

Friday, 15 January 2021

1  
2 (10.00 am)  
3 **SIR BRIAN LANGSTAFF:** Good morning, Professor Collins.  
4 **THE WITNESS:** Good morning, Sir Brian.  
5 **SIR BRIAN LANGSTAFF:** My apologies for speaking from and  
6 behind a mask, if you can't hear me very clearly.  
7 I hope you can. Obviously, you can see me.  
8 Let me describe the scene to you that you're  
9 facing but, first of all, you're at home, I think.  
10 **THE WITNESS:** That's correct, yes.  
11 **SIR BRIAN LANGSTAFF:** Your wife is in the house?  
12 **THE WITNESS:** Yes, she's here, yes.  
13 **SIR BRIAN LANGSTAFF:** Right. You are talking to  
14 an Inquiry chamber which, although I know you had  
15 hoped to be here to see it in person, it's a big room,  
16 will seat about 200 people and, at the moment, we have  
17 a total of eight people in it, all very socially  
18 distanced, as you might imagine, all wearing masks  
19 except, at the moment, for Ms Scott who is going to  
20 ask you the questions. Mary, in a moment or two, will  
21 ask you to take the oath.  
22 Beyond the Inquiry room, there will be  
23 something in the region of 100 to 200, there were just  
24 over 200 yesterday, watching either on a direct Zoom  
25 platform or on YouTube. So those are the people

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1 could be transmitted through blood and blood products?  
2 **A.** It would have been some time over the next year or so.  
3 **Q.** Can you recall during your medical training what, if  
4 anything, you were taught about the seriousness of  
5 non-A, non-B as a disease?  
6 **A.** I can't remember specifically what we were taught  
7 about non-A, non-B. We were taught that after  
8 transfusion there was the risk of hepatitis. I can't  
9 remember anything that was described about the risk  
10 of -- the severity of that or whether it would develop  
11 chronic hepatitis.  
12 **Q.** Can you recall whether you ever had an understanding  
13 that it was anything other than a serious -- or it  
14 could be a serious disease and could be chronic?  
15 **A.** Yes, I think I always understood it could be a chronic  
16 disease and could be serious, yes.  
17 **Q.** You then undertook various house officer roles in  
18 surgery and medicine between August 1986 and  
19 February 1989; is that correct?  
20 **A.** That's correct, yes.  
21 **Q.** Was your first haematology post February 1989 as  
22 a Senior House Officer in Royal London Hospital?  
23 **A.** That was the first formal haematology, although in my  
24 medical rotation at Oldchurch Hospital I covered some  
25 haematology there as well. But my first formal

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1 you're speaking to. I imagine there will be probably  
2 a number of people from Wales, in particular, who will  
3 be interested to know what you have to tell us about  
4 that.  
5 Mary, please would you ask Professor Collins to  
6 take the oath.  
7 **PETER WILLIAM COLLINS, affirmed**  
8 **Questions by MS SCOTT**  
9 **MS SCOTT:** Good morning, Professor Collins.  
10 **A.** Morning.  
11 **Q.** I'm going to start off by asking you some questions  
12 about your CV. So we know from your witness statement  
13 that you qualified, you completed your medical  
14 training in 1986?  
15 **A.** That's correct.  
16 **Q.** Can you recall what you learnt during that medical  
17 training about the risk of viral infection via blood  
18 and blood products, particularly in relation to HIV  
19 and non-A, non-B?  
20 **A.** I was aware from medical school training that  
21 hepatitis could be transmitted by blood products.  
22 I don't think I was aware at that time about HIV being  
23 transmitted. I was aware that -- I was aware of AIDS.  
24 That had been mentioned in my undergraduate training.  
25 **Q.** Can you recall when you did become aware that HIV

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1 training post in haematology was at the Royal London.  
2 **Q.** Was that under Professor Colvin?  
3 **A.** Well, it was -- Professor Newland was the -- managed  
4 the leukaemia side and the bone marrow transplantation  
5 and Dr Colvin the coagulation and thrombosis side.  
6 **Q.** You then became an honorary lecturer in haematology in  
7 February 1990 at The Royal London; is that correct?  
8 **A.** That is correct, yes.  
9 **Q.** Was that a post that involved teaching?  
10 **A.** No, it was really a research post, rather than  
11 a teaching post.  
12 **Q.** So during that post, how much of your role involved  
13 the treatment of those with bleeding disorders?  
14 **A.** I would cover bleeding disorders out-of-hours on-call  
15 and I would go on ward rounds where people with  
16 bleeding disorders were being treated as in-patients.  
17 **Q.** You then had a post between September 1991 and  
18 June 1993 as the Leukaemia Research Fund Clinical  
19 Research Fellow at the Royal London. Did you spend  
20 any time during that post working with those with  
21 bleeding disorders or were your duties in relation to  
22 those of leukaemia?  
23 **A.** I was employed at that time doing a thesis on  
24 thrombotic complications of bone marrow  
25 transplantation, so that was the focus of the work

4

1 then. However, I did continue throughout all of that  
2 time to be involved in the care of people with  
3 bleeding disorders, particularly out-of-hours.

4 **Q.** Were you involved during that time in any of the  
5 testing of patients for HCV (hepatitis C)?

6 **A.** No, I wasn't involved.

7 **Q.** Then between July 1993 and July 1995 you were  
8 a lecturer and honorary senior registrar in  
9 haematology at the Royal London Hospital; is that  
10 right?

11 **A.** I think I was at the Royal Free Hospital, or is that  
12 next?

13 **Q.** No, it may be the Royal Free Hospital. I've got the  
14 Royal London but it could be that it's the Royal Free.  
15 Great Ormond Street I've got next.

16 **A.** Well, no from the Royal London I rotated for two years  
17 to the Royal Free Hospital and then after two years  
18 I rotated for one year at Great Ormond Street  
19 Hospital.

20 **Q.** That must be the Royal Free Hospital then. Then  
21 August 1991 for a year at Great Ormond Street  
22 Hospital?

23 **SIR BRIAN LANGSTAFF:** 1995.

24 **MS SCOTT:** 1995, sorry.

25 **A.** Yes.

5

1 shared the on-call.

2 **Q.** Then in September 2001, you were appointed a Professor  
3 of Haematology at the School of Medicine in Wales and  
4 an honorary consultant haematologist at the Cardiff  
5 Haemophilia Centre at the University Hospital Wales.

6 **A.** I was initially appointed as a senior lecturer and  
7 then after that was promoted to reader and then  
8 subsequently promoted to professor. So it was all the  
9 academic track after that, yes.

10 **Q.** Is it right that from September 2001 approximately  
11 50 per cent of your time was devoted to your academic  
12 duties, teaching and so on, and 50 per cent of your  
13 time to clinical work?

14 **A.** That was what my job plan was but I spent  
15 substantially more than 50 per cent of my time doing  
16 clinical work because of the volume of clinical work  
17 and I always prioritised the clinical work over  
18 research and teaching, if there was any conflict.

19 **Q.** Then in 2017 you stepped down as the Chair of the  
20 Cardiff Centre and was succeeded by Dr Rayment; is  
21 that right?

22 **A.** That's correct, yes.

23 **Q.** Then the other point I wanted to just to touch on on  
24 your CV was your involvement with the UKHCDO. You  
25 became a member of UKHCDO when you became a director

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1 **Q.** Then in September 1996 you took up your consultant  
2 haematologist post at University Hospital Wales?

3 **A.** That's correct, yes.

4 **MS SCOTT:** At the same time you became the Director of the  
5 Cardiff Haemophilia Centre, which was then called the  
6 Arthur Bloom Haemophilia Centre; is that correct?

7 **A.** Yes.

8 **Q.** So between 1996 and 2001 can you estimate how much of  
9 your time was spent working within the haemophilia  
10 centre and treating those with bleeding disorders?

11 **A.** It was probably about 80 to 90 per cent. My other  
12 roles -- because I had to manage people with venous  
13 thrombotic disorders, anti-coagulation and see people  
14 generally around the hospital who were having abnormal  
15 bleeding so, for example, after childbirth or after  
16 cardiac surgery, I would be involved in treating  
17 bleeding in those situations.

18 **Q.** Do I understand from your witness statement that  
19 between 1996 and 2005 you were the only consultant on  
20 call for those with bleeding disorders?

21 **A.** That's correct, yes.

22 **Q.** Then in 2005 that changed because you took on -- well,  
23 Dr Rayment took up her post as a consultant at the  
24 centre?

25 **A.** Yes. So she took up her post then and after that we

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1 of the Cardiff centre in 1996; is that right?

2 **A.** Yes, that is correct.

3 **Q.** You have been on a number of working parties for the  
4 UKHCDO, including the inhibitor working party,  
5 von Willebrand disease working party, genetics working  
6 party, paediatrics, rare disorders, and data  
7 management, and you were the Vice-Chair between 2016  
8 and November 2020; is that correct?

9 **A.** That is all correct, yes.

10 **Q.** I'm going to move on now to ask you some questions  
11 about the facilities and services at the Cardiff  
12 centre. So, first of all, when you took up your  
13 directorship as director of the centre in  
14 September 1996 can you describe the physical  
15 facilities that the centre had at that time?

16 **A.** Yes. The facilities were relatively poor at that  
17 time. We had a waiting room, we had one treatment  
18 room and we had an office next door, and within that  
19 treatment room we obviously had to manage all of the  
20 people attending the centre. So it was a very -- very  
21 cramped in terms of the physical space.

22 **Q.** Where were the records kept at that stage, during that  
23 period?

24 **A.** The records were kept in the office, which was next  
25 door to the treatment room, so that if people arrived

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1 the records were readily available to be consulted.  
 2 **Q.** Then in 2000 a new haemophilia centre was built; is  
 3 that right?  
 4 **A.** Well, the first thing that happened was that, before  
 5 I arrived, it had been agreed that the haemophilia  
 6 centre would be -- the physical haemophilia centre  
 7 would be disbanded and people with bleeding disorders,  
 8 haemophilia and other bleeding disorders, would be  
 9 treated on a new haematology day unit. This caused  
 10 significant concern among the patient group and, as  
 11 I arrived, this was one of the first issues that I was  
 12 confronted with.  
 13 I think that to combine a comprehensive care  
 14 haemophilia centre and a haematology day unit is not  
 15 suitable, particularly as we were treating adults and  
 16 children, and so we had to go through, with the  
 17 patient group and myself, a process of advocating to  
 18 have a new haemophilia centre built that was separate  
 19 from the day unit and that's the position you're  
 20 describing then. So the first step that there was  
 21 a joint haematology day unit and haemophilia centre,  
 22 which I don't think was adequate for the work we were  
 23 trying to do.  
 24 **Q.** Your witness statement says that happened in 1998.  
 25 Does that sound right?

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1 Oxford Haemophilia Centre, and obviously he had worked  
 2 at the Cardiff Haemophilia Centre for some time.  
 3 I was very reliant on his clinical expertise because  
 4 he was clearly a more experienced and knowledgeable  
 5 haemophilia doctor than I was when I took up that post  
 6 immediately from training. So I was very fortunate to  
 7 have someone of that competence and knowledge to be  
 8 present at the centre at that time.  
 9 **Q.** And there was a haemophilia nurse there,  
 10 Sister Jennifer Jones?  
 11 **A.** Yes, that's correct.  
 12 **Q.** You had a physiotherapist, Mrs Fiona Hall, and you had  
 13 a social worker, Mr Timothy Hunt, whose role,  
 14 I understand, was limited at that point to social work  
 15 for patients who'd been infected with HIV; is that  
 16 right?  
 17 **A.** That is all correct, yes.  
 18 **Q.** Is it also right that while you added additional staff  
 19 to the centre over the years, you have always had  
 20 nursing staff, physiotherapists and social workers at  
 21 the centre?  
 22 **A.** Yes, throughout the whole of the period, and we have  
 23 expanded the number of nurses and the number of  
 24 physiotherapists throughout that time and added, in  
 25 particular -- particularly important, paediatric

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1 **A.** That's correct, yes.  
 2 **Q.** Then in 2000 the new haemophilia centre was built.  
 3 Can you describe --  
 4 **A.** Yes.  
 5 **Q.** Is that where the centre remains?  
 6 **A.** That's where the centre remains now, yes, yes.  
 7 **Q.** What are the facilities there, the physical facilities  
 8 there?  
 9 **A.** So, again, we have a waiting area, with an area for  
 10 adults and a second waiting area for children,  
 11 although it is the same physical space. We have  
 12 a consulting room and we have two treatment rooms.  
 13 One of those treatment rooms is shared with the  
 14 haematology day unit. We have an area of a reception  
 15 desk, behind which we keep all of the notes, and we  
 16 have office space as well, both physically within that  
 17 area of the haemophilia centre and then across the  
 18 corridor we have two other offices that we have access  
 19 to.  
 20 **Q.** When you took up your post in 1996, I understand from  
 21 your statement that Dr Dasani was in post and you were  
 22 the two doctors at the centre.  
 23 **A.** Yes, that's correct. Dr Dasani was an extremely  
 24 experienced and knowledgeable haemophilia doctor. He  
 25 had worked at Lord Mayor Treloar, he had worked at

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1 specialist nurses have -- are now -- been working at  
 2 the centre for many years.  
 3 **Q.** We've touched on this already but you have now -- you  
 4 have got additional consultants at the centre. We  
 5 talked about Dr Rayment being appointed in 2004 but  
 6 coming to take up her post in 2005, Dr Alikhan  
 7 in 2008, Dr Heledd Roberts and Dr Obaji in 2019. So  
 8 there are five consultants now at the centre?  
 9 **A.** Since I wrote that statement there has been another  
 10 consultant appointment, Dr Gosrani, and he is  
 11 specialising in paediatrics. And that is deliberate  
 12 succession planning, so that when I retire he will  
 13 take over the management of children with bleeding  
 14 disorders. So we now have six consultants.  
 15 **Q.** And your statement says also that you have a data  
 16 manager.  
 17 **A.** Yes. So relatively early on we appointed a data  
 18 manager. I think that's very important because until  
 19 then that was falling onto the medical and nursing  
 20 staff to undertake data management duties such as  
 21 returns to the National Haemophilia Database, and so  
 22 we appointed a data manager relatively soon after  
 23 I was appointed, within a couple of years, I think.  
 24 **Q.** You also have a play specialist or play specialists.  
 25 Can you tell us a bit about them?

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- 1 A. So we have a play specialist who works with the  
2 children, and their role is to get children to be used  
3 to having intravenous access, particularly with the  
4 central lines and peripheral access, because obviously  
5 some children are very nervous and afraid of having  
6 treatment, and their role is to help with that  
7 process, of gaining confidence of the child to have  
8 treatment.
- 9 Q. Then in 2012 a psychology service was set up, the All  
10 Wales Psychology Service for Inherited Bleeding  
11 Disorders, which operates out of the centre; is that  
12 right?
- 13 A. Yes. So that was set up in 2012 and continues today.
- 14 Q. So is that part of the haemophilia centre?
- 15 A. Yes. That's part of the haemophilia centre and it's  
16 separate to the psychology service through the Welsh  
17 infected blood scheme. They have a separate  
18 psychology service which is not associated with the  
19 haemophilia centre, so that people can choose either  
20 to have psychology input from psychologists associated  
21 with the centre or independent of the centre.
- 22 Q. The psychology service that's part of the centre  
23 provides counselling and psychology services for those  
24 with bleeding disorders infected with HIV and  
25 hepatitis and their families; is that right?

13

- 1 for people who are attending the centre as patients,  
2 it's for their families as well, and some of the  
3 relatives of people who have lost family members have  
4 accessed the service of psychology support as well.
- 5 Q. Now, the centre is the Comprehensive Care Centre for  
6 mid-and South Wales; is that right?
- 7 A. Yes, that's correct.
- 8 Q. It runs two bleeding disorder clinics a month --
- 9 A. Two a week.
- 10 Q. -- sorry, a week --
- 11 A. Two a week.
- 12 Q. -- and has a 24-hour service through an out-of-hours  
13 service.
- 14 A. Yes, that's right. There's an out-of-hours service  
15 24/7 and people with bleeding disorders can access  
16 that at any time.
- 17 Q. In addition, you have a system where people can be  
18 visited at home.
- 19 A. Yes, that's correct and that's been very important  
20 over the last nine or ten months, that in order to  
21 reduce the number of people coming to the hospital,  
22 a lot of our care has now been delivered in patients'  
23 homes. So the physiotherapists go to patients' homes,  
24 the psychologist and the nurses will go to patients'  
25 homes for blood tests, so as to prevent people coming

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- 1 A. Well, they provide psychology service for everybody  
2 who attends the centre but with a specific remit to  
3 work with people who have been affected by  
4 transfusion-transmitted disease.
- 5 Q. That service has a consultant clinical psychologist  
6 for one day a week, a principal counselling  
7 psychologist for one day a week, and a highly  
8 specialist clinical psychologist for three days  
9 a week; is that correct?
- 10 A. That's correct and one of those posts is based in the  
11 Swansea Haemophilia Centre so that we can have  
12 appropriate access to care, more local to people's  
13 homes. As part of that service, a psychologist was  
14 also appointed in North Wales, associated with the  
15 Bangor Haemophilia Centre but, in Cardiff, we're  
16 not -- we're not involved in treatment in North Wales  
17 but as part of that All Wales psychology service, that  
18 happened at the same time.
- 19 Q. Do you know how much uptake there's been for that  
20 service?
- 21 A. I think, to be fair, relatively slow. I think that  
22 initially the uptake was slow but I think the uptake  
23 is now very good and there are -- and I think that, as  
24 people have got used to that service, more and more  
25 people have come forward. Of course, it's not only

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- 1 to the hospital.
- 2 Q. Some of the centre staff also carry out school visits.  
3 What does that encompass?
- 4 A. Well, this is if a child is either starting school or  
5 changing school. This is to make sure that the staff  
6 at the school understand the bleeding disorder and  
7 that the child is able to access and be involved in  
8 all of the activities in the school, and it's mainly  
9 to reassure the staff of the school that there  
10 shouldn't be any significant impairment in what the  
11 child is allowed to do.
- 12 Q. The centre also has a role, as I understand it from  
13 your statement, in co-ordinating the care of all of  
14 those diagnosed with bleeding disorders in south and  
15 west Wales. Can you explain a little bit about what  
16 that means.
- 17 A. So the haemophilia services in south, west and  
18 mid-Wales are set up as a clinical network and this  
19 has been led by Dr Rayment over the last three to four  
20 years, so that there is not a haemophilia consultant  
21 now in the Swansea Haemophilia Centre and the staff  
22 from Cardiff go to Swansea to provide the care in  
23 Swansea, so that someone from Cardiff will go there  
24 once a week to see patients and to do out-patient  
25 clinics. We're available all the time for the nurses

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1 at the Swansea Haemophilia Centre and will react to  
2 any issues that arise there.

3 The reason for that, that we had to set the  
4 service up that way is that we were unable to appoint  
5 a consultant to replace Dr Al-Ismail when he retired  
6 and so we had to provide the service as outreach from  
7 Cardiff. We also provide outreach to Nevill Hall  
8 Hospital in Abergavenny and, before the travel  
9 restrictions, I would go there once a month to do  
10 a joint clinic with the consultant there. But we  
11 still provide day-to-day clinical advice to the centre  
12 in Abergavenny.

13 **Q.** So are all patients with bleeding disorders registered  
14 at the Cardiff Centre or are they registered in  
15 Swansea and Abergavenny as well?

16 **A.** So patients could be registered at Swansea, at  
17 Abergavenny, or in Cardiff, or jointly, they could be  
18 registered both at Swansea and in Cardiff. So  
19 certainly patients are joint registered but some are  
20 only registered in Swansea and some are only  
21 registered in Abergavenny.

22 **Q.** You also provide advice on management of bleeding  
23 disorders to all hospitals in the south and west of  
24 Wales; is that right?

25 **A.** That's correct, so if a person has a problem they

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1 in 1997 because that gives us quite a useful snapshot  
2 of what was going on in 1997. Soumik, it's  
3 HCDO0000280\_061.

4 We can see from the first page that this is  
5 a covering letter dated 4 June 1997, dictated 23/5/97  
6 from Frank Hill, and it looks like copied to Dr Ludlam  
7 and Dr Colvin. Were they undertaking the audit?

8 **A.** Dr Hill undertook the audit. I think he's probably  
9 copying it to Dr Ludlam and Dr Colvin because they  
10 would have been the chair of UKHCDO at the time.

11 **Q.** So the audit's fairly soon after you arrive at the  
12 centre. If we go over to page 2 of the document --

13 **A.** The audit was delayed. The audit should have happened  
14 the year before in 1996 but it was delayed until  
15 I took up post.

16 **Q.** We can see at the first hole punch there "Haemophilia  
17 patients registered". So out of those 328 patients  
18 with inherited bleeding disorders registered in  
19 Cardiff, of those is it right that these are the  
20 haemophilia patients: severe haemophilia A 41, severe  
21 haemophilia B 17, moderate haemophilia A 33, and  
22 moderate haemophilia B 12; does that sound right?

23 **A.** It doesn't sound quite right to me. There are too  
24 many people with moderate haemophilia. The proportion  
25 of moderate haemophilia is much lower than for severe,

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1 might go to the hospital in Haverfordwest, which isn't  
2 a haemophilia centre, but that might be their closest  
3 hospital and then the consultant haematologist is very  
4 likely to ring us at the Cardiff centre and ask our  
5 advice and we will advise on what should be done.  
6 Either we can advise directly on what treatment should  
7 be given or sometimes we advise that the patient  
8 should be transferred to Cardiff if there is a more  
9 serious problem.

10 **Q.** So you're describing there a patient going to their  
11 local hospital because an event has occurred rather  
12 than for their routine management?

13 **A.** Yes. It's not for routine management, no, not for  
14 routine out-patient appointments. It's because they  
15 have had an injury or, you know, they've been admitted  
16 through casualty with abdominal pain or something like  
17 that.

18 **Q.** In your statement, you've given us some figures as to  
19 how many patients have been registered at the Cardiff  
20 centre over the years, and you say that in 1996 there  
21 were 328 patients with inherited bleeding disorders  
22 registered with Cardiff, 239 of those were over 18 and  
23 87 of those were under 18; is that correct?

24 **A.** Yes.

25 **Q.** Can I ask you to look at the audit that was undertaken

18

1 so those figures don't quite ring true to me, I'm  
2 afraid.

3 **Q.** Then we can see there medical staff, as we touched on  
4 earlier, you and Dr Dasani, nursing staff, you've got  
5 two nursing staff at that stage, a social worker and  
6 the physiotherapist, Ms Hall.

7 **A.** Correct, yes.

8 **Q.** Then if we go over to the next page please, Soumik, we  
9 can see there that under "Other Services for  
10 Children", you've got mention there of home therapy  
11 and prophylaxis, so 15 to 18 of the 24 severe  
12 haemophilia A boys are on prophylaxis. Then, just  
13 over the page to page 3, while we're on this document,  
14 we can see surgery. It sets out that there's genetic  
15 counselling and then surgery, emergency surgery,  
16 dental surgery and all the arrangements for  
17 gynaecology, orthopaedic surgery and physiotherapy.  
18 Does that look familiar and accurate?

19 **A.** Yes, that looks familiar and accurate.

20 **Q.** So I was asking you questions about numbers of  
21 patients. You can take that down now, Soumik. We'll  
22 come back to that document on another point a little  
23 later on.

24 **SIR BRIAN LANGSTAFF:** I wonder if I can just ask  
25 a question. You've told -- can we go back to page 1

20

1 of this document, and page 2. Thank you.

2 If we look at the haemophilia patients  
3 registered there, the total comes to something just  
4 over 100. What you were describing a moment or two  
5 ago to Ms Scott from your statement was that in 1996  
6 there were 328 people over the age of 18 with  
7 an inherited bleeding disorder and 87 under the age of  
8 18, which is 405. So there's a very big difference in  
9 numbers. The inherited bleeding disorders, what comes  
10 within the scope of that? How many people with  
11 an inherited bleeding disorder will not be people who  
12 you would define as suffering from either severe or  
13 moderate or mild haemophilia A or B?

14 **A.** A considerable number of people would have  
15 von Willebrand's disease. There would be people with  
16 inherited disorders of fibrinogen, Factor XI, platelet  
17 disorders. The figures that I have given in my  
18 statement I derived from the National Haemophilia  
19 Database and so I think that would explain why there  
20 is a discrepancy from what we said here.

21 Of course, this isn't showing mild haemophilia  
22 either. There would be a lot of people with mild  
23 haemophilia who aren't included in those figures.

24 **SIR BRIAN LANGSTAFF:** The other question -- go back to  
25 page 1 -- now Ms Scott may be coming to this, I don't

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1 Now, of course, all of those aspects, they  
2 required within the hospital structure to get -- to be  
3 put in place and I think what he was there saying was  
4 that he hoped that the audit that he had written would  
5 be helpful for me to make propositions to the  
6 management that we could make these improvements.

7 I think after Professor Bloom died, I took my  
8 post up about four years later and there had been  
9 three different people acting as consultant in that  
10 time. So there hadn't been a stable consultant in  
11 charge looking at a more long-term strategy, and  
12 I think that that is reflected in this situation that  
13 I found when I arrived.

14 **SIR BRIAN LANGSTAFF:** So the reference to update the  
15 centre, in Dr Hill's view it had fallen behind the  
16 curve, had it, during the previous four years, at any  
17 rate, the years before you came?

18 **A.** I think there were some aspects that were very good  
19 and there were some aspects that, yes, had fallen  
20 behind the curve. I'd come directly from Great Ormond  
21 Street where I had worked with Professor Hann and  
22 there was a much more proactive view on prophylaxis in  
23 children, particularly young children, to prevent the  
24 progression or the development of joint damage, and  
25 that was something I really needed to introduce in

23

1 know, but there Dr Hill says, in his second sentence:

2 "I hope it will help you in your efforts to  
3 improve and update the Centre."

4 So had you discussed with Dr Hill plans to  
5 improve and update the centre?

6 **A.** Yes. I mean, I read this audit through in the last  
7 couple of days, and it sort of brought things back to  
8 me as to the situation when I arrived in Cardiff.  
9 There were, for example, no routine out-patient  
10 clinics for anybody. Dr Dasani was seeing people in  
11 the haemophilia centre on a sort of *ad hoc* basis. He  
12 would contact people and they would come up and be  
13 reviewed or they would present with a specific problem  
14 and he would then review them overall. The number of  
15 children on prophylaxis was clearly not appropriate.  
16 We had to put in place prophylaxis for the other  
17 children.

18 So I think that there was a lot that we needed  
19 to sort out. There were no -- the joint clinics, for  
20 example, that we were setting up with the HIV  
21 physician and the joint clinics with the orthopaedic  
22 consultant, these were all things that I discussed  
23 with Dr Hill that we were putting in place and  
24 planning to do and that's, I think, what he was  
25 saying.

22

1 Cardiff because, certainly, we were behind the curve  
2 at that time in introducing prophylaxis for young  
3 children and, of course, that's very important for  
4 their long term well-being, because the joint damage  
5 in your 20s and 30s is caused by bleeds in your first  
6 two or three years of life.

7 **SIR BRIAN LANGSTAFF:** Yes. Yes, thank you very much.

8 **MS SCOTT:** Sir, for your note, in fact, the figures in  
9 Professor Collins' witness statement are 328 people in  
10 total with inherited bleeding disorders, 239 over the  
11 age of 18.

12 **SIR BRIAN LANGSTAFF:** Well, paragraph 26 reads "There are  
13 328 with an inherited bleeding disorder registered in  
14 Cardiff". I see, yes, you are right. I beg your  
15 pardon. I misread it. My fault. It's still a rather  
16 different figure than the just over 100, which was the  
17 point.

18 **MS SCOTT:** Indeed, yes.

19 **A.** I agree it is a very different figure. I can't  
20 explain it more fully.

21 **Q.** Then by 2019, your statement says that there are 802  
22 patients with inherited bleeding disorders registered  
23 with Cardiff, 640 over the age of 18 and 162 under the  
24 age of 18. Those figures more or less remain accurate  
25 or has there been an increase since then?

24

- 1 A. There is always a steady increase in the number of  
2 people registered. Yes, steadily more people are  
3 being registered with -- as diagnosis, such as mild  
4 von Willebrand's disease or a number of people who  
5 have clearly had evidence of bleeding but we can't  
6 find anything wrong on their laboratory tests. We  
7 look after quite a few people in that category.
- 8 Q. Of those 802 patients what would be your best estimate  
9 to how many of those patients were people with  
10 haemophilia?
- 11 A. Now?
- 12 Q. Yes.
- 13 A. Now. Probably about 150/160 something like that  
14 I would have thought. One of the reasons I'm  
15 struggling is, of course, we're now directly looking  
16 after all the people with haemophilia in Swansea as  
17 well, and that again might be a cause of the  
18 discrepancy in those figures because whether someone's  
19 registered with Swansea and Cardiff, as we discussed  
20 earlier, it's not always clear-cut where you allocate  
21 to which centre.
- 22 Q. So some of those 802 people may be registered in more  
23 than one place?
- 24 A. That's right, yes, exactly.
- 25 Q. Your statement tells us that currently registered

25

- 1 hepatitis C that you were treating?
- 2 A. That's correct, yes.
- 3 **SIR BRIAN LANGSTAFF:** Just to clarify, Ms Scott, the  
4 13 with HIV and the 66 with HCV, that's the entirety  
5 of the cohort is it? So the 13 co-infected are the  
6 13 who have HIV and 13 of the 66?
- 7 **MS SCOTT:** That's my understanding. Is that correct --
- 8 **SIR BRIAN LANGSTAFF:** So it's not an additional category?
- 9 **MS SCOTT:** Is that correct, Professor Collins?
- 10 A. Yes, that's not an additional category. The 66 with  
11 hepatitis C include the 13 people who have HIV.  
12 Again, just to make sure it's clear that some of those  
13 people with HIV may also be registered in Swansea, and  
14 so the numbers that Dr Al-Ismael gave you, you can't  
15 add those two numbers together to give a South Wales  
16 number because they will be being treated in both  
17 centres.
- 18 Q. I'm going to ask you some questions about the  
19 arrangements for the supply of product and treatment  
20 to the Cardiff centre over the years, and also what  
21 treatment's been provided to patients. But before  
22 I do, I'm going to -- before I get on to your time  
23 from 1996, you've exhibited to your statement some of  
24 the treatment policies that were in place during  
25 Professor Bloom's time at the Cardiff centre.

27

- 1 patients -- of the registered patients from the  
2 centre, 13 of them have HIV, 13 of them are  
3 co-infected with HIV and hepatitis C, 66 are infected  
4 with hepatitis C, and four are being treated for  
5 hepatitis B; is that right?
- 6 A. Yes, all those figures are correct, yes.
- 7 Q. Can you recall what the numbers of patients infected  
8 with HIV and hepatitis C were in 1996 when you arrived  
9 at the centre? How many patients you were treating  
10 for HIV and HCV?
- 11 A. The figure that I was told and that I've always  
12 assumed was 45 people had been infected with HIV --  
13 some of them of course had died before I arrived in  
14 Cardiff -- and also one partner had also been infected  
15 with HIV, and the figure of the people infected with  
16 hepatitis C was either 108 or 118. There are two  
17 figures that are given there.
- 18 Of course, many, many more people would have  
19 been infected with hepatitis C but they had died  
20 before the hepatitis C test became available.
- 21 Q. So when you arrived in 1996 there were some number  
22 between 13 and 45 patients infected with HIV that you  
23 were treating in 1996?
- 24 A. Yes.
- 25 Q. And some number between 66 and 108 or 118 with

26

- 1 Do you have any firsthand knowledge yourself of  
2 how those treatment protocols or treatment policies  
3 were implemented in Cardiff?
- 4 A. Well, clearly I wasn't in Cardiff then so I don't have  
5 firsthand knowledge but, to the best of my knowledge,  
6 those treatment protocols were implemented in Cardiff.
- 7 Q. But given, professor, that you have no firsthand  
8 knowledge yourself of what was happening in Cardiff,  
9 I'm not intending to ask you any questions in relation  
10 to the implementation or otherwise of those policies  
11 and procedures -- protocols, sorry.
- 12 A. I understand.
- 13 Q. So what were the arrangements for -- how did the  
14 centre purchase products, blood products, in 1996,  
15 when you took over as director?
- 16 A. So, the blood products were all initially purchased by  
17 the Welsh Blood Service and so they went to the --  
18 which is the transfusion centre. So they were  
19 purchased by the transfusion centre and held at the  
20 transfusion centre, and then all the hospitals in  
21 South Wales would have the blood products delivered to  
22 their hospital, so Cardiff would have the blood  
23 products from the Transfusion Service, and Swansea,  
24 blood products from the Transfusion Service, so other  
25 hospitals would do the same. So the purchasing was

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1 directly from the Transfusion Service and then it was  
 2 allocated to the hospitals, and then we would be  
 3 cross-charged by the Transfusion Service for the cost  
 4 of the product.  
 5 **Q.** So is that both for NHS product and for commercial  
 6 product?  
 7 **A.** Correct. So the -- certainly when I arrived in 1996  
 8 all of the product went to the transfusion centre and  
 9 then came to the centre. Since then, things have  
 10 changed because a lot of the product now is home  
 11 delivered so it doesn't go to the transfusion centre,  
 12 it's delivered directly to people's homes, and so  
 13 that's a different mechanism. But at that time, in  
 14 1996, the Cardiff Haemophilia Centre didn't buy any  
 15 product directly, it all went through the transfusion  
 16 centre.  
 17 **Q.** So when you -- in your statement, when you say you and  
 18 Dr Dasani chose the blood products that were going to  
 19 be used at the centre, was that out of the products  
 20 that the Blood Transfusion Service was holding or  
 21 could you say to the Blood Transfusion Service: could  
 22 you purchase us X and Y?  
 23 **A.** Yes, we could go to the transfusion centre and say: we  
 24 would like you to start holding a stock of this other  
 25 treatment, and then we would use it. So we could

29

1 consider the relative risk of blood products from the  
 2 point of view of infection.  
 3 **Q.** So is this fair, that at that stage you and Dr Dasani  
 4 would have considered that all of the products were  
 5 much of a muchness in terms of safety of viral  
 6 transmission, and if there had been any issues with  
 7 a particular product you would have expected that to  
 8 have been brought to your attention by the Blood  
 9 Transfusion Service?  
 10 **A.** I think -- well, this of course was at a time when  
 11 recombinant blood products were just becoming  
 12 available, so both myself and Dr Dasani were  
 13 completely agreed that we would prefer to use  
 14 recombinant blood products than plasma-derived blood  
 15 products because of the potential of risk of  
 16 infection.  
 17 I would have thought that if there were any  
 18 issues relating to the risk of infection, I'm more  
 19 likely to have been told by UKHCDO or by the companies  
 20 themselves than by the transfusion centre.  
 21 **Q.** So when you started at the centre, you say in your  
 22 statement that your patients were receiving blood  
 23 products and people with haemophilia A were being  
 24 treated with the BPL 8Y heat-treated plasma product  
 25 and Replenate, people with haemophilia B with a high

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1 certainly -- we were the people choosing what products  
 2 to use, not the Transfusion Service.  
 3 **Q.** Can I ask you about a paragraph in your witness  
 4 statement. It's WITN4029001 and it's at internal  
 5 page 15. It's paragraph 75. You say:  
 6 "Structures or decision-making bodies that  
 7 considered the risk of infections associated with  
 8 blood and blood products would have been led through  
 9 the Blood Transfusion Service rather than through the  
 10 haemophilia centre."  
 11 What do you mean by that paragraph?  
 12 **A.** Well, I think that by that time the risk of infections  
 13 from the products we were using in the haemophilia  
 14 service were much, much lower.  
 15 **Q.** Because the products were -- why was that?  
 16 **A.** Because the products were by then all heat-treated and  
 17 had been for over ten years, and by then had very good  
 18 safety records in terms of HIV and hepatitis C. So  
 19 that response -- the question was, in 74, whether  
 20 there were any advisory or decision-making structures  
 21 that covered the centre; the answer was no, there  
 22 weren't any. And I've made the point that if there  
 23 were any, it would be through the Blood Transfusion  
 24 Service not through the haemophilia centre.  
 25 There were no specific structures there to

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1 purity Factor IX product, Replinine, and patients with  
 2 von Willebrand's were being treated either with  
 3 BPL 8Y, DDAVP or Haemate P. Is that right?  
 4 **A.** It is. A very small number of people were also by  
 5 then on recombinant Factor VIII. I think there were  
 6 four people on recombinant Factor VIII, because they  
 7 had been involved in a clinical trial of recombinant  
 8 Factor VIII (the product was Kogenate) and at the end  
 9 of the clinical trial they had remained on that  
 10 recombinant Factor VIII. So a very small number were  
 11 on recombinant at that time.  
 12 **Q.** We can see that in the audit document.  
 13 So if we can go back to, Soumik, please,  
 14 HCDO0000280\_061, and go to page 5 of that document.  
 15 Under "Availability of Blood Products", it  
 16 says:  
 17 "These are stored in the Haemophilia Unit.  
 18 Children are currently treated with BPL 8Y apart from  
 19 PUPs who have presented in the last 2 years ..."  
 20 So presumably since 1995:  
 21 "... and 4 previously untreated patients who  
 22 were recruited into a trial of recombinant  
 23 Factor VIII. Four adults are also in this study."  
 24 So it looks like there's three cohorts of  
 25 patients in that study. Does that accord with your

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1 recollection?

2 **A.** Yes. So the four people on recombinant Factor VIII,  
3 that's correct to say that they were people who had  
4 been recruited in the trial and carried on.

5 The previously untreated patients, I don't  
6 remember there having been any previously untreated  
7 patients in the previous two years before I arrived,  
8 but what we would have done is that had there been any  
9 we would have treated with recombinant Factor VIII.

10 **Q.** You also say in your statement that -- and that you  
11 just mentioned -- this was the point at which  
12 recombinant Factor VIII was becoming available and you  
13 were very keen for your patients to be put onto that.  
14 Can you talk us through how that occurred.

15 **A.** Yes. So almost the moment I arrived, within a couple  
16 of weeks, the patient group had come to me and said  
17 that they wanted to be pushing for recombinant  
18 Factor VIII. Of course, recombinant Factor VIII was  
19 substantially more expensive and so I had to put  
20 together cases based on the improved safety of  
21 recombinant Factor VIII to make the case for the  
22 increased funding.

23 It was quite complicated because we were  
24 treating people from all areas of south, mid-and west  
25 Wales, and so we were having to go to a number of

33

1 them to recombinant Factor VIII. We are in the  
2 process of doing this and hopefully will have all  
3 patients on recombinant Factor VIII in 3 to 4 months'  
4 time."

5 So in December 1997 it looks like you are  
6 hoping that that will be in place by April 1998; can  
7 you recall whether that was the time at which point  
8 all your patients had been switched over?

9 **A.** I can't remember exactly. I don't think that they had  
10 all been switched over by April 1998, based on  
11 information I'd seen from the National Haemophilia  
12 Database. I think it probably took another year for  
13 everyone to be changed over.

14 I think one of the things that this letter --  
15 just to make a point of this, I think this is  
16 an important role of a comprehensive care centre that  
17 I had been informed by UKHCDO about variant CJD and  
18 I had cascaded that information to all of the  
19 haematologists in south and mid-wales so that they  
20 were -- to make absolutely sure that they were aware  
21 of this information because, of course, the  
22 information had gone to haemophilia centres and not  
23 all hospitals.

24 **Q.** The next paragraph is also probably worth looking at  
25 here, talking about the situation with recombinant

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1 different health authorities to get the funding. We  
2 put the case and, in 1997, there was an agreement that  
3 everyone in Wales, including North Wales, whose  
4 patients we weren't looking after, would have access  
5 to recombinant Factor VIII, and the additional funding  
6 required was put in place to fund that.

7 **Q.** If we can turn to a document that might help us with  
8 that, it's WITN4029013. This might help put some  
9 dates on when that actually took place. So this is  
10 a letter on 15 December 1997. It says "Dear  
11 Dr Blank", and if we turn over to the second page we  
12 can see it's signed by you and copied to a number of  
13 your colleagues. We can see there Dr Al-Ismael, for  
14 example.

15 So if we turn back to the first page of that  
16 document, and to the second paragraph, so just putting  
17 this in context, you are enclosing a letter that's  
18 been circulated by the UKHCDO regarding vCJD in the  
19 treatment of haemophilia. Then you go on in the  
20 second paragraph:

21 "From our point of view, we are very fortunate  
22 that we have agreement to treat all patients with  
23 recombinant blood products, and it would seem sensible  
24 to change all our patients to recombinant Factor VIII  
25 rather than to American-based plasma before changing

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1 Factor IX being more difficult, because it is not yet  
2 available in the UK, likely to become available in the  
3 next six months. Therefore, there's a choice:  
4 "... of continuing with the BPL product made  
5 from UK plasma, or changing to a Factor IX  
6 manufactured from American donors. Realistically,  
7 this would mean purchasing the Factor IX from Alpha.  
8 At the present time we are discussing this issue with  
9 individual patients and, if they show a strong  
10 preference for changing to USA plasma, we will change  
11 their product. However, if no strong preference is  
12 expressed, we will continue with the high purity BPL  
13 product until recombinant becomes available."

14 Why were you suggesting that patients should  
15 have a strong preference before changing them over to  
16 American plasma?

17 **A.** Well, I don't think that's -- looking at it,  
18 I wouldn't use the word "strong preference". If  
19 a patient had said they had a preference to change,  
20 then I would have changed. I don't think there was  
21 any resistance to that.

22 The reality was that, from my memory, that  
23 people were resistant to changing to US plasma because  
24 of the concerns they had in the past. It's important  
25 to remember at this time, 1997, is that the

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1 information being given to us was that there was only  
2 a hypothetical risk of variant CJD in UK plasma and,  
3 indeed, there was, as we may come on to later, there  
4 was advice that we shouldn't be telling the patients  
5 at all about this issue, which UKHCDO disagreed with  
6 and I disagreed with.

7 So there was -- the level of risk being told to  
8 us was that, essentially, it was thought that there  
9 wasn't a risk and, of course, everybody at this time  
10 who was eating meat was being exposed to variant CJD  
11 through that mechanism and so these were some of the  
12 conversations I would have had to have had with the  
13 patients about what their choice wanted to be, because  
14 some people might well take the view that they were  
15 being exposed through the food chain anyway.

16 My memory is that -- and I think I'm correct in  
17 this -- no-one wanted to change to US plasma and, of  
18 course, later on the next year BPL started to make all  
19 of its products from US plasma and that did cause some  
20 people some concern, that their product was now being  
21 made from US plasma and, obviously, because they were  
22 very well aware of the problems of the past.

- 23 **Q.** The Inquiry's heard evidence from some clinicians who  
24 describe putting their patients or some of their  
25 patients onto recombinant factor products and then

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1 often haemophilia centres are then required to use  
2 a certain proportion of different recombinant  
3 Factor VIIIs, and so I was certainly involved in the  
4 centre of ensuring that we complied with those tender  
5 arrangements.

6 I think it is just worth pointing out that from  
7 the point of view of the NHS, that tenders process has  
8 saved a phenomenal amount of money for the NHS,  
9 because the UK has acted as a single entity in these  
10 tender arrangements. Before, each individual sort of  
11 area would have to make a tender and so would get  
12 nothing like as good a price.

- 13 **Q.** So just picking up on the point about centres having  
14 to use a minimum proportion of particular named  
15 Factor VIII products, if, for example, the tender is  
16 for, I don't know, five Factor VIII products, do you  
17 have to use all five of those or how does it work?  
18 **A.** No, it would work -- let's say that there are, as you  
19 say, a certain number of Factor VIII products. For  
20 the top two in the tender we would have to use  
21 a certain proportion of those. The top one we would  
22 have to use the most, then after that, but for the  
23 rest of it there's a proportion where we can use  
24 anything we want, and so we would then have to discuss  
25 with individuals about changing products. I would

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1 there being a shortage and having to switch them back  
2 to plasma products. Did you have difficulties with  
3 that? Did that happen with any of your patients?

- 4 **A.** We didn't have to change anyone back to plasma-derived  
5 products. We did have to reduce usage. We had to  
6 reduce prophylaxis in some people and for a while  
7 suspend prophylaxis in some people, and we had to  
8 delay surgery. But we were able to maintain everybody  
9 on recombinant. No-one was required to change back to  
10 plasma-derived.

- 11 **Q.** Can I now move on to the current purchasing  
12 procedures, if I can put it like that.

13 We understand from your statement that  
14 since 2005 products used at the centre have been  
15 purchased nationally via the national tender process.  
16 What role do you or the centre have in that process,  
17 if any?

- 18 **A.** Well, I play a role because I represent Wales on the  
19 sort of UK-wide committee. There's a UK-wide  
20 committee run by the commercial medicine unit and they  
21 put a tender out on behalf of the whole UK and myself  
22 and people from the Welsh Commissioners represent  
23 Wales on that committee. So we give our opinions.

24 The tender goes out and as the result of the  
25 tender, dependent on what -- the specific tender, very

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1 always tell people that the reason the product was  
2 changing was for price and that, you know, we would  
3 discuss that it was for the benefit of the NHS  
4 overall, although of course some of that saving has  
5 been reinvested in haemophilia care in various ways,  
6 particularly in access to increased amounts of  
7 Factor VIII, so that the amount of Factor VIII we've  
8 used over the years has gone up substantially and  
9 that's funded in part by the savings in the contract.

10 But, of course, if some people for whatever  
11 reason said they didn't want to change product, then  
12 we wouldn't change their product. If they wanted to  
13 stay on their product for any reason, they could stay  
14 on it. There was no -- if someone had that view, they  
15 were allowed to stay on their product. There was no  
16 products that were specifically unavailable.

- 17 **Q.** I'm going to come back and ask you some questions  
18 about your consent process in a moment as well, but  
19 just sticking then with products that are available  
20 that you provide to your patients at the centre.  
21 People with haemophilia A, are they treated with third  
22 generation recombinant Factor VIII products? Is that  
23 how I understand your witness statement?

- 24 **A.** Yes. So at the moment they are treated with either  
25 third generation recombinant Factor VIII products or

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1 enhanced half-life recombinant Factor VIII products  
 2 or, now, over the last sort of year or so,  
 3 increasingly more people are treated with the -- with  
 4 Emicizumab, which is a non-Factor VIII product. It's  
 5 the bispecific antibody, and the advantage to that is  
 6 it can be given subcutaneously rather than  
 7 intravenously and can be given weekly or every two  
 8 weeks. So more people with haemophilia are opting to  
 9 go on to that product over time.

10 **Q.** People with haemophilia A and inhibitors treated with  
 11 Factor VIIa and FEIBA; is that right?

12 **A.** Yes, and Emicizumab.

13 **Q.** And people with haemophilia B, are they treated with  
 14 recombinant Factor IX products and some with plasma  
 15 products?

16 **A.** So -- yes, so when recombinant Factor IX came in,  
 17 everybody was offered recombinant Factor IX, and to my  
 18 memory everyone decided they wanted to go onto  
 19 recombinant Factor IX. However, some people who --  
 20 their experience was that they did not think that the  
 21 recombinant Factor IX worked as well to treat or  
 22 prevent bleeds as the plasma-derived, and so a small  
 23 number opted to change back to plasma-derived  
 24 Factor IX.

25 **Q.** And some remain on that product?

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1 use at the moment is called Voncento. We don't use  
 2 Factor 8Y for von Willebrand's disease anymore. We  
 3 did when I first arrived but we haven't for a long  
 4 time.

5 We are just about to get access to recombinant  
 6 von Willebrand factor and we are just waiting for the  
 7 authorisation from the Welsh Commissioners to be able  
 8 to start using that in some people with  
 9 von Willebrand's disease.

10 **Q.** I'm just going to ask you some more questions on the  
 11 consent process. You have already touched on this but  
 12 can I ask you what conversations you would have with  
 13 a patient when you are discussing with them the type  
 14 of treatment that you're going to give them? I'm  
 15 going to split this up between, if you like, type of  
 16 treatment, so you are choosing between different kinds  
 17 of treatment either plasma products, recombinant  
 18 products or half-life products, and then go on to look  
 19 at, within those types, different brands of treatment.

20 So when you are deciding what type of treatment  
 21 a patient should have, what information would you give  
 22 the patient about the risks and benefits of the type  
 23 of treatment?

24 **A.** Well, this conversation predominantly happens in the  
 25 context of young children with severe haemophilia and

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1 **A.** A very small number -- one or two, I think.

2 Now we're using the enhanced half-life  
 3 Factor IX product which can be given once a week or  
 4 sometimes even once every two weeks, the enhanced  
 5 half-life Factor IX products. So everyone with  
 6 haemophilia B has been offered -- with severe  
 7 haemophilia B, on prophylaxis, has been offered the  
 8 opportunity to go onto enhanced half-life. Some  
 9 people prefer to stay with the product they know and  
 10 have stuck with the standard half-life Factor IX which  
 11 is BeneFix.

12 **Q.** What is the first line of treatment for people with  
 13 mild haemophilia?

14 **A.** Well, with mild haemophilia, the first line of  
 15 treatment would be desmopressin, DDAVP, and everybody  
 16 with mild haemophilia would have a DDAVP trial so that  
 17 we can see how well they respond to that, because  
 18 there are some bleeds that might well respond to DDAVP  
 19 but very serious bleeds, if we're not getting good  
 20 enough levels, they might not respond. So if there is  
 21 an inadequate response we would use recombinant  
 22 Factor VIII.

23 **Q.** For von Willebrand's patients it's plasma-derived  
 24 product and DDAVP and/or Factor 8Y; is that right?

25 **A.** Well, yes. So it's plasma-derived. The product we

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1 often this conversation takes place before the child  
 2 is born because we offer antenatal diagnosis at about  
 3 32/33 weeks of gestation. An amniocentesis can define  
 4 whether the child has severe haemophilia or not. So  
 5 before the child is born we will have discussions with  
 6 the parents.

7 The key risk at the moment with recombinant  
 8 Factor VIII is the development of a Factor VIII  
 9 inhibitor. That's the most important side effect of  
 10 treatment, and then the child will be resistant to  
 11 Factor VIII treatment. We discuss, specifically on  
 12 the basis of a paper called the SIPPET study, which  
 13 was a randomised control study comparing the rate of  
 14 inhibitor formation with plasma-derived Factor VIII in  
 15 these previously untreated children versus recombinant  
 16 and it showed that children treated with  
 17 plasma-derived had less risk of inhibitor.

18 So we discuss that particular finding with the  
 19 parents and then, you know, the discussion is do they  
 20 want plasma-derived or do they want recombinant?  
 21 Every single parent that I've ever spoken to with  
 22 regard to this would prefer recombinant because they  
 23 would prefer the recombinant product, even if there is  
 24 a small increased risk of inhibitors.

25 We also discuss the enhanced half-life

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1 products. Although, with Factor VIII they are  
2 enhanced half-life, in young children it doesn't make  
3 a huge difference, because in young children the  
4 half-life of Factor VIII is quite short anyway, and it  
5 gets longer, the half-life of Factor VIII, as the  
6 child gets older into adulthood. So we do discuss  
7 enhanced half-life Factor VIII and many, many parents  
8 choose to go with half-life Factor VIII.

9 Just recently, we have started to discuss the  
10 role of Emicizumab in the management of severe  
11 haemophilia, and that some parents may wish to start  
12 with Emicizumab rather than Factor VIII because one of  
13 the big advantages of that is you don't have to put  
14 a central line in and it can be given subcutaneously.  
15 The downside is that we have much less experience with  
16 Emicizumab in young children and so we would have  
17 quite a long and in-depth discussion about the choice  
18 of Emicizumab or Factor VIII replacement in a young  
19 child.

20 **Q.** What information, if any, do you give to patients or  
21 parents of patients during those sorts of  
22 conversations about potential risk of pathogenic  
23 transmission?

24 **A.** Well, I always discuss with the parents that in the  
25 past Factor VIII has transmitted HIV and hepatitis and

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1 of time so that -- you know, because obviously people  
2 have a discussion, go away have more questions and  
3 come back, and that's something we always make clear  
4 that that is available. It's, of course, not just  
5 myself and other consultants doing this, the nursing  
6 staff will also often will visit the individual's home  
7 and have a discussion about treatment choices because  
8 it's not just a product that you're having, it  
9 involves whether it's likely that the child will need  
10 an intravenous catheter to deliver the treatment and  
11 what it's like living with a child with haemophilia is  
12 something that we go through in some detail.

13 **Q.** Would those sorts of discussions be recorded in notes,  
14 in patients' notes?

15 **A.** Yes.

16 **Q.** How do you record those discussions in notes?

17 **A.** I record it in the medical notes to say what we've  
18 discussed. I particularly record the discussion about  
19 inhibitor formation and that I have reassured with  
20 regard to infectious diseases, and then also the  
21 letter to the GP is now routinely copied to the  
22 patient, so that, again, they can -- and I think  
23 that's really quite helpful because, quite often, once  
24 I've done the letter to the GP or one of my colleagues  
25 has, then the individual will come back having read

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1 I always do that because if someone looks it up on the  
2 internet that's one of the first things they will come  
3 across. So I do that in the context of reassuring  
4 them that the products we use are safe from that point  
5 of view.

6 It's also, of course, very important to note  
7 that many of the women who are giving birth to  
8 children now with severe haemophilia have lost family  
9 members because of HIV or they are living with family  
10 members who have HIV. So, for example, their father  
11 may have had HIV. So I have that discussion with  
12 them, really it's to try and reassure that the current  
13 recombinant products are not made in any way with  
14 human or animal derived products and so can be  
15 considered essentially safe, from the point of view of  
16 transmission of those diseases.

17 **Q.** Would you provide any written materials to patients?  
18 Is that part of your practice when making these sort  
19 of treatment decisions?

20 **A.** We do provide some written material, yes, but we tend  
21 mainly to spend time talking. These conversations  
22 aren't one-off conversations. We will have  
23 discussions. Sometimes these sorts of discussions  
24 happen before the woman is pregnant. We will have  
25 these discussions and they are over a prolonged period

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1 the letter and say this is something that, you know,  
2 I'm not sure about and I want more information. So  
3 I think that that's quite important.

4 **Q.** So you will have those types of discussions for  
5 children, even before they are born, presumably you  
6 also have those types of discussions when new products  
7 become available, new types of treatments become  
8 available, you would have those with your existing  
9 patients?

10 **A.** That's right. So over the last two or three years  
11 we've had extensive discussions with people who, for  
12 example, are on prophylaxis the standard half-life  
13 Factor VIII, and we discussed the options of changing  
14 to an enhanced life Factor VIII or more recently to  
15 Emicizumab and quite a few people now are opting for  
16 Emicizumab, and that is all in the context of the  
17 discussion about what the individual person is wanting  
18 to achieve with their prophylaxis, because often the  
19 intensity of the prophylaxis depends on the intensity  
20 of the physical activity the individual wants to  
21 undertake.

22 **Q.** It sounds from what you have said that those  
23 discussions with patients, adult patients or existing  
24 patients, is not a one-off conversation for those.  
25 When new products can come online, it sounds like it's

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1 an ongoing dialogue that may take a few sessions; is  
 2 that right?  
 3 **A.** Yes, that is right. I mean, my experience with  
 4 Emicizumab is that a number of people I have discussed  
 5 Emicizumab with them and initially they have said,  
 6 "Oh, I will stick with Factor VIII", and as time has  
 7 gone on, a subsequent conversation is, "Well, I've now  
 8 decided I want to try the Emicizumab treatment", and  
 9 that's what happens. So, yes, people will obviously  
 10 change their minds as they get more of a feel for  
 11 a new product, and obviously people in South Wales  
 12 with haemophilia talk to each other.  
 13 **Q.** What's your practice in terms of the balance between  
 14 giving patients information about products and leaving  
 15 it entirely up to them to make a decision versus, you  
 16 know, you as the clinician making a recommendation to  
 17 the patient as to what you think would be best for  
 18 them. What's your practice? Where do you sit along  
 19 that continuum?  
 20 **A.** Well, the first thing I just want to say is that  
 21 I think that -- it's not the clinician, it's the  
 22 haemophilia centre, so the haemophilia centre in terms  
 23 of the nurses, the physiotherapists -- everyone is  
 24 involved in this. It's not clinician-led anymore  
 25 specifically, it's a team, a holistic team approach.

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1 certain half-life products where the half-life is  
 2 prolonged because essentially the Factor VIII or the  
 3 Factor IX is recirculated through the -- kind of  
 4 recycled through the endothelial cell system. That's  
 5 one type. The other type is where a molecule called  
 6 polyethylene glycol is added to the Factor VIII and  
 7 that will extend the half-life. So there are  
 8 different mechanisms.  
 9 All of them come out with a half-life  
 10 essentially -- that they all prolong the half-life by  
 11 essentially the same. So the amount of Factor VIII  
 12 that the individual has is the same essentially for  
 13 all the products and so those are, you know,  
 14 discussions that are had.  
 15 Similarly, with Factor IX it's the same. There  
 16 is the option of the pegylated Factor IX or there are  
 17 two recycling mechanisms of Factor IX, one because the  
 18 Factor IX is bound to albumin and the other the  
 19 Factor IX is bound to what is called the Fc receptor.  
 20 So there are different mechanisms. With Factor IX,  
 21 importantly, the pharmacokinetics are different, so  
 22 the way that you use the product is different  
 23 dependent on the mechanism, and so that has to then be  
 24 taken into consideration as well.  
 25 **Q.** So you give information about the different ways that

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1 Our view is that the individual with haemophilia has  
 2 the control of the situation and it's for them to  
 3 decide what type of product they want to use and, of  
 4 course, some people will try a product, find it suits  
 5 them well or find it doesn't suit them well and  
 6 they'll try something different.  
 7 So it's entirely down to the individual as to  
 8 which type of product they want to try.  
 9 **Q.** Then once you have made a decision about what kind of  
 10 treatment, then the patient then has another choice,  
 11 do they, as to which brand or which particular product  
 12 that they are going to use; is that right? Do you  
 13 offer them -- so they have decided they want to have  
 14 a half-life product, do you then say, "There's this  
 15 one, this one and this one"?  
 16 **A.** Well, we do, but it's in the context of cost as well,  
 17 because different products cost different things,  
 18 different amounts. So we discuss the different types  
 19 of extended half-life product.  
 20 **Q.** So typically the information you would give about each  
 21 extended half-life product, for example, balanced  
 22 against the other, what sort of type of information  
 23 would you be giving?  
 24 **A.** Well, we would give information about the mechanism by  
 25 which half-life products are prolonged. There's

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1 the products work. You've said that you give  
 2 financial information as well so you give the patient  
 3 information about how much each product costs. Is  
 4 that right?  
 5 **A.** Well, we don't say specifically how much they cost but  
 6 we say that certain products are -- cost less than  
 7 others and that, all things being equal, that might be  
 8 something to consider in the choice.  
 9 **Q.** You've already told us that sometimes you're saying to  
 10 patients, "Look, in order to comply with our  
 11 obligations under the tendering process we need to  
 12 think about switching you to a new product", and you  
 13 would give them that information as part of that  
 14 discussion?  
 15 **A.** At the moment the current tender does not require you  
 16 to use a certain amount of any product. You can use  
 17 any product you want off the tender. In the past, we  
 18 did have to use a certain amount and we would explain  
 19 to the person, "Look, the reason we want to change you  
 20 is because of this national tender, it's going to save  
 21 the NHS money", and I've never had any person really  
 22 showing concern about that. Some people wanted to  
 23 stay on their same product because they preferred to  
 24 and then that was fine. We would agree to that.  
 25 **Q.** So the impact on the tender, in terms of choice of

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1 product, was very much a request to the patient rather  
2 than saying, "In order for us to comply with our  
3 tendering obligations you must switch product"?

4 **A.** Yes. So it was never a compulsion. It was always  
5 explained. But the people I talked to I think buy  
6 into the concept of the NHS and the kind of the cold  
7 resource that is the NHS, and in South Wales the NHS  
8 is a very important part of the social fabric, because  
9 of course it came from South Wales, and so people will  
10 fully understand these concepts. So I've never --  
11 some people, as I say, would prefer to stay on the  
12 product they're on and then that would be absolutely  
13 fine.

14 **Q.** So, again, when you're talking with patients about the  
15 different choices they have got of half-life products,  
16 for example, is the choice entirely up to them or is  
17 that a choice or was that a little bit more  
18 clinician-led, or centre-led, because of aspects like  
19 price?

20 **A.** Everyone has access to enhanced half-life products and  
21 we would not in the end dictate to people what they  
22 wanted. We would explain the pros and cons of each  
23 product.

24 I think that -- to put it into context, of  
25 course, Efficizumab is substantially more expensive

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1 **MS SCOTT:** I'm going to ask you some questions now about  
2 testing for infections. I understand from your  
3 statement that all the patients at Cardiff had been  
4 tested both for HIV and HCV (hepatitis C) and told of  
5 their infections by the time you arrived at the clinic  
6 in 1996.

7 **A.** Yes, that's correct.

8 **Q.** Was there anything you heard from patients or from the  
9 staff that had been at the centre under  
10 Professor Bloom about the way that that was managed by  
11 Professor Bloom?

12 **A.** I have heard the statements of the patients and I've  
13 obviously heard the oral evidence of the patients and  
14 much of the oral evidence I knew before I saw that,  
15 because they explained that to me. The only person  
16 who was working at the haemophilia centre at the time  
17 that the information about HIV would have been related  
18 to the patients was Jenny Jones. Dr Dasani wasn't  
19 working there at that time. I think he started in  
20 1989. The other person who would have been there  
21 would be Dr Elizabeth Moffat, who was the research  
22 registrar around that time.

23 It's difficult for me to really give any  
24 further answer. The person who might well have  
25 directly observed this is Sister Jenny Jones.

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1 than Factor VIII to treat a person who doesn't have an  
2 inhibitor and we give open access to people to  
3 Efficizumab, so price is not the defining issue; if  
4 someone wants to go on Efficizumab, that's  
5 a significant cost increase in their care, but  
6 people -- you know, if people want to, then we change.

7 **MS SCOTT:** Sir, I was going to go on to a different topic  
8 now and I note the time so I wonder if now is a good  
9 time for a break.

10 **SIR BRIAN LANGSTAFF:** Yes.

11 We take a break, as you may have realised,  
12 during the morning, and it's normally about  
13 half-an-hour so we will meet again at 5 to 12.

14 What I tell all witnesses is that they mustn't  
15 discuss their evidence, being under oath, either the  
16 evidence you have given or that which you think you  
17 may be asked to give in due course. That includes  
18 discussing with your wife. You can talk about  
19 anything else you like but not that. So we will see  
20 you back at 5 to 12.

21 **A.** Okay. Thank you.

22 (11.27 am)

(A short break)

24 (11.55 am)

25 **SIR BRIAN LANGSTAFF:** Yes.

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1 **Q.** Do you recall any conversations with her about that  
2 time and the events that unfolded at that time and how  
3 they were managed?

4 **A.** I don't specifically remember her describing --  
5 I mean, she did describe some specific cases to me but  
6 we clearly can't discuss specific events. But in  
7 terms of general terms, she didn't say to me anything  
8 specifically about how people were informed of their  
9 HIV infection. Of course, the person who informed  
10 most people about their hepatitis C infection was  
11 Dr Dasani because he was working at the haemophilia  
12 centre at that time, and also Dr Simon Davies, who was  
13 the locum consultant around 1991 -- sorry, 1992. He  
14 took over as locum consultant when Arthur Bloom died.  
15 So he would have been -- both him and Dr Dasani would  
16 have been there when people were told of their  
17 hepatitis C result.

18 **Q.** So most of your knowledge about how testing for  
19 infections and delivering results to people, and so  
20 on, was managed comes from the patients directly  
21 either to you or through the information they'd given  
22 and that you have become aware of to the Inquiry?

23 **A.** Yes, that's correct, yes.

24 **Q.** I also understand from your statement that partners of  
25 those hepatitis C-infected patients had also been

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1 tested prior to your arrival at the centre in 1996 and  
2 they'd been tested by Dr Dasani and they were all  
3 negative; is that right?

4 **A.** That's right. Dr Dasani undertook a sort of  
5 comprehensive process of offering testing to partners  
6 and it is correct they were all negative for  
7 hepatitis C.

8 **Q.** So the testing that has taken place since your arrival  
9 in 1996 has been of partners of those infected with  
10 HIV; is that right?

11 **A.** Yes, we offer HIV tests for partners of people who  
12 were infected with HIV and that's been going on ever  
13 since I've been there and continues to today.

14 **Q.** You say in your statement that that was led by  
15 Dr Dasani. Have you been involved in that process  
16 yourself?

17 **A.** Yes. I've been involved in that process but  
18 Dr Dasani -- I think it is important to recognise that  
19 Dr Dasani was an expert in the management of HIV and  
20 he took the lead in these sorts of processes related  
21 to HIV. But, certainly, I will have been involved in  
22 offering tests to partners on a fairly regular basis.

23 **Q.** You also say that patients who were treated with  
24 pooled plasma products and who were HIV or HCV  
25 negative were also tested regularly for those viruses.

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1 particularly about the implications of the test and  
2 with HIV what the -- why it's possible that the  
3 individual may be at risk of having contracted HIV.  
4 This often is for people who have moved in from abroad  
5 and who may have been treated with blood products in  
6 the past and so we don't have a record of the blood  
7 products.

8 The patient group in Cardiff really is quite  
9 stable. Relatively few people leave South Wales,  
10 relatively few people come so it's a very unusual  
11 event. But we will also discuss implications for  
12 insurance and mortgages and life insurance, so we have  
13 those sorts of discussions. But it must be 20 years  
14 since I've had this sort of discussion with anybody.

15 There was one case I remember, one individual,  
16 where we made a diagnosis of hepatitis C of a lady  
17 with von Willebrand's disease, who had not been to the  
18 centre for a long time and that was made after  
19 I started working in the centre. Again, we discussed  
20 with her the reason for wanting to do that, it's  
21 because we thought she might possibly have received  
22 a pool blood product in the past and it did  
23 unfortunately prove that that was the case.

24 **Q.** When you arrived at the centre, you had a policy to  
25 keep patients on the same batch of product where

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1 **A.** Yes. So when I arrived there was already  
2 a surveillance programme in place where people were  
3 tested every six months if they were on plasma-derived  
4 products, and that continued until we introduced  
5 recombinant, after which we stopped doing that, once  
6 recombinant products had been introduced.

7 **Q.** So for those very few patients who remain on plasma  
8 products, do they still get testing?

9 **A.** No, no.

10 **Q.** You also say that you tested new patients coming in  
11 from other centres and from abroad for HIV and  
12 hepatitis C.

13 **A.** Yes. We inherited quite a few people who were  
14 infected with HIV or hepatitis. Often they were  
15 coming to Cardiff to attend the university and we  
16 would take over their care whilst they were at  
17 university. They all already knew of their HIV or  
18 hepatitis C status but we retested them when they  
19 arrived with their full knowledge and agreement.

20 **Q.** What is the process when you need to test somebody for  
21 HIV or hepatitis C? What's the conversation that you  
22 have with them in order to get their consent?

23 **A.** This hasn't happened for many, many, many years.  
24 I don't remember doing this for a very long time. But  
25 the discussion is around what the test is,

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1 possible to reduce donor exposure. Presumably that  
2 has fallen by the wayside has it with the recombinant  
3 products?

4 **A.** To a degree. We still tend to try to stick to similar  
5 batch numbers, although there isn't really any  
6 compelling reason to do that. I think it's out of  
7 habit that we just continue to do that.

8 **Q.** You also describe in your statement how vaccinations  
9 were offered against hepatitis A and hepatitis B. Can  
10 you just explain why those vaccinations were offered  
11 in 1996 when the plasma products patients were  
12 receiving were virally inactivated?

13 **A.** I think it was mainly because there was a small risk  
14 from blood transfusions still, from red cells, and  
15 that people with bleeding disorders are more likely  
16 than other people to need a red blood cell transfusion  
17 and so that was the reason. Of course, when I arrived  
18 people were on plasma-derived products and although  
19 there had been safety for ten years, there was always  
20 this underlying concern that perhaps there would be  
21 a kind of a breakdown in the manufacturing process  
22 that led to another -- a problem, which was one of the  
23 main arguments from my point of view for recombinant.

24 **Q.** Do you still offer those vaccines to patients?

25 **A.** No, we don't routinely at the moment, no. Children

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- 1 I think get routinely vaccinated for hepatitis B  
2 anyway now but we don't routinely offer hepatitis A  
3 vaccination now.
- 4 **Q.** Why is it that those with bleeding disorders are more  
5 likely to need red blood cell transfusion?
- 6 **A.** Well, at that time, because a lot of people were not  
7 on prophylaxis so if they started to, for example,  
8 have a bleed from a stomach ulcer, they might bleed  
9 a lot more than other people. Whilst people with  
10 bleeding disorders are more prone to that, because the  
11 vast majority of people with severe haemophilia are  
12 now on prophylaxis to some degree that's mitigated  
13 against.
- 14 **Q.** I'm going to ask you now about the current treatment,  
15 the clinics that you hold for your patients and the  
16 reviews that you undertake. How frequently would you  
17 see somebody with severe haemophilia in a clinic?
- 18 **A.** Well, if someone's stable, it would be every  
19 six months. Younger children it might well be every  
20 three or four months, particularly when they are very  
21 young and are initiating treatment. And we also have  
22 a policy of open access. So essentially if someone  
23 wants to discuss something or has an intermittent  
24 bleed, they can come to the centre at any time and be  
25 seen or, if it's not that urgent, they can ring in and

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- 1 would be taken to get a blood count, for a patient  
2 infected with HIV, a CD4 count, a liver function test,  
3 viral loads for an HIV-infected patient, and later on  
4 HIV virus resistance tests and, as you've described,  
5 there was a period where regular testing for  
6 hepatitis C and HIV were undertaken if the patient was  
7 negative for those viruses.
- 8 **A.** Correct.
- 9 **Q.** For testing for hepatitis C genotype and PCR testing  
10 when that became available. In a clinic where you see  
11 a patient today, what tests are you doing on a regular  
12 basis?
- 13 **A.** In a clinic today we are mainly doing tests to look  
14 for anaemia and iron deficiency, which would be a full  
15 blood count and a ferritin. We would be testing for  
16 Factor VIII inhibitors on a regular basis and we would  
17 do liver function and renal function tests.
- 18 People with HIV have their tests ordered or  
19 requested by the blood-borne virus clinic and then  
20 they come to the haemophilia centre with those forms  
21 for the tests to actually be done. So we are no  
22 longer involved in requesting the tests for monitoring  
23 for HIV.
- 24 For hepatitis C, people will be monitored  
25 routinely through the haemophilia centre, and what we

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- 1 be slotted into the next clinic. So anyone can  
2 essentially come when they want to if they have  
3 a problem.
- 4 **Q.** What about a patient with moderate haemophilia?
- 5 **A.** So, again, every six months. We would offer people  
6 with moderate haemophilia an appointment every six  
7 months. People with mild haemophilia it might be once  
8 a year, would be the average. But if a person has  
9 hepatitis C or HIV they would be seen more often, at  
10 least every six months if they had active hepatitis C.
- 11 **Q.** And a patient with von Willebrand's? How often would  
12 they be seen?
- 13 **A.** Type 3 severe von Willebrand's, at least every  
14 six months. There are some people with  
15 type 3 von Willebrand's who have a really quite  
16 significant bleeding pattern, they would be seen at  
17 least every six months in a formal clinic, but people  
18 with type 1 von Willebrand's, where it's a more mild  
19 disease, maybe once a year or often once every  
20 two years. Some people have -- they can go 10 or  
21 15 years with no problems and then they might have an  
22 issue, for example, related to when they need  
23 a surgical procedure.
- 24 **Q.** You described in your statement that at every  
25 appointment or that every appointment blood samples

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- 1 now have is the joint clinic with Dr Srivastava, who  
2 is the consultant hepatologist. He will advise us on  
3 what blood tests to perform, and so we follow the  
4 advice dependent on what he is suggesting.
- 5 **Q.** Can you describe for us the consent process that you  
6 would undertake with a patient at a six-monthly  
7 regular clinic appointment for those tests.
- 8 **A.** For a routine clinic appointment, we would just say to  
9 the patient, we're going to do your routine tests,  
10 we'd you know, test for anaemia, look for an inhibitor  
11 which is what people are aware. We certainly don't  
12 take more formalised consent than that.
- 13 **Q.** So if you were testing for a particular virus,  
14 a parvovirus, or something of that nature, would you  
15 have a more formal consent process?
- 16 **A.** We certainly would now, yes.
- 17 **Q.** What would be the nature of that conversation? Can  
18 you describe that typical conversation you might have,  
19 if you were testing for parvovirus, for example?
- 20 **A.** Well, that hasn't come up for a very, very long time,  
21 although it did come up this week. I wasn't the  
22 clinician involved in that discussion and it's  
23 a discussion about an individual case, so we probably  
24 best not. But we would have no reason to test for  
25 parvovirus, so I don't think that would come up unless

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- 1 the individual patient requested it at the moment.
- 2 **Q.** So are there circumstances in which you have, in  
3 a regular clinic, have to go into a more in-depth  
4 discussion with patients in order to obtain consent  
5 for particular tests, particular blood tests or --
- 6 **A.** Genetic tests we have a more in-depth process and we  
7 have a system of written, signed consent for taking  
8 genetic tests, those to look for the mutation that is  
9 causing haemophilia A or B, but now it's much more  
10 possible to test for all sorts of genetic disorders  
11 because of the huge progress that has been made in  
12 genetic testing over the years. So we are now  
13 offering genetic tests for families with  
14 von Willebrand's disease or with Factor XI deficiency  
15 or with platelet disorders and so we would go through  
16 a much more formal consent process and we have  
17 a written patient information sheet and a consent form  
18 and they would sign written consent for that process.
- 19 **Q.** I understand from your statement that the centre no  
20 longer stores samples; is that correct?
- 21 **A.** That's correct. Since we transferred to recombinant,  
22 there didn't seem any reason to continue to do that,  
23 so that was -- we stopped storing samples when people  
24 converted to recombinant.
- 25 **Q.** What's happened to the stored samples?

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- 1 **Q.** Can I take you to a document to see how this might  
2 have worked in practice. It's WITN4029008.
- 3 We can see here this is an article "Long-term  
4 follow up of patients treated with intermediate  
5 Factor VIII concentrate BPL 8Y", and your name along  
6 with Dr Dasani and Dr Brown as authors. If we see the  
7 summary, second sentence:
- 8 "Long-term surveillance [first sentence]  
9 studies of clotting factor concentrates are important  
10 to detect infrequent or delayed complications and to  
11 provide data against which newer products can be  
12 compared. We have assessed the long-term use of  
13 BPL 8Y Factor VIII ... concentrate ..."
- 14 So that's the purpose of the study. We can see  
15 that you collected data from 33 patients treated over  
16 96 months. You tell us in your witness statement  
17 that, as this was a surveillance study, this is not  
18 something that you sought ethical approval for or  
19 consent from the patients; is that right?
- 20 **A.** Yes, that's correct. We thought that this was put in  
21 the criteria of a service evaluation rather than  
22 a clinical study.
- 23 **Q.** If we turn over the page, Soumik, there's "Patients  
24 and methods", we can see there the method that was  
25 used, 33 patients treated exclusively with BPL 8Y:

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- 1 **A.** I can't answer that for definite. What I can say is  
2 that the stored samples are no longer present. No-one  
3 can tell me exactly when they were destroyed. It is  
4 possible that they were destroyed after there was  
5 a failure of one of the virology freezers but people  
6 can't tell me definitively. What they can tell me  
7 definitively is that they no longer hold any samples.
- 8 **Q.** When you were storing samples, what were patients told  
9 about that when routine blood tests were taken, were  
10 they told that their samples were being stored back in  
11 1996/97?
- 12 **A.** Yes, they were told that we were storing samples in  
13 case there was a problem with another infectious agent  
14 and that we might need to test those samples in the  
15 future. So that was the discussion that was had  
16 regarding those samples.
- 17 **Q.** So was that discussion a process by which you were  
18 obtaining consent from the patient to test for future  
19 viruses or was it a discussion on the basis that you  
20 would then come back to get their consent to test for  
21 those viruses if that became appropriate?
- 22 **A.** It was on the basis that if, for example, a test for  
23 variant CJD became available, we would go back to the  
24 individual and discuss whether they wanted that test  
25 to be done or not.

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- 1 "The patients' notes were reviewed and data  
2 collected."
- 3 Then at the top of the next column:  
4 "Virological testing had been carried out on  
5 a six-month basis."
- 6 So that, presumably, is a reference to the  
7 testing that had been undertaken at the clinic  
8 reviews; is that right?
- 9 **A.** That's correct, yes.
- 10 **Q.** Then moving down to the end of that paragraph:  
11 "Stored sera were used for parvovirus ...  
12 antibody testing by ELISA ..."
- 13 So it's really that that I wanted to ask you  
14 about. In this study, were you testing the stored  
15 sera for parvovirus?
- 16 **A.** In some cases, those were tested on stored sera. In  
17 some cases, the individuals were invited up to the  
18 haemophilia centre to have samples taken for the  
19 parvovirus test.
- 20 **Q.** So while -- and if this sera -- if the testing was  
21 done on stored sera, are we to understand then that  
22 the patients wouldn't have consented to that test?
- 23 **A.** Yes, that's correct.
- 24 **Q.** So some of the patients in this study would have  
25 consented to parvovirus testing but wouldn't have

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1 understood that it was to be reported in this article;  
 2 is that right?  
 3 **A.** I don't know. I wasn't directly involved in that  
 4 conversation. That would have been Dr Dasani and  
 5 Dr Brown directly involved in that conversation. So  
 6 I don't know exactly what was said.  
 7 **Q.** Should the patients have consented to their stored  
 8 sera being tested for parvovirus?  
 9 **A.** I think in retrospect, looking at this now, I think  
 10 that they should have been asked to have their stored  
 11 sera tested for parvovirus, yes.  
 12 **Q.** Do you know whether the patients were told the results  
 13 of the tests for the parvovirus?  
 14 **A.** I don't know the answer to that, I'm afraid.  
 15 **Q.** Would that have fallen to Dr Dasani?  
 16 **A.** Possibly, or to Dr Brown. I think the other point  
 17 just to make about the results is that I think that --  
 18 because I've obviously read this paper again now.  
 19 This was written soon after I started in Cardiff and,  
 20 reading it again now, I'm not sure that we have  
 21 interpreted the results correctly with regard to those  
 22 parvovirus results. The reason I say that is that  
 23 these people, by definition, were receiving 8Y. 8Y  
 24 has immunoglobulin in it and it is possible that the  
 25 parvovirus antibody that we were picking up in that

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1 that I don't think those samples should have been  
 2 tested.  
 3 **Q.** I'm anticipating from your previous answer that you  
 4 won't know the answer to this but were those patients  
 5 followed up as a result of what was thought to be  
 6 positive parvovirus tests?  
 7 **A.** Well, they were all being followed up regularly. Of  
 8 course that test is a test that if it is positive  
 9 shows past parvovirus infection, not current  
 10 parvovirus infection, and something like 50 to  
 11 60 per cent of the UK population will be  
 12 parvovirus IgG positive because they have had  
 13 parvovirus in the past.  
 14 So it's not a disease that leads to chronic  
 15 problems. You have parvovirus, you get over it. It's  
 16 sort of a classic childhood illness, a little bit like  
 17 measles, you have it, you get over it, and then that  
 18 is -- there's no further consequences of that.  
 19 So all of these individuals would have been  
 20 being followed up through the clinic and, you know,  
 21 any clinical symptoms would have been investigated  
 22 appropriately. But I don't think parvovirus would  
 23 have been an issue in that situation.  
 24 **Q.** Sticking then with treatment of patients at the  
 25 centre. Again, a similar question to the one I asked

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1 test was, in fact, coming from the concentrate rather  
 2 than a demonstration that the individual had had  
 3 parvovirus in the past.

4 So I think it's difficult to interpret the  
 5 results of that, and that's something I've become  
 6 aware of when I've re-read this paper and looked at it  
 7 again with fresh eyes. I think, however, there is no  
 8 doubt that we should not have tested those stored sera  
 9 without talking directly to the individuals involved.  
 10 **Q.** Equally, should the patients have been told what the  
 11 outcome of those tests were?  
 12 **A.** I think they should have been told the outcome of  
 13 those tests but, as I say, it is possible we would  
 14 have given them the wrong information or potentially  
 15 misleading information. I think the conclusion that  
 16 I reach now is that we shouldn't have tested them at  
 17 all because we could not derive a clear understanding.  
 18 The reason this was of such significance at that time  
 19 was because there had been a case report from the  
 20 Royal Free Hospital of an individual who had  
 21 contracted parvovirus apparently from concentrate and  
 22 developed significant anaemia, and parvovirus was  
 23 being seen as an important sort of potential marker  
 24 for pushing the introduction of recombinant  
 25 Factor VIII around that time. However, I fully agree

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1 you earlier about testing for infections. Is there  
 2 anything that you've heard from patients or from, in  
 3 particular, Dr Dasani or Sister Jones about the way  
 4 that patients' treatment was managed by  
 5 Professor Bloom during his directorship of the centre?  
 6 **A.** No. All I know about the treatment is from the two  
 7 protocols that I've submitted, from 1983 and 1985.  
 8 That's all I really know about the treatment. I know  
 9 from discussion with patients that there wasn't a full  
 10 discussion about the different types of treatment or  
 11 necessarily all the potential risks of treatment.  
 12 That's all I know. I don't know anything further.  
 13 Again, Jenny Jones would have been present at  
 14 those discussions, Elizabeth Moffat would have been  
 15 present at those discussions, and they may be able to  
 16 give a better answer than I can.  
 17 **Q.** Your knowledge of the protocols and procedures that  
 18 you have exhibited to your witness statements come  
 19 simply from those documents, do they, rather than from  
 20 anything you've gleaned about how they were  
 21 implemented from discussions with patients or  
 22 Dr Dasani or Sister Jones?  
 23 **A.** That's correct. I was unaware of those documents  
 24 until we received the request from the Inquiry for  
 25 documents. I went through everything I could find and

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1 those were documents that -- I was unaware of their  
2 existence until I looked through sort of the old kind  
3 of files that I'd inherited from Professor Bloom's  
4 office.

5 **Q.** So you didn't have conversations from -- someone  
6 saying, "Well, you know, this is the treatment  
7 protocol we used to apply, see this document"?

8 **A.** No, I didn't, no. But Jenny Jones would have followed  
9 those protocols. She would have worked directly off  
10 those protocols.

11 **Q.** Moving on then to how HIV is managed and has been  
12 during your tenure at the centre.

13 You have already told us that Dr Dasani was an  
14 HIV expert. The Inquiry's heard evidence from  
15 Dr Winter, who described himself I think as an HIV  
16 physician. Is that the same situation that Dr Dasani  
17 was in?

18 **A.** Yes, Dr Dasani had -- because HIV was a very new  
19 disease and he had been looking after people with HIV  
20 since it was first recognised, he was probably as  
21 knowledgeable about the management of HIV as anybody  
22 at the time. He attended British HIV Association  
23 meetings, he kept up-to-date with the literature, and  
24 I think he was -- he could be considered as an HIV  
25 physician in the same way that Dr Winter could be.

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1 done that all the time I'd been in Cardiff. The  
2 people with HIV who were being looked after in the  
3 haemophilia centre expressed a very strong opinion  
4 that they wanted to stay under the care of Dr Dasani,  
5 and so they continued to be looked after by him, with  
6 Dr Freedman doing joint clinics. So it was really  
7 only after Dr Dasani retired that the expertise within  
8 the haemophilia centre needed to be more formally  
9 supported by the blood-borne virus clinic, and it was  
10 after that time that we started to -- people started  
11 to go to the blood-borne virus clinic specifically so  
12 that they could see specialists, because of course we  
13 weren't -- in the way that Dr Dasani was, we weren't  
14 specialists in HIV management.

15 **Q.** So is this right, that currently all patients with  
16 HIV, their HIV is managed by the blood-borne virus  
17 clinic and the blood-borne virus clinic runs clinics  
18 on the same day as the haemophilia centre so, while  
19 there aren't joint clinics, the patients only need to  
20 attend the hospital on one day?

21 **A.** That's correct. We tried very hard to make that the  
22 case, so that the individual would go to the  
23 blood-borne virus clinic first, they would be given  
24 their blood tests, they'd come to the haemophilia  
25 centre, we would review any issues related to

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1 **Q.** You've also said that you were able to refer some of  
2 your patients to the infectious diseases team led by  
3 Professor -- and I'm not going to be able to pronounce  
4 his name correctly -- Bory --

5 **A.** Borysiewicz.

6 **Q.** How frequently did you refer such patients?

7 **A.** Well, this was before I'd arrived. Dr Dasani told me  
8 that he would sometimes seek Professor Borysiewicz's  
9 opinion on patients. It was certainly not a formal  
10 thing. That was all before I arrived. One of the  
11 very first things I did after arriving in Cardiff was  
12 to approach the consultant in infectious diseases,  
13 called Dr Freedman, and he was, again, an expert  
14 in HIV. And we then started working jointly with  
15 Dr Freedman, both myself and Dr Dasani, to look after  
16 people with HIV, and Dr Freedman started to come to  
17 the haemophilia centre and do joint clinics with us so  
18 that he could advise people directly. And so he and  
19 Dr Dasani then -- all treatment-related decisions in  
20 terms of what anti-HIV medication, the decision taken  
21 jointly by Dr Freedman and Dr Dasani after that time.

22 **Q.** Then at some point the HIV care moved to the  
23 blood-borne virus clinic. Was that a new service that  
24 was set up?

25 **A.** No, Dr Freedman ran a blood-borne virus clinic and had

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1 haemophilia and add any blood test, like inhibitors or  
2 whatever, and then the haemophilia nurses would take  
3 bloods. So that's the process.

4 **Q.** Presumably is there a mechanism by which you can  
5 discuss patients with your colleagues from the  
6 blood-borne virus clinic so there's joined up  
7 multidisciplinary care?

8 **A.** Yes., at any time I can contact a member of the  
9 blood-borne virus team and discuss an individual that  
10 I might have some concern about. They are very  
11 accessible and very easy to contact.

12 **Q.** Then moving on to arrangements for managing patients  
13 with hepatitis, in your statement you say that prior  
14 to your arrival patients had been managed by  
15 Dr Dasani, with referrals being made to England for  
16 second opinions and some liver transplants having been  
17 undertaken in London and Cambridge; is that right?

18 **A.** That is correct, yes.

19 **Q.** Are we to understand from that that there was no  
20 hepatology expertise within Wales at that stage?

21 **A.** There was certainly no hepatologist in Cardiff.  
22 I don't know within Wales. It may be that there were  
23 none in Wales. There was certainly no liver  
24 specialist that could, for example, undertake liver  
25 transplantation in Wales and there still aren't.

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1 That's a service that is not available in Wales, liver  
2 transplantation. But in Cardiff there was no -- when  
3 I started in 1996 there was no hepatologist in  
4 Cardiff. If you wanted to have an opinion locally you  
5 would have to talk to a gastroenterologist who  
6 certainly had more knowledge than we did about chronic  
7 liver disease but they weren't a hepatology  
8 specialist.

9 **Q.** You have already described to us that, when you  
10 started, you started a regular out-patient clinic for  
11 those with hepatitis. Were you running those clinics  
12 with advice from Dr Freedman? Is that how it worked?

13 **A.** So Dr Freedman was a specialist in treatment to  
14 eradicate hepatitis C because he was an infectious  
15 disease doctor. Dr Freedman wasn't a specialist in  
16 the management of chronic liver disease. So when it  
17 came to the eradication of hepatitis C, Dr Dasani  
18 [and] Dr Freedman would jointly come to decisions on  
19 what treatment should be offered. If we were  
20 concerned about an individual having progression of  
21 liver disease, we would have to seek the opinion of  
22 a gastroenterologist, or Dr Dasani would sometimes  
23 contact one of his contacts elsewhere in the UK and  
24 directly refer the individual.

25 So, for example, if there was concern about

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1 wasn't just people with inherited bleeding disorders.  
2 This was everyone in the Cardiff area. There was no  
3 access to hepatology service for anybody, so it wasn't  
4 a specific issue for bleeding disorders but, of  
5 course, because so many people with bleeding disorders  
6 have hepatitis, it was disproportionately affecting  
7 their care.

8 **Q.** Then you describe in your statement how between 2003  
9 and 2009 you were able to establish a joint clinic  
10 with Professor Godkin who is a hepatologist --

11 **A.** Yes.

12 **Q.** -- and able to review patients with more progressive  
13 liver disease that way and then make referrals to  
14 Birmingham in some cases.

15 **A.** Yes, correct. So Professor Godkin came to the  
16 haemophilia centre did joint clinic with either myself  
17 or Dr Dasani, and we were -- and people with liver  
18 disease would be seen in that clinic. He would see  
19 them, examine them, advise them and, if necessary, he  
20 would make the referral to the centre in Birmingham.

21 **Q.** You have also described how that wasn't part of  
22 Professor Godkin's brief, as it were. He had to fit  
23 that in on top of his existing commitments and so it  
24 wasn't something that lasted beyond 2009?

25 **A.** That's correct. It wasn't in his job description and

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1 an individual having progressed liver disease, he  
2 might refer to London or to Cambridge to say, should  
3 this individual be assessed for a liver transplant,  
4 and the answer would come back yes or no and we would  
5 refer like that.

6 About -- sorry.

7 **Q.** Sorry.

8 **A.** About one or two years after I started in Cardiff, one  
9 of the gastroenterologists did a secondment to the  
10 liver unit in Birmingham and, I think, spent about  
11 a year there as, sort of, part of, sort of, more  
12 specialist training. That was Dr Thomas and when he  
13 came back to Cardiff, we started to use him as our  
14 hepatology consult and, because of his links with  
15 Birmingham, people were then starting to be referred  
16 to Birmingham if they had problems with liver disease  
17 that were progressing.

18 **Q.** So is this right: up until, I think, 2003 you were  
19 managing your patients who were infected with  
20 hepatitis C, you were managing their care with  
21 assistance from, at various times Dr Freedman or  
22 Dr Thomas, once he came back in, I think you said in  
23 your statement, 1998?

24 **A.** Yes, that is all correct. We didn't have access to  
25 formal hepatology and, just to make the point, this

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1 he -- I obviously don't know the exact ins and outs of  
2 it, but he has explained to me that he was told that  
3 he couldn't continue to provide that service because  
4 it wasn't part of his job plan. But I don't know the  
5 exact -- how those exact discussions went ahead.

6 Even though he stopped coming to the joint  
7 clinics, he still was available. So if, for example,  
8 I was concerned about someone, or one of my colleagues  
9 was concerned, we could still go and knock on his door  
10 or contact him by email and say "This is the  
11 situation", and then he would see the individual very  
12 quickly in one of his clinics. He was still  
13 available, it's just that he wasn't available to come  
14 and do that joint clinic.

15 **Q.** So, again, the reviewing and monitoring was left to  
16 you on a day-to-day basis with escalation to  
17 Professor Godkin when you thought that was  
18 appropriate?

19 **A.** Yes. So we had to undertake the surveillance for  
20 liver disease, which I think was clearly something  
21 that I don't think was optimal care because we're not  
22 trained in what we were being asked to do, and when  
23 Dr Godkin was coming to the joint clinic he was,  
24 obviously, appropriately assessing people, we were,  
25 I think, not providing optimal care during that period

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- 1 because that wasn't a possibility.
- 2 **Q.** You've explained in your statement and exhibited  
3 various documents that show that this gap in service  
4 was identified, and a specific recommendation was  
5 made, to ensure appropriate consultant and specialist  
6 hepatology input into the treatment of patients  
7 in 2011, and you were involved in that process --
- 8 **A.** Yes, so -- sorry.
- 9 **Q.** Yes?
- 10 **A.** So that was a ministerial review of inherited bleeding  
11 disorders in Wales and the key -- a number of findings  
12 came out of it but an absolute key finding was that  
13 the haemophilia centre in Cardiff needed access to  
14 a consultant hepatologist who could do the joint  
15 clinics and who could manage the patients optimally.  
16 By this stage Swansea Haemophilia Centre did have  
17 a consultant hepatologist who was seeing patients  
18 there and one or two of the people from Cardiff went  
19 to Swansea to be seen by that hepatologist so that  
20 they could access services that were appropriate to  
21 their needs.
- 22 **Q.** You were also involved in the inherited bleeding  
23 disorder action plan, which seems, as I read it, that  
24 funding was confirmed in 2014/2015 for a consultant  
25 hepatologist. Is that your understanding as well?

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- 1 but I can't say that with real authority.
- 2 **Q.** You've said very candidly that that was not optimal  
3 care. What impact do you think that has had on your  
4 patients, the fact that, certainly from 2009, there  
5 hasn't been hepatology input, other than as described  
6 when escalated, for your patients with hepatitis C or  
7 hepatitis?
- 8 **A.** I think that's a very difficult question because  
9 I knew I was going to be asked that question. It  
10 comes down to individual cases and the question of  
11 whether individual cases could have been managed  
12 better had they been -- more proactively been followed  
13 up in hepatology is a very difficult question to  
14 answer.
- 15 We certainly, I think, picked up a number of  
16 severe liver-related complications quite quickly,  
17 because we were doing regular ultrasounds of the liver  
18 and regular blood tests to detect liver tumours.  
19 Whether they would have been picked up more quickly  
20 had they been in a formal hepatology clinic, it is  
21 possible, but I don't know. That's a very difficult  
22 question to answer.
- 23 **Q.** So currently patients with hepatitis are being managed  
24 through joint clinics with you and Dr Srivastava and  
25 there's also -- the blood-borne virus clinic also has

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- 1 **A.** I wouldn't like to be sure to say what my  
2 understanding was. I wasn't involved in the  
3 discussions because there would have been discussions  
4 between the Welsh Commissioners and the Cardiff and  
5 Vale board about the funding arrangements, which  
6 I wasn't involved in in that process at all. So  
7 I don't know how those discussions panned out or what  
8 was said.
- 9 **Q.** Do you know why it took from 2011 to 2016 for  
10 a hepatologist to be engaged?
- 11 **A.** Again, the information that will give the clearest  
12 answer would come from the hospital board, who would  
13 have been -- it would have been their role to make  
14 that appointment.
- 15 My understanding was that the post had been  
16 advertised earlier but a suitable candidate hadn't  
17 come forward and the suggestion that has been said to  
18 me but, again, I can't say this with complete  
19 authority, was that the job plan had included that  
20 that individual would also have to undertake other  
21 general medical duties, as well as being  
22 a hepatologist and, therefore, it was thought unlikely  
23 that you would get someone who really wanted to be in  
24 hepatology to come and take that post on.
- 25 That's what I've been, sort of, led to believe

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- 1 a roll. What role does that clinic take?
- 2 **A.** So Dr Srivastava in the joint clinic, the role there  
3 is to monitor people with regard to progression of  
4 liver disease and undertake surveillance. So, for  
5 example, some people will be on a surveillance  
6 programme of regular ultrasound, regular blood tests,  
7 some people require regular endoscopy to look for  
8 oesophageal varices. So that will be the role of the  
9 clinic with Dr Srivastava.
- 10 In Wales, when the funding for the new  
11 hepatitis C treatments came in, these are the  
12 non-interferon-based treatments, that funding was  
13 allocated so that people would be treated with the  
14 blood-borne virus clinic to offer treatments to  
15 eradicate the hepatitis C virus. So the hepatitis C  
16 eradication therapy is done through the blood-borne  
17 virus clinic and that has all now been completed. So  
18 no-one is attending the blood-borne virus clinic for  
19 hepatitis C eradication therapy because everyone who  
20 has elected to have treatment has had the virus  
21 eradicated, so there is, at the moment, no-one  
22 attending that. That clinic was run by Dr Healy and  
23 he was one of the -- again, an infectious disease  
24 microbiology expert and he took the role on of  
25 managing hepatitis C eradication throughout the whole

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1 of the Cardiff area for all patients with hepatitis C.  
 2 **Q.** Now I'm going to ask you some questions about medical  
 3 records. Can I start by asking you this: the  
 4 Inquiry's heard evidence from a number of patients  
 5 treated at Cardiff before you arrived by  
 6 Professor Bloom and they have told the Inquiry that  
 7 there were a number of key records missing from their  
 8 medical records, gaps in their medical records, and so  
 9 on.

10 Is that something that you found yourself when  
 11 you came to Cardiff and were treating patients? Was  
 12 key information missing or key documents missing?

13 **A.** I think the only key documents that were missing which  
 14 came up in the audit by Dr Hill was that the people's  
 15 HIV results were filed -- they were all filed  
 16 together, separate from the notes. As far as I'm  
 17 aware, those are the only key documents that were not  
 18 in the notes that one would have expected to be in the  
 19 notes.

20 When I arrived in Cardiff, all of the notes of  
 21 the people who had died of HIV were in a cupboard in  
 22 the office that I inherited and we have kept those  
 23 notes ever since.

24 I am not aware that those notes have -- we just  
 25 kept them. We haven't -- I haven't been through them

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1 **A.** It's the policy of the haemophilia centre to keep  
 2 those. I think the policy in general in the NHS would  
 3 be not to keep records of people who have died, you  
 4 know, only for a period and I think that if someone  
 5 doesn't attend the hospital for maybe ten years or so  
 6 the policy might be not to retain the records. Of  
 7 course, someone with a bleeding disorder might not  
 8 attend for 20 years and then come with a problem, and  
 9 so we needed to retain the notes.

10 **Q.** The hospital tolerates your policy, do they, of  
 11 keeping notes for the life of the patient and after  
 12 their death?

13 **A.** Yes, there is no issue with that in the current  
 14 situation. As you are aware, there was a time when  
 15 there was -- I can't remember how long ago it was but  
 16 the Inquiry has the documents, where there had been  
 17 this issue of trying to not store these documents for  
 18 life, and I made the point that I thought we should.  
 19 And I didn't get any push-back on that apart from to  
 20 say, "Well, you find the space then", which is what  
 21 we've done.

22 **Q.** Can I ask you now some questions about links with  
 23 pharmaceutical companies. You've told us in your  
 24 statement that three companies gave donations that  
 25 helped build the new centre in 2000. Who managed that

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1 to look to see if there are key documents missing or  
 2 elements that I think should have been there.  
 3 I haven't been through the notes to make that  
 4 assessment. So the only thing I'm aware of is this  
 5 issue of filing HIV notes separately.

6 **Q.** So when you come to treat patients, do you, would you  
 7 have to look through their notes to find key pieces of  
 8 information? Is that something you would have  
 9 noticed? Would you have noticed that key documents  
 10 are missing from the patients that you are treating  
 11 from 1996 onwards?

12 **A.** I think if there had been any systematic issue,  
 13 I would have noticed, yes. I think -- I can't  
 14 remember a case where I have been unable to find the  
 15 information that I was expecting to find. It was all  
 16 to me clear what was there. So, yes, I can't think of  
 17 any issues.

18 **Q.** You also say in your statement that it's -- you told  
 19 us it's your policy to keep records of those infected  
 20 with HIV after they've died. You've also said it's  
 21 your policy to keep records for the life of your  
 22 patients.

23 Do you know whether that's become formal  
 24 hospital policy or is that simply the policy of your  
 25 centre?

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1 process with the pharmaceutical companies? Was that  
 2 something that you were involved with?

3 **A.** The money was paid into an endowment fund. So  
 4 I wasn't directly involved in the transfer of the  
 5 money. That went through the finance department. But  
 6 I was involved in sort of discussing with various  
 7 companies whether they would be prepared to make  
 8 a donation.

9 The problem was that we had the agreement --  
 10 because, as I've said earlier, all -- the haemophilia  
 11 centre had been disbanded and the people being treated  
 12 in the haematology day unit. Having made an argument  
 13 that we needed a new centre, a stand-alone haemophilia  
 14 centre -- and this was very strongly supported by the  
 15 local patient group. We had a number of meetings with  
 16 senior management, myself and the local patient group,  
 17 to put this -- to advocate for this. The agreement  
 18 then was that, "Okay, you can have a stand-alone  
 19 haemophilia centre, but you are going to have to fund  
 20 the cost of it" and that's why we were obliged to look  
 21 for sources of funding. We had a number of different  
 22 sources of funding that went to build the new centre.

23 **Q.** What sort of sums were the pharmaceutical companies  
 24 contributing then to the building of the new centre?

25 **A.** It was around about 10,000 to 20,000 from my memory.

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1 Q. For each company?  
 2 A. Yes, that's from my memory.  
 3 Q. Were they companies that you were -- companies whose  
 4 products you were using at the time?  
 5 A. Yes, they were recombinant Factor VIII product  
 6 companies. So we approached all of the companies with  
 7 the same request and they either agreed or didn't  
 8 agree.  
 9 Q. What do you do or what do you do at the centre, or you  
 10 personally, to guard against any risk that companies  
 11 contributing to the centre's work doesn't influence  
 12 the decisions that you make about prescribing  
 13 products?  
 14 A. I think we've always been very independent about what  
 15 products we would use. Of course, with the national  
 16 tenders, we followed the national tender. So that  
 17 doesn't -- that then becomes much less of an issue  
 18 because we are -- you know, we essentially have to  
 19 fulfil the requirements of the tender. And I think  
 20 that is a very big advantage of the tender because it  
 21 does remove the possibility or even perception that  
 22 there may be influence on prescribing.  
 23 So I don't think that that process of donations  
 24 to fund the building of the haemophilia centre had any  
 25 influence on our decision to prescribe any specific

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1 across correspondence between him and pharmaceutical  
 2 companies in any of the documentation that was left at  
 3 the centre and that you've inherited?  
 4 A. I haven't. I'm aware of some of the documentation  
 5 that I've been shown by the Inquiry but I haven't come  
 6 across any documentation regarding an interaction  
 7 between Professor Bloom and pharmaceutical companies.  
 8 I didn't come across anything like that, no.  
 9 Q. Knowing what you do about the way that documents are  
 10 stored and the way that correspondence is generated,  
 11 certainly in '96, where do you think that  
 12 correspondence would have sat? Where do you think it  
 13 would have been kept?  
 14 A. Well, I don't know. I would have thought that if  
 15 there had been any correspondence it would be in  
 16 Professor Bloom's office, and I inherited his office  
 17 when I went there. Three people, as I said, have been  
 18 consultant for the centre in between Professor Bloom  
 19 dying and myself going there, so I didn't directly  
 20 inherit his office. So I don't -- as I say, I didn't  
 21 come across this sort of documentation.  
 22 Professor Bloom of course died suddenly, so his  
 23 office would have been left sort of in the state that  
 24 he was using it. There would have been no -- it  
 25 wasn't as if he retired and might have decided to get

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1 brand of Factor VIII.  
 2 Q. You also described in your statement how  
 3 pharmaceutical companies continue to fund clinicians  
 4 attending educational meetings and activity patient  
 5 days?  
 6 A. Correct.  
 7 Q. Given what you said about the national contract, what  
 8 do you think the pharmaceutical companies are getting  
 9 out of that funding?  
 10 A. Well, the -- clearly from the point of view of the  
 11 pharmaceutical company they want to influence the  
 12 prescription of their product. Whether that is the  
 13 case or not, I don't know. I think that you will have  
 14 discussed this with many haemophilia doctors. I mean,  
 15 I might be supported to go to a meeting by a different  
 16 company each time. My colleagues might well be. So  
 17 there is a sort of a balance there. As I say, I think  
 18 that, from my perspective, I don't feel that I've been  
 19 influenced in prescribing policy because the policy,  
 20 as I describe, is sort of dictated by the national  
 21 contract. That's my sort of understanding of the  
 22 situation.  
 23 Q. Can I -- you have mentioned earlier on this morning  
 24 that when you took over the centre you inherited some  
 25 files of papers from Professor Bloom. Have you come

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1 rid of documents. He died suddenly while still in  
 2 post. So I can't explain -- so, for example, I've not  
 3 come across any even UKHCDO minutes from  
 4 Arthur Bloom's time, so I just don't know where all  
 5 those documents went.  
 6 MS SCOTT: Sir, I notice it's 1 o'clock. I think I've got  
 7 probably about 15 minutes more to go, so what I was  
 8 going to suggest is that I continue for the next  
 9 15 minutes and then we take a break so that  
 10 Core Participants can ask any questions that they wish  
 11 to of me to put to --  
 12 SIR BRIAN LANGSTAFF: Might it be more convenient, do you  
 13 think, to come back at 2.00 and ask the 15 minutes  
 14 then, having picked up the questions they may have to  
 15 ask in the meantime?  
 16 MS SCOTT: I'm happy to proceed on that basis.  
 17 SIR BRIAN LANGSTAFF: Let's -- oh, all right, let's go on  
 18 for 15 minutes. Are you happy to go on for 15 minutes  
 19 and then take a break or would you rather take a break  
 20 now?  
 21 A. No, I'm happy to continue for another 15.  
 22 MS SCOTT: We've already looked at -- I'm moving on to  
 23 a new topic now, which is just a question on research.  
 24 We've already looked at one of your studies -- one of  
 25 our articles, rather.

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1 What I would like to ask you is the difference  
2 between, in your view, research studies and service  
3 evaluations. So the article we looked at previously  
4 was a service evaluation, and you have said in those  
5 circumstances you wouldn't get ethical approval and  
6 you wouldn't seek patient consent, but you would if it  
7 was a research study.

8 I just wanted to explore with you where the  
9 bright line is, in a sense, particularly given that  
10 the example we looked at previously involved testing  
11 of stored sera, for example.

12 So could you just explain to us where your  
13 bright line is between a research study and a service  
14 evaluation.

15 **A.** So my understanding is that if a person or a patient  
16 group are being treated by standard practice of the  
17 centre and that routinely collected information is  
18 reported, then that is a service evaluation.

19 A research study is asking a specific question.  
20 So you may say: we're going to change treatment and  
21 see what happens. That would be a research study and  
22 would require ethical approval and informed consent.

23 I note that in -- the Inquiry's ethics  
24 specialty group has specifically mentioned the  
25 difficulty of drawing the line between research and

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1 Committee, we did get it passed by the ETSA(?) so we  
2 did take written informed consent from the individuals  
3 concerned.

4 So that's broadly where I'm seeing the line.

5 **Q.** Sorry. Carry on.

6 **A.** I could give another example in my work in post partum  
7 haemorrhage, so I've done about 10 or 12 years now  
8 work with colleagues in Cardiff trying to improve the  
9 care of women who have bleeding after childbirth and  
10 one of the main drivers for that is to try and reduce  
11 the amount of blood transfusion people require after  
12 childbirth.

13 Now, we've done a number of studies where we  
14 have recruited women, we've been to ethics committees,  
15 the women recruited into the study give written  
16 informed consent, and they are research studies. But  
17 once we've completed that research, we then applied  
18 the knowledge gained from the research to change the  
19 way post-partum haemorrhage was treated throughout  
20 Wales, as part of a quality improvement programme and  
21 that was a two-year quality improvement programme  
22 based on the understanding that we gained from that  
23 research.

24 Now, that involved, essentially, all the women  
25 giving birth in Wales because all obstetric units in

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1 service evaluation and I think it is a difficult  
2 situation that -- that does need to be seriously  
3 considered.

4 So let's say, for example, that we have a group  
5 of people -- an example of this is that we wrote  
6 a paper about unclassified bleeding disorders. We --  
7 over the years we've looked after people with  
8 unclassified bleeding disorders. These are people who  
9 have bleeding during invasive procedures or at other  
10 times but we can't find anything in the laboratory  
11 that explains that bleeding so they are called  
12 unclassified bleeding disorders. We've managed them  
13 according to standard practice and so we have reported  
14 that as a service evaluation. That's the way we have  
15 reported it. So we didn't apply for ethical approval  
16 and we didn't seek informed consent.

17 On the other hand, one of our team has done  
18 a PhD looking for the underlying cause of unclassified  
19 bleeding. And that we submitted to the Ethics  
20 Committee, we invited people up, we explained the  
21 study and we took written informed consent, and tests  
22 were done that aren't routine laboratory tests, but  
23 tests were done to see if we could find the underlying  
24 cause for the unclassified bleeding disorder. That is  
25 clearly research, and we did go to the Ethics

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1 Wales took on this quality improvement programme. We  
2 have collected information from that quality  
3 improvement programme and demonstrated a very  
4 substantial improvement in the quality of care,  
5 a reduction in the number of women with severe  
6 bleeding and very major reduction in the number of  
7 women receiving a red cell transfusion.

8 However, that's a quality improvement  
9 programme. In order to report that, that isn't going  
10 to go to an Ethics Committee, we haven't taken written  
11 informed consent from the 60,000 women involved, we  
12 are reporting that as an evaluation of the service  
13 across Wales.

14 So those are kind of a broadly where I see the  
15 difference but I do agree that it is often difficult  
16 to know where to draw the line between these things  
17 and on the paper on 8Y that you showed me earlier  
18 I think we drew the line in the wrong place. Looking  
19 at that back now, I think we drew the line in the  
20 wrong place.

21 **Q.** Is the fact that the information is going to be --  
22 albeit the information about the patients is going to  
23 be anonymised, the fact that it's going to be  
24 published, it's going to be able to be accessed by  
25 many people and analysed, and so on, is that relevant

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1 to the question about whether or not one gets consent,  
 2 even if not relevant to whether or not one goes to  
 3 an ethical committee?

4 **A.** No, I don't think -- I think if you don't have to seek  
 5 ethical approval then I think it is reasonable to  
 6 publish the aggregate data from the haemophilia centre  
 7 and, as I said, we publish in the aggregate data for  
 8 all the births in Wales over a two-year period. If we  
 9 weren't able to do that, then all of that knowledge,  
 10 which would substantially improve the quality of care,  
 11 would be lost because it's impossible to go and seek  
 12 consent from 60,000 people.

13 So I think there has to be some  
 14 proportionality, I think that's the word that is used  
 15 by Ethics Committees and the Health Research  
 16 Authority, the NHS Health Research Authority does have  
 17 guidelines on where you try and draw the line. But it  
 18 sometimes isn't completely clear.

19 **SIR BRIAN LANGSTAFF:** Is perhaps part of the problem the  
 20 word "evaluation"? I can understand the difference  
 21 between reporting what is happening, on the one hand,  
 22 making research into why it is happening, which is  
 23 a separate issue, and making recommendations into what  
 24 should be done, which is a question of judgment or  
 25 policy or proposal. All three are quite distinct in

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1 the patient, the NHS number, the date of birth,  
 2 information on their diagnosis, their factor levels or  
 3 the subtype of von Willebrand's disease, information  
 4 is held about HIV status, hepatitis C status. There's  
 5 a large section about variant CJD, about people who  
 6 were designated in the at-risk group for variant CJD  
 7 and whether or not they have received implicated batch  
 8 in that context. That's all held there.

9 There's a whole section which is called  
 10 Haemtrack, which is patient-reported information. So  
 11 an individual will -- on their phone they will have  
 12 an app, every time they give themselves Factor VIII or  
 13 the Factor IX they enter the information into their  
 14 app and that is uploading to the National Haemophilia  
 15 Database, and then the haemophilia centre can see  
 16 their own patients' data. So if a person in west  
 17 Wales enters that they have had a severe bleed in the  
 18 knee, we in Cardiff, we could be alerted to that, so  
 19 we might then phone up and say "Are you okay, can we  
 20 help", that sort of thing.

21 They are very useful in clinic because we can  
 22 then go back six months and we can see the pattern of  
 23 bleeds over the last six months, and if an individual  
 24 has forgotten bleeds, we might say "Back in June you  
 25 had this knee bleed, what was that about", and then

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1 you can see them as being quite distinct but they  
 2 shade into each other. But the word "evaluation"  
 3 suggests that somebody at some stage is making  
 4 a judgment about something, rather than simply  
 5 reporting what is, organising the data to show what  
 6 is.

7 Is there any truth in that observation or not?

8 **A.** I don't know. It's not my word. It's the wording of  
 9 the NHS Health Research Authority. They have  
 10 a specific section called "service evaluation" and in  
 11 that it is, as I've tried to describe, that it's  
 12 observation of routine care and routine collected  
 13 information then being reported in an anonymised  
 14 aggregate way.

15 They use the term "service evaluation" for  
 16 that. It may be that a better term might be helpful  
 17 but that is the currently used term.

18 **MS SCOTT:** I wanted to ask you some questions about the  
 19 National Haemophilia Database Research Registry, which  
 20 you talk about in the UKHCDO section of your witness  
 21 statement, ie with your UKHCDO hat on.

22 Can you just tell us what sort of information  
 23 is held within that research registry?

24 **A.** Yes. So the information held there is named the name  
 25 of the patient -- it's not anonymised -- the name of

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1 they are reminded. So that's very useful and that's  
 2 patient-reported information, and it can then show  
 3 whether if after an individual -- say, for example,  
 4 an individual's on Factor VIII prophylaxis and then  
 5 they convert to Emicizumab, does that mean that their  
 6 bleed rate goes down? Do they get improved outcomes?  
 7 So very useful clinically.

8 The other information that's connected is about  
 9 people's joint scores, and so this is one of the most  
 10 important markers of how well people are being looked  
 11 after because if their joints deteriorate over time,  
 12 it suggests something is not quite right. If the  
 13 joints are staying perfect over time it suggests that  
 14 good quality haemophilia care is ongoing.

15 So that information -- and it's all collated  
 16 within the National Haemophilia Database and, as you  
 17 know, from Professor Hay's discussion, this goes back  
 18 to, I think, 1969 and has evolved progressively over  
 19 the years with different types of information either  
 20 being collected or not collected.

21 **Q.** So when you talk in your statement about the research  
 22 registry, that is actually the database itself? It's  
 23 not a separate part of the database?

24 **A.** It technically is separate because the database is the  
 25 database, the National Haemophilia Database. That has

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1 a number of functions. It has the function of direct  
2 patient care, for example through this Haemtrack  
3 mechanism and the issuing of patient bleeding disorder  
4 cards; so that's important and it has a role for sort  
5 of service planning. So the Department of Health  
6 might want to know what the trend is of Factor VIII  
7 usage over time and we can give that information.

8 Now, the research registry was set up so that  
9 the individual's data that was held in the database  
10 for those purposes could then, on top of that, be used  
11 for research purposes and, until that time, then  
12 people weren't -- people were informed that their  
13 information was going to the database and could be  
14 used for research purposes but they hadn't given  
15 express consent. So the idea of starting the research  
16 registry was so that we would then go to each  
17 individual and give them the opportunity to say: the  
18 information held on the National Haemophilia Database  
19 I'm either happy or not happy for it to be used for  
20 research purposes.

21 And that process we put that to an ethics  
22 committee, because the database was then submitted to  
23 an ethics committee to consider that. Patient  
24 information sheets were produced and passed by the  
25 ethics committee and the said process was passed by

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1 drafted, I believe, in September, needs to bear in  
2 mind that there's been an update about the consent  
3 process which was given in evidence by Professor Hay  
4 when he gave evidence to the Inquiry?

5 **A.** Absolutely, that the process has changed, and it's  
6 because the advice -- and the advice changed. And it  
7 does make it difficult to do the right thing when  
8 advice is changing.

9 **Q.** So is the position now that third parties may be able  
10 to access patient not un-anonymised, if I can put it  
11 that way, so patient data, I mean the detailed patient  
12 information that you have described, without the  
13 patients being asked for their consent?

14 **A.** Yes. So -- well, no-one can access the data apart  
15 from UKHCDO so only UKHCDO can access the data, and we  
16 have a data management working party that controls  
17 access to that data and that has on it patient  
18 representatives, representatives of the Haemophilia  
19 Nurses' Association, the physiotherapists' association  
20 and representatives of the Commissioners, and they  
21 have the overview of what can be done.

22 We also have a group called the data analysis  
23 group which meets every month which -- if a proposal  
24 for information comes to the National Haemophilia  
25 Database, so, for example, if that's a proposal from

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1 the ethics committee. And then we started on this  
2 process of individually seeking consent in each  
3 haemophilia centre in the UK to do that. That's the  
4 process that had been going on for -- you know, two to  
5 three years, that process had been going on.

6 Professor Hay then explained in his evidence  
7 that that was then superseded by the NHS Health  
8 Research Authority Confidentiality Advisory Group, who  
9 then came back, after we had gone through all of  
10 this -- and many of us were very keen on continuing  
11 with this process because we thought it was a good  
12 thing to do -- he was then informed that he should  
13 stop doing that and that we would apply for  
14 a section 251.

15 So we have throughout this process I think, and  
16 I think Professor Hay described this quite well, is  
17 that getting advice is one thing but getting  
18 consistent advice is difficult. Even from the  
19 authorities that are supposed to be advising us we get  
20 different advice, and it changes with time. It does  
21 make it very difficult for us to, with authority, know  
22 where we should be going. But that's kind of the  
23 brief outline of the National Haemophilia Database  
24 research register.

25 **Q.** So anyone reading your witness statement, which was

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1 NHS England, for example, we would discuss that at the  
2 data analysis group -- and again, that includes  
3 representatives of the patients, it includes  
4 representatives of haemophilia nurses and  
5 physiotherapists, and we decide whether that  
6 information is reasonable to give.

7 So that is the situation. So the situation now  
8 is that a proportion of people have given express  
9 consent for their data to be used for research and in  
10 Cardiff we've got quite a lot of people have written  
11 and done their informed consent, you know, well in the  
12 hundreds, but now there's a group that hasn't because  
13 we've been told to stop the process. So it is, in my  
14 view, a bit unsatisfactory the advice that we've  
15 received from the Confidentiality Advisory Group on  
16 how this is going.

17 **Q.** Forgive me if this is my fault, but is the research  
18 that can be done simply by the UKHCDO, it's not by  
19 pharmaceutical companies? They wouldn't have access  
20 to that information if they made an application --

21 **A.** They would not have access. No-one has access, apart  
22 from UKHCDO.

23 **Q.** So all the research would be within the UKHCDO?

24 **A.** It would be and the people who do the analyses, the  
25 statisticians, they don't see -- they see anonymised

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1 data, so they don't see anything like the patient's  
2 name or date of birth or anything. They see  
3 anonymised data and they would then do the analyses.  
4 They, essentially -- it's aggregate data so, you know,  
5 people receiving treatment X would have this number of  
6 bleeds per year on average. That's the sort of  
7 information that is available.

8 **Q.** Then just lastly before -- I've gone slightly over my  
9 15 minutes' time estimate, but can I just ask you two  
10 more questions.

11 The first one arises out of what you wrote at  
12 paragraph 320 of your witness statement, and it's  
13 this:

14 "The transmission of HIV and hepatitis to  
15 patients with bleeding disorders has dominated my  
16 consultant practice and the way I approach the  
17 management of people with bleeding disorders."

18 I just wanted to ask you to expand on that if  
19 you can, the ways in which the infection of patients  
20 with bleeding disorders has dominated your practice.

21 **A.** Well, I think this is all through my career, both in  
22 training and as a consultant. It has always been --  
23 a major aspect of looking after people with bleeding  
24 disorders is the management of the complications of  
25 the infectious diseases that were transmitted.

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1 very difficult for people to deal with because they  
2 know the history, they are then are being told that  
3 maybe this might be another problem. But, again, we  
4 don't really know. That's very difficult for people  
5 to have to listen to and understand.

6 The other way that this is really dominating,  
7 continues to dominate, as I explained earlier, many of  
8 the mothers who look after and have children with  
9 haemophilia nowadays, they've lost members of the  
10 family to HIV or hepatitis C, and it's always with  
11 them and when you're seeing those families, you know  
12 it's always with them, and you have to discuss things  
13 in the context of understanding how they might feel  
14 about having a child with haemophilia, knowing the  
15 problem that it's caused their family member.

16 I think both for myself and for all the people  
17 who work in Cardiff, it does dominate our thinking in  
18 terms of how we try to approach things, because  
19 clearly we can't put anything right but I think  
20 acknowledging what has gone wrong is very important.

21 **Q.** Lastly from me before we break, the Inquiry  
22 understands that the statue of Professor Bloom has  
23 been removed from the centre and that the centre is no  
24 longer named after him. Can you tell us how that  
25 decision came to be made and why?

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1 When I first arrived in Cardiff people were  
2 still dying of AIDS because the highly effective  
3 treatment was -- only really, sort of, came in early  
4 in 1997, so people were still dying of AIDS and we had  
5 to look after people in that very difficult situation.

6 Since 1997, in Cardiff, we haven't had anyone  
7 die of AIDS. Obviously, people with AIDS have died  
8 potentially of complications related to that but not  
9 died specifically of AIDS, because the treatment has  
10 improved, but still dominates your thinking when you  
11 are seeing patients that, clearly -- the treatment  
12 that has been given by the centre has caused major  
13 problems for an individual is always very high in your  
14 mind when you are talking to people and it's the same  
15 with hepatitis C. You always know and you always  
16 understand that.

17 I think then the variant CJD issue did come to,  
18 in many ways, really dominate things in the early  
19 2000s as we had to then go to people and say "Look,  
20 you are going to be put into what's called at-risk  
21 group for variant CJD for public health purposes", and  
22 then explain what that meant, because that's not  
23 a difficult -- that's not an easy conversation to have  
24 and, again, that became a dominant feature of our  
25 practice at that time, because the uncertainty was

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1 **A.** We were contacted by Haemophilia Wales and there  
2 was -- from what I understand, Haemophilia Wales did  
3 not want the bust of Professor Bloom to be removed and  
4 the centre renamed. They wanted to wait for the  
5 outcome of the Inquiry and for the Inquiry to give  
6 their views and, once that was known, Haemophilia  
7 Wales wanted to then make a decision on whether to  
8 change the name of the haemophilia centre and remove  
9 the bust.

10 I discussed this with Haemophilia Wales on  
11 multiple occasions and that was their consistent view.  
12 They wanted to wait for all the evidence to be  
13 presented before a decision was made.

14 However, they got to a position where they were  
15 experiencing pressure to remove the bust and they  
16 approached me and said that rather than the  
17 haemophilia centre becoming the centre of the story,  
18 they wanted us to remove the bust and wait for the  
19 Inquiry to give its opinion. So that's my  
20 understanding of what happened. Clearly, Haemophilia  
21 Wales can give their understanding and their version  
22 of that, but that's the way I felt it happened. The  
23 day that Haemophilia Wales said that they wanted us to  
24 take the bust down we took it down, and that wasn't  
25 the unanimous decision of Haemophilia Wales, but it

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1 was the, as I understand it, consensus decision.

2 **SIR BRIAN LANGSTAFF:** Well, let's take a break then, shall

3 we, until -- will 2.25 be all right for you,

4 Professor Collins?

5 **A.** Sorry, what was the time again?

6 **SIR BRIAN LANGSTAFF:** 2.25 be all right for you?

7 **A.** That will be very good, thank you.

8 **SIR BRIAN LANGSTAFF:** So 2.25 then.

9 **A.** Okay, thank you.

10 (1.27 pm)

11 (Luncheon Adjournment)

12 (2.25 pm)

13 **SIR BRIAN LANGSTAFF:** Yes.

14 **MS SCOTT:** Professor Collins, I've now going to ask you

15 a handful of questions from Core Participants.

16 First of all, did you ever -- Professor Bloom

17 died four years before you arrived in Cardiff. Did

18 you ever meet him and speak to him?

19 **A.** No, I never met or spoke to Professor Bloom.

20 **Q.** You exhibited some of the treatment protocols that

21 were in existence in Professor Bloom's time. You

22 exhibited those to your witness statement. Do you

23 know where those treatment protocols were found?

24 **A.** Yes, they were in a file. There was an arch lever

25 file that was in the haemophilia centre when I looked

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1 know.

2 Do you know whether Professor Bloom held any

3 files relating either to the centre or to patients at

4 his home?

5 **A.** I don't know. I have heard I think it was a radio

6 programme on BBC Wales to suggest that might have been

7 the case but I have no knowledge as to whether that's

8 true or not.

9 **Q.** Just a couple of questions then about links with

10 pharmaceutical companies. I asked you some questions

11 about the funding provided by pharmaceutical companies

12 in 2000, so five years before the national tender

13 process came into place. What steps at that time --

14 so before the national tender process was in

15 existence, so around 2000 or before -- what steps were

16 taken, if any, at the centre to ensure funding

17 received by pharmaceutical companies of the centre did

18 not influence product selection?

19 **A.** So there were three pharmaceutical companies involved

20 and there were three brands of recombinant

21 Factor VIII. They all donated roughly the same amount

22 of money, so it wasn't as if one was more influential

23 than the others.

24 My opinion at the time was that all three of

25 those recombinant Factor VIII products were equally

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1 through all the documents to see what would be of

2 relevance to the Inquiry.

3 **Q.** You mentioned that when you joined the haemophilia

4 centre there was still some of Professor Bloom's

5 documents in his room which then became your room.

6 What documents had he left?

7 **A.** Well, those were the documents that I've just

8 described.

9 **Q.** So there were the treatment protocols.

10 **A.** Well, there were lots of documents there. There were

11 various letters that I've submitted to the Inquiry

12 about the use of different concentrates. There was --

13 importantly, I think, there was a whole two arch lever

14 files of reports to solicitors about individual people

15 who had contracted HIV, which again I've declared to

16 the Inquiry. They are about individuals, of course.

17 Then there were lots of documents about the

18 day-to-day management of things that I didn't think

19 had any relevance to the Inquiry. So my

20 understanding -- because I didn't submit -- I didn't

21 make the submission to the Inquiry on behalf of

22 Cardiff and Vale UHB, that was made by the people. My

23 understanding was that they sent all of it but I don't

24 know if that's definitely true.

25 **Q.** We can make inquiries about that. The Inquiry will

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1 safe and as efficacious. I think they all were good

2 quality products and all could have been used.

3 I can't remember exactly what products we were using

4 at that time. I think we were probably using all

5 three. That's the best I can do, I'm afraid, on that.

6 **Q.** Does the fact that the national tender system that's

7 currently in place, the fact that you have complete

8 freedom to prescribe from any of the medications on

9 the list, on the approved list of purchased products,

10 mean that there is still scope, in your view, for

11 there to be -- for donations from or support from

12 pharmaceutical companies to influence prescribing

13 policy? So, in other words, the fact that there is

14 a tender system in place, is there not still scope for

15 funding from pharmaceutical companies to influence

16 prescribing policy at the centre?

17 **A.** I think there is the potential risk that there would

18 be influence, yes. I think that this is an issue that

19 affects many areas of healthcare and many areas of

20 public life. I do not think that the prescribing in

21 Cardiff, or now that we are involved in treating

22 people in Swansea, I do not think that it has ever

23 influenced our decisions with regard to which products

24 to use.

25 **Q.** A couple of questions on the research database, the

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1 UKHCDO research database. Given the process that you  
2 described, of getting informed consent from patients  
3 and the fact that you'd actually got quite far through  
4 the process in Cardiff, when the UKHCDO was advised to  
5 stop that process, is it right to say that it would  
6 have been practical, at least from -- would it be  
7 practical to obtain informed consent from patients to  
8 the use of their data for research purposes?

9 **A.** It was definitely practical to obtain written informed  
10 consent from the very large majority of patients. The  
11 database holds quite a lot of information on people  
12 who are no longer seen in any haemophilia centre, they  
13 are essentially lost to follow up, and Cardiff has  
14 some people in that category: very difficult to reach  
15 those people.

16 I think that we could have taken written  
17 informed consent from 90 to 95 per cent of people and  
18 that was completely practical. I think there was  
19 always going to be a small group that would be very  
20 hard to reach and, as I said earlier, my personal  
21 preference would have been to be allowed to have  
22 carried on doing that, had the Confidentiality  
23 Advisory Group not changed their advice to us.

24 **Q.** Why can't the data that's held in the research  
25 registry part of the database, why can't that data be

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1 hepatologist hadn't been appointed was revisited.

2 So certainly the Deputy Chief Medical Officer  
3 has had quite a lot of interaction with regard to the  
4 Inherited Bleeding Disorders Service with that review.

5 **Q.** And, lastly, when meetings were held between clinician  
6 groups and the Department of Health, how was the Welsh  
7 Government represented from 1996 onwards? Are you  
8 able to answer that question?

9 **A.** I can't answer that question. I don't think I have  
10 any knowledge. These are meetings between the  
11 Department of Health in Wales and the Department of  
12 Health in England? Is that the question?

13 **Q.** I think -- no, between clinician groups in Wales and  
14 the Department of Health in Wales is what I imagine.

15 **A.** I mean, apart from the ministerial review, I don't  
16 remember any really significant interactions. There  
17 were some letters and information about things like  
18 Skipton Fund and that sort of thing, but I didn't have  
19 any discussions with any of the politicians with  
20 regard to that. So I don't remember anything  
21 directly, I'm afraid.

22 **MS SCOTT:** Sir, those were the questions from the Core  
23 Participants.

24 ///

25 ///

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1 held anonymously, so as to protect patients being  
2 identified when that data's being used for research  
3 purposes?

4 **A.** There aren't two registries. There's one registry and  
5 the one registry is used for the direct patient care  
6 for the research and for the public health planning.

7 When the data is used for research purposes, it  
8 gets anonymised, or perhaps better pseudo-anonymised,  
9 so that the analysis is based on pseudo-anonymised  
10 data. But the database itself doesn't change, it's  
11 always there. So the fields that identify people are  
12 hidden when the analyses are done.

13 **Q.** Moving on to a new topic now, what role has the Welsh  
14 CMO (Chief Medical Officer) played in the management  
15 and oversight of the haemophilia centre since you've  
16 been there?

17 **A.** I have -- well, with Chief Medical Officer I've not --  
18 I can't remember any direct interaction, but with the  
19 Deputy Chief Medical Officer, Dr Chris Jones, he of  
20 course has had interaction with the haemophilia  
21 centre, and he chaired the ministerial review in 2011,  
22 and he chaired a follow-up review -- I think it was  
23 around about 2015 -- particularly looking to see  
24 whether the recommendations had been implemented, and  
25 of course at that time the question of why the

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Questions by SIR BRIAN LANGSTAFF

2 **SIR BRIAN LANGSTAFF:** Yes, thank you. Well, I have one or  
3 two of my own.

4 Can I just pick up on that last question that  
5 you were asked and link it to what you were saying  
6 earlier about the role of the Transfusion Service in  
7 Wales, which looked after the supply to you of  
8 products. At the time you were talking about that,  
9 the thought went through my mind: suppose a new virus  
10 happened to be identified in blood. I appreciate that  
11 now blood products tend to be recombinant by and large  
12 but some still aren't. So it's a possible risk to  
13 blood products, it's certainly a risk to the blood  
14 supply more generally.

15 You said that you would expect to be told or  
16 learn about possible hazards in blood, be told by the  
17 Blood Transfusion Service or through UKHCDO; so the  
18 question then arises how they know. They presumably  
19 will know in the usual way, that some doctor or some  
20 surveillance authority in some country in some part of  
21 the world identifies that something has happened,  
22 something has happened that deserves to be reported,  
23 and so it's reported, and then someone writes about it  
24 in a peer review journal and other people begin to  
25 take notice, and fortunately, in the modern world,

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1 with the internet and so on, news can agreed quite  
 2 rapidly and probably, one hopes, faster than the  
 3 virus.  
 4 But would that not come to your notice in that  
 5 way, it would come to your notice, you would expect,  
 6 through UKHCDO or the Transfusion Service? The reason  
 7 I link that with the relations with the Welsh  
 8 Government relates to this: part of the landscape that  
 9 I'm looking at in this Inquiry involves the DHSS.  
 10 Largely, the evidence will relate to what happened in  
 11 London but, of course, healthcare is now a devolved  
 12 issue, more strictly than it ever was, and so the  
 13 Welsh Government has the same role, perhaps, it might  
 14 be thought, in respect of what happens in Welsh  
 15 hospitals as the DHSS different in those days across  
 16 most of the UK. Plainly, the medical division of the  
 17 DHSS were kept informed and had their own views about  
 18 what was happening and what the risks were, and so on.  
 19 So how do you see it working if a new virus is  
 20 identified somewhere which has a threat to blood  
 21 products or blood supplies or, for that matter, not  
 22 necessarily a virus, something like a prion?  
 23 **A.** I think for the blood supply, for example, in red  
 24 cells, platelets, FFP, cryoprecipitate that is  
 25 produced by the Welsh Blood Service I would expect

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1 and that looks at risks of blood products, both  
 2 recombinant and plasma-derived. It may well be that  
 3 information would come through that reporting system  
 4 early and quickly. So I think it's difficult to know  
 5 exactly where the information is most likely to come  
 6 from in respect of if there is a completely new, out  
 7 of the blue threat to the blood supply. I would have  
 8 hoped to receive the information from multiple sources  
 9 very rapidly.  
 10 **SIR BRIAN LANGSTAFF:** Would one of those sources be the  
 11 database?  
 12 **A.** Possibly it will be the database, though the database  
 13 is, of course, reporting retrospectively, and so if  
 14 a new treatment was causing serious side effects, the  
 15 data may not pick that up for you know three or four,  
 16 five, six months after these events started happening.  
 17 But there is an example within the database of -- one  
 18 of the recombinant Factor VIII concentrates was  
 19 thought to be associated with more inhibitors than  
 20 other recombinant Factor VIII concentrates, and the  
 21 database very quickly looked at the information held  
 22 in the database and was able to confirm that that did  
 23 look like it was the case, and that led to people in  
 24 the UK using different concentrates. So that did  
 25 happen quite quickly.

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1 that they would be the first to become aware and alert  
 2 and make sure that that was known. I would have  
 3 thought that immediately they would be in discussion  
 4 with the Welsh Assembly Government about a threat of  
 5 that severity but I don't personally know what  
 6 committees or what groups would do that because it's  
 7 not part of my remit.

8 What I was saying about more likely to be  
 9 hearing things from UKHCDO would be that, if there was  
 10 a problem with a concentrate, I would expect that that  
 11 would be known in the haemophilia world and would be  
 12 picked up by one of my colleagues and I would be more  
 13 likely to, you know, very rapidly hear about it from  
 14 there. So let's say, for example, variant CJD,  
 15 I heard about it through Professor Ludlam sending me  
 16 a letter in 1977 (sic), even though, as I've explained  
 17 that at that time the suggestion was that this wasn't  
 18 anything to be concerned about and that we weren't  
 19 supposed to be telling patients.

20 So I think that that is from the point of view  
 21 of the concentrates, so I would have thought it might  
 22 well be that UKHCDO or a member of that UKHCDO might  
 23 hear first.

24 There's a reporting system within Europe called  
 25 EUHASS, which is run by Professor Makris at Sheffield,

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1 So the database does have the ability to look  
 2 at this sort of thing but it is, as I say,  
 3 retrospective.  
 4 **SIR BRIAN LANGSTAFF:** Obviously a lot may depend upon the  
 5 precise data that goes into database in respect of  
 6 what are at first anecdotal reports of reaction or  
 7 illness. Does anyone keep a close weather eye on the  
 8 database or does it come into play only when it's  
 9 responding to the worries of others?  
 10 **A.** No, there is a reporting system. So every month the  
 11 database sends an email to every haemophilia centre  
 12 saying: do you have any adverse events to report? And  
 13 names certain adverse events, like thrombotic events,  
 14 infections, I can't remember the other -- neurological  
 15 events because of -- you know, might we start picking  
 16 up variant CJD issues? So it specifically asks every  
 17 month: have you had any of these events? Our data  
 18 manager in Cardiff emails all the consultants in  
 19 Cardiff and says: have you seen any events? And if we  
 20 have, they get reported.  
 21 The reports then are reviewed by the director  
 22 of the database, who's Dr Hay at the moment,  
 23 Professor Hay at the moment, but also there is  
 24 a working party called the Co-Morbidities Working  
 25 Party, and if there's any serious adverse event, like,

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1 for example, a thrombosis or somebody has been given  
2 a treatment and they have had a heart attack or  
3 something, that committee will review the  
4 circumstances of that event, and they will review it  
5 with the clinician who's reporting the event, so there  
6 will be some kind of the Zoom meeting and clinician  
7 will report it, and that group will then come to the  
8 conclusion whether they think that the event is likely  
9 to be causally related to the product or not.

10 They will then report that on to the  
11 manufacturer and to the authorities to say that this  
12 adverse event has been reported. And of course if  
13 there's a serious event as well, then the protocol is  
14 that UKHCDO will email the whole membership to  
15 say: a person has been treated with treatment X and  
16 they developed a heart attack immediately after, you  
17 should be aware that this has happened. And that  
18 would be the process that has been put in place to do  
19 that.

20 So the events don't sort of disappear into  
21 a black hole, as it were. There is some attempt to  
22 scrutinise the severity and the likelihood or  
23 causality and then to communicate that if necessary.

24 **SIR BRIAN LANGSTAFF:** So what you are describing -- sorry.

25 **A.** Sorry, I was going to say that's a relatively recent

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1 patient that that report has gone in.

2 **SIR BRIAN LANGSTAFF:** If you happen to be the individual  
3 clinician, what would you think you would do?

4 **A.** I think that for a serious adverse event that we were  
5 reporting, we would -- I think we probably would talk  
6 to the patient now. I think, to be completely honest,  
7 before this Inquiry started I probably may not have  
8 done. I have been made to reflect on keeping people  
9 better informed of what is being done with their  
10 information and I think that's something that UKHCDO,  
11 as a whole, has been reflecting on.

12 **SIR BRIAN LANGSTAFF:** The reason I ask is probably  
13 obvious, is that there have been a number of comments  
14 made to the Inquiry that the individuals who had been  
15 told they have had HIV or hepatitis C or, for that  
16 matter, hepatitis B weren't told, though it was  
17 hypothesised that it was the case, where they got it  
18 from and they weren't told that they had it from  
19 infected blood. So I think you may well be right that  
20 they are expressing an interest in knowing of the  
21 source if it is known or hypothesised. That's,  
22 I think, the outcome of your own ruminations from what  
23 you've been saying.

24 **A.** Yes, I think that that is the case, yes. I think  
25 there is also that we need to think that haemophilia

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1 thing that we've set up over the last few years.

2 **SIR BRIAN LANGSTAFF:** From the way you are describing  
3 that, that is something that has happened?

4 **A.** It has happened, yes. So events have happened and  
5 clinicians have discussed with the group who is  
6 overseeing the events and decisions have been come to  
7 as to whether they think the event is related to the  
8 product or not, and that information has then been  
9 disseminated to the membership. That has happened,  
10 yes.

11 **SIR BRIAN LANGSTAFF:** What information, do you know, has  
12 been given to the patient about the fact that their  
13 data or their event has been reported in this way?

14 **A.** I think that -- well, I don't know. I think that  
15 would be down to the doctor looking after them in the  
16 centre that has submitted the information. Clearly,  
17 the patient will know that the event has happened,  
18 because it's happened to them.

19 In addition to reporting to UKHCDO, you have  
20 a duty to report through the yellow card system as  
21 well, you know. So if product X causes someone to  
22 have a heart attack, you've a duty to report through  
23 that yellow card system completely separately.

24 So there are multiple ways forward. I think it  
25 would be up to the individual clinician to inform the

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1 doctors looking after people with bleeding disorders  
2 now, many them are young consultants who may not be  
3 aware what people have been told in the past and so  
4 may not be aware that people haven't had all the  
5 information that they may reasonably expect, and  
6 I think that that is something, again, that we are  
7 considering as a group, how that should be addressed.

8 **SIR BRIAN LANGSTAFF:** That leads me on to something I was  
9 going to ask, actually a bit later in the questions  
10 which I have for you, but you may recall that when the  
11 Inquiry was in Cardiff, at the Royal College of Music,  
12 you and I had the odd conversation and in one of them  
13 you were saying how listening, reacting to the  
14 evidence which had been given, that you hoped or  
15 wanted some of your staff or your juniors to come and  
16 hear what was being said.

17 Did that happen?

18 **A.** Yes. So a number of members of staff were at the  
19 hearings in Cardiff, there for a number of reasons,  
20 both to really to hear the testimony of the people  
21 giving evidence, because some of these people that the  
22 evidence was about had died long before the staff were  
23 part of the haemophilia centre, and even before I was  
24 at the haemophilia centre, and I thought it was very  
25 important that people knew and understood what had

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1 happened because I think it is so important in trying  
2 to provide a service for this group of people.

3 But they were also there to try and lend, as it  
4 were, moral support to the people giving evidence  
5 because many of the people giving evidence the staff  
6 knew very well and they knew it was a very difficult  
7 situation for these people to tell their story, and we  
8 thought it was important that members of staff were  
9 there to help people. We discussed this in advance  
10 with Haemophilia Wales to make sure that they thought  
11 that that was the right thing to do and they said that  
12 they did. Some members of staff who had long left the  
13 haemophilia centre or who had retired came to the oral  
14 evidence in Cardiff, specifically -- and I'm thinking  
15 here of some of the social workers who had retired --  
16 specifically to help give support to people who had  
17 been giving their evidence.

18 **SIR BRIAN LANGSTAFF:** Insofar as younger staff may have  
19 learnt something, what messages, what lessons do you  
20 think they took away from listening to the evidence of  
21 those who gave it, in what you say was courageous  
22 evidence to give?

23 **A.** I think there are a lot of things that have come  
24 through but one of the most important is that although  
25 these events may have been in the 1970s and 1980s,

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1 ripples are as small as they have to be?

2 **A.** Well, I mean, I think the fact that we are having this  
3 Inquiry is a major part of that process. Ever since  
4 I started in Cardiff, people have been coming to me  
5 saying that they think that there needs to be a full,  
6 open, transparent inquiry into what happened, so as to  
7 understand the process. And I think most of the  
8 people I talk to in Cardiff, it's that they want to  
9 understand clearly and fully what happened and not  
10 have this residual concern that things aren't being  
11 uncovered and aren't being said.

12 So I think that will be absolutely crucial to  
13 how the events are -- as you say, ripple down the  
14 generations, as to whether it can -- the outcomes of  
15 this Inquiry can resolve the questions that the  
16 patient group are asking. I think that's absolutely  
17 key to what happens. I think that -- I've always felt  
18 that we needed this sort of inquiry. When I went to  
19 Cardiff I hadn't considered that but, talking to the  
20 patient group from very early on, they persuaded me  
21 that it was the only way that things would move  
22 forward, and I think that that is very important, that  
23 we look -- that we have a clear understanding of what  
24 happened and as far as possible why it happened.

25 **SIR BRIAN LANGSTAFF:** And perhaps do what it can to ensure

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1 before some of the members of staff were even born,  
2 they are still very important and resonant to the  
3 people that -- that they were affected, both the  
4 individuals and their families. And I think that we  
5 mustn't think about this as all being events in the  
6 past. These are events now. People are still living  
7 with the events. So it's not a historic thing that  
8 we're looking at, it's ongoing. And it will echo down  
9 the generations, I'm sure of it, that -- as I've  
10 explained, people who have children with haemophilia  
11 now may have lost their father, and it will continue  
12 to be very important for a very long time.

13 **SIR BRIAN LANGSTAFF:** In one sense I suppose you came to  
14 Cardiff after what may be seen by some as a question  
15 of history, although you see the ripples extending  
16 down into the future, you'll have some similarities in  
17 your position, looking back, as we do at the Inquiry,  
18 looking back on what has happened without knowing from  
19 firsthand what was happening. You have this  
20 advantage, that you have taken over the reins and are  
21 being involved in the treatment of those who suffered  
22 and related to their families and carers and so on, on  
23 an ongoing basis. So you have a lot of involvement in  
24 that sense. What lessons would you learn for the  
25 future that we might all use to ensure that the

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1 that something like it never happens again.

2 **A.** Well, I think very important that we minimise the  
3 chances of anything like this happening again.  
4 I think it's -- you never know what's round the corner  
5 and it is very important that everything that can  
6 possibly be done to prevent further serious  
7 complications of treatment that are being given to  
8 people with bleeding disorders, that everything is  
9 done to prevent that. I'm not just thinking about  
10 infectious disease but complications of other  
11 treatments. We have to have as much -- do as much as  
12 we possibly can to prevent further problems.

13 **SIR BRIAN LANGSTAFF:** Changing the topic just a little,  
14 though it's got a link to what we've just been  
15 discussing, it always struck me listening to the  
16 evidence that we've been having as to the past that  
17 being a congenital disease -- or a condition, I'm  
18 sorry, I shouldn't call it disease, condition --  
19 haemophilia is always going to be recognisable most  
20 often in very young children. And that may be with  
21 parents who, because of the nature of the genetics  
22 involved, may not themselves have any familial  
23 experience of haemophilia. So they are on their own  
24 and they are lost a little bit with a child that has  
25 a condition they don't perhaps fully understand. And

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1 the child needs to come to terms with it too.  
 2 So why wasn't a paediatrician or someone with  
 3 an RCPH -- what is it? The Royal College of  
 4 Paediatrics and Child Health qualification involved?  
 5 Well, you have in your Cardiff centre, from what you  
 6 were describing, thoroughly involved paediatrics. You  
 7 have a consultant who is primarily focused on  
 8 children. You're plainly equipped with play  
 9 specialists to assist the child, particular nurses who  
 10 have paediatric experience, which reassures me that at  
 11 least in one centre that has been the model.  
 12 How common is it across the whole country, by  
 13 which I mean the UK?  
 14 **A.** Most children in the UK are looked after in paediatric  
 15 haemophilia centres, so centres like Great Ormond  
 16 Street, for example, would only look after children.  
 17 Other centres where both adults and children are  
 18 looked after, for example in Oxford, they have  
 19 a paediatric haemophilia consultant who looks after  
 20 the children. So I think it's the case now that there  
 21 is certainly a recognition that children should be  
 22 looked after by people who specialise -- who are  
 23 paediatricians who specialise in looking after  
 24 children with bleeding disorders. I think that would  
 25 be the general standard of care.

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1 help with training with venous access, and this sort  
 2 of thing. So I think that there is certainly  
 3 a significant focus on trying to make sure that  
 4 children are well looked after. In addition, in the  
 5 Cardiff centre we have a general paediatrician who  
 6 comes and does joint clinics with us. So she's not  
 7 a haemophilia doctor but she is a general  
 8 paediatrician. So she comes and does the joint clinic  
 9 with one of the haemophilia doctors, so that if the  
 10 children or the parents bring up  
 11 a non-haemophilia-related issue then we have the  
 12 expertise to address that.  
 13 **SIR BRIAN LANGSTAFF:** The only other thing that I wanted  
 14 to ask you was, when you have been discussing with  
 15 patients what treatment they might prefer, whether  
 16 they want to stay on what they have had, go on to  
 17 recombinant, if not what sort of recombinant, these  
 18 sorts of discussions, how long roughly do those  
 19 discussions take? You have said it was a process and  
 20 plainly that must be right and sensible but, roughly,  
 21 how long the initial conversations and how long  
 22 overall do you think you might end up discussing, in  
 23 the average case?  
 24 **A.** In the average case, if it's a question of changing  
 25 medication, I would say on average, it will be

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1 Again, another example would be Bristol. It  
 2 has a combined adult and paediatric centre but the  
 3 paediatric centre essentially stands alone with  
 4 paediatric haematologists and haemophilia doctors and  
 5 nurses looking after their patients and there are  
 6 examples all round the country. Glasgow would be  
 7 another good example of the two centres, adults and  
 8 children.

9 I think it is the case that children are looked  
 10 after by paediatric specialists, certainly the  
 11 severely affected children.

12 **SIR BRIAN LANGSTAFF:** That's true, of course, in the  
 13 bigger centres. What about the centres and the  
 14 associate centres? Do they have any such involvement  
 15 or do they simply refer children on to the reference  
 16 centre or the care centre?

17 **A.** I think -- well, it's difficult for me to comment  
 18 outside of South Wales. In South Wales children are  
 19 looked after through the -- their treatment is  
 20 co-ordinated by Cardiff through the comprehensive care  
 21 centre but the treatment might be delivered through  
 22 a clinic in Swansea or Abergavenny, where one of us  
 23 goes out and sees the person more locally. Our nurses  
 24 will travel all the way out to west Wales, you know  
 25 100 miles or more to visit patients in their home to

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1 ten minutes on a first consultation and then  
 2 ten minutes some time later once the person has  
 3 thought about it.

4 In addition, the nurses will have separate  
 5 conversations about the issues and, sometimes, these  
 6 issues will go on for many months as people consider  
 7 whether they want to change treatment or not. So  
 8 I would say it's roughly that sort of time.

9 But there are different -- so changing from one  
 10 standard half-life Factor VIII to another standard  
 11 half-life Factor VIII is not a huge jump, because  
 12 you'll be -- it's a very similar treatment but  
 13 changing from, for example, Factor VIII to Emicizumab,  
 14 that's a very big change that will almost certainly  
 15 require multiple conversations to understand the  
 16 implications of that change and whether people want to  
 17 go ahead and do that, because -- partly because it's  
 18 such a new treatment the consequences of receiving the  
 19 new treatment may not all be known and there may be  
 20 consequences of receiving that treatment that we are  
 21 not currently aware of.

22 So some people see the advantages of once  
 23 a week subcutaneous, but others see the kind of  
 24 reassurance of being on the treatment they've been on  
 25 for 20 years and why do they want to change.

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1 **SIR BRIAN LANGSTAFF:** That's all that I have to ask.  
 2 Ms Scott?  
 3 Further questions by MS SCOTT  
 4 **MS SCOTT:** Sir, one question has arisen out of a response  
 5 that Professor Collins gave to a question asked by you  
 6 and it's this.  
 7 Professor Collins, could you explain what the  
 8 yellow card system is and how it works.  
 9 **A.** Well, if an adverse event, a side effect, relating to  
 10 a drug occurs, then the clinician will complete what  
 11 used to be called a yellow card. It's now online.  
 12 You go through a website and you put in the  
 13 information related to that adverse event so that if  
 14 a number of different clinicians are saying the same  
 15 thing, then the regulators will note that very early  
 16 and be able to take action if appropriate.  
 17 **Q.** So the online system is run by whom?  
 18 **A.** I'm not sure I can answer that, I'm afraid.  
 19 **Q.** Okay.  
 20 **A.** I don't want to give an inaccurate answer. But it's  
 21 an official system. It's not -- you know, it is an  
 22 official system but I don't say which agency, I'm  
 23 afraid, is in charge of running it.  
 24 **Q.** Thank you.  
 25 Professor, is there anything that you would

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1 about the local grouping in South Wales is that,  
 2 despite the huge challenges and the grief that has  
 3 often been associated with their individual stories,  
 4 the local patient group has always worked very closely  
 5 and very constructively with the haemophilia centre to  
 6 improve care for people with bleeding disorders across  
 7 the whole of Wales. Some of their notable  
 8 achievements in enhancing care have been that they  
 9 were instrumental in Wales becoming the first country  
 10 in the world to establish recombinant for all, they  
 11 campaigned for the new stand-alone haemophilia centre  
 12 in Cardiff, they greatly enhanced physiotherapy across  
 13 all of Wales and they established the psychology  
 14 service dedicated to people with bleeding disorders.  
 15 They also were instrumental in improving the  
 16 hepatology service. These achievements would not have  
 17 been possible without the tireless work of Haemophilia  
 18 Wales, and I think it's of great credit to them that  
 19 these have been achieved. However, the most important  
 20 thing that I want to say is that the staff working at  
 21 all the haemophilia centres in South Wales are acutely  
 22 aware of the suffering that the treatment with  
 23 infected blood has caused. Many people have died long  
 24 before their time and they are all greatly missed.  
 25 People and their families have had to live with the

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1 like to say?  
 2 **A.** So I would like to say a few words particularly about  
 3 the extraordinary group of people that have attended  
 4 the haemophilia centres in South Wales over the last  
 5 24 years, and these are people that I've come to know  
 6 very well.  
 7 They were absolutely central to the campaign  
 8 that led to this public Inquiry and they battled at  
 9 times against what must have seemed enormous obstacles  
 10 but they never lost focus in that and that was clear  
 11 from the moment I first came to Cardiff.  
 12 It is I think a great sadness that many of  
 13 these people have not lived to see their work achieve  
 14 the outcome that they wanted, particularly that they  
 15 have not been able to hear the evidence and that they  
 16 are not going to be able to hear the outcome of the  
 17 Inquiry.  
 18 Of particular note from the local patient group  
 19 I would say that establishing The Birchgrove Group was  
 20 an outstanding and defining achievement, and I think  
 21 it's one that has had significant influence over very  
 22 many years. I've learnt an enormous amount from  
 23 talking with this group of people and I have to say  
 24 I'm very proud to be able to be part of their lives.  
 25 I think it's very important when we're thinking

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1 appalling consequences of this tragedy and they  
 2 continue to do so.  
 3 I am sorry that these patients and their  
 4 families, who I and my colleagues have had the  
 5 privilege to care for, have had to experience the pain  
 6 and suffering caused by these events.  
 7 Thank you.  
 8 **SIR BRIAN LANGSTAFF:** Thank you very much. I have to  
 9 thank you for a number of things, not least I know  
 10 that you would have wanted to be here in person to say  
 11 what you have just said, as well as give your  
 12 evidence, and I'm very grateful to you for being  
 13 prepared to change your arrangements at short notice  
 14 because of the way in which the timetabling had to be  
 15 worked out in the light of the current virus and its  
 16 restrictions. So thank you for being prepared to do  
 17 that.  
 18 But thank you also for giving us the view of  
 19 somebody who was pretty much at the centre, given your  
 20 involvement in the national committee as you have  
 21 spoken about, UKHCDO and Cardiff, of what life as  
 22 a haemophilia consultant and director has been like in  
 23 the last 20-odd years, and in particular all the  
 24 challenges that you have faced and the challenges that  
 25 you have had to experience following on from the

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1 tragedy, as you call it, which you've just described.  
 2 I don't need to repeat it. It's clear.  
 3 And for giving your evidence in such a clear,  
 4 direct and helpful way. So thank you very much  
 5 indeed.  
 6 **A.** Thank you for the opportunity.  
 7 **MS SCOTT:** Sir, we're not sitting next week.  
 8 **SIR BRIAN LANGSTAFF:** No.  
 9 **MS SCOTT:** Then the following week, on the Tuesday and  
 10 Wednesday, the 26th and the 27th is going to be the  
 11 medical ethics group panel.  
 12 **SIR BRIAN LANGSTAFF:** Yes. So that will be a panel  
 13 presentation of the sort that those of you who were  
 14 here will have seen before, when we had our previous  
 15 expert groups. So this, of course, will be online,  
 16 which will be a new online experience for us but we  
 17 shall manage it and we shall make progress then too.  
 18 That's the whole of the next session will be the  
 19 medical ethicists. That will be the Tuesday and the  
 20 Wednesday and, if necessary, further in that week.  
 21 I think just the Tuesday and the Wednesday will  
 22 probably be sufficient.  
 23 **MS SCOTT:** Yes, that's the plan at the moment.  
 24 **SIR BRIAN LANGSTAFF:** So for those of you who are watching  
 25 online, we sign off now until Tuesday week,

1 26 January. Thank you very much.  
 2 (3.16 pm)  
 3 (Adjourned until Tuesday, 26 January 2021 at 10.00 am)  
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<p><b>MS SCOTT:</b> [19] 2/9 5/24 6/4 24/8 24/18 27/7 27/9 54/7 55/1 92/6 92/16 92/22 98/18 109/14 115/22 133/4 137/7 137/9 137/23</p> <p><b>SIR BRIAN LANGSTAFF:</b> [41] 1/3 1/5 1/11 1/13 5/23 20/24 21/24 23/14 24/7 24/12 27/3 27/8 54/10 54/25 92/12 92/17 97/19 109/2 109/6 109/8 109/13 116/2 119/10 120/4 121/24 122/2 122/11 123/2 123/12 124/8 125/18 126/13 127/25 128/13 130/12 131/13 133/1 136/8 137/8 137/12 137/24</p> <p><b>THE WITNESS:</b> [3] 1/4 1/10 1/12</p> <hr/> <p>'96 [1] 91/11</p> <hr/> <p><b>0</b></p> <p><b>061 [2]</b> 19/3 32/14</p> <hr/> <p><b>1</b></p> <p><b>1 o'clock [1]</b> 92/6 <b>1.27 pm [1]</b> 109/10 <b>10 [2]</b> 62/20 95/7 <b>10,000 [1]</b> 88/25 <b>10.00 [2]</b> 1/2 138/3 <b>100 [3]</b> 1/23 21/4 24/16 <b>100 miles [1]</b> 130/25 <b>108 [2]</b> 26/16 26/25 <b>11.27 [1]</b> 54/22 <b>11.55 [1]</b> 54/24 <b>118 [2]</b> 26/16 26/25 <b>12 [3]</b> 19/22 54/13 54/20 <b>12 years [1]</b> 95/7 <b>13 [6]</b> 26/2 26/2 26/22 27/5 27/6 27/11 <b>13 who [1]</b> 27/6 <b>13 with [1]</b> 27/4 <b>15 [3]</b> 20/11 30/5 92/21 <b>15 December 1997 [1]</b> 34/10 <b>15 January 2021 [1]</b> 1/1 <b>15 minutes [5]</b> 92/7 92/9 92/13 92/18 92/18 <b>15 minutes' [1]</b> 105/9</p>	<p><b>15 years [1]</b> 62/21 <b>150/160 [1]</b> 25/13 <b>160 [1]</b> 25/13 <b>162 [1]</b> 24/23 <b>17 [1]</b> 19/21 <b>18 [8]</b> 18/22 18/23 20/11 21/6 21/8 24/11 24/23 24/24 <b>1969 [1]</b> 100/18 <b>1970s [1]</b> 125/25 <b>1977 [1]</b> 118/16 <b>1980s [1]</b> 125/25 <b>1983 [1]</b> 72/7 <b>1985 [1]</b> 72/7 <b>1986 [2]</b> 2/14 3/18 <b>1989 [3]</b> 3/19 3/21 55/20 <b>1990 [1]</b> 4/7 <b>1991 [3]</b> 4/17 5/21 56/13 <b>1992 [1]</b> 56/13 <b>1993 [2]</b> 4/18 5/7 <b>1995 [4]</b> 5/7 5/23 5/24 32/20 <b>1996 [23]</b> 6/1 6/8 6/19 8/1 8/14 10/20 18/20 19/14 21/5 26/8 26/21 26/23 27/23 28/14 29/7 29/14 55/6 57/1 57/9 60/11 77/3 86/11 115/7 <b>1996/97 [1]</b> 66/11 <b>1997 [9]</b> 19/1 19/2 19/5 34/2 34/10 35/5 36/25 106/4 106/6 <b>1998 [4]</b> 9/24 35/6 35/10 78/23</p> <hr/> <p><b>2</b></p> <p><b>2.00 [1]</b> 92/13 <b>2.25 [3]</b> 109/3 109/6 109/8 <b>2.25 pm [1]</b> 109/12 <b>20 years [3]</b> 59/13 87/8 132/25 <b>20,000 [1]</b> 88/25 <b>20-odd [1]</b> 136/23 <b>200 [3]</b> 1/16 1/23 1/24 <b>2000 [5]</b> 9/2 10/2 87/25 111/12 111/15 <b>2000s [1]</b> 106/19 <b>2001 [3]</b> 6/8 7/2 7/10 <b>2003 [2]</b> 78/18 79/8 <b>2004 [1]</b> 12/5 <b>2005 [4]</b> 6/19 6/22 12/6 38/14 <b>2008 [1]</b> 12/7 <b>2009 [3]</b> 79/9 79/24 83/4 <b>2011 [3]</b> 81/7 82/9 114/21 <b>2012 [2]</b> 13/9 13/13</p>	<p><b>2014/2015 [1]</b> 81/24 <b>2015 [2]</b> 81/24 114/23 <b>2016 [2]</b> 8/7 82/9 <b>2017 [1]</b> 7/19 <b>2019 [2]</b> 12/7 24/21 <b>2020 [1]</b> 8/8 <b>2021 [2]</b> 1/1 138/3</p> <p><b>20s [1]</b> 24/5 <b>23/5/97 [1]</b> 19/5 <b>239 [2]</b> 18/22 24/10 <b>24 [1]</b> 20/11 <b>24 years [1]</b> 134/5 <b>24/7 [1]</b> 15/15 <b>251 [1]</b> 102/14 <b>26 [1]</b> 24/12 <b>26 January [1]</b> 138/1 <b>26 January 2021 [1]</b> 138/3 <b>26th [1]</b> 137/10 <b>27th [1]</b> 137/10</p> <hr/> <p><b>3</b></p> <p><b>3.16 pm [1]</b> 138/2</p> <p><b>30s [1]</b> 24/5 <b>32/33 [1]</b> 44/3 <b>320 [1]</b> 105/12 <b>328 [5]</b> 18/21 19/17 21/6 24/9 24/13 <b>33 [4]</b> 19/21 44/3 67/15 67/25</p> <hr/> <p><b>4</b></p> <p><b>4 June 1997 [1]</b> 19/5 <b>405 [1]</b> 21/8 <b>41 [1]</b> 19/20 <b>45 [2]</b> 26/12 26/22</p> <hr/> <p><b>5</b></p> <p><b>50 [1]</b> 71/10 <b>50 per cent [3]</b> 7/11 7/12 7/15</p> <hr/> <p><b>6</b></p> <p><b>60 per cent [1]</b> 71/11 <b>60,000 [2]</b> 96/11 97/12 <b>640 [1]</b> 24/23 <b>66 [5]</b> 26/3 26/25 27/4 27/6 27/10</p> <hr/> <p><b>7</b></p> <p><b>74 [1]</b> 30/19 <b>75 [1]</b> 30/5</p> <hr/> <p><b>8</b></p> <p><b>80 [1]</b> 6/11 <b>802 [2]</b> 24/21 25/8 <b>802 people [1]</b> 25/22 <b>87 [2]</b> 18/23 21/7 <b>8Y [11]</b> 31/24 32/3 32/18 42/24 43/2 67/5 67/13 67/25 69/23 69/23 96/17</p>	<p><b>9</b></p> <p><b>90 [1]</b> 113/17 <b>90 per cent [1]</b> 6/11 <b>95 per cent [1]</b> 113/17 <b>96 months [1]</b> 67/16 <b>97 [2]</b> 19/5 66/11</p> <hr/> <p><b>A</b></p> 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118/21 119/7 131/25 132/8 134/2 134/19</p> <p><b>I wouldn't [2]</b> 36/18 82/1</p> <p><b>I wrote [1]</b> 12/9</p> <p><b>I'd [5]</b> 23/20 35/11 73/3 74/7 75/1</p> <p><b>I'm [40]</b> 2/11 8/10 20/1 25/14 27/18 27/22 28/9 31/18 37/16 40/17 43/10 43/14 48/2 55/1 61/14 69/14</p>	<p>69/20 71/3 74/3 85/2 85/16 86/4 91/4 92/16 92/21 92/22 95/4 101/19 112/5 115/21 117/9 125/14 126/9 128/9 128/17 133/18 133/18 133/22 134/24 136/12</p> <p><b>I've [36]</b> 5/13 5/15 26/11 30/22 44/21 47/24 49/7 52/21 53/10 55/12 57/13 57/17 59/14 69/18 70/5 70/6 72/7 82/25 88/10 90/18 91/5 92/2 92/6 95/7 98/11 105/8 109/14 110/7 110/11 110/15 114/17 118/16 126/9 127/17 134/5 134/22</p> <p><b>I've never [1]</b> 52/21</p> <p><b>I've submitted [1]</b> 72/7</p> <p><b>idea [1]</b> 101/15</p> <p><b>identified [4]</b> 81/4 114/2 116/10 117/20</p> <p><b>identifies [1]</b> 116/21</p> <p><b>identify [1]</b> 114/11</p> <p><b>ie [1]</b> 98/21</p> <p><b>if [103]</b> 1/6 3/3 7/18 8/25 16/4 17/25 18/8 19/12 20/8 20/24 21/2 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<p><b>issues [9]</b> 9/11 17/2 31/6 31/18 75/25 86/17 120/16 132/5 132/6</p> <p><b>issuing [1]</b> 101/3</p> <p><b>it's [104]</b> 1/15 5/14 13/15 14/25 15/2 16/8 18/13 18/14 19/2 24/15 25/20 27/8 27/12 29/12 30/4 30/4 30/5 34/8 34/12 36/24 41/4 42/23 42/25 46/6 46/12 47/4 47/8 47/9 47/11 48/25 49/21 49/21 49/24 49/25 50/2 50/7 50/16 51/15 52/20 54/12 55/23 59/2 59/10 59/20 60/6</p>
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53/22 66/24 68/13 75/4 77/4 82/23 93/8 98/18 105/18 108/4 108/7 108/12 108/18 108/23 124/15 131/13 134/14 136/10</p> <p><b>wanting</b> [2] 48/17 59/20</p> <p><b>wants</b> [3] 48/20 54/4 61/23</p>	<p><b>ward</b> [1] 4/15</p> <p><b>was</b> [307]</p> <p><b>wasn't</b> [24] 5/6 28/4 37/9 55/18 64/21 69/3 72/9 77/15 79/1 79/3 79/21 79/24 79/25 80/4 80/13 81/1 82/2 82/6 88/4 91/25 108/24 111/22 118/17 129/2</p> <p><b>watching</b> [2] 1/24 137/24</p> <p><b>way</b> [25] 17/4 46/13 51/22 55/10 72/3 73/25 75/13 79/13 91/9 91/10 94/14 95/19 98/14 103/11 105/16 107/6 108/22 116/19 117/5 122/2 122/13 127/21 130/24 136/14 137/4</p> <p><b>ways</b> [5] 40/5 51/25 105/19 106/18 122/24</p> <p><b>wayside</b> [1] 60/2</p> <p><b>we</b> [324]</p> <p><b>we'd</b> [1] 64/10</p> <p><b>We'll</b> [1] 20/21</p> <p><b>we're</b> [13] 14/15 14/16 16/25 20/13 25/15 42/2 42/19 64/9 80/21 93/20 126/8 134/25 137/7</p> <p><b>we've</b> [19] 12/3 40/7 47/17 48/11 87/21 89/14 92/22 92/24 94/7 94/12 95/13 95/14 95/17 104/10 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<p><b>W</b></p> <p><b>who... [46]</b> 70/20 73/15 75/2 77/5 78/19 79/10 81/14 81/15 81/17 82/12 82/23 84/19 85/21 87/3 87/25 94/8 95/9 99/5 102/8 104/24 107/8 107/17 110/15 113/12 122/5 123/14 124/2 125/12 125/13 125/15 125/16 125/21 126/10 126/21 128/21 129/7 129/9 129/19 129/22 129/22 129/23 131/5 136/4 136/19 137/13 137/24</p> <p><b>who'd [1]</b> 11/15</p> <p><b>who's [2]</b> 120/22 121/5</p> <p><b>whole [10]</b> 11/22 38/21 84/25 99/9 110/13 121/14 123/11 129/12 135/7 137/18</p> <p><b>whom [1]</b> 133/17</p> <p><b>whose [3]</b> 11/13 34/3 89/3</p> <p><b>why [16]</b> 21/19 30/15 36/14 59/2 60/10 61/4 82/9 88/20 97/22 107/25 113/24 113/25 114/25 127/24 129/2 132/25</p> <p><b>wide [2]</b> 38/19 38/19</p> <p><b>wife [2]</b> 1/11 54/18</p> <p><b>will [76]</b> 1/16 1/20 1/22 2/1 2/2 12/12 15/24 16/23 17/1 18/5 21/11 22/2 27/16 35/2 35/6 36/10 36/12 44/5 44/10 46/2 46/22 46/24 47/6 47/6 47/9 47/25 48/4 49/6 49/9 50/4 51/7 53/9 54/13 54/19 57/21 59/11 63/24 64/2 71/11 82/11 84/5 84/8 90/13 99/11 99/11 109/3 109/7 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