122/10	Louise [3] 77/24 80/1
K	107/17 108/4 108/12	leave [1] 71/16	lifestyle [2] 9/13	164/23	81/2
	114/5 119/6 119/22	lecture [2] 81/21	104/11	locate [1] 152/5	Louise Marsden [2]
Kaposi's [3] 10/3 11/1	120/19 121/15 128/18	101/6	light [11] 7/20 40/5	located [2] 81/21	77/24 80/1
11/6	135/6	led [3] 73/4 99/12	51/17 52/16 54/7	166/18	low [1] 72/4
keep [2] 97/18 121/15	lack [5] 32/16 32/20	141/7	63/13 88/20 96/2	location [1] 127/10	lower [1] 24/12
keeping [7] 100/17	99/10 100/21 124/20	Lee [1] 173/11	140/24 153/8 159/7	locked [2] 76/10	Lowry [3] 140/2 142/5
134/6 144/22 145/2	laid [1] 75/12	left [5] 4/14 6/7	like [5] 35/4 54/2	82/18	142/17
145/4 146/15 148/1	Lancet [8] 9/7 9/22	148/16 166/4 167/12	85/24 117/13 173/23	logged [1] 103/11	lunch [3] 97/1 97/9
kept [6] 64/23 72/5	10/5 34/23 37/8 37/25	legacy [1] 147/10	likeliest [1] 66/2	logic [1] 154/16	97/10
76/10 145/14 145/17	38/12 43/5	length [1] 122/4	likely [12] 15/6 15/16	logically [1] 39/8	Luncheon [1] 97/6
146/1	Lane [1] 42/18	lengthy [3] 56/17	21/14 21/20 22/2	London [11] 16/2 16/2	lunchtime [1] 9/2
Kernoff [2] 9/4 14/13	language [1] 92/13	56/25 162/11	22/21 117/13 126/16	23/9 24/15 45/7 94/1	lung [1] 10/2
key [2] 43/4 48/8	large [5] 5/15 27/10	Leonard [1] 146/17	126/19 132/4 140/8	94/1 102/8 115/2	
Kien [1] 11/1	32/14 32/18 47/11	lesions [1] 27/8	140/13	157/17 162/7	<u>M</u>
Kilpatrick [1] 77/4	largely [2] 28/21 46/1	less [2] 28/25 47/3	Likewise [3] 99/25	long [5] 26/15 79/14	Macfarlane [1] 172/13
kind [3] 73/3 90/16 150/18	largely with [1] 28/21	let [4] 13/24 93/11	133/14 134/17	138/15 145/8 148/15	Macfarlane Trust [1]
	larger [1] 30/23	94/5 151/15	limited [2] 99/11	longer [1] 96/25	172/13
Kingdom [3] 38/17 73/25 155/11	last [28] 16/4 16/14	Let's [1] 49/18	144/11	look [70] 3/6 4/2 11/9	Machin [1] 68/22
	20/15 22/13 22/13	lethal [1] 102/16	Limiting [1] 31/12	13/14 15/1 18/8 20/6	MACK0001300 [1]
Kirkpatrick's [1] 118/13	44/15 48/20 50/8	lethargy [1] 127/7	line [3] 20/22 139/8	22/12 23/21 25/7	157/5
knew [3] 104/5 133/14	60/21 67/14 67/16	letter [85] 9/24 14/9	140/15	25/12 33/21 38/15	made [15] 8/11 20/5
143/7	67/18 68/7 68/8 79/25	14/10 14/12 14/16	lines [5] 23/11 140/6	40/9 41/8 48/4 53/11	41/19 57/6 65/7 86/13
know [51] 13/24 14/6	97/17 99/9 113/3	18/4 19/12 19/13 20/1	159/3 161/20 169/15	64/10 66/17 70/5 74/4	90/17 107/2 110/1
14/21 19/9 23/25 25/2	135/17 140/6 142/4	25/4 25/10 26/25 28/5		78/11 81/5 83/6 84/24	110/4 127/14 128/21
25/4 26/4 37/1 43/12	143/13 144/1 145/20	43/1 43/5 48/23 48/24		86/11 91/11 91/12	130/11 158/25 159/1
74/22 78/7 83/2 84/23	146/19 149/16 159/3	62/24 65/10 66/20	106/20 160/5	93/1 93/22 93/24	magazine [2] 59/22
85/12 86/1 86/5 86/20	161/15	68/21 69/1 69/4 69/12	listed [9] 31/25 68/2	94/20 96/24 98/6	60/10
87/8 87/8 87/10 88/6	late [12] 9/3 9/4 37/8	69/16 69/20 69/21	69/3 73/14 105/16	99/16 99/20 105/23	magazine/journal [1]
88/7 88/9 90/15 90/24	39/4 39/9 61/25 65/10	70/17 72/18 73/15	106/13 151/10 157/18	106/9 106/10 108/14	59/22
92/1 92/18 93/11 94/6	68/11 69/23 85/5 90/1	73/19 83/11 84/3	160/6	111/12 111/19 112/23	magnitude [1] 40/14
1 251 251 10 00/11 07/0		1 0 4 10 E 0 E 10 0 O 10 E 0 4 10	listen [1] 99/1	113/25 117/24 118/12	main [5] 53/9 66/17
95/17 95/22 96/8	136/12	84/25 85/3 89/25 91/8			
95/17 95/22 96/8	later [26] 1/15 6/20	91/18 92/3 92/10	lists [2] 159/21	118/22 123/8 130/15	81/22 113/24 136/24
96/10 97/15 103/13	later [26] 1/15 6/20 7/4 7/15 8/25 17/3	91/18 92/3 92/10 92/12 93/7 93/12	170/19	135/1 139/23 140/5	mainly [1] 13/16
96/10 97/15 103/13 109/22 110/17 110/25	later [26] 1/15 6/20 7/4 7/15 8/25 17/3 18/1 40/25 43/1 55/22	91/18 92/3 92/10 92/12 93/7 93/12 93/14 93/17 93/23	170/19 litigation [15] 10/9	135/1 139/23 140/5 141/10 143/24 147/17	mainly [1] 13/16 maintain [1] 9/12
96/10 97/15 103/13 109/22 110/17 110/25 111/4 122/20 124/1	later [26] 1/15 6/20 7/4 7/15 8/25 17/3 18/1 40/25 43/1 55/22 65/10 68/9 80/1 90/15	91/18 92/3 92/10 92/12 93/7 93/12 93/14 93/17 93/23 93/24 93/25 94/7	170/19 litigation [15] 10/9 12/1 12/7 19/5 26/20	135/1 139/23 140/5 141/10 143/24 147/17 149/9 150/17 150/25	mainly [1] 13/16 maintain [1] 9/12 major [2] 38/24 39/10
96/10 97/15 103/13 109/22 110/17 110/25 111/4 122/20 124/1 126/5 140/24 143/21	later [26] 1/15 6/20 7/4 7/15 8/25 17/3 18/1 40/25 43/1 55/22 65/10 68/9 80/1 90/15 106/10 107/1 107/5	91/18 92/3 92/10 92/12 93/7 93/12 93/14 93/17 93/23 93/24 93/25 94/7 94/10 94/21 95/6	170/19 litigation [15] 10/9 12/1 12/7 19/5 26/20 33/12 36/7 36/12	135/1 139/23 140/5 141/10 143/24 147/17 149/9 150/17 150/25 151/24 152/23 155/16	mainly [1] 13/16 maintain [1] 9/12 major [2] 38/24 39/10 majority [5] 68/8
96/10 97/15 103/13 109/22 110/17 110/25 111/4 122/20 124/1 126/5 140/24 143/21 154/12 155/22 161/4	later [26] 1/15 6/20 7/4 7/15 8/25 17/3 18/1 40/25 43/1 55/22 65/10 68/9 80/1 90/15 106/10 107/1 107/5 116/12 123/4 123/5	91/18 92/3 92/10 92/12 93/7 93/12 93/14 93/17 93/23 93/24 93/25 94/7 94/10 94/21 95/6 97/11 97/13 97/23	170/19 litigation [15] 10/9 12/1 12/7 19/5 26/20 33/12 36/7 36/12 38/19 40/10 42/25	135/1 139/23 140/5 141/10 143/24 147/17 149/9 150/17 150/25 151/24 152/23 155/16 157/5 157/19 157/25	mainly [1] 13/16 maintain [1] 9/12 major [2] 38/24 39/10 majority [5] 68/8 127/23 161/23 162/12
96/10 97/15 103/13 109/22 110/17 110/25 111/4 122/20 124/1 126/5 140/24 143/21 154/12 155/22 161/4 161/23 162/3 162/7	later [26] 1/15 6/20 7/4 7/15 8/25 17/3 18/1 40/25 43/1 55/22 65/10 68/9 80/1 90/15 106/10 107/1 107/5 116/12 123/4 123/5 124/9 135/8 136/9	91/18 92/3 92/10 92/12 93/7 93/12 93/14 93/17 93/23 93/24 93/25 94/7 94/10 94/21 95/6 97/11 97/13 97/23 98/4 106/11 106/16	170/19 litigation [15] 10/9 12/1 12/7 19/5 26/20 33/12 36/7 36/12 38/19 40/10 42/25 43/3 50/6 50/18 58/20	135/1 139/23 140/5 141/10 143/24 147/17 149/9 150/17 150/25 151/24 152/23 155/16 157/5 157/19 157/25 158/18 159/2 159/17	mainly [1] 13/16 maintain [1] 9/12 major [2] 38/24 39/10 majority [5] 68/8 127/23 161/23 162/12 168/10
96/10 97/15 103/13 109/22 110/17 110/25 111/4 122/20 124/1 126/5 140/24 143/21 154/12 155/22 161/4 161/23 162/3 162/7 knowing [1] 171/8	later [26] 1/15 6/20 7/4 7/15 8/25 17/3 18/1 40/25 43/1 55/22 65/10 68/9 80/1 90/15 106/10 107/1 107/5 116/12 123/4 123/5 124/9 135/8 136/9 136/12 162/19 172/17	91/18 92/3 92/10 92/12 93/7 93/12 93/14 93/17 93/23 93/24 93/25 94/7 94/10 94/21 95/6 97/11 97/13 97/23 98/4 106/11 106/16 110/15 111/1 114/4	170/19 litigation [15] 10/9 12/1 12/7 19/5 26/20 33/12 36/7 36/12 38/19 40/10 42/25 43/3 50/6 50/18 58/20 little [15] 7/4 11/13	135/1 139/23 140/5 141/10 143/24 147/17 149/9 150/17 150/25 151/24 152/23 155/16 157/5 157/19 157/25 158/18 159/2 159/17 160/13 164/13 174/5	mainly [1] 13/16 maintain [1] 9/12 major [2] 38/24 39/10 majority [5] 68/8 127/23 161/23 162/12 168/10 make [8] 31/5 51/5
96/10 97/15 103/13 109/22 110/17 110/25 111/4 122/20 124/1 126/5 140/24 143/21 154/12 155/22 161/4 161/23 162/3 162/7	later [26] 1/15 6/20 7/4 7/15 8/25 17/3 18/1 40/25 43/1 55/22 65/10 68/9 80/1 90/15 106/10 107/1 107/5 116/12 123/4 123/5 124/9 135/8 136/9	91/18 92/3 92/10 92/12 93/7 93/12 93/14 93/17 93/23 93/24 93/25 94/7 94/10 94/21 95/6 97/11 97/13 97/23 98/4 106/11 106/16	170/19 litigation [15] 10/9 12/1 12/7 19/5 26/20 33/12 36/7 36/12 38/19 40/10 42/25 43/3 50/6 50/18 58/20	135/1 139/23 140/5 141/10 143/24 147/17 149/9 150/17 150/25 151/24 152/23 155/16 157/5 157/19 157/25 158/18 159/2 159/17	mainly [1] 13/16 maintain [1] 9/12 major [2] 38/24 39/10 majority [5] 68/8 127/23 161/23 162/12 168/10

(58) just... - make

75/20 108/11 46/16 46/24 47/4 96/13 96/20 97/11 100/23 101/4 102/1 М 51/16 54/17 60/2 97/23 98/1 98/14 measured [1] 54/6 102/8 102/11 124/23 minute [1] 96/25 make... [3] 97/22 60/11 67/10 88/21 98/23 99/19 106/25 measures [7] 35/12 124/24 174/20 minutes [12] 14/2 142/22 175/4 89/11 98/19 105/10 107/14 110/2 110/4 50/19 65/24 114/13 member [4] 6/1 71/24 14/5 18/5 33/19 42/12 making [3] 34/9 72/2 110/7 130/13 136/5 110/22 112/23 112/24 169/24 170/4 171/13 162/21 175/1 61/12 71/21 90/18 122/3 116/13 148/13 165/18 154/9 154/15 113/4 113/22 115/1 media [5] 35/7 36/10 members [17] 5/5 Makris [1] 162/5 matter ... the [1] 115/11 115/15 116/11 40/3 96/6 98/19 12/3 12/4 14/17 40/1 175/1 Malachy [2] 75/6 96/9 98/19 118/7 120/3 120/17 mediated [1] 46/14 55/4 59/3 62/7 65/2 miracle [2] 6/9 118/6 males [1] 9/10 120/24 123/9 126/11 medical [20] 15/21 78/20 79/21 83/14 matters [11] 1/3 5/9 misconceptions [1] man [1] 16/24 50/17 100/18 113/7 84/8 95/6 105/1 105/7 128/10 128/24 129/6 26/11 40/1 81/24 66/4 manage [2] 138/21 127/3 148/12 150/10 129/8 130/9 130/16 94/18 107/8 107/12 161/8 misconduct [1] 164/2 139/18 154/18 169/6 172/16 131/2 131/11 134/10 113/16 123/2 144/24 membership [1] misplaced [1] 88/13 managed [2] 111/22 136/10 138/14 138/17 maximum [2] 87/20 144/25 145/13 145/14 172/7 missing [2] 39/19 111/23 139/24 139/25 140/6 116/1 145/17 146/1 154/19 memo [2] 159/20 148/5 management [7] 156/23 158/3 160/16 may [79] 7/8 17/17 140/12 141/2 142/13 159/20 **MLSO [1]** 76/12 29/20 111/20 112/7 18/5 19/6 24/4 24/18 142/14 143/21 144/4 172/8 memory [2] 45/21 MMWR [4] 11/12 115/18 128/15 135/5 24/24 25/25 27/4 149/11 149/25 150/19 medically [1] 51/15 82/7 23/24 24/1 24/5 136/15 27/19 35/16 35/17 151/2 151/6 152/20 medicine [12] 10/19 men [2] 10/3 11/2 MMWRs [1] 24/17 Manchester [2] 13/5 36/8 37/3 40/6 40/25 152/23 153/8 153/14 10/22 10/25 17/16 mode [3] 22/2 22/16 mention [1] 18/8 mentioned [4] 5/14 41/7 45/21 46/11 155/9 156/21 157/1 35/2 35/3 39/8 39/22 100/11 mandatory [1] 103/2 46/13 46/20 48/23 157/6 157/18 159/7 39/23 111/24 112/8 moderate [5] 1/7 29/6 27/4 130/24 139/12 manifestations [1] 51/5 52/9 54/1 55/22 159/12 160/6 162/24 112/11 merely [3] 58/13 30/1 30/8 69/6 115/4 56/7 63/25 64/21 172/20 172/24 173/6 medium [1] 50/16 120/9 135/14 moderately [4] 2/14 manner [6] 102/3 71/11 77/3 80/12 173/8 175/2 meet [3] 81/11 101/22 met [2] 101/19 133/24 69/5 72/17 135/22 103/5 124/14 139/21 82/16 82/25 84/3 84/4 Mayne's [63] 2/1 6/21 124/2 Methods [1] 107/15 modes [1] 100/16 161/7 167/3 modest [1] 159/12 88/5 88/12 90/3 90/9 8/22 10/9 11/25 28/5 meeting [76] 12/13 meticulously [1] manufactured [1] 13/5 13/7 13/8 16/1 91/1 91/25 96/15 33/12 34/2 39/13 42/3 145/15 modifications [1] 21/23 42/25 44/1 44/13 18/2 18/6 18/10 18/17 mid [4] 8/5 58/22 96/18 99/19 107/18 167/5 many [19] 2/11 27/12 107/24 108/2 108/5 48/16 51/6 53/9 53/22 19/5 19/6 19/10 19/21 58/25 120/15 moment [5] 11/9 27/15 64/17 64/24 110/10 110/15 113/7 54/9 55/5 55/23 57/11 24/15 25/2 25/24 26/1 mid-'70s [1] 58/25 14/21 40/23 83/8 99/11 113/2 114/20 117/19 118/17 121/7 66/17 68/14 68/17 26/2 26/8 26/22 27/1 mid-1970s [2] 58/22 160/11 131/3 132/3 132/7 122/16 122/20 126/18 70/3 70/21 73/17 27/4 27/19 27/25 120/15 moments [1] 69/4 134/12 134/24 135/10 127/25 130/14 134/15 74/12 76/13 78/11 31/23 31/25 32/3 mid-1990s [1] 8/5 monitoring [1] 151/17 144/2 145/23 152/9 135/7 136/4 137/6 79/18 79/24 81/5 35/11 35/15 36/4 middle [1] 20/18 month [9] 16/25 37/22 154/23 170/15 137/24 139/1 140/21 86/21 87/18 88/1 41/23 41/24 42/4 Middlesex [2] 45/7 37/23 38/4 38/9 38/13 March [22] 1/1 19/12 42/10 42/11 42/17 141/14 148/7 148/7 88/18 91/18 93/3 68/23 90/4 113/2 141/18 19/14 20/11 25/14 151/2 151/18 153/7 97/12 101/3 104/18 42/20 42/21 44/24 might [35] 3/21 7/19 monthly [7] 2/21 3/4 25/22 33/17 67/25 154/11 154/12 158/6 105/12 105/13 110/18 59/2 61/12 61/15 9/22 10/6 12/4 15/17 98/20 102/1 124/22 68/1 70/21 74/19 75/1 159/6 163/22 164/12 117/20 120/22 124/14 61/19 63/23 63/25 18/21 21/21 22/22 135/22 135/23 76/18 77/10 77/10 Mayne [150] 2/8 3/6 126/13 126/25 136/21 71/21 71/24 77/2 23/25 24/13 30/12 months [10] 2/13 18/6 85/3 85/6 85/14 89/10 3/15 5/2 5/7 6/11 8/14 136/25 138/11 141/23 77/10 77/23 78/1 78/3 31/14 35/12 36/6 67/18 67/19 69/17 90/1 115/15 123/25 8/23 9/20 10/8 10/14 142/24 153/12 156/14 78/4 78/24 80/2 80/8 40/17 47/8 60/4 68/19 76/1 90/8 101/21 March 1983 [1] 33/17 12/14 13/11 14/18 157/11 158/5 160/8 80/15 80/19 80/25 80/24 83/5 83/11 136/1 149/16 March 1984 [2] 68/1 86/10 101/23 104/11 14/20 16/6 17/19 18/9 172/6 172/17 173/18 81/7 82/6 82/15 83/2 months further [1] 75/1 19/4 19/12 24/11 25/2 McNulty [2] 143/20 86/14 89/19 96/9 110/12 113/6 123/18 69/17 March 1985 [2] 77/10 25/25 26/3 26/4 26/20 98/11 98/13 101/5 more [43] 1/8 2/16 8/7 157/1 125/3 125/3 127/20 90/1 26/24 27/24 29/6 McNulty's [2] 143/24 101/10 143/12 155/22 130/2 138/12 152/11 9/8 13/3 14/4 24/2 March 1988 [1] 70/21 31/15 31/25 32/21 155/16 157/15 166/14 174/17 152/12 29/17 30/15 44/3 48/6 March 1996 [1] me [17] 36/25 45/22 33/17 34/14 36/14 48/19 49/15 60/17 175/2 mild [5] 1/7 29/25 123/25 meetings [49] 14/3 42/7 42/11 42/17 43/5 47/24 59/23 76/16 30/7 73/8 73/16 77/4 83/19 87/15 March 2 [1] 115/15 46/8 48/23 49/14 50/1 95/12 95/14 99/12 31/23 35/18 41/23 mildly [12] 2/13 4/12 87/25 92/22 97/25 Marsden [3] 77/24 50/12 52/21 55/16 104/10 118/18 138/22 54/24 57/13 59/19 27/6 27/13 28/23 29/4 99/7 99/17 101/23 78/13 80/1 59/21 61/3 64/3 64/9 138/22 139/12 139/22 61/16 61/17 61/20 29/15 30/13 31/17 104/9 104/18 110/16 Marsden's [1] 81/2 66/22 67/4 68/21 143/17 144/2 149/18 61/21 61/25 66/6 74/4 62/25 136/1 140/4 113/6 114/20 119/4 material [13] 63/17 70/19 71/24 72/2 mean [1] 85/8 74/8 74/10 74/18 75/3 mind [1] 97/12 125/13 129/18 130/6 69/10 69/21 73/21 75/18 76/18 77/8 77/9 72/13 72/19 73/1 meaningful [1] 156/20 minimal [1] 97/19 134/21 142/7 146/14 85/1 85/13 85/25 77/18 77/20 78/16 73/19 74/10 75/10 means [3] 27/10 minimally [1] 161/13 147/23 148/11 148/13 95/18 125/15 128/2 76/9 78/4 78/14 79/25 103/21 113/5 78/19 79/18 81/11 minimise [1] 50/23 151/16 158/6 168/5 144/18 148/3 150/14 81/8 82/9 83/21 85/6 meant [3] 46/18 113/6 | 81/18 82/4 83/21 89/4 minor [2] 27/7 167/4 171/18 172/18 materials [2] 41/9 85/19 86/9 86/15 136/18 89/9 89/18 90/18 minority [1] 162/3 morning [3] 6/20 7/23 97/25 86/18 90/22 91/16 measles [1] 134/1 90/23 90/24 91/2 minus [1] 108/11 162/25 matter [19] 8/16 17/17 measure [2] 32/18 99/18 100/4 100/8 92/24 94/5 95/13 minus 20 degrees [1] mortality [3] 16/13

(59) make... - mortality

	100/2 100/6 100/25	navirala my [41, 442/40	100/0 100/0 100/10	match and [2] 76/0	muma [4] 114/2
<u>M</u>	102/3 102/6 102/25 103/13 119/2 119/19	neurology [1] 112/10 never [5] 73/3 116/1	128/2 129/3 129/19 130/11 134/2 135/13	notebook [2] 76/9 103/12	nurse [1] 114/3 nutshell [1] 165/21
mortality [2] 16/14	125/20 128/6 138/14	174/1 174/4 174/6	135/24 138/22 140/2	noted [4] 20/24 96/22	
20/18	139/12 139/20 139/21	new [9] 10/18 10/20	142/3 142/8 143/7	155/20 156/1	0
most [22] 2/1 15/16 17/25 21/14 21/20	145/11 168/10 170/2	10/21 16/24 17/16	143/21 144/14 153/21	notes [5] 19/2 145/18	o'clock [5] 96/23 97/2
22/2 22/5 24/6 53/13	171/10	35/1 39/7 47/23	155/2 168/3 170/3	146/12 146/13 168/13	97/4 175/15 175/15
66/16 69/9 71/7 103/3	myself [8] 5/25 54/5	106/18	no intention [1] 91/15		obliged [1] 86/2
104/19 116/2 127/6	73/5 79/12 92/5 131/3 162/23 163/1	New England [2] 35/1 39/7		112/25	observation [2] 88/12 130/16
136/25 136/25 140/8	102/23 103/1	New England Journal	143/7 155/2	nothing [3] 11/25 69/21 80/12	observations [2]
149/1 149/17 168/22	N	[1] 17/16	45/18 52/14 52/23	notice [1] 9/1	39/14 50/12
mostly [4] 111/23	naively [1] 130/25	New York [1] 16/24	120/11 120/11 120/12	notification [21]	observe [1] 80/13
112/7 112/9 159/22	name [2] 150/13	news [3] 9/16 104/1	120/12 121/4 121/4	160/9 160/17 160/19	observed [1] 21/7
mother [1] 162/17 move [4] 1/24 8/15	150/13	149/16	128/4 128/23 128/23	161/2 165/8 165/10	obtain [2] 4/11 173/12
31/23 160/7	named [5] 149/6	next [66] 4/3 6/17	131/12 131/12 131/15	165/21 165/24 166/3	obtained [7] 6/25 64/8
moved [2] 151/2	151/4 152/1 154/17	8/15 10/9 11/16 15/1	131/15 131/19 131/19	166/11 166/16 166/24	108/12 122/12 122/18
165/4	172/24 namely [3] 9/18 43/23	17/14 18/8 20/19 21/25 22/12 30/11	132/5 132/5 133/17 133/17 133/20 133/20	167/2 167/5 167/8 167/11 168/19 168/24	123/25 140/19 obtaining [1] 144/24
Mr [11] 75/6 75/7 77/4	50/23	32/24 34/14 35/21	153/4 153/4	169/14 171/22 172/1	obvious [1] 5/24
81/8 81/15 84/25	names [3] 87/9 103/9	38/15 44/11 45/9	non-A [11] 7/13	notified [1] 23/6	obviously [23] 14/3
88/23 89/25 96/1	150/21	54/10 58/9 58/17	120/11 120/12 121/4	November [13] 14/6	26/2 38/16 40/24 43/3
118/13 120/24 Mr Devlin [3] 75/7	narrative [3] 8/3 35/18	59/21 63/22 65/19	128/23 131/12 131/15	14/10 14/25 15/23	54/17 61/25 68/9
84/25 89/25	36/12	65/24 67/21 68/21	131/19 132/5 133/17	20/10 21/10 37/9	68/23 70/13 73/23
Mr Hamilton [1] 81/8	national [7] 58/2 59/5	70/1 87/15 95/1 98/23	133/20	67/23 67/24 145/10	77/11 79/19 82/7 90/4
Mr Kilpatrick [1] 77/4	165/2 165/22 166/1 166/6 172/18	99/16 102/7 108/7	non-B [12] 7/14	146/10 158/9 165/25	93/13 95/18 119/9 120/6 121/8 125/16
Mr Kirkpatrick's [1]	nationally [2] 122/10	108/14 112/18 113/16 114/21 115/2 115/8	120/11 120/12 121/4 128/23 131/12 131/15	November 1982 [3] 14/6 15/23 20/10	163/20 164/11
118/13	164/23	123/16 126/21 127/16	131/19 132/5 133/17	November	occasion [2] 79/10
Mr Malachy [1] 75/6	nature [9] 53/6 88/13	129/3 130/10 130/12	133/20 153/4	1982-version [1]	127/19
Mr Nigel [1] 120/24	117/12 117/17 141/24	131/2 131/22 132/1	non-home [1] 45/18	21/10	occasional [1] 130/4
Mr Simon [1] 88/23	149/7 153/11 159/8	132/22 135/6 135/19	non-treatment [2]	November 1983 [1]	Occasionally [1] 30/5
⊥rusia i 1/4 1⊿/11 /2/19	ı		,		
Ms [6] 1/9 14/11 72/19 149/11 150/19 151/3	167/11	136/10 137/15 139/7	52/14 52/23	37/9	occasions [7] 12/10
Ms [6] 1/9 14/11 72/19 149/11 150/19 151/3 Ms Fraser Butlin [1]	near [1] 118/3	139/14 145/25 154/3	52/14 52/23 none [4] 6/13 54/2	37/9 November 2000 [2]	occasions [7] 12/10 16/1 26/6 28/2 42/2
149/11 150/19 151/3 Ms Fraser Butlin [1] 1/9	near [1] 118/3 nearby [1] 82/17	139/14 145/25 154/3 155/6 160/7 161/1	52/14 52/23 none [4] 6/13 54/2 77/10 87/6	37/9 November 2000 [2] 145/10 146/10	occasions [7] 12/10 16/1 26/6 28/2 42/2 58/3 101/22
149/11 150/19 151/3 Ms Fraser Butlin [1] 1/9 Ms Spooner [5] 14/11	near [1] 118/3 nearby [1] 82/17 nearly [1] 121/1	139/14 145/25 154/3 155/6 160/7 161/1 163/12 165/7 165/12	52/14 52/23 none [4] 6/13 54/2 77/10 87/6 nor [5] 31/11 56/16	37/9 November 2000 [2] 145/10 146/10 November 2002 [1]	occasions [7] 12/10 16/1 26/6 28/2 42/2 58/3 101/22 occupation [1] 79/2
149/11 150/19 151/3 Ms Fraser Butlin [1] 1/9 Ms Spooner [5] 14/11 72/19 149/11 150/19	near [1] 118/3 nearby [1] 82/17	139/14 145/25 154/3 155/6 160/7 161/1 163/12 165/7 165/12 170/8 174/3	52/14 52/23 none [4] 6/13 54/2 77/10 87/6 nor [5] 31/11 56/16 69/15 79/14 130/20	37/9 November 2000 [2] 145/10 146/10 November 2002 [1] 165/25	occasions [7] 12/10 16/1 26/6 28/2 42/2 58/3 101/22
149/11 150/19 151/3 Ms Fraser Butlin [1] 1/9 Ms Spooner [5] 14/11 72/19 149/11 150/19 151/3	near [1] 118/3 nearby [1] 82/17 nearly [1] 121/1 necessarily [2] 52/11 56/3 necessary [5] 30/6	139/14 145/25 154/3 155/6 160/7 161/1 163/12 165/7 165/12 170/8 174/3 NHS [2] 27/16 157/3 NI [2] 44/22 46/19	52/14 52/23 none [4] 6/13 54/2 77/10 87/6 nor [5] 31/11 56/16	37/9 November 2000 [2] 145/10 146/10 November 2002 [1] 165/25	occasions [7] 12/10 16/1 26/6 28/2 42/2 58/3 101/22 occupation [1] 79/2 occurred [5] 8/7 9/9 34/15 75/3 109/17 Octapharma [1]
149/11 150/19 151/3 Ms Fraser Butlin [1] 1/9 Ms Spooner [5] 14/11 72/19 149/11 150/19 151/3 much [16] 29/17	near [1] 118/3 nearby [1] 82/17 nearly [1] 121/1 necessarily [2] 52/11 56/3 necessary [5] 30/6 82/16 82/24 114/14	139/14 145/25 154/3 155/6 160/7 161/1 163/12 165/7 165/12 170/8 174/3 NHS [2] 27/16 157/3 NI [2] 44/22 46/19 niece [1] 73/3	52/14 52/23 none [4] 6/13 54/2 77/10 87/6 nor [5] 31/11 56/16 69/15 79/14 130/20 norm [2] 119/7 119/15 normal [3] 80/7 138/15 140/10	37/9 November 2000 [2] 145/10 146/10 November 2002 [1] 165/25 now [31] 20/25 40/17 41/3 42/5 42/14 43/25 49/18 49/25 51/4	occasions [7] 12/10 16/1 26/6 28/2 42/2 58/3 101/22 occupation [1] 79/2 occurred [5] 8/7 9/9 34/15 75/3 109/17 Octapharma [1] 173/10
149/11 150/19 151/3 Ms Fraser Butlin [1] 1/9 Ms Spooner [5] 14/11 72/19 149/11 150/19 151/3	near [1] 118/3 nearby [1] 82/17 nearly [1] 121/1 necessarily [2] 52/11 56/3 necessary [5] 30/6 82/16 82/24 114/14 154/7	139/14 145/25 154/3 155/6 160/7 161/1 163/12 165/7 165/12 170/8 174/3 NHS [2] 27/16 157/3 NI [2] 44/22 46/19 niece [1] 73/3 Nigel [1] 120/24	52/14 52/23 none [4] 6/13 54/2 77/10 87/6 nor [5] 31/11 56/16 69/15 79/14 130/20 norm [2] 119/7 119/15 normal [3] 80/7 138/15 140/10 Northern [28] 1/14	37/9 November 2000 [2] 145/10 146/10 November 2002 [1] 165/25 now [31] 20/25 40/17 41/3 42/5 42/14 43/25 49/18 49/25 51/4 62/14 73/10 91/13	occasions [7] 12/10 16/1 26/6 28/2 42/2 58/3 101/22 occupation [1] 79/2 occurred [5] 8/7 9/9 34/15 75/3 109/17 Octapharma [1] 173/10 October [16] 31/23
149/11 150/19 151/3 Ms Fraser Butlin [1] 1/9 Ms Spooner [5] 14/11 72/19 149/11 150/19 151/3 much [16] 29/17 30/14 30/23 73/4	near [1] 118/3 nearby [1] 82/17 nearly [1] 121/1 necessarily [2] 52/11 56/3 necessary [5] 30/6 82/16 82/24 114/14 154/7 necessitated [1] 79/2	139/14 145/25 154/3 155/6 160/7 161/1 163/12 165/7 165/12 170/8 174/3 NHS [2] 27/16 157/3 NI [2] 44/22 46/19 niece [1] 73/3 Nigel [1] 120/24 night [2] 79/13 80/5	52/14 52/23 none [4] 6/13 54/2 77/10 87/6 nor [5] 31/11 56/16 69/15 79/14 130/20 norm [2] 119/7 119/15 normal [3] 80/7 138/15 140/10 Northern [28] 1/14 1/19 2/9 32/23 44/12	37/9 November 2000 [2] 145/10 146/10 November 2002 [1] 165/25 now [31] 20/25 40/17 41/3 42/5 42/14 43/25 49/18 49/25 51/4 62/14 73/10 91/13 94/23 95/4 97/1	occasions [7] 12/10 16/1 26/6 28/2 42/2 58/3 101/22 occupation [1] 79/2 occurred [5] 8/7 9/9 34/15 75/3 109/17 Octapharma [1] 173/10 October [16] 31/23 31/25 33/11 66/21
149/11 150/19 151/3 Ms Fraser Butlin [1] 1/9 Ms Spooner [5] 14/11 72/19 149/11 150/19 151/3 much [16] 29/17 30/14 30/23 73/4 78/22 79/8 82/23 84/17 100/1 101/21 104/2 104/7 122/16	near [1] 118/3 nearby [1] 82/17 nearly [1] 121/1 necessarily [2] 52/11 56/3 necessary [5] 30/6 82/16 82/24 114/14 154/7 necessitated [1] 79/2 need [13] 32/6 37/22	139/14 145/25 154/3 155/6 160/7 161/1 163/12 165/7 165/12 170/8 174/3 NHS [2] 27/16 157/3 NI [2] 44/22 46/19 niece [1] 73/3 Nigel [1] 120/24 night [2] 79/13 80/5 nine [1] 127/11	52/14 52/23 none [4] 6/13 54/2 77/10 87/6 nor [5] 31/11 56/16 69/15 79/14 130/20 norm [2] 119/7 119/15 normal [3] 80/7 138/15 140/10 Northern [28] 1/14 1/19 2/9 32/23 44/12 44/22 44/24 45/4 45/7	37/9 November 2000 [2] 145/10 146/10 November 2002 [1] 165/25 now [31] 20/25 40/17 41/3 42/5 42/14 43/25 49/18 49/25 51/4 62/14 73/10 91/13 94/23 95/4 97/1 101/17 124/1 128/24	occasions [7] 12/10 16/1 26/6 28/2 42/2 58/3 101/22 occupation [1] 79/2 occurred [5] 8/7 9/9 34/15 75/3 109/17 Octapharma [1] 173/10 October [16] 31/23 31/25 33/11 66/21 67/17 67/21 68/23
149/11 150/19 151/3 Ms Fraser Butlin [1] 1/9 Ms Spooner [5] 14/11 72/19 149/11 150/19 151/3 much [16] 29/17 30/14 30/23 73/4 78/22 79/8 82/23 84/17 100/1 101/21 104/2 104/7 122/16 123/5 127/21 175/12	near [1] 118/3 nearby [1] 82/17 nearly [1] 121/1 necessarily [2] 52/11 56/3 necessary [5] 30/6 82/16 82/24 114/14 154/7 necessitated [1] 79/2	139/14 145/25 154/3 155/6 160/7 161/1 163/12 165/7 165/12 170/8 174/3 NHS [2] 27/16 157/3 NI [2] 44/22 46/19 niece [1] 73/3 Nigel [1] 120/24 night [2] 79/13 80/5 nine [1] 127/11 no [83] 1/11 3/23 5/14	52/14 52/23 none [4] 6/13 54/2 77/10 87/6 nor [5] 31/11 56/16 69/15 79/14 130/20 norm [2] 119/7 119/15 normal [3] 80/7 138/15 140/10 Northern [28] 1/14 1/19 2/9 32/23 44/12 44/22 44/24 45/4 45/7 59/4 71/5 75/13	37/9 November 2000 [2] 145/10 146/10 November 2002 [1] 165/25 now [31] 20/25 40/17 41/3 42/5 42/14 43/25 49/18 49/25 51/4 62/14 73/10 91/13 94/23 95/4 97/1	occasions [7] 12/10 16/1 26/6 28/2 42/2 58/3 101/22 occupation [1] 79/2 occurred [5] 8/7 9/9 34/15 75/3 109/17 Octapharma [1] 173/10 October [16] 31/23 31/25 33/11 66/21
149/11 150/19 151/3 Ms Fraser Butlin [1] 1/9 Ms Spooner [5] 14/11 72/19 149/11 150/19 151/3 much [16] 29/17 30/14 30/23 73/4 78/22 79/8 82/23 84/17 100/1 101/21 104/2 104/7 122/16 123/5 127/21 175/12 multi [1] 34/18	near [1] 118/3 nearby [1] 82/17 nearly [1] 121/1 necessarily [2] 52/11 56/3 necessary [5] 30/6 82/16 82/24 114/14 154/7 necessitated [1] 79/2 need [13] 32/6 37/22 38/9 40/9 73/7 98/8	139/14 145/25 154/3 155/6 160/7 161/1 163/12 165/7 165/12 170/8 174/3 NHS [2] 27/16 157/3 NI [2] 44/22 46/19 niece [1] 73/3 Nigel [1] 120/24 night [2] 79/13 80/5 nine [1] 127/11	52/14 52/23 none [4] 6/13 54/2 77/10 87/6 nor [5] 31/11 56/16 69/15 79/14 130/20 norm [2] 119/7 119/15 normal [3] 80/7 138/15 140/10 Northern [28] 1/14 1/19 2/9 32/23 44/12 44/22 44/24 45/4 45/7 59/4 71/5 75/13 107/10 107/11 107/18	37/9 November 2000 [2] 145/10 146/10 November 2002 [1] 165/25 now [31] 20/25 40/17 41/3 42/5 42/14 43/25 49/18 49/25 51/4 62/14 73/10 91/13 94/23 95/4 97/1 101/17 124/1 128/24 136/4 139/19 140/24	occasions [7] 12/10 16/1 26/6 28/2 42/2 58/3 101/22 occupation [1] 79/2 occurred [5] 8/7 9/9 34/15 75/3 109/17 Octapharma [1] 173/10 October [16] 31/23 31/25 33/11 66/21 67/17 67/21 68/23 69/16 71/24 92/11
149/11 150/19 151/3 Ms Fraser Butlin [1] 1/9 Ms Spooner [5] 14/11 72/19 149/11 150/19 151/3 much [16] 29/17 30/14 30/23 73/4 78/22 79/8 82/23 84/17 100/1 101/21 104/2 104/7 122/16 123/5 127/21 175/12 multi [1] 34/18 multi-transfused [1]	near [1] 118/3 nearby [1] 82/17 nearly [1] 121/1 necessarily [2] 52/11 56/3 necessary [5] 30/6 82/16 82/24 114/14 154/7 necessitated [1] 79/2 need [13] 32/6 37/22 38/9 40/9 73/7 98/8 100/20 101/17 127/1 131/6 147/24 148/12 171/16	139/14 145/25 154/3 155/6 160/7 161/1 163/12 165/7 165/12 170/8 174/3 NHS [2] 27/16 157/3 NI [2] 44/22 46/19 niece [1] 73/3 Nigel [1] 120/24 night [2] 79/13 80/5 nine [1] 127/11 no [83] 1/11 3/23 5/14 5/24 16/19 21/3 23/13 32/6 32/8 32/11 36/12 42/10 44/9 45/17	52/14 52/23 none [4] 6/13 54/2 77/10 87/6 nor [5] 31/11 56/16 69/15 79/14 130/20 norm [2] 119/7 119/15 normal [3] 80/7 138/15 140/10 Northern [28] 1/14 1/19 2/9 32/23 44/12 44/22 44/24 45/4 45/7 59/4 71/5 75/13 107/10 107/11 107/18 107/21 108/20 112/20 113/9 124/25 128/18	37/9 November 2000 [2] 145/10 146/10 November 2002 [1] 165/25 now [31] 20/25 40/17 41/3 42/5 42/14 43/25 49/18 49/25 51/4 62/14 73/10 91/13 94/23 95/4 97/1 101/17 124/1 128/24 136/4 139/19 140/24 147/23 148/18 152/3 154/11 160/8 160/13 160/23 162/15 164/11	occasions [7] 12/10 16/1 26/6 28/2 42/2 58/3 101/22 occupation [1] 79/2 occurred [5] 8/7 9/9 34/15 75/3 109/17 Octapharma [1] 173/10 October [16] 31/23 31/25 33/11 66/21 67/17 67/21 68/23 69/16 71/24 92/11 92/20 93/23 94/2 98/13 107/22 149/11 October 1983 [1]
149/11 150/19 151/3 Ms Fraser Butlin [1] 1/9 Ms Spooner [5] 14/11 72/19 149/11 150/19 151/3 much [16] 29/17 30/14 30/23 73/4 78/22 79/8 82/23 84/17 100/1 101/21 104/2 104/7 122/16 123/5 127/21 175/12 multi [1] 34/18 multi-transfused [1] 34/18	near [1] 118/3 nearby [1] 82/17 nearly [1] 121/1 necessarily [2] 52/11 56/3 necessary [5] 30/6 82/16 82/24 114/14 154/7 necessitated [1] 79/2 need [13] 32/6 37/22 38/9 40/9 73/7 98/8 100/20 101/17 127/1 131/6 147/24 148/12 171/16 needing [1] 66/3	139/14 145/25 154/3 155/6 160/7 161/1 163/12 165/7 165/12 170/8 174/3 NHS [2] 27/16 157/3 NI [2] 44/22 46/19 niece [1] 73/3 Nigel [1] 120/24 night [2] 79/13 80/5 nine [1] 127/11 no [83] 1/11 3/23 5/14 5/24 16/19 21/3 23/13 32/6 32/8 32/11 36/12 42/10 44/9 45/17 45/19 56/4 57/24	52/14 52/23 none [4] 6/13 54/2 77/10 87/6 nor [5] 31/11 56/16 69/15 79/14 130/20 norm [2] 119/7 119/15 normal [3] 80/7 138/15 140/10 Northern [28] 1/14 1/19 2/9 32/23 44/12 44/22 44/24 45/4 45/7 59/4 71/5 75/13 107/10 107/11 107/18 107/21 108/20 112/20 113/9 124/25 128/18 147/13 155/20 156/18	37/9 November 2000 [2] 145/10 146/10 November 2002 [1] 165/25 now [31] 20/25 40/17 41/3 42/5 42/14 43/25 49/18 49/25 51/4 62/14 73/10 91/13 94/23 95/4 97/1 101/17 124/1 128/24 136/4 139/19 140/24 147/23 148/18 152/3 154/11 160/8 160/13 160/23 162/15 164/11 172/16	occasions [7] 12/10 16/1 26/6 28/2 42/2 58/3 101/22 occupation [1] 79/2 occurred [5] 8/7 9/9 34/15 75/3 109/17 Octapharma [1] 173/10 October [16] 31/23 31/25 33/11 66/21 67/17 67/21 68/23 69/16 71/24 92/11 92/20 93/23 94/2 98/13 107/22 149/11 October 1983 [1] 92/20
149/11 150/19 151/3 Ms Fraser Butlin [1] 1/9 Ms Spooner [5] 14/11 72/19 149/11 150/19 151/3 much [16] 29/17 30/14 30/23 73/4 78/22 79/8 82/23 84/17 100/1 101/21 104/2 104/7 122/16 123/5 127/21 175/12 multi [1] 34/18 multi-transfused [1]	near [1] 118/3 nearby [1] 82/17 nearly [1] 121/1 necessarily [2] 52/11 56/3 necessary [5] 30/6 82/16 82/24 114/14 154/7 necessitated [1] 79/2 need [13] 32/6 37/22 38/9 40/9 73/7 98/8 100/20 101/17 127/1 131/6 147/24 148/12 171/16 needing [1] 66/3 needles [1] 102/21	139/14 145/25 154/3 155/6 160/7 161/1 163/12 165/7 165/12 170/8 174/3 NHS [2] 27/16 157/3 NI [2] 44/22 46/19 niece [1] 73/3 Nigel [1] 120/24 night [2] 79/13 80/5 nine [1] 127/11 no [83] 1/11 3/23 5/14 5/24 16/19 21/3 23/13 32/6 32/8 32/11 36/12 42/10 44/9 45/17 45/19 56/4 57/24 61/10 62/3 63/19 65/6	52/14 52/23 none [4] 6/13 54/2 77/10 87/6 nor [5] 31/11 56/16 69/15 79/14 130/20 norm [2] 119/7 119/15 normal [3] 80/7 138/15 140/10 Northern [28] 1/14 1/19 2/9 32/23 44/12 44/22 44/24 45/4 45/7 59/4 71/5 75/13 107/10 107/11 107/18 107/21 108/20 112/20 113/9 124/25 128/18 147/13 155/20 156/18 160/22 161/9 166/21	37/9 November 2000 [2] 145/10 146/10 November 2002 [1] 165/25 now [31] 20/25 40/17 41/3 42/5 42/14 43/25 49/18 49/25 51/4 62/14 73/10 91/13 94/23 95/4 97/1 101/17 124/1 128/24 136/4 139/19 140/24 147/23 148/18 152/3 154/11 160/8 160/13 160/23 162/15 164/11 172/16 number [35] 5/15	occasions [7] 12/10 16/1 26/6 28/2 42/2 58/3 101/22 occupation [1] 79/2 occurred [5] 8/7 9/9 34/15 75/3 109/17 Octapharma [1] 173/10 October [16] 31/23 31/25 33/11 66/21 67/17 67/21 68/23 69/16 71/24 92/11 92/20 93/23 94/2 98/13 107/22 149/11 October 1983 [1] 92/20 October 1985 [4]
149/11 150/19 151/3 Ms Fraser Butlin [1] 1/9 Ms Spooner [5] 14/11 72/19 149/11 150/19 151/3 much [16] 29/17 30/14 30/23 73/4 78/22 79/8 82/23 84/17 100/1 101/21 104/2 104/7 122/16 123/5 127/21 175/12 multi [1] 34/18 multi-transfused [1] 34/18 multidisciplinary [2]	near [1] 118/3 nearby [1] 82/17 nearly [1] 121/1 necessarily [2] 52/11 56/3 necessary [5] 30/6 82/16 82/24 114/14 154/7 necessitated [1] 79/2 need [13] 32/6 37/22 38/9 40/9 73/7 98/8 100/20 101/17 127/1 131/6 147/24 148/12 171/16 needing [1] 66/3 needles [1] 102/21 needn't [2] 38/14	139/14 145/25 154/3 155/6 160/7 161/1 163/12 165/7 165/12 170/8 174/3 NHS [2] 27/16 157/3 NI [2] 44/22 46/19 niece [1] 73/3 Nigel [1] 120/24 night [2] 79/13 80/5 nine [1] 127/11 no [83] 1/11 3/23 5/14 5/24 16/19 21/3 23/13 32/6 32/8 32/11 36/12 42/10 44/9 45/17 45/19 56/4 57/24 61/10 62/3 63/19 65/6 65/13 68/5 68/6 68/18	52/14 52/23 none [4] 6/13 54/2 77/10 87/6 nor [5] 31/11 56/16 69/15 79/14 130/20 norm [2] 119/7 119/15 normal [3] 80/7 138/15 140/10 Northern [28] 1/14 1/19 2/9 32/23 44/12 44/22 44/24 45/4 45/7 59/4 71/5 75/13 107/10 107/11 107/18 107/21 108/20 112/20 113/9 124/25 128/18 147/13 155/20 156/18 160/22 161/9 166/21 167/1	37/9 November 2000 [2] 145/10 146/10 November 2002 [1] 165/25 now [31] 20/25 40/17 41/3 42/5 42/14 43/25 49/18 49/25 51/4 62/14 73/10 91/13 94/23 95/4 97/1 101/17 124/1 128/24 136/4 139/19 140/24 147/23 148/18 152/3 154/11 160/8 160/13 160/23 162/15 164/11 172/16 number [35] 5/15 12/10 12/15 15/25	occasions [7] 12/10 16/1 26/6 28/2 42/2 58/3 101/22 occupation [1] 79/2 occurred [5] 8/7 9/9 34/15 75/3 109/17 Octapharma [1] 173/10 October [16] 31/23 31/25 33/11 66/21 67/17 67/21 68/23 69/16 71/24 92/11 92/20 93/23 94/2 98/13 107/22 149/11 October 1983 [1] 92/20 October 1985 [4] 69/16 71/24 92/11
149/11 150/19 151/3 Ms Fraser Butlin [1] 1/9 Ms Spooner [5] 14/11 72/19 149/11 150/19 151/3 much [16] 29/17 30/14 30/23 73/4 78/22 79/8 82/23 84/17 100/1 101/21 104/2 104/7 122/16 123/5 127/21 175/12 multi [1] 34/18 multi-transfused [1] 34/18 multidisciplinary [2] 112/13 171/8 multiple [4] 28/1 101/13 110/11 127/25	near [1] 118/3 nearby [1] 82/17 nearly [1] 121/1 necessarily [2] 52/11 56/3 necessary [5] 30/6 82/16 82/24 114/14 154/7 necessitated [1] 79/2 need [13] 32/6 37/22 38/9 40/9 73/7 98/8 100/20 101/17 127/1 131/6 147/24 148/12 171/16 needing [1] 66/3 needles [1] 102/21 needn't [2] 38/14	139/14 145/25 154/3 155/6 160/7 161/1 163/12 165/7 165/12 170/8 174/3 NHS [2] 27/16 157/3 NI [2] 44/22 46/19 niece [1] 73/3 Nigel [1] 120/24 night [2] 79/13 80/5 nine [1] 127/11 no [83] 1/11 3/23 5/14 5/24 16/19 21/3 23/13 32/6 32/8 32/11 36/12 42/10 44/9 45/17 45/19 56/4 57/24 61/10 62/3 63/19 65/6 65/13 68/5 68/6 68/18 70/3 71/18 72/22	52/14 52/23 none [4] 6/13 54/2 77/10 87/6 nor [5] 31/11 56/16 69/15 79/14 130/20 norm [2] 119/7 119/15 normal [3] 80/7 138/15 140/10 Northern [28] 1/14 1/19 2/9 32/23 44/12 44/22 44/24 45/4 45/7 59/4 71/5 75/13 107/10 107/11 107/18 107/21 108/20 112/20 113/9 124/25 128/18 147/13 155/20 156/18 160/22 161/9 166/21 167/1 Northern Ireland [1]	37/9 November 2000 [2] 145/10 146/10 November 2002 [1] 165/25 now [31] 20/25 40/17 41/3 42/5 42/14 43/25 49/18 49/25 51/4 62/14 73/10 91/13 94/23 95/4 97/1 101/17 124/1 128/24 136/4 139/19 140/24 147/23 148/18 152/3 154/11 160/8 160/13 160/23 162/15 164/11 172/16 number [35] 5/15 12/10 12/15 15/25 26/5 32/9 34/5 42/1	occasions [7] 12/10 16/1 26/6 28/2 42/2 58/3 101/22 occupation [1] 79/2 occurred [5] 8/7 9/9 34/15 75/3 109/17 Octapharma [1] 173/10 October [16] 31/23 31/25 33/11 66/21 67/17 67/21 68/23 69/16 71/24 92/11 92/20 93/23 94/2 98/13 107/22 149/11 October 1983 [1] 92/20 October 1985 [4] 69/16 71/24 92/11 107/22
149/11 150/19 151/3 Ms Fraser Butlin [1] 1/9 Ms Spooner [5] 14/11 72/19 149/11 150/19 151/3 much [16] 29/17 30/14 30/23 73/4 78/22 79/8 82/23 84/17 100/1 101/21 104/2 104/7 122/16 123/5 127/21 175/12 multi [1] 34/18 multi-transfused [1] 34/18 multidisciplinary [2] 112/13 171/8 multiple [4] 28/1 101/13 110/11 127/25 multiplicity [1] 59/6	near [1] 118/3 nearby [1] 82/17 nearly [1] 121/1 necessarily [2] 52/11 56/3 necessary [5] 30/6 82/16 82/24 114/14 154/7 necessitated [1] 79/2 need [13] 32/6 37/22 38/9 40/9 73/7 98/8 100/20 101/17 127/1 131/6 147/24 148/12 171/16 needing [1] 66/3 needles [1] 102/21 needn't [2] 38/14	139/14 145/25 154/3 155/6 160/7 161/1 163/12 165/7 165/12 170/8 174/3 NHS [2] 27/16 157/3 NI [2] 44/22 46/19 niece [1] 73/3 Nigel [1] 120/24 night [2] 79/13 80/5 nine [1] 127/11 no [83] 1/11 3/23 5/14 5/24 16/19 21/3 23/13 32/6 32/8 32/11 36/12 42/10 44/9 45/17 45/19 56/4 57/24 61/10 62/3 63/19 65/6 65/13 68/5 68/6 68/18 70/3 71/18 72/22 74/17 74/21 74/25	52/14 52/23 none [4] 6/13 54/2 77/10 87/6 nor [5] 31/11 56/16 69/15 79/14 130/20 norm [2] 119/7 119/15 normal [3] 80/7 138/15 140/10 Northern [28] 1/14 1/19 2/9 32/23 44/12 44/22 44/24 45/4 45/7 59/4 71/5 75/13 107/10 107/11 107/18 107/21 108/20 112/20 113/9 124/25 128/18 147/13 155/20 156/18 160/22 161/9 166/21 167/1 Northern Ireland [1] 167/1	37/9 November 2000 [2] 145/10 146/10 November 2002 [1] 165/25 now [31] 20/25 40/17 41/3 42/5 42/14 43/25 49/18 49/25 51/4 62/14 73/10 91/13 94/23 95/4 97/1 101/17 124/1 128/24 136/4 139/19 140/24 147/23 148/18 152/3 154/11 160/8 160/13 160/23 162/15 164/11 172/16 number [35] 5/15 12/10 12/15 15/25	occasions [7] 12/10 16/1 26/6 28/2 42/2 58/3 101/22 occupation [1] 79/2 occurred [5] 8/7 9/9 34/15 75/3 109/17 Octapharma [1] 173/10 October [16] 31/23 31/25 33/11 66/21 67/17 67/21 68/23 69/16 71/24 92/11 92/20 93/23 94/2 98/13 107/22 149/11 October 1983 [1] 92/20 October 1985 [4] 69/16 71/24 92/11
149/11 150/19 151/3 Ms Fraser Butlin [1] 1/9 Ms Spooner [5] 14/11 72/19 149/11 150/19 151/3 much [16] 29/17 30/14 30/23 73/4 78/22 79/8 82/23 84/17 100/1 101/21 104/2 104/7 122/16 123/5 127/21 175/12 multi [1] 34/18 multi-transfused [1] 34/18 multidisciplinary [2] 112/13 171/8 multiple [4] 28/1 101/13 110/11 127/25 multiplicity [1] 59/6 must [6] 2/11 39/19	near [1] 118/3 nearby [1] 82/17 nearly [1] 121/1 necessarily [2] 52/11 56/3 necessary [5] 30/6 82/16 82/24 114/14 154/7 necessitated [1] 79/2 need [13] 32/6 37/22 38/9 40/9 73/7 98/8 100/20 101/17 127/1 131/6 147/24 148/12 171/16 needing [1] 66/3 needles [1] 102/21 needn't [2] 38/14 167/16 needs [5] 30/4 51/3 51/12 51/16 51/18 negate [1] 3/1	139/14 145/25 154/3 155/6 160/7 161/1 163/12 165/7 165/12 170/8 174/3 NHS [2] 27/16 157/3 NI [2] 44/22 46/19 niece [1] 73/3 Nigel [1] 120/24 night [2] 79/13 80/5 nine [1] 127/11 no [83] 1/11 3/23 5/14 5/24 16/19 21/3 23/13 32/6 32/8 32/11 36/12 42/10 44/9 45/17 45/19 56/4 57/24 61/10 62/3 63/19 65/6 65/13 68/5 68/6 68/18 70/3 71/18 72/22	52/14 52/23 none [4] 6/13 54/2 77/10 87/6 nor [5] 31/11 56/16 69/15 79/14 130/20 norm [2] 119/7 119/15 normal [3] 80/7 138/15 140/10 Northern [28] 1/14 1/19 2/9 32/23 44/12 44/22 44/24 45/4 45/7 59/4 71/5 75/13 107/10 107/11 107/18 107/21 108/20 112/20 113/9 124/25 128/18 147/13 155/20 156/18 160/22 161/9 166/21 167/1 Northern Ireland [1] 167/1 not [208]	37/9 November 2000 [2] 145/10 146/10 November 2002 [1] 165/25 now [31] 20/25 40/17 41/3 42/5 42/14 43/25 49/18 49/25 51/4 62/14 73/10 91/13 94/23 95/4 97/1 101/17 124/1 128/24 136/4 139/19 140/24 147/23 148/18 152/3 154/11 160/8 160/13 160/23 162/15 164/11 172/16 number [35] 5/15 12/10 12/15 15/25 26/5 32/9 34/5 42/1 45/19 45/20 49/6	occasions [7] 12/10 16/1 26/6 28/2 42/2 58/3 101/22 occupation [1] 79/2 occurred [5] 8/7 9/9 34/15 75/3 109/17 Octapharma [1] 173/10 October [16] 31/23 31/25 33/11 66/21 67/17 67/21 68/23 69/16 71/24 92/11 92/20 93/23 94/2 98/13 107/22 149/11 October 1983 [1] 92/20 October 1985 [4] 69/16 71/24 92/11 107/22 October 1986 [1]
149/11 150/19 151/3 Ms Fraser Butlin [1] 1/9 Ms Spooner [5] 14/11 72/19 149/11 150/19 151/3 much [16] 29/17 30/14 30/23 73/4 78/22 79/8 82/23 84/17 100/1 101/21 104/2 104/7 122/16 123/5 127/21 175/12 multi [1] 34/18 multi-transfused [1] 34/18 multidisciplinary [2] 112/13 171/8 multiple [4] 28/1 101/13 110/11 127/25 multiplicity [1] 59/6 must [6] 2/11 39/19 50/17 154/16 155/20	near [1] 118/3 nearby [1] 82/17 nearly [1] 121/1 necessarily [2] 52/11 56/3 necessary [5] 30/6 82/16 82/24 114/14 154/7 necessitated [1] 79/2 need [13] 32/6 37/22 38/9 40/9 73/7 98/8 100/20 101/17 127/1 131/6 147/24 148/12 171/16 needing [1] 66/3 needles [1] 102/21 needn't [2] 38/14 167/16 needs [5] 30/4 51/3 51/12 51/16 51/18 negate [1] 3/1 negative [11] 67/1	139/14 145/25 154/3 155/6 160/7 161/1 163/12 165/7 165/12 170/8 174/3 NHS [2] 27/16 157/3 NI [2] 44/22 46/19 niece [1] 73/3 Nigel [1] 120/24 night [2] 79/13 80/5 nine [1] 127/11 no [83] 1/11 3/23 5/14 5/24 16/19 21/3 23/13 32/6 32/8 32/11 36/12 42/10 44/9 45/17 45/19 56/4 57/24 61/10 62/3 63/19 65/6 65/13 68/5 68/6 68/18 70/3 71/18 72/22 74/17 74/21 74/25 75/18 75/21 75/23 76/17 77/8 82/5 82/19 84/22 85/20 85/22	52/14 52/23 none [4] 6/13 54/2 77/10 87/6 nor [5] 31/11 56/16 69/15 79/14 130/20 norm [2] 119/7 119/15 normal [3] 80/7 138/15 140/10 Northern [28] 1/14 1/19 2/9 32/23 44/12 44/22 44/24 45/4 45/7 59/4 71/5 75/13 107/10 107/11 107/18 107/21 108/20 112/20 113/9 124/25 128/18 147/13 155/20 156/18 160/22 161/9 166/21 167/1 Northern Ireland [1] 167/1 not [208] not infected [1] 110/19	37/9 November 2000 [2] 145/10 146/10 November 2002 [1] 165/25 now [31] 20/25 40/17 41/3 42/5 42/14 43/25 49/18 49/25 51/4 62/14 73/10 91/13 94/23 95/4 97/1 101/17 124/1 128/24 136/4 139/19 140/24 147/23 148/18 152/3 154/11 160/8 160/13 160/23 162/15 164/11 172/16 number [35] 5/15 12/10 12/15 15/25 26/5 32/9 34/5 42/1 45/19 45/20 49/6 67/12 74/13 74/14 76/7 84/13 89/18 94/13 98/21 98/21	occasions [7] 12/10 16/1 26/6 28/2 42/2 58/3 101/22 occupation [1] 79/2 occurred [5] 8/7 9/9 34/15 75/3 109/17 Octapharma [1] 173/10 October [16] 31/23 31/25 33/11 66/21 67/17 67/21 68/23 69/16 71/24 92/11 92/20 93/23 94/2 98/13 107/22 149/11 October 1983 [1] 92/20 October 1985 [4] 69/16 71/24 92/11 107/22 October 1986 [1] 98/13 off [4] 38/13 81/21 95/2 108/2
149/11 150/19 151/3 Ms Fraser Butlin [1] 1/9 Ms Spooner [5] 14/11 72/19 149/11 150/19 151/3 much [16] 29/17 30/14 30/23 73/4 78/22 79/8 82/23 84/17 100/1 101/21 104/2 104/7 122/16 123/5 127/21 175/12 multi [1] 34/18 multi-transfused [1] 34/18 multidisciplinary [2] 112/13 171/8 multiple [4] 28/1 101/13 110/11 127/25 multiplicity [1] 59/6 must [6] 2/11 39/19 50/17 154/16 155/20 155/25	near [1] 118/3 nearby [1] 82/17 nearly [1] 121/1 necessarily [2] 52/11 56/3 necessary [5] 30/6 82/16 82/24 114/14 154/7 necessitated [1] 79/2 need [13] 32/6 37/22 38/9 40/9 73/7 98/8 100/20 101/17 127/1 131/6 147/24 148/12 171/16 needing [1] 66/3 needles [1] 102/21 needn't [2] 38/14 167/16 needs [5] 30/4 51/3 51/12 51/16 51/18 negate [1] 3/1 negative [11] 67/1 67/14 67/17 68/7 68/9	139/14 145/25 154/3 155/6 160/7 161/1 163/12 165/7 165/12 170/8 174/3 NHS [2] 27/16 157/3 NI [2] 44/22 46/19 niece [1] 73/3 Nigel [1] 120/24 night [2] 79/13 80/5 nine [1] 127/11 no [83] 1/11 3/23 5/14 5/24 16/19 21/3 23/13 32/6 32/8 32/11 36/12 42/10 44/9 45/17 45/19 56/4 57/24 61/10 62/3 63/19 65/6 65/13 68/5 68/6 68/18 70/3 71/18 72/22 74/17 74/21 74/25 75/18 75/21 75/23 76/17 77/8 82/5 82/19 84/22 85/20 85/22 89/12 89/21 91/15	52/14 52/23 none [4] 6/13 54/2 77/10 87/6 nor [5] 31/11 56/16 69/15 79/14 130/20 norm [2] 119/7 119/15 normal [3] 80/7 138/15 140/10 Northern [28] 1/14 1/19 2/9 32/23 44/12 44/22 44/24 45/4 45/7 59/4 71/5 75/13 107/10 107/11 107/18 107/21 108/20 112/20 113/9 124/25 128/18 147/13 155/20 156/18 160/22 161/9 166/21 167/1 Northern Ireland [1] 167/1 not [208] not infected [1] 110/19 note [21] 18/4 19/4	37/9 November 2000 [2] 145/10 146/10 November 2002 [1] 165/25 now [31] 20/25 40/17 41/3 42/5 42/14 43/25 49/18 49/25 51/4 62/14 73/10 91/13 94/23 95/4 97/1 101/17 124/1 128/24 136/4 139/19 140/24 147/23 148/18 152/3 154/11 160/8 160/13 160/23 162/15 164/11 172/16 number [35] 5/15 12/10 12/15 15/25 26/5 32/9 34/5 42/1 45/19 45/20 49/6 67/12 74/13 74/14 76/7 84/13 89/18 94/13 98/21 98/21 116/23 116/25 123/6	occasions [7] 12/10 16/1 26/6 28/2 42/2 58/3 101/22 occupation [1] 79/2 occurred [5] 8/7 9/9 34/15 75/3 109/17 Octapharma [1] 173/10 October [16] 31/23 31/25 33/11 66/21 67/17 67/21 68/23 69/16 71/24 92/11 92/20 93/23 94/2 98/13 107/22 149/11 October 1983 [1] 92/20 October 1985 [4] 69/16 71/24 92/11 107/22 October 1986 [1] 98/13 off [4] 38/13 81/21 95/2 108/2 offer [2] 65/7 130/17
149/11 150/19 151/3 Ms Fraser Butlin [1] 1/9 Ms Spooner [5] 14/11 72/19 149/11 150/19 151/3 much [16] 29/17 30/14 30/23 73/4 78/22 79/8 82/23 84/17 100/1 101/21 104/2 104/7 122/16 123/5 127/21 175/12 multi [1] 34/18 multi-transfused [1] 34/18 multidisciplinary [2] 112/13 171/8 multiple [4] 28/1 101/13 110/11 127/25 multiplicity [1] 59/6 must [6] 2/11 39/19 50/17 154/16 155/20 155/25 mutual [1] 105/3	near [1] 118/3 nearby [1] 82/17 nearly [1] 121/1 necessarily [2] 52/11 56/3 necessary [5] 30/6 82/16 82/24 114/14 154/7 necessitated [1] 79/2 need [13] 32/6 37/22 38/9 40/9 73/7 98/8 100/20 101/17 127/1 131/6 147/24 148/12 171/16 needing [1] 66/3 needles [1] 102/21 needn't [2] 38/14 167/16 needs [5] 30/4 51/3 51/12 51/16 51/18 negate [1] 3/1 negative [11] 67/1 67/14 67/17 68/7 68/9 83/10 84/2 91/14	139/14 145/25 154/3 155/6 160/7 161/1 163/12 165/7 165/12 170/8 174/3 NHS [2] 27/16 157/3 NI [2] 44/22 46/19 niece [1] 73/3 Nigel [1] 120/24 night [2] 79/13 80/5 nine [1] 127/11 no [83] 1/11 3/23 5/14 5/24 16/19 21/3 23/13 32/6 32/8 32/11 36/12 42/10 44/9 45/17 45/19 56/4 57/24 61/10 62/3 63/19 65/6 65/13 68/5 68/6 68/18 70/3 71/18 72/22 74/17 74/21 74/25 75/18 75/21 75/23 76/17 77/8 82/5 82/19 84/22 85/20 85/22 89/12 89/21 91/15 91/20 92/20 94/15	52/14 52/23 none [4] 6/13 54/2 77/10 87/6 nor [5] 31/11 56/16 69/15 79/14 130/20 norm [2] 119/7 119/15 normal [3] 80/7 138/15 140/10 Northern [28] 1/14 1/19 2/9 32/23 44/12 44/22 44/24 45/4 45/7 59/4 71/5 75/13 107/10 107/11 107/18 107/21 108/20 112/20 113/9 124/25 128/18 147/13 155/20 156/18 160/22 161/9 166/21 167/1 Northern Ireland [1] 167/1 not [208] not infected [1] 110/19 note [21] 18/4 19/4 25/11 25/25 28/18	37/9 November 2000 [2] 145/10 146/10 November 2002 [1] 165/25 now [31] 20/25 40/17 41/3 42/5 42/14 43/25 49/18 49/25 51/4 62/14 73/10 91/13 94/23 95/4 97/1 101/17 124/1 128/24 136/4 139/19 140/24 147/23 148/18 152/3 154/11 160/8 160/13 160/23 162/15 164/11 172/16 number [35] 5/15 12/10 12/15 15/25 26/5 32/9 34/5 42/1 45/19 45/20 49/6 67/12 74/13 74/14 76/7 84/13 89/18 94/13 98/21 98/21 116/23 116/25 123/6 124/10 127/12 136/8	occasions [7] 12/10 16/1 26/6 28/2 42/2 58/3 101/22 occupation [1] 79/2 occurred [5] 8/7 9/9 34/15 75/3 109/17 Octapharma [1] 173/10 October [16] 31/23 31/25 33/11 66/21 67/17 67/21 68/23 69/16 71/24 92/11 92/20 93/23 94/2 98/13 107/22 149/11 October 1983 [1] 92/20 October 1985 [4] 69/16 71/24 92/11 107/22 October 1986 [1] 98/13 off [4] 38/13 81/21 95/2 108/2 offer [2] 65/7 130/17 offered [8] 65/6 86/22
149/11 150/19 151/3 Ms Fraser Butlin [1] 1/9 Ms Spooner [5] 14/11 72/19 149/11 150/19 151/3 much [16] 29/17 30/14 30/23 73/4 78/22 79/8 82/23 84/17 100/1 101/21 104/2 104/7 122/16 123/5 127/21 175/12 multi [1] 34/18 multi-transfused [1] 34/18 multidisciplinary [2] 112/13 171/8 multiple [4] 28/1 101/13 110/11 127/25 multiplicity [1] 59/6 must [6] 2/11 39/19 50/17 154/16 155/20 155/25 mutual [1] 105/3 my [35] 2/22 9/1 9/6 15/1 20/21 26/14	near [1] 118/3 nearby [1] 82/17 nearly [1] 121/1 necessarily [2] 52/11 56/3 necessary [5] 30/6 82/16 82/24 114/14 154/7 necessitated [1] 79/2 need [13] 32/6 37/22 38/9 40/9 73/7 98/8 100/20 101/17 127/1 131/6 147/24 148/12 171/16 needing [1] 66/3 needles [1] 102/21 needn't [2] 38/14 167/16 needs [5] 30/4 51/3 51/12 51/16 51/18 negate [1] 3/1 negative [11] 67/1 67/14 67/17 68/7 68/9 83/10 84/2 91/14 94/17 106/21 151/12	139/14 145/25 154/3 155/6 160/7 161/1 163/12 165/7 165/12 170/8 174/3 NHS [2] 27/16 157/3 NI [2] 44/22 46/19 niece [1] 73/3 Nigel [1] 120/24 night [2] 79/13 80/5 nine [1] 127/11 no [83] 1/11 3/23 5/14 5/24 16/19 21/3 23/13 32/6 32/8 32/11 36/12 42/10 44/9 45/17 45/19 56/4 57/24 61/10 62/3 63/19 65/6 65/13 68/5 68/6 68/18 70/3 71/18 72/22 74/17 74/21 74/25 75/18 75/21 75/23 76/17 77/8 82/5 82/19 84/22 85/20 85/22 89/12 89/21 91/15 91/20 92/20 94/15 94/15 99/24 102/21	52/14 52/23 none [4] 6/13 54/2 77/10 87/6 nor [5] 31/11 56/16 69/15 79/14 130/20 norm [2] 119/7 119/15 normal [3] 80/7 138/15 140/10 Northern [28] 1/14 1/19 2/9 32/23 44/12 44/22 44/24 45/4 45/7 59/4 71/5 75/13 107/10 107/11 107/18 107/21 108/20 112/20 113/9 124/25 128/18 147/13 155/20 156/18 160/22 161/9 166/21 167/1 Northern Ireland [1] 167/1 not [208] not infected [1] 110/19 note [21] 18/4 19/4 25/11 25/25 28/18 50/9 61/14 87/9 96/22	37/9 November 2000 [2] 145/10 146/10 November 2002 [1] 165/25 now [31] 20/25 40/17 41/3 42/5 42/14 43/25 49/18 49/25 51/4 62/14 73/10 91/13 94/23 95/4 97/1 101/17 124/1 128/24 136/4 139/19 140/24 147/23 148/18 152/3 154/11 160/8 160/13 160/23 162/15 164/11 172/16 number [35] 5/15 12/10 12/15 15/25 26/5 32/9 34/5 42/1 45/19 45/20 49/6 67/12 74/13 74/14 76/7 84/13 89/18 94/13 98/21 98/21 116/23 116/25 123/6 124/10 127/12 136/8 139/10 140/8 144/23	occasions [7] 12/10 16/1 26/6 28/2 42/2 58/3 101/22 occupation [1] 79/2 occurred [5] 8/7 9/9 34/15 75/3 109/17 Octapharma [1] 173/10 October [16] 31/23 31/25 33/11 66/21 67/17 67/21 68/23 69/16 71/24 92/11 92/20 93/23 94/2 98/13 107/22 149/11 October 1983 [1] 92/20 October 1985 [4] 69/16 71/24 92/11 107/22 October 1986 [1] 98/13 off [4] 38/13 81/21 95/2 108/2 offer [2] 65/7 130/17 offered [8] 65/6 86/22 87/20 89/3 103/1
149/11 150/19 151/3 Ms Fraser Butlin [1] 1/9 Ms Spooner [5] 14/11 72/19 149/11 150/19 151/3 much [16] 29/17 30/14 30/23 73/4 78/22 79/8 82/23 84/17 100/1 101/21 104/2 104/7 122/16 123/5 127/21 175/12 multi [1] 34/18 multi-transfused [1] 34/18 multidisciplinary [2] 112/13 171/8 multiple [4] 28/1 101/13 110/11 127/25 multiplicity [1] 59/6 must [6] 2/11 39/19 50/17 154/16 155/20 155/25 mutual [1] 105/3 my [35] 2/22 9/1 9/6 15/1 20/21 26/14 38/13 45/21 54/2 54/6	near [1] 118/3 nearby [1] 82/17 nearly [1] 121/1 necessarily [2] 52/11 56/3 necessary [5] 30/6 82/16 82/24 114/14 154/7 necessitated [1] 79/2 need [13] 32/6 37/22 38/9 40/9 73/7 98/8 100/20 101/17 127/1 131/6 147/24 148/12 171/16 needing [1] 66/3 needles [1] 102/21 needn't [2] 38/14 167/16 needs [5] 30/4 51/3 51/12 51/16 51/18 negate [1] 3/1 negative [11] 67/1 67/14 67/17 68/7 68/9 83/10 84/2 91/14 94/17 106/21 151/12 negativity [1] 92/2	139/14 145/25 154/3 155/6 160/7 161/1 163/12 165/7 165/12 170/8 174/3 NHS [2] 27/16 157/3 NI [2] 44/22 46/19 niece [1] 73/3 Nigel [1] 120/24 night [2] 79/13 80/5 nine [1] 127/11 no [83] 1/11 3/23 5/14 5/24 16/19 21/3 23/13 32/6 32/8 32/11 36/12 42/10 44/9 45/17 45/19 56/4 57/24 61/10 62/3 63/19 65/6 65/13 68/5 68/6 68/18 70/3 71/18 72/22 74/17 74/21 74/25 75/18 75/21 75/23 76/17 77/8 82/5 82/19 84/22 85/20 85/22 89/12 89/21 91/15 91/20 92/20 94/15 94/15 99/24 102/21 103/2 103/9 106/5	52/14 52/23 none [4] 6/13 54/2 77/10 87/6 nor [5] 31/11 56/16 69/15 79/14 130/20 norm [2] 119/7 119/15 normal [3] 80/7 138/15 140/10 Northern [28] 1/14 1/19 2/9 32/23 44/12 44/22 44/24 45/4 45/7 59/4 71/5 75/13 107/10 107/11 107/18 107/21 108/20 112/20 113/9 124/25 128/18 147/13 155/20 156/18 160/22 161/9 166/21 167/1 Northern Ireland [1] 167/1 not [208] not infected [1] 110/19 note [21] 18/4 19/4 25/11 25/25 28/18 50/9 61/14 87/9 96/22 99/16 123/6 137/4	37/9 November 2000 [2] 145/10 146/10 November 2002 [1] 165/25 now [31] 20/25 40/17 41/3 42/5 42/14 43/25 49/18 49/25 51/4 62/14 73/10 91/13 94/23 95/4 97/1 101/17 124/1 128/24 136/4 139/19 140/24 147/23 148/18 152/3 154/11 160/8 160/13 160/23 162/15 164/11 172/16 number [35] 5/15 12/10 12/15 15/25 26/5 32/9 34/5 42/1 45/19 45/20 49/6 67/12 74/13 74/14 76/7 84/13 89/18 94/13 98/21 98/21 116/23 116/25 123/6 124/10 127/12 136/8 139/10 140/8 144/23 147/2 150/10 150/17	occasions [7] 12/10 16/1 26/6 28/2 42/2 58/3 101/22 occupation [1] 79/2 occurred [5] 8/7 9/9 34/15 75/3 109/17 Octapharma [1] 173/10 October [16] 31/23 31/25 33/11 66/21 67/17 67/21 68/23 69/16 71/24 92/11 92/20 93/23 94/2 98/13 107/22 149/11 October 1983 [1] 92/20 October 1985 [4] 69/16 71/24 92/11 107/22 October 1986 [1] 98/13 off [4] 38/13 81/21 95/2 108/2 offer [2] 65/7 130/17 offered [8] 65/6 86/22 87/20 89/3 103/1 139/16 139/18 139/20
149/11 150/19 151/3 Ms Fraser Butlin [1] 1/9 Ms Spooner [5] 14/11 72/19 149/11 150/19 151/3 much [16] 29/17 30/14 30/23 73/4 78/22 79/8 82/23 84/17 100/1 101/21 104/2 104/7 122/16 123/5 127/21 175/12 multi [1] 34/18 multi-transfused [1] 34/18 multidisciplinary [2] 112/13 171/8 multiple [4] 28/1 101/13 110/11 127/25 multiplicity [1] 59/6 must [6] 2/11 39/19 50/17 154/16 155/20 155/25 mutual [1] 105/3 my [35] 2/22 9/1 9/6 15/1 20/21 26/14 38/13 45/21 54/2 54/6 61/13 62/21 63/7	near [1] 118/3 nearby [1] 82/17 nearly [1] 121/1 necessarily [2] 52/11 56/3 necessary [5] 30/6 82/16 82/24 114/14 154/7 necessitated [1] 79/2 need [13] 32/6 37/22 38/9 40/9 73/7 98/8 100/20 101/17 127/1 131/6 147/24 148/12 171/16 needing [1] 66/3 needles [1] 102/21 needn't [2] 38/14 167/16 needs [5] 30/4 51/3 51/12 51/16 51/18 negate [1] 3/1 negative [11] 67/1 67/14 67/17 68/7 68/9 83/10 84/2 91/14 94/17 106/21 151/12	139/14 145/25 154/3 155/6 160/7 161/1 163/12 165/7 165/12 170/8 174/3 NHS [2] 27/16 157/3 NI [2] 44/22 46/19 niece [1] 73/3 Nigel [1] 120/24 night [2] 79/13 80/5 nine [1] 127/11 no [83] 1/11 3/23 5/14 5/24 16/19 21/3 23/13 32/6 32/8 32/11 36/12 42/10 44/9 45/17 45/19 56/4 57/24 61/10 62/3 63/19 65/6 65/13 68/5 68/6 68/18 70/3 71/18 72/22 74/17 74/21 74/25 75/18 75/21 75/23 76/17 77/8 82/5 82/19 84/22 85/20 85/22 89/12 89/21 91/15 91/20 92/20 94/15 94/15 99/24 102/21 103/2 103/9 106/5 108/4 110/3 110/20	52/14 52/23 none [4] 6/13 54/2 77/10 87/6 nor [5] 31/11 56/16 69/15 79/14 130/20 norm [2] 119/7 119/15 normal [3] 80/7 138/15 140/10 Northern [28] 1/14 1/19 2/9 32/23 44/12 44/22 44/24 45/4 45/7 59/4 71/5 75/13 107/10 107/11 107/18 107/21 108/20 112/20 113/9 124/25 128/18 147/13 155/20 156/18 160/22 161/9 166/21 167/1 Northern Ireland [1] 167/1 not [208] not infected [1] 110/19 note [21] 18/4 19/4 25/11 25/25 28/18 50/9 61/14 87/9 96/22 99/16 123/6 137/4 137/21 144/23 145/1	37/9 November 2000 [2] 145/10 146/10 November 2002 [1] 165/25 now [31] 20/25 40/17 41/3 42/5 42/14 43/25 49/18 49/25 51/4 62/14 73/10 91/13 94/23 95/4 97/1 101/17 124/1 128/24 136/4 139/19 140/24 147/23 148/18 152/3 154/11 160/8 160/13 160/23 162/15 164/11 172/16 number [35] 5/15 12/10 12/15 15/25 26/5 32/9 34/5 42/1 45/19 45/20 49/6 67/12 74/13 74/14 76/7 84/13 89/18 94/13 98/21 98/21 116/23 116/25 123/6 124/10 127/12 136/8 139/10 140/8 144/23 147/2 150/10 150/17 151/20 157/17 169/4	occasions [7] 12/10 16/1 26/6 28/2 42/2 58/3 101/22 occupation [1] 79/2 occurred [5] 8/7 9/9 34/15 75/3 109/17 Octapharma [1] 173/10 October [16] 31/23 31/25 33/11 66/21 67/17 67/21 68/23 69/16 71/24 92/11 92/20 93/23 94/2 98/13 107/22 149/11 October 1983 [1] 92/20 October 1985 [4] 69/16 71/24 92/11 107/22 October 1986 [1] 98/13 off [4] 38/13 81/21 95/2 108/2 offer [2] 65/7 130/17 offered [8] 65/6 86/22 87/20 89/3 103/1
149/11 150/19 151/3 Ms Fraser Butlin [1] 1/9 Ms Spooner [5] 14/11 72/19 149/11 150/19 151/3 much [16] 29/17 30/14 30/23 73/4 78/22 79/8 82/23 84/17 100/1 101/21 104/2 104/7 122/16 123/5 127/21 175/12 multi [1] 34/18 multi-transfused [1] 34/18 multidisciplinary [2] 112/13 171/8 multiple [4] 28/1 101/13 110/11 127/25 multiplicity [1] 59/6 must [6] 2/11 39/19 50/17 154/16 155/20 155/25 mutual [1] 105/3 my [35] 2/22 9/1 9/6 15/1 20/21 26/14 38/13 45/21 54/2 54/6 61/13 62/21 63/7 95/14 95/16	near [1] 118/3 nearby [1] 82/17 nearly [1] 121/1 necessarily [2] 52/11 56/3 necessary [5] 30/6 82/16 82/24 114/14 154/7 necessitated [1] 79/2 need [13] 32/6 37/22 38/9 40/9 73/7 98/8 100/20 101/17 127/1 131/6 147/24 148/12 171/16 needing [1] 66/3 needles [1] 102/21 needn't [2] 38/14 167/16 needs [5] 30/4 51/3 51/12 51/16 51/18 negate [1] 3/1 negative [1] 67/1 67/14 67/17 68/7 68/9 83/10 84/2 91/14 94/17 106/21 151/12 negativity [1] 92/2 neither [3] 56/16 79/14 130/20 Neurologist [1]	139/14 145/25 154/3 155/6 160/7 161/1 163/12 165/7 165/12 170/8 174/3 NHS [2] 27/16 157/3 NI [2] 44/22 46/19 niece [1] 73/3 Nigel [1] 120/24 night [2] 79/13 80/5 nine [1] 127/11 no [83] 1/11 3/23 5/14 5/24 16/19 21/3 23/13 32/6 32/8 32/11 36/12 42/10 44/9 45/17 45/19 56/4 57/24 61/10 62/3 63/19 65/6 65/13 68/5 68/6 68/18 70/3 71/18 72/22 74/17 74/21 74/25 75/18 75/21 75/23 76/17 77/8 82/5 82/19 84/22 85/20 85/22 89/12 89/21 91/15 91/20 92/20 94/15 94/15 99/24 102/21 103/2 103/9 106/5	52/14 52/23 none [4] 6/13 54/2 77/10 87/6 nor [5] 31/11 56/16 69/15 79/14 130/20 norm [2] 119/7 119/15 normal [3] 80/7 138/15 140/10 Northern [28] 1/14 1/19 2/9 32/23 44/12 44/22 44/24 45/4 45/7 59/4 71/5 75/13 107/10 107/11 107/18 107/21 108/20 112/20 113/9 124/25 128/18 147/13 155/20 156/18 160/22 161/9 166/21 167/1 Northern Ireland [1] 167/1 not [208] not infected [1] 110/19 note [21] 18/4 19/4 25/11 25/25 28/18 50/9 61/14 87/9 96/22 99/16 123/6 137/4 137/21 144/23 145/1 147/25 148/11 152/7	37/9 November 2000 [2] 145/10 146/10 November 2002 [1] 165/25 now [31] 20/25 40/17 41/3 42/5 42/14 43/25 49/18 49/25 51/4 62/14 73/10 91/13 94/23 95/4 97/1 101/17 124/1 128/24 136/4 139/19 140/24 147/23 148/18 152/3 154/11 160/8 160/13 160/23 162/15 164/11 172/16 number [35] 5/15 12/10 12/15 15/25 26/5 32/9 34/5 42/1 45/19 45/20 49/6 67/12 74/13 74/14 76/7 84/13 89/18 94/13 98/21 98/21 116/23 116/25 123/6 124/10 127/12 136/8 139/10 140/8 144/23 147/2 150/10 150/17	occasions [7] 12/10 16/1 26/6 28/2 42/2 58/3 101/22 occupation [1] 79/2 occurred [5] 8/7 9/9 34/15 75/3 109/17 Octapharma [1] 173/10 October [16] 31/23 31/25 33/11 66/21 67/17 67/21 68/23 69/16 71/24 92/11 92/20 93/23 94/2 98/13 107/22 149/11 October 1983 [1] 92/20 October 1985 [4] 69/16 71/24 92/11 107/22 October 1986 [1] 98/13 off [4] 38/13 81/21 95/2 108/2 offer [2] 65/7 130/17 offered [8] 65/6 86/22 87/20 89/3 103/1 139/16 139/18 139/20 offering [3] 65/17
149/11 150/19 151/3 Ms Fraser Butlin [1] 1/9 Ms Spooner [5] 14/11 72/19 149/11 150/19 151/3 much [16] 29/17 30/14 30/23 73/4 78/22 79/8 82/23 84/17 100/1 101/21 104/2 104/7 122/16 123/5 127/21 175/12 multi [1] 34/18 multi-transfused [1] 34/18 multidisciplinary [2] 112/13 171/8 multiple [4] 28/1 101/13 110/11 127/25 multiplicity [1] 59/6 must [6] 2/11 39/19 50/17 154/16 155/20 155/25 mutual [1] 105/3 my [35] 2/22 9/1 9/6 15/1 20/21 26/14 38/13 45/21 54/2 54/6 61/13 62/21 63/7	near [1] 118/3 nearby [1] 82/17 nearly [1] 121/1 necessarily [2] 52/11 56/3 necessary [5] 30/6 82/16 82/24 114/14 154/7 necessitated [1] 79/2 need [13] 32/6 37/22 38/9 40/9 73/7 98/8 100/20 101/17 127/1 131/6 147/24 148/12 171/16 needing [1] 66/3 needles [1] 102/21 needn't [2] 38/14 167/16 needs [5] 30/4 51/3 51/12 51/16 51/18 negate [1] 3/1 negative [11] 67/1 67/14 67/17 68/7 68/9 83/10 84/2 91/14 94/17 106/21 151/12 negativity [1] 92/2 neither [3] 56/16 79/14 130/20	139/14 145/25 154/3 155/6 160/7 161/1 163/12 165/7 165/12 170/8 174/3 NHS [2] 27/16 157/3 NI [2] 44/22 46/19 niece [1] 73/3 Nigel [1] 120/24 night [2] 79/13 80/5 nine [1] 127/11 no [83] 1/11 3/23 5/14 5/24 16/19 21/3 23/13 32/6 32/8 32/11 36/12 42/10 44/9 45/17 45/19 56/4 57/24 61/10 62/3 63/19 65/6 65/13 68/5 68/6 68/18 70/3 71/18 72/22 74/17 74/21 74/25 75/18 75/21 75/23 76/17 77/8 82/5 82/19 84/22 85/20 85/22 89/12 89/21 91/15 91/20 92/20 94/15 94/15 99/24 102/21 103/2 103/9 106/5 108/4 110/3 110/20 118/9 119/10 120/4	52/14 52/23 none [4] 6/13 54/2 77/10 87/6 nor [5] 31/11 56/16 69/15 79/14 130/20 norm [2] 119/7 119/15 normal [3] 80/7 138/15 140/10 Northern [28] 1/14 1/19 2/9 32/23 44/12 44/22 44/24 45/4 45/7 59/4 71/5 75/13 107/10 107/11 107/18 107/21 108/20 112/20 113/9 124/25 128/18 147/13 155/20 156/18 160/22 161/9 166/21 167/1 Northern Ireland [1] 167/1 not [208] not infected [1] 110/19 note [21] 18/4 19/4 25/11 25/25 28/18 50/9 61/14 87/9 96/22 99/16 123/6 137/4 137/21 144/23 145/1 147/25 148/11 152/7 172/5 172/19 174/24	37/9 November 2000 [2] 145/10 146/10 November 2002 [1] 165/25 now [31] 20/25 40/17 41/3 42/5 42/14 43/25 49/18 49/25 51/4 62/14 73/10 91/13 94/23 95/4 97/1 101/17 124/1 128/24 136/4 139/19 140/24 147/23 148/18 152/3 154/11 160/8 160/13 160/23 162/15 164/11 172/16 number [35] 5/15 12/10 12/15 15/25 26/5 32/9 34/5 42/1 45/19 45/20 49/6 67/12 74/13 74/14 76/7 84/13 89/18 94/13 98/21 98/21 116/23 116/25 123/6 124/10 127/12 136/8 139/10 140/8 144/23 147/2 150/10 150/17 151/20 157/17 169/4 numbers [3] 36/23	occasions [7] 12/10 16/1 26/6 28/2 42/2 58/3 101/22 occupation [1] 79/2 occurred [5] 8/7 9/9 34/15 75/3 109/17 Octapharma [1] 173/10 October [16] 31/23 31/25 33/11 66/21 67/17 67/21 68/23 69/16 71/24 92/11 92/20 93/23 94/2 98/13 107/22 149/11 October 1983 [1] 92/20 October 1985 [4] 69/16 71/24 92/11 107/22 October 1986 [1] 98/13 off [4] 38/13 81/21 95/2 108/2 offer [2] 65/6 130/17 offered [8] 65/6 86/22 87/20 89/3 103/1 139/16 139/18 139/20 offering [3] 65/17 88/5 142/18
149/11 150/19 151/3 Ms Fraser Butlin [1] 1/9 Ms Spooner [5] 14/11 72/19 149/11 150/19 151/3 much [16] 29/17 30/14 30/23 73/4 78/22 79/8 82/23 84/17 100/1 101/21 104/2 104/7 122/16 123/5 127/21 175/12 multi [1] 34/18 multi-transfused [1] 34/18 multidisciplinary [2] 112/13 171/8 multiple [4] 28/1 101/13 110/11 127/25 multiplicity [1] 59/6 must [6] 2/11 39/19 50/17 154/16 155/20 155/25 mutual [1] 105/3 my [35] 2/22 9/1 9/6 15/1 20/21 26/14 38/13 45/21 54/2 54/6 61/13 62/21 63/7 95/14 95/16	near [1] 118/3 nearby [1] 82/17 nearly [1] 121/1 necessarily [2] 52/11 56/3 necessary [5] 30/6 82/16 82/24 114/14 154/7 necessitated [1] 79/2 need [13] 32/6 37/22 38/9 40/9 73/7 98/8 100/20 101/17 127/1 131/6 147/24 148/12 171/16 needing [1] 66/3 needles [1] 102/21 needn't [2] 38/14 167/16 needs [5] 30/4 51/3 51/12 51/16 51/18 negate [1] 3/1 negative [1] 67/1 67/14 67/17 68/7 68/9 83/10 84/2 91/14 94/17 106/21 151/12 negativity [1] 92/2 neither [3] 56/16 79/14 130/20 Neurologist [1]	139/14 145/25 154/3 155/6 160/7 161/1 163/12 165/7 165/12 170/8 174/3 NHS [2] 27/16 157/3 NI [2] 44/22 46/19 niece [1] 73/3 Nigel [1] 120/24 night [2] 79/13 80/5 nine [1] 127/11 no [83] 1/11 3/23 5/14 5/24 16/19 21/3 23/13 32/6 32/8 32/11 36/12 42/10 44/9 45/17 45/19 56/4 57/24 61/10 62/3 63/19 65/6 65/13 68/5 68/6 68/18 70/3 71/18 72/22 74/17 74/21 74/25 75/18 75/21 75/23 76/17 77/8 82/5 82/19 84/22 85/20 85/22 89/12 89/21 91/15 91/20 92/20 94/15 94/15 99/24 102/21 103/2 103/9 106/5 108/4 110/3 110/20 118/9 119/10 120/4 122/13 122/24 125/14	52/14 52/23 none [4] 6/13 54/2 77/10 87/6 nor [5] 31/11 56/16 69/15 79/14 130/20 norm [2] 119/7 119/15 normal [3] 80/7 138/15 140/10 Northern [28] 1/14 1/19 2/9 32/23 44/12 44/22 44/24 45/4 45/7 59/4 71/5 75/13 107/10 107/11 107/18 107/21 108/20 112/20 113/9 124/25 128/18 147/13 155/20 156/18 160/22 161/9 166/21 167/1 Northern Ireland [1] 167/1 not [208] not infected [1] 110/19 note [21] 18/4 19/4 25/11 25/25 28/18 50/9 61/14 87/9 96/22 99/16 123/6 137/4 137/21 144/23 145/1 147/25 148/11 152/7 172/5 172/19 174/24	37/9 November 2000 [2] 145/10 146/10 November 2002 [1] 165/25 now [31] 20/25 40/17 41/3 42/5 42/14 43/25 49/18 49/25 51/4 62/14 73/10 91/13 94/23 95/4 97/1 101/17 124/1 128/24 136/4 139/19 140/24 147/23 148/18 152/3 154/11 160/8 160/13 160/23 162/15 164/11 172/16 number [35] 5/15 12/10 12/15 15/25 26/5 32/9 34/5 42/1 45/19 45/20 49/6 67/12 74/13 74/14 76/7 84/13 89/18 94/13 98/21 98/21 116/23 116/25 123/6 124/10 127/12 136/8 139/10 140/8 144/23 147/2 150/10 150/17 151/20 157/17 169/4 numbers [3] 36/23 47/11 90/10	occasions [7] 12/10 16/1 26/6 28/2 42/2 58/3 101/22 occupation [1] 79/2 occurred [5] 8/7 9/9 34/15 75/3 109/17 Octapharma [1] 173/10 October [16] 31/23 31/25 33/11 66/21 67/17 67/21 68/23 69/16 71/24 92/11 92/20 93/23 94/2 98/13 107/22 149/11 October 1983 [1] 92/20 October 1985 [4] 69/16 71/24 92/11 107/22 October 1986 [1] 98/13 off [4] 38/13 81/21 95/2 108/2 offer [2] 65/7 130/17 offered [8] 65/6 86/22 87/20 89/3 103/1 139/16 139/18 139/20 offering [3] 65/17 88/5 142/18 office [1] 76/10

(60) mortality... - officer

	ı		I		
0	99/18 107/4 136/12	105/25 126/14 137/20	149/1 149/2 149/10	155/17	paragraph 117 [1]
offset [1] 66/6	144/17 146/11	144/7 144/23 145/1	149/22 150/14 150/20	page 9 [1] 111/11	174/5
often [5] 53/24 122/12	open [5] 59/8 78/1	164/5 172/5	153/24 162/8	pages [12] 23/11	paragraph 18 [2]
122/17 156/5 156/7	78/4 78/16 112/3	out [55] 1/12 3/14	OXUH0000451 [1]	23/15 23/22 109/3	138/8 138/13
1	opening [2] 27/2 59/7	4/15 8/13 12/5 13/3	157/12	118/22 120/21 128/5	paragraph 19.1 [1]
oh [1] 148/11	openness [1] 126/23	15/7 16/9 18/5 20/11		139/14 160/4 164/10	29/23
old [8] 16/25 69/2	operate [1] 23/2	25/12 29/22 30/11	P	169/4 171/24	paragraph 2.1.1 [1]
69/22 80/15 81/23	Operating [1] 171/16	33/1 42/24 45/3 50/18	pack [2] 56/21 56/23	paid [1] 9/13	121/12
82/1 95/20 101/6	operation [2] 112/6	55/15 64/6 64/6 65/21	paediatric [4] 70/4	pain [1] 50/23	paragraph 2.1.2 [1]
ominous [1] 143/9	112/9	65/25 66/3 69/11 73/1	100/6 149/15 169/21	pamphlets [1] 174/15	121/17
omit [1] 155/12	opinions [3] 40/2 40/6		page [252]	Panel [1] 172/8	paragraph 2.2 [1]
omitted [1] 99/16	40/8	77/9 79/14 79/17	page 1 [1] 71/17	panic [1] 97/18	117/24
once [2] 129/25	opportunistic [1] 10/2		page 10 [6] 13/12	paper [11] 9/6 9/12	paragraph 2.6 [1]
156/17	opportunity [5] 4/16	86/24 87/5 87/14	32/2 78/13 91/12 93/2	15/20 20/4 20/11	74/15
one [99] 1/8 6/9 14/13	75/15 87/8 103/4	89/17 93/9 93/24	155/9		
16/1 16/20 16/23	i e			21/11 33/17 33/18	paragraph 20.4 [1]
16/23 17/7 21/5 26/16	156/20	111/13 115/21 122/9	page 11 [2] 12/20	173/7 174/20 175/2	30/17
34/10 41/23 43/12	opposed [3] 32/14	122/14 134/15 141/2	81/6	papers [1] 156/23	paragraph 20.6 [1]
43/22 44/13 44/14	47/3 97/24	141/18 150/11 151/13	page 12 [1] 75/9	paragraph [120] 2/8	30/20
45/24 45/25 46/6	opposite [1] 7/3	155/10 156/20 164/20	page 13 [3] 88/22	3/14 12/20 16/14	paragraph 3 [1] 21/17
47/12 47/19 47/22	optimistic [1] 117/17	168/17 169/7 175/3	143/3 173/20	17/14 20/2 20/15	paragraph 3.10.1 [1]
48/6 48/19 48/25 49/4	option [3] 52/22 56/17	outbreak [2] 10/2	page 14 [1] 95/10	21/12 21/13 21/17	91/13
49/9 50/18 50/22	86/19	173/14	page 140 [1] 164/15	21/25 22/8 22/13	paragraph 3.16 [1]
52/25 67/14 67/16	options [1] 117/13	outbreaks [1] 11/5	page 144 [2] 164/17	26/15 27/2 28/15	143/24
68/4 68/15 69/3 70/18	or [203]	outcome [3] 63/24	164/21	29/23 30/11 30/17	paragraph 3.19 [1]
72/5 72/9 72/15 73/14	or rather [1] 158/15	92/15 92/16	page 150 [1] 167/13	30/20 31/1 33/3 33/22	155/18
77/22 78/11 81/18	oral [8] 74/15 75/8	outline [1] 174/22	page 153 [1] 167/24	34/14 39/14 40/8	paragraph 3.2 [1]
83/16 84/6 84/25	77/22 85/2 96/1 99/14	outlined [1] 26/7	page 155 [1] 168/18	46/10 47/21 49/3 56/9	118/22
86/10 87/9 88/10	122/8 122/25	outlining [1] 162/16	page 156 [1] 168/23	57/3 58/18 59/21	paragraph 3.4 [1]
89/12 90/15 90/18	order [5] 74/9 151/13	outpatients [1]	page 158 [1] 169/1	63/22 64/16 64/19	120/2
90/23 93/18 98/14	154/7 156/4 158/16	111/23	page 16 [1] 145/11	65/19 66/3 66/5 69/8	paragraph 33.11 [1]
101/3 103/14 105/17	organisation [3] 12/3	outside [2] 102/16	page 163 [2] 169/6	74/15 88/22 89/15	114/12
105/18 105/20 106/15	44/25 141/17	149/22	169/9	91/13 93/2 93/6 95/1	paragraph 33.3 [1]
106/16 107/8 107/14	organisations' [1]	over [54] 6/17 14/23	page 164 [1] 169/10	95/11 97/17 98/23	64/16
107/25 108/18 109/6	147/11	15/12 17/5 20/17	page 165 [1] 169/11	99/8 99/9 99/21 102/7	paragraph 33.4 [1]
109/12 109/18 110/16	organised [2] 8/8 45/4		page 166 [1] 169/22	102/10 107/15 108/7	64/19
110/23 111/9 111/16	original [1] 121/25	29/22 30/17 34/22	page 17 [1] 29/8	108/15 109/4 111/12	paragraph 33.8 [1]
111/16 111/17 113/12	originally [1] 59/23	34/24 37/15 43/11	page 25 [1] 8/22	111/13 114/12 114/25	66/3
114/22 115/10 118/7	other [52] 6/1 6/24	46/1 47/20 57/14 59/5	page 26 [1] 64/3	115/8 117/24 118/22	paragraph 33.9 [1]
124/9 128/6 137/1	7/23 14/13 16/20 25/8	59/13 60/5 69/20 70/9	page 27 [1] 113/25	120/2 120/22 121/12	66/5
137/6 137/18 138/24	25/9 27/22 30/20 32/2	85/5 99/2 99/21	page 28 [2] 55/7	121/13 121/17 122/17	paragraph 4 [1] 139/4
139/2 141/6 142/24	39/7 42/7 55/13 55/24	100/25 104/20 106/9	62/14	124/12 127/1 127/16	paragraph 4.1 [2]
143/7 150/14 154/12	58/4 66/11 67/5 70/18	106/9 111/11 111/19	page 3 [1] 98/15	129/7 131/22 132/17	137/16 139/7
154/23 155/2 157/23	73/21 73/24 76/11	114/25 117/17 132/1	page 30 [1] 53/11	132/23 133/4 133/19	paragraph 4.2 [1]
159/11 160/6 160/12	82/21 84/13 88/10	133/18 134/23 138/18	page 31 [1] 56/11	135/1 135/2 135/17	93/2
163/23 166/9	88/18 88/18 90/14	138/25 139/14 140/15	page 32 [1] 10/10	137/11 137/16 138/8	paragraph 43.1 [1]
one's [1] 68/19	90/24 90/25 95/3	144/3 149/24 158/15	page 33 [1] 33/13	138/13 139/4 139/7	56/9
ongoing [3] 106/8	103/20 108/24 110/14	161/5 161/25 165/6	page 35 [1] 89/15	141/10 143/3 143/4	Paragraph 47.1 [1]
106/19 166/20	111/20 112/14 114/14	165/23 166/13 166/22	page 36 [1] 99/8	143/24 145/21 145/25	58/18
only [38] 14/5 17/7	115/10 124/23 138/12	167/20 167/23 168/16	page 4 [2] 70/22 72/1	147/7 147/17 153/18	paragraph 5 [2] 129/7
23/21 44/4 44/8 49/4	141/16 142/21 145/23	169/4 169/10	page 40 [1] 50/7	155/18 158/9 158/18	137/11
49/9 71/5 72/8 76/11	146/2 146/3 151/21	over-optimistic [1]	page 41 [1] 131/10	159/2 161/1 164/16	paragraph 5.2 [1]
80/14 81/20 83/15	153/20 157/8 157/11	117/17	page 46 [1] 2/4	165/9 165/12 165/16	147/7
84/23 86/18 87/7 88/6	162/2 163/10 163/18	overall [4] 44/18 46/4	page 5 [3] 18/13	166/2 166/15 166/23	paragraph 5.4 [2]
89/22 94/17 98/19	170/21	96/19 123/1	86/11 143/20	167/10 167/25 167/25	120/22 147/17
103/20 104/22 109/9	others [8] 10/20 11/1	overjoyed [1] 4/12	page 51 [1] 153/13	168/9 169/13 170/8	paragraph 50 [1]
109/12 110/22 117/5	12/15 14/12 63/15	overoptimistic [1]	page 6 [1] 117/23	171/6 173/20 174/5	95/11
120/20 133/24 137/21	80/20 94/10 118/18	138/7	page 60 [1] 145/8	paragraph 1 [2] 21/12	
137/23 139/12 139/20	otherwise [9] 32/10	oversaw [1] 146/6	page 7 [5] 74/12	28/15	99/21
144/11 146/10 152/18	48/15 48/16 63/10	own [7] 28/1 59/22	76/17 76/24 77/1	paragraph 10 [1]	paragraph 54.5 [1]
162/3 163/9 171/14	72/25 131/17 133/20	101/3 125/11 128/13	143/21	47/21	102/10
onwards [7] 60/7 66/1	153/23 159/8	165/17 173/18	page 70 [1] 173/25	paragraph 11.1 [1]	paragraph 6.2 [2]
2	our [10] 49/1 66/25	Oxford [9] 72/20	page 8 [2] 12/16	173/20	143/3 143/4
					(04) 65 (
					(61) offset - paragraph 6.2

(61) offset - paragraph 6.2

P parties [3] 148/11 51/6 51/25 Peter [2] 9/4 34/23 play [1] 134/15 68/14 69/13 70/25 149/1 153/23 patients [294] Peter Kernoff [1] 9/4 please [14] 2/4 8/21 71/6 75/25 83/16 84/2 paragraph 63 [1] 40/8 PFL [1] 159/22 partner [4] 46/7 68/15 patients' [5] 2/10 8/23 16/4 23/22 53/10 85/8 92/3 92/6 92/19 paragraph 63.1 [1] 105/17 108/18 31/12 119/3 125/2 53/19 55/7 79/25 81/6 92/21 93/14 93/20 pharmaceutical [11] 132/17 partners [5] 65/21 173/1 127/12 172/21 172/25 85/17 91/12 111/11 94/2 94/24 95/13 paragraph 69.1 [1] 104/17 104/25 105/3 patronising [2] 173/4 173/17 173/22 153/13 99/23 103/8 103/17 105/6 124/16 125/6 174/2 174/7 174/11 pleased [1] 92/1 103/18 105/2 106/2 paragraph 76 [1] 174/13 174/23 106/3 106/14 109/8 partners and [1] paucity [1] 125/5 plenty [1] 90/3 153/18 104/17 Phone [1] 98/8 109/16 113/1 113/8 pausing [5] 45/23 plight [1] 52/17 paragraph 83 [1] plus [3] 35/7 83/9 52/9 76/15 133/11 phoning [1] 161/16 115/24 124/6 124/8 parts [2] 7/23 49/25 164/16 party [10] 12/19 14/1 phrase [4] 6/9 6/11 133/24 135/12 140/18 134/7 172/3 paragraph 84.1.1 [1] 14/17 17/11 19/21 PCP [3] 10/20 11/6 32/11 129/1 pm [5] 97/5 97/7 151/11 152/9 165/9 37/6 101/14 120/11 37/10 physically [1] 119/22 148/21 148/23 175/17 positivity [5] 70/23 paragraph 84.1.3 [1] 120/14 157/14 pneumonia [2] 10/20 72/3 72/11 135/14 Peake [1] 173/11 **physician** [5] 51/6 165/16 pass [1] 80/24 pecuniary [1] 174/4 51/25 51/25 53/2 80/11 141/12 paragraph 84.1.7 [1] passage [4] 9/7 15/3 pejorative [1] 60/1 60/14 point [19] 1/12 8/11 possession [2] 51/2 166/2 29/24 129/4 people [13] 29/25 physicians [5] 35/10 14/19 37/1 44/3 48/20 51/11 paragraph 84.2.2 [1] passages [3] 56/9 34/7 55/3 57/8 74/13 43/21 51/1 82/3 112/8 64/13 71/18 72/2 possibilities [2] 75/16 166/15 88/18 164/13 76/11 86/2 86/4 88/6 pick [21] 1/3 2/7 29/7 87/14 87/25 88/4 81/9 paragraph 84.2.5 [1] passed [3] 59/23 88/8 91/24 103/3 33/13 34/13 44/15 92/23 103/1 117/25 possibility [7] 13/18 166/23 45/10 49/16 66/19 142/10 143/14 148/14 92/23 149/22 116/22 22/10 34/12 47/16 paragraph 84.2.8 [1] per [17] 16/14 38/23 70/22 75/9 95/11 56/18 94/10 98/25 past [2] 90/4 135/15 155/10 167/10 paternalism [1] 52/3 44/20 44/21 44/23 96/22 131/10 137/11 pointer [1] 47/18 possible [28] 9/16 paragraph 85.1.8.5 [1] patient [101] 5/1 5/24 71/1 71/2 71/3 71/7 143/3 144/21 155/6 policies [2] 146/25 13/1 15/12 15/17 167/25 7/1 30/4 30/14 45/16 71/8 78/25 104/8 167/24 168/18 169/6 19/24 21/21 25/17 175/10 paragraph 89.1.1 [1] 47/7 47/13 47/22 104/9 109/9 109/10 picked [2] 24/11 policy [15] 27/17 33/23 36/4 55/24 56/1 169/13 47/25 51/2 51/6 51/13 56/6 58/1 63/4 65/9 113/2 140/17 113/15 28/13 29/2 29/12 paragraph 91.1.6 [1] 75/24 79/14 79/16 51/25 53/3 57/6 58/1 picking [12] 6/3 16/12 29/14 31/16 64/23 percentage [2] 44/18 171/6 65/20 68/24 69/14 71/12 92/2 96/7 97/14 80/19 114/5 122/6 42/23 43/8 47/20 140/21 paragraphs [5] 39/16 97/21 104/25 147/7 69/19 70/11 70/13 perception [1] 7/20 58/20 70/2 98/15 129/15 131/23 136/14 45/10 53/7 98/16 70/16 72/7 72/21 73/5 performance [1] 73/6 116/12 122/23 133/3 147/11 136/16 149/18 164/18 114/1 73/7 73/12 73/16 80/6 perhaps [25] 9/20 142/10 politely [1] 45/2 167/17 paramount [2] 122/11 84/25 85/23 87/2 39/13 42/23 46/14 picks [2] 8/11 48/20 pool [1] 27/10 possibly [8] 15/14 155/24 87/12 87/19 89/22 48/18 49/16 79/8 picture [3] 105/11 pools [2] 21/22 49/1 21/16 23/3 40/22 67/7 parcel [1] 59/3 90/6 93/4 93/18 93/18 82/21 84/16 87/14 116/12 168/19 Popov [1] 38/1 74/24 77/20 83/15 parents [4] 95/14 Popovic [2] 37/25 post [3] 82/4 156/18 93/19 94/2 94/3 94/15 96/23 96/25 104/7 piece [2] 77/19 95/16 161/23 162/15 95/20 96/7 96/16 117/16 133/4 135/25 159/13 167/12 part [12] 2/5 3/4 28/19 pieces [3] 96/17 103/14 103/17 109/18 137/6 140/23 145/7 population [8] 9/19 postdates [1] 160/8 36/7 37/16 48/4 55/19 110/5 110/16 110/19 146/19 148/14 158/6 11/22 18/20 43/20 156/22 172/23 postponed [2] 87/4 59/3 66/16 120/22 111/2 111/3 111/4 163/14 173/9 174/24 pioneering [2] 6/8 97/20 99/11 162/2 87/6 126/14 174/20 112/6 113/17 114/22 period [14] 17/6 22/4 118/6 163/21 potential [4] 5/19 6/15 participants [2] 115/7 115/9 117/4 64/21 65/19 66/1 place [18] 1/17 9/21 63/20 138/18 porcine [2] 157/1 157/16 157/18 118/24 120/16 122/14 67/20 69/25 85/4 90/2 54/25 57/4 61/21 173/7 potentially [6] 41/20 participate [1] 89/13 122/19 124/5 124/7 90/8 106/8 126/4 64/24 81/13 85/16 90/5 102/9 122/16 portering [2] 78/20 participating [2] 4/16 124/18 129/13 130/1 130/8 136/7 85/17 86/7 89/9 101/8 127/23 139/2 79/21 156/21 135/15 136/5 136/14 147/12 147/23 155/21 posed [6] 2/6 29/10 peripheral [1] 72/24 practicable [2] 47/3 participation [1] 137/2 137/12 137/16 permanent [1] 116/3 162/19 168/7 169/24 53/12 58/19 63/18 129/23 159/18 practical [4] 56/16 137/22 138/9 140/1 permission [1] 122/9 placed [1] 41/21 103/15 particular [28] 8/1 141/22 149/6 149/19 permit [1] 103/6 places [2] 86/10 poses [1] 64/18 71/14 79/14 171/7 11/10 16/20 17/23 150/1 150/11 151/10 permitted [1] 76/11 155/25 position [22] 16/11 practice [20] 2/9 3/9 18/10 29/2 33/25 152/1 152/4 152/15 person [11] 51/10 plan [1] 35/12 28/8 28/25 29/24 4/10 27/11 28/6 29/17 42/10 50/22 90/12 152/21 153/18 153/22 52/1 70/16 79/16 planned [1] 81/11 31/21 33/11 40/16 31/13 62/22 91/9 90/13 93/3 94/2 97/24 156/8 158/11 158/23 83/25 85/8 93/5 94/8 planning [1] 100/2 41/1 44/5 44/10 93/16 97/16 97/20 97/22 100/11 103/16 110/19 161/2 162/21 163/1 100/11 100/12 125/11 plans [1] 75/12 110/5 111/12 116/16 119/2 119/19 121/14 118/13 123/18 125/14 163/4 172/25 personal [4] 24/8 51/2 plant [1] 173/10 117/20 142/7 144/8 122/8 125/9 125/11 126/6 127/24 129/15 plasma [8] 9/18 15/18 | 144/15 165/2 166/5 patient's [16] 51/3 76/13 94/7 130/13 155/11 140/1 144/12 150/22 51/12 51/18 76/6 87/5 21/22 21/23 46/13 personally [2] 43/12 171/20 174/22 practices [2] 125/17 152/4 154/17 93/19 95/7 96/14 146/6 48/25 163/4 163/19 position's [1] 148/8 175/10 particular in [1] 33/25 128/20 130/12 135/20 persons [1] 108/21 platelet [1] 22/3 positive [48] 38/23 practising [1] 53/14 particularly [6] 40/4 150/7 150/12 158/4 platelets [2] 16/22 45/14 45/16 45/18 pragmatic [1] 171/11 perspective [4] 63/16 43/25 115/19 140/23 46/6 64/17 67/2 67/13 158/17 168/12 116/10 169/25 172/3 17/1 precarious [1] 69/18 155/23 164/6 precautions [2] 22/19 patient-physician [2] pertaining [1] 5/10 plausibility [1] 48/15 67/15 67/17 68/3

(62) paragraph 63 - precautions

121/9 128/22 130/12 112/4 117/12 126/24 168/8 P 12/23 18/14 25/19 re-tested [1] 122/1 133/22 146/23 147/9 26/7 26/19 32/5 43/7 149/1 150/8 154/20 query [1] 72/21 Re: [1] 19/18 precautions... [1] 163/15 167/5 175/6 43/10 44/2 44/5 79/10 159/23 160/2 164/24 question [58] 1/4 3/7 Re: Acquired [1] 155/15 80/23 141/16 149/12 169/3 174/1 4/3 6/23 8/1 13/21 prism [1] 19/15 19/18 preceding [1] 34/17 prison [1] 43/23 173/11 173/12 provides [4] 96/2 14/22 29/10 32/4 reaction [1] 173/1 precise [6] 10/22 35/4 privacy [1] 155/23 Professor Allain [4] 106/11 127/10 160/19 41/11 41/13 41/14 read [6] 51/8 60/10 119/6 120/19 124/20 83/5 140/23 164/19 probably [15] 7/8 21/5 43/7 43/10 44/2 44/5 providing [8] 8/1 62/1 52/16 53/11 53/12 134/14 54/25 67/9 72/4 86/25 Professor Bloom [7] 74/2 124/14 124/17 54/10 54/14 55/8 166/17 precisely [5] 12/5 88/17 92/8 95/25 12/21 12/23 18/14 144/19 169/8 172/24 55/13 55/23 57/17 reading [5] 39/13 34/13 51/14 51/20 118/23 126/15 133/16 25/19 26/7 26/19 32/5 Province [1] 71/9 58/19 59/14 59/15 52/25 56/5 65/25 66/2 101/7 138/15 154/23 163/3 Professor Bridges [1] Province's [1] 97/19 60/16 61/6 62/14 realise [1] 73/10 precluded [1] 5/23 problem [13] 17/13 149/12 provision [7] 7/24 62/16 63/2 63/7 64/4 realised [1] 154/6 predicated [1] 52/24 35/24 40/15 41/12 **Professor Eric** 55/18 57/16 148/10 64/18 66/13 68/10 realistic [2] 34/12 predict [1] 75/24 43/15 43/19 61/1 69/9 Preston [1] 141/16 152/24 159/18 160/3 74/4 79/19 86/2 86/4 56/17 prefix [1] 76/5 96/5 103/15 141/8 reality [1] 63/10 Professor Peake [1] provoked [1] 11/7 87/12 87/13 87/16 prepare [2] 15/18 161/12 163/5 173/11 PRSE0002647 [1] 88/2 88/4 91/15 really [4] 87/23 88/3 21/22 problematic [2] prognosis [1] 134/14 15/24 104/24 106/22 114/9 88/4 143/7 prepared [3] 14/24 130/22 170/9 **programme** [6] 2/15 PRSE0004440 [1] 122/10 126/19 134/24 reason [9] 23/20 15/21 18/24 problems [7] 2/24 4/13 4/17 9/14 129/19 31/24 135/2 147/15 152/16 47/17 80/12 82/19 preparing [1] 57/1 47/12 73/25 78/17 143/12 PRSE0004476 [1] 155/14 164/22 167/14 103/4 108/4 110/20 presence [4] 34/16 78/23 104/5 135/25 programmes [1] 62/2 9/23 169/7 169/23 151/17 152/14 56/23 75/22 134/1 questions [10] 2/6 4/4 prudent [1] 155/13 problems associated progressed [2] 4/14 reasons [3] 65/11 present [22] 13/11 [1] 104/5 134/16 public [11] 22/24 23/8 4/5 57/16 59/9 59/9 69/18 127/25 15/17 19/4 21/21 25/2 procedure [4] 167/20 progression [1] 23/24 40/2 100/15 104/20 114/9 125/2 reassurance [3] 27/24 32/1 32/7 33/24 168/17 168/21 171/4 154/19 103/23 104/17 169/25 153/14 117/16 117/17 138/7 33/25 34/18 69/15 procedures [3] 154/6 prolong [1] 50/24 170/4 170/8 170/18 quickly [1] 138/19 reassured [1] 116/5 69/21 78/6 101/10 publication [5] 10/18 recall [33] 6/5 6/6 170/20 173/13 prolonged [1] 16/18 quietly [1] 163/2 122/8 127/17 127/20 prominent [1] 162/21 8/10 9/20 12/12 32/12 proceed [1] 136/15 10/24 34/21 34/23 quite [5] 97/21 122/12 137/7 167/16 173/7 promiscuity [4] 15/13 38/3 141/20 142/1 142/6 proceedings [1] 79/7 32/20 38/4 38/13 174/20 42/12 44/17 44/23 process [19] 2/7 21/4 21/15 23/14 publications [9] 10/15 presentation [2] 56/25 60/18 64/10 promising [1] 141/20 10/17 11/4 34/15 54/18 58/5 61/10 125/5 144/23 83/7 90/8 91/4 96/3 proof [2] 32/8 32/11 34/20 35/7 37/17 radically [1] 103/8 61/14 68/17 74/6 presented [3] 36/3 105/23 106/8 106/19 proper [1] 87/7 101/15 156/25 radio [2] 35/8 66/6 75/19 77/21 79/9 79/9 102/13 radio/TV [1] 66/6 106/24 108/5 116/19 properly [2] 41/6 publicise [1] 99/13 82/11 84/10 92/7 presenting [2] 44/24 120/1 166/3 167/2 51/22 publicity [2] 26/9 raised [6] 32/3 56/19 92/11 110/18 111/1 prophylaxis [1] 116/4 88/2 126/9 131/16 167/15 175/3 39/22 118/16 119/1 121/25 presently [3] 141/15 process in [1] 167/2 proposed [2] 1/13 published [3] 9/6 170/7 122/24 126/14 168/3 145/3 148/1 107/11 119/10 raises [6] 68/10 73/23 processes [3] 145/2 165/11 recalling [2] 118/5 press [2] 35/8 144/7 PUP [1] 157/6 79/19 94/10 152/15 146/25 148/1 **proposing [3]** 33/2 168/2 Preston [2] 141/16 produced [5] 14/7 114/23 172/15 purer [1] 157/9 164/1 recalls [1] 170/9 173/12 raising [1] 98/25 49/1 69/12 101/21 prospect [1] 5/21 purity [1] 157/3 receipt [7] 1/7 6/15 presumably [3] 44/4 purpose [7] 5/8 6/24 random [1] 157/22 9/17 43/17 86/23 101/23 prospects [1] 125/21 85/25 105/19 26/8 42/2 104/16 range [7] 42/7 66/6 94/18 165/14 product [17] 16/20 protect [2] 104/16 prevalent [1] 120/7 16/21 46/21 47/12 153/19 153/20 receive [4] 4/8 40/25 125/17 132/20 132/21 156/4 prevent [2] 39/5 39/10 140/10 147/13 47/19 48/6 49/10 72/5 purposes [8] 3/11 83/10 115/7 protocol [2] 157/6 previous [8] 26/14 72/9 110/12 154/8 3/16 57/10 69/21 rapidly [2] 83/12 157/21 received [42] 4/25 5/4 32/10 64/2 70/17 103/15 157/9 165/14 166/25 103/11 112/19 137/7 6/5 16/25 18/12 18/21 protocols [2] 17/9 76/20 79/13 80/5 rare [2] 11/5 58/5 170/15 171/25 174/12 128/18 167/17 39/22 45/14 48/21 81/19 rate [4] 16/13 20/18 proved [3] 29/16 54/19 70/7 70/9 72/8 production [1] 43/3 pursued [1] 54/5 previously [12] 28/24 70/25 125/25 products [26] 1/19 30/16 103/8 put [4] 1/16 4/11 81/12 83/13 83/23 29/3 55/14 55/15 63/1 provide [7] 8/9 57/18 rates [2] 48/18 70/20 4/21 13/2 13/18 38/6 77/21 169/24 87/19 89/1 89/23 70/21 79/9 81/1 89/17 rather [16] 21/17 43/17 44/7 47/14 48/7 59/25 60/2 100/8 puts [4] 46/23 65/18 93/16 94/14 99/15 128/16 132/5 145/24 54/3 54/13 57/21 63/3 138/20 167/22 65/22 90/5 33/20 43/1 53/2 59/19 109/7 116/22 122/6 primarily [1] 67/7 109/8 111/6 119/22 provided [39] 2/3 4/23 63/20 66/13 83/1 88/8 127/21 141/18 146/16 primary [1] 115/12 151/18 157/1 159/21 41/18 50/4 54/15 99/17 116/3 130/25 149/8 151/4 161/9 prime [1] 100/8 160/1 161/14 163/4 quality [2] 145/22 154/9 158/15 172/17 161/24 162/5 163/7 54/22 56/10 57/5 principles [1] 147/5 163/19 165/10 165/24 146/12 175/6 57/19 58/1 58/2 58/13 163/16 163/18 166/1 print [1] 29/9 ratings [1] 71/2 quantity [1] 140/16 174/8 58/14 60/13 60/16 170/5 170/15 174/4 printouts [1] 57/24 profession [1] 40/1 quarantine [1] 171/14 ratio [2] 52/14 52/24 61/3 62/11 62/12 174/6 175/9 prior [17] 54/24 57/13 63/15 65/3 84/9 84/15 quarantined [2] rationing [1] 85/24 received AZT [1] 70/9 professional [2] 57/21 64/13 66/13 164/2 173/23 84/18 87/17 87/24 170/14 171/4 razor [1] 139/20 receiving [9] 4/12 68/7 89/21 95/12 queries [2] 78/22 re [3] 75/6 98/8 122/1 Professor [17] 12/21 89/8 101/14 105/6 72/22 85/13 85/15

(63) precautions... - receiving

R 33/9 34/4 34/11 35/11 regarded [2] 28/3 142/17 142/23 143/1 14/24 19/5 20/8 20/10 response [42] 50/3 37/1 38/11 42/4 42/13 88/15 144/8 144/20 145/2 25/13 26/20 33/12 53/17 53/22 54/9 receiving... [5] 118/5 56/2 58/19 63/23 regarding [22] 19/2 148/1 149/4 152/15 36/8 36/12 37/7 38/18 55/21 59/1 62/15 63/7 119/21 132/8 159/12 63/25 70/11 75/18 33/1 33/4 35/13 36/4 153/22 154/22 156/24 42/25 43/3 50/6 50/8 66/14 74/12 78/12 163/4 82/25 86/13 89/14 40/2 40/14 51/3 51/11 156/25 157/2 157/8 50/14 53/8 58/20 81/7 84/17 86/12 recent [11] 2/1 19/20 91/23 96/21 97/15 60/23 66/7 72/21 157/10 158/23 159/25 70/21 75/5 111/14 86/21 87/18 88/1 19/21 22/5 24/6 26/9 107/1 108/1 128/9 75/16 78/16 101/12 160/9 161/25 164/14 112/20 144/23 88/23 91/19 92/25 104/19 136/25 137/23 131/7 142/24 143/19 127/4 158/11 168/19 165/1 166/1 166/6 reported [11] 10/4 93/9 96/5 97/11 151/8 160/10 143/22 147/18 150/22 168/25 169/24 170/3 166/10 166/20 168/19 11/12 17/8 20/23 22/6 103/15 105/7 114/8 recently [3] 21/2 21/6 118/24 120/16 120/22 157/13 157/20 159/10 171/2 169/13 170/4 172/4 32/5 36/10 37/13 23/12 159/11 162/4 162/20 regardless [2] 46/13 173/16 174/23 175/6 109/24 149/14 151/11 126/13 126/22 126/25 recognised [3] 34/8 175/10 165/19 173/25 47/17 reporters [1] 40/3 128/7 129/6 130/16 34/10 103/17 referenced [1] 165/17 regards [1] 161/3 relations [1] 100/14 reporting [6] 18/15 134/23 143/4 147/20 recollection [11] 6/13 18/24 19/24 20/3 23/2 references [3] 50/9 regional [8] 32/22 relationship [4] 13/1 152/20 158/5 159/13 9/7 81/7 94/15 94/16 23/24 90/25 96/24 66/21 67/6 106/15 51/7 51/25 173/21 169/7 101/18 104/19 141/9 referencing [1] 73/12 107/17 108/4 108/11 relative [2] 5/19 104/3 reports [6] 12/25 14/1 responses [3] 78/11 170/3 171/11 171/19 referred [17] 1/13 112/21 relative's [2] 91/7 18/18 36/2 37/19 57/9 128/16 136/21 recollections [1] 6/12 responsibility [2] 9/25 33/14 33/15 regions [2] 44/20 92/13 representatives [1] recommendation [2] 35/15 76/16 80/2 167/3 relatively [4] 156/13 42/8 109/1 142/14 35/20 39/9 rest [3] 45/15 52/18 105/13 118/2 118/20 regrettable [1] 125/4 163/2 163/9 171/15 request [8] 4/15 20/5 recommendations [7] 120/9 137/1 138/4 65/11 151/6 151/25 regular [5] 65/20 relatives [12] 6/4 69/12 26/22 27/5 29/11 39/3 145/5 147/14 172/7 102/6 128/11 144/5 54/20 57/9 59/2 59/9 156/7 158/2 158/4 restricted [1] 50/25 39/6 62/20 62/24 172/12 144/6 83/9 89/3 90/5 99/25 requested [5] 23/1 restriction [1] 27/21 recommended [1] referring [14] 10/24 regularly [3] 128/10 102/14 116/23 156/5 53/13 76/1 152/6 result [40] 5/19 6/15 116/1 21/18 26/19 33/17 132/4 132/7 relatives' [1] 137/22 54/3 64/8 67/14 67/15 168/4 reconcile [1] 142/8 requesting [1] 124/18 34/25 35/6 37/4 40/11 reimbursement [1] relay [2] 91/20 124/25 67/17 67/17 68/3 68/8 record [8] 94/12 69/14 69/15 75/25 49/14 55/16 55/24 49/12 relayed [2] 105/8 requests [2] 151/18 144/22 145/2 145/4 78/7 87/10 88/7 88/7 56/7 92/9 143/25 reiterate [1] 104/10 105/11 151/19 146/8 146/15 148/1 refers [63] 2/17 7/9 88/9 91/14 91/18 92/2 rejected [2] 31/3 relaying [1] 91/14 require [3] 40/6 175/2 10/1 10/8 21/25 22/4 83/12 relevance [3] 9/11 103/18 122/8 93/4 93/14 93/21 94/2 record-keeping [5] required [5] 74/3 94/17 96/9 96/10 22/19 26/20 27/1 relate [3] 66/1 133/11 11/10 15/20 144/22 145/2 145/4 29/10 33/19 34/20 146/11 relevant [14] 1/22 135/13 169/21 170/4 97/15 103/13 103/14 146/15 148/1 35/21 36/17 37/7 related [10] 70/11 8/16 50/1 51/5 53/15 170/11 105/3 105/14 106/18 recorded [4] 98/24 37/20 38/2 39/20 80/10 94/24 113/18 65/15 66/16 105/8 requirement [1] 175/6 123/18 123/21 123/24 112/1 155/7 168/12 47/20 48/24 48/24 140/8 149/13 150/5 112/9 137/25 147/12 requiring [1] 172/25 124/7 124/8 130/8 records [24] 12/10 147/14 164/12 174/24 50/17 50/22 54/13 152/12 153/4 159/4 reread [1] 4/25 result confirmed [1] 16/1 36/1 37/10 42/12 56/4 58/9 61/22 63/22 relates [4] 70/15 reliable [2] 5/23 31/11 research [13] 15/22 69/14 72/24 94/18 123/2 65/17 65/19 69/1 69/5 110/5 110/18 151/14 39/24 59/11 60/9 results [40] 30/24 relocated [1] 146/4 126/11 144/24 144/25 78/4 95/1 98/16 102/7 114/6 153/15 153/16 38/21 45/3 45/8 66/25 relating [24] 47/12 relocation [1] 146/7 145/13 145/14 145/17 104/23 109/4 111/2 50/2 53/7 57/16 66/4 remain [2] 54/4 153/19 156/14 156/16 68/9 76/8 83/10 83/13 145/22 146/1 146/1 121/3 125/16 132/14 75/7 77/3 84/12 84/13 147/23 156/20 156/22 158/3 84/23 86/5 86/20 87/8 146/2 146/5 147/9 142/18 143/11 147/7 85/1 87/22 96/1 96/18 reservation [1] 5/25 89/23 91/5 91/8 91/25 remaining [2] 108/21 147/19 147/22 148/5 151/8 158/10 163/12 98/2 116/9 122/13 92/6 95/9 96/3 99/13 108/23 reservations [2] 5/24 148/25 165/9 165/11 165/15 125/15 144/18 150/15 103/11 104/14 104/22 remains [2] 58/16 115/23 recount [2] 6/13 117/5 151/25 154/5 156/14 165/23 166/2 166/5 105/25 106/11 107/23 91/3 reserve [1] 27/15 redacted [4] 68/24 166/19 168/1 169/14 residential [2] 127/7 122/4 122/6 123/4 158/3 171/25 remarkable [1] 10/2 70/14 150/1 150/12 169/19 170/13 171/1 relation [88] 1/13 1/25 127/18 129/22 129/22 129/24 remarkably [1] 22/17 reduce [4] 62/17 65/8 171/3 171/19 174/16 2/5 4/4 4/6 6/10 6/18 remember [8] 82/17 resolve [2] 13/21 133/7 134/9 134/12 65/12 65/14 reflect [2] 65/1 167/5 136/22 140/9 141/19 8/1 17/20 25/16 25/19 82/18 104/7 104/9 51/16 refer [15] 2/1 7/3 115/19 127/17 127/18 reflected [3] 28/6 28/5 28/25 29/3 29/4 resorted [1] 30/18 145/18 11/23 19/5 41/23 40/13 62/21 29/24 29/25 30/18 140/3 respect [9] 5/10 6/1 retained [5] 76/9 49/25 56/3 69/3 82/6 reflection [7] 40/21 31/16 32/15 43/6 44/1 remembered [1] 7/12 7/14 40/4 64/7 109/2 112/16 128/17 88/17 118/23 123/7 42/24 50/3 50/4 63/24 48/3 48/9 48/18 49/15 81/17 80/16 114/10 114/17 147/9 129/4 148/24 167/16 90/9 91/1 50/12 53/4 56/8 60/19 remind [1] 12/9 respected [2] 43/11 retention [4] 146/24 reference [61] 12/13 refrain [1] 104/13 61/4 62/25 64/21 reminded [1] 9/11 96/11 147/4 147/11 147/15 13/14 14/13 14/19 70/16 73/24 74/23 refurbished [1] 82/3 remote [1] 13/17 respiratory [1] 112/11 retested [1] 121/15 16/13 17/6 17/9 17/11 refusal [4] 56/20 84/11 84/12 91/13 removed [1] 102/19 respond [1] 91/17 retired [2] 143/21 18/2 18/10 19/19 122/15 122/18 122/22 93/17 95/19 97/16 repeated [1] 46/12 responded [1] 96/20 144/4 19/21 20/15 20/17 refused [1] 87/6 104/25 105/22 114/22 repeats [1] 129/8 responding [1] retirement [1] 160/8 20/21 22/10 23/17 regard [7] 37/18 43/13 115/12 116/16 117/21 replacement [1] 49/13 158/11 retrospective [5] 23/18 25/24 26/24 105/21 116/17 135/4 119/4 120/1 123/10 report [29] 10/10 12/1 responds [2] 118/7 38/25 40/21 66/24 27/2 28/17 29/9 30/9 135/11 138/6 137/25 141/6 142/11 12/8 12/17 13/15 14/7 124/15 95/2 108/9

(64) receiving... - retrospective

n	violalle amodit [4] EQ/44	00/00 04/04 404/45	06/42 07/47 07/02	440/00 447/0 404/40	15/10 15/10 10/04
R	risk/benefit [1] 52/14 risks [33] 1/24 5/19	92/20 94/24 121/15 121/25 122/1 122/2	96/13 97/17 97/23 99/21 100/18 101/24	112/22 117/3 121/12 121/13 129/7 137/10	15/10 15/16 43/24 47/17 64/14 66/2
retrospectively [1]	5/20 6/14 7/12 7/15	samples [12] 45/5	102/12 105/1 108/8	139/8 140/15 141/4	77/19 88/8 90/8
109/20	7/21 53/18 54/16	67/5 67/11 68/5 74/23	108/15 109/5 112/24	157/12 158/8 165/24	113/12 172/9
retrospectoscope [1]	54/23 55/10 57/5	76/4 83/1 83/3 95/2	113/22 114/1 115/16	166/16 166/24	seen [31] 2/16 2/21
40/18	57/20 58/21 59/10	128/9 128/11 128/16	115/22 118/8 119/1	secondly [2] 100/9	28/8 28/16 32/17
return [8] 1/10 28/19	59/17 60/20 60/24	San [2] 9/10 17/4	119/5 119/18 120/3	101/25	46/24 57/7 63/17 71/3
52/18 56/14 56/24	61/5 62/8 63/5 63/11	San Francisco [2]	120/15 120/18 120/24	secretarial [2] 91/21	73/23 90/6 107/25
65/5 149/18 160/2 returned [3] 49/12	64/7 66/14 66/15 74/2	9/10 17/4	121/4 121/17 123/11	145/16	109/13 110/14 113/15
83/12 156/18	89/5 114/10 118/4	sarcoma [3] 10/3 11/2		secretariat [2] 154/4	122/5 128/2 129/15
returning [1] 118/21	118/17 126/10 164/18	11/6	127/16 128/10 129/9	154/14	135/22 135/23 136/1
returns [8] 1/5 28/17	169/8	Saturday [1] 162/25	129/17 130/19 131/2	secretaries [1] 87/9	136/4 136/14 142/12
48/8 48/9 102/10	Rizza [5] 19/10 101/14		131/20 131/22 132/2	secretary [2] 76/13	143/22 145/23 151/20
149/2 149/4 149/5	151/6 152/3 152/20	142/24 165/17 168/15	132/16 132/22 133/5	114/3	153/8 154/21 159/24
reused [1] 171/5	RNA [1] 129/13 role [2] 116/6 173/8	say [41] 6/10 7/11 19/8 27/18 28/13 31/4	133/20 135/2 135/11 136/10 139/8 140/15	secrets [1] 134/6 section [2] 42/24	166/9 seminars [1] 82/4
reveal [1] 173/16	roles [1] 1/23	35/5 49/15 57/7 60/1	141/10 143/5 143/11	146/2	send [1] 92/3
revealing [1] 172/10	room [3] 81/16 82/18	61/4 67/3 70/10 72/5	143/13 145/13 145/20	sections [2] 50/14	sending [1] 151/3
revelations [1] 9/15	86/16	72/13 73/18 83/22	146/6 147/8 149/12	145/19	sends [1] 18/5
reversion [2] 32/4	rotation [1] 129/16	84/17 93/15 97/10	151/9 152/7 153/15	see [99] 4/2 8/23 9/24	sense [2] 51/12
56/12	rotunda [1] 81/25	99/2 103/2 105/7	153/24 155/9 155/17	12/16 14/9 15/2 16/4	109/12
revert [1] 39/3	Roughly [1] 148/15	105/11 107/13 117/16	156/17 157/15 158/10	16/6 16/7 16/9 18/9	sensitive [1] 154/17
reverting [1] 56/18 review [2] 64/23	routine [9] 103/19	124/9 126/13 126/25	158/18 159/3 159/20	18/11 18/13 19/12	sent [13] 14/16 14/19
169/19	123/23 128/21 129/1	131/18 131/19 135/24	161/2 161/10 162/6	20/15 20/17 25/13	25/5 26/23 35/20 95/2
reviewing [1] 149/13	130/2 130/10 135/7	138/8 145/9 150/12	162/22 163/13 164/2	26/7 28/20 29/9 33/2	108/2 139/11 150/14
reviews [1] 135/20	135/19 135/19	152/23 156/6 157/10	166/23 168/9 169/12	33/17 34/14 34/20	150/21 157/6 161/7
revised [1] 171/1	routinely [4] 3/15	164/8 169/3 172/2	171/5 173/25 174/9	34/25 42/6 42/17	161/21
revision [1] 40/6	81/13 87/24 132/24 Royal [13] 28/9 66/22	saying [28] 31/16 32/21 34/14 36/8 41/1	174/19 says in [1] 140/15	55/17 58/18 60/5 60/20 64/15 68/6	sentence [10] 7/6 33/16 43/8 43/24
revolutionised [2]	74/19 78/18 81/14	41/7 53/5 54/21 59/16	sceptical [1] 45/2	68/24 69/5 69/8 70/6	60/22 99/24 120/3
5/22 47/6	89/10 108/13 111/24	68/17 72/14 75/11	Schanker [1] 10/19	70/8 70/10 72/1 74/9	143/13 144/1 145/20
rhesus [1] 16/25	112/6 143/17 160/16	76/19 76/21 77/12	schedule [1] 147/4	75/5 75/10 78/14	sentences [2] 22/14
rhetorical [1] 64/18	163/10 170/10	85/6 86/15 91/6 93/10	scheduled [2] 81/13	86/12 93/22 94/4	51/4
RHSC0000040 [1] 98/10	rumours [1] 66/7	120/16 126/11 126/18	81/18	95/15 98/3 98/10	separate [4] 11/21
RHSC0000067 [1]	runs [1] 164/16	128/7 137/16 140/6	school [5] 56/22	98/14 98/16 107/7	145/19 146/2 160/7
70/20	rural [1] 155/23	153/9 155/1 159/8	93/23 94/5 94/9	108/7 111/8 111/20	separately [1] 11/24
Richard [3] 140/2	RVH [1] 78/19	says [172] 2/2 2/2 2/8	170/10	114/25 115/7 118/7	September [15] 11/8
142/5 142/17	S	2/19 3/8 3/15 4/6 5/2 5/7 5/7 6/25 7/18 7/25	Schroff [1] 10/19	120/15 121/12 123/9	12/14 13/9 14/3 36/18
Richard Lowry [3]	sad [2] 73/6 127/20	8/24 10/14 11/3 11/16	science [4] 38/3 39/23 39/25 41/4	126/9 130/16 136/8 137/15 138/7 139/3	37/25 67/23 67/24 67/25 106/11 106/20
140/2 142/5 142/17	sadly [4] 73/10 82/4	12/7 15/8 15/10 15/15		140/6 142/11 142/13	119/17 158/5 166/3
right [18] 5/17 18/4	103/7 131/5	21/19 22/4 22/14	40/5 43/13 59/11	142/17 143/25 145/10	175/1
24/13 24/18 25/25	safe [1] 118/16	22/20 23/5 23/11 24/8	114/4 174/19	145/12 146/22 146/23	
28/18 33/19 46/5	safest [1] 46/20	26/15 27/3 29/18 30/2	Scotland [9] 1/15 1/20		11/8 14/3
54/21 83/24 87/7 110/8 122/21 129/11	safety [1] 151/18	30/21 31/7 33/22	46/17 46/19 102/2	150/9 150/19 151/1	September 1983 [1]
145/1 154/11 154/12	said [27] 6/11 8/9	35/23 36/14 37/21	124/23 125/10 125/15	151/5 151/17 151/25	36/18
165/13	13/2 39/9 40/19 57/4	38/5 38/16 38/19 39/2	166/25	152/3 152/9 152/19	September 1985 [1]
ring [1] 162/17	59/19 60/21 74/10	39/14 40/7 40/11	Scott [2] 33/8 37/8	157/6 157/13 158/8	106/20
rise [2] 96/15 151/20	76/17 76/24 85/19	42/20 43/7 43/18 44/8	Scottish [4] 157/3	158/23 160/6 165/8	September 1992 [1]
rises [1] 109/10	85/20 86/15 92/24 95/16 108/5 110/20	44/16 46/10 48/17	157/8 161/13 166/20	165/19 166/17 166/22 168/16	158/5 September 1994 [1]
risk [29] 4/19 4/24	121/14 122/18 126/3	50/13 50/20 52/13 52/22 58/13 59/1	screen [3] 1/17 55/6 77/22	seeing [1] 127/19	September 1994 [1] 175/1
5/10 8/19 11/15 17/20	141/7 144/22 147/3	59/21 61/3 62/10	screened [1] 139/5	seek [1] 168/5	September 2004 [1]
18/22 27/9 34/9 34/9	147/4 147/25 157/9	62/19 63/6 64/20	screening [1] 137/13	seeking [1] 142/25	166/3
41/16 41/21 50/3	sake [2] 25/6 88/21	64/22 65/5 65/7 65/8	seating [2] 79/5 80/17	seem [6] 31/14 46/15	septicaemia [1]
50/13 50/13 50/15	salmonella [1] 113/18	66/23 68/15 70/4	seats [1] 81/25	52/25 69/11 79/9 93/1	113/18
52/14 52/24 55/21 60/24 62/15 62/18	same [14] 8/20 37/22	70/22 70/24 72/20	second [32] 1/12	seemed [9] 3/12 3/22	sequelae [1] 141/15
65/15 90/5 126/12	70/15 70/16 72/2	74/16 74/24 78/9	13/10 15/1 15/9 16/24	77/4 81/1 82/8 87/7	sequence [1] 90/13
126/19 138/16 170/18	90/23 93/13 93/24	78/15 79/25 81/8	20/1 32/1 43/8 67/16	104/10 122/11 171/17	sequential [1] 76/6
171/4	109/22 110/10 167/2	82/22 83/8 85/11	75/4 94/9 98/13	seemingly [2] 93/7	sera [8] 66/25 67/6
risk' [1] 11/22	167/3 167/4 171/12 sample [8] 76/5 76/6	88/24 89/14 90/22 93/7 93/8 94/22 95/11	106/17 107/13 107/15 109/4 111/12 111/13	129/1 seems [12] 15/5	67/11 106/5 108/2 108/10 108/12 109/15
	Campic [0] 10/0 10/0	JUL 3010 34122 30111	100/4 111/12 111/10	acema [12] 10/0	100/10 100/12 109/13
·	t	·	·		(CE) retreamentively, save

(65) retrospectively - sera

32/10 social [3] 98/12 112/4 | 172/5 S 21/3 21/15 22/10 59/3 65/17 78/20 23/13 102/22 102/24 significant [9] 6/14 146/18 Soumik [18] 2/3 8/21 78/22 79/21 83/15 series [7] 2/6 6/16 103/20 104/13 105/19 26/2 67/13 69/9 82/7 society [8] 58/2 58/14 10/11 15/2 18/13 91/21 99/4 124/3 57/15 77/20 106/3 126/10 126/12 117/2 117/6 128/15 59/5 60/10 159/15 23/22 58/18 74/6 127/8 171/16 114/8 153/14 Sexually [1] 114/19 135/10 161/8 162/22 165/16 79/25 97/9 111/11 staffing [2] 66/9 114/2 serious [3] 45/25 share [1] 139/20 significantly [1] Society's [1] 172/8 118/22 120/21 128/6 stage [10] 15/21 141/14 159/8 shared [3] 116/14 130/21 solely [1] 14/16 145/7 146/15 153/13 55/22 57/12 69/23 seriousness [1] 155/3 155/5 some [104] 4/14 6/3 169/13 90/15 101/21 142/20 sill [1] 174/25 133/19 | sounds [3] 35/4 82/13 | 146/12 147/24 154/25 similar [9] 1/25 4/2 7/23 11/23 13/4 17/23 sharing [1] 153/22 seroconversion [15] **sharp [1]** 61/2 20/23 21/9 22/17 18/20 24/23 31/8 33/4 85/24 stark [2] 63/10 63/19 17/25 66/19 67/15 29/23 53/6 133/25 34/16 34/19 34/20 source [4] 23/23 start [11] 8/20 8/21 she [288] 67/18 67/20 69/12 she'd [1] 166/4 166/15 35/18 37/12 38/25 46/13 109/18 129/17 12/12 20/7 20/20 50/6 70/19 92/17 93/13 she's [25] 12/5 29/11 Simon [2] 88/23 143/4 44/20 45/1 48/8 49/15 **sourced [1]** 46/17 74/11 117/19 125/25 109/17 109/18 110/3 34/6 34/25 35/17 37/4 50/11 52/12 56/15 sources [1] 101/12 simple [2] 85/18 126/1 126/3 110/24 111/9 151/13 40/10 41/14 57/17 102/18 59/12 63/15 63/17 **space [5]** 79/3 80/9 started [1] 59/23 seroconversions [4] 58/23 62/14 62/16 simply [7] 14/21 67/5 71/1 72/8 74/7 80/14 80/16 82/23 starts [1] 164/15 67/1 68/6 68/12 73/15 63/2 65/22 76/21 39/11 50/9 88/5 88/13 80/22 83/18 84/2 spaced [1] 2/12 state [8] 13/23 17/20 seroconvert [1] 48/1 96/13 98/6 104/24 90/9 138/22 84/16 84/20 85/3 **Spain [1]** 21/5 40/3 54/7 67/9 72/23 seroconverted [3] 105/5 143/25 144/12 simultaneously [1] 85/21 91/6 92/19 speakers [2] 59/6 135/12 145/12 45/19 68/18 72/14 153/17 164/22 169/11 92/21 93/15 94/19 110/11 stated [2] 41/13 seroconverting [1] since [8] 20/23 22/9 99/14 101/2 104/15 speaking [3] 7/6 66/5 174/1 128/16 111/3 107/2 107/23 110/17 Sheffield [3] 161/18 22/23 72/23 116/17 127/19 statement [84] 2/1 2/5 serum [3] 68/5 85/7 161/21 162/1 120/14 148/9 149/16 112/1 115/3 116/24 special [10] 11/15 4/25 6/9 6/21 7/17 121/15 shock [1] 9/16 single [4] 56/4 71/12 116/24 117/5 117/15 25/24 27/1 35/11 7/24 8/22 13/22 24/12 service [5] 22/25 short [4] 13/11 49/22 110/15 171/5 118/5 123/4 123/13 63/22 89/18 130/5 29/7 40/10 48/17 107/22 108/21 111/24 103/21 148/22 sir [49] 1/3 4/24 7/22 130/3 130/5 130/8 130/6 130/11 134/19 49/14 50/19 53/10 148/9 8/15 12/9 13/22 17/17 132/13 133/11 133/22 55/5 55/17 55/19 56/4 shortage [1] 86/1 **specialist [3]** 107/3 services [4] 98/12 23/20 24/18 32/12 133/25 134/5 135/7 142/25 169/17 shortly [1] 53/5 56/8 61/23 62/3 62/10 108/23 112/4 174/1 should [64] 1/22 4/24 135/14 136/8 136/23 33/19 36/6 37/23 specialists [1] 112/9 62/11 62/13 66/1 session [1] 104/7 6/10 6/16 8/17 12/8 42/12 46/5 46/25 48/2 137/21 137/23 137/24 specific [16] 9/8 66/17 68/15 68/17 sessions [2] 169/16 18/4 19/3 19/4 20/20 138/3 140/16 140/20 16/19 29/1 30/4 30/9 70/3 74/12 77/24 48/18 49/15 49/25 169/20 27/8 32/24 40/21 51/5 56/6 60/11 65/4 54/22 120/4 122/12 78/15 79/19 85/22 143/14 144/13 145/3 set [16] 16/9 19/23 41/13 41/17 41/18 66/16 67/3 70/13 74/6 149/3 149/16 151/16 122/17 128/14 131/24 86/13 86/14 88/2 42/24 50/18 55/15 42/5 42/14 49/12 77/2 81/21 84/4 84/10 153/8 154/24 156/15 134/11 151/25 156/7 88/23 96/21 97/24 64/2 69/11 89/17 53/20 54/11 57/7 64/2 88/2 92/12 96/19 97/3 156/22 156/25 157/2 159/19 171/24 99/7 99/19 104/19 93/24 101/18 111/13 157/3 157/11 157/25 105/13 113/24 116/13 67/3 70/10 73/18 97/8 101/17 122/24 specifically [5] 8/6 144/5 150/11 163/23 75/15 81/3 83/22 86/6 125/16 131/7 137/4 159/7 159/12 160/1 36/13 38/17 124/24 117/11 118/1 118/8 163/24 168/17 87/7 87/14 88/17 89/2 140/2 144/20 148/20 160/1 160/5 164/10 118/13 119/25 120/23 129/20 sets [9] 15/7 20/11 148/24 160/13 172/5 91/10 92/24 99/2 171/14 171/23 171/24 specimens [1] 140/19 121/10 124/11 124/16 29/22 30/11 33/1 99/12 99/15 107/13 175/16 172/17 172/19 172/22 spectrum [1] 63/21 126/6 129/5 130/24 65/25 115/21 164/20 115/7 115/9 117/16 site [1] 170/11 173/3 173/8 speculate [3] 46/12 136/25 143/5 143/20 169/7 118/1 118/20 118/23 situation [19] 11/17 someone [3] 72/16 125/3 125/8 143/25 144/10 144/14 setting [4] 12/5 141/2 120/2 124/1 131/8 30/9 33/1 79/15 83/14 123/20 155/22 145/6 145/9 145/13 **spell [1]** 3/14 143/22 175/3 97/18 100/9 100/10 138/8 141/21 142/22 146/14 146/17 153/9 something [4] 9/25 Speywood [3] 172/22 seven [5] 23/23 24/3 145/4 145/9 146/16 114/5 122/13 124/22 19/6 70/22 98/11 173/2 173/6 153/12 155/16 156/17 24/19 24/21 33/20 149/17 151/15 155/3 160/22 162/14 162/16 160/11 164/9 164/10 **sometimes [2]** 123/5 **spoke [1]** 59/13 several [9] 15/5 17/1 157/10 158/5 161/6 162/24 164/4 164/5 123/5 sponsored [2] 127/11 164/16 165/3 166/18 18/6 76/1 87/6 101/22 164/24 164/25 169/17 168/6 170/22 somewhat [1] 42/22 173/6 173/18 174/18 175/9 141/12 149/16 162/11 shouldn't [1] 155/5 six [6] 2/13 23/11 somewhere [2] 86/9 sponsorship [2] statements [34] 28/2 severally [1] 4/14 show [5] 7/22 48/19 98/20 108/23 135/23 155/21 173/3 174/16 36/15 44/13 44/14 severe [10] 1/7 45/25 51/23 92/24 134/1 160/23 soon [6] 122/5 129/15 Spooner [5] 14/11 53/14 55/25 56/2 56/7 52/8 52/13 69/6 69/6 showed [4] 109/16 six-monthly [1] 98/20 129/22 129/23 136/14 72/19 149/11 150/19 57/8 61/4 67/4 74/9 72/17 79/6 135/23 123/14 135/14 136/13 sixth [1] 71/23 149/18 74/13 78/13 79/24 151/3 158/19 showing [1] 136/19 slides [1] 174/15 sorry [24] 6/16 15/1 spouse [5] 45/16 46/6 81/5 84/7 88/19 91/6 severely [13] 2/14 shown [1] 71/6 slightly [2] 117/24 20/20 25/21 26/13 68/15 87/12 96/14 91/7 107/1 117/15 28/11 30/15 31/19 shut [2] 82/2 170/11 144/21 33/3 33/13 48/24 spouses [3] 97/16 117/15 118/2 129/7 47/22 70/25 71/7 small [6] 34/5 47/5 104/16 105/3 sibling [1] 139/2 58/17 68/24 70/9 132/13 133/11 134/8 72/15 79/5 109/9 sic [1] 107/18 49/7 76/2 140/20 71/18 75/3 96/21 99/8 spouses/partners [1] 137/2 137/5 138/12 109/12 109/14 135/21 Sick [1] 28/9 155/21 106/9 107/20 115/1 105/3 139/2 141/6 142/25 severity [4] 1/6 29/6 side [4] 86/17 87/1 **SNBTS [3]** 165/24 128/6 135/1 137/9 States [9] 10/4 12/25 **spread [1]** 22/17 69/7 135/20 114/5 115/20 13/15 16/15 17/10 166/24 168/20 143/21 145/10 146/22 squarely [1] 65/22 sexual [12] 15/13 significance [2] 17/24 so [201] sought [2] 137/20 staff [13] 6/1 42/19 18/18 24/24 24/25

(66) series - States

S	48/3 76/3 87/16 138/6
States [1] 25/1	sufficiently [1] 41/5
statistics [4] 37/11	suggest [12] 11/14
44/16 46/2 154/14	12/1 53/25 69/22
stats [1] 154/5	71/11 85/14 91/9
status [5] 3/3 3/20	99/12 125/13 138/12
85/12 154/18 159/5	141/20 173/6
STD [1] 102/6	suggested [3] 100/14
step [1] 82/20	130/9 145/1
stepping [1] 174/25	suggesting [3] 40/20
steps [4] 55/9 55/11	72/3 84/21
66/13 164/25	suggestion [9] 28/15 49/11 64/12 70/2
stick [2] 55/6 58/17	
stigma [2] 66/5 98/2	87/16 90/17 95/3 99/4 100/17
still [4] 85/15 89/7	
106/19 148/12	suggests [15] 1/17 3/23 21/12 22/5 24/6
Stockholm [2] 18/16	30/17 36/21 44/2
35/23	67/19 93/16 101/9
stop [2] 32/6 63/10	129/19 129/25 135/9
store [1] 106/5	173/21
stored [6] 66/25 67/6	suicide [1] 111/16
67/11 68/5 108/10	summarise [2] 137/20
109/15	172/6
straightforward [4]	summarised [1] 51/21
31/11 47/9 85/18	summarises [1] 169/9
171/15	summarising [1]
stream [1] 102/15	16/10
stress [1] 2/11	summary [5] 14/5
strictest [1] 149/21	144/18 158/19 160/20
striking [1] 124/4	165/7
strong [1] 52/21	summer [1] 92/22
students [1] 81/24	superior [1] 145/22
studies [3] 153/15 153/16 156/22	supplied [1] 1/19
study [5] 38/11 66/24	supplies [1] 27/15
157/2 157/7 157/10	supply [1] 32/22
subject [3] 12/6 36/14	support [8] 79/12
40/24	80/23 130/17 130/20
submissions [1]	139/16 145/16 169/12
40/24	169/18
subsequent [2] 40/5	suppressive [1] 15/9
82/11	sure [7] 74/6 77/21
subsequently [2]	92/11 94/23 139/3
110/1 132/6	140/2 152/10
substantive [2] 50/8	surgical [6] 80/15
172/11	81/23 170/12 170/13
substitute [1] 60/12	171/2 171/14
subtypes [1] 134/18	surprised [2] 133/6
succession [1] 89/4	133/16
such [22] 2/24 15/17	surveillance [5] 23/7
21/21 27/10 35/7 40/8	35/13 37/5 70/4
43/11 57/4 57/9 57/21	149/15
60/3 82/20 86/24	survey [5] 23/2 150/4
89/21 118/19 123/20	151/8 151/12 151/13
144/8 153/23 154/18	surveying [1] 152/8
168/23 171/7 175/5	suspect [1] 88/5 suspected [5] 26/17
suffer [2] 34/7 73/8	36/19 36/23 53/18
suffering [3] 26/17	132/3
104/4 139/19	suspension [2]
suffice [1] 52/10	
	147/19 147/22 switchover [1] 111/5

76/3 87/16 138/6 ciently [1] 41/5 est [12] 11/14 53/25 69/22 1 85/14 91/9 2 125/13 138/12 /20 173/6 ested [3] 100/14 /9 145/1 esting [3] 40/20 84/21 estion [9] 28/15 1 64/12 70/2 6 90/17 95/3 99/4 /17 ests [15] 1/17 21/12 22/5 24/6 7 36/21 44/2 9 93/16 101/9 /19 129/25 135/9 21 ide [1] 111/16 marised [1] 51/21 85/16 85/17 90/8 marising [1] mary [5] 14/5 /18 158/19 160/20 mer [1] 92/22 erior [1] 145/22 olied [1] 1/19 olies [1] 27/15 oly [1] 32/22 ort [8] 79/12 3 130/17 130/20 /16 145/16 169/12 oressive [1] 15/9 **[7]** 74/6 77/21 1 94/23 139/3 /2 152/10 ical [6] 80/15 23 170/12 170/13 /2 171/14 rised [2] 133/6 eillance [5] 23/7 3 37/5 70/4 ey [5] 23/2 150/4 /8 151/12 151/13 eying [1] 152/8 pect [1] 88/5 pected [5] 26/17 9 36/23 53/18 ension [2] /19 147/22

25/12 70/11 127/5 130/14 131/4 133/15 syndrome [16] 8/25 10/1 12/25 13/1 13/13 13/16 13/25 15/6 16/9 16/12 18/14 19/18 20/24 22/7 29/21 35/8 synopsis [1] 75/6 system [4] 19/23 46/15 103/10 146/21 **systemic [1]** 73/25 take [24] 1/17 2/20 30/4 49/18 55/9 61/21 62/15 62/17 74/5 81/13 82/20 94/12 96/25 99/17 101/8 103/16 125/19 148/14 148/18 159/10 162/13 162/19 168/7 174/20 marise [2] 137/20 taken [23] 3/12 17/18 41/17 50/2 66/14 marises [1] 169/9 91/24 114/13 116/10 122/1 122/2 125/18 128/10 128/11 154/16 155/15 156/11 161/3 161/19 164/23 164/25 taking [4] 83/1 103/19 142/14 142/20 talk [5] 32/13 37/16 59/7 119/24 166/7 talking [3] 7/8 65/22 77/7 talks [15] 7/24 28/1 30/21 35/19 38/1 55/17 64/15 66/3 66/5 66/9 99/8 115/1 115/1 119/15 165/12 Task [1] 24/9 tea [2] 82/5 100/25 teaching [1] 81/24 team [1] 171/8 techniques [1] 118/10 Tedder [2] 106/17 108/1 telephone [3] 94/9 99/3 168/2 telephonists [2] 98/25 99/5 television [1] 35/8 tell [8] 57/3 57/11 58/12 87/23 89/7 104/21 105/9 159/19 telling [6] 74/20 91/4 93/3 95/12 96/3 104/2 tells [3] 13/10 107/15 110/23 ten [13] 16/17 22/6

symptoms [7] 20/16 24/13 24/18 33/21 72/9 113/2 175/15 175/15 Ten o'clock [2] 175/15 175/15 ten years [1] 72/9 tend [1] 45/24 tenure [1] 107/6 term [2] 105/20 120/12 termed [1] 131/15 terms [37] 10/6 17/22 21/9 28/15 28/23 31/22 41/22 42/14 42/15 42/18 52/21 54/14 55/5 55/15 60/1 60/20 61/24 62/1 71/14 77/18 84/24 90/13 91/4 95/8 100/19 105/12 108/3 113/22 117/12 124/5 144/16 144/16 148/10 156/3 165/21 171/8 173/15 terrified [1] 99/25 terrorist [1] 79/2 test [51] 75/20 75/21 75/22 75/23 78/8 79/17 85/8 85/10 85/18 86/3 87/3 88/6 88/9 89/23 90/20 91/14 91/18 92/15 94/16 95/9 99/23 103/19 103/22 104/22 105/25 107/23 108/1 117/3 117/3 119/19 120/4 122/13 122/15 122/18 122/22 123/12 123/21 123/23 128/21 128/24 129/22 129/22 129/23 131/25 132/19 133/1 133/7 133/23 135/13 136/13 136/19 tested [41] 6/19 6/23 45/5 78/5 83/3 83/16 83/18 84/22 86/6 86/16 87/19 89/11 89/20 89/25 90/7 90/11 94/16 94/18 95/4 96/8 97/16 101/11 103/4 103/17 103/18 105/3 106/15 108/2 109/8 109/16 116/25 122/1 122/2 122/2 122/20 124/5 129/20 130/3 134/1 138/9 138/9 testimony [4] 74/7 95/25 99/15 123/1 testing [79] 3/4 3/11 3/16 4/5 6/18 38/21 23/17 23/19 24/5 24/7 38/25 42/14 45/3

64/10 64/13 65/17 65/20 65/21 74/17 74/21 74/25 76/4 76/17 76/19 76/21 77/9 77/12 82/12 82/13 83/22 85/5 86/20 86/22 86/25 87/2 87/6 89/3 89/21 89/21 90/2 90/7 90/13 90/14 90/25 94/20 96/5 100/3 101/8 103/1 103/1 103/5 103/24 104/25 105/23 106/7 106/19 107/18 108/9 108/19 109/4 109/4 113/13 116/19 117/2 117/21 118/21 119/5 119/6 119/12 120/1 120/19 122/4 122/13 123/9 123/15 124/8 130/1 132/18 134/16 136/7 136/8 137/2 144/19 testing in [1] 74/21 tests [34] 3/3 3/6 3/17 30/25 74/22 74/23 103/8 106/12 107/24 119/25 120/10 121/2 121/5 121/8 121/22 121/23 122/3 122/9 123/2 124/6 129/10 129/12 131/14 131/16 131/21 132/20 132/22 133/22 134/9 134/11 135/4 135/18 138/10 141/20 than [31] 1/8 18/19 21/18 24/2 29/17 33/20 44/21 48/6 53/2 55/13 58/4 59/19 63/20 66/13 68/9 83/1 92/23 96/25 104/9 107/5 110/15 110/16 111/21 112/14 116/3 138/11 148/13 154/9 157/9 172/17 175/7 thank [10] 49/20 77/17 97/3 143/25 146/23 148/20 159/11 169/13 175/12 175/16 thankfully [2] 48/1 110/2 thanking [1] 42/19 that [606] that in [1] 30/18 that's [97] 5/17 6/11 6/23 9/22 10/5 11/20 12/7 15/23 17/4 17/15 18/3 23/18 23/24 23/24 24/8 25/11 25/13 25/15 31/21 33/9 33/11 33/14 23/2 31/5 32/18 34/9

33/18 34/2 34/22 36/25 37/3 37/24 42/11 43/9 46/4 48/7 48/17 48/22 49/13 53/1 53/8 54/17 55/2 55/22 58/19 60/11 60/12 62/10 62/23 63/23 66/11 66/16 68/13 69/11 74/20 76/25 77/11 78/1 78/3 79/18 80/12 83/20 88/1 90/22 91/23 93/12 94/6 97/11 97/21 97/23 100/17 101/1 102/9 104/18 105/11 109/22 110/8 119/25 121/10 124/9 126/3 136/24 137/18 138/24 144/18 144/25 146/12 147/6 150/14 150/14 154/22 156/10 157/23 158/4 159/14 164/7 164/19 165/21 166/17 174/17 175/8 thawing [1] 56/25 theatre [5] 80/15 81/21 81/23 101/6 171/16 their [102] 2/22 3/1 3/2 3/20 5/4 5/21 6/1 6/19 6/25 9/13 21/5 26/10 35/9 35/13 36/5 40/12 47/14 50/16 51/21 54/20 55/4 56/21 56/22 57/9 59/8 59/22 60/9 60/13 62/7 65/2 65/9 65/12 78/7 78/21 78/23 83/7 83/10 83/25 84/1 84/7 84/10 84/21 89/3 89/20 90/5 91/5 91/6 91/7 91/18 91/25 94/3 94/12 94/18 95/22 96/3 98/13 99/13 100/7 103/6 103/13 104/3 104/11 104/14 104/22 106/25 108/5 109/1 111/21 116/20 116/23 117/4 118/4 118/25 119/20 122/6 128/8 128/13 128/14 129/22 131/13 132/8 132/13 135/6 136/13 136/18 136/22 137/17 138/10 144/24 149/7 150/8 152/16 152/21 153/17 154/6 156/5 156/8 161/15 161/23 162/9 165/1 170/16 their HIV [1] 106/25 them [42] 3/10 17/25

(67) States... - them

35/10 60/7 75/23 79/7 71/23 72/12 73/21 128/5 140/10 94/4 94/11 94/16 transparency [1] 80/7 81/20 92/22 74/9 78/13 80/9 85/19 three years [1] 43/2 95/14 95/15 99/23 126/23 them... [36] 36/23 96/11 102/19 103/21 86/2 87/14 88/17 through [24] 9/23 103/9 104/8 104/22 transport [1] 80/19 43/22 50/22 56/5 104/10 123/17 127/7 88/19 90/23 91/23 19/15 36/10 37/16 117/6 117/8 118/3 travel [1] 174/19 56/22 57/2 57/11 129/14 133/15 92/8 95/4 95/10 95/24 39/18 42/9 43/16 128/8 130/8 131/18 travelled [1] 124/22 57/12 59/20 62/9 these [28] 3/12 4/5 101/1 102/9 110/2 46/14 50/15 56/1 133/8 133/16 136/22 treat [4] 31/17 34/1 83/17 89/5 92/5 95/17 6/8 12/1 16/23 30/24 110/6 110/7 110/14 102/1 102/3 102/20 138/10 138/14 138/22 63/4 66/12 104/11 104/13 117/1 31/8 39/21 43/24 110/20 116/5 116/15 114/24 126/17 147/1 147/21 treated [31] 5/1 28/9 118/25 122/21 123/7 59/19 68/11 71/20 119/11 120/12 120/21 164/11 164/16 164/19 28/10 28/11 28/21 tolerance [1] 46/14 127/19 129/21 130/4 125/13 130/9 136/20 73/10 75/3 84/24 166/17 167/2 167/19 tomorrow [6] 116/16 31/20 44/18 45/12 134/6 136/21 137/13 138/1 144/15 148/8 96/17 100/18 112/3 137/17 139/1 139/11 169/5 169/15 47/13 47/22 48/6 49/5 137/20 146/13 151/24 112/5 113/3 115/23 139/17 141/8 143/3 throughout [7] 28/2 175/13 175/14 49/7 71/8 85/13 85/25 154/23 160/6 161/16 34/15 48/3 96/6 97/19 127/2 138/2 145/22 145/7 147/1 148/16 too [4] 39/4 39/9 100/5 106/23 106/25 161/16 161/17 162/17 151/1 158/16 163/15 152/18 154/15 155/1 155/11 174/10 46/23 61/25 109/19 109/24 110/23 164/13 171/17 157/1 158/25 159/1 thrust [1] 175/9 took [13] 9/21 54/25 111/6 111/9 116/2 theme [11] 36/6 36/8 they [108] 2/20 2/23 159/24 164/3 171/11 thus [3] 39/3 47/14 57/4 64/24 75/25 87/9 123/1 132/4 140/17 84/11 117/10 117/14 3/11 3/12 3/19 3/22 thinking [1] 164/7 127/22 89/9 90/1 123/22 142/13 149/21 150/23 124/13 124/13 134/7 3/24 5/11 5/18 7/12 third [22] 14/25 15/12 tiered [1] 81/25 144/3 156/18 163/2 treating [6] 29/15 135/16 138/5 144/22 7/14 9/3 11/21 12/6 20/22 25/13 46/1 46/5 time [91] 1/15 4/10 171/11 43/21 44/6 115/24 themes [4] 84/6 13/25 16/6 20/7 30/14 49/3 67/19 101/5 5/10 8/6 9/8 11/10 top [23] 6/17 8/23 116/6 142/22 116/20 116/24 138/3 30/18 40/15 48/5 108/15 113/25 115/14 13/23 14/19 17/3 11/16 20/20 33/15 treatment [95] 1/8 themselves [8] 11/14 21/17 24/23 30/24 34/25 35/21 38/13 2/16 2/18 2/21 3/5 4/3 50/21 51/4 52/11 125/11 135/1 135/2 20/7 54/20 77/18 54/22 60/9 61/1 76/8 137/9 148/11 149/1 33/6 34/5 37/1 37/11 53/22 58/9 88/22 4/6 4/8 4/9 4/13 4/13 94/12 96/16 117/4 78/7 81/12 81/13 153/23 158/18 167/25 40/3 41/4 46/21 48/19 113/16 122/23 123/16 4/16 5/12 5/13 5/13 127/14 83/15 84/21 84/23 168/25 53/15 54/7 54/8 59/5 126/21 131/2 132/1 5/24 6/2 7/7 7/8 16/19 then [277] 86/2 86/5 86/5 86/6 thirdly [1] 102/2 61/1 61/9 69/15 69/25 136/10 139/14 153/2 27/8 27/13 28/3 28/16 then-known [1] 60/24 86/19 87/3 87/7 88/6 this [302] 75/20 76/3 82/23 154/3 165/8 174/3 29/2 30/3 31/12 35/14 theoretically [4] 30/22 83/19 84/19 85/4 87/1 88/7 88/20 89/12 those [72] 1/23 2/13 topic [3] 41/23 148/25 36/5 36/20 39/24 56/14 135/23 135/24 2/14 2/17 2/20 3/4 4/4 87/21 87/25 90/2 89/19 90/19 90/20 160/7 45/13 45/17 45/18 theories [2] 15/5 15/7 5/20 6/12 9/17 14/2 91/8 91/22 92/4 95/21 92/19 92/21 96/22 total [2] 100/4 105/21 45/21 45/24 46/5 theory [2] 15/9 31/14 96/7 96/25 97/15 99/5 22/9 24/25 25/20 28/8 100/24 101/19 101/19 totally [1] 30/16 46/12 46/16 47/1 48/1 therapeutic [1] toward [1] 99/5 101/15 103/4 103/8 29/4 29/5 30/18 31/16 102/8 102/8 102/9 50/16 50/23 51/1 52/8 115/17 103/12 103/12 104/3 31/19 39/6 41/5 41/20 103/1 106/8 114/3 towards [11] 11/18 52/11 52/12 52/14 therapy [10] 5/9 7/7 104/8 104/9 104/12 44/4 44/5 45/15 45/23 115/18 118/11 118/14 11/20 12/16 16/12 52/15 52/18 52/22 27/23 32/5 59/11 104/14 104/15 104/22 46/5 51/4 52/9 53/17 121/23 122/4 122/10 20/14 20/18 33/21 52/23 56/12 57/21 60/17 60/19 72/4 72/8 106/25 113/9 114/19 58/4 59/12 61/3 61/17 123/4 123/13 123/15 81/10 93/6 133/3 57/22 60/9 62/1 62/2 72/8 117/7 122/20 125/24 61/22 62/6 65/3 66/12 123/19 123/23 124/7 137/11 63/11 63/13 63/19 there [181] 127/14 127/20 127/20 66/15 67/12 68/3 74/8 124/20 125/18 126/15 63/20 64/23 70/7 trace [1] 48/5 there's [53] 1/11 128/8 128/13 130/2 128/22 130/8 130/21 traced [1] 109/19 72/23 73/22 74/2 74/10 84/7 86/22 11/25 17/9 18/1 19/19 131/16 131/18 131/18 90/16 90/19 92/20 131/14 131/15 133/25 tragedy [1] 99/22 81/12 89/1 99/24 20/21 22/10 23/17 131/19 131/20 132/9 100/13 101/10 106/14 134/15 134/19 135/7 tragic [1] 85/2 102/18 102/20 103/20 36/12 49/15 55/17 132/9 133/8 133/8 106/23 107/24 112/15 135/10 135/13 135/14 training [1] 60/18 105/15 106/24 109/7 60/15 60/17 61/2 133/12 133/14 133/14 113/23 115/21 125/21 139/9 139/17 142/16 115/7 115/9 117/13 transfer [2] 146/4 64/11 65/6 65/10 133/15 133/16 133/16 127/23 129/22 129/23 144/4 146/6 147/12 146/5 118/4 118/6 118/15 65/11 65/13 69/20 134/2 134/4 134/8 135/21 136/7 142/15 148/12 156/16 156/19 transfused [2] 16/22 129/18 135/21 136/16 72/9 75/18 85/19 135/24 135/25 137/16 145/23 154/8 155/25 159/9 167/3 170/21 34/18 138/19 142/15 142/19 85/22 91/5 94/15 138/6 151/20 153/16 156/3 156/10 171/9 172/2 173/14 transfusion [7] 15/14 149/8 150/8 151/3 106/10 106/20 108/4 154/4 154/6 161/6 172/15 173/15 times [7] 2/12 29/16 21/16 23/3 32/23 38/7 154/6 154/7 165/1 115/6 115/15 117/6 though [3] 77/8 82/13 161/14 60/23 88/13 122/15 102/20 107/22 170/5 121/12 125/14 127/22 transfusions [1] 22/3 treatments [5] 6/8 6/9 they've [2] 91/24 106/24 122/19 140/10 141/2 143/19 146/20 149/8 thought [11] 12/5 timing [1] 135/19 transmissible [1] 52/5 52/10 59/10 147/3 147/23 156/25 things [2] 8/4 39/7 18/19 22/21 81/2 title [1] 121/3 22/16 trial [8] 157/14 157/16 157/19 157/25 158/2 think [83] 7/22 8/3 83/11 90/17 100/2 to [1232] transmission [14] 157/21 157/24 158/1 159/10 159/11 160/4 14/12 23/16 24/2 24/4 115/21 123/18 130/25 to May [1] 151/2 16/21 22/3 22/11 64/7 158/2 158/12 159/19 162/4 162/20 168/14 24/12 24/14 24/17 141/13 today [6] 53/25 100/11 100/16 103/20 trials [1] 156/22 168/20 169/1 172/10 103/21 104/12 105/19 tried [2] 124/24 24/20 24/24 28/12 threat [1] 39/17 109/23 111/1 129/4 thereabouts [2] 61/18 146/16 172/16 114/11 126/10 126/12 29/1 37/23 37/24 38/1 three [21] 9/2 11/12 161/11 93/18 39/19 41/14 45/9 48/2 13/16 15/7 16/22 21/4 together [2] 77/19 164/18 true [1] 155/23 thereafter [6] 2/20 Trust [7] 146/15 49/13 51/10 52/3 22/1 43/2 61/21 69/16 79/22 transmit [1] 102/23 64/11 65/23 100/24 54/21 55/12 57/7 77/20 78/16 100/4 told [32] 3/20 4/19 transmitted [4] 38/6 146/18 146/20 147/8 143/14 161/17 106/13 106/17 109/6 63/24 65/25 66/11 62/5 69/14 84/9 91/8 102/22 114/19 126/17 147/10 172/13 172/14 therefore [16] 22/25 66/16 67/6 67/9 71/3 111/16 113/14 122/3 91/25 92/4 93/20 94/1 transmitting [1] 27/9 Trust's [1] 146/21

(68) them... - Trust's

Т	Ulster [4] 107/8	unexposed [2] 27/14	68/25 70/2 70/5 70/22	159/21	views [4] 34/3 44/1
	107/12 113/15 156/23	28/24	75/9 76/7 77/21 79/12		51/6 133/19
trustee [1] 172/12	ultimately [5] 13/21	unfortunately [3] 39/4		56/14 60/24 71/12	vigorous [1] 102/24
Trusts [1] 175/7	53/1 96/15 124/21	57/3 78/24	98/15 101/19 113/3	124/6	VIII [15] 16/19 21/22
try [2] 13/3 94/19	140/21	unheated [2] 85/15	113/15 116/12 122/23		22/22 23/4 31/12
trying [5] 77/19 97/18	unavailable [1] 80/8	151/14	131/10 132/25 133/4	usually [1] 51/12	36/24 47/5 49/1
130/22 144/4 152/4	unaware [1] 116/25	unique [2] 154/21	137/11 142/10 143/4	utilised [2] 47/10	109/19 109/24 111/10
turn [16] 10/10 44/11	uncertain [1] 84/17	170/22	143/6 143/22 144/5	116/1	138/17 157/13 157/15
53/10 57/14 111/11	unchanged [1] 45/8	unit [2] 80/6 158/14	144/21 149/20 155/6	utter [1] 118/19	157/22
113/24 114/21 116/18	unclear [8] 58/16 67/9		156/18 158/17 159/2		viral [9] 4/19 4/24
120/21 121/7 129/5	91/3 95/4 97/22	13/15 16/15 17/10	159/21 161/16 164/12	V	47/16 81/9 118/4
141/4 156/13 169/11	110/11 111/6 123/19	18/18 38/17 73/25	167/24 168/18 169/6	vaccine [1] 15/22	122/9 129/13 132/10
173/19 173/24	unclottable [1] 80/5	155/11	up-to-date [2] 149/20	vaccines [2] 15/19	134/16
turned [1] 65/6	uncomfortable [1]	United Kingdom [3]	159/21	21/18	viral load [1] 134/16
turning [1] 106/22	82/1	38/17 73/25 155/11	update [4] 32/25 89/4	valuable [1] 51/17	Virologist [1] 9/4
turns [1] 80/13	uncovered [1] 127/23	United States [4] 10/4		value [1] 78/3	virologists [1] 127/13
TV [1] 66/6	under [14] 10/12 15/3	12/25 16/15 18/18	updated [1] 20/9	values [1] 140/11	virology [3] 45/6
twenties [1] 16/24	32/2 32/25 50/10	units [1] 17/1	updates [1] 169/18	variable [1] 72/10	106/15 121/14
twenty [1] 109/6	57/15 64/23 70/22	universal [5] 52/7	upheld [1] 52/15	various [6] 20/25 28/2	virus [32] 66/21 67/6
twenty-three [1]	75/11 107/14 109/3	52/10 91/9 118/3	upon [13] 8/11 21/14	37/17 49/25 117/20	75/17 75/21 75/22
109/6	135/2 143/16 150/9	155/11	51/16 52/25 68/19	172/1	76/5 85/8 89/6 94/25
two [38] 1/3 17/7	underestimate [1]	universally [1] 54/21	70/2 71/11 76/20	vary [1] 140/9	96/6 102/14 102/16
22/13 23/22 25/8 25/9	40/16	unknown [6] 12/2	122/23 142/20 147/5	vCJD [9] 160/9 164/15	
28/11 30/12 33/4	underestimated [1]	12/2 132/25 140/16	159/7 172/17	164/18 164/25 167/18	108/11 108/17 117/12
36/18 37/12 53/24	41/3	145/3 148/2	urgent [1] 166/14	169/8 169/24 171/21	119/7 121/18 123/13
73/2 76/11 78/17	undergo [1] 170/17	unless [2] 77/2 90/20	urgently [1] 162/17	172/4	128/18 131/5 131/25
81/16 83/12 88/18	underhand [1] 156/9	unlike [2] 122/12	urinary [1] 108/22	vein [1] 118/9	132/5 133/25 134/18
90/24 92/20 92/23	underlines [1] 127/1	141/13	us [21] 9/11 10/7	ventilators [1] 170/14	135/15 140/9 142/23
95/14 105/22 106/2	underlying [2] 14/4	unlikely [5] 15/11	13/10 22/24 23/4 51/9	venture [1] 143/23	143/6 143/10
106/6 106/14 109/3	47/17	21/13 78/2 101/20	57/4 57/11 58/12	venue [5] 79/1 79/4	viruses [2] 132/25
109/13 113/3 118/22	understand [5] 33/9	104/8	59/25 60/2 74/21	80/7 81/20 81/22	141/12
137/6 139/14 140/10	40/9 110/5 134/4	unnecessarily [2]	87/23 89/7 105/9	veracity [1] 45/2	visit [5] 2/11 83/13
156/10 156/23 160/4	138/21	73/20 99/13	107/15 110/23 144/15	verb [1] 39/19	115/2 135/7 135/19
160/25 162/7	understandable [2]	unpick [1] 122/16	148/7 149/14 151/15	verbal [2] 6/25 12/17	visited [2] 92/5
two further [1] 105/22	151/19 152/14	unpicked [1] 147/24	US commercial [1]	verify [1] 48/14	129/14
two weeks [1] 81/16	understanding [9]	unpleasant [1] 104/1	23/4	versed [1] 3/9	visiting [1] 93/5
two-year [1] 92/23	34/3 94/19 125/9	unprepared [1] 9/16	USA [6] 14/2 21/6	versed in [1] 3/9	visits [7] 105/9
type [2] 1/8 104/6	125/20 141/3 141/23	unprotected [1]	21/24 22/23 46/17	version [5] 14/7 14/24	
typed [1] 146/8	153/9 159/23 164/20	126/12	102/4	20/9 21/10 40/10	128/10 128/12 168/5
typical [2] 30/13	understands [1]	unreceptive [1]	usage [6] 1/15 46/24	versions [1] 50/18	vivid [1] 74/7
84/16	51/18	174/11	65/9 65/12 65/14	versus [4] 52/14	vivo [1] 31/10
U	understate [1] 40/16	unrelated [1] 111/17	120/14	52/23 157/15 157/22	von [4] 27/7 28/20
	understated [2] 41/2	unsuitable [3] 79/4	use [27] 15/14 20/5	very [23] 17/12 20/25	29/21 150/23
UK [21] 17/7 18/21	41/12	80/16 80/17	22/23 27/21 30/6	26/2 34/12 51/17	von Willebrand's [2]
21/5 23/1 23/7 26/16	understood [8] 1/23	unsurprisingly [2]	30/21 30/22 42/15	65/18 74/7 82/1 82/7	28/20 150/23
33/5 36/19 37/9 38/21 44/18 44/25 45/16	5/15 5/18 41/16 90/19	9/20 45/1	46/22 54/12 63/3 63/8	97/2 98/7 135/10	vulnerable [1] 102/17
49/4 71/1 124/24	125/24 131/8 152/17	untenable [1] 52/20	92/25 93/8 116/10	136/1 138/18 141/13	
125/15 150/4 161/13	undertake [2] 5/23	until [17] 49/18 87/4	121/7 123/23 128/22	145/8 156/5 156/7	<u>W</u>
163/21 170/22	148/6	119/11 120/17 121/6	129/1 129/1 130/1	160/10 164/8 168/2	W1371's [1] 86/14
UK-wide [1] 163/21	undertaken [16] 3/17	121/24 123/4 128/21	151/14 156/3 161/14	172/2 175/12	wait [1] 163/14
UKHCDO [23] 11/23	31/1 35/12 37/2 37/6	129/2 131/24 132/25	171/18 174/7 174/12	via [2] 92/3 105/19	waiting [1] 170/19
12/10 29/11 41/22	67/12 82/14 85/5 90/2	136/23 143/6 148/19	used [19] 6/9 6/12	vials [1] 47/6	Wales [1] 44/21
44/25 61/12 62/21	91/1 94/20 107/25	163/14 167/24 175/18	15/18 21/22 29/20	Victoria [9] 66/22	walk [1] 82/17
62/24 101/13 120/10	114/10 119/13 123/3	untreated [2] 29/3	31/2 32/18 33/25	74/19 78/18 81/14	want [10] 2/1 85/12
153/24 154/2 154/12	156/15	63/1	47/25 49/10 52/12	89/10 108/13 111/24	88/6 88/7 97/15
154/20 154/24 161/20	undertakers [1]	up [60] 1/3 1/16 2/7	52/21 56/21 58/7	112/6 143/18	117/19 128/1 155/6
165/11 165/20 172/6	155/14	6/3 8/11 16/12 18/25	58/10 82/3 103/9	Vienna [1] 173/10	160/7 161/23
173/9 174/25 175/2	undertaking [1] 113/4		110/16 153/19	view [10] 2/22 14/5	wanted [9] 77/14 78/7
175/6	undue [1] 123/19	33/13 34/13 42/23	useful [2] 160/19	27/22 28/1 32/6 51/9	86/5 86/20 90/20
UKHCDO's [4] 101/18	unduly [2] 2/25 40/16	43/8 44/15 45/10	165/7	51/21 81/1 96/19	91/25 95/16 97/22
120/13 154/13 157/13	unexpected [2] 11/5	47/13 47/20 48/20	usefully [1] 55/12	165/13	162/3
	126/17	49/16 58/20 66/19	users [2] 102/21	viewed [1] 171/3	wanting [3] 52/7 88/9
					(00) ()
					(69) trustee - wanting

(69) trustee - wanting

w	97/2 100/15 104/5	whatever [2] 7/15	110/23 111/2 115/16	will [40] 7/3 8/6 8/12	143/19 155/17
	110/12 116/6 119/13	146/10	116/21 116/21 117/14	12/12 13/21 23/6	WITN1371001 [1]
wanting [1] 94/5	120/12 123/15 126/1	when [49] 1/4 4/2 7/6	123/21 125/15 128/24	32/12 32/20 38/9	77/23
wants [1] 105/20	131/17 133/4 133/9	8/5 9/21 26/3 57/4	133/9 141/12 143/3	42/12 49/12 54/18	WITN1382001 [1]
ward [5] 78/18 81/14	140/19 141/25 148/18	57/12 57/25 58/3 58/5	144/22 145/4 146/5	56/5 65/4 68/17 74/6	138/2
81/17 82/17 146/1	175/12	61/7 65/7 65/11 75/3	149/4 151/21 154/23	85/9 92/7 92/11 92/18	WITN1382003 [1]
Ward 37 [1] 81/14 Warfarin [1] 58/7	well-known [1] 96/6	76/8 79/16 81/9 82/2	155/24 159/6 160/7	96/25 99/19 101/17	141/4
warned [2] 54/15 61/5	Welsh [1] 161/14	84/9 87/19 92/4 93/10	160/8 160/11 160/18	111/1 116/15 118/7	WITN2569001 [1]
warnings [2] 54/23	went [2] 95/15 101/22	94/19 95/13 95/15	162/15 164/16 164/17	118/12 122/24 131/6	138/25
118/9	were [236]	95/25 96/7 99/22	164/25 166/4 167/23	140/2 141/21 144/14	WITN2570001 [1]
warrant [1] 27/20	weren't [2] 131/20	101/15 108/19 109/16	171/8 172/9 173/21	147/24 148/18 149/20	137/9
was [437]	153/16	114/14 117/6 122/13 125/7 129/8 130/1	175/4	149/22 150/20 162/17 162/19 164/12	WITN257001 [1] 137/8
was provided [2] 57/5	what [153] 1/22 2/2 3/14 3/15 3/19 4/22	130/5 132/19 133/16	while [1] 36/15 whilst [8] 6/21 9/15	Willebrand's [4] 27/7	WITN2607004 [1] 94/21
84/9	4/22 5/2 5/7 7/18 7/25	134/11 139/9 144/3	31/15 83/23 117/25	28/20 29/21 150/23	WITN2655002 [1]
wasn't [12] 19/4 50/4	8/4 8/16 8/17 12/7	144/8 144/10 155/19	124/11 163/24 174/25	willing [1] 114/16	139/25
74/3 95/13 111/5	14/6 14/15 17/18	169/2 170/10	White [2] 35/2 35/6	window [1] 74/25	WITN2658002 [1] 75/4
138/20 139/10 139/16	24/11 28/2 29/11	where [24] 7/24 22/2	who [75] 6/5 6/7 16/25		WITN2658008 [2]
141/8 148/2 167/10	30/12 31/4 34/2 34/6	22/14 45/10 56/2	17/2 17/3 18/21 28/8	wish [7] 36/6 54/2	95/24 97/9
171/21 way [11] 25/17 41/14	36/9 36/14 36/25 37/3	58/10 58/17 64/3	29/4 30/12 31/17	84/4 87/10 96/10	WITN2658009 [1]
59/1 64/9 88/10 90/15	40/19 40/23 41/1 41/3	65/20 74/3 76/17 78/4	31/19 31/19 34/7	168/11 169/17	84/24
102/21 133/25 151/1	41/7 41/11 41/12	84/3 91/24 94/3	43/12 44/19 45/23	wished [7] 84/23	WITN3082020 [1]
154/13 156/9	41/16 41/16 41/17	106/16 109/23 109/25	48/5 51/10 53/14 55/3	89/12 103/13 104/22	107/7
we [443]	42/5 42/13 43/6 44/2	110/9 150/15 163/9	57/8 59/12 61/3 63/15	170/16 171/9 171/10	WITN3449007 [1]
we'll [11] 4/2 11/9	46/3 46/3 46/8 46/18	164/12 164/19 166/18	65/2 67/12 68/13	wishes [4] 87/5 96/8 96/11 168/12	146/17 WITN4027001 [2]
16/6 24/17 25/7 26/6	46/23 48/17 50/2 50/4 50/8 50/17 51/18	whereby [1] 160/1 whether [35] 1/5 6/18	68/15 68/18 72/14 72/16 73/4 73/9 74/1	with [219]	145/8 164/14
33/2 111/20 145/10	52/22 53/20 54/10	13/22 14/16 14/18	74/13 81/11 84/7	withheld [1] 69/24	witness [45] 7/17 8/22
145/12 148/5	55/11 55/15 55/16	36/7 41/13 44/9 46/16	86/22 87/10 88/25	withholding [1]	29/7 36/15 44/13 53/9
we're [4] 6/21 62/5	55/20 57/3 57/5 57/18	46/23 47/2 48/5 54/14	90/19 93/18 94/14	163/23	55/5 55/25 61/23
70/9 124/11	58/12 58/23 58/24	57/12 60/12 68/10	94/15 100/4 100/6	within [18] 43/19	66/17 78/25 79/24
we've [51] 12/9 15/3 19/14 25/17 26/5 28/7	59/1 59/15 59/19 60/3	78/7 84/22 84/23 86/5	101/10 103/18 105/17	45/17 46/15 58/11	86/13 86/14 86/15
28/16 32/9 32/17 42/1	60/16 60/20 61/2 61/3	86/6 86/19 87/25 89/1	106/13 106/21 109/7	63/7 67/16 73/24	86/24 91/18 99/7
46/24 48/9 57/7 62/23	62/5 62/10 62/15	89/12 89/22 90/12	109/13 109/14 110/1	78/17 80/1 97/13	104/19 116/13 117/14
63/17 70/20 72/15	62/17 63/24 64/5 64/8	95/5 111/3 117/2	110/6 110/19 110/25	99/10 109/2 112/16	117/15 118/8 120/23
73/23 90/6 93/17	64/11 64/16 65/22	126/19 159/1 161/5	112/15 116/22 125/21	145/17 146/1 146/15	121/10 123/12 124/11
107/25 110/14 112/18	66/13 67/3 67/7 68/5	163/6 164/1 which [119] 2/17 3/11	127/24 136/3 141/7	147/5 166/18 without [13] 6/19 6/24	125/4 126/5 126/11
121/20 123/6 125/13	68/10 72/13 76/16 76/23 82/9 87/23 89/7	3/17 7/3 7/18 8/6 8/10	142/15 158/19 158/20 160/23 162/12 163/7	23/25 38/3 38/12 88/9	126/15 126/22 127/2 128/7 129/6 130/17
127/22 128/2 129/3	90/9 90/22 92/24 93/7	8/25 9/9 9/17 10/7	163/16 163/18 170/5	119/20 122/14 126/5	134/8 139/8 143/5
137/1 137/3 137/20	94/4 97/12 97/23 98/6		170/14 171/9	153/16 153/20 155/22	144/14 155/16 160/11
142/12 142/20 143/22	99/2 102/23 104/8	14/17 14/20 17/23	whole [3] 73/6 106/20		164/9 166/18 175/9
144/22 145/1 149/3	105/5 105/10 106/17	17/25 18/5 19/2 22/22	126/4	WITN0265001 [1]	witness' [2] 123/24
150/12 151/1 151/20 152/18 153/8 154/21	110/20 113/5 113/6	23/25 29/10 30/9	whom [14] 21/2 23/12		130/24
156/23 159/24 166/9	113/22 114/9 115/6	31/23 32/3 32/24	43/12 52/16 53/13	WITN0736001 [9]	witness's [1] 123/11
172/7 172/11 172/19	115/9 115/21 121/14	33/16 34/4 34/5 34/10	65/8 68/2 74/14 94/8	74/11 76/17 76/25	witnesses [3] 127/17
172/21	122/20 123/20 125/3	35/12 36/6 37/8 37/23	102/4 111/17 162/24	81/4 88/22 93/2	137/21 141/6
Wednesday [2] 1/1	125/20 126/6 131/7	38/1 38/8 38/13 40/9	164/22 170/15	117/22 143/2 155/8	wonder [2] 6/10 118/6
161/22	131/20 136/10 138/5 140/24 141/25 142/1	40/14 40/17 44/3 45/24 47/23 48/7	whose [9] 22/16 29/5 30/6 41/20 48/25	WITN0736005 [4] 78/12 86/10 91/11	wooden [1] 82/2 word [3] 93/1 93/8
week [4] 13/7 90/4	142/6 143/7 146/20	48/19 49/1 49/9 49/14	110/5 112/16 115/24	121/11	word [3] 93/1 93/8 121/7
161/16 162/19	147/1 148/8 152/16	51/9 51/16 54/20	141/6	WITN0736006 [2]	words [3] 53/24
weekend [5] 8/8 127/8	152/23 153/8 155/1	54/25 55/17 55/20	why [10] 53/19 63/5	44/14 79/23	118/17 118/19
127/18 143/11 143/15	155/7 155/17 157/9	55/25 56/9 56/18 57/9	86/4 90/1 90/3 104/21	WITN0736007 [1]	work [6] 12/18 33/1
weekly [1] 82/3	158/6 159/7 159/15	59/15 61/25 62/21	109/11 126/3 127/25	129/5	37/2 156/25 159/13
weeks [1] 81/16 well [35] 3/9 3/21	161/7 165/22 165/25	64/9 64/14 71/13	128/24	WITN0736009 [10] 2/4	
12/15 14/20 24/4 25/7	167/15 167/21 169/7	73/21 74/1 78/1 78/24	wide [1] 163/21	8/21 29/7 53/10 89/15	worked [2] 102/4
26/11 37/24 38/14	172/4	81/21 81/25 82/2 85/5	widely [1] 2/12	99/8 113/24 131/9	145/24
39/11 44/23 46/7	what's [10] 14/15	88/4 89/25 92/13	wider [1] 77/8	153/13 173/19	working [12] 1/23
46/20 60/11 77/11	59/16 69/11 74/10	93/16 94/17 96/18	widespread [1] 86/25	WITN0736010 [1]	12/18 13/25 14/17
83/5 83/5 85/4 96/6	89/24 90/1 93/24	100/21 103/7 106/16	widow [1] 140/3	112/18 WITN0024004 [2]	15/22 17/11 19/21
	108/5 136/18 152/25	107/9 108/10 109/19	wife [2] 78/25 130/24	WITN0921001 [2]	37/6 101/13 120/11
	L	L		L	(70) wanting working

(70) wanting... - working

	l		1	I
W	40/17 41/2 44/15 48/3			
working [2] 120/13	69/2 69/22 81/10	58/18 77/21 78/14		
157/14	92/23 113/17 150/24	84/10 86/12 93/22		
workplace [1] 56/22	154/8 154/8	you've [1] 76/16		
world [5] 9/14 18/17	years [18] 39/21 43/2	young [1] 16/23		
35/22 36/11 37/11	48/8 59/13 72/9	youngest [1] 16/18		
worldwide [1] 39/22	110/22 124/9 128/9	your [12] 46/4 46/25		
worried [1] 134/5	132/3 132/7 133/22	53/16 61/8 62/18 64/2 66/25 72/21 106/1		
worries [1] 78/21	136/8 137/23 139/10 140/8 142/13 150/17	147/2 149/19 151/10		
worry [2] 36/4 123/19	156/1	yours [1] 49/9		
worth [3] 39/13 92/8	yes [44] 4/1 7/10	yourself [2] 41/9		
137/6	23/18 24/11 24/13	141/22		
would [89] 3/1 3/19	24/16 24/22 24/25			
6/11 13/2 14/17 14/20	26/14 34/13 38/10	Z		
17/18 18/16 18/25	41/16 45/9 46/2 49/18	Z8 [3] 1/15 1/18 157/9		
19/11 26/23 27/17	49/24 52/4 70/8 76/23	' '		
30/22 31/15 39/4 39/9	77/6 77/11 77/16 86/1			
44/4 45/24 45/25	88/3 88/11 88/17			
46/19 50/25 52/10	103/2 110/14 111/7			
52/19 52/25 56/15 60/8 63/12 64/17	119/12 119/15 119/18			
69/11 69/22 73/14	125/23 126/1 126/5			
78/5 85/14 86/4 86/16	141/1 142/6 148/15			
88/8 91/22 92/1 93/1	148/18 153/3 153/5			
93/10 95/21 101/8	153/6 155/4 175/12			
101/10 103/3 103/7	yesterday [11] 1/4			
103/9 103/10 103/11	1/13 1/21 29/24 32/21			
103/16 103/18 103/22	71/11 71/14 107/9			
104/7 104/9 106/7	112/19 172/16 172/21			
106/18 106/23 108/25	yet [3] 11/11 27/20			
109/11 111/5 112/12	93/20			
115/21 115/25 116/9	York [1] 16/24			
118/18 119/2 122/8	you [95] 1/4 7/23 8/11			
123/20 124/21 125/14	8/13 12/9 12/12 13/21			
126/16 128/1 128/14	17/17 23/10 24/18 32/12 32/20 33/19			
130/1 130/9 131/5	36/6 41/8 42/12 44/9			
134/1 135/25 136/15	46/3 46/3 47/4 48/19			
138/15 138/22 139/19	49/20 51/5 53/16			
140/20 141/8 146/10	53/20 54/11 54/18			
148/13 159/23 161/22	54/18 55/2 55/9 56/5			
163/14 171/16	57/18 60/11 61/7			
wouldn't [1] 146/11	62/15 62/17 63/3 64/6			
wrestle [1] 154/24	65/4 68/17 68/24			
write [1] 19/10	71/16 74/6 77/17			
writes [1] 42/18 writing [4] 42/17 85/6	77/22 84/4 86/4 88/2			
160/21 162/14	88/8 88/18 90/17 92/1			
written [18] 4/11 69/1	92/7 92/11 92/12			
73/3 84/25 93/25	92/18 92/18 92/21			
96/13 98/7 99/15	92/22 92/24 94/6			
122/9 122/25 123/6	94/23 96/19 97/3			
132/13 137/4 137/20	99/17 99/20 109/11			
145/18 147/25 172/5	111/1 118/7 122/24			
172/19	125/16 131/6 131/7			
wrong [2] 92/1 158/16	137/4 137/5 140/2			
wrote [3] 43/5 141/25	143/20 140/1 140/10			
142/1	146/23 148/16 148/16			
v	148/20 149/17 151/15 153/1 155/22 159/11			
<u>Y</u>	160/13 160/21 161/4			
year [17] 2/13 10/4	161/7 169/13 175/12			
11/19 38/24 39/10	175/16			
	110/10			
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(71) working... - Z8