Witness Name: Dr Patricia Hewitt
Statement No.: WITN3101006
Exhibits: WITN3101007-008
Dated: 25 October 2021

INFECTED BLOOD INQUIRY

SECOND WRITTEN STATEMENT OF DR PATRICIA HEWITT

I provide this statement in partial response to an amended request under Rule 9 of the Inquiry Rules 2006 dated 14 August 2020.

I, Dr Patricia Elizabeth Hewitt, will say as follows: -

Section 1: Introduction

1) Name, address, date of birth and professional qualifications.

1. My name is Dr Patricia Elizabeth Hewitt.

2. My date of birth is GRO-C 1951.

3. My professional qualifications are MB ChB (Leeds), FRCP, FRCPath. I trained in medicine at Leeds University. I qualified in 1975.

1) Employment history including the various roles and responsibilities held throughout my career, as well as the dates.

1. I attach [WITN3101007] a copy of my curriculum vitae and List of Publications.

4. In brief, I was appointed to a Consultant Haematologist post at the (then) North London Blood Transfusion Centre (NLBTC) in **1984**. NLBTC was one of 14 Regional Blood Transfusion Centres which together made up the National Blood Transfusion Service. I occupied a role in charge of donor health and blood collection. One of my first responsibilities was to implement within NLBTC the Confidential Unit Exclusion (CUE) questionnaire, based on one in operation at the New York Blood Centre, designed to encourage blood donors at risk of HIV infection to confidentially indicate to the blood service that their blood donation should not be used. The questionnaire had been devised by Professor Dame (then Doctor) Marcela Contreras and Dr John Barbara, senior colleagues at NLBTC, after they had made a trip to the New York Blood Centre to study the operation of the questionnaire to consider whether we should adopt this practice.

5. In **1985**, on introduction of HIV screening of blood donations, I managed the HIV lookback programme for NLBTC, which covered the area of the North West Thames Regional Health Authority (central and north west London and the north west Home Counties: Bedfordshire, Hertfordshire and parts of Berkshire).

6. Subsequently, I was Lead Consultant in Transfusion Microbiology for the London and South East Zone of the National Blood Service (NBS) from **1995** to **2000**, and National Lead Consultant in Transfusion Microbiology from **2000** to **2005**. In these positions, I managed the HCV lookback programme for NLBTC and the South Thames Regional Transfusion Centre (**1995**) and the national HTLV lookback programme (**2002**).

7. I also was Principal Investigator, with Professor Robert Will of the National CJD Research and Surveillance Unit, of a research project

(the Transfusion Medicine Epidemiology Review [TMER]) which commenced in **1997** and was designed to investigate whether there was any link between blood transfusion and CJD.

8. After the formation of the National Blood Authority (NBA) and then the current organisation NHS Blood and Transplant (NHSBT), I retained the national (clinical) lead role for Transfusion Microbiology until my retirement from full time employment in **June 2018**. I continued in the work of the TMER, and also contributed to a study (**2012/2013**) looking at the blood safety implications of hepatitis E virus (HEV). The results of this study led to the introduction of HEV screening of blood donations.

9. The national (clinical) lead role for Transfusion Microbiology involved overall responsibility for the management of blood donors who were found through the routine screening of blood donations to be infected with blood-borne infections, and overall responsibility for managing investigation of reported cases of possible transfusion-transmitted infection. In addition, I was required to ensure that clinical matters relating to transfusion microbiology were represented in any relevant NHSBT initiatives and projects.

10. Prior to my employment with NHSBT and its predecessor organisations, I was employed as a Lecturer in Haematology at Middlesex Hospital Medical School, and was involved in treatment of patients with a variety of haematological disorders, including clotting disorders.

11. I am now retained by NHSBT to provide occasional assistance and advice as and when required.

2) Membership of past or present committees/groups relevant to the Inquiry's Terms of Reference.

1. Joint UK Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee ("JPAC") Standing Advisory Committee on Care and Selection of Donors (SACCSD);

12. JPAC Standing Advisory Committee on Transfusion-Transmitted Infection (SACTTI);

13. UK Blood Services Prion Assay Working Group;

14. Serious Hazards of Transfusion ("SHOT") Steering Group;

15. CJD Clinical Incidents Panel;

16. Advisory Committee on Dangerous Pathogens ("ACDP") Transmissible Spongiform Encephalopathy ("TSE") Risk Assessment Working Group;

17. ACDP TSE Risk Management Working Group;

18. ACDP TSE Sub Group;

19. Council of Europe Committee of Experts on Blood Transfusion and Immunohaematology;

20. Skipton Fund Appeal Panel;

21. EIBSS Appeal Panel.

Section 2:

22. I make this statement in partial response to the request to NHSBT to provide:

(1) evidence on the work of the organisations listed below to identify, trace, and warn recipients of blood transfusions who are or were at potential risk of Hepatitis C virus ("HCV") and HIV (references to HIV include HTLV-III):

a) **The National Directorate of the National Blood Transfusion Service (1988-1993);**
b) **The National Blood Authority ("NBA") (1993 – 2005);**
c) **NHSBT (2005 to present date);**
d) **Joint UK Blood Transfusion and TissueTransplantation Services Professional Advisory Committee ("JPAC") (1999 – to present date).**

23. I have been identified as a person appropriate to address questions **1, 4, 5, 6-9**, and **23** and to add to responses on questions **14-19 inclusive** and **27** of the amended Rule 9 request dated August 2020.

QUESTIONS AND RESPONSES

Question1. In the document titled 'Draft Report from the MSBT Subcommittee' (NHBT0005791 page 2) discussing the merits of introducing an HCV "Look-Back" policy, it is stated:

"Despite these reservations it is recognised that there is a duty of care that needs to be exercised towards these patients and the implicated donors"

a. When was this duty of care to patients and donors first recognised by NHSBT?

b. Provide an account of how this duty of care was discharged:

i. prior to the look-back in 1995; and

ii. in respect of those patients not identified by the look-back exercise.

24. As I have set out above, in my first Consultant role with the blood service from 1984 I had responsibility for donor health and blood collection at NLBTC. From the start of my career with the blood service it was emphasised that we owed a duty to *donors* who were altruistically giving up their time and donating their blood for no benefit to themselves and without whom there would be no blood service. It was also recognised that we owed a duty to the *recipients* of blood and blood products in so far as was within our control, to ensure the supply was as safe as possible.

Historical Background

25. It was clear from the early days that the blood service had a double duty – the need to protect both donors and recipients. For example, with respect to donors, the blood service always followed up carefully any donor who experienced side-effects of blood donation, whether this might involve a bruise at the site of the blood donation, a faint during or after donation, or other more serious consequences. The follow up could involve a face to face visit in the case of a badly bruised arm, and advice on management. The service would also advise on the advisability of future donation, for example in the case of a severe faint.

26. Donors who were found to have low iron levels at presentation for donation received appropriate advice, with referral to the GP if necessary. It used to be said that the blood service was responsible for

the early diagnosis of colon (bowel) cancer in one or two blood donors per year, through the careful management of those with low iron levels and referral to the GP for further investigation. Occasionally, possible serious conditions such as chronic myeloid leukaemia and auto-immune anaemia were detected through testing after donation, or at the time of blood processing, and the donor would be contacted, informed, and be referred to the GP.

27. In the case of transfusion-transmissible infections, blood donations had been tested for evidence of syphilis infection since the inception of the service in the 1940s, and donors found to have positive tests were notified and advised about the need for further investigation and treatment. There were also further actions with respect to jaundice, as I describe in more detail below [paras 33-86].

28. Blood service consultants contributed to national guidelines aimed at ensuring as far as possible the safety of donors and recipients and standardising practice, given the fragmented nature of the service across 14 Regional Transfusion Centres all funded and accountable to different Regional Health Authorities.

29. On **28 July 1988** the National Directorate of the National Blood Transfusion Service ("NBTS") was formed, with the aim of formally co-ordinating the work of the Regional Transfusion Centres. The first formal publication of national guidelines (which later became the Red Book) was in **1989** [NHBT0000027_030] but that was a codification of knowledge and practice that had been built up, discussed and shared over decades.

30. Dr Bill Wagstaff as Chairman of the Joint UK Blood Transfusion Service and National Institute for Biological Standards and Control Liaison Committee (JPAC) wrote the introduction to the Guidelines in

September 1989. The Guidelines were based on quality assurance and standard operating procedures, including those which applied at both blood and plasma donor sessions. They included codified Guidelines for the selection and exclusion of donors. The donor guidelines were based on practices which had been developing ever since hepatitis was first observed in the **1940s** as a result of occurrences in transfused soldiers during World War II, as described below.

31. On **16 January 1943** a "memorandum prepared by Medical Officers of the Ministry of Health" was published in The Lancet entitled "Homologous Serum Jaundice" [NHBT0000091_011]. The article listed details of a number of historic incidents where jaundice had been noted following administration of a vaccine. It noted that "*unfortunately, as is to be expected when special interest is aroused only long after the event, very few clinical notes are available. In addition, there is the difficulty of judging whether serum from any given batch was or was not a factor in the subsequent development of jaundice".*

32. The article also stated that *"in no single case of hepatitis could it be proved that natural causes were not operative, but on the epidemiological evidence the majority of the investigators concluded that the causal factor resided in K60 and K488 (both batches of measles serum)…the appearance of this phenomenon was anticipated at the Ministry of Health…a meeting of the principal blood transfusion officers was called to inquire whether this was an isolated case or whether transfusion was more frequently followed by hepatitis…since [*the meeting*] the condition has been observed at three other hospitals and the total of known cases following transfusion is now 12".*

33. Under the "*Comment"* section, the article stated "*the examples of homologous serum jaundice collected in this paper make it clear that*

the subject is one of major importance. Our understanding of the mechanism has not advanced since 1937…one conclusion is now, however evident: any doubt as to the reality of the association is removed by the frequency with which hepatitis has followed the injection of human blood products. The probability that further cases will occur, particularly after transfusion, must be faced. It is unlikely that the problem will be easily solved or that a radical method for preventing the phenomenon will readily be found. Since there can be no question of withholding transfusion in emergency, ***prevention will for the time being depend on the identification and withdrawal of icterogenic batches of serum and plasma.*** *Timely identification may be possible only under exceptional circumstances:* ***it will depend on the care with which batch numbers are recorded at the time of transfusion, and on the speedy notification by practitioners to transfusion officers of cases of jaundice following, after a long interval, the injection of blood products'.*** [my emphasis]

34. On **26 March 1945**, a meeting was held at the Ministry of Health [DHSC0100008_105]. Those attending included Sir Wilson Jameson as Chairman, Drs Drury and Panton from the Blood Transfusion Services, Dr A Stewart from the MRC and Drs Hutchinson, Bradley and MacKenzie of the Ministry of Health (with others representing each of the Armed Forces, and both the Canadian and American Army). The Chair opened by indicating that the Ministry of Health proposed to carry over into peacetime "*something of the transfusion arrangements that had been in operation during the war*". However, it was beginning to appear that a large number of transfused persons subsequently developed jaundice and that some died.

35. It was noted that: *"information concerning this puzzling condition was at present being collected independently by several persons and* [the Chair] *was anxious to establish an orderly system of accumulating and*

using the information". After considering the information available from each of the attendees, it was summed up that *"there was some reason for believing that hepatic jaundice may follow blood transfusion and that some transfused persons died of hepatic necrosis, but the position was not clear".*

36. Under "*Propaganda"* it was noted that *"it was agreed that nothing which might cause public alarm or discourage transfusion in necessitous cases should be done"* but it was also noted that *"sometimes transfusions were performed unnecessarily and it might be wise to send some publication to institutions"*

37. From that point on, the development of jaundice following blood transfusion was followed up. From the start, there was a focus on good transfusion practice (only using blood transfusion when it was absolutely necessary, ensuring the recording of batch numbers etc), and highlighting the importance of using whole blood rather than dried plasma, which came from pools obtained from many different donations. It should be noted that, at this time, blood was collected in glass bottles. Separation into blood components was not possible until plastic blood collection bags were introduced at a later date. In the period in question, all blood transfusions were provided as whole blood. A proportion of donations had the plasma removed, pooled, and dried, and all plasma was in the form of dried plasma. This is not the same product as the current day plasma (FFP).

38. On **13 August 1946**, Dr Robb-Smith at the Radcliffe Infirmary, Oxford, wrote to Dr Panton at the Ministry of Health [DHSC0100008_189]. He advised that at a recent meeting of the Association of Clinical Pathologists, Dr J Vaughan had presented a paper on the follow-up of plasma and blood transfusions for development of jaundice. Dr Robb-Smith queried the position in respect of legal liability on the

hospitals and the transfusion service "*because no doubt quite a lot of plasma is given not from clinical necessity but from clinical convenience and in such cases, where in fact the better treatment would have been blood, the question does arise as to liability".*

39. Dr Panton referred this query to Miss Long at the Ministry of Health and his note summarises the situation at that date (**22 August 1946**) [DHSC0100008_191]*: "while homologous serum jaundice follows the use of whole blood in very few of the recipients, the use of dried plasma is followed by the development of jaundice in about 10% of those receiving it. This incidence is probably halved if plasma is used which is made from plasma pools derived from the blood of only ten donors, instead of from large pools … this lower incidence has yet to be confirmed by the completion of surveys now in hand. All plasma now being dried for the Ministry by the MRC is made from small pools but "large pool" plasma is still in use. The jaundice is usually mild, and only rarely fatal … it must be assumed that all batches … are potentially icterogenic until experience has shown that they are not …* ***in discussing this problem with the CMO it was suggested that all users of dried plasma provided by the BTS should be warned of its potential dangers so that they would use the material carefully and after full consideration of the relative risks involved".*** [my emphasis]

40. Miss Long obtained legal advice from Mr J M Keidan, Solicitor [DHSC0100008_192] dated **29 August 1946** that:

"*it will be difficult to make the BTS liable [where plasma has been issued by the BTS to a hospital and the hospital have then issued to a patient] if they give full warning of the potential dangers and they take all reasonable steps to withdraw or destroy any batch which they know or ought reasonably to know is particularly dangerous".*

41. The advice also recommended the recording of batch numbers at the time of use in order that the batch could be withdrawn if any case of jaundice developed. Finally, it also stated: "I think that a [clinician] who gave plasma to a patient would not be liable for any jaundice … if after full consideration of the relative risks involved he honestly and reasonably decided that the risk was worth running in the circumstances, and took all reasonable steps to reduce the risk to the lowest possible level. I do not think that 'clinical convenience' would be a useful defence".

42. On 21 September 1946, the British Medical Journal published a study: "The incidence, incubation period and symptomatology of homologous serum jaundice" authored by Dr N Spurling, Dr J Shone and Dr J Vaughan [RLIT0000052]. The study followed-up patients five months after they had received a transfusion of blood or plasma in the North West London area. It found that among surviving patients, 7.3% of those receiving pooled serum or plasma developed jaundice. None of the patients receiving whole blood developed jaundice. The character of the jaundice was, with one exception, mild and it was noted that "the symptomatology and incubation period noted were in accord with previous accounts".

43. On 26 September 1946, Dr Aubert, RBTO (Regional Blood Transfusion Officer) in Sheffield wrote to all Medical Superintendents, Pathologists and those in charge of Blood Banks and Plasma Stores (it is not clear if this was just in his area) highlighting the BMJ article and stating "hospitals are strongly advised to use blood rather than plasma wherever possible, until the problem of producing a plasma free from this risk has been solved. It is desirable that the use of plasma (or serum) should be confined to those cases where the administration of

blood products is essential, but the use of whole blood would be less effective or impracticable". [DHSC0100008_212]

44. On 7 August 1947, Mr Barnett Janner, MP for Leicester West, asked the Minister for Health Mr Aneurin Bevan how many deaths had occurred due to blood transfusion and whether in all cases the blood of donors was examined and passed as healthy before use. Mr Bevan responded that "the answer to the first part is not known. On the second, while there can be no absolute guarantee from tests, all possible precautions are taken by testing every sample of blood before transfusion and by questioning donors about their health". [RLIT0000719]

45. Dr Maycock, who was consultant adviser on blood transfusions to the Ministry of Health from 1946-1978, had provided this detail beforehand (by note of 1 August 1947). He noted that there were 'no reliable statistics giving the number of deaths attributable to transfusions, hospitals being under no obligation to report to the Blood Transfusion Service deaths attributed to transfusion or the number of cases transfused'. He also included in his note that "There are at present no methods of detecting an individual capable of transmitting jaundice in his blood. Each donor is asked if he has recently suffered from jaundice and all plasma is now made from small batches of blood and each of it is numbered so that if a case of jaundice is associated with a certain batch of plasma, all bottles of that batch are withdrawn. In addition, all hospitals have been informed that the use of plasma involves a risk of jaundice and that its use should, therefore, be restricted to transfusion in emergencies. The widest publicity has been given to this in the medical press". [DHSC0100009_018]

46. On 21 October 1947 Dr Maycock wrote to Dr Clegg, the Editor of the British Medical Journal, stating "there still seems to be a large number

of doctors who do not appreciate that both plasma and serum carry a risk of homologous serum jaundice … we are gradually increasing the output of small-pool plasma which will probably significantly diminish the risk of the disease; meanwhile, we label each bottle clearly with a warning of the risk which may attend its use and try by other means to make the profession realise the dangers of its indiscriminate use. We are particularly keen to have cases reported to the Regional Transfusion Centres, so that bottles of suspected icterogenic batches can be withdrawn. This object is often defeated by the omission to make a record of the bottle numbers in the case notes … I have been told by the [RBTO] at Bristol that descriptions of 3 cases are being submitted to you for publication in the BMJ and I wondered whether you would consider this an appropriate time for a leader or annotation on the disease". [DHSC0100009_066]

47. On 14 January 1948, Dr Maycock chaired a meeting of the RBTOs and reported that in the last 18 months 78 cases of haemotogenous hepatitis had been reported to the Ministry of which 25% had died, and they did not have any record of the outcome of half of the remaining cases. Dr Maycock had prepared a formal report form to be used and all RBTOs agreed to try to collect information on such cases. It was also discussed that the parents of a patient who had died following transfusion were considering taking legal action against the Ministry. Dr Maycock again impressed the need to ensure all hospitals were warned of the dangers of the indiscriminate use of plasma and that the advantages should be weighed against the risk of transmitting hepatitis. Dr Maycock reminded the RBTOs to ensure warning labels were regularly included in all shipments of plasma [DHSC0100054].

48. By letter of 6 December 1951 GM Denning, Medical Liaison Officer, to The Under Secretary of State, and the War Office, wrote [DHSC0100011_184] re: Sterilisation of Whole Blood and plasma that

at a meeting held the previous day, Dr Oliphant stated that he had failed to inactivate the virus of hepatitis by ultra-violet irradiation.

49. On 27 March 1952, Dr Maycock wrote to Dr R Bevan, Cardiff Regional Transfusion Centre [DHSC0100011_202], noting the contents of a report and that it was 'the first case of cirrhosis of the liver following homologous serum jaundice that I have heard of in this country.' He added that there were almost certainly others that had occurred, but had not been recorded.

50. Between 21 and 26 July 1952, the WHO Expert Committee on Hepatitis met in Liege. The group had been convened by the Third World Health Assembly noting "the high incidence and wide distribution of epidemic hepatitis and the serious practical problem involved by the possible conveyance of serum hepatitis by blood transfusions and parenteral application of human blood derivatives". [RLIT0000215]

51. Their first report was published in March 1953 and agreed that, for the purposes of discussion "two viruses – A and B – would be considered, although the possibility that these may be only two variants of a single virus, or that there may be more than two viruses, could not be excluded".

52. The committee considered that it was justified to add hepatitis to the list of notifiable (reportable) diseases. At section 10, the report noted that the "committee is of the opinion that the dangers of serum hepatitis are not appreciated by many sections of the medical profession, largely owing to the long incubation period which conceals the relationship between a transfusion and subsequent hepatitis. It also appears to the committee that many non-essential transfusions of blood and plasma are given. Therefore, the committee recommends that national health authorities should call the attention of the medical profession in their

countries to the dangers of transmitting hepatitis by transfusion of plasma and whole blood, and also by the use of certain blood derivatives and should advise that plasma, particularly large pool plasma, should not be used unless the advantages likely to be gained by its transfusion outweigh the risk of transmitting the disease" [RLIT0000215].

53. The Committee also suggested that "each patient receiving a potentially icterogenic blood product should be given a card explaining that jaundice sometimes occurs as a late complication of the treatment and that if it should occur at any time up to 160 days after the treatment he should visit his own doctor or the hospital". It was suggested that such a follow-up system could be trialled in selected areas in the first place and only adopted on a large scale if the results justified it. [RLIT0000215]

54. On 8 August 1952, Dr Maycock wrote to all RBTOs regarding the WHO meeting [DHSC0100011_222], informing them of their recommendation to exclude any blood from plasma pools where it had been obtained from a donor who had had jaundice at any time and advised that blood from such donors should be used for emergency whole blood transfusion only where the results of serum bilirubin and a flocculation (eg thymol turbidity) fell within normal limits. Dr Maycock wrote that in view of this recommendation, "I consider that the [NBTS] should in future not accept as donors any persons who give a history of jaundice, and that exclusion of such donors should begin at once". [my emphasis] Dr Maycock had been invited to provide his views in advance on control measures for the prevention of spread of hepatitis virus in blood products [DHSC0100011_212].

55. By letter of 15 October 1952, the Chairman of the Coventry & District Voluntary Blood Donors' Association, Mr A Jacques, wrote to Dr

Maycock [DHSC0100011_236] indicating that the new policy had caused "considerable concern" among donors. He stated that "we have always received a categorical reassurance that no diseases can be transmitted from donor to patient. In view of the fact it has now been ascertained that a disease such as jaundice can be transmitted, doubts have been raised in the minds of donors as to the transmissibility of other diseases. Can donors be given an assurance that so far as is known to science at the present time no other diseases can be transmitted by blood transfusion?"

56. The letter raised further queries in respect of whether testing had been developed to detect the virus, whether donors would still be able to give blood for emergency whole-blood transfusions, and how the policy would work if the donor themselves could not recall if they had had a history of jaundice. The letter also asked whether donors could be given "a proper leaflet on this matter, explaining the reasons … and accompanied by, if not a personal letter, at least one in facsimile, so that the donor might think he or she is being treated as a person and not a cipher". Finally, the letter queries why there had been no public press announcement of the decision, suggests that it had been handled in a "furtive way" and that it may have been better to have a temporary suspension of jaundiced donors whilst further research was carried out; "it is thought that if this had been done in a proper manner, with adequate explanation, it would have been much better received by the affected donors".

57. On 27 October 1952, Dr Maycock responded [DHSC0100011_238] making the following points:

a. The step was taken after careful deliberation with the sole intention of shielding the recipients of transfusion fluids from "a hazard of which comparatively little is known";

a. There were no methods to permit the detection of individuals who had jaundice but there is "evidence to suggest that persons who have had jaundice may remain infective for long periods although to all intents and purposes quite well";

b. "I doubt whether it has ever been categorically stated that no disease can be transmitted from donor to patient, for it is well known that certain diseases may be transmitted eg malaria and care is taken not to accept as donors, people whose blood may transmit such diseases".

58. On 23 December 1952, an article was published in the Daily Express under the headline "Blood Banks plan SOS to replace 1,000" [DHSC0100012_013]. The article's opening paragraph stated "more than 1,000 blood donors have been told: 'your blood is no longer safe to use – you have had jaundice'" and continues to state that "research experts have now discovered that the jaundice germ can live in the blood stream for a long time'. It quotes an "official in Manchester" as stating "it may be rare for a person receiving a blood transfusion to contract jaundice, but we must take no chances".

59. In early 1953, other publications including the East Anglian Times, The Scotsman and Edinburgh Evening News also carried articles about jaundice being transmitted in blood [DHSC0100012_022, DHSC0100012_020, DHSC0100012_021].

60. On 17 May 1957, Dr Drummond wrote to Dr Maycock indicating that the Cardiff RTC was to proceed to follow-up recipients of blood from donors who were implicated in cases of serum jaundice [DHSC0100013_134]. He noted that most of their RTC records had been destroyed after three years (although common practice amongst

RBTOs was to destroy after one year) and he queried whether it would be better to keep them for 20 years. This proposal from Dr Drummond may have been the first instance of a 'look back' exercise in this context.

61. In 1965, "The Practitioner" was published. A chapter entitled "Complications of Blood Transfusion" was authored by Dr Jean Grant, Director of the Oxford RTC. Within the section "transmission of disease" it was stated that "the development of homologous serum hepatitis is a hazard which besets rather less than 1% of recipients of whole blood or small pool plasma … some patients suffer no upset from the transmitted virus, some may have only a transient liver dysfunction with or without jaundice and yet others may develop a rapidly fatal hepatic necrosis. The incubation period of infective hepatitis is about 20 to 40 days whereas that of homologous serum hepatitis is 40 to 160 days". It is concluded that "the practitioner should satisfy himself that it is really necessary to give blood and that no other treatment would be equally efficacious." [PRSE0003897]

62. On 6 September 1969, the BMJ published a letter [PRSE0003714] by Drs Whittaker and Brown on "serum hepatitis" in a haemophiliac patient who had had spontaneous bleeding into his knee and was treated with a total of 162 units of cryoprecipitate over a three-month period, but then died two months later. At post-mortem the liver had been noted to show extensive hepatocellular damage and it was concluded that death was due to serum hepatitis.

63. The letter observed that the occurrence of serum hepatitis following cryoprecipitate was "unusual" with only one previous reported case in 1966. It concluded that "cryo represents a considerable advance in the management of the severe haemophiliac. This and other centres have used many thousands of units without mishap and we do not know of a

similar case in Britain. It is important to re-emphasize the potential danger of cryo to ensure its use only when strictly needed". Penrose reported this letter as the first report in the UK of hepatitis transmission by use of cryoprecipitate.

64. On 13 May 1970, Dr Maycock wrote to his colleagues at the Department of Health and Social Security, Dr J Thomson, Dr W Obank and Mr R Hughes [DHSC0100019_100], regarding a letter received by the Brentwood RTC by a solicitor. This includes a summary of the position at that time. He writes that, as at that date, only three surveys had been undertaken to determine the incidence of icteric hepatitis after transfusion of blood:

a. *Spurling et al (1946) BMJ 2 409* – **1114** patients surveyed, **no** cases
b. *Leanne et al (1949) BMJ 2 572* – **2796** patients surveyed, **22** cases (**0.8%)**
c. *MRC Survey (1954) The Lancet 1 1328* – **2538** patients surveyed, **4** cases (**0.16%)**

65. He stated that a survey was in progress at that time to determine the incidence of both icteric and non-icteric hepatitis but the results were not available. He wrote of the measures employed to exclude donors who might transmit hepatitis, including exclusion of any donors who had had jaundice in the past and deferral of donors who had been in contact with a case of jaundice.

66. He wrote that no liver function tests such as serum transaminase or thymol turbidity were used as they were "*regarded as of no value for detecting carrier donors. They have never been used here and the decision not to use them was made many years ago by MRC Transfusion Research Committee*". Further, he wrote that there were at

that time two kinds of tests for detecting the Australia antigen but these were "*not routinely used anywhere as far as I know*". The Australia antigen had been identified in the **mid-1960s**, and was shown by Blumberg in a **1970** report to be a hepatitis virus which occurred more frequently in people who had received transfusions.

67. Dr Maycock published an article in the British Medical Journal in **May 1972** entitled "*Hepatitis in Transfusion Services*" [CBLA0000123]. He observed that "*the transmission of viral hepatitis is the most serious complication of use of blood and blood products. Two forms of hepatitis may be transmitted this way. One has a short incubation period of some 15-40 days and is generally referred to as infectious hepatitis, a disease usually transferred by the oro-faecal route and assumed to be caused by an agent known as virus A or IH virus. The other form is serum hepatitis, one of the characteristics of which is a prolonged incubation period of some 40-150 days, occasionally 180 days. It is assumed to be caused by an agent known as virus B or SH virus*".

68. Under the heading *"Control of Risk of Transmitting Hepatitis by Blood and Blood Products",* Dr Maycock stated*: "the exclusion of donors in whose blood the presence of Australia antigen is detected will diminish the risk of transmitting hepatitis … and the practice of testing all donations has been adopted or is being introduced by transfusion services … when the presence of antigen or antibody has been confirmed, the donor's name should be removed permanently from the panel*".

69. Dr Maycock concluded that *"the extent of the diminution [of risk], which can be measured only by epidemiological surveys of patients treated with blood or blood products, will depend upon the sensitivity of the methods used to screen blood donations … Terms such as "safe blood" and "safe blood products" were applied to blood in which the antigen*

had not been detected. At the present time both terms are misleading because treatment with blood and blood products … continues to carry the risk, admittedly a diminished one, of transmitting hepatitis. Blood and blood products known to be potentially icterogenic should be used with discrimination: they should be administered only when the benefits outweigh the risk to which their use exposes him. The implications of the presence of Australia antigen or its antibody in the blood of apparently healthy individuals must await the outcome of clinical and epidemiological observations made over considerable periods of time".

70. I discuss below in responding to question 4 the development of knowledge of AIDS and the response by the blood services in seeking to screen out *at risk* donors - before the virus had been identified and a screening test was available - and in following up cases of transfusion-transmitted HIV and donors who tested positive once the test was available.

Duties to Donors and Duties to Recipients

71. Whilst I believe that a duty to both donors and recipients has been recognised in one form or another for as long as there has been a blood transfusion service, there is some difference between the patient and the donor from the perspective of the NBTS, NBA, NHSBT and JPAC, and predecessor or associated organisations as above, which is that the blood services do not have a direct therapeutic relationship with patients who are the recipients of blood, blood components or plasma products.

72. Diagnostic and treatment decisions in respect of individual patients, and communication with those patients, are the responsibility of their attending clinicians. NHSBT, and its predecessor organisations, has and had a direct relationship with donors who attend at a donation

centre run by the blood services, and will be attended by employees of NHSBT/their predecessors.

73. In general, those best placed to advise and counsel patients as to the risks and benefits of treatment would be the clinicians responsible for their care. The blood services did, and do, have a role, which has increased over the years, in advising and educating clinicians about the risks of blood and blood products and on their appropriate use. There are many examples of how the blood services have carried out this role, for example, advice about avoiding single unit transfusion and guidance in the use of component therapy rather than whole blood.

74. The blood services have to some extent to strike a balance between their duties to donors and to recipients and this was illustrated by the advent of AIDS. I have discussed below how consideration was given as to the extent of probing of sexual behaviour and practices of donors in order to identify who might be at risk. It was appropriate to try to identify and exclude from the blood supply those likely to be at risk of having and of transmitting HIV. Donors are in general public- spirited people who give their blood altruistically to save and improve the lives of others. Without them there would be no blood service and very many life-saving and life-enhancing treatments would not be possible. AIDS struck at a time when the blood services were striving to increase the supply of UK plasma to achieve self-sufficiency in fractionated plasma products and any approach which drove donors away in significant numbers would be counter-productive to the aim of having a supply of voluntary blood donations sufficient to avoid the need for less safe imported blood products.

75. The European Commission Background Document for the Meeting of National Experts on Donor Selection and Screening of Donations held on **24-25 May 1997** in Luxembourg noted that pursuant to a request

from the Council of Ministers in December **1991**, the European Commission prepared a Communication on blood safety and self-sufficiency which addressed inter alia, concerns about the quality and safety and efficacy of blood and blood products in the European Community. The Commission recommended that in order to improve confidence in the safety of the blood transfusion chain and promote Community self-sufficiency, a Community blood strategy was needed. It proposed several strategies to achieve this. These are described below, but by that date, there is no express mention of a duty of care to the donor or to the patient.

76. In its resolution of **2 June 1995** on blood safety and self-sufficiency in the Community, the Council adopted all six activities of the Commission and proposed to add one more, but invited the Commission to collaborate with the Member states in carrying forward this strategy, to submit proposals in the specific areas mentioned and to encourage the development of a coordinated approach [NHBT0041267_012].

77. This collaboration was taken forward in the Commission's support to the Colloquium on blood safety and self-sufficiency organised by the Irish Presidency in Adare in **September 1996**, where the ideas and strategy were explored in greater depth. The Commission in implementing its strategy concentrated on donor selection and the testing of donations [NHBT0044112].

78. The Commission stated that the safety of blood and plasma collection involved two main activities: the clinical process of enquiry between a blood transfusion service professional and the donor (selection) and the laboratory examination of the sample of donation to determine specific biological parameters and to detect the presence of agents that are associated with communicable diseases (testing). It noted that donor selection processes differed across the Community and that it

would be beneficial if agreement could be reached regarding the rules and practices for donor selection, including new and repeat donors as well as whole blood, cellular components and plasma to be applied across the community.

79. The conclusions of the Adare Colloquium addressed issues relating to:

a) the processing of **donor** information, the **donor** screening questionnaire, the need for interviews;
b) the collection and analysis of epidemiological data on the prevalence of infectious markers;
c) the incidence of seroconversion among **donors** and the information to be provided to **donors**.

80. In respect of donor screening, the Communication referred to the quality, safety and efficacy requirements for the industrially manufactured products derived from blood and plasma laid down by **Directive 89/381/EEC** and the exclusion of whole blood, blood cells of human origin and plasma not used for these purposes. Differing testing requirements existed within the Community. The Adare Colloquium raised concerns that standard procedures, or criteria for standardisation, of confirmatory tests did not currently exist and that quality assurance criteria were needed to ensure satisfactory safety and performance of tests. To ensure adherence to common standards, national authorities should inform their counterparts of tests, including batch releases that they had licensed or relicensed as well as those rejected or withdrawn. The reason for rejection or withdrawal should be given together with identification data.

81. The **Adare recommendations** included:

a) Reviewing existing guidelines with a view to making proposals for common criteria to be used in the European Community;
b) Establishing criteria at Community level regarding donor identification;
c) Determining the core elements and risk behaviours that should be identified through a donor screening questionnaire;
d) Establishing a system for the collation and analysis of epidemiological data on the pattern of diseases in the Community;
e) Research on the use of questionnaires for new and repeat donors in respect of the identification of donors with high risk behaviour;
f) Intensification of efforts towards the principle of voluntary non-remunerated donation pursuant to **Directive 89/381/EEC**;
g) A minimal set of screening tests to apply in all Member States for the testing of whole blood and components for transfusion as well as plasma for fractionation;
h) That specific safety and evaluation standards were required in the field of blood;
i) That measures should be taken to reach agreement on criteria for standardisation of confirmatory tests;
j) That the Community should set up appropriate systems to implement the licensing of screening tests by national authorities to meet mutual screening requirements.

82. The meeting of national experts was to make proposals on these issues.

83. The above explains how in general European blood services developed processes to protect **recipients** of blood and so far as they were involved, relevant fractionated plasma products.

84. Specifically, in relation to the HCV lookback, this issue is addressed in detail elsewhere in NHSBT's response by Dr Angela Robinson, who

was the Medical Director of the National Blood Authority at the time of the lookback and was responsible for its implementation.

Legal Advice on Duty of Care

85. In terms of my own relevant involvement, in relation to HCV infection and the duty of care to donors, on **10 June 1996**, I wrote [NHBT0009730] to Dr Peter Flanagan, who was Chair of SACTTI, concerning *'Duty of care to donors'*, noting that at the last SACTTI meeting on **16th April 1996**, I had been asked to obtain a legal opinion on the duty of care to donors. I had had a very full reply from the lawyer which set out all the arguments. The advice concluded as follows:

"In conclusion, I would say that there is an arguable basis for considering that a legal duty of care is owed to a donor which would require the Blood Service to contact them, establish whether they are HCV-infected and offer counselling and treatment but that other factors need to be taken into account before deciding to set up an administrative system aimed at giving effect to the discharge of the duty of care. These factors are the value to donors of any counselling or treatment which might be provided, the practicality of contacting donors and the degree of probability that donors so contacted would prove to be HCV-infected".

86. I noted that I was not certain that this helped us very greatly, that it would seem that cases would need to be considered on an individual basis and that no set rules could be made, at least on legal grounds. I thought that perhaps this item would merit further discussion at a future meeting.

87. In relation to HCV lookback and recipients, although I cannot recall the date, I have a clear recollection of a meeting held prior to January 1995

and chaired by Dr Fereydoun Ala, Director of the West Midlands transfusion centre, to make the case to the Department of Health that HCV lookback should take place. There had been general consternation within the blood service that a lookback had not been mandated by the Department, although HIV lookback had taken place many years earlier. The arguments put forward by the Department for not carrying out an HCV lookback at the time of the introduction of HCV screening in 1991 could equally well have been made at the time of the HIV lookback in 1985: that the identification of infected recipients of blood transfusion would cause untold worry and stress, and that there was no effective treatment available for those identified. The stance of the Department seemed illogical to the blood services and there was increasing concern about the failure to identify those patients who had received blood transfusions including blood from donors later shown to be infected with HCV. I have been shown document [NHBT0009383] which is minutes of a meeting on 5 August 1994 and believe that this is likely to be the relevant meeting.

88. In a letter of **20 September 1995** [NHBT0015661] I sought legal advice from Mr Janisch at Dr Robinson's request, relating to duties to donors and recipients in the HCV lookback. I explained that during the course of the HCV lookback, we (Consultants at the transfusion centres) on occasions received a view from a general practitioner that, in the GP's opinion, a patient was unsuitable for notification and counselling on the possibility of HCV transmission from blood transfusion. In some cases, this was because of dementia, general medical condition, (terminal malignancy) or that the patient would be emotionally unable to cope with the information.

89. In these cases, I generally discussed the matter with the GP and noted, if we jointly came to such a decision, that we had agreed that the patient should not be notified. The question had now been asked "from

a medico-legal point of view should the patient's next of kin be informed?"

90. The initial reaction of Dr. Robinson and others was that it should not be necessary to inform the next of kin, but we would be grateful for a medico-legal view. I assumed that this would come under our "duty of care" to the patient. Dr. Robinson was hoping that she could raise this matter, together with his advice, at the next MSBT meeting on **13th October**.

91. Mr Janisch replied by letter dated **26 September 1995** [NHBT0015660] in which he said that in his letter to Dr Robinson of **16th December 1994**, he discussed the medico-legal implications of the proposed lookback procedure and confirmed that the first approach should be to establish what is good medical practice, having regard to the interests of donors and recipients. Giving advice to recipients of HCV-infected blood was considered to be in accordance with good practice, subject to variation in special cases. Giving such advice was to be regarded as part of the **general duty of care** owed to recipients by the National Health Service. He thought it was quite clear that this duty of care was not to be exercised in a uniform way in the case of each and every individual recipient. My letter of **20th September** described patients who were obviously unsuitable for notification. In such a case, it was for the patient's medical advisers (probably the General Practitioner in most such cases) to give careful consideration as to what information should be given to the patient and how the overall care of the patient should be managed in the light of the information about possible HCV infection.

92. It seemed to him that the principles here were similar to those which applied to other fields of medical treatment. The obvious example was where a patient was suffering from a terminal condition such as cancer,

yet the judgment of his medical advisers was that the full prognosis should not be disclosed to the patient. In such cases, a balanced judgment had to be made by the medical advisers as to how much information was given to the patient.

93. The information about the patient's condition was subject to the general medical duty of confidentiality. If, for perfectly appropriate reasons, it was not disclosed to the patient, he did not think it followed that it must (or even may) be disclosed to any other person. He did not consider that the concept of "next of kin" had any specific medico-legal significance.

94. Whether or not information about a patient's condition and prognosis may be disclosed to his close relatives was primarily a matter of ethics and professional conduct. He believed that the guidance given by the General Medical Council to doctors was this: *'If in particular circumstances the doctor believes it undesirable on medical grounds to seek the patient's consent [i.e. to disclosing confidential information] information regarding the patient's health may sometimes be given in confidence to a close relative or person in a similar relationship to the patient'.*

95. There was a qualification to this guidance, but it only referred to giving contraceptive advice to a minor and was not therefore relevant. He agreed that it was not necessary to inform the next of kin. They may, however, be informed even though the consent of the patient had not previously been obtained, in the "particular circumstances" mentioned in the GMC's guidance. It should be emphasised that the guidance required information to be given in confidence to the relative or other individual.

96. We did frequently obtain legal advice on points such as these, which at the time seemed far from straightforward. To date these are the relevant advice identified.

97. How best to discharge our duty to both donors and recipients has always been difficult at times when we knew very little about the incidence or type of risk under discussion or whether any given individual was in fact at risk – and if so of what. What were we to tell people, if we did not know there was an actual risk to them, when there was no treatment for the condition and no hope that could be offered if by some small chance they were at risk - and might we be doing more harm than good?

98. The basis of the duties owed and of the ethical position were further tested and debated in these respects later in the 1990s in respect of CJD. Legal advice was obtained dated **25 February 1999** by Alan Slopecki, Quality Manager NBA [NHBT0004389] on "Identification of Potential Donors" relating to the practice of tracing recipients of blood donated by a donor who had died of vCJD (through the Transfusion Medicine Epidemiology Review TMER) but not informing the recipient, on the basis there was no test for vCJD in life and it was not known (at that time) to be transmissible by blood.

99. These issues had been much debated by the CJD Clinical Incident Panel, and varying ethical advice had been given. Crucially, in relation to the TMER, which was a research study designed to investigate whether there was a link between blood transfusion and CJD, the advice of the Lothian Ethical Research Committee (the Ethical Research Committee local to the National CJD Research and Surveillance Centre in Edinburgh, and responsible for giving ethical permission for the research to be carried out), was that identified recipients should not be informed. During the conduct of the study,

several living recipients were identified who had received blood from donors who later developed vCJD, and although many of them may well have been ineligible to give blood because of their underlying medical condition, the blood services came to the decision that they could not take the risk that any of them might present as blood donors in the future. There would therefore need to be a system in place to ensure that their names were "flagged" so that should any of them present as a donor, the blood would be discarded. This issue led to serious conflicts and concerns within the blood services, which will be covered more fully when vCJD is considered.

100. The legal and ethical issues raised are discussed in the legal advice obtained in **1999** and there is a reference to earlier advice to me dated **25 June 1996** headed '*Proposed CJD Lookback'* [NIBS0000331_003] (in relation to the TMER study.) This advice raised a possible legal duty on behalf of NBA to take some form of action with regard to individual recipients of blood donated by someone subsequently diagnosed as suffering from CJD. Even if there was no treatment available, the lawyer was not able to advise that there was no legal duty to advise them. It was a mixed legal and ethical issue and the legal position remained unclear. There is also reference to ethical advice provided to the DH in **1997**. This was separate from the advice given by the Lothian Ethical Research Committee. The advice given by the lawyer however, was that if the donor did not know the true intention with regard to the donation (that blood from "flagged" donors would be discarded on a precautionary basis) then it was a sham and there was no informed consent. He could see no good reason for treating these donors any differently from those who were virology-positive. He gave data protection advice relating to flagging of donor records without their knowledge. He referred to donor records probably being treated as medical records even though NBA was not responsible for the 'general

care' of donors and concluded that the donor's right would extend to being told of the flagging.

101. There is a subsequent letter of **21 October 1999** to Dr Angela Robinson marked 'Strictly Private and Confidential' – *Donors and Duty of Care* [NHBT0004385_001], which encloses the lawyer's notes of a meeting on **6 October 1999** at the Department at Health at which there was discussion of how to deal with this issue and the flagging of potential donors who had received implicated blood components. Dr Robinson was present and referred to the earlier ethical advice which had been not to inform such recipients. There was suggestion of obtaining advice from Treasury Counsel and someone asked what would happen to those who did not present as donors. This was noted to be a separate issue that someone else was looking at. It was agreed they would have to be told, but that it was not clear that the blood service was best-placed to do this. It was also agreed that up to date ethical advice was needed; that donors needed to be sent to an appropriate expert and there would need to be a protocol for the necessary actions.

102. There was discussion as to whether anyone in the hospital service was looking at consent to transfusion and it was noted that a leaflet had been written. The three individuals who had been identified to date as being potentially affected were to be flagged, a protocol was to be written and the other 'territorials' (UK blood services) were to be told.

103. These were not easy decisions and we were having to learn to an extent as we went along. Blood transfusion practice was developing throughout the second half of the 20th century in response to numerous challenges. We were trying to ensure that we did not do more harm than good, whilst also trying to protect future recipients of blood. We were in effect operating according to the precautionary principle, just in

case, for example, vCJD became a real issue, which it did some years later when the first blood-borne transmission was identified in **2003.**

104. In the 1980s we learned from our American colleagues of serious problems when HIV testing was introduced early without an understanding of the meaning of test results. Notification of "positive" test results to donors apparently led to panic and even suicides. We always endeavoured to ensure that in trying to maintain a safe and sufficient supply of blood, we balanced the rights of, and our duties to, donors with those of the ultimate recipients. We needed to understand the value of the test in our population, its accuracy, what the results meant in terms of disease transmission, what the results meant in terms of future disease. When transmission of sporadic CJD through Human Growth Hormone treatment became evident in the 1980s, notification of recipients of such treatment led to serious psychological trauma in some cases. In the case of vCJD we also needed to consider what we were to tell donors and recipients and all those potentially at risk in the absence of any diagnostic blood test, and what the consequences of that knowledge might be a terms of possible treatment, or possible detriment with no hope of treatment (at the time, and still in relation in CJD).

105. With hindsight, I think the difficult issues and strongly held views from both sides (those who supported notification of the possibly affected, despite the potential for psychological harm, and those who felt that such harm outweighed the benefits) may have led to erring on the side of not acting soon enough to impart potentially devastating news in terms of possible exposure to HCV and vCJD for which there was at the time no effective therapy and no clear knowledge of the prognosis. I would also add that generally those working within the blood services were in favour of notification, and worked hard to lead to a point where

this was agreed. I have discussed the position in relation to HIV in detail later in this response.

106. b) I discuss the position in relation to recipients who were not identified by the HCV lookback below (in response to question 1(b)(ii) and it is also covered by Dr Robinson and Dr Williamson, both former Medical Directors of the national blood service, in their responses.

4. An account of all steps taken to identify and warn patients who may have been treated with HIV infected blood and/or blood products, since the virus was conclusively identified in 1984. Please include any 'look-back' patient notification exercises and details of any awareness campaigns to publicise the risk, including exercises and campaigns that were considered but rejected.

107. I am not aware of any awareness campaigns by the blood services aimed at the general public to publicise the risk of HIV transmission by blood transfusion. In general a public awareness campaign would fall within the remit of the Government/Department of Health, although there would be involvement of the blood services in the underlying advice through representation on relevant committees, including UK Working Party on Transfusion-Associated Hepatitis, and the government Advisory Committee on the Virological Safety of Blood (ACVSB) later the committee on the Microbiological Safety of Blood and Tissues for Transplantation (MSBT) which are explained more fully by Dr Robinson in her response. Dr Gunson also attended the Expert Advisory Group on Aids at which Health Education Authority campaigns were discussed.

108. The Government's awareness campaign, including the role of the blood services, is set out in document NHBT0007976_001 of **26 September 1985**, a Press release entitled, "*The Fight Against AIDS- More Government Money*", Department of Health and Social Security (DHSS). This notes that the Department had already allocated £1 million towards combatting the disease, in addition to the resources committed by Health Authorities and would be providing a further £1 million that year, partly to help the three Thames Regions who were carrying the heaviest AIDS burden to provide treatment and counselling to those exposed to the infection. It was also to be used to support the counselling work of Haemophilia Reference Centres and the voluntary sector for the valuable information and advice work they were doing. It noted that:

109. *"A programme of public education must be the lynch-pin of our strategy to control the spread of the disease. We are urgently considering proposals for a national co-ordinated campaign of public education to improve understanding of the disease by those most at risk of contracting AIDS and also by the general public, and the ways in which its spread can be controlled. We must also extend our understanding of what services need to be provided for those who are infected with the virus.*

110. *"Important steps are being taken to safeguard recipients of blood and blood products from the AIDS infection. Preparations for the introduction of routine screening of all blood donations in mid-October are well advanced. The blood clotting agent Factor VIII needed by haemophiliacs is now being heat treated. And the major redevelopment, costing £38 million, of the Blood Products Laboratory in Elstree should ensure our self-sufficiency in blood products by the end of 1986.*

111. *"The Government fully understands public concern about AIDS. This terrible disease is being tackled on a broad front and with the continuing co-operation of all concerned and particularly those in the at-risk groups. I am hopeful that together we will be able to control the spread of the infection and reduce the appalling suffering which accompanies the disease."*

112. The NOTES FOR EDITORS listed details of the additional funding being provided and the major measures already taken and planned to control the spread of the disease as:

Funding

* health education
* screening of blood donations
* other blood testing
* heat treatment of blood products
* counselling
* research
* information for health professionals
* co-operation with the voluntary sector
* setting up of an advisory group of experts
* confidentiality.

It continued by noting that besides funding various research projects the Government had contributed:

£50,000 for the training programme for counsellors

£58,000 for evaluating screening tests at PHLS

£80,000 for evaluating screening tests in the NBTS

£750,000 for testing blood samples at PHLS

£25,000 for the Terrence Higgins Trust

£15,000 for the Haemophilia Society

£978,000

And on – ' *Health Education*

The main at-risk groups are homosexual and bisexual men; intravenous drug abusers; haemophiliacs who have received contaminated blood products; and the sexual contacts of people in these groups. Information leaflets have been produced by the Health Education Council, the Haemophilia Society and the Terrence Higgins Trust. A leaflet warning those in the at-risk groups not to give blood has also been produced for the National Blood Transfusion Service (NBTS).

Screening of Blood Donations

The risk of contracting AIDS from a blood transfusion is already extremely small, but the planned introduction of a screening test within the NBTS will reduce this risk still further. All the commercially available screening tests have been evaluated by the Public Health Laboratory Service (PHLS) and two kits are now being tested in the NBTS. Routine screening of all blood donations should be introduced by mid-October.

Other Blood Testing

Health authorities are also making arrangements for blood samples to be taken in sexually transmitted disease clinics and elsewhere so that people who are worried that they may have been exposed to the virus can have their blood tested to discover whether they are antibody positive.

Counselling

Anyone whose blood is found to contain antibodies to the AIDS virus will be offered counselling, which will also extend to families and

friends. A counselling training course has been developed at St Mary's Hospital, Paddington, and over 180 people will be trained by the time the blood test becomes available in October.

113. A further example of an awareness campaign is given in the minutes of the 31st meeting of the Department of Health's Expert Advisory Committee on AIDs on **12 June 1990** [NHBT0008409_064/NHBT0008409_001] :

'*Item 10 -Health Education Authority*
The mass media campaign mentioned at the last meeting had now finished. During the campaign the number of callers to the National AIDS Helpline had risen to 21,000 a week from 11,800 in the comparable period last year - over half the calls were attributable to the campaign. A qualitative review had shown a high level of recall among the young and the adverts were respected rather than liked. A holiday campaign was about to start and would use billboards and radio. There were plans for TV and cinema campaigns towards the end of the year.'
It appears that Health Education Authority was a standard item at EAGA meetings. There are other examples of discussions in eg NHBT0008406_002 minutes for **8 October 1991**.

114. The most important awareness campaign conducted **by the blood service** to publicise the risk of HIV transmission by blood transfusion was that directed at blood donors and potential donors, and this started well before the introduction of screening of blood donations for evidence of infection in **October 1985**. The first information leaflet for donors and potential donors ("AIDS leaflet") was published in **September 1983**, with the intention that it was to be provided to all individuals before they donated blood. The aim of the leaflet was to discourage those who recognised themselves to be at risk of AIDS to self-exclude from donation. Both the mass media campaign run by the

Health Education Authority and the awareness campaign aimed at donors and potential donors would have heightened general awareness about the risk of transmission through blood and blood products.

115. Prior to the identification of HTLV-III (HIV) there was little scope for identifying and warning patients who may have been treated with HIV infected blood or blood products. Instead, the focus of the blood transfusion service was to minimise as far as was reasonably achievable the number of donors donating blood which was positive for any possible infectious agent causing AIDS. A precautionary, exclusionary approach was adopted. A key aspect of achieving this exclusion was the AIDS information leaflet.

116. The need to identify and inform patients who were recognised to have been at risk of HIV infection through transfusion of **blood components** before the start of screening of blood donations was incorporated in the plans which were prepared for the introduction of screening tests. These plans included the need for lookback.

117. The task to identify and warn patients who had been at risk of HIV infection through the use of **fractionated plasma products** was a separate issue. Clinicians who managed the care of people with clotting disorders, predominantly those with haemophilia, were in the best position to identify and warn patients of the risk of infection. A proportion of these patients were treated with imported commercial products, which were not provided by the UK blood services. Others received only NHS Factor VIII, and the risk of infection was recognised and managed within the Haemophilia Centres. Less severely affected haemophiliac patients who only received cryoprecipitate were at much less risk of infection but they would have been included in the HIV lookback if relevant.

Tracing efforts prior to the identification of HTLV-III by Gallo: September 1983 to April 1984

118. This is the period prior to the identification of HTLV-III (HIV) by Gallo, although Montagnier's discovery had been reported in *Science*. In this period the transfusion service moved towards implementing processes for identifying and tracing implicated donations. These early attempts were made without the benefit of HTLV-III (HIV) testing, and thus were necessarily limited.

119. On **18 January 1983** at a meeting of the UK Working Party on Transfusion-Associated Hepatitis chaired by Dr Gunson, Dr Craske summarised the current situation regarding AIDS and advised that in the US it had been recommended that homosexuals with AIDS be deferred from donating blood. Dr Craske said he would be studying the effects of US Factor VIII in UK recipients and examining immunological markers, "*although the field is currently very confused*". [NHBT0000023_002]

120. On **24 January 1983** Dr Craske was present at a meeting chaired by Professor Bloom with the drug company Immuno. Dr Craske advised that precautions being taken in the US included discouraging homosexuals from donating blood. US protocols were being considered by the UK Working Party on Transfusion-Associated Hepatitis, and US fractionation companies were understood to be taking some unspecified measures to screen out high risk donors. [PRSE0002647]

121. It appears that on **28 March 1983**, the UK National Institute for Biological Standards and Controls ("NIBSC") suggested in a letter that

the problem of AIDS in relation to blood products should be considered at a meeting of the Committee on Safety of Medicines (CSM) and referred to steps being taken in the US to avoid using blood from high risk groups in the preparation of certain blood products. It appears that the term "blood products" was used here to refer to fractionated plasma products. Blood components, which are prepared by blood transfusion centres, are also blood products within the conventional use of the term, but do not fall within the remit of the CSM. The letter recommended that Professor Bloom attend to advise the meeting. [CBLA0000043_034]

122. In circumstances where the method of transmission of AIDS was not understood, the US approach was to attempt to identify donors at high risk of transmitting AIDS, and to encourage them to exclude themselves from blood donation. This approach to encourage self-exclusion was adopted by the transfusion service in the UK and progressed from **mid-1983**.

123. On **20 April 1983** at a UK Working Party on Transfusion-Associated Hepatitis meeting chaired by Dr Gunson [NHBT0000023_003], Dr Craske reported that there had been zero AIDS cases in UK haemophiliacs, though there were 6 likely cases in UK homosexuals. Dr Gunson asked members to bear the topic in mind and to consider the possibility of a pamphlet for donors illustrating the AIDS risk groups. Dr Gunson said he was aware this might have adverse repercussions for donor recruitment. Dr Gunson also noted that, because of AIDS, the use of cryoprecipitate would probably rise in the UK (because of the AIDS risk associated with fractionated plasma products). It was likely that haemophiliacs who had not previously received Factor VIII concentrate would be treated preferentially with cryoprecipitate. Increased production of cryoprecipitate in blood

centres would mean a drop in supply of plasma to BPL, and therefore of source material for production of BPL Factor VIII.

124. The situation in the US was further advanced than in the UK. The UK blood services began to consider methods for minimising risk to recipients, while not jeopardising a sufficient blood supply to meet the needs of patients. I discuss sufficiency of the blood supply further in response to Question 9.

125. Documents suggest that on **22 April 1983** Dr. Lane of BPL produced a short paper on AIDS for the upcoming CBLA meeting [CBLA0001697]. He noted in this paper that AIDS was being kept under regular review. BPL would adopt a "*wait and see*" approach of continued Factor VIII concentrate production with continued attention to research on viral inactivation.

126. On **27 April 1983** the CBLA held its fifth meeting chaired by Mr Smart [BPLL0003987_002]. In attendance were Professor Bloom, Dr Gunson, and Dr Lane. Dr Gunson reported that the Regional Transfusion Directors had considered all the American literature on the subject, and at the next meeting of their committee it would be recommended that no further measures be taken, apart from those already being carried out, which included the progression of the AIDS leaflet for blood donors.

127. On **28 April 1983,** Dr Gunson, as Chair of the Regional Transfusion Directors' Committee Working Party on Transfusion-Associated Hepatitis, and Dr Barbara, prepared a paper summarising the matters discussed at the three preceding meetings of the Working Party [CBLA0001703]. The paper reported that the Working Party had followed information from the USA and considered recommendations with respect to donor selection. It was noted that there had been no

cases reported following transfusion of blood or blood products in the UK. The report set out the agreement that, until further information was available, the Working Party would not recommend changes to present practices for donor selection or use of blood products.

128. At this time, it appears that the transfusion service continued to take its lead from the US. Consideration was being given to the available preventative measures. While no further steps were taken at this point, changes were later made as advice domestically and from Europe developed.

129. On **13 May 1983** there was a special meeting of the Haemophilia Reference Centre Directors to discuss AIDS [HCDO0000003_008]. The minutes report that the Directors thought there was "*clearly a need for Haemophilia Centre Directors to discuss what should be done with regard to surveillance and reporting of suspected cases and management of patients*". There was a discussion of one UK haemophilia patient suspected to be suffering from AIDS, and in London that there were 10 cases of confirmed AIDS in homosexual males. Concerns about diagnosis, progression to "*full-blown*" AIDS, and maintaining the use of concentrates because of their "*immense benefits to therapy*" were discussed. The meeting noted that the Blood Transfusion Centre Directors were due to meet to discuss the problem of donor selection in relation to AIDS. The news of this meeting was apparently welcomed by the Haemophilia Reference Centre Directors.

130. In **May 1983**, Dr Spence Galbraith, Director of the CDSC, wrote to Dr Ian Field at the DHSS [CBLA0000043_040] suggesting that blood products (i.e. fractionated plasma products) made from blood donated in the USA after 1978 should be withdrawn from use in the UK until the risk of AIDS transmission by these products was clarified. It appears that this suggestion was not followed.

131. The interlocking roles of different bodies such as CDSC, the CSM, and the Haemophilia Reference Centre Directors are important in understanding the steps taken by the transfusion service. There were competing pressures coming from those bodies, including continued high demand for fractionated products from haemophilia clinicians.

132. Between **16 and 19 May 1983** the Committee of Experts on Blood Transfusion and Immunohaematology of the Council of Europe held a meeting in Lisbon. Dr Gunson attended as the UK member and Rapporteur. He subsequently produced an informal report [NHBT0017430] dated **19 May 1983** and a final report [CBLA0001710] dated **13 June 1983**. He reported that AIDS dominated the meeting.

133. The recommendations from the meeting were lengthy. However, among the general recommendations was to provide all donors with information on AIDS so that those in high-risk groups would refrain from donating. Dr Gunson noted that steps were in hand in the UK to reduce the risk of taking donations from individuals who may have AIDS by selective questioning before donation. He noted that a leaflet on AIDS had been prepared but held in reserve. He wondered whether further consideration ought to be given to the matter. The formal version of the report more expansively discussed informing patients and donors about AIDS. The leaflet on AIDS for donors was at that time pending publication by the DHSS, and additional questions were proposed to be asked of donors to dissuade those in high-risk groups from donating. It was also noted that, since **mid-April 1983**, US commercial companies had tightened their medical examination of donors providing plasma for the preparation of Factor VIII.

134. On **9 June 1983** Dr Gunson wrote to the CMO, Sir Henry Yellowlees, on the issue of AIDS. [NHBT0001067] He described it as "a strong

possibility" that the syndrome was caused by a transmissible infectious agent and had been implicated in transfusion of blood and blood products. He noted that one haemophilia patient was suffering with the condition, with another possibly infected haemophilia patient. He informed the CMO of the steps being taken with pamphlets and questions to try to ensure that high risk groups for AIDS were not enrolled as blood donors. He also noted the move towards self-sufficiency in the medium term through the new facilities for BPL at Elstree. His view appears to have been, based on what was then known, that AIDS was "*not a major problem in this country at present and, frankly, we do not know whether it will be in the future*". However, he explained it was being taken seriously in European Countries and he noted the recommendations to the Ministers of the Council of Europe designed to minimise the effect of AIDS. He explained the situation with respect to the transfusion of blood products, that the incidence of AIDS had been closely observed by the transfusion service for some time, and that press coverage had led to a reconsideration of the problem.

135. Dr Gunson also raised the important consideration of the role of self-sufficiency in fractionated plasma products in the medium term, and in particular the consistent concern of the blood service to maintain sufficiency of the blood supply.

136. On **23 June 1983** the Committee of Ministers of the Council of Europe adopted the Committee of Experts on Blood Transfusion and Immunohaematology's recommendations in relation to preventing the possible transmission of AIDS from affected donors to patients receiving blood or blood products [NHBT0010651_004]. This included a recommendation to take all necessary steps and measures to inform attending physicians and selected recipients, such as haemophiliacs, of the potential health hazards of haemotherapy and possibilities of

minimising these risks; and, to provide all blood **donors** with information on AIDS so that those in risk groups would refrain from donating.

137. On **14 July 1983**, Lord Glenarthur answered a parliamentary question from Baroness Dudley, as to how widespread AIDS was in the UK and Europe and what steps were being taken to prevent it spreading in the community [PRSE0001886]. He advised that 14 cases of AIDS had been reported to the CDSC and a further two were under investigation. The MRC had established a working party and co-ordinated research into the disease. The CDSC was operating a national surveillance system, which included making available information for doctors about the incidence, identification and methods of control of the disease. Although there was no conclusive evidence that AIDS was transmitted by blood or blood products, the DHSS was considering the publication of a leaflet indicating the circumstances in which blood donation should be avoided.

138. The DHSS was involved in writing and producing the donor leaflet. There was a concern about causing distress to donors, which was consistent with the duty the transfusion service held to its donors. This concern was particularly so in the context of an ill-understood disease. Donors were central to the service, and from a supply perspective, and a wellbeing perspective, the transfusion service acted with their interests as an important consideration. However, as is indicated by the introduction of the leaflet and the steps taken in respect of it, those concerns had to be balanced with the risks to recipients.

139. On **1 September 1983** the DHSS published the leaflet "*A.I.D.S and how it concerns blood donors*" [BPLL0007247]. Two parts of that leaflet are particularly relevant:

Can AIDS be transmitted by transfusion of blood and blood products? Almost certainly yes, but there is only the most remote chance of this happening with ordinary blood transfusions given in hospital. However, in the USA a very small number of patients suffering from haemophilia, an illness in which the blood will not clot, have developed AIDS. Haemophiliacs are more susceptible to AIDS because they need regular injections of a product called Factor VIII. This is made from plasma obtained from many donors. Should just one of the donors be suffering from AIDS, then the Factor VIII could transmit the disease.

How can the risks be reduced? At present, there is no screening test the Transfusion Service can use to detect people with AIDS. So, until there is and until more is known about this disease, donors are asked not to give blood if they think they may either have the disease or be at risk from it.'

140. In **September 1983** the DHSS prepared a note for the Meeting of the Council of Europe's Public Health Committee. In that it was noted that the US Food and Drug Administration (FDA) had initiated, in **March 1983,** new regulations for the collection of plasma, designed to exclude donors from high-risk groups. It noted that some stock available in the UK, and some awaiting shipment in the US, was made from this pre-March plasma. However, the FDA had decided not to ban the use of similar stocks in the US because of the threat of a crisis of supply, and the DHSS said the same considerations applied in the UK [NHBT0010667].

141. It seems that at that point, in this country in general, the balance of risk was regarded as being in favour of continuing existing treatment and maintaining their supply. In this early period, prevention was the focus of the transfusion service to manage this unknown disease. As testing was not possible for HTLV-III, the service was necessarily restricted in

what it could do to inform patients (or the treating clinicians of patients) that they may have been treated with infected blood products. The transfusion service did not have that information. Efforts were, instead, focused on minimising the possibility of such transmission, in circumstances where it was not known with complete certainty whether the blood was in fact transmitting an infectious agent. Other bodies (UKHCDO and CDSC) were also in the early stages of looking at follow-up and surveillance of infected haemophiliacs.

142. The donor leaflet was an important feature of the transfusion service response. The success of the leaflet, in discouraging individuals at high risk of AIDS from donating blood, became evident when HIV screening commenced and lookback took place. The leaflet is considered further in response to **Question 9,** but from this point is only referred to in this answer where directly relevant to the identification and warning of patients identified in the question.

143. The UKHCDO Hepatitis Working Party held a meeting on **14 September 1983**, chaired by Dr Craske [HCDO0000270_031]. Dr Lane was in attendance. The occurrence of AIDS in haemophilia A patients treated with commercial Factor VIII was reviewed. It was noted that there had been two cases in the UK. Dr Craske said that the protocol for a study of the follow up of the products received by the two patients could be discussed at the annual meeting of the Haemophilia Centre Directors.

144. On **27 September 1983**, the UK Working Party on Transfusion-Associated Hepatitis held a meeting, chaired by Dr Barbara in Dr Gunson's absence [PRSE0001299]. The current position on AIDS was summarised by Dr Craske. The first UK haemophilia patient with AIDS was diagnosed in **April 1983** in Cardiff. The only identified risk factor was treatment with Factor VIII concentrate. The

products used since **1 January 1980** had been reviewed: the patient had received material from nine batches of commercial concentrate and a similar number of NHS concentrate. It was noted that attempts would be made to trace other recipients of these batches.

145. The second haemophiliac with AIDS was diagnosed in Bristol. From **1973**, he had been treated with cryoprecipitate and a few NHS batches of Factor VIII. He received no commercial concentrate until **December 1981**, when he was transfused from three different batches. Three weeks later, he developed NANB hepatitis and in **September 1982** was found to be HBsAg positive. He continued to deteriorate until his death on **23 August 1983**. It was noted that all batches of NHS and commercial concentrate and cryoprecipitate used since **1 January 1980** would be followed up. It is presumed that this follow up would have involved tracing other people who had been treated with the same batches.

146. It was agreed that Dr Gunson would be asked to canvass Regional Transfusion Directors to decide criteria for guidelines on follow-up of donors involved in possible AIDS transmission where only cryoprecipitate was involved, and also where both cryoprecipitate and concentrate were involved. At this time there was no blood test available to detect HIV infection. The possibility of non-specific (surrogate) tests, such as TPHA (a test for exposure to syphilis infection), aimed at identifying donors in high-risk AIDS groups, was also raised. All blood donations had been tested for evidence of syphilis infection since the 1940s. The anti-HBc test was mentioned as a possible "surrogate marker" for donors at high risk of AIDS. It is a marker of hepatitis B exposure, and had been associated with cases of NANB hepatitis, but its use was considered problematic.

147. The UKHCDO held a meeting on **17 October 1983**, chaired by Professor Bloom, which also included some attendees from the BPL, SNBTS and NIBSC [PRSE0004440]. Dr Gunson was invited but unable to attend. Dr Craske presented a paper on AIDS. He also outlined his proposals for investigating cases of AIDS in UK haemophiliacs and suggested a three year follow up of patients who had received "suspect" batches of concentrate. He proposed including a control group of haemophiliacs and spouses of haemophilia A patients who had received concentrates. Dr Craske was to send out details regarding his proposals to the Haemophilia Directors as soon as possible.

148. On **28 February 1984** there was a meeting of the CBLA. Dr Gunson attended as chairman, with Prof Bloom, Dr Lane, and Dr Rizza attending [PRSE0001972]. Prof Brownlie and Dr Wallington were invited to attend this meeting. While the majority of the meeting involved discussion of a study to screen blood donations with non-specific (surrogate) tests designed to identify donors at high risk of AIDS, there was also a report from Dr Thomas of a meeting with commercial manufacturers on the implications of AIDS. It was thought that an effective scheme was required in the UK for indicating awareness if an AIDS patient had contributed (as a donor) to a plasma pool. While PHLS had recently informed Dr Lane of such a case, Dr Gunson pointed out it was an informal mechanism. Dr Smithies said they (the Department of Health) would follow this up.

149. On **5 March 1984** Dr Galbraith, director of the CDSC, wrote to Dr Gunson on the issue of AIDS at the suggestion of Professor Bloom [NHBT0010821_005]. He identified that the CDSC was responsible for maintaining national surveillance of AIDS and that he was anxious that they provide to Dr Gunson, as Chairman of the AIDS committee of the NBTS, all the data that was available. He also sought Dr Gunson's

views on the surveillance system and particularly problems which might arise where an AIDS patient has previously been a blood donor. He proposed a meeting to discuss this.

150. The meeting took place on **4 April 1984**, with Dr Gunson, Dr Galbraith and Dr McEvoy of the CDSC to discuss surveillance of AIDS in relation to blood transfusion [CBLA0001833]. Dr Gunson prepared a note which recorded that:

1. CDSC will inform the appropriate RTD when a patient is diagnosed with AIDS. If the patient admits to donating blood, contact will be by telephone.

1.1 Investigation will be undertaken to find out whether the person is registered as a donor.

1.2 If the answer is NO, CDSC will be informed.

1.3 If the answer is YES, further action will be:

1.3.1 Trace the fate of the blood donations, with respect to all products, given during the previous FIVE years.

1.3.2 If plasma has been sent to BPL for fractionation Dr. R.S. Lane will be informed as soon as possible.

1.3.3 The appropriate hospitals should be asked to identify the patients who received the blood products, provide any information they have on the subsequent progress of the patients and the name of the patients' family doctors.

1.3.4 Subsequent to consultation with the Defence Organisations a communication will be sent to the family doctor informing him of the circumstance and a copy of the letter sent to CDSC who will carry out any further follow-up.

1.3.5 CDSC should be kept informed of progress.

2. CDSC will inform the appropriate RTD when a patient is diagnosed with AIDS who has stated that he/she has received a transfusion of blood and/or blood products.

2.1 If the patient has received blood products derived from pooled plasma which may involve a large number of donors, Dr. McEvoy will discuss with the RTD the practicalities of follow-up within the resources available. If the patient is a haemophiliac, Dr. J. Craske, Consultant Virologist, P.H.L.S., Manchester will also be involved. If the patient has received NHS products derived from pooled plasma, Dr. R. S. Lane will be informed.

2.2 If the patient has received blood products which have been prepared and issued from the RTC the following action will be taken.

2.2.1 Identification of the donors from whose blood the products were prepared.

2.2.2 Again, after consideration of the practicalities of the situation with respect to the particular case in discussion with Dr. McEvoy, it may be necessary to recall the donors for:

(a) Interview and medical examination.

(b) Collection of blood sample to carry out non-specific tests.

Where this is done and by whom will be at the discretion of the RTD.

2.3 If none of the donors fall into high-risk groups for AIDS, CDSC will be informed.

2.4 If any donor is suspected of having AIDS then referral should be made for further medical examination and an investigation carried out with respect to previous donations as detailed in paragraph 1.3 above.

3. Dr Galbraith suggested that a further RTD meeting could be held at which RTDs could discuss the procedures with respect to AIDS and be given information on other aspects of the work of CDSC.

151. This document appears from the information available to set out the first clear process by which the transfusion service, with the assistance of the CDSC, would identify at-risk donations and follow-up such donations to identify the recipient(s) of any blood components prepared from the donation. This is therefore the first attempt at what later became known as HIV lookback, starting with an ex-donor identified as suffering from AIDS. In addition, it was proposed to carry out an investigation when a recipient who had received blood or a blood product subsequently developed AIDS: the process generally called traceback or reverse lookback. Furthermore, it set out the need for lookback to include plasma which had been sent for fractionation into pooled plasma products, and to investigate pooled products when a recipient was diagnosed with AIDS. The proposed process reflected that the transfusion service had no direct relationship with a blood component recipient. In the case of recipients of pooled plasma products, the blood service's responsibility was to provide information to the fractionator so that suspect batches could be identified and notified to Haemophilia Centres, and to receive information from the fractionator about suspect batches in an attempt to identify the source of infection. The document set out how information would be passed along to general practitioners, treating physicians, and other relevant parties (e.g. CDSC or BPL).

152. At a meeting of the Regional Transfusion Directors on **11 April 1984** [CBLA0001836], Dr Gunson reported on the meeting with Dr Galbraith to formalise a standard procedure in cases of AIDS in relation to blood transfusion. It was agreed that Communicable Diseases reports, which carried an AIDS update, would be circulated to RTDs by Dr Galbraith.

153. On **16 April 1984** Dr Craske provided a letter to Haemophilia Centre Directors with an updated list of the batches of Factor VIII that had been transfused to two cases (A/1 and A/4) within 5 years of the onset

of AIDS [HCDO0000273_072]. There was an appended list of batch numbers. The letter included information on how these batches would be followed-up.

154. At a meeting of the Regional Transfusion Directors on **11 July 1984** [DHSC0002245_002] it was noted that Dr Gunson had approached the Medical Defence Union, who advised that if a patient had been given "*at risk*" blood, an adequate precaution was that their GP should be informed in confidence. However, previous experience with cases of venereal disease in donors led some members to doubt this procedure. It is noted that a DHSS working group may be set up and the legal implications could be considered. It is also noted that comments in respect of the draft AIDS leaflet for donors had been sent to Dr Smithies by the Divisions, and revisions would be made.

155. The interaction with the MDU reflects some of the comments in the note from **4 April 1984** [CBLA0001833]. The transfusion service continued to progress its plans for the follow-up of implicated donations and transfusions, in a way which reflected that the transfusion service had no direct treatment relationship with an individual who had been given implicated blood or products. This was a new and uncertain situation which was developing quickly and the blood services followed the available advice at the time and passed on information as appropriate.

156. On **3 July 1984**, Dr Gunson wrote to Dr Smithies at the DHSS to provide details of a meeting held on **28 June** with Dr David Tyrrell, Chairman of the MRC Committee on AIDS, Dr Richard Tedder, consultant virologist at Middlesex Hospital, Dr Wallington and Dr Contreras [PRSE0003901]. The meeting took place following a letter Dr Gunson received from Dr Tyrrell at the end of May suggesting that the MRC could help in setting up a study on blood donors using the

detection of anti-HTLV-III as a possible marker for donors who may be at high risk of transmitting AIDS.

157. Dr Gunson advised that considerable pressure would be placed on the transfusion service when an anti-HTLV-III test was introduced in the US. However, it was agreed that at the present time, the test should be regarded as a research project and should not be introduced into routine screening of blood donations without proper appraisal. It was important, however, that a study should be started as soon as possible. The most important development in the study would be the availability of a viable test for anti-HTLV-III. The work of Dr Tedder and Dr Weiss was very promising and although it was early days, there was reason to believe that a radio-immune assay may be available within the foreseeable future.

158. Studies would be performed upon patients in high-risk groups of contracting AIDS. With respect to studies on blood donations, included in the general protocol was:

- **Stage 3:** Donations would be tested at the Manchester RTC and Bristol RTC whilst tests would continue at the North West Thames RTC, thus giving a broad view of the country as a whole. At this stage, donations would be tested prior to issue, plasma would be saved from the donation and donors would be followed up. In Manchester, if donors found to be positive had given blood within the last 8-9 months, a previous sample of stored serum would be available for testing. If this proved positive, then identification of the patients receiving the products would be made and follow-up pursued.

159. On **19 October 1984** a memo responded to questions from the CMO concerning AIDS and blood donations [DHSC0002323_009]. The

memo comments on the "*position about blood transfusion/plasma related AIDS in the UK and its controls*". It noted that officially there were three cases of AIDS in people with haemophilia, of whom one had died; in view of the approximately 35% prevalence of HTLV-III antibodies in people with haemophilia there were likely to be more cases of AIDS. PHLS was following up other recipients of the batches of US-derived Factor VIII received by two of the patients with AIDS. The DHSS had allocated research funds to this study.

160. Someone (name redacted) was also said to be following up, through the Haemophilia Centre Directors, concerns about recipients of recent batches known to be associated with ex-donors who had developed AIDS, both from the US and one from Wessex. The memo noted that the only protection for recipients of blood and blood products from contracting AIDS from donors was the publicity given to the possibility of transmission from high-risk groups.

161. In a redacted letter dated **24 October 1984** from BPL to the DHSS there are some details of the batch HL3186 recall [PRSE0001658]. It refers to follow-up being done by another, and not BPL, but does not identify who. It provides detail of the recall procedure operated by BPL. The letter also concludes by noting issues in relation to quarantine periods for finished products.

162. In **November 1984** a paper was circulated to members of the Advisory Committee on the NBTS's Working Group on AIDS in advance of their first meeting on **27 November 1984,** [CBLA0001934_003] which appears to have been prepared by the Chairman, Dr M Abrams of the DHSS. The paper set out various issues on which the Group's views were sought in order to protect the blood supply from the increasing prevalence of AIDS.

163. The paper advised that facilities would be required to confirm the results of any positive tests. As the number of positive results was likely to be small, it was queried whether it might be preferable for confirmation to be centralised in one place. Once a positive donor was identified, a retrospective survey of previous donations would be required. The extent of the survey would depend on the number of previous donations, how they were used and where they were given. It would probably be necessary to ask the donor directly for the latter information.

164. The first meeting of the Advisory Committee on the NBTS's Working Group on AIDS was held on **27 November 1984**, chaired by Dr Abrams at the DHSS. Transfusion service members included Dr Gunson, Dr Contreras and Dr Fraser. The Group's terms of reference were to consider the implications for the transfusion service of testing blood donations for antibody to HTLV-III and to report [CBLA0001934_002]. Dr Abrams subsequently prepared a memo summarising the main points. The points relevant to this question were that: [DHSC0002251_011]

- There was a unanimous, strong view that the antibody test for HTLV-III must be used for all NBTS donors as soon as possible. It was hoped that the Tedder/Weiss test could be scaled up very quickly.

- Donors with positive results should be informed, although there was no unanimity on who should do it or how. Follow up of donors and patients, counselling and contact tracing arrangements were being considered by IMCD (this appears to refer to the DHSS Communicable Diseases Division). One suggestion was for a regional immunology service to deal with such issues at special centres.

- National surveillance by the CDSC of test results.

165. On **30 November 1984** Dr Craske provided a letter to Haemophilia Centre Directors detailing how retrospective studies into the batches that were given to the patients who had developed AIDS in **1983** would work [HCDO0000392_107]. He concluded there were several difficulties with undertaking such study because of i) "the prevalence of the antibody to HTLV-3 in haemophiliacs treated with commercial factor VIII is between 50 and 80% in different Centres"; ii) "[t]he number of infected batches may be quite high"; and, iii) "[t]he limited sera available". Dr Craske therefore noted:

We have therefore concluded that retrospective studies of clusters of patients will usually fail to correctly identify batches of factor VIII contaminated with HTLV-3 unless a large number of persons are transfused and the proportion infected is high.

166. He then went on to consider prospective studies in light of the shortage of tests. At this stage testing was to be used to investigate patients with clinical features of AIDS-related illness. In addition, it would be used for prospective studies involving possibly infected batches so as to identify the risk of infection and development of the syndrome.

167. On **14 December 1984**, Professor Bloom sent a document entitled *"AIDS Advisory Document"* to all Haemophilia Centre Directors, intended to express the position adopted at a meeting four days earlier and outlining observations and recommendations made [HCDO0000270_007]. In the UK, there had been **102** cases of AIDS including **three** haemophiliac patients, with other cases no doubt developing in the haemophilia population. It was recommended that haemophilia patients should be tested for HTLV-III antibody. Tests were

available via Professor Tedder at the Middlesex Hospital and Dr Mortimer at the PHLS. The test should be repeated if positive.

168. The document notes that whilst antibody positivity probably correlated with exposure to imported concentrates, there had been two recent episodes where HTLV-III had probably been incorporated into at least one BPL and one Scottish batch of UK Factor VIII. Recipients were being followed up. Those who were antibody positive should be considered at risk of transmitting or developing AIDS, although antibody negativity did not exclude infectivity. Antibody positive people should be informed, reassured and counselled regarding transmission to spouses etc., including the use of contraception.

169. At this time UKHCDO and the haemophilia clinicians were understandably pushing for the testing of their patients. While testing of small numbers of patients was possible in some specialised virology laboratories, mass screening of blood donations was still some way off.

170. On **20 December 1984** Dr Acheson, CMO at the DHSS, issued a press release concerning an infected donation [BART0000814]. The press release concerned a donation by a man who was subsequently admitted to hospital, in **October 1984**, and was later identified to be suffering from AIDS. Dr Acheson set out that "*[h]is donations of both blood and blood plasma have been traced, and all possible remedial action taken.*" Three recipients of blood donations were identified and followed up. All three tested positive for HTLV-III antibodies. The infected donor's plasma was identified as used in a batch of Factor VIII produced at BPL. When the diagnosis of AIDS became known, the remainder of the batch was withdrawn, but it had already been received by **38** patients with haemophilia. The patients were traced and monitored. Dr Acheson noted that it would not be possible to say whether any who tested positive for HTLV-III antibodies would have

been infected by this batch of BPL Factor VIII or other, commercial, products. All recipients were said to not show clinical signs of developing AIDS.

171. This is another example of the follow-up that was being undertaken prior to the institution of HTLV-III screening for donors. Because of the lack of *screening*, as opposed to *diagnostic*, tests the approach was necessarily reactive rather than pro-active. This approach maps to the protocol recorded on **4 April**.

172. On **3 January 1985** there was a meeting between Dr Tedder, Dr Mortimer, and Dr Craske to consider a proposal for testing of haemophilia patients to the UKHCDO [BART0000821]. The proposals were that:

HTLV-3 ANTIBODY SURVEY PATIENTS

a) *All patients treated with factor VIII and IX concentrate in U.K. Haemophilia Centres would be offered an antibody test for HTLV-3 antibody within the period* ***February to April, 1985****. This would provide a clear picture to each Director of the number of patients at risk of developing AIDS, and assist in counselling patients and their relatives, and also assist in the investigation of AIDS related disease. It would also make it easier to devise strategies for the use of NHS factor VIII concentrate during the period before heat treated factor VIII concentrate became widely available.*

b) *Family contacts of patients. It was also hoped to offer HTLV-3 antibody tests to relatives of patients who were found to be HTLV-3 positive. In view of the shortage of reagents, this would be better done by carrying out limited family studies to determine the risk of spread of infection before offering a test to all relatives.*

c) *Follow-up of sero-positive patients. It was essential that this should be carried out on a large sample of patients and that this should be*

related to reports of AIDS related illness to obtain an accurate picture of the prognosis of HTLV-3 infection.

d) *Future HTLV-3 antibody prevalence studies. Much information might be obtained by repeating the survey in one year's time to obtain an objective picture of the sero-conversion rates in one year; This could be related to treatment as reported in the Oxford returns during any year.*

173. There was also a discussion of how the above would be achieved, along with prospective studies for the use of heated Factor VIII.

174. On **1 October 1985** there was a meeting of the Department of Health's Expert Advisory Group on AIDS - EAGA [MRCO0000001_068]. This meeting included a discussion with Mr Barney Hayhoe who was Minister of State for Health. He reported on the lack of available funding for AIDS. In the AOB section of the meeting Dr Contreras said "*that AIDS patients should be asked if they had donated blood within the last five years so a follow-up could be done. Dr Tedder said the scheme should be extended to cover all HTLV III positive patients.*"

175. On **8 October 1985** there was a meeting of the Regional Transfusion Directors at BPL [CBLA0002263]. There was a discussion of HTLV-III positive donations in the Northern Region. There had been five in the period, of which four had been processed. They were included in the production of 5 batches of non-heat-treated Factor VIII. The minutes then discussed notification, screening, and withdrawal of batches:
Dr Snape referred to other similar cases that had been notified in the last few months. The implications for BPL were of concern as many batches may have to be withdrawn from release.
Screening had begun nationally on 14 October. It had been agreed that any positive donor would be retrospectively looked at for the five years previous. BPL would then be required to review the progress of any

likely positive donations through the production process. BPL would need to clear its plasma/intermediate stocks of known positivity.
Dr Lane advised that Fraction II products had the highest potential for problems. There was a requirement to show that Fraction II does not transmit HTLV-III. At the moment, one could only minimise any risk by withdrawing any donations linked to new positive donors. Previous donors that would not now be tested (because self-excluded) were a problem to plasma stocks at BPL. It was unlikely that plasma stocks could be cleared of positive donations. A potential risk would still exist until methods were proved to eliminate any risk of viral transmission.

176. The EAGA's Screening Test Subgroup had held a further meeting on **28 March 1985,** chaired by Dr Smithies, DHSS [DHSC0001571]. Dr Gunson was in attendance. The minutes note that due to the great logistical problems in seeking "informed consent" at sessions, RTDs should be consulted and devise agreed procedures on providing information to donors. It was agreed that all anti-HTLV-III positive donors must be informed of their results because of the danger to their health and that of others. The follow-up of positive donors' past donations was considered at a subsequent meeting on **10 June 1985**.

177. At the meeting on **10 June 1985,** chaired by Dr Smithies, DHSS [NHBT0000186_033] with Dr Gunson in attendance, Dr Mortimer provided an update from PHLS in respect of the ongoing evaluation of test kits which was discussed in detail. There was a discussion of the procedure for the field trials of test kits, the role of donor GPs, and how donors would be told of positive tests. The sub-group also considered the follow up of earlier positive donations. It was agreed that where long-standing donors were found to be antibody positive, only physicians should be informed (via the hospital Consultant Haematologist) and it would be for the physician to decide further action.

178. This marks the earliest consideration of follow-up of past donations relying on HTLV-III testing of donations, rather than notification of a diagnosis of AIDS in a donor. This early position appears to have been that follow-up (lookback) would be undertaken, but passing on information to the recipient would be the responsibility of the treating clinician.

179. At a meeting of RTDs held on **10 July 1985** [CBLA0002212], the Chairman reported on a number of meetings regarding AIDS. It appears to have been agreed that donors must be informed that anti-HTLV-III testing would be carried out and that the donor leaflet should be updated accordingly. HTLV-III positive donations would be destroyed. The NBTS would make the initial approach to a positive donor and counselling would be essential. The RTDs would look to the EAGA for guidelines, however it was considered that GPs should be involved, with the donor's consent. It appears to have been agreed that follow up of previous donations of plasma should be for **3-5 years**. The Chairman requested the approval of the meeting to let the group (this appears to refer to the Working Party of the RTDs' Committee) draft a flow diagram for AIDS testing and follow up of donations. The meeting the next day would then pass on recommendations to the EAGA.

180. By this stage the time period for follow-up of previous donations was being considered. In 1985 a period of 3-5 years represented possible follow-up back to 1980, when AIDS appears to have first emerged in the UK around 1982.

181. A report dated **11 July 1985** was prepared by the Working Party of the RTDs' Committee entitled *"Screening of Blood Donations for Anti-HTLV-III in Regional Blood Transfusion Centres"* [DHSC0000406].

This stated that in accordance with the resolution of the EAGA, Dr Smithies, of DHSS, consulting with the NBTS on the screening of blood donations for anti-HTLV-III, the RTD Committee had formed a Working Party comprised of six RTDs from the NBTS (including Dr Gunson) and Dr McClelland from the SNBTS. The contents of the report were approved by the Directors of both the NBTS and SNBTS and subsequently endorsed by the EAGA on **30 July 1985** (see below). This report laid down the framework for the introduction of routine screening throughout the UK, including a target start date of **October 1985**. It outlined recommended procedures for informing donors that their blood would be tested, the management of positive results, the care of positive donors and significantly, **lookback** in respect of recipients of donations originating from donors who later tested HIV positive. The approach to testing with a degree of urgency, so that there could be implementation in **October 1985**, was discussed.

182. In respect of the follow up of recipients of previous donations given by donors found to be anti-HTLV-III positive (i.e. lookback), it was recommended at section seven of the report that:

> *7.1 "Efforts will be made to determine the names of any patients who received blood and components from the donations taken during the past **five years*** [my emphasis] *and the information regarding the known or possible seropositivity of the donation given to the Consultant in charge of the patient.*
>
> *7.2. If plasma from any of the donations was sent for fractionation, full follow-up of all patients receiving coagulation factor concentrates may be difficult or impossible. Since patients suffering from haemophilia A and B are being investigated for anti-HTLV-III at present, it is recommended that no additional follow up be carried out".*

183. The follow-up section seems to be the first fully articulated policy for lookback post-introduction of HTLV-III testing. It adopts the 5-year period considered earlier. It identifies the distinction between blood components and fractionated plasma products, particularly looking at coagulation products. It explains why full follow-up may be difficult or impossible. It acknowledges that haemophilia clinicians were already testing their patients for HTLV-III. It was thought that proactive testing of patients with haemophilia could avoid the logistical difficulties of performing lookback on plasma donations which had been used to prepare pooled fractionated products.

184. On **30 July 1985,** the EAGA held its fifth meeting, chaired by Dr Acheson, DHSS [PRSE0002628] which Dr Gunson attended. The report by the Working Party of the RTD Committee on the screening of blood donations dated **11 July 1985** was discussed. Of note is the consideration of the follow up of blood donations previously given by donors identified as antibody positive. Dr Smithies advised that the Screening Test Sub-group had recommended that the Haematologist in charge of the hospital blood bank should be informed if it was believed that an earlier donation could have transmitted HTLV-III infection. The Haematologist would be asked to identify the recipient of the donation and to inform the clinician in charge of the patient when the blood had been transfused. Members agreed the recommendations and considered it would be up to the clinician in charge of the patient to decide on what subsequent investigations should be made. It was also agreed that although there might be practical difficulties, follow up for donations should go back a minimum of five years from the date of the donation.

185. A minimum follow-up period of five years would put the follow-up back to, at least, mid-1980. The recommendations emphasise the relationship of treating clinicians with the recipient patient.

186. On **26 November 1985,** the EAGA held its seventh meeting, chaired by Dr Acheson (am) and Dr Abrams (pm), DHSS [DHSC0002287_060]. Under *"Any Other Business",* Dr Tedder, on behalf of Dr Contreras, asked clinical members whether they would consider asking seropositive patients as a matter of routine if they had donated blood since **1978** and in cases where blood had been donated, if they would refer their patients to the RTC in order that recipients of donations could be followed up. The Chairman noted that this issue needed to be considered by the full Group at its next meeting.

187. The comments by Dr Tedder reflect an important difficulty with what NBTS could achieve by screening of blood donations. The NBTS could only screen donations from active blood donors. Donor education and encouragement of those who recognised themselves to be at risk of HIV infection to self-exclude from blood donation had been extremely successful, so that by the time that screening of blood donations commenced in October 1985, very few HIV positive donors were detected. The HIV status of those who had self-excluded would remain unknown, unless reports were made when any such individual was found to be HIV positive outside the blood donation setting. We therefore had to rely on clinicians and/or seropositive individuals themselves to come forward and inform the blood service. Only then could lookback on such donations be possible.

188. A meeting of the RTDs was held on **24 and 25 April 1986** [CBLA0002307] at which anti-HTLV-III testing was discussed. Dr Fraser drew attention to an epidemiological survey of the HTLV-III virus by the BTS, the aims of which were summarised in a circulated letter from Dr Wallington. This appears to refer to a proposed epidemiological study of recipients of anti-HTLV-III blood, as referred to in future

meetings/correspondence. Dr Fraser anticipated that Dr Wallington would be in touch with all RTDs within the next three weeks and sending out a portfolio of documents and pro-formas in connection with the study.

189. On **10 September 1986** Dr Craske produced a paper concerning the retrospective study of HIV infections associated with a number of infected batches of NHS Factor VIII and Factor IX [DHSC0001039]. It provided information explaining how the batches were identified, how the patients were currently tested, and how monitoring and follow-up would proceed going forwards. It appears this paper was prepared for a UKHCDO meeting. Also on **10 September 1986** Dr Craske produced an update on HIV-related illness [DHSC0001039]. The report included details about the second HIV antibody survey, and the review of the batches of Factor VIII for HIV. The report included a discussion of reporting patients to Oxford, and that steps would be taken to provide a list of patients notified to Oxford to Centres to identify overlooked patients. Dr Craske also noted the importance of identifying the date of seroconversion so that patients could be linked to long-term follow-up.

190. At an RTD meeting on **8 October 1986,** chaired by Dr Fraser [CBLA0002345], it was noted that Dr Wallington had completed the papers for his epidemiological study of recipients of anti-HIV positive blood. The Chairman of the BMA's Ethical Committee had advised that the proposal should be put to seven ethical committees selected at random, starting with Southmead Hospital. The response was unfavourable, with two physicians on the panel stating that in no circumstances would their patients be approached to take part in such a study. Dr Wallington proposed to approach six other ethical committees in due course.

191. Arising from this, there was also some discussion about informing recipients of HIV infected blood. It was agreed that as a first step, the physician or surgeon in charge of the recipient's case should be approached. Opinion was divided as to how to proceed if the clinician was unwilling to take further action. It was felt that, particularly with younger patients, other steps should be considered if this was judged to be in the patient's interest. It was also pointed out that when tracing the recipients of earlier donations of donors found to be HIV positive, the fact that the recipient was dead was not necessarily the end of the story, since their organs may have been used for transplantation and could transmit the infection to the organ recipient.

192. I had no knowledge of Dr Wallington's proposed study. It is not clear why the question of informing recipients of HIV infected blood was being discussed again in **1986**, when lookback had been incorporated in the protocol for the introduction of screening of blood donations in **1985**. It appears (see below) that Dr Wallington was proposing to try to identify HIV-infected ex-blood donors, who had self-excluded from blood donation before October 1985, through contact with treating clinicians, such as in Sexual Health clinics. It appears that Dr Wallington's study did eventually go ahead, but there seems to be limited available documentary evidence about it.

193. This meeting included some of the first discussion of not necessarily following the views of the treating clinician, which was an important step-change from the usual approach at the time. There was also discussion of following through implicated donations even when an individual had died. This is an important feature of monitoring transfusion-transmitted infections, as practiced today.

194. On **25 March 1987** Dr Gunson, together with Dr Richard Lane, Mr BJ Crowley, Dr TJ Snape and Dr JK Smith (all of BPL) gave evidence to

the House of Commons Social Services Committee on the problems associated with AIDS [LDOW0000247]. Dr Gunson submitted a memorandum on the consequences of AIDS for the blood transfusion service. He described the incidence of anti-HIV positive blood donors in the UK as being among the lowest in the world, below the USA and many European countries by a factor of 10, and being comparable to Scandinavian countries. He noted the problem of donations in the window between infection and anti-HIV formation, but estimated the risk of this as less than one in one million. He did, however, note that there had been an example of a donation in the window period which led to HIV infection in the recipients. Dr Gunson also noted that the majority of donors who were anti-HIV positive did not consider they were in a risk category, often because of how long before the relevant risk activity had taken place.

195. In his closing remarks Dr Gunson noted patients' fear about receiving or having received a transfusion. Dr Gunson said that: *Although one cannot state categorically that blood transfusions are absolutely safe, the chance of contracting HIV infection or AIDS from blood transfusion is extremely remote. The fact that only two patients receiving* [sic] *blood products from one donor have contracted HIV infection in the use of 3.5 million donations since anti-HIV testing was introduced illustrates the point. Whilst it can be said that the British Blood Transfusion Service is one of the safest in the world, it is only with continuing vigilance that this can be maintained*".

196. On **6 May 1987**, Dr Wallington wrote to Dr Gunson in respect of his coordinated study of transfusion-transmitted HIV infection [NHBT0004202]. He stated that as Dr Gunson knew, it had been agreed within the NBTS that an attempt would be made to identify, *investigate and help patients and their household contacts (where necessary) who had received transfusions which might have infected*

them with HIV. In a subsequent letter dated **22 July 1987**, Dr Wallington clarified that the two main aims of the study were to identify HIV positive donors who may have given potentially infectious donations **before screening was introduced** and **to facilitate the follow up of patients who received these donations so as to allow their proper counselling and treatment,** and the collection of epidemiological data concerning them and their contacts (my emphasis).

197. Dr Wallington referred to enclosed study documents which were designed to introduce the project and allow Dr Gunson to start it in his region, as well as collect data for local and central analysis. The project would be coordinated from Bristol but virtually all of the work, interviewing donors and blood recipients once the link had been established, would be done by local staff organised at RTC level. Dr Wallington asked Dr Gunson to send the enclosed letter and documents for **task one**, *donor* tracing and study, to colleagues who might know of relevant donors. In respect of **task two**, *recipient* tracing and study, Dr Wallington acknowledged possible concerns about approaching blood recipients with such a diagnosis and also the investigation of their household contacts. However, he noted that opinion had been changing rapidly and most people now believed infected persons should be identified wherever possible for public health reasons. As this part of the study would undoubtedly prove controversial, he asked Dr Gunson to send the enclosed letter and documents for **task two** to Haematologists in his region so they would be fully informed about the project before being presented with notification of a donation thought to be infectious. He confirmed that all RTCs in England and Wales had now received the study documents.

198. It thus appears that Dr Wallington's study was an attempt to identify HIV-infected ex-blood donors who had ceased donation before October

1985, through contact with clinicians who were caring for AIDS patients, who would then report the details of the ex-donor to the RTC. The RTC would then carry out lookback and identify recipients who could be offered testing. Further investigation would then identify whether infection had been transmitted from infected recipients to partners or other secondary contacts. The ethical issues of Dr Wallington's study were clearly a significant consideration at the time. There was much concern about confidentiality of people diagnosed with AIDS, and reluctance, and even outright resistance, to passing on names to a separate organisation, even when other individuals may have been put at risk. This concern with confidentiality was a significant barrier to the blood service being informed about ex-donors who were now known to be HIV positive.

199. On **26 May 1987**, Dr Vanessa Martlew (the RTD in Liverpool) sent a memo to Dr Gunson with her comments on Dr Wallington's study of transfusion transmitted HIV infection [NHBT0004200]. She foresaw difficulties in obtaining the cooperation of consultant colleagues, particularly in GUM (Sexual Health) clinics, unless there was funding for completing the initial questionnaires for HIV positive ex-donor patients. The detailed interrogation of recipients and especially their families might also be resisted locally on the grounds of generating panic in the community. The special attention paid to HIV positive subjects would be difficult to conceal, notwithstanding confidentiality, and may well have unpleasant social consequences. In principle, she agreed this was a good way to determine projections for heterosexual spread of the virus and would be happy to complete the form for those positive donors and the occasional recipient she followed up. She did not see the need to pass on the recipient's name to the coordinating centre as the registration number should suffice until politeness demanded an introduction to the epidemiologist, which might be adequately managed on a first name basis.

200. This letter reflects the resource difficulties that undertaking this proposed lookback would entail. It also reflects the relative lack of control that clinicians had over each other. There was no directive from the DHSS or CMO to undertake this study. There was no way of compelling other clinicians to undertake the necessary reviews, particularly in GUM clinics, where confidentiality was crucial and an overriding concern. There was also a more general and understandable ethical concern about maintaining confidentiality.

201. On **22 July 1987**, Dr Wallington sent a further letter to Dr Gunson in respect of his study on transfusion transmitted HIV, advising that he had received very little response regarding the project since distributing the papers [NHBT0004199]. He said that any feedback on the project as a whole or completed questionnaires would be helpful. There was particular epidemiological interest in donors who had been identified by screening and did not belong to a high-risk group and also (it appears) patients who had already been identified with transfusion-transmitted HIV infection either because they had become symptomatic or because of tracing past donations of positive donors. Even if the form could not be fully completed for such patients, this information would allow him to begin collating and some of them may be prepared to allow the more extensive epidemiological enquiries previously detailed.

202. Dr Gunson's request to colleagues, and the letter from Dr Wallington, reflect some of the difficulties in the lookback epidemiological study. A questionnaire on blood transfusion and AIDS in England and Wales covers data up to **31 December 1989** [NHBT0019308_003]. It reports that screening of blood and plasma donations for anti-HIV **1 began in October 1985** and that routine screening for **anti-HIV-1 +2** would commence on **1 June 1990**. With respect to lookback, it was recorded "no" with an asterisk to the question whether, on a donor positive test, a

lookback programme was carried out on patients having received blood products from the same donor. The asterisk recorded:

A look-back programme was instituted in 1986 and involved 30-40 HIV 1 seropositive donors. Many of the patients had died from their primary disease and it was decided to abandon the study.
During 1989 several seroconversions of donors previously found HIV seronegative have been found and consideration is being given to reinstating the lookback programme.

203. It was recorded that, if a patient (recipient) had a positive test, research would be carried out to see whether it was transfusion-associated. On insurance, it was noted the state covered claims by patients.

204. I do not understand the information contained in the report. The HIV lookback programme commenced in 1985, when HIV screening of blood donations commenced, and was never abandoned. It may be that this comment referred to the Dr Wallington study. At NLBTC we continued with HIV lookback from 1985 onwards, and we also performed lookback on the previous (tested negative) donation of donors who were found to have seroconverted (from HIV antibody negative to HIV antibody positive).

205. On **15 December 1987** Dr Craske produced a paper for future surveillance of infections transmitted by Factor VIII and Factor IX [HCDO0000427]. The proposal was that the system would involve membership from the Haemophilia Centre Directors, BPL, DHSS and PHLS, and that the results would be reported annually to the DHSS, BPL and the Haemophilia Centre Directors. The report produces a plan of action of how this proposal would be taken forward.

Look-back in the 1990s

206. On **19 February 1990** Dr Gunson produced a report on anti-HIV-I testing of blood in the UK [NHBT0015578_001]. A number of tables of data were included. He also noted the process of recall. He explained that attempts were made to recall all confirmed anti-HIV positive donors to the RTC for interview and counselling as appropriate. The "majority" responded. A summary of risk activities was provided. Of recipients he said: *Investigations of the recipients of products from seronegative donations from a donor who subsequently became seropositive have not, in general, been carried out. In those that have been followed up the patient has either succumbed to the primary disease or has been seronegative. One instance was found in Glasgow where two patients seroconverted following the transfusion of products from a donor who was anti-HIV negative in **July 1986** and positive in **October 1986**.* This was the first formally documented instance of a "window period" transmission in the UK, where a tested (antibody negative) donation was subsequently shown to have been infectious, and to have transmitted infection to recipients.

207. On **6 March 1990** there was an EAGA meeting at which Dr Gunson attended [NHBT0008216_002] and introduced his paper dated **19 February 1990** (discussed above). There was further discussion of the transmission in Scotland. There was discussion that in **1987** NBTS had carried out an exercise which looked back to see how many donations had been given in the previous 6 months by donors who had seroconverted. There was no lookback programme on the outcome for recipients of blood from donors who *subsequently* seroconverted. This comment is difficult to understand, given that the case in Scotland was recognised through precisely the lookback which is stated not to be taking place.

208. In **September 1990** Dr Gunson undertook an investigation of the procedures in place at Regional Transfusion Centres for the investigation of donations transmitting HIV and HBsAg [NHBT0003763]. The focus of this review was the initial stages of investigation so BPL could be informed of any plasma donations that may be at risk, and follow-up of the donor so that s/he could be removed from the panel of active donors. The body of the report also has some limited consideration of recipient follow-up, although it was not the focus of the paper. Overall, Dr Gunson commented that:

The majority of RTCs have procedures for investigating donors implicated in transfusion-associated infections. These involved contacting the donor and retesting of an additional sample using reference laboratories for confirmatory testing.
I am generally confident that procedures are satisfactory to ensure the withdrawal of suspect donors from the panel if appropriate.

However, procedures do vary, particularly with the reporting of suspect donations to BPL and in some RTCs this could take a significant time. With BPL stocks reducing it is imperative that notification of such donations to BPL are carried out with the minimum of delay.

Draft specifications for the notification of non-conforming plasma donations are being considered at present and when agreed will be circulated to RTCs.

209. The variation of procedure demonstrated in the above paragraph again highlights that the lack of a nationally managed blood service in England limited Dr Gunson's ability to influence practices. He only had persuasive authority. This caused real difficulty in implementing national schemes like the lookback.

210. A report dated **11 September 1990** was prepared by Dr Janet Mortimer at the PHLS entitled *"NBTS "LOOK-BACK" October 1985 – December 1989* [NHBT0015574_002], which was tabled at the EAGA meeting on **2 October 1990.** The report provides a summary of the follow-up of previous donations from donors found to be anti-HIV positive during the routine screening of blood donations from its introduction in **October 1985** to the end of **1989.** It confirms that **67** repeat donors were found to be anti-HIV positive during this period. **33** were homosexual or bisexual, **18** (ten female) were exposed heterosexually outside of Africa, **three** were African or had lived in Africa, **one** was exposed through IVDU (drug use) and **one** by transfusion. For **eight**, a probable route of transmission had not been established. The report provides a table of the year of the positive donation and sex of the donors.

211. At the time of the report, information about the follow-up of previous donations from these donors had been received for **64** of them. They had given at least **419 donations** between them. Most of the donations involved in this lookback were made before routine anti-HIV testing started, however **39** of them had been given since the introduction of screening. The fact that **39** such donations were included in the data is a clear demonstration that previous tested donations from donors who subsequently seroconverted were included in lookback, contrary to the comment above (in para 199*).* All but **one** of these were **negative**. For those donors where further information had been supplied, no seroconversions had been observed in the recipients of their blood. However, because of patient deaths from underlying causes, difficulties in identifying recipients and reluctance to alarm patients, follow-up was not complete. Therefore, the possibility that HIV transmissions from screened blood had taken place could not be ruled out.

212. The **12** anti-HIV positive recipients of blood or components identified through lookback resulted from donations taken *before* the introduction

of screening from **ten** donors. A donation from **one** of them was known to have infected **two** out of **24** recipients of unheated Factor IX produced from it. Another of the **ten** donors, whose blood was given to an accident victim who died shortly after, passed HIV infection to the recipients of the heart and kidneys of the victim.

213. A summary of the donation history and follow up reported for each of the anti-HIV positive repeat donors identified by screening is appended to the report, although it is clarified that the summary did not cover all recorded transfusion-associated transmissions of HIV from RTCs in England, Wales and Northern Ireland as those found as a result of the investigation of **positive recipients** (i.e through traceback or reverse lookback) were not included. The report notes that the summary revealed differences in the follow up capacity and practice between RTCs and advised that the lack of computerised records could be a limitation. While some RTCs pursued every identifiable donation, others curtailed lookback when they identified one negative recipient, or had evidence that the donation pre-dated infection. There were also gaps when donors had moved between regions.

214. The report advises that greater uniformity of practice seemed desirable and made the following recommendations for consideration:

1. *That when more than one transfusion centre is concerned the centre where a positive donor is identified is the one responsible for collating the lookback data.*
2. *That wherever possible lookback continues retrospectively through the previous donations until either a) all have been investigated, or b) an anti-HIV negative recipient is identified, unless there is any doubt about the accuracy of the record keeping which makes further lookback desirable.*

3. *That lookback should be applied in the same way to all donors, however discovered to be anti-HIV positive, and not only to those identified by donation screening.*
4. *That the results of the lookback be recorded on a form such as the one used to produce this summary (Appendix 2) and collected and collated centrally on an annual basis.*

215. This document provides recommendations on how lookback should be approached going forward. It is one of the more complete records of some of the work that the blood services did on lookback.

216. At an EAGA meeting on **2 October 1990,** chaired by Sir Donald Acheson and Dr Rubery, DHSS [NHBT0008213_002] Dr Gunson presented the paper prepared by Dr Janet Mortimer (dated **11 September 1990**) which provided recommendations on the follow-up of recipients of donations from seropositive donors. Whilst accepting the limitations, members considered that the lookback study was very important and should continue. Members agreed to the proposed uniform procedure for follow-up but recommended that previous donations should be investigated until **two anti-HIV negative recipients** had been identified rather than just **one**, as proposed by Dr Mortimer.

217. This paragraph reflects the transfusion service's commitment to continue with lookback, notwithstanding the difficulties identified. It was also important work in the context of the ex-gratia payment schemes that had been (and would be) implemented by the government. It happened without a unified structure for the English blood service, and relied to a large extent on consensus for compliance by all RTDs.

218. In **January 1991** Dr Gunson and Vi Rawlinson produced their report on HIV testing in **1990** [NHBT0006833]. In 1990 1.73 million of 2.82 million donations were tested with a **combined anti-HIV 1 and 2** test (61%). **Thirty-three** donations were identified as HIV-1 positive and **one** was HIV-2 positive. Risk activities were reviewed in the report. Follow-up had been attempted with patients receiving blood from previous seronegative donations of donors found seropositive, with "limited success". The report quotes from the NBTS lookback report to EAGA dated **2 October 1990** from Mrs Janet Mortimer of the CDSC:

For those about whom further information had been supplied no seroconversions had been observed in the recipients of their blood. However, because of patient deaths from underlying causes, difficulties in identifying recipients and reluctance to alarm patients, follow-up has not been complete. Therefore, the possibility that HIV transmissions from screened blood have taken place cannot be ruled out.

219. The report notes that one instance of transmission had been recorded. It also notes that routine screening of blood donations was essential and that consideration perhaps should be given to alternative means of self-exclusion of donors at risk. It explained that in the USA opinion was moving towards an **interview of the donors** as the most successful means of securing such self-exclusion. It noted that this would pose many problems to introduce. The report concluded noting that the rate of HIV-1 seropositivity of blood donations in the UK continued to remain at a low level.

220. On **9 May 1991** Mrs J Mortimer of PHLS provided to Dr Gunson a copy of the letter sent on **8 May 1991** to RTDs [NHBT0004801] on behalf of Dr Gunson, headed: "[f]ollow-up of anti-HIV positive recipients of blood". It concerned making a national summary of information on anti-HIV positive recipients of blood. This relates to recipients found to

be HIV positive, who had a history of transfusion, and whose case was reported to the RTC for investigation. The Directors were asked to complete a form for each positive transfusion recipient to provide relevant information on those for whom investigation had identified a donor subsequently found to be positive, those for whom transfusion had been ruled out as the likely source of infection, and those for whom the position was unresolved. As part of the follow-up, Mrs Mortimer noted that she would check the databases at CDSC "*in confidence*" to see if any of the identified donors that the centres had not been able to contact had been reported as HIV positive or as an AIDS case. To do this she would need to interrogate CDSC records to see if there was a match, through using date of birth and Soundex code. Soundex codes permit confidential reporting of names in such a way that the code is not unique to a single name, but with the date of birth allows for identification of likely matches. Staff in transfusion centres would translate the names of untraceable donors into Soundex codes, and send this, with the date of birth, to CDSC for searching of their records.

221. In **1991** Dr M P Busch published an article in the journal "Transfusion" on HCV and HIV lookback [PRSE0004329], in particular, considering the lessons which could be taken from the latter when undertaking the former. While the article is mainly relevant to the USA, and mainly relevant to prospective lookback for HCV, the following is notable:

In sum, these studies show that the overall yield and efficacy of HIV lookback programs were poor. Standard, targeted look-back was limited, ironically, by the effectiveness of early self-exclusion measures, in that almost all of those responsible for HIV infections had stopped donating before they could be identified by HIV screening. Additional limits were created by the high death rate of recipients who were identified by tracing transfused components from infected donors, as well as the delay in and logistics of manual record searching and

individual recipients tracing and notification through hospitals and private physicians. We estimate that even IMBC's expanded, targeted lookback program has thus far identified only about one-half of the projected 2100 living, infected recipients in that region. The best evidence for the poor yield of general lookback is the continued identification of large numbers of previously untested transfusion recipients through IMBC's targeted lookback efforts. Transfusion recipients were aware of the CDC's initial announcement and who had received a general look-back letter from their hospital but never sought testing often learn that they are infected when they are tested after receiving a letter indicating that a donor of the blood transfused to them had recently developed AIDS. ***Thus, even in San Francisco, where lookback probably has been pursued more aggressively than anywhere else in the world, a substantial proportion of HIV-infected transfusion recipients are undoubtedly still unaware of their infection more than 6 years after screening was implemented****.* (my emphasis)

222. This is an important paper which discussed many of the difficulties that the transfusion service was experiencing with lookback in the UK. It particularly notes that success in encouraging self-exclusion of at-risk donors would make look-back significantly harder. As set out above, the UK appeared to have been successful in implementing self-exclusion. The paper also repeats some of the practical difficulties of paperwork, funding and time, which are reflected in the experience in the UK. Although circumstances were different in the US, where the blood services were even more fragmented, the negative outcome for the lookback in San Francisco was influential – including perhaps as to whether to introduce lookback with screening for HCV in the UK.

223. In a paper dated **5 September 1991** addressing revision of the AIDS leaflet [NHBT0097471_009] it is noted that in the six years following

introduction of testing in October 1985, **15,815,526** donations had been tested, of which **195** were confirmed anti-HIV positive. One individual was identified as having donated in the window period and transmitted HIV to recipients. The paper considers what was a "largely successful" exclusion scheme.

224. In **February 1992** Dr Gunson and Mrs Rawlinson produced their report on anti-HIV tests on blood donations in the UK for 1991 [NHBT0006882] This recorded that **2.95 million donations** were tested in 1991 for **anti-HIV 1 + 2**. **Twenty-six** donations were HIV-1 positive, and of **443,000 new donors, fourteen** were **seropositive**. There were **no anti-HIV-2 positive** donations. A higher ratio of men to women being positive was noted. It was also noted that the distribution of HIV seropositive donations was, pro-rata for the population, highest in the four Thames regions and in Scotland, corresponding to the distribution of HIV positive individuals reported to CDSC.

225. The report notes that "*[e]very effort is made to recall HIV seropositive donors but the results in 1991 are so far disappointing in that no information is available on **16** donors of the **26** found seropositive*". It was thought further information might become available. Risk factors of the identified donors were then discussed. The report went on to note that of 12 repeat donors, 10 had been previously found anti-HIV negative, and the remaining two had not donated since 1985.

226. On **21 February 1992** a meeting took place between the Department of Health, CDSC, and NBTS concerning the ex-gratia payment scheme for HIV infection [DHSC0002941_006]. Dr Gunson was in attendance for the NBTS. Part of the meeting considered the information that would be available from NBTS for identifying possible recipients (a separate part addressed information from CDSC). With respect to NBTS:

Pre 1985 library samples of donations in RTCs would be very rare. RTCs hold stored samples for last 2-3 years, and <u>may</u> have stored samples post 1985.
NBTS holds the donation number of all HIV positive donations, full records of the positive donations held at RTCs.
All HIV positive donors who could be traced (about 90%), have been informed of their HIV positivity, and told not to donate again.
NBTS would be in a position to find the donation number from the hospital and trace it back to the donor. (Note: this statement appears to relate to cases where a recipient is notified to be HIV positive: the traceback/ reverse lookback situation, and not to lookback). ***Where a donor moves from one RTC to another a transfer note should be held to enable the donor to be traced***. [my emphasis, but we would only hold such a note where the donor had notified us] *Difficulties could arise where perhaps as many as 30 units used in one transfusion would need to be traced.*
During 1987, Dr Tim Wallington, Bristol RTC undertook a look back study, and was able to trace recipients from only one third of the seropositive donors due to resistance from Consultants and ethical committees. Clinical opinion about the potential benefits of early diagnosis of HIV was now changing and this together with the potential for payments to the patients concerned should lead to greater cooperation.
Dr Gunson raised the question of funding the additional work that providing information for validation of claims would create.

227. The minutes also address CDSC information. CDSC noted that it did not have names of individual recipients or donors. It was accepted that, with legal advice, it could write to Consultants of patients on the matter. Similarly, after legal advice, CDSC may be able to give the Department

an indication in a report after consulting NBTS about donations. CDSC explained it may be able to review some applications:

'CDSC might be able, subject to legal advice, to check an application in confidence before it went to the panel. CDSC would be able to say, in a particular case, whether they were aware of the case and had followed it up, and if so whether the follow up had established transfusion using HIV positive blood. If it was a new case, CDSC would ask for a report from the consultant'.

228. The report went on to note that CDSC and NBTS' objectives "*are not to spoil either the donor base or the voluntary reporting system*". The minutes note under "*other points*" that *"care would need to be taken that there is no implication of negligence on the part of the health authority*".

229. On **24 April 1992** the DHSS issued a policy for an extension to the schemes of payment for persons infected with HIV and related persons [EILN0000016_001]. A process for identifying potential beneficiaries was provided, which was noted to include seeking CDSC and NBTS records, and circularising NHS Consultants and GPs (among other routes).

230. On **30 April 1992** a letter was sent on behalf of Dr K C Calman, CMO, to **all hospital consultants in the NHS, all GPs in contract with the NHS, regional directors of public health, district directors of public health, regional general managers, district general managers, chief executives of NHS trusts, and general managers of postgraduate SHAs** [OXUH0001251_004] regarding the extension of special payments to those haemophiliac patients infected with HIV to others infected as a result of blood transfusion or tissue transfer. The letter asks for help in identifying patients who may be entitled to

payments under the scheme. It reports that the CDSC will write on a confidential basis to Consultants who already have reported possible cases. It also notes that the NBTS Directorate was asking RTDs to check records and remind Consultants of any donations from donors subsequently found to be HIV positive. However, the letter asked more broadly for all Consultants and GPs to consider whether they had patients who may fall into the scheme. The relevant application form was to be completed, to be returned to Dr Rejman in confidence.

231. On **11 May 1992**, Dr Gunson sent a letter to all RTDs in England regarding the HIV and blood transfusion/tissue transfer payment scheme [NHBT0015108]. The Department of Health had asked RTCs to identify any possible blood donations which may be implicated in transmitting HIV to patients as a result of transfusion. He asked RTDs **to identify the blood donors they had found to be confirmed HIV antibody positive since the commencement of testing and send a list of the donation numbers of the previous donations (if any) from these donors, together with the dates of delivery, to the Consultant Haematologist at the hospital concerned**. He acknowledged that some RTDs may already have this information available from lookback programmes. He said the Department of Health was anxious that no potential beneficiaries were over-looked and as these extended to spouses and dependent children, the data should still be forwarded to the hospital even if RTDs were aware that the patient had died subsequently to the transfusion.

232. This correspondence marks a further attempt at lookback, prompted by the widening of the payment scheme. A distinction from the earlier approach, however, is the direct involvement and direction by the CMO to all clinicians. This provided considerably more weight than Dr Gunson trying to convince clinical colleagues by persuasion.

233. On **18 May 1992** Dr Ala, director of the RBTC in Edgbaston, Birmingham, replied to Dr Gunson's letter of **11 May 1992** [NHBT0015106] to say that products from HIV seropositive donors which were issued to hospitals in his region had been notified to Consultant Haematologists. The recipients had been identified and, if surviving, samples of their blood tested for anti-HIV. Dr Ala noted the lookback had extended as far as 1979 and expressed the view that the onus was on Haematologists to notify the CMO in respect of those who qualified for payments. He noted what steps he would take in the alternative if this was not the appropriate approach, which would be an extended lookback. Dr Ala also noted that Dr Gunson had suggested identifying spouses and dependents of patients who had died. Dr Ala noted that they would not have this information available for patients who had died of their original illness before HIV screening could be carried out. A great deal of work would be required if these were to be found.

234. Dr Gunson replied to Dr Ala on **29 May 1992** [NHBT0015106] confirming that, in the case of previously documented cases the onus was on the patient and Haematologist to notify the CMO for those persons who might qualify for payments. For those patients who died of their primary illness, at least evidence of HIV seropositivity prior to death or at least that products received were HIV seropositive, was needed. In those cases, a special panel would have to adjudicate, and Dr Ala would be asked if there were frozen stored samples from donation at some time in the future. The Department of Health had been warned that samples were unlikely to be available for prior to 1985.

235. On **29 May 1992** Dr Gunson also wrote to me, responding to my earlier letter [NHBT0015104]. He noted that: '*One of the problems in sending out a standard letter to all RTCs is that the RTCs are*

not "standard". He advised on some practical matters relating to notifying the Department of Health of infected recipients and that it was preferable that patients were not missed. In those cases, where I had notified Consultant Haematologists of the donation numbers of blood and blood products which may or may not have been infected, he thought there were no further steps that I was obliged to take at present. However, hospitals might request further information. As to patients who died from their primary disease, Dr Gunson was of the view that a time limit could not be set. He said that, for the payment to be made, the Department of Health would require evidence that either the patient was confirmed HIV seropositive prior to death or that the blood or blood components he received were HIV seropositive. In the latter case the special panel may be required to adjudicate, and there may be a request for stored samples (as advised to Dr Ala above). Any further information I thought would assist should be sent to Dr Rejman.

236. In my own centre, I retrieved the files of all the HIV lookback investigations we had carried out since the introduction of HIV screening of blood donations. I wrote to all the clinicians who were recorded as responsible for the care of the identified infected recipients, informed them about the ex-gratia payment scheme for individuals infected with HIV through blood transfusion, and advised that their patient would be eligible to make a claim.

237. In a press release issued by the European Commission in **December 1992** [NHBT0000237_011], the UK was recorded as having not undertaken measures (by searching patient files) to trace patients who received blood products before the introduction of HIV-antibody tests to offer them an interview and an HIV-antibody test. The same was recorded for Belgium, Germany (with a lookback programme since 11 Feb 1983), Netherlands, and Japan. The situation for other countries was more complex. France was from 4 January 1993 targeting people

receiving blood 1980-1985. Italy was targeting haemophilia patients. A date was not provided. Switzerland was *yes* from 1987, looking at people receiving blood products prior to 1985. A look-back study was started in 1993. Canada was *yes* in three provinces, looking at people receiving blood products in 1980-1985. USA was *yes* with August 1986 as lookback for people **receiving products** 1978-1986; July 1985 for cases with **donor positives**; and, June 1993 in the case of **seroconversion** of the donor.

238. This document appears to miss the progress in lookback in the UK which is set out above. In my view the release is incorrect as the UK had taken, and continued to take, measures to trace patients who received blood products before the introduction of anti-HIV testing.

239. Dr Angela Robinson, Medical Director of the National Blood Authority, sent a letter to Professor S R McCann, Medical Director of the Blood Transfusion Service Board in Ireland, on **19 May 1995** summarising her recollection of lookback in the UK [NHBT0003037_001]. She explained that following the introduction of HIV testing in **October 1985,** all donors identified as positive were counselled and risk factors were assessed to try to establish when the infection could have been acquired. Most RTCs kept archived samples of blood donations for two years (possibly only one year in 1985) and the sample from the preceding donation was tested if available. If positive, the recipient(s) were identified and the clinician in charge of the patient was notified. It was then left to the discretion of the clinician responsible for the recipient to determine whether to inform the patient, counsel and HIV test. If there were no archived samples from previous donations available for testing, a staged lookback exercise was undertaken, tracing back donations to 1977. Where live recipients were identified, if three successive negative live recipients were found, no further lookback was undertaken.

240. Dr Robinson understood that lookback in the early days was not completed very well, but was pursued again energetically from 1992 when the UK government introduced a scheme for ex-gratia payments for transfusion recipients who had been infected with HIV through blood transfusion. A scheme for people with haemophilia had been introduced earlier, in 1990. The BTS was instructed to undertake a comprehensive review to ensure that all potential recipients who might have received HIV infected blood from positive donors were identified. The vast majority of these recipients were infected before the introduction of screening of blood donations in **October 1985**. Dr Robinson was the Director of the Yorkshire RTC at that time and recalled that every effort was made to ensure that clinicians in charge of **pre-October 1985** identified recipients were aware that if their patient had acquired transfusion transmitted HIV infection, they could apply for a payment. She referred Professor McCann to me at the North London BTC, as I was co-ordinating the HIV look-back exercise in north London or Dr Andrez Rejman at the Department of Health, who she thought would be best placed to assist if he needed any further information.

SHOT

241. In recent times cases of transfusion-transmitted HIV have been reported through the SHOT (Serious Hazards of Transfusion) scheme. This scheme is a separate but parallel scheme to the 'Yellow Card" scheme which covers medicinal products, including fractionated plasma products (e.g. Factor VIII concentrate).

242. The SHOT scheme began as a voluntary reporting scheme for complications of transfusion of blood and blood components, both infectious and non-infectious. Non-infectious complications have always predominated in terms of complications.

243. At the launch, it was pointed out that: *It is critical that any infectious complications (bacterial or viral) suspected to be due to transfusion of a blood component are rapidly reported to your supplying transfusion centre, so that other implicated components can be withdrawn. SHOT is not intended to replace local systems which are already in place for this, but in addition confirmed reports of transfusion-transmitted infection will be sent from Transfusions Centres to the PHLS Communicable Disease Surveillance Centre, Colindale.*

244. On **18 March 1998** the first SHOT report was published covering the years **1996-1997** [NHBT0057437_001]. This report identified that there had been one HIV-related transfusion incident in **1996**, which resulted in 3 infections. The case first came to light when a recipient who had received over 100 units of red cells and platelets over a 7-month period, was later found to be HIV positive. Archived samples of all involved donations were retrieved and tested retrospectively for HIV RNA, which was not at that time a screening test applied to blood donations. One sample, relating to a platelet component, was HIV RNA positive. The donor was recalled and tested anti-HIV positive at that point. Lookback was then carried out to identify the recipients of the red cells and the fresh frozen plasma produced from the infectious donation. Both were subsequently shown to have also been infected with HIV by transfusion, although one recipient had died of non-HIV-related causes by the time of follow-up.

245. On **5 July 2004** the SHOT annual report for 2003 was published [NHBT0114981]. One confirmed and one predicted HIV incident were reported. Both incidents were detected by lookback. In each case, a previously anti-HIV negative donor was noted to have seroconverted for HIV, and routine retrieval and testing of the archived sample stored from the previous (tested anti-HIV **negative**) donation demonstrated

that it was HIV **RNA positive**. Lookback detected an infected recipient from the first donation. In the second case, the recipient had died from his/her underlying condition within 24 hours of receiving the implicated blood component and there was no post-transfusion blood sample available for retrospective testing, but transmission was predicted. In both of the above cases, the level of viraemia in the implicated donation was sufficient to have been detected by pooled PCR testing, although this was not part of routine testing in England and Wales at the time.

246. The most recent SHOT annual report is for 2019[1] and was published in **July 2020.** In the transfusion-transmitted infection section it includes a table (20.3) which records the incidents from **pre-1996** to **2019.** The two incidents of HIV discussed above are recorded. The implicated components are recorded as 2 red blood cells, 1 pooled platelet and 1 fresh frozen plasma. There are no other HIV-related incidents recorded on the table. A footnote to the HIV does, however, go on to say:

The 2 HIV incidents were associated with window period donations (anti-HIV negative/HIV RNA positive) before HIV NAT screening was in place. A third window period donation in 2002 was transfused to an elderly patient, who died soon after surgery. The recipient's HIV status was therefore not determined and not included.

Conclusions

247. The cases referred to above, and reported in SHOT, illustrate the careful and methodical approach which the modern day UK blood services apply to lookback. What they do not illustrate is how much

[1] https://www.shotuk.org/shot-reports/report-summary-and-supplement-2020/2020-annual-shot-report-individual-chapters/

activity has taken place over the last 20 years for the very reason that with the exception of the cases reported above, all HIV lookback investigations have revealed negative results: recipients have been traced, identified and offered testing, but there have been no other documented cases of HIV transmission. Indeed, it would be expected that any further transmission of HIV would be exceedingly rare since HIV RNA screening of blood donations was introduced.

248. Over my time as national Clinical Lead for Transfusion Microbiology for NHSBT I was extensively involved in HIV lookback as I personally oversaw all potential cases of lookback, discussed with the relevant centre clinician the need for lookback in individual cases, and ensured that I received a final report for each case, so that I was satisfied that all appropriate actions were complete. Not every case of seroconversion in a blood donor was followed by lookback. In some cases, there was a very clear exposure incident which post-dated the last tested negative donation, but in cases where there was any doubt about the risk exposure and timing of infection in the infected donor, or where there was no archived sample of the previous donation available for testing, lookback was always conducted.

249. In view of the overwhelming negative results of lookback, I suggested to my colleagues that we should write up and publish the results of HIV lookback conducted by NHSBT. I particularly wanted to simulate discussion on whether there was a need for lookback when the archived donation sample from the last tested negative donation was retrieved and tested negative by the most sensitive technique available: individual sample HIV PCR testing. The first of our papers summarised the results of HIV lookback in NHSBT during the years **1995** to **2008** and was published in "Transfusion" in **June 2011**. This summarised the results of HIV lookback on **129** HIV positive donors who had tested negative on a previous donation (seroconvertors). No

lookback was conducted for **16** donors, who either had a documented negative test **after** the last negative blood donation, a clear risk exposure after the last negative donation, or whose blood donation did not lead to a transfused blood component. For **93%** of the donors the stored archive sample from the last donation was available for retrospective HIV RNA testing: all but **2** (described above) were negative. For those cases where there was a negative HIV RNA test on the previous donation sample, **114** components from **97** donors had been transfused to **113** recipients, **48%** of whom were deceased at the time of lookback. For **83%** of living recipients, a current negative HIV test result was obtained. For the remainder, some already had a negative HIV test recorded, in **3** cases an active decision was taken not to carry out a test, and in **3** cases the outcome remained unknown despite repeated requests for further information.

250. Our conclusion was that lookback is a relatively labour intensive process that has provided little public health benefit since the introduction of HIV NAT screening of blood donations.

251. In **2017** we updated the NHSBT data on HIV look-backs with an oral presentation at the British Blood Transfusion Society annual meeting. We summarised the results of lookback in the years **2009 to 2016**. There were **65** donors who seroconverted in this time period. Stored archive samples were available for **51** of the donors, and all were HIV RNA negative. Some of the seroconverting donors had evidence of very recent infection, and for others there was further clinical and test history indicating that the donor had acquired infection after the last negative blood donation. Lookback was conducted on **31** donations. Of the **30** identified recipients, **17** tested HIV negative, **9** were deceased, and **4** were not tested.

252. I was extensively involved in lookback for much of my career with the blood service. I have tried to explain the steps taken to identify and warn patients who may have been treated with HIV infected blood and/or blood products, both before, and since, the virus was conclusively identified in 1984. I appreciate that looked at from the outside it seems a simple and straightforward thing to find those infected. In reality there were practical obstacles of many kinds which restricted our success, in common with international experience. The blood services themselves introduced the haemovigilance reporting system SHOT which was originally voluntary but is now a very comprehensive and valuable tool. It shows the effect of steps taken to minimise the risks of transfusion-transmitted infection since the 1980s and that the majority of transfusion incidents are not related to viral transmission.

253. I know that those of us who worked in blood transfusion were committed to providing the safest possible blood supply, to identifying any failures, and to trying to find those who had suffered harm as a result. To the extent that we did not succeed in that, we would I am sure feel that we had failed and I am personally very sorry.

5 An account of the steps taken to warn patients of the risk of HCV being transmitted through the use of blood and/or blood products since 1989 when the HCV virus was first isolated. Please include any 'look-back' patient notification exercises and details of any awareness campaigns to publicise the risk, including exercises and campaigns that were considered but rejected.

254. This question is primarily being addressed by Dr Robinson who was responsible as National Medical Director for the implementation of the HCV lookback scheme. This was very different from the HIV lookback

because it was nationally coordinated and it was ordered by the Chief Medical Officer, as Dr Robinson will describe.

255. I would only add that the transfusion service expected to implement lookback when HCV testing was introduced but the decision was made not to proceed with it at the time for the reasons Dr Robinson will explain. I think most of the transfusion doctors were surprised by this decision and keen to implement lookback if – and as soon as – possible.

6. After the introduction of HCV screening, what, if any, guidance and assistance was provided to donors found to be HCV positive in relation to the management of their illness? Please include all anti-HCV screening, pre and post September 1991, and any pilot screening programmes.

256. In preparation for the screening of blood donations for HCV antibodies, a unified UK policy was devised for the management of donors found to be anti-HCV positive. The policy covered donor notification, "counselling" and further investigation.

257. Although the term "counselling" is widely used throughout the discussions and documents, I would like to make it clear at this point that the term 'counsel' is used in the sense of imparting information in a sensitive situation and not in the modern day meaning of a counselling service where a professional person gives often extended advice on how to deal with issues facing the person receiving the 'counselling'. We have been criticised on occasion for failing to provide what is effectively a modern counselling service but this was not our role. In my own practice in NLBTC, I insisted that we did not use the terms "counselling" and "counsellors", since these were inappropriate descriptions of our activities. We referred to the process as a "post-test

discussion". When I assumed clinical responsibility for transfusion microbiology nationally within the NBS, this is the term that was used by the clinicians accountable to me in all English blood centres, but the term 'counselling' has continued to be used widely by others.

258. In summary, when a donor was identified to have a confirmed positive test for HCV, which was defined as confirmed in writing by a Reference Laboratory, the donor was sent a letter informing him/ her of the positive test result. The letter was accompanied by an information leaflet giving further information about HCV. The donor was asked to telephone to make an appointment to be seen by a blood centre clinician. Initially, we offered a face-to-face interview to all donors, but this was not always taken up. On some occasions, the donor preferred a telephone interview, sometimes because of travel difficulties.

259. The discussion with the donor included information about the tests carried out, what the test results signified, and their implications for the future health of the donor. We also discussed possible risk to others, such as sexual partners, children, and possible occupational issues.

260. Particular concerns raised by the donor would be addressed. Many donors wanted to know how they might have become infected with HCV, and it was our practice to complete a short epidemiological questionnaire looking at the recognised risks for HCV infection. The epidemiological information was collated and was used in discussions about the effectiveness of donor selection procedures.

261. We advised the donor that, although there was (at that time) no treatment for HCV, the donor should be referred to a specialist service (usually, but not always, a hepatology clinic), for further investigation and management. Such a referral was best carried out through the GP, and we would inform the GP and give appropriate advice. For donors

who were not registered with a GP, we stressed the importance of now doing so, and for a minority of donors we arranged direct referral to an open-access hepatology clinic, where GP referral was not required. In some areas of the country there was an arrangement for the blood service to refer directly to the local hepatology or infectious diseases service.

262. In London and the south-east of England, we drew up a resource sheet listing all appropriate specialist services within the area, and provided this to GPs. We had made contact with all these specialist services in advance of the date for commencement of HCV screening of blood donations so that we were certain we had up-to-date contact details and approval of our procedures with respect to the HCV positive donors. Finally, we made it clear to the donors that we would be available for further discussions if we could assist.

263. We worked on the basis that (as with the recipient process) every effort should be made to see the donor who had tested positive as soon as possible. We tried to make sure that we had sufficient resources at each blood centre for this to happen. On the other hand, a proportion of donors did not respond to the initial invitation to make an appointment, and we would always send further letters to encourage them to do so.

264. Our procedures were modified as time went on. For example, when treatment for HCV was licensed for use in the UK, we changed our information leaflet to reflect this development, and changed our discussion with the donor appropriately.

265. As I understand Dr Robinson has explained, the process for notifying donors that they were positive depended on having a reliable confirmatory test for HCV, and that was not available for some time, as discussed below. In the early days, we were dependent on what is

termed “supplementary tests”, which could not necessarily give absolute confirmation of infection. This point is illustrated in the following paragraphs.

266. There were numerous meetings and decisions during the period of testing and piloting of HCV screening kits and leading up to the formal introduction of testing. The following is not an exhaustive discussion of all of those meetings or decisions, but some of the relevant points in the process.

267. At the meeting of ACVSB on **21 November 1990** [NHBT0000073_018] the Chair summed up the previous meeting on hepatitis C testing and the advice to Ministers and emphasised that the reference to no look-back procedure in the previous minutes referred only to work done on the pilot study. A decision on this aspect of routine screening of donors was deferred to a subsequent meeting of the ACVSB (paragraph 5). Dr Gunson said that it was necessary to identify which of the “screen positive” donors should be counselled. Both Dr Gunson and Dr Mitchell felt that if the results of the pilot study giving 6 true positives out of 10,000 donors were borne out in practice, then counselling would be manageable. Dr Zuckerman pointed out that the two tests being piloted did not identify the same donors as being positive and Professor Tedder confirmed this. The committee then agreed with a proposal by the Chairman that on the introduction of screening, any donation yielding a repeatedly positive test result from either Abbot or Ortho tests, would be set aside and a sample sent to the reference laboratory for a repeat screening test and supplementary testing. The donor would not be notified unless the results were confirmed positive by the reference centre.

268. Dr Gunson went on to introduce his paper on counselling of HCV positive donors (paragraphs 20-22). He said that the UK BTS Advisory

Committee on Transfusion Transmitted Diseases would be meeting to discuss problems of counselling positive donors. Dr Mitchell thought that Scotland had already discussed the problem of counselling and that they had produced a draft document which could form the basis of the discussion at the UKBTS meeting.

269. At the sixth meeting of the National Directorate of NBTS, UK Advisory Committee on Transfusion Transmitted Diseases on **8 January 1991** [NHBT0000073_028 and NHBT0000042_067] there was extensive discussion of the implications of screening for HCV which included consideration of Dr Gillon's paper for SNBTS on counselling of donors (paragraph 4.6). A paper by Dr Contreras was also discussed and it was agreed that Dr Gillon would amend his paper to reflect her comments. At this meeting, there was also discussion of the flow-chart prepared by Dr Mitchell, noting that it was recognised that the definition of a positive result was crucial and that differentiation between reactive results which differed from the manufacturer's criteria for a positive result should be made.

270. Dr Gillon's draft paper dated **23 November 1990** is document PRSE0000515 - *Report for National Medical Director on HCV donor counselling*, prepared by Dr Gillon, Dr Crawford, Dr Galea and Dr Davidson, all of SNBTS. The authors of the paper assume that a highly sensitive and specific confirmatory test will be available, since the guidelines relate to the counselling of donors with a **positive confirmatory test.** The assumption is therefore made that all donors counselled will be regarded as potentially infectious. It noted that the duty was to inform the donor personally, i.e. at an interview with a member of SNBTS medical staff or another doctor recruited for that purpose. The decision on the need for further investigation or referral to either the donor's GP or a local specialist should be taken by the Consultant responsible in the Regional Transfusion Service in

conjunction with the doctor carrying out the primary counselling. The paper recommended that a second counselling visit would usually be useful, and that the decision on the need for investigation or referral should be based on additional information including, where possible, a physical examination and the results of liver function tests. In addition to the information documents enclosed with the report, RTC's should ensure that 'counselling' doctors received written guidance for positive donors which included some background information and advice on protecting others. Each RTC should identify one or more suitable hospital physicians who would be willing to evaluate cases with possibly significant liver disease and to offer appropriate therapy as available.

271. The paper discusses what information to give to donors and points out that SNBTS had responsibility to inform donors of test results which suggest they may be infectious; the percentage of the population likely to be HCV positive, how to notify donors, including notifying by letter, first interview and breaking the news. It provides background information for SNBTS medical officers 'counselling' anti-HCV positive donors and detailed guidance on many different areas, including breaking the news, areas to cover in the interview, likely questions that might be raised, etc. Reading through this draft document, it is striking now, 30 years later, to see what large gaps there were in our knowledge about hepatitis C.

272. The document summarised that information was to be provided at a meeting which would usually be scheduled for a minimum of one hour once the process started and was comprehensive, but there was still much that was not known.

273. The SNBTS document produced by Dr Gillon was used as a basis for the detailed procedures adopted within England for the management of

HCV positive donors, with some variations reflecting the difference in arrangements between England and Scotland.

274. On **13 February 1991**, Dr Gunson wrote to Dr Rejman, Senior Medical Officer at the Department of Health [NHBT0000191_072] enclosing the minutes of the meeting of the ACTTD of **8 January 1991** which included references to routine screening for anti-HCV, referral for supplementary and confirmatory tests, and arrangements for 'counselling' of donors. He referred to several matters which needed to be discussed at the next meeting, scheduled for **25 March 1991**, including the fate of plasma and the return of donors to active panels when donations were not confirmed as repeatedly reactive and detailed guidelines for 'counselling' of donors, which would be contained in the revised paper by Dr Gillon, referred to in the minutes.

275. At the ninth meeting of the Advisory Committee on the Virological Safety of Blood on **25 February 1991** [NHBT0000042_058] the Committee considered Dr Gillon's final draft document, which had been previously circulated and agreed it was excellent. The Committee proposed and agreed that the latter pages be used as Guidelines in leaflet form for use by the RTCs.

276. Document PRSE0000515 dated **25 March 1991** is Appendix III to Dr Gillon's draft on HCV infected donors which again outlines the detailed recommendations for counselling of HCV seropositive donors.

277. At the seventh meeting of the UK Advisory Committee on Transfusion Transmitted Diseases on **25 March 1991** anti-HCV screening and donor counselling were discussed [NHBT0000073_063]. Dr Contreras asked for the minutes of the last meeting to be amended to reflect that she had expressed concern that no extra funding would be made available for hepatitis C testing and that in some areas there was a

shortage of hepatologists able to provide expert advice to donors who were found to be positive.

278. At a meeting of the UK Advisory Committee on Transfusion-Transmitted Diseases, Sub-committee on Laboratory Aspects on **3 June 1991**, [NHBT0086153] it was noted that HCV screening and confirmatory assays should be reviewed as they developed and that this was likely to be a rapidly evolving field for some time. The minutes have as Appendix II the Action chart for anti-HCV testing and Appendix III – *Recommendations for Counselling of HCV positive donors.* This included the list of Q&As for 'counselling' donors.

279. At the eighth meeting of the UK Advisory Committee on Transfusion Transmitted Diseases on **10 June 1991** [NHBT0000074_047] the appropriate sections of Dr Gillon's report on donor 'counselling' were agreed with amendments. It was noted (paragraph 4.2) that there was concern by some members that because of financial constraints the ideal policies on handling of donations and donors found ELISA anti-HCV positive may not be feasible. Finance would not be available at some RTCs to carry out the 'counselling' of donors by RTC staff and the implications of this omission would be that this workload would be transferred to the hospital service or general practitioners.

280. Again there was discussion of the issue with regard to a reliable confirmatory test. As with other confirmatory tests, more work was needed on PCR testing. There was a possibility that this could be achieved at least in part from the work being carried out on the two anti-HCV trials in progress at the time. It was concluded that it was possible to operate a confirmatory system without including the PCR test, although this may mean that this test would have to be performed

in all likelihood by the service performing the clinical follow-up of the donor.

281. Paragraph 4.4 notes that in the standard letter the donor should be informed the test which was positive was for hepatitis and specifically hepatitis C, to reassure them that HIV infection was not involved. The references to donors informing dentists and the Occupational Health Service (for healthcare workers) that they were carriers of hepatitis C were deleted. It was agreed that the GP should be informed and every effort should be made to ensure that this was done and a record made.

282. It was agreed (at paragraph 4.4.2) that the amended paper should be issued to RTCs to be used as guidance for the preparation of their local Standard Operating Procedures.

283. It was also agreed that plasma sent for fractionation should be anti-HCV negative, with a definition of what that meant. The Action Chart for Anti-HCV testing and Appendix III – Recommendations for Counselling of HCV seropositive donors are attached. The question – '*Should I tell anyone else apart from my spouse; my employers for instance?'* has been amended to read: '*At present there are no official guidelines and therefore no requirement exists to inform any other person. It is recommended however that your GP should be informed*.'

284. The minutes of a meeting of the UK Advisory Committee on Transfusion Transmitted Diseases Ad Hoc Group [NHBT0000075_054] to consider implications of anti-HCV testing of blood donations on **13 September 1991** set out a chronology of events from 1 September 1989 regarding the introduction of HCV screening. There was discussion of the duty to donors and the difficulties created by false positives. Under the heading '*Advice to be given to Donors*', the minutes record that:

'5.1 It was clear from the trials of both first and second generation tests that a significant proportion of repeatedly reactive results using the ELISA test were falsely positive. It was apparent also that false negative results could occur.

5.2 It was not until the meeting of ACVSB on ***24 November 1990*** *that Dr Mortimer and Professor Tedder were able to report that a combination of RIBA and PCR could provide useful confirmatory tests.*

5.3 As an indication of false positivity, only 6 of the 65 repeatedly reactive results found in both the first and second phases of the multi-centre trials were RIBA positive/indeterminate and PCR positive.

5.4 The Blood Transfusion Service has an obligation to their donors to provide medical advice when this is necessary. The uncertainties of the significance of the HCV antibody positives by ELISA made it impossible to distinguish between false and true positives'.

285. I have tried to explain the difficulties we faced in terms of what we were able to tell donors as well as the practical and logistical difficulties of funding, resources and having everything necessary in place once we had an acceptable confirmatory test. It is clear that there was follow up of donors found to be positive whilst we were piloting the screening kits prior to the formal national introduction of HCV screening on 1 September 1991, but there may have been local variation/differing practices at different RTCs pending the national advice formulated and disseminated by the relevant committees.

286. It is worth saying that there was no internet at that time. Information within the blood service had to be passed on by letters or memos sent by post and then circulated at local centres, by minutes, attendance at

meetings and by word of mouth, with the result that communication took far longer than in the modern day, and may not always have been fully accurate and consistent, or received by all relevant parties at the same time.

287. I have also seen a letter of 13 October 1995, which I wrote to Dr Robinson, relating to an issue apparently raised by Dr Rejman at the Department of Health, and a donor who had been under the care of Dr Graeme Alexander for 3-4 years since being detected as HCV positive [DHSC0003538_003]. This letter demonstrates some of the difficulties we faced in communications with donors. A colleague, Dr Angela Gorman, had tried several times to persuade the donor to attend for counselling but she had declined. The donor was convinced that she had been infected by a blood transfusion during Caesarean section, but it transpired that no transfusion had been given. Her partner who was also a donor, had subsequently also been screened as positive for HCV. They had been given conflicting advice by various different organisations, but the donor had been under the care of a hepatologist throughout.

288. I raised with Dr Robinson the problem of how much we could address in a letter to a donor and how much should be left for counselling. Some donors never attend for counselling – so where did that leave our responsibility if there isn't detailed information in the letter? On the other hand, we knew that raising the issue of sexual transmission had led in some cases to serious issues between the partners in a relationship, including the threat of separation or divorce, based on the mention of sexual transmission of hepatitis C in a letter. This meant that we were 'damned if we do (mention sexual transmission), and damned if we don't'.

289. I concluded by saying that the three London centres were working hard at present to standardize communications at least so far as sexual transmissions were concerned. We had to be aware that we would cause upset or anxiety to some donors whatever we did. We would ensure that our information was up to date as far as possible and could be supported by current evidence.

290. I have not so far seen any response which Dr Robinson may have sent.

7. Please identify and explain any differences between HIV/AIDS and HCV look-back patient notification exercises and awareness campaigns.

291. The main differences between the HIV and the HCV lookbacks were the timing of the implementation and the numbers involved.

292. The discussions during **1985** about the introduction of anti-HTLV III (hereafter referred to as HIV) screening of blood donations, anticipated that HIV lookback would commence when screening of blood donations was introduced. The policy was set out just prior to the introduction of testing. PRSE0000636 includes the RTD working party comments on what would be done with follow-up (as discussed above in the response to Q4). Thus, lookback commenced with the initiation of screening. Although, as discussed in the response to Q4, lookback was not complete and not always methodically performed, there should have been no delay in performing the lookback.

293. In contrast, HCV lookback was not introduced at the same time as the introduction of anti-HCV screening of blood donations in September 1991. This situation has been discussed in the answer to Question 10. Those of us who were working in the relevant areas in the blood

service fully expected to be carrying out lookback as soon as we identified HCV positive blood donors who had a history of blood donation prior to the introduction of screening. It was a concern to us that this was not the case, but we had no mandate to carry out HCV lookback. Without a central directive from the Department of Health there was little prospect of persuading Consultant Haematologists in charge of hospital blood transfusion laboratories to divert their already hard-pressed resources into an activity which was not mandated, and not supported with additional resources.

294. Thus, when HCV lookback was eventually mandated in early 1995, a further 3.5 years had elapsed from the point when lookback could have started. As the majority of HCV infected donors were identified in the first 12 months of screening, we had lost vital time from first knowing of a donor whose previous donations would require investigation. The time delay was not so great a problem for blood centres, but produced serious difficulties in hospital laboratories, where records were generally kept for a finite number of years: often 10-12 years. By the time lookback started, 3 or 4 years of earlier hospital laboratory records would have been disposed of, preventing the tracing of recipients who had received potentially infectious blood components and who could have been traced if the lookback had started in 1991. Although approximately 50% of blood components are transfused to individuals who die of their underlying condition within 12 months of transfusion, and a further number of blood recipients will die in the following years, the opportunity was lost to identify and trace a small number of surviving recipients transfused in the early 1980s, because the hospital laboratory records had been destroyed in the years 1991 to 1995.

295. The second main difference between the HIV and the HCV lookbacks was in the numbers involved. The success of the AIDS self-exclusion campaign was a significant factor. This success clearly had an effect in

improving the safety of the blood supply in the period between the autumn of 1983 and the introduction of HIV screening tests in **October 1985** and reduced the numbers of HIV infected donors who might otherwise have been detected when donation screening commenced. While self-exclusion was the intended outcome, it did have the effect of making it far harder to find seropositive donors who donated prior to 1985 and self-excluded. See the comments on the success of the policy in e.g. NHBT0000030_019 and NHBT0000030_018.

296. This feature is also identified as important in the Busch article (PRSE0004329), and by Dr Liekola at the Council of Europe event ,[NHBT0000018_019; NHBT0004514_001]. It meant that only small numbers of HIV infected donors were detected when screening commenced, and the HIV lookback was correspondingly small-scale. Any single hospital blood transfusion laboratory probably only had one or two HIV lookback requests to investigate from the laboratory records, and the scale of the task was easily manageable within existing resources.

297. In contrast, when HCV screening was introduced in **September 1991** it became clear that donor self-exclusion for HCV risk had been much less effective. HCV had a greater prevalence in the general population than HIV, so absolute numbers were higher. In addition, approximately 50% of donors found to be HCV positive on donation screening had a risk for HCV infection which should have led to self-deferral, and the number of infected donors was many times higher than for HIV. The most common identified risk for HCV infection in donors was exposure to intravenous drugs, but this was often a one-off or very limited exposure which had most commonly occurred when the individual went to university in the late 1970s/early 1980s. The reasons for failing to self-defer are multiple and complex. It may be, for example, that the exposure was so distant in the past, and possibly something which had

subsequently been suppressed or completely forgotten, that the donor failed to recognise its importance. Nevertheless, the introduction of HCV screening led to identification of many more infected donors than had been the case with HIV screening.

298. Because HCV lookback did not start immediately in **1991**, when individual donors and their previous donations would have been added to the lookback as and when they were detected, by the time it was introduced in **1995** there was a whole cohort of infected donors and their previous donations waiting to be traced. Thus, the lookback began as a "big bang" with each hospital blood transfusion laboratory receiving a list of all the blood components they were required to trace. In my own centre, our two largest volume hospital users each received a list of over 100 blood components which required tracing. This was not a task which could generally be undertaken without additional resources.

299. Finally, when the main thrust of the HIV lookback took place in the 1980s, there was no national organisation of the English blood service. Although there was cooperation, there was no national mechanism for collecting data, for example the results of lookback, and there were difficulties in ensuring uniformity of practice. By the time that the HCV lookback took place in 1995 there was a nationally managed blood service, and the Medical Director had authority to mandate activities and to ensure that resources were allocated to enable new initiatives to proceed.

300. Insofar as it is useful to have my assessment, with the full benefit of hindsight, as to what could be done differently, based on experience with the HIV and HCV lookbacks:

- **Timing:** a properly planned and executed lookback should occur as soon as is feasible after the availability of testing. There should be an initial burst as the donor population is first tested (raising a run of initial lookback cases), and then more systematic look-back should continue responding to 1) seropositive donors identified at later stages through routine screening; and, 2) seropositive donors who have not donated since the introduction of testing. Acting from the outset fast and all at once gives the best chance of not missing people and laying the groundwork for a lookback scheme that continues in a consistent and low-key way after the initial burst of activity.

- **Funding**: resources are needed to have enough people to do the job properly. People should not be expected to perform such an important function out of goodwill in their free time, and funds should be sufficient to ensure that it is cost neutral for everyone involved. Other budgets should not have to suffer to pay for lookback. In reality, when NHSBT was created as a Special Health Authority directly funded by the Department of Health as the Blood Services had advocated for many years that it should be, most of these problems were immediately addressed.

- **Management**: there should be a clear structure and process that everyone understands. It should be followed properly with one centralised point of management. The lookback should not be piecemeal in scope. It should be one system being operated to cover all cases so odd cases do not fall through the cracks. There was a central, national and highly orchestrated process for the HCV lookback but even then, numerous difficulties and practical problems were encountered as will be discussed by Dr Robinson in her response.

- **Authority:** the individual or group running the lookback should have the authority to require clinicians to comply in answering questions and disseminating information to implicated individuals. There should be no scope for stalling or frustrating the process by delay.

301. By the time that HTLV-1 screening of donations was introduced in 2002, the above lessons had been learned. The blood service accompanied its proposals for the introduction of cost-effective screening by including the requirement to commence lookback immediately that screening commenced. The lookback programme was managed centrally from the Department of Transfusion Microbiology at Colindale, databases were developed and maintained by staff within the Department, and outcome of lookback was recorded with cooperation of the Epidemiology Unit, also based at Colindale. Thus, the whole process had a clear structure, with one senior member of staff accountable to the Medical Director for the process. Despite these improvements, hospital blood transfusion laboratories continued to struggle to direct resources to the work required to complete the lookback, as summarised in the publication of the final results of the lookback.

302. This was written up in the journal "Transfusion": *Human T-lymphotropic virus lookback in NHS Blood and Transplant (England) reveals the efficacy of leukoreduction* February 2013 53(10) **[Exhibit WITN3101008]**

303. I have been asked whether NHBT0015574_002 is the final report of the HIV look-back. The short answer is that it does not appear to be so.

304. First it is limited to the **period October 1985** to **December 1989**. Based on the documents already seen, we know that there was

lookback before and after these dates. Before these dates it was primarily not informed by anti-HTLV-III testing, and was not called look-back, but it was follow-up of recipients in respect of possibly infected blood. After these dates there were ongoing attempts at lookback. So, in that sense, this is not a complete report of HIV lookback.

305. The document appears to also be limited to lookback on donors who were tested as part of routine screening **post-October 1985**. It does not cover any lookback which was conducted into donors who stopped donating prior to the introduction of anti-HTLV-III testing. There is no indication it took in any of the work of Dr Wallington (for example) also.

306. What this appears to be instead is a summary document provided for discussion at the EAGA meeting on **2 October 1990** [NHBT0008213_002]. It is unclear, but it appears a decision at that meeting was going to be taken on whether to continue some form of lookback. It may have been commissioned to inform that discussion. It also provides comments on suggested improvements going forwards, which seem to assume that further lookback will occur. As far as I can see, it does not purport to be a final report of anything. Indeed, as we know lookback did continue, so it clearly cannot be the final report.

307. Based on the documents available currently, there does not appear to be a "final" report on HIV lookback. To date not all of the NHSBT and predecessor documents have been reviewed and it is difficult to say whether such a report exists.

Lessons learned from HIV lookback

308. I cannot now recall and have not seen any documents which deal specifically with lessons learned from HIV and how they could be applied to HCV. This does not mean such a document does not exist,

but I have not seen it in the documents currently available to me and cannot recall it now from memory.

309. The NBTS lookback report referenced in Q20 (NHBT0015574_002) really deals with advice on how to improve the HIV lookback. In principle though, these points could have been applied in some way to HCV.

8. Please explain the impact that any HCV and HIV/AIDS look-back patient notification exercises and awareness campaigns had on the volume and number of blood donations.

310. I cannot recall the HIV/AIDS lookback having an impact on the volume and number of donations. I have not seen a document as part of the process of answering this question which has identified any such impact.

311. As to HIV/AIDS lookback awareness campaigns, I am not sure what this is referring to. The lookback was not an advertised scheme but instead a series of processes undertaken by the blood services and other bodies. For the reasons described above, there was not a specific co-ordinated lookback programme for HIV in the same way as there was for HCV. There was no public announcement that HIV lookback was to take place, so general awareness about lookback was lacking.

312. Donors will have been aware of HIV testing and that such tests, if positive, would be investigated, but there was no "awareness campaign" in the formal sense. For that reason, it is difficult to imagine how the HIV lookback programme could have had an impact on the number of blood donations. Again, as I noted above, I have not seen a

document as part of the process of answering this question which has dealt with any such impact other than the following brief references:

BPLL0011017 – minutes of a meeting of CBLA on **20 November 1985**: '*The impact of AIDS on blood donations was discussed. Dr Gunson said that donations had decreased initially but the situation had been reversed and donations had now actually increased'.*

NHBT0087416 - minutes of a meeting of CBLA on **29 January 1987** which record a discussion between Dr Moore and Dr Gunson about plasma supply and a recent drop due to media interest in AIDS. Dr Gunson hoped the official opening of BPL would assist with recovering numbers.

313. My response is based on the documents available to date. It may be that as and when further documents are available or reviewed, some information will be available to address this question.

9. Please explain how, if at all, concerns over the need to ensure sufficient supply of blood donations to meet clinical demand influenced the nature and scope of any HCV and HIV/AIDS look-back patient notification exercises and awareness campaigns.

314. I do not remember any concerns over the need to ensure sufficient supply of blood donations to meet clinical demand influencing the nature and scope of any HIV/AIDS lookback patient notification exercises and awareness campaigns. Save for a few comments about documents below, I have not seen a document as part of the process of answering this question which has raised such concerns.

315. The comments made in Question 8 regarding HIV/AIDS lookback awareness campaigns also apply here. I am not sure what this question is referring to. Please read that paragraph in the Question 8 answer. Save for a few comments about documents below, I have not seen a document as part of the process of answering this question which has raised such concerns.

316. The difficulties of the HIV/AIDS lookback, are set out in detail in the answer to Question 4. However, none of the difficulties which the blood service experienced raise issues about the sufficiency of the blood supply.

317. There is one document where sufficiency of the blood supply is arguably raised. I say arguably as it is not entirely clear to me what the passage means. This appeared in a note of a meeting from **21 February 1992** [DHSC0002941_006]. The important line is that CDSC and NBTS' *objectives "are not to spoil either the donor base or the voluntary reporting system*". It is provided in the context of the document.

318. On **21 February 1992** a meeting took place between the Department of Health, CDSC, and NBTS [DHSC0002941_006]. Dr Gunson was in attendance for the NBTS. This meeting concerned the ex gratia payment scheme for HIV infection. Part of the meeting considered the information that would be available from NBTS for identifying possible claimants (a separate part addressed information from CDSC) who were believed to have been infected through blood transfusion. Implicit in this is that these possible claimants had not been identified by lookback. With respect to NBTS:

Pre 1985 stored archive samples of donations would be very rare in RTCs. RTCs hold stored samples for last 2-3 years, and may have stored samples post 1985.

NBTS holds the donation number of all HIV positive donations, full records of the positive donations held at RTCs.

All HIV positive donors who could be traced (about 90%), have been informed of their HIV positivity, and told not to donate again.

In the case of recipients believed to be infected through blood transfusion, NBTS would be in a position to obtain the donation numbers of blood components transfused to the patient from the hospital blood transfusion laboratory and trace these back to identified donors. Where a donor moves from one RTC to another a transfer note should be held to enable the donor to be traced. Difficulties could arise where perhaps as many as 30 units used in one transfusion would need to be traced, because of the resources required.
Dr Gunson raised the question of funding the additional work that providing information for validation of applications for payments would create.

319. I had previously been unaware of this meeting and the contents of the discussions. At NLBTC we had always carried out investigations when a blood recipient was reported to have been possibly infected with a blood-borne infection through blood transfusion. This we considered part of our duty of care to blood recipients. We had a well-documented process for carrying out such investigations and I ensured that these were rolled out within the London and S.E. Zone and then nationally when I had the overall responsibility. In our own case at NLBTC, therefore, the question of funding for additional work was totally irrelevant as the work was carried out within our existing resources.

320. The minutes also address CDSC information. CDSC noted that it did not have names of individual recipients or donors. It was accepted that, with legal advice, it could write to Consultants of patients on the matter. Similarly, after legal advice, CDSC may be able to give the Department (of Health) an indication in a report after consulting NBTS about donations. CDSC explained it may be able to review applications:

CDSC might be able, subject to legal advice, to check an application in confidence before it went to the panel. CDSC would be able to say, in a particular case, whether they were aware of the case and had followed it up, and if so whether the follow up had established transfusion using HIV positive blood. If it was a new case, CDSC would ask for a report from the Consultant.

321. The report went on to note that CDSC and NBTS' objectives "*are not to spoil either the donor base or the voluntary reporting system*". The minutes note under "*other points*" that *"care would need to be taken that there is no implication of negligence on the part of the health authority*".

322. It is unclear what the concern in the final paragraph was, which may be a result of compression in the minutes of the meeting.

323. More fundamentally, and for the reasons below, it is not clear how lookback could have any significant *further* impact on the sufficiency of the blood supply over the interventions already taken by the transfusion service. From 1983/1984 the service has taken positive steps through the donor leaflet to try to exclude at-risk donors from donating. At one point in 1984 it also considered surrogate testing to exclude such donors, which would have further reduced the pool of available donors. Discussions about surrogate testing were overtaken by the availability

of HIV screening tests for blood donations, which were introduced in October 1985. Because the transfusion service had taken various positive steps to intentionally reduce the available donor pool by reference to possibility (or actuality) of infection with HIV/AIDS, it is not clear how lookback created any further pressure on donors not to donate. Indeed, lookback was not generally publicised or necessarily an issue about which donors would have been aware. It was an activity which took place in the background, and as such was unlikely to have any impact on donors' willingness to donate.

324. Further, and repeating the answer from Question 8, even if it were to have impacted upon the sufficiency of the blood supply, that may not necessarily have been a problem. If prospective donors were concerned about an HIV/AIDS lookback, that might suggest they were an at-risk donor who should not donate anyway. The vast majority of donors are conscientious in their wish to help others, and it has generally been my experience that the very few repeat donors who are found to be infected with a blood-borne agent are exceedingly worried when they realise that they might have put recipients at risk through coming forward to volunteer to donate blood.

325. It may be that when further documents are available or reviewed, more information will be available to address this question.

14. At pages 1 and 2 of the document titled 'Notes of Decisions and Actions from First Meeting of Hepatitis C Look Back Working Party' dated 20 January 1995 (NHBT0009715), under the heading, "Look back exercise", the following agreed action is recorded:

"It was agreed that the look back exercise should be concentrated in the first instance upon donors who had given blood prior to September 1991 and been found to be HCV anti-body positive on a subsequent visit. The services would not try to trace donors who had not come back to a Transfusion Centre since then. The work involved in doing so would be disproportionate to the benefit."

a. Please explain the work involved in tracing donors who had not returned to a Transfusion Centre and why, having regard to the duty of care owed to patients, this was considered to be disproportionate.

326. There are many reasons why it may be difficult to trace donors who have not re-attended to donate. In any event, the vast majority of donors, whether active or lapsed, are unlikely to be infected with blood-borne agents. Attempts to trace donors who did not return to donate blood after the start of HCV screening of blood donations were unlikely to have identified many positive donors whose previous donations could then be followed up.

327. When individuals attend to donate blood, personal details (name, address, and date of birth) are collected for identification purposes. In the 1980s and early 1990s, all communication with donors was in writing. Appointment reminders were in the form of a postcard. All other communication was by letter. Telephone numbers were not routinely collected. Mobile telephones did not exist. For donors who attended blood collection sessions at work places, their place of work would usually be collected.

328. Each year a proportion of blood donors lapse from donation. Some of these donors leave the donor panel permanently, usually through retirement (there was an upper age limit for blood donation in the

1980s), or ill health, even death. Others move house or change their place of work so that they lose the opportunity to donate. Some take a temporary break from donation, for example because of an intercurrent illness or pregnancy, and lose contact with the blood service. Others stop donating blood because they have suffered an ill effect of blood donation or decide that they do not want to continue.

329. If a donor has not returned to a Blood Centre, the reason may or may not be known to the Blood Centre. For example, those who had reached the retirement age for blood donation would be obvious. On the other hand, for the remainder of people who lapse without making any contact with the Blood Centre, the reason for them lapsing will not usually be known, and there can be no assurance that they remain at their last known address, or even that they are still alive. Even if they remain at their last known address, if they have made a positive decision to stop donating blood, there is no reason to expect that they would respond positively to a communication asking them to return.

330. In today's world, mobile telephone numbers and e-mail addresses are collected, and are used to communicate with donors. Even those who move home or work usually have a personal mobile telephone number and/or e-mail address listed. Contact is therefore direct and rapid. In the case of individuals for whom neither is available, there is also the facility of using the NHS database of people registered with a GP in England. Everyone who is currently registered with a GP will be listed on this database, with last known contact details (address and usually telephone number). The blood service routinely uses this database for the purpose of tracing donors or patients they need to contact. If there is no response to communications sent to the individual's address, there is the facility to send a message to the GP, asking for communications to be forwarded. None of this was available in 1995.

331. When the HCV lookback commenced in April 1995, those donors who had not attended since the introduction of HCV screening in September 1991 had been out of contact for at least 4.5 years. The chance of being able to trace any individual diminishes as time passes. The only method of contact would be by letter to the last known address. For those who had moved home, post would no longer be forwarded to a new address.

332. Each year, approximately 10-15% of the donor panel lapses from donation. For a donor panel of 2 million individuals, this amounts to at least 200,000 individuals. If the lookback was to include attempting to contact donors who had lapsed from donation before September 1991, this would mean contacting at least 200,000 people for each year prior to 1991, sending a letter to the last known address, and presumably asking the individual to attend to have an HCV test, to determine whether any of these lapsed donors could have been infected with HCV before they lapsed from donation. Assuming that even a proportion of these lapsed donors remained at the same address and responded to a request to give a blood sample for testing, this would be an enormous exercise.

333. Contacting individuals with whom there has been no contact for many years can be fraught with difficulty, as there is no way of knowing the individual's current situation and circumstances. There would be the risk of sending letters to people who had died, or who were suffering from serious illness, and no way of knowing what distress might be caused. Nowadays, we would not contact a lapsed donor after a significant number of years without checking with the GP that an approach would be appropriate, but in 1995 we had no way of identifying a GP for a blood donor.

334. Given the above, and the fact that the confirmed HCV positive rate in 1991 was in the order of 1 in 1,000, and assuming that it was unlikely to be significantly different in the 1980s, then the likelihood of identifying an HCV infected donor who had lapsed before 1991 and whose donations could be included in the lookback was very low. The resources required to attempt the contact of possibly hundreds of thousands of lapsed donors, and to obtain blood samples for testing from those who responded, would have been enormous. Furthermore, approximately 50% of blood components were transfused to recipients who died of their underlying illness within one year of the transfusion, and more would die within the next few years, so the chance of finding a living recipient for any given blood component after a lapse of 4.5 years was much less than 50%.

335. It is likely that all these arguments were considered by the HCV Lookback Working Group and led to their conclusion that attempting to trace lapsed donors would be disproportionate.

336. Efforts have been made in a number of different ways to consider how to address this, some set out here, and explored in the US, Europe and internationally, with limited success, including the Penrose recommendation, the implementation of which is discussed by Dr Williamson in her response to part of this request, as the Medical Director of NHSBT at the time this recommendation was made.

b. With reference to the words, "in the first instance", please provide an account of all subsequent actions.

337. In relation to the proposed staged approach implicit in the reference to 'in the first instance' this was a huge, time-consuming and costly exercise. I have discussed elsewhere in this response the limited success of general lookback and the reasons for this. I assume, for the

reasons explained, that the intention was to target efforts and the resources that were available to enquiries that were likely to be the most efficient and then to extend the lookback if/when we could, as did in fact happen by extension of the lookback to indeterminate test results, discussed below in response to question 23.

15. In a letter to Dr McGovern dated 19 August 1998 (NHBT0015135_002), Dr Angela Gorman writes:

"However I feel that it is unlikely that all of Mrs [redacted] donors will either be contactable now or will have donated again since the index donation. This is not for any sinister reasons, but simply because a significant percentage of donors cease to donate every year."

Given the awareness that significant numbers of donors ceased to donate blood every year, why was the HCV look-back exercise designed to target only the recipients of repeat blood donors?

338. Most developed nations approached the issue of trying to identify who might have been infected with HCV before the introduction of screening of blood donations by carrying out targeted lookback, as was done in the UK. This is because targeted lookback concentrates on targeting those who could be identified as most at risk, because they had received blood components donated by donors who were later shown to be HCV positive. By targeting in this way, the chance of identifying, contacting, and notifying those most at risk is achieved with maximum efficiency.

339. In countries where there was no unified or national blood service, even targeted lookback was impossible. Some countries, such as France, tried to tackle the problem by encouraging those who knew they had

received a blood transfusion to come forward to be tested for HCV. The problem with that approach is that many people are not aware they have received a blood transfusion, and the information will not always be available in their GP records. There is no national database in the UK of patients who have received a blood transfusion. Attempting to identify all those who have received blood transfusions by interrogating hospital blood transfusion laboratory records would be a huge task, and taking that forward to then have a process for contacting, notifying, and offering testing to all those individuals would require enormous resources for a small return, as the vast majority of individuals who have received a blood transfusion were not infected with HCV.

340. I do not know whether the HCV Lookback Working Party set up by the Department of Health ever considered extending lookback beyond the targeted lookback which was carried out. Any extension beyond this would be outwith the remit of the blood services and would require massive public awareness campaigns. But as I have explained, even then, many people would not have come forward as they simply did not have the knowledge that they had received a blood transfusion.

341. In my answer to Question 14 I have set out the difficulties in attempting to contact donors who have lapsed from donation, explaining why I believe the Hepatitis C Look Back Working Party considered that it would be disproportionate to attempt to trace donors who had not come back to donate since the introduction of HCV screening of blood donations.

342. Certainly, the blood service always made it clear that targeted lookback would never identify all those who had been infected with HCV before the introduction of screening of blood donations, but it was not within the resources of the blood service to extend look-back beyond this.

343. Dr Gorman's letter to Dr McGovern, referred to above, was not in fact discussing lookback. It was addressing a completely different point. This was the issue of requests from clinicians for an investigation into cases of HCV infection identified in individuals who had a history of blood transfusion prior to the introduction of HCV screening in September 1991. Such requests were not infrequently received. The patient, not unnaturally, wanted to know whether the infection had been transmitted through the blood transfusion. Dr Gorman was making the point that it was inevitable that many such cases would be difficult or impossible to fully investigate, because one or more of the donors was/ were likely to have lapsed from donation, and furthermore, be no longer contactable. Thus, the almost inevitable conclusion of such an investigation was that it had not been possible to identify a definite source of infection.

344. Such a conclusion was frustrating for the blood service, the requesting clinician, and the infected patient.

345. I was involved in an exchange of correspondence on this issue at the time.

346. On 6 March 1996, Dr Caffrey, my colleague at the Cambridge blood centre, wrote to me [NHBT0009461] seeking advice on an enclosed letter which raised a number of issues. She referred to having heard me say that we had no mandate to carry out any lookback studies other than those specifically sanctioned by the Department of Health. Dr Caffrey's colleague, Dr Graeme Alexander, felt quite strongly that if patients were HCV positive and had a known history of blood transfusion, there was a clinical need to establish if the two were connected. Dr Caffrey felt it unlikely that the donors had continued to donate after 1991 or that any information would be available, but she had commenced the task of tracing records, but had concerns about

the ethics of contacting the donors after a period of years. She asked for advice.

347. I replied to Dr Caffrey by letter of on 14 March 1996 [NHBT0009463] noting that I fully understood the concern to establish as clearly as possible the source of the hepatitis C infection in patients with hepatitis C-related liver disease,but was not sure how identifying the source of the infection would influence the management of the disease. I noted that we all knew that the lookback would solve a number of hepatitis cases, but we had never pretended that it would identify all individuals infected by a transfusion before September 1991. I suggested that it was turning the problem on its head by investigating every case of hepatitis C where there was a blood transfusion prior to 1991 as a formal post transfusion hepatitis or transfusion-transmitted infection investigation. A number of issues arose:

- Firstly, none of us disputed the need to investigate where hepatitis C had apparently been transmitted since the start of routine screening of blood donations. We knew that there were deficiencies in the early tests use and suspected that although the sensitivity and specificity of the screening tests had improved immensely, they would still not be 100% accurate all of the time. For these cases I did not think there was any dispute.
- The problems arose in patients transfused with unscreened blood. If these recipients had not been identified in the lookback (as recipients of blood donated by individuals subsequently shown to be HCV positive), then we were into a law of diminishing returns; a proportion of donors would have lapsed from donation and would not therefore have been tested for hepatitis C.
- Provided hospital records were available, we could identify the donors whose blood had been transfused to any individual recipient and confirm whether those donors have been tested for HCV.

These donors could then be excluded as a possible source of infection. We had done this exercise on a number of occasions. Although it virtually never gave a complete answer, in those cases where all donors have been tested, it could at least point to another source of infection.

- Our difficulties lay in the area where one or more donors had lapsed and not been tested for HCV. The clinician who was caring for the patient would no doubt have explored other possible sources of HCV infection and may have to reach a view on whether the blood transfusion was the most significant factor. Obviously in a multi-transfused recipient of unscreened blood, the likelihood of infection through transfusion was quite high. The reverse was not always true.
- There were huge ethical and operational difficulties in attempting to contact donors who lapsed from donation before 1991, which were, in no particular order:
  1. The donor may have died.
  2. The donor may have moved; this was not insurmountable as we had become adept at tracing donors through the FHSA and GPs.
  3. The donor may have developed a serious illness and received blood transfusions. We had had more than one example of donors who had received multiple transfusions for leukaemia, in whom the issue of now testing was of questionable validity as an indication of their status prior to treatment.
  4. The donor may have excluded him/herself for a valid reason and not wish to respond to attempts to contact them for the very reason that they knew they were ineligible to donate. This was particularly an issue in those at risk of transmitting HIV before 1985.
  5. The donor may have retired from donation having reached the retirement age.

- We were always treading a delicate balance between the needs of the recipient and the treating clinician to have questions answered versus our duties to the donor. Where there was a long time interval between the donation and the attempt to trace, the chances of any positive contact with the donor diminished dramatically and the damage which could be done to that donor became significantly greater. The counter position was that the identification of someone who was infected with hepatitis C ten years ago would be to their benefit, but this must be a secondary issue as otherwise we would have large scale testing for HCV in the general population.
- We had to be careful not to be seen to be seeking out individuals to 'blame' who then had a burden of guilt for the very reason that they had been sought out as possible sources of HCV infection. This was very different from identifying donors during routine screening of blood donations and notifying them of these results. These individuals were never informed that they might have transmitted infection to others. Those donors who were recalled for post-transfusion hepatitis investigations were very often seriously concerned that their voluntary act of blood donation could have caused harm to others. This is a very heavy burden to give an individual and we had to bear this in mind, without being paternalistic.
- I noted that Dr Caffrey and I shared views on this. I was sure that Graeme Alexander would like the issue discussed more widely and I wanted to take it to SACTTI to see whether our views were shared or whether his question should be actively pursued.

348. I observed that it was a long letter as I had wanted to set out the issues which concerned us all. It was not an easy subject and I said that I would welcome wider views at SACTTI.

349. I then wrote to Peter Flanagan on **18 March 1996** [NHBT0091492_006] noting that Liz Caffrey at Cambridge was under pressure from a local hepatologist to investigate all cases of presumed hepatitis transmission due to transfusion of unscreened blood, including the recall of lapsed donors. In one case the transfusion had been in **1984**. I enclosed Dr Graeme Alexander's letter together with Liz's letter and her reply and continued that in her Zone they had undertaken to review donation and donor records in such cases and provide information about the number of donors who had been subsequently tested and those whose HCV status was unknown. Graeme Alexander was asking them to do more and to recall lapsed donors specifically to ascertain their HCV status. I had tried to highlight the relevant issues in my letter to Liz Caffrey but would welcome a wider discussion on this subject to ensure we were not out of line with colleagues elsewhere in the UK and would be grateful if the subject could be discussed at SACTTI.

350. The Minutes of meeting 2/96 of the UK BTS/NIBSC Standing Advisory Committee on Transfusion Transmitted Infections (SACTTI) on **16 April 1996** [NHBT0000088_013] under the heading – *13. Investigation of Possible Transfusion-Associated Hepatitis* note that the issue was discussed of how far lapsed donors should be contacted and investigated in the context of management of patients found to have viral markers which may have arisen from previous transfusion. It was agreed that the precise ascertainment of the source of infection was of no benefit to the management of the patient. The meeting therefore broadly supported the concerns and conclusions set out in my letter to Dr Caffrey. The only point of issue was whether there remained any duty of care to lapsed donors to contact them in the event of a possible transmission. It was agreed that I and Dr Gillon would seek the relevant legal opinions on this matter within the NBTS and SNBTS respectively.

351. On **10 June 1996**, I wrote to Dr Flanagan [NHBT0009730] noting that I had had a very full reply from Mr. Janisch (the solicitor), which set out all the arguments. The conclusion was as follows:

"In conclusion, I would say that there is an arguable basis for considering that a legal duty of care is owed to donor which would require the Blood Service to contact them, establish whether they are HCV-infected and offer counselling and treatment but that other factors need to be taken into account before deciding to set up an administrative system aimed at giving effect to the discharge of the duty of care. These factors are the value to donors of any counselling or treatment which might be provided, the practicality of contacting donors and the degree of probability that donors so contacted would prove to be HCV-infected".

352. I commented that I was not certain that this helped us very greatly and that it would seem that cases would need to be considered on an individual basis and that no set rules could be made, at least on legal grounds. I thought that perhaps this item would merit further discussion at a future meeting.

353. In my experience, although I cannot recall the number of cases involved, investigation of reported cases of HCV infection in recipients of unscreened blood never led to a definite conclusion that transfusion was the source of infection. In some cases, we could conclude that transfusion was not the source of infection.

354. In making the decision that such cases would not be fully investigated with attempted recall of donors who had not been in contact with the blood service for many years we took into account several factors:

- The resources which were required, balanced against the experience that investigations never led to a positive conclusion
- The fact that no such investigation was required for a claim to be made for an ex-gratia payment under the Skipton Fund. Proof that an infected donor had been identified was not required for payment to be made. This provision had been written into the protocols for the Skipton Fund, in recognition of the fact that requiring an investigation of every case submitted for an ex gratia payment would totally paralyse the blood service because of the numbers and the resources required. In contrast, the Eileen Trust for HIV infection usually requested confirmation that the blood service had investigated the case and was satisfied that transfusion was the definite or probable source of infection before awarding a payment.
- The duty of care to donors was considered, but it was felt that this duty was even more arguable in the case of donors who had lapsed from donation, and not maintained contact with the blood service. The blood service always attempted contact with lapsed donors, sending further invitations to donate blood, usually on 3 occasions, before ceasing to communicate with the ex-donor. The lack of contact was not therefore because of a decision by the blood service, and it could be argued that the service did not continue to have a duty of care to people who had removed themselves from blood donation after years had elapsed.

16. Where a former donor tested anti-HCV positive in some context other than a repeat donation of blood (e.g. during medical treatment), was a look-back conducted on their previous donations?

355. If the blood service was informed that a former donor had now tested positive for HCV, then their previous (untested) donations would be included in the HCV lookback. If there were records indicating that

previous donations had been screened and found HCV negative, then these donations would not usually be included in lookback, unless there was clear information that the most recent negative donation could have been donated in the window period before development of a positive anti-HCV test.

Question 17

17. **In the article titled 'The contribution of transfusion to HCV infection in England' by K. Soldan (NHBT0097156_006) it is estimated that: Page 588: "This estimated the number of transfusion-transmitted HCV infections from components that entered the lookback programme but fell out of the process prior to recipient testing to be 3373 HCV infections."**

Page 590: "Using this adjustment resulted in an estimated extra 19525...anti-HCV-positive components issued after 1 January 1980 that did not enter the lookback programme. The entry of these extra anti-HCV positive components into the path - with the use of a 0.75 probability of infection transmission for these components (i.e. the observed proportion of anti-HCV-positive donation also positive for HCV RNA) - predicted an extra 12 606...transfused components, and an extra 9455...HCV-infected recipients of which at least 5794...are expected to have died by the end of 1995. "

Given that, according to Soldan's assessment, the HCV look-back exercise only identified a small percentage of people infected with HCV through blood transfusions, what steps, if any, were taken to address the deficiencies of the 1995 HCV look-back?

356. This is really the same question as those which I have dealt with above and I am sorry that I am not able to explain it any further than I have done already.

Question 18

18. Within document NHBT0009715, under the heading, "Look back exercise", it is further stated:

***Working Party considered the testing of serum samples stored from before September 1991 and agreed that Ministers should be advised that the testing of such samples would also be disproportionate, although a legal view on this should be obtained.*"**

a. Please explain the work involved in testing stored serum samples and why this was also considered to be disproportionate, having regard to the duty of care owed to patients.

b. Please provide, as an exhibit to the written statement, any legal advice obtained on this issue.

357. It has not been possible to find any legal advice on the point in the documents so far released to us following searches against all relevant terms we can think of. If such an advice becomes available, we will provide it.

358. Any such advice may have been obtained by the Department of Health as this document is by Jeremy Metters the DH, Chair of MSBT, and it refers to advice to Ministers which is likely to have been obtained via DH.

359. There is a legal advice from Mr. Janisch to Alan Slopecki (NBA) re: *Legal aspects of long term storage of samples* [NHBT0017507_002] (replying to a letter dated 01/06/1995).

360. Mr Janisch notes that in Alan Slopecki's letter of **1st June 1995** he had asked whether there was any legal precedent which might help the blood service determine how long samples from blood donations should be stored, given that some products prepared by pooling plasma from donations might not be transfused for up to five years post-donation. Mr Janisch was not aware of any legal precedent in the sense of a case having been decided by the courts on substantially that issue and it was therefore necessary to consider the point under general legal principles.

361. Mr Janisch advised as follows:

The National Blood Authority, as the body responsible for the National Blood Service, owes a common law "duty of care" to patients who receive blood or blood products in the course of treatment and are therefore likely to be adversely affected by any infection present in the donated blood. To discharge the duty of care, the NBA should (in his view) take all reasonable steps to ensure the safety of blood used for transfusion or for blood products. These steps would include the retention of stored samples so that, in the event of a patient developing an infection from transfused blood or a blood product, a lookback could be undertaken and arrangements made to ensure that the donor concerned did not give further blood and so enable other patients to be infected.

It should be noted that the use of the term "lookback" in the context of investigating a possible blood transfusion source of infection in a blood recipient is misleading. The term "lookback" is conventionally, and internationally, used to describe the process of tracing donations which have been obtained from donors who are later identified to be infected, or to otherwise present a possible risk to the recipient. In the case of lookback, the starting point is the identification of a donor who is

infected. In the situation where it is a blood recipient who is identified to be infected, and an investigation is undertaken to determine whether the infection originated from a blood donor, the accepted term is "traceback" or "reverse lookback".

362. In his letter of **1st June**, Mr Janisch had summarised the procedure for testing a sample of every donation of blood. He believed that these tests were performed immediately after donation so that the blood in question was not released for transfusion or for use in blood products unless testing had shown that it was safe. (He was not clear what was meant by saying that if tests were "repeatedly positive", donations were not used for patients). He asked how many times the tests were performed *before the blood was released for use?* I have explained this above in relation to initial and repeat reactives and reference laboratory testing).

363. In relation to the situation in which a patient becomes infected, having been transfused with blood or having received a blood product, a frozen sample (of the original donation(s) is then thawed and re-tested. He presumed that this procedure was aimed (a) at identifying the source of the patient's infection and (b) ensuring that any donor shown to be implicated was removed from the donor panel.

364. The current practice was to store these samples for at least two years. This involved maintaining a store of about five million samples. He presumed it followed that to increase the period of storage to (say) four years would mean doubling the capacity to ten million samples. Storage obviously had cost implications. If the cost of storage was high, then it was clearly a factor to be weighed in the balance in determining whether it was legally justifiable to increase the period of storage.

365. If a patient who received a product became infected and the infection was diagnosed only after any stored sample has been destroyed, he presumed that it became much more difficult to demonstrate a link between the donor and the infection of the patient. Clearly, it would not be impossible because a record would still exist of the donors who contributed to the blood involved and direct contact could be made with them for testing purposes. He appreciated, however, that the degree of certainty or probability of any link would be reduced if the date when the donor became infected could not be conclusively demonstrated.

366. Mr Janisch continued: *Would this problem affect the treatment of the infective* [sic] *patient, however? In other words, would it make any difference to the treatment offered to the patient if it could or alternatively, could not be shown that the infection had originated in the blood of a specific donor?* This was a medical issue on which he was not qualified to comment but he could well imagine that it would make no significant difference. If not, then it seemed to him that the "premature" destruction of the stored sample could not be said to be a breach of the duty of care owed to the patient concerned. The destruction of the stored sample would, for reasons discussed above, make it more difficult to demonstrate a link between the donor and the incidence of infection in the patient. It might therefore be less easy for the Service to justify removing one or several donors from the panel because of the incidence of infection. Not removing an infected donor would of course create the risk that further patients would become infected from subsequent donations. These circumstances could therefore be said to amount to a breach of the duty of care in respect of those patients.

367. However, the cost of maintaining millions of samples in cold storage may well be a factor in determining what was reasonable. If, for instance, we were able to show that the vast majority of problems

would be picked up within the period of two years for which samples were currently stored, the law of diminishing returns would apply to any extension of the period. He did not think that the period of storage necessarily had to equal or exceed the maximum period between donation and transfusion of some products.

368. He concluded his advice by noting that apart from common law principles, liability may also arise under the Consumer Protection Act 1987.

369. The blood service retains a small aliquot of each blood donation. Within NHSBT, at the time in question, most blood centres kept samples for 2 years, although some may have had samples for longer (see paragraph 7 above, where the lawyer has referred to the storage time of approximately 2 years). A meeting of the Lookback Working Party in 1995 discussed the testing of samples taken prior to the introduction of HCV screening in September 1991. These samples would not have existed within English blood centres at the time of the meeting. It is relevant that most of the attendees at the meeting were not employed by the English blood service, and simply did not know enough about the workings of the blood service to understand that this discussion was superfluous as far as England was concerned. SNBTS, on the other hand, would have had samples available to test, as there was a longer period of retention of samples in Scotland. Two of the attendees were from SNBTS.

370. Aliquots of each blood donation, each consisting of a couple of hundred microlitres of plasma, are removed from the sample tube which is taken at the time of blood donation and used for laboratory tests associated with the blood donation, after all tests have been completed. In England, the sample of plasma is pipetted into a well in a microtitre plate. Each plate consists of 96 wells, and each well contains

plasma derived from a different donation. Nowadays, a computer programme ensures that each sample in each well of the plate can be related back to the originating donation.

371. Such programmes did not exist in 1991, and records would have relied on manual worksheets to relate the samples back to the records of the individual donations. Once all samples have been added to the micro titre plate, the plate is frozen and transferred to long term storage. Retrospective testing of these frozen samples, had they been available, would have involved retrieval of the frozen microtitre plates, thawing of the plates, transfer of the samples from the wells by pipetting each sample into a test tube. The tubes containing the thawed samples would need to be individually numbered so that they were identifiable. Then each tube would be tested.

372. These tests would have represented the number of HCV antibody tests that would normally be carried out over two years, which would be a huge task, but as no samples would have been available in England, no such testing could in fact have been carried out.

373. The length of time for which samples should be stored was addressed by Dr Contreras in a letter to Dr Gunson of **24 October 1990** relating to the draft recommendations for plasma failing to meet BPL specification [NHBT0000077_053] in which she said:

'*With reference to 3.5, again, I find that the recommendation to store frozen samples for two years is an odd recommendation. If we are interested in HBV, then one year is enough. On the other hand, if we are interested in HIV, then we will need 10 years or more. This is the reason why we have decided to store samples for 11 years.*'

Question 19

19. Was it possible for Regional Transfusion Centres and Haematology Departments to opt out of the 1995 look-back exercise? If so:

a. Please provide a list of Centres and Departments that did not participate in the 1995 look-back exercise.

b. Why was the 1995 look-back exercise not made mandatory?

c. What steps were taken to encourage Centres and Departments to participate?

374. I understand that the detail of the HCV lookback process has been discussed by Dr Robinson in her response to these questions. The HCV lookback was ordered by the Chief Medical Officer. As National Medical Director of the NBS, Dr Robinson was responsible for the NHSBT arm of the lookback, Lookback, by its very nature, required the participation of both the blood service and hospital blood transfusion laboratories, so that identified donations could be traced through to named recipients. As matters progressed – or in some cases didn't - Dr Robinson suggested a further formal communication by the Department of Health to encourage particularly slow hospitals, but this suggestion was not thought appropriate. It was therefore left to the blood service to offer "under-performing" hospital laboratories encouragement, advice, and reminders.

375. It was not possible for Regional Transfusion Centres or Haematology Departments to opt out of the HCV lookback. As far as I am aware, no Regional Transfusion Centre would have wanted to opt out. The blood service had been frustrated by the delay in starting the lookback and was acutely aware that tracing of blood components would become more difficult as time elapsed. Records within hospital blood transfusion laboratories were not kept indefinitely, and the more time

that elapsed before starting the lookback, the more records would no longer be available, meaning that potentially infected recipients would not be traced.

376. I was very involved in the logistics of the HCV lookback and in trying to tackle some of the practical issues that arose. We visited our local hospital laboratories to explain the process in advance and did what we could to prepare them and help them understand what was required. Although it was not possible for them to opt-out, as will be clear from Dr Robinson's response, the speed and efficiency with which different hospital laboratories and individual clinicians engaged in the process was very variable.

377. Not all hospitals or individual clinicians were enthusiastic. Some did not understand the process; many did not have any available resource for what could be a significant exercise and there were often gaps in the information they were able to provide. For example, the hospital laboratory would not have access to details of cause of death where the recipient had died. Regional Transfusion centres were often able to trace donations back to the early 1980s, but many hospital laboratories would have destroyed records from that period.

378. It had been hoped that treating clinicians or GPs who had an existing, and often ongoing, relationship with patients would communicate with, and offer testing to, those who were traced through hospital records. Blood service clinical staff would be a fallback position for this role. In practice, GPs in particular felt they did not have the necessary knowledge about HCV to carry out this role, and despite being provided with information and written resources more often than not declined to participate. Blood Service clinicians therefore took on the role, with the attendant inconvenience for patients, who often needed to travel to a blood centre for a meeting. One advantage, however, was that the

blood service was able to operate a streamlined system for referring blood samples from the recipients direct to a reference centre, and this usually meant that results were available with a shorter turnaround time than would otherwise have been the case.

379. On **26 March 1996**, I replied to a memo of Dr Sue Knowles of 21 March 1996, [NHBT0009962_002] in which she had summarised the outcome of the Zonal directors' meeting, noting that the response about the 'problem hospitals' was disappointing since we had been led to believe that the Department would be willing to offer help (with a further letter to hospitals). The issue had been addressed at a Clinical Directors Meeting on 20 March 1996, for which the minutes [NHBT0009889_001] note:

'*Bottlenecks*
Approximately 550 LBF3 forms (these were the forms documenting the outcome of the lookback for an individual blood component) have now been received for entry onto the National Database. AR suggested that to speed the response from some Trust hospitals a letter needed to be sent from the DoH to Chief Executives of those Trusts. It was agreed that the letter should be general rather than directed to specific hospitals/trusts and should result in CEs having to review their own hospital's performance.
ACTION:- AR to draft a proposed letter to ask for the MSBT Secretariat to arrange for this to be sent from DoH to CE's of Trusts to try to overcome 'bottlenecks.'

380. The issue was discussed again on **22 May 1996** at a NBA Clinical Directors' Meeting at which it was minuted [NHBT0009899_001] that the approach via the MSBT for a circular letter to be sent to all CEs of hospitals concerning the slow response of hospitals to requests for information to the HCV lookback exercise had not been approved. The

MSBT wanted the specific 'poor performer' hospitals to be identified. Peter Flanagan asked how we should define 'a non-performing/poor performing' hospital and Dr Robinson responded that it was necessary to use personal knowledge of each hospital and ask if they had really tried their best, or whether their performance was due to a lack of resources. The recorded ACTION was for the three Zonal Directors to send a list of hospitals to Dr Robinson and she would then write to each hospital. She was to circulate the latest figures re HCV lookback to each Clinical Director.

381. I wrote to consultant haematologists at the hospitals supplied by North London BTC on **10 June 1996** [NHBT0076980].

382. In spite of the obstacles, and in some cases apparent lack of cooperation, we persisted and chased for outstanding responses as much as we could. I recall that I sent frequent reminders to those Consultant Haematologists in charge of blood transfusion laboratories which had not been returning any information. One of the Haematologists in a hospital supplied by NLBTC wrote a complaint against me to the RTD (Dr Contreras) accusing me of harassment.

383. In the case of the London and South East Zone of the NBS, I believe that we did as much as we could to try and ensure that as many people as possible were traced through the lookback. In my view, the delay from September 1991, when HCV screening commenced, and early 1995, when the lookback was finally initiated, must have led to failure to identify some recipients who had been infected, because records were no longer available. I am disappointed and sorry that more people were not traced. I am not sure though even now what more we could have done in the circumstances.

Question 23

23. ~~13~~. Annex A to the letter of the Chief Medical Officer dated 3 April 1995 (NHBT0002737) states:

'Where the final HCV test result is deemed to be indeterminate this should be recorded, but no further action is required at the present time.'

a. How were indeterminate test results recorded?

b. How, if at all, were indeterminate test results followed up?

c. Were donors with indeterminate test results informed? If so, how?

384. Annex A to the letter of the Chief Medical Officer dated 13 April 1995 (DHSC0006572_112) stated: "*Where the final HCV test result is deemed to be indeterminate this should be recorded, but no further action is required at the present time".*

385. This statement was in relation to test results on blood donations, and indicated that at that point, donations originating from donors whose test results were indeterminate were not to be included in the HCV lookback. There is an implication that there could be consideration of including such donations at some point in the future.

386. As Dr Robinson will explain, HCV Indeterminate donations were added to the HCV Lookback as a "second phase" in 1996, but this second phase uncovered very few recipients who were alive and could be offered testing for HCV.

387. I note that I wrote to Dr Angela Robinson on 8 March 1996 [NHBT0100773] confirming that we had discussed the extension of the lookback to include the defined group of HCV indeterminates, did not

expect it would present any problems and saw it as a natural extension of previous activity.

388. A letter written on 12 March 1998 by my colleague, Dr M C Moore, to one of the Consultant Haematologists in our area, summarising the results of the HCV lookback at NLBTC to date, illustrated the extremely low return in terms of recipients who were likely to be infected with HCV [NHBT0022113_001].

389. In essence:

a. All blood centres had records of test results on all blood donations. Blood donations which passed all routine screening tests (at this time, in **April 1995**, this would be a serological test for syphilis, a test for hepatitis B surface antigen [HBsAg] and an HCV antibody test) would have a negative test result recorded against each blood marker. These results would be held in the Donation Testing Laboratory database, and also transferred to the master computer record for that donation and donor.

Any test result which was not negative was logged as initially reactive (IR). The test would then be repeated in duplicate, using the same screening test, and any sample which was not clearly negative on both of the duplicate repeat tests would be deemed repeatedly reactive (RR). This result would be held on the Donation Testing Laboratory database. A donation with RR results was disposed of, and the donation sample was referred to the Reference Laboratory for further testing.

After completion of testing, the Reference Laboratory would send a written report on the further tests, indicating whether the sample was confirmed positive or not. In the case of syphilis and HBV, most

RR results on the screening test would be confirmed positive in the Reference Laboratory. In the case of HCV, a much larger proportion of RR screening results could not be confirmed as clearly positive or negative. These results were termed indeterminate. The Reference Laboratory result would be entered into the Testing Laboratory database and the master computer record for the donation and the donor. At any point, each blood centre could draw up a list of HCV indeterminate test results by interrogating the laboratory database. The instruction that "*where the final test result is deemed to be indeterminate this should be recorded.....*" was thus superfluous as far as blood centres were concerned.

b. All "not negative" donation screening test results were reviewed by clinicians with responsibility for transfusion microbiology, so that appropriate actions could be taken with respect to the donor. As has been stated above, the donation in question would already have been disposed of, so the clinical action was with respect to the donor. It has always been policy to inform blood donors of test results which might be of significance to their health. Furthermore, it is policy to inform a donor if test results indicate that future donations cannot be used, even if there is no concern about the health of the donor. Further action is required in the case of indeterminate test results for HCV, because even though the test results indicate that the donor is unlikely to be (currently) infected with HCV, the results may represent past exposure to HCV, and further assessment is advisable to ensure that there is no question of current (active) infection.

   Although the Reference Laboratory carries out an HCV PCR test as part of the reference work, we had taken advice from experts about the management of individuals who had HCV indeterminate test results, and the consensus was that there should be two negative

HCV PCR tests, ideally 6 months apart, before concluding there was no active HCV infection. This was important information which should be relayed to the donor and to the GP of the donor. In addition, HCV indeterminate test results will be consistent in the case of future donations: such test results do not "disappear" in a few months. Therefore, waiting a few months for another donation to be made and tested (in the hope that the screening test might have reverted to negative) is not an option. Thus, in the case of HCV indeterminate test results, there are two reasons to inform the donor: because further investigation, in the form of a repeat HCV PCR test, is advised, and because further donations cannot be taken.

c. For the two reasons outlined above, all donors with indeterminate test results are notified of the results by letter, accompanied by an information leaflet. They are invited to telephone for a discussion with a clinician. The test results and their implications are explained: they indicate that there is a possibility of past exposure to HCV, but no evidence on current test results of active infection. A detailed history is taken to establish whether any risk for HCV infection can be established. Further discussion, in the case of an obvious risk for HCV being uncovered, might also focus on who else might be at risk (children, sexual partner). Questions and concerns are discussed. The donor is advised that the results will be forwarded to the GP. A donor may refuse consent to pass on the results, but all are strongly advised it is in their best interest. In the case of donors not registered with a GP, appropriate advice is given about the importance of registering and receiving further investigation.

When HCV screening was first introduced, advice was sought from a panel of expert hepatologists, who indicated that a second HCV PCR test should be performed, preferably after an interval of 6

months, and if the second test was negative then no further action was required. There was no indication to refer these people for specialist advice. This advice is transmitted to the GP and to the donor. The donor is encouraged to make an appointment with the GP and to ensure that the repeat tests are arranged. The donor is advised that further blood donations are not possible, since the test results will not disappear, likely for many years. Finally, the donor is thanked for volunteering.

390. Management of HCV indeterminate results in blood donors continues to follow the process outlined in paragraph 5.

Question 27

27. ~~17.~~ Accepting that the recommendation of the Penrose Inquiry, that everyone who had a blood transfusion before September 1991 be tested for HCV, was directed to Scottish Government, please provide an account of any steps taken by NHSBT in response to this recommendation

391. Dr Williamson was Medical Director of NHSBT at the time of the Penrose report and she reviewed the central recommendation and the findings.

392. I have tried to explain elsewhere in this response the difficulties inherent in tracing recipients of blood transfusions both because of problems with records and knowledge relating to the recipient and failures by clinicians to link a death many years later to a long forgotten or unknown of transfusion and for reasons inherent in identification through lookback from donors. I have also tried to explain the scale of this exercise which would cover many millions of people.

35. In the document titled 'Protocol for clinical investigation of the significance of isolated anti-HBc or anti-HBc/anti-HBs <0.1 IU/L' (NHBT0007906_001), reference is made to a proposed Hepatitis B look-back study being conducted, following the same procedure as the HCV look-back. Assuming that the proposal and protocol was agreed, please provide an account of this HBV look-back study, and exhibit any interim and final reports.

393. I was involved in this study and attach a copy of the paper [NHBT0000112_034] published in the British Journal of Haematology which shows that we performed HBV lookback as part of the study.

394. Dr Williamson had collaborated in an earlier, smaller study with Professor J-P Allain (Cambridge University) which looked at screening blood donations in East Anglia for anti-HBc, (*Allain J-P, Reeves I, Kitchen AD, Wenham D and Williamson LM; Transfusion Medicine 1995: 259-265. Feasibility and usefulness of an efficient anti-HBc screening programme in blood donors*) [NHBT0004108_045]. Anti-HBc is a marker of exposure to the hepatitis B virus, but not a marker of infectivity. Document NHBT0006068 is also relevant to this. The conclusion reached in this earlier study was that although the algorithm devised by the researchers allowed anti-HBc screening of blood donations to be done efficiently and at moderate cost, none of the **9,238** donations tested were positive for HBV DNA, which is the ultimate indicator of infectivity for HBV. It was not clear whether this was due to limitations of the test, or because no donors were actually carrying the virus. The published paper suggested therefore that a larger study of 50,000 or 100,000 donors would be needed to answer this question.

395. I was involved in that larger study, again led by Prof J-P Allain, in collaboration with colleagues in London. The results of the study were

published in 1999 as *Allan J-P, Hewitt PE, Tedder RS, Williamson LM. Evidence that anti-HBc but not HBV DNA testing may prevent some HBV transmission by transfusion. Brit J Ham 1999; 107: 186-195* [NHBT0000112_034]. The purpose of the study was to establish whether anti-HBc screening of blood donations could identify additional donors with the potential to transmit hepatitis B, despite them being negative on hepatitis B surface antigen testing.

396. A total of 103,869 donors from the East Anglia and South Thames blood centres were tested for additional hepatitis B markers (anti-HBc, anti-HBs and HBV DNA) under routine donor consent procedures, which made provision for use of donation samples in the assessment of new virus tests. Tested donors fell into 5 categories: (1) negative for anti-HBc and anti-HBs; (2) anti-HBc negative, anti-HBs positive; (3) anti-HBc positive, anti-HBs > 0.1 IU/ml (the level considered protective); (4) anti-HBc positive, anti-HBs positive but < 0.1 IU/ml; (5) anti-HBc positive and anti-HBs negative.

397. Approval for a lookback exercise as part of this study was obtained from the Ethics Committees of all 64 participating hospitals. For donors in categories 4 or 5, all donations in the previous 5 years were traced from blood centre records. In addition, age and sex-matched control donors were selected for lookback from those in category 3. The blood components made from the previous donations were traced through hospital records, and the case records of the recipients were examined. The recipient's GP was contacted and asked whether it would be appropriate to contact the recipient with a view to taking part in the study. If the GP agreed, the patient was contacted by letter, with an explanatory leaflet and the phone number of the study nurse. Patients who were interested in taking part had a telephone discussion with one of the study team, before giving written permission for a blood sample to be taken. Blood samples were tested for markers of

hepatitis B infection as well as liver function tests. Test results were given to patients by telephone as soon as available and confirmed in writing to the patient and GP. Further advice was provided to the patient and GP as needed. A telephone interview was conducted using a questionnaire in use at the North London Transfusion Centre, to try to establish whether the patient had any risk factors for hepatitis B infection.

398. Components made from previous donations from the **171** category 4 and **5** donors were entered into the lookback, resulting in **278** identified recipients. **Twelve** recipients had markers of hepatitis B infection, none with a history of clinical hepatitis. **Six** recipients had other risk factors for acquiring hepatitis B, such as being born in, or brought up in, a country with a high prevalence of HBV. Of the remaining **six**, an association with blood transfusion was considered probable in **two** and possible in **four**, suggesting that 1 in **52,000** donations (**1.92/100,000** donations, confidence intervals 0.3-78/100,000) contained infectious hepatitis B virus. The donors of these donations were tested for HBV DNA and all were negative **6-40** months after giving the donation which had been transfused to the recipient found to be positive for markers of HBV. As HBV DNA testing was not a routine test at the time of the study, it was unknown whether these donors were positive for HBV DNA at the time of the donation which may have transmitted the virus,

399. In summary, **none** of the donations were HBV DNA positive - as had been the case in the earlier smaller study described by Dr Williamson, and very few recipients had markers of HBV. It was not possible to establish whether these markers may have been pre-existing. This situation is usually the case when investigating HBV markers in a very mixed and cosmopolitan population who could have been exposed to HBV before their transfusion.

400. The conclusions from the study were that adding anti-HBc to the routine test for hepatitis B surface antigen could identify additional donors capable of transmitting hepatitis B.

401. In practice, anti-HBc was never recommended for routine use. Instead, routine testing for HBV DNA was introduced.

Additional Information/Closing Comment

402. I have listened to, and read, much of the evidence given to the Inquiry over the last 2 years. The testimony of those infected and affected has been difficult to hear. They have described with great dignity, and often with some difficulty, their experiences and the enormous effects of HIV and HCV infection on their lives, and on their families and loved ones.

403. It is a tragedy that treatments given so many years ago, intended to save and improve lives, had the opposite effect in so many cases, and that improvements in therapies, both for haemophilia and for HIV and HCV infections, have come too late for so many. I really am very sorry for this.

404. I know that I am not alone, amongst those who have spent their working lives striving to make the blood supply as safe as it can be, in feeling great sorrow that improvements did not come earlier. I also know that in saying that I speak not only personally, but also for NHSBT as an institution.

405. The Inquiry is fulfilling an important role in helping to understand the events of so many years ago. It has been faced with a considerable task, especially given the time which has elapsed and the absence of so many key individuals. I wish the Inquiry well in its work, and I look

forward to being able to assist with other matters as and when required.

Statement of Truth

I believe that the facts stated in this witness statement are true.

Signed GRO-C

Dated 25th October 2021

Table of exhibits:

Table of exhibits:

Date	Notes/ Description	Exhibit number
	Dr Patricia Hewitt's Curriculum vitae and List of Publications	WITN3101007
01/09/1986	Journal article "AIDS: A problem for the transfusion service?" from John A Barbara/ Marcela Contreras, British Journal of Hospital Medicine	NHBT0000027_030
16/01/1943	The Lancet 'Homologous serum jaundice'	NHBT0000091_011
	Meeting Minutes, from the Ministry of Health, regarding a discussion on 'Jaundice Following Transfusion.'	DHSC0100008_105

13/08/1946	Extract of letter from Dr. A.H.T. Robb-Smith, discussing the development of jaundice after blood or plasma and if litigation could occur.	DHSC0100008_189
22/08/1946	Note from Dr Maycock's to 'Legal Branch' of the Ministry of Health regarding the risks of administering dried plasma.	DHSC0100008_191
29/08/1946	Legal advice surrounding liability for jaundice infections following plasma transfusion.	DHSC0100008_192
21/07/1952	Expert Committee on Hepatitis, The World Health Organisation (1953)	RLIT0000215
26/09/1946	Plasma and Serum warning sent to Medical Superintendents, Pathologists, Officers in Charge of Blood Banks and Officers in Charge of Plasma Stores from Dr. Aubert, Regional Transfusion Officer.	DHSC0100008_212
01/02/2013	Human T-lymphotropic virus lookback in NHS Blood and Transplant (England) reveals the efficacy of leukoreduction	WITN3101008
01/08/1947	Draft Answer to Parliamentary Question (written by W d'A Maycock) regarding the safety of plasma products and risk of post transfusion jaundice in 1947.	DHSC0100009_018
21/10/1947	Letter from Maycock to Dr. Clegg	DHSC0100009_066
01/02/1948	Minutes of a meeting of Regional Blood Transfusion Officers on 14 January 1948.	DHSC0100054
06/12/1951	Letter, from GM Denning, Medical Liaison Officer, to The Under Secretary of State, and the War Office, entitled 'Secret: British Joint	DHSC0100011_184

	Services Mission (Army Staff): Sterilisation of Whole Blood and Plasma.'	
27/03/1952	Note from Dr W d'A Maycock, to Dr R Bevan, Cardiff Regional Transfusion Centre, regarding a post-mortem report of a patient who died from cirrhosis of the liver following jaundice.	DHSC0100011_202
		RLIT0000719
08/08/1952	Letter, from Dr W d'A Maycock, Ministry of Health, to Regional Transfusion Directors, regarding a change of policy in regards to homologous serum jaundice.	DHSC0100011_222
19/06/1952	Letter from Dr Payne, World Health Organisation (WHO) to Dr Maycock at the Ministry of Health, advising that the WHO is holding an Expert Committee on Viral Hepatitis next month	DHSC0100011_212
15/10/1952	Letter from A.J.Jacques, Chairman of the Coventry and District Voluntary Blood Donors' Association, to Dr Maycock regarding the exclusion of jaundiced donors.	DHSC0100011_236
27/10/1952	Letter, from Dr W d'A Maycock to Mr Jacques, regarding the incidence of jaundice and transmission.	DHSC0100011_238
23/12/1952	Newspaper Article, published in the Daily Express, entitled 'Blood Banks Plan SOS to Replace 1,000.'	DHSC0100012_013
08/01/1953	Newspaper Article, from the East Anglian Times, titled 'Virus in Blood of Donors: Official Statement to East Anglian.'	DHSC0100012_022

15/01/1953	Newspaper Article, from Edinburgh Evening News, entitled 'Blood Donors Who Have Had Jaundice: Could Kill Receivers.'	DHSC0100012_020
15/01/1953	Newspaper Article, published in the Scotsman, entitled 'Health Experts Warning: Danger of Jaundice in Blood Transfusions.'	DHSC0100012_021
17/05/1957	Letter to Dr Maycock from Dr Drummond	DHSC0100013_134
03/07/1984	Letter from H.H. Gunson to Dr A. Smithies regarding Anti-HTLV III and A.I.D.S. informing the most important development in the study is the availability of a viable test for anti-HTLV III.	PRSE0003901
01/08/1965	Complications of Blood Transfusion' by Jean Grant, Director, Regional Transfusion Centre, Oxford. Article published in the Practitioner Vol 195.	PRSE0003897
13/05/1970	Letter from Dr Maycock to Dr Thomson, Dr Obank, and Mr Hughes, responding to a letter from Basil Greenby & Co	DHSC0100019_100
01/01/1972	Journal Article, from Dr W d'A Maycock, 'Hepatitis in Transfusion Services' (1972) British Medical Bulletin (Volume 28, Number 2).	CBLA0000123
30/06/1995	Extract of the Official Journal of the European Committees, 'Council resolution of 2 June 1995 on blood safety and self-sufficiency in the Community'	NHBT0041267_012
04/09/1996	Conclusions and Recommendations Report re: Blood Safety and Self-sufficiency: An agenda for the European Community, from Colloquium	NHBT0044112

	held on 4-6 September 1996 in Ireland	
10/06/1996	Letter from Patricia Hewitt to Dr Peter Flanagan, re: duty of care to donors	NHBT0009730
09/08/1994	Minutes of Ad Hoc Assembly to Consider the Merits of an HCV "Look-Back" Policy, held 5 August 1994 at West Midlands BTS Centre	NHBT0009383
20/09/1995	Letter from Dr. P. E. Hewitt, to S. A. Janisch, Le Brasseur J Ticke, re: HCV look-back and obtaining view about a situation	NHBT0015661
26/09/1995	Letter from S. A. Janisch, Le Brasseur J Tickle Solicitors and Privy Council Agents, to Dr. P. E. Hewitt, National Blood Transfusion Service, re: HCV look-back.	NHBT0015660
25/02/1999	Letter from Stephen Janisch, Le Brasseur J Tickle Solicitors and Privy Council Agents, to Mr A Slopecki, National Blood Authority, re: Identification of Potential Donors.	NHBT0004389
30/04/1992	Letter from Dr K. C. Calman, Department of Health asking clinicians to: "consider whether they have any patients who are HIV positive and where a blood transfusion... may be implicated as the cause of infection."	OXUH0001251_004
21/10/1999	Letter from S. Janisch, Le Brasseur J Tickle, to Dr E. A. Robinson, National Blood Authority, re: Donors and Duty of Care	NHBT0004385_001
26/09/1985	Press release, "The Fight Against AIDS- More Government Money", Department of Health and Social Security (DHSS). Includes "Notes for Editors" which highlights information around	NHBT0007976_001

	funding, health education, screening of blood donations, other blood testing, heat treatment of blood products, counselling, research, information for health professionals, co-operation with the voluntary sector, setting up of an advisory group of experts and confidentiality.	
	Minutes of the 31st meeting of the Expert Advisory Group on AIDS held on 12 June 1990	NHBT0008409_064
02/10/1990	Agenda for 32nd Meeting EAGA : 2 October 1990 and Minutes of the 31st Meeting of the Expert Advisory Group on AIDS.	NHBT0008409_001
	Minutes of the 36th Meeting of the Expert Advisory Group on Aids, 8 October 1991.	NHBT0008406_002
22/04/1983	Minutes of the 3rd meeting of the UK Working Party of Transfusion-Associated Hepatitis, 20 April 1983	NHBT0000023_002
	Minutes of the Sixth Meeting Held at the North Western Regional Health Authority on Tuesday 8th January 1991	NHBT0000073_028 NHBT0000042_067
28/03/1983	Letter from J W G Smith, NIBSC, to Dr. L. K. Fowler, DHSS, re: AIDS	CBLA0000043_034
01/09/1989	Guidelines for the Blood Transfusion Services in the United Kingdom , First Edition,1989.	NHBT0000023_003
22/04/1983	Report by Dr. R.S. Lane, BPL: "Acquired Immune Deficiency Syndrome (AIDS)"	CBLA0001697
27/04/1983	Minutes for the Central Blood Laboratories Authority meeting, 27th April 1983	BPLL0003987_002

28/04/1983	Paper by Dr Gunson and J Barborough for the Regional Transfusion Directors' Committee: "Working Party on Transfusion-Associated Hepatitis" (RTD(83)8), with attached pro-forma and sheet of recipient and donor data.	CBLA0001703
13/05/1983	Minutes of Meeting of Haemophilia Reference Centre Directors	HCDO0000003_008
09/05/1983	Letter from Nicol S. Galbraith, Public Health Laboratory Service Board (PHLSB), to Dr. Ian Field, Department of Health & Social Security (DHSS)	CBLA0000043_040
19/05/1983	Committee of Experts on Blood Transfusion and Immunohaematology - Informal report by H. H. Gunson on the proceedings of meeting held 16-19 May 1983	NHBT0017430
13/06/1983	Paper titled "Central Blood Laboratories Authority: Acquired Immune Deficiency Syndrome (AIDS): Report on the discussion at the meeting of Expert Committee on Blood Transfusion and Immuno-haematology of the Council of Europe, Lisbon, 16-20 May 1983", by Dr. H. Gunson.	CBLA0001710
09/06/1983	Letter from H. H. Gunson to Sir Henry Yellowlees, Department of Health and Social Security, re: information on AIDS. Self-sufficiency.	NHBT0001067
	Appendix I - Recommendations of the committee of ministers to member states on preventing the possible transmission of AIDS from affected blood donors to patients	NHBT0010651_004

	receiving blood or blood products	
30/07/1985	Expert Advisory Group on AIDS - Minutes of the Fifth Meeting discussing AIDS surveillance	PRSE0002628
01/01/1983	Leaflet, from the National Blood Transfusion Service, entitled 'AIDS and how it concerns blood donors.'	BPLL0007247
01/09/1983	United Kingdom note on Acquired Immune Deficiency Syndrome in accordance with item 7 of Appendix C to CD-P-SP(83)14 in the Council of Europe Public Health Committee, September 1983	NHBT0010667
14/09/1983	Minutes of the UK Haemophilia Directors Hepatitis Working Party Meeting held 14 September 1983	HCDO0000270_031
14/07/1983	Lords Questions re: AIDS - Incidence and Control. Baroness Masham of Ilton	PRSE0001886
19/10/1984	Memo/note re: AIDS and testing of blood donations and blood transfusion/plasma related AIDS in the UK (author unknown)	DHSC0002323_009
	Minutes of the 3rd Meeting of the Central Committee for Research and Development in Blood Transfusion on 28th February 1984.	PRSE0001972
05/03/1984	Letter from N. S. Galbraith to Dr. Harold Gunson re AIDS and providing all the data they have available for maintaining the national surveillance	NHBT0010821_005
	Agenda and Minutes from the 191st meeting of the Regional Transfusion Directors, held 11 April 1984	CBLA0001836

16/04/1984	Letter from J.Craske to Haemophilia Centre Directors regarding 'Future Plans For the Haemophilia AIDS Investigation - An Update'. Encloses a list of batch numbers of factor VIII transfused to cases within 5 years of the onset of AIDS.	HCDO0000273_072
	Minutes of the 192nd Regional Transfusion Directors Meeting held on 11/07/1984.	DHSC0002245_002
	Notes of a meeting between Dr Galbraith, CDSC, Dr McEvoy, CDSC and Mr Gunson, regarding the "Surveillance of AIDS cases in relation to Blood Transfusion", held 4 April 1984.	CBLA0001833
04/04/1991	SNBTS Report - "Let's look at human immunodeficiency virus look-back before leaping into hepatitis C virus look-back"	PRSE0004329
21/09/1946	"The Incidence, Incubation Period, and Symptomatology of Homologous Serum Jaundice". N. Spurling, J. Shone, and J. Vaughan	RLIT0000052
24/10/1984	Letter from [unknown], Blood Products Laboratory, to [unknown], DHSS, re: recall of factor VIII batch HL3186: Donor Acquired AIDS; follow-up of patients who received this batch	PRSE0001658
	Paper by the Working Group on Aids titled: "The Arrangements for the Collection and Testing of Blood Donations in the National Blood Transfusion Service (NBTS)"	CBLA0001934_003
01/11/1984	Advisory Committee on the National Blood Transfusion Service regarding the Working	CBLA0001934_002

	Group on AIDS with list of members and Terms of Reference.	
27/11/1984	Memorandum from M. E. Abrams to Dr. Harris, re: Advisory Committee on the National Blood Transfusion Service Working Group on AIDS - Arrangements for the Collection and Testing of Blood Donations in the National Blood Transfusion Service (NBTS)	DHSC0002251_011
30/11/1984	Letter from J. Craske, Public Health Laboratory Service, to Director re: Future plans for the investigation of the role of HTLV-3 in the causation of AIDS in haemophiliacs	HCDO0000392_107
14/12/1984	United Kingdom Haemophilia Centre Directors' Organisation (UKHCDO) AIDS Advisory Document, 14 December 1984.	HCDO0000270_007
21/12/1984	Memo from Alun Williams, to all Regional Transfusion Directors, enclosing CMO's Press Release	BART0000814
03/01/1985	Minutes of Meeting held at the Middlesex Hospital Medical School on Thursday January 3rd, 1985	BART0000821
	Minutes of the Expert Advisory Group on AIDS meeting, on 1/10/85	MRCO0000001_068
08/10/1985	Notes from Dr N Pettet regarding the meeting of Regional Transfusion Directors at BPL	CBLA0002263
28/03/1985	Note of meeting of the Expert Advisory Group on AIDS	DHSC0001571
	Expert Advisory Group on AIDS Note of meeting on 10 June 1985 of Expert Advisory	NHBT0000186_033

	Group on AIDs.	
30/09/1985	Minutes of the 196th meeting of Regional Transfusion Directors held 10 July 1985	CBLA0002212
11/07/1985	Report from the Working Party of the Regional Transfusion Directors' Committee re Screening of Blood Donations for Anti-HTLV III in Regional Blood Transfusion Centres.	DHSC0000406
24/01/1983	Notes of Meeting With Immuno at London Airport - 24 January - Hepatitis Reduced Factor VIII and Factor IX Concentrates for Haemophilia Therapy.	PRSE0002647
	Expert Advisory Group on AIDS, minutes of the 7th meeting, includes update on HTLV III testing, counselling courses, testing facilities, AIDS surveillance; Consent, children at school infected, Hepatitis B vaccine	DHSC0002287_060
16/06/1986	Minutes of Regional Transfusion Directors' meeting held on 24th and 25th April 1986	CBLA0002307
10/09/1986	Report titled 'Retrospective study of HIV Infection Associated with Unheated NHS Factor VIII and IX'.	DHSC0001039
	Minutes of the Regional Transfusion Directors Meeting, held at DHSS Hannibal House on 8 October 1986.	CBLA0002345
23/03/1987	Minutes of evidence before the Social Services Committee in the House of Commons, entitled "Problems associated with AIDS", Wednesday 25th March 1987 together with memorandum submitted by Professor Ian Kennedy "AIDS:	LDOW0000247

	The ethical and legal issues"	
06/05/1987	Letter from Dr Tim Wallington to Dr Harold Gunson regarding the co-ordinated study of transfusion-transmitted HIV infection	NHBT0004202
26/05/1987	Memo from Dr V. J. Martlew to Dr H. H. Gunson regarding co-ordinated study of transfusion - Transmitted HIV infection	NHBT0004200
22/07/1987	Letter from T. B. Wallington to Dr Harold Gunson regarding a co-ordinated study of transfusion transmitted HIV infection	NHBT0004199
	Questionnaire on Blood Transfusion and Aids	NHBT0019308_003
15/12/1987	Appendix C: Recommendations for the Future Surveillance of Infection Transmitted by Factor VIII and IX Concentrates, by J. Craske, 1987.	HCDO0000427
19/02/1990	Anti-HIV 1 Testing of Blood Donations in the U.K. 1985 - 1989 by H.H. Gunson	NHBT0015578_001
	Minutes of The Expert Advisory Group on AIDS meeting, 6 March 1990. Chairman: Dr Abrams	NHBT0008216_002
17/09/1990	Report, "Investigation of Donations Transmitting HIV and HBsAg", by H. H. Gunson, September 1990.	NHBT0003763
11/09/1990	NBTS "Look-Back" October 1985 - December 1989" by Janet Mortimer PHL CDSC	NHBT0015574_002
	Minutes of The Expert Advisory Group on AIDS meeting, 2 October 1990. Chairman: Sir Donald Acheson	NHBT0008213_002
01/03/1989	Report re Unpublished AIDS/HIV quarterly Surveillance Tables The Data to End March	NHBT0006833

	1989	
09/05/1991	Note from Janet, Public Health Laboratory Service (PHLS), to Dr H. H. Gunson, re: letter from J. Mortimer to Director on follow-up of anti-HIV positive recipients of blood and form attached.	NHBT0004801
17/10/1983	Draft minutes of the 14th UK Haemophilia Centre meeting, Chaired by Prof A Bloom	PRSE0004440
05/09/1991	Revision of AIDS Leaflet	NHBT0097471_009
01/02/1992	Report on ANTI-HIV test on blood donations in the United Kingdom for the year 1991 by H. H. Gunson et al.	NHBT0006882
21/02/1992	Note on meeting Department of Health Meeting on HIV infected Blood/Tissue Recipients note of meeting 21/02/1992	DHSC0002941_006
24/04/1992	Scheme of payments for those infected with HIV through blood or tissue transfer, signed on behalf of the Secretary of State and dated 24 April 1992	EILN0000016_001
23/11/1990	"Recommended procedure for the management of Anti-HCV positive donors" guidance by J Gillon. Also includes report for National Medical Director about Donor Counselling (HCV).	PRSE0000515
11/05/1992	Letter from H. H. Gunson, National Director of NBTS, to all Regional Transfusion Directors, re: HIV and blood transfusion/tissue transfer payment scheme	NHBT0015108

29/05/1992	Letter from Dr F A Ala to Dr Harold Gunson, re: HIV and Blood Transfusion.	NHBT0015106
29/05/1992	Letter from H. H. Gunson, national director National Blood Transfusion Service to Dr. P. E. Hewitt, re: HIV and blood transfusion/tissue transfer payment scheme	NHBT0015104
08/12/1992	Press Release from the Commission of the European Communities, re: Committee for Proprietary Medicinal Products, Meeting of 3-4 December 1992. AIDS, HIV, Hepatitis C.	NHBT0000237_011
19/05/1995	Letter from Dr E. Angela E. Robinson, National Blood Authority to Prof S. R. McCann, The Blood Transfusion Service Board.	NHBT0003037_001
18/03/1998	Serious Hazards of Transfusion (SHOT) Annual Report, 1996-1997, by Dr. L.M. Williamson, S. Lowe, Dr. E. Love, Dr. H. Cohen, K. Soldan, Dr. D.B.L. McClelland, Dr. P. Skacel and Dr. J.A.J. Barbara	NHBT0057437_001
05/07/2004	Annual report 2003 of Serious Hazards of Transfusion (SHOT) by the SHOT steering group	NHBT0114981
	Minutes of the Advisory Committee on the Virological Safety of Blood 8th meeting, 21 November 1990	NHBT0000073_018
06/09/1969	Article titled, 'Serum Hepatitis in a Haemophiliac' British Medical Journal, dated 6th September 1969.	PRSE0003714
11/07/1985	Screening of blood donations for anti HTLV-III in Regional BTCs - report from working party of	PRSE0000636

	the Regional Transfusion Directors' Committee	
13/02/1991	A letter from Dr H H Gunson (National Director of NBTS) to Dr A Rejman (Senior Medical Officer, DoH) enclosing a report on anti-HIV tests on blood donations in the UK and minutes from a meeting of the UK Advisory Committee on Transfusion Transmitted Diseases (8 January 1991).	NHBT0000191_072
15/09/1988	Meeting report of the Council of Europe's European Health Committee, Committee of Experts on Blood Transfusion and Immunohaematology's 11th meeting at Vienna, 3-6 May 1988	NHBT00000042_058
	Appendix III, Recommendations for Counselling of HCV Seropositive Donors and Recommended Procedure for the Management of anti-HCV Positive Donors	PRSE0000515
03/06/1991	UK Advisory Committee on Transfusion Transmitted Diseases - Sub-committee on Laboratory Aspects report	NHBT0086153
10/06/1991	Minutes of eighth meeting of UK Advisory Committee on Transfusion Transmitted Diseases on 10th June 1991	NHBT0000074_047
05/09/1992	Minutes of NBTS's U.K. Advisory Committee on Transfusion Transmitted Diseases meeting re: availability of HCV antibody tests (Ortho and Abbott correspondence chronologies), introduction of HCV antibody testing and advice to be given to blood donors.	NHBT0000075_054

13/10/1995	Letter from Patricia E. Hewitt, National Blood Service, to Dr. Angela Robinson, The National Blood Authority, re: HCV positive donors and sexual transmission. Discussion of discrepancies in advice between different organisations	DHSC0003538_003
	Minutes of fourth UK Working Party on Transfusion-Associated Hepatitis meeting on 27 September 1983	PRSE0001299
25/02/1991	Minutes of the ninth meeting of the advisory committee on the virological safety of blood	NHBT0000030_019
23/06/1986	Abstract from International Conference on Acquired Immunodeficiency Syndrome (AIDS), 'Approaches to the Reduction of the Risk of HTLV- III Transmission by Blood Transfusion' by J. Barbara et al, Paris, June 23-25, 1986.	NHBT0000030_018
19/01/1983	Minutes of the UK Working Party of Transfusion-Associated Hepatitis Second Meeting	NHBT0000018_019
	Survey of Anti-HIV Tests on Blood Donations and Related Matters, compiled by H. H. Gunson, for the Committee of Experts on Blood Transfusion and Immunohaematology 11th Meeting on 3-6 May 1988 in Vienna.	NHBT0004514_001
13/04/1995	Annex A of the Procedural Guidance for the 'Programme to Identify Recipients of Blood Infected with Hepatitis C Virus (HCV)" April 1995.	DHSC0006572_112
15/08/1995	Letter from Angela E Robinson to Dr. J Metters re HCV Look Back	NHBT0002727_001

20/11/1985	Minutes of Central Blood Laboratories Authority twenty-first meeting on 20/11/85 in the Crest. Attached letter from W. P. N. Armour to Members of the Central Blood Laboratories Authority dated 12/11/1985.	BPLL0011017
	Minutes of the twenty - eight meeting of the Central Blood Laboratories Authority held on the 29th January 1987	NHBT0087416
25/02/1992	Letter from D E Burrage to Dr Gunson, re: HIV blood/tissue recipients.	DHSC0002640_011
06/03/1996	Letter from Dr. E. Caffrey, University of Cambridge, to Dr. P. Hewitt, North London Blood Centre, re: Look Back Studies.	NHBT0009461
14/03/1996	Letter from P. E. Hewitt, to Dr. E. Caffrey, East Anglian Blood Centre, re: Source of Hepatitis C Infection & HCV Look-back.	NHBT0009463
16/04/1996	Minutes of meeting 24/96 of UKBTS/NIBSC Standing Advisory Committee on Transfusion Transmitted Infections (SACTTI), held on 16/4/1996 at North London Transfusion Centre.	NHBT0000088_013
06/09/1995	Letter from S. A. Janisch to Alan Slopecki (NBA) re: Legal aspects of long term storage of samples (replying to a letter dated 01/06/1995)	NHBT0017507_002
24/10/1990	Letter from M. Contreras (Director, North London Blood Transfusion Centre) to Dr H. Gunson (National Director, National Blood Transfusion Service) re: Draft recommendations for plasma failing to meet BPL specification	NHBT0000077_053

26/03/1996	Memorandum from Dr. P. Hewitt to Dr. S. Knowles, Dr. Liz Caffrey and Dr. A. Gorman. Subject: HCV look back.	NHBT0009962_002
10/06/1996	Letter from Dr P. E. Hewitt to Consultant Haematologist, Blood Transfusion Laboratories, National Blood Service, re: update on the Hepatitis C Lookback. Enc: Hepatitis C Lookback exercise: Progress report 7th June 1996.	NHBT0076980
25/06/1996	Letter from S. A. Janisch, Le Brasseur J. Tickle, to P. E. Hewitt, National Blood Transfusion Service, re: Proposed CJD Lookback	NIBS0000331_003
08/03/1996	Letter from Patricia E. Hewitt, NBS London and The South East to Dr Angela Robinson, The National Blood Authority, re: extension of HCV look- back to include a defined group of HCV indeterminate donors	NHBT0100773
	Article from British Journal of Haematology, 'Evidence that anti-HBc but not HBV DNA testing may prevent some HBV transmission by transfusion'	NHBT0000112_034
30/05/1995	Scientific Journal Article titled: "Feasibility and usefulness of an efficient anti-HBc screening programme in blood donors", by J-P. Allain et al.	NHBT0004108_045
10/07/1995	Protocol for clinical investigation of the significance of isolated anti-HBc or anti-HBc / anti-HBs <0.1 IU/ml.	NHBT0006068