

Friday, 15 January 2021

(10.00 am)

SIR BRIAN LANGSTAFF: Good morning, Professor Collins.

THE WITNESS: Good morning, Sir Brian.

SIR BRIAN LANGSTAFF: My apologies for speaking from and behind a mask, if you can't hear me very clearly.

I hope you can. Obviously, you can see me.

Let me describe the scene to you that you're

facing but, first of all, you're at home, I think.

THE WITNESS: That's correct, yes.

SIR BRIAN LANGSTAFF: Your wife is in the house?

THE WITNESS: Yes, she's here, yes.

SIR BRIAN LANGSTAFF: Right. You are talking to an Inquiry chamber which, although I know you had hoped to be here to see it in person, it's a big room, will seat about 200 people and, at the moment, we have a total of eight people in it, all very socially distanced, as you might imagine, all wearing masks except, at the moment, for Ms Scott who is going to ask you the questions. Mary, in a moment or two, will ask you to take the oath.

Beyond the Inquiry room, there will be something in the region of 100 to 200, there were just over 200 yesterday, watching either on a direct Zoo platform or on YouTube. So those are the people

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could be transmitted through blood and blood products?

A. It would have been some time over the next year or so.

Q. Can you recall during your medical training what, if anything, you were taught about the seriousness of non-A, non-B as a disease?

A. I can't remember specifically what we were taught about non-A, non-B. We were taught that after transfusion there was the risk of hepatitis. I can't remember anything that was described about the risk of -- the severity of that or whether it would develop chronic hepatitis.

Q. Can you recall whether you ever had an understanding that it was anything other than a serious -- or it could be a serious disease and could be chronic?

A. Yes, I think I always understood it could be a chronic disease and could be serious, yes.

Q. You then undertook various house officer roles in surgery and medicine between August 1986 and February 1989; is that correct?

A. That's correct, yes.

Q. Was your first haematology post February 1989 as a Senior House Officer in Royal London Hospital?

A. That was the first formal haematology, although in my medical rotation at Oldchurch Hospital I covered some haematology there as well. But my first formal

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you're speaking to. I imagine there will be probably a number of people from Wales, in particular, who will be interested to know what you have to tell us about that.

Mary, please would you ask Professor Collins to take the oath.

PETER WILLIAM COLLINS, affirmed

Questions by MS SCOTT

MS SCOTT: Good morning, Professor Collins.

A. Morning.

Q. I'm going to start off by asking you some questions about your CV. So we know from your witness statement that you qualified, you completed your medical training in 1986?

A. That's correct.

Q. Can you recall what you learnt during that medical training about the risk of viral infection via blood and blood products, particularly in relation to HIV and non-A, non-B?

A. I was aware from medical school training that hepatitis could be transmitted by blood products. I don't think I was aware at that time about HIV being transmitted. I was aware that -- I was aware of AIDS. That had been mentioned in my undergraduate training.

Q. Can you recall when you did become aware that HIV

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training post in haematology was at the Royal London.

Q. Was that under Professor Colvin?

A. Well, it was -- Professor Newland was the -- manage the leukaemia side and the bone marrow transplantation and Dr Colvin the coagulation and thrombosis side.

Q. You then became an honorary lecturer in haematology in February 1990 at The Royal London; is that correct?

A. That is correct, yes.

Q. Was that a post that involved teaching?

A. No, it was really a research post, rather than a teaching post.

Q. So during that post, how much of your role involved the treatment of those with bleeding disorders?

A. I would cover bleeding disorders out-of-hours on-call and I would go on ward rounds where people with bleeding disorders were being treated as in-patients.

Q. You then had a post between September 1991 and June 1993 as the Leukaemia Research Fund Clinical Research Fellow at the Royal London. Did you spend any time during that post working with those with bleeding disorders or were your duties in relation to those of leukaemia?

A. I was employed at that time doing a thesis on thrombotic complications of bone marrow transplantation, so that was the focus of the work

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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.

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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
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 was

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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 201
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 no

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 Ali Khan

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 Wales
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?

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- 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-hour
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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at the Swansea Haemophilia Centre and will react to any issues that arise there.

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

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

A. So patients could be registered at Swansea, at Abergavenny, or in Cardiff, or jointly, they could be registered both at Swansea and in Cardiff. So certainly patients are jointly registered but some are only registered in Swansea and some are only registered in Abergavenny.

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

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

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in 1997 because that gives us quite a useful snapshot of what was going on in 1997. Soumik, it's HCDO0000280_061.

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

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

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

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

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

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

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

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

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

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

A. Yes.

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

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

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

A. Correct, yes.

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

A. Yes, that looks familiar and accurate.

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

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

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(5) Pages 17 - 20

of this document, and page 2. Thank you.

If we look at the haemophilia patients registered there, the total comes to something just over 100. What you were describing a moment or two ago to Ms Scott from your statement was that in 199 there were 328 people over the age of 18 with an inherited bleeding disorder and 87 under the age of 18, which is 405. So there's a very big difference in numbers. The inherited bleeding disorders, what comes within the scope of that? How many people with an inherited bleeding disorder will not be people who you would define as suffering from either severe or moderate or mild haemophilia A or B?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MS SCOTT: Indeed, yes.

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

Q. Then by 2019, your statement says that there are 80 patients with inherited bleeding disorders registered with Cardiff, 640 over the age of 18 and 162 under the age of 18. Those figures more or less remain accurate or has there been an increase since then?

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- 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

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- 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 entire
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.

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- 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

28

(7) Pages 25 - 28

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 199
 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 it
 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, Replinate, 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 the
 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

32

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 BP

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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information being given to us was that there was on ly a hypothetical risk of variant CJD in UK plasma and , indeed, there was, as we may come on to later, ther was advice that we shouldn't be telling the patient at all about this issue, which UKHCDO disagreed wit and I disagreed with.

So there was -- the level of risk being told to us was that, essentially, it was thought that there wasn't a risk and, of course, everybody at this tim who was eating meat was being exposed to variant CJ through that mechanism and so these were some of th conversations I would have had to have had with the patients about what their choice wanted to be, beca use some people might well take the view that they were being exposed through the food chain anyway.

My memory is that -- and I think I'm correct in this -- no-one wanted to change to US plasma and, o course, later on the next year BPL started to make all of its products from US plasma and that did cause some people some concern, that their product was now bei ng made from US plasma and, obviously, because they we re very well aware of the problems of the past.

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

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

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

Q. So just picking up on the point about centres havin to use a minimum proportion of particular named Factor VIII products, if, for example, the tender i for, I don't know, five Factor VIII products, do yo have to use all five of those or how does it work?

A. No, it would work -- let's say that there are, as you say, a certain number of Factor VIII products. For the top two in the tender we would have to use a certain proportion of those. The top one we would have to use the most, then after that, but for the rest of it there's a proportion where we can use anything we want, and so we would then have to discuss with individuals about changing products. I would

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

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

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

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

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

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

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

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

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

A. Yes. So at the moment they are treated with either 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 wit
 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 the
 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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products. Although, with Factor VIII they are enhanced half-life, in young children it doesn't make a huge difference, because in young children the half-life of Factor VIII is quite short anyway, and it gets longer, the half-life of Factor VIII, as the child gets older into adulthood. So we do discuss enhanced half-life Factor VIII and many, many parents choose to go with half-life Factor VIII.

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

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

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

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

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

A. Yes.

Q. How do you record those discussions in notes?

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

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

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

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

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

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

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

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

Q. It sounds from what you have said that those discussions with patients, adult patients or existing patients, is not a one-off conversation for those. 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; i
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 it
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 col
 7 resource that is the NHS, and in South Wales the NH
 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 absolute
 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 i
 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, Emicizumab 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 Emicizumab, so price is not the defining issue; if
 4 someone wants to go on Emicizumab, 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)
 23 (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 relating
 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 vaccination
 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 no
 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, a
 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 w
- 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. S
 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 there
 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 of
 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 clinic
 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 patient
 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 I
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 was not
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 200
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 you

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

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 a little
 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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(22) Pages 85 - 88

1 Q. For each company?
 2 A. Yes, that's from my memory.
 3 Q. Were they companies that you were -- companies whos
 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 companie
 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 wh at
 15 products we would use. Of course, with the nationa
 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 pharmaceutica
 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 ar
 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 offic
 17 when I went there. Three people, as I said, have been
 18 consultant for the centre in between Professor Bloo
 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 th at
 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 clinician
 4 attending educational meetings and activity patient
 5 days?
 6 A. Correct.
 7 Q. Given what you said about the national contract, wh at
 8 do you think the pharmaceutical companies are getti ng
 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 h ave
 14 discussed this with many haemophilia doctors. I me an,
 15 I might be supported to go to a meeting by a differ ent
 16 company each time. My colleagues might well be. S
 17 there is a sort of a balance there. As I say, I th ink
 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 com

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

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

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

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

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

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

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

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

Q. Sorry. Carry on.

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

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

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

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

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

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

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

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

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

Q. Is the fact that the information is going to be -- albeit the information about the patients is going to be anonymised, the fact that it's going to be published, it's going to be able to be accessed by 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 see
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

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

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

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

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

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

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

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

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

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

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

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

Q. So anyone reading your witness statement, which was

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

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

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

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

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

A. It would be and the people who do the analyses, the statisticians, they don't see -- they see anonymise

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

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

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

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

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

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

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

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

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

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

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

Since 1997, in Cardiff, we haven't had anyone die of AIDS. Obviously, people with AIDS have died potentially of complications related to that but no one died specifically of AIDS, because the treatment has improved, but still dominates your thinking when you are seeing patients that, clearly -- the treatment that has been given by the centre has caused major problems for an individual is always very high in your mind when you are talking to people and it's the same with hepatitis C. You always know and you always understand that.

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

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

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

However, they got to a position where they were experiencing pressure to remove the bust and they approached me and said that rather than the haemophilia centre becoming the centre of the story they wanted us to remove the bust and wait for the Inquiry to give its opinion. So that's my understanding of what happened. Clearly, Haemophilia Wales can give their understanding and their version of that, but that's the way I felt it happened. The day that Haemophilia Wales said that they wanted us to take the bust down we took it down, and that wasn't 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 do not

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 patient
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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1 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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with the internet and so on, news can agreed quite rapidly and probably, one hopes, faster than the virus.

But would that not come to your notice in that way, it would come to your notice, you would expect, through UKHCDO or the Transfusion Service? The reason I link that with the relations with the Welsh Government relates to this: part of the landscape that I'm looking at in this Inquiry involves the DHSS. Largely, the evidence will relate to what happened in London but, of course, healthcare is now a devolved issue, more strictly than it ever was, and so the Welsh Government has the same role, perhaps, it might be thought, in respect of what happens in Welsh hospitals as the DHSS different in those days across most of the UK. Plainly, the medical division of the DHSS were kept informed and had their own views about what was happening and what the risks were, and so on.

So how do you see it working if a new virus is identified somewhere which has a threat to blood products or blood supplies or, for that matter, not necessarily a virus, something like a prion?

- A. I think for the blood supply, for example, in red cells, platelets, FFP, cryoprecipitate that is produced by the Welsh Blood Service I would expect

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and that looks at risks of blood products, both recombinant and plasma-derived. It may well be that information would come through that reporting system early and quickly. So I think it's difficult to know exactly where the information is most likely to come from in respect of if there is a completely new, out of the blue threat to the blood supply. I would have hoped to receive the information from multiple sources very rapidly.

- SIR BRIAN LANGSTAFF: Would one of those sources be the database?

- A. Possibly it will be the database, though the database is, of course, reporting retrospectively, and so if a new treatment was causing serious side effects, the data may not pick that up for you know three or four, five, six months after these events started happening. But there is an example within the database of -- one of the recombinant Factor VIII concentrates was thought to be associated with more inhibitors than other recombinant Factor VIII concentrates, and the database very quickly looked at the information held in the database and was able to confirm that that did look like it was the case, and that led to people in the UK using different concentrates. So that did happen quite quickly.

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

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

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

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

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So the database does have the ability to look at this sort of thing but it is, as I say, retrospective.

- SIR BRIAN LANGSTAFF: Obviously a lot may depend upon the precise data that goes into database in respect of what are at first anecdotal reports of reaction or illness. Does anyone keep a close watch on the database or does it come into play only when it's responding to the worries of others?

- A. No, there is a reporting system. So every month the database sends an email to every haemophilia centre saying: do you have any adverse events to report? And names certain adverse events, like thrombotic events, infections, I can't remember the other -- neurological events because of -- you know, might we start picking up variant CJD issues? So it specifically asks every month: have you had any of these events? Our data manager in Cardiff emails all the consultants in Cardiff and says: have you seen any events? And if we have, they get reported.

The reports then are reviewed by the director of the database, who's Dr Hay at the moment, Professor Hay at the moment, but also there is a working party called the Co-Morbidities Working Party, and if there's any serious adverse event, like,

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

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

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

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

A. Sorry, I was going to say that's a relatively recen

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patient that that report has gone in.

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

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

SIR BRIAN LANGSTAFF: The reason I ask is probably obvious, is that there have been a number of commen ts made to the Inquiry that the individuals who had been told they have had HIV or hepatitis C or, for that matter, hepatitis B weren't told, though it was hypothesised that it was the case, where they got i from and they weren't told that they had it from infected blood. So I think you may well be right that they are expressing an interest in knowing of the source if it is known or hypothesised. That's, I think, the outcome of your own ruminations from wh at you've been saying.

A. Yes, I think that that is the case, yes. I think there is also that we need to think that haemophili

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

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

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

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

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

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

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

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

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

Did that happen?

A. Yes. So a number of members of staff were at the hearings in Cardiff, there for a number of reasons, both to really to hear the testimony of the people giving evidence, because some of these people that the evidence was about had died long before the staff w ere part of the haemophilia centre, and even before I was at the haemophilia centre, and I thought it was ver important that people knew and understood what had

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

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

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

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

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ripples are as small as they have to be?

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

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

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

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

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

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that something like it never happens again.

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

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

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the child needs to come to terms with it too.

So why wasn't a paediatrician or someone with an RCPH -- what is it? The Royal College of Paediatrics and Child Health qualification involved? Well, you have in your Cardiff centre, from what you were describing, thoroughly involved paediatrics. You have a consultant who is primarily focused on children. You're plainly equipped with play specialists to assist the child, particular nurses who have paediatric experience, which reassures me that at least in one centre that has been the model.

How common is it across the whole country, by which I mean the UK?

- A. Most children in the UK are looked after in paediatric haemophilia centres, so centres like Great Ormond Street, for example, would only look after children. Other centres where both adults and children are looked after, for example in Oxford, they have a paediatric haemophilia consultant who looks after the children. So I think it's the case now that there is certainly a recognition that children should be looked after by people who specialise -- who are paediatricians who specialise in looking after children with bleeding disorders. I think that would be the general standard of care.

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help with training with venous access, and this sort of thing. So I think that there is certainly a significant focus on trying to make sure that children are well looked after. In addition, in the Cardiff centre we have a general paediatrician who comes and does joint clinics with us. So she's not a haemophilia doctor but she is a general paediatrician. So she comes and does the joint clinic with one of the haemophilia doctors, so that if the children or the parents bring up a non-haemophilia-related issue then we have the expertise to address that.

- SIR BRIAN LANGSTAFF:** The only other thing that I wanted to ask you was, when you have been discussing with patients what treatment they might prefer, whether they want to stay on what they have had, go on to recombinant, if not what sort of recombinant, these sorts of discussions, how long roughly do those discussions take? You have said it was a process and plainly that must be right and sensible but, roughly, how long the initial conversations and how long overall do you think you might end up discussing, in the average case?

- A. In the average case, if it's a question of changing medication, I would say on average, it will be

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

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

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

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

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

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

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

So some people see the advantages of once a week subcutaneous, but others see the kind of reassurance of being on the treatment they've been on 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 a
 14 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 factor, 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 describe d.
 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 previou
 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 th
 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,

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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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