Presentation Note on Early Lookback Investigations

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Introduction

1. This Note addresses attempts to trace infected blood and blood products in the UK blood service prior to the formal HCV lookback which commenced in 1995. It is divided into three distinct areas: (i) historical jaundice enquiries; (ii) HBV lookback; and (iii) HLTV III / HIV lookbacks. The period examined focuses on the 1940s to the 1980s. Some examples are drawn from the 1990s and 2000s.

2. It is thought that the term "lookback" was first used in 1986 following the introduction of screening tests for HIV.[1] Broadly, there are two types of lookback. The first is when a donation is tested and indicates that a donor is infected. The possible recipients of the donation are traced to see if he or she is infected. This is commonly described as a "targeted lookback". The second type of lookback is known as "reverse lookback" which is when a patient presents with signs and symptoms of an infection and an investigation is undertaken to see if that patient has ever received blood or blood products. In these circumstances the treating clinician then notifies local or national blood banks that there is likely to be an infected donor.

3. The underlying documents set out in this Note represent a sample of the relevant documents received by the Inquiry rather than a detailed account of all the available material. This Note is drawn from a reading of contemporary material. It is likely that it will be supplemented by the oral witness evidence that will be heard in the forthcoming Inquiry hearings.

4. Overall, it is difficult to draw firm conclusions about these lookback investigations due to differences in the particular time period, geographic location, the type of infection and the absence of a complete contemporaneous documentary picture. However, some broad themes emerge. There were, it seems, challenges in tracing blood and blood products due to failures in recording batch numbers of those products. In addition to batch numbers, there were repeated problems with record keeping. Another theme is the failure of individual blood donors to respond to requests for information about their health. There were voiced concerns about alienating blood donors by asking too many questions about their health and domestic lives. Another key theme across the time period and different geographic locations is that members of regional blood services and clinicians raised issues of the lack of resources and highlighted the administrative burden of tracing donors and reviewing patients.

[1] See PRSE0004042, which refers to Menitove JE, 'Status of recipients of blood from donors subsequently found to have antibody to HIV', *New England Journal*, 1985, 315, 1095

5. Each of these themes is addressed below in relation to each type of infection, arranged chronologically where possible.

Historical Jaundice Enquiries

6. Broadly, the outcome of enquiries into jaundice was that contaminated batches were removed from the donor pool and efforts were made to trace and test donors.

7. This section sets out examples of investigations from the 1940s onwards. It then examines some of the common issues in tracing blood and blood products following episodes of post-transfusion hepatitis. This section focuses on reports of jaundice to local and regional blood transfusion centres and the subsequent reporting to central government. However, this Note does not address in detail the internal decision making of the DHSS or its outward policy towards regional transfusion centres.[2]

Investigations

8. The Inquiry has seen examples of investigations into jaundice from the 1940s onwards. These investigations are relevant to subsequent lookback exercises because they provide some evidence as to the nature of, and difficulties with, both reporting and record keeping. This section gives a sample of such investigations chronologically from the 1940s to the 1980s.

(i) 1940s

9. Dr Hewitt, Consultant Haematologist at the North London Blood Transfusion Centre ("NLBTC") from 1984, has provided a witness statement to the Inquiry.[3] Dr Hewitt describes that on 16 January 1943 the Medical Officers of the Ministry of Health published a memorandum in the *Lancet* entitled '*Homologous Serum Jaundice*', which described '*a number of historical incidences where jaundice had been noted following*

[2] These issues will be addressed as appropriate in presentations and/or in oral evidence. This section also does not address the state of knowledge of hepatitis, including the relevant emerging literature, or the actions taken outside of the blood transfusion service (for example, those by haemophiliac clinicians and the UKHCDO). These aspects have been or will be addressed by the Inquiry in other presentations and/or oral evidence.
[3] WITN3101006

administration of a vaccine.'[4] The article made an association between cases of hepatitis and the injection of human blood products, and raised the possibility of infection following transfusion. It further emphasised the need for an accurate record of batch numbers and '*the speedy notification by practitioners to transfusion officers of cases of jaundice following, after a long interval, the injection of blood products'*.

10. From the late 1940s cases of jaundice following blood transfusion were investigated. In a note, dated 1 August 1947, Dr Maycock[5] stated:

> '*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'*.[6]

11. On 14 January 1948 Dr Maycock chaired a meeting of the Regional Blood Transfusion Centres where it was reported that in the last 18 months 78 cases of haematogenous hepatitis had been reported to the Ministry of Health, of which 25% of those individuals had died. There was no record of the outcome of half of the remaining cases. Dr Maycock emphasised the need to establish a reporting system and emphasised the risk of using plasma.[7]

12. The Inquiry has seen examples from the 1940s onwards of infected donors being removed from the donor pool. Investigations into contaminated blood and blood products were carried out by local and regional transfusion services. An example from Wales: on 25 October 1949 Dr G. D. Lewis completed a report on behalf of the National Blood Transfusion Service for Wales about suspected cases of '*homologous serum jaundice*'.[8] The report is described as a '*routine survey*' on '*all cases of suspected homologous serum*

[4] §33 of WITN3101006
[5] Dr Maycock was the consultant adviser on blood transfusions to the Ministry of Health from 1946-1978.
[6] DHSC0100009_018
[7] DHSC0100054
[8] DHSC0100011_006

jaundice.' The utility of obtaining this information is described in the following standard terms set out at the top of each template form:

'As the disease may prove fatal, it is very desirable to have precise information (for pooling of knowledge) concerning individual cases... It is most essential that [the] identity of blood donors, or serial numbers of batches of plasma (or serum) used in transfusions be recorded. Suspected donors can then be traced and removed from the panels (and investigated), while suspect batches of plasma (or serum) can be withdrawn and the incidence of the disease thus greatly reduced.'

13. However, another theme apparent from the documents is that there was a concern amongst regional transfusion centres that some clinicians failed to report, or under-reported, cases of post-transfusion hepatitis. For example, on 1 December 1947 a Regional Transfusion Officer wrote to Dr Maycock at the Ministry of Health about a case of jaundice following a plasma transfusion at the Booth Hall Hospital, Manchester.[9] The patient underwent surgery on 24 September 1947 and 20 October 1947 and had a transfusion of plasma. The batch numbers are provided in the letter. The author of the letter shows a mild frustration about the lack of jaundice cases being reported by clinicians:

'I have been making enquiries [around]the hospitals and talking to R.S.0 but in spite of the fact that I have told them many times that we wish to have cases of jaundice reported to us I fear that quite a number in this area have not been reported'

14. The letter also refers to an impression that the source of the blood product was not from the UK:

'the general impression I have gained, however, is that the officers who have been in the hospitals for sometime consider the Canadian plasma has been the cause of the trouble.'

(ii) 1950s

15. There are examples of completed forms for suspected cases of post-transfusion jaundice in the 1950s from Wales. For example, a form was completed by a Dr Smith at Chepstow & District Hospital for a patient who was born in 1870, who had received plasma in 1945

[9] DHSC0100009_103

and whole blood in 1950.[10] The patient was noted to have recovered after severe jaundice that lasted nine weeks. Batch numbers were supplied on the form. The report stated that the donor, who supplied the whole blood the patient received prior to surgery, had not had jaundice, whereas the donor who supplied the blood administered post-operatively: '*did not reply to letter*.' The plasma was noted to be Canadian.

16. In 1952 Dr Maycock noted '*the first case of cirrhosis of the liver*' in a case of a patient with homologous serum jaundice.[11] In August of the same year Dr Maycock wrote to inform Regional Blood Transfusion Centres that the World Health Organisation had recommended excluding blood 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.*'[12] Dr Maycock's advice was for such donors to be excluded as soon as possible.[13]

17. This prompted a reaction in the media about the removal of blood from the national donor pool.[14]

(iii) 1960s

18. There are many examples of investigations into cases of post-transfusion hepatitis in the 1960s. The most common outcome of these investigations was the removal of a blood donor from the pool and destruction of the infected blood or blood product. On 22 May 1962 Dr Drummond, the Medical Director of the Cardiff Regional Transfusion Centre, wrote to Dr Maycock at the Lister Institute about the issue of post-transfusion hepatitis.[15] The letter states that there had been a previous discussion between the two men at a '*recent MRC meeting*' about '*tracking down cases of HSJ*'.

[10] DHSC0100011_011
[11] DHSC0100011_202
[12] §56 of WITN3101006 and DHSC0100011_212
[13] DHSC0100011_212. See also DHSC0100011_236 and DHSC0100011_238
[14] See examples of press responses in §60-61 of WITN3101006
[15] DHSC0100015_241

'*It is, I hope, a fair statement of fact that our methods have produced, and are producing, results in the way of cases of post-transfusion serum hepatitis. More cases could be traced, but the work has now become too great to be adequately coped with, as I hinted in a previous letter.*'

19. He then used the following hypothetical example to demonstrate the extent of the task of tracing donors:

'*It is worth considering what is involved in a hypothetical case which has had, for example, 7 bottles of blood and 3 of S.F. Dried Plasma (of different batches). Suppose the donors of the 7 bottles of blood have, between them, donated on 30 occasions. The fate of each donation has to be accounted for - that may mean going back 10 years, or more, in some donors. For each donation transfused, the recipients must be contacted. We have to ascertain via the hospital, then GP, whether patient still survives. If alive, we must ascertain from the patient whether he, or she, had jaundice in the six months following transfusion; several cases have come to light in this way. In the case of donations used for plasma, the fate of the plasma must be ascertained and recipients traced, as above. Finally, in case of S.P. plasma, all the donors (if this region) contributing to the pools must be accounted for and all donations they have given back-traced as above.*'

20. Dr Drummond stated that more resources needed to be put into this exercise '*if this work is worthwhile*'. The need for more staff and greater resources is a theme that is reflected throughout historical investigations into post-transfusion hepatitis. He made the following suggestion for obtaining more staff:

'*I would suggest that for a trial period of one year, we be authorised to utilise the services of one of our bleeding session doctors one full day a week here. She would need clerical assistance and we would think, be able to allocate this (shorthand typist) from R.D.O's department - say 3 afternoons a week.*'

21. The documents reveal evidence of a successful system of tracing donors in the 1960s. For example, in a letter on 14 December 1964 Dr Zeitlin, Director of the South London Transfusion Centre, informed Dr Maycock about a patient suspected to have homologous serum hepatitis. Dr Zeitlin stated that '*the usual follow-up of donor [was] being undertaken.*'[16] On 4 January 1965 Dr Zeitlin wrote to Dr Maycock with an update.[17] He stated that:

[16] DHSC0100016_294
[17] DHSC0100017_002

'*… three recent donations from the implicated donor have been traced back.*

One, as you know, went into post-vaccinial pool no. 50 which has now been destroyed. The second was transfused at Orpington in 1962. A recent follow-up of the recipient shows no evidence of any trouble whatsoever and certainly no jaundice. The third was transfused at Cuckfield Hospital in July, 1963. A report has now been received to the effect that the recipient was followed up for 12 months after transfusion and there is no record of any jaundice resulting.'

22. A further example is on 27 May 1965 when a homologous serum jaundice report was completed by the Director of the North East Metropolitan Regional Transfusion Service.[18] It was noted that the donors had been successfully contacted: '*right donors have been contacted and deny a history of jaundice or contact with a case*.'

23. However, there are other examples which suggest possible difficulties in the reporting and donor removal process. This was highlighted by Dr Drummond,[19] of the Cardiff Regional Transfusion Centre, to Dr Maycock in a 19 July 1965 letter.[20] Dr Drummond's view was plain: '*we have felt for some years that the Cardiff Royal Infirmary does not notify us as many cases as it ought*.' Nine cases of serum hepatitis were reported by the Cardiff Royal Infirmary from 1954 to 1964 of a total of 116 being notified to the Welsh BTS. A request was made of the Ministry of Health's statistician to consider this issue because Dr Drummond thought that there was underreporting by the Cardiff Royal Infirmary.

24. Dr Maycock responded on 2 August 1965.[21] He stated that he had not:

'*been able to do anything about your letter… as the Medical Statistician of the Ministry of Health has recently left to take up a position in Scotland. I shall show your letter to his successor when he has been appointed. It certainly looks on the face of it that a number of cases of serum hepatitis are not being detected at the Cardiff Royal Infirmary, although I am not sure whether the figures are large enough to make the difference significant*.'

[18] DHSC0100017_027
[19] The signature is hard to decipher but the reference at the top of the headed note paper is to 'RD'
[20] DHSC0100017_034
[21] DHSC0100017_047

25. Dr Maycock then referred Dr Drummond to the article 'Post-Transfusion Anicteric Hepatitis' by Hampers et al in the *New England Journal of Medicine* 1964 271, page 747. He stated:

'...in the previous 4 years in the Medical Services of the Philadelphia General Hospital have found an incidence of 5 cases per 10,000 transfusions. It seems clear from the context that this means 10,000 units of blood administered. This is an incidence of 05 per cent, i.e. slightly higher than that found in the Welsh Region excluding the Cardiff Royal Infirmary. However, he found an attack rate of anicteric hepatitis equivalent to 870 per 10,000 units transfused, i.e. an incidence of 8.7 per and concludes that in Philadelphia General Hospital there may have been over 100 cases of anicteric hepatitis for each icteric case diagnosed. His figures are statistically significant.'

26.

27. A further example may be found in a letter dated 21 July 1965 when Dr Jenkins, Director of the Brentwood Blood Transfusion Centre, wrote to Dr Maycock about a case of jaundice in a patient.[22] The letter is of particular interest because it suggests a link between this infection and a case of jaundice nine years earlier in 1956. Dr Jenkins states:

'*It is interesting and possibly significant that a previous donation from this man was given during 14th-15th October, 1956, to another patient, [redacted], who seven months later also developed jaundice. At the time, I thought that because of this very long incubation period, this complication was "unlikely to be post- transfusion jaundice", and you agreed in a letter[23] dated 12th February, 1958.*

Negative histories were given by the other donors involved in the [1956] case and by all but two of the donors contacted in the [1965] case.

Between 3rd February, 1957 and 9th August, 1963, [The donor] has made seven donations with no record of jaundice following subsequent transfusion. In the circumstances,

I am inclined to refuse further donations from him but I would appreciate your guidance.'

28. There are, however, examples of clinicians reporting to local blood transfusion centres cases of post-transfusion hepatitis even when there were questions about the appropriateness of the administration of the infected product. For example, on 25 October

[22] DHSC0100017_035

[23] DHSC0100014_004: Dr Maycock wrote –'*incubation period probably rules out Homologous Serum Hepatitis*.'

1965 Dr Weiner, Director of the Birmingham Regional Transfusion Centre, wrote to Dr Maycock of his '*disgust*' in reporting a case of hepatitis:

'*My disgust is mainly due to the fact that he received just one bottle of blood (unnecessarily I daresay) with an initial haemoglobin of 14.0gm% which was found to be 15.2gm% after the operation. The patient lives in Wales and the hospital has been informed by his G.P. I cannot, therefore, give you the usual details. I know the bottle number and that the patient has hepatitis. Nevertheless, I am enclosing the usual form.*'[24]

29. There are examples of reports of cases of post-transfusion jaundice in Birmingham in the late 1960s. One case involved the death of a 39 year old man who was admitted in GRO-A 1968 following '*severe gastrointestinal haemorrhage. Three operations were required to stop this, including vagotomy and pyloroplasty and partial gastrectomy. Patient then apparently well until a few days prior to the final admission, when he developed jaundice and rapidly lapsed into coma. He died 24 hours after admission*.' [25] 24 batch numbers are set out in the report.

30. In addition, the documents demonstrate that in the late 1960s the press were reporting on cases of hepatitis. On 10 April 1969 a Mr Stone, of the Brentwood Regional Transfusion Centre, wrote to Dr Maycock about a '*belated report*' of a case only received by Mr Stone the morning of the letter.[26] He wrote:

'*You will see from the attached snippet from the Evening Standard, of 28th February, that it is the one that also achieved a certain press publicity*.'

31. Mr Stone queried whether this was a case of homologous serum jaundice due to the short incubation period and gastrointestinal symptoms. In relation to the steps taken, Mr Stone wrote:

'We have nevertheless withdrawn the donor concerned from our panel. Her only previous donation became outdated, the plasma being sent to you for drying on 27.7.67. and subsequently, returned as batch 2J/5528. We have had the good luck to find all five bottles on our shelves - being due to go out with the next allocation!'

[24] DHSC0100017_065
[25] DHSC0100113_006
[26] DHSC0100113_007

(iv) 1970s

32. As a result of a letter from a solicitor to Brentwood Regional Transfusion Centre, Dr Maycock in May 1970 stated that there had been three surveys undertaken into the incidence of icteric hepatitis after transfusion of blood.[27] A document from 30 October 1970 identifies a list of post-transfusion hepatitis reports.[28] There was a single report in 1955 rising to 11 reports in 1970.

33. On 14 June 1971 G. C. Turner from the Public Health Laboratory Service wrote to Dr Lehane of the Liverpool Regional Transfusion Centre about a case of post-transfusion hepatitis for a patient who received three units of blood at the Walton Hospital in December 1970.[29] He was then admitted to Southport General Infirmary in April 1971. In this letter the issue of length of intubation period was raised by Mr Turner. He describes an '*added interest*' because the '*latest positive case*' at Sefton also involved an incubation period over 100 days:

'*This makes me wonder whether the long incubation period may be a low-dose effect and whether the donors in such cases may also be serology negative but EM[30] positive.*'

34. In light of this particular interest, the request was made to increase the speed in which the donors could be tested. Mr Turner wrote:

'*In view of the special interest in this matter I wonder whether it would be possible to obtain specimens fairly soon from the donors involved in the transfusions given to Mr. [patient A] and also, perhaps, those involved in the case of [patient B], another long incubation case about whom I wrote to you at the end of last week.'*

35. On 21 March 1975 a report of a possible case of post-transfusion hepatitis was made at St Peter's Chertsey.[31] The patient had been transfused on multiple occasions between June

[27] DHSC0100019_100
[28] DHSC0100019_111
[29] NHBT0124154_011
[30] Electron-microscopy
[31] DHSC0100018_172

and October. Her jaundice symptoms became apparent in December with an estimated incubation period of 181 days. Tests for Australian antigen were negative. All donors were retested and one was found to be '*very weakly positive*' and the conclusion of the Director of the South London Regional Transfusion Centre was: '*it is a fair assumption that this is indeed a case of post transfusion jaundice*.'

36. The available documents demonstrate Dr Maycock requested an early form of lookback in the late 1970s. On 1 February 1978 Dr Maycock wrote to Dr Cleghorn of the North London Blood Transfusion Centre and stated that a batch of factor VIII concentrate (Batch HL1363), together with cryoprecipitate, was reported to have been '*associated with hepatitis surface antigen B positive hepatitis*.' [32] Dr Maycock informed Dr Cleghorn that he had received 212 bottles. He then stated:

'*Perhaps you would let me know if you hear of any cases of hepatitis associated with their use*.'

37. At a meeting of Regional Transfusion Directors on 22 February 1978 the issue of staff shortages was highlighted. Directors stated that they had advertised for positions '*without result*.'[33] It was noted that:

'*Altogether there were 10 vacancies, including one Deputy Directorship. There were 2 vacancies in Newcastle, Liverpool and South London. Bristol had one vacancy. Brentwood and Cambridge each had a vacancy, but had not received any applications. There was one vacancy at Cardiff. Professor Stratton emphasised the need to improve the quality of supporting staff available to Directors since the burden of administration work was a great discouragement to doctors interested in joining the NBTS. He invited the Department to consider what could be done to improve the state of affairs.'*

(v) 1980s

38. The requirement to report cases of post-transfusion hepatitis to the DHSS can be seen from a 15 April 1982 letter from the Director of the North London Blood Transfusion Centre to a treating clinician, enclosing a post transfusion hepatitis form to be completed

[32] CBLA0003753
[33] NHBT0018353

and explaining that *"We are required by the Department of Health and Social Security to report this"*.[34]

Batch numbers

39. From the 1940s onwards, there were a number of problems in relation to investigating the causes of post-transfusion hepatitis. A repeated issue was the failure of treating clinicians to properly record batch numbers of blood and blood products. Unsurprisingly, the failure to record the batch numbers made tracing blood donors challenging.

40. An example from Wales in the late 1940s: on 25 October 1949 Dr G. D. Lewis completed a report on behalf of the Cardiff Regional Transfusion Centre about suspected cases of '*homologous serum jaundice*'.[35] This particular completed form relates to – in language of the time – a case of '*haemorrhage and obstetric shock*'.[36] For this patient, batch numbers of the blood products used in a transfusion given at home in the middle of the night were not kept '*in the excitement of the moment*'. This perhaps suggests that the standard practice during this period in Wales would be to record batch numbers. The patient is noted to have had no contact with any patient with hepatitis in the previous six months. There were no other cases of jaundice in the hospital at the time. The onset of her jaundice was noted to have occurred about 130 days after a transfusion of two bottles of plasma.

41. However, the Inquiry has seen another example from Wales where missing batch numbers did not appear to be an obstacle to identifying a donor. On 24 July 1944, Dr Drummond, the Regional Blood Transfusion Officer from the Welsh Board of Health, wrote to Dr Panton at the Ministry of Health about a case of '*delayed transfusion jaundice*'.[37] The letter describes a 50 year old woman who underwent surgery on 25 April 1944 where she was given a '*bottle of reconstituted dried plasma*'. She was then given '*400 c.cm of concentrated red cells (blood of two donors)*'. On 28 April 1944 she received *'a further 450 c.cm concentrated red cells'* from two group A donors. The patient was admitted to

[34] NHBT0114074
[35] DHSC0100011_006
[36] DHSC0100011_006
[37] DHSC0100008_054

hospital on 20 July 1944 for '*jaundice, pain in joints, headache, anorexia*'. On the day the letter is written, her jaundice was described as '*very intense*' but '*on the wane*'. It is stated that the surgeon did not record the batch number of the bottles of plasma. Notwithstanding this, the identity of the donor was stated to be known. It is not clear from the letter how the donor was identified in the absence of batch numbers.

42. Mr Drummond then asked whether any blood should be taken from the patient and states:

'*Also is it worth while [sic] our trying to contact to donors. They are apt to be a bit touchy when questioned.*'[38]

43. This may suggest a hesitancy about investigating the cause of the jaundice and an acknowledgement that approaching blood donors to question them about their health could be a difficult issue.

Record keeping

44. In addition to issues around the failure to properly record batch numbers, the Inquiry has seen evidence of other types of issues with records keeping. The first is that it appears there was no adequate system for recording a change in donors' names upon marriage. For example, on 30 July 1965 the Director of the Newcastle Regional Transfusion Centre wrote to Dr Preston at the Oxford Regional Transfusion Centre stating that they had '*now*' been able to contact a donor:

'*the delay was due to her having changed her name on marriage ... it was just by coincidence that we found this out.*'[39]

45. Another difficulty was the failure to have an adequate system for knowing when donors moved address. For example, on 13 June 1969 Mr Stone wrote to Dr Maycock about a reported case of homologous serum jaundice following a transfusion.[40] Three donors were

[38] DHSC0100008_054
[39] DHSC0100017_044
[40] DHSC0100113_017

identified. Of these three, one donor had been previously reported to Dr Maycock in March 1961 about a case in the London hospital:

'*Since then he has made 15 donations all with apparently good effect. In the circumstances, however, his name has been withdrawn from our panel of donors. I have been able to obtain a full donation of serum from him which I have sent off this morning to Dr. Zuckerman at the London School of Hygiene and Tropical Medicine.*'

46. It appears that Mr Stone had difficulty locating another donor*: 'I am afraid that she has returned to her native Scotland - address unknown - the search continues!'*

Screening of donors

47. Some documentation seen by the Inquiry demonstrates the difficulties in relying on blood donors to accurately report their own health and/or make blood transfusion centres aware of any subsequent change to their health following a donation. For example, a report of a case of serum hepatitis was made after the death of a patient at West Suffolk General in Bury St Edmunds after receiving transfusions in July 1969.[41] The case involved an incubation period of 69 days. One of the bottles was noted to be '*A positive*'. The post mortem noted '*acute yellow atrophy (viral hepatitis)*.' In response to the question about the validity of a diagnosis of serum hepatitis: '*almost certain*' is written on the form. In the accompanying letter to Dr Maycock, dated 5 December 1969, Dr J Damborough, Director of the Regional Transfusion Centre at Cambridge, stated that one of the donors involved '***now*** *tells us that: "I had sickness/diarrhoea bug after the donation*" (emphasis added).'[42] Dr Darnborough's proposal was to remove him from the panel but noted that the donor '*is due to attend a session next month and I am proposing that we let him attend, bleed him into a dry bottle and have his serum tested by Dr Zuckerman*.'

48. Dr Darnborough then described the usual mechanism of testing such donors:

'*We have, in fact, introduced routinely machinery whereby any donors involved in any of these cases will ultimately have samples tested by Zuckerman, but this one seemed*

[41] DHSC0100112_017
[42] DHSC0100112_016

particularly significant and it just may be that a full serum donation might be of some use.'[43]

49. There are examples where donors (or more frequently their treating clinicians) acted quickly to report a deterioration in their health which led to a removal of their donations from the pool. For example, a donor donated blood on 21 July 1976, which was then transfused into a patient at the Chest Hospital in Hampshire. The donor's GP then notified the Medical Director[44] on 2 August 1976 that the donor had developed jaundice after the donation.[45] The donor was then removed from the donor pool, notwithstanding the fact that the donation had tested negative for HBV due to '*the possibility of transmitting short incubation period hepatitis*'. However, in this case it appears the reporting happened because of a rapid and visible deterioration in the donor's health. It is unclear whether this infected donation would have been picked up if the donor's GP had not raised the issue.

HBV

50. This section addresses investigations into cases of hepatitis B ("HBV") following transfusion. It sets out the variety of challenges for those investigating cases of HBV in both patients and donors.

51. HBV was originally known as Australian Antigen and was identified in around the mid-1960s.[46]

Investigations

52. The Inquiry has received documents which demonstrate a range of examples of investigations undertaken when a concern arose about the potential contamination of blood and blood products with HBV. Such investigations took place from the early 1970s

[43] DHSC0100112_016. Dr Maycock agreed with this approach: DHSC0100112_018
[44] It is unclear if this is the medical director of the hospital or transfusion service, or another organisation
[45] NHBT0108941
[46] §68 of WITN3101006

to the 2000s. The breadth and depth of investigations varies across the relevant time period.

53. There is evidence of Dr Snape of BPL asking Professor Zuckerman at the London School of Hygiene and Tropical Medicine to test a range of samples for HBV in July 1974.[47] A donor card, where the first donation took place on 25 July 1974, for a Welsh donor is stamped with '*HB Ag positive*' in red ink.[48]

54. The main trigger for an investigation into a possible case of HBV appears to be the screening of blood donations for HBV antigen. For example, in June 1978, Dr V. James of the Sheffield Regional Transfusion Centre requested that a donor who had tested positive for HBV antigen be reviewed at a local hospital.[49]

55. In the early 1970s there was a discussion between some clinicians and Dr Maycock of BPL about the potential use of batches infected with HBV. For example, on 18 February 1974 Dr Maycock wrote to Professor Stewart of the Middlesex Hospital, enclosing a list of bottles of concentrate. Three batches had been prepared '*from a pool into which, we learnt later, an HB Ag positive donation had been put.*'[50] Dr Maycock then went onto suggest that Professor Stewart could use these donations as findings in *the Lancet* in 1973 [51] stated that '*complex formation should not give rise to trouble.*' The Inquiry has not yet identified a copy of any reply drafted by Professor Stewart.[52] However, the minutes of the meeting of Haemophilia Centre Directors[53] on 1 November 1974 records his view on the use of such concentrate:

'*There was a discussion contributed to by Professor Stewart and Drs. Mibashan, Rainsford, Prentice and Biggs about the problems arising from the use of therapeutic materials which might be contaminated with various hepatitis viruses. Prof Stewart said that he thought material identified as containing hepatitis B antigen need not be*

[47] CBLA0013949
[48] NHBT0102671
[49] NHBT0030476_526
[50] CBLA0005911
[51] Reference: The Lancet 1973, 2, 1347
[52] CBLA0009016 states there was a letter from Professor Stewart to Dr Maycock on 25 July 1974.
[53] Dr Maycock was also noted to be present.

withdrawn from use since this material could be given to patients known to have hepatitis B antibody or to have had hepatitis.'[54]

56. The outcome of this discussion at the meeting was that Dr Craske was to undertake a study of the incidence of various types of hepatitis at different Centres and the relationship of infection to the various types of material used.

57. There are examples of HBV infection investigations throughout the 1980s. In one example Dr Hewitt, Deputy Director of the North London Blood Transfusion Centre, investigated a case of possible post-transfusion hepatitis in a patient who had received Red Cross blood in addition to NBTS blood. The patient received blood transfusions in 1971, 1977 and 1981 and was then positive for HBsAg.[55] Three units came from the Centre and four from Red Cross donors. Dr Hewitt wrote:

'*we would not usually pursue an enquiry involving donors from outside the National Blood Transfusion Service, but because hepatitis B was involved we decided to contact the three donors. We have now had samples from all three and none of them have any markers for hepatitis B. Thus we must assume that if the hepatitis B in [redacted] was due to blood transfusion, it must have been from one of the donors bled outside the NBTS. On the other hand, there has been a long gap between the 1981 blood transfusion and the discovery of the HBV status of the recipient, and I do not know if any other cause of the hepatitis B infection has been explored. We have closed our enquiry.*'

58. Dr Hewitt wrote to Dr Gunson, National Director of the NBTS, in June 1990 on the issue of post-transfusion HBV reports from 1986 to 1989.[56] It was noted that in that period there were a total of 14 reports of HBV which '*we felt we likely to be associated with blood transfusion.*' The NLBTC investigated three to four cases of '*possible/probable post-transfusion hepatitis B each year.*' The investigations in relation to these cases were set out as follows:

(a) Two of these related to transfusions abroad and so there was no recall.

(b) In two further cases: '*there was no donor follow-up because the reports involved an incidental finding of HBsAg positivity in a multi-transfused recipient, without any*

[54] HCDO0001017
[55] NHBT0114082
[56] NHBT0003770

indication of date of seroconversion (or indeed, proof of a previous HBsAg negative status).'

(c) In eight of the remaining cases, '*an attempt was made to contact all involved donors*.' The response rate from these donors was described as '*high, although not complete'*. Specifically:

(i) In three cases the donors were negative.

(ii) In a further three cases, one resampled donor was anti-HBc positive and '*withdrawn as "possibly implicated"*.'

(iii) One case was noted to be '*predicted by us, when a donor was detected HBsAg positive at the next donation, the previous donation was subsequently confirmed HBsAg negative. This donor was obviously in the early infectious stage of hepatitis B infection, but below the level of detection in HBsAg screening tests, at the time of the implicated donation*.'

(iv) The final case was noted as being '*fully documented*.'

(d) For the remaining two cases it was noted that the '*number of donors involved were huge and recall of all donors thought to be logistically impossible. Examination of records revealed a common donor, found to be anti-HBc positive on recall*.'

59. Dr Hewitt concluded that from the above investigations: '*the checking of original HBsAg results on donors involved in PTHB enquiries is unlikely to be of help to BPL in deciding the fate of "held" products. Our latest report to BPL (J2/90) involving 183 donors and 120 plasma donations forwarded to BPL required 15 hours of Senior Scientific Officer time to check original HBsAg results. If the checking of previous HBsAg test results is now to be part of BPL's requirements, we shall obviously require additional resources!*'

60. The available documents reveal investigations into possible HBV infections during the 1990s[57] and 2000s. Dr Gunson authored a report dated 24 May 1990, into events leading to the recall of products by the CBLA following a report of jaundice in a patient. The

[57] See for example, BPLL0001895 and NHBT0011150_005

North London RTC had been informed by a hospital on GRO-A 1989 that a patient who had died at the hospital had suffered from hepatitis B. It is noted that the RTC did not report this fact to BPL for a year. The report stated that it was accepted by the RTC that the delay in reporting the incident was unacceptable and that procedures had been put in place to avoid a repeat incident. Dr Gunson stated in the report that it was not possible to take immediate action on an initial notification of an incident since such reports were generally incomplete and upon investigation were shown not to involve transfusion transmitted infection. He noted that immediate notification to BPL would lead to unnecessary quantities of plasma being withdrawn.[58]

61. Following this report, Dr Gunson wrote to all RTDs informing them that he would be conducting a review of all standard operating procedure at RTCs for the investigation of the transfusion history of patients who developed hepatitis following transfusion of blood and blood products, including BPL notification. He requested details from each RTC to assist with his review resulting in a detailed report.[59]

62. Dr Gunson further addressed the issue at the CBLA meeting on 1 June 1990. He outlined the errors that had been made at the RTC in relation to the infected batch of plasma and the subsequent recall process. It was noted that, had BPL been informed of the infected batch in a timely manner, they could have quarantined it which would have prevented the incident. Dr Gunson stated that he could make no excuse on behalf of such operation.[60]

63. Some investigations into HBV infections show fairly lengthy delays. For example, one enquiry into post-transfusion HBV took almost three years to investigate. The rationale given for this delay is that '*it took about two years to persuade UCH that there was a related cluster of infections, and this is why the whole matter has dragged on for so long.*' [61]

[58] NHBT0003780
[59] NHBT0005397 and NHBT0003763
[60] NHBT0000066_012
[61] NHBT0023823

64. In another example of delay: on 14 December 1999 Dr Orr, Consultant Microbiologist, wrote to Dr Wallis at the Freeman hospital regarding a deceased patient who had seroconverted to HBV after a liver transplant.[62] Investigations had been carried out which revealed that the infection was acquired at or around the time of the first transplant. The recommendation was that any donation transfusion in a six month period up to 6 March 1997 should be investigated. In view of the time passed since that date, Dr Orr concluded the letter by stating: '*I am sorry that it has taken so long to reach this conclusion, however, some of the testing we required was far from routine and unfortunately lead to delays*.'

65. In contrast there are examples of quick and efficient investigations, such as that by Dr Angela Gorman of the North East Thames Regional Transfusion Centre in 1991.[63]

66. In 2002 a patient, who had been receiving treatment for myeloma since 1996, presented with flu like symptoms and tested positive for HBV.[64] He had never previously been tested for HBV and had received blood donations in July and September 2001. Investigations revealed that these were donations from the Birmingham Blood Centre. Computerised records were sent to the National Blood Service at Birmingham so investigations could be undertaken. It is of note that this case of HBV and potentially infected batches came from a patient presenting with ill health rather than any national or local monitoring or tracing scheme.

67. In 2008 a patient was diagnosed with HBV. Dr Hewitt chased information from King's College London after the HBV notification form went unanswered.[65] She wrote:

> *'I would stress that we have not received the minimum information necessary in order to document the details of this case. In particular, donation numbers have been provided in an email and not from a computer laboratory print-out. We therefore cannot vouch for the accuracy of the donation numbers provided to us.*
>
> *If you could now provide the information requested, we can include it in the file and confirm that the correct donations have been investigated. Otherwise, I am now closing*

[62] NHBT0030404_007
[63] NHBT0056556_007
[64] NHBT0026536
[65] NHBT0016619

our investigation with the conclusion that [the patient] hepatitis B infection was not due to the transfusion of the 4 units of "blood products" notified to us in Mark's email. We have assumed that the blood products in question were red cells.

This case will be reported to SHOT[66], according to our usual procedure. No doubt an investigation into other possible sources of infection will now be carried out at King's College Hospital.'

Batch numbers and missing donors

68. As with post-transfusion hepatitis, the available documents demonstrate two problems with tracing donors. The first was a failure to record batch numbers of an implicated blood product. The second was an inability to make contact with a donor. Reports from 1974 demonstrate both of these issues. Such reports also demonstrate success in confirming or ruling out infections with HBV after retesting of batches. However, Dr Maycock's feelings about testing and tracing donors are noted in the report: '*You will appreciate the immense labour involved in tracing and recalling donors for retest. Usually one or two are untraceable.*' [67]

69. A report from September 1974 sets out reports on six patients. One case was a fatal case reported in November 1973 and the donors of the blood had been retested. One of the donors had been found to be HBV positive and had been removed from the panel. However, it is interesting to note that '*looking at his record [the donor], together with other donors, was associated with a case of hepatitis in 1964, but none of this subsequent donations until the one given to [the deceased] were associated with the occurrence of hepatitis as far as it is known.*' The testing on batches was undertaken by Regional Transfusion Centres and the queried batches were from BPL and Immuno.

70. However, there are also examples of donors being successfully traced following suspicions of HBV. In October 1974, Dr Maycock reported four cases where a diagnosis of HBV had been raised in patients who had received transfusion.[68] In the case of the first

[66] Serious Hazards of Transfusion scheme
[67] DHSC0100018_053
[68] DHSC0100018_056

patient, the donor had been successfully found and retested; they were positive for HBV. The second case was said to be '*doubtful*' for HBV as the patient tested negative and only one donor tested positive on one occasion. For the third patient, there was '*no indication that the 10 donors all of whom were tested by the most sensitive technique available, were responsible for transmitting hepatitis B to this patient*.' In the final case, the diagnosis of HBV was not in doubt but '*unfortunately no record of the batch number was kept.*' This therefore was not an issue about being unable to find a known donor, but being unable to find who the donor was.

71. A further report from 30 October 1974 shows that the sources of potential HBV infection were still in the course of being investigated.[69] Further, Dr Maycock noted that another patient, who had become jaundiced 60 days after transfusion, had tested negative for HBV 10 days after the onset of jaundice. However, his wife had tested positive for HBV after she became jaundiced 118 days after the onset of her husband's illness. A further two cases were noted to have '*occurred some time ago and only recently came to light. The relevant donors are at the present time Au negative*.' It is not clear from the report why these cases of HBV had not been reported earlier.

72. The Director of the South London Regional Transfusion Centre completed a report for a queried case of post-transfusion hepatitis for a patient who had been transfused at the St Olave's hospital in early January 1974.[70] All donors, bar one, had been tested for HBV antigen and antibody and the results had come back negative. It was reported that there had been '*repeated attempts*' to contact the remaining donor but that he failed to respond: '*His name suggests that he might be an immigrant from a tropical area but, unfortunately, our records do not confirm this*.' It is unclear from the report whether there was any proper basis for the suggestion that the donor was not from the UK. In light of a missing donor, it was concluded that no '*firm conclusion can be drawn on this case*.'

73. The issue of being able to contact and retest donors remained during the 1980s and 1990s. An example of a missing donor is provided in the correspondence between Dr

[69] DHSC0100018_082
[70] DHSC0100018_101

Hewitt of the North London Blood Transfusion Centre and Dr Samson, of the Charing Cross Hospital. The letter, dated 26 November 1985, concerned a case of post transfusion HBV infection reported in May 1984. [71] The patient was HBV negative in January 1984 but developed acute HBV in May 1984. The patient had been in hospital continuously in this period and had received blood and fresh frozen plasma from a total of 32 blood donors. An attempt was made to contact and resample all the donors:

'*A total of 28 donors have given repeat samples and none has any marker of past hepatitis B infection.*

Unfortunately, we have been unable to contact the remaining 4 donors, all of whom are young males and who have not responded to letters or attended any blood donor clinics in the interim, despite requests to contact us. We are making one final effort to contact these four in an attempt to close this enquiry. I apologise for the long delay in sending this report to you, but unfortunately we have been unable to reach a definite conclusion.'

Record keeping

74. In addition to the failure to record batch numbers, poor record keeping or the total absence of medical records has posed a problem for tracing donors.

75. For example Dr Parker-Williams, Consultant Haematologist at St George's Hospital, explained in correspondence to Dr Hewitt on 7 August 1996, that they had been unable to trace blood due to the absence of records:

'*The blood bank at Atkinson Morley's Hospital was closed down 2.5 years ago. We can trace three of the units, but one has sunk without trace; no record exists of its fate either in the AMH records or our own at St George's (blood was transferred down here after two weeks at AMH, and you resupplied AMH with newer units). I am returning all four report forms. The St George's reports will take some time to come through. There are 82 of them, and all the old record books have to be gone through to pick them up - its laborious!*'[72]

76. Dr Hewitt responded with the offer of an additional staff member:

'*Please could you bear in mind that we can offer help going through old record books, if your laboratory staff would feel that an additional person would indeed be a help and not a hindrance! The majority of hospitals are able to complete this task quite easily, because*

[71] NHBT0115650_030
[72] NHBT0012414

the records are on computer. If this is not the case at St George's, then we would do everything possible to lighten the load on your staff. We are expecting to employ a student (whose brother is a medical student at St George's!) to help in the next few weeks, so do please get back to me if you could use some of his time.'[73]

The creation of a national register

77. In the late 1980s a national register of blood donors found positive for HBV was created at the North London Blood Transfusion Centre, Colindale ("NLBTC").[74] The 1987 report demonstrates that each Regional Blood Transfusion Centre in the UK was invited to return annual data for blood donors for central analysis at NLBTC. It was noted that this exercise should '*be analogous to the centre returns of the anti-HIV data analysed at the Manchester Transfusion Centre.*'

78. It was noted that there were disadvantages in compiling a national register for HBV. The first was the '*lack of an integrated detailed reporting system at the onset of HBsAg screening for donors in 1971/1972*' as well as the issue of incomplete returns of data. The following advantages were noted:

'*a) easier confirmation of reactivity since the specificity of HBsAg results can be readily determined (test for antigen and not for antibody)*
b) good understanding of the serological markers defining the clinical and infectivity status of donors found positive for HBsAg,
c) theoretically, access to accumulate historical data.'

79. The NLBTC produced data broken down into regional variations, breakdown by sex, as well as the positivity rate for first-time donors. It was noted that there were '*striking differences between centres and this merits further investigation*.' The report further states:

'*We regret that this has taken so long to produce but future update of the computer files will now be easier. There is a vast range of useful information that can be generated and we are aware of the large amount of time that must be spent in collecting the initial data*.'

[73] NHBT0012414
[74] NHBT0001542

80. Dr Cash was sent the data and analysis from this study '*at long last*' in August 1990.[75] Dr Barbara noted that the report was preliminary in nature and was '*the first attempt to do this on a national scale and therefore we would welcome comments and suggestions for ways in which the report might be improved in the future*.' The Inquiry has been unable to find any subsequent reports from this register.

Lookback

81. In 1995 a study into the incidence of HBV in the donor population was undertaken. The purpose of the study was to assess the transmissibility of HBV in blood donations negative for hepatitis B surface antigen (HBs) but positive for antibody to hepatis B core (anti-HBc).[76] A Hepatitis B Core Study Group was created, comprising of individuals from Abbott, Cambridge, North London Transfusion Centre, South Thames Blood Centre and London & South East Zone of the National Blood Service.[77] Part of the study required a lookback exercise to be undertaken. This exercise was influenced by the HCV lookback. The minutes record that Dr Lorna Williamson, University of Cambridge / East Anglian Blood Centre, was to contact Dr Angela Robinson[78] '*to suggest that this [i.e. lookback] be done immediately following HCV Look Back. The same staff should be employed for both*.'

82. Dr Robinson wrote to Dr Jeremy Metters at the Department of Health on 24 August 1995 giving her support to this study, describing it was an '*excellent study design*' which had '*attracted external funding*'.[79] Dr Robinson noted that a lookback exercise was required in order to complete the study. She described this in the following terms:

> '*At present this is an unresolved controversial issue and this well designed study should provide the answer of whether or not anti-HBc positive donors with or without low levels of anti-HBs can cause transfusion transmitted HBV disease.*
>
> *I hope you will have sufficient time to read through Loma Williamson's protocol for this study which I have enclosed as it is very clear and has very clear objectives. It again has*

[75] NHBT0001542
[76] NHBT0006068
[77] NHBT0040454_001. The protocol for the study is here: NHBT0006068
[78] Medical Director of the National Blood Authority.
[79] NHBT0010807

full NBA support, but I recognise the sensitivity of this issue and promised that I would let you have full details of what was being proposed before any such study went ahead.'

83. She further stated:

'As you know we have all been subjected to adverse publicity over this issue and part of our response has been to state that we are undertaking further studies to determine whether or not anti-HBc screening in this country could significantly improve the safety of the blood supply. This study should give us accurate information on both the incidence and the potential transmission rate of HBV from anti-HBc only positive donors and I would very much like it to go ahead.'

84. The view from Dr Metters was that the study should take place after the HCV lookback had been completed:[80]

'*To avoid confusion, it might be prudent to wait until after the HCV look-back has been completed. The HCV look-back will also provide experience of Consultant Haematologist and GP co-operation.'*

85. Dr Williamson, responding to Dr Metters' comments, stated that the phase of the study which would involve patient identification and tracing was due to begin in the New Year '*by which time hospitals will have completed tracing of patients in the HCV look-back. The study will not generate any extra work for hospitals, as each of the 2 participating centres will have a research nurse to undertake this work'*.[81] She further noted that Drs Richard Tedder and John Barbara had joined the study since the protocol was drafted.

86. As part of the study individual GPs were contacted.[82] GPs of patients who were positive for anti-hepatitis B core were asked:

'a) Whether you think this person could appropriately be contacted for entry into this study, since there will be rare cases where you will feel that enrolment is not appropriate?

b) If so, may we contact [the patient] directly by letter, or would you prefer to do this yourself?

[80] NHBT0040739_002. He also made suggestions, amongst other things, in relation to the need for a virologist.
[81] NHBT0040738
[82] NHBT0041363_003

c) Whether you would be willing to take a 10 ml blood sample from the patient? (We would provide pre-paid addressed packaging for you to return the sample to us at the East Anglian Blood Centre. If you felt unable to take the sample the research nurse attached to the study, Mrs Joanna Griffiths, could arrange to sample the patient).'

87. Dr Williamson further stated that:

'Results of the hepatitis B testing should be available within 10 days of us receiving the sample. A negative result, which will form the vast majority, will be rapidly communicated by us to the patient by telephone and letter, and to yourself by letter. In the rare cases where the patient is confirmed positive for hepatitis B, we would discuss with you how this should be communicated to the patient.

Although this study may raise anxieties about the safety of transfusions, we do have a duty to explore all means to further improve transfusion safety. Studies like this are really the only way the value of extra tests on donors can be assessed and your assistance in carrying out this study will be very much appreciated. We would be grateful if you would complete the enclosed form indicating your approval for the patient to be approached, whether this should be done by ourselves or you and whether or not you are willing to take the blood sample.'

88. In cases where it was not possible to reach the patient via their GP, the authors of the study wrote to the relevant hospital where treatment had been given. An example of such a letter is one sent on behalf of Dr Hewitt, who explained that where they were unable to contact the patient via the GP there was a:[83]

'*a logistical difficulty for us as we have patients from all over the London and South East Zone, so we are asking whether your team would agree to sample this patient for us.*

I have spoken to Mrs Gail Cooper who has agreed that we could approach your department. [The patient] will have already been sent all the necessary sample tubes for your convenience and if you are agreeable to take the sample, we. would ask the following:
a) The patient has a consent form with her and we would be grateful if the attendant who is taking the sample can obtain written consent before sampling takes place. The patient will already have agreed to the sampling and will be fully informed of the situation. Anxieties about the outcome of the blood test will naturally enough still be there, but the patient can be assured that the likelihood of the virus being transmitted is very small indeed

b) A 10m1 blood sample.

[83] NHBT0030632_021

c) The patient will have a sample box and a pre-paid jiffy bag with her, so the sample together with the consent form can be returned to us via BTS transport.'

89. Despite GP and hospital contact, some donors remained untraceable.[84]

90. An extract of the data produced by this study in October 1996 from South Thames and East Anglia regions revealed that a total of 158 donors in South Thames were confirmed as anti-HBc positive with 44 donors as anti-HBc positive in East Anglia.[85] 1112 and 204 components respectively were traced and the following breakdowns for lookback given:

	South Thames	East Anglia
GPs contacted:	18	92
~ Patients deceased	2	3
~ Patient unsuitable /transferred	4	20
~ Patients contacted	2	66
~ Patients tested	0	56

91. The Inquiry has not at present identified the final report for this study.

92. It appears that in 1999 there were still patients being flagged by the study that were being located. For example, a letter from Dr Hewitt, dated 24 March 1999, to Dr Townley, Consultant Haematologist at the NBS Northern Zone, stated:

'...this is one of the last few remaining from an enormous post transfusion hepatitis B enquiry[86] and this poor gentleman has tried in 4 places to have a blood sample taken without success. He has moved to the West Midlands.'[87]

93. By 1996 Dr Hewitt, in correspondence to Dr James of the Trent Regional Transfusion Centre, described a policy of annual testing of blood donors who are found to be HBsAg.

[84] See for example, NHBT0030267_002 and NHBT0010671
[85] NHBT0007899
[86] It seems likely that this is a reference to the Williamson study.
[87] NHBT0011122_007

She described a two-fold purpose: '*to assess the serological status and evidence (or lack of) for liver dysfunction, and to keep these donors away from blood donor sessions*!'[88]

94. In 2009 a new method of testing blood donors was introduced.[89] Donors were tested for evidence of HBV infection using both serology and a test for HBV DNA. This led to finding new cases of HBV in donors.[90]

HTLV III / HIV Lookbacks

95. This section addresses the lookback conducted by the NBTS in response to the issue of the presence of HTLV III in the national donor pool. Similar lookback investigations had taken place in the United States, following calls for such investigations by American Association of Blood Banks, the American Red Cross, and the Council of Community Blood.[91]

96. The lookback into HTLV III in the UK benefited from Regional Transfusion Centres' previous experience with historical jaundice and HBV. Broadly, the HTLV III lookback was more centralised and structured in comparison to the hepatitis lookbacks.[92]

97. Unlike lookbacks for historical jaundice and HBV, the HIV lookback had a temporal limit. There was a five year temporal limit looking backwards from 15 October 1985 when blood in the UK started to be screened for HIV.[93]

1984 Surveillance procedure

98.

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[88] NHBT0029662_003
[89] NHBT0031596
[90] See for example, NHBT0031097
[91] See *New England Journal of Medicine* in October 1986: PRSE0000488.
[92] Statements in relation to NIBTS (WITN2681026), Wales (WITN6876001) and SNBTS (WITN3530085) confirm that all four nations operated in the same way in relation to the HTLV3 lookback.
[93] CBLA0001833; See the section below.

99. On 4 April 1984 a meeting was held between Dr Galbraith, Director of CDSC,[94] Dr McEvoy of CDSC, and Dr Gunson, of the Manchester RTC, to determine the surveillance required in relation to the risk of HTLV III for blood transfusions.[95] The notes of that meeting, drafted by Dr Gunson, set out the steps to be taken when a patient is diagnosed with AIDS.

100. The first step of the lookback identified by Dr Gunson was that CDSC would inform the appropriate Regional Transfusion Director ("RTD") when a patient is diagnosed with AIDS. If the patient said they had donated blood then that contact would be by telephone. There would then be an investigation to see if the individual is registered as a blood donor. If the individual is not a blood donor then the CDSC will be informed. If the individual is a blood donor then the following steps were proposed:

'*1.3.1 Trace the fate of 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 circumstances 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.'

101. The document also addressed the situation when the infected individual has themselves received a transfusion and/or blood products. In those circumstances, the proposal was that the CDSC would inform the relevant RTD:

'*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.*

[94] Communicable Disease Surveillance Centre
[95] CBLA0001833

Craske, Consultant Virologist, P.H.L.S., Manchester will also be Involved. If the patient has received I~HS products derived from pooled plasma, Dr. R.S. Lane will be informed.'

102. In circumstances where the infected individual received blood products prepared and issued from the RTC the following steps were envisaged:

'*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 involved 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.'

103. A letter drafted by Dr Gunson the day before this guidance was drawn up noted that Regional Transfusion Centres '*already have systems available for the follow-up of donors who are implicated in patients who develop Transfusion Associated Hepatitis.*'[96] His view was that he did '*not see that fundamentally the proposal to follow-up donors implicated in patients who develop AIDS or the follow-up of donations given by persons who subsequently develop AIDS is significantly different.*'

104. An issue appears to have arisen over whether the patient who had been given "at risk" blood had to be informed directly or whether it was sufficient to tell their GP. At a meeting of the Regional Transfusion Directors on 11 July 1984, advice from the Medical Defence Union that informing the GP was sufficient was reported. It was also noted that some members doubted this.[97] It was suggested that a DHSS working group might be set

[96] DHSC0006923_071
[97] DHSC0002245_002

up to consider the legal implications. However, to date, the Inquiry has not identified such a group

105. In November 1984, the Working Group on AIDS identified as an issue that a *"retrospective survey of previous donations"* would be required once a positive donor was identified.[98]

106. At the first meeting of the Advisory Committee on the NSBT's Working Group on AIDS on 27 November 1984 it was noted that the question of follow up of donors and patients was being considered by the IMCD. It was recorded that *"there are very difficult and complex issues to be taken on board: one suggestion was a regional immunology service to deal with all this at special centres"*.[99]

107. Tracing back donations of those subsequently identified as suffering from AIDS continued to be undertaken during 1984: a point that was included in a press release by Dr Donald Acheson, Chief Medical Officer, on 20 December 1984 in response to media coverage of a man who was diagnosed with AIDS. Dr Acheson emphasised that the donations that he had previously given *"have been traced, and all possible remedial action taken"*. He noted that the three recipients of the blood and blood products had tested HTLVIII positive.[100]

108. While discussions about screening blood were ongoing, reference was then made to the need for lookback procedures arising from any positive results from the screening. At their meeting on 10 July 1985, the Regional Transfusion Directors agreed that follow up of previous donations of plasma should be for 3-5 years. They agreed that a sub-committee would put forward a flowchart, for AIDS testing and following up of donations, to the Expert Advisory Group on AIDS.[101] The Working Party report dated 11 July 1985 recorded that in relation to lookback *"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 and the information regarding the known or possible*

[98] CBLA0001934_003
[99] CBLA0001934_002 and DHSC0002251_011
[100] BART0000814
[101] CBLA0002212

seropositivity of the donation given to the Consultant in charge of the patient". In addition, if plasma was sent for fractionation, *"full follow-up of all patients receiving coagulation factor concentrates may be difficult or impossible"* and because all patients with haemophilia A or B were being tested for HTLV3 then no additional follow up was considered to be required.[102]

109. At their meeting on 30 July 1985, the Expert Advisory Group on AIDS recorded a slightly different approach. Dr Smithies reported that the Screening Sub-Committee had recommended that the haematologist in charge of the blood bank would be notified if it was believed that the donor had made previous donations and they would be asked to identify any recipients of those earlier donations.[103] The haematologist would then be asked to inform the clinician in charge when the earlier blood was transfused and *'it would be up to the clinician in charge of the patient to decide on what subsequent investigations should be made".* It was noted that *"The BTS was aware of the importance of good record keeping to enable the follow up of donations".*[104]

110. The five year notification process was also adopted in Scotland.[105] According to evidence given to the Penrose Inquiry, from a starting point of 39 anti-HIV positive donors with previous donations, a targeted lookback by SNBTS found nine anti-HIV positive patients.[106] Ad hoc reports from clinicians treating patients with HIV who had received blood transfusions also led to an additional eight cases being identified.[107]

111. There is correspondence that suggests that not all were supportive of the five year rule for tracing back donations. For example, Dr V. James wrote to Dr Jones at Nottingham City Hospital on 4 December 1985 about a HTLV III positive donor:

'I personally am not quite sure what the Transfusion Service hopes to achieve by this type of follow-up but I am told that it would be helpful if you could find out who received that

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[102] DHSC0000406
[103] For the minutes of the Sub-Committee meeting see DHSC0000406.
[104] PRSE0002628
[105] PRSE0004042
[106] See page 9 of PRSE0004042
[107] See page 9-10 of PRSE0004042. There was one additional case but there appears to have been insufficient information to allow SNBTS to investigate. See page 10 onwards for SNBTS' consideration of the reasons why the numbers were relatively low.

donation and inform the Consultant in charge of the patient of this finding. I have to ask you to ensure that the recipient is not told because the worry inflicted on the poor recipient would be out of all proportion to the possible risk. Could you please let me know therefore who received the donation. With a little bit of luck it was not used at all.'[108]

112. As part of the notification process, regional blood transfusion services notified hospitals about infected batches and instructed clinicians to destroy batches that had not been transfused into patients.[109] However, Dr Hewitt has stated that in light of donor education many of those donors who recognised themselves as being at risk of HIV infection had self-excluded and would not become known to the blood services. Consequently, unless clinicians and/or seropositive individuals came forward and informed the blood services, a lookback could not be pursued.[110] This issue is reflected in a question raised by Dr Tedder, on behalf of Dr Contreras, at the EAGA meeting on 26 November 1985 in which he asked clinical members whether they would consider asking seropositive patients if they had donated blood since 1978.[111]

113. The Inquiry has seen a number of examples of this notification process in action. For example, on 21 February 1986 a senior technician at BPL wrote to Dr Tovey at the Leeds Regional Transfusion Centre confirming that a reported batch had been fractionated and went into un-heat-treated factor VIII and IX batches.[112] The onus was then on Dr Tovey to arrange follow-up of patients treated with this batch. The assistance of Dr Craske was offered and Dr Tovey was reminded that Dr Craske should have been provided with the names of all patients treated with this batch.

114. Another example of the notification process in practice is demonstrated by a letter (produced after a telephone call) from R. M. Barnes the Deputy Medical Director of the Wessex Regional Transfusion Centre to Dr Snape at BPL, reporting that a male donor had been admitted to Bournemouth hospital with a clinical diagnosis that was '*almost certainly AIDS*'.[113] The donor's previous donations were listed along with batch numbers.

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[108] NHBT0011051_010
[109] PARA0000016; see also PARA0000040
[110] See page 68 para 189 of WITN3101006
[111] DHSC0001736
[112] PARA0000072
[113] CBLA0000010_209

In relation to two of the donations, R. M Barnes wrote: '*we are not getting in touch with the clinicians involved until the diagnosis is confirmed*.' He also raised the possibility of an additional donation:

'*There is also a possibility of a donation before November 1982 in this region, which we are attempting to trace. I will, of course, contact you again when definite information is available.*

We are also obtaining more information from the Haemophilia Centres, as you requested yesterday evening, which I will pass on to you.'

115. Dr Snape then produced a report into this matter, dated 23 October 1984.[114] Dr Snape's observations were:

'*5.2 In this particular instance, the last (and most damaging) donation was received at BPL on 6th April 1984, pooled for fractionation on 17th May 1984 and issued for clinical use on 10th August 1984. This timetable is consistent with the five week period of quarantine presently supportable for fresh frozen plasma and the irreducible six to eight week delay from pooling plasma to release of factor VIII concentrate for clinical use.*

Enforcement of a three month quarantine period would not in this instance have avoided the loss of resource resulting from the plasma pool being compromised by a single donation; it would almost certainly have avoided patient exposure to the product however.

Enforcement of a six month quarantine period would have prevented release of the batch for clinical use; it would also have allowed the donation to be excluded before pooling, thus avoiding a very expensive reject situation. This incident must be an extremely cogent argument for the establishment of cold-storage facilities capable of supporting a six-month quarantine of fresh frozen plasma.

5.3 The appearance of this donor at three different Centres within two years clearly underlines a fundamental problem when carrying out follow-up of donor incidents of this sort. Surely central co- ordination of donor records is unavoidable.'

116. Just under four years later Dr Craske responded to Dr Lane of BPL about batch 3186.

[115] Dr Craske was critical about the follow up:

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[114] DHSC0001111
[115] CBLA0000010_202

'*The follow-up we were doing eighteen months ago of this incident was bedevilled at that time by the reluctance of Haemophilia Centre Directors to cause, what they considered to be, an unnecessary worry to their patients, so that a follow-up of the recipients who received this product has not been carried out in the formal sense…*[116]

Your letter prompts me to re-open this enquiry, as we do need to know the outcome of patients who received this and other batches which may have been contaminated with HIV. I will consult my files and let you have a report as to what is known at the present time. It should be easy enough to identify where the recipients are now who received this and other batches which may have been infected.

One problem is that most of the batches of material followed-up had only one or two patients where one could be certain that HIV infection was likely to have been associated with the suspect batch. This is due to the fact that in many cases antibody test results are only available after the suspect batch was transfused. It is, therefore, possible that a patient could have been infected prior to receiving the one under investigation and could have been antibody positive for say one or two years prior to this event. We do, however, have good data for one batch and this combined with the investigations in Edinburgh will give us a consistent picture and will go in some way to establishing the likely outcome in terms of risk of seroconversion after receiving a batch contaminated with HIV.'

117. Dr Craske's plan was to discuss the issue with Dr Rizza at the annual meeting in Dublin and to revert. The Inquiry has been unable to find a response from Dr Craske to Dr Lane on this issue, following the Dublin UKHCDO meeting which took place on 29 September 1988.

An epidemiological study of HTLV III

118. In 1986 an epidemiological study into HTLV III was proposed by the Blood Transfusion Service.[117] The draft documents accompanying the study highlighted that individuals infected by transfusions '*have not yet been identified.*'[118] It is emphasised that these individuals are likely to fall outside high risk groups and that it can '*be argued these people and their close contacts should be identified and counselled for their own sakes.*' The project was based at Bristol. The suggested starting point was donors identified by screening since 14 October 1985. It was further noted that there were '*instances in which*

[116] A similar view is stated by Dr Rejman of the DOH in an internal government memo in 1992: DHSC0002585_004
[117] SBTS0000033_066
[118] DHSC0002480_047

patients infected by blood transfusions have brought the problem to light and a donor can be found by back tracing.'

119. In May 1987 Dr Wallington at the South Western Regional Transfusion Centre wrote to Dr Gunson following agreement within NBTS that '*an attempt be made to identify, help and investigate patients who have received transfusions which might have infected them with HIV [and] also where necessary their household contacts.*'[119] He enclosed study documents to introduce the project and to allow Dr Gunson to start the project in his region. Although the project was coordinated from Bristol it was noted that:

'*virtually all of the work, interviewing donors and blood recipients having established the link between them, will have to be done by local staff and organised at Regional Transfusion Centre level. This will involve considerable effort and this study is totally dependent on the cooperation of Health Service staff who become involved.*

120. Dr Wallington recognised that there were ethical concerns about recipient tracing:

'*people have been very worried about the idea of approaching blood recipients a proportion of whom will be well and unsuspecting with such a dread[ed] diagnosis and even more in doubt about investigation of household contacts. Opinion has been changing rapidly and most people now believe that infected persons should be identified wherever possible for public health reasons. As this part of the study will undoubtedly prove controversial I think colleagues in Haematology should be fully informed before being presented with notification of a donation thought to be infectious.*'

121. On 22 July 1987 Dr Wallington wrote to Dr Gunson again stating that he had received '*very little comment or information*' since he distributed the material in May.[120] It appears that the study had not yet got off the ground by November 1986. On 4 November 1986 Dr Gunson wrote to Dr Wallington referring to the '*enormity of the task*'.[121] It appears the study was abandoned in the early 1990s despite some RTCs sending data to Dr Wallington.[122]

Other investigations

[119] NHBT0004202
[120] NHBT0004199
[121] NHBT0017052
[122] NHBT0004810 and NHBT0000052_033

122. At the Fourth International AIDS Conference in June 1988 in Stockholm the lookback exercise carried out by Drs Hewitt, Moore and Barbara at the North London Blood Transfusion Centre was described.[123] The results of the investigation were that:

'*Previous donations had been given by 9 of 17 current donors, 4 ex-donors and 2 identified as anti-HIV positive through infected recipients. Of 44 blood com- ponents made, 6 were unused, 9 not traced by the hospital and 4 incorporated.in plasma pools for factor VIII. Of recipients who could be traced; 11 were deceased, 8 were not infected, 3 were anti-HIV positive and 4 were not tested. Seven recipients were notified as infected. In 2 cases donors were implicated, 2 cases could not be solved despite contact of all available donors, 1 could not be pursued due to inadequate hospital records and 2 are incomplete*.'

123. The conclusion of the study was not enthusiastically set out. This investigation was noted to be '*time-consuming*'. One of the highlighted problems was that '*hospital records are often deficient'*. It was noted that '*the benefit produced by these enquiries has been little'*. However, on the positive side it was noted that three blood recipients were identified as seropositive '*and spread to their sexual partners [was] possible averted*.'

124. In 1993 Dr Hewitt produced a paper investigating the possible transmission of HIV by blood transfusion.[124] Her findings were:

'*Five HIV infected recipients were identified, who had not previously been known to be infected. In addition, the RTC became aware of 2 recipients known to be anti-HIV positive but previously unreported. All infected recipients were transfused before 1985 with unscreened blood or components. Of the possible transfusion- transmitted HIV infections, one third were considered not due to transfusion, one third 2 thought likely (without the identification of a culprit donor) and 5 donors were identified as likely to have been responsible for 6 reported cases. One case could not be investigated through lack of records and one is still under investigation.*'

125. Her conclusion were:

'*Investigations failed to reveal any infection arising after screening of blood donations commenced in 1985. Overall, 42% of identifiable recipients died within 6 months of transfusion. Eight of 32 (25%) living recipients were infected with HIV and 5 of these were newly detected through the investigation. Laboratory record keeping was generally*

[123] NHBT0057880
[124] DHSC0006351_032

deficient prior to 1985; accurate recording of transfusion details in patient medical records remains a conspicuous problem up to the date of the report. The investigation confirms the exceedingly small chance of transmission of HIV by transfusion of screened blood and blood components in the United Kingdom.'

126. Evidence given to the Penrose Inquiry by the Scottish National Blood Transfusion Service ("SNBTS") states that the Department of Health requested information of all HIV patients identified by lookback but that '*there is no information on the outcome of this exercise, which was never published.*'[125] Some documents referred to a renewed lookback in 1992 when the issue of government compensation for those infected with HIV was made available.[126]

Limitations of HTLV III / HIV lookbacks

127. Janet Mortimer of CDSC produced a report, dated 11 September 1990, about the NBTS' lookback from October 1985 to December 1989.[127] Anti-HIV screening of all blood donations had identified 67 positive donors who had given blood before, who were described as '*repeat donors*'. Of those, the follow-up of previous donations had been received for 64 out of the 67. She concluded: '*most of the donations involved in this look-back had been made before routine anti-HIV testing started, but thirty-nine of them had been given since the introduction of screening. All but one was negative.*' Janet Mortimer set out the changes she would like to see to the lookback process:

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 look-back data.*
2) *That wherever possible look-back continues retrospectively through the previous donations until either a) all have been investigated, lor b) an anti-HIV negative recipient is identified, unless there is any doubt about the accuracy of the record keeping which makes further look-back desirable.*
3) *That look-back 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 look-back be recorded on a form such as the one used to this produce summary (Appendix 2) and collected and collated centrally on an annual basis.*

[125] PRSE0004042
[126] NHBT0003037_001
[127] NHBT0008409_005

128. This report was presented at the meeting of the Expert Advisory Group on AIDS on 2 October 1990 by Dr Gunson. The minutes record that members accepted the limitations of the lookback but considered it was important and should continue. They agreed to Dr Mortimer's proposed procedure but recommended that lookback should continue until two anti-HIV negative recipients had been identified.[128]

129. A key concern within the HTVL III / HIV lookback investigations was whether publicity generated by AIDS had led donors who may have been implicated to stop donating[129] and stopped engaging with requests for information. As at August 1992 it was recognised by Dr Hewitt that there remained '*not solved*' cases where '*several donors*' remained untraced.[130]

130. Another problem highlighted by lookback investigations is that the success of tracing donors largely depended on the donor re-attending to give blood. This issue is described by Dr Hewitt in an August 1991 letter.[131]

> '*As you will know, routine screening of blood donations for evidence of HIV infection did not start until 1985. It was in September 1983 that the Department of Health issued advice about the exclusion of certain individuals from blood donation who might be at risk of HIV infection. It is likely that once we have traced the donors involved in [this patient's] case, we will find that a proportion have donated since 1985 and will therefore have been tested for anti-HIV. Our problem is what to do about the rest. It is possible that one or more of the donors ceased donating before 1985 in response to requests from the Blood Transfusion Service to self-exclude from blood donation. In these cases, especially if we have no recent record of an address, attempts at contact with these ex-donors have been singularly successful. We will, however, examine our records and then determine what action is necessary. Even if we decide to investigate no further, we strongly believe that all cases of possible transfusion transmitted infection should be notified to the National Blood Transfusion Service so that we may at least document the case*.'

131. The issue of the absence of reappearing donors continued to be a problem during the 1990s.[132] In May 1991, Dr Gunson proposed making a national summary of information

[128] NHBT0008213_002
[129] See for example, NHBT0092313
[130] NHBT0015096_002. See also: NHBT0059590_006
[131] NHBT0099107
[132] See for example, NHBT0015135_002

on anti-HIV positive recipients of blood, with RTDs completing a form for each positive transfusion recipient and the use of the CDSC databases to try and identify donors who had not donated subsequent to the screening tests.[133]

132. For an investigation in August 1998 about a high number of transfusions in the early 1990s, Angela Gorman of the NBS at Brentwood, was unable to provide a timeframe of when her investigations would be complete: '*I am afraid I do not know when I will have this information, as we are in the middle of a change over period from one archive system to another and my IT colleague tells me that he simply does not have access to such files at the moment. We have made the appropriate representations to try to rectify the situation.'* She considered it unlikely that all of the donors would be contactable: *'This is not for any sinister reasons, but simply because a significant percentage of donors cease to donate every year*.'

133. A further example of untraced donors was in March 1993 from the South Thames Blood Transfusion Service where of 23 implicated donors, 11 were '*lost to follow-up*.'[134] It was noted that '*a significant number were from a local college and have moved on*.'

134. In relation to counselling of donors Dr Robinson, writing in 1995, described the counselling process as follows:[135]

'*It was then left to the discretion of the clinician responsible for the recipient to determine whether or not to inform the patient, counsel and HIV test. If there were no archived samples from previous donations, a staged Look Back exercise was undertaken, tracing back donations to 1977. Where live recipients were identified, if 3 successive negative live recipients were found no further Look Back was undertaken. This exercise was not completed very well but when the UK government offered compensation for transfusion recipients (In February 1992 - haemophiliacs were offered compensation in January 1990) who had developed transfusion transmitted HIV infection pre October 1985, we were instructed to undertake a comprehensive Look Back to accurately determine all the potential recipients who might have received HIV infected blood from identified positive donors pre 1985*.'

135. Her overall view of the HIV lookback was:

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[133] NHBT0004801
[134] DHSC0014978_092
[135] NHBT0003037_001

'*So the answer to your question is yes, an HIV Look Back did take place in the UK. It began at the time of instituting HIV screening in October 1985 and was pursued energetically 1992 onwards because of the government compensation scheme.*'

136. For completeness' sake, it is noted that there is evidence of HIV infections from blood donations as late as 1997 and an associated lookback procedure being undertaken.[136]

137. In addition, infections due to transfusions were at times discovered very late. For example in a 2001 investigation, concerning transfusions given in 1977, it was not possible to find any of the donors despite the existence of batch numbers and dates of transfusions.[137] Due to the passage of time, the view of the national lead clinician for transfusion microbiology was that the risk was '*minimal.*' The matter was therefore not progressed any further. The Inquiry has seen evidence of HIV infections via transfusions that were discovered as late as 2003.[138]

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[136] NHBT0081212_013 DHSC0014981_036; DHSC0014981_063; NHBT0081212_028
[137] NHBT0099408_001
[138] NHBT0064187