INFECTED BLOOD INQUIRY:

ST THOMAS' HAEMOPHILIA CENTRE

A. The Centre

1. The Haemophilia Centre at St Thomas' Hospital, London ('the Centre'), was one of the major haemophilia centres in England.

2. From 1956 until 1979 Professor G I Ingram[1] was the key protagonist in the Department of Haematology at St Thomas' Hospital ('STH').[2] In 1970 there were 157 registered patients.[3] In around 1973 the Centre became recognised as a Regional Haemophilia Centre.[4]

3. Professor Ingram was a member of the Medical Research Council's Cryoprecipitate Working Party[5] and on the Factor IX Working Party.[6] He was a member of the Expert Group on the Treatment of Haemophilia, which was founded in March 1973.[7] He was co-Chairman of the UKHCDO from 1978 to 1979.

4. From 1979 until 2006 Professor[8] Savidge was the Director of the Centre. The main focus of this note is the period from 1979 to 1990. However, where relevant, individual sections are divided into (i) the period prior to 1979, and (ii) the period after 1979.

5. There is no single document that describes the number of patients that the Centre treated from 1979 onwards. Available documentation provides a snapshot only. For example, the annual return from 1983 states that the Centre had 90 haemophilia A patients, 13 patients with von Willebrand's disease and 23 patients

[1] Frequently addressed by his middle name, Ilsley.
[2] Which was also known as the Louis Jenner Laboratory.
[3] DHSC0100026_084
[4] DHSC0100005_061
[5] OXUH0000831_001
[6] OXUH0000967_004
[7] DHSC0100007_010
[8] For simplicity this document uses "Professor" throughout. He was a Professor of Coagulation Medicine at King's College, London.

with haemophilia B.[9] For haemophilia A, the most used product for home treatment was Armour Factorate and Hyland Hemofil for inpatient and outpatient use respectively. The most used product for von Willebrand's patients was Hyland Hemofil. For haemophilia B patients, NHS factor IX was the most used product.

6. In a document covering 1981 to 1983 the Centre is described as having '*a very aggressive approach towards surgery in haemophilia and carry out a large number of joint-replacement operations.*'[10]

7. One particular feature of the Centre was that it treated patients in a wide geographic area in contrast to some other centres. An internal memo from Cutter in November 1985 describes that the Centre at that time had 250 to 300 patients. It was stated that STH distributed blood products to most of the haemophilia centres in the South East Thames region.[11] This geographic reach was also raised during the Working Party on Supraregional Services and Haemophilia Reference Centres on 29 January 1986.[12] It was noted that the Centre was offering a tertiary care service across London and right down to the coast. Many centres were referring patients to the Centre and orthopaedic surgery was recognised as a particular strength. During that January 1986 meeting Dr Kernoff stated that Professor Savidge had produced convincing evidence that there were major financial advantages in the service being organised from large centres with good evidence that orthopaedic surgery was cost effective. It was therefore agreed to recommend the Centre for supraregional designation, with special reference to the orthopaedic surgery aspect.

B. Geoffrey Savidge

8. Professor Savidge's medical educational background was different to that of most haemophilia centre directors. In evidence to the Archer Inquiry he described his background as a '*physician and as a medical scientist, not as a conventional*

[9] HCDO0000166_003 and HCDO0000166_005
[10] IPSN0000584_003
[11] CGRA0000605
[12] DHSC0002293_019

haematologist'.[13] He graduated from Queen's College, Cambridge following a degree in Natural Sciences in 1962.[14] He had a number of junior hospital roles before working for a year as a junior GP partner.[15]

9. From 1968 Professor Savidge worked abroad. He worked in Vass, Finland doing a residency in Neurology and Psychiatry before undergoing postgraduate training in the Department of Neurology at the Karolinska hospital, Stockholm, in 1969. From 1970 to 1973 he worked as a physician in the Department of General Medicine & Cardiology at the Saint Göran Hospital, Stockholm. In 1973 he started postgraduate training in clinical chemistry, haematology and coagulation, also in Stockholm. From 1977 to 1979 he was a Research Associate at the Karolinska Institute, Stockholm. In 1979 he became Senior Lecturer in the Department of Blood Coagulation, Stockholm.

10. On 18 September 1979 he became the Centre's Director and retired in September 2006. He died in 2011.

C. The emergence of factor VIII and factor IX products

11. As with the trend nationally, the evidence of infected individuals and their families treated at the Centre is that in the 1970s and 1980s there was a shift away from hospital-based treatment to home treatment with factor VIII and factor IX.

(i) Pre-1979

12. Professor Ingram was a key advocate of home treatment. In November 1970 Professor Ingram discussed with Dr Obank, from the DHSS, the first few examples of home treatment.[16] Professor Ingram, in correspondence with Dr

[13] ARCH0000011
[14] A full CV is at page 23 of SHPL0000594_006
[15] Specifically he worked at St Bart's, London from 1962 to 1965 for his clinical studies. From 1966 to 1968 he worked as a House Officer in surgery at the Luton and Dunstable Hospital. He also worked as a House Officer at the Prince of Wales Hospital, London and then at the North Middlesex Hospital, London.
[16] DHSC0100026_091

Maycock of BPL in 1972 (requesting more supplies of EHF[17] or '*preferably the equivalent in the new type of factor VIII concentrate, which, I understand, you will shortly be supplying*'), stated that he was '*pressing on with training as many severe haemophiliacs as possible to give themselves their own treatment.*'[18] Professor Ingram was part of a trial for home treatment in 1975 and 1976 funded by the DHSS,[19] and in 1979 produced an article on the clinical, social and economic advantages of home treatment.[20]

(ii) Post-1979

13. Professor Savidge continued with Professor Ingram's practice of home treatment and the use of factor products. Professor Savidge attended the 11th meeting of Haemophilia Reference Centre Directors held at STH on 22 September 1980. This was the second meting of the HRCDs that Professor Savidge had attended. At this meeting a trend towards prophylactic treatment was noted and the findings of the Home Treatment Working Party were discussed.[21] Professor Savidge asked about the policy of HRCDs regarding the '*use of cryoprecipitate for the treatment of haemophiliac patients and for home therapy and Professor Bloom said that it was a matter for the individual Directors to decide.*' Professor Bloom referred to the 5th meeting of the HRCDs in January 1978 (before Professor Savidge was in post) where '*the matter of cryoprecipitate versus factor VIII concentrates for home therapy had been discussed at considerable length and the Reference Centre Directors had agreed that factor VIII concentrates were preferred for home therapy.*'[22]

14. The evidence of infected individuals and their family members was that they were not informed of the risks of moving from cryoprecipitate to factor VIII and IX products. For example, one haemophiliac registered at the Centre from his birth in

[17] Defined elsewhere as Elstree Haemophilic Factor.
[18] CBLA0006658
[19] BPLL0003761; BPLL0003662
[20] 'Home treatment in haemophilia: clinical, social and economic advantages.' G.I.C Ingram, S.R. Dykes, A.L Creese, P. Mellor, A.V. Swan, J. Kaufert, C. R. Rizza, R.J.D Spooner and R. Biggs, 1979: DHSC0002191_019
[21] HCDO0000406, p. 6
[22] HCDO0000406, p. 6

1946 until 1994 describes being treated by Professor Ingram, then by Professor Savidge and then by Dr David Bevan. He had severe haemophilia A and was at the hospital '*over 100 times before [he] turned 10.*'[23] He was treated with BPL, Cutter and Armour products. He states: '*I was never given any information as to the risk of any infection caused by the blood products. In fact, I used to work in the medical field, therefore it could not be something widely known about. I assume that it might have been known amongst the haemophilia professionals.*'[24] The extent of Professor Ingram's and Professor Savidge's knowledge about the risk posed by blood products is addressed in section H of this note.

D. Sourcing of blood products

(i) Pre-1979

15. Throughout the 1970s Professor Ingram had a steady stream of correspondence with Dr Maycock about home treatment and supply of factor products. This is addressed in the self-sufficiency section, E, below.

(ii) Post-1979

16. The available evidence demonstrates that Professor Savidge took an active role in sourcing blood products for the Centre.

17. This active approach is evident from the very outset of his appointment. In November and December 1979 there is correspondence between David R. Williams, the Director of Speywood Laboratories Ltd, and Professor Savidge following a meeting in October.[25] They discussed a porcine factor VIII product.[26] Professor Savidge had tested the product and declared it '*unsuitable*.' The available documents also demonstrate interactions between Professor Savidge and

[23] W1195 (3)
[24] W1195 (8). As an adult he had day-to-day treatment at Lewisham hospital because he worked there.
[25] IPSN0000323_007. Koate is offered at a price of 9.5 pence per unit for annual purchase in the region of 500,000.
[26] IPSN0000323_006 and IPSN0000323_005

Inter-Pharma about the provision of Cutter and Hyland factor VIII in January 1981.[27]

18. During his evidence to the Archer inquiry Professor Savidge described the role of haemophilia centre directors in the purchase of blood products. He stated that when he started in 1979 at the Centre he inherited a '*rather low funding level'*. The funding was challenged from the DHSS down to the Regional Health Authority. Funds were divided up between the different departments. His evidence was that 85% of haemophilia department budgets were spent on blood products. Blood products were available from either the Blood Transfusion Organisation that supplied cryoprecipitate, fresh frozen plasma or product from BPL. He described the English and Welsh supplies as being based at Elstree as well as at Oxford and that sourcing blood product meant: '*a little bit here and a little bit there*'.

19. At the Archer Inquiry he described the financial structure for purchasing blood products:

'*Now, obviously, because there was never enough money, one way of dealing with this, which certainly I pursued, was to go along to the Regional Health Authority and say, "It is a bit silly to do this on a district basis, why don't you top-slice regionally?" So you'd take your haemophilia money out of your starting pot and then distribute district-wise, in which case each district paid a proportion, because we were getting patients from all over the district, we were getting a proportion of those districts' monies being top-sliced and that meant that the renal physicians and the cardiologists could bathe in the money that they would have got, but didn't.*'

[27] BPLL0001351

E. Self-sufficiency

(i) Pre-1979

20. Prior to Professor Savidge's arrival at the Centre, Professor Ingram had repeatedly raised concerns about the inadequacies of supplies of blood product. He highlighted the issue of the availability of '*haemophilic material*' due to increasing need as early as 1970.[28] In the same year he raised the possibility of pooling cryoprecipitate as a response to shortages.[29]

21. During the 1970s Professor Ingram was informed by BPL and the DHSS that there was no further funding.[30] In 1974 he proposed the idea of a central '*clearing house*' on more than one occasion to Dr Maycock to make the purchase of commercial factor VIII '*less haphazard.*'[31] He also faced questions from BPL about his level of factor use.[32]

22. In 1974 he wrote a letter to the Editor of *The Lancet* in support of Dr Biggs' request for a realistic supply. He wrote:

    'We know that treatment material is being provided within the Health Service in increasing amounts, but it is still far short of what we need. Until the NHS provision is adequate, it is cruel not to make good the shortfall from the large supplies of good commercial material which, as Dr Biggs says, are now available.'[33]

23. On 9 February 1978 Professor Ingram, in correspondence to Dr Maycock, set out the shortfalls that the Centre was continuing to experience:

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[28] DHSC0100026_084, item 12.
[29] DHSC0100026_091
[30] For example, see BPLL0001351_039, CBLA0000210 and DHSC0002191_016
[31] DHSC0100005_125
[32] DHSC0100006_126
[33] HSOC0022702

'*Since we already distribute nearly all our monthly allocation from the BPL, it looks as though more and more commercial material will have to be brought to satisfy our demands for home treatment alone, let alone our needs for surgery and patients with antibodies. In fact, our own monthly allocation is only sufficient for 75% of our Home Treatment needs at this Centre as it is. We are of course also using considerable quantities of commercial material for surgical cover…. Can anything further be done to increase NHS production*'.[34]

24. These pleas for more BPL product were repeated in August of the same year.[35] He was again told by Dr Maycock that there was no more product: '*I regret that the small increases in the flow of plasma that I mentioned to you some time ago have ceased and never in fact amounted to very much.*'[36]

25. Professor Ingram took up this issue with the DHSS and was informed that the '*working target*' was for 50 million i.u of factor VIII per annum for England and Wales but that Dr Lane of BPL thought it would be '*much higher within a few years.*'[37] He was invited by Dr Sheila Waiter of the DHSS to contribute to setting a target. However, it appears from DHSS internal documentation that Professor Ingram was possibly perceived by some inside the Department as raising difficult questions. For example, an internal memo from Dr Harris refers to Professor Ingram's 1979 paper on home treatment as a '*provocation*' because of the criticisms it made about the Department's inability to put a price on the cost per unit of factor VIII.[38]

(ii) Post-1979

26. Professor Savidge was a critic – both contemporaneously and latterly – of BPL.

27. In his evidence to the Archer inquiry Professor Savidge described BPL as '*antiquated*' and an organisation that '*exhibited poor manufacturing practices*

[34] CBLA0000728. The response is also DHSC0100005_117
[35] CBLA0000830
[36] CBLA0000833
[37] For example, DHSC0002191_016
[38] DHSC0002193_090

leading to excessive product recalls and QA failures'.[39] His conclusion was that from 1979 to 1986 decisions regarding blood products were '*prioritised by the financial and political consideration of the Blood Transfusion Services and by the BPL plasma fractionation facility*.'

28. He stated that:

'*one must attribute the failures to poor leadership relying on the assumed safety of BPL's products and reluctance to endorse intensive research into heat treated inactivated products, and inferior reaction management to restructure the Blood Transfusion Service to introduce greater safety aspects with donor selection and improved productivity and efficiency to achieve self sufficiency*.' [40]

29. He estimated that '*because there was always a shortfall and that shortfall went down to perhaps as much as 60%... there had to be a source of money to purchase blood products, usually from the United States*.'

30. He described an overall '*lack of political will to spearhead*' essential changes that were '*quite evident by 1978 for hepatitis and 1982 for HIV*'.

31. However, he also raised concerns about self-sufficiency and BPL contemporaneously. For example, at the 11th meeting of Haemophilia Reference Centre Directors held at STH on 22 September 1980 Professor Savidge was concerned that the estimate for the amount of blood product required each year did not include blood product used during surgery, particularly orthopaedic surgery.[41] He was informed that data for surgery use had been collected during the first two to three years of the collection of national data but this information '*was no longer collected because of the large amount of work required at individual haemophilia centres*.'[42]

32. In his evidence to the Archer Inquiry he stated:

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[39] ARCH0002508_002
[40] ARCH0002508_002
[41] HCDO0000406, p. 3.
[42] HCDO0000406, p. 4.

'the figures were quite difficult because the data they were getting from the UKHCDO in general, was always two years out of date anyway, and with escalating demand for more product to treat patients at home, for example, or for preventative treatment in children, the figures were always wrong, but one anticipated that those figures should be doubled, and so usually in one's negotiations -- because I negotiated for St Thomas's over the road, I always estimated that it would probably be twice as much as needed.'

F. Heat-treatment

33. One of the key features of Professor Savidge's practice, and by association the Centre's, was a belief in the need to heat-treat blood products.

34. In his evidence to Lord Archer Professor Savidge referred to a product developed in Germany in 1978, where 34 patients showed no biochemical evidence of transmission of non-A non-B using a pasteurised product. He stated:

'*I first start[ed] using heat-treated products in '82, after going through lots of discussions with the Americans in '81. That was for the first trial, and the second trial was started about 84/85.*

For trial purposes it cost absolutely as much as BPL's product; namely, zero. But, because it was quite clear that in some patients -- and it was meant to treat non-A/non-B hepatitis, to prevent it. So you had to use naive patients, patients who had not been exposed before, because the majority of the data that came out, shall we say, one year to one and a half years later, after the trial started, was very encouraging and it looked as if that particular combination of 38 degrees Celsius for 72 hours was enough.

My view was very much: well, that must be better, even if it costs something, than giving a patient what I know for sure that it is loaded in 100 per cent of cases with non-A/non-B hepatitis; namely, the BPL product. So although I never used any BPL products, it all went to the 26 smaller centres in the south-east because they had the first bite of it from the Blood Transfusion Service. I was always left with

nothing at the end of the year. So I had to survive on money initially from the district and subsequently from top-slicing of the region. So I knew most of these companies and it was quite easy to get involved, as the trial coordinator over here, to test out the first products which were heat-treated and available for research.

I couldn't get any of the German stuff, which I really wanted, for the simple reason that, after they came over here in discussion with some doctors and some people in 1981, they were scared away. They never decided to come back. So it was a bit difficult to get any product. I think they had such negative vibes here that they thought: well, let us stick to France, Belgium, Sweden, the United States and the rest of the world.'

35. During his evidence he described a different perception amongst his fellow HCDs:

'*[there was a] perception amongst quite a number of haemophilia treaters that the BPL product was safer, relatively safer -- I can't quantify it -- than the American commercial product because there were slightly fewer donors in the large donor pool. But, if you are talking about 10 per cent less donors from a donor pool of 2,000, that is not really all that significant. But that was a perception which was maintained almost through to 1984/85. It even goes through to the final recommendations in 85 that say, "Use heat-treated product but if you can't get any and you have not got any money, or you are too lazy to speak to the Americans, your second choice is BPL's product which "-- Crown immunity still existed and it was still 100 per cent loaded with non-A/non-B, and people were still using it, even after 85. "Getting rid of old stocks", I believe, was cited in the literature.*

36. He described his commitment to heat-treated product in the following terms:

'*Lots of people tried to explain it on other bases but the most logical thing is the fact that you kill the virus, it is not there. So we felt perfectly justified in going out and completely disobeying the current ethical concepts and everything else, which*

I was accused -- I was accused of being a charlatan at one stage, which I thought was quite nice.'

37. There is evidence of Professor Savidge stating that he was '*dumping*' un-heat-treated factor VIII.[43]

38. Professor Savidge's position on heat-treatment was discussed in a statement from an affected wife as follows: '*I understand that Professor Savage [sic] former Head of St Thomas' Haemophilia Centre, wouldn't give factor VIII products to patients at the time. He apparently knew there was a risk of spreading infections. I don't know where he was at that time, as it was before he met [my husband]. He was pissed off to say the least that people were contaminated from these blood products.*'[44]

39. However, Professor Savidge's commitment to heat-treatment did not equate to all of his patients receiving heat-treated product and/or being free from infection. For example:

    a. An internal Baxter memo in January 1983 refers to Professor Savidge knowingly giving virgin haemophiliacs non-treated product: *'Dr. G Savidge is very keen to have product immediately as he has had to treat 3 of his 5 initial virgin haemophiliacs with non-treated product and so now has only 2 patients left in the trial. It has therefore been decided to supply product on a Prescription Release basis until full Clinical Trial Exemption approval has been received.'*[45]

    b. An internal Armour memo refers to one of Professor Savidge's patients approaching the Armour stand at the Haemophilia Society annual conference in Bournemouth in March 1986, stating that he had only been on Armour material until recently when he switched to Travenol Haemofil T. He was negative for HTLV III antibody in December 1985 and seroconverted in

[43] PRSE0004577
[44] W0780 (103)
[45] SHPL0000983_002

March 1986 after being on Armour heat-treated products since December 1985. There is reference to the patient having a very '*philosophical attitude*'. The author of the memo states that he is reporting this because '*I don't know whether it would be creating problems to contact Dr Savidge*'.[46]

c. An internal Cutter memo from 22 September 1985 refers to the results from a virgin haemophiliac in Derby using Profilate HT who developed raised transaminases. It was noted that this was suggestive of non-A non-B hepatitis; Dr. Mitchell was noted to be '*disappointed with these results*'. The memo then states: '*it is worth noting that this patient is using a different batch to the one that has caused Non A Non B hepatitis in three of Dr. Savidge's patients*.'[47]

G. Pharmaceutical companies

(i) Pre-1979

40. There is limited evidence of Professor Ingram's interaction with pharmaceutical companies. At the 8th meeting of the Haemophilia Reference Centre Directors, held on 6 April 1979 at STH, there was a discussion about the differing prices of Kyrobulin. The concern was that the product was being sold at two prices, '*the cheaper preparation being made from American plasma*.' It is recorded in the notes that Professor Ingram had '*been in contact with Mr Berry of Immuno*' about this issue.[48] However, it appears from the available documents that Professor Ingram's focus in the 1970s was attempting to persuade BPL to become self-sufficient.

(ii) Post-1979

41. As part of the sourcing of blood products, Professor Savidge interacted with a wide range of pharmaceutical companies. He was often an Investigator as part of

[46] ARMO0000499
[47] BAYP0000007_113
[48] HCDO0000493, although later this was subject to an amendment by Professor Ingram, see PRSE0000539

product licence applications.[49] He also acted as a Medical Adviser / Consultant to clinical trials.[50]

42. At the 12th meeting of the UKHCD on 23 February 1981 it was noted that Professor Savidge had been approached by '*someone who was planning to set up a company to market factor VIII in the U.K. and who would be selling Travenol and Cutter material at a reduced price (TP per unit). He was concerned about this and felt that he should draw the Reference Centre Directors attention to the matter.*'[51]

43. During his evidence to the Archer inquiry, he was expressly asked about the relationship between doctors and pharmaceutical companies:[52]

'Generally speaking, if one had dealings with a commercial company -- and I have probably had more dealings with commercial companies than most – the rules are very simple: they pay for everything to do with the research that they expect you to do. That includes patient travel, patient expenditure, how much it costs to photocopy the notes, et cetera, et cetera, what the lab costs cost, and they get a breakdown of each and every cost before you even embark upon signing anything.

One is expected, as part and parcel of being involved with the research project for a commercial company, to actually present one's data. You can't expect 6,000 people to travel halfway across the world and cram them in St Thomas's dining room. So you have to go where you are requested to go and give a presentation. You may be offered an honorarium or you may not, but that really covers the fact you are up until 2.30 doing a report or something similar and you

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[49] For example, in June 1983 Professor Savidge was listed as an investigator by Ipsen regarding the use of porcine factor VIII product, Hyate C: IPSN0000008.
[50] In November 1987, he acted as a Medical Adviser / Consultant to clinical trials for Hemofil M: SHPL0000595_003 and SHPL0000596_058.
[51] HCDO0000407
[52] He was read evidence from a haemophiliac and asked to comment: '*One thing haemophiliacs would like addressed is the relationship between plasma companies and the doctors. What funding did doctors receive from plasma companies? Were any haematologists acting as paid advisers to companies or received incentives with funding or funding for lectures", et cetera, et cetera and more of that general ilk. Have you any comment*?'

expect perhaps to at least have a few shekels to keep your eyes open. So I think it depends very much upon the individuals of what happens.

In my case, I had funds which existed within the hospital and within the trustees, and money was paid directly from those companies into those trust funds.

So I actually never saw the money, although I did have the luxury of spending it, as I was the only signatory, but it had to be spent on something which related to the project, whether a staff member or the agents or anything else.

I am aware that there were many colleagues, at that time particularly, who were working as consultants for commercial companies and I suppose in a way there were some which were working not necessarily on a remunerative basis for companies such as BPL because BPL required advice, it may well be that perhaps such incentives could be recommendations for this or recommendations for that. I have no idea because I had no dealings with BPL.

So the answer to your question is: probably yes, depending upon the individual. How much? No idea. Because that is directly proportional to greed more than anything else, and really, you know, these things happen all the time in all walks of life without necessarily being related to medicine or HIV or blood product.'

44. The available evidence perhaps suggests a particularly close relationship with Armour. An internal memo written by C R Bishop, dated 6 March 1986, discussed the upcoming UKHCDO meeting to be held at the Centre on 17 March 1986. Professor Savidge is described, alongside Drs Kernoff and Preston, as the '*leading advocates for the "safer wet heat treated" Alpha factor VIII – Profilate.*' The internal memo describes the upcoming UKHCDO meeting, which was to be chaired by Professor Savidge as:

'*I suspect that this could be a very cleverly connived Meeting at the instigation of either these three clinicians or Alpha themselves to convert all Directors to a*

products which can be shown to have a better track record with regard to the elimination of NANB hepatitis. It is also obviously an attempt to expose the potential mid/long term problems associated with liver disease in haemophilia as initially advocated by Hay et al in articles in The Lancet during 1985.'

45. The memo then goes on to say:

'.... Geoff Savidge has kindly agreed to put questions on our behalf to the Panel and this will be an ideal opportunity to obtain an authoritative opinion from the leaders in the field on any subjects which are of particular interest to us and I would suggest that one or two very carefully constructed questions be discussed between us and put to Geoff in advance.' [53]

H. Knowledge of, and response to risk

Non-A Non-B hepatitis / Hepatitis C ('HCV')

(i) Pre-1979

46. The documents indicate that Professor Ingram was aware of the presence of hepatitis within blood and blood products. He was a member of the Medical Research Council's Cryoprecipitate Working Party, which in October 1968 carried out a survey of jaundice in haemophiliacs.[54] In February 1970 he enquired of Dr Rainsford of Treloar's whether two of his paediatric patients there had suffered jaundice after being treated with a suspect batch of EHF (they had not).[55]

47. The evidence suggests that Professor Ingram was testing his patients for hepatitis as early as 1971.[56] It appears that in October 1972 Professor Ingram had written to Dr Maycock directly on the issue of safety of factor IX product.[57]

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[53] ARMO0000505_001
[54] OXUH0000831_001
[55] TREL0000469
[56] CBLA0007855

48. In 1974 Professor Ingram notified the Director of the South London Transfusion Centre of a case of post-transfusion hepatitis and filled out a case report.[58]

49. In 1974 Professor Ingram received correspondence from Dr Mayne, of the Royal Victoria Belfast, about additional testing of a haemophiliac family where the son had developed a '*mild clinical icteric illness*.' She described that he had been '*exposed to blood products from 353 blood donors*.' It was noted that his '*serum during these dates was negative for antigen and antibody. His serum became position for antigen on 22 August 1972, antedating his illness by some time... His liver enzymes have gradually improved but are still in the abnormal range.*'[59] His haemophiliac brother had also been unwell and their mother, father and sister tested. Dr Mayne noted that '*the antigen is so strong that the virology department utilises it as a positive control.*'[60]

50. The available evidence suggests that Professor Ingram was aware of a link between commercial factor products and hepatitis. At the September 1975 meeting of the HCDs held in Glasgow, Professor Ingram highlighted the issue of the difference in pool sizes between NHS factor VIII and commercial factor VIII in the context of the incidence of hepatitis.[61]

51. Professor Ingram was also informed of the existence of hepatitis infections directly by BPL. For example, in September 1976 Professor Ingram received correspondence from Dr Maycock about an infected batch of BPL product and was asked to report '*whether any of the St Thomas's recipients of the above batch developed jaundice or hepatitis.*'[62] Professor Ingram's response was that his patients had not been infected.[63]

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[57] CBLA0006654
[58] DHSC0100018_045
[59] BHCT0000764
[60] BHCT0000764
[61] Specifically, he stated that '*that NHS factor VIII was derived from pools of 500-750 donations whereas the commercial factor VIII was often derived from pools of 2,000 to 6,000 litres of plasma and that the probability of including an infected donation was greater with commercial factor VIII*': OXUH0003735
[62] CBLA0007830
[63] CBLA0007855

52. Further Professor Ingram attended the meeting of Haemophilia Centre Directors at the Middlesex Hospital in January 1977 where Dr Craske presented his findings on hepatitis in haemophilia patients.[64]

53. The available evidence of infected individuals and their families describes instances of cases of non-A non-B hepatitis during the 1970s, in particular experiencing jaundice and feeling unwell. For example:

    a. One individual received his haemophilia diagnosis from Professor Ingram in 1979 at STH. At this stage, Professor Ingram advised in writing that the witness might well respond to DDVAP in an upcoming procedure.[65] In fact, he received factor VIII during a foot procedure carried out by Professor Ingram at STH. The blood products were produced by Armour and Immuno Kryobulin.[66] Prior to discharge he felt unwell and vomited but was still discharged. He then developed jaundice and thought he was suffering from hepatitis. He was then admitted to a local hospital in August 1979 with '*viral hepatitis non-A non-B?*' noted in his records.[67] His records also demonstrate that a blood sample from this hospital was sent to STH.[68] His records state that '*it was confirmed that another patient receiving cryo therapy at St Thomas' in the same batch had also developed jaundice and that [the witness] was suffering from non A non B hepatitis*.'[69] When he went for a check up in 1979 he remembers '*Professor Ingram clearly saying to me that "the factor VIII must have been one of the rogue batches that missed the heat treatment." When I saw Professor Ingram he was very apologetic. In hindsight, looking back, I believe he knew what had been done. I believe this was the reason for him being overly apologetic*.'[70]

[64] PRSE0002268
[65] WITN1258002
[66] WITN1258003
[67] WITN1258004
[68] WITN1258005
[69] WITN1258005
[70] W1258 (11)

(ii) Post-1979

54. In his written and oral evidence to the Archer inquiry, Professor Savidge states that prior to 1979 (the year he became Director of the Centre) he was aware of the risk of non-A non-B hepatitis within blood products. In his written statement to the Archer Inquiry he stated that '*single exposure to [large donor pool factor VIII concentrates] in many cases led to the development of chronic liver disease that in several individuals would have a fatal outcome.*'[71]

55. Professor Savidge, when asked about the timescales about knowledge of non-A non-B hepatitis, described two schools of thought:

'*One school of thought was: this causes problems, and it was backed up by a lot of tissue work biopsies, liver biopsies, which showed progressive liver disease, and then you had another group of individuals, who are quite happy to say that, you know: we just measure it with blood tests and the blood tests stay the same, so we just think it is a little bit of inflammation of blood tests from the liver. So-called transaminitis, which has no clinical connotation and which is merely a figment of a few people's imagination. So, by the time the histology data started coming through and by the time children started developing cirrhosis of the liver, perhaps it was a little bit more than inflammation of blood tests.*

So I think the majority of responsible physicians and people treating these patients knew by the end of the 70s -- in fact pretty closely about 78 I think tipped it -- that large donor pool concentrates, whether it be for Factor 8 or Factor 9 were the cause of non-A/non-B hepatitis. Nobody knew what the agent was but they assumed it was an infective disorder; it came from an infection. And as time moved on, it became proven that was the case.'

56. In 1979 and 1980 Professor Savidge attended his first and second meeting of haemophilia clinicians. In his first meeting of the UKHCDO, on 20 November 1979, Dr Craske spoke on behalf of the Hepatitis Working Party and emphasised

[71] §4 of Professor Savidge's written statement to the Archer Inquiry.

the need to collect data from Directors about the types of material individual patients had received as he '*already had some evidence that there were different Non-A and Non-B viruses and that the presence of the different viruses in therapeutic material might be related to different methods of fractionation.*'[72]

57. In Professor Savidge's second meeting, which was the 11th meeting of the HRCD held at STH on 22 September 1980, non-A non-B hepatitis was also discussed. During a discussion about a hepatitis vaccine Dr Craske stated there had been '*a poor response from Directors to the request for information about patients thought to have developed chronic hepatitis and he proposed to ask the Directors at the annual meeting in Glasgow to send in as soon as possible information about all patients who had shown abnormal LFTs for six months or more.*' It was noted that a study had found that approximately 5% of the donor population in America were '*carriers of Non-A and Non-B virus.*'[73]

58. Documents reveal references to liver function tests being undertaken by Professor Savidge during this period. For example, at the 12th meeting of the Haemophilia Reference Centre Directors, held on 23 February 1981, Professor Savidge raised a question about the management of patients who would not come to the Centre for treatment. As part of this discussion, Professor Savidge stated that he had a '*patient who refused to come for home therapy follow-up appointments and he was particularly concerned about this as liver function tests etc could not be checked.*'[74]

59. In the same year, on 14 September 1981 at the 13th meeting of the HRCDs held at STH,[75] Professor Savidge suggested that hepatitis-free commercial material should be used for anticoagulant reversal in preference to the NHS factor IX concentrate.

60. Despite this acceptance of knowledge by Professor Savidge about the risks of non-A non-B hepatitis, the overwhelming available evidence received by the

[72] HCDO0000015_068, p. 10.
[73] HCDO0000406 p. 6.
[74] HCDO0000407
[75] LOTH0000012_122

Inquiry from infected individuals and their family members is that they were not informed of potential risks of transmission of non-A non-B hepatitis in advance of receiving blood and blood products.

(iii) Patient experiences

61. Many witnesses are critical of the way in which they were informed of their diagnoses with HCV. The Inquiry has received evidence from people who describe being told in a casual manner about their diagnosis, and were not given detailed information about managing their infections or the risk posed to others. Infected individuals and their family members also highlight that the severity of HCV as a disease was downplayed. Many witnesses question whether they should have been informed of their infections earlier.

62. There are also examples of inadvertent or accidental communication of HCV diagnoses. Some patients recall being given their medical records while waiting for appointments and finding out about their infections by flicking through their notes. For some, the impact of this unexpected revelation was exacerbated by the fact that they were unaware they were being tested for an infection. One haemophiliac was wrongly informed he had HCV in 2002. In fact, he had cleared the virus and did not have active infection.[76] He was only informed of the error once he had had an appointment at the Centre and a home visit.[77]

63. One witness describes being informed of his diagnosis and then being called to a group meeting to be given information alongside other patients.

[76] W0002 (2.13)
[77] W0002 (2.16)

HBV

(i) Pre-1979

64. As set out above, the available evidence suggests that Professor Ingram was aware of the presence of hepatitis, including Hepatitis B ('HBV'), within blood products.

65. In October 1976 Professor Ingram wrote to Dr Maycock about a batch of factor VIII. He noted that five patients at the Centre had received this batch between October and December 1974. He could be '*sure*' that four of the patients did not have clinical jaundice but the fifth had an antibody for Hepatitis B antigen detected: '*we saw him in January and March of this year and he was not jaundiced then.*'[78]

66. In November 1978 Armour wrote to the Committee on Safety of Medicine about an infected Factorate batch after Professor Ingram had reported two cases of hepatitis. The plan was to test the batches for presence of HBV antigen.[79]

(ii) Post-1979

67. The documents reveal that in or around 1985 Professor Savidge reported of cases of HBV from Factorate batches.[80] This led to correspondence from the Director of Clinical Services at Armour, who stated that these vials had been '*widely distributed throughout the UK*.' It was stated that Armour had not received any other reports of adverse effects to date but that they would inform Professor Savidge of any further reports of hepatitis or abnormal LFTs.[81]

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[78] CBLA0004172
[79] ARMO0000022. A similar situation arose in October 1979: ARMO0000044
[80] ARMO0000342
[81] ARMO0000348

(iii) Patient experiences

68. There is evidence of cross-infection of HBV between a haemophiliac son and his mother. Contemporaneous medical records state that the son was the likely carrier of the infection and that he likely transmitted it to his mother. She was never informed of the risks to her son, or to herself, as a result of using blood products to treat his haemophilia.

69. Other individuals were informed about their HBV infections alongside other infections. Generally, HBV infection was considered by infected individuals as less serious in comparison to their other infection(s). Other witnesses describe not being informed about their infections with HBV at all. One individual did not find out about his HBV infection until he was preparing his witness statement for the Inquiry.

HTLV III / HIV / AIDS

70. On 13 September 1982 Professor Savidge attended the 14th meeting of HCDs at Manchester.[82] Dr Craske had been asked to look into the report from the US of the AIDS syndrome '*mainly in homosexuals but including three haemophiliacs.*' During this meeting it was noted that there was a '*remote possibility that commercial blood products had been involved.*' Directors were asked to notify Dr Craske if any of their patients developed the syndrome.

71. From this date onward Professor Savidge attended a number of key meetings alongside other HCDs. On 24 January 1983 he attended a meeting at a London airport hotel with a number of clinicians as well as representatives from Immuno. At that meeting there was a discussion about the ethics of treating children and whether they might be safer on cryoprecipitate. The emergence of AIDS was discussed and the note includes reference to a '*barrage of viruses including hepatitis B, non A non B, CMV and many others, possibly transmitted from*

[82] CBLA0001619

asymptomatic healthy blood donors.'[83] Professor Savidge also attended the 16th meeting of UKHCDO on 14 February 1983. During this meeting it was noted that the '*the incidence of AIDS was higher than at first thought [in America] and there was some concern that the haemophilic population of the U.K. who had received American concentrates might be at risk.*' Despite this, no recommendation was made at that time in relation to treatment with commercial blood products. [84]

72. On 13 May 1983 Professor Savidge, along with other Directors, attended STH for a Special Meeting. The minutes of that meeting record the reason for the meeting taking place:

'*The recent publicity in the press, radio and television about the problem of acquired immune deficiency syndrome (AIDS) had caused considerable anxiety to haemophiliacs and their medical attendants as well as to the Department of Health. There was clearly a need for Haemophilia Centre Directors to discuss what should be done with regard to the surveillance and reporting of suspected cases and the management of patients*.' [85]

73. During this meeting it was stated that there would '*seem to be no clinical benefit to be gained by changing to another type of factor VIII*' for those that had developed AIDS.[86] In relation to the general use of factor VIII concentrates: '*it was noted that many directors have up until now reserved a supply of National Health Service concentrates for children and mildly affected haemophiliacs and it was considered that it would be circumspect to continue with that policy. It was also agreed that there was, as yet, insufficient evidence to warrant restriction of the use of imported concentrates in other patients in view of the immense benefits of therapy*.' [87] It was noted that the situation '*shall be kept under constant*

[83] PRSE0002647
[84] HCDO0000411
[85] HCDO0000003_008
[86] HCDO0000003_008, p. 2.
[87] HCDO0000003_008, p. 2.

review.'[88] The day before the meeting the Haemophilia Society met and considered an AIDS-related grant application from Professor Savidge.[89]

74. Professor Savidge further attended the 14th meeting of the HCDs on 17 October 1983, where it was agreed that patients should not be encouraged to go over to cryoprecipitate for home therapy but should continue to receive the NHS or commercial concentrates in their usual way.[90]

75. On 10 December 1984 Professor Savidge attended a meeting at BPL.[91] Access to HTLV III testing was discussed in detail and it was noted that there should be '*no change in therapy except for the holding back of prophylaxis of children by home-treatment. All concentrate is now heat-treated commercial; advice was sought on the use of non-HT Factor V111 and Factor IX.*'[92] It was decided that all patients should be given heat-treated product, if available. Professor Savidge noted that '*this has and would continue to create severe financial problems for treatment centres.*'[93] He further suggested that a case be put to the DHSS for financial support. [94] He was told that the case for more money had already been made.

76. In relation to communication of diagnosis, it was agreed that '*each clinician would decide for each case depending on the facts of the case but in general to provide information if asked for.*' [95] Therefore, each individual clinician had the power to withhold a patient's HIV status from that patient. During this meeting Professor Savidge suggested that a task group be set up to specifically look at the issue of AIDS. He later became a member of that group.

77. Professor Savidge attended the 21st meeting of the Haemophilia Reference Centre Directors at St Thomas' on 30 September 1985.[96] During this meeting there was a

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[88] HCDO0000003_008, p. 3.
[89] HSOC0029476_024, p. 4.
[90] PRSE0004440
[91] BPLL0010734_003, although his surname is incorrectly spelled as "Savage" during these meeting notes.
[92] HCDO0000394_117
[93] HCDO0000394_117
[94] HCDO0000394_117
[95] HCDO0000394_117
[96] PRSE0004271

detailed discussion about five cases of sero-conversion for patients that had been treated with NHS factor VIII. All doctors, including Professor Savidge, were written to and informed that individuals who were '*found to have positive antibody tests, they must receive counselling in order to understand the meaning of the results and to avoid transmitting the infection to others.*'[97]

78. It appears that Professor Savidge had a particular interest in the sexual transmission of the virus. At the 8th meeting of the HCD AIDS Group on 27 January 1986 he asked about this issue[98] and by November of the same year he chaired a session alongside Dr Aronstam on 'Sexual Difficulties'; as part of a course entitled '*An Introduction to Counselling of Haemophilia Patients Exposed to HIV infection'* held at STH.[99]

(iv) Patient experiences

79. The evidence from infected individuals and their families raises concerns about how the issue of HIV was dealt with by the Centre. Some witnesses highlight a lack of transparency about being tested for HTLV III / HIV. For example, they state they were not informed of the purpose of blood being taken and assumed it was a routine blood test. They were then told that they were negative for HIV but were unaware they had been tested at all.

80. The Inquiry has received evidence from individuals who state that they found out about the issue of HIV via the media and they had to make contact with the Centre rather than haemophiliacs and their families being contacted directly by the Centre. Some partners and children of haemophiliacs were also tested. For example:

    a. A widow describes that after her husband's positive HIV test she was called in for a test.[100] This was an ordinary blood test at the Centre. She was tested a

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[97] PRSE0002163
[98] HCDO0000526
[99] CBLA0005436
[100] W2336 (2.19)

few times over the following months. She was not aware that she was also tested for HCV until she went through her husband's medical records for the purpose of the Inquiry. Her son was also tested.[101] She describes this as a '*terrible experience*' as '*we had to physically pin him down in order for Dr Savidge to take blood.*'[102]

81. In the vast majority of cases patients were informed of their HIV infections orally and in person. The available evidence describes poor examples of communication of HIV diagnoses. Some found out in an accidental or casual fashion. Not all conversations communicating the news of an HIV diagnosis took place in private rooms. The Inquiry has received examples of individuals being told in inappropriate places, such as a lift, or in an inappropriate way. For example:

    a. One haemophiliac describes that in 1984/5 he was informed he was HIV positive and had HBV. He had blood tests at STH and was asked to go and see Dr Savidge to get his test results. He thinks this was only around the second time he saw him. He states: '*he put his feet on his desk, lit a cigarette and told me that I was HIV positive. This was the first HIV test that was performed that I know of.*'[103] He was not given any treatment at the time.

82. As with HCV, there is evidence of infected individuals finding out about HIV infections by reading their medical records rather than being informed of their infection by a clinician.

83. Some accounts suggest there was a delay between the positive HIV test result and patients being informed of the diagnosis. For example:

    a. A widow describes that in 1984 her husband went to collect his treatment from STH and was told by a nurse that he was HIV positive. It appears from his records that he was infected sometime between 4 March 1983 and 20

[101] W2336 (2.20)
[102] W2336 (2.20)
[103] W1195 (10)

September 1983.[104] She states that: '*although I can remember hospital attendances for blood tests being stepped up and some prophylactic treatment for PCP being given, it did feel as if we just had to deal with this intrusion into our own lives as best as we could ourselves and had to learn to live with a chronic illness.*'[105]

84. Another widow states that her husband was diagnosed as HIV positive in November 1986 but '*looking at his medical records recently it is clear that the doctors knew that he had it earlier.*'[106] There is 1991 letter in his records that refers to a positive HIV infection between 1980 and 1981,[107] but she states this cannot be correct because there was no HIV / HTLV III test during that period.[108] Prior to the diagnosis of HIV in 1986, he had had some negative tests. She recalls a patch test on his arm in November 1983 '*whereby they put tiny amounts of antibodies into the blood stream rather like an allergy test. I don't know exactly what they put in [his] arm but there were about half a dozen different things to see if the arm would swell up. This would be an indication of whether or not the boy had some kind of immune system to deal with it. I remember that [his] arm blew up very badly and I have kept a picture with the arm blown up.*'[109] Because it blew up, she thought that he had some sort of immunity.

85. Most haemophiliacs at the Centre were informed about their HIV infections in the mid-1980s. However, there is evidence of one infected haemophiliac not being informed of his HIV diagnosis until 1990. A widow of an infected haemophiliac, whose husband was under the care of Professor Savidge at STH, states that her husband found out he had HIV on 31 October 1990 when he was phoned at work by the Haemophilia Centre and informed he was HIV positive. He was told that his CD4 count was low and they wanted to treat him. The witness came home from work and found her husband in tears.[110] She was not offered an HIV test: '*no advice was delivered nor indeed was any support provided of a psychological*

[104] W1020 (22)
[105] W1020 (25)
[106] W2336 (10)
[107] WITN2336004
[108] W2336 (21)
[109] WITN2336003
[110] W0238 (6)

nature to us. I assumed that we could not consider ever having children.'[111] They were later informed that he was also HCV positive '*but again we had no knowledge of the progress or this, and received no support regarding this diagnosis.*'[112]

86. In 1990 another haemophiliac, when he was a young adult, received a letter stating that he might have received contaminated concentrates and he was invited to have an HIV test.[113] He states: '*I was absolutely terrified. The letter arrived at the height of publicity and fear about AIDS, shortly after the tombstone adverts had been playing on the TV.*'[114] He tested negative but at the time did not know he also had HCV.

vCJD

87. Amongst the evidence from infected and affected individuals there is limited evidence about vCJD. Patients received a letter about possible vCJD exposure.[115] The following is a short summary of the meetings attended by Professor Savidge, or a representative on his behalf, on the issue of vCJD.

88. On 20 November 1997 there was an Extra-ordinary meeting of the UKHCDO. Professor Savidge, along with many other haemophilia clinicians, attended this meeting.[116] The meeting was chaired by Dr Ludlam who asked that the content of the meeting should be confidential, as was customary. It was noted that there had been 22 reported cases of vCJD[117] and there was no reliable diagnostic test. It was agreed that recombinant products remained the product of choice and a statement would be drafted and circulated to all Executive Committee members for comment and then publication in *The Lancet*.

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[111] W0238 (8)
[112] W0238 (9)
[113] W1241 (14). The statement doesn't expressly state which hospital this was at. However, within the statement he quotes a letter from Lewisham hospital, so it may be that the letter was not from STH.
[114] W1241 (14)
[115] For example, W0356 (20)
[116] HCDO0000463
[117] It is unclear if this was globally or nationally.

89. On 29 May 1998 the 12th meting of the UKHCDO Executive Committee was held in London. Professor Savidge was represented by Dr M Smith. There was noted to be no confirmed cases in haemophiliacs. It was noted that the government '*had stressed that the risk of vCJD transmission was theoretical.*' Dr Ludlam stated that it was up to individual Centres, in consultation with each other, to decide on the most appropriate concentrate to use.[118]

90. On 7 September 1998 Professor Savidge attended the 12th meting of the UKHCDO Executive Committee held in London. It was noted that there were no cases of vCJD known in haemophiliacs. Dr Ludlam highlighted a new paper studying the possible transmission of vCJD by blood products. Professor Lee and the HIV Working Party agreed to continue to develop the surveillance project.

91. On 1 October 1998 Professor Savidge attended the 30th meting of the UKHCDO, held at Oxford. It was noted that the Executive Committee had released a statement in November 1997 indicating that use of non-UK plasma derived factors VIII and IX concentrates would be likely to reduce the risk of transmission of the infectious agent for nvCJD. The HIV Working Party had been asked to take on the responsibility of the surveillance project for vCJD.[119]

92. On 15 January 2001 the second meeting of the UKHCDO Advisory Committee took place in London. Dr M Smith represented Professor Savidge. At this meeting it was noted that another person who had been a blood donor had been diagnosed with having vCJD. It was decided that UKHCDO needed to set up a mechanism for informing patients. There was debate about what kind of information should be given and to whom. It was agreed that a letter should be produced and all patients should be offered an appointment with a Director, if the patient wanted to have one.[120]

93. On 10 October 2002 Professor Savidge attended the third AGM of the Haemophilia Centre Doctors Organisation, held at Liverpool. During this meeting

[118] HCDO0000466
[119] BART0002368_002
[120] BART0000938

it was noted that there was '*continuing concern about sourced plasma with more reports of vCJD in other European countries*.'

94. On 15 January 2003 there was a UKHCDO Advisory Committee meeting held in London. Dr Rangarajn represented Professor Savidge at the meeting. It was noted that there was a Scottish blood donor who had contributed to the plasma pool and had subsequently developed vCJD. Letters were sent out to all haemophilia patients not just those who had received implicated batches.[121]

95. On 15 September 2003 Professor Savidge attended a UKHCDO Advisory Committee meeting at the Royal Free. At this meeting the Chairman, Professor Hill, informed the committee that there was '*a possibility that all haemophilia centres may not have been made aware of all batches of factor concentrate which were made from donations from individuals who subsequently variant CJD [sic].*'[122] It was felt that the proposed risk score previously made was too conservative.

96. On 9 October 2003 Professor Savidge attended the fourth AGM of Haemophilia Centre Doctors' Organisation, held in Newcastle.[123] The UKHCDO had received correspondence from the National Committee set up to report on the transmission of variant CJD. It was noted that it was '*likely that patients with haemophilia will be considered as low risk from infection and as sources of infection*.' In relation to storage of data, it was stated that if patients had given information to the National Haemophilia Database consent was implied, unless a patient asked for the data to be removed.

97. On 16 September 2004 Professor Savidge attended a UKHCDO Advisory Committee meeting held at the Royal Free. At this meeting a recent publication in *The Lancet* about vCJD following transfusion of a unit of blood from a donor who later died with vCJD was highlighted. The plan was for the Chairman to write to the CJD Incident Panel for clarification on current understanding. There was

[121] BART0000935
[122] BART0000933
[123] HCDO0000502

consensus that the best approach would be to have a blanket approach to the risk of haemophiliacs posed during surgery.[124]

98. At the UKHCDO Advisory Committee Meeting, held on 29 November 2004 at the Royal Free, it was agreed that a Working Party would be established and chaired by Professor Hill. The Centre was represented at this meeting by Dr Madan.[125]

I. Counselling

99. It appears from the available documents that the importance of counselling and psychological support was recognised at STH from quite an early stage.

100. In the context of HIV infections, on 1 October 1985 at the 6th meeting of the AIDS Group, it was agreed that there should be AIDS counselling courses and that '*nurses asked to do this type of work should be senior people who were emotionally stable. Counselling for haemophiliacs was very specialised.*' During this discussion Professor Savidge asked if nurses doing this counselling would get extra pay. He stated that he had already added counselling to the job description of the Centre's haemophilia nurse.[126]

101. Chris Harrington was employed as a clinical nurse specialist at the Centre from 1986 to 1996.

102. In addition to the role of nurse specialist, the Centre also had a psychologist, who specialised in treating people with bleeding disorders. However, it appears that a psychologist was appointed in the late 1990s or early 2000s. It is unclear from the documents whether this was a full-time post and whether she dealt with infected haemophiliacs specifically.

[124] BART0000930
[125] BART0000926
[126] HCDO0000271_090

103. Infected and affected individuals give evidence of being provided with counselling at the Centre. For example:

a. An infected haemophiliac is very positive about the psychological support he and his wife received '*from day one after my diagnosis by St Thomas'. We needed to have counselling and we were positively encouraged to get it. It was provided at the Centre by a specialist senior psychologist, Dr Heather Rawle. An aromatherapist even came especially from Brighton to help treat us. She was lovely.*'[127]

He further states:

'*This support has continued for my wife in the period leading up to and during my treatment. Mine has continued and carries on to this day. It will carry on until I feel I don't need it anymore. I'm not ready to give it up yet.*'[128]

'*As soon as I have attended other centres and hospitals for treatment, where the clinicians do not specialise in work with haemophiliacs, I have that the care and caring attitude seem to fall apart a little sometimes. This service should be available to all victims of the contaminated blood tragedy not just haemophiliacs.*'[129]

b. A child of an infected haemophiliac describes attending the Centre to undertake counselling.[130] She states that it would have been useful to have counselling support during her father's treatment with Interferon.[131]

104. However, the witness evidence received by the Inquiry also suggests that many infected individuals and their families were not provided with counselling. For example:

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[127] W0216 (147)
[128] W0216 (148)
[129] W0216 (149)
[130] W0797 (10)
[131] W0797 (17)

a. A widow, whose husband was informed of his HIV infection in 1990, states that she was not given any counselling: '*to this day I have never received any psychological support from St Thomas' arising out of the tragic events that occurred*'. She has only received limited supported from the McFarlane Trust.[132]

b. An infected haemophiliac had three years of counselling in 1992 but paid for it himself.[133]

105. Other witnesses state that the offer of counselling came too late or was inadequate. For example:

a. One infected haemophiliac states '*I was not offered [counselling] and no-one asked after our welfare at the time of being told I was infected. As the HCV symptoms got worse they should have told me, "stop being so stoic, we think you might need some help".*'[134] He was offered support when he as on Interferon. '*I definitely think the support was inadequate and doctors should have been aware of that inadequacy.*'[135]

b. A widow states that she arranged to see a psychologist herself. This was paid for by the money she received from the EIBSS.[136] She was offered some counselling by the hospice where her husband died and they had had *'a little'* counselling at St Thomas' with Chris Harrington.[137]

106. A minority of witnesses state that they were offered counselling but did not take it up. Another minority state that even if they were offered counselling, they would not have taken it up.

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[132] W0238 (26)
[133] W1490 (46)
[134] W0356 (54)
[135] W0356 (55)
[136] W2336 (7.3)
[137] W2336 (5.38)

J. Research

(i) Pre-1979

107. Professor Ingram produced a significant body of published literature on haemophilia. His obituary refers to the publication of more than 100 papers and several books.[138]

(ii) Post-1979

108. As set out above, Professor Savidge was involved in research on behalf of pharmaceutical companies on the efficacy of new blood products. He was also involved in clinical trials for new drugs. For example, during the 19th meeting of the UKHCDO on 25 September 1987, Professor Savidge encouraged his colleagues to enter their patients into a trial on AZT.[139]

109. In relation to HIV, a report by Charles Rizza on '*An Epidemiological study of AIDS'* in January 1983 demonstrates that Professor Savidge was carrying out virological studies on patients treated with 'suspect' batches of factor VIII concentrate.[140]

110. However, his most influential publications (in conjunction with other clinicians) were about the impact of heat-treating factor VIII. In 1985 he was a co-author of a paper entitled '*Transmission of non-A, non-B hepatitis by heat-treated factor VIII concentrate'*, which was published in *The Lancet.*[141] In the same year he was an author of the paper entitled '*Wet heating for safer factor VIII concentrate?*' also published in *The Lancet.*[142] In 1987 Professor Savidge published a paper along with Drs Kernoff, Miller, Machin, Dewar and Preston

[138] https://www.theguardian.com/society/2004/may/28/health.guardianobituaries
[139] PRSE0004377. See also RHAL0000433
[140] HCDO0000414
[141] Colombo, M., Carnelli, V., Gazengel, C., Mannucci, P.M., Savidge, G.F., Schimpf, K. and the European Study Group, *Lancet*, 2, 1, 1985: CBLA0002098
[142] Kernoff, P.B.A., Miller, E.J., Savidge, G.F., Machin, S.J., Dewar, M.S. and Preston, F.E., Lancet, 2, 721, 1985.

entitled: '*Reduced risk of non-A non-B hepatitis after a first exposure to 'wet heated' factor VIII concentrate.*'[143]

111. Within the available documents, it appears that Professor Savidge raised a concern about patient consent and the use of patient data. It is important to stress that it appears that such objections came in 1990 onwards, rather than during the 1980s.[144] For example, on 28 February 1990 Professor Savidge wrote to Mrs Fletcher at Oxford, in the context of a study of 8Y and stated:[145]

'*I have some reservations concerning sending you samples for Hepatitis C, particularly in view of possible litigation and the ethics of the clinical trial. I feel that before one can take such samples one should secure a revised clinical trial protocol which should be cleared by the local ethical committee and a patient consent form should be prepared. A further issue involves what we tell the patient/parents regarding the test and the interpretation of the results we received.*

As you can see, this whole area raises a number of issues which have to be resolved now, and if not could lead to a embarrassment at a later stage. I hope you have the opportunity to discuss these matters with Dr Rizza.'

112. The documents reveal an ongoing dispute between Professor Savidge and the UKHCDO hierarchy about data protection issues. For example, on 4 September 2002, he responded to Dr Hay in relation to data protection. Professor Savidge was unhappy about what had been written in the UKHCDO minutes. He wrote:[146]

'*I am a little surprised at the content, as you seem to have misunderstood, quite comprehensively, my views expressed in previous correspondence ... As my views on Data Protection issues are well known to most of the audience at the meeting, little would have been grained by reiterating the obvious.*'

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[143] Published in the *British Journal of Haematology*, 67, 207-211, 1987.
[144] Professor Savidge stated in the 29 September 1995 meeting of the UKHCDO that legal advice should be taken on the issue of consent.
[145] OXUH0002131_007
[146] HCDO0000266_046

113. He then invited Dr Hay to submit to him (Professor Savidge) a '*business case*' for the future funding of the Data Collection programme.

114. On 23 September 2002 Professor Savidge wrote to Professor Frank Hill about the same issue.[147]. He stated:

'*As you know, I have for many years withheld sending data to the UKHCDO, due to the fact that personal data has been used in manual systems. No patient consent has been obtained and no mandate from the Department of Health to the UKHCDO to collect this data has been made available.*'

115. Professor Savidge was willing to provide this information once the Department of Health had informed his Chief Executive to pass on the data to UKHCDO, when appropriate datasets had been approved by the Department of Health and when patient consent had been obtained.

116. In October 2002 a UKHCDO data management group met and discussed issues over consent under the Data Protection Act. They noted that Professor Savidge had criticised a patient information leaflet produced by the group: '*some of the points he makes are considered serious but others not so.*[148] It was discussed whether implied consent was enough and it was noted that:

'*Professor Savage [sic] is the only person who has not taken this view and the project should go ahead without allowing him to interfere*'.

117. In November 2003, in the minutes of the UKHCDO Management Group it was noted:

'*A letter written by Professor Savidge about the choice of recombinant factor VIII and IX and distributed to his patients was discussed. The general impression is that Professor Savidge is misinforming the patients and some of the facts he listed are inaccurate. Dr Schonfield feels that information given to the patients is wrong*

[147] HCDO0000266_126
[148] HCDO0000109_026

and untrue. The Haemophilia Society had received calls from patients about his letter and had written to Professor Savidge about it.'[149]

118. In 2006 the legal department of STH received correspondence from Dr Charles Hay from UKHCDO, requesting data from STH for the purposes of the National Haemophilia Database.[150] The correspondence stated that STH had not supplied data for several years '*as Professor Geoffrey Savidge has expressed concerns about compliance with the Data Protection Act. I attach the following as evidence that we are complying with the act and are appropriate staffed…'.* The author of the letter stated that he assumed the Trust no longer had concerns about data compliance because STH had submitted extensive data about haemophiliac patients in relation to Recombinant over the past 3 years. There was a suggestion that removal of Comprehensive Care Centre status should follow due to the failure to provide data for the last 3 triennial audits. In response, in June 2006, correspondence from STH set out a concern that the Centre was being asked '*to disclose confidential patient data without either the permission of patients or a clear assurance that the relevant regulations are being complied with.*' This decision was on the basis of '*detailed legal advice'*.[151]

K. UKHCDO

119. Professor Savidge attended his first UKHCDO meeting on 15 October 1979 where he was confirmed as a Reference Centre Director.[152] Meetings were frequently held at STH. Professor Savidge chaired a number of committees of the UKHCDO:

a. At the 18th meeting of the UKHCDO, in October 1986, Professor Savidge was confirmed as Chairman of the Haemophilia Centre Directors' Committee on Re-organisation.[153]

[149] HCDO0000002_066
[150] HCDO0000002_031
[151] HCDO0000002_032
[152] PRSE0000539
[153] PRSE0004317

b. At the 19th meeting of the UKHCDO, in September 1987, Professor Savidge was described as the Chairman of the Constitutional Working Party.[154]

c. At the 12th meeting of the AIDS Group of the Haemophilia Directors, held at STH in January 1987, Professor Savidge was made Chairman of the Working Party on von Willebrand's disease.[155]

d. At the 21st meeting of the UKHCDO, in October 1989, Professor Savidge, along with Drs Jones, Ludlam and Rizza, were noted to have set up a group on litigation in response to the claims being brought against the Secretary of State, Regional Health Authorities and the Committee for Safety of Medicines in front of Ognall J.[156]

120. Contemporaneous records of UKHCO meetings demonstrate that Professor Savidge often took a different view to his fellow Centre Directors, particularly on the issue of heat-treated products. In his evidence to the Archer inquiry on 19 November 2007, Professor Savidge described the UKHCDO as '*more or less [of] a club, rather than a formal organisation, because it really didn't have any affiliations with any of the learned societies or with the Royal Colleges, it was not part of NHS.* '[157] He described it as being made up of ten '*main players*' and '*those players were those centres that were considered to be the largest and the most influential*'.

121. He stated:

'*I think quite a lot of the information -- there was a lot of information that was fed back as and when required on an ad hoc basis on a number of instances. Quite a lot of it went unheeded, particularly some of the projections, particularly some of the concerns with respect to what was going on with immune abnormalities in a lot of patients during 82/83. But there was this all-pervasive thought that,*

[154] PRSE0004377
[155] HCDO0000271_045
[156] HCDO0000015_035
[157] ARCH0000011

because there were fewer donors in the BPL product, it was intrinsically safer but not quantifiably safe.'

122. He was critical of the impact of UKHCDO:

'It was not, shall we say, very much sort of the type of meeting where one could discuss things. It was really information exchange. They set up their own working parties, they presented -- in fact I headed up a few working parties and one did bits and pieces, but, really, at the end of the day, it didn't make much of a contribution because it was very difficult to get anything published that had UKHCDO on it, because invariably it was going to be statistical, it was not really going to influence any form of general medical people. You would not find a renal physician really getting anything about haemophilia, you would not find that, and also the specialist journals thought it was too simplistic. It was very much a sort of DIY job: let us keep the smaller haemophilia centres, which made up 80/90 per cent of the body, with information about what currently is being done nationally on a national basis.

123. He stated:

'*We had very little feedback as a member of the UKHCDO from any other committees, particularly the more influential committees, because there was unofficially -- there was an arrangement of an unofficial delegation whereby the chairman, who sat on all these committees and was so busy changing hats throughout the course of the day from one committee to another, he was really informally delegated to be a representative, to explain the feelings of the UKHCDO or his interpretation of the feelings of the UKHCDO, which we never found out about because we never saw any meetings back, and we had very few reports back about actually what he said, what they answered and what actions were taken. We had no idea.*

So in fact we were functioning more in a sort of information-fed vacuum. And for my purpose, I have a problem with that. That is why I decided to do – go the heat-treated way much earlier -- about two or three years earlier than anybody else,

because I was not prepared to wait around for somebody to tell me that it would be better to use a Crown immune, approved product that I knew was contaminated in preference to a product that I knew had gone through formal FDA-type testing, looking at logs of virus -- model viruses and everything else to see -- and with prior clinical data to show it looked to be infinitely safer. So we swung into that much earlier, to the concern of lots of people'.

124. He further criticised the leadership of the UKHCDO:

'*... certainly from my viewpoint, I think that there should have been far more stringent and dominant leadership from the doctor's side than had currently existed. It was very much, "Let us cobble together some sort of compromise so everybody is happy", which was fine if you are not playing around with a lethal disease.*'

L. The Haemophilia Society

(i) Pre-1979

125. The available documentation suggests that Professor Ingram was a key figure in the Haemophilia Society. During the 1970s he regularly attended meetings of the Haemophilia Society[158] and was a member of the Society's Medical Advisory Panel. He also received grants from the Society.[159] He received the Macfarlane award of the Haemophilia Society.[160]

(ii) Post-1979

126. As with other Centre Directors, Professor Savidge received funding through the Haemophilia Society.[161] In addition, some grants were awarded directly to the Centre. For example, in April 1982, the Haemophilia Society gave a donation of

[158] For example, PRSE0002268.
[159] HS0C0022737
[160] https://www.theguardian.com/society/2004/may/28/health.guardianobituaries
[161] For example, in November 1980, STH received £4,500 for a Mini-Gammacounter for research in co-operation with GOSH, the London Hospital and the Royal Free. In May 1983, £8,000 was awarded for an AIDS-related application for a MSLO.

£7,200 for a refrigerated centrifuge. This was met from the funds provided by an anonymous donation of £20,000 as the Centre had been mentioned in connection with that donation.[162] In November 1986 Professor Savidge was successful in securing funding for a two-year project on von Willebrand's disease. He was granted £14,477 for the first year.[163]

127. However, not all applications for grants were successful. In June 1984 the Haemophilia Society rejected an application from Professor Savidge and Mr Smith for £5,470.50 to supply various pieces of orthopaedic equipment on that basis that '*it was felt that this was of a standard nature and that there was no unusual feature of research involved*'.[164] In July 1984, Professor Savidge's request for £10,772 to fund an AIDS research programme was referred to the Medical Advisory Panel.[165] However, the decision was made not to fund this project.[166] In September 1984 the Haemophilia Society rejected a grant request for a further £10,000, having given a grant in 1983.[167] The object of the study was to continue work on cell mediated immunity in haemophiliacs. The application had been referred to the Medical Advisory Panel who presented a divided opinion. The recommendation from the Executive Committee was that no grant be awarded since it was felt that '*the work, while valuable, was standard and should now be funded from hospital or health authority budgets. This recommendation was approved unanimously, having been proposed by the Chairman and agreed nem con.*'[168]

128. In addition to financial support, Professor Savidge also spoke at Haemophilia Society events. For example, in April 1982 Professor Savidge appeared on the panel at the Haemophilia Society's AGM discussing '*the ways in which modern therapy can prevent joint damage.*'[169] He also attended the Haemophilia Society's annual conference.[170]

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[162] HSOC0019918_035
[163] HSOC0029476_065 and HSOC0019923_019
[164] HSOC0029476_037
[165] HSOC0029476_038
[166] HSOC0029476_040
[167] HSOC0019923_010
[168] HSOC0019923_010
[169] HSOC0023305
[170] For example, the Bournemouth Conference in March 1986: ARMO0000499

129. Professor Savidge seems to have been critical at times of the information produced by the Haemophilia Society. There are two examples of this.

130. First, at the 21st meeting of the Haemophilia Reference Centre Directors, held at STH on 30 September 1985, concerns were raised about the information produced by the Haemophilia Society in their Hemofact sheets in relation to the advice that HTLV III patients should not inform their GPs of their diagnoses. During this meeting Professor Savidge suggested that the Reference Centre Directors should advise the Haemophilia Society on the information to be circulated.[171]

131. Second, in October 1991, Professor Savidge also raised concerns about material produced by the Haemophilia Society Bulletin about 'so called High Purity products.' At the 23rd meeting of UK Haemophilia Centre Directors it was agreed that the Directors would send a letter or paper to the Haemophilia Society for publication in their Bulletin in response to the articles on high purity factor VIII.[172]

M. Treloar's

132. There is evidence to demonstrate that Professor Savidge was being informed about paediatric patients by Dr Wassef of Treloar's. For example, one letter from 12 December 1979 refers to the progress of a patient who had had no bleeds that term and was on prophylaxis in the form of factor IX. The correspondence refers to that child's SGOT[173] levels being '*persistently raised*'.[174]

133. It appears from UKHCDO records in 1981 that Professor Savidge was supportive of the move to designate Treloar's its own Haemophilia Centre.[175]

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[171] PRSE0004271
[172] HCDO0000250_006
[173] Serum glutamic-oxaloacetic transaminase, a liver enzyme.
[174] TREL0000169_021
[175] HCDO0000250_057

N. Litigation and complaints

134. In his evidence to the Archer inquiry Professor Savidge described that he was '*involved in the defence in the haemophilia class action which took place in the early 80s*' on behalf of the Department of Health.[176] He further stated that '*for [his] sins*' he acted on behalf of the claimants in the High Court litigation for HIV and HCV.[177]

135. The available documents demonstrate that on 9 October 1989 Professor Savidge, alongside Drs Jones, Ludlam and Rizza were part of a Regional Haemophilia Centre Directors' Committee addressing litigation.[178] His statements, particularly at the Archer inquiry, should perhaps be read in that context.

136. On 12 February 1990, during the 19th meeting of the AIDS Group held at the Royal Free, there was a discussion about potential litigation by haemophiliacs arising out of hepatitis. There was a discussion about consent and Professor Bloom was noted to have said that he did not see why permission needed to be requested for HCV testing '*as this was just another LFT.*' In response Professor Savidge is noted to have said that '*patients were now becoming more and more conscious of what tests were, so he would advise caution at present.*'[179]

137. In 1999 Professor Savidge was suspended from STH after a complaint about his behaviour at a Moscow medical convention. It was reported that complaints were also made about his management style. The allegation was denied by Professor Savidge as groundless.[180] It appears Professor Savidge was later cleared of any wrong doing by an internal investigation at STH.

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[176] The documents show that Professor Savidge was unhappy with the Defence's pleading, which stated that heat-treated factor VIII was not used until the end of 1984 when he had been using it in 1983: HCDO0000271_014
[177] ARCH0000011
[178] HCDO0000015_035
[179] HCDO0000015_014
[180] HSOC0028862

O. Medical records

138. In correspondence to the Inquiry, the Medical Director's Office has confirmed that the Centre had no '*specific policy on retention and destruction of documents*.' Until 2018 all patient medical records were kept at the Centre '*and only sent to off-site file on the death of the individual. With the advent of electronic records within the Trust, all paper files have been sent offsite in-line with Trust policy.*'[181]

139. Infected individuals and their families have provided evidence about being unable to obtain full copies of their medical records. For example

a. The wife of an infected haemophilic states that: '*Apparently, [my husband's] request for information forms went to St Thomas' and gave all the info they had on the relevant people, but the response from the Haemophilia Centre part of the hospital didn't include the relevant, pink haemophilia department's forms and notes. I am worried that if St Thomas', a good hospital, can manage to not keep adequate records and return all the requested information, then it could surely happen elsewhere.*'[182]

b. An affected widow describes a time limit for obtaining her late husband's medical records for US litigation. She had '*an awful job trying to get hold of them.*'[183]:

'*When I initially approached St Thomas', I was told it was all too long ago and that the records had probably been destroyed. In fact, I was able to obtain some of [his] records through the National Haemophilia database. Unfortunately, they were sent to St Thomas' for security reasons and I had to go to St Thomas' to collect them. When I arrived there, I had an unfortunate incident with the Director of the Haemophilia Centre, Doctor Savidge, who had been [her late husband's] doctor. Unfortunately, instead of keeping our conversation private in a closed office, this doctor decided to open the medical*

[181] Dated 17 July 2019
[182] W0780 (106-108)
[183] W2336 (8.3)

notes in the reception area and talked in a very loud voice about the contents while people were passing by. This greatly upset me and I took the notes away and went to a toilet and cried for about two hours afterwards.'[184]

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2 October 2020

[184] W2336 (8.4)